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# Regulation (EC) 1107/2009 on the Placing of Plant Protection Products on the Market

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European  
Implementation  
Assessment

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STUDY

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**Ex-Post Evaluation Unit**

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# Regulation (EC) 1107/2009 on the placing of plant protection products on the market

## Study

In May 2017, the Committee on the Environment, Public Health and Food Safety of the European Parliament requested an implementation report on Regulation (EC) 1107/2009 on the placing of plant protection products on the market, appointing Pavel POC (S&D, Czech Republic) as rapporteur.

Implementation reports by European Parliament committees are routinely accompanied by European Implementation Assessments, drawn up by the Ex-Post Evaluation Unit of the Directorate for Impact Assessment and European Added Value, within the European Parliament's Directorate-General for Parliamentary Research Services.

### Abstract

Regulation (EC) 1107/2009 lays down the main instruments for placing effective plant protection products (using pesticide substances) on the market that are safe for humans, animals and the environment, while at the same time ensuring effective functioning of the internal market and improved agricultural production.

This European Implementation Assessment found that the above objectives, while largely relevant to real needs, are not being achieved in practice. In particular, the day to day implementation of the main instruments of the regulation – substance approval, plant protection product authorisation and enforcement of the regulatory decisions taken in the frame of the approvals and authorisations – is problematic, which also affects other related EU policies.

Nevertheless, despite the implementation challenges observed, stakeholders including national competent authorities, health/environment NGOs, manufacturers of substances and plant protection products and their users (farmers), agree that the EU is the appropriate level at which regulatory action in the field of pesticides (used in plant protection products) should continue to take place.

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## List of abbreviations

<b>AGRI</b>	European Parliament Committee on Agriculture and Rural Development
<b>BfR</b>	German Federal Institute for Risk Assessment
<b>BPR</b>	Biocidal Product Regulation
<b>CA</b>	Competent Authority
<b>CLP</b>	Classification, labelling and packaging of substances and mixtures
<b>CMR</b>	Carcinogenicity, mutagenicity, reproductive toxicity
<b>cMS</b>	concerned Member State
<b>dRR</b>	draft registration report
<b>ECHA</b>	European Chemicals Agency
<b>EFSA</b>	European Food Safety Authority
<b>EIA</b>	European Implementation Assessment
<b>ENVI</b>	European Parliament Committee on the Environment, Public Health and Food Safety
<b>EPRS</b>	European Parliamentary Research Service
<b>DG SANTE</b>	European Commission, Directorate General for Health and Food Safety
<b>GLP</b>	Good Laboratory Practice
<b>IARC</b>	International Agency for the Research of Cancer
<b>IPM</b>	Integrated Pest Management
<b>izSC</b>	Interzonal Steering Committee
<b>MRL</b>	Maximum Residue Levels
<b>MS</b>	Member State
<b>NGO</b>	Non-governmental organisation
<b>OECD</b>	Organisation for Economic Cooperation and Development
<b>PAFF</b>	Standing Committee on Plants, Animals, Food and Feed
<b>PEST</b>	Special Committee on the Union's authorisation procedure for pesticides with a focus on glyphosate
<b>PPP</b>	Plant Protection Product

<b>PPPAMS</b>	Plant Protection Products Application Management System
<b>PPPR</b>	Plant Protection Product Regulation
<b>REACH</b>	Regulation on registration, evaluation, authorisation and restriction of chemicals
<b>RMS</b>	Rapporteur Member State
<b>SUD</b>	Sustainable Use Directive
<b>zRMS</b>	zonal Rapporteur Member State
<b>zSC</b>	Zonal Steering Committees

## Acknowledgements

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EPRS would like to thank the researchers who drafted the studies on which this European Implementation Assessment is based: Dr Emanuela BOZZINI (University of Trento), Dr Olivia HAMLYN (University of Leicester), Lise OULÈS (Milieu Ltd), Florent PELSY (Milieu Ltd), Dr Dovilė RIMKUTĖ (University of Leiden) and Evelyn UNDERWOOD (IEEP) as well as the peer reviewers of their studies.

The studies published in Annexes I, II, III and IV were written at the request of the Ex-Post Evaluation Unit as follows:

- Study 'Evaluation of the implementation of Regulation 1107/2009 and its impacts. Mapping the usage made by Member States of the derogations granted under Article 53 of the Regulation', written by Florent PELSY and Lise OULÈS from Milieu Ltd (Belgium) and Evelyn UNDERWOOD (Institute for European Environmental Policy, IEEP)
- Study 'Assessing criteria and capacity for reliable and harmonised 'hazard identification' of active substances' written by Dr Emanuela BOZZINI (University of Trento, Italy)
- Study 'Assessing Member States' capacity for reliable "authorisation of PPPs", and its uniformity', written by Dr Olivia HAMLYN (University of Leicester, United Kingdom)
- Study 'Mapping the practices of scientific (risk assessment) evaluation of active substances used in plant protection products', written by Dr Dovilė RIMKUTĖ (University of Leiden, The Netherlands)

## Executive summary

This European Implementation Assessment aims at evaluating the implementation of Regulation (EC) 1107/2009 on the placing of plant protection products on the market, referred to hereafter as the regulation or the PPPR. In particular, it looks at the relevance, coherence, effectiveness (and associated knowledge base), efficiency and EU added value of its practical implementation.

The evaluation relied on self-generated evidence and, in particular, on four major sources of information (studies), annexed to this European Implementation Assessment and conducted between September 2017 and April 2018 at the request of the Ex-Post Evaluation Unit of the European Parliamentary Research Service<sup>1</sup>:

- Study on the 'Evaluation of the implementation of Regulation (EC) 1107/2009 on the placing of plant protection products on the market and its impacts. Mapping the usage made by Member States of the derogations granted under Article 53 of the Regulation';
- Study on 'Assessing criteria and capacity for reliable and harmonised 'hazard identification' of active substances';
- Study on 'Assessing Member States' capacity for reliable 'authorisation of PPPs', and its uniformity';
- Study on 'Mapping the practices of scientific (risk assessment) evaluation of active substances used in plant protection products'.

The authors, scope and data collection tools of each study are presented in the section on methodology of this European Implementation Assessment.

The results presented below aim primarily at supporting the European Parliament Committees on the Environment, Public Health and Food Safety (ENVI) and on Agriculture (AGRI) in their work on a dedicated implementation report. Furthermore, its findings may be of interest to the recently established Special Committee on the Union's authorisation procedure for pesticides with a focus on glyphosate (PEST).

This evaluation revealed a mixed picture of implementation of Regulation (EC) 1107/2009 on the placing of plant protection products on the market when assessed against the key criteria for evaluation: relevance, coherence, effectiveness (underpinned by the knowledge base), efficiency, and EU added value.

While the objectives of the regulation related to health and the environment were found by stakeholders<sup>2</sup> across all categories to be **relevant** to real needs, respondents were in less agreement on the objectives related to internal market and agricultural production. The data available suggests that the regulation should better reflect the need to promote

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<sup>1</sup> Milieu 2018, Annex I here; Bozzini 2018, Annex II here; Hamlyn 2018, Annex III here and Rimkutė, 2018, Annex IV here.

<sup>2</sup> Milieu 2018, Annex I here.

agricultural practices based on integrated pest management (including by setting the development and usage of substances of low risk as an objective), as well as the need for innovation in the field of plant protection products.

As far as **coherence** is concerned, and based on stakeholders' opinions,<sup>3</sup> the objectives and instruments of the regulation do not seem to be in line with EU policies in the field of agriculture, food security, climate change and sustainable use of pesticides and maximum residue levels of pesticides in food and feed. As regards the implementation of regulation's instruments, stakeholders cast similar opinions.

In terms of **effectiveness**, the aim is to assess whether the objectives of the regulation are being achieved. The available evidence<sup>4</sup> shows that the practical implementation of the three main instruments of Regulation (EC) 1107/2009 – approval of substances (a), authorisation of plant protection products containing approved substances (b), and enforcement of regulatory decision taken in the frame of approvals and authorisations (c) – is problematic.

- a) The practical implementation of approvals of active substances (performed by national competent authorities, the European Food Safety Authority (EFSA) and the Commission, together with Member States' experts) is associated with many issues of concern.

A first group of concerns is associated with the evaluation approach (as established by law); in particular, two main elements of the approach – who should produce the evidence for evaluations and the hazard-based approach (as opposed to the risk-based approach) – are questioned because of their practical implications.

A second group of concerns relates to the practical implementation of the established evaluation approach. Two major issues of concern emerged: the incomplete harmonisation of data requirements and methodologies used in some scientific fields (e.g. criteria for endocrine disruptors were established only recently) and the practical work of national and EU authorities involved in the evaluation of substances. The former may lead to direct negative effects on health, environment and agricultural production because evaluators could not yet fully assess substances against all their hazards and risks based on strict data requirements and methodologies. The latter referred in particular to the evaluation of the active substance glyphosate, which provoked doubts among stakeholders and policy-makers from various sides as regards both whether the scientific evaluation was implemented correctly, and whether in this particular case EU evaluators performed their work independently of industry; this evaluation did not find evidence supporting those doubts.

The performance of national competent authorities was found to be a major factor influencing the evaluation of substances. This European Implementation Assessment found that most – but not all – competent authorities (CAs) have the institutional

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<sup>3</sup> Milieu 2018, Annex I here.

<sup>4</sup> The findings of the studies annexed to this European Implementation Assessment: Milieu 2018, Annex I; Bozzini 2018, Annex II; Hamlyn 2018, Annex III and Rimkutė 2018, Annex IV.

capacity to act as a Rapporteur Member State (RMS) and deliver assessment reports to EFSA (although with reports of variable quality across Member States). There are substantial differences among EU Member States as regards available expertise and staff. All CAs appear to be seriously and chronically understaffed based on their self-evaluation. This is the main factor explaining why approvals and renewals of approvals are delayed at the stage of hazard identification and initial risk assessment performed by Member States (which also implies delays in the subsequent authorisations of PPPs at national level). The varying capacities of CAs in terms of expertise and staff and thus the quality of the results from the evaluations of hazard identification and initial risk assessment performed at national level, varies across Member States. As a result, the regulation and relevant supporting legal requirements are not uniformly implemented across Member States with all relevant health and environment implications.

Transparency at the stage performed by CAs is problematic, as the information related to evaluations at CA level becomes available at the EFSA stage, however not always in a user friendly way. The risk management (decision-making) stage of the approval procedure (taking place at EU level) was found to lack transparency, which creates room for decisions that do not necessarily follow evaluators' (CAs, EFSA) advice. This may in turn results in negative effects on health and the environment, lowering public trust in the system regulating pesticide substances (used in PPPs).

- b) As regards plant protection product authorisations, which take place exclusively at national level, this evaluation found that the procedures feature delays in risk management decisions, which are due, among other things, to lack of resources and uneven distribution of evaluation workload across competent authorities, and mistrust in each other's evaluation work.

As a direct result, the delays in risk management decisions lead to a lack of plant protection products (PPPs) at users' disposal. To compensate for this, in some cases, competent authorities authorise PPPs with proven negative effects on health and the environment. Known as derogations under Article 53 of the regulation, their stated main intention is to ensure room for manoeuvre in special circumstances, i.e. when there is danger that could not be contained by any other reasonable measures. This evaluation found though that there are cases where Article 53 is used at national level against this initial intention of the legislator.

Furthermore, as mentioned, delays occur due to lack of trust between CAs, which results in problems in the application of the mutual recognition principle, and distortion in the functioning of the internal market of PPPs.

The ultimate result of the problematic aspects of the practical implementation of the authorisation instrument is a lack of improvement in agricultural production.

Regarding the approval procedure, the harmonisation of guidance is an ongoing process.

As regards the transparency aspects of the authorisation-related activities of competent authorities, it was found that current practices in the Member States examined are problematic, especially in terms of limited publicly available information on

evaluation and the authorisation procedure itself, as well as in terms of access to information.

- c) The findings of this evaluation on enforcement practices suggest that the PPPs available on the market – whether manufactured in the EU or imported from third countries – and their application by users do not necessarily comply with the relevant authorisation conditions as regards their composition and usage. The fact that regulatory risk management decisions (resulting from the approval and authorisation procedures) could not be adequately enforced critically undermines the achievement of all four objectives of the PPPR.

The **efficiency** of the implementation of the regulation was difficult to assess because of data scarcity. Nevertheless, according to stakeholders,<sup>5</sup> the actual implementation results could not have been achieved at a lower price.

Finally, the available data shows that stakeholders<sup>6</sup> (across competent authorities, health/environment NGOs, manufacturers of substances and plant protection products and their users (farmers)) unanimously consider that the implementation of Regulation (EC) 1107/2009 **adds value** to national efforts in achieving its objectives. This assessment shows that the EU is the appropriate level at which the regulatory action in the field of pesticides (used in plant protection products) should continue.

The European Implementation Assessment (EIA) starts by presenting the scope, methodology and data sources of the evaluation project. It then introduces Regulation (EC) 1107/2009 in the broader context of the EU pesticides policy, and the details of its various objectives and implementation and enforcement instruments (procedures). It ends up by presenting the main findings on the practical implementation of the regulation and analysing them against the criteria for evaluation presented above.

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<sup>5</sup> Milieu 2018, Annex I here.

<sup>6</sup> Milieu 2018, Annex I here.

## Scope, methodology and data sources

### Scope and methodology

The main purpose of this evaluation work is to assess the implementation of Regulation (EC) 1107/2009 against the standard set of criteria for evaluation, namely relevance, coherence, effectiveness, efficiency and EU added value. In this particular case, this translates as follows:

- Relevance – whether the set of policy (sub-)objectives laid down by the regulation sufficiently reflect current needs;
- Coherence – whether the PPPR instruments and their practical implementation is in line with other related EU policies and legislation;
- Effectiveness – whether the practical implementation of the regulation's main instruments (approval of substances, authorisation of PPPs, and enforcement of approval and authorisation regulatory decisions) underpins or goes against the achievement of the set objectives;
- Efficiency – whether the existing policy results could have been achieved with less costs/resources;
- EU added value – whether Member States could have achieved existing results better if acting alone (i.e. without policy-making at EU level).

A sixth criterion, knowledge base, was added to the above standard set of evaluation criteria, and was also applied when evaluating the implementation of the regulation. In particular, the sixth criterion is considered as complementing the 'effectiveness criterion', as knowledge base is a *conditio sine qua non* for proper implementation of two of the main instruments of the regulation, namely approval of active substances at EU level and subsequent authorisation of plant protection products (containing approved substances) at national level.

As with any evaluation performed by the Ex-Post Evaluation Unit of EPRS, this one looks at the implementation of the regulation in its entirety. Furthermore, certain aspects of critical importance to the practical implementation of the regulation were given special focus. In particular, since the detailed analysis of the legal framework (as described in the relevant section here below) has shown that Member States act as main players in the implementation and enforcement of the regulation, this evaluation looks at the performance of Member States' competent authorities with an emphasis on their role in the approval of active substances and authorisation of PPPs (including emergency authorisation under derogation). Furthermore, the evaluation sheds light on the risk assessment models applied by key risk assessors worldwide in the case of a few selected substances where assessment raised controversy, including glyphosate.

## Data sources: the annexed studies

This work was performed within four separate studies prepared at the request of the Ex-Post Evaluation Unit, and presented below. The findings of the four projects fed into the section presenting the main findings on the practical implementation of the regulation.

- **Study on 'Evaluation of the implementation of Regulation (EC) 1107/2009 on the placing of plant protection products on the market and its impacts. Mapping the usage made by Member States of the derogations granted under Article 53 of the regulation'**

The study was conducted by Milieu Ltd<sup>7</sup> between October 2017 and March 2018. As the title suggests, it covers the implementation of the regulation as a whole; the data collection involved desk research,<sup>8</sup> complemented with a stakeholder survey. The study also explored Member States practices with what are known as 'emergency' authorisations under 'Article 53' derogations; the data collection involved desk research and interviews with stakeholders.

The results of the study (including relevant recommendations) are presented in Annex I to this EIA. They served as the main basis for drafting, allowing for the practical implementation of the PPPR (i.e. all its instruments) to be measured against all (five plus one) evaluation criteria. In the text of the EIA, the study is referenced as follows: (Milieu 2018, Annex I here).

- **Study on 'Assessing criteria and capacity for reliable and harmonised 'hazard identification' of active substances'**

This study was drafted by Dr Emanuela Bozzini from Trento University between September 2017 and March 2018.

The study focuses on the procedure for approval of active substances and in particular on the work of national competent authorities (CAs) when acting as a Rapporteur Member State. Data was collected via desk research, interviews with national competent authorities, a stakeholder survey (and follow-up interviews requested by the respondents).

The results of the study (including relevant recommendations) are presented in Annex II to this EIA and were used in the analysis of the practical implementation of the procedure for approval of substances. In the text of the EIA, the study is referenced as follows: (Bozzini 2018, Annex II here).

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<sup>7</sup> The team included: Florent Pelsy (Milieu Ltd), Lise Oulès (Milieu Ltd) and Evelyn Underwood (IEEP). Josephine Armstrong (Milieu Ltd) took part in the project between October and December 2017.

<sup>8</sup> The results of the desk research are presented in Part 2 of Milieu's study. It should be noted that each finding presented in that part comes from one reviewed source only, and therefore, should be read and understood in the context of this particular source alone.

- **Study on 'Assessing Member States' capacity for reliable "authorisation of PPPs", and its uniformity'**

This study was drafted by Dr Olivia Hamlyn from Leicester University between September 2017 and March 2018.

The study considers national competent authorities' work in authorising plant protection products. It should be noted that this research paper covers only standard authorisations (performed as a rule), while emergency authorisations under Article 53 derogations are covered in the study drafted by Milieu Ltd. Data was collected via desk research, two surveys (with national CAs and with the secretariats of what are known as zonal Steering Committees), and a stakeholder survey.

The results of the study (including relevant recommendations) are presented in Annex III to this EIA. The results were used to analyse the practical implementation of the (standard) authorisation of PPPs procedure. In the text of the EIA, the study is referenced as follows: (Hamlyn 2018, Annex III here).

- **Study on 'Mapping the practices of scientific (risk assessment) evaluation of active substances used in plant protection products'**

This study was drafted by Dr Dovilė Rimkutė from Leiden University between September 2017 and April 2018.

The study compares the risk assessment regulatory models (for approval of active substances) established in the EU with other risk assessment models (whether regulatory or not) worldwide, such as those followed by the International Agency for Research on Cancer (IARC), the United States Environment Protection Agency, the Australian Pesticides and Veterinary Medicines Agency (APVMA), and the Canadian Pest Management Regulatory Agency (PMRA). In particular, the work of those bodies on the evaluation of certain controversial substances (glyphosate, certain neonicotinoids, bentazone and 2,4-Dichlorophenoxyacetic acid) were explored. Data collection involved desk research, interviews with relevant bodies and a stakeholder survey.

The results of the study are presented in Annex IV to this EIA. They were used to analyse the practical implementation of the procedure on approval of substances. The findings of this study were used only to illustrate or contradict the trends identified in the implementation of the regulation, as they are based on a few selected substances and therefore not indicative of the implementation of the regulation in principle. In the text of the EIA, the study is referenced as follows: (Rimkutė 2018, Annex IV here).

It should be also noted that each of the studies was peer-reviewed by external experts upon the request of the Ex-Post Evaluation Unit of EPRS.

Finally, one should note that this evaluation (in its four elements presented above) involved intensive data collection of both existing (secondary) and raw (primary) data; this latter proved a challenge, as data collection under this project coincided, and somewhat competed, with the data collection programme of the Commission conducted in the frame of the ongoing REFIT evaluation of Regulation (EC) 1107/2009. Nevertheless, national CAs and other stakeholders were very cooperative, although selective, as to which of the proposed data collection activities they took part in. Member States' competent authorities

were the most active respondents.<sup>9</sup> As regards the participation of other stakeholders, the interests represented in the collected data include health/environment, manufacturers/industry, farmers, and the research community, with certain variations across the four studies.<sup>10</sup> It should be underlined that the participation of Member States' competent authorities and other stakeholders was entirely voluntary,<sup>11</sup> and therefore much appreciated.

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<sup>9</sup> It should be noted that the data collection tools used to address Member States in the framework of these research activities exploring Member States' work on approvals of substances and authorisations of PPPs, were designed to collect factual data, which helped the authors to arrive at plausible findings.

<sup>10</sup> See the relevant data collection sections of the four studies for more details.

<sup>11</sup> In contrast to the Commission services, EPRS and the researchers working at its request have no legal powers to conduct audits of national CAs, which would be indeed a powerful data collection tool on the implementation and enforcement of the PPPR.

## **EU Policy on plant protection products (PPPs) - Legal framework**

Plant protection products are substances used to eliminate insects, weeds, and other unwanted organisms harmful to cultivated plants. Plant protection products are also known as 'pesticides', but the two terms are not synonymous, as the pesticides include both plant protection products and biocidal products.<sup>12</sup> PPPs are therefore products used to protect plants before, during and after cultivation. They are mainly used in the agricultural sector but also in forestry, horticulture, amenity areas and in domestic gardens. As for biocidal products, these have different uses, as disinfectants, to protect materials, etc. (Bourguignon 2017).

The European Union put a complex regulatory system in place to harmonise and monitor the placing of plant protection products on its internal market. In 2006, the European Commission adopted a thematic strategy on the sustainable use of pesticides<sup>13</sup> in all Member States. This general strategy now encompasses several pieces of legislation (presented further in this EIA) aiming at promoting a controlled and sustainable use of plant protection products while ensuring the protection of both public health and environment, as well as improving the functioning of the internal market. The main expected output of the strategy was to reduce the overall risks and the negative impacts on human health and the environment of the use of pesticides, by reducing unwanted direct and indirect exposure as well as the hazard levels of the substances used, by using less harmful substances and alternative pest control measures (European Commission 2007).

In this section of this EIA, an overview of the European legislation on plant protection products is given. The entire regulatory framework will not be examined in detail. The goal is to provide an overall picture of the main European legislative texts on which the pesticide policy is based, but its main point of interest is Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market.

The first section of this chapter is dedicated to Regulation (EC) No 1107/2009 and its context, while the second takes stock of the EU legislative framework that underpins the pesticide policy.

### **Policy objectives**

Environmental issues go beyond regional or national issues and concerted actions at European or international level are needed to better understand and address challenges and pressures, as well as to develop efficient and effective strategies and policies.

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<sup>12</sup> Even though the term 'pesticide' is often used interchangeably with 'plant protection product', the first term also covers non plant/crop uses, (pesticides are defined by Directive 2009/128/EC (Article 3) as including either plant protection products or biocidal products. However, it should be noted that the requirements of the directive do not cover biocidal products.

<sup>13</sup> Communication from the Commission to the Council, the European Parliament, the European Economic and Social Committee and the Committee of the Regions – A thematic strategy on the sustainable use of pesticides, [COM\(2006\) 373](#) final.

Over the years, the European Union has put a number of strategies in place and established manifold targets and objectives to meet to protect the environment and public health. In this respect, pesticide policy focuses on ensuring a high level of protection for humans, animals and environment as regards both the use of PPPs in the European Union and the pesticide residues on food and feed of plant and animal origin. At the same time, the pesticide policy pays special attention to other relevant issues such as improving the internal market for PPPs and ensuring competitive agriculture in the EU.

Regulation (EC) No 1107/2009 has two general objectives (according to Article 1(3)): to ensure a high level of protection for humans, animals and environment; and to 'improve the functioning of the internal market through harmonisation', while providing clearer rules to make the approval process for plant protection products more effective.

Other specific objectives of the regulation refer to:

- clarification, harmonisation and coherence of procedures (such as defining clear criteria for risk assessment and risk management, setting centralised procedures for active substance approvals, establishing harmonised rules for controls and monitoring, defining clear responsibilities for EFSA, Member States, and the Commission in active substance approvals);
- simplification and (procedural) acceleration of procedures (for instance simplifying procedures and shortening approval times for active substances and PPPs; implementing simplified data protection; shortening the time for new products to come on the market);
- encouraging mutual recognition of PPP authorisations by Member States (by establishing geographical zones according to the climatic conditions for mutual recognition);
- making relevant information available for applicants, importers, users, public authorities and consumers.

The initial legislative proposal<sup>14</sup> submitted by the European Commission in 2006, which lead to the current regulation, provides a more detailed picture of the general objectives underpinning the new European regulatory approach on pesticides.

## **Policy instruments**

The main policy instrument used is the legal regulation. The European institutions adopted various legislative tools intended to achieve the outcomes that conform to the objectives of EU pesticide policy. Although the focus of this study is Regulation (EC) 1107/2009, other relevant pieces of legislation will also be briefly presented in subsection 1.2.2. Considered

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<sup>14</sup> Proposal for a Regulation of the European Parliament and of the Council concerning the placing of plant protection products on the market, [COM/2006/0388](#) final.

together, they offer a more comprehensive image of the contents of the toolbox that supports pesticide policy at European level.

### **Regulation (EC) 1107/2009: Placing Plant Protection Products on the Market**

Two pieces of legislation govern the marketing of pesticides in the European Union: Regulation (EC) No 1107/2009 on the placing of plant protection products on the market and Regulation (EU) No 528/2012 on biocidal products.<sup>15</sup>

The following subsections deal only with Regulation (EC) No 1107/2009 and its context.

#### **Background**

The 'regulatory interest' in pesticides at European level began in the 1970s. Council Directive 76/895/EEC<sup>16</sup> on maximum levels for pesticide residues in and on fruit and vegetables was the first attempt of legislative harmonisation in the field. Since then, the EU regulatory approach has been strengthened and broadened, notably since the 1990s.

At least three factors contribute to explaining the development of the European regulatory regime of pesticides:

- the general trend launched by the Treaty of Maastricht<sup>17</sup> concerning the need to harmonise the different legislative frameworks on marketing of goods, including chemicals in general and PPPs in particular.
- technological and scientific developments, leading to an awareness of the adverse effects of certain products/substances on both human health and the environment, which also had an impact on the decision-making process and environmental and health protection policies (Dryzek 2005).
- the political context at the beginning of the 2000s, driven by a thriving participatory mood leading to a 'window of opportunity' for participation in the policy processes of organised civil society and public interest groups as well as for institutional and policy innovations (Bozzini 2017).

In this context, an important step in the development of EU pesticide policy was the adoption of Council Directive 91/414/EEC,<sup>18</sup> aiming at harmonising the placing of plant protection products on the market. The directive established a single list of approved active substances in all Member States (Annex I of the directive), as well as a common procedure for placing on the market, applicable in all Member States, for the authorisation, on their territories, of plant protection products containing these active substances. The principle of mutual recognition was also enshrined, meaning that an authorisation granted by one Member State can be recognised by other Member States. Beyond its achievements and deficiencies (it failed to put a single European framework for plant protection products

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<sup>15</sup> Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products, [OJ L 167](#), 27 June 2012.

<sup>16</sup> Council Directive 76/895/EEC of 23 November 1976 relating to the fixing of maximum levels for pesticide residues in and on fruit and vegetables, [IOL 1976 340 R 0026 015](#), 9 December 1976.

<sup>17</sup> Treaty on European Union 92/C 191/01, [OJ C 191](#) of 29 July 1992, p.1-112.

<sup>18</sup> Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market, [OJ L 230](#), 19 August 1991.

completely in place),<sup>19</sup> Directive 91/414/EEC represented a valuable experience that allowed for further improvements.

More than a decade after the adoption of the directive, the European Commission noted that, while the basic approach is still acceptable, the system is overloaded and inefficient. This finding led the Commission to conclude that a new legislative proposal should be submitted, aiming at simplification and better definition and streamlining of the procedures, as well as at an increased level of harmonisation. (European Commission 2006b).

From the mid-2000s onwards, the European approach has been focused on delivering higher levels of consumer and environmental protection.

### **Scope of application of Regulation (EC) 1107/2009**

The scope of application of the regulation is defined according to the type of substances (Article 2). The regulation therefore covers all plant protection products (whether synthetic products or bio-pesticides) as well as their component substances (whether active substances, safeners, synergists, co-formulants or adjuvants) for agricultural and other uses.

### **Key instruments and principles under the regulation for the approval of active substances and the authorisation of plant protection products**

Regulation (EC) 1107/2009 lays down rules for authorising the sale, use and control of plant protection products in the EU. The regulation put forward both procedures and principles to secure the marketing of PPPs across the EU, in accordance with the pesticide policy.

The placing of PPPs on the market must comply with a number of rules of approval for active substances and authorisation of plant protection products. In addition, several principles underpin the EU regulatory regime on pesticides. This blending of rules and principles ensures a unique legal approach, both compared with other pieces of EU legislation on chemicals and other legal approaches on pesticides worldwide.

#### *Approval of active substances*

The approval of active substances takes place at European level. The European Commission is the decision-making authority, but other actors are also involved in the process, at different times and in different ways. The approval procedure starts at national level (Member States' Competent Authorities) and then goes to different EU bodies, namely: the European Food and Safety Agency (EFSA) and the European Commission. The latter has the final say in the approval process.<sup>20</sup>

The approval of active substances is underpinned by both technical/scientific and political considerations, in the sense that there is a distinction between risk assessment and risk

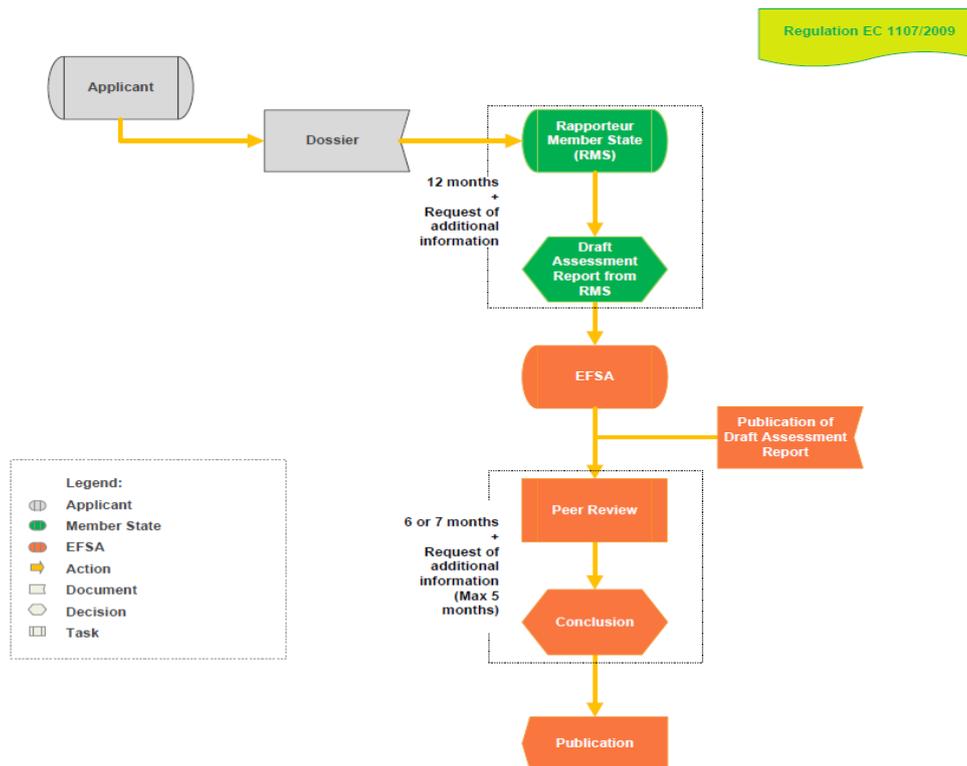
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<sup>19</sup> For a more detailed analysis, see: European Commission, Commission Staff Working Document. Report on the Impact Assessment for a Regulation Replacing Directive 91/414/EEC on Plant Protection Products, [SEC\(2006\) final](#).

<sup>20</sup> The European Parliament has no right to veto an approval.

management. In this respect, risk assessment falls within the competence of Member States (more precisely, the Rapporteur Member State, as described further) and EFSA; as regards risk management, i.e. the actual decision of approving (or not) an active substance, the responsibility lies with the European Commission as follow-up to a PAFF (Standing Committee on Plants, Animals, Food and Feed) comitology decision, composed of representatives of Member States.<sup>21</sup> The picture below presents an overview of the risk assessment process under Regulation (EC) 1107/2009.

Figure 1 – Approval of active substances



Source: European Food Safety Authority (EFSA)

The application dossier is submitted by one or more (industry) applicants to an EU country, known as the Rapporteur Member State (RMS). The dossier contains technical and scientific data, showing that the substance is safe for use, in terms of human and animal health and for the environment, as well as toxicological and ecotoxicological studies, information on residues, and on the fate and behaviour of the substance in the

<sup>21</sup> Following Article 13(2) (in conjunction with Article 79(3)) of the PPPR, active substances (safeners, synergists and co-formulants) are approved following a regulatory (comitology) procedure, as laid down in Articles 5 and 7 of Decision 1999/468/EC (having regard to the provisions of Article 8 thereof).

environment. The competent RMS authority<sup>22</sup> first checks if the applicant has provided tests and study reports and, once the application is accepted, prepares a draft assessment report (DAR). The DAR is sent to the European Food Safety Authority, which coordinates the risk assessment of active substances (by consulting stakeholders and 'peer-reviewing' the application),<sup>23</sup> and EFSA submits its conclusions to the European Commission. The latter, as a risk manager (EFSA and the RMS are only risk assessors), has the responsibility of elaborating a proposal on whether or not to approve the active substance and the associated conditions. All information on the proposal (grouped into a review report) are subject to internal consultations within the European Commission and then discussed in the Working Group on Legislation, in which all EU Member States are represented. The EU Member States finally vote on these proposals in the Standing Committee on Plants, Animals, Food and Feed (PAFF Committee).<sup>24</sup> If the proposal is approved with a qualified majority<sup>25</sup> of Member States, it is then published in the Official Journal of the EU.

An innovation introduced by Regulation (EC) 1107/2009<sup>26</sup> is the existence of cut-off criteria: no approval is granted when a substance to be used in plant protection products (active substance, safener, co-formulant or synergist) is of high risk for human health (carcinogens, mutagens, toxic for reproduction, endocrine disruptors) or environment (persistent organic pollutant - POP; persistent, bioaccumulative and toxic - PBT; very persistent and very bioaccumulative - vPvB). This means that the approval process is governed, at EU level, according to a **hazard-based approach** (substances are eliminated from the approval process based on the hazard posed by those substances),<sup>27</sup> which distinguishes the European regulatory system as drastically more strict than comparable chemical regulations outside Europe or in other EU sectors (Bozzini 2017). Annex II (Bozzini 2018) to this EIA provides a detailed analysis of the way this principle operates in practice, based, on the one hand, on the provisions of the regulation, and, on the other, on the current practices developed by the competent authorities in Member States.

The hazard-based approach is underpinned by another principle of EU environmental legislation: the **precautionary principle**. This principle allows for precautionary measures

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<sup>22</sup> 'Competent authority' means any authority or authorities of a Member State responsible for carrying out the tasks established under the regulation (Article 3 (30)).

<sup>23</sup> The RMS, the other EU Member States, the applicant and the EFSA are all involved in this process.

<sup>24</sup> Composed of national experts who represent EU governments and public authorities; the PAFF Committee delivers opinions on draft measures that the Commission intends to adopt. More details can be found on the dedicated [webpage](#).

<sup>25</sup> If the qualified majority is not reached (which happened several times with the active substance glyphosate, for instance), an Appeal Committee may be convened. In the absence of a qualified majority in this second phase, the European Commission may take a decision without a qualified majority of Member States (for more details on procedures, see the 'Comitology' Regulation: [Regulation \(EU\) No 182/2011](#) of the European Parliament and of the Council of 16 February 2011, laying down the rules and general principles concerning mechanisms for control by Member States of the Commission's exercise of implementing powers).

<sup>26</sup> Compared to the directive it repealed.

<sup>27</sup> Derogations from cut-off criteria can however be accepted when human exposure is negligible.

when scientific evidence regarding an environmental or human health hazard is uncertain and the stakes are high (Bourguignon 2015). The precautionary principle is simultaneously contested and supported, both in the academic and political environment (Bozzini 2017, p.33; Bourguignon 2015), and there is no unanimity regarding its definition. For the European Commission, the precautionary principle should be referred to 'where scientific information is insufficient, inconclusive, or uncertain and where there are indications that the possible effects on the environment, or human, animal or plant health may be potentially dangerous and inconsistent with the chosen level of protection'.<sup>28</sup> In the case of Regulation (EC) 1107/2009, the regulator adopted a strong version of the principle (Bozzini 2017) by calling for precautions to avoid serious and possibly irreversible harm ('if a substance is found to be intrinsically dangerous, then no risk will be taken and its use will be forbidden' - Bozzini 2017). The approval of the active substances is actually driven by the complementarity of the two principles that inform and support the decision-making process/risk management (Bozzini 2018, Annex II here).

Under Regulation (EC) 1107/2009, the European Commission has to prepare a list<sup>29</sup> of substances identified as 'candidates for substitution' (CfS). These CfS are substances used in the PPPs for which national authorities need to conduct an assessment to establish whether more favourable alternatives to active substances exist, including non-chemical methods. When an active substance is identified as a candidate for substitution, products containing that active substance will have to be subject to a comparative assessment at the time of authorisation and will only be authorised if there are no better alternatives. This approach aims at encouraging more sustainable crop protection. The principles of **substitution** and **sustainability** can therefore be considered as constitutive elements of the European approach on pesticides under Regulation (EC) 1107/2009. As for the other principles, there is also a certain criticism regarding substitution, regarding both its 'value' as a regulatory policy principle and its modalities of application (Bozzini 2017).

The approval of active substances set up by Regulation (EC) 1107/2009 also applies to 'basic substances', meaning those substances that are not predominantly used in plant protection products, but might be useful for plant protection, such as beer, fructose, lecithin, mustard seed powder, and vinegar (Bozzini 2018, Annex II here). For this specific category of substances, the application is submitted by the applicant (including Member States) directly to the European Commission, who then transmits it to EFSA for scientific evaluation (within three months of reception of the mandate). Active substances are approved for default period of 10 years (with a maximum of 15 years for 'low risk substances'). The renewal process is always triggered by a request (application).

In conclusion, the approval of the active substances is a complex process based on the intervention of several actors, which begins in Member States but is decided at European level and relies on clearly established procedures and responsibilities, but also on a mixture of several more or less contested principles, such as hazard, precaution, substitution, and sustainability. At the same time, the 'models' followed by the risk assessors involved in the

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<sup>28</sup> Communication from the Commission on the precautionary principle, European Commission, COM(2000) 1.

<sup>29</sup> This current list comprises 77 candidates for substitution.

approval of active substances (at national and European level) add to the complexity of the whole process. Annex IV (Rimkutė 2018) to this EIA, which takes a comparative perspective of the approaches, methods and practices followed by different risk assessors (national, EU, worldwide), gives an explanation of the various aspects of this intricacy (procedures, independence, transparency, reliability).

#### *Authorisation of PPPs*

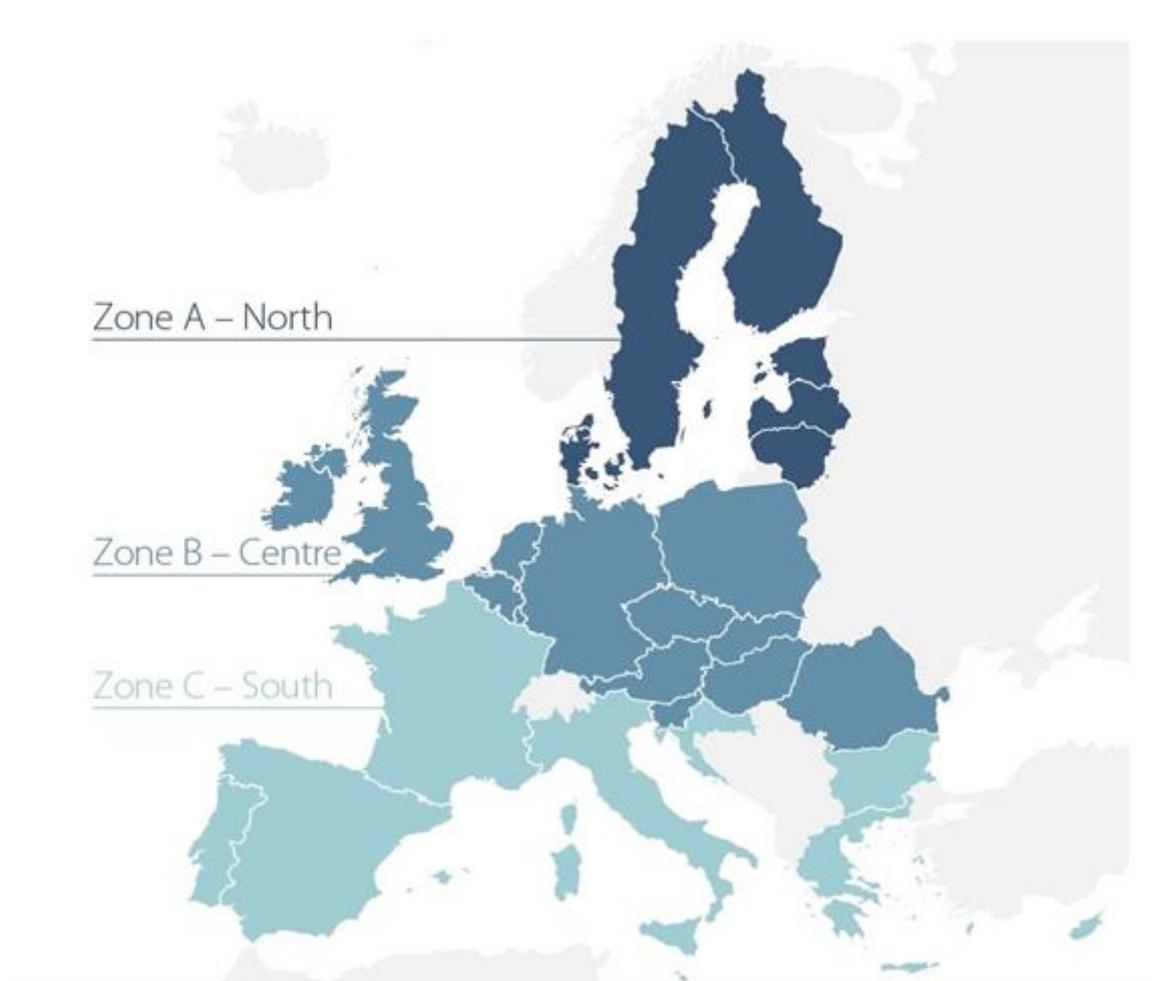
The authorisation of PPPs (containing substances approved at EU level) is a process conducted in Member States by national regulators. Various types of applications can be submitted, according to the intended use of the PPP. The table below presents the requirements and conditions for the different types of applications, as laid down by Regulation (EC) 1107/2009. The authorisation procedure (zonal procedure), as well as the derogations granted under the regulation (mainly emergency authorisation), are detailed in Annex III (Hamlyn 2018), and Annex I (Milieu 2018)) to this EIA. They are considered key elements for the implementation and the functioning of regulation (EC) 1107/2009.

**Table 1 - Overview of the different types of applications that can be submitted**

Type of applications/procedures	Requirements/Conditions
First authorisation/amendment or withdrawal of an existing authorisation of a PPP	<p>The first authorisation of a PPP must undergo the zonal procedure (see description below).</p> <p>The same requirements and process for first authorisations apply for modifying or withdrawing an authorisation.</p>
Emergency authorisation (120 day authorisations) of a PPP (under Article 53)	A Member State can grant temporary authorisations (up to 120 days) to place a PPP (containing non-approved active substances or approved substances with significantly restricted use) on the market for a danger that cannot be contained by any other reasonable means.
Authorisation under the mutual recognition principle	The holder of an authorisation for a PPP in one Member State can apply for authorisation for the same product and the same uses in another Member State, under certain conditions.
Renewal of authorisation of a PPP	<p>The renewal of approval of an active substance triggers an assessment in view of renewal of all PPPs containing that substance.</p> <p>Renewals are carried out at zonal level.</p>
Extension for minor uses	<p>Applications can be made to extend an existing authorisation to include minor uses not already covered by the authorisation.</p> <p>Minor uses refer to the use of chemical pesticides or non-chemical means of crop protection where the potential use is on a not very broad scale, so there is no interest in authorisation from an applicant's perspective (OECD 2014).</p>
Parallel trade permits	A PPP authorised in one EU Member State can be placed on the market in another EU Member State, with a permit, provided that an identical product is already authorised in the second Member State.
Technical equivalence	An active substance can be produced by different methods or from different sources. In this case, technical equivalence of active substances aims at determining the similarity concerning the chemical composition and hazard profile of those active substances.

Regulation (EC) 1107/2009 introduced an authorisation procedure for PPPs based on a 'zonal design' of the EU territory. All Member States were divided into three zones, composed as shown in figure 2 below:

*Figure 2 –EU regulatory zones for PPP authorisation*



*Source: European Parliamentary Research Service (EPRS)*

As regards the application procedure, for each zone, one Member State assesses the complete core dossier, which contains all the data requested in Implementing Regulation (EU) No 284/2013. This is the zonal Rapporteur Member State (zRMS). It has up to one year to issue an assessment, based on which it grants authorisation (or not). The other Member States (cMS) concerned evaluate the assessment of the zRMS and take it into consideration as much as possible, together with any national requirements.

Applications for the authorisation of PPPs take the form of a draft registration report (dRR), to be prepared by the applicant(s), containing three sections: risk management (Part A), data evaluation and risk assessment (Part B), and confidential information (Part C).

Regulation (EC) 1107/2009 requires effective cooperation among Member States within the three geographical zones. In this respect, EU Member States put different forms of cooperation in place in assessing plant protection products, such as Zonal Steering Committees (zSC) and the Interzonal Steering Committee (izSC). A thorough analysis of the authorisation process in practice, as well as of the functioning and benefits of the cooperation established within and among the three zones are given in Annex III (Hamlyn 2018) to this EIA.

The zonal procedure is also supported by one of the principles on which Regulation (EC) 1107/2009 is based, namely **mutual recognition**. First introduced in the legislation on pesticides by Directive 91/414/EEC, mutual recognition relies, in the context of Regulation (EC) 1107/2009, on 'the assumption that any assessment which was already done by one Member State (MS) shall not be repeated by another MS when recognising an authorisation, except for clearly defined circumstances'. The innovation introduced by the 2009 regulation is precisely the link between mutual recognition and the 'climatic' zones, which should facilitate the practical application of the principle.<sup>30</sup> Nevertheless, as national procedures and standards differ when assessing the risks, as shown in Annex III (Hamlyn 2018), one can assume that in practice mutual recognition remains a difficult exercise for the national regulators (Pelkmans 2007).

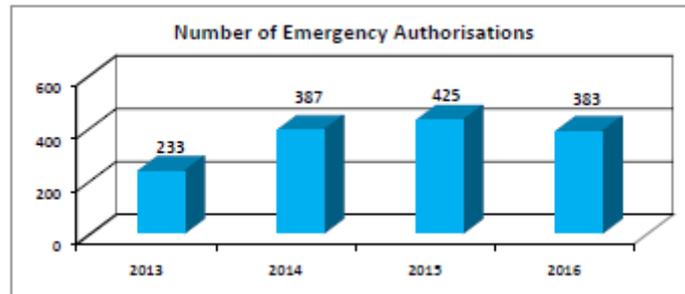
Regulation (EC) 1107/2009 also covers emergency situations that pose a danger to plant production and ecosystems and cannot be contained by any available reasonable means. In such circumstances, since a quick reaction is required, an effective response cannot await the outcome of the normal authorisation process. Therefore, under Article 53 (1), Member States are allowed to grant temporary authorisations for limited and controlled use of PPPs.<sup>31</sup> These authorisations cannot exceed 120 days. The derogations granted on the basis of Article 53 refer to plant protection products containing either non-approved active substances or approved substances with significantly restricted use. Although the regular authorisation process is not followed due to time constraints, the authorities must assess the critical need for emergency authorisations.

The use of this procedure has increased recently, as shown in figure 3 below.

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<sup>30</sup> In Commission staff working document. Report on the Impact Assessment for a Regulation Replacing Directive 91/414/EEC on Plant Protection Products, [SEC\(2006\) final](#), the Commission noted the inefficiency of the principle under Directive 91/414/EEC: 'many companies decide to apply separately for authorisation of the same PPP in each Member State where the PPP is to be placed on the market rather than to apply for mutual recognition' (p.11).

<sup>31</sup> Member States can also grant derogations based on Article 54 for research and development purposes.

Figure 3 – Number of emergency authorisations granted from 2013 to 2016<sup>32</sup>

Source: European Commission

Even though the reasons for the existence of this procedure are obvious, a risk of inappropriate use exists, in the sense that Article 53 can be used as a breach to bypass the regular authorisation procedure (Milieu 2018, Annex I here). This may affect the objective of Regulation (EC) 1107/2009, namely ensuring a high level of protection. Annex I (Milieu 2018) gives more detail on the actual use of derogations by Member States and highlights the most problematic elements related to the use of Article 53.

Regulation (EC) No 1107/2009 sets out clear requirements, procedures and timeframes for authorisation of plant protection products. Nevertheless, the process turns out to be problematic in practice. As the European Commission noted, 'many authorised PPP had not been evaluated against EU standards more than 15 years after the principles for evaluation had been established', 'delays and problems with cooperation between MS were identified for the zonal authorisation system under the regulation', as well as problems concerning 'the misuse of emergency authorisations' (European Commission 2017).

### Controls

Regulation (EC) 1107/2009 provides for control measures, namely record-keeping (Article 67) and monitoring and controls (Article 68).

Several types of obligation are established by Article 67:

- five year record-keeping requirements apply to producers, suppliers, distributors, importers, and exporters of PPPs (to be made available to the competent authorities, under request);
- three year record-keeping obligations concern the professional users of PPPs (to be made available to the competent authorities, upon request);
- third parties (drinking water industry, retailers or residents) may request access to this information by addressing the competent authority. The latter must give

<sup>32</sup> These figures are based on the emergency authorisations communicated to the Commission. As shown in Annex I (Milieu 2018), Member States do not notify the Commission for every emergency authorisation they grant, even if it is mandatory.

access to the information in accordance with applicable national or Community law;

- producers of PPPs must notify the results of any post-authorisation monitoring requested by the competent authorities.
- authorisation holders must provide data relating to the volume of sales of PPPs to the competent authorities of the Member States.

Article 68 sets up monitoring and control obligations for both Member States and the European Commission:

- Member States have control (to enforce compliance with the regulation) and reporting (the scope and the results of the controls) obligations;
- the European Commission has audit obligations (to verify the official controls carried out by the Member States). In addition, the European Commission is required to take action (to adopt legal provision) related to the controls, in particular on the production, packaging, labelling, storage, transport, marketing, formulation, parallel trade and use of plant protection products, as well as to the collection of information and reporting on suspected poisonings.

Nevertheless, according to the amended Article 68 (see Article 161 of Regulation (EU) 2017/625),<sup>33</sup> control and monitoring now lies exclusively with Member States. The new Article 68 reads as follows: 'Member States shall submit to the Commission by 31 August each year a report, for the previous year, on the scope and the outcome of the official controls performed in order to verify compliance with this regulation'. No reference remains to the European Commission's obligations. The new provisions will apply from 14 December 2019.

At the same time, Regulation (EU) 2017/625 enhances the control mechanisms of food and feed law, rules on animal health and welfare, plant health and plant protection products. It includes general provisions on official controls, delegation of control tasks (by the competent authorities), reporting activities, and enforcement, as well as specific rules in relation with plant protection products, such as the official controls undertaken by the competent authorities in relation to PPPs (Article 24).

As regards the requirements on the collection of information and reporting on suspected poisonings, Regulation (EU) 2017/625 states that Commission may, by means of

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<sup>33</sup> Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation), [OJ L 95](#), 7 April 2017.

implementing acts, lay down detailed rules on uniform practical arrangements for the performance of official controls, including on the collection of information, monitoring and reporting on suspected poisonings from plant protection products.

### **Other policy instruments**

As previously mentioned, current EU legislation on plant protection products encompasses a variety of provisions and procedures laid down in different pieces of legislation. The following sections present an overview of this rather broad legislative framework.

#### **Regulation (EC) No 396/2005: Maximum Residue Levels (MRL)**

Regulation (EC) No 396/2005<sup>34</sup> establishes the maximum quantities of pesticide residues (traces) legally tolerated in products of animal or vegetable origin that are intended for human or animal consumption. Maximum residue levels are set by food product and by active substance.<sup>35</sup> All food products for humans and animals are covered.

The regulation is a step forward compared to previous legislation in the field, as it simplifies, clarifies and improves existing procedures. In particular, the regulation:

- lists all EU MRLs; where not explicitly mentioned, the default residue level is < 0.01 mg/kg;
- sets up clear procedures for application;
- divides responsibilities between European Commission, the European Food Security Authority (EFSA) and Member States;
- introduces coordinated tools (such as the sampling programme);<sup>36</sup>
- requires the information on MRLs to be made easily accessible.

Under Regulation (EC) No 396/2005, all interested parties<sup>37</sup> may submit an application to a Member State in view of establishing or modifying a maximum residue level for an active substance.

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<sup>34</sup> Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC, [OJ L 70](#), 16 March 2005.

<sup>35</sup> The MRLs for all crops and pesticides can be found in the Commission's [MRL database](#).

<sup>36</sup> See Commission Implementing Regulation (EU) No 400/2014 of 22 April 2014 concerning a coordinated multiannual control programme of the Union for 2015, 2016 and 2017 to ensure compliance with maximum residue levels of pesticides and to assess the consumer exposure to pesticide residues in and on food of plant and animal origin, [OJ L 119](#), 23 April 2014.

<sup>37</sup> Such as, Member States, farmers, NGOs from the health sector, the plant protection and agri-food industry, and third countries that import food products into the EU.

In the framework of its REFIT programme, the European Commission is currently carrying out an evaluation of the implementation of Regulation (EC) No 396/2005, checking for synergies, gaps, inefficiencies and administrative burdens.<sup>38</sup>

**Regulation (EC) 1272/2008: classification, labelling and packaging of substances and mixtures (CLP)**

Regulation (EC) 1272/2008<sup>39</sup> aims at protecting workers and consumers by informing them of the hazards associated with chemicals. The regulation sets out common rules for classification, labelling and packaging, in line with the globally harmonised system (GHS).<sup>40</sup>

As regards the classification of chemical substances and mixtures, the regulation establishes three different hazard categories: physicochemical, health and environmental. Companies that want to market a substance or a mixture have to identify the hazards posed by the chemical and to classify the substance/mixture accordingly. Moreover, some cut-off criteria for the approval of active substances are based on the classification established by Regulation (EC) 1272/2008.<sup>41</sup>

The European Chemicals Agency (ECHA) must be notified of the classification and labelling of registered or hazardous substances to be put on the market, so that it can include them in the classification and labelling inventory that the regularly updated by the agency.

Member State Competent Authorities, manufacturers, importers or downstream users of a substance can contact the ECHA with a proposal of harmonised classification and labelling. There are five situations in which such requests may occur, the last two being reserved only for Competent Authorities:

- for CMR (carcinogenicity, mutagenicity, reproductive toxicity) or respiratory sensitizer;
- when classification of a substance at EU level, required for other hazards, is justified;
- to add one or more new hazard classes to an existing entry;

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<sup>38</sup> REFIT - Evaluation of the EU legislation on plant protection products and pesticides residues (European Commission [website](#)).

<sup>39</sup> Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006, [OJ L 353](#), 31 December 2008.

<sup>40</sup> For more details, see the United Nations' [report](#) 'Globally Harmonized System of Classification and Labelling of Chemicals (GHS)', 2011.

<sup>41</sup> For hazards of highest concern (carcinogenicity, mutagenicity, reproductive toxicity (CMR) and respiratory sensitizers), as well as for other substances, considered individually, harmonised classification and labelling (CLH) were adopted to contribute to better risk management.

- to revise an existing harmonised entry;
- when the substance to be considered is an active substance in biocidal or plant protection products.

Within the harmonised classification and labelling procedure established by the CLP Regulation, active substances that were approved under Regulation (EC) 1107/2009 may also be assessed by ECHA (as was the case for glyphosate, for instance).<sup>42</sup>

#### **Directive 2009/128/EC: Sustainable Use Directive (SUD)**

Directive 2009/128/EC<sup>43</sup> has its origins in the 2006 thematic strategy on the sustainable use of pesticides.<sup>44</sup> Its goal is to achieve a safer, reduced and more precise use of pesticides in the EU. At the same time, the regulation encourages 'the development and introduction of integrated pest management' as well as 'alternative approaches or techniques such as non-chemical alternatives to pesticides'.

The directive introduces a range of actions to be achieved by Member States:

- adopt national action plans to implement the actions indicated in the directive (training of users, advisors and distributors of pesticides, regular control of pesticide application equipment, interdiction of aerial spraying (exceptions granted only under strict conditions), protection of the aquatic environment and drinking water supply, limitation of pesticides use in sensitive areas, and information and awareness raising about pesticide risks).
- support integrated pest management (IPM), giving 'careful consideration' to 'all available plant protection methods and subsequent integration of appropriate measures that discourage the development of populations of harmful organisms and keep the use of plant protection products and other forms of intervention to levels that are economically and ecologically justified and reduce or minimise risks to human health and the environment' (Article 3 of the directive). General principles of IPM are presented in Annex III of the directive.

The directive does not prevent Member States from applying the precautionary principle in limiting or prohibiting the use of pesticides under specific circumstances.

In October 2017, the European Commission published a report<sup>45</sup> on Member States' national action plans and on progress in the implementation of Directive 2009/128/EC.

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<sup>42</sup> European Chemical Agency, [Glyphosate not classified as a carcinogen by ECHA](#).

<sup>43</sup> Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides, [OJ L 309](#), 24 November 2009.

<sup>44</sup> Communication from the Commission to the Council, the European Parliament, the European Economic and Social Committee and the Committee of the Regions - A thematic strategy on the sustainable use of pesticides, [COM\(2006\) 372](#) final.

<sup>45</sup> Report from the Commission to the European Parliament and the Council on Member State National Action Plans and on progress in the implementation of Directive 2009/128/EC on the sustainable use of pesticides, [COM\(2017\) 587](#) final. See also Overview Report on the Implementation

The report concluded that, although the 'directive offers the potential to greatly reduce the risks derived from pesticide use', in practice, 'until it is more rigorously implemented by Member States, these improvements are limited, and certainly insufficient to achieve the environmental and health improvements the directive was designed to achieve'.<sup>46</sup> Significant gaps in many areas of the plans, as well as the lack of clear targets as regards integrated pest management were also highlighted by the report. In this context, the Commission will undertake several measures in support of Member States, such as improving existing IT tools, guidance and data collection systems.

### **Implementing regulations**

To ensure uniform implementation of Regulation (EC) 1107/2009 in all Member States, the European Commission adopted several implementing regulations.

**Regulation (EU) 540/2011 (approved substances).**<sup>47</sup> Regulation (EU) 540/2011 lays down the list of active substances approved for use in plant protection products, as established by Regulation (EC) No 1107/2009. All substances listed in the Annex of Regulation (EU) 540/2011 are governed by the same general provisions:

- considering the conclusions of the review report for each substance, in order to implement the uniform principles (referred to in Article 29(6) of Regulation (EC) No 1107/2009);
- all reports (except for confidential data) should be kept or made available by Member States to all interested parts.

**Regulation (EU) 546/2011 (uniform principles for evaluation and authorisation of PPPs).**<sup>48</sup> Regulation (EU) 546/2011 sets out uniform principles as regards the evaluation and authorisation of plant protection products, according to the provisions of Regulation (EC) No 1107/2009 (Article 29(6)).

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of Member States' Measures to achieve the sustainable use of pesticides under Directive 2009/128/EC, [DG \(SANTE\) 2017-6291](#).

At the time of publication of this EIA (on Regulation (EC) 1107/2009 on the placing of PPPs on the market), the Ex-Post Evaluation Unit of DG EPRS is conducting an EIA study on the implementation of Directive 2009/128/EC on the sustainable use of pesticides in support of a dedicated implementation report of the Environment, Public Health & Food Safety Committee of the European Parliament.

<sup>46</sup> Report from the Commission to the European Parliament and the Council on Member State National Action Plans and on progress in the implementation of Directive 2009/128/EC on the sustainable use of pesticides, [COM\(2017\) 587](#) final, p. 17.

<sup>47</sup> Commission Implementing Regulation (EU) No 540/2011 of 25 May 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the list of approved active substances, [OJ L 153](#), 11 June 2011.

<sup>48</sup> Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products, [OJ L 155](#), 11 June 2011.

**Regulation (EU) 547/2011 (labelling requirements for PPPs).**<sup>49</sup> This regulation establishes requirements for the labelling of plant protection products that must contain:

- standard indications for special risks to human or animal health or to the environment (as provided for in Annex II).
- standard indications for safety precautions for the protection of animal or human health or the environment (according to Annex III).

**Regulations (EU) 283/2013 (setting data requirements for active substances)**<sup>50</sup> and **Regulation (EU) 284/2013 (setting data requirements for plant protection products).**<sup>51</sup>

Both Regulations (EU) 283/2013 and (EU) 284/2013 update data requirements for active substances and plants protection products, respectively. This update, which occurred only two years following the adoption of another regulation on data requirements (Regulation (EU) 544/2011)<sup>52</sup> appeared necessary in the light of 'current scientific and technical knowledge'. Data requirements cover several areas: physical and chemical properties of the active substance, residues, toxicological and metabolism studies, as well as ecotoxicological studies, and open peer reviewed literature. As the approval of active substances relies on (technical and scientific) data provided by the applicants (industry), the question of data requirements led in practice to heated discussion, especially in the context of the debate on glyphosate (as shown in Milieu 2018, Annex I here and Rimkutė 2018, Annex IV here).

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<sup>49</sup> Commission Regulation (EU) No 547/2011 of 8 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards labelling requirements for plant protection products, [OJ L 155](#), 11 June 2011.

<sup>50</sup> Commission Regulation (EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, [OJ L 93](#), 3 April 2013.

<sup>51</sup> Commission Regulation (EU) No 284/2013 of 1 March 2013 setting out the data requirements for plant protection products, in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market, [OJ L 93](#), 3 April 2013.

<sup>52</sup> Commission Regulation (EU) No 544/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards the data requirements for active substances, [OJ L 155](#), 11 June 2011.

## Implementation of Regulation (EC) 1107/2009 on the placing of plant protection products on the market – key findings

This section presents and analyses the findings on the practical implementation of the regulation against the criteria for evaluation presented above.

### Relevance

This evaluation criterion looks at whether the set of policy (sub-objectives) laid down by Regulation (EC) 1107/2009 sufficiently reflect current needs.

The regulation put forward ambitious objectives that cover:

- health issues: to ensure a high level of protection for humans and animals;
- environmental concerns: to protect the environment;
- agricultural matters: to provide farmers with the protection tools they need and to safeguard the competitiveness of the EU agriculture;
- internal market issues: improving functioning through harmonisation.

As stated by Article 1(3) of the regulation: ' the purpose (...) is to ensure a high level of protection for both human and animal health and the environment and to improve the functioning of the internal market through the harmonisation of the rules on the placing on the market of plant protection products, while improving agricultural production'.

The assessment of relevance of the objectives defined under PPPR relies exclusively<sup>53</sup> on the opinions provided by stakeholders within the survey on the implementation of the regulation carried out in the framework of this evaluation (Milieu 2018, Annex I here).

It appears from the survey that, overall, the objectives of Regulation (EC) 1107/2009 are still relevant to the current needs. Nonetheless, depending on the respondents' profile, the views on what objectives should be emphasised may differ, to the level of antagonism in some cases. As an example, while for certain respondents (environmental NGOs, individuals belonging to national competent authorities and some competent authorities) improving the functioning of the internal market and agricultural production are no longer relevant, for others (a manufacturers' association) the PPPR contains unnecessary measures aimed at meeting the health and environment objectives that adversely impact the international competitiveness of EU agriculture.

Another element on which certain stakeholders (farmers' association) commented relates to harmonisation. Harmonisation of procedures under Regulation (EU) 1107/2009, is an objective to be pursued further, according to some stakeholders

In addition, it appears from stakeholders' opinions, that new elements should be considered under PPPR, leading to the definition of new objectives. In this context, according to the respondents, several elements are worth mentioning, such as: developing new technologies, investing in the use of naturally occurring substances and the protection

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<sup>53</sup> From a methodological perspective, this criterion can only be assessed based on stakeholders' opinions.

of farm ecosystems, stimulating use of substances with low risk, or promoting non-animal methods for assessment of risks of substances and mixtures. Both desk research and environmental and health NGOs (Milieu 2018, Annex I here) highlighted that data requirements under the assessment of active substances and PPPs should better address new emerging risks concerning, inter alia, combined effects of residues of PPPs and of pesticides preparations, non-intentionally added substances, PPP transformation processes, nanomaterials, and EDCs.

It can be concluded that if the objectives of Regulation (EU) 1107/2009 generally meet the current needs, there is room to broaden the approach in order to better cover the various concerns in the field that would require the regulation to consider new objectives. At the same time, it should be noted that the opinions on the importance and prioritisation of objectives, as well as on the elements to be added are highly dependent on the specific (group) perceptions of actors interacting with the regulation.

## Coherence

Evaluation of coherence checks whether the objectives and policy instruments established by Regulation (EC) 1107/2009 and their practical implementation is in line with other related EU policies and legislation.

The assessment against the 'coherence' criterion was informed by the two main data sources of this evaluation: the results from desk research and the stakeholder survey conducted in the frame of the study (Milieu 2018, Annex I here), which were used as a main source, and complemented with the results of the study on the authorisation of PPPs (Hamlyn 2018/Annex III here).

Taking all answers from respondents into consideration (regardless of their recurrence), we can group the inconsistencies observed into the following categories:

- conflicts with other EU environmental legislation and EU policies;
- inconsistency with the objectives and the provisions of the regulation.
- failure to comply with general or environmental principles.

It is of note that, in their answers, the stakeholders considered both the legal provisions of Regulation (EC) 1107/2009 and their implementation. The following lines present the different categories of answers mentioned above in more detail.

Based on the views of environmental and/or health NGOs, associations representing manufacturers, and farmers' associations participating in the survey, it appears that both the objectives of the regulation and the practical implementation of its provisions are not in line with the objectives and the implementation of EU agricultural policy (participating competent authorities were divided on the issue). One respondent (manufacturer) considered that the provisions of the PPPR and its implementation do not support competitive and productive agriculture and even affects agricultural output. Some stakeholders also referred to inconsistencies with food safety and food security, public health, consumer protection, climate change and internal market policies.

Perceived inconsistencies with a number of pieces of EU environmental law were also highlighted by the stakeholders, such as:

- Regulation on registration, evaluation, authorisation and restriction of chemicals (REACH)<sup>54</sup>, Biocidal Product Regulation (BPR)<sup>55</sup> and Regulation on classification, labelling and packaging of substances and mixtures (CLP)<sup>56</sup> and the potential need to streamline the authorisation procedure under the PPPR and BPR.
- Sustainable Use of Pesticides Directive (SUD):<sup>57</sup> the goals of SUD are not reflected in the approval criteria. In addition, one respondent (farmer association) said that the complementarity between SUD and the rules on plant health care should contribute to a more supportive environment that stimulates the development of sustainable plant care strategies. Barriers in the PPPR authorisation procedure impede the development of IPM (Article 53 authorisations involving aerial spraying go against the principles of Directive 2009/128/EC)
- hazard vs risk approach: the hazard-based approach adopted by the regulation contradicts the risk-based approach specific to many other pieces of legislation (manufacturers, competent authorities); one respondent (farmers' association) added that the hazard-based approach also contradicts General Food Law principles.
- individual respondents also considered that the regulation is not in line with the 3R requirements (principles of Replacement, Reduction and Refinement) of Directive 2010/63/EU on animal experiments, nor with the animal welfare (as regards the information/testing requirements by EFSA under Regulation (EC) 1107/2009); there are not enough synergies with the Water Framework Directive; and the PPPR contradicts EU organic and baby food legislation.

As indicated, it appears from the sources that inform this section that the implementation of the regulation fails to comply with some of its own objectives and provisions.

The fulfilment of the objectives defined by Regulation (EC) 1107/2009 should take the principles of integrated pest management (IPM) into consideration, including good plant protection practice and non-chemical and natural methods of plant protection and pest and crop management, wherever possible. However, the findings of this evaluation highlighted limited application of IPM in Member States, and in particular, limited use of low-risk plant protection products (because, for instance, of low profits obtained by

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<sup>54</sup> Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, [OJ L 396](#), 30 December 2006.

<sup>55</sup> Regulation (EU) No 528/2012 of the European Parliament and of the Council of 22 May 2012 concerning the making available on the market and use of biocidal products, [OJ L 167](#), 27 June 2012.

<sup>56</sup> Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006, [OJ L 353](#), 31 December 2008.

<sup>57</sup> Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides, [OJ L 309](#), 24 November 2009.

marketing niche products).<sup>58</sup> The evaluation of the practical implementation of derogations under Article 53 of the regulation also showed that IPM and organic agriculture are among the areas where alternatives to the PPPs authorised under derogation are missing (few products are authorised, so farmers resort to Article 53 on derogations) (Milieu 2018, Annex I here). Some stakeholders (representing organic agriculture) indicated that there were barriers in the authorisation of natural substances (because of ill-adapted criteria) and there was no guidance for risk assessment for some substances of natural and mineral origin (Milieu 2018, Annex I here). The case studies showed that Article 53 authorisations are being used to maintain the use of PPPs which have been withdrawn from the EU market because of the evidence of significant environmental and human health impacts (this is explained by the fact that, since the crop system in which they are used was constructed on the use of these PPPs and would therefore have to adapt economically to a different cropping system if they no longer had access to the chemicals).

Regulation (EC) 1107/2009 is underpinned by several principles (mutual recognition, precaution, sustainability, substitution); it appears from both empirical data and desk research that there is a lack of consistency either in the interpretation or the application of these principles.

First, despite an improvement in the implementation of EU pesticides policy scored by Regulation (EC) 1107/2009 compared to that under Directive 91/414/EEC, the implementation of the regulation is not fully coherent with the principle of mutual recognition (Milieu 2018, Annex I here). The reason seems to be the lack of confidence between Member States to apply this principle in the authorisation of PPPs, which leads them to repeat evaluation of the same products.

As for the other principles (precaution, sustainability<sup>59</sup> and substitution), they are looked at in more detail in the research dedicated to the authorisation process (Hamlyn 2018/Annex III here). The findings of this study show inconsistencies in the understanding and application of these principles. It is of note that the problem of inconsistency is greater with respect to the precautionary principle and sustainability. The problem with substitution relates more to how ambitiously Member States apply it (at the same time, it is a new development, so not much experience exists as yet).

The main elements that could explain these inconsistencies are:

- the principles are not clearly defined and there is not enough guidance from the European Commission on how to apply and interpret them in the context of PPP authorisations;
- lack of harmonised interpretation and methods of application of the precautionary principle at zonal and inter-zonal level;
- it is not clear whether the competent authorities are required to take sustainability into account in the evaluation and authorisation procedures.

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<sup>58</sup> Commission report on Member State national action plans and on progress in the implementation of Directive 2009/128/EC on the sustainable use of pesticides (COM(2017)587 final) as quoted in Milieu 2018, Annex I here.

<sup>59</sup> Although there is disagreement over whether the regulation is underpinned by the principle of sustainability, as the PPPR does not mention sustainability as such.

Based on the information provided by the sources indicated, one can conclude that the implementation of Regulation (EC) 1107/2009, as well as some of its objectives and instruments (as defined by law), contradict certain objectives and provisions defined in other pieces of legislation and EU policies, as well as some of its own provisions and principles.

## **Effectiveness**

The effectiveness criterion measures whether the set policy objectives – related to human/animal health, environment, internal market and agricultural production – are being met. The achievement of the objectives depends on the practical implementation of the relevant policy instruments. In the specific context of Regulation (EC) 1107/2009, the relation between objectives and instruments could be illustrated by the following two examples:

- The two main harmonisation instruments of the PPPR - 'approval of substances' and 'authorisation of plant protection products' (containing approved substances) – are designed to ensure that the marketing of substances and PPPs follows a single standard, guaranteeing human, animal and environmental safety as well as effectively fighting pests; at the same time, these two instruments support an effectively functioning internal market, where approved substances and authorised PPPs move freely because they comply with a single harmonised safety standard; the availability of safe and effective PPPs is among the factors promoting improved agricultural production – i.e. sustainable agricultural production delivering safe agricultural products of high quality.
- The 'enforcement of the regulatory (approval and authorisation) decisions' instrument, which is also enshrined in the PPPR, aims at ensuring that the PPPs on the market and in use comply with the conditions laid down in the relevant authorisations and with the provisions of the PPPR.

The above examples are illustrative. More developed links between objectives and instruments could certainly be established.<sup>60</sup>

In order to assess whether the PPPR objectives are being achieved, one needs to look at the practical implementation of its instruments, as detailed in the sections below.

## **Practical implementation of the main instruments of the PPPR**

The day-to-day implementation of all PPPR instruments<sup>61</sup> is assessed as problematic by a majority of stakeholders (across all categories with the exception of Member States' competent authorities<sup>62</sup> (CA)) (Milieu 2018, Annex I here). In particular, the

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<sup>60</sup> For more details, see the intervention logic used by the Commission in its REFIT Roadmap, published in November 2016.

<sup>61</sup> With the exception of parallel trade with PPPs and their labelling. The practical implementation of these two instruments is therefore not considered in this chapter because obviously they are not associated with problems according to stakeholders' opinions. However, parallel trade was found to be problematic by this project in the context of enforcement and is therefore considered in the dedicated sub-section as appropriate.

<sup>62</sup> It should be noted that CAs are divided on whether mutual recognition (both inside and between the zones) is problematic.

implementation of three instruments is deemed problematic. These are: first, approval (renewals of approvals) of active substances; second, authorisation (renewal of authorisation) of PPPs both under the standard procedure and under derogation; and, third, enforcement by Member States. The practical implementation and related problems of these three main instruments are presented below.

#### **Approval (renewal of approval) of active substances**

It should be recalled that this procedure has three stages and three main actors that intervene at every stage: the stage of hazard identification and initial risk assessment (performed by Member States' competent authorities), the stage of risk assessment review (performed by Member States' competent authorities and the European Food Safety Authority), and the stage of risk management/decision-making (performed by the European Commission together with Member State representatives).<sup>63</sup>

The available evidence shows<sup>64</sup> that three main factors influence the practical implementation of the approval (renewal of approval) of active substances: first, the evaluation approach to hazard identification and initial risk assessment of active substances (as established by law) and its practical implementation; second, the performance of national competent authorities (in their role as rapporteur Member State), and, third, the transparency aspects of the procedure.

#### *The evaluation approach to hazard identification and initial risk assessment of active substances (as established by law) and its practical implementation*

The available evidence shows that the evaluation approach to hazard identification and initial risk assessment (as established by law) and its practical implementation give rise to concerns. As a result, they are vividly debated by stakeholders, regulators and scientists. Both are presented below, illustrated with examples where appropriate.

##### A) Concerns related to the evaluation approach (as established by law)

The findings show that the evaluation approach established by the regulation gives rise to controversy as to its practical implications. In particular, the main controversial points refer to: 1. who should produce the evidence for evaluations, and, 2. the 'hazard-based' approach (as opposed to a 'risk-based' approach).

##### ➤ Who should produce evidence for evaluations?

Regulation (EC) 1107/2009 requires applicants to prove that the substance they want to have approved and marketed is safe. This creates an obligation for the applicant

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<sup>63</sup> It is of note that a CA made a proposal that, for the sake of lowering costs and ensuring a uniform assessment of all substances, all the evaluation work related to approvals (renewals of approvals) of active substances (including basic substances), and also to setting the maximum residue levels should be made at EU level only (i.e. without the involvement of Member States as rapporteurs and co-rapporteurs).

<sup>64</sup> This section follows the results of: first, the desk research section of the study (Milieu 2018) published under Annex I to this EIA and the results from the stakeholder survey published in the latter study; second, the results from the study published under Annex II to this EIA (Bozzini 2018), and; third, the results from the study published under Annex IV to this EIA (Rimkutė 2018).

(manufacturer of the substances) to perform the relevant scientific tests. If the tests give evidence that the substance does not present hazardous (cut-off) properties, it will be further assessed against the risk(s) it poses and if no unacceptable risk(s) for human/animal health and the environment are identified, the substance has a chance to be successfully approved at EU level.

This approach to the production of evidence is disputed by stakeholders (mainly environment/health NGOs) who consider that industry-produced tests are inherently biased and therefore cannot serve as a reliable evidence base for evaluations (Bozzini 2018, Annex II here). Critics advocate for a radical change in the procedure, demanding that applicants pay the costs of the regulatory studies that must be commissioned by public authorities to external laboratories.<sup>65</sup> CAs highlight two arguments supporting the quality and reliability of the current system: first, studies must be carried out according to established protocols and to the principles of Good Laboratory Practice (GLP), to guarantee their quality. Second, according to CAs, applicants are obliged to submit all original findings on which studies and reports are based,<sup>66</sup> so that evaluators are in a position to carry out an original interpretation of data (Bozzini 2018, Annex II here).

Against this background, the use of scientific peer reviewed open literature in the evaluation of substances, required by the legislation,<sup>67</sup> is promoted as a possible tool to balance the claimed deficiencies of the established 'burden of proof' system, which is currently fed almost entirely by industry produced studies as required by the PPPR and related legal acts. Health/environment NGOs claim that scientific peer reviewed open literature is often set aside on debatable grounds, and in particular because those studies have not been carried out according to OECD test standards (including Good Laboratory Practice), even though some of these studies are not suitable for the use of OECD standards<sup>68</sup> (Milieu 2018, Annex I here). Scientific peer reviewed open literature is also set aside because it is sometimes unclear whether peer reviewed studies use the active substance alone or a commercial formulation<sup>69</sup> and no information is provided on the level

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<sup>65</sup> [Corporate Europe Observatory](#) (2017) as quoted in Bozzini 2018, Annex II here.

To the contrary, the industry complains that scientific data submitted by applicants were not taken sufficiently into account due to a lack of dialogue between evaluators and applicants, the rules on admissibility of studies, and the politicisation of certain dossiers (Milieu 2018, Annex I here).

<sup>66</sup> As required by Commission Regulation (EU) 283/2013 setting out the data requirements for active substances, in accordance with Regulation (EC) No 1107/2009. See in particular point 1.5 of the introduction of the Annex to the Regulation.

<sup>67</sup> The current legal framework requires applicants to submit (as an element of the application dossier) any relevant peer reviewed open literature sources.

<sup>68</sup> This opinion is illustrative of the debate provoked by the renewal of the approval of the active substance glyphosate. In particular, this case highlighted the difficult trade-off between regulatory science and research science and between the need for standard testing criteria and the need for research designs that are innovative and promising. See more in E. Bozzini, *Pesticide Policy and Politics in the European Union. Regulatory Assessment, Implementation and Enforcement*, Palgrave Macmillan, 2017 (as quoted in Milieu 2018, Annex I here).

<sup>69</sup> This is of particular relevance to the case of glyphosate, where IARC used peer reviewed studies considering a commercial formulation of glyphosate (i.e. the active substance glyphosate combined with a safer substance, which was banned in the EU following EFSA's opinion), while, in the framework of the approval procedure established in the EU, the relevant EU evaluators and risk

of impurity. Furthermore, there are no standards for reporting peer reviewed studies, so the information available is generally limited/partial (Bozzini 2018, Annex II here).

This evaluation found some significant issues under discussion, in particular on the relevance, reliability, accessibility and transparency of scientific peer reviewed open literature (Bozzini 2018, Annex II here). This type of data source is often considered to be completely free from industry influence, which however, as shown by the results of this research project, could not always be taken for granted. It should also be noted that such literature is available mostly for substances that would apply for renewal of the approval, and virtually non-existent for new ones, which renders any claim to base assessments on this source highly unrealistic. All considered, so far the main function of peer reviewed literature has been to perform 'a signal function', meaning that studies can include findings that alert evaluators to adverse effects that are not seen via standard testing. Some CAs<sup>70</sup> even question the real added value of the assessment of peer reviewed literature (Bozzini 2018, Annex II here).

Another issue (which arises in the context of both approvals of substances and authorisations of PPPs)<sup>71</sup> relates to the asymmetry of information between applicant companies and public (national and EU) authorities that evaluate the applications and take decisions.<sup>72</sup> In the context of approval of substances, the current 'burden of proof' system described above' is one reason that the ability of national and EU authorities (involved in the approval procedure) to achieve and maintain independence has been questioned,<sup>73</sup> since they assess active substances (and PPPs) based almost exclusively on information submitted by the applicant companies (Pelaez, V. et al, 2013).<sup>74</sup>

In the context of the concerns presented above, the Commission has acknowledged<sup>75</sup> the need to strengthen the governance framework for the conduct of studies, and has

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managers dealt with pure substances (i.e. glyphosate) only (Bozzini 2018, Annex II here and Rimkute 2018, Annex IV).

<sup>70</sup> Interviewed in the context of the study published in Annex II to this EIA (Bozzini 2018).

<sup>71</sup> As regards authorisation of PPPs see in Hamlyn 2018, Annex III here.

<sup>72</sup> The issue arises in the context of both approval of active substances (at EU level) and authorisation of PPPs (at national level).

<sup>73</sup> As will be shown in the section on authorisations of PPPs below (but also relevant for CAs' work on approvals), CA independence could be undermined in two further cases: when CAs are funded by the government only (i.e. when they do not charge applicants); as well as by the fact that only a few of the Member States examined report restrictions on recruiting CA Heads from industry or taking employment in industry following their appointment, which may risk undermining their independence from industry. See more details in the study (Hamlyn 2018) published in Annex III to this EIA.

<sup>74</sup> Pelaez, V. et al, Regulation of pesticides: A comparative analysis. Science and Public Policy, 40, 644-656, 2013 as quoted by Milieu 2018, Annex I here.

<sup>75</sup> Commission response to the [European Citizens Initiative 'Ban glyphosate and protect people and the environment from toxic pesticides'](#). The initiative received a total of 1 070 865 statements of support from 22 Member States as of 6 October 2017. This initiative calls on the Commission and Member States to: ban glyphosate-based herbicides, exposure to which has been linked to cancer in humans, and has led to ecosystems degradation; ensure that the scientific evaluation of pesticides for EU regulatory approval is based only on published studies, which are commissioned by competent

highlighted potential actions. In particular, in its reply to the European Citizenship Initiative 'Ban glyphosate and protect people and environment from toxic pesticides', the Commission recalled that the system in place for active substances is similar to those applied in other sectors, such as industrial chemicals, food additives, biocides and pharmaceuticals. In the Commission's words, the principle is that public money should not be used to commission studies that will eventually help industry put a product on the market, especially since individual studies cost between several thousand to several million euro each, and each dossier can contain up to several hundred studies. This is why the PPPR places the burden of proving that an active substance and the products containing it can be used safely and generating the necessary information for such a demonstration on those who stand to benefit from its approval, i.e. the companies manufacturing or marketing the substance and the products. Studies required for application dossiers are commissioned directly by industry on their own initiative. According to the Commission, there are claims that, since industry pays directly for the conduct of the studies, this may be an incentive for the laboratories to deliver results that please their clients in order to secure future business. However, test facilities carrying out such studies are subject to rigorous inspections for their adherence to the principles of good laboratory practice (GLP), and if these test facilities are found to manipulate the results of studies either as part of a regular inspection or a specific study audit, they will lose their GLP certification.<sup>76</sup> For the Commission, a systematic approach that would oblige public authorities to commission all studies for active substances and PPP - while maintaining the principle that the costs are covered by industry - would prove to be challenging given the high number of studies required to support all applications for active substance approval and product authorisation. The Commission announced its intention to submit a legislative proposal to strengthen the governance for the conduct of such studies by May 2018, which could include, for example, the involvement of public authorities in the process of deciding which studies need to be conducted for an application,<sup>77</sup> enhanced auditing of studies conducted in accordance with the principles of Good Laboratory Practice, measures to increase transparency as to the findings of such studies, and the possibility to exceptionally commission ad hoc studies in case of serious doubts or conflicting results, for example, in case of widely used substances. The Commission submitted its proposal on 11 April 2018. The main elements of the Commission proposal are presented in Milieu 2018, Annex I here.

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public authorities instead of the pesticide industry; and set EU-wide mandatory reduction targets for pesticide use, with a view to achieving a pesticide-free future.

<sup>76</sup> Nevertheless, it should be acknowledged that the current approach could be prone to misuse - even though laboratories bear responsibility for the quality of tests under the GLP standard, this is in no way a guarantee that in practice they duly comply with the standard and that all findings from the tests performed are included in the final study protocols which subsequently make up the application dossiers submitted to the CA of the rapporteur Member State. This research project was not able to review the results from inspections of laboratories. Nonetheless, a systematic review of the results from laboratory inspections should be subject to further research effort.

<sup>77</sup> It is of note that, according to Commission Regulation (EU) 283/2013 (prescribing the type and characteristics of tests to be performed), CAs are already supposed to be involved in the decisions on the type of studies to be submitted. Furthermore, during the pre-submission stage, those issues are discussed by applicants and CAs (Bozzini 2018, Annex II here).

➤ 'Hazard-based' or 'Risk-based' evaluations?

In contrast to the previous regulatory system,<sup>78</sup> Regulation (EC) 1107/2009 marked a considerable shift in the evaluation approach by introducing what is known as 'hazard-based' evaluation, which means that each substance is first evaluated for its intrinsic hazardous properties. The evaluators (national competent authorities) use criteria laid down in the regulation itself. Those are known as 'cut off' criteria, i.e. if a substance shows hazardous properties against one of those criteria, the evaluation process ends at the hazard identification stage and a risk assessment is not performed. Therefore, under the new regulatory regime, decisions about active substances are taken on the basis of their intrinsic potential to cause harm, rather than on the likelihood of such harm to occur.

At the time of adoption of the regulation, stakeholders expected that the application of the 'hazard-based' approach would lead to an unnecessary ban on dozens of substances that are potentially hazardous but not risky under real conditions of use (Bozzini 2018, Annex II here). For this reason, the 'hazard-based' approach has opponents, mainly across the industry but also among some CAs. In particular, the industry claims that the current approach is too precautionary, not proportionate to the risks to be managed, not relevant to realistic field conditions and that it does not sufficiently consider the exposure to the identified hazards and relevant risks (Milieu 2018, Annex I here); as regards exposure aspects, animal health NGOs claim that the current hazard-based approach leaves out (in their words) exposure considerations and leads to numerous unnecessary in-vivo testing in animals, in contradiction with the EU's objectives to reduce tests involving animals (Milieu 2018, Annex I here).

However, the results of this evaluation show, that there is little evidence – so far – that active substances have been banned on the sole basis of their intrinsic properties (Bozzini 2018, Annex II here). In particular, bans have been numerous and significant, but they have not resulted from the direct application of cut-off criteria. Instead, full assessments have been performed, taking into account the entire range of toxicological, ecotoxicological and environmental hazards and their respective likelihood. This means that non-approvals of active substances have resulted from the application of strict risk assessment criteria, and therefore that risks associated with non-approved active substances have been evaluated as too serious and/or too uncertain to be taken. Nevertheless, the industry claims that the features of the current regulatory system prevent manufacturers from submitting applications for new substances, and has prevented them from submitting applications for renewals of previously approved substances. In this sense, it could be argued that the hazard-based approach has an indirect effect on the range of available active substances with all relevant impacts on farmers and the application of the integrated pest management system<sup>79 80</sup> (Bozzini 2018, Annex II here).

B) Concerns related to the practical implementation of the evaluation approach

Concerns can be grouped under two broad categories: the status of harmonisation of the evaluation approach and the practical work of national and EU authorities involved in the evaluation of substances. Both groups of concerns are presented below:

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<sup>78</sup> Under Directive 91/414/EEC which was repealed by Regulation (EC) 1107/2009.

<sup>79</sup> Under Directive 2009/128/EC on the sustainable use of pesticides.

<sup>80</sup> See more on the industry estimates of impacts due to the application of the hazard-based approach in the study Milieu 2018, Annex I here.

➤ Status of harmonisation of the evaluation approach

The harmonisation of criteria and procedures for the approval of active substances is a necessary precondition for the achievement of the PPPR objectives, as this would ensure a basis for uniform implementation action across Member States. Thus the status of harmonisation is a key factor influencing the practical implementation of the instrument 'approval of active substances', especially as regards its scientific evaluation aspects.

- *Development of guidance is advanced*

As evidenced by the results of this evaluation, the harmonisation of criteria for hazard and risk assessment, which is a precondition for the proper implementation of the PPPR, has clearly improved since the entry into force of the regulation (Bozzini 2018, Annex II here).

As a positive result, the main actors in the approval procedure (national competent authorities, EFSA and the Commission) can follow a single set of rules on how to proceed with the evaluation of dossiers as regards requirements for the research design of the data to be submitted, and relevant methodologies (e.g. standardised testing) to be used by applicants. This is essential for the relevant authorities to identify hazards and assess the risks using a predictable, reliable and consistent approach in a uniform way. In particular, compared to the situation under the old system, significant progress has been made in terms of achieving shared understanding among CAs about hazard identification and risk assessment approaches, establishing trust, and attenuating considerable procedural differences. EFSA has played an important role in this process, as recognised by stakeholders (mainly CAs) (Bozzini 2018, Annex II here).

The efforts made by experts in the development and harmonisation of guidance documents have resulted in harmonisation of the criteria for the evaluation of active substances.<sup>81</sup> However, the formulation and adoption of criteria and guidance documents demands significant resources and is reported as a very relevant part of the work of national competent authorities, EFSA and DG SANTE (Bozzini 2018/Annex II here).

- *Harmonisation is not complete for all relevant scientific fields*

However, while the establishment of guidance is well advanced in fields such as toxicology and residues, harmonisation is not yet completed in other fields, such as ecotoxicology, environmental fate and behaviour<sup>82</sup> and the development of guidelines in those fields is

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<sup>81</sup> Experts are engaged in a variety of panels and ad hoc working groups at both EFSA and DG SANTE to refine existing and develop new guidelines to catch up with scientific progress as well as to fulfil legal requirements.

It is of note however that there are claims (coming mainly from health/environment NGOs) that the industry is influencing the process of development of methodologies, and that this process should be scrutinised (Milieu 2018, Annex I here).

<sup>82</sup> For example, the data required to conduct environmental risk assessments do not take into account all pesticide transformation processes or the environmental parameters that influence pesticide fate, as it is very difficult to perform risk assessment studies in all kinds of environments (Storck et al, Toward a better pesticide policy for the European Union, Science of the Total Environment, 575: 1027-1033, 2017 as quoted by Milieu 2018, Annex I here).

It is also of note that, according to the stakeholders defending animal health and wellbeing, the requirements of Directive 2010/63/EU on animal experiments are not given sufficient consideration in the development of guidance (Milieu 2018, Annex I here). Furthermore, it appears from EFSA's

ongoing.<sup>83</sup> (Bozzini 2018, Annex II here). Criteria for endocrine disruptors have been adopted only recently (end of 2017), despite the much earlier deadlines laid down in the two pesticides regulations,<sup>84</sup> not least because of paradigm differences between toxicologists and endocrinologists.<sup>85</sup> One could expect that national CAs, EFSA and the Commission would encounter more uncertainty and difficulties in implementing the PPPR in non-harmonised regulatory scientific fields than in the fields with advanced harmonisation. In particular, it is more difficult for them to evaluate the data submitted by applicants because data and testing requirements to check against are not definite, which has also an effect on the quality of CAs' evaluation conclusions and relevant health and environment effects. Missing (or incomplete) guidelines, in particular as regards 'negligible exposure' are a serious shortcoming and one that will have the most relevant consequences in the coming years (Bozzini 2018, Annex II here).

- *Varying nature of guidance documents*

In addition, the available guidance documents are not always legally binding (as they have not been adopted via the relevant comitology procedures).<sup>86</sup> Some Member States

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work that appropriate risk assessment methodology needs to be developed for protection of biodiversity and a range of ecosystem processes, including biological control of pests, food web support and pollination.

<sup>83</sup> Stakeholders (mainly from health/environment NGOs) echo these findings (Milieu 2018, Annex I here) when they comment on the status of knowledge base for evaluations in the context of approvals.

Guidance is also problematic as regards what is known as 'negligible exposure', introduced by the PPPR as a derogation from the 'cut-off' criteria: to the extent that exposure is negligible, a hazardous active substance can be approved; such derogations have been introduced for carcinogenicity, toxicity for reproduction, endocrine disruption, endocrine disruption on non-target organisms, as well as for honeybee health. Draft technical guidelines on the assessment of negligible exposure were published by DG SANTE in June 2015. The published document is incomplete in some relevant sections and therefore constitutes a partial answer to the assessment questions (Bozzini 2018, Annex II here).

Furthermore, debate on the role of epidemiology findings in regulatory risk assessment, as required by the PPPR, is ongoing. The integration of epidemiological findings in risk assessment is however problematic. A main reason is that the attribution of causality between a specific active substance and a specific adverse effect – the ultimate regulatory goal – is uncertain because of multiple hazards and the presence of confounding factors that cannot be kept under control. All considered, the integration of epidemiology and toxicology – as envisaged by EFSA – sees the former in a supporting role to the latter. Epidemiology would alert as to the existence of health concerns whose biological plausibility should be further investigated by toxicologists. The regulatory implications of the integration of plausible epidemiological findings into evaluations – such as revisions of data requirements, provisional bans, etc. – are as yet unclear (Bozzini 2018, Annex II here).

<sup>84</sup> Regulation (EC) 1107/2009 on plant protection (pesticide) products and Regulation (EU) 528/2012 on biocidal (pesticide) products. It should be noted that the delay in adoption of the criteria for endocrine disruptors has negatively affected the implementation of the two regulations in terms of protection of human and animal health.

<sup>85</sup> Bozzini, 2017 as quoted in Milieu 2018, Annex I here.

<sup>86</sup> It is of note that in other regulatory sectors EFSA is in a position to formulate and adopt risk assessment criteria and guidelines, whose application therefore does not require a 'political' vote in comitology. Health/environment NGOs are critical of delays in comitology decisions on guidance

implement non-binding guidance directly (or have introduced it in national law), while others do not recognise such guidance documents and do not apply them in their evaluation work. This creates regulatory uncertainty for applicants, as they cannot know which rules would be applied to their dossiers in each and every Member State (Bozzini 2018, Annex II here).<sup>87</sup> This also puts the results of the approval procedures into question – depending on whether CAs follow existing guidance or not, they would come up with different evaluation conclusions on hazards and risks in each case. Therefore, the fact that guidance documents vary in nature has an ultimate effect that safety cannot be guaranteed in every case, and stakeholders from various sides distrust the approval procedure.

- *Guidance is increasingly complex*

Another concern related to guidance is its increasing complexity. Thus, while CAs initially considered renewals of approvals as a simple updating of the existing dossiers, it became evident that the more complex and demanding guidance eventually provoked much more workload as regards renewals of approvals, which results in delays for renewals (Bozzini 2018, Annex II here).

- Concerns related to the practical work of national and EU authorities involved in the evaluation of substances

The recent controversy related to the renewal of the approval of the active substance glyphosate highlights that trust in the practical implementation of the evaluation approach established in the EU has been seriously undermined.

The background to the controversy is well known, and will not be explained in detail in this introductory EIA.<sup>88</sup> Briefly, the International Agency for Research of Cancer (IARC), on the one hand, and the relevant EU evaluators (the German Federal Institute for Risk Assessment (BfR<sup>89</sup>), the European Food Safety Authority (EFSA) and the European Chemicals Agency (ECHA)),<sup>90</sup> on the other, produced contradictory conclusions on the carcinogenicity of glyphosate. IARC classified the substance as 'probably carcinogenic to humans', while the European Food Safety Authority found it (as a final comment in the evaluation process) unlikely to pose a carcinogenic hazard to humans. The European Chemicals Agency later concluded that glyphosate did not classify as a carcinogen. Several national authorities outside the EU also came to the same conclusion.

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documents and call for their immediate and certain application by all CAs (Bozzini 2018, Annex II here).

<sup>87</sup> Stakeholders (applicants in particular) report that in some cases new guidance requirements are applied retrospectively to dossiers submitted when guidance did not exist (Milieu 2018, Annex I here).

<sup>88</sup> See the sequence of events in detail in Rimkutė 2018, Annex IV here.

<sup>89</sup> Bundesinstitut für Risikobewertung (BfR)

<sup>90</sup> Under Regulation (EC) 1272/2008 on classification, labelling and packaging of substances and mixtures.

These events provoked doubt among stakeholders, policy-makers and scientists as regards both whether the scientific evaluation was implemented correctly,<sup>91</sup> and whether the EU evaluators performed their work in this particular case independently of industry.<sup>92</sup> Both concerns resulted in a European Parliament decision in February 2018 to establish a Special Committee on the Union's authorisation procedure for pesticides with a focus on glyphosate.

This research project, and in particular, the study looking at the work of risk assessors in a comparative perspective (Rimkutė 2018, Annex IV here), did not find evidence that, in the case of glyphosate, the national and EU authorities involved in the evaluation process did not comply with the relevant procedures under the approval (renewal of approval) of substances. However, it was found that the differences in scientific conclusions (reached in the context of the few substances studied, including glyphosate) can be attributed to several factors. A first set of factors relate to differences in the broad institutional environment, in terms of formal mandates and rules (procedures) followed, in which non-regulatory (IARC) and regulatory (BfR, EFSA, ECHA) evaluators<sup>93</sup> operate (Rimkutė 2018, Annex IV here). A second set of factors explaining their diverging conclusions relate to the scientific work performed by regulatory and non-regulatory evaluators. In particular, the variances are: first, the approaches applied by the two types of evaluators when selecting data sources on which to base their evaluations; second, the scientific approaches (methodologies) that they follow for the assessment of the selected data sources; and, third, their interpretations when weighing indefinite results (Rimkutė 2018, Annex IV here). The differences in the conclusions therefore result from the specific procedural framework guiding the evaluations rather than from deficiencies in the practical implementation of the relevant procedures.

Furthermore, there is no evidence pointing, in the case of glyphosate, to some particular dependence of EU evaluators on the applicant beyond the information asymmetry between applicants and evaluators as described above. On the contrary, when it comes to EFSA, the respondents consulted (mainly representatives of national competent authorities) perceive EFSA as a credible regulatory body whose work is authoritative and free from political influence. Furthermore, EFSA is regarded as a transparent, trustworthy

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<sup>91</sup> See [letter](#) from Dr Christopher Portier to Commission President Juncker of May 2017 claiming that, based on his own re-evaluation of the glyphosate data disclosed by EFSA (among others, upon the request of Members of the European Parliament), the German BfR and EFSA evaluations are flawed and should be repeated.

See also the [position paper](#) 'Glyphosate and cancer: Authorities systematically breach regulations', published in July 2017 by a group of health/environment NGOs.

<sup>92</sup> Particularly in the light of the case known as the 'Monsanto Papers'. The release of internal industry documents in the context of lawsuits filed in the United States by patients with non-Hodgkins lymphoma, triggered allegations that the industry sought to influence the scientific evidence. On 11 October 2017, the Committee on the Environment, Public Health and Food Safety and the Committee on Agriculture of the European Parliament held a joint public hearing on the topic.

<sup>93</sup> Strictly speaking, BfR, EFSA and ECHA do not issue regulatory decisions (which are a Commission prerogative). The adjective 'regulatory' is used here to demonstrate that the scientific advice that those EU bodies prepare serve regulatory purposes.

and independent organisation by stakeholders that completed the online survey (Rimkutė 2018, Annex IV here).<sup>94</sup>

### *Member States' competent authorities' performance*

The research project found<sup>95</sup> that most – but not all – CAs have the institutional capacity to act as a Rapporteur Member State (RMS) and deliver assessment reports to EFSA (although reports of variable quality across Member States). There are substantial differences among Member States as regards available expertise and staff. All CAs appear to be seriously and chronically understaffed, based on their self-evaluation. This is the main factor explaining why approvals and renewals of approvals are delayed at the stage of hazard identification and initial risk assessment performed by Member States<sup>96</sup> (which also implies delays in the subsequent authorisations of PPPs at national level).

Another reason for the delays in approval procedures is related to the workload of CAs which is unevenly distributed among Member States. One factor explaining this unbalanced workload is the fact that applicants can choose which Member State is to serve as a rapporteur when it comes to the evaluation of a completely new substance.<sup>97</sup> When it comes to renewal of an expiring approval though, the Commission assigns the dossier to a particular Member State with the aim of establishing a balance in the workload among CAs (through negotiation with the relevant Member State). However, balanced distribution of the significant workload related to renewals of approvals is prevented by differences in staff and resources. Some authorities therefore need to evaluate a large number of renewal applications simultaneously, which explains why delays are more common for renewals of approvals than for approvals of new substances.

In terms of charging fees, only a few Member States adapt the requested fee to the actual costs incurred during the evaluation process or link the fees to the number and type of evaluations to be performed in the context of a dossier. Fees to contribute to the EFSA stage of the procedure for the approval of active substances (e.g. participation in EFSA peer review) are generally not requested. This means that, generally, Member States do not generate own resources that could partially solve the understaffing issue.

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<sup>94</sup> This finding holds true for EFSA's work on the PPPR in general, not only for the glyphosate case (Rimkutė 2018, Annex IV here).

<sup>95</sup> The findings under this section of the EIA follow the results from the Bozzini, 2018 study published under Annex II to this EIA. Wherever the results from the other studies supporting the evaluation project are used, this is specified.

<sup>96</sup> The approval period for over 180 active substances expired between 2011 and 2018, and 200 more will expire in the 2019-2021 period. The Commission planned the renewals by setting differentiated deadlines and by distributing dossiers among Member States. There is evidence that CAs often struggle to meet the strict regulatory deadlines, which has been an issue ever since EU legislation on pesticides was adopted. In particular, renewals experience serious delays. Expiry dates for a large majority of active substances were postponed. A main reason for delays in renewals is found in the heavy workload that these re-evaluations place upon CAs. As mentioned above, most CAs are understaffed and the increase in the number of dossiers caused by the renewal programmes has proved too large a burden (Bozzini 2018, Annex II here).

<sup>97</sup> See more on the arguments for applicants' choice of CAs in the study Bozzini 2018, Annex II here.

The majority of Member States examined offer pre-submission meetings to applicants on request, which is however another source of burden for CAs who need to prepare for those meetings by devoting time and staff resources for preliminary analysis of studies and discussing them with the applicants. As a rule, in the majority of CAs this service is not compensated financially (Bozzini 2018, Annex II here). It appears however that such meetings are not subject to strict rules, which does not create incentives for transparency in those preliminary informal contacts with applicants and it could be considered that this allows for a dependency relationship between the CA and the applicant to establish. The majority of Member States declare they hold such meetings to seek for clarifications on tests, summary of findings or other content included in the dossier. However, other stakeholders are not consulted (Bozzini 2018, Annex II here).

Only a few CAs report they have a formal internal peer review process in place for the individual dossiers, which means that internal control mechanisms are generally missing. Although the PPPR envisages two Member States cooperating (as co-rapporteur Member States) in the delivery of the draft/renewal assessment report, this type of cooperation rarely takes place in practice due to time and resource constraints. The lack of such cooperation practices is a lost opportunity for developing a common understanding of guidelines and thereby facilitating the practical implementation of harmonised standards.

National CAs are also supposed to take part in EFSA's consultation activities on the draft/renewal assessment report. A large majority of Member States, covered by the study,<sup>98</sup> report that they are selective as regards participation in EFSA's peer reviews. They prioritise participation in peer reviews depending on the substances considered to be of more importance to their country; priority is also given to other 'national' procedures, most often to authorisations of PPPs. The reasons range from CAs' substantial lack of staff to the general disappointment expressed by some CAs as a result of the cases where EFSA does not take their comments into account properly), or when the EFSA significantly revises the draft/renewal assessment report following comments submitted during the peer review process.<sup>99</sup> This 'selective' practice is problematic, as EFSA's peer review procedure is expected to address issues of quality in the draft/renewal assessment reports (lack of harmonisation, divergent interpretations etc.), that naturally depend on Member States' participation in the procedure, and is able to perform this function only to a limited extent because CAs' participation in EFSA peer review procedures is selective.

#### *Procedure transparency with a focus on risk management*

The regulation requires that the evaluation process is transparent. In particular, two main aspects need to be considered in the context of transparency – availability and access to information.

This evaluation found that the information related to the approval procedure at CA stage is available mostly via EFSA sources, which means only after the draft/renewal assessment report is submitted by the CA to EFSA, hindering public access to this information during

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<sup>98</sup> Bozzini 2018, Annex II here.

<sup>99</sup> As part of its 'Action plan for improving the peer-review process' adopted in November 2017, EFSA envisages including a more comprehensive and clear summary of divergent views expressed by CAs during peer review processes in the conclusions, as well as providing an indication of the line of reasoning followed.

the CA evaluation stage (Bozzini 2018, Annex II here). This finding, coupled with the fact that stakeholders (except for the applicant/industry) are generally not included in the consultation procedures related to CA evaluation, lowers the level of transparency of the work of the rapporteur Member States.

As regards availability and access to information at the EFSA stage (where peer review control of CA's draft/renewal assessment reports is undertaken), the situation is different. In contrast to the practice at the CA stage, stakeholders (other than the applicant) are included in the risk assessment process, and therefore the relevant information (including the 'sanitised version'<sup>100</sup> of the dossier submitted by the applicant and the draft/renewal assessment reports of the rapporteur CAs) is made available<sup>101</sup> to stakeholders in due course. While most of the information is, in principle, available, as is also claimed by EFSA, access is limited by the variety of sources where the documents are made available, which vary in terms of accessibility and user friendliness (Bozzini, 2018, Annex II here).

Transparency at the risk management stage seems to be lacking. At this stage the main actors – the PAFF (comitology) Committee of Member States' experts and the Commission – take a decision whether or not to approve a substance (including relevant conditions of use). Evidence shows that there is a need for a more transparent and comprehensive risk management stage since most of the time the reasoning behind risk management decisions, the regulatory criteria adopted and how the discussions among decision-makers unfolded is not made explicit or public (Bozzini 2018, Annex II here). The risk management stage of the approval and renewal of approval procedure is also considered problematic by stakeholders (across all categories with the exception of CAs) (Milieu 2018, Annex I here).

To achieve greater consensus on controversial regulatory issues, increased transparency in debates on risks and their acceptability might be valid and legitimate (Bozzini 2017).<sup>102</sup> In particular, transparency in the process and the overall accountability of the system could be improved, if the PAFF Committee decisions<sup>103</sup> over precautionary risk mitigation measures, precautionary bans, and approvals were explained and justified.<sup>104</sup> A second, related, factor are the deficiencies in risk communication (which should normally take place following the risk management decision). The task is to explain and engage with the

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<sup>100</sup> i.e. following relevant confidentiality requirements.

<sup>101</sup> In principle it is possible to find most of the information, including the original dossier, taking rules on confidentiality into account. In this sense, EFSA's argument that 'in practice everything is available' is correct. See the study Bozzini 2018, Annex II here.

<sup>102</sup> Bozzini, E. 'Pesticide Policy and Politics in the European Union. Regulatory Assessment, Implementation and Enforcement', Palgrave Macmillan, 2017 (as quoted in Milieu 2018, Annex I here).

<sup>103</sup> Currently two main sources of information on the PAFF discussions and decisions are available to the general public: the internet register maintained by the Commission and the Commission's annual report on the comitology committees. However detailed minutes on discussions of the Member States' positions and arguments are generally not available (Bozzini 2018, Annex II here).

<sup>104</sup> The very recent case of the candidate for renewal active substance diquat raised concerns as regards the transparency of the risk management stage of the procedure, as reported in [Politico](#), 23 March 2018.

public, providing citizens with information on the line of reasoning behind regulatory choices. At the very minimum, authorities should opt for information campaigns. However, according to respondents, such activities are virtually non-existent in the case of pesticides. The explanation of how decisions have been made, and the reason behind a ban or an approval are not published. Even in a highly controversial case, such as glyphosate, communication to the public is at best restricted to press releases. Overall, the lack of a risk communication strategy appears a serious deficit, since pesticides remain a topic of high concern for EU citizens. The Eurobarometer survey on 'Food related risks' (2010) signalled that citizens were and remain worried about chemical residues and pesticide pollution. In this sense, it seems that stringent regulatory criteria give little reassurance (Bozzini 2017).<sup>105</sup>

### **Authorisation (renewal of authorisation) of PPPs - standard and under derogation ('Article 53')**

Both standard and emergency ('Article 53') authorisations are exclusively granted by Member States' competent authorities. Member States are the sole masters of both risk assessment (evaluation) and risk management (decision). EFSA and the Commission play no role regarding standard authorisations of plant protection products, but may have some role as regards emergency ('Article 53') authorisations under derogation, provided the Commission decides to trigger the scrutiny procedures in Article 53(2) and 53(3) of the PPPR. The sections below look at the practical implementation of both standard and emergency authorisations.

#### *Standard authorisations of PPPs*

The evidence<sup>106</sup> available shows that the main influencing factor in the practical implementation of the authorisation of PPPs and renewals is the performance of the main actor involved in the authorisation of PPPs, i.e. the national competent authorities. Other factors relate, among other things, to the interpretation and practical implementation of the precautionary, sustainability and substitution principles on which the regulation is founded, and to the evaluation approach currently applied to authorisations. These factors are presented below.

#### ➤ CA performance

The findings of this evaluation show that Member States' competent authorities are struggling with the practical implementation of PPP authorisations. In particular, two main challenges emerge: first, delays in the processing of applications and risk management

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<sup>105</sup> Bozzini E. 'Pesticide Policy and Politics in the European Union. Regulatory Assessment, Implementation and Enforcement', Palgrave Macmillan, 2017 (as quoted in Milieu 2018, Annex I here).

<sup>106</sup> This section follows the results of: first, the desk research section (and mainly the relevant Commission audit report on authorisations of PPPs covering seven Member States, 2017) of the study (Milieu, 2018) published under Annex I to this EIA; second, the results from the stakeholder survey published in the latter study; and, third, the results of the study (Hamlyn 2018) published under Annex III to this EIA, covering 12 Member States and the three (Northern, Central and Southern) zones as laid down in Annex I to Regulation (EC) 1107/2009.

decision-making result in non-compliance with legal deadlines, and, second, there are some challenges related to independence and transparency policies currently applied by Member States.

- *Delays in the processing of applications and risk management decision-making resulting in non-compliance with legal deadlines*

In the Member States audited by the Commission,<sup>107</sup> the number of applications for authorisations (renewal) of PPPs awaiting a decision is high. The ultimate results of those delays are negative: on the one hand, products are not available on the market, with negative impacts for users (farmers), and, on the other, and as demonstrated in the next section, the number of what are known as 'emergency authorisations' granted under derogation (Article 53 of the regulation) steadily increases also due to those delays, with a number of negative effects for human/animal health and the environment.

Many factors lead to these delays. A first group of factors relate to a lack of internal capacity in the competent authorities, and particularly a lack of: internal resources;<sup>108</sup> reliable long term planning, including a lack of a reliable tracking system for ongoing applications and key performance indicators to manage the actual capacity of existing resources to deliver.<sup>109</sup>

Another important group of factors emerge when the authorisation work of an individual CA is considered in the light of the authorisation work done by other CAs. Data sources (used in this section of the EIA) show unanimously that, contrary to the relevant PPPR requirement for work sharing, under the zonal system, CAs often do not use work carried out by others and fully or partially re-evaluate dossiers, which creates work duplication and eventually leads to delays beyond the legal PPPR deadlines. The two main reasons for this distrust are: first, harmonised methodologies and models to conduct the evaluations (wherever available)<sup>110</sup> are not used in all cases; and/or, second, Member States apply additional national requirements to address conditions specific for the Member State

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<sup>107</sup> Overview report on a series of audits carried out in seven EU Member States in 2016 and 2017 to evaluate the systems in place for the authorisation of plant protection products, European Commission, 2017 (DG SANTE)2017-6250-MR as quoted in Milieu 2018, Annex I here.

<sup>108</sup> Hamlyn 2018, Annex III here and Commission overview audit report on authorisations, 2017 as quoted in Milieu 2018, Annex I here. It is of note that the participation in zonal-level coordination activities is another resource-consuming activity for CAs on top of their authorisation, approval and enforcement-related work (Hamlyn 2018, Annex III here).

<sup>109</sup> Commission overview audit report on authorisations, 2017 as quoted in Milieu 2018, Annex I here.

<sup>110</sup> As for approvals, the harmonisation of guidance for evaluation of PPP candidates for authorisation is an ongoing process. See in Hamlyn 2018, Annex III here.

concerned, which eventually makes CAs reluctant to accept each other's evaluations (Commission overview audit report on authorisations, 2017).<sup>111 112</sup>

The lack of large scale work sharing under the PPPR is also evidenced by the fact that, despite efforts, CAs still struggle to achieve a balanced distribution of workload among the Member States within each of the three zones (i.e. sharing similar climatic and agricultural conditions) in the context of authorisation renewals, even though the portfolios of authorised PPPs are very similar and the expected renewals of expiring authorisations could be fairly distributed among the CAs of the Member States within each zone (Commission overview audit report on authorisations, 2017).

Nevertheless, CAs value the zonal system particularly as regards its potential for work sharing, harmonisation of evaluation guidance,<sup>113</sup> communication and cooperation (including for sharing information about applications, peer review, expert support and advice), and promotion of mutual understanding (including on harmonisation aspects of

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<sup>111</sup> The application of additional national requirements and re-evaluations of the dossiers are common (as confirmed by industry and farmer stakeholders) in the context of the mutual recognition principle, triggering delays in the marketing of a given product in the re-evaluating Member State(s) (Milieu 2018, Annex I here). According to the Commission overview auditing report (2017), in most cases, the outcome of such (re-)evaluations is either the same or very similar to the original authorisation given in another Member State, but the authorisation is delayed beyond the deadlines.

The so-called 'generic' PPPs (i.e. those equivalent to existing authorised PPPs) are also an example of differences in the evaluation approaches applied by Member States which result in significant variations in the number of generic PPPs on the market across Member States (Commission overview audit report on authorisations, 2017).

The above two practices negatively impact the availability of products on the market. This situation is further complicated by the practice in all seven Member States audited by the Commission to grant authorisations only when the product is deemed effective for the entire territory of the relevant Member State. Products that would be effective for use in a restricted area and climatic conditions are not authorised for marketing which reduces the portfolio of available products in this Member States with relevant negative effects on farmers.

<sup>112</sup> This is how the secretariats (or Member States) of the three zonal Steering Committees explain the distrust phenomenon: The secretariat of the zonal Steering Committee of the Northern zone reports '[g]enerally, there is trust between Member States from the Northern zone'. Disagreements over evaluations are solved 'by direct contact with the zRMS or via teleconferences'. Non-harmonised areas and possible areas of distrust are discussed and resolved during the annual updating of the Northern zone guidance document. The secretariat of the zonal Steering Committee of the Central zone attributed distrust to national differences in methodologies and models used for evaluation, leading to work duplication and different decisions. One Member State belonging to the Southern zone reports differing levels of trust (measured according to the extent to which Member States comment on dRRs) among Southern zone Member States, which it attributes largely to available resources. The only respondent under the dedicated survey praised the Northern and Southern zones as 'working quite well', while the work of the Central zone was assessed as 'very bad'; this assessment of the work of the Central zone was attributed to the poor functioning of the Central zone due to 'high variability in agricultural and climatic conditions, as well as the variety in the size and experience level in' CAs, and stronger national data requirements and competing risk assessment methodologies, representing a greater challenge than that faced by either of the other two zones. (Hamlyn 2018, Annex III here).

<sup>113</sup> In the context of the authorisation procedure, harmonisation of guidance takes place at zonal level.

the evaluation approach). The zonal system is complex and improvements in its operation, for example, harmonisation and work sharing, will take time, as suggested by the secretariat of the Steering Committee of the Central zone. Member States are making progress and it will also take time to build the necessary trust in support of greater harmonisation and more efficient operation (Hamlyn 2018, Annex III here).<sup>114</sup>

Performing 'comparative assessments' (under the substitution requirement introduced by the PPPR) adds to the already substantial workload of CAs, in particular because this type of evaluation requires that products are compared to each other, while national authorities are generally used to checking individual PPPs against the legal requirements (Faust et al., 2014).<sup>115</sup>

As for approvals, contact with applicants are possible in the pre-submission stage and although not always requested by applicants, these meetings are praised for their capacity to improve the quality of dossiers submitted (Hamlyn 2018, Annex III here).

In conclusion, renewals of authorisations, zonal authorisations, authorisations of PPPs for minor uses and the mutual recognition principle were unanimously assessed by stakeholders (across all categories)<sup>116</sup> as some of the most problematic instruments to implement (Milieu 2018, Annex I here). Some stakeholders (mainly PPP manufacturers and farmers) are particularly concerned by the implementation problems observed related to Member States' work, leading to delays and missed deadlines during the authorisation procedure. In their opinion, the system should be reviewed and efficiency improved. As regards the problems associated with 'minor uses', the industry and (conventional) farmer stakeholders also propose that a single list of major and minor crops is established at EU

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<sup>114</sup> In particular, the feedback from the zones (secretariats/Member States) show that despite problems, Member States seem to be making productive and frequent use of the zonal system. The secretariat of the Steering Committee of the Central zone notes that its Member States are still transitioning from 'operating individually to operating as a zone' and that while this could not be achieved within five years, could be achieved in the longer term. The secretariat of the zonal Steering Committee of the Northern zone considered that the zonal system has enabled the workload to be shared in a way that was not previously possible, that it has resulted in better evaluations and swifter authorisation of PPPs and that the zonal system helps highlights areas of disagreement. The feedback received from the Central and Southern zone indicates that zonal discussion helps solve problems and disagreements over risk assessment methodologies and specific dossiers, leading to an 'increasingly cooperative assessment and authorisation practice' (Hamlyn 2018, Annex III).

The only stakeholder (a manufacturers' association) who submitted a response under the stakeholder survey (conducted in the frame of Hamlyn 2018, Annex III here) also considers that the regulation is encouraging coherence among zonal authorisation procedures 'to a great extent' noting that work sharing within zones has now exceeded that achieved under Directive 91/414/EEC. The stakeholder also recognises that 'Member States to a large extent have the desire to improve harmonisation' (Hamlyn 2018, Annex III here).

<sup>115</sup> Faust et al., Comparative assessment of plant protection products: how many cases will regulatory authorities have to answer? Environmental Sciences Europe, 2014 as quoted in Milieu 2018/Annex I here.

<sup>116</sup> CAs did not assess the renewals of authorisation and zonal authorisations as problematic, but some CAs did assess the practical implementation of the mutual recognition principle to be problematic.

level (or at least, there should be more coordination between Member States),<sup>117</sup> and even that a special authorisation procedure is set up at EU level to increase the availability of PPPs for 'minor uses';<sup>118</sup> health/environment NGOs also consider that authorisations for 'minor uses' should not be general but should instead be limited to either a small area or to a specific crop.

One CA suggested that the detailed procedures set out in the regulation make it difficult to make changes and address new developments or to introduce new timelines for increasingly complex assessments. The respondent therefore proposed that more procedural aspects should be detailed in a Commission regulation, which could be amended when needed, and that this approach could apply to all areas of the PPPR.

- *Independence and transparency of competent authorities*

This project did not identify any deficiencies likely to significantly undermine the reliability of CA decision-making. However, deficiencies as regards both independence and transparency were observed (Hamlyn 2018, Annex III here).

As regards transparency, it was found that current transparency practices in the Member States examined are problematic, especially in terms of limited public availability of information on evaluation and the authorisation procedure itself, as well as access to information. This hampers stakeholders' understanding of the procedural and information basis for PPP authorisation decisions. It is worth recalling that access to information and participation aspects also appear to be problematic in the context of Member States' transparency practices as regards approval of active substances.<sup>119</sup> As for approvals, peer reviews or auditing of decisions is also not the rule in all Member States as regards authorisations of PPPs (Hamlyn 2018, Annex III here).

Furthermore, as mentioned for approvals of substances, participation of interested stakeholders in decision-making on authorisation procedures is limited, which is another factor lowering transparency. It should be noted however that currently the PPPR does not create a legal obligation for Member States to ensure such participation during evaluation in the frame of the authorisation procedure and comparative assessments (Hamlyn 2018, Annex III here).

In terms of independence, it was found that the levels of CAs' formal independence from government and industry vary (Hamlyn 2018, Annex III here).<sup>120</sup> As regards independence from industry, only a few of the Member States examined report restrictions on recruiting CA Heads (Directors or Commissioners) from industry or taking up employment in industry following their appointment, which may risk undermining their independence. As regards independence from the government, while most Member States report sole

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<sup>117</sup> Currently, the same crop is considered major by one Member State and minor by another.

<sup>118</sup> Reportedly, fast-track procedures currently applied in some Member States are not working properly.

<sup>119</sup> See Bozzini 2018, Annex II here.

<sup>120</sup> Formal independence refers to appointment/dismissal procedures. See more in Hamlyn 2018, Annex III here.

responsibility for their decisions (pointing to substantive, i.e. decision-making, independence from the government), most CAs<sup>121</sup> lose organisational autonomy because they are funded by the government; in addition, government control over salaries reduces autonomy further and restricts CA ability to recruit the required staff (Hamlyn 2018, Annex III here); as shown above, this is one of the main reasons leading to delays, and the general ineffectiveness and inefficiency of the authorisation procedure. The above findings on CA independence may also hold true for CAs when it comes to their work related to approvals of substances, provided the authorities in charge of approval-related activities and authorisations are the same.

- Other factors influencing the practical implementation of standard authorisations of PPPs

A few other factors influence the practical implementation of the regulation with effect on the achievement of its objectives. They relate to, first, the interpretation and practical implementation of the precautionary, sustainability and substitution principles on which the regulation is founded and that are of particular relevance to the risk management stage of the authorisation of PPPs procedure; second, certain omissions in the established evaluation approach, and; third, the status of knowledge and use of available knowledge in authorisation decisions.

- *Inconsistent interpretation and implementation of the precautionary, sustainability and substitution principles by CAs*

This project found that the explored CAs interpret and implement the precautionary and sustainability principles differently, which is a problem in terms of guaranteeing that the objectives of the PPPR are being evenly met across Member States. While there is greater consistency in the implementation of the substitution principle across the Member States examined, there is less ambition in its application, which is a problem in terms of comparative assessments. The practices observed do not support uniform implementation of the regulation in the context of authorisation (risk management) decisions, and thus hampers the achievement of its objectives, especially as regards health/environment-related objectives.

- *Concerns stemming from omissions in the evaluation approach currently applied (combined effects)*

There is a growing consensus among experts that health and environmental risks could be significantly underestimated if cumulative effects are not evaluated. EU legislation requires the assessment of intentional mixtures, combinations of chemicals that result from the intentional mix of different active substances, such as commercial formulations composed of a combination of active substances including ready for sale plant protection products subject to authorisation at national level. Much less attention is paid to unintentional mixtures, such as those formed during the user handling of different products, or coincidental mixtures formed in the environment following the use of a variety of active substances. At present there is no systematic and integrated approach

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<sup>121</sup> Especially those that do not charge fees on applicants for authorisations.

across different (or even within single) pieces of legislation. An assessment methodology is currently under development. (Bozzini 2018, Annex II here).

The assessment of cumulative risks of PPP residues is also problematic in terms of authorisations of PPPs as witnessed mostly by health/environment NGOs, organic farmers and CAs (half of the respondents), while industry, conventional farmers and some CAs do not share this opinion (the other half of respondents) (Milieu 2018, Annex I here).

- *Concerns related to the status of knowledge and its use*

Stakeholders are divided as to whether knowledge is sufficient for decision-making needs and whether it is adequately used by policy-makers.

According to the biopesticides industry, the level of knowledge of alternative PPPs varies greatly across Member States, and leads to different results from the authorisation procedures applied by the different Member States. The same stakeholder mentioned that for biological PPPs a separate authorisation procedure should be established at EU rather than national or zonal level.

One CA mentioned that there are many uncertainties in the final calculated risk ratio used in decision making, and, as a consequence, the interpretation of standard of proof is ultimately a policy (i.e. political) level issue, rather than a scientific issue.

#### *'Article 53' derogations*

Article 53 of the PPPR envisages the possibility for Member States' competent authorities to authorise, in special circumstances, the prohibited use in this Member State of a PPP. This derogation cannot be for a period longer than 120 days. Such authorisations may be allowed when a danger could not be contained by other reasonable means. The provision requires Member States to immediately notify the Commission and all other Member States of the Article 53 authorisations granted, enabling the Commission to scrutinise the decisions of Member States in implementing Article 53. In 2013, the Commission issued a guidance (working) document laying down the procedures to be followed by Member States when granting authorisations under Article 53.

The sections below present the main findings as regards the practical implementation of authorisations under Article 53.<sup>122</sup>

#### ➤ Practical implementation of Article 53

The number of PPPs authorised under derogation has steadily increased in the last 10 years from 59 in 2007 to almost 400 in 2017. The great majority of authorisations are granted for PPPs containing approved substances, which under the derogation, are authorised for

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<sup>122</sup> This section follows the results of the study (Milieu 2018) published under Annex I to this EIA exclusively, and more specifically, first, its desk research section (in particular the two Commission overview audit reports on authorisations and on controls published in 2017, and the 'Bee Emergency Call' report published by a group of NGOs in 2017); second, the section of Milieu's study dedicated to the practical implementation of Article 53 emergency authorisations; and, third, the section of Milieu's study presenting the results from the stakeholder survey.

different uses than those initially granted; those containing non-approved substances represented 9 % of the total number of PPPs authorised under derogation in 2017. Evidence shows that this type of authorisation is repeated over the years – a third of the authorisations granted under derogation in 2017 had already been granted in 2016.

Furthermore, in some cases, Article 53 is used in contradiction with the Commission guidance (working) document; it relates to cases where derogations for PPPs containing non-approved substances have been granted not to fight a single species but to disinfect soils,<sup>123</sup> or where derogations are repeated over the years, which also goes against the Commission guidance. This demonstrates that Article 53 is not always used according to its original purpose.

The notifications accompanying the derogation dossiers (submitted by some Member States) often do not comply with the requirements of Article 53. In particular, sufficient justification of the nature of the danger to be contained is missing; the notifications fail to list any alternative means of controlling pests and to provide information to prove limited and controlled use; the majority of derogations are not related to special circumstances, as required under the regulation.

➤ **Reasons provoking Article 53 derogations**

The findings of this evaluation show that two main reasons lead to the granting of authorisations under derogation.

- *Lack of available products on the market*

One of the reasons for derogations, including their repetition over the years, stems from the problems related to the implementation of the standard authorisation procedure (and the preceding approval of substances). In particular, those problems relate to non-compliance with legal deadlines which result in delayed marketing of PPPs, the problematic application of the mutual recognition principle and the lack of manufacturer investment in preparing application dossiers for minor use PPPs.<sup>124</sup> It should be noted that some of the repeated authorisations were granted for products awaiting standard authorisation for many years. Furthermore, this research project found that authorisations granted under Article 53 but not on emergency-related grounds are permitted due to lack of available alternatives to the products authorised under derogations.

- *Established agricultural practices*

The second reason is revealed by the results from the three case studies performed under this research project – on chemical soil fumigants, on insecticides for use in mass trapping and on neonicotinoids – show that some of the Article 53 authorisations are being used to

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<sup>123</sup> See in detail the results from the three case studies on chemical soil fumigants, on neonicotinoids, and on insecticides for used in mass trapping included in the study Milieu 2018/Annex I here.

<sup>124</sup> The opinions of industrial and farming stakeholders suggest that the reason for this lack of investment lies in the problematic implementation of the mutual recognition principle, in particular, an improved implementation of the mutual recognition principle would result in cheaper applications that would encourage the industry to request authorisations for PPPs for minor uses (Milieu 2018, Annex I here).

maintain the use of pesticides with proven significant environmental and human health impacts, because the crop system in which they are used has been built up on the use of these pesticides and because farmers would have to adapt to a different cropping system if they no longer had access to the chemicals.<sup>125</sup>

➤ CA performance in implementing Article 53 derogations

In the absence of concrete rules in the PPPR, all Member States<sup>126</sup> examined have procedures in place for the review of requests for Article 53 authorisation. However, they are neither documented nor legally binding. Furthermore, there are no tailor-made procedures for granting derogations for PPPs containing non-approved substances which imply the highest risks.<sup>127</sup>

None of the Member States examined have specific strategies in place aimed at limiting the use of repeated derogations.

There are no specific inspection strategies for Article 53 authorisations to ensure that the authorisation has been performed according to the conditions of the granted derogation.

In almost all Member States examined, CAs publish the decisions granting emergency derogations (as requested in Article 57 of the PPPR); however, they do not publish the application dossier and related evaluations performed internally (e.g. assessment of alternatives and justifications) and public access to information is therefore limited. In addition, public consultations with interested stakeholders do not take place, which may result from the lack of such a requirement in the PPPR.

There are no strict rules in the PPPR or within national legal orders as to who can apply for a derogation. In 2017, 31 % of all applications for authorisation under derogation were submitted by industry (PPP and seed manufacturers),<sup>128</sup> agricultural and forestry companies (37 %), CAs (23 %), and agricultural and agronomy research institutes or consultants (9 %).

In order to notify the Commission and other Member States of the derogations granted, CAs use the Plant Protection Products Application Management System (PPPAMS).

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<sup>125</sup> See in detail the results from the three case studies included in the study, Milieu 2018 published under Annex I to this EIA.

<sup>126</sup> Included in Milieu's sample. See the details in Milieu 2018, Annex I here.

<sup>127</sup> The PPPR does not require Member States to establish such specific procedures, nor does the Commission working document; the latter only proposes some recommendations on how Member States should deal with authorisations of non-approved substances.

<sup>128</sup> In one of the Member States examined, only farmers and their associations can submit applications for derogations under Article 53 so that expressions of commercial interest from the PPP industry are avoided; in another Member State, in cases of applications submitted by industry, the CA verifies whether such applications are carried out on behalf of farmers' interests (Milieu 2018, Annex I here). This evaluation did not result in findings on the reasons why industry is allowed (in some Member States examined) to submit applications for Article 53 derogations. This practice could however be questioned in the light of the fact that some Member States examined, as shown above, have limited industry participation in the application process.

Notifications of derogations granted have never been available to the public. Furthermore, Member States do not submit all notifications, and/or not immediately (as required by Article 53),<sup>129</sup> which is also acknowledged by a Commission representative interviewed in relation to this research project (Milieu 2018, Annex I here). In the respondent's opinion, the Commission has never launched and is unlikely to launch infringement procedures against non-compliant Member States.<sup>130</sup> Several notifications were found to contain very little information, which is a problem in terms of the Commission's monitoring and, possibly, scrutiny activities on the implementation of Article 53.

- Commission performance in scrutinising Article 53 derogations performed by Member States

Since the entry into force of the PPPR, the Commission has only once used the possibility to request an opinion from EFSA under Article 53(2). In September 2017, the Commission requested EFSA examine Article 53 emergency authorisations granted in 2017 by seven Member States concerning three neonicotinoid substances with very restricted use (since 2013) – clothianidin, imidacloprid and/or thiamethoxam – applied to sunflower and maize, oilseed rape seeds, spring rape and spring turnip rape seeds. According to a European Commission representative, the Commission has limited power to trigger an infringement procedure in case of misuse of Article 53 emergency authorisations. The respondent considers that since the authorisation of PPPs fall under the exclusive competence of Member States it is difficult to challenge Member State decisions under this procedure. He stresses that the Commission has neither the capacity nor the competence to carry out a systematic and full review of individual Article 53 authorisations granted in specific geographic areas across the EU.

### **Enforcement**

While the above approval and authorisation activities of Member States' competent authorities are *per se* implementation of the PPPR, enforcing the PPPR means that Member States carry out official controls to ensure that the PPPs available on the internal market – whether manufactured in the EU or imported from third countries – and their application by users comply with the relevant authorisation conditions as regards their composition and usage. Enforcement is therefore an instrument of the PPPR aimed at ensuring compliance with the authorities' regulatory decisions.

Available evidence shows<sup>131</sup> that the enforcement of regulatory decisions under the PPPR is insufficient (or even non-existent according to stakeholders, mainly from

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<sup>129</sup> A possible reason would be that the PPPAMS is still being used by CAs on a voluntary basis, which is an obstacle to Member States' compliance with the notification obligation of Article 53.

<sup>130</sup> It appears that, in order to ensure compliance, the Commission is using alternative methods, such as bilateral discussions with non-compliant Member States or announcing the non-compliance at the PAFF Committee meetings attended by experts of all Member States. Given that non-notification cases persist, 'naming and shaming' does not seem to be very effective.

<sup>131</sup> This section follows the results of the study (Milieu 2018) published under Annex I to this EIA exclusively, and more specifically: first, the sections presenting the results from desk research (in particular, the Commission overview audit report on controls on the Marketing and Use of Plant Protection Products from 2017 covering eleven Member States, and the ad hoc study on the trade of illegal and counterfeit pesticides in the EU, prepared by Agra CEAS Consulting, Arcadia

health/environment NGOs), and as a result, illegal (including counterfeit) products<sup>132</sup> on the market and in actual use is increasing.<sup>133</sup> Stakeholders (across all categories except CAs) also confirm this finding and argue that CAs and EU authorities have not made enough effort to limit the trade with illegal pesticides.

The main factors determining insufficient enforcement lies with the work of national CAs (and/with other relevant authorities (e.g. customs' administration)) at national level, as well some omissions in the legal framework and practice at EU level.

### *National CAs performance*

The control programmes of Member States audited by the Commission, wherever available, demonstrate some deficiencies: first, the systems for the identification of risk and prioritisation of controls is insufficient in most audited Member States, and as a result the frequency of controls on some types of high-risk operators (e.g. manufacturers, importers and re-packers) was insufficient compared to the scale and inherent risk associated with these operators;<sup>134</sup> and, second, all audited Member States plan and implement such control programmes independently despite the highly integrated nature of the pesticides industry, and there is no EU-wide coordinated control programme.<sup>135</sup>

The intensity of sampling and scope of analysis is insufficient to ensure that the authorised PPPs on the market comply with the conditions of the authorisation. Available Commission data shows that the Member States audited test the levels of substances contained in the controlled PPPs and other physical and chemical properties; however,

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International in 2015 at the request of the Commission); and, second, the section of Milieu' study presenting the results from the stakeholder survey.

<sup>132</sup> According to the Commission, the marketing and use of PPPs containing active substances not approved in the EU are illegal; the marketing and use of PPPs that are not authorised or marketed under a parallel trade permit are illegal; the PPPs that do not comply with the detailed conditions of their authorisation or parallel trade permits are illegal; the use of PPP in one Member State can be illegal in a neighbouring Member State, where it may not be authorised (European Commission audit report on control systems, 2017 as quoted in Milieu 2018, Annex I here).

<sup>133</sup> See more detail in the EPRS In-depth analysis, 'EU policy and legislation on pesticides', 2017 as quoted in Milieu 2018, Annex I here.

<sup>134</sup> Most Member States audited had not recognised the importance of, and the risks associated with, large central distribution points in the PPP distribution system in their control programmes, and therefore did not conduct sufficient controls on this category of operator. Furthermore, at some large ports and in some large Member States audited, the risks associated with the importation of PPPs had not been considered when prioritising controls, resulting in an absence of risk-based controls on PPP imports in these Member States and ports. Controls of exports (destined for non-EU countries) are also problematic in some Member States audited. It is also worth recalling that there are no specific inspection strategies for Article 53 authorisations to ensure that the product is being used according to the conditions of the granted derogation.

<sup>135</sup> This explains why, especially as regards controls on imports, the types, place and frequency of official controls vary significantly between Member States, ranging from the existence of well-structured and risk-based import control policies in some Member States, to a minimum level of control in others (AGRA CEAS Consulting, Arcadia International ad hoc study from 2015 as quoted in Milieu 2018, Annex I here).

detection of many illegal PPPs on the EU market require sophisticated analytical techniques, which are only applied by some Member States audited. Furthermore, controls by manufacturers in most of the Member States audited are limited to checking labels of finished products, storage conditions and health and safety related issues.

As shown in the previous sections on approvals of substances and authorisations of PPPs, the implementation of the PPPR creates substantial workload for CAs. Few human resources remain (from what was already identified as an understaffed system) for carrying out effective controls – a view shared by stakeholders mainly across CAs<sup>136</sup> and the industry.

In some Member States, records of the PPPs that are actually on the market are limited, which is also confirmed by a finding on practices related to authorisations of PPPs, i.e. the data in electronic registers is often incomplete and it is impossible for the authorities to trace PPPs and perform controls against a valid background. Furthermore, in almost all audited Member States, inspectors do not have live electronic access to detailed data on registered and revoked PPPs,<sup>137</sup> which is an obstacle to control, as without access to this information, inspectors cannot check whether the controlled PPPs comply with their defined formulation in accordance with the conditions of the relevant authorisations.

In some Member States, the coordination and cooperation between CAs (under the PPPR) and/or with other relevant enforcement institutions (as for example the national authorities controlling imports at the EU external borders) is ineffective or, according to Commission data, does not exist in some cases.

#### *Legal framework and practice at EU level*

Article 2 (1) of the PPPR creates some interpretation problems at national level because CAs have different understandings of what is meant by '[products], in the form in which they are supplied to the user', to which the enforcement requirements of the regulation must apply. Some Member States interpret this as not encompassing, for instance, PPPs in their bulk or active substances as such. Provisions concerning goods in transit – i.e. through a Member State but destined for another Member State – are equally subject to different interpretations and result in different enforcement practices. Furthermore, some Member States do not control PPPs without their final label.

In contrast to other regulations in the field of food safety,<sup>138</sup> the PPPR does not oblige Member States to lay down rules on sanctions and take measures to apply them. This

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<sup>136</sup> It should be noted though that the CAs carrying out approval- and authorisation-related work are not necessarily the authorities enforcing regulatory decisions.

<sup>137</sup> The reason for this is that the precise formulation details of PPPs are commercially sensitive and are treated as confidential by CAs.

<sup>138</sup> For example, Article 25 of Regulation (EC) 1935/2004 on food contact materials (FCM Regulation) stipulates that Member States must lay down the rules on sanctions applicable to infringements of the provisions of the FCM Regulation and must take all measures necessary to ensure that they are implemented. The sanctions must be effective, proportionate and dissuasive.

makes enforcement at national level a rather soft exercise for reasons related to an omission in the EU legal framework itself – if sanctions cannot be imposed, then controls are purposeless.

Even though the PPPR initially envisaged (in Article 68) that the Commission must adopt a regulation setting out provisions for controls,<sup>139</sup> this regulation has never been adopted, which resulted in an insufficient level of harmonisation and EU coordination in official controls performed by Member States, as noted above and also echoed by stakeholders. This obligation for the Commission has been recently (in 2017) deleted from Article 68 and converted into an option for the Commission.<sup>140</sup>

The current EU rules on parallel trade seem to allow the infiltration of illegal PPPs into the market, which is also confirmed by stakeholders mainly from industry and CAs; however, the evidence available does not explain the precise mechanisms leading to the phenomenon observed, which would require further research.

There is room for greater leadership by the European Commission on international cooperation. The Commission might play a key role in establishing a dialogue with those non-EU countries where illegal PPPs originate, with a view to identifying competent authorities in those countries and, where possible, agreeing upon shared solutions to address illegal trade.<sup>141</sup>

### **Final assessment of implementation against the effectiveness criterion and relevant impacts**

The opinions of stakeholders on whether the objectives of the PPPR are being met differ (Milieu 2018, Annex I here). Stakeholders (across all categories with the exception of environment/health NGOs, organic food and farming, and the biopesticides industry), consider that the health and environment objectives of the regulation have been met. Although a slight majority considered that overall the internal market objective has been met, respondents were divided (including within the same category): associations of manufacturers and farmers claimed it had not been met, while a majority of individual companies said it had been met. The objective that, according to stakeholders (across all categories) had not been met, relates to improving agricultural production.

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<sup>139</sup> In particular on the production, packaging, labelling, storage, transport, marketing, formulation, parallel trade and use of plant protection products.

<sup>140</sup> Following an amendment of the PPPR from 2017 (with Regulation (EU) 2017/265 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulation (EC) 1107/2009 on the placing of Plant Protection Products on the market as well as many other pieces of EU legislation), this obligation for the Commission was removed, and as from 14 December 2019 (when the amendment will be applicable), the Commission will have a choice whether to adopt such rules or not; more specifically, following Article 24 (4) of Regulation (EU) 2017/265, the Commission *may* lay down detailed rules on uniform practical arrangements for the performance of official controls, including on the collection of information, monitoring and reporting on suspected poisonings from plant protection products.

<sup>141</sup> AGRA CEAS Consulting, Arcadia International ad hoc study from 2015 as quoted in Milieu 2018, Annex I here.

These results are based on stakeholders' subjective perceptions and the relevant interests they represent, and could therefore have been expected. However, our evaluation approach to assessing effectiveness requires that a link is established between the way instruments are applied in practice and the achievement of the relevant objectives. The findings of this evaluation (presented in the above sections on the effectiveness criterion) show that the practical implementation of the three main instruments under the regulation – approval of substances, authorisation of PPPs and enforcement of regulatory decisions – is associated with a number of problems and thus none of the PPPR objectives could be considered as having been achieved.

- Approval/renewal of substances and the achievement of the PPPR objectives

A major issue of concern observed above is the incomplete harmonisation of data requirements and methodologies used in the evaluation process in some scientific fields. It is worth recalling that criteria for endocrine disruptors were established only recently. This may lead to direct negative effects on health, environment and agricultural production because evaluators are not yet able to fully assess substances against all their hazards and risks based on strict data requirements and methodologies.

CAs have varying capacities in terms of expertise and staff and the quality of the results from the evaluations of hazard identification and initial risk assessment performed at national level therefore varies across Member States. As a result, the PPPR and relevant supporting legal requirements are not uniformly implemented across Member States with all relevant health and environment implications.

Furthermore, for reasons related to variations in capacity and workload, CA's work results in delays, which lead to subsequent delays in authorisations of PPPs, which, in their turn lead, as explained below in the context of 'emergency authorisations' under Article 53, to negative effects on health, environment, market and agricultural production.

The risk management (decision-making) stage of the approval procedure (at EU level) was found to lack transparency, which creates room for decisions that do not necessarily follow evaluators' (CA, EFSA) advice, which in turn may result in negative effects on health and the environment and therefore creates public distrust of the system regulating pesticide substances.

- Authorisation of PPPs and the achievement of the PPPR objectives

As mentioned above, the authorisation of PPPs is characterised by delays in risk management decisions, which are due, among other things, to lack of resources, uneven distribution of evaluation workload and mutual distrust in CA evaluation work. This leads as a direct result to a lack of availability of PPPs for users. In order to compensate for this, in some cases CAs authorise PPPs containing prohibited substances (or certain prohibited usages of PPPs containing approved substances) under derogation, with proven negative effects on health and the environment. Furthermore, as mentioned, delays occur due to lack of trust between CAs, which results in problems in the application of the mutual recognition principle, and subsequent distortion of the functioning of the internal market. The ultimate result of the problematic aspects of the practical implementation of the authorisation instrument observed is lack of improvement in agricultural production, a conclusion which is also shared by stakeholders across all categories.

- Enforcement and the achievement of PPPR objectives

The enforcement problems mentioned above suggest that the PPPs available on the market, whether manufactured in the EU or imported from third countries, and their application by users, do not necessarily comply with the relevant authorisation conditions as regards their composition and usage.

This is therefore a factor that critically undermines the achievement of all four objectives of the PPPR, because regulatory risk management decisions (resulting from the approval and authorisation procedures) cannot be properly enforced.

## **Efficiency**

The assessment of the efficiency of Regulation (EC) 1107/2009 addresses the question whether the existing policy results could have been achieved with less costs/resources. The evaluation is exclusively based on the perceptions expressed by the participants in the survey on the implementation of the regulation (Milieu 2018, Annex I here).

As a general remark, the opinions of the participants in the survey as regards the cost-benefit ratio are (equally) divided. Some of the respondents indicated that the current results could not have been achieved with lower costs (environmental NGOs, some competent authorities and some manufacturers), while others (manufacturers, animal welfare NGOs, a small number of authorities (including individuals belonging to competent authorities and one farmers' association) claimed the opposite.<sup>142</sup>

The competent authorities were also asked to give their opinion on enforcement costs. On this issue the views expressed were equally divided between: high or very high, and reasonable.<sup>143</sup> Similarly, manufacturers were asked to express their views as regards compliance costs. A slight majority responded that the costs are high or very high, while other respondents considered the costs to be reasonable.<sup>144</sup>

Data collected under this project (and desk research) do not provide complete information to allow for a full understanding of the elements to be considered under this criterion. It is therefore impossible to clearly state whether the implementation of regulation is or is not efficient.

## **EU added value**

In the context of Regulation (EC) 1107/2009, the question of EU added value refers to whether Member States could have achieved the same results better without this regulation.

Two sources support this assessment:

- the survey on the general implementation of the regulation, collecting stakeholders' perceptions (Milieu 2018, Annex I here);

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<sup>142</sup> A comparable number (even if lower) selected the 'don't know' option.

<sup>143</sup> The same number of respondents selected the 'don't know' option.

<sup>144</sup> Few respondents selected 'don't know' or did not answer this question.

- the empirical data collected through a self-completed questionnaire addressed to Member States (competent authorities) within the research on the authorisation of Plant Protection Products (Hamlyn 2018, Annex III here).

The evidence available shows that there is a positive overall perception of the EU added value of Regulation (EC) 1107/2009, as well as appreciation of the benefits brought by some of the innovations introduced by the regulation. It is of note that none of the stakeholders taking part in this survey considered that Member States would do better without the regulation.

As a concrete illustration of the added value, we can refer to the zonal system. The 'ambition' of Regulation (EC) 1107/2009 was to make progress as regards the approval and authorisation procedure, after years of experience gained from the implementation of its predecessor, Directive 91/414/EEC. In this respect, one of the innovations introduced by the current regulatory regime is the zonal system. Accordingly, Member States (and Norway) are divided into three zones with comparable 'agricultural, plant health and environmental (including climatic) conditions' (Northern, Central and Southern), in order to avoid duplication of work, reduce the administrative burden on industry and Member States, increase harmonisation, and facilitate mutual recognition of authorisations (Article 29). The competent authorities (CAs) participating in the survey suggested that the system already has a positive impact on the authorisation process. Its benefits mainly refer to harmonisation, work sharing and resolution of disagreements between CAs. Nevertheless, it is of note that the zonal system is still 'under construction' and it is too early to draw firm conclusions about its real operation.

The data available do not allow for a more detailed assessment of the EU added value, therefore we can reasonably assume, according to respondents' opinions (both competent authorities' experience and other stakeholders' perceptions) that intervention at European level enhances the value of the efforts and actions that MSs could have undertaken themselves.

## Conclusions

This evaluation revealed a mixed picture of implementation of Regulation (EC) 1107/2009 on the placing of plant protection products on the market, when assessed against the key criteria for evaluation: relevance, coherence, effectiveness (underpinned by the knowledge base), efficiency, and EU added value.

While the objectives of the regulation related to health and the environment were found by stakeholders<sup>145</sup> across all categories to be **relevant** to real needs, respondents were in less agreement on the objectives related to internal market and agricultural production. The data available suggests that the regulation should better reflect the need to promote agricultural practices based on integrated pest management (including by setting the development and usage of substances of low risk as an objective), as well as the need for innovation in the field of plant protection products.

As far as **coherence** is concerned and based on stakeholders' opinions,<sup>146</sup> the regulation's objectives and instruments do not seem to be in line with EU policies in the field of agriculture, food security, climate change and sustainable use of pesticides and maximum residue levels of pesticides in food and feed. As regards the implementation of the regulation's instruments, stakeholders expressed similar opinions.

In terms of **effectiveness**, the aim is to assess whether the objectives of the regulation are being achieved. The evidence<sup>147</sup> available shows that the practical implementation of the three main instruments of Regulation (EC) 1107/2009 - approval of substances (a), authorisation of plant protection products containing approved substances (b), and enforcement of regulatory decisions taken in the frame of approvals and authorisations (c) - is problematic.

a) The practical implementation of approvals of active substances (performed by national competent authorities (CAs), the European Food Safety Authority (EFSA) and the Commission, together with Member States' experts), is associated with many issues of concern.

A first group of concerns is associated with the evaluation approach (as established by law); in particular, two main elements of the approach - who should produce the evidence for evaluations, and the hazard-based approach (as opposed to the risk-based approach) - are questioned because of their practical implications.

A second group of concerns relates to the practical implementation of the established evaluation approach. Two major issues of concern emerged: the incomplete harmonisation of data requirements and methodologies used in some scientific fields (e.g. criteria for endocrine disruptors were established only recently) and the practical work of national and EU authorities involved in the evaluation of substances. The former may lead to direct

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<sup>145</sup> Milieu 2018, Annex I here.

<sup>146</sup> Milieu 2018, Annex I here.

<sup>147</sup> The findings of the studies annexed to this European Implementation Assessment: Milieu 2018, Annex I; Bozzini 2018, Annex II; Hamlyn 2018, Annex III and Rimkutė 2018, Annex IV.

negative effects on health, environment and agricultural production because evaluators could not yet fully assess substances against all their hazards and risks based on strict data requirements and methodologies. The latter referred in particular to the evaluation of the active substance glyphosate, which raised doubt for stakeholders and policy-makers from various sides as regards both whether the scientific evaluation was implemented correctly and whether the EU evaluators performed their work in this particular case independently from the industry; this evaluation did not find evidence supporting those doubts.

The performance of national competent authorities was found to be a major factor influencing the evaluation of substances. This European Implementation Assessment found that most – but not all – competent authorities have the institutional capacity to act as a Rapporteur Member State (RMS) and deliver assessment reports to EFSA (although with variable report quality across Member States). There are substantial differences among Member States as regards available expertise and staff. All CAs appear to be seriously and chronically understaffed, based on their self-evaluation. This is the main factor explaining why approvals and renewals of approvals are delayed at the stage of hazard identification and initial risk assessment performed by Member States (which also implies delays in the subsequent authorisations of PPPs at national level). The varying capacities of CAs in terms of expertise and staff and thus the quality of the results from the evaluations of hazard identification and initial risk assessment performed at national level, varies across Member States. As a result, the regulation and relevant supporting legal requirements are not uniformly implemented across Member States with all relevant health and environment implications.

Transparency at the stage performed by CAs is problematic, as the information related to evaluations at CA level becomes available at the EFSA stage, however not always in a user friendly way. The risk management (decision-making) stage of the approval procedure (taking place at EU level) was found to lack transparency, which creates room for decisions that do not necessarily follow evaluators' (CAs, EFSA) advice. This may in turn result in negative effects on health and the environment, lowering public trust in the system regulating pesticide substances (used in PPPs).

b) As regards authorisation of plant protection products, which takes place exclusively at national level, this evaluation found that the procedures feature delays in risk management decisions, which are due, among other things, to lack of resources and uneven distribution of evaluation workload across competent authorities and, distrust between CAs regarding evaluation work.

As a direct result, the delays in risk management decisions lead to a lack of plant protection products (PPPs) available to users. To compensate, in some cases, competent authorities authorise PPPs with proven negative effects on health and the environment. Known as derogations under Article 53 of the regulation, their stated main intention is to ensure room for manoeuvre in special circumstances, i.e. when there is danger that could not be contained by any other reasonable measures. This evaluation found though that there are cases where Article 53 is used at national level against this initial intention of the legislator.

Furthermore, as mentioned, delays are due to lack of trust between CAs, which results in problems in the application of the mutual recognition principle, and distortion in the functioning of the internal market of PPPs.

The ultimate result of the problematic aspects of the practical implementation of the authorisation instrument is a lack of improvement in agricultural production.

As for the approval procedure, the harmonisation of guidance is an ongoing process.

As regards the transparency aspects of the authorisation-related activities of competent authorities, it was found that current practices in the Member States examined are problematic, especially in terms of limited public availability of information on evaluation and the authorisation procedure itself, as well as in terms of access to information.

c) The findings of this evaluation on enforcement practices suggest that the PPPs available on the market – whether manufactured in the EU or imported from third countries – and their application by users do not necessarily comply with the relevant authorisation conditions as regards their composition and usage. The fact that regulatory risk management decisions (resulting from the approval and authorisation procedures) could not be adequately enforced critically undermines the achievement of all four objectives of the PPPR.

The **efficiency** of the implementation of the regulation was difficult to assess because of data scarcity. Nevertheless, according to stakeholders,<sup>148</sup> the actual implementation results could not have been achieved at a lower price.

Finally, the data available shows that stakeholders<sup>149</sup> (across competent authorities, health/environment NGOs, manufacturers of substances and plant protection products and their users (farmers)) unanimously consider the implementation of Regulation (EC) 1107/2009 **adds value** to national efforts in achieving its objectives. This assessment shows that the EU is the appropriate level at which regulatory action in the field of pesticides (used in plant protection products) should continue.

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<sup>148</sup> Milieu 2018, Annex I here.

<sup>149</sup> Milieu 2018, Annex I here.

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## **Annex I**

### **Evaluation of the implementation of Regulation (EC) No 1107/2009 and its impacts. Mapping the usage made by Member States of the derogations laid down by Article 53 of the Regulation**

**Research paper  
by Milieu Ltd and IEEP**

#### **Abstract**

This research paper provides a detailed analysis of the use of derogations under Article 53 of Regulation (EC) No 1107/2009. In addition, it presents the results of thorough desk research of the available literature and of a targeted stakeholder survey on the implementation of Regulation (EC) No 1107/2009.

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## **Executive summary**

This research paper was commissioned by the Ex-post Evaluation Unit of the European Parliamentary Research Service (EPRS) to support the work of the European Parliament's Committee on the Environment, Public Health and Food Safety in producing a dedicated report on the implementation of Regulation (EC) No 1107/2009 (the Plant Protection Products Regulation – PPPR).

This research paper has three main components. Part 1 focuses on the practical use made by Member States of the authorisation under Article 53 of the PPPR. Part 2 presents the results of a general review of the available literature, followed by a stakeholder survey on the implementation of the PPPR. Part 3 assesses the implementation of the PPPR against the five evaluation criteria (i.e. relevance, coherence, effectiveness, efficiency and added value) based on the findings of Part 1 and Part 2, and presents recommendations to improve the implementation of the PPPR.

### **1. Implementation of Article 53 of the PPPR**

This part of the research paper covers the description of Article 53 core requirements and related Commission working document guidance, the use of these authorisations in Member States, the impact of Article 53 authorisations through three case studies (Article 53 authorisations on soil fumigants, neonicotinoids and insecticides for use in mass trapping), the practical application of procedures for granting emergency authorisation in eight Member States and the implementation of Member State obligations to inform other Member States and the Commission of the authorisations granted, and the Commission review of emergency authorisations and the role of EFSA. This part is based on general desk research on the implementation of the PPPR (See Part 2), the review of the notifications of Article 53 authorisations granted by Member States in 2016 and 2017, eight country fiches covering mainly the procedural aspects of Article 53 authorisations, and interviews with competent authorities (CAs) and other national stakeholders (e.g. PPP producer associations, farmer/user associations, environmental and public health associations), three case studies on the impact of Article 53 authorisations, and interviews with selected EU stakeholders and a Commission representative involved in 'Pesticides and placing on the market' at DG SANTE.

#### *Introduction to Article 53 authorisations*

The purpose of Article 53 is to allow Member States, in exceptional cases, to authorise PPPs that do not comply with the conditions provided for in the PPPR, where such authorisation is necessitated by a danger or threat to plant production or ecosystems that cannot be contained by any other reasonable means. Article 53 contains three core provisions which set out some conditions on the use of the derogation, an obligation of information to other Member States and the Commission on the use of Article 53 derogations, and the power of the Commission to request an opinion from EFSA or scientific or technical assistance on a Member State derogation, and the relevant measures that can be adopted on foot of that opinion. In February 2013, the Commission adopted a revised version of a working

document on Article 53 emergency situations, which lays down the procedure for Member States to grant an authorisation under Article 53.

*Use of Article 53 authorisations*

The number of Article 53 authorisations granted by Member States has increased significantly since 2007, from 59 in 2007 to almost 400 in 2017. These authorisations are mostly granted for PPPs containing approved substances. Around 9% of Article 53 authorisations were granted in 2017 for PPPs containing non-approved substances. There is a clear tendency in Member States to repeat Article 53 authorisations, with around one-third of the Article 53 authorisations granted in 2017 having already been granted in 2016.

To a certain extent, the use of Article 53 contradicts the Commission's working document on emergency situations, as derogations for PPPs containing non-approved substances have been granted for cases which are not connected to a single species but, rather, for soil disinfection purposes. In addition, many derogations have been repeated several years in a row. The misuse of Article 53 authorisations for minor uses has also been observed.

The review of the notifications suggests that a relatively small number of Article 53 authorisations are granted for emergency situations, with the majority of such authorisations not relating to special circumstances, as provided in Article 53.

Article 53 authorisations that are not granted for emergency cases can be explained, in part, by the lack of alternatives. According to manufacturers' and farmers' associations, the range of authorised substances has been significantly reduced since the implementation of the work programme for the examination of active substances, leaving farmers with little or no option for the control of certain pests. However, this argument overlooks the fact that only around 9% of the Article 53 authorisations granted in 2017 concerned PPPs containing non-approved substances.

Article 53 derogations are also used to provide access to biopesticides and mineral or plant-based substances for use in IPM and organic agriculture. Associations representing the biocontrol industry and organic food and farming indicated that ill-adapted criteria in the authorisation process present barriers to the authorisation of natural substances, as does the lack of guidance for risk assessment for certain categories of substances of natural and mineral origin. Another argument advanced by these associations and the CAs is that such substances have a small market and are often non-patentable, which, given the low return on investment, does not provide an incentive for manufacturers to submit dossiers.

The large number of PPPs undergoing an authorisation procedure, together with the large number of repeated Article 53 authorisations, suggests that such authorisations are also used to solve structural problems occurring in the authorisation procedures and the extension of authorisations of PPPs, such as delayed authorisation procedures, deficiencies in mutual recognition, or the lack of manufacturers' investment in preparing dossiers for minor uses.

Article 53 is thus not used according to its original purpose, and may operate against some of the principles of the working document on emergency situations.

*Case studies on the impact of Article 53 authorisations*

The case studies show, inter alia, that some of the Article 53 authorisations are used to maintain the use of pesticides with proven significant environmental and human health impacts because the crop systems in which they are used have been built on the use of these pesticides and would require economic adaptation to a different crop system if access to these chemicals was forbidden.

The case study on chemical soil fumigants suggests that the continued use of Article 53 authorisations for chemical soil fumigants is not aligned with the principles of sustainability, precaution and substitution. These fumigants involve active substances such as dichloropropene and chloropicrin, considered by EFSA to pose unacceptable risks to the environment and human health, including evidence of groundwater and surface water pollution. Alternatives to chemical soil fumigants are available, with the principal argument against their use being the economic cost imposed on the horticulture industry due to the need for longer rest periods between crops and/or crop rotations. However, there is also evidence that alternatives can be cheaper than pesticide applications.

The case study on insecticides for use in mass trapping demonstrates that the main drivers for the use of these Article 53 authorisations are a lack of capacity in the regulating authority to process authorisations without delay, a lack of industry support, or international trade agreements that do not correspond to the pesticide regulatory situation in the EU. However, under the PPPR, such cases should be dealt with using Article 51 extensions of minor use instead of Article 53 authorisations.

The case study on Article 53 authorisations on neonicotinoids outlines the significant adverse effects of these substances on bees (including honeybees, bumblebees and solitary bees), and other invertebrates, such as butterflies, aquatic macro-invertebrates and predatory and parasitoid wasps and bugs. It shows that there are alternatives available for almost all of the crop pests targeted by neonicotinoid seed treatments, provided an integrated pest management approach is used and a crop rotation system is followed. The case study suggests that the introduction of more diverse crop rotations would bring wider economic benefits in the long-term, as well as helping to adapt to the loss of neonicotinoid seed treatments. The Article 53 authorisations on neonicotinoids are thus unlikely to fulfil the principles of sustainability, precaution and substitution and the Article 53 criteria.

*Member State procedures for granting emergency authorisations*

In all but one of the eight selected Member States, the Article 53 procedure is not detailed in law but, rather, in non-binding guidance documents that include the application forms and documents for applicants. Most involve authorities other than the CA and/or scientific bodies in the decision-making process. However, there is no public consultation foreseen in the Article 53 authorisation procedure.

All eight of the selected Member States make their application forms available online. These application forms follow the notification template prepared by the Commission, as well as the recommendations set out under the Commission working document. A large share (38%) of the Article 53 authorisations granted in 2017 were requested by agricultural or forestry companies and associations; 31% were requested by PPP manufacturers or the

seed industry; 23% were requested by authorities, and a small number by other types of applicants such as agricultural and agronomy research institutes and consultants (6%), or producers of animal health products or feed (1%)<sup>1</sup>. In one selected Member State, applications are only accepted from farmers or farmers' associations, in order to combat the commercial interests of PPP producers. Similarly, in one selected Member State, where applications are led by PPP producers, the CA verified that the application is undertaken on behalf of farmers/ farmers' associations. In all selected Member States, the same procedure applies to all Article 53 authorisations. There are no specific evaluation procedures for PPPs containing non-approved substances or repeated Article 53 derogations, although the evaluation by the authority can be more thorough in these cases.

Almost all selected Member States publish their decisions granting emergency authorisations on the CA website. However, public awareness of the purpose and use of Article 53 authorisations is very low.

None of the selected Member States has a specific strategy to limit the use of repeated Article 53 authorisations.

There are no specific inspection strategies/programmes for Article 53 authorisations. Rather, these authorisations are controlled as part of the routine inspections of PPP authorisations.

*Notifications by Member States to other Member States and the Commission*

Since early 2017, Member States have sent their notifications on their use of Article 53 authorisations via PPPAMS. Prior to that, notifications were sent and saved via CIRCABC. Notifications have never been available to the public. Their access is restricted to the Commission and Member State CAs.

Some Member States are unlikely to notify all derogations, or derogations are notified but not 'immediately', as required under Article 53 of the PPPR. According to the assessment of the sample of notifications covering the years 2016 and 2017, several notifications were almost empty, with only very limited information available.

The Commission is unlikely to launch infringement procedures for non-compliance on information requirements under Article 53. However, a representative of the Commission stresses its efforts to ensure that Member States comply with this obligation through bilateral discussions with Member States or through 'naming and shaming' at the Standing Committee meetings. On consultation on notifications by other Member States, almost all Member State CAs mentioned that these notifications have little value.

*Commission review of emergency authorisations and the role of EFSA*

As of February 2018, since the entry into force of the PPPR the Commission had request an opinion from EFSA only once (under Article 53(2) of the PPPR). In September 2017, EFSA was requested to examine Article 53 emergency authorisations granted by Romania (six

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<sup>1</sup> 1% of the applicants could not be identified through desk research.

authorisations), Bulgaria (one authorisation), Estonia (two authorisations), Finland (two authorisations), Latvia (two authorisations), Lithuania (two authorisations) and Hungary (nine authorisations) concerning severely restricted PPP containing three neonicotinoid substances clothianidin, imidacloprid and/or thiamethoxam in 2017, used in sunflower and maize, oilseed rape seeds, spring rape and spring turnip rape seeds. According to DG SANTE, the Commission has limited power to trigger an infringement procedure in cases of misuse of Article 53 emergency authorisations. Given that the authorisation of PPPs is under the exclusive competence of Member States, it is difficult to challenge Member State decisions under this procedure, and DG SANTE stressed that the Commission has neither the capacity nor the competence to carry out a systematic and full review of individual Article 53 authorisations granted in specific geographical areas across the EU.

## 2. Desk research on the implementation of the PPPR

The PPPR entered into force in June 2011. In comparison to the previous legislation on PPP (Council Directives 79/117/EEC and 91/414/EEC, repealed by the PPPR), it introduces, among other things, new provisions at EU level on the categorisation of active substances with certain properties. The PPPR provisions are implemented by the Member States, the Commission and EFSA. The research team identified the documents for the desk research based on a set of criteria (e.g. the scope of documents focusing on the implementation of the Regulation, documents produced or commissioned by main actors involved in the implementation of the PPPR, documents produced by independent academic research, by stakeholders concerned).

The desk research identified six main issues relating to the implementation of the PPPR:

- Control and enforcement measures in place in Member States to tackle illegal PPP.
- Use of Article 53 authorisations by Member States.
- Governance aspects of authorisations at Member State level.
- Transparency of the regulatory process and the communication by CAs on risk.
- Assessment of hazards and risks of PPP.
- Use of IPM and low-risk PPPs.

Several documents reviewed (produced or commissioned by the Commission) highlighted that Member States must improve their control and enforcement measures, in particular in tackling illegal and counterfeit pesticides (which have significantly increased in the recent past), and must ensure that the conditions of use of PPPs adopted at the authorisation phase are correctly applied by PPP users. For example, they mention the limited or non-existent records of PPPs on the market in some Member States. There is a lack of coordination between CAs in Member States, a lack of resources to carry out effective controls, a lack of a centralised EU database or a reference laboratory for product composition, and an insufficient level of harmonisation and EU coordination of official controls.

Several documents produced by the Commission and NGOs raised the issue of Member States' failure to properly implement Article 53 authorisations. They highlighted concerns that, over the years, this authorisation operates by way of a loophole in the legislation to

circumvent bans or restrictions on the use of PPPs at national level. Some of the documents reviewed showed an increase of Article 53 authorisations, together with a high number of repeat authorisations. One document raised some concerns about Member State non-compliance with Article 53 of the PPPR, the large proportion of Article 53 authorisations based on PPP producers' applications, the absence of the Commission in monitoring Article 53 authorisations, and the lack of transparency and public scrutiny in the implementation of Article 53.

Different types of sources (Commission, NGO, PPP manufacturers and users, Member State authorities) felt that Member States struggle to implement the authorisation procedure of PPP, and pointed to the need for improvements in some significant areas if the procedure is to be implemented adequately. These implementation issues concern, *inter alia*, the lack of resources to properly grant authorisations, deficiencies in long-term planning, difficulties to use the work done by other Member States, incomplete information in electronic registers, imbalance in the number of applications between some Member States within the same zone, non-compliance with deadlines during authorisation, inadequate cooperation in the re-registration of PPPs, differences in how Member States evaluate applications for authorisations of 'generic' products, and Member State difficulties in dealing with comparative assessments.

One academic source (Bozzini, 2017) described a lack of transparency in the regulatory committee procedure for the adoption/rejection of active substances. It also pointed to deficiencies in risk communication after decisions are adopted. According to another academic article (Storck, 2017), although, EFSA contributes to the transparency of pesticide authorisation by releasing conclusions on peer reviews of risk assessment for each approved active substance, these documents are almost incomprehensible for non-experts, yet contain insufficient detail for researchers. In response, the Commission, in its December 2017 reply to a European Citizens' Initiative to ban glyphosate, provides some potential actions to improve transparency and risk communication.

Several documents (NGO reports, academic studies, reports commissioned by the Commission) highlighted the need to enhance the hazard and risk assessment of active substances and PPP to ensure adequate health and environmental protection. For example, they consider there to be a lack of assessment of the combined effects of residues of PPP and pesticides preparations. There is a need to include biodiversity in risk assessment, particularly soil biodiversity, as well as Developmental Immunotoxicity and Developmental Neurotoxicity.

By contrast, some of the other documents reviewed (reports commissioned by Member States, reports commissioned by PPP producer associations) stressed that the PPPR assessment process should be less stringent and focus on risk rather than intrinsic hazard properties. For example, stakeholders (*i.e.* PPP manufacturers and users) consulted within the preparation of the Biointelligence report (Biointelligence Service, 2012) stated that they found the assessment process too precautionary and not proportionate to the risks that need to be managed. They also pointed to the need to rely on field studies, and stated that exposure is not sufficiently considered in PPPR.

One academic article (Pelaez et al., 2013) highlighted the difficulties encountered by EU and national CAs in achieving and maintaining independence in the assessment of hazard and risks from active substances and PPPs, as they rely on studies commissioned by industry applicants. One document (PAN Europe, Generation Futures 2018) pointed out the involvement of industry-linked experts in the development of scientific evaluation methods. Another academic article (Rimkutė, 2015), based on a case study on the ban of neonicotinoid, assumed that the Commission could influence EFSA's scientific conclusions. In response, the Commission, in its reply to a European Citizens' Initiative 'Ban glyphosate', provided related explanations and highlighted potential actions to strengthen governance in scientific studies.

One academic source (Bozzini, 2017), based on the EFSA/ECHA and IARC opinion on glyphosate, stressed the difficult trade-off between regulatory science and research science, and between the need for standard testing criteria to be shared as widely as possible and the need for research designs that are innovative and promising. It also pointed out the difficult trade-off between testing in laboratory conditions and testing in realistic conditions.

Finally, the same source (Bozzini, 2017) was of the opinion that there is an ongoing 'paradigm war' between toxicologists and endocrinologists for the definition of Endocrine Disruptors Criteria, which affects the implementation of the EDC cut-off criteria under the PPPR.

Commission reports highlighted the limited application of IPM in Member States and pointed to the room for improvement in this domain (e.g. lack of measurable criteria for IPM). They also stressed the limited use of low-risk PPPs in Member States. One academic source (Chandler, 2011) provided some explanations for such limited use (e.g. low profits from niche market products, high fixed costs for small user groups, risk aversion, and IPM portfolio economies).

### **3. Results of stakeholder survey on the implementation of the PPPR**

To complement and cross-check the results from the desk research, a targeted online stakeholder survey was carried out from 16 January to 16 February 2018 to collect opinions about the implementation of the PPPR. The survey covered the five evaluation criteria (effectiveness, efficiency, relevance, coherence and EU added value) and other important aspects for the implementation of the Regulation, such as the knowledge base for authorisation decisions. The survey received 33 individual responses from all major stakeholder categories (with the exception of the academic community).

**Relevance:** The majority of respondents considered the objectives of the PPPR still relevant to the current needs. Several respondents highlighted that the PPPR should better satisfy the need to promote an IPM-oriented agriculture. Several respondents also felt that innovation should be added to the objectives.

**Knowledge base:** A slight majority of respondents considered available scientific knowledge sufficient to meet decision-making needs regarding the approval of active substances at EU level and the authorisation of PPPs at national level. However, the majority of respondents felt that the available scientific knowledge is not adequately used in these procedures. According to environment and health NGOs, relevant scientific literature is too often put aside on debatable grounds (that were usually not carried out according to OECD test protocols, including GLP, even though some of these studies are not amenable to GLP). Manufacturers' associations and individual manufacturers indicated that scientific data from applicants were not sufficiently taken into account due to a lack of dialogue between evaluators and applicants, the rules on admissibility of studies, and the politicisation of certain dossiers.

**Coherence:** Respondents considered the objectives of the PPPR, and its practical implementation, to conflict with the objectives and implementation of EU agriculture policy, and - to a lesser extent - with food security policy. One-third of respondents stated that there is a conflict between the objectives of the PPPR and the Directive on the sustainable use of pesticides, while coherence with climate policy divided respondents. In their comments, respondents mentioned coherence problems with the Directive on sustainable use of pesticides, the Biocidal Products Regulation (BPR), other chemical regulations (REACH), or the Water Framework Directive.

**Effectiveness:** With the exception of environmental/health NGOs, and associations representing the interests of organic food and farming and biocontrol, the majority of respondents considered the objectives to protect human and animal health, and the environment, to be met. Overall, the majority of respondents stated that the PPPR has not succeeded in meeting its objective to improve agricultural production, for different reasons. Environmental/health NGOs, some CAs, and associations representing the biocontrol industry and organic food and farming, argued that the Regulation fails to improve agricultural production as it does not promote the development of an IPM-oriented agriculture. Manufacturers' and farmers' associations indicated that the objective was not met, and that the competitiveness of the agricultural sector was damaged because the number of available active substances had been reduced, while new active substances and PPPs entered the market only very slowly.

With the exception of parallel trade and the labelling of PPPs, most respondents considered the day-to-day implementation of the different instruments under the PPPR to be problematic.

**Efficiency:** There was no clear majority in respect of whether or not current results could be achieved at a lower cost. Manufacturers' associations and individual manufacturers identified inefficiencies in approval procedures for active substances and authorisation procedures of PPPs at national level, leading to increased cost and burden for applicants and CAs (e.g. flaws in the implementation of mutual recognition, duplication of work) and increased time to market for PPPs. Some CAs also indicated that the increasing complexity of the risk assessment methodology for approvals of active substances creates significant administrative burden.

**Impacts:** The majority of respondents considered the impact of the PPPR on human and animal health, the environment and consumers to be generally positive. However, environmental/health NGOs indicated that current failures in implementation result in very negative impacts for human health and ecosystems in agricultural areas. The majority of respondents considered the impacts on farmers and competitiveness to be negative.

**EU added value:** The majority of respondents considered the implementation of the PPPR to add value to national efforts to achieve the relevant health, environment and market objectives. None of the respondents stated that Member States would do better without the PPPR.

Finally, in light of the findings of the Article 53 analysis, the desk research and the targeted survey on the general implementation of the PPPR some recommendations to improve the implementation of the PPPR were developed under Part 3.

## List of abbreviations

<b>ADI</b>	Acceptable Daily Intake
<b>AOEL</b>	Acceptable Operator Exposure Level
<b>ARfD</b>	Acute Reference Dose
<b>BPR</b>	Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products
<b>CA</b>	Competent Authority
<b>CCD</b>	Colony Collapse Disorder
<b>CLP Regulation</b>	Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures
<b>DIT</b>	Developmental Immunotoxicity
<b>DNT</b>	Developmental Neurotoxicity
<b>ECHA</b>	European Chemicals Agency
<b>EDC</b>	Endocrine Disrupting Chemicals
<b>EFSA</b>	European Food Security Agency
<b>EIA</b>	European Implementation Assessment
<b>EPRS</b>	European Parliamentary Research Service
<b>GAP</b>	Good Agricultural Practices
<b>GLP</b>	Good Laboratory Practices
<b>IARC</b>	International Agency for Research on Cancer
<b>IPM</b>	Integrated Pest Management
<b>MLR</b>	Maximum Residue Level
<b>MS</b>	Member State
<b>MUCF</b>	Minor Use Coordination Facility
<b>NAP</b>	National Action Plan
<b>NGO</b>	Non-Governmental Organisation
<b>NTA</b>	Non-Target Arthropods
<b>PPP</b>	Plant Protection Product
<b>PPPAMS</b>	Plant Protection Product Application Management System
<b>NIAS</b>	Non-Intentionally Added Substances
<b>PPPR</b>	Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives
<b>PPP</b>	Plant Protection Product
<b>OECD</b>	Organisation for Economic Cooperation and Development
<b>OPEX</b>	Operator exposure
<b>PAFF Committee</b>	Standing Committee on Plants, Animals, Food and Feed
<b>PBT</b>	Persistent, Bioaccumulative and Toxic
<b>REACH Regulation</b>	Regulation (EC) No 1907/2006 on the Registration, Evaluation, Authorisation and Restriction of Chemicals
<b>TTC</b>	Toxicological Threshold Concentration
<b>SDS</b>	Safety Data Sheets
<b>UN</b>	United Nations
<b>WFD</b>	Water Framework Directive
<b>WHO</b>	World Health Organization

## Introduction to the study

In 2006, the Commission published a Thematic Strategy on the Sustainable Use of Pesticides<sup>2</sup>. This strategy aimed to improve controls on the use and distribution of pesticides and reduce the levels of harmful active substances by substituting the most dangerous with safer (including non-chemical) alternatives, in order to reduce the overall risks and negative impacts on human health and the environment from the use of pesticides. As a result of this strategy, Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market (PPPR)<sup>3</sup> was adopted in 2009. This formed part of a legislative package, which also included Directive 2009/128/EC establishing a framework for Community action to achieve a sustainable use of pesticides (the Sustainable Use Directive)<sup>4</sup>. These two pieces of legislation, together with Regulation (EC) No 396/2005 on maximum residue levels of pesticides, are the main EU regulatory frameworks on pesticides.

The PPPR specifies strict criteria for the approval of substances, in order to ensure a high level of protection for human and animal health and the environment, prohibiting the use of any active substances in plant protection products (PPPs) unless they have been approved for that purpose in accordance with the PPPR. Carcinogens, mutagens, endocrine disruptors, substances toxic for reproduction or which are very persistent, will not be approved unless their exposure to humans is negligible. The procedure also applies to applications for approval of new safeners and synergists for use in PPPs. The PPPR obliges those wishing to place PPPs on the market to seek approval, rather than imposing a general prohibition on the placing on the market and use of PPPs containing active substances. The PPPR, as well as its predecessor Directive 91/414/EEC, thus establishes a 'dual' system whereby the Commission approves the active substances contained in the products at EU level, along with any safeners or synergists, while PPPs containing these substances are authorised at Member State level, together with any adjuvants.

The PPPR provisions are implemented by the Member States (e.g. comprehensive hazard identification of active substances, authorisation of products at national level, enforcement measures), the Commission (e.g. audits in Member States) and EFSA (e.g. peer review of Member States' hazard identification of active substances).

This research paper on the implementation of the PPPR has three main components. Part 1 focuses on Member States' practical use of the derogation under Article 53(1) of the PPPR (Task 2.2 of the Terms of Reference<sup>5</sup>). Part 2 presents the results of general desk research of

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<sup>2</sup> Communication from the Commission to the Council, the European Parliament, the European Economic and Social Committee and the Committee of the Regions - A thematic strategy on the sustainable use of pesticides {COM (2006) 373 final} {SEC (2006) 894} {SEC(2006) 895} {SEC(2006) 914} /\* COM/2006/0372 final.

<sup>3</sup> Regulation (EC) No 1107/2009 of the European Parliament and of the Council of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC. OJ L 309, 24.11.2009, pp. 1-50.

<sup>4</sup> Directive 2009/128/EC of the European Parliament and of the Council of 21 October 2009 establishing a framework for Community action to achieve the sustainable use of pesticides (Text with EEA relevance) OJ L 309, 24.11.2009, pp. 71-78.

<sup>5</sup> Mapping the usage made by Member States of the derogations provided under Regulation (EC) 1107/2009.

the available literature (Task 2.1 of the Terms of Reference<sup>6</sup>), followed by a stakeholder survey on the implementation of the PPPR. Finally, Part 3 assesses the implementation of the PPPR according to the five evaluation criteria and based on the findings of Part 1 and Part 2 (Task 2.3 of the Terms of Reference)<sup>7</sup>. All sections include an introduction setting out the tasks and methodology.

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<sup>6</sup> Desk research of available literature on the implementation of Regulation (EC) No 1107/2009.

<sup>7</sup> Assessment of the implementation of Regulation (EC) 1107/2009 and associated impacts.

## Part 1: The implementation of Article 53 of Regulation (EC) No 1107/2009

### Key findings

- The **number of derogations** granted by Member States **has increased significantly** since 2007, from 59 in 2007 to almost 400 in 2017.
- Derogations are mostly granted for PPPs containing approved substances. Around 9% of derogations were granted in 2017 for PPPs containing non-approved substances.
- There is a **clear tendency to repeat derogations**. Around one-third of the derogations granted in 2017 were previously granted in 2016.
- **Article 53 was used** in slightly less than one-sixth of the analysed derogations **against the principles of the Commission working document on emergency situations**, as derogations for PPPs containing non-approved substances are granted for expected and routine uses such as soil disinfection or insecticide seed treatment, and derogations are often repeated.
- **Article 53 is not used according to its original purpose**. Less than a third of derogations granted in 2017 referred to special circumstances in the notification form. **Article 53 is mostly used to fix structural problems** such as gaps in the availability of products, delays in authorisations procedures of PPPs, or deficiencies in authorisations for minor uses.
- In most of the notifications examined in the sample, Member States applied **no restrictions that specify use of available alternative methods or integrated pest management (IPM) techniques** (such as pest monitoring), and the Article 53 authorisations provide **little evidence that the economic impacts cannot be changed within a year or that there is a research programme in place seeking alternative** acceptable solutions.
- Article 53 authorisations are used for a **significant number of biopesticides, such as bacterial and viral preparations**, which either have an application pending at EU level or are not yet authorised.
- The case studies showed that Article 53 authorisations are used to maintain the use of PPPs which have been withdrawn from the EU market **because of the evidence of significant environmental and human health impacts**, since the crop system in which they are used has been built on the use of these PPPs and would require economic adaptation to a different crop system if access to those chemicals were prohibited.
- There are **significant deficiencies in the way in which some Member States notify their derogations to the Commission**. Derogations are often notified late. A small number of Member States do not fill in the template, other than for basic information. Information on the size and effects of dangers, and the assessment of potential alternatives, is often limited. **The Commission aims to improve compliance** of notifications through bilateral discussions with Member States and discussions on derogations at the Standing Committee meetings but does not envisage infringement procedures.
- **Full notification dossiers are not available to the public**. Their access is restricted to the Commission and Member State competent authorities (CAs).
- In the absence of concrete rule in the PPPR, all selected Member States have procedures in place for the review of requests for Article 53 authorisation, which are neither set out on paper nor legally binding. Most Member States involve authorities other than the CA and/or

scientific bodies in the decision-making process. However, there are no public consultations, likely due to the lack of such requirements in the PPPR and relevant legally binding rules in the Member States in question.

- In all selected Member States, **the same procedure applies to all derogations**. There are no specific evaluation procedures for derogations for PPPs containing non-approved substances or repeated derogations, although the evaluation by the authority can be more thorough in these cases.
- **Almost all selected Member States publish decisions granting emergency authorisations** on the CA website. However, they **do not publish the applications and related evaluations** (e.g. assessment of alternatives and justifications) or any other documents.
- There is **low public awareness** of the purpose and use of Article 53 authorisations.
- There are **no specific inspection strategies/programmes** for Article 53 authorisations. Article 53 authorisations are controlled as part of the routine inspections of PPP authorisations.
- Since the entry into force of the PPPR, **the Commission has requested an opinion from EFSA only once**, in September 2017, on the derogations granted for PPPs containing three neonicotinoid substances by seven Member States in recent years.
- Since the entry into force of the PPPR, the Commission has never launched a procedure under Article 53(3) allowing either the extension or repetition of the Article 53 authorisation or its withdrawal or amendment.

## 1. Introduction

Member States may authorise the placing on the market of PPPs for limited and controlled use, by way of derogation under Article 53 of the PPPR, where such a measure appears necessary because of a danger which cannot be contained by any other reasonable means. However, concerns have been raised over the years that Article 53 authorisations granted by Member States do not always fulfil the purpose of this Article and operate by way of a loophole in the legislation to circumvent banned or restricted use of PPPs at national level, as outlined in a 2017 report by the European Beekeeping Coordination, PAN Europe, Client Earth and Romapis (PAN Europe, Client Earth, European Beekeeping Coordination, Romapis, 2017) and in an audit report on the authorisation of PPPs (European Commission 2017d).

This Chapter focuses on the implementation of Article 53 by Member States and the Commission. It includes seven sections, on the description of Article 53 core requirements and related Commission working document guidance, the use of these authorisations in Member States, the impact of Article 53 authorisations through three case studies (Article 53 authorisations on soil fumigants, neonicotinoids and insecticides for use in mass trapping), Member State procedures for granting emergency authorisation and informing other Member States and the Commission of the authorisation granted, and the Commission review of emergency authorisations and the role of EFSA.

## 2. Methodology and sources of information

This part of the research paper is based on general desk research on the implementation of the PPPR (See Part 2), the review of the notifications of derogations granted by Member States in 2016 and 2017, eight country fiches covering mainly the procedural aspects of Article 53 authorisations and including interviews with competent authorities (CAs) and other national stakeholders, four case studies on the impacts of Article 53 authorisations, and interviews with selected EU stakeholders and a Commission representative involved in 'Pesticides and placing on the market' at DG SANTE.

### *Sample of notifications and country fiches*

On 4 December, the Commission provided the study team with all of the notifications submitted through the Plant Protection Products Application Management System (PPPAMS)<sup>8</sup> in 2017. Notifications submitted after 4 December 2017 were not taken into account. This batch of notifications chiefly contained notifications of derogations granted in 2017 and some granted in 2016. In addition, the Commission provided the study team with notifications submitted in 2016 (for derogations granted in both 2015 and 2016). As these notifications were not submitted through PPPAMS, the collection and processing of the notification files required some effort on the part of the Commission. Consequently, these notifications were sent in several batches during the course of the study. The completeness of the sample of notifications submitted in 2016 is uncertain, therefore it may be that not all derogations granted in 2016 were reviewed. In addition, fewer notifications were received by some Member States compared to the number of authorisation decisions published on the CA websites, which confirmed that the sample reviewed for the study did not include all derogations granted in the past two years.

The sample reviewed for this study contained 391 notifications of derogations granted by Member States in 2017 and 227 notifications of derogations granted in 2016. Using the notification files provided by the Commission, the study team created a database of derogations containing information on the product, active substance, crops, targeted pest, applicant, and the justification provided in the notification, which enabled comparison and the identification of trends in the types and grounds for derogations. This work is presented in Section 4. The analysis is based on the notifications sent to the Commission for practical reasons (one point of contact – the Commission – instead of 28 CAs, and all notifications are in English) and for comparability and consistency reasons (all notifications follow the same template and guidelines and should therefore provide similar information). The analysis presented in Section 4. depends on the quality of the notifications, which varies across the sample, ranging from almost empty notifications (containing only basic information, such as the name of the applicant, product, substance, function of the product and date of validity) to very detailed notifications.

Based on the sample of notifications for 2017 received from the Commission on 4 December 2017, the research team selected eight Member States to complete country fiches. These Member States were selected based on the high number of notifications of Article 53 authorisations they sent to the Commission in 2017 and by PPPR geographical zone

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<sup>8</sup> An online system, established by the European Commission, for the submission of Article 53 notifications, among other applications under the PPPR.

(North/Central/South). Altogether, the selected Member States granted 71% of the derogations in 2016 and 2017 (based on the notifications provided by the Commission). As described above, this does not mean that the selected Member States are those that granted the most Article 53 authorisations within the relevant zones. Country fiches were thus completed for Latvia and Sweden (Northern zone), Portugal, Spain and Greece (Southern zone) and Belgium, Slovakia and Germany (Central zone) by Milieu national experts. These country fiches covered the procedural aspects of Article 53 authorisations in these Member States, including the transparency of the procedure (e.g. availability of documents to the public and involvement of third parties), whether or not the procedure is detailed in national law, the timeframe, the content of the application, whether or not there is a specific procedure for authorisations concerning substances that are not approved or concerning repeated use, coordination with other authorities, the enforcement and control measures in place, and strategies to reduce (repeated) use of Article 53 authorisations. To that end, Milieu's national experts interviewed stakeholders concerned by the implementation of the PPPR (i.e. representatives of producers of PPP, NGOs focusing on the risks of PPPs for the environment and public health, farmers and cooperatives, and fruit and vegetable growers) and representatives of Member State CAs.

#### *Case studies*

Three case studies examined Article 53 authorisations concerning soil fumigants, neonicotinoids and insecticides for use in mass trapping, respectively, based, inter alia, on information from the sample of notifications of Article 53 authorisations.

These three case studies were selected to illustrate the impacts of Article 53 authorisations in different crop systems and to illustrate Article 53 authorisations for active substances with different situations of approval at the EU level: unapproved (soil fumigants); approved but banned for specific uses (neonicotinoids); and approved but not for the use specified in the derogation (insecticide mass traps). These case studies covered several Article 53 authorisations in more than one Member State, different types of farming sectors (intensive horticulture, field arable crops, fruit crops) and application methods (fumigants, seed treatments and insect traps) in various parts of the EU. The soil fumigants and neonicotinoid seed treatment cover a total of 56 out of the 453 notifications in 2017, and 17 out of 220 notifications in 2016. They therefore represent a significant proportion of the notifications in the sample available for review. There were seven notifications on insect traps over the two years in the sample analysed for the study.

The case studies were also selected because they involved several Member States using Article 53 for similar reasons over several years, enabling the extraction of more generally valid conclusions.

The case studies examined: intended use, status of EU approval and whether or not the active substances are candidates for substitution; reason given for the derogation; the evidence for environmental and health impacts; the availability of approved chemical or non-chemical alternatives used by others in the sector. The case studies assessed the economic and social impacts on the users and compared their use of the products to non-users in the sector, based on the available literature. The environmental, economic and

social sustainability of pest or disease management strategies of the non-users in the sector were compared to the use(s) of the derogated pesticides in that sector.

#### *EU stakeholder interviews*

The research team carried out several interviews<sup>9</sup> with organisations representing the relevant stakeholders at EU level (EU umbrellas). These stakeholders were selected based on their interest in the fulfilment of the objectives of the PPPR (high level of protection of both human and animal health and the environment, improvement of the functioning of the internal market, improvement of agricultural production) and their involvement as legal dutyholders under the PPPR.

This includes EU associations protecting the interests of:

- Producers of active substance and PPPs, including producers of biocontrol solutions.
- The environment and public health, against risks from PPPs.
- Farmers and cooperatives, fruit and vegetable growers, including organic farmers.

These organisations have members in most or all Member States. They usually have a mandate to consult these members and to represent their view in the EU policy process. They are therefore considered to represent a significant number of relevant stakeholders across the EU concerned with the implementation of the PPPR.

The research team carried out five phone interviews with representatives of: EU producers of active substances and PPPs; EU producers of biocontrol solutions; two EU associations involved in the protection of environment and public health against risks from PPPs; and EU farmers and cooperatives. It was not possible to interview representatives of EU organic farmers or EU representatives of fruit and vegetable growers, despite several invitation requests. Information from these interviewees was used to complement the information gathered through the notification sample and country fiches.

### **3. Introduction to Article 53 authorisations**

Section 1 sub-section 6, on authorisation, under Chapter III of the PPPR, 'plant protection products', sets out two derogations to the obligation to place on the market or use only PPPs authorised by the Member State concerned, in accordance with the PPPR. These derogations apply to both PPPs used for experiments or tests for research or development purposes (Article 54), and in case of emergency situations in plant protection (Article 53).

Directive 91/414/EEC, the previous EU legal framework on PPPs, already included a similar derogation procedure under its Article 8(4)<sup>10</sup>.

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<sup>9</sup> The list of interview questions could be submitted upon request.

<sup>10</sup> Article 8(4) of Directive 91/412/EEC states: 'By way of further derogation from Article 4, in special circumstances a Member State may authorise for a period not exceeding 120 days the placing on the market of plant protection products not complying with Article 4 for a limited and controlled use if such a measure appears necessary because of an unforeseeable danger which cannot be contained by other means. In this case, the Member State concerned shall immediately inform the other Member States'.

### Official text of Article 53 of the PPPR

1. By way of derogation from Article 28, in special circumstances a Member State may authorise, for a period not exceeding 120 days, the placing on the market of plant protection products, for limited and controlled use, where such a measure appears necessary because of a danger which cannot be contained by any other reasonable means.

The Member State concerned shall immediately inform the other Member States and the Commission of the measure taken, providing detailed information about the situation and any measures taken to ensure consumer safety.

2. The Commission may ask the Authority for an opinion, or for scientific or technical assistance. The Authority shall provide its opinion or the results of its work to the Commission within one month of the date of the request.

3. If necessary, a decision shall be taken, in accordance with the regulatory procedure referred to in Article 79(3), as to when and under what conditions the Member State:

(a) may or may not extend the duration of the measure or repeat it; or

(b) shall withdraw or amend its measure.

4. Paragraphs 1 to 3 shall not apply to plant protection products containing or composed of genetically modified organisms unless such release has been accepted in accordance with Directive 2001/18/EC.

As outlined in Recital 32 of the PPPR, the purpose of Article 53 is to allow Member States, in exceptional cases, to authorise PPPs not complying with the conditions provided for in the PPPR, where it is necessary to do so because of a danger or threat to plant production or ecosystems that cannot be contained by any other reasonable means.

Article 53 contains three core provisions which set some conditions on the use of the derogation (i.e. in special circumstances, a period not exceeding 120 days, limited and controlled use, where such a measure appears necessary because of a danger which cannot be contained by any other reasonable means), impose an obligation to inform other Member States and the Commission on the use of the Article 53 derogations and, the powers of the Commission to request an opinion from EFSA, or for scientific or technical assistance on a Member State derogation, and the relevant measures that can be adopted subsequently.

In February 2013, the Commission adopted a revised version of a working document on Article 53 emergency situations (European Commission, 2013), which lays down the procedure for Member States when granting an authorisation under Article 53. It also provides non-binding guidance to Member States on how to use Article 53 derogations. Annex I to this working document contains a notification template that can be used by Member States to fulfil their obligations to inform other Member States and the Commission on their use of derogations<sup>11</sup>.

On the use of Article 53, this Commission working document highlights that:

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<sup>11</sup> This template was used for the derogation procedure under Directive 91/412/EEC and is now outdated. A new template is used by Member States via PPPAMS (See Section 2.3.2). It should also be noted that the introduction of information in the PPPAMS remains voluntary at present.

- The use of this derogation should be exceptional and restricted to cases of obvious danger to plant production or ecosystems that cannot be contained by any other reasonable means.
- This use shall not jeopardise the purposes of the PPPR and shall be proportional.
- In their applications, Member States should justify the authorisation.
- Such authorisations should not be granted as a routine alternative to extension of use or other forms of standard authorisation.

Concerning the use of emergency authorisations relating to PPPs containing approved active substances authorised for other uses or with no authorised use in a Member State, the Commission working document suggests that:

- Such emergency authorisations should not be repeated in the following crop seasons unless the emergency continues and clear reasoning has been provided. This reasoning may take into consideration the time necessary to prepare, evaluate and issue a standard authorisation, or extension of use.
- Full and clear reasoning should be provided, following the notification template under this guidance.

Concerning the use of emergency authorisations relating to PPPs containing non-approved active substances, the Commission working document stresses that Member States should:

- Provide a complete and detailed report following the Annex I Commission working document notification template.
- Safeguard the protection of human health and the environment.
- Bear in mind that the use should generally be connected to a single pest species, or related group of pest species where the use is not for disinfection purposes.
- Confirm that no other reasonable means of control is available (either stand-alone or in combination).
- Explain how the use is limited and any conditions that have been set.
- Bear in mind that use should preferentially be based on the proven presence of the pest (group) on individual farms, if applicable.
- Monitor use, and deliver exact data on the dose and frequency employed and the area treated.
- Take all steps to avoid repeated authorisations.

Where repeated Article 53 authorisations of PPPs containing non-approved substances are unavoidable, the working document suggests that Member States should ensure that:

- Economic evidence is provided by the applicant, proving that the socio-agronomic system cannot be changed within one year, and that temporary continuation of the non-approved active substance is necessary to avoid unacceptable damage to local society.
- Use is limited, by setting a maximum frequency of treatment per production unit (field or farm) that stimulates the maximum combined use of other existing, partially effective measures.
- A research programme is in place to identify acceptable alternative solutions.

- Yearly reports should be made available to the Commission and Member States including details on the objectives of the programme, a concrete time schedule and actions planned and/or taken.

Point 3 of this Commission working document also contains 10 recommendations on how Member States should inform the Commission and other Member States on the use of Article 53 authorisations via the notification template annexed to the working document. For example, Member States should provide information on all possible alternative methods of control, including the reasons why possible alternatives are not reasonable, research undertaken to solve the danger in a sustainable way, risk mitigating measures, proposed good agricultural practices, time period allocated, compliance with existing Maximum Residue Levels (MRLs), and a consumer risk assessment, with a proposal for a temporary MRL where applicable.

Finally, this Commission working document stresses that it may be helpful to develop further criteria to define emergency situations over time, in the light of experience. It recognises the imminent need to make better use of the alternatives already in place and to develop new solutions and alternatives, outlining research as a general principle to be strengthened to limit the use of Article 53 in the long term. DG SANTE believes that the working document should be revised soon, in the wake of the opinion of EFSA on the derogations for severely restricted PPPs containing three neonicotinoids substances (clothianidin, imidacloprid and/or thiamethoxam; see Section 7. ).

## **4. The use of Article 53 by Member States in the period 2016-2017**

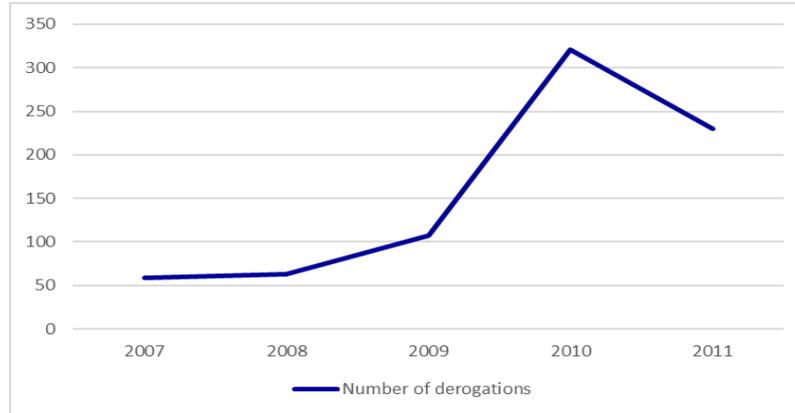
This section mostly draws on Milieu's analysis of the notifications of derogations granted by Member States in 2016 and 2017, as provided by the Commission. As stated in Section 1.1, the figures provided below should be treated with caution as the sample of notifications received might be incomplete and, given the large number of empty notifications, certain information could not be retrieved from the whole sample.

### **4.1 Overview of derogations granted**

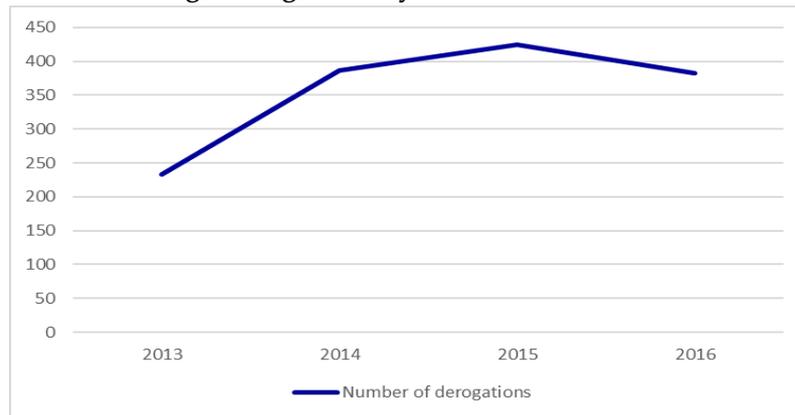
Figures compiled by the Commission (European Commission, 2017) and NGOs (PAN Europe, 2017) showed that, since 2007, the number of derogations granted by Member States has increased significantly. According to the NGO PAN Europe, the number of derogations increased from 59 in 2007 to 203 in 2011, with a peak of 321 in 2010<sup>12</sup>.

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<sup>12</sup> Figures provided by PAN Europe as part of the stakeholder consultation.

**Figure 1: Number of derogations granted by Member States from 2007 to 2011**

Figures provided by the Commission for the period 2013 to 2016 confirm that the upward trend has continued, levelling out between 2014 and 2016, with the number of derogations being close to, or in excess of, 400.

**Figure 2: Number of derogations granted by Member States from 2013 to 2016**

According to the information provided by the Commission in December 2017, at least 391 derogations were granted in 2017, suggesting that the number of derogations has stabilised around 380-390 in recent years.

The study by Pan Europe also indicated that the number of Member States using Article 53 has increased since 2007, and that only a handful of Member States did not grant any derogations in 2011 (Estonia, Luxembourg, Finland, Romania and Slovenia). Based on the notifications provided by the Commission, at least 25 Member States granted derogations in 2016 and in 2017. Taken together, all Member States granted at least one derogation in the past two years.

The countries that granted the largest number of derogations in 2017, based on the sample of notifications received, were Spain (75), Slovakia (51) and Germany (42). As the sample might not be complete, comparisons between countries should be made cautiously. The largest number of derogations was granted in the Central zone, which also includes the

highest number of countries. The Southern zone, with only nine countries, granted almost 40% of the derogations.

**Table 1: Number of derogations granted in 2016 and 2017 by zone**

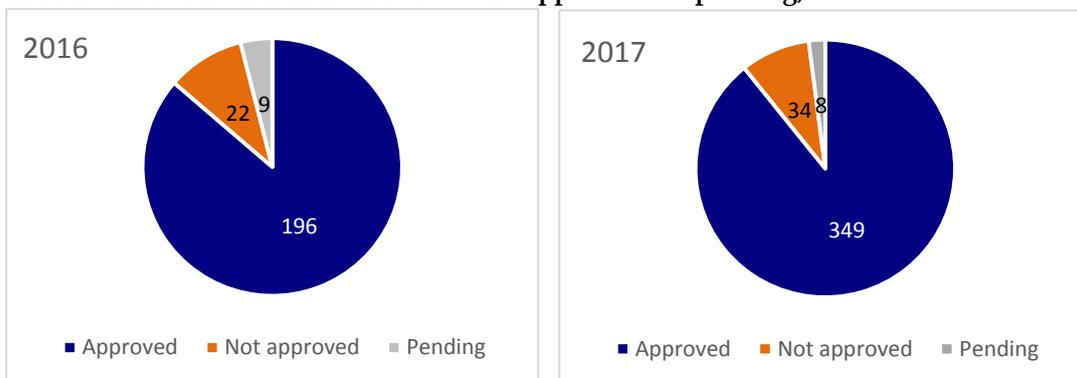
	North	Central	South
2016	35	85	107
2017	48	196	147

The eight selected Member States (see Section 2. of this chapter) granted 71% of the derogations in the 2016 and 2017 samples. In six of the selected Member States, the CA confirmed that there has been an increase in the number of derogations requested since 2007, although the number of requests has stabilised in recent years. Only one CA noticed a decreasing trend in the period 2015-2017.

## 4.2 PPPs and active substances authorised through derogations<sup>13</sup>

The majority of derogations granted in 2016 and 2017 were for products containing active substances that are approved at EU level. In 2016, around 12% of derogations concerned products containing non-approved active substances (at the time the derogation was granted) and in 2017, around 9.5% of derogations concerned non-approved substances.

**Figure 3: Number of derogations for PPPs containing approved, banned active substances or active substances for which approval was pending, in 2016 and 2017**



**Table 2: Number of derogations for PPPs containing non-approved substances in 2016 and 2017 (by substance)<sup>14,15</sup>**

Substance	2016			2017			Total
	North	Central	South	North	Central	South	
Asulam		1		1	6		8

<sup>13</sup> Although this was required in the terms of reference for this research paper, it was not possible to calculate the share of Article 53 derogations against the total number of PPPs authorised under the regular authorisation procedure, as the list of authorised PPPs differs from one Member State to another.

<sup>14</sup> Some PPPs contain more than one substance, which explains why the number of derogations presented in Table 2 is higher than the number of derogations presented in Figure 3.

<sup>15</sup> Derogations for PPPs containing picoxystrobin and iprodione were not included, as the approvals of both substances were not renewed in August and November 2017, respectively, after the derogations were granted.

Substance	2016			2017			Total
	North	Central	South	North	Central	South	
Beauveria bassiana strain BB1					1		1
Chlorophacinone		1			1		2
Chloropicrin		1	3		1	1	6
Cyclanilide						1	1
1,3-Dichloropropene			7			12	19
Dichlorvos			1			1	2
Flufenzin (diflovidazin)		1					1
Hexazinone		1					1
Ioxylnil	1						1
Lavandulyl senecioate			1			1	2
Metarhizium brunneum strain Cb15-III					1		1
Molinate			1			1	2
Natural seed extract of Camellia sp.			1			1	2
Potassium oleate				1			1
Quinclorac			1			1	2
Thidiazuron			1			1	2
Trifloxysulfuron			1				1
2,6,6-Trimethylbicyclo[3.1.1]hept-2-ene (alpha-Pinen)				1			1
2-Methyl-3-buten-2-ol				1			1
2-Methyl-6-methylene-2,7-octadien-4-ol (ipsdienol)				2			2
4,6,6-Trimethyl-bicyclo[3.1.1]hept-3-en-ol,((S)-cis-verbenol)				2			2

Of these substances, three were not approved at EU level because they did not fulfil the criteria (asulam in 2011, 1,3-dichloropropene in 2011 and dichlorvos in 2007), and four were not renewed (chloropicrin and cyclanilide in 2011, molinate in 2014, and ioxylnil in 2015). Seven substances<sup>16</sup> were not included in Annex I of Directive 91/414/EEC because no application was submitted at the time they were reviewed as part of the programme of work for the examination of active substances and no application has since been submitted. Finally, four substances were never notified and were thus never evaluated at EU level<sup>17</sup>.

<sup>16</sup> Thidiazuron, quinclorac, flufenzin, 6,6-trimethylbicyclo[3.1.1]hept-2-ene (alpha-Pinen), 2-methyl-3-buten-2-ol, 2-methyl-6-methylene-2,7-octadien-4-ol (ipsdienol) and 4,6,6-trimethyl-bicyclo[3.1.1]hept-3-en-ol,((S)-cis-verbenol).

<sup>17</sup> Natural seed extract of camellia sp.; trifloxysulfuron, Lavandulyl senecioate, beauveria bassiana strain BB1.

Soil fumigants<sup>18</sup> (PPPs containing 1,3-dichloropropene and chloropicrin) and herbicides (containing asulam) made up over half of the derogations containing banned substances. The high number of derogations concerning soil fumigants goes against the recommendations of the Commission working document on emergency situations, according to which derogations of PPPs containing non-approved substances should be connected to a single pest species, or related group of pest species where the use is not for disinfection purposes. According to the stakeholders interviewed (manufacturers' and farmers' associations) and DG SANTE, the lack of viable alternatives to banned PPPs for soil disinfection makes the use of Article 53 necessary.

31 derogations (14%) in 2016 and 65 (17%) in 2017 concerned PPPs containing active substances approved as candidates for substitution, either because they meet two of the criteria to be considered as a Persistent, Bioaccumulative and Toxic (PBT) substance, because their acceptable daily intake (ADI), their acute reference dose (ARfD) or acceptable operator exposure level (AOEL) are those of the majority of the approved active substances within groups of substances/use categories, because they are classified as toxic for reproduction 1A/1B under the CLP Regulation<sup>19</sup> or considered to have endocrine disrupting properties.

**Table 3: Number of derogations for PPPs containing substances approved as candidates for substitution**

Substance	CfS criteria	2016	2017	Total
Aclonifen	Meets two PBT criteria	1		1
Bifenthrin	Meets two PBT criteria		1	1
Bromadiolone	Low ADI / ARfD / AOEL	1		1
Copper compounds (copper hydroxide, copper oxide, copper oxychloride)	Meets two PBT criteria	2	13	15
Cyprodinil	Meets two PBT criteria		1	1
Difenacoum	Low ADI / ARfD / AOEL; Meets two PBT criteria	1		1
Difenoconazole	Meets two PBT criteria		1	1
Dimethoate	Low ADI / ARfD / AOEL	6	1	7
Diquat (dibromide)	Low ADI / ARfD / AOEL; Meets two PBT criteria	1	1	1
Epoxiconazole	Meets two PBT criteria; classified under CLP as toxic for reproduction 1a/1b; considered to have endocrine disrupting properties		1	1
Etofenprox	Meets two PBT criteria	1	1	1

<sup>18</sup> Soil fumigants are PPPs which, once applied to the soil as liquids, form a gas to control pests living in the soil (such as nematodes, fungi, bacteria, insects or weeds). Soil fumigants are applied before crops are planted. See definition from the US EPA: <https://www.epa.gov/soil-fumigants/what-are-soil-fumigants>

<sup>19</sup> Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures.

Famoxadone	Meets two PBT criteria		1	
Fenamiphos	Low ADI / ARfD / AOEL	1	1	1
Fipronil	Low ADI / ARfD / AOEL	1		1
Fludioxonil	Meets two PBT criteria	6	16	22
Imazamox	Meets two PBT criteria		5	5
Lambda-Cyhalothrin	Low ADI / ARfD / AOEL; Meets two PBT criteria	8	10	18
Metam (incl. -potassium and -sodium)	Low ADI / ARfD / AOEL		1	1
Myclobutanil	Meets two PBT criteria	1		1
Oxadiazon	Meets two PBT criteria		2	2
Oxamyl	Low ADI / ARfD / AOEL		1	1
Paclobutrazol	Meets two PBT criteria		2	2
Pendimethalin	Meets two PBT criteria		4	4
Prochloraz	Meets two PBT criteria		1	1
Propiconazole	Meets two PBT criteria	3	1	4
Tebuconazole	Meets two PBT criteria		4	4
Tebufenpyrad	Meets two PBT criteria		1	1
Thiacloprid	Considered to have endocrine disrupting properties	3	2	5

In addition, quite a high number of derogations concerned PPPs containing approved active substances but for a use not covered by the approval. These derogations particularly concerned PPPs containing neonicotinoid (insecticide) substances that were restricted by Regulation (EU) 485/3013 prohibiting the use and placing on the market of certain seeds treated with clothianidin, thiametoxam or imidacloprid. The derogations in the Northern and Central zones presented in the table below all concerned seed treatment of rapeseed, maize and sunflower seeds, all banned since 2013. Prior to the expiry of the approval of the insecticide Fipronil in September 2017, the substance was restricted for use as a seed treatment, and further restricted by Regulation (EU) 781/2013 in respect of the treatment of seeds intended to be sown in greenhouses and to the treatment of seeds of leek, onions, shallots and the group of Brassica vegetables intended to be sown in fields and harvested before flowering. The derogation granted for the PPP Goldor bait containing Fipronil, in 2016, was for use as a soil treatment in potato production.

**Table 4: Number of derogations for PPPs containing approved substances but for a use not covered by the approval<sup>20</sup>**

	2016			2017			Total
	North	Central	South	North	Central	South	
Clothianidin	2	4	0	5	14	1	26
Imidacloprid	0	5	1	0	5	0	11
Thiamethoxam	2	3	2	5	11	1	24
Fipronil <sup>21</sup>	1	0	0	0	0	0	1

<sup>20</sup> The list in Table 4 focuses on PPPs containing neonicotinoid approved substances for a prohibited use. There may have been other derogations for PPPs containing approved substances for uses not covered by the approval.

<sup>21</sup> As of September 2017, Fipronil is a non-approved substance.

In addition to the derogations mentioned above, 12 derogations in seven countries were granted in 2017 for aerial spraying of PPPs either as the sole method of application or as a complementary method of application. Article 9 of the Sustainable Use Directive provides for derogations to the ban on aerial spraying under certain conditions, including the requirement for PPPs to be explicitly approved for aerial spraying by the Member State. The use of Article 53 therefore goes against the principles of the Sustainable Use Directive.

Very few derogations concerned PPPs containing substances pending first approval in the past two years (4% in 2016 and 2% in 2017).

Finally, among the 391 derogations granted in 2017, 76 derogations (approx. 20%) were for biopesticides, which are PPPs derived from natural sources, including naturally occurring chemicals, pheromones, bacteria, fungi and insect predators<sup>22</sup>. The 76 derogations concerned 32 active substances, most of which are suitable for use in organic farming and for IPM. The majority of these substances are approved at EU level, except for four non-approved/not evaluated substances and one pending approval. In 2016, 61 derogations (27%) were granted for biopesticides, containing 25 different active substances.

### 4.3 Types of danger referred to in notifications<sup>23</sup>

On the notification form, applicants (usually agricultural companies or associations, manufacturers of PPPs, and authorities) are required to describe the type of danger and the context in which it arises, in order to justify the urgency of the situation. However, less than one-third of derogations granted in 2017 (27%) referred explicitly to special circumstances in the text of the notification form. Around 18% of the derogations referred specifically to the control of a new or growing pest, with 32 derogations indicating that the targeted pest was an emerging pest<sup>24</sup>. The most widespread emerging pest is the *Drosophila suzukii* coming from Asia, detected in Europe in 2009<sup>25</sup>, and now present in 19 EU Member States. In 2017, 39 derogations (around 10%) were granted for the control of this pest, mainly in the cases of berries, stone fruit and grape production. In addition, 38 derogations (around 10%) referred specifically to a recent increase in the pest infestation or the spread of a disease, suggesting that if the pest was not new, its geographical spread was increasing.

A small number of derogations (11) referred to a pest (or its vector) listed as a quarantine pest or disease<sup>26</sup>. These cases concern the American grapevine leafhopper (vector of the grapevine flavescence dorée), the pear psyllid (vector of the pear decline phytoplasma),

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<sup>22</sup> Definition provided by the BioPesticide DataBase (BPDB), managed by the University of Hertfordshire. The database was used to identify derogations granted to biopesticides. The database is available at: <https://sitem.herts.ac.uk/aeru/bpdb/index.htm> (last accessed 28 February 2018).

<sup>23</sup> For this section and the next (4.4), information for 2016 could not be fully compiled and analysed, as a large number of notifications for the year were provided to the study team late in the data collection process. These sections are, however, based on fully processed information for 2017.

<sup>24</sup> A pest recently identified in the geographical area, whose incidence or geographical spread is increasing.

<sup>25</sup> According to one notification form.

<sup>26</sup> Pests or diseases listed in Annex I Part A and Annex II Part A of Council Directive 2000/29/EC listing harmful organisms that may be targeted by specific control measures when found in the EU for the first time or in an EU country where its presence was previously unknown.

the sawyer beetle in pine trees, the red palm weevil in palm trees, and the fire blight caused by the bacteria *Erwinia amylovora*, affecting pome fruit. Finally, 27 notifications referred to emerging or established pesticide resistance to alternative products as one of the main reasons for requesting the derogation.

The text provided in many notifications suggests that the targeted pest is a common seasonal pest, with likely annual infestation of the same crop. Although 16% of derogations referred to weather conditions, generally, to explain the conditions in which the pest or disease develops, few notifications (5%) specifically mentioned an exceptional outbreak of a disease or infestation of pest linked to unexpected weather conditions in 2016 and 2017. In addition to the type of danger, applicants are required to provide an estimate of the size and magnitude of the danger, in order to provide evidence of the gravity and exceptional nature of the situation. Around 30% of the notifications provided an indication of the geographical area at stake, although in most cases by providing an indication of the area cultivated, without a clear indication that it was the geographical scope of the infestation or the area to be treated with the PPP. Only 8% of notifications referred explicitly to the affected area or area to be treated. In addition, 66 derogations granted in 2017 targeted several categories of crops, and around half of the derogations targeted several pests. This suggests that many derogations refer to recurring problems rather than exceptional and localised issues, and that some are based on assumptions of the scale of the problem rather than on the actual presence of the pest, contrary to the recommendations of the Commission's working document on emergency situations, whereby the use of Article 53 should be exceptional and limited to cases of 'obvious danger'.

#### **4.4 Absence of alternatives**

The majority of the 2017 notifications justified resorting to Article 53 due to the lack of an alternative product authorised for this particular use (either for a particular crop or a particular method of application, or for application at a specific stage of development of the crop), the lack of authorised products with the same efficacy as those for which the derogations have been requested, or the limitations of the authorised products with respect to dose or frequency of application. Of the notifications, 39 derogations cited the lack of effective products with different modes of action in sufficient numbers that would allow for pesticide resistance to be avoided or reduced; 70 notifications explicitly referenced the insufficient nature of non-chemical (e.g. mechanical weeding, use of mesh nets, crop rotation, soil solarisation etc.) or biological means to control the pest. Eight notifications specifically stated that the product was needed as no other option was suitable for organic farming.

#### **4.5 Timeframe and duration of derogations**

The samples of 2016 and 2017 notifications shows that derogations are granted for a large variety of crops in all seasons. The majority of the derogations granted in 2016 and 2017 were granted for the maximum authorised period, 120 days. In 2017, around 50 derogations were granted for a duration of 100 to 120 days; 86 derogations for a duration of 50 to 99 days; and 18 derogations for a period of less than 50 days. In 2016, very few

derogations were granted for a duration of 100 to 120 days (16) and less than 100 days (32). The length of the derogation is not, however, directly related to the status of the substance, as the majority of derogations for PPPs containing non-approved substances were granted for 120 days.

#### **4.6 Repeated derogations**

The analysis of the sample of 2016 and 2017 notifications indicated a clear tendency to repeat the derogation from one year to the next. Around one-third of the derogations granted in 2017 had already been granted in 2016 (the same PPP for the same crop, the same pest and roughly the same period of time). This concerns both derogations for PPPs containing approved and non-approved active substances. Derogations for soil fumigants, for instance, were granted in both years for the same crops to eliminate nematodes, and, as far as can be ascertained based on the sample of notifications reviewed, similar derogations were granted in 2015 in Spain. The same observation can be made for derogations of PPPs containing the non-approved substances asulam, quinclorac, molinate, dichlorvos, thidiazuron, chlorophacinone, lavandulyl senecioate and natural seed extract of camellia sp., as well as for derogations containing the neonicotinoid substances clothianidin, thiamethoxam and imidacloprid. In addition, a small number of derogations (around 10) were repeated during 2017.

#### **4.7 Derogations for PPPs for which an authorisation procedure is ongoing**

In 2017, 105 notifications stated that an application for authorisation for the PPP concerned (either a standard authorisation or an extension of authorisation for minor uses) was ongoing, in preparation, or planned in the near future. In addition, 13 notifications stated that an application was ongoing for a PPP that could be an alternative to that concerned by the derogation. Altogether, slightly less than one-third (30%) of the derogations granted in 2017 concerned an ongoing authorisation procedure. The majority of these derogations referred to a standard authorisation (zonal authorisation and/or mutual recognition). 29 derogations mentioned an ongoing extension of an authorisation for minor uses. A further 13 derogations stated that, although there is no authorisation procedure ongoing, the PPP in question is authorised in the Member State for other uses, which suggests that minor uses could account for at least 10% of the derogations granted in 2017. In 2016, 55 (24%) notifications mentioned that an authorisation procedure for the PPP concerned was ongoing or planned in the near future.

#### **4.8 Conclusions on the use of Article 53**

The review of all known notifications<sup>27</sup> of derogations granted in 2016 and 2017 shows that the use of Article 53 often contradicts the Commission's working document on emergency situations, as derogations for PPPs containing non-approved substances or approved

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<sup>27</sup> Based on the data provided by the Commission.

substances with restricted uses (e.g. neonicotinoids banned for use as seed treatment) have been granted for cases not connected to a single species but for soil disinfection purposes or as seed treatment. Many of these derogations have been repeated several years in a row. The misuse of derogations for minor uses has also been noted.

The review of the notifications also suggests that a relatively small number of derogations are granted for emergency situations. These can be attributed to: the emergence of new invasive pests, such as the *Drosophila suzukii*; increases as a result of climate change and global trade; the necessity to contain quarantine pests; or exceptional seasonal weather conditions. The references to recurring infestations and large geographical areas, the fact that in certain cases derogations are granted for several PPPs and target several crops and several pests, the limited context provided in the notifications, and the repetition of derogations from one year to the next, indicate that the majority of derogations do not relate to special circumstances, as provided in Article 53. Most CAs and stakeholders interviewed (both EU and national) confirmed this conclusion, with one CA estimating that only around one-quarter of requests for derogation concerned real emergency cases (e.g. pests/diseases that are not normally an issue in the country).

Derogations that are not granted for emergency cases can be explained, in part, by the lack of alternatives. The large number of derogations granted for soil disinfectants suggests that there might be some gaps in the availability of active substances, and therefore of PPPs, in certain areas. This argument has been put forward by several CAs and manufacturers' associations interviewed for the study. According to these stakeholders, the range of authorised substances was significantly reduced after the implementation of the work programme for the examination of active substances, leaving farmers with little or no options for the control of certain pests. This argument, however, overlooks the fact that only around 20% of the derogations granted in 2017 concerned PPPs containing non-approved substances or approved substances for prohibited uses.

Article 53 derogations are also used to provide access to biopesticides and mineral or plant-based substances for use in IPM and organic agriculture. As discussed above, around 20% of derogations are granted for substances of natural origin. Stakeholders representing organic food and farming and the biocontrol industry indicated (in the targeted survey, see Part 3) that there were barriers in the authorisation of natural substances due to ill-adapted criteria in the authorisation process and the lack of guidance for risk assessment for certain categories of substances of natural and mineral origin. Another argument advanced by these stakeholders - and confirmed by three of the CAs from the eight selected Member States - is that such substances have a small market, and are often non-patentable, which, given the low return on investment, does not provide an incentive for manufacturers to submit dossiers.

The large number of derogations for PPPs undergoing an authorisation procedure, together with the large number of repeated derogations, suggests that Article 53 derogations are also used to fix structural problems occurring in authorisation procedures

of PPPs<sup>28</sup> and extending authorisations of PPPs for minor uses, such as delayed authorisation procedures, deficiencies in mutual recognition, or the lack of manufacturer investment in preparing dossiers for minor uses. This was confirmed by most of the CAs and EU stakeholders interviewed for the study, most of whom pointed out that deadlines in the zonal authorisation process are not respected, leading to several years' delay in certain cases, in particular for Member States that have several pending authorisations without the resources necessary to conduct them. In addition, stakeholders highlighted the inefficiency of the mutual recognition process, as Member State authorities may not sufficiently trust each other and thus may apply specific national requirements.

**The review of the notifications and the opinions provided by EU and national stakeholders interviewed suggested that the use of Article 53 is not in line with its original purpose and is, in fact, against some of the principle of the working document on emergency situations.**

## **5. Case studies on the impacts of Article 53 authorisations**

As described in the methodology section, the research team selected three case studies assessing, respectively, the impact of three types of Article 53 authorisations concerning soil fumigants, neonicotinoids and insecticides for use in mass trapping.

### **5.1 Case study on neonicotinoids: sustainability, precaution and substitution**

This case study (the neonicotinoid insecticide containing active substances imidacloprid, thiamethoxam, and clothianidin) was selected to illustrate the impact of Article 53 authorisations on field crops, as well as the case of active substances approved but banned in the EU for specific uses. The case study also shows the repeated use of derogations for a routine (expected) use of pesticides in several Member States.

#### *Products and intended use*

Imidacloprid, thiamethoxam, and clothianidin are neonicotinoid chemicals which are used as broad-spectrum insecticides. They are marketed for use as seed treatments, soil treatments and foliar sprays on growing crops and trees. Two other neonicotinoid active substances (acetamiprid and thiacloprid) are similarly marketed as seed treatments, soil treatments and foliar sprays in the EU.

#### *Authorisation at EU level*

The neonicotinoids, imidacloprid, thiamethoxam and clothianidin, are subject to a temporary restriction on their use as seed treatments on flowering field crops (oilseed rape, sunflowers, maize, etc.) in the EU. This partial ban came into force on crops planted in the spring of 2014. The substances are not candidates for substitution. In March 2017, the European Commission proposed a permanent ban on the use of the three active substances

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<sup>28</sup> See more on the practical application of PPP authorisations in Hamlyn, 2018 published under Annex III to the European Implementation Assessment.

as seed treatments, soil treatments and foliar sprays on all field crops, restricting their use to crops in permanent greenhouses, and, at the time of drafting this report, the Member States are due to vote on the proposed ban, as part of the work of the Standing Committee on pesticide approvals (PAFF).

#### *Reasons for authorisations under Article 53*

Based on the information provided by the Commission for this report, nine Member States granted Article 53 authorisations for one or more of the banned neonicotinoids in 2016 and/or 2017<sup>29</sup>. According to a mandate from the Commission to EFSA in September 2017 (EFSA 2017a), Bulgaria has repeatedly granted derogation since the ban came into force, but there is no related derogation information in the sample provided by the Commission for this report.

Romania has granted Article 53 authorisations for clothianidin and imidacloprid on oilseeds and maize in every year since the ban. The 2016 Article 53 authorisation was granted for the oilseed rape area in the south and southeast. The crop was affected by flea beetles (*Phyllotreta* and *Phyllodes* species) which built up their populations in the soil due to prolonged drought in 2015 and 2016. The 2017 Article 53 authorisation was granted for spring rape, and for sunflower and maize against the Maize Leaf Weevil *Tanymecus dilaticollis* and wireworms (*Agriotes* species).

Hungary granted Article 53 authorisations for clothianidin and thiamethoxam on oilseeds (mainly oilseed rape) on 250,000 ha in 2016, also justified by flea beetle and wireworm damage to newly sown crops, and on oilseed rape, sunflower and maize in 2017, against maize leaf weevils (*Tanymecus* species), Western Corn Rootworm (*Diabrotica virgifera virgifera*), and wireworms. The Hungarian Article 53 authorisation argues that 'intensified production is only guaranteed with insecticide seed treatment with long-lasting effect'.

Article 53 authorisations were also granted by Bulgaria, Estonia, Finland, Latvia and Lithuania for use on spring rape in 2017 and in previous years (EFSA, 2017a). Denmark, Germany and the UK gave derogations in years immediately following the ban, but have not done so recently.

#### *Related environmental impacts*

In February 2018, EFSA published a systematic review of the scientific literature and other data on effects on bees (EFSA, 2018). The review concluded that for all of the outdoor uses of these substances, at least one aspect of the assessment indicated a high risk, leading them to conclude that, overall, these neonicotinoids represent a risk to bees (including honeybees, bumblebees and solitary bees). Exposure occurs through both the pollen and nectar of the crop, and through dust drift onto neighbouring plants. In some situations, the pesticide may persist and accumulate in the soil, with residue ending up in the pollen and nectar of the newly grown crop, as well as in weeds and field margin plants. EFSA thus concluded that a high risk to honeybees and bumblebees was indicated for all uses except greenhouse use, both on the treated crop and the succeeding crop. At the time of drafting this report, the EFSA conclusion and accompanying evidence is being debated by Member

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<sup>29</sup> Denmark, Estonia, Finland, Hungary, Latvia, Lithuania, Portugal, Romania and Spain.

State representatives and experts at the PAFF Committee. The environmental impacts of the neonicotinoid insecticides have been summarised by the Worldwide Integrated Assessment (WIA) on systemic insecticides (Pisa et al., 2017). The WIA concluded that there is evidence of high toxicity to invertebrates including wild bees, aquatic macroinvertebrates and predatory and parasitoid natural enemies. There is also evidence of sublethal effects on fish, reptiles, frogs, birds, and mammals, showing deleterious impacts on growth, reproduction, and neurobehaviour of most of the species tested (see references in Pisa et al., 2017). There is evidence that the exposure occurs through the pollen and nectar of treated crops and the next crop, and through weeds and bordering vegetation, by the accumulation of residue in the soil, which is taken up by plants (Botías et al., 2015; David et al., 2016). Several field scale studies have found evidence of population level effects on wild bees, including bumblebees and solitary bees (Rundlöf et al., 2015; Woodcock et al., 2017). The evidence of impacts on honeybees is more mixed, as neonicotinoid treated crops had neutral or beneficial effects on honeybee colonies in some contexts (Henry et al., 2015; Woodcock et al., 2017).

#### *Health impacts*

EU risk assessments do not rank the neonicotinoid substances as having significant impacts on human health, indicating the possibility of developmental/reproductive effects but with no data (PPDB, 2018). However, there is little scientific information available with which to evaluate the health risks, making it impossible to assume no risk. A recent systematic review of the evidence found suggestive but methodologically weak associations between chronic neonic exposure and adverse developmental or neurological outcomes, including tetralogy of Fallot, anencephaly, autism spectrum disorder, and a symptom cluster including memory loss and finger tremor (Cimino et al., 2017).

#### *Economic and social impacts*

The neonicotinoid ban on flowering crops resulted in a slight fall in the area of the affected crops in the years immediately following the ban, primarily due to farmers deciding not to plant the crops. Yield reports for oilseed rape crops in the UK for 2014-2015 indicated that yields reached predicted levels but the area cultivated decreased by 3.3% on the year immediately before the ban (DEFRA & NS, 2015). Across the EU as a whole, the oilseed rape area fell slightly in 2015-2016, which was attributed by the European farmers' organisation, Copa-Cogeca, to farmers deciding not to plant the crop (AgraFacts, 2016). There is no evidence of an overall effect on production, although production of oilseed rape and sunflower have increased over the last five years in the EU (DG AGRI 2017). Some areas, such as Scotland, have been little affected (Hughes et al., 2015).

A study used farm survey data to examine the impact of the restrictions on pest management practices on maize, oilseed rape and sunflower in eight regions of seven Member States in the first season after the ban (Kathage et al., 2018). In five of the eight regions, farmers switched to using unrestricted neonicotinoid or pyrethroid-treated seeds, while, in the other regions, farmers stopped using seed treatments, as no chemical alternatives were authorised. In five regions, farmers increased the use of soil or foliar treatments, with pyrethroids as the principal insecticide class. Farmers also used other strategies, including increased sowing density and more frequent scouting for pests.

There are indications that the use of neonicotinoids may have had negative economic impacts on beekeepers due to the proven sublethal effects of the substances on honeybees. For example, a study revealed a correlation between honeybee colony losses and national-scale imidacloprid (a neonicotinoid) usage patterns across England and Wales over an 11-year period (Budge et al., 2015). Monitoring of honey and honeybees during the foraging season has found multiple pesticide residues (e.g. Kiljanek et al., 2016). However, the field scale experimental evidence of impacts on honeybees is mixed, as stated above, and it is difficult to establish rigorous controls that do not have any neonicotinoid contamination, or to disentangle the influence of other drivers of honeybee mortality (Goulson et al., 2015).

#### *Availability of alternatives*

The neonicotinoid ban triggered the use of alternatives by farmers across the EU. A study of the use of neonicotinoids and their alternatives in Germany, the Netherlands, Spain and the UK found that in about half of the crop situations analysed, neonicotinoids could be replaced by an alternative with little or no environmental impact (Allema et al., 2017). In one-third of the crop-country combinations, the main alternative remains another pesticide with a high environmental impact, or the use of crop rotation. In about one-sixth of the situations, no reliable alternative is presently available for at least one of the neonicotinoids. Apart from a minor portion of the oilseed rape in Germany and the UK, these situations apply to crops for which neonicotinoids are still allowed, i.e. a quarter of the apple area in Germany and the Netherlands, and some of the sugarbeet area in Germany, the Netherlands and the UK.

For oilseed rape, the main economically damaging pests vary across countries and planting seasons. For example, in the UK, the main pests are flea beetles (*Phyllotreta* and *Phyllodes* species), which are primarily economically damaging for freshly planted oilseed rape plants, where they can cause complete crop loss. In Germany, the major pests are the Cabbage Root Fly (*Delia radicum*) in the north, and the Rape Stem Weevil (*Ceutorhynchus napi*) in the south. The main alternative strategies to avoid flea beetle infestations are crop rotation and early drilling, minimum tillage, and trap cropping with turnip rape (Allema et al., 2017).

For maize, the two main target soil pests can be effectively controlled by crop rotation. The Western Corn Rootworm (*Diabrotica virgifera virgifera*) can be effectively minimised by crop rotation of maize with a non-host crop every few years (Sivčev et al., 2012). The pest is therefore only an economically significant problem in maize monoculture in the EU (FCEC, 2009). Wireworms (*Agriotes* species) are difficult to control once the field is infested, but their numbers can be kept low by rotation with leguminous crops and by avoiding grass or cereal as the pre-crop to maize (Allema et al., 2017). Maize Leaf Weevil (*Tanymecus dilaticollis*) is primarily economically damaging for freshly sprouted maize plants and is most effectively controlled by crop rotation with cereals and legumes.

#### *Sustainability, precaution and substitution*

The Hungarian and Romanian Article 53 authorisations argue that there is no alternative chemical seed treatment available that is as effective as neonicotinoids against the target pests, although they provide no evidence for alternative products or methods. However,

alternatives are available for almost all of the crop pests targeted by neonicotinoid seed treatments, provided an IPM approach is used and a crop rotation system is followed. The use of neonicotinoid seed treatments is not compatible with IPM strategies, as the pesticides kill the natural enemies of the pests and so prevent their populations from building up sufficiently to control the pests.

Oilseed rape crop damage by flea beetles varies greatly from year to year, depending on weather conditions at and before sowing. Similarly, maize damage by wireworms varies considerably, depending on infestation levels. An appropriate policy support for IPM approaches could therefore be the use of crop insurance for farmers using such methods. The economic rationale for alternative strategies also needs to be considered in the context of the whole crop system. For example, in eastern England, the intensive wheat-oilseed rape crop system is affected in many places by other pest problems such as Blackgrass (*Alopecurus myosuroides*) and by loss of soil organic matter, which can be effectively countered by more diverse crop rotation and temporary leys of grass and/or legumes. The introduction of more diverse crop rotations would therefore bring wider economic benefits in the long-term, as well as supporting adaptation to the loss of neonicotinoid seed treatments.

The use of pyrethroid sprays is not a sustainable alternative to neonicotinoids, as pest resistance to pyrethroids is increasing. The Hungarian Article 53 authorisation reports that oilseed rape flea beetles have developed a high level of resistance to pyrethroid active substances. A survey of the level of resistance in flea beetles (*Psylliodes chrysocephala*) to pyrethroid sprays in Denmark, Germany and the UK indicated an alarming increase in incidence and spread of resistance to pyrethroids (Højland et al., 2016). Pyrethroids also have negative impacts on bees (Baron et al., 2014).

#### *Conclusion of the case study on Article 53 authorisations on neonicotinoids*

Member States have not justified the derogations for the continued use of neonicotinoid seed treatments on crops subject to the current partial ban because of emergency situations (i.e. new or emerging pests that were not anticipated at the time of the EU partial ban). Instead, the derogations refer to the dominant pests of the region whose abundance increased in certain years due to climatic fluctuations. The derogations also conflict with the recent EFSA opinion, which concluded that there is now a substantial body of evidence that neonicotinoids have significant adverse effects on bees (including honeybees, bumblebees and solitary bees), and other invertebrates such as butterflies, aquatic macro-invertebrates and predatory and parasitoid wasps and bugs.

Alternatives are available for almost all of the crop pests targeted by neonicotinoid seed treatments, provided an IPM approach is used and a crop rotation system is followed. The use of neonicotinoid seed treatments is not compatible with IPM strategies, as the pesticides kill the natural enemies of the pests and so prevent their populations from building up sufficiently to control the pests. The economic rationale for alternative strategies also needs to be considered in the context of the whole crop system. For example, in eastern England, the intensive wheat-oilseed rape crop system is affected in many places by other pest problems such as Blackgrass (*Alopecurus myosuroides*) and by loss of soil organic matter, which can be effectively countered by more diverse crop rotation and

temporary leys of grass and/or legumes. The introduction of more diverse crop rotations would therefore bring wider economic benefits in the long-term, as well as supporting adaptation to the loss of neonicotinoid seed treatments.

## **5.2 Case study on chemical soil fumigants (1,3-dichloropropene and chloropicrin)**

This case study was selected because it covers several Article 53 authorisations in more than one Member State for a specific application method (fumigants). The soil fumigants represent also a significant proportion of the notifications in the sample available for review. Finally, the active substance used in soil fumigants is not approved at EU level.

### *Products and intended use*

1,3-dichloropropene is a nematicide developed for use on bare soil before the cultivation of fruiting vegetables, in protected areas (glasshouses) and open fields. It is injected or applied with drip lines into the soil in liquid formulations and it then diffuses through the soil as a vapour. The current formulated products are GF-3035 for field application by injection (sold as TELONE II (XRM-5048)) and GF-3036 for drip application in glasshouses (sold as TELONE EC (EF-1478)). These pesticides are targeted for use on fruiting vegetables, solanaceous (tomato, pepper and eggplant) and cucurbitaceous crops (cucumber, zucchini, melon and water melon) once every two years. Chloropicrin is a broad-spectrum soil fumigant with insecticidal, fungicidal, nematicidal and herbicidal properties, also developed for use on bare soil before planting.

### *Authorisation at EU level*

The active substances are not approved at EU level and are thus excluded from the list of candidates for substitution.

1, 3-dichloropropene was not authorised in the EU under the Directive 91/414 CE Annex I revision process, and this decision entered into force on 10 February 2011. The manufacturer Dow AgroSciences presented a new dossier for authorisation under Regulation (EC) No 1107/2009, and the Draft Assessment Report was published by the Commission in February 2017 (European Commission, 2017a).

Chloropicrin approval for use on all crops under Directive 91/414 CE ended on 23 June 2013. The European Chloropicrin Group submitted a new technical dossier under Regulation (EC) No 1107/2009 at the end of 2013, to obtain a new EU approval for the use of chloropicrin as a pre-planting soil fumigant. The Draft Assessment Report was published for public consultation by the Commission in February 2018 (European Commission, 2018a), recommending approval for use in permanent glasshouses (but not open fields).

### *Reasons for authorisations under Article 53*

Since 2014, derogations have been used for non-approved soil fumigants in fruit and nursery production and other horticulture crops in Spain, Italy, Belgium, France, the UK, Cyprus, Malta, and Greece (López-Aranda et al., 2016). Portugal reported a derogation for

chloropicrin in 2016 and 1,3-dichloropropene in 2017. Spain used derogations for both products in 2016 and 2017, with Greece and Malta doing the same for both in 2016 and 1,3-dichloropropene in 2017. In 2016, Cyprus and France reported derogations for 1,3-dichloropropene, while Belgium and Hungary reported derogations for chloropicrin. The UK had a derogation for chloropicrin in 2017.

Spain's rationale for the derogation stated that the intensive horticulture crop cycles do not permit rotation or the use of alternatives. The Spanish authority therefore concluded that disinfection with pesticides is an economic necessity.

Belgium argued that the withdrawal of active substances for soil disinfestation would result in more harvest losses and a reduced supply of high-quality products, thereby having a major impact on the economic feasibility of the crops. It would also increase the use of fungicides and insecticides during the crop growing period, which is 'not a good agricultural practice' and leads to a greater risk of pesticide residue in the marketed product. The derogation stated that crop rotation or field rotation is not possible for strawberry growers because the economic investment in irrigation infrastructure (etc.) obliges them to produce the same crop as continuously as possible. Belgium also argued that they must use the derogation because other Member States are doing so: 'it will only be a fair competition if European countries give the same'.

#### *Environmental impacts*

1,3-dichloropropene: in its 2009 evaluation, EFSA found a high amount of applied 1,3-dichloropropene is expected to volatilise from soil, even though it is injected below the soil surface or applied via drip irrigation systems, and that 1,3-dichloropropene is also absorbed into plants, translocated and degraded (EFSA, 2009). It identified a high acute risk from outdoor use to earthworm-eating and insectivorous birds and mammals, as well as a long-term risk to earthworm-eating and insectivorous mammals. The Draft Assessment Report of February 2017 found that, depending on the dose rate, 1,3-dichloropropene has various secondary effects (insecticidal, herbicidal, fungicidal) on a variety of organisms (European Commission, 2017a). Field studies designed to assess the potential adverse effects of Telone II injection on soil dwelling arthropod communities in commercial arable fields indicated that beetle (*Coleoptera*) and ant (*Formicidae*) populations are affected for two years or more, probably due to a toxic effect on the soil-dwelling larvae, while *Diplopoda* and *Isopoda* populations are affected for more than a year (European Commission, 2017a). Effects were found on other soil invertebrates for up to seven months, although populations recovered within a year. The main route of environmental exposure is through volatilisation into the air but monitoring of groundwater wells confirmed residues of the pesticide metabolite 3-chloroacrylic acid in the Cáceres region of Spain, the Manche region of France, and in Italy. River monitoring found 1,3-dichloropropene in the Basque region (Balaguer et al., 2018).

Chloropicrin: the DG SANCO<sup>30</sup> review report published in 2011 identified concerns about the risks for groundwater contamination and long-range atmospheric transport, as well as the risk to aquatic organisms and to birds and mammals (DG SANCO, 2011). The applicant

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<sup>30</sup> Now DG SANTE.

for approval of the active substance (European Chloropicrin Group) provided insufficient information to assess exposure in groundwater, natural surface water and sediment, effects on sediment-dwellers, earthworms, non-target plants, and the potential oral and contact risk to bees from exposure to residue. The Draft Assessment Report found unacceptable risks to earthworms, soil micro-organisms and aquatic organisms, and could not rule out chronic/ reproductive risk to birds and mammals from exposure to chloropicrin via inhalation, due to lack of evidence (European Commission, 2018). It classifies chloropicrin and its metabolite DCNM as potential groundwater contaminants.

#### *Health impacts*

1,3 dichloropropene is moderately toxic to mammals, and is a recognised skin and respiratory tract irritant (PPDB, 2018). EFSA has since identified concerns regarding mammalian toxicology and consumer exposure (EFSA, 2009). Contrary to its 2005 assessment, the Draft Assessment Report recently stated that the weight of evidence indicates that 1,3 dichloropropene is an in-vivo genotoxic agent for mammalian somatic cells (European Commission, 2017a). A review of the evidence by the California Department of Pesticide Regulation concluded that it should set the risk thresholds for long-term carcinogenicity at higher levels than Spain's Draft Assessment Report, i.e. that the substance is more strongly carcinogenic (DPA, 2017).

Chloropicrin has a high toxicity classification (class III) (PPDB, 2018), and the DG SANCO review report published in 2011 identified concerns about the risk to operators (DG SANCO, 2011). It causes sensory irritation at very low concentrations, and moderate concentration of exposure to the volatilised gas causes severe respiratory dysfunction within six to eight hours. It is not classified as either mutagenic or carcinogenic (European Commission, 2018; PPDB, 2018) but other assessments include evidence for carcinogenicity (CEPA, 2012).

#### *Economic and social impacts*

The arguments put forward by the Member States using derogations for soil fumigants are that the use of non-chemical methods would require six to eight weeks between crop periods, possibly during the summer or autumn season, and this would reduce productivity by 20-30%. Member States also argue that the use of soil disease resistant crop varieties is not economically feasible, and that crop resistance breaks down quickly in the intensive monoculture production cycles. Thus, the main arguments put forward to maintain the use of chemical soil fumigants are based on the economic necessity of maintaining a highly intensive monoculture of vulnerable crop varieties to produce vegetables and fruits at a price that is competitive on the EU and world markets. Chemical soil fumigants also have an additional benefit for growers, as they stimulate extra root growth.

Soil fumigants are used in intensive horticulture systems in temporary and permanent greenhouses, in which there are two or more crop cycles each year. The rapid expansion of greenhouse agriculture in southern Spain has led to increasing conflicts between economic development priorities and nature conservation, combined with the loss of traditional agriculture and rural populations (Quintas-Soriano et al., 2016). The local population values the greenhouse horticulture industry highly for its employment opportunities and

creation of economic development, but also associates it with social inequality and worker exploitation. Locals also perceive the negative environmental impacts of greenhouse horticulture on the water supply and water quality, soil erosion, and pollution through pesticide and plastic use (Quintas-Soriano et al., 2016).

#### *Availability of alternatives*

Chemical alternatives are metam and dazomet but from May 2015 (dazomet) or July 2016 (metam sodium/ potassium), only one application in three seasons was permitted, and the maximum rate was limited to 490 kg/ha for dazomet and to 153 kg/ha for metam sodium or potassium. Dazomet requires a 40-day interval between application and crop planting. The new active substance dimethyl-disulfite has an EU application pending for use as a soil fumigant. The Spanish government reports the testing of various other chemicals in the growing conditions of the southeast, but these are highly toxic (propylene oxide, sodium azide, cyanogen).

Non-chemical alternatives have been researched for a number of years. Spain and the Netherlands have publicly funded a number of research projects (e.g. ILVO, 2016). However, an EU-funded LIFE project (LIFE SustUse Fumigants, 2012), which aimed to develop non-chemical practices for the control of soil-borne pathogens in the horticultural sector in Mediterranean conditions (Italy, Greece), and central Europe (Poland), shows no evidence that producers have stopped using chemical fumigants and switched to non-chemical alternatives. The project improved good practices in the application of chemical soil fumigants, however, by training users and developing site fumigation plans.

An alternative in open fields is to grow a cover crop after the harvest of the main crop and thus incorporate the residue into the upper soil layer before the next crop. Marigold (*Tagetes patula*), for example, is known to have a nematode-suppressing effect, while members of the Brassicaceae family have biocidal properties. Anaerobic soil disinfestation is a technique in which fresh organic matter (e.g. grass cuttings) is incorporated in the top soil layer, irrigated and then covered with an impermeable plastic film (Korthals et al, 2014). Soil biofumigation is the application of manure and plant residue and extracts with allelopathic compounds (Dominguez et al, 2016). A six-year commercial field scale study in the Netherlands found anaerobic soil disinfestation and marigold to be effective alternatives to chemicals for the control of plant-parasitic nematodes and the soil fungal disease *Verticillium dahliae* (Korthals et al, 2014). These treatments increase crop yield without permanent negative changes in the chemical or physical aspects of the soil.

Soil solarisation works through the effect of the sun on bare soil covered by clear plastic mulch. A study in commercial strawberry cultivation beds in Spain found the combination of soil biofumigation and soil solarisation to be a promising sustainable option for strawberry production, as well as being 20% cheaper than 1,3-dichloropropene and chloropicrin (Dominguez et al, 2016). Arguments against the technique, however, are that the soil must be fallow during summer and a minimum of six weeks is needed before crop planting, thereby reducing the time available for production of crops. It does not control nematodes below 25 cm soil depth.

The integrated use of seaweed extracts has been shown to have benefits as a replacement for the increased growth response provided by soil fumigants in strawberry production across the nursery and fruit sectors (Mattner et al, 2018).

Steam rototilling is effective at controlling soil pathogens but is considered very expensive and requires a lot of energy. While nematode-resistant varieties or grafts are available, growers tend to not use them because of the risk of resistance breaking down under the intensive monoculture, or because they are not considered to meet market demands.

#### *Sustainability, precaution and substitution*

The continued derogations on chemical soil fumigants do not appear to correspond to the principles of sustainability, precaution and substitution. The urgent need for alternatives to chemical soil fumigation in European horticulture has been recognised by researchers for many years, but unauthorised pesticides (such as 1,3-dichloropropene and chloropicrin) have continued to be available in some Member States through the use of derogations. Applications have been submitted for re-authorisation but EFSA has already concluded that both substances pose an unacceptable risk to the environment and human health, including evidence of groundwater and surface water pollution. Although both applications state that they contain new supporting evidence of low risk, the assessment reports found some significant environmental risks, as well as insufficient evidence to rule out other potential risks.

Alternatives to chemical soil fumigants are available, with the principal argument against their use being the imposition of economic costs on the horticulture industry due to the need for longer rest periods between crops and/or crop rotations. However, there is also evidence that alternatives can be cheaper than pesticide applications and it is likely that non-chemical alternatives result in healthier soil, which also reduces the incidence of other pest and disease problems.

#### *Conclusion of the case study on chemical soil fumigants*

Continuing Article 53 authorisations on chemical soil fumigants does not appear to correspond to the principles of sustainability, precaution and substitution. The urgent need for alternatives to chemical soil fumigation in European horticulture has been recognised by researchers for many years, but unauthorised PPPs (containing, for example, 1,3-dichloropropene and chloropicrin) continue to be available in some Member States through the use of Article 53 authorisations. Applications have been submitted for re-authorisation, but EFSA has already concluded that both substances pose unacceptable risks to the environment and human health, including evidence of groundwater and surface water pollution. Although both applications state that they contain new supporting evidence of low risk, the assessment reports found some significant environmental risks, as well as insufficient evidence to rule out other potential risks.

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### 5.3 Case study on insecticides for use in mass trapping

This case study was selected because it covers several derogations for similar substances and similar uses in neighbouring Member States, primarily for the unapproved use of approved active substances, but also for a low-risk use of an unapproved active substance.

#### *Products and intended use*

Mass trapping is used both for pest control and for pest monitoring. It consists of a combination of a solid or liquid food attractant together with an insecticide-containing system to trap target insects. Traps have been developed for use in various permanent crops, containing the insecticides deltamethrin, lambda-cyhalothrin, dichlorvos, and others. Examples include:

- CONETRAP by Probodelt, containing the attractant AMPHOS-DACUS and 7.5 mg of microencapsulated lambda-cyhalothrin for control of Olive Fruit Fly (*Bactrocera oleae* / *Dacus oleae*).
- FLYPACK® dacus, containing an attractant specific for Olive Fruit Fly (*Dacus oleae*) and deltamethrin.
- CERATIPACK® ES 00042 by SEDQ and Decis trap by Bayer, containing deltamethrin for control of Mediterranean fruit fly (*Ceratitidis capitata* Wied).
- Nadel trap with sex pheromone (Trimedlure) (e.g. attractant ECONEX TRYPACK®) and dichlorvos dispenser for control of Mediterranean fruit fly (*Ceratitidis capitata*), including KENOSTRIP by Kenogard S.A. with dichlorvos, ECONEX DDVP unit by CRISARA or DDPV insecticide strip by Agrisense-BCS Ltd.

#### *Authorisation at EU level*

Deltamethrin is authorised at EU level as an insecticide in olives, pome fruits, tree nuts, strawberries, vegetables, mushrooms, arable crops, forestry, flowers and ornamentals, as well as non-crop uses. Lambda-cyhalothrin is authorised at EU level as a foliar insecticide spray on wheat and potato. It is included in the list of candidates for substitution because the Acceptable Operator Exposure Level (AOEL) is significantly lower than that of most of the approved active substances within the group of insecticides, and it meets the criteria to be considered a bioaccumulative and toxic substance (European Commission, 2018). Both active substances have been approved by a large number of Member States for a range of uses, including use by non-professional users in gardens (e.g. in the UK, see RHS, 2017).

Dichlorvos is not approved at EU level since 2007, due to uncertainties regarding its genotoxic and carcinogenic properties, making it impossible to rule out toxicity of breakdown products and health risks from operator, worker and bystander exposure.

#### *Reason for Article 53 authorisations*

Spain has granted Article 53 authorisations for the use of mass trapping with deltamethrin, dichlorvos and lambda-cyhalothrin for several years. The authorisations are for the use of bait traps in olive groves (with deltamethrin or lambda-cyhalothrin) to control Olive fruit fly, bait traps in greenhouse pepper cultivation (with deltamethrin), and bait traps in citrus (with dichlorvos) to control Mediterranean fruit fly. In 2017, Portugal granted an Article 53

authorisation for the use of mass trapping with deltamethrin in olive groves to control Olive fruit fly.

These Article 53 authorisations against Olive fruit fly were granted because Spain and Portugal have not registered any products to allow control of the Olive fruit fly using mass trapping. The dichlorvos authorisation was granted because the US requires adherence to the US citrus export workplan in citrus production units destined for export to the US, which, in the case of clementines, includes a mandatory monitoring programme using dichlorvos dispensers placed inside traps with a sexual pheromone attractant. The Article 53 authorisations for mass trapping in greenhouse pepper cultivation with deltamethrin was given to control an outbreak of Mediterranean fruit fly, which moved onto pepper crops at the end of the citrus season.

#### *Environmental impacts*

The traps are designed to capture only the targeted insect, in contrast to attract-and-kill type traps in which the insecticide is exposed on a panel or in an open trap, and which kill many non-target beneficial organisms such as pollinators and natural enemies. It is nonetheless recommended that the traps should not be kept in the field during the flowering period, to avoid exposing or trapping and killing bees and other insect pollinators.

#### *Health impacts*

The traps should be set and filled by workers using protective gloves, and all traps should be removed from the crop after use. Mass trapping with attractants is considered to have a low risk of exposure to operators, as the traps are generally sold with the insecticide already inside and do not require refilling. The older traps require frequent refilling, raising the risk of operator exposure, and they may also release insecticide vapours. The technique leaves no residue on the fruit, so the health of consumers is considered sufficiently protected. However, dichlorvos is not approved at EU level due to concerns about its genotoxic and carcinogenic properties and those of its breakdown products, and health risks from operator, worker and bystander exposure.

#### *Economic and social impacts*

Olive fruit fly larvae can consume a significant part of the olive pulp, causing production loss of table olives because the attacked fruits drop prematurely from the tree, as well as permitting the entry of fungal infections. Olives with a high incidence of the pest produce an oil of lower quality with higher acidity (expressed as oleic acid) and peroxide, and lower conservation capacity.

The Mediterranean fruit fly (*Ceratitis capitata*) is one of the most important pests in the Spanish citrus industry, as it is a quarantine pest and causes major problems if it is found in exports.

The use of mass trapping to control insect infestations is considered effective at reducing pest populations with little environmental impact. For example, the use of mass trapping against Olive fruit fly in Catalonia, Spain, has been rolled out to replace aerial insecticide spraying, which has been prohibited under Spain's national pesticide action plan. In 2014,

the mass trapping system was tested in 1,000 ha of olive groves, and, in 2015 and 2016, the method was applied in 19,000 ha of olive, with an exceptional authorisation.

*Availability of alternatives*

Olive Fruit Fly: Spain has registered a deltamethrin product (Deltamethrin 0,0187 %RB, n° de Register 25.562) for olive fly control using the attract-and-kill technique. This method differs from mass trapping by exposing the insecticide on the outside, which results in a risk of contact with leaves and fruit and operator exposure. It also requires two applications per season (June and September) rather than one.

Mediterranean Fruit Fly: the most widely used biological control method for the Mediterranean Fruit Fly is the release of large numbers of mass-reared sterile males into an infested area, where they mate with female conspecifics and pass on sperm carrying dominant lethal mutations, preventing the female from producing viable progeny. The Sterile Insect Technique is one of the most environmentally sensitive methods of control but it has a high economic cost, the logistics of release are complicated, and there is a risk that the reduced fitness of sterilised males limits its efficacy (Rogers, 2011).

*Sustainability, precaution and substitution*

Capture traps are fully compatible with IPM, as they are used for initial monitoring before decisions are made on the intervention needed to reduce levels and damage of the pest. The use of mass trapping to control insect infestations is considered effective at reducing pest populations with little environmental impact. Traps may need to be serviced regularly to prevent clogging with retained flies and to prevent the trapping mechanism from drying out.

Capture traps are more sustainable than other traps as they do not result in resistance problems. By contrast, the use of other attract-and-kill techniques can generate resistance problems to the insecticide, as the insects in contact with the insecticide do not remain confined in the trap and, if they are only sub-lethally affected, may recover and pass on their resistance to others.

The use of dichlorvos in capture traps is not compatible with the principles of precaution and substitution, as its authorisation in the EU was withdrawn due to concerns about the health risks it poses. The reason for the Article 53 authorisations is the US import requirement for clementines, which is not compatible with the EU pesticide regime.

*Conclusion of the case study on insecticides for use in mass trapping*

Article 53 authorisations are being used by Spain and Portugal to give growers access to PPPs for specific use in horticulture and permanent crops, using application techniques that are compatible with IPM and low PPPs crop systems. In these cases, the main drivers for the use of Article 53 authorisations seem to be a lack of capacity in the regulating authority to process authorisations without delay, a lack of industry support, and international trade agreements that are not compatible with pesticide regulations in the EU. Under the PPPR, however, such cases should be dealt with using Article 51 extensions of minor use instead of Article 53 authorisations.

## **6. Member State procedures for granting emergency authorisations and informing other Member States and the Commission of the authorisations granted**

### **6.1 Procedures in place in selected Member States to grant emergency authorisation**

As mentioned in the introduction to the methodology, a sample of eight Member States was selected for a detailed assessment of their procedural aspects for granting emergency authorisations. These Member States were selected based on their high number of notifications of Article 53 authorisations in 2017 and by PPPR geographical zone (Northern/Central/Southern). These eight country studies were carried out by Milieu experts and entailed both desk research and interviews with CAs and relevant national stakeholders. Since very limited information was available online on the procedures in place in Member States, interviews were the main sources of information to complete this analysis. The research team also assessed the procedural aspects of Article 53 authorisations in selected Member States because there are no such requirements under the PPPR, thus this procedure is under the competence of Member States. Furthermore, the preliminary findings from the desk research and analysis of notifications identified some concerns relating to certain procedural aspects of Article 53 authorisations (e.g. lack of transparency and public scrutiny).

A comparative overview, together with the main findings on the different procedural aspects covered in these country fiches, is presented below.

#### *Article 53 procedures regulated by law*

In all but one of the selected Member States<sup>31</sup>, the Article 53 procedure is not detailed in law but, rather, is contained in non-binding guidance documents that include the application forms and documents for applicants. Several of the CAs consulted consider this an internal administrative procedure which has its legal basis set out in the PPPR, thus the procedure is not further detailed in national law.

#### *CAs in charge of granting Article 53 authorisations*

In most selected Member States, the CA responsible for granting the Article 53 authorisation is the Ministry in charge of agriculture. In two selected Member States, the CAs are the Ministry of Public Health, Food safety and Environment, and the Agency in charge of chemicals, respectively.

#### *Coordination and consultation in place with other public authorities and scientific institutes*

In all but one of the selected Member States, the CAs consulted mentioned that other CAs and/or scientific institutes can, to some extent, be consulted or involved in the decision-making process to grant an Article 53 authorisation. In one Member State, the Food Safety Agency, the Ministry of Employment, regional authorities, public health, veterinary and

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<sup>31</sup> In one Member State, a draft legal decision has been prepared (but not yet adopted as of February 2018) detailing the steps for the Article 53 authorisation procedure.

agrochemical research institutes are all involved in the decision to grant an emergency authorisation. In another Member State, the Ministry of Health (toxicology, residue, operators' exposure) and the Environment (water, soil) and the University of Veterinary Medicine and Pharmacy (ecotoxicology) are consulted. In a third Member State, other public authorities in charge of agriculture and forestry are consulted to identify alternatives, while public authorities in charge of food safety are consulted for residue evaluation (MRLs and analytical methods).

In one Member State, the CA can decide to initiate consultations with other CAs only if it is deemed appropriate. In another Member State, other public authorities and research institutes are only consulted in case of the use of aerial spraying for PPPs. There, the consulted CA considered the timeframe of the application process too tight to request technical support from other research institutes. In a third Member State, a scientific institute is involved only in cases where MRLs need to be determined.

#### *Applicants to the authorisation procedure*

A large share of the derogations granted in 2017 (38%) were requested by agricultural or forestry companies and associations, 31% were requested by PPP manufacturers or the seed industry, 23% were requested by authorities, and a small number by other types of applicants, such as agricultural and agronomy research institutes and consultants (6%) or producers of animal health products or feed (1%)<sup>32</sup>. A small number of CAs state that they try to avoid applications based solely on commercial interest. In two of the selected Member States, applications are, in principle, only accepted from farmers or farmers' associations, in order to avoid commercial interests from PPP producers, while, in another, the CA verifies that applications submitted by PPP manufacturers are carried out on behalf of farmers/ farmer' associations.

#### *Timeframes for applicants to request an Article 53 authorisation*

In all eight selected Member States, there are no strictly binding timeframes for applicants, due to the need to react rapidly against an emergency. The Member State CAs consulted provided the following information on application timeframes:

- Applications should ideally be submitted three months before the spraying of the PPP.
- Applications should not be submitted before the problem arises but should be made while there is still an opportunity for effective intervention.
- A request can be submitted very close to when the spraying should normally start (sometimes as little as three weeks).
- If the need to use a product is foreseeable, the request is made in advance and the authorisation is issued approximately two/three months before the start of the emergency authorisation. In some cases, the situation is unpredictable (bad weather development) and rapid treatment is needed (e.g. long-term rains and the inability to apply any products, after which immediate application of fungicides is required but with a short protection period before harvesting). In cases like this, an authorisation can be granted within a few days.

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<sup>32</sup> 1% of the applicants could not be identified through desk research.

- Ideally, the applicant should submit their application between one and two months before the spraying of the PPP.
- An application should be submitted at least one month before the spraying of PPPs. The applicant is welcome to apply as soon as he/she identifies the need for a derogation.

*Content of the application form*

In all of the selected Member States, application forms are available online. The CAs consulted mentioned that these application forms follow the notification template prepared by the Commission and the recommendations set out in the Commission working document. One Member State CA explained that applicants can attach studies and test results to the application. Similarly, another Member State CA mentioned the option to submit additional documents, complementing the form and clarifying or complementing some of its aspects, as an annex (e.g. supporting letters from farmers' associations or plant health services, confirming or highlighting the need and importance of the requested product). One of the selected Member States has prepared a guidance document to support applicants in completing the form.

According to one NGO representative in a selected Member State, applicants have no interest in providing alternative solutions, and may, in fact, lack knowledge about such alternatives. This NGO representative therefore suggests that the CAs should request information from stakeholders/NGOs/experts on alternative measures and non-chemical products, in order to ensure a real assessment of alternatives by the CAs in their decision to grant or reject an authorisation.

*Specific procedures for non-approved active substances compared to approved substances*

None of the selected Member States had specific procedures for non-approved active substances compared to approved substances, with the same procedure in place for all applications. One Member State CA explained that there is no specific procedure but a more stringent approach is taken to the risk assessment (consumer, operator, environment), focusing on the elements that triggered the non-approval. According to another Member State CA, a derogation has never been granted for the use of a product with a non-approved active substance, thus no specific procedure is needed. This CA stressed that the approval of a substance is a prerequisite for granting an Article 53 authorisation. Another Member State CA stated that they have almost no experience of handling Article 53 applications for products with non-approved active substances and that, in theory, special information needs to be obtained for risk handling for such substances.

According to an environmental NGO representative in one selected Member State, there should be a highly detailed and highly specific procedure for the granting of Article 53 authorisations for non-approved substances, since they could entail excessive threats to both the environment and public health. A much more elaborate and stringent procedure should be adopted in such cases.

*Specific procedures for repeated Article 53 authorisations*

None of the selected Member States have specific procedures for repeated authorisations. In one Member State, a draft legal decision envisages a prohibition on the submission of an application for more than two years if a conventional authorisation application can be submitted instead. According to one CA, the conditions for granting an authorisation are more stringently assessed for each repeated authorisation, evaluating applicants' proposals for avoiding the use of Article 53 authorisations.

*Transparency and availability of information*

In almost all of the selected Member States, decisions to grant an Article 53 authorisation (including past decisions) are available online<sup>33</sup>. However, decisions to reject an authorisation are not available online. In two selected Member States, Article 53 authorisation decisions are not available nor are any other related documents. The CA of one of the Member States in question stated that Article 53 authorisations are not published online as they only concern a particular applicant.

None of the selected Member States publish the applications and related evaluations (e.g. assessment of alternatives and justifications) or any other documents. The representative of one CA stated that they provided such information on request (e.g. the application, evaluation), except where it relates to confidential information on the composition of the product. One Member State has prepared its first yearly summary of all of the emergency authorisations granted in 2017 but, at the time of writing this report, that summary report was not yet available online.

Some environmental NGO representatives consider the information available on Article 53 authorisation decisions insufficient, pointing out that authorisation decisions do not always contain a separate section with a detailed analysis of the justifications concerning, inter alia, the absence of alternatives.

DG SANTE holds that Member States must publish information on Article 53 authorisation because of the application of Article 57 of the PPPR, which requires Member States to keep information electronically available to the public on PPPs authorised or withdrawn in accordance with the PPPR, containing at least:

- name or business name of the holder of the authorisation and the authorisation number;
- trade name of the product;
- type of preparation;
- name and amount of each active substance, safener or synergist which it contains;
- classification, risk and safety phrases;
- use or uses for which it is authorised;
- reasons for withdrawal of an authorisation if they relate to safety concerns;
- list of minor uses.

This information must be readily accessible and updated at least once every three months.

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<sup>33</sup> Certain Member States do not publish all past authorisations but only those issued during a limited range of years (e.g. previous year or within the three last years).

*Consultation and involvement of third parties in the decision-making process*

Almost none of the selected Member States have put in place a third-party consultation procedure as part of the Article 53 authorisation procedure. One of the selected Member States, in a draft legal decision, plans to set a three-week public consultation, during which the main elements of the application for an authorisation must be available online for any stakeholders to submit comments and opinions. Several NGO representatives expressed their concern about the lack of consultation procedures, which limits their capacity to challenge dossiers and justifications provided by applicants.

According to a representative of an EU association of PPPs, the purpose of Article 53 is to allow Member States to act quickly and unilaterally to deal with urgent situations and to inform other Member States and the Commission immediately thereafter. This emergency does not allow for stakeholder/public consultations. It is a technical decision that must be made by the CAs, including technical institutes, laboratories and public administrations.

*Strategies to limit the use of (repeated) Article 53 authorisations*

None of the selected Member States have specific strategies in place to limit the use of repeated Article 53 authorisation. However, several Member State CA representatives provided examples of actions to reduce the use of (repeated) authorisations:

- For new pests, like the *Drosophila Suzukii*, or in cases of development of some well-known pests' resistance (with which many emergency authorisations are concerned), new possibilities to tackle these plant protection problems are being explored and made available by public research institutes.
- The National Action Plan for the sustainable use of phytosanitary products includes measures to facilitate the availability of phytosanitary products (e.g. favouring the availability and registration of new phytosanitary products, with special attention to minor uses).
- Applicants are encouraged to apply for mutual recognition. Applicants are also encouraged to talk with the holder of the PPP so that the holder can apply for authorisation. A 'minor use' project is ongoing, examining ways for PPPs to be authorised in different cultures.

*Enforcement and control*

None of the selected Member States have put in place specific inspection strategies/programmes for Article 53 authorisations. Rather, these are controlled as part of the routine inspections of PPP authorised for use in selected Member States. Inspectors are made aware of the use and related geographical area of PPPs authorised under Article 53, but such inspections are not prioritised.

A representative of a Member State CA mentioned that Article 53 authorisation holders must report on the use of Article 53 authorised PPPs, the quantity of products brought to the market or used, and the territories where the product was used, after the expiration of the authorisation's timeframe. Such reports must also include the development of the infestation (weather conditions, estimate on future infestations), information on the

specific application (area of use, average dose, evaluation of the product's success, use in organic cultivation and ways to solve the problem in other EU Member States), information about the effects of the use of this product (health issues, effect on the ecosystem, harm to honeybees, acceptance issues among the population) and the future of this type of emergency application (alternative ways to tackle the pest, likelihood of application for regular authorisations).

One Member State CA explained that 290 municipalities perform official controls on marketing and use of PPPs, while it is itself responsible for compiling data on those official controls of PPPs (including marketing and use) performed by municipalities. This CA had found no specific compliance issue relating to the use of Article 53 authorised products.

#### *Public awareness of the use of Article 53 authorisations*

All stakeholders consulted in the preparation of country fiches considered there to be low public awareness of the purpose and use of Article 53 authorisations. Environmental NGO representatives stated that a limited number of environmental NGOs have knowledge of, or focus on, the implementation of this authorisation procedure. They stressed that this lack of awareness is due to the limited information, if any, available on the authorisation procedure, together with the lack of consultation opportunities during this procedure.

According to one CA representative, civil society and environmental NGOs do not have adequate technical and scientific skill to be usefully involved in the authorisation procedure. One CA representative was of the view that Article 53 authorisations involve highly technical issues, attracting little attention from the media and the public. According to a national PPP producer association representative, limited information is available on Article 53 authorisations and usually only in sectoral sites and magazines/websites dedicated to agriculture.

## **6.2 Conclusion on the procedures in place in selected Member States to grant emergency authorisations**

The analysis of the procedural aspects in these selected Member States demonstrates that there are several areas to be improved in the implementation of Article 53 authorisations. In particular, these authorisation procedures, rarely set in law, are not sufficiently transparent, impeding adequate public scrutiny and raising some concerns about the discretionary powers of CAs and their impartiality in respect of the interests of applicants.

## **6.3 Views of EU stakeholders on the implementation of Article 53 authorisations by Member States**

This sub-section summarises the views of EU stakeholders on the implementation of Article 53 authorisations by Member States.

#### *Concerns relating to the implementation of Article 53 authorisations*

According to a representative of an EU farmers' association, Article 53 has been properly implemented. In certain cases, Member States have granted an emergency authorisation too late and farmers have not been able to use it. In general, however, it has been adequately implemented.

By contrast, a representative of an EU biocontrol producers' association stated that most Member States have not implemented this authorisation properly, as a high number of authorisations are repeated each year for the same PPPs and for the same 'emergency' use. Similarly, a representative of an EU environmental NGO felt that the procedure is not implemented adequately. The same authorisations are granted year after year, which is no longer an 'emergency procedure' but a systematic use of non-authorised PPPs. There is no proper assessment of alternatives.

According to a representative of an EU PPP producers' association, there have been some issues with the implementation of Article 53 authorisation which are mainly due to the lack of authorised PPPs for certain crops and uses. This is particularly the case for minor uses and speciality crops that are very important in some Member States<sup>34</sup>. Despite the existence of fast track procedures for minor crops in some Member States, this solution is not optimal as it only works when there is a product normally authorised for a major crop that can serve as a reference for the minor use. Even with a reference PPP authorisation, authorities often undertake new risk evaluations for the minor use, which increases delays. Therefore, according to the representative of the EU PPP producers' association, in practical terms, Article 53 authorisations are needed to address the lack of authorised PPPs. An example of an emergency authorisation that is repeated year after year is Tidiazuron. No application has been submitted for approval of the active substance at EU level, but Article 53 authorisations of PPPs based on this active substance are regularly granted in the Member States.

#### *Suggested changes in the implementation of Article 53 authorisations*

According to a representative of an EU farmers' association, nothing should be changed in the implementation of Article 53 authorisations. Rather, the focus should be on exchanging the hazard-based approach of the PPPR for a risk-based approach, as well as the lack of mutual recognition from Member States.

A representative of an EU biocontrol producers' association believed that Article 53 authorisations should be used only in true emergencies and not as a tool to cope with deficiencies in other areas of the PPPR. A case study should be prepared for each Article 53 authorisation and be publicly available for challenges to be made. Promising solutions of low-risk evaluated and registered PPP by other OECD states should first be considered before using PPPs with active substances categorised as candidates for substitution and/or withdrawn from the EU market.

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<sup>34</sup> Minor uses are uses for niche crops (or speciality crops) with a high economic value for farmers, but usually of low economic interest for the PPP industry.

According to a representative of an EU PPP producers' association, several steps could be taken to improve the implementation of Article 53 authorisations:

- Increase the effectiveness of the mutual recognition of PPP authorisations among Member States.
- Accelerate the current EU approval process to authorise products in a timely manner.
- Implement the zonal authorisation process under the PPPR more effectively.
- Developing and implement a simple and pragmatic process to extend approvals to minor crops/uses.
- Develop a risk/benefit evaluation and approval process that permits the retention of crop protection solutions where no fully authorised method (chemical or not) exists and until such a method is identified, approved and in force. Such a process exists in REACH (the chemicals regulation) to retain necessary products under controlled conditions where no alternatives exist.
- Sufficient time for PPP manufacturing should be considered, as it may not be in stock when an emergency authorisation is signed.

According to a representative of an EU environmental NGO, every application for an Article 53 authorisation should be sent to EFSA, and authorisations should not be granted in the absence of its positive opinion.

#### **6.4 Notifications by Member States to other Member States and the Commission**

According to DG SANTE, in order to improve the implementation of the Member States' obligation to immediately inform other Member States and the Commission of the use of Article 53 authorisations, the Commission has integrated the possibility for Member States to complete and submit notification forms on the individual uses of Article 53 authorisations into the PPPAMS<sup>35</sup>. DG SANTE stressed that notifications have been sent via the PPAMS since the beginning of 2017. Before 2017, notifications were sent and saved via CIRCABC<sup>36</sup>. Notifications have never been available to the public, with their access restricted to the Commission and Member State CAs.

According to a Commission representative, the implementation of the PPAMS notification system has led to better implementation of the Member States' obligation to immediately inform other Member States and the Commission of the use of Article 53 authorisations. However, some Member States remain unlikely to notify all derogations, or, where they notify derogations, do not do so 'immediately', as required under Article 53 of the PPPR. Again, as confirmed by the Commission in an email, the system is not currently legally

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<sup>35</sup> According to the DG SANCO website: 'PPPAMS was developed by the European Commission to enable industry users to create applications for PPPs and submit these to Member States for evaluation. Member States then manage these applications within the system, concluding with authorisation of the PPP or refusal of the application. The system is designed to support Member States in fulfilling their legal obligations under [PPPR] notably Article 57(1) and (2)'. According to an interview with a Commission representative, as at February 2018, PPPAMS remained a pilot test for Article 53 notifications.

<sup>36</sup> Communication and Information Resource Centre for Administrations, Businesses and Citizens, which is a collaborative platform allowing the distribution and management of documents.

binding, which hampers the implementation of the requirement of immediate notification under Article 53(1).

The review of the sample of notifications showed that a large share of the notifications (110 (28%) in 2017 and 73 (32%) in 2016) were not completed at all. This was, however, the case in only three or four Member States, depending on the year. In addition, many notifications provided only very limited information. As described in Section 6.4, the part of the notification template related to the size and effect of the danger often lacked precise information on the area infested, period of infestation and its possible extension, as required in the Commission working document on emergency situations. Only around 30% of the notifications provided an indication of the geographical area at stake, although they generally referred to the area cultivated. Very few notifications referred explicitly to the affected area or the area to be treated. Regarding the effects of the infestation, although many derogations mentioned damage to production and economic loss in qualitative terms, only around 26% provided a quantitative estimate of economic loss, mostly expressed in percentage yield loss, based on the previous year's experience or examples from other countries. The justification for the absence of reasonable alternatives was often very brief, and merely stated the absence of alternatives, with only 40% of the derogations mentioning a specific alternative, mostly other authorised active substances or PPPs.

According to the Commission representative, the Commission is unlikely to launch infringement procedures for non-compliance with notification requirements under Article 53. However, he stressed that the Commission is trying to ensure that Member States adequately comply with this obligation through bilateral discussions or through 'naming and shaming' at the Standing Committee for Plants, Animals, Food and Feed (PAFF Committee)<sup>37</sup>.

The list of countries that have notified derogations and the related active substances are presented by the Commission at the meetings of the PAFF Committee. DG SANTE indicated that there are limited discussions on the notifications and related derogations at the PAFF Committee, since it is only one item of discussion on a comprehensive agenda. He stressed that derogations are discussed in other forums, such as in the zonal steering committees<sup>38</sup> or the Minor Use Coordination Facility (MUCF)<sup>39</sup>.

Almost all of the eight Member State CAs consulted stated that notifications from other Member States were of no real use:

- Notifications of other Member States are consulted only when the authorisation (under Article 53 derogation) was granted for a problematic situation similar to the situation at home. Such notifications do not, however, influence the decision taken by the CA.

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<sup>37</sup>As mentioned on the Commission website, the PAFF Committee is composed of representatives of all Member States and presided over by a European Commission representative.

<sup>38</sup> There are four Steering Committees for each zone, with a rotating Member State Presidency and a fifth, which is a coordinating interzonal steering committee, chaired by a Commission Representative.

<sup>39</sup> According to its website, the aim of the MUCF is to coordinate and support minor use work among all Member States and stakeholders, available at: <https://www.minoruses.eu/> (last accessed in February 2018).

- As each application must be assessed in view of the national context (area of use, availability of authorised products at national level, importance of the crop, etc.), notifications from other Member States are used for information only, when considered necessary.
- There is no need to interfere in other Member State decisions on emergency authorisations if the authorised use is subject to compliance with a valid MRL.

One Member State CA considered it useful to consult notifications from other Member States and seek harmonisation with similar emergency authorisations granted elsewhere.

## 6.5 Conclusion on the implementation of notifications

The Member State obligation to immediately inform other Member States and the Commission is not correctly implemented. Some Member States are unlikely to notify all derogations, or, where such derogations are notified it is unlikely to 'immediately', as required under Article 53 of the PPPR. Some notifications are submitted but have not been completed, while others provide only very limited information. Finally, the Commission has, at the time of writing this report, played a limited role in ensuring that Member States comply with this obligation through naming and shaming, and it is unlikely to undertake an infringement procedure for such cases of non-compliance.

## 7. Commission review of emergency authorisations and the role of EFSA

Under Article 53(2) of the PPPR, the Commission may ask EFSA for an opinion, or for scientific or technical assistance concerning the use of Article 53 derogations by Member States. Following such a request, EFSA must provide its opinion or the results of its work to the Commission within one month. Where the Commission concludes its intervention is justified, it may, under Article 53(3) present a proposal to the PAFF Committee providing for the Member State to extend or repeat the authorisation, or requiring the Member State to withdraw it.

As of February 2018, since the entry into force of the PPPR, the Commission has used the possibility to request an opinion from EFSA only once. In September 2017, EFSA was requested by the Commission to examine Article 53 emergency authorisations granted in 2017 by Romania (six authorisations), Bulgaria (one authorisation), Estonia (two authorisations), Finland (two authorisations), Latvia (two authorisations), Lithuania (two authorisations) and Hungary (nine authorisations) concerning severely restricted PPPs containing three neonicotinoid substances clothianidin, imidacloprid and/or thiamethoxam, used in sunflower and maize, oilseed rape seeds, spring rape and spring turnip rape seeds<sup>40</sup>. The Commission requested EFSA to:

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<sup>40</sup> European Commission DG Sante, 15 September 2017, Mandate for technical assistance to assess the emergency authorisations for the use of clothianidin, imidacloprid and/or thiamethoxam granted by Romania, Bulgaria, Estonia, Finland, Latvia, Lithuania and Hungary, SANTE/E44/SH/df (2017)4995956.

Available as of February 2018 at:

<http://registerofquestions.efsa.europa.eu/roqFrontend/questionsListLoader?panel=ALL>

- Assess whether or not the granting of these emergency authorisations and their wide scope were necessary because of a danger which could not be contained by any other reasonable means.
- Review the summary provided by each Member State in question.
- Produce a technical report on the Member State notifications in respect of their justifications due to a danger which could not be contained by any other reasonable means.

In its request, the Commission suggested that EFSA should use the EFSA protocol for the evaluation of data concerning the necessity of the application of insecticides containing active substances to control a serious danger to plant health which cannot be contained by other available means, including non-chemical methods, which was published on 5 April 2017<sup>41</sup>. The Commission stated that since most notifications were issued before the publication of this protocol, the Member States concerned should have the opportunity to update their notifications in relation to the data requirements and methodology proposed in the protocol.

In November 2017, EFSA replied to accept the mandate<sup>42</sup>. In its reply, EFSA provided the Member States in question with a reporting template and the data collection form to update their notifications in accordance with the protocol. EFSA provided a short overview of the methodology and practical assistance via a conference call with the Member State representatives. Member States had three months to update their notifications. Following this three-month timeframe, EFSA must prepare seven technical reports which discuss whether or not the justifications provided indicated the need for the emergency authorisations due to a danger which could be contained by any other reasonable means, thus ensuring that the protocol methodology for insecticide active substances is consistently applied. After providing the Member States concerned with the opportunity to comment on the draft reports, EFSA must publish the final version of the seven technical reports by 15 May 2018<sup>43</sup>.

According to a European Commission representative, the Commission has limited power to trigger an infringement procedure in case of misuse of Article 53 emergency authorisations. As the authorisation of PPPs are under the exclusive competence of Member States, it is difficult to challenge Member State decisions under this procedure. He stressed that the Commission has neither the capacity nor the competence to carry out a systematic and full review of individual Article 53 authorisations granted in specific geographical areas across the EU. However, he outlined that the Commission has recently taken action and requested an opinion from EFSA on derogations for substances used on major crops that it has identified as high-risk since 2012 and that were repeatedly granted over a long period of time, suggesting that it was unlikely to be an unforeseeable situation.

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<sup>41</sup> Protocol can be found at: <https://www.efsa.europa.eu/en/supporting/pub/1201e> (accessed in February 2018).

<sup>42</sup> EFSA, 24 November 2017, Ref. BU/JVT/at (2017)-out-18991892, available at: <http://registerofquestions.efsa.europa.eu/roqFrontend/questionsListLoader?panel=ALL> (accessed in February 2018).

<sup>43</sup> This research paper was completed before the EFSA technical reports were published.

## **7.1 Views of EU stakeholders on the role of the Commission and EFSA**

The EU stakeholders interviewed had differing views on the involvement of the Commission and EFSA in the monitoring and review of Article 53 authorisations.

The representative of EU PPP manufacturers felt that since authorisations of PPPs are the prerogative of Member States, the Commission and EFSA should have a limited role in the monitoring and review of Article 53 authorisations, as currently prescribed in this Article. Similarly, the representative of EU farmers believed the Commission and EFSA to be sufficiently involved in the monitoring and review of Article 53 authorisations.

By contrast, a representative of biocontrol solutions manufacturers and a representative of an environmental NGO both held the view that the Commission and EFSA have not sufficiently reviewed and monitored Article 53 authorisations granted by Member States.

The representative of an environmental NGO stated that the Commission had been inactive, despite its awareness of the misuse of Article 53 authorisations by Member States and their ongoing non-compliance with the requirements of this Article. The interviewee acknowledged the Commission's requested EFSA opinion on the emergency authorisations granted for three neonicotinoid active substances, but considers this to fall short of sufficient intervention.

## **8. Conclusion**

The number of Article 53 authorisations granted by Member States has increased significantly since 2007. These authorisations are mostly granted for PPPs containing approved substances. Around 9% of Article 53 authorisations were granted in 2017 for PPPs containing non-approved substances. There is a clear tendency in Member States to repeat Article 53 authorisations year after year. The review of the notifications suggests that a relatively small number of Article 53 authorisations are granted for emergency situations, e.g. in line with the original intention of Article 53. The majority of Article 53 authorisations are not related to special circumstances. Such authorisations can be explained, in part, by the lack of alternatives. Another area lacking alternatives is IPM and organic agriculture. Such findings tend to show that Article 53 authorisations are often used to fix more structural problems occurring in authorisation procedures of PPPs and extension of authorisations of PPPs for minor uses, such as delayed authorisation procedures, deficiencies in mutual recognition, or the lack of manufacturers' investment in preparing dossiers for minor uses. This suggests that the use of Article 53 is not aligned with its original purpose and it is, in fact, used contrary to some of the principles of the working document on emergency situations.

The three case studies concerning soil fumigants, neonicotinoids and insecticides for use in mass trapping show that some of the Article 53 authorisations are used to maintain the use of pesticides with proven significant environmental and human health impacts, because the crop system in which they are used has been built on the use of these pesticides

and would require economic adaptation if those chemicals were prohibited. They demonstrate that Article 53 authorisations do not always fulfil the principles of sustainability, precaution and substitution of the PPPR.

In all but one of the selected Member States, the Article 53 procedure is not detailed in law but, rather, in non-binding guidance documents that include the application forms and documents for applicants. Most involve authorities other than solely the CA and/or scientific bodies in the decision-making process. However, no public consultation is foreseen. A large share of the Article 53 authorisations granted in 2017 (38%) were requested by agricultural or forestry companies and associations, 31% were requested by PPP manufacturers or the seed industry, 23% were requested by authorities, and a small number by other types of applicants, such as agricultural and agronomy research institutes and consultants (6%) or producers of animal health products or feed (1%)<sup>44</sup>. Almost all of the selected Member States publish their decisions granting emergency authorisations on the CA website. However, they do not publish the applications and related evaluations. None of the selected Member States have specific strategies in place to limit the use of repeated Article 53 authorisations, nor are there any specific inspection strategies/programmes for such authorisations.

Notifications by Member States to other Member States and the Commission are not available to the public. There is no obligation for the Commission or Member States to publish the notifications. Some Member States do not notify all derogations or, where derogations are notified, this is not done 'immediately', as required under Article 53 of the PPPR. According to the assessment of the sample of notifications covering the year 2016 and 2017, several notifications were almost empty, with very limited information available. The Commission is trying to ensure that Member States adequately comply with this obligation through bilateral discussions or 'naming and shaming' at the Standing Committee meetings. With respect to the powers of the Commission, as of February 2018, since the entry into force of the PPPR the Commission had requested an opinion from EFSA only once, and has limited powers to trigger an infringement procedure in cases of misuse of Article 53 emergency authorisations.

Overall, the implementation of Article 53 is not adequate and there are several areas where improvements are needed in order to ensure that Article 53 authorisations comply with the PPPR requirements and its principles of sustainability, precaution and substitution, and to safeguard its use according to its original purpose, i.e. emergency circumstances.

## 9. Recommendations

These recommendations are based on information gathered throughout the compilation of this research paper and the main findings identified in the sections on the use of Article 53, the case studies on impacts of Article 53 authorisations, Member State procedures for granting emergency authorisation and informing other Member States and the Commission of the authorisation granted, and the Commission review of emergency authorisations and the role of EFSA.

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<sup>44</sup> 1% of the applicants could not be identified through the desk research.

*Article 53 procedures regulated by law*

For better legal certainty, security and more public visibility, the Article 53 procedure could be detailed in national law instead of being considered an internal administrative procedure in Member States.

*Content of the application form*

Member States should ensure that the application forms follow the updated template for notifications prepared by the Commission and the Commission working document guidance. The EFSA protocol for the evaluation of data concerning the necessity of the application of insecticide active substances to control a serious danger to plant health which cannot be contained by other available means, including non-chemical methods, could also be used by Member States to require information on the assessment of alternatives. Another possible option would be to adopt a binding Commission Regulation detailing the content of the application forms for Article 53 authorisations.

*Assessment of grounds from industry applicants*

When receiving applications from PPP producers for Article 53 authorisations, Member States should ensure that these applications have been prepared on behalf of farmers/users. If PPP producers cannot demonstrate that this application was carried out on behalf of farmers and users, it should be rejected.

*Coordination and consultation with other public authorities and scientific institutes*

Member States should ensure that there is a systematic consultation procedure for all Article 53 authorisations, where relevant public authorities (e.g. health and environment Ministries) and scientific bodies can provide their opinions. This consultation should not hinder the application of an emergency procedure.

*Information availability and third-party consultation*

Member States should ensure that the evaluation of applications includes a public/stakeholder consultation procedure, thus allowing third parties to provide comments on justifications and assessment of alternatives. This consultation procedure should be limited in time (two-three weeks) in order to respect the 'emergency' nature of the applications. Member States should also prepare a yearly report summarising how Article 53 of the PPPR was applied.

*Strategies in place to limit the use of (repeated) Article 53 authorisations*

Member States together with the Commission and EFSA should develop strategies to limit the use of (repeated) Article 53 authorisations, which could include, for example, targeted research programmes on alternatives to PPP repeatedly authorised under Article 53, or further enhancements to the development and implementation of IPM techniques.

*Enforcement and control at Member State level*

Member States should put in place specific inspection strategies/programmes for Article 53 authorisations, or at least prioritise inspections for such authorisations.

*Public awareness of the purpose and use of Article 53 authorisations*

Member States and the Commission should develop awareness campaigns and better communicate the purpose and use of Article 53 authorisations.

*Notifications by Member States to other Member States and the Commission*

To ensure greater transparency and allow the public a detailed overview of Article 53 authorisations granted across EU Member States, notifications to the Commission should be made publicly available and published on the Commission's website. The Commission should also prepare a yearly report based on information in the notifications, highlighting trends on the use of Article 53 in Member States and assessing the quality of the notifications prepared by Member States.

Member States should ensure that Article 53(1) notifications are sent 'immediately' to the Commission and other Member States via PPAMS, after the issue of Article 53 authorisation decisions. Member States should ensure that notifications are correctly filled in, with all sections completed.

*Involvement of the Commission and EFSA in the control of Article 53 authorisations*

The Commission should enhance its monitoring of Article 53 authorisations by regularly requesting opinions from EFSA on those Article 53 authorisations concerning PPPs containing non-approved active substances, at a minimum. Furthermore, the Commission capacity for comprehensive and regular review of the authorisation granted under Article 53 should be enhanced.

*Commission working document guidelines*

The 2013 Commission working document guidelines should be revised or amended following the EFSA opinion on the assessment of Article 53 authorisations concerning severely restricted PPPs containing three neonicotinoids substances, clothianidin, imidacloprid and/or thiamethoxam.

*Implementation of the authorisation procedure of PPPs*

Member States should, with the support of the Commission, assess and reform the ways in which they implement the authorisation procedures of PPPs in order to ensure that there is less administrative burden for applicants and authorities, deadlines are respected, less overlaps and more coordination between Member State authorities. Reforms leading to more efficient authorisation procedures should limit the use of Article 53 authorisations for PPPs subject to pending and delayed authorisations in Member States.

## Part 2: Desk research and stakeholder consultation on the implementation of Regulation (EC) 1107/2009

### 1. Desk research

#### Key findings

- **Control and enforcement measures to tackle illegal and counterfeit PPPs**

Several of the documents reviewed highlighted that Member States must improve their control and enforcement measures to tackle illegal and counterfeit pesticides that have significantly increased in recent years.

- **Implementation of Article 53 derogations**

Several of the documents found that Member States are not properly implementing Article 53 derogations and raised concerns that this derogation operates as a loophole in the legislation to circumvent bans or restrictions on the use of PPPs at the national level.

- **Governance aspects of authorisations at Member State level**

Several of the documents stressed that Member States struggle to implement the authorisation procedure of PPP and that significant improvements are needed in certain areas to ensure adequate implementation of this procedure.

- **Transparency and risk communication**

One document highlighted a lack of transparency in the regulatory (PAFF) Committee procedure for the adoption/rejection of active substances. It stated that there are deficiencies in risk communication after decisions are adopted. According to another reviewed document, although EFSA contributes to the transparency of pesticide authorisation by releasing conclusions on peer review of risk assessment for each approved active substance, these documents are almost incomprehensible for non-experts yet contain insufficient detail for researchers. In response, the Commission, in its reply to a European Citizens' Initiative to ban glyphosate, provided some potential actions to improve transparency and risk communication which led in April 2018 to the adoption of a Regulation proposal on the transparency and sustainability of the EU risk assessment in the food chain, amending, inter alia, the PPPR.

- **Concerns related to the assessment of hazards and risks of active substances and PPPs**

Several of the documents reviewed highlighted the need to enhance the hazard and risk assessment of active substances and PPPs to ensure adequate health and environmental protection, while others, by contrast, stressed that the PPPR

assessment process should be less stringent and should focus on risk rather than intrinsic hazard properties.

Some documents pointed to the difficulties encountered by EU and national CAs in achieving and maintaining independence in the assessment of hazard and risks from active substances and PPPs, given their reliance on studies commissioned by industry applicants. One document pointed out the involvement of industry-linked experts in the development of scientific evaluation methods. Another, based on a case study on the ban of neonicotinoid, assumed that the Commission has some influence over EFSA's scientific conclusions. In response, the Commission, in its reply to a European Citizens' Initiative to ban glyphosate, provided related justifications and highlighted some potential actions to strengthen governance for the conduct of scientific studies.

One document, based on the EFSA/ECHA and IARC opinion on glyphosate, stressed the difficult trade-off between regulatory science and research science, and between the need for standard testing criteria to be shared as widely as possible and the need for research designs that are innovative and promising. It also pointed to the difficult trade-off between testing done in laboratory conditions and testing done in realistic conditions.

Finally, one document held that there is an on-going 'paradigm war' between toxicologists and endocrinologists for the definition of Endocrine Disruptors Criteria, thus affecting the implementation of the EDC cut-off criteria under the PPPR.

- **IPM and low-risk PPPs**

Two documents highlighted the limited application of IPM in Member States, pointing to the room for improvement in this domain. They also stressed that there is a limited use of low-risk PPPs in Member States and provided some explanations for such limited use.

The PPPR entered into force in June 2011. In comparison to the previous legislation on PPPs<sup>45</sup>, it introduced, among others, new provisions on the categorisation of active substances at EU level with certain properties (e.g. basic substances with unlimited time approvals, low-risk substances, candidates for substitution, substances that meet cut-off criteria). The PPPR provisions are implemented by the Member States (e.g. comprehensive hazard identification of active substances, authorisations of PPP at national level, enforcement measures), the Commission (e.g. audits in Member States) and EFSA (e.g. peer review of Member States' hazard identification of active substances). There is considerable literature on the implementation of the PPPR, and the research team therefore selected a number of documents based on a set of criteria:

- Scope of the documents, covering core aspects of the implementation of the PPPR (e.g. approval of active substances, authorisations of PPPs, enforcement, role of implementing actors).
- Documents produced or commissioned by main actors involved in the implementation of the PPPR (i.e. Member States, the Commission, EFSA).

<sup>45</sup> Directive 91/414/EEC concerning the placing of plant protection products on the market.

- Documents on implementation of PPPR produced by academic research.
- Documents from stakeholders concerned by the implementation of the PPPR<sup>46</sup>.
- Relatively recent documents covering the period of implementation of PPPR (2011-January 2018).
- Documents written in English.

For each document, the research team provided a summary of the main implementation issues identified by completing Excel templates for each document and then preparing an overview of the main implementation issues.

This desk research focuses solely on the implementation of PPPR and covers scientific controversies only in respect of this aspect. The PPPR is a rather new EU regulation and there are very limited academic sources on this specific field, thus the desk research primarily relied on documents produced or commissioned by actors involved in its implementation (e.g. Member States /Commission/EFSA) or by stakeholders interested in the fulfilment of the objectives of this Regulation. Given the scope and timeframe of the project, the desk research could not analyse the methodology and sources used to produce these documents in any detail. It is not, therefore, a proper literature review but, rather, serves to flag potential PPPR implementation issues and to provide a source of information for the EPRS analysis.

## **1.1 Selected documents reviewed during desk research**

The following section provides a brief description of the scope and purpose of the selected documents used for the desk research on the implementation of the PPPR, classified by the main authors. The results of the stakeholder survey on the implementation of PPPR completed as part of this research paper (see Part 2) is also summarised here, with cross-references to the relevant sub-sections of this survey.

### **1.1.1 Reports published by the Commission**

Although the Commission, as of February 2018, has not yet issued a comprehensive evaluation of the implementation of the PPPR<sup>47</sup>, it has developed several reports that provide detailed information on the implementation of the PPPR and related concerns and issues.

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<sup>46</sup>These documents were selected, inter alia, because they were produced or commissioned by stakeholder associations that have interest in the fulfilment of the objectives of the PPPR (high level of protection of both human and animal health and the environment, improvement of the functioning of the internal market, improvement of agricultural production) and/or because of their involvement as legal dutyholders under the PPPR. Note that stakeholders defend their vested interest in the documents they produce.

<sup>47</sup> On November 2016, the Commission published a roadmap on the Refit Evaluation of the EU legislation on PPPs and pesticide residue. As of February 2018, several consultations and surveys have been completed (e.g. public consultation and an online survey of stakeholders), according to the DG SANTE website. The Commission reply to the European Citizens' Initiative 'Ban glyphosate and protect people and the environment from toxic pesticides' stated that the outcome of the REFIT evaluation will be presented in a report to the European Parliament and to the Council in early 2019.

- *Overview report on a series of audits carried out in EU Member States in 2016 and 2017 to evaluate the systems in place for the authorisation of plant protection products (European Commission 2017c)*

This 2017 report provides an overview of the result of audits carried out in seven Member States (Germany, the UK, Luxembourg, Portugal, France, Lithuania and Spain). The report explains that the objectives of the audit series were to assess the systems in place for authorisation of PPPs laid down in the PPPR to improve cooperation and coordination among the CAs evaluating applications for authorisation of PPPs, to provide information to EU policy-makers regarding the implementation of the PPPR, and to share good practice among Member States. The scope of the audits did not include quality aspects of the evaluations of the individual applications for authorisation of PPPs performed by Member States.

- *Overview report on a series of audits carried out in EU Member States in 2015 and 2016 to evaluate the control systems in place for the marketing and use of plant protection products (European Commission 2017d)*

This 2017 report provides an overview of audits carried out by DG SANTE in 11 Member States (Austria, Belgium, France, Greece, Croatia, the Netherlands, the Czech Republic, the UK, Luxemburg and Portugal) in 2015 and 2016 to assess the control systems in place for the marketing and use of PPPs under the PPPR and some elements of Directive 2009/128/EC on the sustainable use of pesticides, and the actions taken to address recommendations arising from previous audits on PPPs. These audits examined (in greater detail) some of the weaknesses in control systems that were highlighted in the previous audit series conducted during 2012-2014.

- *Commission Report on the establishment of a European fund for minor uses in the field of plant protection products (European Commission 2014)*

This Commission Report was published in 2014, with the objective (as outlined under its Section 1.2) of providing information on minor uses as reported by Member States and stakeholder organisations, presenting the strategy offered in Regulation (EC) No 1107/2009 on minor uses and the options for action considered in the preliminary study funded by the Commission, and informing the European Parliament and the Council about the Commission's conclusions on a possible legislative proposal for the establishment of a European minor uses fund.

- *Commission Report on Member State National Actions Plans and on progress in the implementation of Directive 2009/128/EC on the sustainable use of pesticides (European Commission, 2017e)*

The objective of this 2017 report was to assess the National Action Plans adopted by Member States, which must contain quantitative objectives, targets, measurements and timetables to reduce the risks and impacts of pesticide use and to assess progress in the implementation of Directive 2009/128/EC on the sustainable use of pesticides. This report fulfils the reporting obligations under Article 4(3) and Article 16 of the Directive.

- *Communication from the Commission on the European Citizens' Initiative 'Ban glyphosate and protect people and the environment from toxic pesticides' December 2017 (European Commission, 2017f)*

In December 2017, the European Commission published a Communication replying to the European Citizens' Initiative '*Ban glyphosate and protect people and the environment from toxic pesticides*' that met the requirements set out on Regulation (EU) No 211/2011 on the Citizens' Initiative, having received a total of 1,070,865 statements of support from 22 Member States as of 6 October 2017. This initiative calls on the Commission and Member States to:

- Ban glyphosate-based herbicides, exposure to which has been linked to cancer in humans and has led to ecosystems degradation.
- Ensure that the scientific evaluation of pesticides for EU regulatory approval is based only on published studies, which are commissioned by competent public authorities instead of the pesticide industry.
- Set EU-wide mandatory reduction targets for pesticide use, with a view to achieving a pesticide-free future.

The Commission Communication first provides the current state of play on the rules and procedures for placing PPPs on the market in the EU. The second section then analyses the requests of the European Citizen's Initiative and provides related responses, including future Commission actions.

### **1.1.2 Studies commissioned by the Commission**

- *Ad-hoc study on the trade of illegal and counterfeit pesticides in the EU (Agra CEAS Consulting, Arcadia International 2015)*

The Commission requested the contractor to identify patterns of trade of illegal and counterfeit pesticides within the EU and entering the EU, and assess the existing regulatory framework in the EU. Information was gathered for this study via a literature review, exploratory semi-structured personal interviews with experts and Commission staff, consultation with two networks of experts, a survey of EU-28 CAs, two surveys of the PPP industry, a survey of the OECD network on illegal trade of pesticides, and six port-specific case studies (Antwerp, Genoa, Greece (national level), Hamburg, Le Havre and Rotterdam).

- *Study on the regulatory fitness of the legislative framework governing the risk management of chemicals (excluding REACH), in particular the CLP Regulation and related legislation (RPA<sup>48</sup> 2017)*

As outlined in its executive summary, this RPA-led study aimed to support the fitness check on chemicals legislation, with its objective being to evaluate the CLP Regulation and its interlinkages with other related chemicals legislation, including legislation governing hazard identification and communication, and legislation establishing risk management measures linked to the CLP, such as the PPPR. The evaluation was based on five criteria (effectiveness, efficiency, coherence, relevance and EU added value), as required by the Commission's Better Regulation guidelines.

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<sup>48</sup> Risk Policy Analysis.

### 1.1.3 EFSA reports

- *Scientific Opinion addressing the state of the science on risk assessment of plant protection products for non-target arthropods (EFSA, 2015)*

The abstract states that this scientific opinion from the Panel on Plant Protection Products and their Residues was developed following a request from EFSA. It includes a review of the science to support the development of a risk assessment scheme of PPPs for non-target arthropods. The current risk assessment scheme was reviewed, taking into consideration recent workshops and scientific progress. Proposals were made for specific protection goals aiming to protect important ecosystem services, such as food web support, pest control and biodiversity.

### 1.1.4 Publications of the European Parliamentary Research Service (EPRS)

- *EU policy and legislation on pesticides (EPRS, 2017)*

This is an in-depth analysis of EU policy and legislation on pesticides, prepared in 2017 by the EPRS. It describes the policy context leading to the adoption of the EU legislation in this area, presents the impacts of these products, and reports on the debate surrounding this issue. It provides a summary of the EU legislation on PPPs and biocidal products, with a focus on the approval process for active substances and product authorisation. It stresses potential opportunities and challenges associated with the legal framework and reflects the views of the different stakeholders and the European Parliament. Finally, it describes the measures that the European Commission is expected to adopt in the near future.

### 1.1.5 Reports/studies commissioned by Member States

- *Simplification of the EU pesticides regulatory regime, biointelligence, 2012 (Bio Intelligence Service, 2012)*

The objectives of this study, commissioned by DEFRA<sup>49</sup> and carried out by biointelligence, were to review different aspects of the PPPR in order to identify options for its simplification in line with the UK government's Better Regulation Strategy, and to evaluate the costs and benefits of selected simplification options. The results of this study were meant to support DEFRA in its contribution to the future review of the PPPR.

- *European Union (EU) policy on pesticides: implications for agriculture in Ireland (Jess, 2014)*

This report assesses the impacts of the implementation of EU policy and the PPPR in Northern Ireland and the Republic of Ireland. It was funded by the Department of Agriculture and Rural Development of Northern Ireland.

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<sup>49</sup> Department for Environment Food and Rural Affairs.

### 1.1.6 Reports prepared or commissioned by stakeholders with vested interests in the implementation of the PPPR

- *European Beekeeping Coordination, Bee Emergency Call, 2017 (PAN Europe, 2017)*

This report was published in 2017. It was prepared by three NGOs, Beelife, ClientEarth and PAN Europe. It analyses the use of Article 53 derogations under the PPPR and proposes recommendations to the Member States and the Commission to ensure that such derogations are adequately used and cannot circumvent the prohibitions and restrictions of use on active substances under the PPPR.

- *Greenpeace, the EU pesticides blacklist 2016 (Greenpeace, 2016)*

This report was published in 2016. It sets out a scoring system to evaluate the risk of all active substances approved for use under the PPPR (i.e. 520 substances). The aim of the report is to identify the most dangerous of the many active substances used in PPP and to call for their replacement as a matter of priority.

- *Global 2000, glyphosate and cancer: Authorities systematically breach regulations (Global 2000, 2017)*

This report, published by Global 2000, Friends of the Earth Austria and supported by several environmental NGOs, looks at the scientific and regulatory framework for assessing carcinogenicity. It then applies this framework to the available data to make an assessment consistent with the legislation. Finally, it presents a critique of the assessment by the authorities and their arguments used to dismiss glyphosate as a carcinogen.

- *PAN Europe and generation futures, industry writing its own rules, January 2018 report (PAN Europe, Generation Futures, 2018)*

This recent report by PAN Europe aims to present the extent of industry advocacy when implementing EU laws, by taking a sample of risk assessment methodologies that lower protection for EU citizens, animals, the environment and its ecosystems. The analysis is based on a selection of risk assessment methodologies (criteria) from the opinions produced by EFSA that are in actual use, focusing on those that question the adverse effects found in pesticide experimental safety testing (alleged 'false positives') and those that tend to lower the level of protection of humans and the environment (alleged 'unrealistic' high level of protection). This report was heavily criticised by an EFSA representative, who considered it to include 'repurposed, unsubstantiated allegations that it had rebutted on numerous occasions'<sup>50</sup>.

- *Banning neonicotinoids in the European Union, an ex-post assessment of economic and environmental costs, HFFA Research GmbH, commissioned by Bayer and Syngenta (HFFA Research GmbH, 2017)*

This study carried out an impact assessment of the economic and environmental costs resulting from the 2013 Commission ban on the use of three neonicotinoids, namely clothianidin, imidacloprid and thiamethoxam. This research aimed to provide a condensed, science-driven and expert-triggered judgement on various economic and

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<sup>50</sup> See article 'EU Pesticides tests 'biased and manipulated'', Niel Roberts, 9 February 2018.

environmental effects of the ban on neonicotinoids in EU agriculture, with a specific focus on oilseed rape<sup>51</sup>.

- *Cumulative impact of hazard-based legislation on crop protection products in Europe, Steward Redqueen, commissioned by European Crop Protection, 2016 (Steward Redqueen, 2016)*

The objective of this study was to determine the economic and environmental effects of the hazard-based regulation for crop protection products in Europe, with the aim of using these findings to proactively inform stakeholders and to enter into fruitful debates based on factual arguments. This study focuses on 75 active substances used in PPPs and regulated in the Water Framework Directive that may be removed as a result of the application of these two pieces of legislation.

### 1.1.7 Academic/research reports

- *Pesticide policy and politics in the European Union. Regulatory assessment, implementation and enforcement, (Bozzini, 2017)*

This book covers various aspects of the EU pesticide policy and its implementation. The first chapter includes a short introduction to the relevant technological developments and describes the importance of agrochemicals for contemporary farming. It also traces developments in toxicology and shows that pesticides have become the subject of numerous tests and controls. It then introduces regulatory issues by highlighting the most important global treaties. Finally, the chapter shows the stringency of EU provisions for authorisation of pesticides and tolerance of residue on food in comparison to other jurisdictions, paying specific attention to the US. The second chapter analyses EU pesticide regulation and its related principles and procedures. The third chapter describes the policy processes that led to the adoption of EU pesticide regulations, focusing specifically on the procedure for the approval of active substances, as provided by the PPPR. The fourth chapter focuses on three issues that proved particularly controversial in the last 10 years and required sustained debates among policy-makers, scientists and activists, i.e. the precautionary ban of neonicotinoids for their adverse effects on pollinators, the debate over the renewal of the approval of glyphosate, and the definition of criteria for the assessment of endocrine disrupting properties of active substances used in PPPs<sup>52</sup>. Finally, chapter five sheds light on developments during the early years of enforcement, assessing the problematic transition towards the new system and evaluating how the new criteria for approval have been translated into practice.

- *Comparative assessment of plant protection products: how many cases will regulatory authorities have to answer? Environmental Sciences Europe 2014 (Faust, 2014)*

This study investigated the resulting workload in terms of the number of cases for comparative assessments that regulatory authorities may have to face because of the

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<sup>51</sup> It is mentioned in this report that the European Crop Protection Association, the European Seed Association, the European Farmers and European Agri-Cooperatives support this new scientific evidence.

<sup>52</sup> The definition of criteria for the assessment of endocrine disrupting properties of active substances cover both active substances in PPPs and in biocidal products.

inclusion of the substitution principle in the PPPR. Germany was used as a sample case study for the analysis.

- *The development, regulation and use of biopesticides for integrated pest management, Royal Society, 2011 (Chandler et al., 2011)*

This report discusses the challenges and opportunities for IPM in developed economies, with emphasis on the EU. It focuses on a set of crop protection tools known as biopesticides. This report endeavours to understand the factors that hinder or facilitate the commercialisation and use of new biopesticide products.

- *Regulation of pesticides: A comparative analysis (Pelaez et al., 2013)*

This paper compares three internationally representative regulatory frameworks for pesticides, the US, Brazil and the EU, identifying similarities and differences between these frameworks.

- *Explaining differences in scientific expertise use: the politics of pesticides (Rimkutė, 2015)*

This article, based on a case study assessing how EFSA, on foot of a Commission mandate, conducted an independent scientific evaluation on neonicotinoid pesticides, demonstrates that the interaction between high external pressure and high internal capacity to respond to this pressure leads to the strategic substantiating use of expertise, in which scientific evidence is used to promote the inclinations of actors upon which the agency depends most<sup>53</sup>.

- *Toward a better pesticide policy for the European Union, Science of the Total Environment (Storck et al., 2017)*

This opinion article aims to foster the debate about EU PPPs. It provides detailed insights into the pros and cons of PPPs, and points out weaknesses in the current pesticide environmental risk assessment procedures. Possibilities for improving the robustness and reliability of the pesticide regulatory framework are also discussed.

## 1.2 Main findings of the desk research

This section focuses on six main issues relating to the implementation of the Regulation on placing of PPP on the market that were identified through the desk research:

- Control and enforcement measures in place in Member States to tackle illegal and counterfeit PPPs.
- Use of Article 53 authorisations by Member States.
- Governance aspects of authorisations at Member State level.
- Transparency of the regulatory process and the communication by CAs on risk.
- Assessment of hazards and risks of PPPs.

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<sup>53</sup> In February 2018, EFSA (at the Commission's request to perform an updated risk assessment on the risks to bees from the use of the three neonicotinoid pesticides active substances, clothianidin, imidacloprid and thiamethoxam, applied as seed treatments and granules) published an updated opinion, which considers most uses of neonicotinoid pesticides to represent a risk to wild bees and honeybees, <http://www.efsa.europa.eu/en/press/news/180228> (accessed in February 2018).

- Use of IPM and low-risk PPPs.

Other implementation issues were identified during the desk research and these were also included in the respective review tables<sup>54</sup>.

### **1.2.1 Inadequate control and enforcement measures on illegal PPPs**

Enforcement under the PPPR involves the control of whether or not the PPPs used are illegal, and whether or not the PPPs authorised are used according to the conditions of use set out in their authorisations. The desk research identified some concerns with regard to the control and enforcement measures on illegal PPPs.

According to the Commission's audit report on control systems, PPPs can be illegal for many reasons:

- Marketing and use of PPPs containing active substances not approved in the EU.
- Marketing and use of PPPs that are not authorised or marketed under a parallel trade permit.
- PPPs that do not comply with the detailed conditions of their authorisation or parallel trade permits.
- The use of PPP in one Member State can be illegal in a neighbouring Member State, where it may not be authorised.

According to a 2105 study on illegal pesticides, there two categories of illegal PPPs:

- Substandard PPPs: products which contain substances not approved under EU legislation (or which contain no active substances) and falsified PPPs (e.g. falsified content, falsified country of origin, products not authorised in the EU).
- Counterfeit PPPs: illegal copies of legitimate, branded products. These may be difficult to distinguish from legal products due to high quality branding and packaging. This category includes trademark and patent counterfeit PPPs (Agra CEAS Consulting, Arcadia International, 2015).

The following concerns relating to the control and enforcement measures to tackle illegal PPPs were raised in the documents reviewed.

- *Increase of illegal pesticides placed on the market and rationale*

The placing on the market of illegal pesticides first occurred in the early 2000s, and gained momentum from 2006 to 2008. Imported counterfeits come mainly from China, enter the EU via the major ports in north-western Europe and then transit to their destination, contravening the parallel trading system in the process. Lower costs and the desire to continue using products that are no longer authorised may explain why users knowingly buy counterfeit products (EPRS, 2017).

- *No records, or limited records, of PPPs on the market in some Member States*

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<sup>54</sup> The review tables could be submitted upon request.

In some Member States, tracing and keeping records of PPPs once they are on the market is considered almost impossible (Agra CEAS Consulting, Arcadia International, 2015).

- *Lack of coordination between CAs in Member States*

Coordination and cooperation between the CAs responsible for controls on the marketing of PPPs, together with customs (the CA for control of imports) was often not effective, to the extent of being virtually non-existent in some cases (European Commission, 2017d).

- *Lack of resources to carry out effective controls*

In many cases, the resources available within CAs appeared to be a significant factor in constraining the effectiveness of controls (Agra CEAS Consulting, Arcadia International, 2015).

- *Different interpretations of some definitions under the PPPR among Member States*

The interpretation of the definition of PPPs enshrined in Article 2 par. 1 of the PPPR ('products in the form in which they are supplied to user') is interpreted by some Member States as excluding, for example, PPPs contained in bulk, or active substances as such. Provisions concerning goods in transit through a Member State but destined for another Member State or a non-EU country are equally subject to different interpretations, which ultimately results in diverging national enforcement practices. Such a loophole is exploited by unscrupulous operators (2015 study on illegal pesticides). Similarly, some Member States do not control PPPs without their final label (European Commission, 2017d).

- *Lack of EU centralised database for PPPs authorised at national level and EU reference laboratory for product composition*

The absence of an EU centralised database gathering all national PPPs authorisations - similarly to that currently in place for active substances - is the most pressing legislative gap that needs to be addressed. The establishment of an EU reference laboratory for product composition is another step that could be taken with a view to ensuring a level playing field across the EU (European Commission, 2017d).

- *Insufficient level of harmonisation and EU coordination in official controls*

Type, place and frequency of official controls on PPPs intended for import into the EU appear to vary significantly between Member States, ranging from the existence of well-structured and risk-based import control policies in certain national contexts to a minimum level of control in others (2015 study on illegal pesticides). All Member States (audited by the Commission) planned and implemented control programmes independently, despite the highly integrated nature of the EU PPP industry. There is no EU-wide coordinated control programme. The establishment of such a programme, particularly in the context of controls on importers, manufacturers and re-packers, could help to provide clear direction to Member States in this area (European Commission, 2017d). In the PPPR survey, all respondents stressed that cooperation among enforcement authorities between Member States should be improved (see 'effectiveness' section).

- *Need for greater leadership from the Commission on international cooperation against illegal pesticides*

There is room for greater leadership from the European Commission on international cooperation. It could play a key role in establishing a dialogue with the non-EU countries from which illegal PPPs originate, with a view to identifying CAs in those countries and, where possible, agreeing shared solutions to address illegal trade (Agra CEAS Consulting, Arcadia International, 2015).

- *Discrepancies in the quality of information on registered and revoked PPPs*

The quality of information on websites (and the functionality of those websites) on registered and revoked PPPs varies widely, with inaccurate or incomplete information in some cases (European Commission, 2017d).

- *Failure to provide inspectors with live electronic access to information on registered and revoked PPPs*

The failure to provide staff involved in controls with live, electronic access to detailed data on registered and revoked PPPs, while not explicitly required in legislation, limits the efficiency and effectiveness of controls in almost all of the Member States audited. The precise formulation details of PPPs are commercially sensitive and are treated as confidential by CAs. Nevertheless, without access to this information, inspectors cannot conduct some types of controls, such as checking manufacturers to ensure that the products manufactured comply with their defined formulation as per their conditions of authorisation (European Commission, 2017d).

- *Insufficient systems in place to identify and prioritise controls*

The system for the identification of risks and prioritisation of controls was not sufficient in most of the Member States audited. Consequently, the frequency of controls on some types of high-risk operators (e.g. manufacturers, importers and re-packers) was not sufficient, given the scale and inherent risks associated with these operators (European Commission, 2017d).

- *Lack of control to verify that PPPs were manufactured using approved active substances*

Most of the Member States audits had no controls to verify that PPPs were manufactured using active substance(s) from the approved source(s) and with the correct quantity of the other specified ingredients, as defined in the authorisation. Inspections of manufacturers were generally confined to label checks of the finished product, storage conditions and health and safety related issues (European Commission, 2017d).

- *Risk of importing of illegal PPPs not considered in large Member States and Ports*

There were large ports, and indeed large audited Member States, where the risks associated with the importing of PPPs had not been considered when prioritising controls, resulting in an absence of risk-based controls on PPP imports in these Member States and ports (European Commission, 2017d). Under the PPPR survey, two respondents (individual, NGO) indicated that there should be more control of imports because, compared to the strictness of requirements for authorised PPPs, controls on parallel imports are lax and almost non-existent. Under the PPPR survey, one NGO specified that there are not enough controls on residues in imported products (see 'effectiveness' section).

- *Risk associated with large central distribution points is hardly considered*

Most of the Member States audited had not recognised the importance of, or the risks associated with, large central distribution points in the PPP distribution system in their control programmes, and therefore did not conduct sufficient controls at this category of operator (European Commission, 2017d)

- *Non-compliance with the obligation to conduct controls on PPPs for other Member States and for non-EU countries*

Almost all of the Member States audited failed to comply with the obligation to conduct controls on PPPs destined for other Member States and for non-EU countries (European Commission, 2017d)

- *Inadequate sampling and scope of analysis*

In all of the Member States audited, the intensity of sampling and scope of analysis was considered insufficient to ensure that the PPPs placed on the market complied fully with the conditions of their authorisation. Audited Member States analysed samples for the level of active substance and some physical chemical properties, with some conducting more sophisticated analysis. Many illegal PPPs in the EU, however, require sophisticated detection techniques (European Commission, 2017d). Similarly, one CA respondent to the PPPR survey recommended more frequent analysis of PPPs to grasp the scope of illegal trade of PPPs, as well as more communication between competent authorities and end-users (See 'effectiveness' section).

- *Deficiencies in parallel trade leading to the introduction of illegal pesticides*

In the PPPR survey, two respondents (manufacturers' association and CA) mentioned that the rules governing parallel trade should be improved. One of the respondent stated that the current rules allow too many options for misuse and abuse and create opportunities for the introduction of illegal pesticides (see 'effectiveness' section).

In the PPPR survey, respondents provided some general comments on the enforcement of the PPPR by Member States, with all respondents stressing that cooperation among enforcement authorities within Member States should be improved (see 'effectiveness' section).

## 1.2.2 Implementation of Article 53 derogations

Some reports consider Member States to be improperly implementing Article 53 derogations, raising concerns that this derogation has become a loophole to circumvent the ban or restriction on the use of PPPs at national level<sup>55</sup>.

- *Increase of the use of Article 53 derogations*

There is a clear increase in the use of emergency authorisations since 2007. This upward trend in the number of emergency authorisations can be attributed to delays in regular authorisations, and affects the fulfilment of the health protection objective of the PPPR (European Commission, 2017d).

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<sup>55</sup> For further information on Article 53 authorisation, see Part 1 of this research paper.

- *High number of repeated Article 53 derogations*

Some Member States showed a high number of repeated emergency authorisations, which they claimed was due to the absence of effective and economically viable alternatives for controlling pests. In some cases, repeated applications involved PPPs awaiting a final decision for regular authorisation. This might indicate that there are weaknesses in the authorisation of PPPs which make it difficult to achieve longer term solutions to plant health problems (European Commission, 2017c).

- *Concerns that Member States do not fulfil Article 53 PPPR requirements*

A considerable number of emergency PPP authorisations do not meet Article 53 criteria (authorised for a period of 120 days to contend with a 'danger which cannot be contained by any other reasonable means'). They do not provide information on the nature or impact of the 'danger', or the 'other reasonable means' that could be used and are thus granted by Member States without sufficient justification. Frequent shortcomings include omitting evidence of the threat, failure to list any alternative means of pest control, and failure to provide information to prove 'limited and controlled' use (PAN Europe, 2017).

- *Large share of Article 53 derogations based on PPP producers' applications*

Emergency authorisations are intended to be used by farmers or public authorities in the public interest, but a large share of the applications for Article 53 authorisation comes from plant protection producers – 86% of emergency authorisation applications between 2013 and 2016 were made by PPP producers<sup>56</sup> (PAN Europe, 2017).

- *Lack of involvement of the Commission in the monitoring of Article 53 derogations*

Although there are tools available to the Commission to challenge non-compliant Article 53 derogations from Member States, the Commission had not made use of them (at least) concerning bee-harming pesticides (PAN Europe, 2017)<sup>57</sup>.

- *Lack of transparency and public scrutiny*

As Member States and the Commission do not publish the notifications of derogations, they could not be subject to public scrutiny<sup>58</sup>. The lack of transparency poses an obstacle to the opportunity to challenge unjustified derogations (PAN Europe, 2017).

- *Inappropriate use of Article 53 authorisations impeding the development of alternatives*

In the PPPR survey, the association representing the biocontrol industry stated its belief that the inappropriate use of emergency authorisations does not provide sufficient incentives for farmers to find alternative solutions, as they can prolong the use of prohibited products. This prevents alternatives from accessing the market and destroys innovation in Europe (see 'effectiveness' section).

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<sup>56</sup> See detailed findings in Section 1.5 on Article 53 authorisations. There are discrepancies with the findings here on the share of applicants from PPP producers.

<sup>57</sup> Since the publication of this report, the Commission has requested EFSA to provide an opinion on Article 53 authorisations granted in seven countries concerning PPPs containing three neonicotinoids active substances.

<sup>58</sup> See detailed findings in Section 1.5 on Article 53 authorisations.

### 1.2.3 Governance aspects of authorisations at Member State level

Several reports stress that Member States are struggling to implement the authorisation procedure for PPPs, and that significant improvements are needed in certain areas to ensure adequate implementation of the procedure.

- *Lack of resources to properly grant authorisations*

Four of the Member States audited identified the lack of resources as a constraint on delivering the work on time, chiefly due to restrictions on public service recruitment. These restrictions occurred even though Member States may apply fees and charges to recover costs associated with authorisation of PPPs (European Commission, 2017c).

- *Deficiencies in long-term planning*

Deficiencies in long-term planning were identified, meaning that the systems in place were not sufficient to ensure that applications were, or would be, processed within legal deadlines. With respect to the authorisation system, the administrative factors contributing to delays include the lack of a reliable tracking system for ongoing applications, and the lack of key performance indicators to manage the actual capacity of the existing resources to deliver the work. Other administrative factors were also identified, such as inefficient processes relating to purely administrative tasks, and delays in taking risk management decisions (European Commission, 2017c).

- *Difficulties in using work done by other Member States*

One important aspect relating to the overall management of the authorisation system is the difficulty faced by Member States in using the work done by others, as provided for in the current legal framework for authorisation of PPPs. Where work-sharing systems are implemented effectively, the workload of repeated evaluations could decrease significantly, releasing resources and allowing Member States to ensure a fair division of the workload. Huge duplication of work was observed in the audited Member States. In most cases, the main impediments to relying on the work of others were the lack of use of harmonised methodologies and models to conduct the evaluations, or the existence of additional national requirements to address conditions particular to the Member State concerned. This lack of harmonisation makes Member States reluctant to accept the evaluation outcomes of others that were obtained using different methodologies and models (European Commission, 2017c).

In the PPPR survey, several manufacturers' associations highlighted the lack of trust among CAs as a key issue in the non-application of the mutual recognition principle, as national evaluators tend to re-evaluate dossiers which were already evaluated by the zonal Rapporteur Member State. Consequently, timelines cannot be respected and the administrative burden is higher for CAs than it should be (see 'knowledge base' section).

- *Incomplete information in electronic registers*

In several of the Member States audited, the information in the electronic register was incomplete, in particular for emergency authorisations of PPPs. In 40% of these Member States, the electronic register lacked specific mandatory information related to PPPs (e.g.

information on emergency authorisations, toxicity product classification, or the full Good Agricultural Practices (GAP)) (European Commission, 2017c).

- *Imbalance in the number of applications between some Member States in the same zone*

There is an imbalance in the number of applications between some Member States in the same zone and of similar size and agricultural conditions (e.g. France is responsible for 15 times more applications than Spain). This imbalance in the pattern of applications, together with the difficulties for Member States to cooperate and share the work, undermine the aim of the Regulation to ensure a fair division of workload (European Commission, 2017c).

- *Non-compliance with deadlines during the authorisation*

Deadlines for the processing of applications are not respected by the Member States audited, with the number of decisions very low compared to the number of applications. Significant delays were also commonplace for the re-registration of PPPs. Moreover, these Member States have difficulties in meeting deadlines within the context of the authorisation by mutual recognition. For example, some re-evaluate applications for mutual recognition of authorisations, either fully or partially, to satisfy specific national requirements or their own evaluation criteria. In most cases, the outcome of the evaluation is either the same or very similar to the original authorisation, but the authorisation has been delayed beyond the deadline (European Commission, 2017c).

In the PPPR survey, several respondents (manufacturers' associations, farmers' associations, individual manufacturers, and CAs) stressed that deadlines in processing applications for authorisation of PPPs remain a major concern. They also flagged non-respect of deadlines in the renewal of authorisations of PPPs (see 'effectiveness' section).

- *Member States grant authorisation only when suitable for the entire territory of the country despite different climate conditions*

All of the Member States audited grant authorisations when the PPP is suitable for the entire country, i.e. PPPs must satisfy all models for all different scenarios if they are to be authorised. Thus, a product which might be accepted for use on a specific crop in the dry climate conditions of a region could not be authorised because the evaluations show a negative impact in the wetter regions of the same Member State (European Commission, 2017c).

- *Inadequate cooperation in the re-registration of PPPs*

In relation to re-registration of PPPs, Member States also experience difficulties in cooperating to achieve fair distribution of work. The portfolio of authorised PPPs is very similar between Member States with the same climatic and agricultural conditions. However, there were difficulties in achieving a balanced share of the work (European Commission, 2017c).

- *Differences in how Member States evaluate applications for authorisations of 'generic' products*

The audit series revealed differences in Member States' evaluation of applications for authorisation of PPPs equivalent to existing authorised PPPs, resulting in significant variation in the number of generic PPPs on the market (European Commission, 2017c).

- *Member States' difficulties in dealing with comparative assessments*

Due to the high number of cases to be evaluated (because of the application of the substitution requirements under the PPPR), the new task of comparative assessments of PPPs may pose a formidable challenge to CAs. Existing organisational arrangements are only designed for checking compliance of individual PPPs with legal acceptability criteria and were not developed for comparing products to one another. New data handling systems, assessment procedures and decision rules may be required to cope with the high number of cases expected. In Germany, regulatory risk assessment reports for individual PPPs currently exist in the form of text files only, and the same may well be true of most other Member States. To perform a comparative assessment, all of the relevant risk indicators must therefore be compiled manually from the individual assessment reports (Faust, 2014).

- *Lack of consistency of assessment processes*

According to the stakeholders consulted, a major issue is the lack of consistency among assessment processes conducted by Member States, which generates uncertainty for the industry. It remains common for individual Member States to request additional or different information outside the original dossier submissions (Bio Intelligence Service, 2012).

- *Difficulties in the implementation of authorisation for minor crops*

The majority of respondents to the PPPR survey considered the authorisation process for PPPs for crops with minor uses to be incorrectly implemented. Currently, each Member State has its own list of minor crops, some of which are not publicly available. This creates problems in zonal authorisations when the same crop is considered a major crop in some countries and a minor crop in others. Three respondents (two manufacturers' associations and one individual manufacturer) indicated that the Minor Use Coordination Facility, created by the Commission, is not sufficient and lacks the resources to support the availability of PPPs for minor use or to invest in the necessary data gathering for new authorisations (see 'effectiveness' section).

#### **1.2.4 Concerns relating to the lack of transparency of the regulatory committee procedure and lack of risk communication at the stage of risk management and risk communication**

If greater consensus is to be achieved on controversial regulatory issues, more transparency in debates on risk and acceptability might be a valid and legitimate procedure. The lack of transparency relating to the comitology negotiations<sup>59</sup> was criticised in interviews with

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<sup>59</sup> According to Articles 13 and 79(3) of the PPPR, read in conjunction with Articles 5 and 7 of Decision 1999/468/EC laying down the procedures for the exercise of implementing powers conferred on the Commission, the PAFF Committee, composed of representatives of all EU countries, must provide an opinion on the Commission proposal for the approval/non-approval of active substances. The Commission must adopt the regulation if it is in accordance with the opinion of the regulatory Committee. In cases where the Committee does not approve the Commission proposal, the EU Parliament and the Council are involved in the procedure, as described under Article 5 of Decision 1999/468/EC.

many institutional and social actors<sup>60</sup>. The transparency of the process and the overall accountability of the system could be improved if PAFF Committee<sup>61</sup> decisions on precautionary risk mitigation measures, as well as precautionary bans and approvals, were further explained and justified. A second related factor is the deficiencies in risk communication. Ideally, this is the third stage of risk analysis: after scientists have performed hazard and risk assessment and regulators have decided on risk management, a sustained action of risk communication should follow. The task is to explain and engage with the public, providing citizens with information on the line of reasoning behind regulatory choices. At the very minimum, authorities should opt for a one-way information action. In the case of pesticides, however, according to respondents, such activities are virtually non-existent. The explanation of how decisions have been made and the reason behind a ban or an approval are not given. Even in a highly controversial case, like that of glyphosate, communication to the public is left to press releases, at best. Overall, the lack of a risk communication strategy appears to be a serious deficit, especially since pesticides remain a very high concern for EU citizens. Eurobarometer data<sup>62</sup> signal that people continue to worry about chemical residue and pesticide pollution. In this sense, it seems that stringent regulatory criteria have had little effect in reassuring them (Bozzini, 2017).

Similarly, an article published in 2017 (Storck, 2017) considers that, although EFSA contributes to the transparency of pesticide authorisation by releasing conclusions on peer review of risk assessment for each approved active substance, these documents are almost incomprehensible for non-experts and yet contain insufficient detail for researchers. The article concludes that this leads to delayed emergence of risks and, meanwhile, the environment and public health may be endangered.

In the PPPR survey, one farmers' association indicated that the European Commission and Member States have a strong role to play in communicating on risk management in order to avoid misinterpretations from the public and should thus do more in this regard. According to the respondent, this is essential to build confidence in the European food safety system and the high standards within European production (see 'final questions' section).

In its December 2017 reply to the European Citizens' Initiative 'Ban glyphosate and protect people and the environment from toxic pesticides', the Commission proposed changes to the legislation to increase the transparency of studies commissioned by industry that are submitted in application dossiers (while respecting the principles set in the Treaty regarding the protection of legitimate confidential business information), including measures such as public access to raw data from study reports. Such measures would reduce the need for stakeholders to have recourse to access to documents procedures (European Commission, 2017f).<sup>63</sup>

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<sup>60</sup> These interviews were carried out within the framework of the preparation of the book of Emanuela Bozzini (Bozzini, 2017).

<sup>61</sup> Standing Committee on Plants, Animals, Food and Feed.

<sup>62</sup> Eurobarometer, 2010, Food-related risks, Brussels.

<sup>63</sup> Note that as a follow-up to the Commission reply to the European Citizens' Initiative 'Ban

### 1.2.5 Concerns relating to the assessment of hazards and risks of PPP

Some reports highlight the need to enhance the hazard and risk assessments of active substances and PPPs to ensure adequate health and environmental protection (see Section 1.2.6) while others propose that the PPPR assessment process should be less stringent and focus on risk rather than on the intrinsic hazard properties of PPP (Section 1.2.7). Some reports highlight the difficulties encountered by EU and national CAs in achieving and maintaining independence in the assessment of hazard and risks of active substances and PPPs, as well as the involvement of industry-linked experts in the development of scientific evaluation methods. In response, the Commission, in its reply to a European Citizens' Initiative to ban glyphosate, provided some explanations and proposed potential actions to strengthen governance for the conduct of scientific studies (Section 1.2.8). One source outlined, based on the EFSA/ECHA and IARC opinion on glyphosate, the difficult trade-off between regulatory science and research science, and between the need for standard testing criteria to be shared as widely as possible and the need for research designs that are innovative and promising. It also points out the difficult trade-off between testing done in laboratory conditions and testing done in realistic conditions (Section 1.2.9). Finally, the literature suggests that there is an ongoing 'paradigm war' between toxicologists and endocrinologists for the definition of Endocrine Disruptors Criteria, which affects the implementation of the EDC cut-off criteria under the PPPR (see Section 1.2.10 below).

### 1.2.6 The need for more stringent and detailed hazard and risk assessments

- *Additional data requirements needed to address health and environmental risks*

Scientific studies<sup>64</sup> suggest that the combined effects of PPP residue may be significantly higher than the sum of the effects of each residue taken separately. These cumulative effects are not currently considered in EFSA's annual reports on pesticide residue. An assessment methodology is still being developed (EPRS, 2017). In the PPPR survey, NGOs (environment/health) generally commented that cumulative risks posed by residue are not considered, arguing that although individual products can be found to be relatively safe, the cumulative impact of their residue on food and in the environment may still be unacceptable (see 'knowledge base' section).

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glyphosate and protect people and the environment from toxic pesticides', the Commission adopted as of 11 of April a proposal of Regulation on the transparency and sustainability of the EU risk assessment in the food chain, amending, inter alia, the PPPR. It proposes under Union food law new requirements on risk communication, a new register of studies commissioned by business operators to obtain an authorisation under Union food law, enhanced consultation of third parties, the possibility for EFSA to commission studies to verify evidence used in its risk assessment process, new EFSA transparency requirements, new rules on confidential treatment of information and protection of personal data, new standard data formats to allow documents to be submitted, searched, copied and printed, while ensuring compliance with regulatory requirements (European Commission (2018b)).

<sup>64</sup> The EPRS quotes the following study as an example: Graillet et al., 2012, Genotoxicity of pesticide mixtures present in the diet of the French population, *Environmental and Molecular Mutagenesis*, 53, 173-184.

The combination effects of pesticide preparations are not considered in the assessment of PPP and there is no publicly available information on such effects. While the active ingredient is usually the effective (and most toxic) compound in a pesticide product, adjuvants added to the tank or 'inert' ingredients can enhance toxicity and change environmental behaviour. Publicly available toxicity information for pesticide formulations is generally limited to some acute effects. Information about the inert ingredients in pesticide formulations is not publicly available due to corporate confidentiality. In the EU, only ingredients classified as dangerous substances under Regulation (EC) No 1272/2008 must be specified, e.g. in the Safety Data Sheet (SDS) of the formulation. Co-formulants (adjuvants)<sup>65</sup> of glyphosate, polyethoxylated tallow amines (POEA), are long known to be of high toxicity, leading Germany to withdraw authorisation for such substances (Greenpeace, 2016).

Similarly, in the PPPR survey, two environmental NGOs indicated that since data generally refer to active substances, single products or single use, scientific knowledge was lacking on the total impact and combination effects of all pesticides used in one area and over the years (see 'knowledge base' section).

The focus of risk assessment for non-target arthropods (NTAs) has been on species that are beneficial in IPM for more than two decades. The assessment of the effects on biodiversity is not explicitly addressed under the existing guidance documents. Appropriate risk assessment methodology needs to be developed to protect biodiversity and a range of ecosystem processes, including biological control of pests, food web support and pollination (EFSA PPPR Panel, 2015).

Possible harmful effects on soil biodiversity, which supports numerous ecosystem services such as food production or climate regulation, are a particularly relevant issue. To tackle this issue, EFSA proposed new specific protection goals covering ecosystem services potentially affected by the use of pesticides. It also suggested the development of a new environmental risk assessment framework to assess the temporal and spatial ecological recovery of non-target organisms exposed to regulated stress factors, including pesticides. However, these new concepts have not yet been fully implemented in a new regulatory framework, except for aquatic organisms in edge-of-field surface waters, according to the guidance on aquatic risk assessment (Storck, 2017).

Developmental Immunotoxicity (DIT) and Developmental Neurotoxicity (DNT), while recognised as very important, are not covered by risk assessments required for the approval of active substances. There are no systematic data on these two effects (Greenpeace, 2016). In the PPPR survey, this statement is supported by an environmental NGO (see 'knowledge base' section of the targeted stakeholder survey).

Data for environmental toxicity are based on endpoints for acute toxicity for a limited number of species, which might not be the most sensitive species (Greenpeace, 2016). Similarly, one NGO (environment/health and animal health) respondent to the PPPR survey, specified that more attention should be given to the impacts of pesticides on fauna

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<sup>65</sup> Co-formulants and adjuvants are subject to different sets of PPPR provisions.

(e.g. wild pollinators, soil arthropods and fungi, amphibians and reptiles) (see 'knowledge base' section).

Greater hazard assessment of Non-Intentionally Added Substances (NIAS), which stem from chemical impurities, reaction and degradation products is needed for plant protection products (RPA, 2017).

The data required to conduct environmental risk assessments do not take into account all pesticide transformation processes or the environmental parameters that influence pesticide fate, as it is very difficult to perform risk assessment studies in all kinds of environments. For instance, pesticide degradation, estimated according to the OECD 307 (2002) guideline, imposes testing in three soils, which do not necessarily originate from the three different pedo-climatic zones for authorisation and may not be enough to predict pesticide transformation in the various situations found across Europe, particularly in the context of climate change (Storck, 2017).

- *Missing classifications of active substances under the CLP*

The process of classification and labeling by the European Chemical Agency (ECHA) seems to be particularly slow. More than 130 synthetic pesticide substances approved for use in the EU are not classified according to the CLP Regulation (CLP) as amended. Among those unclassified pesticides are some which have been on the market for decades (terbuthylazine, oxyfluorfen, bromadiolone, metiram) and some newer ones believed to pose severe risks to human health and/or the environment (thiacloprid, emamectin benzoate) (Greenpeace, 2016).

- *Comparative in vitro metabolism assessment across species not considered scientifically robust*

According to one stakeholder consulted, the requirement to conduct comparative in vitro metabolism assessment across species is not considered scientifically robust and relevant to the protection of human health (Bio Intelligence Service, 2012).

- *Concerns relating to the application of the precautionary principle*

On 24 May 2013, the Commission published Implementing Regulation (EU) 485/2013, where it rules that 'the uses as seed treatment and soil treatment of plant protection products containing clothianidin, thiamethoxam or imidacloprid should be prohibited for crops attractive to bees and for cereals except for uses in greenhouses and for winter cereals'<sup>66</sup>. This regulation bans the use of the three neonicotinoids for most crops. The decision was welcomed by NGOs but strong opposition was expressed by some Member States and industry representatives<sup>67</sup>. The core of the controversy revolved around how to

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<sup>66</sup> Commission Implementing Regulation 485/2013 of 24 May 2013 concerning the conditions of approval of the active substances clothianidin, thiamethoxam and imidacloprid, and prohibiting the use and sale of seeds treated with plant protection products containing those active substances.

<sup>67</sup> Two PPP manufacturers brought a legal case before Court of Justice of the European Union against this Regulation in 2013. As of April 2018 the procedure is on-going. See the website of the EUCJ:  
<http://curia.europa.eu/juris/fiche.jsf?pro=&lgrec=fr&nat=or&oqp=&lg=&dates=&language=en&i>



According to one NGO (animal health) respondent to the PPPR survey, toxicological and ecotoxicological data requirements specified in the PPPR have fallen behind the 3R best practices and should be revised. The respondent also stated that a process should be implemented to schedule and streamline future revisions to data requirements (such as an annual review of new OECD test guidelines and associated guidance) (see 'knowledge base' section).

### **1.2.7 The need for less stringent hazard and risk assessments, with a focus on risk rather than intrinsic hazard properties of PPP**

- *Evaluation process too precautionary and not proportionate to the risks that need to be managed*

According to several stakeholders consulted (PPP producers and users), the evaluation process is perceived to be too precautionary and not proportional to the risks that need to be managed. They consider it to be influenced by the political context. The data requirements on environmental fate are excessively demanding. Environmental risk evaluation is perceived to often result in highly conservative assessments for both consumers and the environment, with no clear links with protection goals (Bio Intelligence Service, 2012).

- *Focus on hazard properties rather than on adverse effects*

The approval of active substances and the authorisation procedure under the PPPR includes not only risk assessment but also consideration of intrinsic hazard properties. This emphasis was believed to result in the removal of a large share of active ingredients, which may have a major impact on crop yield. Pesticides should be regulated based on adverse effects and not the mechanisms that execute those effects. Such effects are highly dependent on concentration and may not be realised in practice (Jess, 2014).

Similarly, a report assessing the cumulative impact of hazard-based legislation on PPPs in the EU considers the significant share of active substances removed from PPPs due to the EU legislation's hazard-based approach to have major impacts on staple crop yields and agricultural production in the EU and also on CO<sub>2</sub> emissions (*Steward Redqueen, 2016*)

In the PPPR survey, a farmers' association and a manufacturers' association mentioned that the hazard-based approach is not the most accurate, as it does not consider on-field conditions. According to these respondents, the risk-based approach should be preferred (see 'effectiveness' section). One CA mentioned that the shift from a risk approach to a hazard approach in decision-making was noticeable, and argued that if hazard and risk are not weighed together, this shift could lead to lower-risk substances but higher exposure, leading to a detrimental net effect (see 'knowledge base' section).

- *Economic and climate change impacts of hazard cut-off criteria*

According to the 2016 Steward Redqueen study, the application of the hazard cut-off criteria under the PPPR would lead to significant lower yields for seven staple crops (potato, barley, wheat, sugar beet, rapeseed, maize and vine) and 24 speciality crops. This study stressed that the removal of active substances due to the application of the hazard

cut-off criteria would mean that the EU is likely to depend on imports for more than 20% of its staple crop demand, bearing the risk of selling crop produced with non-EU standards on the European market. The study estimates the removal of these active substances to create the need for an additional nine million ha farmland to feed Europe, leading to a significant increase of greenhouse gas (GHG) emissions and putting the CO<sub>2</sub> aims of European legislation at risk (Steward Redqueen, 2016).

- *Certain data requirements to be removed*

Some stakeholders consulted stressed that the following data requirements should be removed: metabolism, distribution and expression of residues in fish, and feeding studies in rotational crop residue (second tier)<sup>71</sup> (Bio Intelligence Service, 2012).

- *Need to rely on field studies*

According to one stakeholder (PPP producer), there is often a lack of acceptance of costly field studies, compared to the reliance on the conservative interpretation of laboratory studies, even though the results of field studies are closer to real-life situations. Results from field studies should therefore be given more importance than results from in vitro studies (Bio Intelligence Service, 2012).

- *Better use of alternative approaches to field or laboratory studies*

Several stakeholders (PPP producers and PPP users) suggested a wide range of alternative approaches to field or laboratory studies in order to improve the balance between the cost of risk assessments and the delivery of useful results (UK OPEX<sup>72</sup>, the UK surface water and groundwater modelling, the Toxicological Threshold Concentration (TTC) or the US approach of eliminating the efficacy data) (Bio Intelligence Service, 2012).

- *Exposure not sufficiently considered in PPPR*

Several stakeholders (PPP producers and PPP users) stated that exposure is not sufficiently considered in the current framework. Greater acceptance of all available risk management options could be promoted and implemented at a national level. The choice of the best option would require inputs from all stakeholders, with harmonised guidance provided for mitigation actions. Restricted approval, with risk management measures, could be put forward as an alternative to prohibition (Bio Intelligence Service, 2012).

Similarly, two NGOs working on animal health issues and one individual manufacturer stated that the current hazard-based approach (exposure considerations aside) leads to numerous unnecessary in-vivo testing, contradicting the EU's aim to reduce tests involving

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<sup>71</sup> Regulation EU) No 283/2013 of 1 March 2013 setting out the data requirements for active substances requires, under Point 6.6 of Section 5 of its Annex, that for second tier studies on residue in rotational crops, additional data must be submitted to enable appropriate evaluation of dietary risks and establishment of MRLs. These studies shall cover the common crop rotation practice. Trials shall be conducted as closely as possible to agricultural practice on representative crops from major crop groups. At least four trials per crop shall be conducted across the Union in one year. These trials shall be performed in the main production areas across the Union at the highest application rate for the preceding crops. If annual applications of persistent active substances result in higher plateau concentrations in soil than a single application, the plateau concentration shall be taken into account. The necessary residue trials data shall be set up in consultation with the national CAs in the Member States.

<sup>72</sup> Operator exposure to chemicals.

animals. The two NGOs also criticised the tendency to impose blanket requirements for additional in-vivo tests as a default approach and called for streamlining data requirements in line with the REACH Regulation and OECD guidelines (see 'knowledge base' section).

### **1.2.8 Concerns relating to the lack of independence of competent authorities and scientific agencies during the evaluation process**

- *Issues relating to the independence of regulatory agencies relying on applicant companies' information to assess active substances and PPPs*

According to this academic article, regulatory agencies encounter difficulties in achieving and maintaining independence as they assess active substances and PPPs based almost exclusively on information submitted by the applicant companies. These companies must provide test data on agronomic performance and on human and environmental toxicology. The number and range of tests to be assessed can be multiplied by the high number of applications for new registrations, including the assessment of new active substances in a variety of formulations and packaging. With such a diversity of active substances and so much differentiation amongst formulations, the potential for regulatory agencies to replicate studies done by companies is totally beyond the reach of the public sector. Thus, assessments carried out by regulatory agencies do not include corroboration of empirical test results presented by applicants and are instead restricted to analysing their coherence and consistency. This type of asymmetry of information is a structural feature of the regulation of chemical substances, in which the limits of agencies' assessment capabilities impose the transfer of their testing responsibilities to the regulated industry. Moreover, when a new active substance is submitted to the regulatory agencies for approval, the toxicological data and agronomic tests provided by the companies are protected in the EU for 15 years. This means that during this protective period the data are not available for public scrutiny, providing yet another element of asymmetry of information (Pelaez et al., 2013).

In response, the Commission, in its reply to the European Citizens' Initiative 'Ban glyphosate and protect people and the environment from toxic pesticides' provided some justifications and highlighted potential actions from the Commission.

The system in place for active substances is similar to those applied in other sectors, such as industrial chemicals, food additives, biocides and pharmaceuticals. The principle is that public money should not be used to commission studies that will eventually help industry to put a product on the market, especially since individual studies cost between several thousand to several million euro each, and each dossier can contain up to several hundred studies. This is why the PPPR places the burden of proof to demonstrate that an active substance and the products containing it can be used safely, and to generate the necessary information for such demonstration, on those who stand to benefit from its approval, i.e. the companies manufacturing or marketing the substance and the products. Studies required for application dossiers are commissioned directly by industry on their own initiative. There are claims that since industry pays for the studies to be carried out, this may be an incentive for the laboratories to deliver results that please their clients and thus

secure future business. However, test facilities carrying out such studies are subject to rigorous inspections for their adherence to the principles of good laboratory practice (GLP), and if these test facilities are found to manipulate the results of studies either as part of a regular inspection or a specific study audit, they will lose their GLP certification. A systematic approach that would oblige public authorities to commission all studies for active substances and PPP (while maintaining the principle that the costs are covered by industry) may well prove challenging, given the high number of studies required to support all applications for active substance approval and product authorisation. The Commission will propose to amend the legislation to strengthen the governance for the conduct of such studies, which could include for example, the involvement of public authorities in the process of deciding which studies need to be conducted for an application dossier, enhanced auditing of studies conducted in accordance with the principles of GLP, measures to increase transparency of the findings of such studies, and the possibility to commission ad-hoc studies by exception, in case of serious doubts or conflicting results, for example, in cases of widely used substances (European Commission, 2017f).

In the PPPR survey, respondents expressed differing views on the independence and objectivity of the evaluation process (See targeted stakeholder survey 'knowledge base' and 'effectiveness' sections for further details).

- *Involvement of industry-linked experts in the development of scientific evaluation methods*

In nine of the 12 (75%) risk assessment methods studied by the Pesticide Action Network, industry-linked experts managed to get a seat on EU and global panels where these methods were produced. Generally, there were only a handful of experts on the panels, whose work was to decide on far-reaching opinions about the methods in question. Only rarely were those experts actively involved in conducting experimental scientific work. In any case, little science is used for drafting opinions on risk assessment methods in panels. Rather, 'expert judgement' is the prevailing practice, which is simply the opinions and beliefs of those present. The global scientific societies that include the hundreds of thousands of scientists engaged in scientific research are not involved, nor are they asked to do a peer review of these methods of risk assessment, which is the standard procedure for scientific work. None of the 12 studies had been peer reviewed by independent academic scientists. Since a solid conflict-of-interest policy was lacking at the beginning of this century in most agencies, many expert panels have been dominated by experts that support the views of industry. In the case of TTC (Threshold of Toxicological Concern; a method to design safe levels for pesticides), up to 77% of the experts (10 of 13) in the EFSA Working Group were linked to industry and had promoted industry interests in the past (PAN Europe, Generation Futures, 2018).

- *Case study on the ban of neonicotinoid, suggesting the influence of the Commission on EFSA scientific conclusions*

As a result of a case study analysing how EFSA, based on a Commission mandate, conducted a scientific evaluation on the neonicotinoid pesticides, an academic article concluded that the interaction between high external pressure and high internal capacity to respond to this pressure leads to substantiating use of expertise, in which scientific evidence is used to promote the inclinations of those actors on which EFSA most depends. This empirical evidence of a single case study suggests that the line between risk assessor

(EFSA) and risk manager (the Commission) is blurred, as the Commission in this case played an important role in predefining the conditions under which specific tasks should be carried out. The article argues that the narrow and stringent EFSA mandate provided a basis for one-sided scientific conclusions right from the outset. EFSA was implicitly asked to apply a rigid validation criterion towards evidence coming from pesticide manufacturers, i.e. field research, which led to the exclusion of the majority of industry-funded research. This, in turn, led to the more rigorous regulation of the neonicotinoid pesticides that was introduced in the logic of the precautionary principle (Rimkutė, 2015).

- *Concerns related to the integrity of EFSA and ECHA assessments of glyphosate*

Serious concerns about the integrity of the EFSA and ECHA assessments of glyphosate arise from their failure to comply with Regulation (EC) No 1272/2008 and the applicable OECD and ECHA guidance documents and guidelines. In particular:

- Violation of the recommendations in OECD (2012) and ECHA (2015 guidance for the statistical analysis of tumour incidences).
- Failure to detect eight additional significant increases of tumour incidences not mentioned in the study reports by industry.
- Failure to acknowledge existing dose-response relationships for kidney tumours and malignant lymphoma in at least three different studies. These studies support the conclusion that the observed increases in tumour incidences are a true effect, visible at least from the mid-dose group.
- Failure to consider multi-site responses seen in five different studies as supporting the strength of evidence. Regulation (EC) No 1272/2008 defines multi-site responses as an important factor in strengthening the evidence for carcinogenicity.
- Use of false statements that carcinogenic effects by glyphosate were only seen at excessive toxicity levels, not taking into consideration existing dose-response relationships, manufacturing an alleged 'limit dose' of 1,000 mg/kg, and misinterpreting reduced body weight gain.
- Use of historical control data in flawed and false ways in order to dismiss the observed increased tumour rates in glyphosate-treated animals.
- Exclusion of certain studies, such as a study supporting the conclusion that glyphosate could induce malignant lymphoma (Global 2000, 2017).

### 1.2.9 The glyphosate case and concerns relating to trade-offs between 'regulatory science' and 'research science' and between laboratory tests and tests in realistic conditions

- *Concerns related to the difficult trade-off between 'regulatory science' and research science, as illustrated in the glyphosate case*

The glyphosate case illustrates the difficult trade-off between 'regulatory science' and 'research science', that is, between the need for standard testing criteria to be shared as widely as possible and the need for research designs that are innovative and promising. International standards on GLP have been developed to ensure reliability and quality in assessments. In this sense, standards are used to make sure that manufacturers deliver good research to regulators and to assure consistency in evaluations. By contrast, academic and peer review papers tend not to employ OECD or international criteria in their studies.

This is for the very good reason (from an academic point of view) that standard designs produce standard results, unlikely to be original or interesting, and are therefore unlikely to be publishable. Furthermore, academic literature can be scant, thus conclusions can be partial. A point generally overlooked in the political argument is that the same IARC report that classified glyphosate as likely carcinogenic gave the green light to two insecticides – tetrachlorovinphos and parathion – that are both banned in the EU (Bozzini, 2017).

- *Concerns relating to the difficult trade-off between testing done in laboratory conditions and testing done in realistic conditions, as illustrated in the glyphosate case*

The glyphosate case reveals a trade-off between testing done in laboratory conditions and testing done in realistic conditions. Tests conducted by manufacturers according to OECD guidelines on Good Agricultural Practice (GAP) focus on pure glyphosate. Studies included in the open literature do not necessarily test the active substance but, rather, some of its formulations, i.e. specific (commercial) products that contain glyphosate plus many other chemicals acting like surfactants and synergists. Furthermore, they often report exposure to a number of pesticides or to what could be called a ‘representative chemical cocktail’. This is an important difference, since EU regulations ask EFSA for an assessment of the active substance only, without consideration of its potential additive and synergetic effects when mixed with other ingredients. This second step in the analysis is left to national regulators. Once the basic chemical is approved at EU level, specific formulations will be assessed by the national authorities that authorise products, in view of the agro-ecological conditions of their territories. This is a limitation of the EU regulations. One of the merits of these non-standard academic studies reporting on a mix of substances is to signal potential dangers. Farmers – as well as bystanders – are never exposed to the single, pure active substance (Bozzini, 2017).

### **1.2.10 Concerns relating to the ‘paradigm war’ between toxicologists and endocrinologists for the definition of endocrine disruptors**

Among the cut-off criteria for the evaluation of active substances, the PPPR includes ‘endocrine disruption’, meaning the adverse interference of a substance with the normal functioning of the hormone system. Endocrine disruption is both a topical and a very complex issue. The scientific and public interest exploded in the mid-1990s, when a series of publications suggested that some chemicals commonly used in pesticides, pharmaceuticals, and cosmetics could have the capacity to disrupt the connection between hormones and their receptors, leading to serious damage to the reproductive and cognitive capabilities of humans and wildlife. Since the mid-1990s, efforts to investigate and define endocrine disruptors criteria have been made by OECD, the UN and the WHO, as well as the USA and EU authorities, with little consensus on definitions and methodologies. Experts are deeply divided on scientific definitions, methodologies and practices. The Commission, which was required to adopt endocrine disruptor criteria in 2013, published its draft Implementing Regulation in 2016<sup>73</sup>. The European Commission proved unable to

<sup>73</sup> As of February 2018, the draft Regulation setting out scientific criteria for the determination of endocrine disrupting properties was adopted by Member State experts during the PAFF Committee on December 13, 2017 (18 Member States in favour representing 65.79% of the EU population, three Member States against (5%) and seven Member States abstaining (29.21%). The European Parliament and the Council have a three months scrutiny

deliver this requirement because it was caught in a scientific controversy that, with relatively little risk of oversimplification, could be described as a paradigm war between toxicologists and endocrinologists. Disagreements among scientists persist on almost every aspect of the issue, including the definition of endocrine disruptor criteria and the ‘boundaries’ of the endocrine system. Put simply, the argument is that endocrine disruptor criteria can be described as an ‘intractable issue’, where disagreements are not limited to lack of data, as in the case of neonicotinoids, or differences concerning interpretations, as in the case of glyphosate. Rather, disagreements obstinately remain and have given rise to a paradigm war, because they are about the very definition of the phenomenon and the type of evidence needed to assess it (Bozzini, 2017).

### 1.2.11 IPM and low-risk PPP

Two main sources of information highlight that the application of IPM<sup>74</sup> is still limited in Member States and that there remains room for improvement. One of the reasons for such limitation is the insufficient use of low-risk PPP in Member States.

- *Lack of availability of low-risk PPP hindering IPM developments*

At the time of drafting this report<sup>75</sup>, only 10 substances are approved as low-risk PPP out of a total of almost 500 (European Commission, 2017e).

Member States highlighted the insufficient availability of low-risk and non-chemical pesticides as a barrier to further IPM development. Incentives for the registration of low-risk and non-chemical products are mentioned in only a few national action plans. Therefore, the authorisation and promotion of low-risk and non-chemical pesticides [that are subject to the approval and authorisation procedure laid down by the PPPR] is another important measure to support low pesticide-input pest management (European Commission, 2017e).

In the PPPR survey, an individual (from a CA) expressed concern that there is a tendency to make low-risk criteria as flexible as possible and to consider an increasing number of substances as low-risk, although they are not (see ‘effectiveness’ section).

- *Economic reasons that hinder the development and adoption of non-chemical low-risk PPP*

Some of the features of the agricultural economy make it difficult for companies to invest in developing new biopesticide products, while also making it hard for farmers to decide to adopt new technology. Factors such as low profits from niche market products, high

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period with one month of extension if needed, as of the adoption of the Regulation. In the meantime, a public consultation was launched by ECHA and EFSA on the draft guidance to identify endocrine disruptors, ending 28 January 2018.

<sup>74</sup> IPM is defined under Directive 2009/128/EC establishing a framework for community action to achieve a sustainable use of pesticides as: ‘a careful consideration of all available plant protection methods and subsequent integration of appropriate measures that discourage the development of populations of harmful organisms and keep the use of plant protection products and other forms of intervention to levels that are economically and ecologically justified and reduce or minimise risks to human health and the environment. Integrated pest management emphasises the growth of a healthy crop with the least possible disruption to agro-ecosystems and encourages natural pest control mechanisms’.

<sup>75</sup> This report was published in October 2017.

fixed costs for small user groups, risk aversion, and IPM portfolio economies mean that conventional chemical pesticides can be difficult to replace with alternatives such as biopesticides (Chandler, 2011). In the PPPR survey, one CA stated that since possible low-risk substances are treated a high-risk from the beginning, the costs of the dossiers and the approval process are often too high for the niche markets they represent (see 'effectiveness' section).

- *Lack of regulator expertise on biopesticides poses a regulatory risk for innovation*

Where regulators lack expertise with biopesticides, they tend to delay the adoption of a decision and may request more data from the applicant. There is also a risk that the regulator – using the chemical pesticide registration model – requests information that is not appropriate (Chandler, 2011).

- *National Action Plans (NAPs) do not specify how to measure the application of IPM*

All of the NAPs<sup>76</sup> include some measures on the promotion of IPM, to encourage availability of IPM guidelines and the provision of training or demonstration farms. Nevertheless, the plans do not specify how the application of IPM by farmers can be measured, nor do they set targets or indicate how implementation will be ensured. IPM is a cornerstone of the Directive and implementation of IPM is the intended means to reduce the dependency on pesticide use in sustainable agriculture, thus the lack of clear steps that can be assessed, measured and enforced is a significant area for improvement in the ongoing review of NAPs by Member States (European Commission, 2017e).

- *Lack of measurable criteria for IPM can lead to a focus on short-term solutions, such as Article 53 emergency authorisations*

Member States have not converted the IPM principles into prescriptive and assessable criteria. While Member States take a range of measures to promote the use of IPM, this does not necessarily ensure that the relevant IPM techniques are actually implemented by users. While IPM techniques are sustainable from a long-term perspective, IPM can mean a higher economic risk in the short-term. As an example of a short-term approach, Romania granted Article 53 emergency authorisations for using neonicotinoids as seed treatment in an undefined area of maize, without investigating the potential of crop rotation as an alternative (European Commission, 2017e)

- *Room for adopting IPM techniques on a more widespread basis*

Awareness of IPM techniques has increased but this has not always led to significant increases in the level of implementation, nor are IPM principles used to their full potential (European Commission, 2017e).

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<sup>76</sup>According to Article 4(1) of Directive 2009/128/EC establishing a framework for community action to achieve a sustainable use of pesticides, Member States shall adopt NAPs to set up their quantitative objectives, targets, measures and timetables to reduce risks and impacts of pesticide use on human health and the environment and to encourage the development and introduction of IPM and of alternative approaches or techniques in order to reduce dependency on the use of pesticides. These targets may cover different areas of concern, for example worker protection, protection of the environment, residue, use of specific techniques or use in specific crops.

## 2. Stakeholder survey

### Key findings

**Relevance:** The majority of respondents considered the objectives of the PPPR still relevant to the current needs. Several respondents highlighted that the PPPR should better satisfy the need to promote IPM-oriented agriculture. Several respondents also believed that innovation should be added to the objectives.

**Knowledge base:** A slight majority of respondents considered the available scientific knowledge to meet the decision-making needs for the approval of active substances at EU level and the authorisation of PPPs at national level. However, the majority of respondents considered the available scientific knowledge to be inadequately used in these procedures. According to environment and health NGOs, independent scientific literature is too often excluded on debatable grounds (usually that such studies were not carried out according to OECD test protocols, including GLP, even though some of these studies are not suitable for GLP). Manufacturers' associations and individual manufacturers indicated that scientific data from applicants were not sufficiently taken into account, due to a lack of dialogue between evaluators and applicants, the rules on admissibility of studies and the politicisation of certain dossiers.

**Coherence:** Respondents considered the objectives of the PPPR, and its practical implementation, to conflict with the objectives and implementation of EU agriculture policy, and to a lesser extent with food security policy. One-third of respondents stated that there is a conflict between the objectives of the PPPR and the Directive on sustainable use of pesticides, and coherence with climate policy divided respondents. In their comments, respondents mentioned coherence problems with the Directive on sustainable use of pesticides, the BPR, other chemicals regulations (REACH) or the Water Framework Directive.

**Effectiveness:** With the exception of environmental/health NGOs, and associations representing the interests of organic food and farming and biocontrol, the majority of respondents considered the objectives of protection of human and animal health, and protection of the environment to be met. The majority of respondents considered the PPPR unsuccessful in meeting its objective to improve agricultural production, for different reasons. Environmental/health NGOs, some CAs and associations representing the biocontrol industry and organic food and farming, argued that the Regulation fails to improve agricultural production, as it does not promote the development of IPM-oriented agriculture. Manufacturers' and farmers' associations indicated that the objective was not met and that the competitiveness of the agricultural sector was damaged because the number of available active substances has been reduced and new active substances and PPPs are entering the market very slowly.

With the exception of parallel trade and the labelling of PPPs, most respondents considered the day-to-day implementation of the different instruments under the PPPR to be problematic.

**Efficiency:** There was no clear majority on whether or not current results could be achieved at a lower cost. Manufacturers' associations and individual manufacturers identified inefficiencies in approval procedures of active substances and authorisations procedures of PPPs at national level, leading to increased costs and burden for applicants and CAs (e.g. flaws in the implementation of mutual recognition, duplication of work) and increased time to market for PPPs. Some CAs also indicated that the increasing complexity of risk assessment methodology for approval of active substances creates a high administrative burden.

**Impacts:** The majority of respondents considered the impacts of the PPPR on human and animal health, the environment and consumers to be generally positive. However, environmental/health NGOs indicated that current failures in implementation result in very negative impacts for human health and ecosystems in agricultural areas. The majority of respondents considered the PPPR to have had a negative impact on farmers and competitiveness.

**EU added value:** The majority of respondents considered the implementation of the PPPR to add value to national efforts to achieve the relevant health, environment and market objectives. None of the respondents stated that the Member States would do better without the PPPR.

## 2.1 Introduction

To cross-check and complement the desk research, an online targeted stakeholder survey was carried out from 16 January to 16 February 2018 to collect opinions from stakeholders on the implementation of the PPPR. The survey covers the five evaluation criteria (relevance, coherence, effectiveness, efficiency and EU added value) and other important aspects for the implementation of the Regulation, such as the knowledge base for authorisation decisions. The questionnaire consisted of closed questions, requesting respondents to choose between fixed response choices, and open-ended questions, where respondents could comment on their responses to the closed questions and/or provide additional comments on a particular aspect of the implementation of the PPPR.

The survey was disseminated to a list of selected stakeholders, each belonging to one or more of the following three categories:

- Stakeholders with legal obligations under the Regulation in terms of compliance, implementation and enforcement (PPP and seed manufacturers, as well as CAs).
- Stakeholders affected by the implementation of the Regulation and/or with a legitimate interest in the achievement of its objectives, such as environmental NGOs, human and animal health NGOs, consumer organisations, animal health services and veterinarians' associations, farmers, food and feed industry.

- Academic experts, research organisations or networks ensuring the knowledge base for policy-making in the field.

In addition to the 29 CAs of the EU Member States and Norway, 149 organisations and individuals (mostly academic experts) were preselected and contacted. The survey received 33 individual responses.

It should be noted that the organisations that responded represent the main stakeholders mapped in this particular policy area. With the exception of the academic community, the 33 individual opinions chiefly represented stakeholders with legal obligations under the PPPR (industry and Member State CAs), as well as those concerned by the implementation of the PPPR and those interested in the achievement of its objectives. Therefore, although it is difficult to ascertain the representativeness of the survey results, they could be considered a (broadly) representative sample of the stakeholders in the policy area of placing of PPPs on the market. In view of the confidentiality terms of the survey, the stakeholders could not be individually identified; however, their opinions are quoted at the level of the stakeholder category they represent.

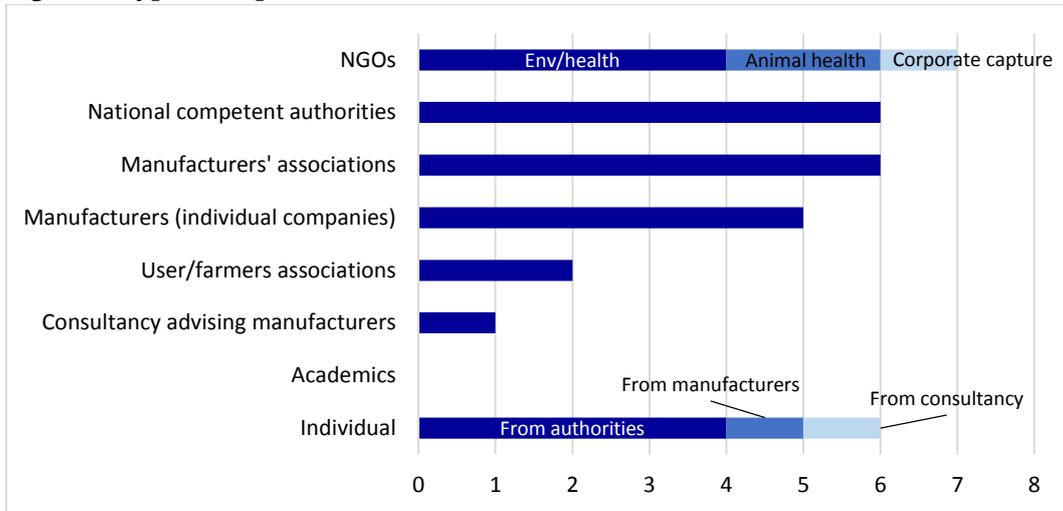
## 2.2 Profile of respondents

The largest group of respondents is PPP producers, with six associations representing manufacturers (responding on behalf of the association or their members) and five manufacturers (individual companies), followed by seven health and environmental NGOs and six official positions of CAs. NGOs comprise four environmental (and/or health) NGOs, two NGOs focusing on animal health, and one NGO focusing on corporate practices<sup>77</sup>. On the few occasions where their opinions diverged, this is mentioned in the analysis. Individuals belong either to CAs, manufacturers (individual companies) or consultancies providing services to companies. It should be noted they spoke in a personal capacity and therefore their position could not be viewed as an official position of the organisation or authority to which they belong, thus they were put in a separate category. Where relevant, however, their replies were grouped with the stakeholder category to which they belong. It is also worth noting that responses in the manufacturers' associations group varied between manufacturers of chemical PPPs and manufacturers of biocontrol tools. Similarly, among the farmers' associations, differences in the patterns of responses can be identified between the association representing conventional agriculture and the association representing organic food and farming. These differences have been taken into account in the analysis. Finally, the consultancy that responded to the questionnaire advises chemicals manufacturers, and its responses mostly follow a similar pattern to those of manufacturers and manufacturers' associations.

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<sup>77</sup>This organisation was not part of the original selection of stakeholders but provided a spontaneous contribution, which was accepted because it satisfied the selection criteria.

**Figure 4: Type of respondents**

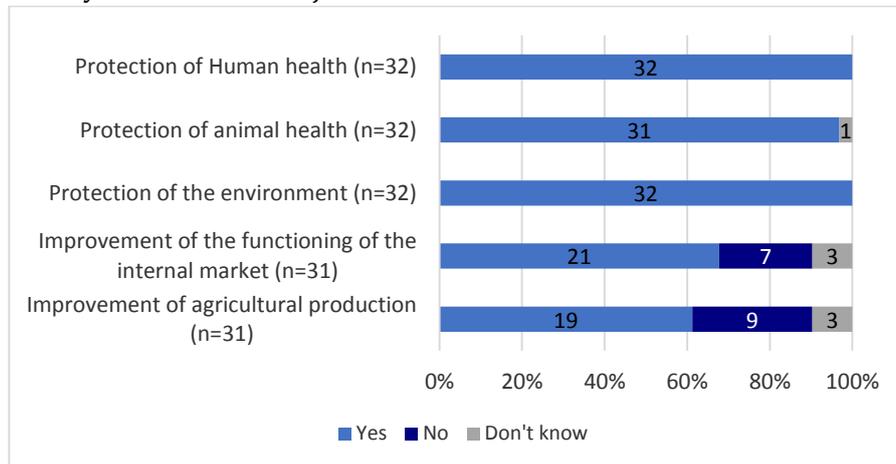


### 2.3 Relevance

*Do you think those objectives are still relevant to current needs?*

The majority of respondents considered the objectives of the PPPR still relevant to the current needs. For this closed question, and the following closed questions, results have been presented in charts to facilitate their reading. However, given the low number of respondents, the charts have been included for illustrative purposes rather than for establishing trends.

**Figure 5: Do you think those objectives are still relevant to current needs?**



Respondents who considered the objectives of improving the functioning of the internal market and improving agricultural production no longer relevant to the current needs were environmental NGOs, individuals belonging to national CAs and CAs.

Nineteen respondents commented on their answers. Some (environmental/health NGOs) stressed that environmental and health are still relevant objectives under the PPPR

considering the intensification and concentration of agricultural production, the increased use of PPP (doubled from 2009 to 2017), the lack of development of IPM, the decline in biodiversity, the increase in chronic illness, and the widespread contamination of water resources. These objectives should therefore be a major concern under the PPPR. They suggested that more emphasis should be placed on achieving these two goals. Similarly, one farmers' association respondent stated that environment and health should be a major priority of the PPPR, by focusing on sustainable plant health to address the long-term resilience of agro-ecosystems.

One manufacturers' association respondent was of the view that the PPPR contains unnecessary hurdles to meet the health and environment objectives, thereby impacting the international competitiveness of EU agriculture. Similarly, a consultancy respondent considered the implementation of PPPR to have been focused on delivering safety-related goals (protection) rather than on competitiveness, innovation and productivity of EU agriculture.

Some respondents (farmers' association, consultancy) highlighted that the objective to fulfil the internal market is very relevant, as there is still a lot of work to be done to harmonise Member State procedures. One manufacturers' association respondent believed that there is a need to harmonise rules by applying the same safety criteria under different environmental conditions.

Some respondents (manufacturers (individual companies), manufacturers' associations, and one CA) indicated that the PPPR objectives are still all valid and relevant. The CA respondent, however, considered the PPPR to have a negative impact on agricultural production in practice.

One animal welfare NGO stated that the objective of animal health is still relevant, and suggested the development and adoption of best and safest testing practices, without the use of animals.

***Do you consider that more objectives need to be added?***

20 respondents answered this question, several of whom (manufacturers' associations, individuals, consultancy) stated that innovation and development, together with a reference to new technologies, should be added to the objectives.

One NGO stated that the objective to phase-out synthetic PPPs should be added, while another environment/health NGO suggested that the objective to improve agricultural production must be more specific if it is to be sustainable. One respondent (users and farmers associations) suggested adding investment in use of naturally occurring substances and the protection of farm ecosystems as objectives.

One CA felt that the Regulation should set a clear objective for stimulating substances with low-risk. This could be done by implementing an approach based on the principle of 'approval unless proven not safe' instead of 'no approval unless proven safe'.

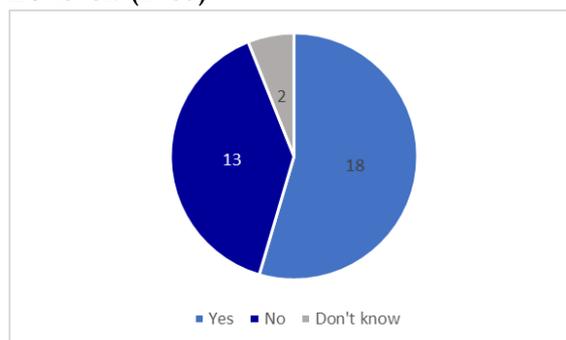
One animal welfare NGO recommended adding the promotion of non-animal methods for assessment of risks of substances and mixtures" as an overarching purpose of the legislation.

## 2.4 Knowledge base

*Do you consider that the available scientific knowledge on pesticides (plant protection products) is up to decision-making needs especially as regards approval of active substances at EU level?*

A slight majority of respondents considered the available scientific knowledge on PPPs to meet decision-making needs for the approval of active substances at EU level. However, NGOs mostly replied negatively to the question, as did the association representing the biocontrol industry (unlike other manufacturers' associations), while manufacturers (individual companies) were divided on this issue, as were the associations representing farmers (between conventional and organic agriculture).

**Figure 6: Do you consider that the available scientific knowledge on pesticides (plant protection products) is up to decision-making needs especially as regards approval of active substances at EU level? (n=33)**



Twenty-one respondents commented on their answer. Eight respondents from individual manufacturers, manufacturers' associations and CAs stated that there is a wealth of information on PPPs, significantly higher than for other marketed products or in other areas of chemicals legislation. However, a number of respondents underlined areas where scientific knowledge should be developed. According to the association representing the biocontrol industry, scientific knowledge is lacking on biological active substances, while the association representing organic food and farming mentioned that specific guidelines for substances of mineral origin need to be developed (along the lines of those already developed for several categories of natural occurring substances).

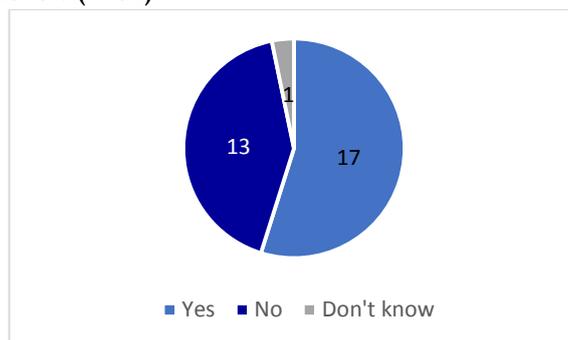
According to the environment/health and animal health NGOs, risk identification in certain areas, such as developmental neurotoxicity, immunotoxicity, endocrine disrupting properties, multigenerational effects, nanomaterials, complex mixtures, or chronic and indirect effects, is insufficient and requires both stricter data requirements and better test regimes. One NGO also specified that more attention should be given to the impacts of pesticides on fauna (e.g. wild pollinators, soil arthropods and fungi, amphibians and reptiles).

According to one animal health NGO, toxicological and ecotoxicological data requirements specified in the PPPR have fallen behind the 3R best practices and should be revised. The respondent also stated that a process should be implemented to schedule and streamline future revisions to data requirements (such as an annual review of new OECD test guidelines and associated guidance).

***Do you consider that the available scientific knowledge on pesticides (plant protection products) is up to decision-making needs especially as regards authorisation of PPPs at national level?***

A slight majority of respondents considered the available scientific knowledge on PPPs to meet decision-making needs for the authorisation of PPPs at national level. While CAs, manufacturers' associations and manufacturers (individual companies) mostly replied positively, NGOs generally considered the available knowledge insufficient for PPP authorisation. The association representing the biocontrol industry also replied negatively, unlike other manufacturers' associations. Associations representing farmers were divided on this issue (between conventional and organic agriculture).

**Figure 7: Do you consider that the available scientific knowledge on pesticides (plant protection products) is up to decision-making needs especially as regards authorisation of PPPs at national level? (n=31)**



Twenty-two respondents commented on their answer (four mentioning that their comments mirrored those of the previous question). Six respondents from individual manufacturers, manufacturers' associations and CAs stated that available scientific knowledge on pesticides is up to decision-making needs. All of these respondents had expressed the same opinion in the previous question.

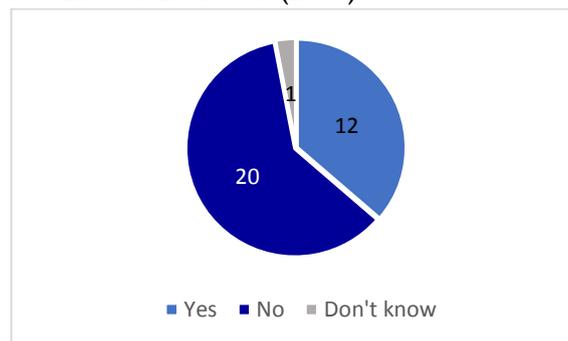
Among the respondents who stated that available scientific knowledge is not up to decision-making needs for authorisations of PPPs, two NGOs indicated that, since data generally refer to active substances, single products or single use, scientific knowledge was lacking on the total impacts and combination effects of all pesticides used in one area and over the years. The association representing the biocontrol industry mentioned that the level of knowledge of alternative PPPs varies greatly between Member States, leading to different considerations of alternatives in the authorisation procedure across countries.

Two CAs raised reservations on the level of available knowledge and the treatment of uncertainties, with one indicating that there are often grey zones in some evaluation areas. The other authority mentioned that there are uncertainties which are not taken into account in the risk assessment procedure and are therefore not expressed in the final calculated risk ratio used for decision-making. As a consequence, the interpretation of standard of proof is ultimately a policy issue rather than a scientific one.

***Do you consider that the available scientific knowledge is adequately used in the relevant decision-making procedures under the PPPR, in particular as regards approval of active substances at EU level?***

The majority of respondents considered the available scientific knowledge to be inadequately used in the approval of active substances at EU level. All NGOs and most manufacturers (individual companies) and manufacturers' associations replied negatively. Respondents who considered the available knowledge to be adequately used were largely CAs (and some of the individuals belonging to CAs). Associations representing farmers were divided on this issue (between conventional and organic agriculture).

**Figure 8: Do you consider that the available scientific knowledge is adequately used in the relevant decision-making procedures under the PPPR, in particular as regards approval of active substances at EU level? (n=33)**



Twenty-three respondents commented on their answer. Many comments made in the two previous questions have been taken into account here and in the following question, as they addressed the use of scientific knowledge in decision-making rather than its availability and/or quality.

The respondents who considered scientific knowledge to be adequately used underlined the positive role of EFSA and of the peer review process that ensures that available knowledge is used appropriately.

The use of scientific knowledge – and the issue of which types of evidence should be used – greatly divided respondents who replied 'no', between environment and health NGOs on one side, and manufacturers' associations, individual manufacturers and a few CAs on the other.

According to the NGOs, academic scientific literature is systematically disqualified, usually on the grounds that studies were not carried out according to OECD test protocols

(Including GLP), even though these studies are not suitable for GLP (such as epidemiological studies). Some of these NGOs saw this reasoning as a pretext for discarding relevant data, and proof of industry's influence on evaluation methods. Conversely, three manufacturers' associations and one large individual manufacturer indicated that scientific data from applicants were not sufficiently taken into account, due to a lack of dialogue between evaluators and applicants, the rules on admissibility of studies, and the politicisation of certain dossiers. Regarding the rules on admissibility of studies, according to a manufacturers' association and a CA, the non-inclusion of additional data provided by applicants in the course of the procedure led to the non-approval of substances that would have been approved if the additional data had been taken into account. The manufacturers' association added that, given the length of the approval procedure (three to five years), it is likely that a dossier considered complete at the time of submission is considered incomplete at the time of decision, penalising the applicant, whose additional information submitted is not admissible.

On the same issue, the consultancy estimated that, contrary to NGO statements, during the evaluation of active substances, independent studies not complying with OECD guidelines and GLP were given too much weight in the decision-making process, compared to studies carried out according to these rules. This statement was supported by one CA, which stated that scientific knowledge should be incorporated into the risk assessment only when thoroughly discussed and validated across available methodology and modelling of exposure/effects.

Another issue raised by the respondents was the use of a risk-based or hazard-based approach in the approval of active substances. One CA mentioned that the shift from a risk approach to a hazard approach in decision-making was noticeable, arguing that if hazard and risk are not weighed together, this shift could lead to lower-risk substances but higher exposure, leading to a detrimental net effect. The same authority added that in this (hazard-based approach) context it could be anticipated that highly effective PPPs will not be available as a means for correction within an IPM system.

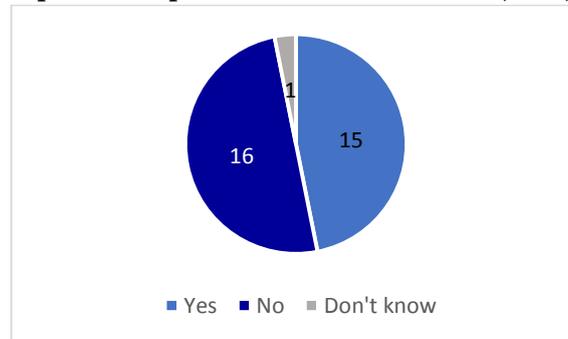
NGOs working on animal health issues and one individual manufacturer stated that the current hazard-based approach (putting aside exposure considerations) is leading to much unnecessary in-vivo testing, contrary to the EU's aim to reduce tests involving animals. The two NGOs also criticised the tendency to impose blanket requirements for additional in-vivo tests as a default approach and called for streamlining data requirements in line with the REACH Regulation and OECD guidelines.

***Do you consider that the available scientific knowledge is adequately used in the relevant decision-making procedures under the PPPR, in particular as regards authorisation of plant protection products at national level?***

Respondents are divided on the use of available scientific knowledge in the authorisation of PPPs at national level. Half of the respondents considered scientific knowledge to be inadequately used in the authorisation of PPPs at national level, while slightly less than half stated that it is adequately used. All NGOs and most manufacturers (individual companies) replied negatively. CAs and manufacturers' associations (except the association representing the biocontrol industry), however, considered scientific

knowledge to be properly used in the authorisation procedure. Associations representing farmers were divided on this issue (between conventional and organic agriculture).

**Figure 9: Do you consider that the available scientific knowledge is adequately used in the relevant decision-making procedures under the PPPR, in particular as regards authorisation of plant protection products at national level? (n=32)**



Nineteen respondents commented on their answer (four mentioning that their comments mirrored those of the previous questions). A number of these comments repeated statements made in the previous questions, and the comments that were more specific to national authorisation procedures are summarised below.

NGOs reiterated their concerns about the impartiality of the evaluation process, stating that environmental and health aspects are often underestimated at national level, as there is often no equity between the leading agricultural Ministry and the environmental (and health) Ministry in the authorisation process.

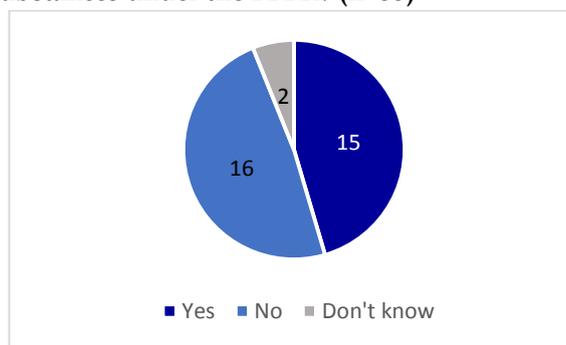
Manufacturers' associations and individual manufacturers typically commented on the administrative and organisational problems in the authorisation procedures at national level. They called for a review of authorisation procedures, in order to increase their efficiency in terms of timelines, application of the principle of mutual recognition, coordination of each zone, and harmonisation of the application of evaluation criteria by Member State authorities. According to several manufacturers' associations, the lack of trust among CAs leads to the non-application of the mutual recognition principle, as national evaluators tend to re-evaluate dossiers which were already evaluated by the zonal Rapporteur Member State. Consequently, timelines cannot be respected and the administrative burden is higher for CAs than it should be.

The association representing the biocontrol industry indicated that a separate authorisation procedure should be created for biological PPPs to ensure their approval at EU level rather than at zonal or national level. This comment is likely related to one of the organisation's previous comments on the lack of expertise in biological alternatives in many Member States.

***Do you consider that the cumulative risks posed by residues of plant protection products are adequately taken into account in the authorisation of PPPs and approval of active substances under the PPPR?***

Respondents were divided on the integration of risks posed by residue in decision-making procedures. Around half of the respondents believed that cumulative risks posed by PPP residue are not adequately taken into account in the authorisation of PPPs and approval of active substances, while the other half believed that they are. All NGOs replied negatively, while most manufacturers' associations (except the association representing the biocontrol industry) and manufacturers (individual companies) replied positively. CAs were divided (with three replying yes and three replying no), although all individual respondents belonging to CAs replied negatively. Associations representing farmers were divided on this issue (between conventional and organic agriculture).

**Figure 10: Do you consider that the cumulative risks posed by residues of plant protection products are adequately taken into account in the authorisation of PPPs and approval of active substances under the PPPR? (n=33)**



Respondents who considered the cumulative risks posed by residues to be adequately taken into account (CAs, manufacturers' associations and individual manufacturers) indicated that provisions under the PPPR and Directive 396/2005 on maximum residue levels are protective enough to avoid risks to consumers. They argued that the MRL-setting process uses conservative safety margins for individual substances (based on the highest amount of active substance residue expected in products when PPPs are applied correctly), which are sufficient to cover cumulative effects.

One CA, however, stated that no cumulative risk assessment is currently performed. In addition, one NGO mentioned that Germany will start considering cumulative risks for human health through a stepwise approach, although this will be limited to the assessment of formulated products or products in typical tank mixtures and will not, therefore, assess multiple residue exposure. Several authorities also mentioned that considering cumulative risks of residues would be complex and challenging, and would require guidance and the development of calculation methods.

NGOs (environment/health) commented generally that cumulative risks posed by residue are not considered and argued that although individual products can be found relatively safe, the cumulative impact of their residues on food and in the environment may still be unacceptable.

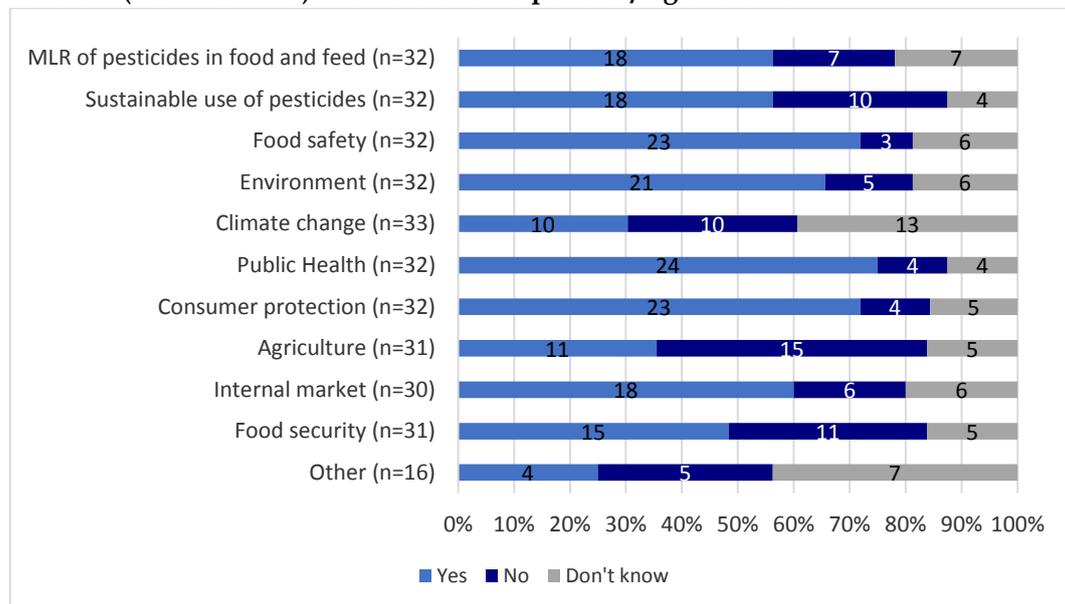
Finally, one consultancy proposed that substances belonging to the same group should be reviewed together in order to avoid discrepancies between assessments and take better account of cumulative effects.

## 2.5 Coherence

*Do you think that the policy objectives and instruments of the PPPR are coherent (not in conflict) with relevant EU policies /legislation?*

Respondents mainly observed coherence problems between the PPPR and EU agriculture policy, and to a lesser extent with food security policy and climate policy. Climate change also divided respondents, although the high number of respondents who replied 'don't know' makes it difficult to draw conclusions.

**Figure 11: Do you think that the policy objectives and instruments of the PPPR are coherent (not in conflict) with relevant EU policies /legislation on:**



The analysis of responses by type of stakeholder shows the following:

- Regarding MLRs, respondents who indicated that there are coherence issues were mostly manufacturers' associations.
- NGOs (environment and/or health) and farmers' associations considered the objectives of the PPPR to conflict with the Directive on sustainable use of pesticides. Among the manufacturers' associations, the biocontrol industry association replied 'no', unlike the others.
- NGOs (environment and/or health) and farmers' associations also indicated that conflicts existed between the objectives of the PPPR and climate policy.
- NGOs (environment and/or health), manufacturers' associations and farmers' associations considered the objectives of the PPPR to conflict with those of agricultural policy, while CAs were divided on the issue.

- A number of manufacturers (one), manufacturers' associations (two), farmers' associations (one) and individuals (one, from a CA) stated that the PPPR conflicts with the good functioning of the internal market.
- Regarding food security, respondents who found coherence issues were mostly manufacturers' associations and farmers' associations, while CAs were divided on the issue.

Twenty respondents commented on their answer, of whom four (individuals, CAs, environment/health NGOs, farmers' associations) considered the PPPR poorly aligned with the goal of the Directive on sustainable use of pesticides. One of these respondents (user farmer association) added that to create a more supportive environment that stimulates the development of sustainable plant care strategies, EU policies such as the EU Directive on sustainable use of pesticides must clearly complement the EU rules on plant health care.

Three respondents (individual manufacturers, manufacturers' associations, CAs) stated that the hazard-based approach laid down in PPPR is contrary to many other pieces of legislation, which are risk-based. According to the individual manufacturer, this affects agriculture output, contrary to the objectives of food security based on optimisation of resources. Similarly, one farmers' association indicated that, according to the General Food Law principles, food safety regulation is based on risk, with the hazard-based PPPR being the only exception. This inconsistency leads to disjointedness with other policies, such as agriculture, food security and official controls. This is clearly not in line with the objectives of more liberalised trade and international agreements.

According to one individual from a CA, the handling of endocrine disruptors in the PPPR conflicts with the precautionary principle (as the burden of proof is now on the authorities' rather than on the applicants' side).

One environment/health NGO stated that the policy objectives and instruments are coherent, but issues of coherence arise at the implementation phase.

One CA stated that the objectives of the PPPR should be coherent with the objectives of the Water Framework Directive.

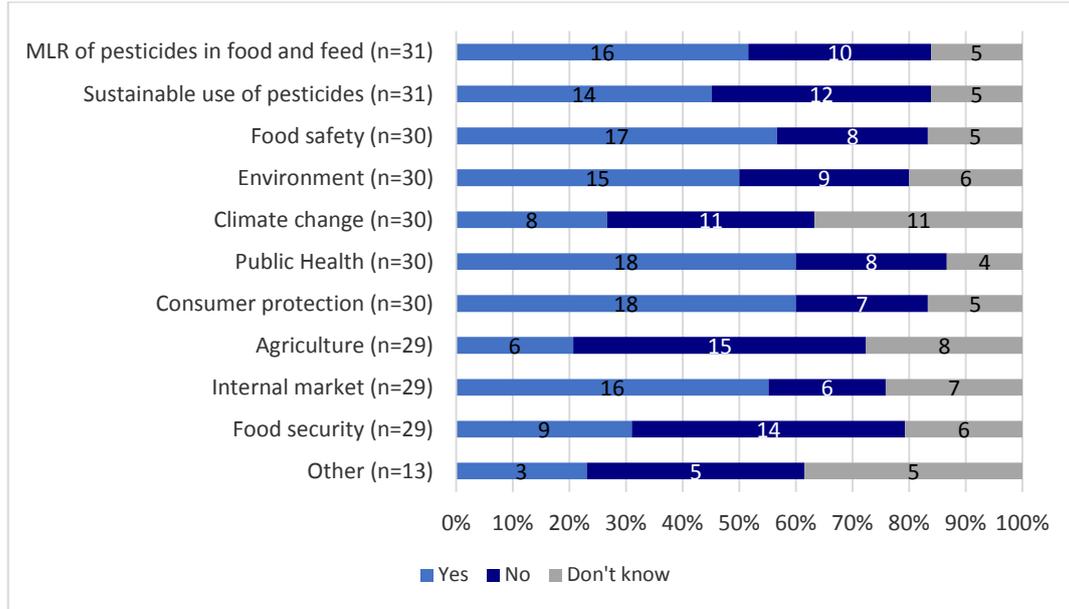
According to one manufacturers' association, the PPPR does not adequately address pesticide drift contaminating organic production, thereby directly contradicting EU organic and baby food regulations.

According to one CA, the PPPR is not entirely coherent with other chemicals legislation, such as the REACH and Biocidal Product Regulation, which have a different approach to defining key common concepts (making available and placing on the market) on the application phase (at import for REACH, when placed on the market for PPPs, when made available for Biocides). REACH is the only legislation that requires a legal entity within the EU (e.g. the only representative under Article 8).

*Do you think that the day-to-day implementation of the provisions of the PPPR are coherent (not in conflict) with relevant EU policies?*

Regarding the day-to-day implementation of the legislation, respondents also found inconsistencies between the PPPR and agriculture and food security policies. As in the previous question, the issue of climate change divided respondents but the large number of respondents who replied 'don't know' makes it difficult to interpret this result. The number of respondents who replied negatively is, in general, higher than in the previous question for all suggested policies/legislation.

**Figure 12: Do you think that the day-to-day implementation of the provisions of the PPPR are coherent (not in conflict) with relevant EU policies on:**



The analysis of responses by type of stakeholder showed very similar results to the previous question. However, while NGOs (environment and/or health) did not consider the objectives of the PPPR to conflict with food safety, environmental, public health and consumer policies, the environmental NGOs indicated that the day-to-day implementation of the PPPR conflicted with those policies. Contrary to other manufacturers' associations, the association representing the biocontrol industry was of the same view as NGOs on these issues. Concerning agriculture, the internal market and food security, replies are relatively similar to the previous question.

Twenty-one respondents commented on their answers. Three respondents (two manufacturers' associations, one individual manufacturer) considered the implementation of the provisions of the PPPR to conflict with EU policies on agricultural competitiveness and the functioning of the internal market. Regarding agriculture, the PPP does not help to provide farmers with the tools they need to fight against pests and diseases and the EU agriculture goals of being competitive and productive are unlikely to be met. Regarding the harmonisation of the internal market, the lack of trust among Member State authorities, and the non-application of the principle of mutual recognition leads the system to increase the administrative burden, duplication of work and technical barriers between Member States. Other policies, such as environment or public health, are guaranteed with the application of hazard-based criteria, but they would also be guaranteed with a risk-based approach that would allow more solutions to be made available to farmers.

According to one individual from a CA, in the PPPR, protection of biodiversity does not take place in practice. Environmental protection levels are not clearly defined and there is no reference to the Water Framework Directive and Nature Directives, so that levels of protection under the PPPR may be lower (less protective) than those required by other legislation. This respondent stressed that climate change is not considered in the PPPR practice. The goals of the Directive on sustainable use of pesticides are not reflected in the approval criteria. Instead of supporting a shift to real sustainability, the PPPR practice is strongly aimed at protecting 'chemical-based agriculture'.

One manufacturers' association mentioned that farmers' ability to use PPPs also impacts on the safety of crops (e.g. mycotoxins), while the lack of adequate PPPs may affect public health and consumer protection. At EU level, there is no lack of food but whatever is lost as food in the EU due to lack of adequate pest control tool weighs in the global agricultural output.

One environment/health NGO respondent stated that the implementation of the PPPR is not in line with the precautionary principle, which has been insufficiently applied for both active substances and PPPs. There have been delays in the implementation of provisions to secure human and environmental well-being (e.g. cut-offs like PBTs and EDCs). On the other hand, provisions to secure pesticide use and commercial viability (e.g. emergency authorisations) have been implemented at such a high level that it undermines health and environmental protection goals and hinders innovation, in view of non-chemical plant protection and/or low-risk pesticides.

One animal welfare NGO considered the PPPR information/testing requirements by EFSA to have fallen behind the animal welfare and 3R requirements of Directive 2010/63/EU on animal experiments.

One CA indicated that the approval criteria and the water quality standards derived for surface water (based on the PPPR and the Water Framework Directive, respectively) are not aligned. In practice, it happens that the Water Framework Directive standards are exceeded even when the product is used according to the authorisation. This creates problems when maintaining the quality of the surface water. This is reinforced by the confidentiality of the approval dossier, which prevents the exchange of toxicological endpoints between both frameworks. Also, the analysis methods available in the approval dossier are often inadequate for analyses of surface water up to the level of the water quality standard.

Finally, one farmers' association highlighted the importance of a consistent approach between different pieces of legislation (PPPs, biocides, contaminants), as some substances fall under different categories, leading to different requirements for similar purposes. The respondent stated that this is especially the case for rodenticide control in mice, or biocides used for disinfection in IPM.

## 2.6 Effectiveness

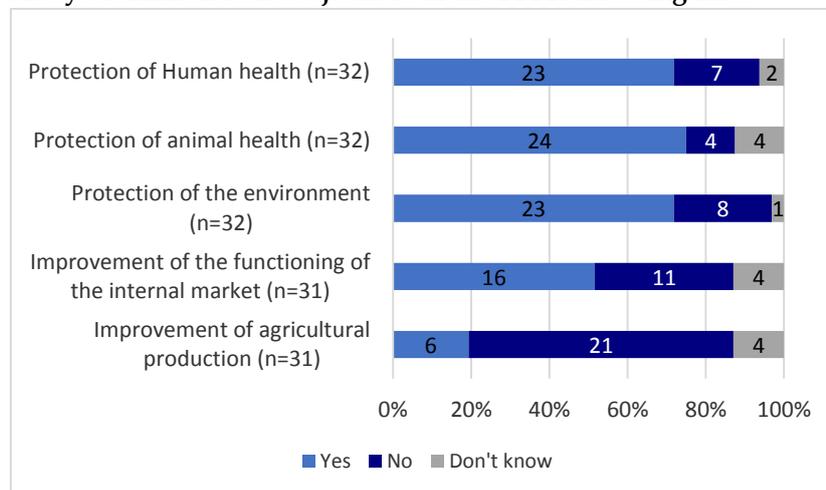
### *Do you think that the objectives of the PPPR are being met?*

The majority of respondents considered the objectives of protection of human and animal health, and protection of the environment to be met. However, NGOs (environment and/or health) and associations representing the interests of organic food and farming and biocontrol generally considered the PPPR ineffective at protecting human health and the environment.

Respondents were more divided on the functioning of the internal market, where only a slight majority found that the objective was met. PPP producers' associations (and individuals related to them), and associations of users and farmers largely felt that the objective was not met. It should be noted, however, that manufacturers (individual companies) who responded to the survey disagreed with manufacturers' associations on this particular point, with four out of five considering the PPPR to have improved the functioning of the internal market.

Finally, the majority of respondents (made up of manufacturers' associations (five), individual manufacturers (two) and farmers' associations (two), half of the CAs (three), some NGOs (two), all individuals (six), and the consultancy) considered the PPPR to have failed to meet its objective of improving agricultural production. Of those that stated that the PPPR had succeeded in meeting its objective of improving agricultural production, half were manufacturers (individual companies - three), others were NGOs (environment/health - two) and one was a CA.

**Figure 13: Do you think that the objectives of the PPPR are being met?**



Seventeen respondents commented on their answer, with most comments relating to the two objectives that most stakeholders thought were not met, i.e. improving agricultural production and the good functioning of the internal market.

Concerning the improvement of agricultural production, five stakeholders (an environmental/health NGO, CAs/individuals belonging to CAs, associations representing the biocontrol industry and organic food and farming) argued that the

Regulation does not promote the development of IPM-oriented agriculture, thereby contradicting the objectives of the Directive on sustainable use of pesticides and failing to improve agricultural production in the long-term. Some of them called for a greater focus on the development and marketing of low-risk biological tools.

A few manufacturers' or farmers' associations, together with the consultancy, argued that the objective of improving agricultural production was not met and that the competitiveness of the agricultural sector was damaged, because the number of available active substances has been reduced and new active substances and PPPs are entering the market very slowly. As substances banned in the EU are authorised in third countries, this leads to a long-term loss of competitiveness for the EU in comparison with third countries. One respondent added that the reduction of available active substances also led to increased pesticide resistance problems – as farmers are overusing the same substances – which negatively impacts productivity. The same respondent also mentioned that the costs linked to approvals and renewals of approvals of existing active substances prevents manufacturers from investing in research and development and thus hinders innovation.

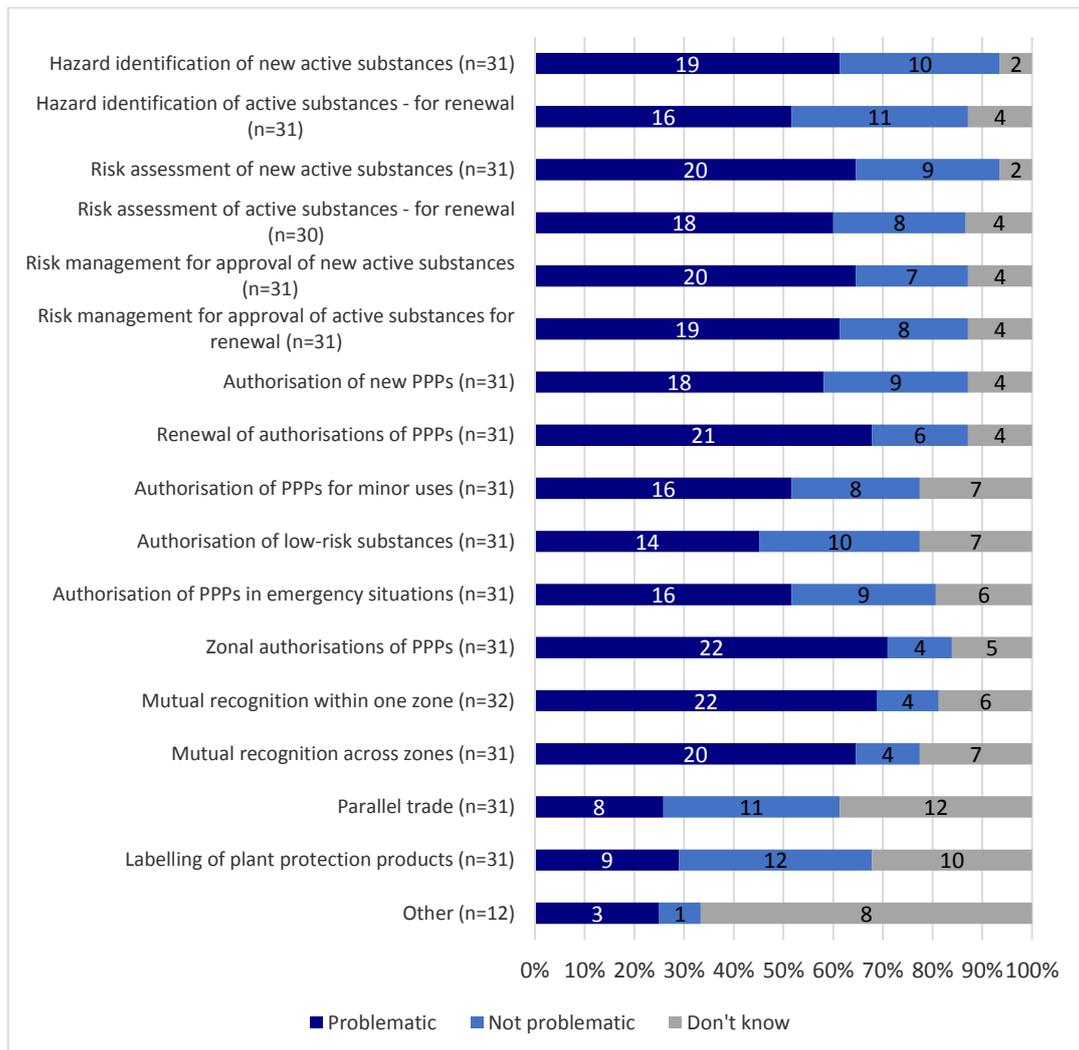
The same manufacturers' and farmers' associations stated that inefficiencies in the authorisation procedures of PPPs (delays in zonal authorisations, Member States not using mutual recognition efficiently and redoing evaluations or imposing national requirements) presented an obstacle to the proper functioning of the internal market.

One animal health NGO argued that the objective of protecting animal health was not met, as the approach to testing still relies on the use of animals. The NGO suggested that it should be addressed through the development of a work plan to phase-out the use of animals under this Regulation.

***Please assess the day-to-day implementation of the following instruments under the PPPR***

With the exception of parallel trade and the labelling of plant protection products, most respondents considered the day-to-day implementation of the different instruments under the PPPR problematic.

**Figure 14: Please assess the day-to-day implementation of the following instruments under the PPPR:**



Some stakeholder groups had relatively similar patterns of answers for all instruments:

- With the exception of mutual recognition (both within and across zones), while half of the CAs indicated that implementation was problematic, CAs generally stated that other instruments are not problematic (at least half of the authorities replied 'not problematic').
- Between half and two-thirds of manufacturers' associations found the implementation of all instruments problematic. Manufacturers (individual companies) are split (two replied problematic, two replied not problematic, and one did not reply) in respect of all instruments related to the approval of active substances, as well as emergency authorisations and labelling. However, the majority (three out of four) considered all instruments related to the authorisation of PPPs to be problematic (implementation of authorisation (and renewal) of PPPs, authorisations for minor uses, zonal authorisations, and mutual recognition (both within and across zones)). All manufacturers who provided an answer to this question (i.e. four) did not consider provisions on parallel trade problematic.

- Environment/health NGOs found the implementation of all instruments problematic, except hazard identification of new active substances and candidates for renewal. All NGOs (environment/health) replied 'don't know' regarding the provisions on parallel trade and labelling.
- Both farmers' associations agreed on most of the instruments, finding the implementation of most instruments problematic, with the exception of the provisions on labelling, which they both found not problematic. They only disagreed on minor use and emergency situations, where the association representing organic food and farming replied 'not problematic', unlike the other association, and on parallel trade, where the association representing organic food and farming replied 'don't know'.

Twenty-six respondents commented on their answer, typically only on some of the instruments listed in Figure 14. Their comments are summarised below.

#### *Approval of active substances*

- Hazard identification and risk assessment

Regarding the approval of active substances, NGOs (mostly environment/health) commented that the industry has a major influence on hazard identification and risk assessment. Consequently, one NGO suggested that it is very important to scrutinise methodologies used in risk assessment, including by whom they were developed, implying that the role of the International Life Sciences Institute should be investigated in this respect. One NGO added that the effectiveness of hazard identification is hindered when guidelines are missing, as in the case of EDCs. The same NGO stated that companies should not be responsible for risk assessment but should bear the costs. According to the NGO, manufacturers could contribute to a publicly managed fund responsible for allocating contracts to independent laboratories, thus ensuring the independence of the evaluation.

One farmers' association and one manufacturers' association mentioned that the hazard-based approach is not the most accurate, as it does not consider on-field conditions. According to this respondent, the risk-based approach would be better.

On a similar note, an animal health NGO stated that the emphasis on hazard assessment rather than risk assessment has had significant impacts on animal welfare and that the requirements of Directive 2010/63/EU on animal experiments are not given sufficient consideration in the development of agency guidance or test orders. Another animal health NGO also stated that hazard identification and risk assessment should be improved in order to avoid unnecessary tests on animals. It proposed the establishment of a roadmap for the development and implementation of non-animal integrated testing approaches.

The consultancy and one individual (from a CA) indicated that the lack of leadership during approval procedures, especially regarding hazard identification, risk assessment, and hazard classification, makes the procedure complex and chaotic, because different opinions are issued by the authorities involved in the process (European Commission, Member States' authorities, EFSA and ECHA).

- Approval (and renewal of approval) procedures

One CA suggested that because the review of each active substance individually on a fixed timetable leads to inefficient and piecemeal decision-making, which cannot properly take into account cumulative impacts of approvals, the current renewal system should be replaced by the review of a group of substances, reducing the administrative burden and enabling more informed decision-making.

The same authority indicated that rules disallowing the submission of additional data by applicants during the course of the procedure could, in practice, prevent applicants from clarifying points of concern and lead to unnecessary non-approval/renewal decisions.

One CA suggested that the approval of active substances, basic substances and the setting of MRLs should be done only at EU level, in order to ensure uniform assessment for all substances, without the inclusion of Member States as RMS and co-RMS. According to the respondent, the costs of approving new active substances and the costs of renewal of approval of active substances would be considerably lower under such a system.

Two CAs suggested that more coordination between the PPPR and the Biocidal Products Regulation (BPR), in particular on exchanges of studies and evaluations, could reduce the number of animal tests, and lower the workload and administrative burden for the CAs. One option could be to have one single procedure for PPPs and BPs.

- Approval of low-risk substances and PPPs containing them

Three respondents suggested facilitating the placing on the market of low-risk substances. One CA stated that since possible low-risk substances are treated from the beginning as high-risk, the costs for the dossiers and the approval process are often too high for the niche market they represent. One farmers' association indicated that fast-track procedures for PPPs containing low-risk substances are not respected, while an animal health NGO suggested that there should be incentives for the use of low-risk active substances.

However, an individual (from a CA) expressed concern about the tendency to make low-risk criteria as flexible as possible and to consider an increasing number of substances as low-risk, although they are not.

- Approval of naturally occurring active substances

An association representing organic food and farming indicated that the approval of naturally occurring substances as active substances meets serious difficulties in risk assessment because criteria are not adapted to those substances. The respondent suggested that a central evaluation of naturally occurring active substances, separate to the approval procedures for other substances, would be more effective, provided the assessment is carried out by specialised evaluators.

#### ***Authorisation of PPPs***

Several manufacturers' associations, farmers' associations, individual manufacturers, and CAs reported problems in the day-to-day implementation of the zonal authorisations procedures for PPPs, namely:

- Flaws in the application of the principle of mutual recognition: Member States reevaluate PPPs already evaluated by other Member States, either because they do

not trust the evaluations by other authorities or because they impose specific national requirements for the authorisation of PPPs in their own country. This is considered a major problem by several manufacturers' associations, individual manufacturers and farmers' associations, as it leads to duplication of work and a greater administrative burden, as well as increasing the timeframes for authorisation of PPPs.

- Delays in processing applications for authorisation of PPPs: these delays, according to manufacturers' associations and individual manufacturers, defer the reevaluation of PPPs according to new scientific evidence, and make the EU less attractive for innovative research and development. They remain, therefore, a major concern.
- Delays in the renewal of authorisations of PPPs: an authority and a manufacturers' association stated that deadlines set out in Article 43 of the Regulation (e.g. the applicant should submit an application for renewal of the product authorisation within three months of the approval of the active substance) are very difficult for applicants to meet. The authority then stated that this causes delays in the whole procedure and creates a high administrative burden for authorities.
- Problems related to the submission of additional data in renewal of authorisations of PPPs: one manufacturers' association highlighted that the PPPR leaves the responsibility to decide what data is necessary to the applicant or authorisation holder, which leads to misunderstandings, the submission of unnecessary data, and the cancellation of authorisations on the grounds that data – unanticipated at the time of the submission of the dossier – is missing.

One CA suggested that the detailed procedures set out in the Regulation make it difficult to make changes and address new developments, such as improvements to operational efficiency, or to introduce new timelines for increasingly complex assessments. The respondent therefore proposed that more procedural aspects should be detailed in subsidiary Commission Regulation, which could be amended when needed. This could apply to all areas of the PPPR.

#### *Parallel trade*

Two respondents (manufacturer's association and a CA) mentioned that the rules governing parallel trade should be improved. One of the respondents stated that the current rules allow too many opportunities for misuse and abuse, and create opportunities for the introduction of illegal pesticides.

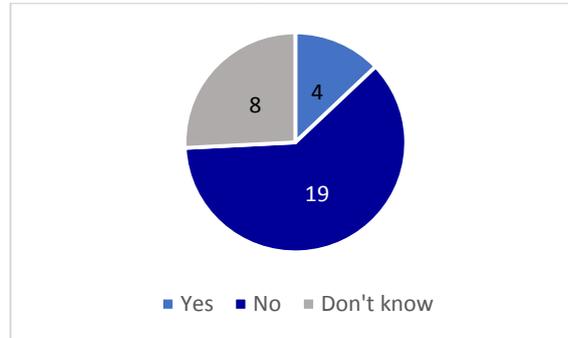
Comments on minor uses and emergency authorisations have been taken into account in the question on minor use (below) and in the question on impacts, respectively.

#### *Do you consider that the authorisation process for plant protection products for crops with minor uses is correctly implemented?*

The majority of respondents considered the authorisation process for PPPs for crops with minor uses incorrectly implemented. The four respondents who replied positively were national CAs (including one individual belonging to a national CA).

Respondents who replied negatively to the question were invited to indicate the areas needing to be improved in the implementation of the PPPR to ensure a more efficient and less expensive authorisation for minor uses.

**Figure 15: Do you consider that the authorisation process for plant protection products for crops with minor uses is correctly implemented? (n=31)**



*If no, what are the areas to be improved in the implementation of the PPPR to ensure a more efficient and less expensive authorisation for minor uses?*

Eighteen respondents replied to this question. According to five respondents from different stakeholder groups (one manufacturers' association, one individual manufacturer, one farmers' association, one consultancy and one individual from a consultancy), a list of major and minor crops should be established at EU level, or, at least, there should be more coordination between Member States. Currently, each Member State has its own list of minor crops, some of which are not publicly available. This creates problems in zonal authorisations when the same crop is considered a major crop in some countries and a minor crop in others (one respondent gave the example of oilseed rape). Two respondents (a farmers' associations and a CA) also supported the establishment of a European authorisation of PPPs for minor uses, instead of the zonal authorisation in place.

Two manufacturers' associations and one CA suggested that specific authorisation procedures should be established to make PPPs more available for minor uses, as current procedures in certain Member States are not working properly. Two respondents (one manufacturers' association and one farmers' association) also mentioned that improving the implementation of mutual recognition would make applications much cheaper and would therefore encourage potential applicants to request authorisations of PPPs for minor crops.

Three respondents (two manufacturers' associations and one individual manufacturer) indicated that the Minor Use Coordination Facility, created by the Commission, is not sufficient and lacks the resources to support the availability of PPPs for minor use or to invest in necessary data gathering for new authorisations.

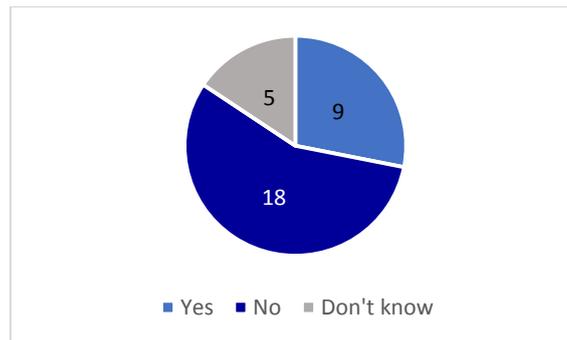
Finally, two environmental NGOs stated that the authorisation process for PPPs for minor uses should be limited to either a small area or to a specific crop (and not a general one). One individual (from a CA) stated that the applicant should submit data for at least some

minor crops in the authorisation dossier to enable extrapolation or more accurate risk assessment for minor uses.

***Do you consider that Member States adequately enforce the PPPR at national level?***

The majority of respondents considered that Member States do not adequately enforce the PPPR at national level. The respondents who replied positively were mainly national CAs (including an individual belonging to a national CA).

**Figure 16: Do you consider that Member States adequately enforce the PPPR at national level? (n=32)**



Twenty respondents commented on their answers, with several pointing to Member State difficulties in implementing the legislation, but not enforcement as such (which refers to inspections/controls and sanctions).

Two respondents (environment/health NGOs) considered enforcement to be neglected, stating its belief that voluntary controls by industry fail to work in most cases. Another NGO specified that there are not enough controls on residue in imported products.

Two respondents (consultancy and an individual belonging to a consultancy) considered enforcement to be sufficient. Implementation by Member States remains the main concern, due to lack of resources to implement the PPPR and comply with deadlines. One individual manufacturer stated that CAs do not have sufficient numbers of experienced staff.

One CA mentioned that enforcement is increasingly difficult to achieve, due to excessive workload. Another CA considered the level of compliance to be relatively high in general, thus enforcement is adequate but can always be improved.

***What are the areas where improvement is needed related to the enforcement of the PPPR by Member States?***

Of the 22 respondents replying to this question, 16 did not comment on improving enforcement but on the implementation of the PPPR (e.g. more technical and human resources for risk assessment and risk management in CAs and concerns with non-compliance with deadlines).

Three NGOs suggested that controls should be carried out by a fully independent institution on a regular basis and that sanctions (fines, shutdown) should be imposed in case of non-compliance. Two respondents (individual, NGO) indicated that there should be more control of imports because, compared to the strictness of requirements for authorised PPPs, controls on parallel imports are lax and almost non-existent. One CA suggested maintaining a high level of marketing, as this is an effective way to enforce compliance downstream. The same respondent also recommended more frequent analysis of PPPs to grasp the scope of illegal trade of PPPs, as well as more communication between CAs and end-users.

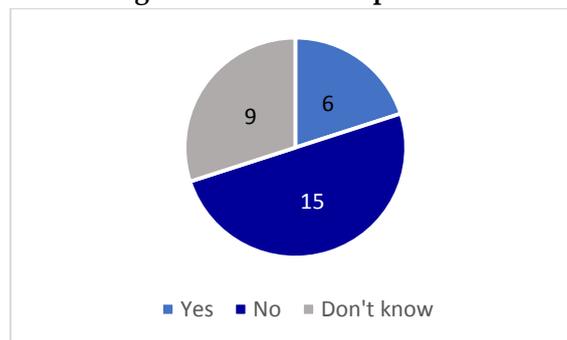
***Is there due cooperation between the different enforcement (competent) authorities within a Member State and between Member States?***

Seventeen respondents replied to this question, with most comments relating to cooperation in the implementation of authorisation procedures rather than to enforcement as such. All respondents stressed the need for improved cooperation among enforcement authorities within and between Member States. One manufacturers' association stated that SilverAxe operations demonstrated the lack of cooperation between enforcement authorities but resulted in a framework that enhanced such cooperation. According to this respondent, this initiative deserves expansion and follow-up. One CA suggested that an enforcement coordination body could be established for the enforcement of the PPPR, based on the model of the REACH Enforcement Forum, to promote cooperation and the sharing of best practice between Member States.

***Do you consider that Member States and the Commission have made enough efforts to limit the trade of illegal and counterfeit pesticides in the EU?***

The majority of respondents considered Member State and Commission efforts to be insufficient to limit the trade of illegal and counterfeit pesticides in the EU. The respondents who replied positively were mainly national CAs.

**Figure 17: Do you consider that Member States and the Commission have made enough efforts to limit the trade of illegal and counterfeit pesticides in the EU? (n=30)**



Sixteen respondents commented on their answers. Five respondents indicated that measures against trade in illegal and counterfeit products are insufficient, with environment/health NGOs (two respondents) taking a stronger stance, stating that there is little or no attention paid to illegal and counterfeit pesticides in Member States. Two

individual manufacturers and one consultancy believed that, although the situation has improved, trade in illegal and counterfeit products does not get the attention and resources it deserves, as Member States' resources are focused on PPP authorisations.

One manufacturers' association acknowledged the work done on illegal and counterfeit pesticides at the EU level, such as the SilverAxe<sup>78</sup> operations involving an increasing number of Member States and enforcement authorities (inspectors, police, customs) and improving cooperation and efficiency in enforcement.

In addition, DG SANTE initiated a coordination between Member State enforcement authorities leading to better coordinated and intensified enforcement. According to one CA, the work within SilverAxe is effective, in view of the numbers of PPPs captured.

Two respondents (manufacturers' associations) indicated that enforcement could be improved through the implementation of best practice in sea ports, better cooperation between the police, customs and pesticides and food safety authorities, the increase of Member State resources and farmers' awareness on this issue. In addition, one CA suggested strengthening controls on parallel trade products.

***What are the areas to be improved in the implementation of the PPPR to limit the trade of illegal and counterfeit pesticides in the EU? (please specify)***

Seventeen respondents answered this question and suggested the following areas of improvements:

- More control at the borders and follow-up cases (individuals, individual manufacturers).
- Focus on parallel imports and controls at ports (individuals, individual manufacturers).
- Development of a mutual alert system (individuals).
- Prohibition of parallel trade and parallel traded products (manufacturers' associations).
- Obligation for manufacturers of active substance to insert a 'marker compound' in their active substances. Analytical methods to determine this marker should be made available to the CAs in charge of quality control of PPPs (individual from one CA).
- Obligation to control all packaging after use and to include a single code on the package (consultancy).
- Development of a pesticide tax and labelling (environmental/health NGO).
- Adoption of implementing rules for official controls (manufacturers' associations).
- Clarification of definitions in PPP-related legislation identified as currently subject to different interpretations by Member States (manufacturers' associations).

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<sup>78</sup> See Europol press release of SilverAxe second operation, available at: <https://www.europol.europa.eu/newsroom/news/122-tons-of-illegal-or-counterfeit-pesticides-seized-during-operation-silver-axe-ii> (accessed in February 2018).

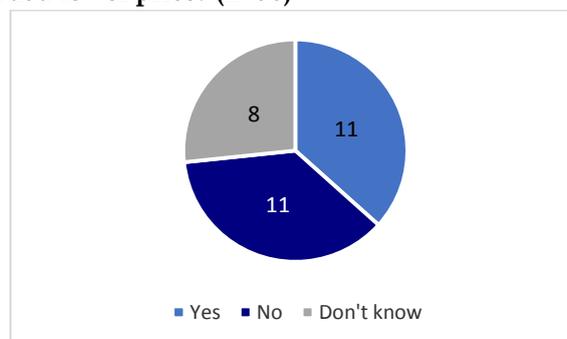
- Bridging legislative gaps with an EU database for PPP authorisations (manufacturers' associations).
- Enhancing awareness and knowledge via EU and national training (manufacturers' associations).
- Long-term international cooperation with the non-EU countries most frequently pointed out as a source of illegal PPPs (manufacturers' associations).
- Obligation for transport operators to require authenticated identification of their customers (manufacturers' associations).
- Improvement of national control authorities' cooperation (manufacturers' associations, individual manufacturers).
- Proportional and harmonised sanctions against criminals (manufacturers' associations).
- Guidance on the implementation of parallel trade to reduce opportunities to misuse the system (manufacturers' associations).
- Development of enhanced support for project similar to SilverAxe (manufacturers' associations).
- Simplify and unify regulation of biological inputs, agree on functional definitions and label claims (manufacturers' associations).
- Enforcement authorities should be entitled to test the imported batches of PPPs (CA).

## 2.7 Efficiency

*Could the current results (stemming from the implementation of the PPPR) have been achieved at a lower price?*

Respondents are divided on the efficiency of the PPPR, with equal numbers believing that the current results both could and could not be achieved at a lower price. Almost one-third of respondents provided no opinion (either by not answering or replying 'don't know'). Respondents stating who that the results could not be achieved at a lower cost were environmental NGOs, some CAs and some manufacturers (individual companies), while those indicating that the results could be achieved at a lower cost were manufacturers' associations, animal welfare NGOs, a small number of authorities (including individuals belonging to CAs) and one farmers' association.

**Figure 18: Could the current results (stemming from the implementation of the PPPR) have been achieved at a lower price? (n=30)**



Twenty-one respondents commented on their answer. Manufacturers' associations, individual manufacturers (companies) and the consultancy identified two areas where efficiency could be gained by streamlining authorisation procedures – the placing on the market of PPPs and renewals of active substances and PPPs. As these respondents already stated in previous questions, efficiency could be gained in the implementation of authorisation decisions if mutual recognition was better implemented, thus avoiding duplication of evaluations by different Member States. Two respondents (manufacturers' associations) added that there are opportunities for more cooperation between zonal rapporteurs in PPPs evaluations, e.g. carrying out one single evaluation for all zones for elements of the dossier that are common to all Member States, such as chemistry or analytical methods. Regarding renewal procedures for active substances and PPPs, several respondents (manufacturers' associations, individual manufacturers (individual companies) and one consultancy) stated that procedures could be streamlined, pointing to the high number of new studies requested to support the renewals of active substances that have been on the market for the long time, as well as the systematic re-evaluation of studies that were already evaluated during the approval procedure. These inefficiencies lead to unnecessary administrative burden for authorities and applicants. The same respondents questioned the efficiency of the provisions of Article 43 on the renewal of authorisation of PPPs, highlighting, for example, the burdensome nature of the repeated evaluation of the product every time one active substance contained in the product is under renewal. This burden is imposed on both authorities and applicants, in particular for products containing several active substances, as the dossier must be updated every time. According to the same respondents, streamlining these procedures would enable authorities to focus resources on new product authorisations, minor uses and illegal trade, all of which need more investment.

Three CAs mentioned that the increasing complexity of risk assessment methodology (and guidance) for approvals of active substances creates high administrative burden for Member State authorities without always having proven benefits for the protection of health and the environment. Guidelines for risk assessment have reached a high level of complexity, making their application in harmony with other Member States and EFSA very resource intensive for authorities, causing difficulties in complying with the timelines set in the Regulation and leading to complaints from applicants that the predictability of the evaluation decision is decreasing. One authority recommended that changes to guidance undergo an impact assessment to ensure that they are not disproportionate for authorities and are relevant for the purpose of protecting health and the environment. Another authority suggested that risk assessment and management should focus on the elements critical for decision-making. The third authority, however, mentioned that costs for CAs will decrease over time, as more harmonisation is reached.

The two NGOs focusing on animal health indicated that efficiencies could be gained by shifting the current hazard-based approach to a risk-based approach, which would lead to a significant number of avoided tests. A better data-sharing system, fostering cooperation between companies requesting authorisation for the same substances, and a case-by-case discussion among CAs on data requirements could also reduce the number of tests performed and eventually reduce costs.

CAs and individuals belonging to CAs (10 respondents) were asked to answer the following two questions:

***How would you assess the enforcement costs (stemming from the day-to-day enforcement of the PPPR) for your authority?***

Three respondents replied that costs were high or very high, three stated that costs were reasonable, and three replied 'don't know'.

Four CAs and individuals belonging to authorities commented on their answers, two to say that the authority is not responsible for enforcement (one authority and one individual). The other two (CAs) referred to implementation costs. One authority (which had stated that enforcement costs are reasonable) specified that costs could eventually become high or very high, given the number of PPPs to be evaluated per year. The other authority indicated that EU standards were helpful to reduce costs.

***Do you consider that your authority is equipped with due resources (relevant procedures, funding, staff, available/accessible expertise, technical equipment) to adequately enforce the PPPR at national level?***

Five respondents stated that their authority did not have adequate resources, three stated that they did, while two replied 'don't know'.

Two CAs (responding on behalf of the authority) commented on their answer. One mentioned that small Member States do not have sufficient numbers of qualified and experienced staff to carry out all of the procedures laid down in the Regulation efficiently, and to comply with deadlines. The other authority mentioned that the impact is underestimated.

Manufacturers' associations, manufacturers (individual companies) and individuals belonging to one of the two groups (12 respondents) were asked to answer the following two questions:

***How do you assess the compliance (regulatory and administrative) costs stemming from the implementation of the PPPR?***

Seven respondents (five manufacturers' associations, and three manufacturers/individual companies) indicated that compliance costs were high or very high, two stated that the costs were reasonable, and one replied 'don't know'. Two respondents (one manufacturer and one individual from a manufacturer) considered the costs to be reasonable, while the rest of the respondents either replied 'don't know' or did not provide an answer.

Four manufacturers' associations and four manufacturers (individual companies) commented on their answers. Two manufacturers' associations (who said compliance costs were very high) argued that the PPPR greatly increased the costs of placing PPPs on the market, as well as the time to market new PPPs. As a result, the number of new substances for which a dossier has been submitted is low (55 since 2011) and the number of new substances that have PPP authorisation and have therefore reached the market is even lower (eight since 2011). Another manufacturers' association mentioned that regulatory costs for placing a PPP on the market are particularly high for SMEs.

One manufacturer (individual company) stated that compliance costs are high but not unreasonably high for new active substance approval and new PPP authorisations, given the importance of ensuring high standards of human and environmental protection. However, the respondent considered the compliance costs for renewal of approval of active substances and re-authorisation of PPPs too high for applicants and CAs, such that repeated high investments are not justified. The same manufacturer also stated that data requirements for risk assessment should remain reasonable, and that any change in the guidance should undergo an impact assessment before adoption.

***In your opinion, are the relevant costs to get the approval of a chemical substance a barrier to innovation and development of new PPPs?***

Six respondents (four manufacturers – three companies and one individual from a company – and two manufacturers’ associations) considered the costs to obtain approval of a chemical substance to present a barrier to the development of new PPPs. Three respondents replied that costs are not a barrier (two manufacturers’ associations and one manufacturer/individual company), while one respondent replied ‘don’t know’.

***How the compliance costs could be reduced while still achieving an efficient authorisation process ensuring the protection of public health and the environment?***

Five manufacturers’ associations and two manufacturers (individual companies) responded to this question, generally repeating some of the elements already mentioned in previous questions, namely that costs reduction can be achieved through:

- Greater reliance on the weight of evidence and on risk assessment rather than hazard assessment.
- Increased cooperation and work-sharing between Member States within and across zones for PPP authorisations.
- More efficient implementation of mutual recognition.
- Introduction of requirements for data-sharing between applicants.

On the last point, one manufacturer (individual company) proposed a ‘Data Call-In approach’ for the renewal of approval of active substances, where the demand for investment in new studies would be specified in advance and the focus of the re-evaluation defined in a mandate (e.g. evaluation of safety to pollinators, and resident and bystander exposure). Additional dossier elements and authority evaluations would then concentrate on these aspects. This approach would facilitate the creation of industry ‘task forces’, thus reducing the duplication of tests by different applicants.

One manufacturer’s association proposed that lower requirements should be introduced for naturally occurring substances. In the previous question, one manufacturer (individual company) had also suggested that fees should be lower for biological PPPs, as it is in the US.

## **2.8 Impacts**

The majority of respondents considered the PPPR to have had a generally positive impact on human and animal health, the environment and consumers. However, while

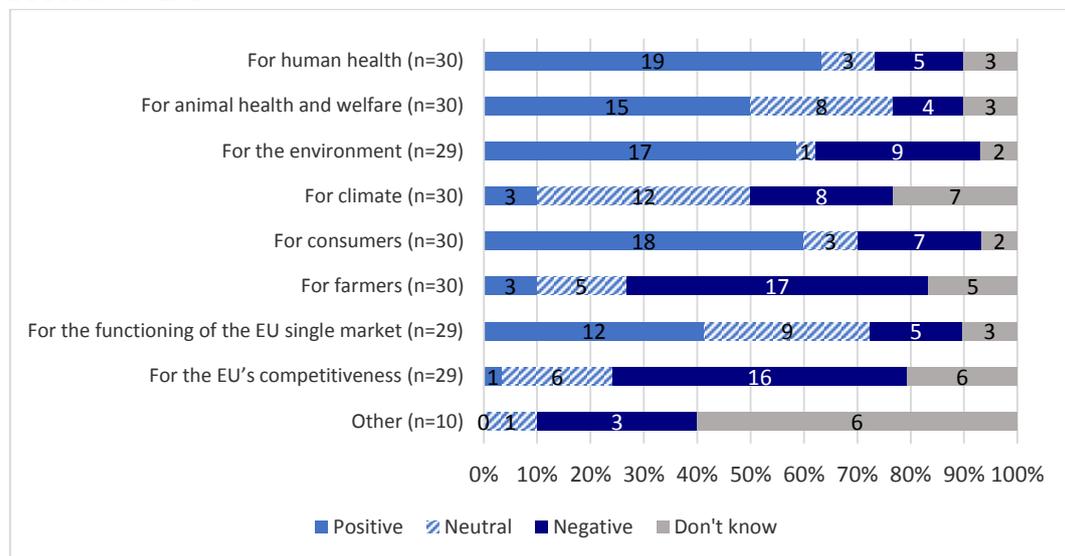
manufacturers' associations (except for the association representing the biocontrol industry), manufacturers, and CAs were generally positive (and neutral on climate), NGOs considered the PPPR to have had a negative impact on human health, the environment, climate and consumers. Farmers' associations were divided on these impacts, with the association representing organic food and farming stating that environmental and climate impacts are negative, while the association representing conventional agriculture considered the impacts on environment, health and consumers to be generally positive.

Respondents were more divided on the impacts of the PPPR on the functioning of the internal market. CAs (and some individuals belonging to CAs), NGOs and one farmers' association generally considered the impacts to be positive, while most manufacturers and manufacturers' associations were neutral or considered the impacts to be negative.

The majority of respondents felt there had been a negative impact on farmers and competitiveness. Farmers' associations, manufacturers (individual companies), manufacturers' associations, and some CAs (or individuals belonging to CAs) considered the impact on farmers to be negative. Other stakeholders were neutral, with only a small number of CAs stating that the impacts on farmers were positive.

Manufacturers (individual companies), manufacturers' associations, individuals and some CAs believed the PPPR to have had a negative impact on EU competitiveness. Other stakeholders were mostly neutral.

**Figure 19: How would you assess the impacts stemming from the implementation of the PPPR as a whole?**



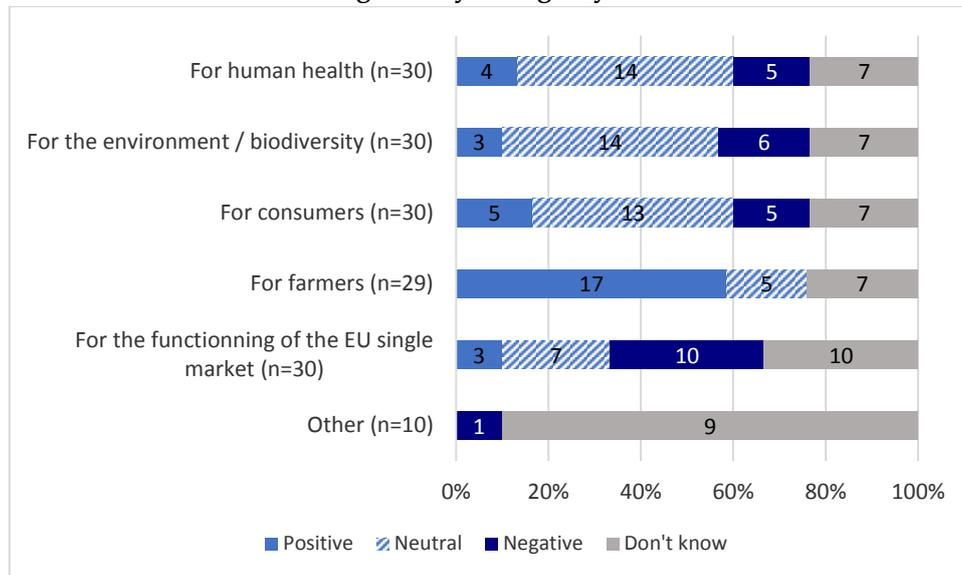
***How would you assess the impacts stemming from the implementation of Article 53 of the PPPR concerning 120-day emergency authorisations?***

Few respondents provided an opinion on the impacts of 120-day emergency authorisations. With the exception of impacts on farmers, where a majority of stakeholders

(manufacturers, manufacturers’ associations, one farmers’ association and CAs) indicated that the impacts were positive, the respondents were mostly neutral on other impacts. Environmental NGOs and the association representing the biocontrol industry generally considered emergency authorisations to have had a negative impact on human health, the environment and biodiversity and consumers.

Regarding the functioning of the internal market, the 10 respondents reporting a negative impact of emergency authorisations were mostly manufacturers’ associations, NGOs, and individuals (either from CAs or manufacturers (individual companies)).

**Figure 20: How would you assess the impacts stemming from the implementation of Article 53 of the PPPR concerning 120 day emergency authorisations?**



Sixteen respondents commented on their answers, although most comments were not related to the impact of the PPPR. (Comments already made by the same respondents in relevance and effectiveness questions are not repeated here.)

Three NGOs stated that proper implementation of the Regulation would achieve positive results for the environment and health, and support sustainable innovations in agriculture, but that current failures in implementation result in very negative impacts for human health and ecosystems in agricultural areas.

Several respondents provided an opinion on Article 53 emergency authorisations. Two CAs stated that the impact of emergency authorisations can be positive for farmers, with one adding that impacts are positive if risks for human health, environment and consumers are properly weighed against the urgency of the situation, and not given too freely, which can prevent farmers from adopting innovative agricultural practice. This last point was also raised by the association representing the biocontrol industry, which stated that the inappropriate use of emergency authorisations does not provide sufficient incentives for farmers to turn to alternatives solutions, as they can simply prolong the use of prohibited

products. As a result, alternatives are prevented from accessing the market, destroying innovation in Europe.

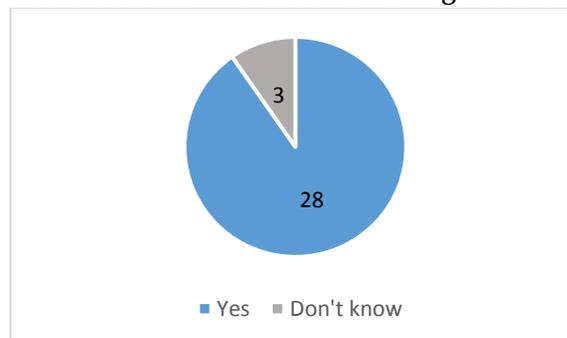
Two manufacturers' associations and a farmers' association stated that although emergency authorisations are necessary, they are not the most desired tool, as they require another approval procedure, the outcome of which is not guaranteed. In addition, once the authorisation is granted, the PPP is not always in stock as it is not registered. This leads to delays in the distribution of the PPP, which often comes at the peak of the emergency. According to these three respondents, an improved authorisation system would be better than reliance on Article 53.

## 2.9 EU added value

*Do you think that the actual practical implementation of the provisions of the PPPR adds value to national effort in achieving the relevant health-, environment- and market-related objectives or the implementation of the Regulation is counterproductive, and Member States would do better without this EU Regulation?*

The majority of respondents believed that the implementation of the PPPR adds value to national efforts, with none of the respondents stating that Member States would do better without the PPPR.

**Figure 21: Do you think that the actual practical implementation of the provisions of the PPPR adds value to national effort in achieving the relevant health-, environment- and market-related objectives or the implementation of the Regulation is counterproductive and Member States would do better without this EU Regulation?**



Eighteen respondents commented on their answers, the majority of whom considered implementation of the PPPR to add value to national efforts. None of the respondents stated that Member States would do better without the PPPR.

Several respondents (individuals, manufacturers' associations, farmers' associations) highlighted the benefits of having an EU Regulation (despite its flaws) compared to using the 28 different legal frameworks to ensure harmonisation of criteria for decision-making and consistent implementation. One respondent underlined the key roles of the Commission and EFSA to ensure this harmonisation. Finally, one individual indicated that without the EU Regulation, more hazardous active substances would be on the market.

Several respondents, while acknowledging the importance of the PPPR and its added value, suggested that more harmonisation is needed at EU level. One manufacturers' association specified that Member States should have less competence in the authorisation procedure or that there should be more coordination between Member States, at least, to apply the principle of mutual recognition and improve zonal authorisation. Another manufacturers' association stated that the PPPR should limit the opportunities for Member States to circumvent the uniform principles and impose different – often higher – criteria than those imposed by the Regulation.

One CA stated that while some form of PPP regulation is necessary, different approaches could be envisaged, without specifying any such approaches.

### 3. Final question

*If you consider it important, please comment on issues which could not have been raised answering the above questions and also express your recommendations for improvement of the implementation of the PPPR.*

Sixteen respondents replied to this question, the majority of which reiterated issues raised in previous questions. These comments have been integrated into the summaries of the relevant questions. Only those responses raising new issues are summarised below.

- *Supporting the shift to more sustainable agriculture*

Two health and environmental NGOs indicated that Directive 2009/128/EC on sustainable use of pesticides should be the core legal framework for PPPs instead of the PPPR. They believed that PPPs should first be assessed on their capacity to be used in IPM, and IPM-methods should be mandatory for every farmer.

- *Communication on the regulation of pesticides in Europe*

One farmers' association indicated that the European Commission and Member States have a strong role to play in communicating on risk management and avoiding misinterpretations from the public, and should therefore act more in this regard. According to the respondent, this is essential to build confidence in the European food safety system and the high standards within European production.

- *Role of EFSA*

One CA suggested that EFSA, in addition to its substantive role in substance approval and the development of guidance documents, could provide more procedural and administrative assistance to CAs, but without taking over the responsibility of these authorities, following the ECHA model under the Biocidal Product Regulation (BPR).

## Part 3 Assessment of the implementation of Regulation (EC) No 1107/2009

This section assesses the implementation of the PPPR against the criteria for evaluation (relevance, coherence, effectiveness, efficiency and EU added value), based on the information collected throughout the study. Finally, the section provides recommendations for actions to improve implementation of the PPPR. The assessment is based on the results from the research conducted on Article 53 emergency authorisations (Part I), the general desk research on implementation and the stakeholder survey on the implementation of the PPPR (Part 2). The information gathered through these sources does not cover all aspects of the implementation of the PPPR and only allows for a partial assessment, often based solely on the opinions of the stakeholders surveyed.

The assessment of the PPPR looks at the objectives, actions and inputs required to implement the Regulation and the expected outputs and results of those actions. This section takes for reference the 'intervention logic' provided in the Roadmap for the REFIT evaluation of Regulation (EC) No 1107/2009 and Regulation (EC) No 396/2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin (European Commission, 2016).

The PPPR has three overarching objectives:

- Ensuring a high level of protection of both human and animal health and the environment.
- Improving the functioning of the internal market through the harmonisation of the rules on the placing on the market of plant protection products.
- Improving agricultural production.

### *Relevance*

As defined in the Commission's Better Regulation guidelines<sup>79</sup>, the analysis of relevance should identify, inter alia, if there is any mismatch between the objectives of the intervention and the (current) needs or problems. In other words, in the context of the PPPR, the analysis of relevance should consider whether this Regulation adequately addresses evolving needs in the context of PPPs. The PPPR survey and the desk research undertaken here are the main sources of information for the assessment of relevance which led to two somewhat contradictory findings:

- Environment and health objectives should be reinforced compared to the other PPPR objectives, given the intensification and concentration of agricultural production, increased use of PPP, lack of development of IPM, decline in biodiversity, increase in chronic illness, and widespread contamination of water resources. The PPPR should focus on sustainable plant health, addressing the long-

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<sup>79</sup> Better Regulation guidelines - Evaluation and fitness checks:

<https://ec.europa.eu/info/sites/info/files/better-regulation-guidelines-evaluation-fitness-checks.pdf>

term resilience of agro-ecosystems. Objectives on phasing-out synthetic PPPs and investing in use of low-risk substances and the protection of farm ecosystems should be added. The objective on improving agricultural production should be specified in terms of its sustainability (environmental/health NGOs, farmers' associations).

- The objective to fulfil the internal market should be reinforced, as there is still a lot of work to be done on the harmonisation between Member State procedures (farmers' association, consultancy).
- Data requirements for the assessment of active substances and PPPs should better address new emerging risks concerning, inter alia, combined effects of residues of PPPs and pesticides preparations, NIAS, PPP transformation processes, nanomaterials and EDCs (Part 2 Desk research and environmental/health NGOs).

### *Coherence*

As defined in the Commission's Better Regulation guidelines, the evaluation of coherence involves looking at how well or poorly different actions work together, highlighting areas where there are synergies which improve overall performance or pointing to tensions (such as objectives and approaches) which are potentially contradictory and cause inefficiencies. In the case of the PPPR, this entails assessing whether or not this Regulation is coherent (e.g. potential overlaps, inconsistencies, synergies to be improved) with other EU policies (e.g. EU agricultural and environmental policies) and other EU legislation, international rules or agreements. The PPPR survey here is the main source of information, highlighting some coherence issues between the PPPR and other EU policies and EU legislation, together with limited findings from the desk research and the analysis of Article 53. Therefore, this analysis of coherence relies chiefly on the views of the different categories of stakeholders (e.g. CAs, manufacturers (individual companies) and/or manufacturers' associations, farmers' associations, and NGOs). The main findings were as follows:

- Implementation of PPPR is not always in line with the precautionary principle.
- Provisions of the PPPR may conflict with the EU policies on agriculture, as the EU agriculture goals of being competitive and productive are unlikely to be met.
- The PPPR is unlikely to be aligned with the goal of Directive 2009/128/EC on the sustainable use of pesticides. There are barriers in the PPPR authorisation procedure impeding the development of IPM. Article 53 authorisations involving aerial spraying go against the principles of Directive 2009/128/EC.
- Inconsistencies exist between the PPPR and other chemicals legislation (i.e. REACH, BPR, CLP) and there is a potential need to streamline the authorisation procedure under the PPPR and BPR.
- Insufficient synergies between the PPPR and the Water Framework Directive, whose standards can be exceeded even where PPPs are used according to their authorisation requirements.
- PPPR information/testing requirements are not in line with the animal welfare and 3R requirements of Directive 2010/63/EU on animal experiments.
- The PPPR does not adequately address pesticide drift contaminating organic production, and directly contradicts EU organic and baby food regulations.

### *Effectiveness*

Effectiveness considers the extent to which an EU intervention has been successful in achieving the objectives that it was intended to achieve. It aims to determine whether or not observed changes or effects that have taken place since the adoption of the legislation correspond to its objectives, as well as to identify the factors driving or hindering progress towards the objectives and how they are linked to the intervention. The information gathered through the survey and the desk research does not allow for an assessment of effects from the PPPR but nonetheless provided insights on the factors driving or impeding progress towards the achievement of the objectives.

### *Ensuring a high level of protection of both human and animal health and the environment*

The PPPR aims to facilitate the substitution of hazardous substances, ensure the safety of users, consumers (including vulnerable groups) and the environment, and make relevant information available to applicants, users, importers, public authorities, and consumers. These objectives were intended to be achieved through the assessment of the risks of active substances prior to their approval and the approval of PPPs, the application of hazard-based cut-off criteria, and the setting of MLRs at EU level (European Commission, 2016).

Based on information gathered under the analysis of Article 53, the desk research and the PPPR survey, some factors were identified that could potentially impede progress toward the achievement of a high level of protection of both human and animal health and the environment:

- Article 53 authorisations are used to maintain the use of PPPs with proven significant environmental and human health impacts, as the crop systems in which they are used has been built on the use of these pesticides and would require economic adaptations if these chemicals were prohibited (Article 53 analysis).
- PPPs with non-approved substances or heavily restricted substances are increasingly and repeatedly used under the Article 53 authorisation procedure and not always under emergency circumstances (Article 53 analysis).
- Major deficiencies exist in the enforcement of the PPPR at Member State level to tackle illegal and counterfeit PPPs and to ensure that authorisation conditions are correctly applied (Part 2 Desk research and all stakeholder categories in the PPPR survey).
- Data requirements are insufficiently stringent to ensure adequate health and environmental protections (Part 2 Desk research, NGO and biocontrol industry stakeholders).
- The EU and CAs cannot achieve and maintain independence in the assessment of hazards and risks from active substances and PPPs, as they rely on studies commissioned by industry applicants or scientific methods influenced by industry (Desk research Part 2, NGOs in the PPPR survey). However, independent studies not complying with OECD guidelines and GLP were given too much weight in the decision-making process, compared to studies carried out according to these rules (PPP producer stakeholders in the PPPR survey).

- An ongoing ‘paradigm war’ between toxicologists and endocrinologists for the definition of EDCs, which affects the implementation of the EDC cut-off criteria under the PPPR (Part 2 Desk research).
- Lack of scientific knowledge, leading to scientific uncertainties on how to adequately address the impacts of PPPs under the PPPR (e.g. EDCs, cumulative effects) (stakeholders).
- Lack of scientific knowledge on new types of substances used in PPPs, such as biological active substances (biocontrol industry in the PPPR survey), substances of mineral origin (organic food and farming stakeholders in the PPPR survey).
- Data requirements under the PPPR are in line with the 3R practices to limit animal tests and improve animal health (NGO animal health stakeholder in the PPPR survey).
- Lack of incentives to develop low-risk PPPs and the inadequacy of the PPPR authorisation procedure for these PPPs (Part 2 Desk research, organic food and farming and biocontrol industry stakeholders and some CAs in the PPPR survey).

*Improving the functioning of the internal market through the harmonisation of the rules on the placing on the market of PPPs*

The improvement of the internal market was intended to be achieved through the harmonisation of procedures and standards for the authorisation of PPPs and the setting of MLRs (European Commission, 2016). The stakeholder survey and the desk research highlighted a number of factors or implementation failures that hinder the harmonisation of standards and procedures and create obstacles to the free movement of PPPs:

- Member States imposing national requirements and reevaluating PPPs instead of applying the mutual recognition principle.
- Lack of an EU definition of minor crops.
- Lack of interzonal cooperation in evaluation of PPPs.
- Lack of coordination between authorities responsible for enforcement in Member States on enforcement activities.
- Frequent use of Article 53 for non-emergency cases.

*Improving agricultural production*

This objective was intended to be achieved through the establishment of efficient procedures for the approval of active substances and authorisation of PPPs, thus ensuring the timely availability of safe and effective PPPs, facilitating the placing of new products on the market and promoting innovation and the development of new PPPs.

The majority of respondents surveyed felt that the PPPR had not succeeded in meeting its objective of improving agricultural production. Manufacturers’ and farmers’ associations indicated that the objective was not met and that the competitiveness of the agricultural sector was damaged because the number of active substances available to farmers in the EU has been reduced despite still being authorised in third countries. In addition, manufacturers’ associations argued that the costs of placing new products on the market, and the time to market of new products, was negatively impacted by the PPPR, hindering investments in research and development and innovation. Stakeholders also stressed that

the PPPR is poorly adapted to biological pesticides and hinders their placing on the market, a situation that is exacerbated by the lack of regulator expertise on biological pesticides.

However, stakeholders had different interpretations of improving agricultural production. Environmental/health NGOs, some CAs, and associations representing the biocontrol industry and organic food and farming argued that the Regulation fails to improve agricultural production, as it does not promote the development of an IPM-oriented agriculture.

### *Efficiency*

As defined in the Commission's Better Regulation guidelines, efficiency considers the 'relationship between the resources used by an intervention and the – positive or negative – changes generated by the intervention' and provides an understanding of the extent to which the costs of implementing a legislation justifies the benefits, and of the factors influencing its efficiency. The information gathered through the desk research and the stakeholder survey did not provide a sufficient understanding of the precise costs and benefits of the PPPR, or the extent to which they might be proportionate. However, the stakeholder survey, interviews with EU and national stakeholders for Part 1 (on Article 53 derogations) and the desk research all provided insights on factors and/or implementation failures influencing the compliance and enforcement costs, administrative burden and time to market of PPPs linked to the implementation of the Regulation:

- **Increased complexity of risk assessment methodology for approvals of active substances:** this creates high administrative burden for Member State authorities. This argument was made by stakeholders in the survey.
- **Duplication of work in the authorisation of PPPs:** Stakeholders stated that the non-implementation of the principle of mutual recognition leads to Member States of the same zone each carrying out their own assessment of the product, on top of the assessment done by the zonal rapporteur, increasing the administrative burden for both applicants and authorities. The Commission's *Overview report on the authorisation of Plant Protection Products* (European Commission, 2017c) came to the same conclusion, e.g. the lack of cooperation between Member States leads to significant duplication of work, noting that the underlying reasons are the lack of harmonised methodologies and models to conduct the evaluations, or the existence of additional national requirements to address conditions particular to the Member State concerned. Both the survey and the desk research found that this situation leads to significant delays in the registration and thus time to market of PPPs.
- **Duplication of work in renewal of approval of active substances:** the systematic re-evaluation of studies that were already evaluated during the approval procedure was considered by some stakeholders to be inefficient and to create unnecessary administrative burden for authorities and applicants.
- **Difficulties in meeting the deadlines laid down in Article 43** (for applicants and then in turn for CAs) for the re-registration of PPPs. This argument was made by stakeholders in the survey.
- **Lack of data sharing between applicants in the preparation of application dossiers.**

- **Unequal distribution of work between Member States within the same zone and lack of cooperation between authorities in the re-registration of PPPs.** The Commission's *Overview report on the authorisation of Plant Protection Products* (European Commission, 2017c) indicated that the workload relating to the registration and re-registration of PPPs is not evenly shared, which can create an important administrative burden for some authorities and thus increase delays.
- **The use of Article 53 for non-emergency cases:** the increasing and repeated use of Article 53 for PPPs undergoing a parallel zonal authorisation procedure or an extension of authorisation for minor use leads to increased workload for CAs and applicants.

### *EU added value*

The assessment of EU added value considers the benefits and changes resulting from the implementation of an EU intervention that are additional to those that could reasonably have been expected from national actions by the Member States. The information gathered through the desk research does not allow for a substantial assessment of the EU added value of the PPPR. However, stakeholder opinions on whether or not the PPPR adds value to national effort in achieving the relevant health, environment and market-related objectives of the Regulation, were gathered in the PPPR survey. Respondents unanimously considered the implementation of the PPPR to add value to national efforts, with none of the respondents stating that Member States would do better without the PPPR.

### *Impact on the implementation of the Regulation*

There is not enough information in the research paper to identify the relevant impacts and related impacted stakeholders stemming from the current implementation of the PPPR.

On Article 53 authorisations, the case studies demonstrate that Article 53 authorisations are used to maintain the use of PPPs with proven significant environmental and human health impacts, because the crop systems in which they are used has been built on the use of these pesticides and would require economic adaptation if those chemicals were prohibited.

The current Member State difficulties in implementing the PPP authorisation procedure lead to economic impacts on both users of PPPs and PPP producers. However, the information collected for this research paper does not allow for these impacts to be quantified.

### *Recommendations on the implementation of the PPPR*

In light of the findings of the Article 53 analysis, the desk research and the survey on the general implementation of the PPPR, the following recommendations address improvements to the implementation of the PPPR:

- Article 53 authorisations granted by Member States should comply with the PPPR requirements, its principles of sustainability, precaution and substitution, and

should be used according to their original purpose in special circumstances. In particular, this could mean that:

- Article 53 procedures are detailed in national law instead of being considered an internal administrative procedure in Member States.
  - Member States ensure that the application forms follow the updated template for notifications prepared by the Commission and the Commission working document guidance, at a minimum.
  - Member States ensure that PPP producers' applications have been prepared on behalf of farmers/users. Member States ensure that there is a systematic consultation procedure for all Article 53 authorisations where relevant public authorities and scientific bodies could provide their opinion. This consultation procedure should not hinder the application of an emergency procedure.
  - Member States ensure that the evaluation of applications includes a public/stakeholder consultation procedure allowing third parties to provide comments on justifications and assessment of alternatives.
  - Member States prepare a yearly report summarising how Article 53 of the PPPR was applied.
  - Member States, together with the Commission and EFSA, develop strategies to limit the use of (repeated) Article 53 authorisations.
  - Member States put in place specific inspection strategies/programmes for Article 53 authorisations, or at least prioritise inspections for such authorisations.
  - Member States and/or the Commission should develop awareness campaigns and better communicate the purpose and use of Article 53 authorisations.
  - Notifications to the Commission are made available to the public and published online on the website of the Commission.
  - Notifications are sent 'immediately' to the Commission and other Member States via PPPAMS after the issuing of Article 53 authorisation decisions. Member States should ensure that notifications are correctly filled in, with all sections completed.
  - The Commission enhances its monitoring of Article 53 authorisations and launches infringement procedures for non-notifications under Article 53.
  - The 2013 Commission working documents guidance is revised or amended following the EFSA opinion on the assessment of Article 53 authorisations concerning severely restricted plant protection products containing three neonicotinoids substances, clothianidin, imidacloprid and/or thiamethoxam.
- The control and enforcement of illegal PPPs must be improved and enhanced, which would entail, inter alia:
    - Better records of PPPs on the market in Member States.
    - Better coordination between CAs within Member States.
    - Better harmonisation and EU coordination on official controls.
    - Development of an EU centralised database and EU reference laboratory for product composition.

- More involvement of the Commission on international cooperation against illegal pesticides.
  - Providing inspectorate bodies with more efficient tools (e.g. live electronic access to information on registered PPPs, adequate sampling and analysis) better strategies (e.g. identification of risks) and more human and financial resources to carry out controls.
  - Improvement of the rules governing parallel trading.
- Member States, with the support of the Commission, should assess and reform the way in which they implement the authorisation procedures of PPPs in order to ensure that there is less administrative burden for applicants and authorities, deadlines are respected, less overlaps and more coordination between Member State authorities. This would entail, inter alia:
    - More cooperation and trust between Member States in the implementation of the principle of mutual recognition.
    - Better distribution of work and cooperation between Member States within the same zone for the authorisations and renewal of authorisations of PPPs.
    - Better planning within Member State CAs and more financial resources to ensure that CAs comply with authorisation deadlines.
    - More attention from the Commission and Member States for minor crop PPPs in order to remove barriers to the authorisation of such products.
    - Support for Member States to cope with the high number of challenging comparative assessments.
- Member States and the Commission should ensure that the implementation of the PPPR is more transparent, and that efforts are made to communicate their decisions on the risk and potential impacts of active substances and PPPs to the public. This could entail, for example:
    - More transparency in the adoption of Commission decisions for the approval/non-approval of active substances within the framework of the PAFF Committee.
    - More efforts from EFSA to ensure that their documents are easily accessible and readable for non-experts.
    - Better risk communication strategy from EFSA and the Commission, including more public awareness actions on how risks from active substances and PPPs are addressed so as to protect the environment and public health.
- The Commission and Member States should further support research programmes to address scientific uncertainties relating to the environmental and health impacts of PPPs under the PPPR. This could entail, inter alia, more funding:
    - On the development of scientific methods to assess endocrine disruptor effects of chemical substances.
    - To assess the risks from combined effects of PPP residues, and from combination effects of pesticide preparations.
    - To assess the impact of PPPs on soil biodiversity.

- The Commission and Member States should further support the development of low-risk and biological PPPs. This might include:
  - Assessment of the regulatory and economic barriers to authorisations of low-risk PPPs.
  - Development of research programmes on biological active substances and substances of mineral origin in PPPs.
  - Development of training programmes for CAs responsible for PPP authorisations on the specific features of PPPs based on biological active substances.

The outcome and findings of this research paper suggest that further investigations on the implementation of the PPPR would be necessary, in particular on:

- All Article 53 authorisations granted in Member States since the entry into force of this derogation procedure.
- Barriers to the development of low-risk PPPs and IPMs.
- Relationship between the PPPR and the Directive on the sustainable use of pesticides.
- Enforcement measures in place in all Member States to control the use of illegal pesticides and to ensure that the users of PPPs comply with the conditions of use in their authorisations.
- Impacts of a hazard-based approach versus a risk-based approach under the PPPR.

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## **Annex II**

### **Assessing criteria and capacity for reliable and harmonised 'hazard identification' of active substances**

**Research Paper  
By Dr Emanuela Bozzini**

## **AUTHOR**

This research paper has been written by **Dr Emanuela BOZZINI** of the University of Trento at the request of the Ex-Post Evaluation Unit of the Directorate for Impact Assessment and European Added Value, within the Directorate General for Parliamentary Research Services (DG EPRS) of the General Secretariat of the European Parliament.

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## Acronyms

<b>ADI</b>	Admissible Daily Intake
<b>AOP</b>	Adverse Outcome Pathways
<b>CA</b>	(National) Competent Authority
<b>CMR</b>	Carcinogenic, Mutagenic and Reprotoxic
<b>DAR</b>	Draft Assessment Report
<b>dRAR</b>	Draft Renewal Assessment Report
<b>ECPA</b>	European Crop Protection Association
<b>EFSA</b>	European Food Safety Authority
<b>EMA</b>	European Medicines Agency
<b>EPPO</b>	European and Mediterranean Plant Protection Organisation
<b>IPM</b>	Integrated Pest Management
<b>LOAEL</b>	Lowest Observed Adverse Effect Level
<b>NOAEL</b>	No Observed Adverse Effect Level
<b>PAN</b>	Pesticide Action Network
<b>PNEC</b>	Predicted No-Effect Concentration
<b>PBT</b>	Persistent, Bioaccumulative, and Toxic
<b>POP</b>	Persistent Organic Pollutants
<b>PPP</b>	Plant Protection Product
<b>RAR</b>	Renewal Assessment Report
<b>SCoPAFF</b>	Standing Committee on Plant, Animals, Food and Feed
<b>SUD</b>	Sustainable Use Directive (Directive 128/2009)
<b>vPvB</b>	very Persistent very Bioaccumulative

## Executive Summary

The goals of this study are to assess to what extent national and EU authorities follow a harmonised approach towards the identification of the hazards associated with active substances. Further the study also assesses whether Member States' competent authorities possess the necessary institutional capacity a) to deliver independent and transparent – and hence reliable – hazard and risk assessments and b) to contribute to EU procedures of approvals of active substances.

The research design employed different tools: semi-structured interviews with national Competent Authorities (CAs) and EU institutions (EFSA and DG Sante); documentary analysis; structured questionnaire targeting applicants and stakeholders such as NGOs working on health and environmental issues, organisations representing agricultural interests; follow-up interviews with a selection of applicants and stakeholders participating in the survey.

Regulation (EC) 1107/2009 set ambitious goals: to ensure a high level of protection for human health; to protect the environment; to provide farmers with the defence tools they need and safeguard the competitiveness of EU agriculture.

This study takes as a starting point that the harmonisation of criteria and procedures for the approval of active substances is a necessary precondition to deliver on these goals.

The research shows that harmonisation of criteria for hazard and risk assessment has clearly improved since the entry into force of Regulation (EC) 1107/2009, but that it is far from complete. The formulation and adoption of criteria and guidance documents demands significant resources and is reported as a very relevant part of the work of national competent authorities, EFSA and DG Sante. The research also shows that most – but not all – CAs have the institutional capacity to act as Rapporteur Member State (RMS) and deliver assessment reports to EFSA. There are however relevant differences in terms of staff and resources.

The rest of this Executive summary presents a list of main findings:

→ According to interviewees, data requirements for pesticides are likely to be the most demanding ones in the context of EU regulations. Most testing has been institutionalised and protocols are agreed upon at the EU and international level, such that data are supplied according to specific research designs, methodologies, and techniques.

Yet it is important to stress that different areas of inquiry are characterised by different degrees of harmonisation. In general terms, guidance documents on residues and toxicological hazards are well-established, while guidelines on environmental fate and behaviour and on ecotoxicology are less consolidated.

Experts are engaged in a variety of panels and ad hoc working groups at both EFSA and DG Sante to refine existing guidelines and develop new ones to catch up with scientific progress as well as to fulfil legal requirements. The effort of CAs, EFSA and DG Sante – and more extensively the network of experts involved – is reported as a very relevant part of their work, one that demands significant resources.

→ There is a clear sense that requirements and guidelines are becoming increasingly demanding and complex over time, an aspect frequently stressed by CAs.

Guidelines are still missing on some data requirements, in particular in the context of environmental fate and behaviour and ecotoxicology, and others are under development. Notably, guidelines on endocrine disruption have been recently finalised in December 2017. A relevant point is that manufacturers complain that new guidance documents are applied 'retrospectively' to already submitted dossiers.

→ Some guidelines are available but not formally adopted by risk managers in SCoPAFF and therefore have no legal validity. Some CAs do not agree to apply guidance documents that have not been properly adopted at EU level, while others are more willing to do so and/or have included guidelines in national provisions. This introduces regulatory uncertainty.

It is of note that in other regulatory sectors EFSA is in position to formulate and adopt risk assessment criteria and guidelines, whose application therefore does not require a political vote in comitology.

→ As envisaged by the principle of precaution, the burden of proof is on applicants: it is up to them to provide evidence about the safety of active substances. Accordingly, manufacturers perform the test activities in order to collect data, either in-house, or by commissioning studies conducted by external certified laboratories that are specialised in carrying out testing according to OECD/EU and international protocols.

The reliance on tests that are supplied by the industry has been characterised by NGOs as inherently biased and therefore inadequate to constitute a sound evidence-base to be used in risk assessment. CAs highlight two relevant characteristics to support the quality and reliability of the current system: first, studies must be carried out according to established protocols and to the principles of Good Laboratory Practice (GLP), to guarantee their quality. Second, applicants are obliged to submit all original findings on which studies and reports are based, so that evaluators are in position to provide an original interpretation of data.

The debate is still ongoing on a range of issues that are of direct relevance for the assessment of hazards and risks associated with active substances.

→ Regulation (EC) 1107/2009 introduces a relevant derogation from cut-off criteria: to the extent that exposure is negligible, a hazardous active substance can get approved

The derogation from cut-off criteria for negligible exposure has been introduced for carcinogenicity (point 3.6.3 of Annex II of Regulation (EC) 1107/2009) toxicity for reproduction (3.6.4), endocrine disruption (3.6.5), endocrine disruption on non-target organisms (3.8.2) as well as for honeybees' health (3.8.3). The other cut-off criteria – mutagenicity – does not include considerations of exposure (3.6.2), as well as the main 'environmental criteria' of persistence, bioaccumulation and toxicity for the environment. Draft technical guidelines on the assessment of negligible exposure have been made public by DG Sante in June 2015. The published document is incomplete in some very relevant sections and therefore constitutes a partial answer to the issue. It does provide, however, clear indications of the logic to be applied when performing assessments of derogations from hazard-based cut-off criteria. The most consequential statement is that 'negligible

exposure' is a condition to be actively searched and achieved by the introduction of risk mitigation measures, like obligation to wear protections etc. The approach adopted by the Commission in the draft technical guidelines is contested by some CAs, since it seems to 'dilute' the hazard-based approach that informs Regulation (EC) 1107/2009. According to critics, exposure is negligible if 'the product is used in closed systems or in other conditions excluding contact with humans'.

→ The standard procedure for hazard and risk assessment follows a chemical-by-chemical logic, in which each active substance is tested for its own intrinsic hazards and evaluated for its risks.

However, there is a growing consensus among experts that health and environmental risks might be significantly underestimated if cumulative effects are not evaluated.

EU legislation requires the assessment of intentional mixtures, combinations of chemicals that result from the intentional mix of different active substances, like commercial formulations composed of a combination of active substances. Much less attention is given to unintentional mixtures – like the ones that are formed during the handling of different products on the part of users – or coincidental – mixtures that get formed in the environment after the use of a variety of active substances. At present there is no systematic and integrated approach across different pieces of legislation. In the pesticide sector, guidelines are currently under development.

→ Regulation (EC) 1107/2009 requires evaluators to take into account epidemiological evidence. The integration of epidemiological findings in risk assessment is however problematic. A main reason is that the attribution of causality between a specific active substance and a specific adverse effect is uncertain because of multiple hazards and the presence of confounding factors that can not be kept under control. All considered, the integration of epidemiology and toxicology – as envisaged by EFSA – sees the former in a supporting role to the latter. Epidemiology would alert on the existence of health concerns whose biological plausibility should be further investigated by toxicologists. The discussion among expert is still going on. At this stage it is important to note that the regulatory implications of the integration of plausible epidemiological findings into evaluations – such as revisions of data requirements, provisional bans, etc - are still to be spelled out.

→ From interviews with CAs and stakeholders, it emerges that the inclusion of peer-reviewed literature in the dossier is both very important and problematic. There are some significant issues under discussion, in particular on the relevance, reliability, accessibility and transparency of studies. All considered, so far the main function of peer-reviewed literature has been to perform 'a signal function', meaning that studies can include findings that alert evaluators to adverse effects that are not seen via standard testing. There are however some CAs that question the real added value of the assessment of peer-reviewed literature.

According to Regulation (EC) 1107/2009 the process for the approval of active substances is carried out in cooperation between MS and EU authorities. In all MSs (plus Norway) is

possible to identify the CA who is responsible for the implementation of Regulation (EC) 1107/2009.

→ MSs set up different organisational structures to act as CAs in the context of evaluation of pesticides. Four main models can be distinguished: 1) a single independent regulatory agency is in charge with risk assessments; 2) a web of two to four agencies divide dossiers according to area of expertise; 3) a government department takes responsibility for assessments that are performed by external certified research centres and universities; and 4) risk assessments are delivered by one or more governmental departments.

→ There are relevant differences in the distribution of workload among CAs. This is a consequence of the possibility given to manufacturers to choose RMSs. Applicants cannot choose their RMS in the case of renewals, and dossiers are allocated by the Commission on the basis of a 'negotiation' with each CA. The distribution of procedures according to a centralised procedure favoured some geographical distribution of the workload and made it possible for some countries to build experience with approvals. However, a 'balanced' distribution of dossier is prevented by differences in staff and resources among CAs.

→ There are huge differences among MSs in terms of available expertise. A very serious issue is that all CAs are understaffed. This appears the most relevant factor to explain delays in assessments of active substances, as well as limited participation in EFSA procedures.

→ Only few MSs adapt the requested fee to the actual costs incurred during the evaluation process or link the fees to the number and type of evaluations to be performed in the context of a dossier. Fees to contribute to the European stage of the procedure for the approval of active substances are generally not requested.

→ Regulation (EC) 1107/2009 establishes clear deadlines for each stage of the procedure of approvals. However, delays are common. Most delays have been recorded in the cases of renewals, because a large number of dossiers have to be evaluated simultaneously. It is also of note that over time the scope of the renewal procedure changed and has been significantly extended. It was initially thought of as an update of the existing dossiers, a relatively fast process meant to focus on new data requirements. However, it became apparent that old studies needed to be re-assessed in light of new guidelines and new scientific interpretations of findings.

→ As far as transparency is concerned, it is of note that in principle it is possible to find most of the information, including the original dossier, taking into account rules for confidentiality. The EFSA Register of Questions and the EU pesticide database provide a large number of documents for each active substance. The accessibility of information is considered low, and a better valorisation of available information would be important to improve on transparency.

→ All interviewed CAs declared to offer pre-submission meetings to applicants who request them. Pre-submission meetings are of help to both parties, mainly because they

help avoid delays when the formal process of evaluation starts. However, meetings are also a burden for CAs who have to devote time and resources to analyse and discuss studies. Notably, only few MSs charge applicants who request advice and meetings before submitting an application.

→ In the past, each CA had different procedures for the assessment of the admissibility of dossiers. Today it emerges that procedures have been largely aligned, thanks to more precise guidance documents that clarify the type and characteristics of tests, as well as the introduction of a standardised format for presenting studies.

→ In the evaluation stage, the most common arrangement is based on a small team composed of experts with different specialisations and coordinated by a project manager. The dossier is divided according to the area of competence – toxicology, ecotoxicology, etc. – and each is usually given to one or two officers.

Formal and informal meetings are needed to compare results, clarify the implications of each sectoral assessment for the overall evaluation of the active substances, and deliver the DAR/RAR. Only few CAs organise a formal internal peer review process of individual assessments.

During evaluations, contacts with applicants are possible and take place whenever there is the need for clarifications on tests, summary of findings, or some related content included in the dossier. Only two among the interviewed CAs declared not having exchanges with applicants during this stage. Other stakeholders are not consulted.

→ Regulation (EC) 1107/2009 foresees that in the evaluation of new active substances and in renewals, two MSs cooperate in the delivery of the DAR/RAR. This might be highly relevant to facilitate harmonisation, develop a common understanding of guidelines, and for capacity building. Most of the time the Co-RMS comments on the first version of the DAR / RAR that has been compiled by the RMS. A division of labour in terms of areas of the dossier to be evaluated is another option for cooperation. This, however, implies a mechanism for the coordination of the two national teams and possibly the organisation of joint meetings to finalise the report. Because of resource and time constraints, such types of coordination only seldom take place.

→ The EFSA peer review procedure is a key factor in promoting consistency in the process, in favouring the harmonised application of regulatory guidelines, and in facilitating a learning process. According to EFSA, all DARs and RARs are significantly revised following comments submitted during the peer review process.

However, it clearly emerges that participation is not systematic on the part of national CAs. All but one interviewed CA affirmed being selective, meaning that they prioritise some active substances over others to comment on.

Some MSs also express criticism to EFSA for not taking into account their comments properly. More generally, according to these CAs, EFSA conclusions do not often reflect agreed conclusions since they tend to be too precautionary.

It is important to note that EFSA started a reflection on its peer-review practices in June 2016 and in November 2017 adopted an 'Action plan for improving the peer-review process'. The purpose is to ensure that each dossier is reviewed by an adequate number of

experts and make sure that sufficient expertise is at disposal. Further, a more comprehensive and clear summary of divergent views expressed by CAs during peer-review processes is to be included in the conclusions, as well as indication of the line of reasoning followed.

→ The risk management stage takes place in SCoPAFF. There is the impression – shared by Commission officials – that over time the risk management stage is getting increasingly politicised. From interviews it clearly emerges that there is a need for a more transparent and comprehensive risk management stage, since most of the time the reasoning behind risk management decisions, the regulatory criteria adopted and how the discussion among decision-makers unfolded is not made explicit or public.

## I Introduction

Over the decades, thousands of different plant protection products (PPPs) have been developed to control pests, reduce yield losses and preserve the use of both labour and energy.<sup>1</sup> Together with fertilizers, pesticides are a central feature of contemporary farming and are seen as indispensable to the delivery of sufficient and stable food supplies.<sup>2</sup> Yet, as the preamble of Regulation (EC) 1107/2009 states, 'plant protection products can however also have non-beneficial effects on plant production. Their use may involve risks and hazards for humans, animals and the environment, especially if placed on the market without having been officially tested and authorised and if incorrectly used'.<sup>3</sup>

The policy debate in the pesticide sector is characterised by a constant tension between competing views of the advantages and disadvantages of pesticides. On the one hand, farmers and chemical industries consider their use essential to guarantee productivity. In the words of the European Crop Protection Association (ECPA): 'PPPs are to plants the equivalent of medicines for humans'.<sup>4</sup> In contrast to this view, many organic farmers and environmental NGOs support chemical-free agricultural methods, emphasising the adverse effects of pesticides and arguing that farmers should re-discover how to keep pests under control through a variety of methods, only utilising chemical solutions 'as a last resort in rare cases of heavy pest infestations...'.<sup>5</sup>

Adopted in 2009, the EU regulation on pesticides is informed by the view that this tension can be reconciled. Accordingly, 'the purpose of this regulation is to ensure a high level of protection of both human and animal health and the environment and at the same time to safeguard the competitiveness of Community agriculture'.<sup>6</sup>

To achieve these goals, the EU regulation prescribes the evaluation of active substances and PPPs in order to assess their efficacy as defence tools as well as their safety for humans and ecosystems before they enter the EU market. In short, the procedures enacted under Regulation 1107/2009 are finalised to grant pre-market approvals and authorizations. The distinction between active substances and PPPs just mentioned is of a high relevance to one's understanding of the working of the EU's pesticide regulation. Active substances are chemical elements (occurring both naturally or by manufacture) 'having general or specific action against harmful organisms or on plants, part of plants or plant products'.<sup>7</sup> In other words, active substances are molecules proved to be both effective against pests and safe in terms of the effects of usage. PPPs are commercial formulations that contain one or more

<sup>1</sup> Cooper, J. and Dobson, H. (2007). 'The benefits of pesticides to mankind and the environment', *Crop Protection* 26

<sup>2</sup> Conway, G. (2012). *One Billion Hungry. Can We Feed the World?* Ithaca: Cornell University Press; Paarlberg, R. (2010). *Food Politics. What Everyone Needs to Know*. Oxford: Oxford University Press.

<sup>3</sup> Recital 7, European Parliament and Council. Regulation of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EC and 91/414/EEC. Regulation (EC) 1107/2009

<sup>4</sup> ECPA. (2013). "Registering plant protection products in the EU." ECPA, Bruxelles p.1.

<sup>5</sup> Greenpeace. (2015). "Europe's Pesticides Addiction. How Industrial Agriculture Damages our Environment." Greenpeace Germany, Berlin p.3.

<sup>6</sup> Recital 8, Regulation (EC) 1107/2009

<sup>7</sup> Strictly speaking, Regulation (EC) 1107/2009 defines substances rather than active substances.

active substances as ingredients. For example, the active substance 'glyphosate' is used in hundreds of PPPs, such as Roundup by Monsanto and Touchdown by Syngenta.

The regulatory regime, based on this distinction, is characterised as being a dual system: the active substances are assessed at EU level and – if found safe – granted an approval valid across all 28 MSs. Once an active substance is declared safe by EU authorities, each PPP containing it has to be further assessed and authorised at the national and zonal level, thus taking local conditions of use and all associated risks thereof into account.<sup>8</sup> National regulators cannot authorise the diffusion of a commercial pesticide whose active ingredient has not been previously approved by EU regulators.<sup>9</sup> Passing the EU assessment is therefore a precondition to placing any pesticide on the market.<sup>10</sup>

This report deals specifically with the first stage of the dual procedure, i.e. the approval of active substances. It will describe and assess the criteria and the procedure in use since the adoption of Regulation (EC) 1107/2009 for the hazard and risk assessment of chemicals and micro-organisms to be used as active substances in the production of PPPs. It is important to note from the start that the approval of active substances is a complex procedure that involves both MSs and EU authorities. Each MS has a designated competent authority (CA) that delivers a first draft assessment of the hazards and risks posed by a chemical. The draft is subsequently discussed by all CAs and EFSA officials, who have to agree on the merit of the assessment of the active substance under investigation. The final stage takes place at the Commission, where DG Sante officials and representatives of MSs decide on approvals in the context of the comitology committee, the 'Standing Committee on Plant, Animals, Food and Feed' (SCoPAFF).

The goals of this study are to assess to what extent national and EU authorities follow a harmonised approach towards the identification of the hazards associated with active substances. Further the study also assesses whether Member States' competent authorities possess the necessary institutional capacity a) to deliver independent and transparent – and hence reliable - hazard and risk assessments and b) to contribute to EU procedures of approvals of active substances.

Specifically, after this introduction, the report is structured in three main parts:

Part II first describes the four stages in which the risk assessment procedure is structured according to EU practice: hazard identification, hazard characterisation, exposure assessment, and risk characterisation. In relation to this, an introduction to the basic distinction between the concepts of hazard and risk informing this structure is also provided. The basic logic of Regulation (EC) 1107/2009 is explained, with a focus on its reliance on the hazard identification stage as the criteria for regulatory decision-making and for the substitution of hazardous chemicals with low-risk ones. The final sections provide an overview of the results of regulatory action (in terms of the number of active

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<sup>8</sup> See the study (Hamlyn, 2018/Annex III to the European Implementation Assessment) on Member States' practices of standard authorisations of PPPs.

<sup>9</sup> Unless under derogation from Regulation (EC) 1107/2009, which is allowed by its Article 53 under certain circumstances. See Milieu, 2018/Annex I to the European Implementation Assessment.

<sup>10</sup> The same dual logic informed the previous Directive 414/1991, repealed after the entry into force of Regulation (EC) 1107/2009.

substances approved and banned) and opinions on the application of the hazard-based approach, the principle of substitution and, more generally, on the goals of Regulation (EC) 1107/2009.

Part III is devoted to a discussion of the harmonisation of both the criteria and guidelines for hazard assessment, providing a description of how guidance documents and test methods have been developed in the areas of toxicology, environmental fate and behaviour, ecotoxicology, and endocrine disruption. This section shows how the level of harmonisation is very different across these areas of inquiry, as well as how this has a direct impact on the working of CAs and the reliability of hazard identification. This is followed by a description of a series of open and controversial issues in the field of hazard identification: the assessment of negligible exposure to hazards, the evaluation of hazards associated with chemical mixtures, the use of epidemiological data in assessments, and the contribution of the peer-reviewed literature to evaluations.

Part IV addresses organisational and procedural issues. It first describes the procedural characteristics of the evaluation of active substances as envisaged in the legal text. It then highlights four critical issues characteristic of the implementation phase of the Regulation that are central topics for discussion among regulators and stakeholders: the distribution of workload among CAs, the delays that have been recorded on procedures, the independence of CAs from applicants, and the transparency (availability and accessibility of documentation) of the procedure. This section then proceeds with a description of the organisational models in place across MS, providing an overview of the regulatory agencies, governmental departments and research centres involved with different competences in hazard and risk assessments. It also discusses problematic issues raised by the serious understaffing of most CAs.

The second part of Part IV describes how CAs manage the different stages of the appraisal of active substances: the pre-submission phase, the organisation of the proper evaluation and the delivery of the draft report. It subsequently discusses the strengths and limitations of the peer review of reports as organised by EFSA. The final sub-section - before some concluding remarks - provides a short discussion of some risk management issues.<sup>11</sup>

A concluding part (V) provides a summary of the findings and recommendations.

Before turning to the analysis of hazards and risks in the regulation of active substances, the next section describes the research design and the methods that inform the study.

## **1. Research design and method**

As briefly described in the preceding section, this report addresses a broad range of technical and policy-related issues. Accordingly, the research design employed different tools. The evidence collected for this report comes from a variety of sources:

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<sup>11</sup> It is of note that the risk management stage is beyond the remit of this study. For reasons of completeness however, the report will address some emerging issues that are currently under discussion.

- 1) Semi-structured interviews with national Competent Authorities (CAs) and EU institutions (EFSA and DG Sante);
- 2) Documentary analysis;
- 3) Structured questionnaire targeting applicants and stakeholders;
- 4) Follow-up interviews with a selection of applicants and stakeholders participating in the survey.

1) Interviews with risk evaluators and managers are the most relevant source informing this study. Contact was made in October 2017 and again in November 2017 (if required) with the relevant agencies and institutions of all 28 MSs, and at the EU level, requesting a phone meeting. A total of 18 MSs gave a positive reply, as well as EFSA and DG Sante. Most of the time, the conversation involved more than one officer, according to their areas of expertise. In countries where multiple agencies/institutions are involved in approval of active substances, two different interviews were scheduled. At the end of the process, a total of 33 evaluators had been involved, participating by means of either individual or group interviews. Meetings went on for a minimum of 30 minutes to a maximum of 1 hour 20 minutes, depending on the time respondents had at their disposal, the number of respondents participating, as well as their disposition to discussing the relevant issues, providing examples, etc.

The interview for CAs was structured around three main themes: a) the organisational characteristics of the CAs in terms of remit, staff, as well as opinions on workload and relationship with other actors; b) the procedures and practices employed for the evaluation of active substances; c) opinions on the harmonisation of criteria and the adequacy of their ability to deliver reliable hazard and risk assessment<sup>12</sup>. The questions used for EFSA and DG Sante were similar to those for CAs; however, they were adapted to reflect differences in both roles and policy competences.

It is of note that all interviews were semi-structured, meaning that the question list included a predetermined set of open questions that informed the conversations and that needed to be covered. However, respondents had the opportunity to go in-depth on topics of a particular relevance to their point of view, to explain them in their own terms, as well as to add further themes of their choice. As a result, the adoption of this technique allowed for the collection of reliable and comparable qualitative data combined with in-depth insights on the most pressing issues currently under discussion in the pesticide sector. Interviews have been recorded and subsequently transcribed. As agreed with interviewees, anonymity has been guaranteed, so that individual positions and opinions are not identifiable in the study.

- 2) The documentary analysis included:
  - a) Official guidelines and documents published by EFSA and DG Sante to inform applicants, stakeholders, and/or the public of risk assessment-related issues;

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<sup>12</sup> The complete list of questions informing the interviews could be submitted upon request.

- b) position papers drafted by CAs and stakeholders to contribute to EU policy debates on pesticide-related issues;
- 3) The online questionnaire aimed at collecting views from stakeholders on the implementation of Regulation (EC) 1107/2009<sup>13</sup>.

For each question, respondents were asked to choose from a pre-determined set of items. However, it is very relevant to note that they were also given the opportunity to add comments for each of the questions, without a word limit, to further specify their opinions. The list of invited stakeholders included:

- manufacturers who had a least one approval procedure finalised in the period 2016-2017.
- Umbrella organisations representing industry and agricultural interests; NGOs active in the field of environment and public health.

A total of 140 invitations were sent in December 2017 and again in January 2018. However, the survey attracted a very limited number of respondents: 10. We can only speculate on the reasons for the limited number of replies: first, while the number of affected and interested parties is potentially broad, the number of actors that systematically take part in policy debates is limited to a few umbrella organisations representing private interests (chemical industry, agriculture) and NGOs working on environment and/or public health issues. These were among the respondents to the online survey. Further, respondents include manufacturers who have been directly involved in approval procedures. Second, the survey on the approval of active substances was launched in parallel to others research initiatives - including the Refit programme carried out on behalf of the European Commission - presumably targeting a similar list of stakeholders. As a consequence, consultation fatigue cannot be ruled out. Nevertheless, respondents' contributions represent all invited categories (industry, farmers and health/environment NGOs) and form a valuable basis for analysis.

4) As a follow-up to the survey, respondents were interviewed by phone upon their request. The interviews were not structured: each took, as a starting point, comments written in the context of the online survey and asked respondents to freely elaborate on them. This proved to be very important to the further clarification of controversial issues and the collection of data.

The implementation of the research design adopted for this study delivered some promising results, whilst simultaneously encountering some difficulties.

In terms of completeness, taken together, the 18 MSs who agreed to be interviewed acted as the RMS for the majority of the procedures that were finalised and included in the EU pesticide database. Specifically, they account for 88% of the total number of assessments. It seems safe to argue therefore that the analysis of the strengths and weaknesses of the implementation of Regulation (EC) 1107/2009 both identified and reported herein is comprehensive. Further, the desk and documentary analysis revealed that the amount of material that is available for each of the regulatory aspects covered herein is very broad and forms an important source of information. In this sense, it seems safe to argue that the

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<sup>13</sup> The complete list of questions could be submitted upon request.

analysis reflects, with a high level of accuracy, the on-going debate among the most active evaluators. However, because it was not possible to interview CAs that happened to have a more marginal role in the approvals of active substances, their opinions can be under-represented in this study.

There are other limitations. The most relevant one is the low response rate for the stakeholder survey, which has both a substantial and a methodological shortcoming. From a substantial point of view, no claim of a full representativeness of stakeholders can be advanced. There are however two considerations that mitigate this deficiency. Opinions on pesticides tend to be both highly polarised and homogenous within each of the opposing sides of the debate. Furthermore, the number of actors who specialise in the issue and are systematically present in debate is relatively limited. As previous research has suggested,<sup>14</sup> in this sector everyone knows everyone else and there is a very good knowledge of their respective arguments.<sup>15</sup> In this sense, the opinions reported here are generally shared views expressed by manufacturers, farmers or environmentalists. Further, to improve reliability - whenever possible - opinions collected via the survey have been backed by statements expressed in position papers.

The second shortcoming of the low response rate is methodological. The tool was meant to provide quantitative data on opinions expressed by applicants and other stakeholders, but the clearly unsatisfactory number of replies prevents any analysis of this type. However, as noted, the survey gave respondents the opportunity to leave comments - without a word limit. All but one respondents gave detailed explanations of their views on the issue under investigation. Combined with the analysis of policy papers published by stakeholders, comments included in the survey proved useful in the analysis and references to them are made thorough the report.

Because of the difficulties and limitations that characterised the stakeholder survey, this report should be mainly regarded as a study of CAs, their institutional characteristics and procedures. This constitutes an important and yet under-research topic that deserves better attention. As it will be explained, CAs play a fundamental role in delivering the goals of Regulation (EC) 1107/2009. Their daily activities are crucial to both public health and the environment. This study contributes to the formation of a better understanding of the factors that facilitate or constrain their capacity to fulfil this role.

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<sup>14</sup> Bozzini, E. (2017). *Pesticide Policy and Politics in the European Union. Regulatory Assessment, Implementation and Enforcement*. London: Palgrave Macmillan.

<sup>15</sup> This is not unique of the pesticide sector. Baumgartner and Jones noted that policy communities tend to be stable and that opposed actors are usually well aware of their competing arguments and preferences. See Baumgartner, F. R. and Jones, B. D. (2009). *Agendas and Instability in American Politics. Second Edition*. Chicago and London: The University of Chicago Press.

## II Hazard and risk in the approval of active substances

Part II presents an overview of the defining features of Regulation (EC) 1107/2009. The next section II.1 describes the stages in which regulatory risk assessment is structured and the difference between the concepts of hazard and risk that informs this structure. Section II.2 illustrates the logic that underpins Regulation (EC) 1107/2009 and its main goals. Section II.3 provides an overview of regulatory action and of competing opinions on its effectiveness.

### 1. Regulatory notions of hazard and risk

In the field of risk regulation, it is a well-established convention to divide the process of risk analysis into three phases: assessment, management, and communication.<sup>16</sup> Risk assessment – the main focus of this report – provides a quantitative and/or qualitative evaluation of hazards and risks for human health and the environment that derive from the exposure to an agent, in our case an active substance used to control pests.<sup>17</sup> Risk management integrates risk assessment findings with social, economic, and political considerations to deliver a decision on the appropriate policy option to deal with a hazard and mitigate or eliminate risks. Risk communication provides citizens with information about risk assessment and management and crucially comprises stakeholders' dialogue and public consultations.

As many commentators have observed, the distinction between the three phases is not as clear-cut as could be imagined, nor is it desirable.<sup>18</sup> A sustained dialogue between risk assessors and risk managers is crucial to guarantee that scientific appraisals address 'policy-relevant' issues and that management decisions are fully informed by sound evidence.<sup>19</sup> Furthermore, risk communication is not meant to be simply the final step in the process, of relevance only when authorities make risk analysis public to citizens. Rather, risk communication takes place along the entire process. In short, there are interactions and feedback effects among the three risk analysis tasks.

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<sup>16</sup> Black, J. 2010. "The Role of Risk in Regulatory Processes." Pp. 302-48 in *The Oxford Handbook of Regulation*, edited by Baldwin, R., Cave, M. and Lodge, M. New York, USA: Oxford University Press.

<sup>17</sup> In the scholarly literature and in policy documents, many formal definitions of risk assessment can be found. A very clear one is proposed in the Codex Alimentarius, where risk assessment is defined as a 'process intended to calculate or estimate the risk to a given target organism, system, or (sub)population, including the identification of attendant uncertainties, following exposure to a particular agent, taking into account the inherent characteristics of the agent of concern as well as the characteristics of the specific target system'. See Codex Alimentarius. Principles and guidelines for the conduct of microbiological risk assessment.

<sup>18</sup> Black, J. 2010.; Delogu, B. (2016). *Risk Analysis and Governance in EU Policy Making and Regulation. An Introductory Guide*: Springer International Publishing.

<sup>19</sup> On the relation between risk assessment and management see SCHER, SCENIHR and SCCS. (2011a). "Improvement of Risk Assessment in View of the Needs of Risk Managers and Policy Makers " European Commission, Bruxelles.

The EU's risk regulatory regime is, however, based on an institutional distinction between risk assessment and risk management, which are under the responsibility of different institutions. Risk analysis of pesticides is not different from this general EU approach. Regulation (EC) 1107/2009 affirms that 'it should be clarified that the Authority [EFSA] performs a risk assessment whilst the Commission should perform the risk management role and take the final decision on an active substance'.<sup>20</sup> Accordingly, criteria, actors, and procedures that characterise the stages of risk assessment and management are different and can be distinguished for analytical purposes. Since, as noted above, this report focuses mainly on risk assessment, the rest of this section will describe in more detail what is involved in this specific stage of the risk analysis process.

Risk assessment is structured into four distinct stages, each characterised by a defined set of goals and tasks: hazard identification, hazard characterisation, exposure assessment, and risk characterisation. A relevant point to bear in mind is that this structure of the process of risk assessment is based on the distinction between the concepts of hazard and risk:<sup>21</sup> hazard is defined as the intrinsic potential of a substance to cause harm, while risk is the likelihood of hazard to occur under certain specific circumstances.<sup>22</sup>

On the basis of this distinction, risk assessment is meant to proceed in an incremental way, starting with the identification of potential hazards and proceeding to the study of conditions under which damages can materialise and to the assessment of risks, i.e. the probability of harm. More specifically, according to the Commission Communication on Risk assessment:<sup>23</sup>

**Hazard identification** involves 'the identification of a risk source capable of causing adverse effect(s)/event(s) to humans or the environment, together with a qualitative description of the nature of these effect(s)/event(s)'.<sup>24</sup> It is the first step in a risk assessment and has as its main goal the clarification of human health and environmental issues of concern. Hazard identification, in other words, serves the purpose of identifying all the adverse effects that an active substance can potentially cause to human health and to the environment. In this sense, the main purpose is to recognise and classify the intrinsic properties of an active substance that can cause – for example – eye irritation, skin sensitization, or cancer. The hazard identification stage also informs the communication to users and to the general public: notably, pictograms used in the context of the Regulation 1272/2008 on Classification, Labelling, and Packaging of chemicals (CLP) refer to the hazards associated with chemicals.

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<sup>20</sup> Recital 12 Regulation (EC) 1107/2009

<sup>21</sup> The distinction between hazard and risk is very relevant and often overlooked. As Delogu noted, in EU regulation 'terms like risk and hazard are in some cases used without definition and distinction, and sometimes both appear to be used interchangeably in the same text.' Delogu, B. (2016). *Risk Analysis and Governance in EU Policy Making and Regulation. An Introductory Guide*: Springer International Publishing p.53. However, in the more specific context of risk regulatory processes the two terms are consistently used according to their technical meaning.

<sup>22</sup> Barlow, S., Boobis, A., Bridges, J., et al. (2015). 'The role of hazard- and risk-based approaches in ensuring food safety', *Trends in Food Science & Technology* 46:176-88

<sup>23</sup> European Commission. (2000b). "First Report on the Harmonisation of Risk Assessment Procedures." European Commission, Bruxelles.

<sup>24</sup> Ibid p. 51

**Hazard characterisation** goes one step further and has the main goal of establishing the dose-response relation, meaning the quantity of a chemical that is needed to trigger a specific adverse effect. It means that for each hazard that has been identified, the dose needed to cause it must be determined. A relevant distinction in this context is between non-threshold and threshold effects. Non-threshold effects can occur at any dose, so that a safe level of exposure does not exist. This is, for example, the case in genotoxic carcinogens and mutagens, that can damage the DNA of a single cell even at low doses. Threshold effects, on the contrary, materialise only above exposure to a certain amount of the chemical. A crucial goal of the hazard characterisation stage is therefore to determine a range of thresholds, such as the Lowest Observed Adverse Effect Level (LOAEL) and No Observed Adverse Effect Level (NOAEL), and establish doses of a chemical that are considered safe, such as the Admissible Daily Intake (ADI) and the Predicted No-Effect Concentration (PNEC).

**Exposure assessment** 'is concerned with the likely actual levels and duration of exposure to the risk source of human and environmental species'.<sup>25</sup> This stage is particularly complicated, to the point that it has become a 'distinct discipline in the study of health risk'.<sup>26</sup> It requires data on the variety of potential exposure contexts, routes' intensity, frequency, and duration of potential contact with the active substance. In the case of pesticides, relevant exposure contexts include farmers and users of the chemical, bystanders, residents and – to take into account dietary exposure – consumers.<sup>27</sup> Furthermore, it is important to acquire knowledge on the characteristics of the exposed population and to account for the presence of vulnerable groups – pregnant women, infants, and children – who must be given special attention (Recital 8 Regulation (EC) 1107/2009). Finally, the determination of the level of exposure requires data on degradation and accumulation of the active substance in the human body and the environment and the exposure of environmental organisms via water, soil, sediment, air.

**Risk characterization** is the final stage of the risk assessment process. The information on hazards and the data on exposure are used in combination to determine the probability that an active substance will cause harm under realistic conditions of use.

Each stage of risk assessment can be characterised by substantial uncertainty. Data gaps and inconclusive or contradictory findings are generally present in any procedure of evaluation.<sup>28</sup> Evaluators involved in risk assessment are required to clarify such uncertainties, as well as areas of disagreement among experts on the interpretation of findings. These aspects need to be explicated in the risk assessment report to inform the risk management stage. As mentioned above, results from the four stages of risk assessment are delivered to decision-makers who are charged with risk management, namely, with decisions on whether a risk can be considered acceptable and on the most appropriate measures to be taken in order to minimize or eliminate risks. For example, for

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<sup>25</sup> Ibid p. 65

<sup>26</sup> SCHER, SCENIHR and SCCS. (2013). "Making Risk Assessment More Relevant for Risk Management." European Commission, Bruxelles p.16.

<sup>27</sup> EFSA. (2014a). 'Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products', *EFSA Journal* 12:3874

<sup>28</sup> For a very recent discussion on different types of scientific uncertainty and to address them, see EFSA. (2018). 'Guidance on Uncertainty Analysis in Scientific Assessments', *EFSA Journal* 16:5123

active substances that are hazardous to eyes, risk managers might make eye protection mandatory for users. For carcinogenic active substances, risk managers can decide on a zero-tolerance policy and ban them to prevent any hazardous contact. Risk managers have also to consider areas of uncertainties that emerged in the scientific risk assessment and decide whether and how to apply the principle of precaution.

## **2. Hazard identification in the context of Regulation (EC) 1107/2009**

The concepts related to the stages of risk assessment are not unique to pesticide procedures but rather apply to risk regulation in general. Depending on the issue at stake, more emphasis is given to one or more of the four stages of risk assessment. For example, the risk assessment of an explosive substance will focus on hazard characterisation (the sequence of accidents that occur to cause an explosion) and risk characterisation (the likelihood of such a sequence of accidents actually taking place). As far as chemicals are concerned, the two relevant stages are usually hazard characterisation and exposure assessment: the most important information are the dose-response relationship and the likely patterns of contact with the chemical.

Active substances to be utilised for PPPs are regulated according to a different approach as long as the emphasis of Regulation (EC) 1107/2009 is on the stage of hazard identification. Article 4 of Regulation (EC) 1107/2009 establishes that an active substance shall only be approved if it is not classified as a carcinogen, a mutagen, toxic for reproduction, persistent and bio-accumulative, toxic for the environment, or an endocrine disrupter for humans and non-target organisms.<sup>29</sup> It means that if the hazard identification stage leads to a classification of the active substance that meets any of the cut-off criteria just mentioned, then it should be banned and therefore its use in PPPs prohibited in the European Union.

The main rationale for the adoption of this approach to pesticide regulation is that these hazards are unacceptable, and the risks associated with them should not be taken, whatever the likelihood they will occur. They are considered so severe that they are not manageable and therefore have been singled out as cut-off criteria for the approval of active substances. Conversely, the risk-based approach that characterised Directive 414/1991 was built on the idea that risks are unavoidable, but some have to be taken, and we can assess and manage them.

This hazard-based approach endorsed by Regulation (EC) 1107/2009 has an important procedural implication: if an active substance meets one of the cut-off criteria, the evaluation will stop at the hazard identification stage and will not proceed to the other stages of hazard characterisation, exposure assessment, and risk characterisation (see

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<sup>29</sup> More precisely, the pertinent CLP classifications for health hazards are: carcinogen 1A or 1B; mutagen 1A or 1B; and toxic for reproduction 1A or 1B. The specifications 1A and 1B refer to the strength of available evidence. For example, hazard categories for carcinogenicity are: 1A, for chemicals known to have carcinogenic potential for humans, on the basis of human evidence; 1B, for chemicals presumed to have carcinogenic potential for humans, on the basis of animal evidence; and Category 2 – ‘suspected human carcinogens’, for which evidence is not sufficient.

section IV.1). The approach also dictates risk management decisions, since 'non-approval' is – in principle – the only option. There are, however, relevant derogations that allow the granting of approval if an active substance is needed to address an emergency outbreak<sup>30</sup> and if exposure to it can be considered negligible (see section III.5).

The approach that requires regulatory decisions on approvals of active substances to be based on their intrinsic hazards is a central point in Regulation (EC) 1107/2009, and at the time of adoption it marked a radical policy change from previous legislation (Directive 414/1991) informed by a risk-based approach. It is also a characteristic that distinguishes the pesticide regulation from other 'cognate' legislative acts in the field of chemicals, which all take into account exposure and risk characterisation. The hazard-based approach also distinguishes EU pesticides regulation from provisions in force in other countries.<sup>31</sup>

Space limitation prevents a description of the policy process that led to the adoption of a highly stringent legislation in 2009.<sup>32</sup> It might be useful to briefly mention that initial proposals were advanced in the early 2000s, in the wake of food-related scandals, that pushed for the adoption of rules informed by a strong version of the principle of precaution.<sup>33</sup> Related to this, awareness of strong public support for strict regulatory standards is also a relevant factor. Chemicals in general – and pesticides in particular – are a source of public concern. For example, according to Eurobarometer data for 72% of EU citizens 'pesticide residues in fruit, vegetables or cereals' is the issue that causes the most concern among food-related risks.<sup>34</sup> Three characteristics help explain the strong public feelings against pesticides. First, pesticides are man-made hazards, which are regarded as being more serious than natural hazards such as earthquakes and flooding. Second, health hazards related to pesticides are perceived to be 'imposed' by farmers and users on individuals who are not in a position to fully control exposure and have no clear benefit from them. Third, pesticides are mainly associated with lethal pathologies, cancer in the first place.<sup>35</sup>

The hazard-based approach was also considered a solution to some of the most serious shortcomings of the implementation of Directive 414/1991: *in primis* delays in risk assessments of active substances. Because of the lack of guidance documents on hazard and risk assessment and deep divergences among MSs, evaluations of active substances could not proceed. Notably in 2001, ten years after the adoption of the Directive, only 30

<sup>30</sup> See the study (Milieu, 2018) on the practical usage made of derogations under Article 53 of Regulation (EC) 1107/2009 published under Annex I to the European Implementation Assessment.

<sup>31</sup> Matthews, G. A. (2016). *Pesticides. Health, Safety and the Environment*. Oxford: John Wiley & Sons.

<sup>32</sup> Bozzini. (2017).

<sup>33</sup> See Loefstedt, R. (2011). 'Risk versus Hazard -How to regulate in the 21st Century', *European Journal of Risk Regulation* 2:149-68; Vogel, D. (2012). *The Politics of Precaution: Regulating Health, Safety, and Environmental Risks in Europe and the United States* Princeton: Princeton University Press; Wiener, J. B. 2011. "The Rethoric of Precaution." in *The Reality of Precaution. Comparing Risk Regulation in the United States and Europe*, edited by Wiener, J. B., Rogers, M. D., Hammitt, J. K. and Sand, P. H. Washington DC & London: RFF Press; *ibid*.

<sup>34</sup> Eurobarometer. (2010). "Food-related Risks." Bruxelles.

<sup>35</sup> Sunstein, C. R. (2004). *Risk and Reason: Safety, Law, and the Environment*. Cambridge: Cambridge University Press; Viscusi, K. (1998). *Rational Risk Policy*. Oxford: Oxford University Press.

out of more than 800 active substances had been assessed.<sup>36</sup> One of the most relevant hurdles was that, as briefly noted above, the determination of likelihood of harm requires complex data on exposure which might prove difficult to collect in a reliable way. As a consequence, it might prove complicated to calculate probability of risks. Serious delays had accumulated in the early 2000s because of extremely time-consuming procedures. In this light, the possibility of stopping the process at the hazard identification stage for obviously hazardous substances seemed attractive since it avoids time-consuming evaluations of likelihood of unacceptable risks. The application of the hazard-based approach therefore promised to simplify and significantly speed up risk assessment procedures (see sections IV.1.2 and IV.3).

It also seemed promising to significantly contribute to achieving a high level of protection for human health and the environment; as noted above, it is one of the most important goals of Regulation (EC) 1107/2009. Notably, the hazards identified as cut-off criteria are not meant only to prevent exposure to seriously harmful active substances. They also inform the application of the principle of substitution, a provision introduced to phase-out hazardous active substances and replace them with 'plant protection products containing active substances which require less risk mitigation' or with 'non-chemical control or prevention methods'.<sup>37</sup> Accordingly, 'some active substances with certain properties [defined by classification according to cut-off criteria] should be identified at Community level as candidates for substitution'.<sup>38</sup> In addition, Regulation (EC) 1107/2009 attempts to incentivise the use of low-risk substances. Recital 17 reads: 'The evaluation of an active substance may reveal that it presents considerably less of a risk than other substances. In order to favour the inclusion of such a substance in plant protection products, it is appropriate to identify such substances and to facilitate the placing on the market of plant protection products containing them. Incentives should be given for the placing on the market of low-risk plant protection products'.<sup>39</sup> Finally, basic substances are those that are not substances of concern, do not cause endocrine disruption, do not have neurotoxic or immunotoxic effects, and – while not predominantly used in the production of PPPs – can be useful in plant protection. Examples of basic substances include beer, fructose, lecithin, mustard seed powder, and vinegar.

A final relevant feature of Regulation (EC) 1107/2009 is that hazard and risk assessments for an active substance need to be updated in light of new legal requirements and scientific advancement.<sup>40</sup> Accordingly, approvals of active substances are temporary: they are generally accorded for a period of 10 years, to be increased to 15 years in the case of low-risk substances and decreased to 7 years in the case of candidates for substitution (see sections IV.1.1 and IV.1.2).

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<sup>36</sup> For a very detailed policy evaluation of delays under Directive 414/1991 see European Commission. (2001). "Technical Annex to Report on the Evaluation of the Active Substances of Plant Protection Products."

<sup>37</sup> Recital 19 Regulation (EC) 1107/2009

<sup>38</sup> Ibid.

<sup>39</sup> It might be worth noting that low-risk substances can be either of biological or synthetic origin.

<sup>40</sup> Articles 14 to 20 Regulation (EC) 1107/2009

To sum up, on the whole Regulation (EC) 1107/2009 is an ambitious legislative act that aims at providing a high level of protection to human health and the environment by adopting strict regulatory criteria for approvals of active substances. It goes in the direction of sustainability by supporting the substitution of high-risk chemicals with low-risk ones by creating incentives for their entry into the market. This is expected to guarantee the competitiveness of EU farming as well as its overall sustainability. The next section is dedicated to the description of regulatory results and of opinions on the strengths and weaknesses of the implementation stage of Regulation (EC) 1107/2009.

### **3. Overview of regulatory action: number, types, and characteristics of approved and non-approved active substances**

Opinions on the overall effectiveness of EU regulatory action to deliver on its goals differ widely among the actors. Two quotations taken from documents published by stakeholders on opposite sides of the debate will help clarify the distance between the positions:

'EU legislation requires the comprehensive testing of active substances, which is increasingly extensive and continuously updated in line with scientific advances. Therefore, the products used today are the safest ever made'.<sup>41</sup>

'Although many hazardous pesticides have been withdrawn from the European market in recent years, there are still many registered for which there are serious, scientifically documented concerns for human health, particularly for longer-term health effects including harm to the nervous, immune, hormone and reproductive systems'.<sup>42</sup>

The rest of this section will present available data on approvals and bans and will describe opinions on some of the defining features of Regulation (EC) 1107/2009 as presented above. Specifically, it reports on views of the application of cut-off criteria and its effects and of the effectiveness of regulatory action to deliver on its goals of protecting human health and the environment, guarantee the competitiveness of EU agriculture, and to apply the principle of substitution.

According to the Commission, since a common pesticide legislation went into force in the early 1990s, 60% of active substances in use across EU countries have been banned.<sup>43</sup> Table 1 below shows the number of procedures on active substances finalised by year, distinguishing between number of approved and number of banned chemicals.

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<sup>41</sup> ECPA. (2013) p.5.

<sup>42</sup> Pesticides Action Network. (2008). "Which Pesticides are Banned in Europe?" PAN Europe, Bruxelles p.3; Pesticides Action Network. (2012). "Twisting and Bending the Rules: In 'Resubmission' all efforts are aimed to get pesticides." PAN, Bruxelles.

<sup>43</sup> European Commission. (2016). "Commission Staff Working Document. Impact Assessment: Defining criteria for identifying endocrine disruptors in the context of the implementation of the plant protection products regulation and biocidal products regulation." European Commission,, Bruxelles.

Table 1: Number of active substances approved and non-approved by year

	Number of approvals	Number of non-approvals (Bans and withdrawals)
Before 2001 <sup>44</sup>	0	31
2001	3	3
2002	5	320
2003	11	3
2004	21	116
2005	19	10
2006	21	11
2007	36	136
2008	10	22
2009	157	4
2010	28	3
2011	48	20
2012	19	3
2013	24	2
2014	30	7
2015	25	6
2016	26	9
2017	26	13
Never applied in EU <sup>45</sup>	--	91
	509 <sup>46</sup>	810

Source: Own elaboration from EU pesticide database

As can be noted, a huge number of active substances had been prohibited in the 2000s. Over the years about 400 active substances have been denied approval because manufacturers withdrew applications under Directive 414/1991 or decided not to submit additional evidence as requested by on-going evaluation processes.<sup>47</sup> Another 10 active substances have been banned because they were included in the list of persistent organic pollutants (POP) agreed upon in the context of the Stockholm Convention on persistent organic pollutants.<sup>48</sup> In other words, a significant number of chemicals were forbidden

<sup>44</sup> Only few active substances have been evaluated by year in the first decade of application of Directive 414/1991. To enhance readability, they have been grouped into a single entry.

<sup>45</sup> This refers to substances that were in use in MSs before the entry into force of EU-wide pesticide regulation and for which an application has never been submitted. These active substances have never been considered for approval and are banned.

<sup>46</sup> The actual number of approved active substances is 494. In Table 1 it is reported as a total of 509, since this includes 15 active substances that were at first approved and later banned.

<sup>47</sup> Taken together, Commission Regulation 2076/2002, Commission Decision 129/2004, and Commission Decision 442/2007 revoked approval of almost 400 active substances for which dossiers were not completed by applicants.

<sup>48</sup> See <http://chm.pops.int/Home/tabid/2121/Default.aspx>. The Stockholm Convention has been ratified in 2004 (Regulation (EC) 850/2004); see also Directive 117/79 that banned 17 organic pollutants of relevance for pesticides.

before Regulation (EC) 1107/2009 went into effect in 2011, a trend that manufacturers strongly criticised. Indeed, back in the mid-2000s when Regulation (EC) 1107/2009 was under discussion, the idea of basing evaluations on intrinsic hazards of active substances and the list of cut-off criteria sparked a lively discussion among experts and decision-makers. Critics dismissed the hazard approach as a partial and essentially flawed method for the regulation of chemicals.<sup>49</sup> They also observed that such a restrictive approach would result in additional unnecessary bans of useful active substances for which risk mitigation measures can be effectively implemented. Notably, over the years a number of CAs and stakeholders published impact assessment reports to appraise the likely number of active substances that would have been banned as a result of the application of the hazard-based approach. Estimations differ widely: a unofficial estimation of the Commission indicated that approximately 5% of active substances could be expected to meet cut-off criteria.<sup>50</sup> In Italy experts increased this proportion to 40%.<sup>51</sup> According to UK estimations, the adoption of cut-off criteria could result in a ban of 80% of active substances.<sup>52</sup> Similarly, Agra CEAS – a think-tank – suggested that a proportion of about 85% of PPPs would be banned or significantly restricted.<sup>53</sup>

Against these estimations it is relevant today to note that at the time of writing, the expected bans resulting from the hazard-based approach did not materialise. It appears from the analysis of data published in the EU pesticide database – and confirmed in interviews with CA – that the application of cut-off criteria has so far directly resulted in one active substance being refused approval. This is the case of Linuron – an herbicide manufactured by Adama, a branch of Chemchina. It was banned from the EU market in 2017 after it was classified 'Repr. 1B', i.e. there was sufficient animal evidence that the chemical is presumably toxic for reproduction (see also section IV.3.3).<sup>54</sup>

As part of the research, during interviews and in the survey, CAs and stakeholders were asked to explain the gap between initial estimations and actual results. A variety of arguments were offered. First, some CAs noted that 'the old hazardous chemicals have already been banned in EU', meaning that for all its shortcomings, the repealed Directive 414/1991 proved effective in protection of human health. Second, replies to the survey from farmers and manufacturers suggest that cut-off criteria have been effective in putting off the market hazardous substances in the sense that chemicals understood to be potentially problematic under EU rules are simply not proposed for approval and renewal of approval. The large number of withdrawals of applications noted above would be an

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<sup>49</sup> Loefstedt. (2011)

<sup>50</sup> Bozzini. (2017)

<sup>51</sup> ENEA. (2011). "Future availability of pesticides in the integrated pest management agricultural programme in Italy in accordance with the application of the new EU Regulation 1107/2009." ENEA, Rome.

<sup>52</sup> UK Pesticide Safety Directorate. (2008). "Revised assessment of the impact on crop protection in the UK of the 'cut-off' criteria and substitution provisions in the proposed Regulation of the European Parliament and of the Council concerning the placing of plant protection products on the market." PSD, York, UK.

<sup>53</sup> AgraCEAS Consulting Ltd. (2008). "Impact Assessment on the proposed changes for authorisation and use of pesticides." Agra CEAS Consulting Ltd., Bruxelles.

<sup>54</sup> Commission Implementing Regulation (EU) 2017/244 of 10 February 2017.

indication of this trend.<sup>55</sup> Third, the full effect of the application of cut-off criteria is understood to have been simply postponed, in particular because of delays in the adoption of guidelines on the evaluation of endocrine-disrupting properties of chemicals, which are generally expected to have a significant impact on authorisations (see III.4). A 2016 study by Steward Redqueen – a consultancy - estimates that because of the full application of cut-off criteria in the coming years 75 of 400 substances currently available to farmers might be withdrawn from the market.<sup>56</sup> Fourth, a more critical view expressed by interviewees argues that cut-off criteria have not been properly implemented and that hazardous substances are still in use.

It seems safe to argue, however, that so far the introduction of the hazard-based approach as a criterion for decisions regarding approval has not resulted in the ‘dramatic’ effects envisaged during the policy discussions over the adoption of Regulation (EC) 1107/2009. In other words, bans have not been dictated by evaluations of the intrinsic properties of chemicals coming from the hazard identification stage of risk assessment, as required by the hazard-based approach. Rather, bans have been decided on the basis of evidence gathered from all the stages of risk assessment (hazard identification and characterization, exposure assessment and risk characterisation), coupled with risk management considerations informed by the principle of precaution. As one CA noted, ‘we are not aware of any active substance which has been eliminated solely on the basis of its intrinsic hazard. All those which have breached the cut-off criteria have also failed risk assessment, which sets high standards of protection’.

Moreover, as it will be addressed in more detail in Section IV.3.1, the adoption of cut-off criteria has not delivered the expected simplification of procedures or approvals.

Independent of the actual reasons that lead to the non-approvals, it is generally recognised that the number of active substances that are available is substantially decreasing. The stringent regulatory criteria – either based on hazard or on risk – that are in use are said to result in unnecessary bans of needed defence tools and to prevent innovation and the introduction of new active substances. This view is widely shared among representatives of conventional farmers and industry. For example, the argument has been made again and again by manufacturers and farmers convened in an event titled ‘The Great Pesticide Debate’ devoted to the promotion of a difficult dialogue between opposing views.<sup>57</sup> It also emerged very clearly during interviews carried out for this study. As one manufacturer observed ‘we have a few insecticides in the pipeline but are reluctant to start a procedure in the EU’. Accordingly, when asked to what extent EU Regulation is effective in providing farmers with the tools they need, their most likely answer is ‘not at all’. According to this view, the problem is particularly severe for specialty crops and minor uses, namely for crops that are grown on relatively small areas and that requires PPPs to target specific pest problems. Further, limitations in the number of active substances prevent the full and

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<sup>55</sup> More generally, industry representatives pointed out in interviews that manufacturers are increasingly likely to avoid the EU, preferring the expanding and more profitable markets in Asia and Latin America.

<sup>56</sup> Steward Redqueen. (2016). "Cumulative impact of hazard-based legislation on crop protection products in Europe." Steward Redqueen, Haarlem (NL).

<sup>57</sup> See <https://www.politico.eu/event/the-great-pesticides-debate/>

correct adoption of Integrated Pest Management (IPM), which - as some CAs observed - requires a broad range of active substances with different modes of action to be practicable.<sup>58</sup>

These regulatory factors combine with research and development complications in limiting the range of available tools. ECPA notes that industry finds it increasingly difficult to discover and develop molecules that are safe (and profitable). In a 2016 study it is affirmed that - worldwide - the number of new active substances introduced or in the development phase in the period 2005-2014 was 73, down from 128 in the period 1990-1999.<sup>59</sup>

The seriousness of the decrease in active substances for EU agriculture is questioned by organisations representing organic farming, public health and environmental interests, who point out the existence of viable alternatives to conventional chemicals. For example, the campaign on low-impact farming promotes ecosystem-based approaches, which are based on 'solid agronomic practices to prevent pest build-up'<sup>60</sup> and on the use of non-chemical alternatives. The substantial reduction of chemical inputs is a main goal of this approach. As mentioned, the adoption of these principles on the part of farmers should be incentivised by application of the principle of substitution and the introduction of low-risk active substances.

However, the effectiveness of EU procedures to incentivise the entry into the EU market of low-risk/basic substances and specifically of biopesticides has been for long put into question. Respondents to the survey - private and public interests alike - affirm that delays in approval of low-risk substances are a factor that strongly negatively affects their opinion on the effectiveness of the implementation of Regulation (EC) 1107/2009.

At the time of writing, the EU pesticide database includes 10 active substances classified as low-risk, of which eight are microorganisms or viruses. In terms of basic substances, a total of 24 dossiers have been included in the EU pesticide database.<sup>61</sup> Supporters

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<sup>58</sup> Integrated Pest Management (IPM) is a set of practices based on the ideas of both reduction of chemical inputs and anticipation and prevention of pest damages. It includes practices such as the use of biological control, meaning the release in fields of insects, fungi, bacteria or viruses that are natural enemies of the unwanted pests; the use of crop rotation and the management of crop residues in order to minimise the diffusion of damaging insects and weeds.

<sup>59</sup> Phillips McDougall. (2016). "The Cost of New Agrochemical Product Discovery, Development and Registration in 1995, 2000, 2005-8 and 2010 to 2014. R&D expenditure in 2014 and expectations for 2019. A Consultancy Study for CropLife International, CropLife America and the European Crop Protection Association." Phillips McDougall. See also: Chapman, P. (2014). 'Is the regulatory regime for the registration of plant protection products in the EU potentially compromising food security?', *Food and Energy Security* 3:1-6

<sup>60</sup> See <http://www.low-impact-farming.info/>; See also Pesticides Action Network. (2015b).

"Integrated Pest Management - Working with nature." PAN Europe, Bruxelles.

<sup>61</sup> Not all of the 24 basic active substances have been approved, since their 'natural' origin does not mean that they do not pose hazards for human health. For example, *Artemisia Vulgaris* L. - a plant utilised as insect repellent but also in medicine - has not been granted an approval as a basic substance because the evaluation identified concerns for operators, workers, bystanders, consumers, and non-target organisms. See Commission Implementing Regulation (EU) 2015/1191 of 20 July 2015.

(including MEPs) suggest that low-risk active substances and products are put at a disadvantage compared to synthetic chemicals. This is mainly because consideration of efficacy in targeting pests (one of the evaluation criteria for approval of active substances) rewards synthetic chemicals. An initiative promoted during the Dutch presidency of the Council and endorsed by the Commission aims at re-assessing the evaluation criteria for active substances that are classified as low-risk in order to weight their lower efficacy against the environmental and health benefits they might provide. In August 2017 the Commission adopted Regulation 1243/2017 in which it specifies the criteria for the classification of an active substance as low-risk. Further action in this field is expected in 2018, following a Resolution of the EP that 'calls on the Commission and the Member States to accelerate the evaluation, authorisation, registration and monitoring of the use of low-risk plant protection products of biological origin while maintaining risk assessment at a high level'.<sup>62</sup>

In summary, opinions are diverse and generally polarised. Organisations representing farmers and those representing manufacturers emphasise a poor performance in guaranteeing that an adequate number and type of PPPs are on the market at disposal of EU agriculture. Deficiencies in effective safeguard of human health and the environment are instead pointed out by environmentalists and public health activists. However, actors on opposite sides of the debate share the view that the implementation of Regulation (EC) 1107/2009 did not prove effective in promoting low-risk active substances.

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<sup>62</sup> European Parliament resolution of 15 February 2017 on low-risk pesticides of biological origin.

### III Harmonisation of criteria for hazard identification

Regulation (EC) 1107/2009 envisages a common EU policy on pesticides that is committed to 'ensure a high level of protection of both human and animal health and the environment', 'to safeguard the competitiveness of Community agriculture', and to remove obstacles to free trade among EU countries. To achieve these ambitious goals, the harmonisation of criteria and procedures for the approval of active substances and PPPs is a necessary precondition. The following sections discuss the harmonisation of regulatory criteria for hazard identification, with a focus on the adverse effects that have been identified as cut-off criteria.

As explained below, the work of CAs is strongly influenced by the existence of official regulatory guidelines, and the need to refine and apply them to deliver reliable and consistent evaluations. Since the inception of EU pesticide legislation in the '90s, many resources have been devoted to climb the 'arduous scientific and methodological learning curve'<sup>63</sup> and develop common guidelines. At present, most testing has been institutionalised and protocols are agreed upon at the EU and international level, such that data are supplied according to specific research designs, methodologies, and techniques. Yet it is important to stress that different areas of inquiry are characterised by different degrees of harmonisation.

First, the area of residues is fully harmonised, following Regulation 396/2005 and the subsequent documents that provide guidance on methods for assessment as well as control.<sup>64</sup>

Second, the area of toxicology is established and consolidated. As Delogu noted, 'health risk assessment is today performed in most cases by conventional methods that have not changed significantly since many decades'.<sup>65</sup> This is not to say that testing of – let us say – carcinogenicity or mutagenicity is a purely technical matter, since the scientific understanding of adverse health effects is constantly developing, and experts involved in regulations necessarily need to take these developments into account. Further, trade-offs are involved in tests, so that their reliability and validity might be a matter of debate and expert opinions among evaluators might differ on interpretations. It is beyond the scope of this report to describe the contents of guidelines on toxicological testing. However, for illustrative purposes, section III.2.1 will briefly describe the evolution of criteria for interpretation of findings for carcinogenicity, as well as some of the issues that are likely to characterise hazard assessments and the relevant areas of uncertainty that might be expected to characterise results from laboratory testing.

A third area of inquiry is about the environmental fate and behaviour of active substances and ecotoxicology. Here guidelines are much more recent, less consolidated and, in some cases, incomplete. Fourth, if guidelines on toxicology, environmental fate and behaviour,

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<sup>63</sup> European Commission. (2001) p.7.

<sup>64</sup> This report will not address the assessment of MRL; the chosen focus is on toxicological, environmental and ecotoxicological cut-off criteria.

<sup>65</sup> Delogu. 2016. p. 85

and ecotoxicology have different degrees of harmonisation, the debate is still ongoing on a range of issues that are of direct relevance for the assessment of hazards and risks associated with active substances. The assessment of endocrine disrupting properties, the evaluation of chemical mixtures, the integration of epidemiology and toxicology, and the utilisation of peer-reviewed literature in hazard assessment are among the most pressing issues under discussion and will be described in some detail.

Overall, it seems safe to argue that scientific and regulatory debates are very lively in the context of pesticide evaluations, as experts are engaged in a variety of panels and ad hoc working groups at both EFSA and DG Sante to refine existing guidelines and develop new ones to catch up with scientific progress as well as to fulfil legal requirements. As an EFSA representative noted, pesticide assessments are often at the forefront of regulatory developments, effectively anticipating (and to some extent testing) methods and solutions that will later be adopted in other sectors. For example, the methodology and the procedure for the assessment of the cumulative effects of active substances and for EDC have been first proposed for pesticides and only later the discussion has been extended to general chemicals (see below III.6). The effort of CAs, EFSA and DG Sante – and more extensively the network of experts involved – is reported as a very relevant part of their work, one that demands significant resources. Regulatory translation of scientific approaches proves time consuming and is often controversial. It systematically takes significantly longer than expected and mandated by legislators. For example, Regulation (EC) 1107/2009 required the Commission to agree on guidelines on EDC by December 2013, but was achieved only recently in December 2017 (see below III.4).

The chapter is organised as follows: I will start by describing data requirements in order to illustrate the characteristics of the typical pesticide dossier. In this section, I will also describe divergent opinions on legal obligations under Regulation (EC) 1107/2009. I will then address health hazards, where harmonisation is at its maximum, to proceed in Section 3 with a description of the testing of environmental hazards – where some of the guidelines are still under development. Sections 4 to 8 are dedicated to open questions that are currently under discussion among experts involved in hazard and risk assessments. The final section provides some conclusive remarks on progress towards harmonisation.

## **1. Data requirements: overview and opinions**

Regulation (EC) 1107/2009 includes provisions on criteria to be adopted for the evaluation of active substances (see above II.2). For criteria to be workable, they need to be complemented by more specific provisions on data requirements as well as detailed indications on guidance documents and protocols that must inform the studies submitted by applicants. The latter consist of technical documents detailing research designs, methodologies and techniques for laboratory testing that have been adopted by OECD, EFSA and/or DG Sante.<sup>66</sup>

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<sup>66</sup> See OECD:

<http://www.oecd.org/chemicalsafety/testing/seriesontestingandassessmentadoptedguidanceandreviewdocuments.htm>;  
EFSA: [http://efsa.onlinelibrary.wiley.com/hub/issue/10.1002/\(ISSN\)1831-4732.GUIDANCE/](http://efsa.onlinelibrary.wiley.com/hub/issue/10.1002/(ISSN)1831-4732.GUIDANCE/)

Accordingly, after the adoption of Regulation (EC) 1107/2009 the Commission published a first implementing Regulation on data requirements in 2011 (Regulation 544/2011). Later in 2013, Regulation 283/2013 repealed Regulation 544/2011 and established a broader list of requirements and provided updated indications about the protocols and/or the guidance documents.<sup>67</sup> Data requirements cover 6 main areas of inquiry:

- Physical and chemical properties of the active substance, including evaluation of efficacy – in this context meaning the desired adverse effect on harmful organisms;<sup>68</sup>
- Toxicological and metabolism studies (see section III.2);
- Residues;
- Fate and behaviour in the environment (see section III.3);
- Ecotoxicological studies (see section III.3);
- Literature data: since Regulation 1107/09 entered into force, it is mandatory to include in the dossier a summary of evidence available in the open peer reviewed literature (see section III.8).

For each area, specific tests are to be included. Kaltenhauser and colleagues (2017) calculate that around 200 studies are to be submitted for the assessment of effects on human health and a similar number for addressing environmental and ecotoxicological issues.<sup>69</sup>

It has often been reported in interviews that data requirements for pesticides are likely to be the most demanding ones in the context of EU regulations. Notably, it has often been pointed out that the available datasets on active substances are considerably larger than the ones at disposal to evaluators in the context of REACH Regulation on chemicals.<sup>70</sup> This is usually perceived as an advantage by evaluators working for competent authorities, who are in position to deliver assessments informed by a broad range of evidence. Yet,

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DG Sante website:

[https://ec.europa.eu/food/plant/pesticides/approval\\_active\\_substances/guidance\\_documents\\_en](https://ec.europa.eu/food/plant/pesticides/approval_active_substances/guidance_documents_en)

<sup>67</sup> A separate Regulation (Reg 284/2103) further details criteria and data requirement for the authorisation of PPPs.

<sup>68</sup> According to the standards developed by the European and Mediterranean Plant Protection Organisation (EPPO), considerations of efficacy in the evaluation of active substance for PPPs have to balance three different aspects: the performance of the active substance in delivering the desired protection of the quantity and/or quality of crops; the negative effects on relevant factors like beneficial organisms or the development of resistance; other potential effects that 'include effects on non-target pests, length of time in which the plant protection product continues to be active, ease of its use, and compatibility with cultural practices and other crop protection measures'. The evaluation of efficacy is not performed in the USA, where the merits of a products for the defence of crops are left to the market to decide: if it is effective in controlling pests it will sell, otherwise it will not.

<sup>69</sup> Kaltenhauser, J., Kneuer, C. and Marx-Stoelting, P. (2017). 'Relevance and reliability of experimental data in human health risk assessment of pesticides', *Regulatory Toxicology and Pharmacology* 88:227-37

<sup>70</sup> Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC

interviewed NGOs identify data gaps, particularly on developmental neurotoxicity. Conversely, manufacturers tend to view EU requirements as demanding, expensive, and not proportionate to the risk to be evaluated. Another pressing issue is that requirements are becoming increasingly complex over time, an aspect frequently stressed by CAs too. Further, new guidelines are not always fit for purpose, meaning that they are not practical to implement. The frequent update of guidelines and legal requirements is another problematic issue, mainly from the applicants' perspective. According to the Commission, the adoption of a new Regulation on data requirement in 2013, only two years after the previous one, has been necessary 'to take into account current scientific and technical knowledge', as well as developments in technical guidelines and test methods. Further, new EFSA and/or DG Sante guidance documents are made public every year. These changes leave manufacturers disappointed, since dossiers already under preparation had to be updated. More importantly, manufacturers complain that new guidance documents are applied 'retrospectively' to already submitted dossiers. A dossier contains data and studies according to requirements in force at the time of submission. However, it is possible that – by the time the dossier arrives at EFSA – new guidelines have been approved. In these cases, additional information will be requested, or data gaps identified in the dossier. In both cases, the procedure of approval is likely to slow down, and its outcome becomes more unpredictable. A manufacturer commented in the survey that 'never ending changes in guidance documents cause delays in submission of new active substances and renewals of existing ones.' Finally, regulatory uncertainty arises from the selective application of guidelines that have been published but not formally adopted by risk managers. These have no legal validity, but it might be the case that CAs decide to utilise them and incorporate them in national provisions. The point has been stressed by manufacturers as well as NGOs. The latter push for a swift adoption on the part of SCoPAFF of updated guidance documents. It might also be noted that this arrangement – guidelines voted by risk managers – is unique to the pesticides regulatory regime. In other regulatory sectors EFSA is in position to formulate and adopt risk assessment criteria, whose application does not require a political vote in comitology.

An additional consideration pertinent to data requirements refers to ongoing efforts to minimise animal testing. Alternatives to animal testing in hazard identification and risk assessment have been advanced for many endpoints.<sup>71</sup> The debate revolves around many proposals for alternative testing that imply a reduction in use, modifications, or the abandonment of this type of study. Much of the search for alternative methods to animal testing have focused on how to replace the *in vivo* tests with *in vitro* and *in silico* (i.e., computational) methods. Opinions differ on the extent to which these methods – while promising – can be considered a reliable substitute to toxicological 'gold standards' like the 2-year rodent carcinogenicity testing. This is particularly true for pesticide regulation,

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<sup>71</sup> Scholz, S., Sela, E., Blaha, L., et al. (2013). 'A European perspective on alternatives to animal testing for environmental hazard identification and risk assessment', *Regulatory Toxicology and Pharmacology* 67:506-30

which appears to be the most demanding and 'conservative' among EU regulations on chemicals.<sup>72</sup>

### 1.1 Asymmetry of information and independence

The dossier on every active substance is put together by applicants, meaning a manufacturer or a consortium of manufacturers.<sup>73</sup> In this sense, the regulatory assessment relies on 'industry-supplied evidence'. The rationale for this provision lies in the logic of the precautionary principle, that puts the burden of proof on applicants. It means that manufacturers who are interested in marketing their plant protection products in Europe have to provide evidence about the safety of active substances contained in them.<sup>74</sup> Accordingly, manufacturers perform the test activities in order to collect data, either in-house, or by commissioning studies conducted by external certified laboratories that are specialised in carrying out testing according to OECD/EU and international protocols. This aspect has become contentious in recent debates, most notably on occasion of the glyphosate controversy. The reliance on tests that are supplied by the industry has been characterised as inherently biased and therefore inadequate to constitute a sound and independent evidence-base to be used in risk assessment. Critics advocated for a radical change in the procedure, asking for applicants to pay the costs of regulatory studies that must be commissioned to external laboratories by public authorities.<sup>75</sup> For example, CEO states that 'to prevent the corporate capture of EU safety assessments, the EU food safety agency must become independent from the companies whose products it evaluates and its assessments must be more transparent. Manufacturers should keep paying for the studies necessary to assess the safety of their products, but the research needs to take place at independent laboratories and findings must be published for scrutiny by the scientific community'.<sup>76</sup>

<sup>72</sup> Joint Research Centre. (2016). "Analysis of carcinogenicity testing for regulatory purposes in the EU. Review of the current demand of in vivo carcinogenicity studies across sectors." European Commission, Luxembourg.

<sup>73</sup> Regulation (EC) 1107/2009 encourages the formation of consortia among manufacturers in order to avoid duplications and reduce the number of animals utilised in testing. Joint applications from at least two manufacturers have been submitted for the renewal of the majority of AIR chemicals, and for some – like glyphosate, 2,4-D – a task force involving all major chemical industries has been set up. See for example: <http://www.glyphosate.eu/> and <http://www.24d.org/>.

<sup>74</sup> It might be relevant to recall that in the past a reverse logic was in place: public authorities had to prove a chemical hazardous in order to ban it. See: European Environmental Agency. (2002). "Late Lessons for Early Warnings." EEA, Copenhagen; European Environmental Agency. (2013). "Late Lessons for Early Warnings II." EEA, Copenhagen.

<sup>75</sup> Corporate Europe Observatory. (2017a). 'Beneath the Glyphosate headlines, a crucial battle for the future of EU pesticide approvals', <https://corporateeurope.org/food-and-agriculture/2017/10/beneath-glyphosate-headlines-crucial-battle-future-eu-pesticide> Accessed 11 January 2018.

<sup>76</sup> Corporate Europe Observatory. (2017b). 'Monsanto Papers hearing at EU Parliament to lift lid on flawed EU pesticide approval process', <https://corporateeurope.org/pressreleases/2017/10/monsanto-papers-hearing-eu-parliament-lift-lid-flawed-eu-pesticide-approval> Accessed 01 March 2018.

Two factors are mentioned by CAs to guarantee the quality of data. First, studies must be carried out according to the principles of Good Laboratory Practice (GLP). GLP is a regulatory standard for laboratory testing that has been developed at the international level to promote the Mutual Acceptance of Data among countries. It includes a list of detailed provisions on the 'organisational process and the conditions under which non-clinical health and environmental safety studies are planned, performed, monitored, recorded, archived and reported'.<sup>77</sup> GLP is therefore a quality system, meant to guarantee transparency and accessibility to laboratory results.<sup>78</sup>

Second, applicants are obliged to submit all original findings on which studies and reports are based. It means that competent authorities have raw data at their disposal to provide an original and independent interpretation of laboratory results, a point frequently underlined in interviews as a crucial aspect.<sup>79</sup> Access to raw data allows evaluators to perform their own re-calculation and analysis, if needed to clarify findings. Notably, the point has been made in relation to the glyphosate controversy, since the availability of raw data and therefore the opportunity to see laboratory findings first hand makes a relevant difference with the evidence-base at the disposal of IARC experts, who have to rely on studies and secondary data and what is made available at the discretion of journals and regulatory agencies (see below III.8).

In April 2018, the Commission published a proposal for a Regulation to ensure greater independence of the EU risk assessment in the food chain.<sup>80</sup> The proposal includes the creation of a 'Union Register of Studies', to double check whether dossiers submitted by applicants includes all studies that have been carried out to test a particular active substance or rather a selection of them. It also establishes a system of controls and audits to ensure the compliance of laboratories and studies with GLP standards. Further, according to the proposal the Commission may ask EFSA to commission additional studies in exceptional circumstances, such as high level of public controversy on a substance.

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<sup>77</sup> OECD. (1998). "OECD Principles on Good Laboratory Practices." OECD, Paris p.14.

<sup>78</sup> OECD. (1998).

<sup>79</sup> The sections of the dossier containing raw data are at the disposal of evaluators but are not disclosed to the general public. Critics pointed out the lack of transparency of the EU appraisal system, asking for the publication of dossiers in their entirety. See more on this point in the section on transparency (IV.1.3).

<sup>80</sup> European Commission (2018) Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the transparency and sustainability of the EU risk assessment in the food chain amending Regulation (EC) No 178/2002 [on general food law], Directive 2001/18/EC [on the deliberate release into the environment of GMOs], Regulation (EC) No 1829/2003 [on GM food and feed], Regulation (EC) No 1831/2003 [on feed additives], Regulation (EC) No 2065/2003 [on smoke flavourings], Regulation (EC) No 1935/2004 [on food contact materials], Regulation (EC) No 1331/2008 [on the common authorisation procedure for food additives, food enzymes and food flavourings], Regulation (EC) No 1107/2009 [on plant protection products] and Regulation (EU) No 2015/2283 [on novel foods], COM(2018) 179 final.

## 2. Health Hazards: Carcinogenicity, Mutagenicity and Toxicity for Reproduction

The list of health hazards to be evaluated in regulatory processes dealing with the approvals of active substances for pesticides includes acute and chronic toxicity, adverse effects on skin and eyes, on respiratory functions, and the hazards usually identified with the acronym CMR, namely carcinogenicity, mutagenicity and toxicity for reproduction. As noted above, CMR are cut-off criteria (see above II.2).

An agent is classified as carcinogenic if it induces or increases the incidence of cancer. Mutagens are substances that may induce permanent and transmissible changes (mutations) in the amount or structure of the genetic material of cells or organisms. It is of note that the term genotoxicity is often found in combination with mutagenicity but there is a difference between the two. Genotoxicity is a broader term since it refers to any effect on DNA, not necessarily to those that involve mutations. Accordingly, while all mutagens are genotoxic, not all genotoxic substances are mutagens. Finally, toxicity for reproduction involves the evaluation of effects of a chemical on the sexual function and fertility in adult males and females as well as their offspring.

In the European Union – as well as around the world – these health effects are tested on the basis of consolidated methods that have been established and refined over the years: the ‘gold standards’ for the test of carcinogenicity is the rodent chronic 2-year bioassays. Mutagens are identified on the basis of a variety of tests; one of the most important that allows for an initial screening is the Ames test, proposed in 1973.<sup>81</sup> On reprotoxicity, Regulation (EC) 1107/2009 requires generational studies (the ‘gold standard’ here is the ‘two generation study’), and developmental studies to investigate prenatal toxicity.

For each test, detailed protocols defining the number of animals, their characteristics, the study design, etc. have been codified into protocols for decades by researchers and regulators. Yet, the type and quantity of information that are derived by such ‘classic’ toxicological testing have changed and increased significantly, as well as the interpretation of results that requires evaluators to keep pace with scientific developments. For example, the assessment of genotoxicity and mutagenicity is mentioned as increasingly complex. EFSA published in 2011 a scientific opinion on genotoxicity and an update in 2017 to further clarify the issue.<sup>82</sup> An interesting debate concerns the extent to which regulators prove able to promptly include scientific advancements into their assessment.<sup>83</sup> For

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<sup>81</sup> For a review of mutagenicity testing see for example:

<https://academic.oup.com/mutage/article/24/4/341/1083227>

<sup>82</sup> EFSA. (2011a). 'Opinion on genotoxicity testing strategies', *EFSA Journal* 9:2379; EFSA. (2017d). 'Scientific Opinion on the clarification of some aspects related to genotoxicity assessment', *EFSA Journal* 15:5113

<sup>83</sup> Boobis and colleagues (2016), for example, argue that hazard assessments are based on an outmoded understanding of carcinogenicity that simply divide chemicals between carcinogens and non-carcinogens without considerations of potency and mode of action. See Boobis, A. R., Cohen, S. M., Dellarco, V. L., et al. (2016). 'Classification schemes for carcinogenicity based on hazard - identification have become outmoded and serve neither science nor society', *Regulatory Toxicology and Pharmacology* 82:158-66

illustrative purposes, some aspects of these ongoing dialogues between regulatory guidelines and scientific research as well as areas of uncertainty that characterise toxicological testing will be described in the next section with reference to carcinogenicity testing.

The table below provides an overview of the classification of active substances by their CMR properties and their status.

Table 2: Number of approved and non-approved active substances according to their CMR classification (Situation in December 2017)

	Approved	Not approved
Carc 1° (cut-off criteria)	0	0
Carc 1B (cut-off criteria)	0	16
Carc 2	26	47
Repr 1A (cut-off criteria)	0	1
Repr 1B (cut-off criteria)	5	17
Repr 2	21	11
Muta 1A (cut-off criteria)	0	0
Muta 1B (cut-off criteria)	0	6
Muta 2	2	8

Source: EU Pesticide Database

As reported, at the time of writing five approved active substances are classified 'Reproductive 1B'. These have been granted an approval under Directive 414/1991 that did not foresee cut-off criteria and are currently under re-evaluation.

## 2.1 A short description of developments in 'gold standard' for carcinogenicity testing

The 2-year bioassay for carcinogenicity was developed in the '60s and its main characteristics have basically remained unchanged since then. In part this is because it has been included in regulatory guidelines in the US and Europe and protocols have been standardised. At the international level, the OECD published the first version of Testing Guidelines for carcinogenicity in the early '80s, subsequently updated in 2009 'in order to reflect recent developments in the field of animal welfare and regulatory requirement'.<sup>84</sup>

The chronic 2-year bioassay for carcinogenicity is one of the most demanding tests in terms of use of laboratory animals: the protocol foresees the use of around 500 rodents divided into 3 dose-groups, plus a control group. Each group is given a specific daily dose of the active substance, for a period that covers around 90% of the animal's lifespan, which is established by OECD guidelines as 18 months for mice and 24 months for rats. The rationale for such a protracted treatment is that cancer usually presents a very long

<sup>84</sup> OECD. (2009a). "OECD Guideline for the testing of chemicals. Carcinogenicity Studies." OECD, Paris.

induction period, meaning that there might be a considerable delay between the initiation of cancer by the chemical substance and the appearance of clinical symptoms. The identification of cancer hazards is therefore performed by collecting data on long-term effects.<sup>85</sup> At the conclusion of the period, a histopathological analysis of every tissue of the sacrificed animals is conducted to evaluate the carcinogenic potential of the administered active substance.

Since its inception, '... the primary aim of carcinogenicity studies is to determine the presence or absence of a carcinogenic response and the potency of that response',<sup>86</sup> namely 'the amount of a substance that is required to produce a specific effect at a specific level of intensity'.<sup>87</sup> However, it is important to note that over the decades the general approach to carcinogenicity testing has changed significantly as a consequence of improvements in understanding the induction and development of the disease. In this context, 'a fundamental breakthrough' has been the discovery that a chemical can cause cancer by a variety of modes of actions.<sup>88</sup>

In this context, modes of actions can be divided into two categories: genotoxic and non-genotoxic. Genotoxic carcinogenicity occurs when the active substance reacts directly with the DNA of an organism, causing an alteration that leads to the formation of tumours. Genotoxic carcinogenicity is the 'default option' and – if not demonstrated otherwise – it is usually considered a non-threshold effect. This means that cancer is assumed to occur at any dose level, including very low ones, and that a threshold below which exposure can be considered 'safe' does not exist. The reason is that even low exposure can induce changes in a single cell that subsequently can lead to uncontrolled cell proliferation and cancer.<sup>89</sup> The effects at low doses will be extrapolated from high experimental doses using a linear model. Here the primary goal of the test is to assess the presence or absence of a carcinogenic effect and consequently categorise the active substance according to a binary classification: it is either carcinogenic or not-carcinogenic.

A second mode of action – non-genotoxic – occurs when the active substance does not react with DNA but triggers a different mechanism that will then cause the insurgence of tumours, like for example interference with the endocrine system, enhancement of cell proliferation and/or inhibition of apoptosis (i.e., the process of programmed cell death that occurs every day in humans).

Contrary to genotoxic carcinogens, non-genotoxic ones are assumed to have a threshold, below which the active substance does not produce the adverse effect. In this light, tests

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<sup>85</sup> It is of note that the same long-term test is also utilised to collect evidence on chronic toxicity. See OECD. (2009b). "OECD Guideline for the testing of chemicals. Combined Chronic Toxicity\Carcinogenicity Studies." OECD, Paris.

<sup>86</sup> Ramsingh, D. 2010. "The assessment of the Chronic Toxicity and Carcinogenicity of Pesticides." in *Hayes's Handbook of Pesticide Toxicology*, edited by Krieger, R. I.

<sup>87</sup> Zoeller, R. T., Bergman, A., Becher, G., et al. (2014). 'A path forward in the debate over health impacts of endocrine disrupting chemicals', *Environmental Health* 13

<sup>88</sup> A mode of action (MoA) is a sequence of events, identified by research, which explains an observed effect.

<sup>89</sup> Ramsingh. (2010).

for non-genotoxic carcinogenicity are similar to tests for non-cancer endpoints and are designed to establish the dose that does not elicit any carcinogenic response.

In short, it became increasingly apparent that the mechanisms for carcinogenicity are extremely more complex and varied than originally thought, and the assessment of carcinogenicity had to reflect such complexity. The 2-year bioassay – while still unchanged in its procedure – is expected to produce much more information than originally envisaged. As Pandiri notes, ‘the cancer bioassay has been evolving from a simple ‘cancer-no-cancer’ screening assay to one that provides more mechanistic information on toxicity and carcinogenicity...’.<sup>90</sup> According to Commission Regulation (EU) 283/2013 – as well as OECD GT 451 – testing includes a number of objectives, such as: to determine the target organs of toxicity, to establish LOAEL and NOAEL for non-cancer endpoints; to describe cumulative effects of prolonged exposure; to assess the potential for the development of tumours; to identify the mode of action and human relevance of any identified carcinogenic response.

As mentioned above, protocols are clearly established, though this does not mean that all aspects of the test are fixed. Chemicals are to be assessed on a case-by-case basis, and laboratory choices have to be made and justified in relation to the known characteristics of the active substance to be tested. I will highlight here two among the most consequential and potentially controversial aspects of the 2-year bioassay: the determination of the appropriate dose of the active substance to be administered to animals and the evaluation of the human relevance of findings.

First, the choice about the dose of the active substance in the diet of animals is crucial. Specifically, given the relatively limited number of rodents employed in each treatment and control group (generally 50), the concentration of test material (i.e., the active substance to be tested) should be high enough to challenge animals but not too high to cause side toxicity effects that negatively impact the life course. For each chemical therefore, a specific Maximum Tolerated Dose (MTD) – defined in EU regulation on REACH as ‘the highest dose level should elicit signs of minimal toxicity, such as a slight depression of bodyweight gain (less than 10 %), without substantially altering the normal lifespan due to effects other than tumours’<sup>91</sup> – has to be established to carry out the test.

The debate in toxicology on the methods for the attainment of MTD has been vast. As Ramsingh observes, ‘there may be a fine line between a dose that is too low and one that is too high. For instance, if carcinogenicity study uses a dose that is considered to be too low, the adequacy of the study and its ability to detect a carcinogenic response is questioned’.<sup>92</sup> However, if the dose is too high, the test might lead to a false positive, since exposure

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<sup>90</sup> Pandiri, A. (2017). ‘The Future of Carcinogenicity Testing’, *Reference Module in Chemistry, Molecular Sciences and Chemical Engineering* p.245-46.

<sup>91</sup> Part B.32 Annex to Council Regulation (EC) 440/2008 of 30 May 2008 laying down test methods pursuant to Regulation (EC) 1907/2006 of the European Parliament and the Council on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH).

<sup>92</sup> Ramsingh. (2010) p.467.

might trigger metabolic or homeostatic mechanisms which in turn will provoke the insurgence of tumours.

Regulation 283/2013 on data requirements for the approval of active substances states that 'doses causing excessive toxicity shall not be considered relevant to evaluations to be made' (paragraph 5.5), and that doses are to be established on the basis of short-term testing and – where available – metabolism and toxicokinetic data. OECD protocols establish that a maximum of 1000mg/kg bw/day can be administered.

A recent example of the problems related to the adequacy of the dose emerged in the assessment of glyphosate, where a study (dismissed in the assessment by EFSA but not by IARC) administered over 1400 mg/kg a day.<sup>93</sup> The study could not convincingly argue that cancer was a direct consequence of glyphosate rather than an effect of the general toxicity induced by the chemical in the rodents.

A second crucial issue is the evaluation of relevance of findings for humans. When the 2-year bioassay was first developed, toxicologists assumed that cancer effects observed in animals as a consequence of exposure would also occur in humans. This was because all substances found to cause cancer in humans on the basis of epidemiological observations were also proven rodent carcinogens. Over the years, however, it became increasingly apparent that while all human carcinogens are also hazardous for rodents, the reverse is not always the case. In other words, rodent cancer bioassay successfully validated evidence of carcinogenicity found in humans, while its predictive potential has limitations.<sup>94</sup> This is because the active substance might cause cancer in rodents by acting via a species-specific mode of action which does not take place in the human body. In these cases, a positive result in animals will be of no relevance for humans. As an interviewee nicely summarises, 'a human being is not a 70 kg rat'. In short, 'the relevance of in vivo rodent studies as a predictor of human disease rests ultimately with the mode of action of the potential carcinogen in question'.<sup>95</sup> To reach a conclusion on the human carcinogenicity on the basis of animal data, experts have to investigate, therefore, how the active substance interacts with organs and if the mechanism triggered is of relevance.

A conclusion on MoA, however, is not straightforward. Regulators have to rely on a number of criteria to decide the significance of findings. This is high if: the active substance induced the insurgence of tumours in more than one species of rodent; the active substance has induced a rare tumour, or it occurred in both sexes or in multiple sites; it has been observed a progression of pre-neoplastic from benign to malignant; finally – in terms of robustness – if findings are replicated in more than one study. Regulation 544/2011 required a long-term oral toxicity and carcinogenicity study on rats and a second

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<sup>93</sup> George, J., Prasad, S., Mahmood, Z., et al. (2010). 'Studies on glyphosate-induced carcinogenicity in mouse skin: a proteomic approach', *Journal of Proteomics* 73:951-64; EFSA. (2015). 'Conclusion on the peer review of the pesticide risk assessment of the active substance glyphosate', *EFSA Journal* 13

<sup>94</sup> Cohen, S. M., Klaunig, J., Meek, M. E., et al. (2004). 'Evaluating the human relevance of chemically induced animal tumours', *Toxicological Sciences* 78:181-86

<sup>95</sup> Marone, P. A., Hall, W. C. and Hayes, A. W. (2014). 'Reassessing the two-year rodent carcinogenicity bioassay: a review of the applicability to human risk and current perspectives', *Regulatory Toxicology and Pharmacology* 68:108-18 p.111.

carcinogenicity study using mice as test species. Regulation 283/2013 makes it possible to avoid this second study, if 'it can be scientifically justified that this is not necessary'. In such cases, applicants can submit findings from alternative carcinogenicity models. In interviews it emerged very clearly that the second study on carcinogenicity is routinely required by evaluators and none of the interviewees could recall a case where a dossier was accepted with a single study on this aspect. Criteria for not requiring it are not detailed and are supposed to be decided on a case-by-case basis. In general terms, a completely negative result on the first carcinogenicity test and negative genotoxicity have been mentioned as possible criteria.

As these brief notes make clear, while the acceptance on the part of regulatory regimes of the 2-year test is 'universal', its relevance and validity have been a matter of debate among toxicologists. Concomitant to developments in cancer research in the last decade, the added value of the 2-year rodent chronic study has been seriously and increasingly questioned.<sup>96</sup>

### **3. Environmental and Ecotoxicological Hazards**

Environmental assessments aim at covering a wide range of likely impacts of an active substance on natural populations and ecosystems. Risk regulatory regimes differ in terms of environmental impacts to be assessed, on the very definition of 'impact' as well as on how to measure them. The EU Regulation (EC) 1107/2009 identifies a range of environmental effects on soil, water, air as well as toxic effects on non-target organisms.

In terms of cut-off criteria, some environmental effects have been singled out and declared 'unacceptable' (see above II.2). These unacceptable effects refer to substances that are not easily degraded, that accumulate in organisms, and have an acute or chronic toxicity. More specifically, Regulation (EC) 1107/2009 states that only active substances that are not classified as Persistent, Bioaccumulative and Toxic (PBT), Persistent Organic Pollutants (POP),<sup>97</sup> very Persistent and very Bioaccumulative (vPvB) can be granted approval for use in the EU.

As Pretty noted, 'although all pesticide products are tested for their toxicity before consent is granted for their commercial use, a full understanding of their effects in the field has often taken many years to unravel'.<sup>98</sup> The assessments of environmental fate and behaviour of chemicals and their ecotoxicological effects are theoretically and methodologically very complex. Compared to human toxicology, that focuses on a single species, ecotoxicology has to take into account a huge number of species and ecosystems and their interrelations.

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<sup>96</sup> See Billington, R., Lewis, R. W., Mehta, J. M., et al. (2010). 'The mouse carcinogenicity study is no longer a scientifically justifiable core data requirement for the safety assessment of pesticides', *Critical Reviews in Toxicology* 40:35-49; Marone, Hall and Hayes. (2014)

<sup>97</sup> The Stockholm Convention on POPs is not specific on pesticides, since it deals with chemicals in general. It is of note however that 9 out of 12 POPs are indeed active substances used in the production of PPPs.

<sup>98</sup> Pretty, J. (2006). "Agroecological Approaches to Agricultural Development." World Bank, Washington, DC.

Further, in ecotoxicology adverse effects are usually assessed at the population level rather than at an individual level as in toxicology. This means that a certain number of affected individuals might be acceptable, proven that the overall population is not, or only transiently, affected.

The heterogeneity of European agronomic and environmental conditions makes any comprehensive prediction of outcomes a very complex undertaking. The point has been underlined regularly in interviews with CAs, who observed that consistency in assessments of environmental effects is difficult and that 'harmonisation is more difficult in ecotoxicology'.

There are different factors to be underlined to characterise procedures of identification of environmental and ecotoxicological hazards.

First, Regulation (EC) 1107/2009 introduced a significant number of new obligations. Notably, Regulation 283/2013 lists around 20 new data requirements, almost all of them in the environmental and ecotoxicological chapters. These includes requirements to submit data on bees (see below), pollen and bee products, on bioconcentration in prey of birds and mammals, on vertebrate wildlife, and on the adverse effects on the endocrine system of non-target organisms.

Second, harmonisation is hampered by the lack of some guidance documents on 'old' (i.e. prior to Commission Regulation 283/2013) and new data requirements (i.e. after Commission Regulation 283/2013). Despite significant efforts and the publication of important guidance documents in the last few years, some guidelines might be either non-existent or discussed and published but not officially adopted. An often-cited example is the case of guidance documents on bees.<sup>99</sup> Other guidelines are under discussion at EFSA, like the appraisal of effects on amphibians.

Third, and related, some guidelines have been finalised too recently to have an impact on evaluation processes. This is, for example, the case of the guidance – agreed by EFSA and OECD in 2016 – on how to conduct terrestrial field dissipation (TFD) studies 'to demonstrate the transformation, transport and fate of pesticides under representative actual use conditions when a pesticide product is used according to the label'.<sup>100</sup>

In short, the definition of regulatory standards for the evaluation of environmental and ecotoxicological effects is still in progress on many issues. It is of note, however, that in terms of restrictions on use of active substances and bans, the area of environmental fate and ecotoxicology has a relevant impact. According to interviews, this is for two main reasons: first, while some guidance documents are still missing, the adoption of a series of important ones allowed for a proper and more complete evaluation of environmental effects, leading to the detection of serious impacts that required restrictions in use. Second, the perduring uncertainty over data and methods for many environmental and

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<sup>99</sup> EFSA. (2013a). 'EFSA Guidance Document on the risk assessment of plant protection products on bees (*Apis mellifera*, *Bombus* spp. and solitary bees)', *EFSA Journal* 11

<sup>100</sup> OECD. Guidance Document for Conducting Pesticide Terrestrial Field Dissipation Studies. Series on Testing and Assessment No. 232

ecotoxicological adverse effects results in the application of the precautionary principle on the part of decision-makers in the risk management phase. In a nutshell, the principle of precaution prescribes that when there are uncertainties in scientific evidence over the risks associated with an active substance, then regulatory action should be taken to reduce potential harm.<sup>101</sup> In this context, the more uncertain is evidence, the more restrictions or bans are likely. The evaluations of the effects of systemic insecticides on pollinators is a case in point in this context.

Arguably, a very important – and possibly one of the most popular – provisions introduced in Regulation (EC) 1107/2009 requires applicants to submit data to prove that the active substance does not adversely affect the health of bees. The issue of bees' health emerged as problematic in the early 2000s when alarmed – but patchy – reports on 'the disappearance of bees' were first made public. Lack of data – as well as lack of an agreed methodology on how to collect evidence – proved a serious barrier to a full understanding of what has been called 'colony collapse disorder' (CCD). In particular, neonicotinoids<sup>102</sup> and fipronil were found to have the potential to adversely affect pollinators in two central ways. First, they harm their sense of direction and memory, so that bees are no longer able to return to their hive and thus die. Second, the ability to forage might be impaired and, as a result, bees will starve and produce fewer queens.<sup>103</sup> The overall effect, it is suspected, is a declining number of insects performing pollination.<sup>104</sup> As a result of the evaluation process, three neonics (clothianidin, imidacloprid and thiamethoxam)<sup>105</sup> and fipronil<sup>106</sup> have been denied approval or significantly restricted in 2013.<sup>107</sup> Because of the high level

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<sup>101</sup> Tosun, J. (2013). 'How the EU handles uncertain risks: understanding the role of the precautionary principle', *Journal of European Public Policy* 20:1517-28; Zander, J. (2010). *The application of the precautionary principle in practice: comparative dimensions*. Cambridge: Cambridge University Press.

<sup>102</sup> Neonicotinoids are 'systemic insecticides' – seeds can be treated with the pesticide and the active substance will diffuse in the growing plant. They are appreciated by farmers because of their proven efficiency against pests and because of the convenience and ease of use – being a treatment for seeds, farmers do not need to spray neonicotinoids on fields, cutting costs significantly.

<sup>103</sup> Simon-Delso, N., Amaral-Rogers, V., Belzunces, L. P., et al. (2015). 'Systemic insecticides (neonicotinoids and fipronil): trends, uses, mode of action and metabolites', *Environmental Science and Pollution Research* 22:5-34; Whitehorn, P. R., O'Connor, S., Wackers, F. L., et al. (2012). 'Neonicotinoid Pesticide Reduces Bumble Bee Colony Growth and Queen Production', *Science* 336:351-52

<sup>104</sup> Pollination is an essential ecosystem service; a UN report affirms that more than 3/4 of grown crops, fruits and vegetables in the world depend on pollinators. See IPBES. (2016). "Summary for policymakers of the assessment report of the Intergovernmental Science-Policy Platform on Biodiversity and Ecosystem Services on pollinators, pollination and food production." Secretariat of the Intergovernmental Science-Policy Platform on Biodiversity and Ecosystem Services, Bonn, Germany.

<sup>105</sup> Regulation (EU) No 485/2013

<sup>106</sup> Regulation (EU) No 781/2013

<sup>107</sup> For a very recent study on the effects of bans of neonics and fipronil on farming practices see Kathage, J., Castañera, P., Alonso-Prados, J. L., et al. (2018). 'The impact of restrictions on neonicotinoid and fipronil insecticides on pest management in maize, oilseed rape and sunflower in eight European Union regions', *Pest Management Science* 74:88-99

of uncertainty that characterise the available evidence, the decision was grounded on the precautionary principle, which adopts cautious and risk adverse policy options in cases where evidence is lacking or insufficient or uncertain.<sup>108</sup>

The classification as persistent, bioaccumulative and/or toxic is the most common one for an active substance to be included in the list of candidates for substitution.

A total of 53 approved active substances meet two out of three PBT criteria and could be phased out as a result of the application of the substitution principle. Notably, these include copper compounds – active substances allowed in organic production – that have been classified as vPvB.<sup>109</sup>

#### 4. Endocrine Disruption

The scientific and public interest for endocrine disruption exploded in the mid '90s, when a series of publications suggested that some chemicals commonly used in pesticides, pharmaceuticals, cosmetics could have the capacity to interfere with and disrupt the connection between hormones and their receptors.<sup>110</sup> The most relevant and discussed interferences are related to growth, sexual development, blood pressure, and metabolism. Health effects resulting from such alterations range from hormone-dependent cancers (breast, prostate, testis), to fertility decline, and reproductive disorders.<sup>111</sup> The scientific debate is open: experts are deeply divided on the very definition of ED, as well as on how to establish cause-effect relations. In this context, the EU has been the first authority to define EDC for regulatory purposes. Regulation (EC) 1107/2009

However, Regulation (EC) 1107/2009 establishes only provisional 'interim criteria' for the assessment of ED and requires the Commission to provide a full proposal to SCoPAFF in two years, i.e. by December 2013. The interim criteria have allowed authorities to evaluate substances and make decisions, but they appear entirely inadequate. All the experts interviewed noted that the criteria are insufficient since they might result in false positives (falsely identify a substance as ED that is not) and false negative (falsely identify a substance as non-ED that has endocrine disrupting properties).

The formulation of criteria for the assessment of ED proved extremely complicated and contentious. Differences in position do not generally reflect 'national' preferences but rather are based on a disciplinary basis. To give but one example, it might be interesting

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<sup>108</sup> Zander. (2010).

<sup>109</sup> See EU pesticide database, available at <http://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/public/?event=activesubstance.selection&language=EN>

<sup>110</sup> Colborn, T., Dumanoski, D. and Peterson Myers, J. (1997). *Our Stolen Future: Are We Threatening Our Fertility, Intelligence, and Survival? A Scientific Detective Story*. New York: Plume Book; Marty, M. S., Carney, E. W. and Rowlands, J. R. (2011). 'Endocrine Disruption: Historical Perspectives and Its Impact on the Future of Toxicology Testing', *Toxicological Sciences* 120:93-108

<sup>111</sup> Diamanti-Kandarakis, E., Bourguignon, J. P. and Giudice, L. C. (2009). 'Endocrine-Disrupting Chemicals: An Endocrine Society Scientific Statement', *Endocrine Reviews* 30:293-342

to briefly describe how toxicologists and endocrinologists differ in their conceptions of dose and potency.

Leading toxicologists maintain that considerations of potency – the amount of a substance that produces a specific effect – should be taken into account to assess whether a chemical is an ED. The ‘golden rule’ in toxicology states that it is the dose of an active substance that makes it – or does not make it – a poison. Accordingly, standard tests in toxicology usually involve the administration of different doses of a chemical to animals in laboratory to detect the effects at each level. Leading toxicologists affirm that assessments of EDC should be kept in line with those performed for other effects, according to a dose-response logic that aims at establishing the potency of the substance. Toxicologists have defended this point forcefully; tellingly, one of their position papers is titled ‘Principles of Pharmacology and Toxicology also govern effects of chemicals on the endocrine system’.<sup>112</sup> Endocrinologists challenge this central assumption in toxicology. They contend that an EDC can have effects at very low-dose levels, namely below the doses that are considered non-effect level (NOEL) for that particular chemical. This is because EDCs have the same characteristics as hormones and work by mimicking or counteracting hormones naturally present in our body to modulate various biological functions, producing overstimulation, or, vice versa, preventing the natural hormone from performing its functions. In short, the very concept of ‘dose’ – and therefore potency – is not entirely appropriate from the point of view of endocrinology.

The regulatory ‘translation’ of scientific controversies like the one on potency has huge implications. The Commission carried out an Impact Assessment to evaluate the consequences of various regulatory possibilities, finding that bans could be around 3% of scrutinised active substances if considerations of potency are included in hazard assessments, and around 7,5% if they are not.<sup>113</sup>

Eventually in December 2017 regulatory criteria have been adopted in SCoPAFF and will be now scrutinised by the Council and the European Parliament. Criteria do not include potency in the hazard-identification stage, a decision in line with the hazard-based approach that informs Regulation (EC) 1107/2009. An active substance is classified as having endocrine disrupting properties if a) it affects the morphology, physiology, growth, development, reproduction or life span of an organism or its progeny; b) it has an endocrine mode of action; c) the adverse effect is a consequence of the endocrine mode of action.

Interviewed representatives of industry and farmers indicate that the number of active substances that could be potentially phased out is in the hundreds. From their point of view this is particularly worrying since a derogation for active substances that are growth regulators has been dropped from the proposed criteria as requested by the European Parliament. Further, there is still substantial uncertainty around the criteria for negligible

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<sup>112</sup> Autrup, H., Frank A. Barile, Bas J. Blaauboer, et al. (2015). ‘Principles of Pharmacology and Toxicology Also Govern Effects of Chemicals on the Endocrine System’, *Toxicological Sciences* 146:11-15

<sup>113</sup> European Commission. (2016).

exposure that will apply to endocrine disrupting active substances (see section III.5). The discussion is therefore still going on at both DG Sante and EFSA and at national level. Areas of disagreement clearly persists on many aspects. The difficulties encountered so far and the ones ahead cannot be underestimated. In this sense, the delivery of criteria for the assessment and the following guidance document in preparation at EFSA and ECHA<sup>114</sup> are viewed as important achievements by a majority of CAs.

## 5. The debate over 'negligible exposure'

Annex II of Regulation (EC) 1107/2009 includes the definition of cut-off criteria for the approval of active substances, namely the hazards that – if met – result in a ban from EU markets (see section II.2). There is however a relevant specification to be taken into account that links the application of cut-off criteria to considerations of exposure: to the extent that exposure may be negligible, a hazardous active substance can get approved.<sup>115</sup>

The derogation from cut-off criteria for negligible exposure has been introduced for carcinogenicity (point 3.6.3 of Annex II of Regulation (EC) 1107/2009) toxicity for reproduction (3.6.4), endocrine disruption (3.6.5), endocrine disruption on non-target organisms (3.8.2) as well as for honeybees' health (3.8.3). The other cut-off criteria – mutagenicity – does not include considerations of exposure (3.6.2), as well as the main 'environmental criteria' of persistence, bioaccumulation and toxicity for the environment.

As the European Commission noted,<sup>116</sup> the different phrasing in provisions included in Annex II suggests that legislators had different policy intentions. First, legislators intended to implement a zero-tolerance approach for mutagenicity, which means that exposure to substances with genotoxic properties cannot be tolerated under any circumstances. Second, legislators foresaw that a certain level of dietary and non-dietary exposure to non-genotoxic carcinogenic,<sup>117</sup> reprotoxic and endocrine disrupting chemicals might be tolerated, provided that the level is negligible.

Legislators however did not specify how to define and assess whether exposure can be considered negligible, and the issue has become a matter of contention for the renewal of some active substances.

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<sup>114</sup> See: <https://www.efsa.europa.eu/en/topics/topic/endocrine-active-substances>

<sup>115</sup> In these cases, the active substance gets an approval for a period of seven years and it is included in the list of candidates for substitution.

<sup>116</sup> European Commission. (2015). "Technical Guidance on the interpretation of points 3.6.3 to 3.6.5 and 3.8.2 of Annex II to Regulation (EC) 1107/2009, in particular regarding the assessment of negligible exposure to an active substance in a plant protection product under realistic conditions of use. Draft May 2015."

<sup>117</sup> The lack of derogations on mutagenicity should rule out the applicability of this derogation to genotoxic carcinogens that are assumed to have no safe threshold. The point is still open for endocrine disrupting chemicals, because it is a matter of debate whether a safe threshold can or cannot be established (see section III .4).

To address the issue, the Pesticide Unit based in DG Sante set up an ad hoc advisory group, gathering experts from competent national authorities. The work of the group resulted in draft technical guidelines that were made public in June 2015.<sup>118</sup> The published document is incomplete in some very relevant sections and therefore constitutes a partial answer to the issue. It does provide, however, clear indications of the logic to be applied when performing assessments of derogations from hazard-based cut-off criteria.

The most consequential statement is that 'negligible exposure' is a condition to be actively searched and achieved: 'available risk mitigation measures should be applied for the proposed uses of the plant protection product, with the aim to minimise exposure of humans to the active substance as much as technically possible',<sup>119</sup> and to the point that it becomes negligible. In turn, the term 'negligible' is defined as 'irrelevant', or more precisely 'so small that it does not appreciably add to the risk and can safely be ignored'.<sup>120</sup>

The technical guidance document then provides working criteria for assessment of dietary exposure, on the basis of provisions already introduced in Annex II of Regulation (EC) 1107/2009, which establishes that 'residues of the active substance, safener or synergist concerned on food and feed do not exceed the default value set in accordance with Article 18(1)(b) of Regulation (EC) No 396/2005'.<sup>121</sup> The document is more vague on non-dietary exposure and establishes some – but not all – criteria for its evaluation. For example, it establishes that for exposure to be considered negligible, an additional safety margin (at least 1000) to the reference toxicological reference value (AOEL) should be demonstrated. Finally, the section on the exposure of non-target organisms is missing.

Since the publication of the draft guidelines, the EC has carried out a public consultation on the document collecting views from stakeholders, but a complete and definitive version has not been finalised. According to interviews, meetings of the advisory group are no longer taking place and further discussion has been postponed until the approval of the guidelines on endocrine disruption (see above III.4).

Yet, evidence on negligible exposure has been requested to applicants in the context of the renewals of approvals,<sup>122</sup> even before guidelines had been made available (if only in draft version). This request has been criticised by applicants who were requested to provide data with no clear indications of legal requirements.<sup>123</sup> Further, the criteria listed in guidelines have already been applied in evaluation processes. Many CAs criticised the

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<sup>118</sup> European Commission. (2015).

<sup>119</sup> Ibid. p.11

<sup>120</sup> Ibid. p.8

<sup>121</sup> Regulation 396/2005 presents maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC. Article 18(1)b states that the products placed on the market as food or feed should not contain any pesticide residue exceeding a default value of 0.01 mg/kg (established for those products for which no specific MRL has been set).

<sup>122</sup> For an explanation of renewals of approvals of active substances see section IV.1.1.

<sup>123</sup> ECPA. (2015). "ECPA comments on the guidance document for negligible exposure." ECPA, Bruxelles.

reference to guidelines that have not been formally approved, pointing out in interviews that 'we are not going to apply draft guidelines' in evaluations.

EFSA was requested to assess negligible exposure on the basis of draft guidelines for two active substances – pymetrozine and isoxaflutole – that have both been proposed for classification as endocrine disrupting chemicals according to interim criteria established in point 3.6.5 Annex II Reg. 1107/2009.<sup>124</sup>

On the basis of additional data submitted by applicants on request of the Commission, EFSA assessment calculated to what extent incremental risk mitigation measures are able to decrease the level of exposure. In its assessment<sup>125</sup> EFSA presents the values of the exposure estimates for different groups (operators, workers, bystanders, residents) under different scenarios. However, in the absence of an official agreement over the interpretation of criteria, EFSA does not provide an overall conclusion on whether dietary and non-dietary exposure can be considered negligible. This is left open for risk managers to decide, and at the time of writing, final decisions on the approval of pymetrozine and isoxaflutole are pending.<sup>126</sup>

It is very relevant to note that the approach adopted by the Commission in the draft technical guidelines is contested.<sup>127</sup> Interviews with CAs reveal that there is an alternative view on how 'negligible exposure' should be defined and assessed. This position refers to the text of regulation where it states that exposure is negligible if 'the product is used in closed systems or in other conditions excluding contact with humans'. According to this interpretation, 'closed system' mainly equates with greenhouses, officially defined in Regulation 1107/09 as 'a walk-in, static, closed place of crop production with a usually translucent outer shell, which allows controlled exchange of material and energy with the surroundings and prevents release of plant protection products into the environment' (Article 3(27)). Accordingly, the legal text already provides a workable definition of 'negligible exposure', so that additional guidelines are not a necessity. More fundamentally, critics observe that the possibility to introduce risk mitigation measures to establish whether exposure is or is not negligible changes the 'spirit of the law'. Specifically, the technical guidance document marks a shift from a hazard-based approach that informed Regulation (EC) 1107/2009, to an approach based on the notion of negligible risk.<sup>128</sup> Once considerations of exposure and risk mitigation are taken into account to inform assessments, the notion that some hazards are unacceptable under any circumstances is substituted by the view that they are manageable. For example, in the case of isoxaflutole, EFSA calculated that the use of workwear exposes operators to a dose

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<sup>124</sup> More specifically, the interim criteria for ED applies since isoxaflutole is classified as a carcinogen category 2 and toxic for reproduction category 2.

<sup>125</sup> EFSA. (2017b). 'Peer review of the pesticide risk assessment for the active substance isoxaflutole in light of negligible exposure data submitted', *EFSA Journal* 15:4731; EFSA. (2017e). 'Statement on the pesticide risk assessment for the active substance pymetrozine in light of negligible exposure data submitted', *EFSA Journal* 15:4678

<sup>126</sup> For both active substances, the SCoPAFF decided in 2017 on an extension of the approval period until the end of June 2018 (see Reg 841/2017).

<sup>127</sup> Interview response.

<sup>128</sup> Notably, the notion of negligible risk is used in the regulation on biocides to allow for derogations from the general norm.

of the active substance that corresponds to 21% of the AOEL. The adoption of additional risk mitigation measures – namely workwear, gloves during mixing, loading and application, use of respiratory protective equipment and the use of drift reducing nozzles – decreases exposure to 0.8% of AOEL, which corresponds to a margin of safety for carcinogenicity of 11,000. In short, data support the point that risk mitigation measures can be effective in making exposure negligible. To the extent that operators take action to reduce the likelihood of harm, they will be able to make exposure negligible. This requirement, however, seems to contradict the very definition of ‘negligible’ as a condition that can be ‘safely ignored’.

An additional line of criticism to the document on negligible exposure expressed by officers from some CAs is that the hazard identification stage should effectively stop the risk assessment procedure if the active substance is found hazardous. Similarly, in a contribution to the public consultation on the draft guidelines, PAN criticises the EC proposals since ‘with this working document the Commission is proposing to continue this time-consuming and expensive risk assessment process, even for chemicals that fall under these “hazard” categories, with the overall aim to identify “safety” and define how these limits can be achieved without banning these harmful pesticides’.<sup>129</sup>

As mentioned, so far the issue of negligible exposure has been of relevance for a couple of active substances under renewal. It is likely to become significantly more important – and possibly controversial – as soon as guidelines on endocrine disruption properties that were approved in December 2017 enter into force.

## **6. The evaluation of hazard and risk associated with chemical mixtures**

Regulation 1107/09 establishes that PPPs should not have any harmful effects on human and animal health, ‘taking into account known cumulative and synergistic effects where the scientific methods accepted by the Authority to assess such effects are available’ (Article 4(3b)).

The standard procedure for hazard and risk assessment – in the EU and elsewhere in the world – follows a chemical-by-chemical logic, in which each active substance is tested for its own intrinsic hazards and evaluated for its risks. What are the consequences for health and the environment of exposure to a combination of chemicals is – most of the time – beyond the scope of regulatory risk assessment regimes: ‘... when several formulated products are used in combination, i.e. for the application of plant protection products in the field or for the use of personal care products at home, the combined resulting risk is

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<sup>129</sup> Pesticides Action Network. (2015a). "Comments on Commission's DG SANTE "technical guidance on the interpretation of points 3.6.3 to 3.6.5, and 3.8.2 of Annex II of Regulation (EC) No 1107/2009, in particular regarding the assessment of negligible exposure to an active substance in a PPP under realistic conditions of use". PAN Europe, Bruxelles.

generally not assessed'.<sup>130</sup> This is problematic since there is growing consensus among experts that health and environmental risks might be significantly underestimated if cumulative effects are not evaluated: the effects of mixtures might be larger than the effect of each component of the mixture taken in isolation, even if each component is present below its threshold doses or concentrations.<sup>131</sup>

Cumulative or cocktail effects have, therefore, become an issue of concern in the last decade. The EP and the EU Council raised the issue on various occasions and the EC published a communication on the matter, planning to present in 2014 'technical guidelines to promote a consistent approach to the assessment of priority mixtures across the different pieces of EU legislation'.<sup>132</sup> At present such cross-sectoral regulatory guidelines are not available, and scientists and experts are still debating and developing scientific methods of assessment of cumulative effects of chemicals on specific issues. For pesticides, EFSA included indications on how to perform cumulative assessments in guidelines on mammalian and birds, aquatic life, terrestrial, in-soil.<sup>133</sup>

In the rest of this section, two main problematic questions that emerged in the debate on mixtures will be highlighted.

A first problematic aspect is the lack of knowledge about how chemicals act and interact. The assessment of combined exposure can be carried out according to two different models, depending on the similarity or dissimilarity of the mode of action of the chemicals included in the mixture.

If the two active substances are known to have similar modes of action, then the response effect results from the concentration of each active substance in proportion to its presence in the mixture and taking into account its potency. This model is called concentration addition to indicate that each chemical contributes to increase the dose and therefore the toxicity of the mixture.

If the two active substances have a dissimilar mode of action, then they will act independently from each other. This case is sometimes taken as the 'default assessment concept in human toxicology'<sup>134</sup>, and it is often assumed that 'if the intended level of protection is achieved for each individual substance, the level of concern for mixtures of dissimilarly acting substances should be assumed as negligible'.<sup>135</sup> In other words, if

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<sup>130</sup> Kienzler, A., Bopp, S. K., van der Linden, S., et al. (2016). 'Regulatory assessment of chemical mixtures: Requirements, current approaches and future perspectives', *Regulatory Toxicology and Pharmacology* 80:321-34 p.321.

<sup>131</sup> Kortenkamp, A., Backhaus, T. and Faust, M. (2009). "State of the Art Report on Mixture Toxicity." European Commission, Bruxelles.

<sup>132</sup> European Commission. The combination effects of chemicals. Chemical mixtures. COM (2012) 252 p.9.

<sup>133</sup> For a review of existing guidelines on the assessment of mixtures see Kienzler, Bopp, van der Landen et al (2016).

<sup>134</sup> Kortenkamp, Backhaus and Faust. (2009) p.6.

<sup>135</sup> SCHER, SCENIHR and SCCS. (2011b). "Toxicity and Assessment of Chemical Mixtures." European Commission, Bruxelles.

residues of each of the active substances with dissimilar MoA are within their legal limits, then it might be assumed there is no cumulative effect. EFSA criticised this approach and noted that 'the use of independent action as an assessment concept for combination effects requires demonstration that modes of action of individual substances in a mixture are strictly independent, a condition that can rarely be met in practice'.<sup>136</sup> As a consequence, all available EFSA guidelines recommend the adoption of the concentration addition model for the assessment of mixtures.

Second, the lack of precise regulatory requirements hinders the assessment of hazard and risks of chemical mixtures. In general terms, EU legislation requires the assessment of intentional mixtures, combinations of chemicals that result from the intentional mix of different active substances, like commercial formulations composed of a combination of active substances. The composition of these mixtures is known and Regulation (EC) 1107/2009 requires MSs to evaluate their associated risks in the procedure of authorisation of PPPs that contain two or more active substances (Article 29 Reg. 1107/2009). Much less attention is given to unintentional mixtures – like the ones that are formed during the handling of different products on the part of users such as tank mixtures – or coincidental – mixtures that get formed in the environment after the use of a variety of active substances. The compositions and concentrations of unintentional and coincidental mixtures are usually unknown and risks to exposure is seldom assessed, 'even if this is the most common situation'.<sup>137</sup> Conversations with epidemiologists note that variations in agricultural practices are extremely high across European regions, making a reliable assessment of mixtures particularly difficult. Indeed, the number of potential combinations is 'almost infinite'<sup>138</sup> and therefore there is a need to define criteria for the identification of priorities to perform cumulative assessments.<sup>139</sup>

An exception of relevance for pesticides is the Water Framework Directive, that prescribes that achieving a good environmental status must take into account the presence of cocktails of different chemicals. As Kienzler and colleagues noted, '... so far there is no systematic, consistent, comprehensive and integrated approach across different pieces of legislation'.<sup>140</sup> However, some inconsistencies have been detected even in the context of evaluating pesticides. Panizzi and colleagues reviewed 11 dossiers evaluated between 2011 and 2015, to study to what extent cocktail effects on non-target organisms are taken into account. Results shows that the majority of mixtures (8 out of 11) include active substances with dissimilar MoA, that the concentration addition model is used, that systematic evaluations have been carried out for birds and mammals, while assessments

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<sup>136</sup> EFSA. (2013b). 'Scientific Opinion on the relevance of dissimilar mode of action and its appropriate application for cumulative risk assessment of pesticides residues in food', *EFSA Journal* 11:3472

<sup>137</sup> Kienzler, Bopp, van der Linden and Berggren. (2016) p.322.

<sup>138</sup> SCHER, SCENIHR and SCCS. (2011b).

<sup>139</sup> EFSA. (2013b)

<sup>140</sup> Kienzler, Bopp, van der Linden and Berggren. (2016) p.322; Evans, R. M., Martin, O. V., Faust, M., et al. (2016). 'Should the scope of human mixture risk assessment span legislative/regulatory silos for chemicals?', *Science of the Total Environment* 543:757-64

for aquatic organisms is not always present. Their conclusion is that 'the ecotoxicological risk assessment of pesticide mixtures under Regulation (EC) 1107/2009 is still carried out in inhomogeneous ways among different organism groups'.<sup>141</sup>

## 7. The use of epidemiological data in hazard identification and characterisation

The main research interest in epidemiology is to investigate the incidence, distribution, and control of diseases in a population. In the specific field of pesticide epidemiology, studies assess the type and frequency, modality of contact of PPPs and people working and living in an agricultural area. As it is apparent, the relevance of these studies for pesticide regulations is potentially very high: findings can shed light on the effects on the ground of exposure to 'cocktails of chemicals' that are currently in use. However, the utilisation of these findings for regulatory purposes has proven difficult and seems safe to argue that so far it has been at best marginal. Notably, EFSA observed that 'within the European regulatory system there is no example of a pesticide active substance approval being influenced by epidemiological data'.<sup>142</sup> This is not unique to the EU: everywhere regulatory assessments are traditionally based on toxicological testing and the debate on how to best utilise epidemiological studies is ongoing at the international level and in different jurisdictions. For example, the US EPA published its first guidance on the matter in December 2016.<sup>143</sup> In parallel, EFSA is debating how to collect, evaluate and integrate epidemiological findings in hazard and risk assessment procedures.

The limited use of epidemiological data is due to different reasons, including a disconnection between toxicology and epidemiology, a division that has been well highlighted in social studies of sciences.<sup>144</sup> As mentioned, epidemiology deals with 'real world' conditions, with the purpose of monitoring the health consequences of actual exposure to chemicals. As a consequence, the complexity of real world conditions is reflected in epidemiological studies that record exposure to a multiplicity of chemicals (not only pesticides), and have limited control on crucial variables affecting health like lifestyles and the timing, frequency, amount of contacts of people with an active substance. The general output of epidemiological studies, therefore, is the detection of associations between a variety of chemicals and health outcomes in a region. However, the attribution of causality between a specific active substance and a specific adverse effect – an essential

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<sup>141</sup> Panizzi, S., Suci, N. A. and Trevisan, M. (2017). 'Combined ecotoxicological risk assessment in the frame of European authorization of pesticides', *ibid.*580:136-46 p.144.

<sup>142</sup> EFSA. (2017c). 'Scientific Opinion of the PPR Panel on the follow-up of the findings of the External Scientific Report 'Literature review of epidemiological studies linking exposure to pesticides and health effects', *EFSA Journal* 15:5007 p.9.

<sup>143</sup> Office of Pesticide Programs. (2016). "Office of Pesticide Programs' Framework for Incorporating Human Epidemiologic & Incident Data in Risk Assessments for Pesticides " US Environmental Protection Agency.

<sup>144</sup> Jasanoff, S. (2004). *States of Knowledge. The co-production of science and social order*. London and New York: Routledge.

regulatory goal – is a problematic issue, because of multiple hazards and the presence of confounding factors.

Toxicology studies rely on laboratory tests performed in highly controlled conditions, and on a chemical-by-chemical basis. Tests are designed on the method of randomised control trials<sup>145</sup> to minimise biases, and causal relations between exposure to a specific dose of a chemical and health outcomes (in rodents) can usually be established in a robust way. However, the use of animals and the need to challenge them with very high doses of the active substance raise questions about the significance of findings for humans (see above III .2). Further, the cumulative effects of different chemicals are not investigated (see above III .6).

In short, as an epidemiologist summarised in her intervention at an EFSA conference,<sup>146</sup> ‘epidemiological studies ask the right question, examine the right species at the right doses but answer it badly. Toxicological studies ask the wrong question, examine the wrong species at high dose, but answer it well’. The integration of epidemiological studies into regulatory processes is therefore a positive step in the direction of better protection of human health from hazardous chemicals.

EU Regulations recognise the value of epidemiological studies and require applicants to collect and review existing available evidence, but do not oblige them to carry out epidemiological studies to present evidence. This means that epidemiological data come from papers published in the peer-reviewed open literature, which must be summarised and included in the dossier according to EFSA guidelines on the literature review (see below III .8).

However, a framework on how to evaluate and weight this information is still lacking. To start a discussion, EFSA conducted an external review of available pesticide epidemiological studies in 2013.<sup>147</sup> The experts reviewed more than 6000 different analyses performed between 2006 and 2012, revealing on the one hand a large availability of data. On the other hand, the review highlighted the shortcomings that contribute to the marginalisation of these studies in regulatory contexts. As reported, ‘authors of the report could not draw any firm conclusions for the majority of the health outcomes’.<sup>148</sup>

The most relevant limitation refers to difficulties in exposure assessment, namely in the exact identification of the active substances people have been in contact with, for how long, etc. An example will clarify the kind of difficulties encountered: pesticides are used intermittently over a growing season – possibly for a few days only – and exposure

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<sup>145</sup> A randomised control trial (RCT) is a study in which animals are assigned to each of the dose groups by chance and in which one of the groups is a control, meaning that animals included will not be treated with the active substance under investigation.

<sup>146</sup> See <https://www.efsa.europa.eu/en/events/event/171121-0>

<sup>147</sup> Ntzani EE, Chondrogiorgi M, Ntritsos G, et al. (2013). "Literature review on epidemiological studies linking exposure to pesticides and health effects." EFSA, Parma.

<sup>148</sup> EFSA. (2017c)

depends on clothing, application techniques, practices for cleaning equipment but also on how many times the farmer re-enters the field after application, etc. Studies that employ questionnaires to collect information from farmers are prone to errors because of recall biases. This is also of relevance in the case of farm workers who do not necessarily have full knowledge of the number and type of pesticides in use,<sup>149</sup> or in the case of residents of agricultural areas. An additional issue is the quality of reporting, a question that will be discussed in more detail in the next section since it is of general relevance for peer-reviewed literature (see III8).

Finally, the availability of epidemiological evidence is uneven, and this has clear regulatory implications. Data are generally non-existent for new active substances, since these are not yet utilised in commercial products and therefore people have never been exposed to them.<sup>150</sup> Epidemiological data might instead be available for active substances that have been on the market for a decade or more, and therefore might form an important part in dossiers for the renewal of approvals.

All considered, the integration of epidemiology and toxicology – as envisaged by EFSA – sees the former in a supporting role to the latter. Epidemiology would alert on the existence of health concerns to be further investigated by toxicologists. For example, the literature review by Ntzani et al. (commissioned by EFSA) suggests an increased risk between exposure to pesticides (in general) and Parkinson's disease (PD) and child leukaemia (CL).<sup>151</sup>

Accordingly, for these correlations that are deemed of relevance, additional analyses might be required to evaluate their biological plausibility. To do so, toxicologists are involved in the development of the Adverse Outcome Pathways (AOP) approach. AOP is a framework to describe the sequence of key events (KE) that have to follow the first interaction of a chemical (MIE: molecular initiating event) with a target to lead to the adverse outcome (AO). The logic is to detect a causal chain: the MIE will trigger a first reaction (KE1) which in turn will trigger another reaction (KE2) and so on until one of the symptoms of the disease appears. In other words, AOP will provide information on the biological mechanisms that link the cause to its effects and in doing so will assess the plausibility of the correlation found in epidemiological studies. In practical terms, the approach requires developing AOPs for each relevant AOs that characterise a disease. For example, in PD, the same adverse effect might be produced by a variety of MIEs through different AOPs. Once scientists have developed and validated an AOP, then it becomes possible to test on the basis of experimental data whether a specific active substance triggers the MIE and the intermediate steps towards the AO.

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<sup>149</sup> Take the example of seasonal workers who pick up strawberries, then grapes then apples moving in different areas.

<sup>150</sup> In principle, it might be possible that an active substance is new not in absolute terms but for the EU market and in this case epidemiological studies could exist.

<sup>151</sup> Ntzani EE, Chondrogiorgi M, Ntritsos G, Evangelou E. and Tzoulaki I. (2013).

This approach to the integration of epidemiology and toxicology finds a substantial agreement among experts convened by EFSA in dealing with the matter. Notably, the development of AOP is an international effort that involves scientists around the world and reflects the more general interest towards MoA and mechanisms that characterise contemporary toxicology. Epidemiologists are more cautious and in the context of an EFSA conference on this subject expressed some criticisms to this approach.<sup>152</sup> The EFSA Scientific Opinion at times seems to suggest that limitations pertain to epidemiology as a discipline, rather than making clear that limitations refer to the delivery of epidemiological findings that are usable in regulatory processes. This is an important distinction, since epidemiology has not undergone a process of standardisation of protocols and methods similar to the one that resulted in the development of 'regulatory toxicology'. In short, 'regulatory epidemiology' does not exist and remains an open question the extent to which such a development is feasible or indeed desirable.

Finally, it is important to note that the regulatory implications of the integration of plausible epidemiological findings into evaluations are still to be spelled out. Emerging evidence from epidemiological studies could lead to revisions of data requirements and/or testing guidelines in order to investigate more in depth the association between an active substance and an adverse effect. For example, a full investigation of the link between some chemicals and PD would be possible only if specific toxicological data are collected.<sup>153</sup> A different – more stringent – approach is also conceivable: for example, PAN requested adopting the precautionary principle and banning active substances on the basis of epidemiological evidence only.<sup>154</sup> Interviews with the Commission reveal that the regulatory discussion is in the preliminary stages, since there is still a lot of work to be finalised on the scientific approach shortly described above.

## **8. The contribution of open peer-reviewed literature to evaluations**

Article 8(5) of Regulation (EC) 1107/2009 requires applicants to add to the dossier for approvals and renewals the 'scientific peer-reviewed open literature' on the 'active substance and its relevant metabolites dealing with side-effects on health, the environment and non-target species and published within the last 10 years before the date of submission of the dossier'. This provision marks an important innovation in regulation: the mandatory studies conducted in accordance with regulatory guidelines are to be supplemented by studies conducted in the context of (mainly) academic research and published in journals after a peer-review process. On the whole, the expectation was to significantly improve the quality of regulatory processes, since – as PAN Europe affirmed published peer-reviewed research in general is of a higher quality and reliability than industry tests.<sup>155</sup>

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<sup>152</sup> See <https://www.efsa.europa.eu/en/events/event/171121-0>

<sup>153</sup> Notably, this would imply asking for additional endpoints to the 2-year chronic bioassay.

<sup>154</sup> See <https://www.efsa.europa.eu/sites/default/files/event/171121-0/171121-0-13-Dermine.pdf>

<sup>155</sup> Pesticides Action Network. (2014). "Missed and Dismissed. Pesticide Regulators ignore the legal obligation to use independent science for deriving safe exposure levels." PAN Europe, Bruxelles.

To implement this provision, EFSA adopted a guidance document to provide instructions on how to identify and select the peer-reviewed papers and how to classify, summarise and report on them in the dossier.<sup>156</sup>

From interviews with CAs and stakeholders, it emerges that the inclusion of peer-reviewed literature in the dossier is both very important and problematic and that there are some significant issues under discussion.

A first sensitive issue is that peer-reviewed studies must be relevant. According to the EFSA guidance document, 'studies relevant to the dossier are those that inform the data requirements set out in Regulation (EC) 1107/2009, including hazard identification, hazard characterization and exposure assessment'.<sup>157</sup> In other words, only data that are proven appropriate for the purpose of the regulatory assessment need to be included in the dossier, in principle excluding 'studies which exceed data requirements or address additional issues [that] may also be of scientific and regulatory importance'.<sup>158</sup> The search for papers is performed by running queries in large databases, such as PubMed.<sup>159</sup> Applicants are required to provide clear indications on the search strategy used to identify papers in scholarly databases – like the keywords used to retrieve papers – and on the criteria used to include and exclude studies. For illustrative purposes, EFSA provides general criteria for the assessment of relevance, that refer to the topics they address and the information on the purity and impurity of the test material (i.e., the active substance under investigation), the robustness of the research design in terms of number of animals and dose levels. In practice, results in terms of the number of papers could vary a lot.

A second issue has to do with the evaluation of reliability, defined by EFSA as 'the extent to which a study is free from bias and its findings reflect true facts'.<sup>160</sup> All selected papers must be assessed for their reliability, which implies considering features like their statistical power, measurement methods, the appropriateness of animal strains and routes of exposure chosen in the study, and the biological plausibility of results. As EFSA wrote 'for peer-reviewed studies available in the open literature the reliability is likely to vary',<sup>161</sup> and most of the CAs interviewed stressed this point. One of the most serious limitations is that it is not always clear what is being tested, either the active substance or some commercial formulation containing it. Further, impurities of the test material are generally not specified, a factor that has been singled out in interviews as a serious limitation to both reliability and the regulatory usefulness of a study.

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<sup>156</sup> EFSA. (2011b). 'Submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No 1107/2009', *EFSA Journal* 9:2092

<sup>157</sup> *Ibid* p. 11

<sup>158</sup> Kaltenhauser, Kneuer and Marx-Stoelting. (2017) p.228.

<sup>159</sup> PubMed is a free search tool that includes 28 million entries in the fields of biomedicine and life sciences. See <https://www.ncbi.nlm.nih.gov/pubmed/>

<sup>160</sup> EFSA. (2011b) p.27.

<sup>161</sup> EFSA. (2011b) p. 27

All these criteria for reliability are often criticised by experts working for NGOs, who point out that the EFSA guidance document is biased in favour of regulatory studies performed according to OECD/EU guidelines and following GLP rules.<sup>162</sup> This is particularly true in cases when – as suggested by EFSA<sup>163</sup> – relevance and reliability are judged on the basis of the Klimisch criteria,<sup>164</sup> that consider ‘the most important parameter for unrestricted reliability ... in the adherence to harmonised technical guidelines and GLP principles’.<sup>165</sup> According to this interpretation, the overall result is to exclude from the dossier too many relevant peer-review studies and/or to dismiss the information contained in them.<sup>166</sup>

A third critical issue is availability, since not all active substances attract academic interest and therefore the amount of available evidence varies a lot from chemical to chemical. For new active substances, peer-reviewed literature is generally non-existent because they have never been available outside the laboratories of the manufacturers who developed them. The analysis of peer-reviewed literature is therefore mainly pertinent in the context of renewals of approvals, namely for active substances that have already been present on the market.<sup>167</sup> However, even for active substances that have been in use for a decade or more, peer-reviewed literature can be scant. For example, for the active substance Metosulam – an herbicide – which is in use in a few countries only the academic literature is limited to a handful of papers on the environmental fate. On the contrary, some active substances have attracted sustained attention. For example, the dossiers on some old conventional chemicals like glyphosate include around 900 studies and total thousands of pages.<sup>168</sup>

A fourth issue is independence from private interests, which is a main advantage of peer-reviewed literature in the opinion of actors who strongly support its inclusion in evaluation procedures. However, a few considerations need to be watched out. First, open peer-reviewed literature is generally thought to be composed of papers published almost exclusively by scholars working for universities. While this is in general terms accurate, it is of note that researchers working for industries as well as for NGOs do publish in peer-reviewed journals. Further, co-authored studies often include both academics and industry-based researchers. In short, you do not necessarily have to be an academic to write a paper that is of interest to academic journals and passes the hurdles of the peer-

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<sup>162</sup> Interview response.

<sup>163</sup> It is important to note that Klimisch criteria are not the only ones in use according to EFSA guidance document.

<sup>164</sup> Klimisch, H. J., Andreae, M. and Tillmann, U. (1997). 'A systematic approach for evaluating the quality of experimental toxicological and ecotoxicological data', *Regulatory Toxicology and Pharmacology* 25:1-5

<sup>165</sup> Kaltenhauser, J., Kneuer, C. and Marx-Stoelting, P. (2017). 'Relevance and reliability of experimental data in human health risk assessment of pesticides', *ibid.* 88:227-37 p.228.

<sup>166</sup> See <http://www.pan-europe.info/old/Resources/Reports/PANE%20-%202014%20-%20Missed%20and%20dismissed.pdf>

<sup>167</sup> Specifically, the obligation came into force in 2011 and therefore is of interest for active substances included in the AIR3 programme (Regulation 844/2012) and AIR4 programmes (Commission Implementing Decision 2016/C 357/05).

<sup>168</sup> See Dovile?

reviewed procedure. In this sense, the equation peer-reviewed author = academic appears to be an oversimplification. Second, and related, academics are assumed to be motivated in their work by norms of disinterestedness and impartiality, and to be free from conflict of interest.<sup>169</sup> In this sense, the work of academics producing peer-reviewed papers is usually opposed to the work of industry-based researchers producing regulatory studies. The recent debate over the so-called 'Monsanto papers', however, put such a clear-cut distinction between research and regulatory studies under question.<sup>170</sup> Briefly, the glyphosate dossier included two peer-reviewed papers<sup>171</sup> published by scholars based in universities who relied on data and evidence provided directly by Monsanto.<sup>172</sup> Moreover, leaked emails from Monsanto operatives seemed to suggest that they acted as 'ghost-writers', giving academic researchers not only raw data but the text of the paper too. The academics involved denied having acted against scientific and ethical rules. The issue is still open for debate and it is beyond the scope of this paper to be fully described here.<sup>173</sup> It highlights, however, a point of general relevance in the context of this report, namely that assumptions on the quality of a study on the basis of its provenance – academic, industry, NGOs – are highly problematic.<sup>174</sup> Ideally, an evaluation on the merit of each piece of evidence according to the maxima 'judge the science, not the scientist' should be the preferred option. However, the credible application of this principle is based on transparent and accessible information, an aspect identified as a fifth problematic issue in this debate.

GLP studies delivered by an industry are kept confidential and not made accessible to outside interested parties. This is because of patent rights granted to manufacturers, who are obliged to submit evidence on their active substances and at the same time are guaranteed that details on their products are not made publicly available. The raw data submitted by manufacturers are at exclusive disposal of CAs and EFSA experts and reports hide bibliographic references. On the other hand, in the case of published papers, access to raw data is generally not available to evaluators and there are no established guidelines

<sup>169</sup> Jasanoff for example distinguishes between research and regulatory science. Jasanoff, S. (1995). 'Procedural Choices in Regulatory Science', *Technology in Society* 17:279-93

<sup>170</sup> The issue of industry funding goes beyond the field of pesticide regulation. For an overview of recent cases see Matthews, D. (2015). 'Is industry funding undermining trust in science? How valid are fears that financial conflicts of interest are damaging confidence in academic research?', <https://www.timeshighereducation.com/features/is-industry-funding-undermining-trust-in-science> Accessed 15 February 2018.

<sup>171</sup> Kier, L. D. and Kirkland, D. J. (2013). 'Review of genotoxicity studies of glyphosate and glyphosate-based formulations', *Critical Reviews in Toxicology* 43:283-31; Williams, G. M., Kroes, R. and Munro, I. C. (2000). 'Safety Evaluation and Risk Assessment of the Herbicide Roundup and Its Active Ingredient, Glyphosate, for Humans', *Regulatory Toxicology and Pharmacology* 31:117-65

<sup>172</sup> It is important to note that the contribution of Monsanto was not a secret since it was explicitly acknowledged in the published paper.

<sup>173</sup> The European Parliament devoted a hearing to discuss the 'Monsanto Papers'. See <http://www.europarl.europa.eu/committees/en/events-hearings.html?id=20171009CHE02661>

<sup>174</sup> For a discussion see McCarthy, E., Borgert, C. J. and Mihaich, E. M. (2012). 'Information Quality in Regulatory Decisionmaking: Peer Review versus Good Laboratory Practice', *Environmental Health Perspectives* 120:927-34

for reporting test results. As Kaltenhauser and colleagues point out, 'there are currently no common standards that would guarantee the same level of assurance across journals and publications'.<sup>175</sup> As a result, studies are not necessarily presented with the level of accuracy and detail that is needed in regulatory contexts. Further, it might be impossible to get access to data or to more detailed information on the study. Universities and research centres have no specific obligation to keep record of laboratory experiments, their characteristics, and results. All interviewed actors pointed out that a lack of detailed information prevents a full utilisation of these studies in regulatory contexts. Applicants and activists alike note that 'academic' practices should improve in terms of transparency and accessibility. Journals are increasingly asking for data to be made available online as supplementary material, however at present this is not a shared policy. There is thus a trade-off between GLP studies fully available to a restricted group of experts recruited by a regulatory agency and open literature papers providing partial information to any interested reader.

All considered, so far the main function of peer-reviewed literature has been to perform 'a signal function', as one respondent put it, to signify that these studies can include findings that alert evaluators to adverse effects that are not seen via standard testing. According to interviews, this has been in play in the context of the evaluation of some active substances, such as Linuron that – as mentioned – is the first chemical banned based on its intrinsic hazardous properties. Some of the respondents from CAs questioned the real added value of including open and peer-reviewed academic literature. While acknowledging their importance, the experience so far is that most of the time the analysis of peer-reviewed papers does not add information that is not already largely available in the dossier. As one respondent put it, 'there might be relevant information, but the effort taken to go through thousands of pages is too much and the real benefit very marginal'.

## **9. Summary of main findings**

Regulation (EC) 1107/2009 set ambitious goals. To achieve them, the harmonisation of criteria and procedures for the approval of active substances and PPPs is a necessary precondition.

→ Data requirements for pesticides are likely to be the most demanding ones in the context of EU regulations. Most testing has been institutionalised and protocols are agreed upon at the EU and international level, such that data are supplied according to specific research designs, methodologies, and techniques.

Yet it is important to stress that different areas of inquiry are characterised by different degrees of harmonisation. In general terms, guidance documents on residues and toxicological hazards are well-established, while guidelines on environmental fate and behaviour and on ecotoxicology are less consolidated.

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<sup>175</sup> Kaltenhauser, Kneuer and Marx-Stoelting. (2017) p.232.

Experts are engaged in a variety of panels and ad hoc working groups at both EFSA and DG Sante to refine existing guidelines and develop new ones to catch up with scientific progress as well as to fulfil legal requirements. The effort of CAs, EFSA and DG Sante – and more extensively the network of experts involved – is reported as a very relevant part of their work, one that demands significant resources.

→ There is a clear sense that requirements and guidelines are becoming increasingly complex over time, an aspect frequently stressed by CAs.

Guidelines still missing on some data requirements, in particular in the context of environmental fate and behaviour and ecotoxicology. Guidelines on endocrine disruption have been recently finalised in December 2017. A relevant point is that manufacturers complain that new guidance documents are applied ‘retrospectively’ to already submitted dossiers.

→ Some guidelines are available but not formally adopted by risk managers in SCoPAFF and therefore have no legal validity. Some CAs do not agree to apply guidance documents that have not been properly adopted at EU level, while others are more willing to do so and/or have included guidelines in national provisions. This introduces regulatory uncertainty.

It is of note that in other regulatory sectors EFSA is in position to formulate and adopt risk assessment criteria and guidelines, whose application does not require a ‘political’ vote in comitology.

→ As envisaged by the principle of precaution, the burden of proof is on applicants: it is up to them to provide evidence about the safety of active substances. Accordingly, manufacturers perform the test activities in order to collect data, either in-house, or by commissioning studies conducted by external certified laboratories that are specialised in carrying out testing according to OECD/EU and international protocols.

The reliance on tests that are supplied by the industry has been characterised by NGOs as inherently biased and therefore inadequate to constitute a sound evidence-base to be used in risk assessment. CAs highlight two relevant characteristics to support the quality and reliability of the current system: first, studies must be carried out according to established protocols and to the principles of Good Laboratory Practice (GLP), to guarantee their quality. Second, applicants are obliged to submit all original findings on which studies and reports are based, so that evaluators are in position to provide an original interpretation of data.

The debate is still ongoing on a range of issues that are of direct relevance for the assessment of hazards and risks associated with active substances.

→ Regulation (EC) 1107/2009 introduces a relevant derogation from cut-off criteria: to the extent that exposure is negligible, a hazardous active substance can get approved

The derogation from cut-off criteria for negligible exposure has been introduced for carcinogenicity (point 3.6.3 of Annex II of Regulation (EC) 1107/2009) toxicity for reproduction (3.6.4), endocrine disruption (3.6.5), endocrine disruption on non-target organisms (3.8.2) as well as for honeybees' health (3.8.3). The other cut-off criteria – mutagenicity – does not include considerations of exposure (3.6.2), as well as the main 'environmental criteria' of persistence, bioaccumulation and toxicity for the environment

Draft technical guidelines on the assessment of negligible exposure have been made public by DG Sante in June 2015. The published document is incomplete in some very relevant sections and therefore constitutes a partial answer to the issue. It does provide, however, clear indications of the logic to be applied when performing assessments of derogations from hazard-based cut-off criteria. The most consequential statement is that 'negligible exposure' is a condition to be actively searched and achieved by the introduction of risk mitigation measures, like obligation to wear protections etc. The approach adopted by the Commission in the draft technical guidelines is contested by some CAs, since it seems to 'dilute' the hazard-based approach that informs Regulation (EC) 1107/2009. According to critics, exposure is negligible if 'the product is used in closed systems or in other conditions excluding contact with humans'.

→ The standard procedure for hazard and risk assessment follows a chemical-by-chemical logic, in which each active substance is tested for its own intrinsic hazards and evaluated for its risks.

However, there is a growing consensus among experts that health and environmental risks might be significantly underestimated if cumulative effects are not evaluated.

EU legislation requires the assessment of intentional mixtures, combinations of chemicals that result from the intentional mix of different active substances, like commercial formulations composed of a combination of active substances. Much less attention is given to unintentional mixtures – like the ones that are formed during the handling of different products on the part of users – or coincidental – mixtures that get formed in the environment after the use of a variety of active substances. At present there is no systematic and integrated approach across different pieces of legislation. In the pesticide sector, guidelines are currently under development.

→ Regulation (EC) 1107/2009 requires evaluators to take into account epidemiological evidence. The integration of epidemiological findings is problematic. A main reason is that the attribution of causality between a specific active substance and a specific adverse effect – the ultimate regulatory goal – is uncertain because of multiple hazards and the presence of confounding factors that can not be kept under control. All considered, the integration of epidemiology and toxicology – as envisaged by EFSA – sees the former in a supporting role to the latter. Epidemiology would alert on the existence of health concerns to be further investigated by toxicologists. The discussion among expert is still going on. At this stage it is important to note that the regulatory implications of the integration of plausible epidemiological findings into evaluations – such as revisions of data requirements, provisional bans, etc - are still to be spelled out.

→ From interviews with CAs and stakeholders, it emerges that the inclusion of peer-reviewed literature in the dossier is both very important and problematic. There are some significant issues under discussion, in particular on the relevance, reliability, accessibility and transparency of studies. All considered, so far the main function of peer-reviewed literature has been to perform 'a signal function', meaning that studies can include findings that alert evaluators to adverse effects that are not seen via standard testing.

## **IV Institutional capacity of competent authorities: procedural and organisational issues**

Part IV investigates the institutional capacity of national and EU competent authorities to deliver reliable hazard and risk assessments. Section IV.1 illustrates processes for the approval and for the renewal of approvals of active substances, as envisaged by Regulation (EC) 1107/2009. In this context, sub-sections IV.1.1, IV.1.2 and IV.1.3 deal with three critical issues: the distribution of workload among national CAs, the timing and delays in delivering assessments, the transparency of the process. Section IV.2 describes the organisational models in place at national level (IV.2.1) and provides info on staff (IV.2.2). Section IV.3 is about procedures for risk assessments: it describes different stages at national level (pre-submission, admissibility check, evaluation) and at EU level (EFSA peer-review procedures). Sub-section IV.3.4 deals with problematic risk management issues.

### **1. Overview on processes of hazard and risk assessment of active substances**

Data requirements for the approval of active substances to be utilised in the production of plant protection products are among the most demanding in the EU regulatory arena. The evaluation of findings is therefore a complex procedure that requires resources, time, and a high level of technical competence. According to Regulation (EC) 1107/2009 the process for the approval of active substances is carried out in cooperation between MS and EU authorities.<sup>176</sup>

The procedure for new active substances starts at the national level: a manufacturer submits an application to a MS of its choice, and that becomes the Rapporteur Member State (RMS) for that specific dossier. The RMS is in charge of the initial phase of the process: checking for the completeness of data submitted (see IV.3.1). If the dossier satisfies data requirements, the RMS notifies EFSA and DG Sante of the new procedure. The RMS then starts the evaluation procedure (see IV.3.2) that will produce a Draft Assessment Report (DAR) on the active substance. According to Article 4(1) of Regulation (EC) 1107/2009, the assessment has to first address whether the active substance meets cut-off criteria. If the active substance under evaluation is not classified as CMR, POP, PBT, vPvB or ED, then the assessment continues with other parts of the report. On the contrary, if the active substance meets one of the cut-off criteria, then the procedure stops, and the dossier is sent to EFSA and then to risk managers. However, the assessment will still go on if the manufacturer asks for the derogation on negligible exposure to be applied (see section III.5).

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<sup>176</sup> The division of tasks between MS and EU in the approval of active substances has characterised pesticide regulation since its inception in the early '90s. Directive 414/1991 included similar provisions. Of course, the most relevant difference is that EFSA did not exist at that time, and the Commission was in charge of both risk assessment and risk management functions. Since the creation of EFSA, the two functions have been separated.

Once finalised, the DAR is sent to EFSA, which organises the peer-review procedure on the dossier (see IV.3.3). It includes a consultation open to all CAs, experts and the public. Comments are discussed by EFSA staff and if areas of uncertainty emerge, then expert meetings will address them. The RMS has the opportunity to reply to comments and has the duty to amend the DAR when needed. The discussion among experts is finalised for the delivery of the document reporting EFSA conclusions on the active substance. The EFSA conclusions are then sent to DG Sante, and findings are discussed in the context of the comitology committee SCoPAFF. A final decision on risk management is taken by a qualified majority (see section IV.3.4) and adopted in the form of an Implementing Regulation.

The procedure for the renewal of approval of active substances is very similar, but there are some differences. First, the RMS is indicated by the Commission and cannot be chosen by applicants.<sup>177</sup> Second, as will be explained below (see section IV.1.2), there are differences in the timing given to each stage of the risk analysis procedure.

### 1.1 Distribution of workload among competent authorities

At the time of writing, the EU pesticide database reports that the total number of active substances approved was 488.<sup>178</sup> Not all 488 active substances are in use everywhere in the EU: whether an active substance is utilised or not depends on the authorization process of the PPPs containing it, which takes place at national and zonal levels. In turn, this will depend on agronomic conditions and farming needs.

The two tables below report two types of data on the distribution of active substances among countries. First, Table 3 reports the number of active substance in use in each MS. Second, Table 4 provides an indication of the geographical diffusion of active substances and reports the number of active substances in relation to the number of MSs that authorised them for use. As shown, only 11 active substances are utilised in all 28 MSs. The median of the distribution is 14, meaning that half of the 488 approved active substances are in use in 14 MS.

Table 3: Number of approved active substances in use in each MS (data in Dec 2016)

Country	Number of a.s.
AT	266
BE	287
BG	204
CY	189
CZ	261
DE	265

<sup>177</sup> Regulation (EC) 844/2012.

<sup>178</sup> The total number of approved active substances does not correspond to the active substances currently in use because of derogations granted according to Article 53 Regulation (EC) 1107/2009. See more on the practice of granting authorisations under Article 53 derogation in the study (Milieu, 2018/Annex I to the European Implementation Assessment).

DK	153
EE	149
EL	287
ES	304
FI	148
FR	317
HR	197
HU	266
IE	215
IT	335
LT	162
LU	219
LV	149
MT	54
NL	266
PL	257
PT	254
RO	224
SE	142
SI	204
SK	221
UK	275
AVERAGE:	224

Source: Own elaboration from EU Pesticide Database

Table 4: Geographical diffusion of active substances: number of active substances in relation to the number of MSs in which they are in use.

Number of MS	Number of a.s. in use
28	11
27	31
26	15
25	20
24	20
23	21
22	8
21	14
20	13
19	15
18	14
17	16
16	9
15	12
14	17
13	12

12	7
11	8
10	14
9	17
8	12
7	10
6	10
5	25
4	12
3	19
2	32
1	30
Authorizations in progress	43

Source: Own elaboration from EU Pesticide Database

The fragmented distribution of active substances among countries matters for a variety of reasons. Obviously, information on the type (and quantity) of chemicals in use in each EU region is of particular relevance for the implementation of Directive 2009/128/EC on the Sustainable Use of Pesticide, a topic not addressed here. It also matters for the issues of market fragmentation. In the context of this study, the distribution of active substances in use in each country is of relevance because – as noted above – manufacturers who want to have a new molecule evaluated and approved can choose the MS that will act as a RMS. A major factor in choosing a specific RMS for the evaluation of a new active substance is the intention to commercialise it in the country. Therefore, differences in the distribution of authorised active substances among countries have an impact on the distribution of dossiers among CAs. Other factors are at play: manufacturers tend to prioritise CAs that are willing to offer meetings and provide feedback (before and during the evaluation process), and CAs that provide more information on their criteria, procedures, etc. One of the consequences over the years of the possibility given to manufacturers to choose RMSs is a very differentiated distribution of dossiers among CAs, as shown in Table 5 below.

Table 5: Distribution of total number of processed dossiers by MS

RMS	Number of Dossiers
UK	118
FR	84
AT	76
DE	67
NL	60
IT	49
ES	45
BE	41
EL	41
IE	34
SE	29

FI	19
PL	17
DK	16
PT	15
HU	13
CZ	5
EE	4
SK	4
LV	3
SI	2
Applications withdrawn	573
<b>TOTAL</b>	<b>1315</b>

Source: Own elaboration from EU Pesticide Database

Differences in the distribution of dossiers are likely to change in the future. As noted above, for new active substances – meaning active substances never approved for use in the EU – manufacturers might choose where to start their applications. However, it is important to note that new active substances are relatively few. Since the entry into force of Regulation (EC) 1107/2009 in June 2011, about 30 new active substances have been proposed for evaluation. The most demanding dossiers refer to renewals of approval of active substances that have already been evaluated and approved under Directive 414/1991. As mentioned, in the case of renewals manufacturers cannot choose their RMS; dossiers are allocated by the Commission.

To organise and plan re-evaluations, the Commission organised four programmes whose acronym is AIR. AIR-1 and AIR-2 re-evaluate dossiers according to criteria as envisaged by Directive 414/1991, since they comprise active substances that expired before the entry into force of Regulation (EC) 1107/2009 in 2011. Rules for AIR-3 and AIR-4 programmes are instead based on the new Regulation (EC) 1107/2009. It means that cut-off criteria and new requirements – such as the inclusion of peer-reviewed literature in the dossier – apply for AIR-3 and AIR-4 but not for AIR-1 and AIR-2 substances.

For each group of active substances, the Commission provides information on new expiry dates (where needed) as well as indications on deadlines for submitting applications and dossiers. The programmes also prioritise procedures according to the characteristics of active substances under evaluation. For example, among the almost 200 active substances under AIR-4, 'presumed low-risk substances and substances that may fail to meet the approval criteria are prioritised in the work programme'.<sup>179</sup> On the whole, the purpose of the AIR programmes is to plan 'the different steps of the renewal procedure to ensure that it functions properly'.<sup>180</sup>

A relevant point is that – as noted above – in the case of renewals of approval of active substances, dossiers are allocated to MSs by the Commission.

<sup>179</sup> DG SANTE. (2017). "Draft Working Document. AIR-4 Renewal Programme."

<sup>180</sup> Recital 3 Regulation 844/2012

The table below shows the distribution of the workload by countries for the four renewal programmes. As can be noted, countries are clearly differentiated, with the number of dossiers ranging from 1 and 2 in the cases of Romania and Lithuania to 38 and 34 for the Netherlands and the UK respectively. Cyprus and Malta do not appear in the table since they are not in charge of dossiers. Some MSs significantly increased the number of dossiers to be completed in the context of AIR-4. For example, Austria, the Netherlands and Sweden more than doubled their commitment to deliver dRARs.

Table 6: Distribution of dossiers for the renewal of active substances by country

RMS	AIR1	AIR2	AIR3	AIR4	Total
AT		2	7	18	27
BE	1	2	8	5	16
BG			1	3	4
CZ		1	6	10	17
DE	1	5	14	11	31
DK			3	7	10
EE			1	4	5
EL		1	5	10	16
ES		1	9	15	25
FI			6	4	10
FR	1	5	14	11	31
HR				4	4
HU		1	5	6	12
IE	1	1	2	4	8
IT		1	12	12	25
LT			1	1	2
LV			3	3	6
NL	1	2	11	24	38
NO				3	3
PL		1	11	4	16
PT			2	1	3
RO			1		1
SE	1	2	10	19	32
SI		1	3	4	8
SK			1	2	3
UK	1	5	14	14	34
<b>Total</b>	<b>7</b>	<b>31</b>	<b>150</b>	<b>199</b>	<b>387</b>

Active substances are allocated by the Commission on the basis of a negotiation with each CA. According to interviewees, most of the time negotiations went on smoothly. Some factors have been mentioned as reasons for agreeing to take a dossier on board, such as previous experience with the active substance and interest in the active substance for the country. CAs also take into account considerations of feasibility and the perceived complexity of the dossier.

The distribution of procedures according to a centralised procedure made it possible for some countries to build experience with approvals. As noted above, some CAs have been chosen very rarely by manufacturers and remained substantially marginal in the regulatory regime. AIR programmes therefore favoured some geographical distribution of the workload. As discussed in the next sections, however, the planning and redistribution of dossiers envisaged by the AIR programmes have not been effective in delivering renewals without delays (see sections IV.1.2. and IV.2.2).

## 1.2 Timing and delays

Since its inception in the early '90s, the main issue of concern in the implementation of EU regulation on pesticides has been delays in assessments (see above II.2).

Regulation (EC) 1107/2009 therefore introduced precise specifications on the duration of each phase of the evaluation process (see below IV.2 and Graph 1). Ideally, the entire process from submission of the dossier to the adoption of the Implementing Regulation upon approval or rejection upon non-approval should be finalised in 26,5 months.

There are also 'stop-the-clock' options to be enacted if during the evaluation process it emerges that some more information is needed on some aspects of the dossier. In these cases, applicants are required to submit the additional data, and time is provided to perform the testing. MSs can ask for more data during the admissibility check, stopping the clock for a maximum of three months. During the evaluation phase, a second stop is possible, adding six months to the process. EFSA is allowed to ask for more information only once in the process, before the start of the peer-review procedure. If needed, applicants are given 90 days to submit the requested additional information,<sup>181</sup> and two more months to the RMS to evaluate it. The final risk management stage in SCoPAFF has to be finalised in six months. If all stop the clock options are taken, the process will go on for 41.5 months, i.e. around 3.5 years. Graph 1 below provides a visualization of stages and their respective timing.

*Graph 1: Stages of the procedure for the approval of new active substances*



The experience with the implementation of Regulation (EC) 1107/2009 is that most of the time evaluation and re-evaluation of active substances are more time-consuming than envisaged in legislation.

<sup>181</sup> Article 12(3) Regulation (EC) 1107/2009

In the period 2016–2017, a total of 65 procedures were finalised and a definitive decision was taken: 46 out of 65 active substances were granted approval, and 19 were not. Out of 65 procedures, 37 refer to renewals, and the remaining 28 to new basic, low-risk or synthetic active substances. For the latter, the majority of procedures were finalised in about four years.

Most delays have been recorded in the cases of renewals. The renewal programme has also been slower than expected, and the Commission adopted Implementing Regulations to postpone the legal deadline of market authorizations. The most famous and controversial case is glyphosate: the approval originally expired in 2012 but was postponed three times until a new agreement was eventually found in December 2017, i.e. five years later. Other less famous cases abound. Notably, in the context of the AIR-3 programme, 112 active substances out of 150 had their deadlines extended. In most of the cases, the legal deadline has been postponed to 31 July 2018. At that time, therefore, it is expected that a significant number of procedures will come to an end. The processes of evaluation, however, are proceeding at different speeds, and further delays cannot be ruled out.

### 1.3 Transparency

Recital 12 of Regulation (EC) 1107/2009 states that ‘provisions should be included to ensure the transparency of the evaluation process’. This subsection is devoted to analysing this crucial aspect of regulation, focussing on two main dimensions of the concept of transparency: the availability of information and the accessibility of information, including the possibility of tracing the evaluation process.

The glyphosate case clearly demonstrated that transparency of the risk assessment process is an issue of concern.<sup>182</sup> NGOs representatives working on health and environmental issues asked for full disclosure of evidence, taking legal action to gain access to confidential documents.<sup>183</sup>

When it comes to ‘availability of information’, it is an over-simplification to speak about ‘documents’. At the very minimum, relevant documents containing information that refer to the risk assessment phase are:

- c) The dossier as submitted by manufacturers in the application;

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<sup>182</sup> A European Citizen Initiative ‘Ban glyphosate and protect people and the environment from toxic pesticides’ has been launched in 2017. The initiative calls on the Commission and Member States to: ban glyphosate-based herbicides, exposure to which has been linked to cancer in humans, and has led to ecosystems degradation; ensure that the scientific evaluation of pesticides for EU regulatory approval is based only on published studies, which are commissioned by competent public authorities instead of the pesticide industry; and set EU-wide mandatory reduction targets for pesticide use, with a view to achieving a pesticide-free future.

Furthermore, in response to the ECI, in December 2017 the Commission announced that a new legislative proposal on the transparency of risk assessment procedures will be published in Spring 2018. In February 2018, the EP set up a Special Committee on the Union’s authorisation procedure for pesticides, its responsibilities, numerical strength and term of office.

<sup>183</sup> For example, in the glyphosate controversy PAN Europe started three court cases to request disclosure of documents, including industry studies.

- d) The evidence-base that informs the dossier, namely, the studies and the raw data;
- e) The summary of the studies containing interpretation of findings;
- f) The initial DARs/RARs submitted by RMS to EFSA;
- g) The EFSA peer review report, including comments received from CAs, experts, stakeholders and possibly the public; and
- h) The EFSA conclusion on the active substance.

Relevant information that pertains to the risk management phase are:

- a) Information on management measures as discussed in the context of comitology meetings; and
- b) The final Implementing act on the active substance, containing explanations for approval/non-approval or for restrictions on admissible uses.

Accordingly, Table 7 below presents a summary of the availability of these different relevant parts in which the complete risk assessment dossier can be distinguished.

Table 7: Overview of available risk assessment and management documents

	Available to:				Where
	EFSA	MS	External experts	Stakeholders	
<b>RISK ASSESSMENT</b>					
<b>Dossier submitted by applicants</b>	X	X	X	Sanitised version	EFSA Register of Question – Section ‘Pesticide Dossier’
<b>‘Raw data’</b>	X	X	X		EFSA restricted website
<b>Summary of studies</b>	X	X	X	X	EFSA Register of Question
<b>DAR/RAR submitted by RMS</b>	X	X	X	X	EFSA website (upon request)
<b>EFSA peer review</b>	X	X	X	X	EFSA journal
<b>EFSA conclusion</b>	X	X	X	X	EFSA journal
<b>RISK MANAGEMENT</b>					
<b>SCoPAFF debate /minutes</b>	X	X	X	X	DG Sante website
<b>Final decision</b>	X	X	X	X	Eur-Lex

As the last column of the table shows, the evidence is available in different locations on the EFSA and the EC websites.

On the EU Pesticide database for each active substance it is possible to find:

- The legislative acts that are of relevance for a specific active substance, *in primis* the Implementing Regulation approving or not approving its inclusion among approved active substances;
- A link to the EFSA risk assessment report;

- The risk management report as finalised in the Standing Committee on Plants, Animals, Food and Feed; and
- Information on MRL, toxicological profile, CLP classifications

The EFSA Register of Questions includes all pesticide dossiers, meaning the sanitised versions on the application sent by manufacturers.

DARs can be downloaded from the EFSA website.<sup>184</sup> Each DAR is also made publicly available during public consultation. It means that for recent applications it is possible to find DARs on the pages dedicated to EFSA public consultations, and they are downloadable directly, without any additional form.

The EFSA journal publishes - for each active substance - the peer review report that forms the EFSA conclusion on the active substance.

The EFSA Register of Questions<sup>185</sup> also provides a more detailed report on the outcome of public consultation. This includes all the comments received from other MSs during the written consultation, as well as the issues discussed during expert meetings. It also includes the feedback given by EFSA that later informs the final concluding risk assessment report to be sent to comitology.

In short, in principle it is possible to find most of the information, including the original dossier, taking into account rules for confidentiality (see below, this subsection). In this sense, EFSA's argument that 'in practice everything is available' is correct.

The accessibility of information is considered low. Part of the problem is that different documents can be accessed from different sources, which vary in terms of accessibility. The EU pesticide database is organised for the general public, and it can be considered user-friendly. The EFSA Register of Question seems oriented towards sharing technical information among experts. It is not user-friendly in the sense that finding information requires time and some familiarity with provisions on the structure of dossiers as well as 'EFSA jargon'. Another criticism that has been advanced is that EFSA documents on peer review procedures are not internally searchable, and therefore areas of interest cannot be easily located.<sup>186</sup>

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<sup>184</sup> Access to DARs is provided upon request. See <http://dar.efsa.europa.eu/dar-web/provision>

<sup>185</sup> See <http://registerofquestions.efsa.europa.eu/roqFrontend/login?0>

<sup>186</sup> In April 2018 the Commission published a proposal for a Regulation on the transparency of EU risk assessment procedures and required EFSA to make all studies submitted to EFSA public, as well as to improve the accessibility of studies. Specifically, stakeholders and the general public should have the possibility to search, download and print submitted studies at the very early stage of the evaluation process. See European Commission (2018) Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the transparency and sustainability of the EU risk assessment in the food chain amending Regulation (EC) No 178/2002 [on general food law], Directive 2001/18/EC [on the deliberate release into the environment of GMOs], Regulation (EC) No 1829/2003 [on GM food and feed], Regulation (EC) No 1831/2003 [on feed additives], Regulation (EC) No 2065/2003 [on smoke flavourings], Regulation (EC) No 1935/2004 [on food contact materials], Regulation (EC) No 1331/2008 [on the common authorisation procedure for

A very important aspect of the evaluation process is availability and readability of data and studies. Applicants are required to submit a dossier according to a harmonised and detailed format that organises information according to a fixed template. DG Sante has published a guidance document to detail the list and the content of each section. The format dossier is based on OECD templates integrated to take into account EU-specific requirements. The dossier includes a series of documents each identified by a letter, from A to O. Documents from A to J provide information on the type of submission, the applicants, the existing provision on the active substance, for example, the MRL already established in the EU and in exporting countries. The core of the dossier is composed of documents K, L and M. The document K contains raw data, document L contains the reference list for the studies submitted and document M includes a summary of the studies. Documents K, L and M are in turn structured into 10 'thematic' sections that reflect the various aspects covered by data requirements.<sup>187</sup> Finally documents from N to O include the overall conclusions on the active substance (as proposed by the applicant), the list of endpoints and information on metabolites. The version of the dossier that is made available to the public and published is the so-called 'sanitized version'. It means that information that is sensitive for commercial reasons is kept confidential and 'deleted' from the dossier.

The controversy over glyphosate prompted a broader discussion on the issues of transparency and confidentiality. A group of NGOs wrote in an open letter to Commissioner Andriukaitis that 'the aim must be that all EFSA assessments, not only on glyphosate, can be reproduced by any expert who wishes to do so. Only in this way will EFSA be able to restore credibility in its work among the scientific community and the public'.<sup>188</sup> Accordingly, they asked for the publication of the full dossier, including raw data. This is rated as 'very important' by NGOs who replied to the survey and have been interviewed on the issue. As noted above (see section III.8) industry studies are often dismissed as inherently biased and the possibility of accessing and double-checking their reliability is therefore considered an essential precondition for transparency. However, it is obvious that reading toxicological studies requires a very high level of competence. In this sense, the added value in terms of public understanding of the issue that derives from the publication of thousands of pages containing laboratory results is all but self-evident. EFSA noted that the authority did not receive a single request to access the glyphosate data after they were made publicly available. This suggests that it is not necessarily the quantity of information available but rather the quality of it that matters. To address these concerns the Commission has recently promoted a reflection on how to improve on the transparency

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food additives, food enzymes and food flavourings], Regulation (EC) No 1107/2009 [on plant protection products] and Regulation (EU) No 2015/2283 [on novel foods]. COM (2018) 179 final.

<sup>187</sup> The 10 sections are: identity of the active substance, physical and chemical properties, additional information, analytical methods, toxicological studies, residues, fate and behaviour in the environment, ecotoxicological studies, literature review, classification and labelling.

<sup>188</sup> Pesticides Action Network. (2015c). "Letter to Vytenis Andriukaitis - European Commissioner for Health and Consumer Policy - concerning : The policy of your DG on the (interim) criteria for endocrine disrupting pesticides." PAN, Bruxelles.

of the procedure, thereby trying to ‘square the circle’ between competing requests for full disclosure and confidentiality.<sup>189</sup>

A final note on transparency: Stakeholders have different opinions on the transparency of each of the stages in which the risk analysis procedure is organised. The drafting of DAR/RAR on the part of MSs receive mixed results, probably reflecting differences in the experience with CAs. The EFSA peer-review procedure is generally perceived as having a good level of transparency. As might be expected, most criticism goes to the lack of relevant information on discussions in the context of SCoPAFF, the comitology committee. This is not unique to pesticides: comitology procedures tend to be obscure in all sectors.<sup>190</sup> The first reason has to do with transparency. ‘The general public has only two systematic sources of information on comitology: the Internet register maintained by the European Commission and the Commission’s annual report of the committees’ activities’.<sup>191</sup> Detailed minutes reporting how the discussion unfolded among risk managers, the positions and arguments of MSs are generally not available. The second, more fundamental reason is the lack of clarity about risk management criteria, an aspect that will be discussed in section IV.3.4.

## 2. Organisational features of CAs

### 2.1 Four organisational models for the assessment of active substances

Article 75 of Regulation (EC) 1107/2009 establishes that each MS must designate a CA to deal with the obligations laid down by the legislation in terms of approvals of active substances and authorization of PPPs. As Table 8 makes clear, all MSs are obliged to observe this requirement, and it is therefore possible to identify who is responsible for the implementation of Regulation (EC) 1107/2009 in each of the 28 EU countries plus Norway.<sup>192</sup>

Table 8: List of national competent authorities, their remits, and staff

	COMPETENT AUTHORITY <sup>193</sup>	Name of Unit in charge of a.s.	Competences of the unit	Staff = evaluators + admin or legal officers
AT	AGES		a.s. fertilisers	40
BE	Federal Public Service Public Health, Food	Plant protection	a.s., PPPs, fertilisers; SUD	28 (FPS)

<sup>189</sup> At the time of writing an online public consultation on this issue is open.

<sup>190</sup> Brandsma, G. (2013). *Controlling Comitology: Accountability in a Multi-Level System*. Basingstoke: Palgrave Macmillan.

<sup>191</sup> Brandsma, G. (2013). P. 427

<sup>192</sup> Norway started the implementation of Regulation (EC) 1107/2009 in 2015.

<sup>193</sup> In this column are listed authorities that are in charge with evaluations and with the delivery of DARs/RARs.

	Chain Safety and Environment + Scientific Institute of Public Health	products and fertilisers		
BG	Bulgarian Food Safety Agency			
CY	Ministry of Agriculture -	Agrochemicals control section	a.s., PPPs, biocides, fertilisers, market controls, SUD	2 + 7
CZ	Ministry of Agriculture Rural Development and Environment, Department of Agriculture + Central Institute for Supervising and Testing in Agriculture	Plant Protection Products and Biocides Board	a.s., PPPs, Biocides, SUD	n.a.
DE	BVL BfR Julius UBA	various	a.s., PPPs, biocides	80 (BfR only)
DK	Danish Environmental Protection Agency	Pesticides and Gene Technology	a.s. PPPs. Biocides, SUD	20 + 7
EE	Pollumajandusamet	Plant Protection Department	a.s., PPPs	n.a.
EL	Benaki Institute	Dept. Pesticide Control and Phytopharmacy	a.s., PPPs	44 total
ES	Ministry of Agriculture (lead organisation) + others government dept + 1 certified independent research institute			13 + 7
FI	Finnish Safety and Chemicals Agency (Tukes)		a.s. PPPs, SUD	10 + 13
FR	ANSES	Regulated Products Assessment Dept	a.s., PPPs, biocides, fertilisers, REACH	150 (total)

HR	Ministry of Agriculture Directorate for Food Quality and Phytosanitary Policy			
HU	National Food Chain Safety Office	Directorate of Plant Protection and Soil Conservation		
IE	Dept of Agriculture, Food and the Marine	Pesticide Registration & Controls Divisions (PRCD)	a.s., PPPs, biocides	
IT	Ministry for Health (lead organisation) + others government dept + 10 certified independent research institutes		a.s. PPPs	variable
LT	Ministry of Agriculture	State Plant Protection Service (VAAT)		
LU	Administration des Services Techniques de l'Agriculture (ASTA)			
LV	Ministry of Agriculture	Plant Protection Division	a.s. PPPs	12 total
MT	Competition and Consumer Affairs Authority	Technical Regulations Division		
NL	Ctgb - Board for the Authorisation of Plant Protection Products and Biocides		a.s., PPPs, biocides	100 + 50
NO	Norwegian Food Safety Authority	National Registrations Department	a.s., PPPs	22 + n.a.
PL	Institute for Plant Protection. National Research Institute			
PT	Ministry of Agriculture and Rural development	Service for means of sanitary defence	a.s, PPPs, SUD	13 + 17

RO	Ministry of Agriculture and Rural Development + Other relevant Dept within government	National Phytosanitary authority		Variable + 5
SE	KEMI	Evaluation of Substances	a.s. PPPs, biocides, REACH	20
SI	Ministry of Agriculture, Forestry and Food + (possibly) external research centres	Administration of the Republic of Slovenia for Food Safety, Veterinary Sector and Plant Protection	a.s., pesticides, biocides	
SK	Central controlling and Testing Institute on Agriculture (UKSUP)			
UK	Health and Safety Executive (HSE)	Chemicals Regulated Division (CRD)	a.s., PPPs, biocides, REACH	25 full time equivalent

Source: Documentary analysis and interviews with CAs

From an organisational point of view, four distinct models for the assessment of active substances can be identified among MSs.

The first model is characterised by the existence of a single regulatory independent agency.<sup>194</sup> In this context, the evaluation is carried out by officers based at the same institution that have in-house competencies on all the relevant parts of the dossier: chemistry, efficacy, residues, toxicology, environmental fate and behaviour and ecotoxicology. This model is adopted in France, the Netherlands, Austria, Sweden and Greece. However, it is of note that these regulatory agencies differ in terms of their remit. For example, the Swedish KEMI and the Dutch Ctgb deal with chemicals, while the Austrian AGES has a broad set of competencies in the field of food safety. The French ANSES seems to have the broader mandate and covers food safety, environment, chemicals, and occupational health and safety.

The second model relies on a group of independent agencies that cooperate to evaluate active substances. Germany and Belgium are prominent examples. In this context, the evaluations are carried out by different institutions, each specialised in a specific area. For example, in Germany dossiers are delivered to BVL (Federal Office of Consumer Protection and Food Safety), which is also in charge of the assessment of physical-chemical properties. The dossier is then distributed among: the BfR (Federal Institute for Risk Assessment), which is responsible for the risk assessment in the area of human health; the

<sup>194</sup> For an overview of scholarly reflection on regulatory independent agencies see the study (Hamlyn, 2018/Annex III to the European Implementation Assessment).

JKI (Federal Research Centre for Cultivated Plants) that carries out risk assessment in the section of efficacy and bees; and the UBA (Federal Environmental Agency) that is responsible for the sections on environmental fate and behaviour and ecotoxicology.

In Belgium the dossier is divided between two institutions: the Federal Public Service Public Health, Food Chain Safety and Environment deals with chemical properties, analytical methods, residues, environmental fate and behaviour, and ecotoxicology; and the Scientific Institute of Public Health (IPH) is responsible for the toxicological section of dossiers.

The third model relies on the cooperation between a governmental body and external research institutes and universities in charge of evaluations of part of the dossier according to their competencies. For example, Italian authorities at the Ministry of Health are responsible for the evaluations that are distributed among accredited research centres. These must meet a set of criteria and must have been selected by a public procedure according to their competencies and qualifications.<sup>195</sup> A similar process is in place in Spain, where the Ministry for Agriculture can authorise independent evaluating organisations to carry out technical assessments.<sup>196</sup> In Slovenia and Portugal<sup>197</sup> national authorities can also rely on external research centres.

The fourth model is characterised by the reliance on one or more governmental institutions as the sole authorities in charge of evaluations. For example, in Ireland the Pesticide Registration & Controls Divisions are part of the Department of Agriculture, Food & the Marine. In Romania the responsible authority is the Ministry of Agriculture and Rural Development that has evaluators from other governmental departments (environment, health) assessing dossiers.

Independent of the organisational model in place, most of the time the specific unit within the agency/institution dealing with the evaluations of active substances is also in charge of PPPs and biocides. At times, fertilisers are also added to the list (see Table 8).

In some countries the same office is in charge of a variety of EU legislations. The example of Cyprus is of relevance here: The Board for PPP and Biocides is working on the approval of active substances, the authorization of PPPs, biocides, fertilisers, animal feed and the SUD.

Fees Regulation (EC) 1107/2009 establishes that applicants pay a fee to CAs to have their active substances evaluated.<sup>198</sup> Each MS can decide the appropriate level of fees to be requested and evidence is that there is significant variation across countries. According to

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<sup>195</sup> See

[http://www.salute.gov.it/portale/temi/p2\\_6.jsp?lingua=italiano&id=1224&area=fitosanitari&menu=sostanze](http://www.salute.gov.it/portale/temi/p2_6.jsp?lingua=italiano&id=1224&area=fitosanitari&menu=sostanze)

<sup>196</sup> Article 13 Real Decreto 971/2014.

<sup>197</sup> In Portugal this possibility has been introduced only recently, in autumn 2017.

<sup>198</sup> Article 74 Regulation (EC) 1107/2009

available information – covering 15 MSs – for a new chemical active substance fees vary from around a minimum of 80.000 Euros to 700.000.

Most MSs have a flat rate that is decided either year-by-year or revised every few years.

In MSs where Models 3 or 4 are adopted, fees are generally set at a fixed level established and collected by the central government – usually the Treasury – and then partially redistributed to assessment services that have no financial autonomy. This means that – as noted by one CA – ‘for some dossiers we cover all costs, but for others, more complex ones, we run a deficit’. Independent regulatory agencies generally have autonomy to decide the level of fees. However, only few MSs adapt the requested fee to the actual costs incurred during the evaluation process or link the fees to the number and type of evaluations to be performed in the context of a dossier. For example, the UK adopted a ‘price list’ to detail the costs of assessment of each part of the dossier.<sup>199</sup>

A relevant aspect is that most of the time, costs for the participation in EFSA peer review procedures are not covered by the fees collected from applicants.<sup>200</sup> It means that fees to contribute to the European stage of the procedure for the approval of active substances are not requested of applicants. This means that the person/month needed to revise DARs and RARs submitted by other CAs as well as travel and accommodation costs must be covered by the general budget of public authorities.<sup>201</sup> For CAs that are not involved in drafting DARs/RARs or for those who are only seldom involved, this means that travel to Parma to take part in peer review procedures is limited to a couple of visits a year. Some CAs – because of financial crisis and budgetary constraints – had to put participation in EFSA meetings on hold.

## 2.2 Staff

During interviews, participants were asked to indicate the number of experts who are employed by each CA to deliver hazard assessments of active substances. The result is that it might be difficult to establish with precision such a number since the competencies of evaluation units are multiple, and accordingly staff can be in charge of a variety of tasks.

The exact estimation is particularly difficult for countries that rely on external experts to deliver DARs and RARs, since their numbers vary according to the dossiers that need to be evaluated, division of tasks among external consultants and possibly subcontracting.

With these warnings in mind, it seems safe to argue that in terms of dedicated staff, there are two main characteristics to point out:

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<sup>199</sup> See <http://www.hse.gov.uk/pesticides/topics/pesticide-approvals/pesticides-registration/streams-and-fees.htm>

<sup>200</sup> A partial exception in this case are fees charged for participation in EFSA meetings when the CA is acting as RMS or Co-RMS.

<sup>201</sup> The option to introduce fees for EFSA was explored a few years ago by the Commission and abandoned. See [http://ec.europa.eu/dgs/health\\_consumer/dyna/enews/enews.cfm?al\\_id=1346](http://ec.europa.eu/dgs/health_consumer/dyna/enews/enews.cfm?al_id=1346)  
See also: [https://ec.europa.eu/food/sites/food/files/safety/docs/adv-grp\\_wg\\_20111202\\_sum.pdf](https://ec.europa.eu/food/sites/food/files/safety/docs/adv-grp_wg_20111202_sum.pdf)

- a) There are huge differences among MSs in terms of available expertise; and
- b) All CAs are understaffed.

As an interviewed expert at a national CA put it, 'we have a public duty to hire enough people to make sure that we can deliver evaluations' and therefore protect public health and the environment in an effective way. In reality, most CAs affirm that they are understaffed. According to interviewees, the authorities that are perceived to be understaffed in relation to the task they are in charge of included all but one which recently finalised a relevant process of recruitment that 'put the agency in balance'.

In some of the cases, limits on staff prevent a MS from acting as RMS. As reported in Table 5, not all 28 MSs have been active as RMS or Co-RMS. Interviews with CAs in these countries shows that most of the time the main limiting factor is staff shortages. It means that CAs have only few trained experts, who – as seen above – might be in charge of a large variety of tasks, including PPP authorizations, controls over compliance and inspections, the implementation of SUD, and possibly biocides and fertilisers. In these cases, resources are devoted to complying with national obligations, *in primis* the authorization of PPPs and mutual zonal recognitions, while EU activities such as the appraisal of active substances are put on hold.

As might be expected, the disciplinary backgrounds of evaluators are very similar across MSs: experts in toxicology, chemistry, ecotoxicology, agronomy and biology are generally present in agencies and/or research centres / government departments that deliver hazard and risk assessments. It might be interesting to note that few CAs mention a specialisation in biopesticides as a strength in their set of competencies. Another point of relevance is that only a couple of CAs mentioned the presence of staff specialised in endocrinology. Epidemiologists are generally not present in evaluation teams.

A very significant dynamic that characterised all interviewed CAs is that the renewal procedure has created problems in terms of workload and staff. As noted above (see section IV.1.1), a large number of dossiers have to be evaluated simultaneously. It is also of note that over time the scope of the renewal procedure changed and has been significantly extended. It was initially thought of as an update of the existing dossiers, a relatively fast process meant to focus on new data requirements. However, it became apparent that old studies needed to be re-assessed in light of new guidelines and new scientific interpretations of findings. As noted in Section III, regulatory criteria need to be updated from time to time to catch up with scientific developments. As a result, each dossier under the AIR programmes proved more demanding than originally expected. In practice, there are few differences in terms of workload between a DAR and a RAR. This emerged with clarity only after the allocation of dossiers among MSs, and some CAs affirmed having accepted a number of dossiers that exceeded their capacity to deliver on time. On the whole these dossiers increased significantly the pressure on national authorities which are not in a position to adjust their personnel in the short term. Even CAs who are equipped to cope with new active substances and PPP authorisations found themselves under stress with the AIR programme. As one interviewee said, '[The renewal programme] represents a peak and we can't organise to have enough people all the time'.

The increase in the workload arrived at a time when public authorities in many countries had adopted a hiring freeze, and blocked the turnover of public officials. In a number of countries, retired staff members could not be replaced by new ones. In addition, CAs report a dynamic at play that is more characteristic of the pesticide sector, which is highly technical. It means that specific training on the regulatory risk assessment issue is essential. As one interviewee pointed out, 'one thing is to be a good toxicologist, another thing is being a good regulatory toxicologist', specifically trained to achieve competencies on legal data requirements, official guidance documents, test methods included in the legislation, procedures, and standards to be adopted in evaluations. These are specific skills that need to be acquired while in office, mainly according to a 'learning by doing' logic. According to one estimation, the learning process takes one year to complete. During this time, more experienced staff work with new recruits, thus slowing down significantly operations. This is therefore a huge investment that requires time and resources to be finalised. Another – and related – issue is that trained regulatory toxicologists become precious resources who are attractive for the private sector, so that some CAs experience a relatively fast turnover of personnel.

In some Model 3 countries, central authorities have less control over staff. Potentially, if the organisation or institutions that have been selected for the evaluations decide not to further participate in the process, then experienced staff based there might be no longer available.

Limitation in staff has been mentioned by interviewed experts as a key factor that influences the overall operation and performance of the CAs. A very relevant consequence are delays in assessments that are mainly due to work overload. As will be explained below (see IV. 3.3), staff limitations also prevent CAs from systematically taking part in the EFSA peer review process.

### **3. Procedures for hazard identification**

The procedures for delivering and discussing DARs and RARs and for taking decisions on active substances is described by Articles 7 to 20 of Regulation (EC) 1107/2009. For analytical purposes, four different stages can be distinguished: first, the RMS has to establish the admissibility of a dossier submitted by an applicant; second, RMS performs the hazard and risk assessment of the active substance and delivers the DAR/RAR; third, the DAR/RAR is peer-reviewed at EFSA; and fourth, the final conclusion on hazard and risk associated with an active substance is discussed by risk managers in comitology and a decision is taken. As mentioned above, each stage must be completed within a time frame that is legally specified (see section IV.1.2).

The following subsections describe how CA, EFSA and DG Sante act in each of the stages just mentioned. Before turning to procedural issues, a note on pre-submission meetings between CAs and applicants.

All interviewed CAs declared to offer pre-submission meetings to applicants who request them. The practice seems therefore diffused and established; however manufacturers signal that not all MSs are in position to schedule meetings. Pre-submission meetings are

of help to both parties, mainly because they help avoid delays when the formal process of evaluation starts. Some CAs mentioned that preliminary exchanges with manufacturers are needed to clarify procedural matters, as well as to address more specific issues, such as the list of representative uses to be considered, or data requirements. Manufacturers noted in the survey and interviews that availability to organise meetings at this stage on the part of CAs is a very important factor in determining the choice of the RMS. From their point of view are also very relevant because discussions with CAs contribute to make the process more predictable, highlighting potential issues in time.

However, meetings are also a burden for CAs who have to devote time and resources to analyse and discuss studies. In interviews with CAs, some critical issues emerged. CAs realised that applicants request meetings to more than one MS, possibly to decide where to apply. CAs also signalled that applicants request more than one pre-submission meeting to the same authority. In this sense, as one interviewee noted, 'applicants benefit from free advice' on the part of evaluators during pre-submission meetings. Notably, only few MSs charge applicants who request advice and meetings before submitting an application, and consequently the activity is onerous.

### **3.1 Admissibility of dossiers**

When the applicant sends the dossier to the RMS of its choice in case of a new active substance or to the designated RMS in case of renewals, the first act is to ascertain the admissibility of the dossier submitted by applicants. Two criteria might inform the evaluation of admissibility: the completeness of the dossier in terms of data requirements and the adequacy of the studies included in it.

What might at first seem a straightforward procedure proved difficult in the past. Notably, under Directive 414/1991 each CA had different procedures that could last from a minimum of three days to more than one year. This is because some CAs went through the list of submitted studies to check for their presence or absence, while others performed an initial evaluation of studies to check for their quality and adequacy.

Today it seems safe to say that procedures have been largely aligned, thanks to more precise guidance documents that clarify the type and characteristics of tests, as well as the introduction of a standardised format for presenting studies (see above section IV.1.3). Both these factors are very relevant to establishing quickly whether a dossier is complete or not. As a normal practice, none of the interviewed CAs perform a preliminary evaluation of the studies in terms of their content. At this stage, evaluators check whether all studies as requested by legislation are included or, if not, whether a statement that justifies the omission is present (and is convincing). A quick review of the quality of the study is generally performed on aspects that are very relevant (like some of the cut-off criteria) or that in pre-submission meetings emerged as potentially problematic. Evaluators also check whether GLP certifications are present and valid. As noted above (see section III.1), these are one of the most important factors for guaranteeing the reliability of laboratory results.

As soon as the dossier is declared 'admissible', the RMS notifies the Commission and EFSA of the new approval procedure and all documents are sent to all CAs. At the same time, the one-year period given to RMSs to perform the evaluation begins.

### **3.2 Evaluation of dossiers**

Most commonly, a small team composed of experts with different specialisations and coordinated by a project manager performs the evaluation of hazards and risks of active substances. The dossier is divided according to the area of competence – toxicology, ecotoxicology, etc. – and each is given to one or two officers. Each expert works on his/her own at this stage, going through laboratory findings as presented by applicants and assessing their relevance and reliability. This model is very similar in its basic terms across CAs, with little variations in terms of number of areas of specialisation identified (from four to six).

There are more relevant differences in how CAs review the assessment delivered by individual officers and how CAs put the complete DAR/RAR together. Most CAs organise internal meetings to discuss individual assessments. Formal and informal meetings are also needed to compare results and clarify the implications of each sectoral assessment for the overall evaluation of the active substances. For example, if the ecotoxicological evaluation reveals potential risks and suggests the need to reduce the number of applications of the active substance on a specific crop, this conclusion has implications for the evaluation of efficacy that is carried out by a different expert. In short, an exchange among the officers included in the evaluation team is necessary to deliver a coherent DAR/RAR. Such internal coordination is generally achieved by exchange during meetings among officers. Only few CAs organise a formal internal peer review process of individual assessments. In these cases, a colleague critically reviews the assessment and comments on it. Only after this phase do cross-sectoral meetings take place.

During evaluations, contacts with applicants are possible and take place whenever there is the need for clarifications on tests, summary of findings, or some related content included in the dossier. Only two among the interviewed CAs declared not having exchanges with applicants during this stage. Other stakeholders are not addressed, meaning that none of the CAs organise any form of consultation with interested third parties. The opportunity for them to comment on evaluation of active substances is opened later in the process of appraisal, during the EFSA peer-review procedure (see below IV.3.3).

A relevant aspect is that Regulation (EC) 1107/2009 foresees that in the evaluation of new active substances and in renewals, two MSs cooperate in the delivery of the DAR/RAR. In short, the RMS is joined by a Co-RMS.

In general terms, an agreement between the two competent authorities is made on a case-by-case basis at the beginning of the evaluation stage. The specific arrangements agreed upon between the RMS and the Co-RMS for the evaluation of a dossier are reported in the

first volume of the DAR. The same report might also include a section where areas of disagreement between the two institutions are highlighted.

According to interviews, most of the time the Co-RMS comments on the first version of the DAR / RAR that has been compiled by the RMS. This is the most common arrangement which reflects the time pressures under which competent authorities work. There are also cases where – contrary to what was initially planned – the Co-RMS does not intervene on the DAR/RAR because of lack of time or delays.

A division of labour in terms of areas of the dossier to be evaluated is another option for cooperation. This, however, implies a mechanism for the coordination of the two national teams and possibly the organisation of joint meetings to finalise the report. Because of resource and time constraints, such types of coordination only seldom take place.

### **3.3 Participation in the EFSA peer review process**

EFSA representatives affirm that the peer review procedure is very important to ‘make sure that the assessments do not vary depending on who the RMS is’. It is therefore a key factor in promoting consistency in the process, in favouring the harmonised application of regulatory guidelines, and in facilitating a learning process. CAs also mentioned that the discussion among experts in EFSA meetings is very important to favouring the harmonisation of procedure of authorization of PPPs that will subsequently be enacted at national and zonal levels.

The EFSA peer review is structured around two moments: the written public consultation and the expert meetings.

The written procedure consists of a request for comments on any technical aspect of the assessment report. The DARs/dRARs are made public on the EFSA website and the procedure is launched, giving interested parties two months to deliver their observations.<sup>202</sup> The procedure is meant to be highly technical; EFSA will not take into consideration comments that are not related to the contents of the document and those that ‘are related to policy or risk management aspects, which is out of the scope of EFSA's activity’. Therefore, comments must refer to specific issues pertaining to one of the sections (toxicology, MRL, ecotoxicology, etc.) of the report. There is an electronic template, which presents a series of tables, one for each section and subsection of the dossier, where comments (of about 10 lines each) can be written. EFSA staff will add their own comments as well as a reply to those submitted by others.

Below, an illustration taken from the current official template gives an idea of what is a typical comment.<sup>203</sup>

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<sup>202</sup> For a list of EFSA consultations see <https://www.efsa.europa.eu/en/calls/consultations>

<sup>203</sup> As reported below, a new Excel template is in preparation.

Table 9: Illustrative example of the EFSA template for written comments on DARs and dRARs

No.	Column 1 Reference to assessment report	Column 2 Comment (restricted to 500 characters, ca.10 lines)	Column 3 Further explanations
(1)	Vol. 3, B.9.1.4	CA: Mean residues are used for risk assessment for birds. Realistic worst-case values should be used.	(Please note that embedded or attached files will not be accepted.)

Two main issues have been pointed out as critical: a) the level of participation of CAs and stakeholders; and b) the use of comments.

a) As EFSA staff said, 'Ideally, all CAs should comment on all active substances'. However, it clearly emerges that participation in the written procedure is not systematic on the part of national CAs. All but one interviewed CA affirmed being selective, meaning that they prioritise some active substances over others to comment on. Dossiers of active substances that are not identified as priorities will not be reviewed by national experts. The need to be selective stems mainly from limitations in personnel and resources. As noted, CAs are understaffed and consequently cannot systematically commit resources to this task, which is perceived as quite demanding. Another relevant issue that contributes to making participation in EFSA peer reviews uneven is difficulties in planning activities on the part of CAs. The timing of the delivery of DARs/RARs to EFSA can vary, depending on stop-the-clock phases and delays in assessments on the part of RMSs. Accordingly, it is difficult to predict in advance when the EFSA written procedure for a specific active substance will start, and this makes planning problematic. EFSA publishes on its website a plan for future consultations; yet interested parties are advised that 'in the case of active substances, the start of the commenting period might be postponed because Member States have not submitted the assessment reports yet or EFSA has received several DARs and RARs at the same time'.<sup>204</sup>

Interviews highlight a number of common factors that CAs take into account when they identify the active substances to comment on. The first is the relevance of the chemical for the farming sector of the country. As reported above, MSs are very different in terms of active substances in use. Accordingly, CAs tend to prioritise the chemicals that are or are expected to be authorised for use in PPPs in their country. The reason is that participation in the EFSA peer review process helps officers to become familiar with the dossier and therefore will facilitate the next regulatory steps at national and zonal levels. Another reason for focusing on a specific chemical is interest in its own intrinsic characteristics: 'some active substances present interesting and original toxicological problems'.

As a result, the number of CAs participating in each peer review process tends to be limited. Notably, stakeholders can also send written comments on any of the active

<sup>204</sup> See: <https://www.efsa.europa.eu/en/consultations/consultationsplanner>

substances under evaluation. Again, surveys and interviews with manufacturers indicate that they are selective as well, taking part only in processes that are of direct interest to their companies.

b) According to EFSA, all DARs and RARs are significantly revised following comments submitted during the peer review process. Modifications to the DAR/dRAR might refer to the content of assessments in cases where experts from CAs express evaluations that differ from those advanced by the RMS. For example, as noted in section II.2, a single active substance has been banned as a result of the direct application of cut-off criteria, an herbicide called Linuron. The RMS has been Italy, whose experts proposed re-approval of the herbicide, with no conditions or restrictions on use. As far as the classification of Linuron as Repr 1B, the RMS considered that the relevance for humans of findings in rodents is debatable. A similar conclusion is proposed for the endocrine-disrupting properties of the active substance. In this case the EFSA expert meetings changed significantly the conclusions published in the dRAR, highlighting significant data gaps, the impossibility of evaluating too many relevant adverse effects and effectively reversing the proposed classification of the active substance. Another example is that of flupyr-sulfuron-methyl – a herbicide – that has not been granted re-approval in 2017. The RMS and Co-RMS (FR and DK) did not propose to ban the active substance in their RARs, but EFSA differed markedly in its conclusion on the substance that has been subsequently banned.<sup>205</sup>

The EFSA peer review process is also relevant to assuring that the quality of each DAR/dRAR is high enough. EFSA representatives state that there are examples of low-quality DARs, usually delivered by RMSs who do not have the necessary experience or do not have resources to properly assess all studies submitted. In these cases, the EFSA peer review procedure is extremely important since it makes it possible to improve first drafts. However, the workload implied by a low-quality DAR/RAR is significantly higher, and this represents an additional factor that prevents a full participation of CAs in EFSA peer reviews. As EFSA representatives said, 'a good quality DAR/RAR is easier to comment on', a view shared by CAs who affirmed that 'if the DAR is good and you agree on the assessment it is faster to send comments to EFSA'.

Some MSs express criticism to EFSA for not taking into account their written comments properly. More generally, according to these CAs, EFSA conclusions do not often reflect agreed conclusions since they tend to be too precautionary. For example, EFSA conclusions usually highlight many areas of concern, at time against the views expressed by national experts convened in EFSA meetings. In this light, critics observe that 'EFSA conclusions are inconclusive'.

EFSA started a reflection on its peer-review practices in June 2016 and in November 2017 adopted an 'Action plan for improving the peer-review process'.<sup>206</sup> The Action plan introduces some relevant changes in current practices:

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<sup>205</sup> EFSA. (2014b). 'Peer review of the pesticide risk assessment of the active substance flupyr-sulfuron', *EFSA Journal* 12:3881

<sup>206</sup> EFSA. (2017a). 'Action plan for improving the peer review process', *EFSA Journal*

- For each active substance to be processed, EFSA staff check in advance with CAs whether they plan to deliver comments or not. The purpose is to ensure that each dossier is reviewed by an adequate number of experts and make sure that sufficient expertise is at disposal. If there is not sufficient expertise, then EFSA will involve external experts in their individual capacities, asking for comments on one or more sections of the dossier. To this end, a 'Decision on the EFSA Executive Director' adopted in September 2015 allows EFSA staff to invite external experts to take part in evaluation procedures. These experts supplement evaluators appointed by MSs and provide advice on specific issues. On this point, stakeholders point out the need for broaden the range of expertise. For example, agricultural scientists have been frequently mentioned by industry and farmers' representatives.
- An accordance check is proposed to further complement the completeness check of data requirements, to verify whether applicants give an adequate level of detail in the summary of laboratory findings (section M of the dossier, see above IV.1.3).
- A more comprehensive and clear summary of divergent views expressed by CAs during peer-review processes is to be included in the conclusions, as well as indication of the line of reasoning followed.
- A review of templates for sending written comments, with more space for details and justifications.

Of course, this is a recent initiative that still has to fully impact on current practices. EFSA representatives pointed out that an improvement in the number and quality of comments is already noticeable in recent processes, and therefore results are encouraging. Because of the importance of EFSA peer review for the quality of assessments and their reliability, a shared view among interviewed experts at both national and EU institutions is that action to facilitate participation is needed and welcome. An important specification is in order on this point: most actors, including a majority of stakeholders, point out that it is highly preferable to maintain current procedures and keep EFSA expert meetings – involving CAs and scientists who declared no conflict of interests – and EFSA stakeholders' consultations clearly separated.<sup>207</sup> In other words, it is participation of CAs – not stakeholders – that needs to be facilitated. At the same time, manufacturers and farmers organisations signal that written comments are not enough and asked for a more sustained dialogue between interested parties and EFSA. In particular, industry representatives note that the opportunity to clarify findings would facilitate the evaluation process and that a lack of dialogue between applicants and evaluators represents a serious limitation.

### **3.4 Risk management decisions in comitology**

The final stage in the process of evaluation of an active substance is the risk management and as noted at the beginning of this study, the Commission and MS representatives sitting in the SCoPAFF are in charge of it. It has also been already noted that an analysis of the risk management stage is beyond the scope of this work that focuses on hazard and risk

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<sup>207</sup> Other EU agencies – such as EMA – have different procedures in place and allow interested parties to participate in meetings as observers.

assessments. However, two issues frequently emerged in interviews and seem worth mentioning. First, most stakeholders affirm that criteria adopted in the risk management phase are obscure. As noted above (see section IV.1.3) SCoPAFF meetings get a very low rating in terms of transparency because the information released is very basic and essential. Consequently, most of the time the reasoning behind risk management decisions, the regulatory criteria adopted and how the discussion among decision-makers unfolded is not made explicit. There is the impression – shared by Commission officials – that over time the risk management stage is getting increasingly politicised. This is perfectly legitimate: decision-makers are required to go beyond scientific conclusions and consider economic and social factors, including public acceptability.<sup>208</sup> However, these factors should be clarified and communicated to the public. Related to this, stakeholders signal a lack of vision or ‘holistic approach’ to regulatory action. Each active substance is evaluated for its specific characteristics and approved or banned on the basis of them. However, a comprehensive reflection on the variety of defence tools at the disposal of farmers is largely missing. Farmers’ representatives ask for a proper impact assessment and more specifically for a cost-benefit analysis to be included in the risk management process. The goal would be to focus on economic and social considerations as well as on the range of products that can be used for each crop and agronomic condition. According to this interpretation, the high number of derogations granted by MSs to tackle emergency outbreaks is a direct result of the lack of adequate number and type of defence tools. In sum, from interviews it clearly emerges that there is a need for a more transparent and comprehensive risk management stage.

The second issue is about ‘confirmatory data’. Active substances can be granted an approval on condition that more data to confirm safety for specific aspects are submitted. This provision was introduced in Regulation (EC) 1107/2009 and was intended to have a limited application. Specifically, approvals conditional to the submission of confirmatory data can be granted ‘where new requirements are established during the evaluation process or as a result of new scientific and technical knowledge’.<sup>209</sup> In 2013 PAN Europe submitted a complaint to the EU Ombudsman to signal a misuse of this provision, and in 2016 DG Sante was ordered to change practices and deliver a report to – among other things – ‘show that the confirmatory data procedure is used restrictively, and strictly in line with the applicable legislation’.<sup>210</sup> CAs expressed different views on the issue; some noted that it is beyond their remit as risk assessors, since it pertains to the risk management stage. However, the completeness of the dossier in terms of data requirements is performed by CAs and peer reviewed at EFSA. Hence, some CAs express the view that it would be preferable to have additional ‘stop-the-clock’ options during the process to address this issue and have the dossier completed before it is sent to DG Sante and a decision is taken. At present this is not possible because applicants cannot submit additional information at this stage of the procedure. As a consequence, any data gaps

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<sup>208</sup> See for example the Commission communication on the precautionary principle: European Commission. Communication on the Precautionary Principle. COM(2000) 1 final

<sup>209</sup> Article 6(f) Regulation (EC) 1107/2009.

<sup>210</sup> See European Ombudsman Decision in case 12/2013/MDC on the practices of the European Commission regarding the authorisation and placing on the market of plant protection products (pesticides)

cannot be addressed, 'even if manufacturers do have the appropriate studies'. However, CAs point out that a complete dossier would be important for approvals of active substances as well as for authorisation of PPPs, since 'it is very problematic for MSs when they have [later] to authorise PPPs if harmonised assessment is not fully available'. Other CAs seem less concerned and affirm that the real issue with the confirmatory data procedure lies in delays of the assessment of the newly submitted confirmatory data, which is dysfunctional. PAN Europe affirmed that nothing has really changed since the verdict of the EU Ombudsman.<sup>211</sup> DG Sante is expected to publish its report on this issue in early 2018.<sup>212</sup>

## 4. Summary of main findings

According to Regulation (EC) 1107/2009 the process for the approval of active substances is carried out in cooperation between MS and EU authorities. In all MSs (plus Norway) it is possible to identify the CA who is responsible for the implementation of Regulation (EC) 1107/2009.

→ MSs set up different organisational structures to act as CAs in the context of evaluation of pesticides. Four main models can be distinguished: 1) a single independent regulatory agency is in charge with risk assessments; 2) a web of two to four agencies divide dossiers according to area of expertise; 3) a government department takes responsibility for assessments that are performed by external certified research centres and universities; and 4) risk assessments are delivered by one or more governmental departments.

→ There are relevant differences in the distribution of workload among CAs. This is a consequence of the possibility given to manufacturers to choose RMSs. Applicants cannot choose their RMS in the case of renewals, and dossiers are allocated by the Commission on the basis of a 'negotiation' with each CA. The distribution of procedures according to a centralised procedure favoured some geographical distribution of the workload and made it possible for some countries to build experience with approvals. However, a 'balanced' distribution of dossier is prevented by differences in staff and resources.

→ There are huge differences among MSs in terms of available expertise. A very serious issue is that all CAs are understaffed. This appears the most relevant factor to explain delays in assessments of active substances, as well as limited participation in EFSA procedures.

→ Only few MSs adapt the requested fee to the actual costs incurred during the evaluation process or link the fees to the number and type of evaluations to be performed in the context of a dossier. Fees to contribute to the European stage of the procedure for the approval of active substances are generally not requested.

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<sup>211</sup> Network, P. A. (2017). "Mid term review of EU Ombudsman's verdict regarding DG SANTE's pesticide decision-taking methods." PAN Europe, Bruxelles.

<sup>212</sup> Not yet available at the time of writing.

→ Regulation (EC) 1107/2009 establishes clear deadlines for each stage of the procedure of approvals. However, delays are common. Most delays have been recorded in the cases of renewals, because a large number of dossiers have to be evaluated simultaneously. It is also of note that over time the scope of the renewal procedure changed and has been significantly extended. It was initially thought of as an update of the existing dossiers, a relatively fast process meant to focus on new data requirements. However, it became apparent that old studies needed to be re-assessed in light of new guidelines and new scientific interpretations of findings.

→ In principle it is possible to find most of the information, including the original dossier, taking into account rules for confidentiality. The EFSA Register of Questions and the EU pesticide database provide a large number of documents for each active substance. The accessibility of information is considered low, and a better valorisation of available information would be important to improve on transparency.

→ All interviewed CAs declared to offer pre-submission meetings to applicants who request them. Pre-submission meetings are of help to both parties, mainly because they help avoid delays when the formal process of evaluation starts. However, meetings are also a burden for CAs who have to devote time and resources to analyse and discuss studies. Notably, only few MSs charge applicants who request advice and meetings before submitting an application.

→ In the past, each CA had different procedures for the assessment of the admissibility of dossiers. Today it emerges that procedures have been largely aligned, thanks to more precise guidance documents that clarify the type and characteristics of tests, as well as the introduction of a standardised format for presenting studies.

→ In the evaluation stage, the most common arrangement is based on a small team composed of experts with different specialisations and coordinated by a project manager. The dossier is divided according to the area of competence – toxicology, ecotoxicology, etc. – and each is usually given to one or two officers.

Formal and informal meetings are needed to compare results, clarify the implications of each sectoral assessment for the overall evaluation of the active substances, and deliver the DAR/RAR. Only few CAs organise a formal internal peer review process of individual assessments.

During evaluations, contacts with applicants are possible and take place whenever there is the need for clarifications on tests, summary of findings, or some related content included in the dossier. Only two among the interviewed CAs declared not having exchanges with applicants during this stage. Other stakeholders are not consulted.

→ Regulation (EC) 1107/2009 foresees that in the evaluation of new active substances and in renewals, two MSs cooperate in the delivery of the DAR/RAR. This might be highly relevant to facilitate harmonisation, develop a common understanding of guidelines, and for capacity building. Most of the time the Co-RMS comments on the first version of the DAR / RAR that has been compiled by the RMS. A division of labour in terms of areas of the dossier to be evaluated is another option for cooperation. This, however, implies a

mechanism for the coordination of the two national teams and possibly the organisation of joint meetings to finalise the report. Because of resource and time constraints, such types of coordination only seldom take place.

→ The EFSA peer review procedure is a key factor in promoting consistency in the process, in favouring the harmonised application of regulatory guidelines, and in facilitating a learning process. According to EFSA, all DARs and RARs are significantly revised following comments submitted during the peer review process.

However, it clearly emerges that participation is not systematic on the part of national CAs. All but one interviewed CA affirmed being selective, meaning that they prioritise some active substances over others to comment on.

Some MSs also express criticism to EFSA for not taking into account their comments properly. More generally, according to these CAs, EFSA conclusions do not often reflect agreed conclusions since they tend to be too precautionary.

It is important to note that EFSA started a reflection on its peer-review practices in June 2016 and in November 2017 adopted an 'Action plan for improving the peer-review process'. The purpose is to ensure that each dossier is reviewed by an adequate number of experts and make sure that sufficient expertise is at disposal. Further, a more comprehensive and clear summary of divergent views expressed by CAs during peer-review processes is to be included in the conclusions, as well as indication of the line of reasoning followed.

→ The risk management stage takes place in SCoPAFF. There is the impression – shared by Commission officials – that over time the risk management stage is getting increasingly politicised. From interviews it clearly emerges that there is a need for a more transparent and comprehensive risk management stage, since most of the time the reasoning behind risk management decisions, the regulatory criteria adopted and how the discussion among decision-makers unfolded is not made explicit or public.

## V Concluding remarks and recommendations

Regulation (EC) 1107/2009 has four main goals: to ensure a high level of protection for human health; to protect the environment; to provide farmers with the defence tools they need and safeguard the competitiveness of EU agriculture. The ambition behind Regulation (EC) 1107/2009 is to find win-win solutions to deliver on all these goals.

There are different opinions on the extent to which these goals have been achieved.

CAs generally express a positive opinion about the extent to which risk assessment procedures deliver on the protection of public health and the environment. They tend to stress the extensive pre-market evaluations that are performed by national and EFSA experts, which make sure that active substances are safe for operators, residents, consumers and the environment. Data requirements and criteria for risk assessment are considered stringent and generally adequate to achieve high level of human and environmental protection. This view is also widely shared by organisations representing manufacturers and farmers. NGOs generally recognise that criteria are stringent but tend to express more critical views about the capability of the overall regulatory regime to meet protection goals.

Farmers and manufacturers point to a lack of vision on the part of risk assessors and managers, who in their opinion do not pay adequate attention to the overall effects of Regulation (EC) 1107/2009 on the range of available defence tools. As such, having a limited – and decreasing – number of approved active substances is not necessarily a positive arrangement from a public health and/or environmental perspective. It is generally recognised that more should be done to expand the number of approved active substances and facilitate entry into the market for low-risk substances, including biopesticides as well as innovative synthetic chemicals. In this sense, manufacturers claim that current regulatory criteria limit the potential for innovation; this view is shared by a majority of CAs.

In particular, critics focus on the impact of the hazard-based approach that informs Regulation (EC) 1107/2009. Indeed, one of the most relevant – and contentious – innovations introduced in 2009 was the replacement of the risk-based approach that underpinned Directive 414/1991 with the hazard-based approach. This means that under the new regulatory regime decisions about active substances are taken on the basis of their intrinsic potential to cause harm rather than on the likelihood of such harm to occur. More specifically, Article 4 of Regulation (EC) 1107/2009 establishes that an active substance shall only be approved if it is not classified as a carcinogen, a mutagen, toxic for reproduction, persistent and bio-accumulative, toxic for the environment, or an endocrine disrupter for humans and non-target organisms.

The hazard-based approach is clearly stringent; it was anticipated that it would result in a unnecessary ban on dozens of substances that are potentially hazardous but not risky under real conditions of use.

There is little evidence – so far – that active substances have been banned on the sole basis of their intrinsic properties. Bans have been numerous and significant, but they have not resulted from the direct application of cut-off criteria. Rather, full assessments have been performed, taking into account the entire range of toxicological, ecotoxicological and environmental hazards and their respective likelihood. This means that non-approvals of active substances have resulted from the application of strict risk assessment criteria, and therefore that risks associated with non-approved active substances have been evaluated as too serious and/or too uncertain to be taken, like in the case of neonicotinoids.

It should also be noted that interviewees representing industry interests are very explicit in their suggestion that the characteristics of the regulatory regime prevent manufacturers from submitting applications for their new compounds. In this sense it might be argued that cut-off criteria have an indirect effect on the range of available active substances. On the whole, it seems that more detailed and systematic research is needed. Accordingly, the following **recommendation** can be proposed: **authorities are encouraged to promote a comprehensive evaluation to clarify the overall effects of the EU pesticide regulatory regime on EU farming.** This would be of relevance for the evaluation of both Regulation (EC) 1107/2009 and the Directive (EC) 128/2009 on the Sustainable Use of Pesticides, which requires farmers to implement Integrated Pest Management and reduce the dependence on chemical inputs.

From the interviews conducted with experts working for national CAs, it is clear that they appreciate the resources and efforts put into the development of regulatory guidance documents. These are essential to allow them perform hazard identification and risk assessment using a predictable, reliable, and consistent approach. It is also clear that efforts to develop and update guidance documents have resulted in a harmonisation of the criteria for the evaluation of active substances. This is particularly evident if we take a long-term perspective and contrast the current regulatory regime with the one in place at the beginning of 2000s, when the last comprehensive policy evaluation was carried out. Notably, some of the interviewees have been involved in this field since the 1990s, when the first legislation on pesticides was adopted by the EU. In their recollection of the history of regulatory work, the sense of progress is particularly evident. At that time, it was pointed out that implementation of Directive 414/1991 was undermined by the lack of shared understanding among CAs about approaches to hazard identification and risk assessment, as well as huge procedural differences, and distrust. Since then, significant progress has been made, and EFSA has played a big role in this process, as recognised by CAs and stakeholders alike. In general terms, guidance documents on residues and toxicological hazards are consolidated, and most of them have been updated to reflect scientific developments in their respective fields. Guidelines on environmental fate and behaviour and on ecotoxicology are – in comparison – less consolidated in terms of criteria and methodology. In short, while harmonisation has clearly improved, it is far from complete. This is particularly evident if we consider that, like Directive 414/1991, Regulation (EC) 1107/2009 was adopted with some provisions missing. At the time of approval by legislators, notable gaps were: the lack of criteria for the assessment of endocrine disrupting properties of active substances, the definition of negligible exposure, the methodology for the assessment of effects on pollinators, for chemical mixtures, for the use of epidemiological data, and for the integration of open peer reviewed literature in

assessments. Since 2009, guidelines have been formulated on all these aspects, either by DG Sante or EFSA. However, the translation of scientific methods into regulatory guidelines is never an easy task, and it systematically takes significantly longer than expected and mandated by legislators. Moreover, not all these guidance documents have been properly finalised; at the time of writing, guidelines on criteria for negligible exposure, for chemical mixtures and for the utilisation of epidemiological findings are available in draft form only or are still under discussion. Guidelines on EDC have been recently finalised after a long discussion and are in the process of getting a definitive approval in the coming months. Other guidelines, such as the guidance document on bees 'health, are available but have not been officially voted on by SCoPAFF, and lack legal validity.

Draft and/or incomplete guidance documents represent a critical issue in the view of both CAs and stakeholders (private and public interest groups alike). While some CAs do not agree to apply guidance documents that have not been properly adopted at EU level, others are more willing to do so. This introduces regulatory uncertainty in the process, one of the most serious shortcomings in the view of applicants. NGOs are also critical of delays in comitology decisions on guidance documents and call for their immediate and certain application on the part of all CAs. In order to overcome this critical issue, the following **recommendations** can be proposed: **authorities are encouraged to discuss and adopt a common approach to the application of guidelines that are currently under development and to prioritise the official adoption of available guidance documents that still lack legal validity.** Another issue that emerges from interviews with CAs and stakeholders is that guidelines are becoming increasingly complex and this makes their application difficult. As a CA noted, 'the harmonisation also depends on the characteristics of guidance documents, which have to be useful and applicable in risk assessment procedures'.

Open peer-reviewed studies can include findings that alert evaluators to adverse effects that are not seen via standard testing. This source is also praised by activists for its perceived independence from industry. The limited availability of relevant peer-reviewed studies makes any claim to base assessments on this source highly unrealistic. Further, the full utilisation of open and peer-reviewed literature is undermined by the deficiencies in the accessibility of data. A wide debate - which reaches beyond the pesticide sector - is going on in academic circles, about how to make findings from publicly funded studies fully accessible. At present, the situation is patchy across MSs and universities. The same could be said for journals, that may or may not request authors to make data available as supplementary material. It seems important to improve transparency in the storage and dissemination of research findings. Accordingly, the following **recommendation** can be proposed: **to improve the utilisation of open peer-reviewed studies, authorities are encouraged to promote better accessibility to data and research findings, especially those supported by EU funds**

The same obligation for transparency seems sensible for industry studies to the extent that their disclosure is needed to fully perform evaluations. Activists have strongly advocated for full availability of industry studies, and to limit current provisions relating to confidentiality. A clear added value of systematic publication of full dossiers did not

emerge from this study, particularly in the light of the non-existent public participation in highly technical risk assessments. Better accessibility to already available information - particular the reports and studies made public on the EFSA website - could achieve a quicker and important improvement in the overall transparency of the regulatory regime. Accordingly, the following **recommendation** can be proposed: **authorities are encouraged to review and improve the accessibility of existing digital document repositories.**

MSs set up different organisational structures to act as CAs in the context of evaluation of pesticides. Four main models can be distinguished: 1) a single independent regulatory agency is in charge with risk assessments; 2) a web of two to four agencies divide dossiers according to area of expertise; 3) a government department takes responsibility for assessments that are performed by external certified research centres and universities; and 4) risk assessments are delivered by one or more governmental departments. Usually, evaluators that perform assessments of active substances are also involved in those concerning PPPs and biocides. MSs have personnel competent in toxicology, ecotoxicology, agricultural sciences, chemistry, biology. The interviewed CAs are able to cover all relevant areas of evaluation and therefore most, but not all, CAs are able to act as RMS. There are significant differences in the distribution of workload among CAs.

The most relevant issue is that - overall - the system is seriously and chronically under-resourced. In most cases it is not possible to clarify whether fees cover all costs (as required by Regulation (EC) 1107/2009) or CAs run a deficit. Accordingly, the following **recommendation** can be proposed: **CAs are encouraged to assess whether fees are adequate to cover evaluation costs.**

Moreover, all but one CAs report that they are understaffed. A first consequence are delays in the delivery of evaluation reports. Regulation (EC) 1107/2009 establishes a clear timing for the procedures of approval and renewals of approvals, i.e. the re-evaluation of active substances after the expiration of their first ten-years period of authorization. Over 180 active substances had their approval period expire between 2011 and 2018, and 200 more in the period 2019-2021. The Commission planned the renewals by setting differentiated deadlines and by distributing dossiers among MSs. There is evidence that CAs often struggle to keep the strict regulatory deadlines and renewals have serious delays. As a matter of fact, a large majority of active substance had their expiry dates postponed. A main reason for delays in renewals is found in the heavy workload that these re-evaluations have put on CAs. As mentioned, most CAs are understaffed and the increase in the number of dossier caused by the renewal programmes proved too large a burden. Delays have also been recorded because of evaluations proved significantly more complex than initially envisaged. As noted above, data requirements have all been significantly modified and expanded in the last decade. The updating of old dossiers is therefore demanding. Further some CAs and EFSA proceeded with a re-interpretation of existing evaluations and old data, to take into account developments in the scientific understanding of laboratory findings. In practice, at present there are few differences, in terms of workload, between the assessment of a new active substance and the re-assessment of an already approved one.

A second consequence of understaffing is that the participation of CAs in EFSA peer-review procedures is, at present, limited. The approval/renewal of an active substance starts at national level, where the CA performs the evaluation of the dossier submitted by the applicant and delivers a DAR/dRAR. These draft reports are made public and open for commentary from – ideally – all other CAs, EFSA, external experts, and stakeholders. They are subsequently discussed by CAs and EFSA in closed expert meetings. The EFSA peer-review procedure is essential to achieving consistent and reliable assessments of active substances; it is also important for subsequent authorisation of PPPs, because officers have the opportunity to become familiar with the dossier. Systematic and large involvement on the part of CAs is therefore hugely important. However there are strong indications that participation of CAs is severely limited. All but one CAs affirmed that they are selective about the dossiers they comment on. A few CAs had to suspend their participation in these EFSA procedure because their limited resources needed to be focused on ‘national’ procedures, *in primis* authorizations of PPPs.

EFSA recently adopted an Action Plan to improve peer-review procedures. A relevant innovation is the possibility of involving external experts in the procedures, should it be ascertained that CAs are not in a position to deliver sufficient expertise. This is clearly an important innovation that goes in the direction of assuring the quality of evaluations. However, it must be noted that the work developed by scientific panels and the peer-review procedures at EFSA have been very relevant in facilitating learning processes among CAs, who have the opportunity to discuss scientific and methodological issues on a regular basis. In this sense, participation in EFSA peer-review procedures should be made a priority. Accordingly, the following **recommendation** can be proposed: **MSs are encouraged to commit resources to make sure that national officers and experts can effectively and systematically contribute to EFSA procedures.**

A criticism that has been advanced during interviews by some CAs is that EFSA makes a limited use of comments received and adopts a highly precautionary approach, at times contrary to the opinion of CAs. A consequence is that EFSA conclusions on active substances leaves too many open issues for risk managers in SCoPAFF to decide, and as some CAs noted, conclusions might be ‘inconclusive’. This criticism is contested: not all CAs share this view. In this context, the following **recommendation** can be proposed: it seems useful to **provide risk managers and the public with more information on the competing views expressed by experts during the evaluations, in order to highlight lines of reasoning and a broader range of considerations.**

A controversial issue is that of data confirmation: active substances can be granted an approval on condition that more data to confirm safety for specific aspects are submitted in the post-approval stage. It would make sense to explore – as was suggested by several CAs - whether applicants should be required and allowed to submit additional studies before the risk management stage, in order to deliver complete dossiers to SCoPAFF. The risk management stage at SCoPAFF should be made more transparent. Most of the time the reasoning behind risk management decisions, the regulatory criteria adopted and how the discussion among decision-makers unfolded is not made explicit.

Accordingly, the following **recommendation** can be proposed: **authorities are encouraged to provide more information on risk management considerations formulated in SCoPAFF.**

The research carried out for this study reveals that the last decade has been characterised by both significant advancement and relevant deficiencies. Some important achievements have the potential to address some of the shortcomings of Regulation (EC) 1107/2009. In particular it seems important to mention that in August 2017 the Commission adopted Regulation 1243/2017 in which it specifies the criteria for the classification of an active substance as low-risk. In December 2017 SCoPAFF adopted criteria for the evaluation of EDC, expected to be approved later this year by the EU Council and EP. Coupled with EFSA technical guidelines, the criteria will make evaluations possible. It is important to note that the EU is a first mover on this very relevant issue, and that the difficulties in translating science into regulatory criteria and reaching a consensus among experts and decision-makers on this issue can not be underestimated. It is also of note that relevant initiatives are going on to improve EFSA peer-review procedures and the overall transparency of the regulatory regime. More could be done to reduce regulatory uncertainty. In particular, the completion and legal adoption of guidance documents should be a priority for both risk assessors and risk managers.

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## **Annex III**

### **Assessing Member States' capacity for reliable 'authorisation of PPPs', and its uniformity**

**Research paper  
by Dr Olivia Hamlyn**

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## Acronyms

<b>BSE</b>	bovine spongiform encephalitis
<b>CA</b>	competent authority
<b>CEFIC</b>	The European Chemical Industry Council
<b>CIRCABC</b>	Communication and Information Resource Centre for Administrations, Businesses and Citizens
<b>CfS</b>	candidate for substitution
<b>CJEU</b>	Court of Justice of the European Union
<b>cMS</b>	concerned Member State
<b>CSO</b>	civil society organisation
<b>CZSC</b>	Central zone steering committee
<b>DG SANTE</b>	Directorate-General for Health and Food Safety
<b>dRR</b>	draft registration report
<b>EFSA</b>	European Food Safety Authority
<b>EPPO</b>	European and Mediterranean Plant Protection Organisation
<b>EPRS</b>	European Parliamentary Research Service
<b>EU</b>	European Union
<b>GFL</b>	General Food Law
<b>IPM</b>	integrated pest management
<b>IRA</b>	independent regulatory authority
<b>izSC</b>	inter-zonal steering committee
<b>MS</b>	Member State
<b>NAP</b>	national action plan
<b>NGO</b>	non-governmental organisation
<b>NZSC</b>	Northern zone steering committee
<b>OECD</b>	Organisation for Economic Co-operation and Development
<b>PIG</b>	public interest group
<b>PPP</b>	plant protection product
<b>PPPAMS</b>	Plant Protection Product Application Management System
<b>PPPR</b>	Plant Protection Product Regulation
<b>REACH</b>	Registration, Evaluation, Authorisation of Chemicals
<b>RR</b>	registration report
<b>SUD</b>	Sustainable Use Directive
<b>SZSC</b>	Southern zone steering committee
<b>TEU</b>	Treaty on the European Union
<b>TFEU</b>	Treaty on the Functioning of the European Union
<b>UK</b>	United Kingdom
<b>zRMS</b>	zonal rapporteur Member State
<b>zSC</b>	zonal steering committee

**Member State CAs and other organisations**

<b>ANSES</b>	Food, Environmental and Occupational Health and Safety (French CA)
<b>BAES</b>	Federal Office for Food Safety (Austrian CA)
<b>BfR</b>	Federal Institute for Risk Assessment (German CA)
<b>BFSA</b>	Bulgarian Food Safety Agency
<b>BVL</b>	Federal Office for Consumer Protection (German CA)
<b>CNOPPP</b>	National Committee for PPP Approval (Romanian CA)
<b>CRAFC</b>	Centre for Risk Assessment on Food Chain (Bulgarian CA)
<b>CRD</b>	Chemicals Regulation Division (UK CA)
<b>Ctgb</b>	Board for the Authorisation of Plant Protection Products and Biocides (Dutch CA)
<b>DAERA</b>	Department of Agriculture, Environment and Rural Affairs (Irish CA)
<b>DAMM</b>	Marketing Authorisation Department
<b>DEPR</b>	Regulated Products Assessment Department (France)
<b>DGAV</b>	General Directorate for Agricultural and Veterinary Affairs (Portuguese CA)
<b>DGFHFSN</b>	Directorate General for Food Hygiene, Food Safety and Nutrition (Italy)
<b>DGSPP</b>	General Directorate of Sustainable Plant Produce (Greece)
<b>DPPP</b>	Directorate of Plant Produce Protection (Greece)
<b>DPPPB</b>	Department of Plant Protection Products and Biocides (Greece)
<b>DPPSC</b>	Directorate of Plant Protection and Soil Conservation (Hungary)
<b>DWP</b>	Department of Work and Pensions (UK)
<b>HSE</b>	Health and Safety Executive (UK)
<b>JKI</b>	Federal Research Centre for Cultivated Plants (German CA)
<b>KEMI</b>	Swedish Chemicals Agency
<b>MCCAA</b>	Malta Competition and Consumer Affairs Authority (Malta)
<b>MRDF</b>	Ministry of Rural Development and Food (Greece)
<b>NFCO</b>	National Food Chain Safety Office (Hungarian CA)
<b>NFSA</b>	Norwegian Food Safety Authority
<b>ORP</b>	Department of Pesticide Registration (Slovakian CA)
<b>PCD</b>	Pesticide Control Division (Ireland)
<b>PRCD</b>	Pesticide Registration and Control Division (Ireland)
<b>PRD</b>	Pesticide Registration Division (Ireland)
<b>SPA</b>	State Phytosanitary Administration (Czech CA)
<b>SPPPF</b>	Service Plant Protection Products and Fertilizers (Belgian CA)
<b>SPPS</b>	State Plant Protection Service (Latvian CA)
<b>SPS</b>	State Plant Service (Lithuanian CA)
<b>Tukes</b>	Finnish Safety and Chemicals Agency

**UBA**  
**ÚKSÚP**  
**UVHVVR**

Federal Environment Agency (Germany)  
Central Control and Testing Institute in Agriculture (Slovakia)  
Administration of the Republic of Slovenia for food safety,  
veterinary and plant protection (Slovenian CA)

## Executive summary

This report was prepared at the request of the Ex-Post Evaluation Unit of the European Parliamentary Research Service (EPRS). It examines the implementation by EU Member States of the Plant Protection Product Regulation (the Regulation) which governs the authorisation of plant protection products (PPP) in the EU. It considers first, whether Member States share the same approach towards the authorisation of PPPs containing active substances (and safeners, synergists, etc.) already approved at EU level, pursuant to Articles 4-13 of the Regulation. Second, it examines whether Member State competent authorities (CAs) possess the necessary institutional capacity to deliver independent, transparent and, hence, reliable 'authorization of PPPs' using active substances (and other substances) approved at EU level. Finally, it assesses whether the national authorisation model(s) support or contradict the key principles on which the Regulation is based; specifically precaution, sustainability and substitution.

Despite major changes in EU policy and regulation of PPPs in the last decade (new legislation was introduced in 2009), EU regulation of PPPs, as a whole, is under-researched. The scope of this research was broad. It generated new data in an area which is generally not well understood and about which there is little knowledge. Given this starting point, and the breadth of the research questions, this report should be regarded as a first step towards understanding the various matters covered. As such, the research seeks, first, to generate new knowledge and understanding of the implementation of the Regulation and operation of the zonal system (described below), secondly, to make recommendations for improvement on the basis of these findings and thirdly to identify areas for further research.

The Regulation divides Member States (and Norway) into zones with comparable 'agricultural, plant health and environmental (including climatic) conditions' (Northern, Central and Southern) in order to avoid duplication of work, reduce administrative burden on industry and Member States, increase harmonisation and facilitate mutual recognition of authorisations.<sup>1</sup> Applications for authorisation are submitted to a Member State, acting as zonal rapporteur, who evaluates the application for the relevant zone. National authorisation decisions are made primarily on the basis of the conclusions of this evaluation.

This research employed mixed methods, encompassing both desk-based and empirical strategies. The former involved review of relevant literature, policy and EU case law. The latter involved surveys of Member State CAs and selected stakeholders, both via self-completion questionnaires consisting largely of closed questions. It also involved a questionnaire of open questions distributed to zonal steering committees.

The report is structured as follows. Section I introduces the research. Sections II-IV comprise the theoretical background to the research and include discussions of independence, transparency, the precautionary principle, sustainability and the substitution principle. Section

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<sup>1</sup> Recital 29 PPPR.

V sets out the method employed for the empirical element of the research. Section VI discusses the zonal evaluation and authorisation procedures including empirical data on Member State evaluation and decision-making and the operation of the zonal system. Section VII presents and discusses the results of the research with respect to the independence and transparency of the CAs and implementation of the precautionary principle, sustainability and the substitution principle. Findings and recommendations are summarised throughout sections VI and VII. Section VIII concludes and summarises the recommendations.

Overall, the area capable of the greatest and most immediate improvement relates to the transparency of CAs, particularly in terms of access to information. In the medium to longer term, it may be appropriate to review Member State practice and/or the Regulation with a view to establishing opportunities for wider public, stakeholder and/or public interest groups (PIG) participation in decision-making, primarily for the contribution such activities can make to transparency. In addition, consistency in interpretation and application of the precautionary principle and sustainability among Member States, and the ambition with which substitution is implemented, could also be improved, for example through clear guidance from the Commission or through co-operation and agreement between Member States at a zonal or inter-zonal level. Finally, as ever, greater resources – financial, technical, expert, personnel – may improve decision-making, both in terms of its quality and speed, and boost the operation of the zonal system overall. More specific findings include the following:

Zonal evaluation and national decision-making procedures are characterised by diversity. For example, Member States differ in terms of the institutional structure of their CAs, the type and extent of communications with applicants during evaluation and decision-making and the nature of the expert advice (binding or consultative) provided to decision-makers. Overall, very few trends within the zones may be identified. The zonal system is valued by Member States for the benefits it delivers, for example harmonisation, work-sharing and resolution of disagreements between CAs. However, it still faces significant challenges, especially in terms of improving harmonisation, sharing work fairly within the zones and further strengthening trust between the Member States. With respect to harmonised procedures and methods for evaluation, a variety of guidance documents covering certain areas of PPP evaluation is available on the Commission website. However, it appears that some areas are still to be agreed and that some guidance is unable to cover every possible scenario. The zonal system is a new and complex system which warrants further research and continued monitoring in order to understand better its development and operation.

With respect to independence, there are varying levels of formal independence of respondent CAs from government. However, most respondent CAs have sole responsibility for their decisions. Lack of formal independence does not necessarily mean unreliable or unfair regulation.

There are also varying levels of independence from industry. However, few of the respondent Member State report restrictions on recruiting CA heads from industry or on employment in industry after their appointment. This may risk undermining their independence from industry. Difficulties with recruitment and retention of the necessary expert staff may increase

information asymmetry between CAs and industry with attendant risks of regulatory capture. Greater remuneration to attract qualified staff and/or in-house training could reduce information asymmetry and perhaps also the risk of capture.

Respondent CAs lose some formal autonomy due to their being funded wholly or partly by government. In addition, government control over salaries reduces autonomy further and is identified by some CAs as restraining their ability to recruit the required staff. However, most respondent CAs regard themselves as possessing sufficient resources (personnel, technical, financial) to fulfil their obligations under the Regulation, although several did report gaps and deficiencies in resources.

Due to the lack of data concerning stakeholder and public views with respect to the fairness and reasonableness of CA decision-making, the extent to which it is trusted and how far the independence of individual CAs (or lack thereof) is regarded as a problem, it is not possible to determine whether strengthening the formal independence of CAs would improve the quality of their decision-making.

With respect to transparency, levels of transparency among CAs are low, overall. This is so firstly, in terms of the availability of information about evaluation and authorisation procedures and secondly, in terms of access to the information on which decisions are based. Both of these are necessary to enable interested parties to gain an understanding of the procedural and informational basis of PPP authorisations.

Wider public, stakeholder or PIG participation in decision-making is important for improving transparency, may improve the quality of decisions and may also counter the risk of regulatory capture. Currently, the Regulation does not require or provide for such participation during evaluation and authorisation procedures and comparative assessment. Furthermore, the zonal system itself acts as a barrier to participation due to the level at which zonal evaluation procedures are conducted; a level which is far removed from most citizens. Given this legal framework, it is not surprising that consultation activities in Member States are extremely limited, if conducted at all.

CAs are subject to differing levels of accountability to national governments and legislatures. Some Member States operate robust systems of peer review and auditing of decisions which should operate to improve the overall reliability of their decision-making. Increasing transparency could also improve accountability.

With respect to the principles of precaution, sustainability and substitution, there is evidence of inconsistent interpretation and application of the precautionary principle and sustainability amongst Member States. Member States exhibit greater consistency in conducting comparative assessment. This is still a relatively new exercise but eventually ambition could be improved.

While this research has not identified any deficiencies which are likely significantly to undermine the reliability of CA decision-making, as summarised above, there are large parts of the zonal procedure and CA decision-making which could be improved. Of these, the most significant deficiency identified relates to the lack of transparency in evaluation and

authorisation procedures. In addition, the research represents a significant contribution in terms of describing and understanding the zonal system. However, despite the above findings, many questions remain unanswered and, as implementation of the Regulation progresses and the zonal system evolves, new questions will arise. A further significant contribution of this research is to identify areas in which more, and more focused, research is necessary to understand the current situation as well as new developments, perhaps once more experience has been gained with the zonal system, zonal evaluation and comparative assessment.

## I – Introduction<sup>2</sup>

The year 2009 saw the introduction of an ambitious new regime regulating plant protection products (PPPs) in the European Union. This regime consists of Directive 2009/128 establishing a framework for Community action to achieve the sustainable use of pesticides (the ‘Sustainable Use Directive’ or ‘SUD’)<sup>3</sup> and Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market (‘the Regulation’ or ‘PPPR’).<sup>4</sup> The latter repeals the two main directives which previously governed the EU’s regulation of PPPs.<sup>5</sup> While the EU has regulated the placing of PPPs on the market since 1979, the introduction of the 2009 regime has been described as a ‘radical change in EU pesticide regulation in terms of goals, instruments and scope’ (Bozzini, 2017, p.58), driven by an awareness of, and desire to address, the failures of Council Directive 91/414/EEC<sup>6</sup> (Bozzini, 2017, chap.3). The Regulation makes many significant changes to the regulation of PPPs, amongst them the provisions relating to the authorisation of PPPs, including the establishment of a system of co-operation between Member States.<sup>7</sup> Despite these major policy and regulatory changes, the regulation of PPPs in the EU, and particularly the 2009 regulatory regime is generally under-researched.<sup>8</sup>

This report was prepared at the request of the Ex-Post Evaluation Unit of the European Parliamentary Research Service (EPRS). It examines the implementation by EU Member States of the provisions governing the authorisation of PPPs in the EU. It considers first, whether Member States share the same approach towards the authorisation of PPPs containing active substances (and safeners, synergists, etc.) already approved at EU level, pursuant to Articles 4-13 PPPR. Secondly, it examines whether Member State competent authorities (CAs) possess the necessary institutional capacity to deliver independent, transparent and, hence, reliable ‘authorisation of PPPs’ using active substances (and other substances) approved at EU level. Finally, it assesses whether the national authorisation model(s) support or contradict the key principles on which the Regulation is based; specifically precaution, sustainability and substitution.

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<sup>2</sup> Thanks are due to the EPRS for their support throughout this project, to Professor Elen Stokes and Dr Steven Vaughan for their valuable comments on this report and aspects of the research and to Kulsum Patel who provided excellent research assistance. Particular thanks are due to Dr Dieter Pesendorfer, who peer reviewed the study at the request of EPRS, for his very helpful comments. Any mistakes are my own.

<sup>3</sup> European Parliament and Council Directive 2009/128/EC establishing a framework for Community action to achieve the sustainable use of pesticides [2009] OJ L309/71.

<sup>4</sup> European Parliament and Council Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC [2009] OJ L309/1.

<sup>5</sup> Council Directive 79/117/EEC prohibiting the placing on the market and use of plant protection products containing certain active substances [1979] OJ L33/36; Council Directive 91/414/EEC concerning the placing of plant protection products on the market [1991] OJ L230/1.

<sup>6</sup> Council Directive 91/414/EEC (n 5).

<sup>7</sup> Described further in section VI.

<sup>8</sup> With some exceptions, for example, (Bozzini, 2017; Hamlyn, 2015).

The research engages with two important principles of governance: the independence and transparency of CAs. 'Reliability', as a characteristic of regulators and their decision-making, is perhaps more commonly discussed in academic literature in terms of 'trust', 'credibility' or 'confidence' (for example, Löfstedt, 2005). Trust is a slippery concept and subject to multiple definitions. Giddens offers a helpful definition which specifically links trust to reliability: '[t]rust may be defined as confidence in the reliability of a person or system, regarding a given set of outcomes or events, where the confidence expresses a faith in... the correctness of abstract principles (technical knowledge)' (Giddens, 2013, p.34). Elsewhere, trust is said to be 'the belief that those with whom you interact will take your interests into account' even when in a position of powerlessness. Further, confidence 'exists when the party trusted is able to empathize with (know of) your interests, is competent to act on that knowledge, and will go to considerable lengths to keep its word'. 'Trustworthiness' is said to be a combination of both (La Porte and Metlay, 1996, p.342). Specifically with respect to risk regulation, Löfstedt argues that the public will trust regulators on the basis either of past decisions, i.e. outcomes, or of a belief that the decision-making process is credible (defined as fair, competent and efficient). Fairness and impartiality are important procedural values. If regulators are regarded as lacking these qualities, for example by not demonstrating that they take everyone's interests into account, they are likely to lose trust. In this context, involvement of stakeholders and public participation (discussed in section III.3) may be important for building trust (Löfstedt, 2005, pp.6-7; La Porte and Metlay, 1996, p.344). A regulator's competence (for example proficiency in handling cases, relevant expertise and experience) is also key to building and maintaining trust (Löfstedt, 2005, p.7; La Porte and Metlay, 1996, p.342).

Thus, trust depends on multiple different factors and there may be multiple explanations for its loss (Löfstedt, 2005, p.xviii), including absence of the qualities discussed above or the inequitable distribution of costs and benefits stemming from regulatory decisions (La Porte and Metlay, 1996, p.342). Others look to historical factors, pointing to the number and size of, often food- or health-related, scandals since the 1990s (Löfstedt, 2004, pp.336-337). Research in the field of risk regulation has focused in particular on the role of risk communication (Löfstedt, 2005, 2006), the ability of experts and regulators to understand and accommodate public attitudes towards risks in decision-making (for example, Wynne, 2001, 1989; EGSG, 2007; Slovic, 1997) and the model of any public engagement conducted in building (or diminishing) trust in regulators (Wynne, 2006; Stirling, 2008). Persistent failure to build or maintain trust may ultimately threaten the legitimacy of the regulator (La Porte and Metlay, 1996, p.342).

The legitimacy of EU policy and regulation tends to be discussed in terms of 'output' legitimacy – the quality and effectiveness of its decisions, and 'input' legitimacy – the fairness and democratic quality of its decision-making processes (Barnard and Peers, 2014, pp.4-7; Scharpf, 1999, chap.1). This may be particularly important for independent regulators, due to their lack of the traditional democratic (input) legitimacy derived from being elected and accountable to an electorate (Larsen et al., 2006, p.2860), discussed further in section II. In areas of regulation, such as pesticides, where knowledge of the impacts of pesticide use emerges slowly and therefore where the consequences of decisions may be impossible to evaluate for

many years, the importance of input legitimacy may increase (La Porte and Metlay, 1996, p.455). The research question defines reliability in this context as composed of independence and transparency, both of which relate to inputs. It is the adherence, by CAs, to these two principles which the report attempts to assess. They are used on the basis of an assumption that fulfilment of these criteria will ensure that authorisation decisions are reliable (or trustworthy).

However, it is acknowledged that the link between inputs and outputs is not automatic. For example, formal independence may not necessarily guarantee fair regulation (Stern, 1997, pp.72-74). Furthermore, given the social and ecological uncertainty characterising the contexts of PPP use (Wynne, 1992b; Meir and Williamson, 2005; Pretty, 2005), assessment of the risks they pose is a highly complex task, beset with uncertainties, which present challenges for regulators (Baldwin, 1996, pp.87-88). Thus, the reliability of any authorisation process premised on a risk assessment (as well as institutional independence and transparency) is also contingent on the reliability of the risk assessment, which may be contested, *especially* in situations of uncertainty (for example, controversies over risk assessments of neonicotinoids, glyphosate and endocrine disrupting chemicals, Bozzini, 2017, chap.4). Assessing the reliability of risk assessment in the context of the Regulation, in terms of the quality both of the actual scientific evidence and its evaluation is beyond the scope of this report. However, EU law requires that risk assessment itself should be conducted 'on the basis of scientific advice founded on the principles of excellence, transparency and independence... to ensure the scientific objectivity of the measures adopted'.<sup>9</sup> These principles<sup>10</sup> aim to raise confidence in the EU's risk assessment procedures (Scott and Vos, 2002, p.283). And these are, indeed, the standards required of the zonal rapporteur Member State (zRMS) under the Regulation, as discussed in sections II and III. This is, therefore, a further justification for assessing the institutions conducting risks assessments under the Regulation for these qualities.

The report is structured as follows. Sections II and III introduce a discussion of the principles of independence and transparency, respectively. The sections are based on a narrative (English language) literature review covering the principles of independence and transparency as well as the more general literature on IRAs. Section IV moves to brief discussions of the principles of precaution, sustainability and substitution. This section is a product of a narrative review of (English language) literature (including grey literature) and doctrinal analysis of EU case law on these principles. All three principles are controversial and open to competing interpretations. Given space constraints and the overall focus of the research, it is impossible to do much beyond giving a flavour of the debates. The discussion therefore concentrates on the interpretation of these principles in an EU context.

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<sup>9</sup> Case T-70/99 *Alpharma v Council* [2002] ECR II-3495, para.183; Case T-13/99 *Pfizer Animal Health SA v Council* [2002] ECR II-3305, para.172.

<sup>10</sup> Elaborated in European Parliament and Council Regulation (EC) No 178/2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety [2002] OJ L31/1, and Commission, White Paper on Food Safety COM(1999) 719 Final.

Sections II-IV provide an account of the theoretical basis for this research and serve to illustrate how theory has informed the empirical tools employed in the research, in particular the survey of Member State CAs, described in section V.1. Finally, they provide a framework for analysing the results of the empirical work, drawing findings and making recommendations in response to those findings, as presented and discussed in Section VII.

Section V describes the empirical methods employed to conduct this research and sets out precisely which elements of the Regulation are being examined. Section VI performs several functions. Firstly, it summarises the zonal evaluation and authorisation procedure established by the Regulation. Secondly, drawing on desk-based research and responses to the Member State survey, it describes the various evaluation and authorisation procedures operating in the Member States. Thirdly, it reports and discusses perspectives on the zonal system of Member States, stakeholders and the zonal steering committees,<sup>11</sup> gathered during the research.

Section VII presents and discusses the results of the empirical work with respect to the independence and transparency of CAs, evaluation and authorisation procedures and the implementation of the principles of precaution, substitution and sustainability. Recommendations are made on the basis of conclusions drawn throughout sections VI and VII. Section VIII concludes and summarises the recommendations made on the basis of these conclusions.

With respect to the scope of this research, Chapter III of the Regulation relates to PPPs and governs a broad range of Member State activities. The report focuses on Articles 28-39, which deal with authorisation requirements and procedure with respect to zonal evaluation and authorisation, and comparative assessment of PPPs containing active substances classified as candidates for substitution,<sup>12</sup> pursuant to Article 50.<sup>13</sup> Member States are examined in their capacity as 'zonal rapporteur Member States' (zRMS) under Article 35 PPPR,<sup>14</sup> in which capacity they conduct evaluations of applications to authorise PPPs, described in more detail in section VI.1. PPPs may also be authorised in Member States through mutual recognition of an authorisation granted by another Member State pursuant to Articles 40-42 PPPR. Due to the specific focus on the evaluation procedure at zonal level, mutual recognition is not considered further in this report (for more on this procedure, see Articles 40-42 PPPR and Commission, 2014b). Finally, as the state of Luxembourg (whose CA is the Minister of Agriculture, Viticulture and Consumer Protection) only accepts applications for mutual recognition due to a lack of capacity to conduct evaluations (DG SANTE, 2016d, pp.7-8), it is also not considered further.

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<sup>11</sup> These are explained in section VI.1.

<sup>12</sup> Article 24, Annex II point 4 PPPR.

<sup>13</sup> Described in more detail in Section III.

<sup>14</sup> This role is discussed in more detail in Section VI.

## II – Independence

Article 36(1) PPPR requires the zRMS to ‘make an independent, objective and transparent assessment in the light of current scientific and technical knowledge using guidance documents available at the time of application’. It imposes no more detailed institutional requirements to achieve this other than that Member States must ‘designate a competent authority or authorities to carry out the obligations of the Member States laid down in this Regulation’.<sup>15</sup>

Since the mid-1970s, Europe has experienced a wave of regulatory reform characterised by increased delegation (at national and supranational levels) to expert independent regulatory authorities (IRAs) operating outside direct control of the central administration (Majone, 1996, pp.3, 10–11, 47–48). The vast majority of this reform occurred in the field of economic regulation, i.e. regulation of the operation of the market, and focused primarily on competition, financial bodies and ‘utilities’ – electricity, gas, water, telecommunications etc. – accompanying the privatisation of these previously state-owned industries (Thatcher, 2002a, pp.126–127; Stern and Holder, 1999, p.35). Similar delegation to IRAs in the field of social regulation (i.e. environmental, health, safety, consumer protection etc.), while much less (Gilardi, 2005, p.85), can still be seen as part of this larger trend across Europe (Thatcher, 2002a, p.143; Hellebø Rykkja, 2004, p.141). The CAs examined in this report, being concerned with risk regulation and protection of human health and the environment, fall into the category of social regulation.

The literature on IRAs reflects the different extent of regulatory reform in these two areas and largely focuses on economic regulators. Nonetheless, this literature offers valuable insights for a study of IRAs in the field of social regulation and forms the basis of the brief discussion of independence as a quality of regulators presented in this section. The section firstly considers reasons for delegation to IRAs relevant to pesticide regulators, the limits of regulatory independence and the characteristics of an IRA.

### 1. Why delegate to IRAs?

Several, largely functionalist and often normative, explanations have been suggested for increased delegation to IRAs (although these are by no means the only explanations (see, for example Thatcher and Stone Sweet, 2002)). The first expresses a desire on behalf of central administrations to achieve policy credibility. The short terms of elected politicians and inability of current legislatures to bind subsequent legislatures may undermine the consistency, permanence and credibility of public policies (Gilardi, 2005, pp.87–88). Governments therefore delegate regulatory powers to separate agencies to demonstrate commitment ‘to regulatory strategies that would not be credible without such delegation’ (Majone, 1996, pp.41–44; Thatcher, 2002a, pp.130–131). Secondly, and relatedly, IRAs are believed to promote stability by enabling policy to be insulated from the electoral cycle and attendant political uncertainty (Majone, 1996, p.289; Gilardi, 2005, p.88) and the greater ease with which they may engage

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<sup>15</sup> Article 75(1) PPPR.

with the public than the executive, for example, due to their freedom from a need to secure votes (Demarigny, 1996; Johannsen, 2003, p.17).

A third reason points to the changing role of the state in the 1980s and 1990s and desires to shift from interventionist policies and to separate administrative tasks from party political influence (Majone, 1996, pp.49, 54, 56). Food and environmental safety scandals, most notably that surrounding bovine spongiform encephalopathy (BSE, also known as 'mad cow disease') in the mid-1990s, also precipitated the creation of IRAs. The separation of policy decisions (remaining with politically accountable actors) and management (executed by neutral institutions) aimed to restore public trust and confidence in decision-making and government authorities and to enhance their credibility and accountability (Thatcher, 2002a, p.132; Hellebø Rykkja, 2004). The BSE scandal also highlighted the dangers of situating responsibility for the conflicting interests of public health and industry within the same (executive) institution (Hellebø Rykkja, 2004, pp.128-129). This provided further incentives for establishing authorities intended to be separate from commercial and economic interests in order to minimise vulnerability to manipulation and 'capture' (Hellebø Rykkja, 2004, pp.135-137; Vos, 2000, p.246), although such outcomes are by no means guaranteed, as discussed further in section II.2.

Fourthly, during the 1980s and 1990s, policy problems increased in complexity and regulation became more technical (Majone, 1996, p.56; Thatcher, 2002a, p.131). Ministers and generalist civil servants were at a disadvantage in decision-making vis-à-vis the expertise and resources concentrated in powerful interests such as industry and NGOs who demonstrated a willingness to challenge government decisions (Thatcher, 2002a, p.132). The expertise of IRAs is often used to invoke their legitimacy (Baldwin, 1996, p.90) and indeed, in the field of risk regulation, their ability to employ outside experts and produce scientific information both to advise citizens and overcome information asymmetries (but see section II.2 for discussion and criticism) with industry is seen as an advantage (Vos, 2000, p.247; Thatcher, 2002a, p.131). Agencies with specialist expertise were deemed better equipped to engage in and implement evidence-based and reasoned decisions (Thatcher, 2002a, p.132) and to do so more efficiently, by lowering the cost of decision-making (Thatcher and Stone Sweet, 2002, p.15).

Fifthly, breaking from previous regulatory styles based on public ownership criticised by some for their secrecy and opaque, ad hoc advice and intervention (Vos, 2000, p.246; Thatcher, 2002a, p.142; Hellebø Rykkja, 2004, p.129), separation from the state, it is argued, endows regulators with identity and clear responsibility (Baldwin, 1996, p.84). The explicit, focused mandates and objectives accompanying delegation (Thatcher and Stone Sweet, 2002, p.19) are said to enable governing institutions and politicians to appear 'responsive and effective in face of crisis' [sic] (Hellebø Rykkja, 2004, p.139) and can enhance openness and transparency (Vos, 2000),<sup>16</sup> although again, this may not necessarily be the case, as discussed in section II.2.

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<sup>16</sup> See section III for more on transparency.

Finally, delegation to IRAs allows politicians to shift blame and avoid controversy by disassociating themselves from unpopular or difficult decisions (Thatcher, 2002a, pp.131, 133; Demarigny, 1996, p.175). Where regulatory decisions concerning health and environmental protection are likely to be based on contested or controversial scientific advice, an aim may be to depoliticise questions of risk assessment and risk management by ensuring both a strict division between managerial and scientific tasks and the independence of scientists (Hellebø Rykkja, 2004, p.127; Vos, 2000, pp.238–239). However, given the close relationship between risk assessment and management and the absence of objective and neutral regulatory science (Lee, 2008, p.42), especially in situations of scientific uncertainty and controversy, such an aim may be unachievable (Vos, 2000, p.248).

## 2. Limits of regulatory independence

Despite the reasons in favour of establishing IRAs, IRAs do not necessarily eliminate all the problems their independent status was designed to address, most notably information asymmetry and immunity from capture by the regulated industry. Carpenter and Moss (2014a, p.13) define ‘regulatory capture’ as ‘the result or process by which regulation, in law or application, is consistently or repeatedly directed away from the public interest and toward the interests of the regulated industry, by the intent and action of the industry itself’. Furthermore, some identify a possible fundamental tension between independence and accountability (Weale, 1996).

With respect to accountability, delegation to IRAs involves the transfer of extensive powers to institutions which are not accountable to the electorate (Majone, 1996, p.4). Thus, while there are good reasons (including accountability) for establishing regulatory authorities that are independent of government, as discussed in section II.1, this separation could in fact weaken IRA accountability to the public via elected officials (Gilardi and Maggetti, 2011, p.201). However, it is rare for political authorities not to retain some control over IRAs and their activities (Demarigny, 1996, p.175) and there are mechanisms for achieving this which fall short of direct interference in decision-making, such as control of appointments, budget allocations, reporting requirements, Parliamentary oversight, procedural requirements, professional standards, public participation and judicial review (Thatcher, 2002a, p.127; Majone, 1996, pp.5, 39–40; Graham, 1998). Ultimately, a balance between the two desirable qualities of accountability and independence is required.

With respect to capture, public interest theories of regulation often assume that regulators pursue collective social objectives which enhance the general welfare of the community (Morgan and Yeung, 2007, p.17). This view has long been criticised (Gönenç, Maher and Nicoletti, 2000, p.42). For example, the economic theory of regulation suggests that regulation is in fact sought by, and operated for the benefit of, industry in order to create and maintain barriers to entry by competitors, rather than prompted by the public interest (Stigler, 1971). It is argued additionally, that where industry does not initially seek regulation, regulation – and regulatory authorities – are generally ‘captured’ subsequently (Mitnick, 1980, p.38). However, empirical support for this theory, and indeed for the inevitability and widespread existence of

regulatory capture for anti-competitive purposes, is mixed (Carpenter and Moss, 2014a; Christiansen, 2011). More recent literature differentiates between both different types and different degrees of capture and argues for its preventability. It also recognises that some degree of influence by industry may in fact benefit the public interest (Carpenter and Moss, 2014b), for example where it leads to productive co-operation between regulator and industry or promotes care in the regulator for the welfare of regulated firms (Ayres and Braithwaite, 1992, chap.3).

With respect to degree, 'strong capture' describes a situation in which the purposes and rationale for the regulation are vitiated and its benefits are outweighed by the costs of capture. By contrast, 'weak capture' refers to the influence of special interests 'compromis[ing] the capacity of regulation to enhance the public interest' although overall regulation still serves the public interest (Carpenter and Moss, 2014a, pp.11–12). With respect to type, Carpenter and Moss propose 'corrosive capture', which describes the securing, by the regulated industry, of regulation which is less costly or less stringent in terms of its 'formulation, application, or enforcement' than that perhaps required by the public interest (Carpenter and Moss, 2014a, pp.16–18). Kwak (2014) has identified the phenomenon of 'cultural capture' which describes how the psychological nature (rather than the substance) of regulator-industry interactions may produce in the regulator a view of the public interest favourable to the regulated industry. Regulators may come to identify with the regulated industry and adopt industry positions due to the perceived higher status of industry or relationship pressures stemming from frequent social interaction or membership of the same social networks. This may represent a particular risk with respect to the weakening of social regulation. The communication between regulator and applicant promoted by the Regulation, discussed in section VI, raises the potential for cultural capture, in particular, in CA evaluation and authorisation of PPPs. Finally, a materialist perspective argues that industry control over regulators may stem from close and sustained contact between both parties through long-term involvement in the same field and the offering of regulator rewards by industry, such as lucrative subsequent employment. Acting against industry interests in this context could damage personal friendships and future prospects of rewards (Mitnick, 1980, pp.211–212).

Much of the regulator's vulnerability to capture is attributed to information asymmetry between regulator and industry which may persist despite an IRA's endowment of expertise and knowledge (Majone, 1996, p.70). Enhanced independence through delegation to expert regulators is not straightforwardly guaranteed: for example, in some fields, it may be difficult to obtain the necessary training and expertise outside industry (McCarty, 2014, pp.99–103). Industry sources of expertise may enhance industry influence. Industry is able to exercise control over information relevant to regulation due to its complexity, associated uncertainty and the bounded rationality of the parties involved. Such control enables industry to frame or manipulate regulator perceptions of industry problems and solutions through the supply of selective or biased information (Mitnick, 1980, pp.209–211; Ferretti, 2007, p.385). Ultimately, regulators may become agents of the industry (Mitnick, 1980, p.207), although relationships between regulators and industry can also be highly conflictual (Thatcher, 1998).

Ensuring sufficient IRA resources may counter information asymmetry and improving working conditions and salaries may counter industry control of regulator rewards (Mitnick, 1980, p.212). Post-employment restrictions may contribute to the latter, although could also inhibit recruitment of 'a regulator with appropriate managerial expertise' (Gönenç, Maher and Nicoletti, 2000, p.43). In addition, Kwak recommends the development by regulators of 'career paths and educational opportunities... that are more autonomous from the regulated industry' to narrow the expertise gap between regulator and industry, and the implementation of 'personnel and ethics policies' to prevent excessive bias towards industry (Kwak, 2014, pp.119-120). Article 75(3) PPPR requires Member States to 'ensure that competent authorities have a sufficient number of suitably qualified and experienced staff so that the obligations laid down in this Regulation shall be carried out efficiently and effectively'. The explicit rationale behind these resource requirements is ensuring the efficiency and effectiveness of the authorisation procedure. However, an additional benefit may be a guard against information asymmetry and consequent risk of regulatory capture, provided sufficient attention is paid to potential problems associated with expert regulators, discussed above, for example the source of their expertise or their over-identification with industry.

Some identify increased transparency, for example the publication of information, and involvement of interested parties as means to reduce the risk of capture (Gönenç, Maher and Nicoletti, 2000, p.44; Majone, 1996, p.26; Mitnick, 1980, p.66). Industry influence may decrease with the increase in participation by other interests (Yackee, 2014 and references therein). It has been argued that IRAs may foster public participation (Majone, 1996, p.41) due to the publicity afforded their activities and their potential function as a space for public debate (Demarigny, 1996, p.162). Some, referring largely to independent utilities regulators, identify increased efforts to consult consumer interests (going further than, or in the absence of, a statutory obligation), publish information and operate openly (Graham, 1998, p.508; Thatcher, 1998, pp.131, 139-140). Such transparency and wider involvement, insofar as it enables public scrutiny of regulatory activities and the relationship between the regulator and government, may weaken the risk of capture by enhancing accountability.<sup>17</sup> Furthermore, returning briefly to the potential tension between independence and accountability, in reality, IRAs must co-operate with multiple actors. If the concept of accountability is broadened to encompass more than direct control by Parliament, independence and accountability may be reconciled (Johannsen, 2003, p.25).

However, some have argued that separation from the central administration may undermine both the transmission of public protests directed at elected officials back to the IRA and the responsiveness of IRAs to direct public engagement (Mitnick, 1980, p.70). Furthermore, participatory processes may be vulnerable to 'information capture' – the costly communication of excessive information by (usually well-resourced) stakeholders, often to establish control over regulatory outcomes for strategic advantage. Less well-resourced participants may be excluded, reducing the pluralism of the process, and regulators may be worn down or diverted

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<sup>17</sup> The potential for transparency to enhance accountability is discussed further in section III.1.

from their overall regulatory objective by the overload (both in terms of volume and technical density) of information (Wagner, 2010).

More generally, Ayres and Braithwaite (1992, chap.3) have proposed the involvement of one or more public interest groups (PIGs) as third players, alongside industry and regulator, as a means to prevent capture. PIGs may be empowered through, for example, the grant of access to all information held by the regulator, a place in negotiations between regulator and industry and powers equivalent to the regulator's to challenge industry. Their ability to prevent capture manifests in two respects. Firstly, the need to capture two separate groups (regulator and PIGs) increases the costs of capture for industry, acting as a deterrent. Secondly, long-term involvement in the regulatory process, relationship-building and the development of trust between the three parties aims at socialising each into new modes of deliberation and behaviour and to internalising 'a concern for the other player that is in the public interest' (Ayres and Braithwaite, 1992, p.93; Schwarcz, 2014, pp.367-370). Furthermore, PIGs seek to enhance participatory democracy, while avoiding the burden of mass participation in all areas of decision-making. They would engage in dialogue with the regulator/industry and contribute different experience and knowledge to the regulatory process. Incentives to seriously consider such information exist in the potential for PIGs to apply political pressure to regulators through media use and public outreach (Schwarcz, 2014). Environmental, public health, consumer and/or occupational health and safety groups (amongst others) could fulfil this role in the context of PPP authorisation. PIGs may be vulnerable to capture themselves but should be protected by the contestability of their position which allows for the empowerment of alternative PIGs (Ayres and Braithwaite, 1992, chap.3; Schwarcz, 2014, pp.367-370).

### **3. Features of an independent regulator**

It is impossible to offer a definitive description of an IRA. They may vary according to country, organisational culture, legal and political system, field of regulation and their tasks and activities (Thatcher, 2002a, p.127; Stern and Holder, 1999, p.34; Hellebø Rykkja, 2004, pp.132-134). They take various institutional forms, for example, statutorily independent, a unit supervised by a ministry or subject to its instructions, or a non-ministerial government department; some may therefore be 'semi-independent' of government (Thatcher, 2002a, pp.127, 129). Furthermore, context, such as level of economic development, dictates the type of independence (whether from government or industry) emphasised (Stern, 1997, p.69).

That said, two predominant forms of regulatory agency may be identified: the agency and commission. The former is a hierarchical organisation with a single head. It may be a separate organisation or an office or division of a larger government division or department. The latter is usually hierarchical and headed by an appointed expert board or 'commission'. It tends to be a separate organisation. Both contain expert staff and heads able to process 'large numbers of cases rapidly and relatively economically through specialisation of function' (Mitnick, 1980, pp.30-31). While agency heads are often career civil servants, commissioners tend to be experts in relevant fields, for example, law, economics or science, such as academics or former staff of organisations in the relevant industry sector (Larsen et al., 2006, p.2862). Suggestions that

commissions make better decisions are arguable. The need for compromise and consensus in this context (as compared to a single-headed agency) may not necessarily result in better decisions and may risk inconsistency (Graham, 1998, p.507).

Several definitions of independence have been suggested (for example, Thatcher, 2002b, p.956; Mitnick, 1980, p.69: see definitions quoted therein). The definition used in this report<sup>18</sup> draws on that proffered by Smith: an arm's-length relationship with industry; an arm's-length relationship with political authorities; and the attributes of organisational autonomy, for example, 'earmarked funding and exemption from restrictive civil service salary rules – necessary to foster the requisite expertise and to underpin those arm's length relationships' (Smith, 1997). This definition demonstrates a sensitivity towards concerns about capture by industry and too much control by government, discussed above. It also emphasises the operational elements of independence. Autonomy is seen as promoted by the following: secure sources of funding established by law; the absence of potential for senior officers to benefit from political processes; the presence of a primary law governing the IRA which sets out key powers and duties including when and how decisions may be overruled; protection for senior officers from unfair or arbitrary dismissal by politicians, e.g. through fixed terms, and a multiparty appointment process (e.g. involving both the executive and legislature); and the definition of professional standards and adequate remuneration levels (Stern and Holder, 1999, p.43; Gönenç, Maher and Nicoletti, 2000, p.43) – restrictive civil service salary rules can inhibit recruitment and retention of well-qualified professional staff, technical expertise reduces the risk of capture and organisational autonomy helps foster and apply technical expertise (Smith, 1997). Article 74(1) PPPR provides that Member States may levy fees in order to cover costs incurred through work conducted within the scope of the Regulation. Implementation of this provision may enhance the operational autonomy of CAs through reducing reliance on central government funds by providing an external funding stream, if fees charged do genuinely match costs incurred. That said, dependence by a regulator on the regulated industry for funding may constitute another mechanism of capture (Kwak, 2014, p.75).<sup>19</sup> This suggests careful structuring of regulator funding is required to promote both organisational autonomy and independence from the regulated industry.

As discussed further in section V.1, the emphasis in this report is on formal independence. However, formally independent regulation may not automatically lead to effective regulation. Effective regulation is highly dependent on the reputation of the regulatory agency for acting fairly and reasonably and involves 'considerable informal as well as formal accountability to the regulated industry, to large and small consumers, to Parliament, and to public opinion' (Stern, 1997, p.73). Formal independence contributes to generating this accountability but it does not necessarily make the most important contribution (Stern, 1997, pp.72–74). Thus, if the CAs examined in this report do not display all the elements of formal independence, this

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<sup>18</sup> For a discussion of its operationalisation, see section V.1.

<sup>19</sup> I am grateful to Dr Dieter Pesendorfer for highlighting this point.

should not be taken to indicate that their authorisation procedures are necessarily ineffective or unreliable.

### **III – Transparency**

As stated in section II, the zRMS is required to make a ‘transparent assessment’ of the application for authorisation.<sup>20</sup> As with independence, few detailed requirements are imposed or suggested by the Regulation with respect to how this should be achieved. Provisions in the Regulation which are relevant to transparency broadly relate to access to information and are briefly discussed in section III.3.

Transparency is now widely accepted as a principle of good governance and is specifically endorsed by the EU. Some have argued it is a general administrative law principle (Fisher, 2010, p.312) and others that it is a general principle of EU law (Craig and De Búrca, 2015, pp.574–575; Lenaerts, 2004, p.321). Introduced in the Treaty of Amsterdam, it grew in importance through the late 1990s and subsequently (Vos, 2005, pp.129–130). A closely related concept, ‘openness’, interpreted as communication about EU activity and decisions in ‘accessible and understandable’ language, was recognised by the Commission (2001b, p.10) as a principle of good governance. Transparency now surfaces in several provisions of the Lisbon Treaty and elsewhere in EU law (Craig and De Búrca, 2015, pp.568–569). Transparency, like independence, was also a significant part of the reform of food safety regulation, post-BSE (Hellebø Rykkja, 2004; Vos, 2000) in an effort to move away from previously non-transparent regulatory processes which had presided over past regulatory scandals (Löfstedt, 2004, p.340). It was central, for example, to the legal framework within which EFSA operates (Fisher, 2010, pp.299–300) and to the operation of the UK FSA (Krebs, 2004).

Transparency is an exquisitely complex concept. Its meaning varies depending on context (Fisher, 2010, p.277) as do the reasons for and against transparency along with its implications (Fisher, 2010, p.283). There are, furthermore, different degrees of transparency, for example in terms of the amount revealed and the size and identity of the permitted audience, and on which its ‘capacity to facilitate knowledge’ depends (Schauer, 2011, p.1345). As such, this short section cannot encompass a comprehensive discussion of the concept. Instead, it offers a brief tour of the following areas. Firstly, it considers arguments for transparency. Secondly, it highlights some of the challenges and limitations of transparency. Finally, it considers various mechanisms for implementing or enhancing transparency.

#### **1. Why transparency?**

According to Fisher, the promotion of transparency is most often associated with making the exercise of power by institutions accessible or visible (Fisher, 2010, p.275). In the context of the Regulation, this would refer to the exercise of power by the zRMS in assessing an application for authorisation and concluding whether or not to recommend authorisation of the PPP in the

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<sup>20</sup> Article 36(1) PPPR.

relevant zone, under Articles 28-39 PPPR. Several, closely related and mutually supportive reasons for transparency exist, discussed below.

The most prominent argument for transparency is that it is necessary to ensure accountability; the public cannot hold an authority to account unless its activities are first made visible (Vos, 2005, p.129). This argument sees transparency as a facilitator of democracy, enabling public control to counter corruption or regulatory capture (Schauer, 2011, pp.1348-1349).<sup>21</sup> Accountability is of particular concern here for two reasons. Firstly, as discussed in section II.2, the rise of IRAs prompted doubts over their accountability due to their separation from elected officials and therefore traditional methods of accountability (Thatcher, 2002a, p.141; Everson, 1995). Doubts also concerned difficulties in identifying the responsible institution resulting from the increasingly complex institutional landscape and the blurring of the boundaries between expert advice and policy (Vos, 2005, p.121; Shapiro, 1997) (although it has also been argued that independence promotes visibility, facilitating control (Vos, 2005, p.125)). Secondly, authorisation decisions are based almost exclusively on scientific evidence, in the form of a risk assessment by the zRMS under Article 36(1) PPPR on the basis of the data submitted by the applicant in support of its application.<sup>22</sup> Where scientific knowledge forms the basis of public decisions with significant implications for human health and the environment, as is the case with PPPs, democratic control 'demands some ability on the part of a polity to evaluate the knowledge claims that justify actions taken on its behalf' (Jasanoff, 2006, p.21). With respect to both, transparency appears as a prerequisite for accountability and indeed supports various accountability mechanisms, for example, judicial review and public participation (Majone, 1996, p.300; Craig and De Búrca, 2015, p.548; Stern and Holder, 1999, p.43).

Some have argued that openness, transparency and honesty increase trust or confidence in organisations, while secrecy destroys it (Löfstedt, 2005, p.xv; Peters, Covello and McCallum, 1997). For example, research has discovered increased levels of trust in companies which share more information and which discuss both their risks and benefits (Löfstedt, 2005, p.xv and references therein). The EU has stated that transparency 'strengthens the democratic nature of the institutions and the public's confidence in the administration' (Declaration No 17 on the right of access to information, annexed to the Final Act of the Treaty on European Union [1992] OJ C191/101; Vos, 2005, p.129; Lenaerts, 2004, pp.318-324). The Court of Justice has elaborated, stating that 'openness... contributes to conferring greater legitimacy on the institutions in the eyes of European citizens and increasing their confidence in them by allowing divergences between various points of view to be openly debated'<sup>23</sup> (Craig and De Búrca, 2015, pp.573-574).

As the Court recognised, the improvement of (input (Barnard and Peers, 2014, p.5)) legitimacy is another argument for transparency. As a principle which facilitates citizen participation in decision-making, it is intended to 'guarantee that the administration enjoys greater legitimacy

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<sup>21</sup> Discussed in section II.2.

<sup>22</sup> Article 33(3) PPPR.

<sup>23</sup> Cases C-39 and 52/05 P *Sweden and Turco v Council* [2008] ECR I-4723, para.59.

and is more effective and more accountable to the citizen' (Lenaerts, 2004, pp.319–320). For example, where a regulatory decision relies on evidence (as here), public reporting, and therefore the possibility of public scrutiny, of the relevant data, models and assessment methods may prevent regulators adjusting that evidence to suit a policy position (Dudley and Wegrich, 2016, p.1143).<sup>24</sup> Such participation may not necessarily improve decisions but it is regarded as having normative value (Schauer, 2011, p.1349).

Finally, transparency may be employed as a response to involvement by private, particularly economic, actors in regulation (Abbot and Lee, 2015, pp.21–24; Fisher, 2010, pp.312–313). Under the Regulation, private, economic actors (applicants) are required to provide the vast majority of the information on which authorisation decisions are based.<sup>25</sup> This is reasonable given the resources available to applicants and regulators respectively (Lee, 2008, p.78) and may increase the cost effectiveness and efficiency of regulation (Abbot and Lee, 2015, p.10). Relying on information provided by applicants does, however, raise concerns related to information asymmetry, discussed in section II.2. Transparency can ensure the public knows who is involved in, and what they are contributing to, the regulatory process, granting opportunities for scrutiny (Abbot and Lee, 2015, p.21) which again supports accountability.

## **2. Limitations of transparency**

The centrality of openness and transparency to 'better regulation', both for risk regulation and regulation generally elevates these principles almost to the status of 'all-purpose remedy for misgovernment' (Hood, Rothstein and Baldwin, 2001, pp.148–149). However, transparency is not without its limitations, nor is its implementation free of challenges. It involves much more than simply 'turning on the light' (Fisher, 2010, p.306) and may have unintended consequences. There is evidence, for example, that institutional responses to pressures for increased transparency often involve blame shifting, avoidance or prevention, for example through the establishment of expert scientific committees to 'bless' decisions, the institutionalisation of ambiguity through dispersal of regulatory responsibilities or the pooling of information on risks from different sources (Hood, Rothstein and Baldwin, 2001, pp.128–129, 164–169). Furthermore, public communication activities that purport to disseminate factual information in the interests of transparency may instead seek to effect social control through manipulating public opinion and influencing behaviour (Yeung, 2005).

Contrary to the arguments in section III.1, it has been argued that transparency does not promote trust and may, in fact, cause harm (Fisher, 2010, p.282). For example, increased transparency may encourage members of public to make their own decisions about risks, instead of relying on the decisions of expert regulators. It may, furthermore, enable development of policy-vacuums often filled by more efficient communicators than the regulators (Löfstedt, 2005, p.xv, 2004, pp.340–341), who may not act in the public interest.

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<sup>24</sup> Although this presupposes that there exist those with the requisite expertise to perform the scrutiny: see section III.2.

<sup>25</sup> Article 33 PPPR.

Lastly, publishing unfiltered scientific findings could cause public alarm with drastic public health consequences (Löfstedt, 2005, p.xv). Furthermore, transparency may precipitate disagreement disruptive of the bases and procedures of decision-making (Fisher, 2010, p.305) especially so, perhaps, with respect to PPPs, where assessments of risk are already contested, as discussed in section I.

These points relate to a more general argument that transparency, in terms of, for example, simply publishing information on a website, is not sufficient (OECD, 2016, p.38). The information itself must be 'intelligible, clear and ultimately accountable' (OECD, 2016, p.45). The corollary to this is the capacity of the recipient of the information to appraise and use that information. Transparency differs little from concealment in a society lacking 'an active interpretive culture willing to criticise and able to make sense' of the disclosed information (Jasanoff, 2006, pp.33–34). In the highly specialised world of plant protection, review by any scientific expert may not be enough; the right expert is required, and even they must be sufficiently detached from the subject matter to ensure unbiased review (Jasanoff, 2006, p.34).

Finally, while transparency is not an unqualified good, so concealment is not an unqualified bad. As such, transparency may have to compete with other important social values which differ, depending on context (Jasanoff, 2006, p.22). Commercial confidentiality, national security and the protection of personal data are all in tension with transparency (Jasanoff, 2006, p.22; Fisher, 2010, p.280; Abbot and Lee, 2015, pp.23–24). Furthermore, non-disclosure may be valuable for promoting honesty and frankness (Fisher, 2010, p.289). Article 63 PPPR protects some of these values, allowing applicants to request information be treated as confidential where it can provide evidence that its disclosure 'might undermine his commercial interests, or the protection of privacy and the integrity of the individual'.<sup>26</sup> Applicants must physically separate that information. The Member State examining the application decides what information is to be kept confidential if access is requested.<sup>27</sup>

The Court of Justice, in *Bayer*,<sup>28</sup> strengthened this protection somewhat, finding that applicants are not required to request confidentiality under Article 63 at the time of application in order

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<sup>26</sup> The Commission has proposed revisions to this article as part of its recent proposal to revise the General Food Law (n 10) and eight other pieces of relevant legislation, including the Regulation, in order to improve the transparency of risk assessment procedures. Revisions will include greater public access to information and requirements to consult stakeholders and the public, <[http://europa.eu/rapid/press-release\\_MEMO-18-2942\\_en.htm](http://europa.eu/rapid/press-release_MEMO-18-2942_en.htm)> accessed 15 April 2018. Beyond the amendments to Article 63, the proposed changes to the Regulation relate to confidentiality and public access to information submitted for the approval of active substances and not the authorisation of PPPs (Commission, Proposal for a Regulation of the European Parliament and of the Council on the transparency and sustainability of the EU risk assessment in the food chain COM(2018) 179 final). Article 59 PPPR also grants data protection to test and study reports submitted with an application for authorisation.

<sup>27</sup> Article 33(4) PPPR.

<sup>28</sup> C-442/14 *Bayer CropScience and Stichting De Bijenstichting v College voor de toelating van gewasbeschermingsmiddelen en biociden* (ECLI:EU:C:2016:890).

to benefit from it. Rather, interpreting Article 63 in light of Directive 2003/4/EC on public access to environmental information,<sup>29</sup> it held that CAs may examine an applicant's objection to the request for access and refuse it on the ground that disclosure 'would adversely affect the confidentiality of commercial or industrial information'.<sup>30</sup> On the other hand, however, the Court endorsed a broad interpretation of 'emissions into the environment, affecting or likely to affect' the environment, finding that it covered emissions of PPPs and the substances contained in them.<sup>31</sup> This is significant: under Article 4(2) Directive 2003/4/EC, CAs may not refuse disclosure of 'information on emissions into the environment'. Although the Court limits information disclosable to that relating to actual or foreseeable emissions under 'normal and realistic conditions of use'<sup>32</sup> and despite remaining ambiguity (Buonsante and Friel, 2017) this interpretation provides a significant exception to the protection of confidentiality under Article 63 PPPR. It may mean large amounts of data and studies are disclosable, according to the guidelines laid down by the Court for CAs, including importantly, information on the medium to long-term consequences of emissions on the environment.<sup>33</sup>

### 3. Implementing transparency

As discussed above, the meaning of transparency may vary depending on context. Narrow definitions would refer to 'minimal openness of process, access to documents and, publication of official measures' (Hofmann, 2014, p.207). Though perhaps minimal, public access to information, in contributing to democratic accountability (Peers, 2014, p.69), is still of course, an important element of transparency and one which has been supported by the Court of Justice and in EU legislation (Craig and De Búrca, 2015, pp.569-574). For example, Regulation (EC) 1049/2001 attributes to 'openness' a guarantee for the administration of greater legitimacy, effectiveness and accountability and a contribution 'to strengthening the principles of democracy and respect for fundamental rights'.<sup>34</sup> In an environmental context, Directive 2003/4/EC recognises the contribution increased public access to environmental information makes to 'a greater awareness of environmental matters, a free exchange of views, more effective participation by the public in environmental decision-making and, eventually, to a better environment'.<sup>35</sup> In reality, however, these ambitious expectations may not be fully realised; 'there is no necessary or automatic link between transparency and other values' (Lee, 2014a, p.197).

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<sup>29</sup> European Parliament and Council Directive 2003/4/EC on public access to environmental information [2003] OJ L41/26.

<sup>30</sup> *Bayer* (n 28) para. 49.

<sup>31</sup> *Bayer* (n 28) para. 76. See also, Case C-673/13 P *Commission v Stichting Greenpeace Nederland and PAN Europe* (EU:C:2016:889), para. 75.

<sup>32</sup> *Bayer* (n 28) paras 76-77, 81. See also, *Stichting Greenpeace Nederland* (n 31) paras 74-75.

<sup>33</sup> *Bayer* (n 28) paras 87-96.

<sup>34</sup> Recital 2 European Parliament and Council Regulation (EC) No 1049/2001 regarding public access to European Parliament, Council and Commission documents [2001] OJ L145/43.

<sup>35</sup> Recital 1 Directive 2003/4/EC (n 29).

More specifically, the Regulation contains its own requirements on access to information, providing some measure of transparency with respect to the PPP in question and the knowledge base for any decisions made about them. Article 57 imposes an obligation on Member States to keep certain information electronically available to the public on PPPs authorised or withdrawn under the Regulation. In addition, Article 60(2) requires Member States to compile and make available on request, lists of test and study reports concerning individual PPPs and the substances they contain including those for which the applicant claimed data protection under Article 59 PPPR. The lists shall include information on whether the reports were 'certified as compliant with the principles of good laboratory practice or of good experimental practice',<sup>36</sup> enabling some scrutiny of the quality of the information used in decision-making. Commission guidance contains further suggestions for improving the transparency of the authorisation procedure. Most importantly, it recommends publication of the final Registration Report 'if legal provisions in the individual MS allow', with redaction and removal of confidential information (Commission, 2014b, p.14). The availability of such information would certainly enhance transparency but this is a limited move and, as mere guidance, is unable to compel or require disclosure by Member States. That said, the contents of registration reports<sup>37</sup> suggest that at least part of these documents would fall within the scope of 'information on emissions into the environment' under Article 4(2) Directive 2003/4/EC and, to that extent, should therefore be made available upon request, as discussed in section III.2.

A requirement that public authorities give reasons for their decisions is perhaps the most straightforward means by which to enhance transparency (Majone, 1996, p.292). This activates accountability mechanisms, including judicial review, allowing citizens to defend their rights and courts to exercise their supervisory functions (Craig and De Búrca, 2015, p.548). It may also encourage decision-makers to balance the pros and cons of a decision more than a decision-maker whose reasoning will not be revealed and thereby helps control discretion (Shapiro, 1992, pp.180–181). The Regulation, however, imposes no such requirement on Member States, representing a significant omission from the transparency toolkit. The closest the Regulation comes to this requirement is Article 57, discussed above, which contains a minimal requirement to make available 'reasons for withdrawal of an authorisation if they are related to safety concerns'.<sup>38</sup> Uniform Principle A.5 second paragraph requires Member States to 'come to a reasoned decision within 12 months of receiving a technically complete dossier'.<sup>39</sup> However, there is no requirement for its publication.

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<sup>36</sup> Article 60(3) PPPR.

<sup>37</sup> See the BVL website for examples:

<[https://www.bvl.bund.de/EN/04\\_PlantProtectionProducts/01\\_ppp\\_tasks/02\\_ppp\\_AuthorisationReviewActSub/02\\_ppp\\_RegistrationReports/psm\\_RegReports\\_node.html](https://www.bvl.bund.de/EN/04_PlantProtectionProducts/01_ppp_tasks/02_ppp_AuthorisationReviewActSub/02_ppp_RegistrationReports/psm_RegReports_node.html)> accessed 25 January 2018.

<sup>38</sup> Article 57(1)(g) PPPR.

<sup>39</sup> Commission Regulation (EU) No 546/2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products [2011] OJ L155/127.

Finally, the Regulation establishes a complex authorisation procedure which may operate differently in different Member States (see section VI). Transparency should extend to the 'rules, data and informational requirements... used to make decisions' (OECD, 2013, pp.51-52), essentially, the 'rules of the game'. Such disclosure is not only necessary for the applicants who need to know the requirements for applications but also for interested parties wishing to understand in more detail the authorisation procedure, actors involved and how the information in the application is used and assessed. Such understanding of internal procedures and expectations is argued to build confidence in the regulator amongst general publics and the regulated industry (OECD, 2013, p.52).

Beyond access to information, more ambitious interpretations of transparency would include openness in the form of public participation in decision-making. This interpretation is adopted here for the following reasons. Firstly, the Commission itself emphasised 'effective and transparent consultation' and a 'reinforced culture of consultation and dialogue', recognising the importance of public participation for good governance generally, (albeit, there, in the context of policy formation rather than regulatory decision-making) (Commission, 2001b, pp.15-17). Secondly, the intimate connection between transparency and public participation is frequently acknowledged. For example, consultation has been described as central to transparency (Deighton-Smith, 2004, p.67) and the improved understanding of regulatory decision-making enabled by transparency is argued to ensure more effective participation (Stern and Holder, 1999, p.43). It has been argued, furthermore, that full transparency is only achieved through knowledge of decision-making acquired by direct participation (Shapiro, 1992, pp.204-205), although full transparency in this sense may not maintain or enhance trust in a regulator unless the public's impression of the reliability of its internal operations also increases as a result (La Porte and Metlay, 1996, p.344). Recital 1, Directive 2003/4/EC states that '[i]ncreased public access to environmental information and the dissemination of such information contribute to... more effective participation by the public in environmental decision-making'. Similarly, recital 3, Directive 2003/35/EC<sup>40</sup> states that '[e]ffective public participation in the taking of decisions enables the public to express, and the decision-maker to take account of, opinions and concerns which may be relevant to those decisions, thereby increasing the accountability and transparency of the decision-making process and contributing to public awareness of environmental issues and support for the decisions taken'. The Lisbon Treaty, too, acknowledges the link between openness, transparency and

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<sup>40</sup> European Parliament and Council Directive 2003/35/EC providing for public participation in respect of the drawing up of certain plans and programmes relating to the environment [2003] OJ L156/17. This Directive implements Aarhus Convention provisions on public participation and access to justice. Article 6(1)(b) Aarhus Convention requires Parties to provide for public participation in 'decisions on proposed activities... which may have a significant effect on the environment'. Decisions authorising PPPs could satisfy this requirement. However, it remains for the Parties to the Convention to 'determine whether such a proposed activity is subject to' this obligation. As such, the EU retains discretion over whether to require public participation in PPP authorisation decision-making.

participation<sup>41</sup> and the General Food Law (GFL) conceives transparency as entailing openness and public consultation.<sup>42</sup> While none of the above EU policy or legislative expressions of support for public participation in decision-making places a clear obligation on Member States to ensure participation in their authorisation of PPPs, they do illustrate the EU's overall commitment to such participation. Finally, as discussed in section III.1, participation provides a link between transparency, in terms of access to information, and accountability through the scrutiny that participation enables.

There are, furthermore, other good reasons for allowing public participation in decision-making, relevant to the authorisation of PPPs and the reliability of the process. Involvement may instil a sense of wider ownership over decisions, promoting implementation (Bloomfield et al., 2001, p.510). The availability of more information and perspectives which wider participation grants to decision-makers may result in better decisions (Parkins and Mitchell, 2005, pp.531-533), for example where scrutiny enables the identification of errors (Lee, 2014a, p.197) or where contributions are valued as resources for problem-solving (Steele, 2001). While risk assessment procedures tend to be closed and technocratic affairs, they need not necessarily be so. The reporting of expert deliberations, uncertainties, ambiguities and disagreements for example, may open up decision-making and enhance transparency (Stirling, 2008). A more instrumental rationale argues that participation can foster trust in the decision-makers (Stirling, 2005, pp.221-222), although it also has the potential to decrease trust (Löfstedt, 2004, p.340). Finally, given the often controversial nature of PPP authorisation decisions and the need for, and inevitability of, value judgments in the assessment and management of risk (Wynne, 1992c, p.116; Royal Society, 1992, p.97; Lee, 2008, pp.41-42), especially in situations of uncertainty, public involvement may benefit decision-making by incorporating citizens' values, evaluating risks and benefits and weighing uncertain benefits against uncertain risks (Steele, 2001, pp.421-427).

In light of the above, in the context of the Regulation, transparency would mean some form of public and stakeholder participation or consultation during the zonal authorisation procedure. There is, however, no provision for this in the Regulation and the achievement of transparency in the PPP authorisation procedure is therefore already disadvantaged.

## **IV – Precaution, substitution and sustainability**

As the discussion in this section illustrates, none of these principles is monolithic, especially so with respect to the precautionary principle and sustainability. It is therefore almost a contradiction to refer to *the* precautionary principle or *the* principle of sustainability. However, the rest of the report does so for shorthand, while acknowledging this circumstance.

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<sup>41</sup> Articles 1, 10 and 11(2)-(3) TEU and Article 15(1) TFEU.

<sup>42</sup> Arts 9, 10, 38 Regulation (EC) No 178/2002 (n 10).

## 1. Precaution

The precautionary principle is a key, yet still controversial and contested, part of risk regulation (for a discussion, see Pesendorfer, 2011). Admitting of multiple interpretations, it is impossible to isolate a single, widely agreed-upon definition. It is stated in the Lisbon Treaty to be a basis for EU environmental policy,<sup>43</sup> and recognised as an autonomous principle of EU law, applying to ‘ensure a high level of protection of health, consumer safety and the environment in all the Community’s spheres of activity’<sup>44</sup> (Lee, 2008, p.75) extending too, to the protection of animal and plant health (Commission, 2000, p.3). The Treaty offers no definition and the closest EU legislation comes to a definition is in Article 7 of the General Food Law,<sup>45</sup> which provides ‘where, following an assessment of available information, the possibility of harmful effects on health is identified but scientific uncertainty persists, provisional risk management measures necessary to ensure the high level of health protection chosen in the Community may be adopted, pending further scientific information for a more comprehensive risk assessment’. The Court of Justice has confirmed this, stating that where the existence or extent of risks are uncertain, ‘protective measures may be taken without having to wait until the reality and seriousness of those risks become fully apparent’.<sup>46</sup>

Furthermore, the interpretation and operation of the precautionary principle may vary widely, depending on context<sup>47</sup> and legal culture (Fisher, 2002) and to such an extent that the wisdom of referring to a singular ‘precautionary principle’ may be open to question. For some, it makes more sense to talk of a ‘precautionary approach’ (Stirling, 2001). Others argue that ‘it is absurd to expect consistent interpretation and application of the principle’ (Fisher, 2009, p.31). The context is, of course, the Regulation, which provides that one of its purposes is to ‘ensure a high level of protection of both human and animal health and the environment’.<sup>48</sup> It provides, further, that its provisions are ‘underpinned by the precautionary principle in order to ensure that active substances or products placed on the market do not adversely affect human or animal health or the environment’ and that ‘Member States shall not be prevented from applying the precautionary principle where there is scientific uncertainty as to the risks with regard to human or animal health or the environment posed by the plant protection products to be authorised in their territory’.<sup>49</sup>

Article 29(1)(e) PPPR provides that a PPP ‘shall only be authorised where following the uniform principles... in the light of current scientific and technical knowledge, it complies with

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<sup>43</sup> Article 191(2) TFEU.

<sup>44</sup> Cases T-74/00, T-76/00 and T-141/00 *Artegodan v Commission* [2002] ECR II-4945, paras 183–184.

<sup>45</sup> Regulation (EC) No 178/2002 (n 10).

<sup>46</sup> Case C-236/01 *Monsanto Agricoltura Italia SpA v Presidenza del Consiglio dei Ministri* [2003] ECR I-8105, para. 111.

<sup>47</sup> For example, the area of law and whether EU or national institutions are applying it.

<sup>48</sup> Article 1(3) PPPR.

<sup>49</sup> Article 1(4) PPPR.

the requirements provided for in Article 4(3)'. Those Article 4(3) requirements include that, 'consequent on application consistent with good plant protection practice, and having regard to realistic conditions of use', it (b) has 'no immediate or delayed harmful effect on human health or animal health' either directly or indirectly (through, for example, water, food or air) 'taking into account known cumulative and synergistic effects'; (c) 'shall not have any unacceptable effect on plants or plant products'; (d) 'shall not cause unnecessary suffering and pain to vertebrates to be controlled'; and (e) 'shall have no unacceptable effects on the environment' having regard to its fate and distribution and its impact on non-target species, including their behaviour. These requirements must be evaluated in light of the Uniform Principles.<sup>50</sup>

The Regulation's predecessor Directive contained wording<sup>51</sup> very similar to Article 4(3)(b) and (e) PPPR which was interpreted in *Sweden v Commission (Paraquat)*,<sup>52</sup> in light of the precautionary principle. In that case, Sweden challenged the Commission's approval of the active substance paraquat on the basis that, *inter alia*, it breached the precautionary principle. The General Court found that those provisions, interpreted in light of the precautionary principle, required 'the existence of solid evidence which, while not resolving scientific uncertainty, may reasonably raise doubts as to the safety of a substance' justifying refusal.<sup>53</sup> It noted too, that the Directive's safety requirements required compliance with the Uniform Principles.<sup>54</sup> It found furthermore that, 'it must be established beyond a reasonable doubt that the restrictions on the use of the substance involved... make it possible to ensure that use of that substance will be in accordance with the requirements of Article 5(1)'.<sup>55</sup>

This is, therefore, an indication from the Court that the available evidence, taking into account restrictions on use, must show 'beyond a reasonable doubt' that a substance is safe. Although these findings related to action by the Commission rather than national CAs and approval of an active substance rather than a PPP, given the similarity of the wording in the Regulation, it may be that Article 4(3)(b) and (e) would be interpreted similarly and that the interpretation would apply to paragraphs (c) and (d) as well. Indeed, the wording in the Regulation has been strengthened slightly and expanded, so it is perhaps unlikely that the standard of proof for the safety of a PPP, as required for authorisation under Article 29(1) PPPR, would be lowered, if this approach is taken. However, it should be noted that in a case decided subsequently to *Sweden v Commission (Paraquat)* but also in the context of active substance authorisation under Directive 91/414/EEC, the Court followed a different approach,<sup>56</sup> discussed below.

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<sup>50</sup> Article 4(4) PPPR; Commission Regulation (EU) No 546/2011 (n 39).

<sup>51</sup> Articles 4(1)(b) and 5(1) Council Directive 91/414/EEC (n 5).

<sup>52</sup> Case T-229/04 *Sweden v Commission (Paraquat)* [2007] ECR II-02437.

<sup>53</sup> 52. <sup>52</sup>para. 161.

<sup>54</sup> 52. <sup>52</sup>paras 163-164.

<sup>55</sup> 52. <sup>52</sup>paras 169-170, 227.

<sup>56</sup> Case C-77/09 *Gowan Comércio Internacional e Serviços Lda v Ministero della Salute* [2010] ECR I-13533.

The Court endorsed quite a high standard of protection of health and the environment with this judgment, reflecting the strong wording in the Directive and Regulation (for example ‘no unacceptable effect’<sup>57</sup>). It does require ‘solid evidence... which may reasonably raise doubts’.<sup>58</sup> However, as the remainder of its analysis shows, this requirement may be satisfied by the existence of a single study conducted in a non-European country in which some conditions of application were not representative of those in Europe.<sup>59</sup> This is not an impossibly high standard.

Although this case is clearly directly relevant to the regulation of PPPs, it should be noted that it creates an inconsistency in EU law generally as regards the interpretation of the precautionary principle and what its implementation requires. The Court, in *Sweden v Commission (Paraquat)*, applying the precautionary principle, apparently interprets the level of protection established in the legislation as a legal burden of proof with which the administration must comply in order to authorise the relevant substance (Anderson, 2014, pp.444–446). This shrinks the administration’s discretion to respond to the available evidence in light of the circumstances of the case in question (Anderson, 2014, pp.444–446). This case is apparently the only example of this approach in the context of risk regulation (Anderson, 2014, p.446) and may perhaps be partly explained by the requirement to apply the Uniform Principles which provide finely detailed guidelines for assessing safety. Elsewhere, it has been held that precautionary action must be based on ‘the best scientific information available’<sup>60</sup> and ‘as thorough a scientific risk assessment as possible’<sup>61</sup> such that the regulator can ‘reasonably’ conclude that protective or preventative measures are necessary to prevent the potential risk.<sup>62</sup> In this (dominant (Anderson, 2014, p.442)) approach to the precautionary principle in risk regulation, risk assessment is regarded as a procedural requirement (Stokes, 2008, p.492) which ‘informs the exercise of political discretion, without dictating outcomes’ (Anderson, 2014, p.440) and the administration, not being bound by the scientific evidence<sup>63</sup> (unlike in *Sweden v Commission (Paraquat)*), retains its discretion.<sup>64</sup> It has been forcefully argued that this line of case law does not require the administration to satisfy a burden of proof (Anderson, 2014, pp.437–439).

The difference in judicial reasoning as to what the interpretation and application of the precautionary principle requires creates confusion in the law and places Member States (and

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<sup>57</sup> Article 4(3)(e) PPPR.

<sup>58</sup> *Sweden v Commission (Paraquat)* (n 52), para. 161.

<sup>59</sup> 52. <sup>52</sup>para. 172-182.

<sup>60</sup> *Alpharma* (n 9), para. 171; *Pfizer* (n 9), para. 158.

<sup>61</sup> *Alpharma* (n 9), para. 175; *Pfizer* (n 9), para. 162. Sometimes the legislative context eliminates the requirement to perform a risk assessment, (Lee, 2014a, p.30); Case C-343/09 *Afton Chemical Limited v Secretary of State for Transport* [2010] ECR I-7027, Opinion of AG Kokott.

<sup>62</sup> *Pfizer* (n 9), paras 160-163; *Alpharma* (n 9), paras 173-176; *Monsanto* (n 46), paras 111-113. See also, in the context of Directive 91/414/EEC, *Gowan* (n 56), paras 72–79.

<sup>63</sup> *Alpharma* (n 9), para. 239.

<sup>64</sup> Whether this discretion is in practice, exercised, is another question, (Lee, 2014b, p.9).

others, primarily applicants) in a difficult position. Do CAs, for example, follow an approach enunciated with respect to wording almost identical to that which binds them? Or do they follow what may be regarded as a different, but dominant, approach to risk regulation? Given this dilemma, we should not be surprised if Member State survey responses indicate differing interpretations of the precautionary principle.

Finally, although the standard of protection established in *Sweden v Commission (Paraquat)* is high, it should not be taken as an endorsement by the Court of the pursuit of 'zero risk'. As a matter of EU law, precautionary action cannot be based a 'hypothetical risk', for science can never provide proof of 'zero risk'.<sup>65</sup> However, Member States are arguably entitled to seek reduction of a known (as opposed to hypothetical) risk to zero, in the absence of complete harmonisation of the field,<sup>66</sup> (Lee, 2008, p.46; de Sadeleer, 2006, p.164) although such measures would still be subject to review under Articles 34 and 36 TFEU.<sup>67</sup>

## 2. Sustainability

'Sustainability' is not mentioned in the Regulation. It is therefore at least arguable that the Regulation is not, in fact, based on the 'principle of sustainability'. If it is, it is not explicit. *Whether* it is, is likely to be a subjective judgment and depend on the preferred interpretation of sustainability. Sustainability, like sustainable development, is a vague term admitting of multiple interpretations (Ross, 2009, p.33; Bosselmann, 2008, p.23). It may be, then, that *one* interpretation of sustainability can indeed be found in the Regulation. It is my opinion, in light of the interpretation I prefer (Hamlyn, 2015), that the Regulation is not based on sustainability.<sup>68</sup> However, the point is contestable and worth exploring, as follows, especially given that EU pesticides policy expressly seeks to achieve 'the sustainable use of pesticides'.<sup>69</sup>

The sole references to 'sustainable use' in the Regulation are to the Sustainable Use Directive<sup>70</sup> and to the *Thematic Strategy on the Sustainable Use of Pesticides*.<sup>71</sup> There are attempts to achieve coherence between the Regulation and these other two instruments. For example, Recital 29 provides that Member States should be allowed to 'impose appropriate conditions having regard to the objectives laid down in the[ir] National Action Plan' (NAP).<sup>72</sup> In addition, the

<sup>65</sup> *Alpharma* (n 9) paras 156–158; *Pfizer* (n 9) paras 143–145.

<sup>66</sup> C-121/00 *Hahn* ECR I-9193, para. 34.

<sup>67</sup> 66. paras 34–37.

<sup>68</sup> A note on terminology: I do not distinguish between 'sustainability' and 'sustainable development' in my discussion. These terms are often used interchangeably. However, for a discussion of their potential differences, see (Paehlke, 2002).

<sup>69</sup> For example, Commission, A Thematic Strategy on the Sustainable Use of Pesticides COM(2006) 372 Final.

<sup>70</sup> Recital 29 PPPR; SUD (n 3).

<sup>71</sup> Recital 36 PPPR; Commission, Towards a Thematic Strategy on the Sustainable Use of Pesticides COM(2002) 349 Final.

<sup>72</sup> Adopted under Article 4 SUD. This is the primary instrument for implementing the SUD.

PPP label should indicate ‘where and under what circumstances a plant protection product may be used’ in order to achieve coherence.<sup>73</sup> Finally, ‘proper use’ of PPPs (as required by Article 55, first paragraph PPPR) requires compliance with the SUD.<sup>74</sup> These explicit links between the Regulation and other legal and policy instruments relating to PPPs are sparse and, on face value, fairly weak. The Regulation could, for example, *require* Member States to consider their NAPs or the goal of ‘sustainable use’ during their authorisation decision-making. This could strengthen mutually supportive operation between the two instruments. However, further research may be necessary to understand fully their relationship.

However, if we look to the rest of EU policy and legislation on sustainability in the context of PPPs, as I have argued elsewhere (Hamlyn, 2015), we will not necessarily be looking to an ambitious understanding of sustainability.<sup>75</sup> Sustainability is a complex concept whose nuances, due to space constraints, cannot be considered fully here. However, it is worth highlighting two elements in particular. Sustainability is often characterised as consisting of three pillars: the environmental, social and economic (Stallworthy, 2008, p.174). It is also closely associated with justice for future generations (World Commission on Environment and Development, 1987). Both these elements are viewed, internationally, as central to sustainable development (United Nations, 2015). More importantly, the EU itself has long acknowledged both these three constitutive pillars and the principle of inter-generational equity as core parts of sustainability/sustainable development (Commission, 2001a; Council of the European Union, 2006; Pallemarts, 2013, p.362).<sup>76</sup> It is argued that the implications for a regulatory regime based on this interpretation of sustainability are that decision-makers should take environmental, social and economic considerations relevant to the product in question and the interests of future generations into account during authorisation decision-making (Hamlyn, 2015).

However, traditionally, ‘sustainable development’ as applied to agriculture has often simply meant ‘optimising (or reducing) the use of synthetic pesticides and minimising environmental impact’ (Carr, 2003, p.170). The interpretation of sustainable use adopted by the SUD and EU policy on PPPs more generally is that of ‘risk reduction’ (Hamlyn, 2015). For example, Article 1 SUD provides that its aim is to ‘achieve a sustainable use of pesticides by reducing the risks and impacts of pesticide use on human health and the environment’.<sup>77</sup> The Regulation seeks a similar goal. This is evident from various provisions. Firstly, the Regulation aims to ‘ensure a

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<sup>73</sup> Recital 36 PPPR.

<sup>74</sup> Article 55, second paragraph PPPR.

<sup>75</sup> Although I acknowledge that the 2009 plant protection products regulatory regime, as a whole, constitutes an ambitious and bold reform of pesticides regulation, (Bozzini, 2017, chap.3).

<sup>76</sup> See also Commission, Next Steps for a Sustainable European Future: European Action for Sustainability COM(2016) 739 Final.

<sup>77</sup> See also, Commission, ‘Thematic Strategy’ (n 69) p.3. NB the SUD does elsewhere also appear to promote reduction of dependence on the use of pesticides. See, for example, Recitals 5 and 18 and Article 4(1) SUD.

high level of protection of both human and animal health and the environment'.<sup>78</sup> This implies the pursuit of safety through reducing risks. Secondly, the Regulation seeks to facilitate and incentivise the placing on the market of 'low-risk' PPPs.<sup>79</sup> Thirdly, as discussed in section IV.3, the Regulation implements the 'substitution principle', requiring the replacement of PPPs containing active substances identified as particularly hazardous with safer PPPs pursuant to comparative assessment,<sup>80</sup> again, in order to reduce risks.<sup>81</sup> It is acknowledged, as discussed in section IV.3, that comparative assessment requires consideration of risks and benefits and specifically the economic disadvantages of replacement.<sup>82</sup> This is, however, a rare acknowledgement of the relevance of the three pillars of sustainability in the Regulation and nowhere can there be found an explicit acknowledgment of inter-generational equity.

In conclusion, the predominant goal of the Regulation is to reduce risks posed by PPPs. As such it reflects the interpretation of sustainability enshrined in the SUD (although it does not explicitly label this approach 'sustainability' or 'sustainable use' as the SUD does) and indeed the interpretation of sustainable development traditionally associated with agriculture. Whether this is the 'true' or best interpretation of sustainability is very much open to debate. Sustainability has been interpreted, including by the EU, more ambitiously to encompass social, economic and environmental dimensions and the interests of future generations. As such, and due to the lack of consensus overall around its meaning (including between different areas of EU policy touching on sustainability), as with the precautionary principle, we should not be surprised if Member States express different understandings of the 'principle of sustainability' in their responses to the survey.

### 3. Substitution

The 'substitution principle' is a key part of the Regulation. As applied to chemicals generally, this principle seeks to foster the systematic replacement of hazardous substances with safer alternatives. Dating from the mid-20<sup>th</sup> century in Sweden (or perhaps even earlier (Öberg, 2014, p.565)) it is now a core part of EU chemicals regulation (Löfstedt, 2014, pp.543–546) and a 'key element of precautionary thinking' (Hansen, Carlsen and Tickner, 2007, pp.399–400). Like many environmental principles, defining it is problematic, although The European Chemical Industry Council (CEFIC) offers a simple definition: 'substitution is the replacement of one substance by another with the aim of achieving a lower level of risk' (quoted in Löfstedt, 2014, p.546). Furthermore, it is labelled a 'principle' and should, like the precautionary principle, be treated as a 'guideline' for consideration by decision-makers alongside other risk management strategies rather than a 'policy tool' (Abelkop and Graham, 2014, pp.582–583) or a rule dictating a clear course of action. Some argue the need for application on a case-by-case basis

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<sup>78</sup> Article 1(3) PPPR.

<sup>79</sup> Recital 17 PPPR.

<sup>80</sup> Article 50 PPPR.

<sup>81</sup> Recital 19 PPPR.

<sup>82</sup> Article 50(1) PPPR.

(Hansson, Molander and Rudén, 2011, pp.455–456; Löfstedt, 2014, p.555). This is acknowledged in Commission guidance (Commission, 2014a, p.9) and indeed in the Regulation.<sup>83</sup>

However, the simplicity of the principle belies the complexity of its implementation and application (UK Royal Society of Chemistry, 2007). Challenges relate to, *inter alia*, insufficient knowledge about substances, lack of commercial incentives to substitute (although REACH introduced some) (Abelkop and Graham, 2014, pp.583–584), slow processes for identifying candidate substances and continuing controversy over whether substitution should be hazard- or risk-based (Löfstedt, 2014, pp.547–551), although this may be a false dichotomy as the current EU approach to substitution often contains elements of both (Öberg, 2014, p.565).<sup>84</sup> While the former promises to accelerate substitution processes, if trade-offs between candidate and alternative substances are not fully considered, it may have unintended environmental, health, social and economic consequences. However, a risk-based approach will certainly slow the pace of substitution down and is under-researched (as is substitution, generally) (Löfstedt, 2014, pp.546, 551–560; Öberg, 2014, p.567). Some guidance on comparative assessment has been produced (Sunley and van Opstal, 2010; UK Royal Society of Chemistry, 2007; EPPO, 2015), including on economic and practical considerations (Sunley and van Opstal, 2010, p.103) but still, there is little legislative tradition of applying the substitution principle outside the Nordic countries (Faust et al., 2014, p.2). Furthermore, any uncertainty associated with hazard-based approaches is not necessarily dispelled by undertaking risk assessment, a process which also struggles to capture uncertainty (Aven, 2014, p.570). Scientific evidence rarely speaks for itself and demands interpretation (Stilgoe, Irwin and Jones, 2006, pp.50, 72); likewise the uncertainties in the knowledge base produced by (comparative) risk assessment require value judgments and the weighing of competing concerns during decision-making (Aven, 2014, pp.570–571). A more conciliatory view argues that each approach can be appropriate, depending on the circumstances and substances and alternatives involved, provided decisions are based on the best available evidence (Hansson, Molander and Rudén, 2011, p.456).

The Regulation establishes a procedure for implementing substitution. Active substances are approved as ‘candidates for substitution’ (CfS) according to a number of hazard-based cut-off criteria set out in the Regulation.<sup>85</sup> This classification triggers an obligation to perform a comparative assessment – the mechanism which delivers substitution – on PPPs containing a CfS (mandatory comparative assessment).<sup>86</sup> The comparative assessment should be done at

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<sup>83</sup> Annex IV.2 PPPR.

<sup>84</sup> For example in European Parliament and Council Regulation (EC) No 1907/2006/EC concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) [2006] OJ L33/1 and the Regulation.

<sup>85</sup> Article 24(1); Annex II.4 PPPR. For more detail on cut-off criteria see the study (Bozzini, 2018) published under Annex II to the European Implementation Assessment.

<sup>86</sup> Derogations are allowed under Article 50(3) PPPR only ‘where it is necessary to acquire experience first through using that product in practice’.

national, rather than zonal, level (Commission, 2014a, p.4) and requires a weighing of risks and benefits between the PPP containing the Cfs and alternative PPPs or non-chemical control or prevention methods.<sup>87</sup> Member States are required to refuse authorisation or restrict the use of the PPP containing the Cfs where the alternative is ‘significantly safer for human or animal health or the environment’; substitution ‘does not present significant economic or practical disadvantages’ and the remaining control and prevention methods ‘are adequate to minimise the occurrence of resistance in the target organism’.<sup>88</sup> The impacts of this provision are highly uncertain. However, one study estimates several thousand cases requiring comparative assessments, imposing a significant burden on CAs (Faust et al., 2014).

In addition, Member States may during evaluation, by way of derogation to Article 36(2) PPPR, comparatively assess a PPP not containing a Cfs or a low-risk active substance, ‘if a non-chemical control or prevention method exists for the same use and it is in general use in that Member State’<sup>89</sup> (optional comparative assessment).

Bozzini argues that the Regulation implements a strong version of the substitution principle (Bozzini, 2017, chap.2). Article 36(2) PPPR illustrates the strength identified by Bozzini in extending substitution to encourage transition to safer control methods even in the absence of a Cfs classification. Indeed, the Commission argues that the principles of comparative assessment and substitution appear throughout the PPP regulatory regime beyond the main regulatory tool in Article 50 PPPR (Commission, 2014a, p.3). In addition, Commission guidance suggests that PPPs containing candidates may be compared with alternative PPPs also containing candidates or even the same candidate even though interpretation of the Regulation may appear to prohibit the latter. Though all candidates are classified on the basis of the high hazards they pose to human health and the environment, comparative assessment may reveal they differ significantly in terms of risks posed in practice (Commission, 2014a, p.6). Moreover, evidence from chemicals regulation suggests the EU seeks to encourage or implement the substitution principle ambitiously. In *Toolex*, a Swedish ban on Trichloroethylene was found to be proportionate under Article 36 TFEU (then Article 30 EC) partly on the basis that the ban implemented the substitution principle.<sup>90</sup> The lightness of the ECJ’s proportionality review suggested a willingness to encourage application of the substitution principle (Heyvaert, 2001).

Furthermore, much of the literature examined in this section stresses the relevance of socio-economic considerations and trade-offs to comparative risk assessment, and the need for value judgments. The inevitability of value judgments inheres in that fact that the concepts of ‘safer’<sup>91</sup>

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<sup>87</sup> Article 55(1), Annex IV PPPR.

<sup>88</sup> Article 50(1)(a)-(c) PPPR.

<sup>89</sup> Article 50(2) PPPR.

<sup>90</sup> Case C-473/98 *Kemikalieinspektionen v Toolex Alpha AB* [2000] ECR I-05681, paras 46–47.

<sup>91</sup> Article 50(1)(a) PPPR.

and 'alternative'<sup>92</sup> are open to interpretation (UK Royal Society of Chemistry, 2007, p.3) and may be deeply contested. The Regulation provides some guidance for CAs making judgments with respect to 'significant difference in risk'<sup>93</sup> and 'significant practical or economic disadvantages'.<sup>94</sup> However, placing all responsibility for the substitution decision on CAs ignores the likelihood of disagreement among citizens (and probably Member States too) over sets of values and attitudes towards risk (Dudley, 2013). There is, additionally, the problem of incommensurability (not comparing like with like) (Hansen, Carlsen and Tickner, 2007, p.401) – substances may be more or less hazardous in different respects (UK Royal Society of Chemistry, 2007, p.5) – making straightforward ranking or comparison of hazard profiles impossible. With respect to 'alternative', substitution may be chemical or functional (Hansson, Molander and Rudén, 2011). The Regulation implements functional substitution (Bozzini, 2017, p.40) focusing on uses and effect on the target organism produced by the alternative control or prevention method<sup>95</sup> rather than requiring the alternative to be a chemical control method *per se*. However, technical functional equivalence is difficult to demonstrate, often requiring long periods to acquire evidence (Lohse et al., 2003, pp.66–67). The Regulation anticipates this<sup>96</sup> but this is again likely to slow the process down. Finally, though helpful, the guidance is also vague due to the use of other concepts also requiring value judgments, such as 'significant', 'sufficient' and 'adequate' in Article 50 and Annex IV.

Article 12(1) PPPR allows public comments on draft assessment reports<sup>97</sup> assessing active substances against the approval criteria set out in Article 4 and presumably therefore on CfS classifications considered therein. However, there is no provision for consultation during comparative assessment making Article 50 PPPR a very closed process. Given the likelihood of disagreement among citizen and stakeholders generally, the benefits of public engagement in decision-making, discussed in section III.3, and the fact that substitution is often driven by public concern (Lohse et al., 2003, p.73), greater public involvement and consideration of public values in comparative assessment could enhance CA decision-making under Article 50 (Sexton, 1999, pp.214–215) and may, as discussed in section II.2, help counter the risk of regulatory capture. Indeed, various authors recognise the role stakeholders (including the public and NGOs) play in implementing substitution (Lohse et al., 2003, pp.70–71) and support the involvement of consumers and other stakeholders (UK Royal Society of Chemistry, 2007, p.6; Girling, 2014, p.595).

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<sup>92</sup> Article 3(8), Annex IV.1 and 3 PPPR.

<sup>93</sup> Annex IV.2 PPPR.

<sup>94</sup> Annex IV.3 PPPR.

<sup>95</sup> Article 50(1)(a) and Annex IV.1 PPPR.

<sup>96</sup> Annex IV.1(c) PPPR.

<sup>97</sup> Article 11 PPPR.

## V – Method

This report is the result of mixed methods research. It involved both desk-based and empirical research, the latter employing both quantitative and qualitative research strategies. Research commenced with a doctrinal analysis of the Regulation's provisions on zonal authorisation (Articles 28-39) comparative assessment (Article 50) and textual analysis of relevant grey literature in order to gain an understanding of the procedures and frameworks (both formal (i.e. established by law) and informal (i.e. contained in guidance)) in place and their operation. A review of the information on CA websites concerning national authorisation models was also conducted.

Secondary sources (such as academic research or EU policy documents and case law) do not always contain all the information required to answer research questions (Burton, 2013, p.55). Due to the variation in availability of information online and in English, it was also necessary to undertake substantial empirical research. The empirical research consisted of three strands, described in sub-sections V.1-3. The broad scope of the research and the number of actors involved made it necessary to strike a balance between depth and breadth, hence the choices of instrument described below. This research, as a whole, is descriptive rather than explanatory, although the critical analysis of Member State practice as a basis for making recommendations gives the work a normative streak. Descriptive work, it is acknowledged, has limitations (Fisher et al., 2009, pp.223-224) but also value, for example, in shaping up the study of pesticides regulation and providing an underpinning for further research (Pedersen, 2014, pp.437-438). Overall, the research seeks to describe a picture of the state of implementation of the Regulation across EU Member States and to gather factual information and/or opinions (subjective perceptions) about the zonal authorisation procedure and its implementation from various quarters. It does not seek to explain the levels of implementation revealed or differences between levels of implementation in different MSs, or to develop, prove or generalise a theory. Furthermore, it does not claim to establish any universal truths or to present a full picture of the implementation of the Regulation, the operation of all CAs or the workings of each zone. As discussed in this section, the data do not allow for such conclusions. Instead, the results reported here should be regarded as a first step towards understanding this complex, enormous and largely under-researched field.

The approach to analysis of the data reflects the largely descriptive nature of the research. The data were collated for the purposes of describing and drawing comparisons between different Member State practices and the experiences of Member States, stakeholders and zSC secretariats and for identifying any trends or similarities (for example, during zonal evaluation) within zones or between Member States. The data were also analysed in light of the theoretical discussions and norms identified in sections II-IV, which enabled interpretation and criticism of Member State/CA practices with respect to their independence and transparency and application of the principles of precaution, sustainability and substitution. On this basis, recommendations were made. The data gathered are presented as directly as possible and the conclusions drawn hold true in light of the available samples.

## 1. Member State survey

A survey of EU Member States and Norway was conducted. The questionnaire<sup>98</sup> contained questions on the zonal system and the zonal authorisation procedure established in the Member State, the application of the principles of precaution, substitution and sustainability and the independence and transparency of the CAs.

### 1.1 Zonal authorisation procedure

Questions 1-7 concerned the zonal authorisation procedure in the respondent Member State and covered the procedure itself, who evaluates the application, the status of expert advice received, frequency and reason for communication with other Member States in the same zone and the benefits of the zonal system for Member States.

### 1.2 Precaution, sustainability and substitution

The questions on precaution, substitution and sustainability were developed by reference to the provisions of the Regulation, EU case law, guidance, in particular on substitution and academic literature, as discussed in section IV. Guidance, policy and literature on these three principles is vast and entire discrete surveys could be conducted on the application by CAs of each. However, in order not to overload CAs (and therefore encourage responses) only a few questions were included on each principle, while acknowledging that it is impossible to capture a full understanding of national interpretations and application of such nuanced and complex concepts on this basis. These questions focused, therefore, on assessing the level of CA ambition in their application and the consistency of interpretation and application, by individual CAs and across Member States, of these three principles. Comparative assessment occurs at national level. However, consistency in its application may still be valuable in terms of the predictability of this procedure from an applicant's point of view. The following questions were asked<sup>99</sup>:

8. The PPPR provides that a PPP may only be authorised if, in the light of current scientific and technical knowledge it has no immediate or delayed harmful effect on human health, it does not have any unacceptable effects on plants or plant products, it does not cause unnecessary suffering and pain to vertebrates to be controlled and it has no unacceptable effects on the environment (Articles 29(1)(e) and 4(3)(b)-(e)). Taking into account all the evidence of the safety of the PPP and the restrictions that may be placed on its use (Article 31), please indicate the **standard of proof** the evidence must meet in order for the PPP to be authorised.

9. Does the competent authority produce and follow any internal guidance in its application of the precautionary principle during the authorisation process?

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<sup>98</sup> The full questionnaire could be submitted upon request.

<sup>99</sup> For the majority of questions in the Member State survey, respondents were provided with several options for response, discussed in greater detail in sub-section VII.3.

11. Does the competent authority take the principle of sustainability into account in its decision-making regarding the authorisation of PPPs?
12. On what basis does the competent authority decide whether or not to take the principle of sustainability into account in its decision-making regarding the authorisation of PPPs?
13. Sustainability can be interpreted in many different ways. Which interpretation does the competent authority apply in its decision-making?
14. Does the competent authority produce and follow any internal guidance, or follow any external guidance when applying the principle of sustainability in order to apply it consistently?
15. Recital 29 PPPR provides that Member States **may** impose ‘**appropriate conditions**’ on the use of PPPs having regard to the objectives of their National Action Plan adopted in accordance with Directive 2009/128/EC establishing a framework for Community action to achieve a sustainable use of pesticides [2009] OJ L309/71. In practice, **how often does the competent authority do this?**
16. Article 50(4) PPPR requires Member States to perform a comparative assessment of PPPs containing a candidate for substitution ‘regularly and at the latest at renewal or amendment’ of its authorisation. How often does the competent authority perform such a comparative assessment on PPPs containing a candidate for substitution?
17. On what PPPs does the competent authority conduct comparative assessment?
18. Does the competent authority produce and follow any internal guidance, or follow any external guidance (e.g. from EPPO, Commission etc.), on substitution/comparative assessment in order to deliver consistent results?

### 1.3 Independence

The questions concerning independence drew heavily on a survey of independent energy regulators in eight European countries conducted by Johannsen (2003) and her operationalisation of the concept of regulatory independence (Johannsen, 2003, pp.31-37). Johannsen’s research took, as its starting point, research into, and a previous survey of, IRAs in the pharmaceutical and electricity sectors in the UK and Italy conducted by Gilardi (2001) which, in turn, drew on research by Cukierman, Webb and Neyapti (1992) into the independence of central banks. Following Johannsen, the survey investigates independence in formal, legal/organisational terms, rather than in terms of the operation of these formal rules in practice.

Johannsen’s operationalisation of the concept of regulatory independence, relies on Smith’s definition of regulatory independence (Smith, 1997): discussed in section II. It measures four key variables: 1. Formal independence from government and the legislature; 2. Independence from stakeholders; 3. Substantive independence (Larsen et al., 2006, p.2860; Johannsen, 2003, p.36) from government and the legislature (concerning competencies and independent decision-making); and 4. Financial and organisational autonomy.

These key variables were largely adhered to. Questions 22-27 concern formal independence from government and the legislature:

22. What is the term of the agency head or commissioners?
23. Is the appointment renewable?
24. Who appoints the agency head or the commissioners?
25. What are the provisions regarding dismissal of the agency head or commissioners?
26. May the agency head or the commissioners hold other offices in government?
27. Is independence a formal requirement for the appointment?

Questions 28-30 concern independence from the regulated industry:

28. According to your national legislation, is it possible for the commissioners/the agency head to have held a position in the plant protection product industry/industrial associations in the years preceding his or her appointment?
29. Are there provisions (in your national legislation) restricting the commissioners'/the agency head's possibilities of accepting a job in the plant protection product industry/industrial associations after their term?
30. Are there any provisions (in your national legislation) forbidding the agency head/commissioners to have any personal or financial interest in the plant protection product industry?

Questions 31, 33, 34 and 36 concern financial and organisational autonomy:

31. What is the source of the competent authority's budget?
33. When the budget has been approved, who controls the budgetary spending?
34. Who decides the competent authority's internal organisation (internal procedures, allocation of responsibility, tasks etc.?)
36. Who is in charge of the competent authority's personnel policy (recruitment, promotion, salaries)?

Question 42 concerns substantive independence:

42. To what extent is the competent authority responsible for the authorisation of new plant protection products under the zonal authorisation procedure?

While many questions were incorporated into this survey with little or no amendment, others were omitted or re-drafted and additional questions were included to reflect the specific features of regulating PPPs and the requirements of this research. Three particular changes may be noted. Firstly, Johannsen's question on the permissibility of 'discussions of pending

cases' between stakeholders and the regulator was omitted as irrelevant to regulator-regulatee relationship in question. Pre-submission meetings between applicants and CAs are encouraged (Commission, 2014b, p.8) and CAs are entitled to contact applicants during the authorisation process for further information.<sup>100</sup> Secondly, due to the EPRS's particular interest in CA resources, Johannsen's questions on financial and organisational autonomy are dealt with under the heading of 'Capacities' and interspersed with questions relating to the sufficiency of these resources. Finally, Johannsen declined to include questions on information asymmetry due to the difficulty of constructing an indicator about which information can be collected (Johannsen, 2003, p.35). Information asymmetry is connected to the matter of (expert) resources so an attempt is made in this survey to tap this concept by introducing three simple questions (Q38-40) regarding the ease (or otherwise) of recruiting and retaining staff and of buying in resources unavailable in-house. It is acknowledged though that these questions can only scratch the surface of this complex concept.

#### 1.4 Transparency and accountability

The questions concerning transparency and accountability were developed on the basis of research into, and guidance on achieving, transparency in regulatory authorities (for example, OECD, 2013, 2016; Jarvis and Sovacool, 2011; Dudley and Wegrich, 2016). These questions aim to get a sense both of the formal, legal obligations of the CA and the CA's practice. Three dimensions of the concept of transparency are assessed. Firstly, clarity with respect to the authorisation rules, procedures and requirements:

43. How much information regarding the zonal authorisation procedure is publicly available (for example on the competent authority website) in the national language(s)? In this question, information includes guidance **addressed to applicants** on how to apply, the required documents, information about the authorisation procedure and how decisions are made.

Secondly, access to, and publication of, information held by CAs:

44. Does the competent authority publish its decisions regarding authorisation of PPPs?

45. To what extent does the competent authority disclose/publish the information sources on which its decisions are based?

46. Is there a clear basis in law or policy for public access to information held by the competent authority, including a clear statement of the limitations to that access (for example, due to commercial confidentiality)?

Thirdly the strength of any consultation processes conducted during zonal authorisation procedures and access to related information:

47. With whom, in addition to the applicant, does the competent authority consult during its authorisation decision-making processes (including comparative assessment)?

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<sup>100</sup> Article 37(1) second paragraph PPPR.

48. If the competent authority consults any of the actors listed in question 47, please briefly state how this consultation/engagement is conducted.

49. If the competent authority consults any of the actors listed in question 47 does the competent authority publish or make publicly available their submissions?

50. Is the competent authority required by law to respond formally to these submissions?

51. If **YES**, are these responses published/made publicly available?

52. Is the competent authority required by law to take into account the comments provided during consultation processes in its decision-making?

The final five questions concerned accountability of the CAs and scrutiny of CA decisions:

53. What are the formal obligations of accountability of the competent authority vis-à-vis the government?

54. What are the formal obligations of accountability of the competent authority vis-à-vis the legislature?

55. Where the competent authority is required to produce an annual report, is this report also made public?

56. Are authorisation decisions reviewed or audited?

57. Article 36(3) fourth sub-paragraph PPPR requires that Member States provide the possibility to challenge a decision refusing authorisation of a PPP 'before national courts or other instances of appeal'. Who, **other than a court**, can overturn the competent authority's decision where it has exclusive competence?

Questions were predominantly closed, incorporating space for additional comments, with some open-ended questions. The questionnaire was lengthy and the aim in choice of question format was to strike a balance between enabling respondents to answer questions quickly and encouraging willing respondents to elaborate on their answers, thereby attempting a balance between depth and breadth. As such, respondents provided information of varying degrees of exhaustiveness and clarity.

## **1.5 Procedure**

The survey took the form of a self-completion questionnaire contained within an MS word document. It was distributed to all 28 EU Member State CAs and the Norwegian CA by email at the end of October with the final deadline set in early December 2017. Twelve CAs responded within the deadline. It should be noted that the participating Member States represent all three zones; each zone is covered by the responses of at least two Member States, which, although not enough to ensure full representativeness for the EU as a whole, allows for some comparison.

Respondents were allowed to specify the level of anonymity accorded their answers. The three options were: consent to direct publication of information provided in the survey identifying the respondent CA; consent to direct publication of information provided in the survey without identifying the respondent CA; and consent to the inclusion of the information provided within statistical data but not to direct publication. The availability of different levels of anonymity was intended to encourage responses, while retaining flexibility for willing Member States to agree to the publication and attribution of their responses. Four CAs selected the first option; three CAs selected the second and five CAs selected the third. Selection of the first two options was regarded as most valuable in terms of the clear presentation of results and the development of an understanding of CA activity across the three zones. Therefore, where CAs provided information regarded as particularly helpful to the research, these CAs were approached individually and asked to waive their chosen anonymity level with respect to the relevant information. Some agreed to this request. Results are presented accordingly, with CAs identified and/or quoted where permitted. Information about the authorisation procedures of the 16 CAs which did not respond, gathered from CA websites (where available) is presented alongside these results. In all cases, the position stated is regarded as the official position of the competent authority.

Of the 12 questionnaires which were returned, six were complete.<sup>101</sup> The reasons for the incomplete questionnaires are unclear. Given the length of the questionnaire, it could have been that questions were accidentally missed, or skipped in the interests of time, if questions were regarded as too time-consuming to respond to. Alternatively, it may be that certain questions were not regarded by the individual respondent as relevant to the CA or perhaps that, despite the guarantee of anonymity, CAs were still loath to provide certain information. It should be noted that this tool allowed for factual information as well as opinions (subjective perceptions) to be collected.

### **1.6. Representativeness of the data collected via the Member State survey**

Given the level of detail of the questions contained in the Member State survey and the CA responses, and the fact that all participating Member States declared their answers to be the official position of the relevant authority, it is considered that the information gathered is factual data by its nature and not just mere perception/subjective opinion. Therefore, although not all Member States took part in this data collection exercise, the collected data can be viewed as fully representative for the 12 Member States that took part in the survey (subject to the qualifications expressed in section VI.2).

## **2. Stakeholder survey**

A survey of stakeholders in the zonal authorisation procedure was conducted. The survey<sup>102</sup> sought stakeholders' views on the zonal authorisation procedure, seeking in particular their

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<sup>101</sup> 'Complete' means all questions relevant to the respondent CA were answered. Most incomplete surveys were missing only one or two answers.

<sup>102</sup> The full list of questions could be submitted upon request.

opinions on the functioning of the zonal system, the consistency in application of the principles of precaution, substitution and sustainability and the level of CA independence and transparency. These questions were developed on the basis of the same desk-based research on which the Member State survey was based. An additional step was taken involving review of the original questions in light of the responses of CAs to the Member State survey. Like the Member State survey, the stakeholder survey contained a mixture of closed and open-ended questions; the former designed to enable swift provision of information and the latter designed to encourage reflection and the expression of opinions. This tool provided primarily for opinions (subjective perceptions) to be collected.

## **2.1 Selection of stakeholders**

Two categories of relevant stakeholders were identified: those with legal obligations under the Regulation and those without such legal obligations but with a legitimate interest in the achievement of the objectives of the Regulation or the implementation of the Regulation and its impacts. Within the first category fell industry, i.e. manufacturers of PPPs.<sup>103</sup> Within the second category fell PPP users and health and environment stakeholders. Stakeholders were selected on the basis of web-based research into their activities.

In the case of industry stakeholders, there exist both European (and international) level industry associations and individual PPP manufacturers. Only the former were approached.<sup>104</sup> This was primarily because these associations were regarded as providing a reliable voice of industry/individual PPP manufacturers on the matters covered in the survey due to their fulfilling the following criteria: operation at a European level, large membership and significant influence and expertise in the area of plant protection and zonal authorisation procedures. Wherever two or more EU level industry associations were found to represent similar sections of the PPP market but only one focused exclusively on PPPs, that one was chosen. At least one industry association representing, at EU level, the manufacturers of synthetic PPPs (including generic PPPs) and biological PPPs was approached; three associations, in total.

With respect to PPP users, there exist European (and international) level associations representing large numbers of smaller member organisations operating at a national level. Only the former were approached for the same reason as above,<sup>105</sup> i.e. that these associations were regarded as providing a reliable voice of their members on the basis of the following criteria: operation at a European level, large membership, significant influence and expertise

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<sup>103</sup> CAs also have legal obligations but were approached in the Member State survey.

<sup>104</sup> Except where no European level association existed, in which case the international level organisation was approached. It was specified in the invitation that the individual members of the selected associations would also be welcome to fill in the survey.

<sup>105</sup> It was specified in the invitation that the individual members of the selected associations would also be welcome to fill in the survey.

in the area of plant protection and zonal authorisation procedures. Three, in total, were approached.

With respect to health and environment stakeholders, there exist both pan-European and national NGOs. The latter NGOs tend to be members of one or more of the former NGOs. A selection of both<sup>106</sup> were approached in order to gather a range of views and experience at both European and national level and on the basis that European-level NGOs might not be able to speak directly to zonal authorisation procedures in individual Member States. Stakeholders in this group were selected on the basis of the following criteria: highest interest in the achievement of the objectives of the Regulation, highest level of concern regarding the environmental and health effects of PPPs, expertise in the area of plant protection and a specific focus on PPP or a declared interest in being consulted. In total, six pan-European NGOs, and ten national NGOs were approached.

Finally, one international level organisation with a membership comprising EU Member States, was approached. In total, 23 stakeholders were approached.

## **2.2 Procedure**

The survey also took the form of a self-completion questionnaire but in this case was constructed and distributed using the online EU survey tool from mid-December 2017 to 22 January 2018. It was distributed to four stakeholders with legal obligations under the Regulation, of whom one responded; and 19 stakeholders with an interest in the achievement of the objectives of the Regulation, of whom none responded. As mentioned above, stakeholders were informed that their members were welcome to complete the survey too. Such members were invited to request access if they wished to do so. However, no additional stakeholders completed the survey. In total therefore, one response to this survey was received, from an industry association. This response was complete. It is unclear why only one response was received. Although the survey was open for over four weeks, it is possible that the timing (over Christmas) combined with its length deterred at least some stakeholders from responding. While a single response is clearly nowhere close to representative of the class of stakeholder to which the respondent belongs (or indeed stakeholders, generally), it did contain valuable information and perspectives on the zonal authorisation procedure, as presented below. Respondents were informed that their answers would not be linked directly to them, thus there is no attribution of information or quotes to individual organisations by name. The respondent stakeholder is referred to below as 'the Stakeholder'.

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<sup>106</sup> It was specified in the invitation that the individual members of the selected associations would also be welcome to fill in the survey.

### 3. Zonal steering committee survey

It was originally intended to conduct semi-structured interviews with the zonal steering committee (zSC)<sup>107</sup> secretariats for the years 2017-2018. Prospective interviewees were approached via email to the secretariats of the three zSCs. However, one of the secretariats of the three zSCs suggested that instead written questions could be provided to which the secretariats would respond in writing. This suggestion was considered positively and applied across all three zones. As such, a questionnaire of open questions<sup>108</sup> was distributed by email to the secretariats from late January to the end of February 2018. The questions focused on the operation of the zonal system and the challenges both the zones and individual Member States face during authorisation procedures as well as the independence and transparency of CAs in each zone and the implementation of the three principles discussed in section IV. Questions were developed on the basis of the desk-based literature review, described at the beginning of section V and once all the responses to the Member State survey and Stakeholder survey had been gathered and reviewed. This allowed questions to be refined on the basis of these responses. All three zSCs responded. The information submitted should not be regarded as the official position of the Member States in each zone but rather as the position of the secretariat of the zSC for the given period. Responses are quoted directly and attributed to zSC secretariats generally, rather than to individual Member States in order to preserve confidentiality.

### 4. Limitations of the research design

This research is, of course, subject to methodological limitations. First, the design emphasises formal independence. Thus, the information gathered is able only to indicate risks of, for example CA vulnerability to excessive governmental influence or regulatory capture rather than identify concrete evidence of either. A fuller understanding of whether CAs are in fact captured or excessively influenced by government would require a more focused and in-depth empirical investigation conducted by a multilingual team of researchers with privileged access to information, as indicated in section VII.1.5. Secondly, the research does not directly review registration reports or authorisation decisions. Given the public unavailability of this information (as identified in section VII.2), the time and resources necessary to gain access (via access to information requests) and language barriers, such an investigation is beyond the scope of this research. This limitation means that it is not possible to track the effect of government or industry influence, or Member State interpretation of the precautionary, sustainability or substitution principle on evaluation and authorisation decision-making. Thirdly, the majority of the research was conducted within a strict timeframe which reduced the time available to gather empirical data. This may have contributed to the low stakeholder response rate, especially where a longer or more flexible timeframe might have enabled less well-resourced stakeholders to participate. Finally, language limitations meant that only

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<sup>107</sup> Discussed in section VI.

<sup>108</sup> The full list of questions could be submitted upon request.

English sources (for example, literature and information on CA websites) could be examined, representing a constraint on the completeness of the implementation ‘picture’ depicted below.

## VI – Zonal authorisation

### 1. Procedure (as laid down by the Regulation concerning the placing of plant protection products on the market)

The Regulation establishes the main framework for authorisation of PPPs, with detail provided in guidance. Article 28 PPPR requires PPPs to be authorised before being placed on the EU internal market. ‘Authorisation’ of a PPP is defined in Article 3(9) PPPR as ‘an administrative act by which the competent authority of a Member State authorises the placing on the market of a plant protection product in its territory’ and is permitted where, following the Uniform Principles<sup>109</sup> a PPP complies with the requirements listed in Article 29 PPPR. These requirements largely relate to the safety of the PPP and include that its active substances, safeners and synergists have been approved, that these components and its residues can be determined, that ‘its physical and chemical properties have been determined and deemed acceptable’ for use and storage and that ‘in light of current scientific and technical knowledge, it complies with the requirements’ in Article 4(3) PPPR. These requirements were discussed in section IV.1 and also largely relate to the effectiveness and safety, for human and plant health and the environment, of the PPP in question.

The procedure is called ‘zonal’ because the Regulation divides Member States (and Norway) into zones with comparable ‘agricultural, plant health and environmental (including climatic) conditions’ (Northern, Central and Southern) in order to avoid duplication of work, reduce administrative burden on industry and Member States, increase harmonisation and facilitate mutual recognition of authorisations.<sup>110</sup> It is acknowledged that ‘authorisation’, in terms of the final decision as whether or not to allow a PPP on the market in a particular Member State is made by that individual Member State. Evaluation, in terms of assessing the application, is conducted at ‘zonal’ level by the zRMS whose conclusions are used as the basis for national authorisation decisions. The terminology in available guidance can sometimes be ambiguous. The phrase ‘authorisation procedure’ is used here to denote the evaluation and decision-making procedure laid down in Articles 28-39 PPPR.

The authorisation procedure and communication and co-ordination between Member States is facilitated by three ‘zonal steering committees’ (zSC), one for each zone, and an ‘inter-zonal steering committee’ (izSC), not provided for in the Regulation. The zSCs are chaired by participating Member States on a yearly rotating basis and meet every two months ‘to discuss specific applications and issues arising which should be fed into the izSC. The izSC meets every two months and is attended by two representatives from each zSC. It discusses co-ordination between zones, with respect to, for example, which Member State evaluates which parts of

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<sup>109</sup> Article 29(6) PPPR; Uniform Principles (n 50).

<sup>110</sup> Recital 29 PPPR.

dossiers that are shared and the evaluation of applications which only require evaluation by one Member State on behalf of all zones, for example applications for the authorisation of PPPs for use in greenhouses etc. under Article 33(2)(b) PPPR. These meetings are chaired and organised by the Commission and participating Member States (Commission, 2014b, pp.5-6, Appendices 1 and 2). Such co-ordination and the efficiencies and harmonisation sought by the zonal authorisation system are facilitated by the EU's online Plant Protection Product Application Management System (PPPAMS). Applicants must submit their applications to Member States using PPPAMS, which works alongside national authorisation procedures rather than serving as a replacement.<sup>111</sup>

Articles 33-39 PPPR establish the evaluation and authorisation procedure. Article 33 sets out what an application for authorisation must contain and provides that an applicant wishing to place a PPP on the market must apply for authorisation (or amendment of an authorisation) to each Member State in which it intends to place the PPP on the market. Applications for authorisation must be made in the form of a 'draft Registration Report' ('dRR') (Commission, 2014b, p.9, 2009).<sup>112</sup>

In addition to the legislative requirements, guidance encourages applicants to notify, at least six months before an application is planned, all zonal contact points in Member States within the relevant zone with a summary of all PPPs for which authorisation will be sought and in which Member States (Commission, 2014b, p.7). Applicants are also advised to request pre-submission meetings with the envisaged 'zonal rapporteur Member State' (zRMS) to enable discussion between zRMS and applicant of the application, its potential problems, quality and strategy (Commission, 2014b, p.8). Again, the aim is efficient and swift operation of the zonal authorisation procedure (Commission, 2014b, p.7).

The applicant should propose which Member State it expects to evaluate the application in the relevant zone,<sup>113</sup> although this should have been proposed during pre-application (Commission, 2014b, p.7). Unless another Member State in the same zone agrees to examine the application, the proposed Member State will act as the zRMS and examine the application.<sup>114</sup> The Regulation does not oblige the zRMS to conduct a 'completeness check' of the application. However, the application requirements set out in Articles 33 and 34 imply its necessity and that where any requirement is missing, the application should not be accepted. Such a completeness check should be administrative, designed to establish the presence of all required elements and conducted within six weeks and within the overall timeframe for

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<sup>111</sup> For more detail, see

<[https://ec.europa.eu/food/plant/pesticides/authorisation\\_of\\_ppp/application\\_procedure\\_en](https://ec.europa.eu/food/plant/pesticides/authorisation_of_ppp/application_procedure_en)>, <[https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides\\_auth-ppp\\_app\\_procedure\\_first\\_authorisation\\_of\\_ppp\\_en.pdf](https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_auth-ppp_app_procedure_first_authorisation_of_ppp_en.pdf)> accessed 2 January 2018.

<sup>112</sup> Currently, as at the date of completion of this manuscript in March 2018, being updated.

<sup>113</sup> Article 33(2)(b) PPPR.

<sup>114</sup> Article 35 first paragraph PPPR.

evaluation. Final review and confirmation of decisions on work allocation pre-submission may be required (Commission, 2014b, p.10).

Under Article 35 second paragraph PPPR, the zRMS may request co-operation with other Member States in the same zone to 'ensure a fair division of the workload'. Under Article 35 third paragraph, other Member States in the same zone are prohibited from proceeding with the file pending assessment by the zRMS to avoid duplication of work (Commission, 2014b, p.4). Where an application has been made in more than one zone, the zRMSs are required to agree on which zRMS will evaluate the data not related to the environment and agricultural conditions (the core dossier) (Commission, 2014b, p.4; Article 35 fourth paragraph PPPR).

The zRMS must make an independent, objective and transparent assessment of the application 'in the light of current scientific and technical knowledge' using available guidance documents and allowing other Member States in the same zone to submit comments for consideration in the assessment.<sup>115</sup> It must apply the Uniform Principles<sup>116</sup> to establish whether the PPP meets the requirements provided for in Article 29 PPPR (above)<sup>117</sup> and must make its assessment available to the other Member States in the same zone (the 'concerned Member States' or 'cMS'). The zRMS has 12 months to decide whether or not the application meets the requirements for authorisation, although this period can be extended for a maximum of six months where the zRMS needs to request additional information from the applicant.<sup>118</sup> The zRMS may do this multiple times and must inform cMSs where it has requested additional information and the impact on the timeline (Commission, 2014b, p.11). The zRMS should also complete its initial assessment within eight months of submission to allow for cMS comments during a suggested period of six weeks (Commission, 2014b, pp.11, 13), leaving ten weeks for the final decision. The zonal dRR should also be sent to the applicant for its comments (Commission, 2014b, p.13). Comments should 'focus on critical issues that affect the risk assessment' (Commission, 2014b, p.13). Following receipt of comments, the zRMS should finalise their assessment and decide whether to grant or refuse authorisation (Commission, 2014b, p.13). The assessment should take the form of a Registration Report (RR) (Commission, 2014b, p.12). Where opinions differ on technical issues and compromise between the zRMS and cMS is not possible, this shall be recorded in the Reporting Table which is to be handled as a supplement to the RR 'for transparency reasons' (Commission, 2014b, p.13).

Where the zRMS is unable to deliver its assessment within the timeframe, it should alert the zSC which will consider whether re-allocation or assistance is possible and appropriate (Commission, 2014b, p.12).

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<sup>115</sup> Art 36(1) first paragraph PPPR.

<sup>116</sup> Uniform Principles (n 50).

<sup>117</sup> Article 36(1) second paragraph PPPR.

<sup>118</sup> Article 37(1) PPPR.

The cMSs are required to grant or refuse authorisations on the basis of the conclusions of the zRMS, including where the zRMS has concluded that the use of the relevant PPP is acceptable in the zone in principle but not in its own territory, due to its specific conditions (Commission, 2014b, p.14). Concerned Member States may still assess their own national requirements and impose appropriate conditions and 'other risk mitigation measures' in their own national authorisations.<sup>119</sup> Where such measures cannot control their concerns over human or animal health or the environment, a cMS may refuse authorisation 'if, due to its specific environmental or agricultural circumstances, it has substantiated reasons to consider that the product in question still poses an unacceptable risk...'.<sup>120</sup> In such cases, the cMS must immediately inform the applicant and Commission and 'provide a technical or scientific justification' for this decision to refuse authorisation'.<sup>121</sup> The cMSs are required to decide whether or not to authorise within 120 days of receipt of the assessment report and copy of the authorisation from the zRMS.<sup>122</sup> Member States are required to provide the possibility of challenging a refusal to authorise a PPP 'before national courts of other instances of appeal'.<sup>123</sup>

The zRMS is required to compile a file for each application containing, amongst other things, a copy of the application and a report with information on the evaluation of and decision on the PPP.<sup>124</sup> This file must be made available to the other Member States, the Commission and EFSA on request.<sup>125</sup>

Guidance raises the possibility of publishing the final RR 'to increase transparency and openness if legal provisions in the individual MS allow' (Commission, 2014b, p.14).

## **2. Evaluation and authorisation models in practice**

This section sets out the zonal evaluation and authorisation procedures reported by Member States in response to the Member State survey. We were reliant on the indulgence of busy CAs for information. The data are therefore sometimes uneven (different Member States provided different levels of detail), sparse and may be incomplete. Where possible, the data provided were cross-checked or supplemented with information gathered during the review of CA websites and other sources, predominantly a series of reports on audits of seven Member States conducted by DG SANTE in 2016-2017 (DG SANTE, 2017, p.1).<sup>126</sup> Some Member States neither responded to the survey, nor provide online information in English about their zonal authorisation procedures.<sup>127</sup> As such, it was not possible to report fully on these Member States. While some trends may be discerned, the picture presented below, therefore, is

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<sup>119</sup> Article 36(2) and (3) PPPR.

<sup>120</sup> Article 36(3) first and second paragraphs PPPR.

<sup>121</sup> Article 36(3) third paragraph PPPR.

<sup>122</sup> Article 37(4) PPPR.

<sup>123</sup> Article 36(4) PPPR.

<sup>124</sup> Article 39(1) PPPR.

<sup>125</sup> Article 39(2) PPPR.

<sup>126</sup> The Member States audited were: France, Germany, Lithuania, Luxembourg, Portugal, Spain and the UK. The report for Spain was unavailable.

<sup>127</sup> Although some websites appear to contain a lot of information in the native language.

inevitably incomplete. The following section begins with an account of the CAs for each Member State before describing the various stages in the authorisation procedure. In some instances, it was not entirely clear which body was the designated CA. These are indicated with square brackets in the tables below. Generally, national zonal authorisation procedures follow the overall shape of the procedure described in section VI.1.

## 2.1 Competent authorities

Article 75(1) requires Member States to ‘designate a competent authority or authorities to carry out the obligations of the Member States laid down in [the] Regulation’. Member States employ a variety of institutional structures as CAs.

### Northern zone

In **Lithuania**, the CA is the State Plant Service (SPS) under the Ministry of Agriculture and headed by a Director. It has responsibility for conducting the evaluation, risk assessment and decision-making. Within the SPS, the PPP Authorisation Division has responsibility for evaluation and preparation of decisions regarding PPP authorisation. Decisions are taken by the director of SPS (DG SANTE, 2016c, p.5). In **Denmark**, the CA is the Danish Environmental Protection Agency, which contains a Pesticides and Gene Technology Unit.<sup>128</sup> The **Estonian** CA is the Agricultural Board.<sup>129</sup> In **Finland**, the CA is the Finnish Safety and Chemicals Agency (Tukes).<sup>130</sup> It contains the Chemicals Department, which is responsible for ‘risk assessment, approvals and registration of plant protection products’.<sup>131</sup> In **Latvia**, the CA is the State Plant Protection Service (SPPS), a direct administrative institution subordinate to the Ministry of Agriculture,<sup>132</sup> managed by a director.<sup>133</sup> The Plant Protection Department is a unit within SPPS, incorporating four divisions: PPP Registration Division, PPP Evaluation Division, PPP Control Division and the Integrated Plant Protection Division.<sup>134</sup> KEMI, the Swedish Chemicals Agency, is the CA in **Sweden**. It is a supervisory authority under the Government.<sup>135</sup> It is headed by a Director-General and contains the Authorisation and Guidance Department which ‘evaluates applications concerning pesticides’.<sup>136</sup> In **Norway**, the CA is The Norwegian Food Safety Authority (NFSA), a governmental body.<sup>137</sup>

<sup>128</sup> <<http://eng.mst.dk/about-us/organisation/>> accessed 23 December 2017.

<sup>129</sup> § 21 Plant Protection Act RT I 2004, 32, 226.

<sup>130</sup> <<http://www.tukes.fi/en/Branches/Chemicals-biocides-plant-protection-products/Plant-protection-products/>> accessed 23 December 2017.

<sup>131</sup> <<http://www.tukes.fi/en/Tieto-meista/About-us-something/>> accessed 24 January 2018.

<sup>132</sup> s. 4(1) Plant Protection Law 1998.

<sup>133</sup> s. 4(2) Plant Protection Law 1998.

<sup>134</sup> <<http://www.vaad.gov.lv/english/about-us/plant-protection/structural-units-of-plant-protection-department.aspx>> accessed 23 December 2017.

<sup>135</sup> <<https://www.kemi.se/en/about-us/our-work>> accessed 23 December 2017.

<sup>136</sup> <<https://www.kemi.se/en/about-us/organisation>> accessed 24 January 2018.

<sup>137</sup> <[https://www.mattilsynet.no/language/english/plants/plant\\_protection\\_products/](https://www.mattilsynet.no/language/english/plants/plant_protection_products/)> accessed 23 December 2017.

	CA	Internal Structure	Status	Responsibilities
<b>Denmark</b>	Danish Environmental Protection Agency	Contains Pesticides and Gene Technology Unit		
<b>Estonia</b>	Agricultural Board			
<b>Finland</b>	Finnish Safety and Chemicals Agency (Tukes)	Contains Chemicals Department		Risk assessment, approvals and registration of PPPs
<b>Latvia</b>	State Plant Protection Service (SPPS)	Contains Plant Protection Department, incorporating four divisions: PPP Registration Division, PPP Evaluation Division, PPP Control Division and the Integrated Plant Protection Division. Managed by director.	Subordinate to Ministry of Agriculture	
<b>Lithuania</b>	State Plant Service (SPS)	Contains PPP Authorisation Division	Under Ministry of Agriculture	Evaluation, risk assessment and decision-making. PPP Authorisation Division of SPS responsible for evaluation and preparation of authorisation decisions. Decisions taken by Director of SPS.
<b>Norway</b>	The Norwegian Food Safety		Governmental body	

	Authority (NFSA)			
<b>Sweden</b>	Kemikalie- inspektionen (KEMI)	Headed by Director-General. Contains Authorisation and Guidance Department	Supervisory body under the Government	Agency head/ director responsible for decisions. Authorisation and Guidance Department evaluates applications.

Table 1: Northern zone competent authorities

Central zone

In **Austria**, the CA is the Federal Office for Food Safety (BAES), a subordinate agency of the Federal Ministry of Agriculture and Forestry, Environment and Water Management,<sup>138</sup> managed by a director. In the **Netherlands**, the CA is the Board for the Authorisation of Plant Protection Products and Biocides (Ctgb), a semi-autonomous agency whose PPP-related activities are overseen by the Ministry of Economic Affairs. The Ctgb consists of a Board and a Board Secretariat which ‘makes preparations – both scientific and administrative – for the decisions’.<sup>139</sup> In **Belgium**, the CA is the Service Plant Protection Products and Fertilizers (SPPPF) of the Directorate General for Animals, Plants and Food which is part of the Federal Public Service Public Health, Food Chain Safety and Environment (FPS-PHFCSE and SPPPF, 2016, p.3). It was difficult to identify the **Hungarian** CA. However, it appears to be the National Food Chain Safety Office (NFCO), within the Ministry of Rural Development and which contains the Directorate of Plant Protection and Soil Conservation (DPPSC).<sup>140</sup> The DPPSC incorporates the Departments of Authorisation and Evaluation. The former grants authorisations for PPPs; the latter ‘summarizes, analyzes and evaluates results of efficacy and residue trials carried out with PPPs..., prepares expert’s [sic] opinions, and prepares the registration documents for decision-making’.<sup>141</sup> In **Luxembourg**, the CA is the Minister of Agriculture, Viticulture and Consumer Protection (DG SANTE, 2016d, p.4). The CA in **Romania** appears to be the National Committee for PPP Approval (CNOPPP) (Government of Romania, 2013, p.7). In the **Czech Republic**, the CA is the State Phytosanitary Administration (SPA) which is subordinate to the Ministry of Agriculture and appears to be responsible for

<sup>138</sup> <<https://www.baes.gv.at/en/about-us/>> accessed 23 December 2017.

<sup>139</sup> <<https://english.ctgb.nl/about-ctgb/board-and-board-secretariat>> accessed 23 December 2017.

<sup>140</sup> <[http://www.ceureg.com/17/docs/presentations/IV\\_6\\_Milan%20Pancel.pdf](http://www.ceureg.com/17/docs/presentations/IV_6_Milan%20Pancel.pdf)> accessed 24 January 2018.

<sup>141</sup> <[http://portal.nebih.gov.hu/hu/web/english/hungarian-forest-management/-/asset\\_publisher/pHBk9pq6UNxK/content/directorate-of-plant-protection-and-soil-conservation/contacts](http://portal.nebih.gov.hu/hu/web/english/hungarian-forest-management/-/asset_publisher/pHBk9pq6UNxK/content/directorate-of-plant-protection-and-soil-conservation/contacts)> accessed 27 December 2017.

registration of PPPs, 'their testing and testing methods of plant protection, supervision of pesticide testing in the Czech Republic'.<sup>142</sup> In **Poland**, the CA appears to be the Department of Plant Breeding and Protection.<sup>143</sup>

In **Ireland**, the CA is the Department of Agriculture, Food and the Marine,<sup>144</sup> which contains the Pesticide Controls Division (PCD) and the Pesticide Registration Division (PRD) (together, the Pesticides Registration and Control Division (PRCD)). The PCD is responsible for implementing the Regulation. The PRD contains five expert units whose scientists evaluate pesticides.<sup>145</sup> **Germany** has designated four CAs: Federal Office for Consumer Protection (BVL) Federal Research Centre for Cultivated Plants (JKI), the Federal Institute for Risk Assessment (BfR) and Federal Environment Agency (UBA). BVL is responsible for co-ordinating the evaluation and authorisation of PPPs and along with JKI and BfR sits under the aegis of the Federal Ministry of Food and Agriculture. UBA sits under the Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety (DG SANTE, 2016a, p.4). In **Slovenia**, the CA is the Administration of the Republic of Slovenia for food safety, veterinary and plant protection (UVHVVR), which is a body within the Ministry of Agriculture, Forestry and Food and contains a PPP Division.<sup>146</sup> In **Slovakia**, the CA is the Department of Pesticide Registration (ORP),<sup>147</sup> within the Central Control and Testing Institute in Agriculture (ÚKSÚP), which is 'a national budget organization directly managed by the Ministry of Agriculture'.<sup>148</sup> In the **UK**, the CAs are the Secretary of State for Environment, Food and Rural Affairs (England and Wales), the Scottish Ministers (Scotland)<sup>149</sup> and the Department of Agriculture, Environment and Rural Affairs (DAERA) (Northern Ireland) (DG SANTE, 2016f, p.5). The English, Welsh and Scottish CAs' functions, in relation to PPPs, are delegated to the Health and Safety Executive (HSE). The HSE is an Executive Non-Departmental Public Body of the Department for Work and Pensions (DWP)<sup>150</sup> and contains the Chemicals Regulation Division (CRD) (DG SANTE, 2016f, p.5). The CRD is responsible for the evaluation and authorisation of PPPs and also acts as the delivery body for DAERA.<sup>151</sup>

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<sup>142</sup> <<http://eagri.cz/public/web/en/srs/portal/about-us/>> accessed 23 December 2017.

<sup>143</sup> <<http://www.minrol.gov.pl/eng/Ministry/Departments-and-offices/The-Department-of-Plant-Breeding-and-Protection>> accessed 23 December 2017.

<sup>144</sup> <<http://www.pcs.agriculture.gov.ie/plantprotectionproducts/>> accessed 27 December 2017.

<sup>145</sup> <<http://www.pcs.agriculture.gov.ie/aboutus/whatareourresponsibilities/>> accessed 24 January 2018.

<sup>146</sup> <[http://www.uvhvvr.gov.si/en/about\\_the\\_authority/organisation/](http://www.uvhvvr.gov.si/en/about_the_authority/organisation/)> accessed 23 December 2017.

<sup>147</sup> <<http://www.uksup.sk/orp-cinnost/>> accessed 23 December 2017.

<sup>148</sup> <<http://www.uksup.sk/charakteristika>> accessed 23 December 2017.

<sup>149</sup> Reg. 3 Plant Protection Product Regulations 2011.

<sup>150</sup> Framework Document Between The Health and Safety Executive and The Department for Work and Pensions 2016, 2016 para. 1.1.

<sup>151</sup> <<https://www.daera-ni.gov.uk/articles/departmental-responsibilities-regarding-pesticides>> accessed 27 December 2017.

	CA	Internal Structure	Status	Responsibilities
<b>Austria</b>	Federal Office for Food Safety (BAES)	Managed by Director	Subordinate agency of the Federal Ministry of Agriculture and Forestry, Environment and Water Management	
<b>Belgium</b>	Service Plant Protection Products and Fertilizers (SPPPF)		Part of Directorate General for Animals, Plants and Food which is part of Federal Public Service Public Health, Food Chain Safety and Environment	Federal Minister of Public Health responsible for decisions.
<b>Czech Republic</b>	State Phytosanitary Administration (SPA)		Subordinate to Ministry of Agriculture	Registration of PPPs, 'their testing and testing methods of plant protection, supervision of pesticide testing in the Czech Republic'
<b>Germany</b>	Federal Office for Consumer Protection (BVL), Federal Research Centre for Cultivated Plants (JKI), the Federal Institute for Risk Assessment (BfR) and Federal		BVL, JKI and BfR: under Federal Ministry of Food and Agriculture. UBA: under Federal Ministry for the Environment, Nature Conservation, Building and Nuclear Safety	BVL: co-ordinating the evaluation and authorisation of PPPs. Agency head/director responsible for decisions.

	Environment Agency (UBA).			
<b>Hungary</b>	[National Food Chain Safety Office]	Contains the Directorate of Plant Protection and Soil Conservation which contains the Departments of Authorisation and Evaluation		Department of Authorisation grants authorisations. Department of Evaluation evaluates applications and prepares documents for decision-making.
<b>Ireland</b>	Department of Agriculture, Food and the Marine	Contains the Pesticide Controls Division (PCD) and Pesticide Registration Division (PRD) (together PRCD)		PCD responsible for implementing Regulation. PRD responsible for evaluation.
<b>Luxembourg</b>	Minister of Agriculture, Viticulture and Consumer Protection			
<b>Netherlands</b>	Board for the Authorisation of Plant Protection Products and Biocide (Ctgb)	Board and Board Secretariat	Semi-autonomous agency. PPP-related activities overseen by Ministry of Economic Affairs.	Board Secretariat 'makes preparations – both scientific and administrative – for the decisions'. Board of Commissioners is responsible for decisions.

<b>Poland</b>	[Department of Plant Breeding and Protection]			
<b>Romania</b>	National Committee for PPP Approval (CNOPPP)			
<b>Slovakia</b>	Department of Pesticide Registration (ORP)		Within Central Control and Testing Institute in Agriculture (ÚKSÚP), which is 'a national budget organization directly managed by the Ministry of Agriculture'	
<b>Slovenia</b>	Administration of the Republic of Slovenia for food safety, veterinary and plant protection (UVHVVR)	Contains PPP Division	Body within Ministry of Agriculture, Forestry and Food	
<b>UK</b>	Secretary of State for Environment, Food and Rural Affairs (England and Wales), Scottish Ministers (Scotland), Department of Agriculture, Environment and Rural Affairs (DAERA) (N. Ireland).	CA functions delegated to Health and Safety Executive (HSE). Contains Chemicals Regulation Division (CRD). HSE: overseen by Board.	HSE: Executive non-Departmental Public Body of Department for Work and Pensions	CRD: evaluation and authorisation of PPPs

Table 2: Central zone competent authorities

### Southern zone

In **Bulgaria**, there are two CAs:<sup>152</sup> the Bulgarian Food Safety Agency (BFSA)<sup>153</sup> which operates under the Minister of Agriculture and Food and the Centre for Risk Assessment on Food Chain (CRAFC). BFSA is headed by an executive director, proposed by the Minister of Agriculture and Food and appointed by the Prime Minister.<sup>154</sup> In **Cyprus**, the CA appears to be the Agrochemicals Control Section of the Department of Agriculture, within the Ministry of Agriculture, Rural Development and Environment.<sup>155</sup> In **Italy**, the CA is Office VII of the Directorate General for Food Hygiene, Food Safety and Nutrition (DGFFHFSN) within the Ministry of Health (DG SANTE, 2016b, p.4). In **France**: the CA is French Agency for Food, Environmental and Occupational Health and Safety (ANSES) which is responsible for assessing the efficacy and risks of PPPs and for their authorisation. However, to ensure the independence of ANSES's scientific expertise, the risk assessment and risk management stages are institutionally separate, the former performed by the Regulated Products Assessment Department (DEPR) and the latter by the Marketing Authorisation Department (DAMM) within ANSES (ANSES, 2015, pp.6–8). The Director General is authorised to issue marketing authorisations (ANSES, 2015, p.5). In **Spain**, it was extremely difficult to determine with certainty the CA but there seemed to be a large amount of information, in Spanish, about PPP authorisation on the website of the Ministry of Agriculture and Fisheries, Food and Environment.<sup>156</sup> In **Greece**, searches for the CA were inconclusive. The Ministry of Rural Development and Food (MRDF) appears to contain the Department of Plant Protection Products and Biocides (DPPPB), the Directorate of Plant Produce Protection (DPPP) and the General Directorate of Sustainable Plant Produce (DGSPP).<sup>157</sup> However, it is unclear where the responsibility lies. In **Malta**, the CA is the Technical Regulations Division, within the Malta Competition and Consumer Affairs Authority (MCCAA).<sup>158</sup> A Minister-appointed Pesticides Control Board advises the Director of the MCCAA on *inter alia*, matters relating to the registration of pesticides.<sup>159</sup> In **Croatia**, the CA is the Ministry of Agriculture. In **Portugal**, the CA is the General Directorate for Agricultural and Veterinary Affairs (DGAV), with responsibility for authorisation assumed by the Pesticides Division of the Sanitary and Defence Directorate (DG SANTE, 2016e, p.5).

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<sup>152</sup> Communication from the Bulgarian Centre for Risk Assessment on Food Chain.

<sup>153</sup> <[http://www.babh.government.bg/en/Page/about\\_us/index/about\\_us/About%20us](http://www.babh.government.bg/en/Page/about_us/index/about_us/About%20us)> accessed 23 December 2017.

<sup>154</sup> Communication from EPRS.

<sup>155</sup> <[http://www.moa.gov.cy/moa/da/da.nsf/page29\\_en/page29\\_en?OpenDocument](http://www.moa.gov.cy/moa/da/da.nsf/page29_en/page29_en?OpenDocument)> accessed 23 December 2017.

<sup>156</sup> <<http://www.mapama.gob.es/es/agricultura/temas/sanidad-vegetal/productos-fitosanitarios/registro/menu.asp>> accessed 23 December 2017.

<sup>157</sup> (DG SANTE, 2015, p.5) See also, <[http://www.minagric.gr/syspest/syspest\\_menu\\_eng.aspx](http://www.minagric.gr/syspest/syspest_menu_eng.aspx)> accessed 24 January 2018. However, a different arrangement is suggested here: <[http://www.minagric.gr/images/stories/en\\_docs/ministry/organogramma\\_apostolou121217\\_eng.pdf](http://www.minagric.gr/images/stories/en_docs/ministry/organogramma_apostolou121217_eng.pdf)> accessed 24 January 2018.

<sup>158</sup> s. 4 Plant Protection Products (Implementation) Regulation 2011.

<sup>159</sup> Article 10 Pesticides Control Act 2001.

	CA	Internal Structure	Status	Responsibilities
<b>Bulgaria</b>	Bulgarian Food Safety Agency (BFSA) and Centre for Risk Assessment on Food Chain (CRAFC)	BFSA headed by executive director	Under Minister of Agriculture and Food	
<b>Croatia</b>	Ministry of Agriculture			
<b>Cyprus</b>	[Agrochemicals Control Section]		Part of Department of Agriculture, within Ministry of Agriculture, Rural Development and Environment	
<b>France</b>	French Agency for Food, Environmental and Occupational Health and Safety (ANSES)	Contains Regulated Products Assessment Department (DEPR) and Marketing Authorisation Department (DAMM)		ANSES: assessing efficacy and risks of PPPs. Authorisation decisions. DEPR: risk assessment. DAMM: risk management. Director General issues marketing authorisations
<b>Greece</b>	[Department of Plant Protection Products and Biocides (DPPPB) and the Directorate of Plant Produce		DPPP is within Directorate-General of Sustainable Plant Production (DGSP) of the Ministry of	

	Protection (DPPP)]	Rural Development and Food (MRDF)
<b>Italy</b>	Office VII of the Directorate General for Food Hygiene, Food Safety and Nutrition (DGFHFSN)	Within the Ministry of Health
<b>Malta</b>	Technical Regulations Division	Within Malta Competition and Consumer Affairs Authority
<b>Portugal</b>	General Directorate for Agricultural and Veterinary Affairs (DGAV)	Contains Pesticides Division of the Sanitary and Defence Directorate
<b>Spain</b>	[Ministry of Agriculture and Fisheries, Food and Environment]	

Table 3: Southern zone competent authorities

As the above information demonstrates, Member States employ a variety of institutional structures for their CAs. Some opt for an agency structure, favoured by Scandinavian Member States and several Member States in other zones. Others choose divisions, services or offices within the relevant ministries or government departments or provide that ministries or departments themselves are the CA. In still other Member States, the CA may be an individual minister or secretary of state. There seems to be no discernible trend or preference for particular structures according to zone. However, CAs seem largely to operate within, or are overseen by, a ministry, government department or the government generally. This would suggest such CAs are semi-independent.

## 2.2 Pre-application

Only the **Netherlands** reports conducting pre-submission meetings with applicants, noting that ‘this meeting has a positive effect on the quality of the dossier submitted’.<sup>160</sup> However, it appears from the website review and zSC survey that in the **UK**,<sup>161</sup> **Belgium** (FPS-PHFCSE and SPPPF, 2016, p.9). **Czech Republic** (SPA, n.d., pp.4–5) **Germany** (BVL, 2012, p.5) and all Northern and Central zone Member States and **Portugal**<sup>162</sup> at least, such meetings are also available.<sup>163</sup> However, not all applicants request them.<sup>164</sup> Almost half of all Member States require advance notification (usually six months) of intention to apply for authorisation (**Belgium** (FPS-PHFCSE and SPPPF, 2016, p.5), **Netherlands**,<sup>165</sup> **Czech Republic** (SPA, n.d., p.4), **UK**,<sup>166</sup> **Germany**<sup>167</sup> **Slovenia**<sup>168</sup> and all **Northern zone** Member States (Northern zone, 2017, p.8)) in accordance with the guidance (above).<sup>169</sup> One Southern zone Member State reports that different Member States in the Southern zone have different methods for accepting applications, based on the resources available and the need to comply with deadlines in the Regulation: some operate a ‘first come, first served’ policy up to an annual limit; others accept applications on a trimestral or annual basis. National plant protection priorities may also be a consideration in the acceptance of applications.

## 2.3 Completeness check and allocation for evaluation

Following submission of the application, based on the website review and Member State survey responses, about a third of Member States appear to conduct a completeness check, or variation thereof.<sup>170</sup> The **UK**, for example, subjects applications to a two-stage sift involving a validation check to determine whether the application is complete and a detailed technical sift

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<sup>160</sup> Member State survey response.

<sup>161</sup> <<http://www.hse.gov.uk/pesticides/topics/pesticide-approvals/pesticides-registration/applicant-guide/the-applicant-guide-zonal-a.htm>> accessed 27 December 2017.

<sup>162</sup> Zonal Steering Committee survey responses.

<sup>163</sup> Such information was not available in English for the remaining Member States.

<sup>164</sup> SZSC survey response.

<sup>165</sup> <<https://english.ctgb.nl/plant-protection/types-of-application/procedure-zonal-application>> accessed 27 December 2017.

<sup>166</sup> <<http://www.hse.gov.uk/pesticides/topics/pesticide-approvals/pesticides-registration/applicant-guide/the-applicant-guide-zonal-a.htm>> accessed 27 December 2017.

<sup>167</sup>

<[https://www.bvl.bund.de/EN/04\\_PlantProtectionProducts/03\\_Applicants/04\\_AuthorisationProcedure/01\\_FormsTemplates/ppp\\_FormsTemplates\\_node.html](https://www.bvl.bund.de/EN/04_PlantProtectionProducts/03_Applicants/04_AuthorisationProcedure/01_FormsTemplates/ppp_FormsTemplates_node.html)> accessed 3 January 2018

<sup>168</sup>

<[http://www.uvhvvr.gov.si/en/areas\\_of\\_competence/plant\\_protection\\_products/authorisation\\_of\\_ppps/authorisation\\_and\\_permits\\_for\\_ppps/authorisation\\_of\\_ppps\\_in\\_zones/#c18302](http://www.uvhvvr.gov.si/en/areas_of_competence/plant_protection_products/authorisation_of_ppps/authorisation_and_permits_for_ppps/authorisation_of_ppps_in_zones/#c18302)> accessed 3 January 2018.

<sup>169</sup> Such information was not available in English for the remaining Member States.

<sup>170</sup> Such information was not available in English with respect to Austria, Belgium, Estonia, Hungary, Luxembourg, Poland, Romania, Slovenia, Slovakia, Sweden and all the Southern zone Member States.

to determine whether the application is of sufficient quality to undergo full evaluation.<sup>171</sup> These decisions are peer reviewed by a senior officer.<sup>172</sup> In the **Netherlands**,<sup>173</sup> risk assessors each check the part of the application which relates to their area of expertise (e.g. ecotoxicology, residues, efficacy, etc.). Some Member States may reject incomplete applications at this stage and require re-submission (for example, **UK**,<sup>174</sup> **Netherlands**); others imply that applicants may still submit the additional information required (**Germany** (BVL, 2012, p.9), **Czech Republic** (SPA, n.d., p.7), **Sweden**,<sup>175</sup> **Belgium** (FPS-PHFCSE and SPPPF, 2016, p.3), **Portugal**,<sup>176</sup> the **Netherlands** (where the missing information can be easily supplied)<sup>177</sup> and one Northern zone Member State).<sup>178</sup> One Southern zone Member State indicates that different Southern zone Member States may start counting down towards the deadline at different times, for example from receipt of application or confirmation of completeness. One Central zone Member State reports that decisions at this stage are peer reviewed by a senior officer. Some Member States (**UK**,<sup>179</sup> **Sweden**,<sup>180</sup> **Netherlands**,<sup>181</sup> and two Central and one Southern zone Member State) appoint a project manager or equivalent to see the application through the authorisation procedure.<sup>182</sup> The **UK** provided more detail about this role, stating that they guide the application through the procedure, communicate with the applicant, co-ordinate the specialist evaluations, collate final documentation and seek comments from other Member States. It is their responsibility to ensure delivery to cost, regulatory quality and adherence to the legal deadline. These project managers appear to perform valuable functions in terms of keeping procedures on track, co-ordination and communication. As such, they form an example of best practice. Overall, with respect to this aspect of the procedure, there seem to be no zone-specific models; there are examples of these procedures in all zones.

## 2.4 Evaluation

At the evaluation stage, the divergence between procedures is slightly greater, although they do largely consist of one or more phases of evaluation, during which additional information

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<sup>171</sup> <<http://www.hse.gov.uk/pesticides/topics/pesticide-approvals/pesticides-registration/applicant-guide/the-applicant-guide-zonal-a.htm>> accessed 27 December 2017.

<sup>172</sup> Member State survey response.

<sup>173</sup> Member State survey response.

<sup>174</sup> <<http://www.hse.gov.uk/pesticides/topics/pesticide-approvals/pesticides-registration/applicant-guide/the-applicant-guide-zonal-a.htm>> accessed 27 December 2017.

<sup>175</sup> <<https://www.kemi.se/en/directly-to/apply-for-authorisation/this-is-how-we-handle-your-application>> accessed 3 January 2018.

<sup>176</sup> Member State survey response.

<sup>177</sup> <<https://english.ctgb.nl/plant-protection/assessment-framework/registration-manual/how-we-handle-application>> accessed 27 December 2017.

<sup>178</sup> Such information was not available in English for the remaining Member States.

<sup>179</sup> <<http://www.hse.gov.uk/pesticides/topics/pesticide-approvals/pesticides-registration/applicant-guide/the-applicant-guide-zonal-a.htm>> accessed 27 December 2017.

<sup>180</sup> Member State survey response.

<sup>181</sup> Member State survey response.

<sup>182</sup> Such information was not available in English for the remaining Member States.

may be requested from applicants. Some respondents provided fairly generic information about their evaluation processes along the lines that during this stage, applications are allocated to the relevant experts and additional information may be sought from applicants. Online information in English about this aspect of the procedure was either unavailable or very limited in most Member States.<sup>183</sup> Available detail (either online or from the Member State survey) is presented below. However, without full access to the information in native languages on CA websites, it is impossible to establish a full picture of the zonal authorisation procedures in operation and their diversity or similarity both across Europe and within each zone.

#### Northern zone

In **Sweden**, evaluation is conducted in-house by the Authorisation and Guidance Department of KEMI<sup>184</sup> (chemists, ecotoxicologists, fate experts and toxicologists, with agronomists and legal advisors in support<sup>185</sup>) and involves assessment of the health and environmental risks of the PPP and evaluation of efficacy (with agronomists at the National Board of Agriculture) and residues (with toxicologists at the National Food Agency).<sup>186</sup> '[S]upplementary documentation' may be requested if necessary.<sup>187</sup> KEMI's website states that if, during evaluation, it appears that an application must be rejected or authorised subject to stricter conditions than those applied for, the applicant will be informed before that decision is taken and given an opportunity to express its views.<sup>188</sup> In **Lithuania**, assessment of the application, including risk assessment for human and animal health, is conducted by the Plant Protection Product Authorisation Division of the SPS.<sup>189</sup> In **Latvia**, the PPP Registration and Environment and Ecotoxicology Divisions prepare assessments as to the compliance of PPPs with the requirements of regulation.<sup>190</sup> In **Norway**, NFSA assesses the possible environmental and health risks of PPPs and assesses whether the product is 'agronomically effective'.<sup>191</sup>

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<sup>183</sup> Austria, Bulgaria, Croatia, Cyprus, Denmark, Estonia, Finland, Greece, Hungary, Ireland, Italy, Latvia, Luxembourg, Malta, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain.

<sup>184</sup> <<https://www.kemi.se/en/about-us/organisation>> accessed 27 December 2017.

<sup>185</sup> Member State survey response.

<sup>186</sup> <<https://www.kemi.se/en/directly-to/pesticides-and-biocides/plant-protection-products>> accessed 27 December 2017; survey response.

<sup>187</sup> Member State survey response.

<sup>188</sup> <<https://www.kemi.se/en/directly-to/apply-for-authorisation/this-is-how-we-handle-your-application>> accessed 27 December 2017.

<sup>189</sup> <<http://www.vatzum.lt/en/activity/fields-of-activity/plant-protection-products-authorisation/>> accessed 27 December 2017.

<sup>190</sup> <<http://www.vaad.gov.lv/english/about-us/plant-protection/structural-units-of-plant-protection-department.aspx>> accessed 27 December 2017.

<sup>191</sup> <

[https://www.mattilsynet.no/language/english/plants/plant\\_protection\\_products/authorisation\\_of\\_plant\\_protection\\_products.20905](https://www.mattilsynet.no/language/english/plants/plant_protection_products/authorisation_of_plant_protection_products.20905)> accessed 27 December 2017.

### Central zone

In **Belgium**, the Authorisation Committee for pesticides for agricultural use (which meets at least once a month (FPS-PHFCSE and SPPPF, 2016, p.4)) and other services and experts, including the Belgian Scientific Institute for Public Health and the Agronomic Research Centre of Gembloux, evaluate each section of the application and perform a risk assessment according to 'agreed European models/Guidance documents'.<sup>192</sup> The expert reports are emailed to the applicant as soon as they are available. Any additional information received will be evaluated by the Authorisation Committee during a meeting, after which further information may be requested (FPS-PHFCSE and SPPPF, 2016, p.16). The conclusions drawn are then examined by an Advisory Board (the Registration Committee).<sup>193</sup> In **Germany**, 'assessment authorities' (BVL, BfR, JKI and UBA) (BVL, 2012, pp.5-6) engage in an initial evaluation of the application. This is followed by 'Assessment phase I' during which the assessment authorities may request additional information from the applicant. 'Assessment phase II' follows submission of this additional information and culminates in the assessment authorities providing a decision on 'consent and their assessments' i.e. their contributions to the dRR (BVL, 2012, p.6). Evaluation is performed by in-house scientific advisers'.<sup>194</sup> In the **Netherlands**, risk assessors in the Board Secretariat assess the risk of the PPP in their respective areas ('fate and behaviour, ecotoxicology, human toxicology, residues, efficacy and physical properties and analytical methods'). Each risk assessor group is peer reviewed. Applicants may be requested to submit additional information.<sup>195</sup> In the **Czech Republic**, two institutions are involved in the authorisation of PPPs: the Czech SPA and the Czech Ministry of Health. The former evaluates ecotoxicology, fate and behaviour, physical chemical properties and efficacy and makes the authorisation decision. The latter contracts evaluation of toxicology, operator exposure and residues out to the Czech National Institution of Public Health which supplies both with its report (SPA, n.d., p.5). The SPA may request further information (SPA, n.d., p.7).

In **Slovenia** evaluation begins with a meeting amongst 'external evaluators from designated institutions [and the dossier is] divided among different parts of evaluation and discussed'. Next the individual evaluations are completed in the form of the zonal registration report and uploaded to a national central documentary programme and the co-ordinator informed.<sup>196</sup> In **Slovakia**, the ORP appears responsible for assessment of PPPs and dossier evaluation.<sup>197</sup> In the **UK**, accepted applications are placed into the appropriate stream. During or after an initial evaluation (occurring in weeks 0-30) a maximum of two requests for additional information may be made, the first generally relating to chemistry, toxicology, residues and fate and behaviour and the second generally relating to operator exposure, ecotoxicology and efficacy.

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<sup>192</sup> Member State survey response.

<sup>193</sup> Member State survey response.

<sup>194</sup> Member State survey response.

<sup>195</sup> Member State survey response.

<sup>196</sup> Member State survey response.

<sup>197</sup> <<http://www.uksup.sk/orp-cinnost/>> accessed 27 December 2017.

In weeks 30-43, this additional information is evaluated.<sup>198</sup> In **Austria**, '[a]ssessment reports and opinions of AGES<sup>199</sup> experts in the fields of toxicology, residue behaviour, environmental fate and ecotoxicology, efficacy and phytotoxicity as well as physico-chemical properties and analytical methods form the basis for the decision on authorisation'.<sup>200</sup> In **Ireland**, evaluation appears to be conducted by the Pesticide Registration Division, which contains 'five expert units consisting of the Chemistry Unit, Ecotoxicology Unit, Efficacy Unit, Environmental Fate & Behaviour Unit and the Toxicology Unit. The expert units are made up of Agricultural Scientists, Biologists, Micro-biologists, Chemists, Ecotoxicologists and Toxicologists'.<sup>201</sup>

#### Southern zone

In **France**, assessment of the application is conducted by DEPR on the basis of studies provided by the applicant in support of their applicant, data from wider literature, ANSES studies and from vigilance and surveillance schemes (ANSES, 2015, p.7). There may be communication with the applicant for further information or clarification. In another Southern zone Member State, the 'detailed evaluation' culminates in a meeting between all experts involved to compare conclusions on different areas of evaluation and define any data gaps, leading to a request for additional information from the applicant and evaluation of the additional data provided. In **Portugal**, following the detailed evaluation, all experts meet to compare the conclusions of their respective evaluations. Any data gaps are defined and requested from the applicant. Once received the additional data are evaluated.

Member States employ a range of services and experts to evaluate applications. Those indicated by respondents are summarised in table 4.

<i>Which of the following evaluates the application?</i>	<i>Individual civil servants</i>	<i>Individual in-house scientific advisers</i>	<i>Individual external experts/consultants</i>	<i>An expert advisory committee</i>	<i>Other</i>
	3	9 Including: Belgium, Germany,	6 Including: Belgium, Netherlands	4 Including: Belgium	1

<sup>198</sup> <<http://www.hse.gov.uk/pesticides/topics/pesticide-approvals/pesticides-registration/applicant-guide/the-applicant-guide-zonal-a.htm>> accessed 27 December 2017.

<sup>199</sup> Austrian Agency for Health and Food Safety.

<sup>200</sup> <<https://www.baes.gv.at/en/plant-protection-products/authorisation-of-plant-protection-products/authorisation-procedure/>> accessed 23 December 2017.

<sup>201</sup> <<http://www.pcs.agriculture.gov.ie/aboutus/whatareourresponsibilities/>> accessed 27 December 2017.

Netherlands, Sweden
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Table 4: Services and experts involved in evaluation

## 2.5 Commenting

The evaluation procedures described above result in the production of a dRR which is sent to the cMSs and applicant for comments. It is on the basis of these comments that the RR is finalised. This process is, indeed, reported by most respondents to the Member State survey and/or described online, although limited or no information about this stage is available in English for many Member States.<sup>202</sup> In **France**, the DEPR ‘endorses a document called “Conclusion of the assessment”, which specifies, for each criterion of the uniform principles, whether or not the result complies with the requirements of European regulations’ and supports the authorisation decision. This is a summary of the RR, part of which is published on ANSES’s website, in the interests of transparency along with the ‘Conclusions’ (ANSES, 2015, p.7). **Slovenia** reports that all comments from Member States ‘are addressed’. **Sweden** reports that ‘all comments will be taken under consideration and the evaluation changed if necessary’.<sup>203</sup> The **Netherlands** reports that the ‘dRR is amended based on the comments. A final risk assessment is drafted with the same peer review within the risk assessors groups’.<sup>204</sup> One Southern zone Member State reports that any comments are provided to the experts who ‘evaluate any emerging data-gaps based on comments received’. Additional information is again requested from the applicant where necessary and evaluated when received. Two other Member States (one Central and one Southern) report similar procedures. In the **Czech Republic**, ‘the SPA processes the other Member States’ comments and incorporates any amendments to the evaluation report highlighted by those comments. The SPA records in the reporting table which observations were incorporated, and which were not’ (SPA, n.d., p.8). In **Portugal**, cMS comments are provided to experts who ‘evaluate any emerging data gaps based on comments received’. Further information is then requested from applicants.<sup>205</sup> This additional information is then evaluated. One Southern zone Member State reports disagreement among Southern zone Member States over whether further information provided in response to requests after the commenting stage require a further round of commenting, which may result in deadlines being missed.

## 2.6 Conclusion of evaluation and authorisation decision-making

Once comments have been received and addressed and the final RR produced, a final decision on authorisation is made. Again, available information indicates that Member States operate

<sup>202</sup> Austria, Bulgaria, Croatia, Cyprus, Denmark, Estonia, Finland, Greece, Ireland, Italy, Latvia, Lithuania, Luxembourg, Norway, Poland, Romania, Slovakia and Slovenia, Portugal, and Spain.

<sup>203</sup> Member State survey response.

<sup>204</sup> Member State survey response.

<sup>205</sup> One Southern zone Member State reports that several Southern zone Member States make such requests.

according to slightly different structures and procedures. However, again limited or no information is available in English in many Member States.<sup>206</sup>

#### Northern zone

In **Sweden**, senior officers meet to discuss the conditions of use which will be included in the authorisation, or reasons for rejection, as applicable. The applicant is then granted an opportunity to comment on 'factual issues' related to the suggested conditions of use or reasons for rejection. Any comments are taken into consideration. Finally, 'the decision is then signed normally by one of the senior officers attending the... meeting and the person responsible for the application'.<sup>207</sup> **Latvian** legislation suggests that the decision is taken by the SPPS.<sup>208</sup> In **Lithuania**, while the PPP Authorisation Division is responsible for the preparation of decisions regarding PPP authorisation, decisions are ultimately taken by the Director of the SPS (DG SANTE, 2016c, p.5).

#### Central zone

In the **Netherlands**, the final RR is submitted to the Board of the Ctgb with non-binding advice as to authorisation or rejection of the application and, 'when applicable mitigating measures or amendments of the authorisation'.<sup>209</sup> The Ctgb website elaborates: the Secretariat of the Ctgb prepares and submits a draft decision to the Board of the Ctgb which checks the decision to make sure it is correct before deciding whether or not to authorise the PPP and on conditions of use.<sup>210</sup> In **Belgium**, the dossier is again placed on the agenda of the Authorisation Committee which produces a final RR and decision on authorisation (FPS-PHFCSE and SPPPF, 2016, p.16). In the **Czech Republic**, the SPA compiles the decision proposal and sends it to the applicant with a 'summary of how the SPA dealt with the applicant's comments to the evaluation report' including grounds for not accepting any comments. The applicant is allowed ten days to comment. 'The coordinator incorporates any observations into the decision granting or refusing marketing authorisation for the plant protection product (SPA, n.d., p.8). In **Germany**, the BVL compiles the comments of Member States and the applicants and sends them to JKI, UBA and BfR 'for consideration for the final assessment'. On this basis the BVL compiles the final RR. If a refusal seems likely, the applicant is allowed a hearing (BVL, 2012, p.7). BVL is required to make the decision on authorisation in consultation with JKI and BfR and in agreement with UBA. Thus, BVL and UBA share competence in risk management, entailing decision-making by consensus (DG SANTE, 2016a, p.5). In **Slovenia**, '[t]he body competent for plant protection products... within the Ministry competent for agriculture... shall decide on the authorisation..., based on consensus granted by the administrative body responsible for

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<sup>206</sup> Austria, Bulgaria, Croatia, Cyprus, Denmark, Estonia, Finland, Greece, Hungary, Ireland, Italy, Lithuania, Luxembourg, Malta, Norway, Romania, Poland, Portugal, Slovakia, and Spain.

<sup>207</sup> Member State survey response.

<sup>208</sup> S. II.5, Cabinet Regulation (LV) No. 509 Adopted 24 July 2012 "Regulations Regarding the Placing on the Market of Plant Protection Products According to Regulation No 1107/2009".

<sup>209</sup> Member State survey response.

<sup>210</sup> <<https://english.ctgb.nl/plant-protection/application-process>> accessed 23 December 2017.

chemicals'.<sup>211</sup> UVHVVR adopts the authorisation decision in agreement with the Chemicals Office within the Ministry of Health.<sup>212</sup> The **UK** notes that where Member States have differing opinions on technical issues, the zRMS and cMS shall try to reach a compromise. Where this is not possible, it will be recorded in a Reporting Table and included as a supplement to the RR, for transparency. Ultimately, the zRMS makes the decision.<sup>213</sup> Authorisations are granted by the CRD of the HSE, on behalf of Ministers.<sup>214</sup> Applicants are given written reasons for a refusal.<sup>215</sup>

#### Southern zone

In **France**, authorisations are prepared by the Marketing Authorisations Decisions unit in DAMM, supported where necessary by the Marketing Authorisations monitoring committee and ANSES guidelines on the criteria for authorisation (ANSES, 2015, p.8). In **Portugal**, the final RR is provided to the cMSs and applicant along with the national authorisation decision and approved draft label. One Southern zone Member State reports that some Southern zone Member States rely on the authorisation decision of the zRMS (Part A of the final RR) without any change, while others issue national Part As.

The nature of the expert advice provided to decision-makers varies between Member States, with six Member States (including **Sweden**) reporting that it was binding and four (including **Belgium** and the **Netherlands**) reporting that it was 'purely consultative'. **Belgium** elaborated that its Advisory Board 'may overrule a risk assessment conclusion, by means of well-argued solution [sic] in order to reach an acceptable risk for which the evaluation was negative', though health and environmental protection remain the priority. One reports in-house scientific advice was binding but that any advice from its expert advisory committee was consultative. No trend with respect to individual zones emerged.

Despite the sparsity and incompleteness of the data, one or two tentative observations may be made with respect to trends within zones. Firstly, in the Northern zone, evaluation seems largely to be conducted in-house in the CA, whereas in the Central zone, there are more examples of evaluation activities being conducted by one or more bodies and there was one example of this in the Southern zone. Secondly, in the Northern zone, decisions appear largely to be made, or at least signed, by the CA director or senior officer(s). In the Central zone, there

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<sup>211</sup> Article 5(2) Plant Protection Products Act (ZFFS-1) (UL RS 83/12), available at <[http://www.uvhvvr.gov.si/en/legislation\\_and\\_documents/plant\\_protection\\_products/si\\_legislation/](http://www.uvhvvr.gov.si/en/legislation_and_documents/plant_protection_products/si_legislation/)> accessed 24 January 2018.

<sup>212</sup> <

[http://www.uvhvvr.gov.si/en/areas\\_of\\_competence/plant\\_protection\\_products/authorisation\\_of\\_ppps/authorisation\\_and\\_permits\\_for\\_ppps/](http://www.uvhvvr.gov.si/en/areas_of_competence/plant_protection_products/authorisation_of_ppps/authorisation_and_permits_for_ppps/)> accessed 23 December 2017.

<sup>213</sup> <<http://www.hse.gov.uk/pesticides/topics/pesticide-approvals/pesticides-registration/applicant-guide/the-applicant-guide-zonal-a.htm>> accessed 27 December 2017.

<sup>214</sup> <<http://www.hse.gov.uk/pesticides/topics/pesticide-approvals/pesticides-registration.htm>> accessed 27 December 2017.

<sup>215</sup> <<http://www.hse.gov.uk/pesticides/topics/pesticide-approvals/pesticides-registration/applicant-guide/what-happens-once-my-application-is-completed.htm>> accessed 24 January 2018.

were more examples of decision-making shared, or a requirement for consensus, between bodies. Data for the Southern zone are too limited to support a similar observation.

Otherwise, Member State practice during evaluation and authorisation is characterised by difference. Member States employ a diversity of institutional structure for their CAs. Most Member States appear to conduct completeness checks but these checks operate differently; for example, they may consist of one or two stages and some may reject incomplete applications at this stage while others may still accept submission of missing data. During evaluation, Member States may differ in terms of the numbers of authorities examining applications, the type and timing of communication with applicants and the structure of their evaluation, for example requests for more information from applicants may occur before or after the commenting stage. Finally, during completion of the evaluation and final decision-making, Member States may differ in terms of where responsibility lies for the preparation of the final registration report and for the ultimate decision, the availability to the applicant of opportunities to comment on, or attend a hearing with respect to, the final decision and the nature of the advice on which the decision is based.

## 2.7 Zonal system

DG SANTE's 2016-2017 audit concluded that the zonal system was 'not working effectively' and that most Member States were not using the system as envisaged by the Regulation (DG SANTE, 2017, pp.I, 18). It identified various problems. Member States generally neither take advantage of work done by each other nor implement work-sharing systems (DG SANTE, 2017, p.5). This was attributed mainly to lack of use of harmonised methods and models for evaluation or the existence of additional national data requirements to address specific national conditions which make Member States reluctant to accept each other's evaluations (DG SANTE, 2017, pp.7-8). A variety of guidance documents covering certain areas of PPP evaluation is available on the Commission website.<sup>216</sup> However, it appears that some areas are still to be agreed (see, for example Commission, 2017, p.2) and that some guidance is unable to cover every possible scenario and instead recommend evaluation on a case by case basis (see, for example EFSA Panel on Plant Protection Products and their Residues (PPR), 2012, p.4). The consequences of the lack of use of harmonised methods and models are delays (DG SANTE, 2017, p.18), a huge duplication of evaluation work and failure to free-up resources. These findings were largely echoed by the **CZSC secretariat**<sup>217</sup> and the Stakeholder, which notes 'a serious imbalance between Member States in their resources'. It reports specifically that duplication results from a lack of trust between Member States which would require time to improve, though it did observe that the number of specific national data requirements was declining. Furthermore, imbalances in the numbers of applications submitted between Member States combined with difficulties of co-operation and work-sharing 'undermine the

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[https://ec.europa.eu/food/plant/pesticides/approval\\_active\\_substances/guidance\\_documents\\_en#dar](https://ec.europa.eu/food/plant/pesticides/approval_active_substances/guidance_documents_en#dar)> accessed 3 April 2018.

<sup>217</sup> CZSC survey response.

aim of the Regulation to ensure a fair division of the workload' (DG SANTE, 2017, p.9), as envisaged by Article 35 second paragraph PPPR.

The results from the Member State and zSC surveys paint a slightly more optimistic picture, indicating that despite problems, Member States seem to be making productive and frequent use of the zonal system. The **CZSC secretariat** notes that its Member States are still transitioning from 'operating individually to operating as a zone' and that while this could not be achieved in the space of 5 years, could be achieved in the longer term. The Stakeholder too considers that the Regulation is encouraging coherence among zonal authorisation procedures 'to a great extent' noting that work-sharing within zones has now exceeded that achieved under Directive 91/414/EEC. It also recognises that 'Member States to a large extent have the desire to improve harmonisation'.

Member States were asked how often they communicate with other Member States during the zonal authorisation procedure. Eight report they communicate 'often' while three selected 'sometimes'. Only one selected 'rarely' and none selected 'never'. Furthermore, 11 out of the 12 respondents find the zonal system/work of the zSC either 'very helpful' (eight) or 'quite helpful' (three). Only one finds it 'neither helpful nor unhelpful'.

Table 5 indicates the range of reasons for communication with the zone. In addition, **Sweden** comments that Member States consult on interpretation of the Regulation. Another Member State reports that the conference calls every two months are used to 'discuss procedural issues and future work planning'. The **Netherlands** reports use of the zonal system to share knowledge and expertise, 'safeguard the quality' and promote co-operation, which it notes has intensified recently. In addition, it reports the establishment of a Directors Conference which backs up voluntary co-operation by ensuring 'Member States commit to the agreements'.

<i>Reason for communication</i>	<i>Advice</i>	<i>Expert support</i>	<i>Technical support</i>	<i>Exchange research practices</i>	<i>Peer review</i>	<i>Share information about application</i>	<i>Regarding comparative assessment</i>	<i>Discuss market-related issues</i>	<i>Other</i>
	6	8	5	1	9	9	3	3	1
	Inc.	Inc.	Inc.						
	Sweden	Germany	Sweden						
		Sweden							

Table 5: Reasons for communication within zones

Member State comments generally indicate a positive attitude towards the zonal system. Seven Member States comment on the role the zonal system has played in harmonising evaluation methods and other procedures between Member States.

**Sweden**/the **NZSC secretariat** comment that the zonal system has enabled the workload to be shared in a way that was not possible before, that it has resulted in better evaluations and swifter authorisation of PPPs and that the zonal system helps highlights areas of disagreement. The **Netherlands** too sees it as a mechanism for facilitating resolution of disagreements and

predicts the system will eventually lead to more efficient use of available capacity amongst CAs. Likewise, the **CZSC secretariat** reports that zonal discussion helps solve problems and disagreements over risk assessment methodologies and specific dossiers, leading to an ‘increasingly cooperative assessment and authorisation practice’. The **SZSC secretariat** reports similar benefits. **Sweden** also reports biennial harmonisation workshops in the Northern zone since 2010 leading to development of Northern zone guidance documents (for example, Northern zone, 2017) (which state harmonised and un-harmonised approaches) including guidance on biological efficacy.<sup>218</sup> The **NZSC secretariat**, in addition, reports coming ‘very far’ in terms of harmonisation and collaboration, ‘better cooperation between experts’, citing regular teleconferences between experts within the areas of expertise, facilitating harmonisation and resolution of ‘difficult evaluation issues’.

The **CZSC secretariat** elaborates, commenting that the zonal system provides an ‘effective peer review process, which greatly improves the credibility of the assessment and safeguards its quality’ and that it promotes co-operation, improves communication and collaboration between Member States. It identifies various achievements which support these activities, including the 2017 establishment of a secretariat to maintain continuity across rotating chairs, establishment of a Director’s Consultation Group to ‘exchange information and reach agreements at a higher level’ and the regular zonal teleconferences and annual meetings. Furthermore, the system improves mutual understanding of each other’s approaches to risk assessment, enabling discovery of harmonised solutions. It feels the Central zone is on course to achieve the aims of the zonal system (avoiding duplication of work, reducing administrative burden on industry and providing more harmonised availability of PPPs)<sup>219</sup> but notes room for improvement.

**Belgium** also notes the role of the zonal system in simulating work-sharing. Another (**Southern zone**) Member State reports it ‘[g]ain[s] experience and knowledge on what is happening in the zone’. The **Netherlands** notes the establishment of working agreements since 2014, development of an inventory of best practices and work on harmonising implementation of guidance documents. Another **Central zone** Member State reports quarterly meetings attended by many Member States ‘to discuss procedural issues and devise new guidance to promote harmonisation’. It also reports that scientists ‘meet frequently but less regularly to discuss shared issues and develop new harmonised guidance’, noting that ‘[h]armonised guidance is essential and has led to major efficiency gains’.

Challenges identified include informing other (Northern zone) Member States about delays,<sup>220</sup> inconsistent implementation of harmonised guidance by Member States which can undermine the processing of zonal applications and the existence of additional, specific national requirements.<sup>221</sup> Indeed, **Germany** notes that the zonal system only works ‘if Member States

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<sup>218</sup> NZSC survey response.

<sup>219</sup> Recital 29 PPPR.

<sup>220</sup> Swedish Member State survey response.

<sup>221</sup> Anonymous survey response (Central zone).

work together towards harmonisation both in procedure and assessment'. In addition, the **NZSC secretariat** reports difficulties in finding out about the progress of an evaluation and whether delays are occurring, though it feels that overall, timelines are kept 'relatively well' in the Northern zone. The **CZSC secretariat** also reports problems with keeping to legal timeframes. Finally, the **SZSC secretariat** reports problems associated with the timing of publication of different parts of the final RR: the applicant is informed of the completion of the evaluation and grant of authorisation by the zRMS while the cMSs only receive the final RR, required for their national decisions, from the zRMS later. It reports, furthermore, that some zRMSs publish different parts of the final RR at different times, sometimes subject to a delay following grant of the authorisation.

Further challenges identified by the **CZSC secretariat** include heavy workload due to large numbers of applications and, despite a desire among all Member States for extensive harmonisation, difficulties achieving harmonisation. The latter it attributed to national level refinement in environmental risk assessment methodologies in guidance documents, existence of national requirements and the fact that the Central zone spans different EPPO zones. The workload, it notes, depends on applicant choice of zRMS and reports difficulty in assessing the fairness of workload distribution due to national differences in agriculture and sizes of Member States and their CAs.

The **SZSC secretariat** identifies several specific challenges, including the following. Firstly, the existence of nationally-specific risk mitigation measures. This, it states, is being addressed by the development of harmonised risk mitigation measures which may be used across the entire zone but adapted to specific national conditions. Secondly, it reports different approaches among Member States to efficacy assessment. Some do not follow Articles 29(1)(a) and 4(3)(a) PPPR and EPPO guidelines on minimum effective dose and do not base authorisation on the efficacy of the uses applied for and the minimum dose for the acceptable efficacy. There is no scope under Article 36(3) PPPR for cMSs to introduce national requirements in relation to efficacy, meaning that cMS CAs have no choice but to authorise uses of PPPs that they would not authorise as zRMS due to the lack of a demonstration of minimum effective dose. Finally, the **SZSC secretariat** reports difficulties due to changes in guidance documents and endpoints relevant to the assessment of PPPs resulting from confirmatory data, which occur during evaluation. This causes incompatibility between the approval conditions of the active substance and the grounds on which a PPP is evaluated and delays, where a reassessment is triggered. It recommends that such changes not be applied to PPPs already under assessment.

The matter of resources was often raised. The **NZSC secretariat** reports that while many Member States are small, with limited resources, there is an attempt to share work fairly and that Member States are open with each other about their resource problems. Likewise, the **CZSC secretariat** reports that not all CAs have the financial wherewithal to accommodate increased demand, though it too attempts to distribute the workload fairly. The **SZSC secretariat** argues that an unforeseen consequence of the zonal system was an increase in the costs associated with co-ordination within the zone. It reports, further, that smaller Member States receive roughly the same number of applications as larger Member States 'meaning that

even as Concerned MS or for Mutual Recognition, the resources are stretched thin just to grant authorisations'. Thus, the **SZSC secretariat** does not regard the overall administrative burden as having been reduced. However, it praised the practice whereby the applicant contacts prospective zRMS to determine their willingness to receive a new application. This, it argues, benefits applicants as they do not wish to submit applications to reluctant CAs and benefits CAs as only those able and willing will receive applications. It also comments on the quality of RRs. It reports the need, with respect to RRs from some zRMSs, for cMSs to scour the entire document to discover the reasoning behind a particular conclusion/authorisation condition and to ascertain whether any limitations imposed by the zRMS result from national specific requirements (permitted under Article 36(3) PPPR) or from EU requirements to act on such national specific requirements. Both require expert resources which could be better employed elsewhere.

ZSC secretariats were asked whether Member States trusted each other and each other's evaluations. The **NZSC secretariat** reports '[g]enerally, there is trust between NZ MS'. Disagreements over evaluations are solved 'by direct contact with the zRMS or via teleconferences'. Non-harmonised areas and possible areas of mistrust are discussed and resolved during the annual updating of the Northern zone guidance document. The **CZSC secretariat** attributed mistrust to national differences in methodologies and models used for evaluation, leading to work duplication and different decisions. The **SZSC secretariat** reports differing levels of trust (measured according to the extent to which Member States comment on dRRs) among Southern zone Member States, which it attributes largely to available resources.

The Stakeholder feels that the Northern and Southern zones are working 'quite well' but that the Central zone is working 'very badly'. It links the level of functioning of each zone to the level of similarity between the zone's Member States, attributing the poor functioning of the Central zone to 'high variability in agricultural and climatic conditions, as well as the variety in the size and experience level in' CAs and more national data requirements and competing risk assessment methodologies, representing a greater challenge than that faced by either of the other two zones. It notes the Southern zone is 'making progress' in terms of harmonisation. It cites language as a problem in all zones and also notes that the 'drafting and quality' of RRs could be improved, reporting that publication of all RRs in one language - English - would benefit all. It also suggests that European funding to support co-ordination would accelerate the improvement of the zonal system.

Finally, the Stakeholder feels that the inter-zonal system is working 'quite badly'. This, it attributes to a lack of priority from Member States already struggling to meet challenges at the zonal level. It notes significant differences in approach even in those areas where harmonising is possible, for example, uses under 'controlled conditions'.<sup>222</sup> The **NZSC secretariat** also

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<sup>222</sup> It is assumed the Stakeholder is referring to those uses specified in Article 33(2)(b) (including use in greenhouses, as post-harvest treatment etc.) where only one Member State need evaluate the application for all zones.

reports co-operation at this level is 'more challenging as there is not much harmonisation and communication between the zones' and that the inter-zonal system in particular can always work better, for example, in terms of harmonisation and efficiency.

The challenges identified are not surprising from a theoretical point of view. The functions of such networks of national regulators may include the spread of regulatory practices across Europe, sharing information and best practices, regulatory convergence (for example common approaches to implementation and development of best practice) and co-operation (Groenleer, 2011). However, the retention of discretion by national regulators (here, for example, over national data requirements) and a lack of mutual trust may limit the harmonisation achievable through co-operation (Groenleer, 2011, p.557), despite attempts to overcome mistrust between Member States, described above. Furthermore, the activities of regulatory science (i.e. science used in regulatory decision-making (Jasanoff, 1990, pp.76-79)) are deeply embedded in national regulatory systems, culture and relations (Rothstein et al., 1999, pp.252-253). Writing in the context of harmonisation of evaluation procedures under Directive 91/414/EEC,<sup>223</sup> Rothstein et al. argue that such harmonisation and standardisation present a challenge for, and even a threat to, the conduct of national regulatory science. Conversely, national regulatory science can act as a barrier to the implementation of harmonised procedures (Rothstein et al., 1999, p.256). The Stakeholder echoes these observations, reporting 'a lot of variation' between Member State zonal authorisation procedures which it attributed to national differences in government structures, financing systems and involvement of external evaluation bodies. It feels complete harmonisation is unrealistic but noted 'much room for improvement'.

### **3. Summary and recommendations**

The picture of the zonal system which emerges is that of both significant progress and significant challenges and even frustration.<sup>224</sup> Both Member States and the Stakeholder appear to value the zonal system for the potential it offers for work-sharing; improved harmonisation, co-operation and collaboration; promotion of mutual understanding; resolution of disagreements etc., and acknowledge the benefits both for Member States and industry that it has so far provided. On the other hand, significant delays persist as a result of the challenges, some of which are regarded as due to unavoidable differences in environmental conditions.<sup>225</sup> Communication between Member States could still be improved and problems relating to the timing of publication and sharing of RRs have been identified. Unsurprisingly, a major challenge is adequate resourcing of CAs. While the zonal system is partly designed to ease the burden of work on CAs, the workload may still be substantial and, despite attempts to share work fairly, may be unevenly distributed. In addition, co-ordination within the zonal system itself and scrutinising RRs (especially poorer quality RRs) require resources. Finally, establishing trust between different CAs has long been difficult (Rothstein et al., 1999, pp.257-258) and remains so, despite evidence of headway. The zonal system is clearly a work in

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<sup>223</sup> Council Directive 91/414/EEC (n 5).

<sup>224</sup> Stakeholder survey response.

<sup>225</sup> Stakeholder survey response.

progress and will likely require a significant amount of effort on the part of Member States to improve its functioning. However, early signs are promising.

Due to the stage of development of the zonal system, as well as the quality of the data currently available, it may also be too early to draw any concrete conclusions about its operation. For example, it is not yet possible to identify the convergence of diverse procedures within the zones towards zonal models for evaluation and authorisation. Although some similarities may be discerned between Member States within zones, these are not strong and overall, diversity and difference largely characterise the institutions and procedures examined in this section.

The zonal system is complex and improvements in its operation, for example, harmonisation and work-sharing, will take time, as the **CZSC secretariat** notes (above). Member States are working on these matters and making progress. It will also take time to build the trust necessary to support greater harmonisation and more efficient operation. Given the potential barriers to trust between Member States (for example, differences in national regulatory science, language or (perceived) resource inadequacies) continued trust-building and even the continuation of the status quo are not necessarily guaranteed.

### Recommendations

Further, longer-term (external) qualitative and quantitative empirical research is recommended to understand better the operation of the zonal system, the challenges each zone faces, how these may be overcome and the potential for improving evaluation and the overall authorisation process. Such research could identify further examples of best practice with a view to promoting sharing and policy learning among Member States. For example, it was unclear whether all Member States assign project managers to manage applications. Further research could investigate Member State experience with the use of project managers and whether, for example, they reduce the occurrence of delays.

**Member States** are encouraged to continue communicating and working together in their zones and to step-up activities designed to improve harmonisation of, for example, methods and models for evaluation and to achieve fairer work-sharing with the aim of strengthening trust between each other. **Chairs of zSCs/zSC secretariats** are encouraged to take particular responsibility for co-ordinating and pushing forward these activities. The **Southern zone**, particularly, could consider introducing guidelines or other measures both governing the timing of RR publication and to improve efficacy assessment within the zone.

Information about, and understanding of, the zonal system more generally could be improved in order to provide an evidence base for possible future action and support. The **Commission** is therefore advised to continue monitoring the zonal system, including stakeholder experiences of the zones, in order to keep track of its progress. The **Commission** and **zSCs** are also encouraged to consider whether it would be feasible and valuable for zSCs to report (for example, annually) to the Commission on progress in their

zones. The Commission is encouraged to provide support, for example financial and administrative, for the production of such reports to ensure their quality. In the interests of transparency, any such reports should be made publicly available.

## VII – Results and discussion

### 1. Independence

As described in section V.1, the questions on independence were divided into four categories: formal independence from government; independence from the regulated industry; organisational autonomy and substantive independence. These questions were also prefaced by three general questions concerning the formal independence of the CA, who is responsible for CA decisions regarding PPP authorisations and the professional background of the current agency head/commissioners. Eleven Member States report that the ‘independence of the competent authority [was] formally stated either in legislation or in the statute of the competent authority’. The final Member State reports that it was not but commented that ‘[t]hose working for the competent authority are bound by the Civil Service Code, which requires (*inter alia*) that they are impartial’. Two Member States report that a Board of Commissioners was responsible for decisions and seven report that the agency head/director was responsible. Of the latter, **Sweden** reports that in practice responsibility for most decisions was delegated to officers of the authority. One reports that responsibility lay with the ‘[e]xpert team evaluating the application incl. their co-ordinator. The Head is only signing the decision prepared [sic]’. It notes further that the decision ‘always follows the conclusions of experts’. **Belgium** reports that the Federal Minister of Public Health was responsible. One Southern zone Member State reports that decisions are sub-delegated to the Deputy Director-General responsible for phytosanitary issues.

The structures of the CAs reported correspond to the categories regulators generally fall into (Larsen et al., 2006, p.2862), being led either by commissions or boards, or by an agency head or director. As discussed in section II.3, it is likely that the decision-making of commissions will lean towards more compromise and consensus than the decision-making of an agency head,<sup>226</sup> although this may not necessarily produce better decisions (Graham, 1998, p.506). Commissioners and board members tend to be experts in different relevant areas. Agency heads tend more to have backgrounds as civil servants (Larsen et al., 2006, p.2862). The two Member States (from the Central and Southern zones) with commission-type CAs did indeed report professional backgrounds of the commissioners in relevant specialist areas. Member States with agency-type CAs (from all zones) report professional background predominantly

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<sup>226</sup> Although note discussion in sub-section VII.2.6 and below in relation to substantive independence, that some Member States require decisions to be made on the basis of consensus *between* different bodies even if the CA itself is an agency with a single head, for example, **Germany**.

in natural sciences, especially plant-related, agricultural, business and management, civil service or law.

### 1.1 Formal independence from government

These questions concerned the status of the agency head/commissioners. One respondent simply referred to its national civil service code in response to these questions and **Belgium** indicated that these questions were not relevant for a Minister. Therefore, the responses of the remaining ten Member States are reported here. In seven Member States agency heads/commissioners are appointed for fixed terms (six of 4-6 years, one of 1-3 years). Q25 asked Member States about the provisions regarding dismissal of the agency head/commissioners. In no Member States is dismissal impossible. However, in four Member States agency heads/commissioners are protected to a certain extent from dismissal during their term; dismissal is only possible 'for reasons unrelated to the substance of authorisation decisions [such as] economic interests in the PPP industry, significant neglect of duties etc.'. Six respondents report that there were no specific provisions for dismissal or that 'dismissal was possible at the appointer's discretion'. Of these, **Germany** reports the position is 'subject to general regulations for civil servants'. Thus, while more than half appeared to accept that independence is enhanced by fixed-term appointments, fewer than half report some protection from dismissal. In addition, most Member States allow appointments to be renewed,<sup>227</sup> which could create incentives to act to please the appointers (Johannsen, 2003, p.45), and potentially reduce independence.

In terms of appointment of the agency head/commissioners, there was a fairly even spread across the various range of appointers: a mix of the legislature and executive: two; the legislature: one; the executive collectively: two; one or two ministers: three. There was no discernible pattern within zones. **Germany** reports the appointer of the President of the CA (BVL) is the Federal Ministry of Food and Agriculture which, as a ministry would probably form part of the executive; the President then appoints the head of the PPP department in BVL. One Member State identified 'the Government' as the appointer. Involvement of the legislature helps ensure independence (Smith, 1997). However, only three in total report its involvement.

In nine Member States, independence is a formal requirement for the appointment and in eight, regulators are prohibited from holding other offices in government. In one this is permitted 'with the permission of the executive'. Only in the **Netherlands** is this possible but is apparently subject to strict conditions relating to conflicts of interest and ongoing monitoring.<sup>228</sup>

Member States were also asked one question relating to substantive, as opposed to formal, independence, i.e. the independence of the CA's actual decision-making. They were asked: '[t]o what extent is the competent authority responsible for the authorisation of new PPPs under the zonal authorisation procedure?'. Eight Member States report that the CA is 'solely

<sup>227</sup> Two once, and five more than once. In the other three, positions have no fixed term.

<sup>228</sup> Detail provided in the Netherlands Member State survey response.

responsible'; three (all Central zone) report that the CA 'shares decision-making power with another institution'. Of the three, **Belgium** notes that 'regional authorities are represented in the Authorisation Board' which makes the decision. One comments that a negative conclusion from its Ministry of Health, which evaluates the effects of the PPP on human health would result in a rejection of the application. **Germany** declined to answer the question, referring instead to the three assessment authorities (JKI, BfR and UBA). As stated in section VI.2.6, BVL decides on authorisation in consultation with JKI and BfR and in agreement with UBA. Thus, BVL and UBA share competence in risk management, entailing decision-making by consensus (DG SANTE, 2016a, p.5).

The Stakeholder comments that CAs may be pressured by their governments in response to 'heavy lobbying from anti-pesticide civil society organisations' although it noted this was more common during EU level of evaluations of active substances. It believes, however, that some governments 'issue legislation that ignores or goes beyond the EU PPPR'.

As the discussions in this section and section VI.2.1 show, several CAs are located within government departments or ministries and therefore may be described as 'semi-independent' of government (Thatcher, 2002a, p.129). Although this research has not compared regulator structures in pesticides regulation with other regulatory domains, other comparative research has identified lower levels of delegation to fully independent IRAs in social regulation (including pesticides regulation) than in economic regulation (Gilardi, 2005, p.85), so this result is perhaps not surprising. It also does not necessarily mean that regulation is unreliable as a result. As discussed in sections I and II.3, formal independence does not automatically guarantee fair and reasonable decision-making (Stern, 1997, pp.72-74); for instance, it may be more important that regulators build a reputation for decision-making with these qualities regardless of institutional structure.

## 1.2 Independence from regulated industry

Independence from the regulated industry may be enhanced by 'maximis[ing] the relational distance from the industry' through prohibiting former employees of industry from being appointed regulators (Johannsen, 2003, p.45). Three (Central zone) Member States employ this measure with respect to the agency head/commissioners while six allow appointments from industry/industrial associations. One (Southern zone) Member State reports it has no specific provisions. No Member States allow the agency head/commissioners to be employed in the regulated industry or industrial associations during their term.

Independence from industry during the appointment may also be enhanced by restricting a regulator's freedom to accept jobs in industry on expiry of their appointment. Only one (Northern zone) Member State reports prohibiting the agency head/commissioners from accepting positions in industry for one or more years following their term, while **Germany** reports that due to the civil service status of the agency head, 'any paid activity after retirement [is] subject to approval by the agency'. Seven Member States report no provisions restricting

employment of the agency head/commissioners in industry following their term.<sup>229</sup> There is some correlation between the power to appoint from industry and the absence of restrictions on employment in industry following the term. Of the Member States exhibiting this correlation, **Sweden** reports that previous employment in industry ‘could be regarded as a disqualification’ according to Swedish administrative law and that conclusion of an employment agreement prior to the end of the term could also be a violation of Swedish administrative law. The **Netherlands** reports that previous employment in industry (and in NGOs or other organisations in this sector, e.g. farmers organisations) ‘in practice... is a reason for rejection in the selection of Board members or head of agency’ and that again ‘in practice [employment in industry following the term] does not happen as it is a violation of the spirit of our integrity code’. There is a trade-off here. While restrictions on appointing former industry employees and on post-appointment industry employment can reinforce independence from industry, it may hinder appointment of regulators with the necessary expertise (Gönenç, Maher and Nicoletti, 2000, p.43).

In eight Member States, there are provisions forbidding the agency head/commissioners from having any personal or financial interest in the PPP industry (seven in relation both to the appointment and individual cases; one in relation to individual cases). Only two (both Southern zone) report no such provisions. Two Member States referred to their policy on conflicts of interest, including annual monitoring.

The Stakeholder considers that CAs are independent from industry/PPP manufacturers in the sense that it is not aware of any CAs in which industry representatives have a vote in authorisation decisions. This answer appears to interpret the requirements for independence rather more narrowly than the approach adopted in this report. The Stakeholder also confirms that opportunities for communication between evaluators and applicants are many.<sup>230</sup> Stakeholders were asked, additionally, whether they believed CAs were independent of civil society organisations (CSOs) which campaign on pesticides. The Stakeholder believes most CAs are but indicated a belief that ‘[s]ome Member States respond in a non-scientific manner to pressure from CSOs by demanding more data than scientifically warranted, or by taking measures that serve political purposes rather than rational ones’. All **zSC secretariats** report a belief that the CAs in their zones are independent of government, industry and green CSOs. Such responses are perhaps unsurprising and it is at least open to question whether zSC secretariats would in fact report any concerns about the independence of CAs in their zones.

It is not unheard of for direct interaction between regulators and the regulated industry to be restricted, for example through a ban on discussions of pending cases (Johannsen, 2003, p.47). However, as discussed in section VI.2, such direct interaction is a key feature of the PPP authorisation process and encouraged. On the one hand, this may lead to efficiency gains and, depending on the nature of the interaction, may help overcome some challenges associated with asymmetric information (Johannsen, 2003, p.47). On the other hand, such ongoing

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<sup>229</sup> One Member State (in addition to the two already mentioned) did not answer this question.

<sup>230</sup> It noted that this was to discuss the results of risk assessment submitted in response to CA requests.

interaction may reduce the relational distance between regulator and industry. As discussed in section II.2, repeated interaction may increase the risk of ‘cultural capture’ whereby the regulator adopts a viewpoint favourable to industry through, *inter alia*, increasing identification with industry interests. That said, as discussed in section VII.2.3, in practice the level of communication between applicants and CAs may vary across the EU. However, **France** appears to be taking steps to address the risks of exposure to attempts by interested parties to influence its CA’s decision-making process (ANSES, n.d., p.1). ANSES has stated it is drawing up a ‘charter on relations with interest groups, to prevent any risk of interference in the Agency’s assessment and decision-making processes, while remaining faithful to its willingness to engage in dialogue’ (ANSES, 2015, p.4). The charter is designed to achieve equity of access for interested parties, guaranteed expression of a plurality and diversity of points of view, transparency and the traceability of interventions and increased awareness amongst staff about interactions with interested parties (ANSES, n.d.). These steps, if implemented well, offer an example of good practice and are therefore worth attending to. Greater understanding of ANSES’s experience with this charter and its success (or otherwise) would be a valuable aim for further research, especially with a view to assessing its potential for adoption by other CAs.

### 1.3 Organisational autonomy

As discussed in section II.3, for regulators to operate independently from the government and legislature, they require a degree of organisational autonomy and exemption from direct control (e.g. overruling its decisions) or indirect control (e.g. cutting its budget) (Johannsen, 2003, p.48). Regulatory independence may be partially guaranteed by exceptions from state budget regulation and restrictive civil service salary rules (Johannsen, 2003, p.48; Smith, 1997). External funding (e.g. a fee levied on applicants) is regarded as more stable than government funding as it may protect authorities from both general cut-backs and politically motivated budget cuts (Johannsen, 2003, p.48) although, as discussed in section II.3, dependence on industry for funding may compromise CA independence from industry. Based on the Member State survey and website review, overall it appears that at least ten Member States, across all zones, levy fees.<sup>231</sup> Seven Member States report that the source of their budget is the Government. Of these, one reports that the fees levied on applicants only cover costs and are not a source of income. **Germany** reports that fees levied on applicants are directed to the Government. The Stakeholder reports a belief that diversion of fees to central budgets occurs much more widely which it believes prevents the relevant CAs from contributing adequately to work-sharing within zones. This is an interesting insight. However, its accuracy would have to be investigated through further empirical research. Five Member States report their budgets derive from a combination of Government and external funding. Of these, the **Netherlands** reports that external funding makes up 85% of its budget; 70% from application fees and 15% from an annual fee levied on all authorisation holders. In addition, DG SANTE found, in its audit, that four Member States (of the eight audited) have decided not to recover costs. It also revealed delays or the lack of a system to update fees to reflect the actual costs involved in the

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<sup>231</sup> As provided for by Article 74(1) PPPR; see section II.3.

authorisation process (DG SANTE, 2017, p.3). These data suggest therefore, fairly low levels of autonomy in this respect due to CA funds deriving largely from government.

Three more questions related to organisational autonomy: who controls budgetary spending, who decides the CA's internal organisation (procedures, allocation of responsibility, tasks etc.) and who is in charge of the CA's personnel policy (recruitment, promotion, salaries). In response to the first two questions, nine Member States selected 'the competent authority' while three selected 'the competent authority and government in co-operation'. In response to the last question, five selected each of the 'competent authority' and 'the competent authority and government in co-operation' while two selected 'the government'. Three Member States referred to some kind of government policy/guidelines governing salaries. **Germany** noted that salary is based on the general civil service pay scale. The **Netherlands** reports that 'salaries... must fulfil the governmental requirements'. This is noteworthy as autonomy over personnel policy is regarded as a defining characteristic of regulatory independence (Johannsen, 2003, p.50; Smith, 1997). Four were fully autonomous according to these three criteria; three from the Central zone, one from the Northern zone.

#### 1.4 Resources

The final category of questions relates to the resources and capacities of CAs. Adequate in-house technical expertise can reduce information asymmetry and counter the risk of regulatory capture and adequate remuneration can facilitate recruitment and retention of such qualified professional staff (Smith, 1997).<sup>232</sup> While most of these questions were designed to gain an insight into the operational challenges CAs face they may also contribute to an understanding of the challenges of information asymmetry (along with targeted questions), which do relate to regulator independence.

Eleven Member States report that their CA's budget is 'adequate to fulfil its duties with respect to the zonal authorisation procedure'. One Member State reports it is not. One Member State did not respond. Nine Member States consider that their CA's 'operational resources support an effective and efficient authorisation procedure'. Three do not. One of these (Southern zone) cites a lack of specialised human resources as the reason.

Q37 concerned available expertise and asked whether the CA possesses sufficient in-house expertise (experts, knowledge, e.g. access to databases, etc.) in all the areas necessary to evaluate the application in house (including comparative assessment) (or access to such expertise from external sources) to make the authorisation decision. Eight Member States report they had sufficient in-house expertise in all or most of the necessary areas. **Sweden** notes it consults 'other agencies in their areas of expertise: Swedish Board of Agriculture for efficacy and National Food Administration for residues'. The **Netherlands** comments that the Ctgb has contracted external scientists, depending on workload. It indicates that it may seek second opinions from other institutions, including universities. Although external experts may bolster regulator independence through the provision of independent advice, academics are still

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<sup>232</sup> See section II.3.

vulnerable to capture (Zingales, 2014). With respect to comparative assessment, the Dutch Inspection Service performs the agricultural assessment on the Ctgb's behalf. One (Southern zone) reports it has sufficient in-house expertise in some of the necessary areas, commenting that evaluation of zonal applications is outsourced to experts. Another (Southern zone) reports it has no in-house expertise but has access to external expertise and one (Central zone) reports it has neither in-house expertise nor access to external expertise. One did not select an answer, instead leaving a comment, the meaning of which was, unfortunately, unclear. Two report deficiencies in expertise. Overall, there is much variation in the levels of in-house expertise and access to external expertise among Member States.

Q41 posed a similar question in relation to technical resources and asked whether the CA possesses or has access to sufficient technical equipment/processes necessary for evaluation and the authorisation decision. Five (all Central zone) Member States report they possess/have access to sufficient, or most of the, technical equipment/processes necessary. Of these, **Germany** comments that BVL has a laboratory but notes its inability to analyse certain types of substance and gaps in its ability to determine various properties of substances. One (Southern zone) Member State reports it possesses/has access to some of the technical equipment/processes and comments that it lacks IT platforms and laboratory capacity for formulation analysis. One Southern zone Member State reports it does not possess/have access to the necessary technical equipment/processes. Five report the question was not relevant, of which **Sweden** comments it does not need to do any technical work during evaluation as this is the responsibility of applicants pre-authorisation.

Three further questions attempted to focus more specifically on information asymmetry. With respect to recruitment, four Member States report that it is 'quite easy' to recruit staff with the necessary expertise, technical skills and experience. However, one of these (**Sweden**), comments that it is 'generally difficult to find' staff with experience specifically in risk assessment of PPPs and regulatory issues. Three report it is 'quite difficult' and five report it is 'very difficult'. No zone-specific trends were discernible. Member State comments indicate that this is a complex and evolving matter. For example, the **Netherlands** comments that two years previously, recruitment was 'very difficult' but is currently 'quite easy' and new staff complete a year-long in house training. Another (Central zone) Member State which selected 'quite difficult' provides more detail: '[u]ntil a decade ago recruiting graduates with two or more years' experience in a relevant industry was relatively easy'. It cites several reasons: fewer people/graduates with relevant experience due to changes in higher education and consolidation in the agrochemical industry; constraints on Civil Service remuneration making posts less attractive and high demand in other areas of industry for science specialists with relevant experience (e.g. toxicologists). This CA has responded to these recruitment difficulties by recruiting 'relatively new graduates and commit[ting] major resources to training them in the required areas'. One other (Southern zone) Member State, who reports that recruitment is 'very difficult' also refers to training experts in house 'for several years'. Another (Central zone) Member State which selected 'very difficult' refers generally to limitations on recruiting new staff in the public sector. DG SANTE reports similarly that four Member States identified 'restrictions on public services in hiring new staff' as contributing to failures to comply with

deadlines in the Regulation (DG SANTE, 2017, p.4). Commitments to in-house training may be identified as best practice. CA provision of opportunities to develop expertise outside industry may enhance independence from industry by reducing both reliance on industry training as a source of staff knowledge and the associated risk of over-identification with industry interests, as discussed in section II.2. Such staff development may be particularly valuable where constraints on remuneration reduce CA ability to attract expert staff from industry or consultancies.

With respect to employee retention, two (both Central zone) report it is 'very easy' to retain such staff. Of these, the **Netherlands**, attributes this to the Ctgb offering 'a challenging working environment and [being] socially relevant, meaning that it is seen as an interesting employer'. Five report it is 'quite easy'. Three report it is 'quite difficult'. Of these, one reports a 'continual turnover of staff trained by the Competent Authority leaving within three years to take up a consultancy post'. This it attributes to increased demand for scientific expertise due to the expansion of regulation (biocides and chemicals) leading to 'a major growth in consultancies... paying at least 50% more in starting salaries with potential to rise much higher'. One (Central zone) Member State reports it is 'very difficult'.<sup>233</sup>

Finally, Member States were asked '[i]f resources (experts, knowledge/e.g. access to databases/, etc.) are not available in house, how easy is it to buy those resources from outside? One (Central zone) reports it is 'very easy'. Two report it is 'quite easy' of whom **Sweden** comments that this occurs rarely. Three report it is 'quite difficult'. Of these, one (Southern zone) attributes the difficulties to '[i]nternal bureaucratic procedure' and states that '[a]t EU level expertise is limited due to high workloads in each member state'. The **Netherlands** comments that 'few partners can meet the quality standards of Ctgb... [which] include preventing conflicts of interest' and that some potential partners are not able to deal with fluctuations in demand. The Ctgb quality standards suggest best practice and further research aimed at understanding the effectiveness of these standards, in practice, at promoting independence in the Dutch experience may be worthwhile. Three report it is 'very difficult', with two attributing the difficulties to limited resources.

## 1.5 Summary and recommendations

In terms of CA relationships with government, most Member States strengthen CA independence through formal requirements of independence both for CAs themselves and appointment as head and by making appointments fixed term. They are weaker with respect to the status of those responsible for making appointments. However, most enjoy substantive independence in terms of having sole responsibility for authorisation decisions.

As discussed in sections I, II.3 and VII.1.1, more important than formal independence from government is that regulators operate fair and reasonable evaluation and decision-making procedures and are seen to do so by all interested parties. Given that only one stakeholder responded to the stakeholder survey, we have limited information on the extent to which

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<sup>233</sup> One Member State misunderstood the question; this answer is not reported.

evaluation and authorisation procedures are seen as fair and reasonable. It is therefore very difficult to make general recommendations on the basis of the above findings. Data are lacking and conditions and difficulties are highly specific to individual Member States. Furthermore, change requires resources. These are, for better or worse, austere times and Member States may already face resource-related pressures. Generic advice may be offered, in terms of recommending introduction of fixed term appointments and enhanced protection from dismissal for commissioners/agency heads. However, where regulation is regarded as fair, such changes may not ultimately be necessary and where regulation is regarded as unfair, increasing formal independence may not target the cause of the problem. More detailed research into national conditions and challenges and the reasons behind may therefore be a wise additional step to take before making more concrete recommendations.

### Recommendations

It is recommended that further qualitative research is conducted. This research should target two specific enquiries. First, it should seek to understand how the zonal evaluation and national authorisation procedures of the CAs are perceived by all stakeholders, including applicants and the general public, and the extent (if at all) to which these procedures are viewed as fair and reasonable. Secondly, it should move beyond study of formal independence to investigate the existence (if any), in practice, of governmental influence on CA decision-making, for example through review of CA decisions and in-depth examination of interaction between CAs and government during decision-making. Such research may provide a stronger basis on which to make substantive recommendations.

The Regulation places no obligation on Member States to report their progress on the implementation of its provisions.<sup>234</sup> While acknowledging the difficulty of amending legislation, given the lack of information about CAs and the operation of the zonal system, the introduction of such a reporting requirement on Member States could provide valuable information and constitute a step towards filling this knowledge gap. The **EU institutions** are encouraged to consider such an amendment. In the interests of transparency, any such reports should be made publicly available.

With respect to CAs' relationship with industry, the picture is one of relative ease in moving between regulator and industry, although restrictions on personal/financial interests in the industry are stronger. Ultimately, Member State models for governing the relationship between regulator and industry/government differ and not all (potential) measures to

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<sup>234</sup> Such reporting requirements exist elsewhere. For example, Member States are required to report on implementation to the Commission every three years, under Article 31(4) European Parliament and Council Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms [2001] OJ L106/1.

maximise independence from industry/government are taken in all Member States. Such measures may be important for guarding against the risk of regulatory capture by maintaining an arm's-length relationship with industry as much as possible.

In terms of countering governmental influence the zonal system may assume greater importance. Majone has argued that isolated national regulators, though committed to fulfilling statutory objectives, may still be too weak to withstand external political pressure. However, he argues, participation in a transnational network of regulators with similar objectives and problems may incentivise regulators to resist political pressures in order to maintain their reputation amongst other regulators and protect their ability to co-operate (Majone, 1996, p.273).<sup>235</sup> Direct interaction with each other, bypassing ministerial departments, may also grant national regulators power vis-à-vis their national governments, increasing their autonomy (Groenleer, 2011, p.556). If the zonal system can evolve into such a system, this could enhance the independence of CAs and consequently perhaps, the reliability of decisions. This may, therefore, represent another reason for supporting and strengthening the zonal system. It is worth raising the possibility that, for similar reasons, the zonal system may also help counter pressure from the regulated industry and indeed green CSOs. However, where such actors also operate at a zonal or EU level, networks of CAs at these levels may remain vulnerable to, for example, industry influence or capture,<sup>236</sup> albeit likely expensive for industry. Nonetheless, the question of the potential for such networks to strengthen independence from industry would be worth further research.

### Recommendations

Regulatory (particularly cultural) capture has been identified as a risk to CAs. However, further empirical research would be required to determine the extent (if at all) to which any CAs are, in practice, influenced or captured by industry. Such research should involve, *inter alia*, qualitative review of registration reports and decisions against information submitted by applicants and modes of interaction between CAs and industry to understand the nature and proximity of the relationship. Recent literature (for example, (Carpenter and Moss, 2014b)) proposes robust methodologies to conduct such research. Greater understanding would provide a stronger evidence base on which to make recommendations. However, pending such research, the following recommendations are made.

**Member States** are encouraged to review their national provisions regarding potential for commissioners/agency heads to have held positions in industry prior to their appointment to CAs and to accept employment in industry post-appointment. In order to reduce the risk

<sup>235</sup> Although, as discussed in section VI.2.7, challenges different regulatory cultures and levels of trust between Member States still need to be resolved or worked around.

<sup>236</sup> I am grateful to Dr Dieter Pesendorfer for this observation.

of regulatory capture, **Member States** are encouraged, furthermore, to consider strengthening restrictions with respect to both.

**Member States** are also encouraged share best practice. For example, Member States may benefit from learning about France's experience with its charter on relations with interest groups (section VII.1.2) and the Netherlands' experience with its quality standards (section VII.1.4). If successful, Member States may wish to implement similar measures.

Involvement of public interest groups (PIGs) in regulatory decision-making was discussed in section II.1.2 as a mechanism for reducing the risk of regulatory capture. Again, further research would be required into, for example, their appropriateness, mechanisms for their support (including funding) and to identify potential candidates. PIGs could operate on a national level and, if the PIG itself transcends national boundaries, on a zonal or EU level too.

Research into the potential for the zonal system to act as a counterweight to external pressure was beyond the scope of this study. Further research may therefore be necessary to investigate this question. If this potential is real, **Member States** and the **Commission** should provide support at zonal and inter-zonal level for developing the networks required to ensure individual CAs can take full advantage of the zonal system as a means to maintain and enhance their independence.

With respect to organisational autonomy, most lose some formal autonomy through being largely government-funded. On the other hand, most retain control over budgetary spending and internal organisation while being not entirely autonomous with respect to personnel policy. That government, in some, still has some say over salaries could be regarded as a possible restriction of independence. This is indeed cited by Member States as a problem for recruitment.

With respect to resources, overall, most respondent CAs regard themselves as possessing or having access to sufficient financial, operational, expert and technical resources to carry out their functions with respect to PPP authorisation. This is partly corroborated by the overall findings of DG SANTE's audit,<sup>237</sup> which found that the 'evaluator staff in all MSs were suitably qualified and trained, and are therefore capable of conducting evaluations to a high standard' (DG SANTE, 2017, p.4). This is a positive finding for the smooth functioning of zonal authorisation procedures. However, there are still several Member States which experience resource-related challenges, some of whom report multiple challenges. The trend looks less healthy when it comes to recruitment and retention of staff, and access to/availability of external resources, where there is evidence of more wide-spread difficulties. No Member State directly mentions having to compete with the PPP industry itself for expert staff, although one

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<sup>237</sup> Of eight Member States.

does mention competition with industry or private consultancies generally. Some Member States indicate their commitment to training experts in-house, which may reduce the magnitude of the problem. However, these difficulties could place some CAs at a disadvantage, in some areas of expertise, vis-à-vis industry with the associated risks of information asymmetry and regulatory capture.<sup>238</sup>

### Recommendations

**Member States** are encouraged to review the means by which CAs are funded and to consider introducing fees covering the costs of evaluation and authorisation, pursuant to Article 74(1) PPPR. However, while securing CA funding through fees levied on industry may promote independence from government, dependence on such fees may reduce independence from industry. A straightforward recommendation with regard to the benefits to CA independence of retaining such fees is therefore not possible. The further research, recommended above, into CA independence in practice from government and industry should generate greater understanding of the relative prevalence or risk of government influence or industry capture. Appropriate funding structures could be designed or adjusted in response to the identified risks.

While pressures on government budgets are acknowledged, given the need for expertise both to ensure the quality of evaluation and decision-making and to counter information asymmetry, **Member States** may wish to consider the following options. Firstly, review and, if appropriate reduction of, the application of constraints on civil service remuneration in order to promote recruitment and retention of the necessary expert staff. Secondly, the development or enhancement of in-house training programmes in order to cultivate sources of expertise other than from within industry, as a further means to counter asymmetric information and industry influence or capture.

## 2. Transparency

As stated in section V.I, the questions on transparency sought to assess three dimensions of this concept. Firstly, clarity with respect to the authorisation rules, procedures and requirements, in other words, the ‘rules of the game’; secondly, access to, and publication of, information; and thirdly the strength of any consultation processes conducted during evaluation and authorisation procedures.

### 2.1 Rules of the game

One question sought directly to assess clarity as to the rules of the game and asked Member States ‘[h]ow much information regarding the zonal authorisation procedure is publicly

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<sup>238</sup> See section II.2.

available (for example on the competent authority website) in the national language(s)?' It specified that this information includes 'guidance addressed to applicants on how to apply, the required documents, information about the authorisation procedure and how decisions are made'. Although the question referred to information 'addressed to applicants', it is important that all potential interested parties (e.g. NGOs, farmers, concerned individuals, researchers etc.) should be able to understand how authorisation decision-making works. As discussed in section III.3, this is important for building confidence and understanding amongst both applicant and other interested parties in the regulator (OECD, 2013, p.52). Eight Member States report that 'comprehensive information is available'. Of these, the **Netherlands** notes that 'manuals on risk assessment and registration procedure are made available to applicants and other stakeholders' on the website, indicating a very high level of transparency in this respect. **Sweden** comments that in 'certain cases clarifications might be needed from the authority'. One Southern zone Member State reports that applicants still like confirmation from the CA, 'especially due to ever changing EU guidance'. Three report that 'most information is available but contact with the competent authority is necessary to gain full information'. One (Southern zone) Member State reports no information is publicly available.

The Stakeholder reports finding it 'very difficult' to access information on zonal authorisation procedures from CAs of zRMSs (e.g. application and information requirements, information on how the application is evaluated etc.). It comments that some CA websites contain 'very comprehensive information on application and data requirements' naming the **UK**, **Netherlands**, **Germany** and **Belgium** as examples; all Central zone Member States. It also comments that '[m]ost Member States provide information upon request, but it is not always clear what is expected of an applicant' indicating too that there is a great deal of variation between Member States in this regard. The Central zone does publish information about its meetings and other information, for example regarding evaluation, on publicly accessible pages on CIRCABC.<sup>239</sup>

## 2.2 Publication and access to information

The next three questions concerned access to, and publication of, information, specifically. As discussed in section III.3, Commission guidance supports publication of RRs (Commission, 2014b, p.14). Q44 asked whether the CA publishes its decisions regarding authorisation of PPPs. Seven Member States report that they publish all decisions. **France** has also committed to making its authorisation decisions publicly available (ANSES, 2015, p.4). Three (all Central zone) report they publish most. Two report they publish some decisions. Of the latter two categories, four Member States comment that they do not publish decisions not to authorise. In light of these answers, it is possible that Member States which report publishing all decisions took the question to refer only to decisions to authorise, rather than reject, applications. The reliability of some of these answers may therefore be open to doubt. Only the **Netherlands**

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<sup>239</sup> CZSC survey response. <<http://circabc.europa.eu/>> accessed 25 February 2018. CIRCABC is an EU online communication and information resource centre, through which Member States share documents relevant to PPP authorisation. An account is required to access it and the location of the publicly available documents relevant to PPP authorisation is not entirely straightforward.

elaborates on the reasoning behind not publishing rejections, indicating that this is considered 'commercially confidential information'. However, it does note that the Ctgb's annual report presents statistics including rejections and amendments. One Southern zone Member State reports that a new IT platform is being developed and it expects to provide 'more detailed information about PPP decisions'.

Q45 asked about the extent to which the CA discloses/publishes the information sources on which its decisions are based. As discussed in section III.1, publication of the knowledge on which decisions are based is important for enabling democratic control of regulatory decision-making (Jasanoff, 2006, p.21), increasing accountability and reducing corruption and the risks of regulatory capture (Schauer, 2011, pp.1348-1349). Two (both Central zone) Member States report they publish all information sources. Of these, **Germany** appears to understand this as meaning the RR, whereas the question was also getting at the data used in the evaluation, for example studies submitted with the application. One (Central zone) reports it publishes most. Three report publishing some of the information sources. Of these, the **Netherlands** comments that it publishes the guidance it uses on the Ctgb website and publishes the assessment report presented to the Ctgb Board in its database. Finally, '[u]pon request, the Ctgb discloses all other information available in the application dossier within the legal limits' of the Regulation. Four report publishing none. Of these, two indicate that sources are still accessible on the basis of national legislation establishing rights of access to information. One did not answer the question.

Reasons for decisions on authorisation are contained in RRs<sup>240</sup> and made available to applicants and other Member States via CIRCABC.<sup>241</sup> However, in terms of access, the **zSC secretariats** report that no Member States publish their RRs, apart from **Germany** and the **Netherlands**, in the Central zone. In addition, as discussed in section VI.2.5, in **France**, ANSES publishes on its website the conclusions of its evaluation and part of the RR for the purposes of transparency. The **NZSC and CZSC secretariats** highlight the potential to access RRs on request and the **CZSC secretariat** comments that PPPAMS could be used to provide information on authorisations to the public. The Stakeholder also notes that RRs are often drafted solely in the national language reducing both their accessibility to 'non-national applicants' and suitability for zonal use. However, the **SZSC secretariat** reports that discussion over publication of final RRs had started amongst all Member States. It should be remembered, that two Member States (**UK** and **Czech Republic**) employ reason-giving or a similar mechanism in order to inform applicants about the grounds for their decisions, and **Germany** provides applicants with a meeting if a refusal looks likely, as set out in section VI.2.7. The **CZSC secretariat** reports that Member States, when acting as cMSs, provide reasons for their decisions to the applicant and inform the other Member States of their decision via CIRCABC. Only two Central zone Member States make these decisions public. The **NZSC secretariat** also

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<sup>240</sup> See Article 39(1) PPPR.

<sup>241</sup> zSC survey responses.

reports that all Northern zone Member States, when acting as cMSs, provide reasons to the applicant for their decision.

The Stakeholder notes that publication of RRs would improve the zonal system's functioning, particularly for secondary applicants (manufacturers of generic PPPs) who may not have access to the original RR. It reports significant variations between Member States in terms of providing access to information on PPP authorisations: some RRs are online; some CAs provide information on request and others refuse to do so. The Stakeholder indicates a belief that this hinders the use of previous decisions by applicants to 'facilitate and harmonise their applications' and that significant improvements in the transparency of evaluation and decision-making are possible and could enhance competition.

Q46 asked more generally whether there is a 'clear basis in law or policy for public access to information held by the competent authority, including a clear statement of the limitations to that access (for example, due to commercial confidentiality)'. Only two respond 'no', while ten Member States respond 'yes'. Each of the ten refers to national legislation on public access to information and three to the Regulation. In addition, the **Netherlands** refers to its national tribunal decision following an Article 267 TFEU referral to the CJEU<sup>242</sup> which ruled that public access to part of the information held by the Ctgb 'is regulated by an exclusive system of public access comprised of Article 63 [Regulation (EC) No] 1107/2009 and Directive 2003/4'.<sup>243</sup> It was the only Member State to refer to the CJEU decision.<sup>244</sup>

### 2.3 Public participation and access to information

The next six questions (47-52) concerned consultation and the accessibility of information deriving from consultation. Q47 asked whom, in addition to the applicant, the CA consults during authorisation decision-making (including comparative assessment). Altogether, five Member States report conducting any consultation of actors outside the CA.<sup>245</sup> Four Member States selected 'other actors involved in plant protection'. One selected 'farmers and other users'. Three selected 'other government departments'. Six consulted no one. Of these, the **Netherlands** notes an exception for '[d]ecisions concern[ing] the first authorisation of a product based on [an] approved active substance not earlier used in the Netherlands'. **Sweden** notes an exception in 'cases of principle nature, for example if a new type of condition for use is introduced'. Neither specifies whom it consults. No Member States consult wider industry, NGOs/CSOs or the general public. It was assumed in this question that all CAs would communicate with applicants. However, the Stakeholder comments that only sometimes is there good communication between applicant and zRMS; other Member States are 'very inaccessible, especially during the evaluation, which makes it unnecessarily difficult to solve upcoming problems'. It also makes the more general comment that zonal evaluation

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<sup>242</sup> *Bayer* (n 28).

<sup>243</sup> Directive 2003/4/EC (n 29).

<sup>244</sup> Discussed in section III.2.

<sup>245</sup> One Member State referred to consultation with other CAs in the same zone. This is assumed and so not included here.

procedures ‘range from reasonably transparent to not transparent at all, depending on the Zonal RMS responsible for the evaluation’.

One (Central zone) Member State reports that it only consults other actors involved in plant protection, farmers and other users and other government departments when ‘sufficient information on the product and alternatives in practice incl. all advantages and disadvantages of both is not available to the agency’. **Sweden** reports that consultation procedures are set up on a case-by-case basis, usually written. The **Netherlands** comments that consultations on decisions last four weeks and submissions during the consultation must be addressed in the final decision. No Member States report publishing any consultation submissions apart from the **Netherlands**, which states ‘[w]hen applicable, in the final decision a summary of the reaction of each stakeholder is given’ and **Sweden**, which reports publication of some decisions, decided on a case-by-case basis. Two refer to the availability of submissions on request. There is information to suggest that the **French** CA, ANSES, generally attempts to improve the openness and transparency of its expert assessments by opening them up to society. It expects, thereby to improve the reliability and quality of decisions and understanding of decisions by all stakeholders.<sup>246</sup> It is not stated, however, whether this is being implemented with respect to PPP evaluations and authorisations.

The Stakeholder reports ‘regular contact with CAs’ at both national and zonal levels on matters other than with respect to a specific application/comparative assessment. These matters included largely procedural and scientific issues, such as ‘dossier formatting, workflow, procedures, and developments in the interpretation and implementation of provisions of the PPPR’ or other dossier requirements and interpretation of application requirements. It also reports participation in annual open zSC meetings in the Central and Southern zones in which similar matters are discussed.

Of the five Member States which conducted consultations, only three report they were required by law to formally respond to submissions. Two of these report that responses are incorporated in the final decision/registration report and so are publicly available. Three report the CA is required by law to take submissions into account in its decision-making and two report that, though not legally required, in practice it does. In addition, the **Netherlands** reports that it is also required to do so for any consultation it conducts. The Stakeholder reports a belief that most Member States ‘listen to and take into consideration’ their comments.

It was clear from the zSC survey that increased participation in zonal evaluation and comparative assessment would not be welcomed by the Member States. Different reasons were provided. Firstly, **zSC secretariats** highlight the scientific nature of the evaluation exercise, the lack of scientific expertise amongst the wider public and risks of non-scientific opinions becoming involved, pressure from NGOs and the triggering of social alarm. Secondly, the **SZSC secretariat** predicts that commercial competitors could pose as members of the public in

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<sup>246</sup> <<https://www.anses.fr/en/content/expert-assessment-and-openness-society>> accessed 28 January 2018.

order to 'foil applications'. Thirdly, the **SZSC secretariat** warns the Uniform Principles could be displaced by public opinion as the basis for authorisation. Fourthly, the **CZSC secretariat** questions the wisdom of making the application publicly available during the application procedure, although it does not provide a reason for this other than data protection. Finally, according to the **SZSC secretariat**, any gains in transparency and the ability to 'say that all concerns raised were addressed' would be outweighed by the drawbacks. With respect, specifically, to comparative assessment, the **SZSC secretariat** feels that wider consultation would only 'trigger discussions on the effectiveness of alternative methods and whether these are enough, without any efficacy trials (following [EPPO] standards) to back those claims'. The **CZSC secretariat** feels wider participation was more appropriate during development of the legislation and guidance documents and indeed, the **NZSC secretariat** reports consulting stakeholders 'on general issue such as [guidance documents] etc.'.

Many of these concerns are legitimate and zSC secretariat scepticism of participation is unsurprising given the additional burden it would impose on CA resources. However, one or two observations may be made. Different types of relevant expertise exist (Wynne, 1992a), and are distributed across society (Steele, 2001). Integration of some of these may benefit the evaluation and decision-making process. Secondly, risk assessment, including comparative assessment, is inherently value-based (Wynne, 1992c, p.116; Royal Society, 1992).<sup>247</sup> Furthermore, given the under-developed nature of comparative assessment, careful input of wider expertise may facilitate its development. Finally, concerns regarding displacement of the Uniform Principles and the onerousness more generally of consultation procedures could be met, to some extent, by the design of the procedure. Wider participation need not mean throwing open every decision to the entire world. Different mechanisms exist which enable participation by more limited groups comprising stakeholders and representatives of wider societal interests, for example, PIGs (discussed in sections II.2 and VII.2.5), consensus conferences (Einsiedel, Jelsøe and Breck, 2001) or citizen juries (Smith and Wales, 2000; see also Fiorino, 1990) and which may be adapted to the procedures established by the Regulation. These may represent a step towards enhancing transparency, especially if publicly reported on. Criteria could be developed to select suitable decisions for wider involvement. It could, further, be provided that inputs thus gathered should be taken into account, rather than regarded as determinative, in order to preserve CA discretion.

The Stakeholder reports opportunities for consultation with most Member States with respect to comparative assessment. However, as no other stakeholders responded to the survey, it is impossible to gauge the level of involvement of other actors. In addition, the Stakeholder notes that experience with comparative assessment is still limited but the indications are that Member States balance the information provided by applicants against that from other sources.

## **2.4 Accountability**

The final five questions concerned the accountability of the CA to the government and legislature and the scrutiny of decisions. As discussed in sections II and III, accountability is

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<sup>247</sup> See also section IV.3.

linked to both independence and transparency. Two questions asked what the formal obligations of accountability of the CA vis-à-vis the government and legislature were, respectively, in terms of producing annual reports. Annual reports, due to their high visibility, can be an important mechanism for improving the transparency and accountability of regulators. They can set out the regulator's operations and progress against its objectives allowing oversight institutions to hold them accountable (OECD, 2016, pp.29, 44). Three report no such obligations vis-à-vis the legislature. The **Netherlands** reports an obligation to present 'an annual report for information only' to both government and the legislature but that once every five years the responsible minister audits the CA's business performance and adherence to legal standards. Two report an obligation to present 'an annual report for approval' to the government. **Germany** commented that the BVL, as an independent higher federal authority under the jurisdiction of the Federal Ministry of Health, reports to the Ministry, though it is independent regarding PPP authorisation decisions. However, overall obligations of accountability are strong: ten CAs report being fully accountable to either the government, the legislature or both. **Belgium** adds that the CA is 'accountable to the responsible minister via an administrative contract'. Finally, five Member States report being required to make any annual report produced public.

The last two questions concerned scrutiny of decisions. Review and scrutiny of decisions, internally, externally or both, may aid reliable decision-making. One Member State reports that all authorisation decisions are audited or reviewed. Seven report that a sample is reviewed/audited. Four refer to an internal audit, often according to an annual plan of audits, one noting that this was not regular. One (Central zone) Member State describes an extensive system of internal peer review of all the work of trainee staff, samples of evaluations, contentious decisions, all refused authorisations alongside an equal number of authorisations and all authorisation documentation before release. This same Member State and two others also report external reviews of decisions, one involving peer review of a 'random sample of applications' by an expert committee and, in the **Netherlands**, an audit of authorisation decisions by a commission of experts every five years. The two providing most detail suggest the review/audit emphasises scientific quality. Four Member States report no system of audit/review. The majority, however, report systems for scrutiny of decisions, although these vary in nature and frequency.

Finally, an appeals mechanism may enhance accountability. Article 36(3) fourth paragraph PPPR requires Member States to provide the ability to challenge a decision refusing authorisation 'before national courts or other instances of appeal'. Q57 asked who, other than a court, can overturn the CA's decision where it had exclusive competence. Eight selected 'nobody'. Two (both Central zone) Member States selected the 'government, with qualifications. Of these, the **Netherlands** indicates that this would be possible only where the Ctgb is guilty of 'serious task neglect'. One (Southern zone) Member State selected the 'government, unconditionally'. **Belgium** reports that the responsible minister could do so. One Member State reports an appeal period of 15 days following issuance of the decision on the application but it is unclear as to whom the appeal would be.

## 2.5 Summary and recommendations

Regarding clarity with respect to the rules of the game – the requirements and operation of the evaluation and decision-making procedures – it appears that while some Member States provide comprehensive and clear information, many do not. The lack of clarity in this regard may cause confusion among applicants and may undermine understanding of the overall authorisation procedure amongst wider interested parties important for transparency generally.

### Recommendation

**Member States** are encouraged to review the amount of information available online about their evaluation and authorisation procedures from the perspective both of applicants and other stakeholders/general publics. It may also be helpful to review other CA websites with high levels of information as examples of good practice. The UK CA website, for example, contains substantial information. In order to enhance transparency with respect to these procedures, **Member States** are encouraged to provide clear and comprehensive information at least in their native language and ideally, eventually, in English.

With respect to access to information, different CAs operate at different levels of transparency. Transparency levels with respect to publication of authorisation decisions are higher overall, but lower with respect to the publication of the information sources on which decisions are based. Very few publish RRs, which should contain reasons for authorisation decisions. On the whole, even if most CAs do not publish comprehensive information of their own accord, in most respondent Member States, there exist avenues by which to access it. That said, as *Bayer* and experience of EU level litigation over access to documents suggest (Lee, 2014a, pp.198–199), even with rights established in legislation, access in practice may not be easy or straightforward. Transparency, of itself, does not guarantee the reliability of decisions. However, the absence of access to information deprives interested parties of the ability to make that judgment. Furthermore, as discussed in section III.2, transparency requires more than publication alone; the information itself must be clear and intelligible (at least). Concerns raised about the quality of some RRs<sup>248</sup> suggest that their publication may foster only limited improvements in transparency.

### Recommendations

**Member States** are encouraged to increase the publication, ideally online, of information on PPPs within the limits of the law, especially the following:

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<sup>248</sup> See section VI.2.7.

- Authorisation decisions
- Registration reports
- The information sources on which evaluation and authorisation are based. Ideally, this should include the conclusions of the zRMS's evaluation
- Any submissions (and responses thereto, if relevant) made during any consultation process

To this end, **Member States** are encouraged to step up discussions amongst themselves regarding the publication of registration reports and other information. These discussions may need to happen alongside the development of measures, for example guidelines or training, designed to improve the quality of registration reports in order to support this measure to enhance transparency.

It is acknowledged that CA resources are limited. However, where possible, publication of the above information in English<sup>249</sup> is encouraged for its potential to enhance access to information for a larger audience and to improve the quality of future applications. Increased public availability of such information would facilitate conduct of the research recommended in section VII.1.5.

Stronger measures to improve access to information may be desirable. The **Commission** is therefore encouraged to consider the possibility of amending the Regulation to introduce a requirement that registration reports (at least) are made publicly available.

The limited consultation activities are unsurprising given the absence of an obligation in the Regulation on Member States to consult stakeholders (including general publics) during zonal evaluation.<sup>250</sup> The Stakeholder comments that consultation with third parties/general publics during evaluation would be 'unworkable' due to the complexity of zonal evaluations, for example having to consult across all other countries in the zone and the inevitable language barriers. It also comments that any such consultation 'would completely paralyse the evaluation system'.

Nonetheless, as discussed in section III.3, public participation can enhance the transparency of evaluation and decision-making procedures, for example by improving understanding of their operation. The absence of a space for such participation may therefore reduce levels of transparency in CAs. More generally, from the point of view of transparency to citizens, a general deficiency of the zonal evaluation system is how far removed it is from citizens. There is no provision for wider participation in the evaluation procedure, despite the contribution it

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<sup>249</sup> Or another widely used EU language. The impact of the UK's departure from the EU may be a factor in choice of appropriate language.

<sup>250</sup> NB. Article 12(1) PPPR requires EFSA to make draft assessment reports on active substances available to the public for comments.

could make, discussed in section III.3. But even if there were, in practice it would be extremely difficult for citizens of one Member State to contribute to a risk assessment performed in a different Member State, particularly perhaps where different languages are spoken in the relevant Member States. It should also be noted that given the limited information about the zonal system available online, it is likely that very few are even aware of its existence.

In addition, there is no provision for consultation during national authorisation decision-making. But again, even if there were, by the time a cMS comes to take the national authorisation decision, it is too late for citizens or CSOs to scrutinise or influence the evaluation or contribute much to the information on which the decision will be based. More importantly for this report, in terms of transparency, the information (i.e. the zRMS conclusions) on which national authorisation decisions will be based will have been generated through a process which is largely closed to and distant from most citizens. As discussed in section III.3, democratic control of decision-making based on scientific knowledge requires some opportunity for citizens themselves to evaluate the knowledge used as justification for the decision (Jasanoff, 2006, p.21). It was noted further, in section III.1, that potential to enhance the quality of decisions has been attributed to wider participation in both policy formation and regulatory decision-making (Steele, 2001; Ferretti, 2007). This potential is therefore lost in the absence of participatory opportunities. Again, there is a trade-off: consultation takes time and its implementation could therefore undermine the already compromised efficiency of CA decision-making procedures. As it is, however, the absence of an opportunity for consultation may reduce transparency to citizens and other stakeholders. It may therefore be worth revisiting the balance struck between efficiency and transparency by the Regulation.

PIGs were discussed in sections II.2 and VII.1 for their potential to guard against regulatory capture. However, they may also function as a mechanism for enhancing transparency through involvement and representation of the relevant interest(s) in regulatory processes (Lodge and Stirton, 2001) and may additionally contribute valuable expertise. Such involvement of national PIGs could improve the transparency of cMS decision-making. Furthermore, formalised involvement of transnational PIG(s) in zonal evaluation processes could represent a means by which to open up such processes while avoiding the messiness and difficulty, discussed above, of wider public participation. Space prevents a fuller discussion of these potential benefits and PIG involvement may face obstacles with respect to preserving the confidentiality of applicants' data (discussed in section III.2), but the question is worthy of further investigation.

In terms of transparency to applicants, the position is different. The availability of pre-submission meetings and the communication which occurs between CAs and applicants, described in section VI.2, suggests greater involvement and therefore transparency, although, as the Stakeholder noted, this may not occur with every CA. Greater transparency to wider industry is also suggested by the 'regular contact' with CAs at national and zonal level outside specific applications reported by the Stakeholder (above). All such contact between industry and CAs is clearly valued for improving the operation of the zonal system and contributing to its efficiency. However, such collaboration may reduce the relational distance between

regulator and industry, potentially increasing the risk of cultural capture and thereby compromising CA independence, as discussed in section II.2. There may therefore be a tension between transparency to, and independence from, industry, as well as between efficiency and independence from industry.

Measures for reducing the risk of capture were also discussed in section II.2 and included increased transparency generally through publication of information and greater involvement of interested parties for example through public participation (Gönenç, Maher and Nicoletti, 2000, p.44; Majone, 1996, p.26; Mitnick, 1980, p.66). However, as the above results and analysis suggest, publication of information by CAs is patchy and there are limited opportunities for wider participation in evaluation and decision-making. It seems unlikely then, that CAs are taking advantage of the potential of such measures to counter risks of capture. In light of these findings, it may be hard for zRMSs to achieve a fully 'transparent assessment' of applications for authorisation, pursuant to Article 36(1) PPPR. To the extent that, as discussed in section I, confidence in the reliability of decisions is gained through a belief that regulators take all views into account, the absence of a means by which views may be expressed may undermine trust in the CAs and in the reliability of their decisions, at least amongst those more likely to be excluded. That said, the Stakeholder itself comments that the reliability of the zonal authorisation system is hard to assess, noting disagreement between applicants and zRMSs over evaluations, lack of transparency and opportunities for applicants to comment and comments being 'insufficiently taken into consideration'.

### Recommendations

Although there is no legislative requirement, **Member States** are encouraged to consider ways to open up their national authorisation decision-making procedures to wider participation. Member States could experiment, for example, with providing opportunities to comment on dRRs during the commenting phase of zonal evaluation (described in section VI) and/or on draft authorisation decisions. Further upstream, wider participation in the definition of national data requirements could improve the transparency of CA decision-making. If opening up such elements of decision-making to stakeholders and the wider public generally is regarded as time-consuming and unmanageable, participation by a limited number of select PIGs could still improve transparency as well as contributing valuable expertise.

Again, although there is no legislative requirement to ensure participation during zonal evaluation procedures, **zonal steering committees** are encouraged to consider ways to enhance the openness of these procedures. While it may be difficult to reach citizens across the entire zone, a starting point may be to identify PIGs or individuals (for example, users, CSOs, university experts) within the zone who can contribute different knowledge and perspectives to the drafting of, for example, zonal guidance documents. Given that the zonal system is still in its early stages, opening up evaluation and decision-making procedures themselves should be considered in the longer-term and may need to be

implemented gradually and sensitively in order not to over-burden CAs. For example, a willing and capable **zRMS** could pilot a programme whereby a PIG participates in the evaluation of an application, following which the zRMS shares its experience with other Member States.

Stronger measures for improving transparency of the zonal authorisation procedure would come from the EU institutions themselves. **Commission** support for Member States wishing to open up their decision-making procedures could include administrative support and expertise, for example in identifying appropriate PIGs or other actors and designing appropriate participatory procedures and online platforms (such as CIRCABC) to facilitate wider participation and sharing of results and experiences between Member States. Longer-term, the **Commission** is encouraged to draw up guidelines (or similar, non-legislative instruments) for increasing the openness of zonal evaluation and authorisation procedures with particular regard to providing opportunities for wider participation.

The strongest measure for improving transparency through participation would be a legislative requirement. Again, in the longer-term, the **European Parliament, Council and Commission** are encouraged to review the provisions of the Regulation in light of the findings of this report and overall EU policy commitments to public consultation and participation (discussed in section III.3) and to consider the possibility of introducing a specific provision governing participation during the zonal evaluation and national decision-making procedures, including comparative assessment.<sup>251</sup>

Given the complex structure of the zonal system and limited resources of CAs, further research is recommended to identify and elaborate potential and feasible participatory mechanisms, including PIGs, consensus conferences, citizen juries etc. appropriate to the zonal system and capacity of CAs.

The picture which emerges in most respondents is that of different strengths of accountability existing simultaneously. While most CAs are fully accountable to a political authority, which may compromise independence, in few can authorisation decisions be overturned by government or other body, apart from a court. In this respect, independence is protected. The extensive system of review described by two Member States could be considered examples of good practice. Due to the nature of the data available, it is not possible to determine how widespread such systems are throughout the non-respondent Member States, but the adoption of such practices could enhance the quality and perhaps reliability of decisions. To the extent that accountability is supported by transparency, it suffers here due to the low levels of transparency, discussed in the rest of this section.

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<sup>251</sup> The benefits of wider participation in comparative assessment were discussed in section IV.3.

### Recommendation

**Member States** who do not already do so are encouraged to produce annual reports as a step towards enhancing the transparency of their operations and thereby also their accountability. Such reports would need to contain information about the CA's operations and progress against its objectives of a sufficient quality and intelligibility to enable proper scrutiny by the relevant oversight institutions and the public.

**Member States** are also encouraged to establish internal and/or external procedures for scrutinising their decisions, for example annual audits of a sample of decisions, where these are not already in operation. There are already examples of good practice and Member States are encouraged to use already established zonal networks to share such practices.

## 3. Precaution

### 3.1 Discussion

Member States were asked two questions on the precautionary principle. Firstly, they were asked to 'indicate the standard of proof the evidence must meet in order for the PPP to be authorised' 'taking into account all the evidence of the safety of the PPP and the restrictions that may be placed on its use'. The question and available answers were designed in light of the Court's decision in *Sweden v Commission (Paraquat)*,<sup>252</sup> discussed in section IV.1. The following answers were available:

- 'a) The evidence must provide certainty that the PPP will meet the requirements in Articles 29(1)(e) and 4(3)(b)-(e);
- b) The evidence must show beyond a reasonable doubt that the PPP will meet the requirements in Articles 29(1)(e) and 4(3)(b)-(e);
- c) The evidence must show, on the balance of probabilities, that the PPP will meet the requirements in Articles 29(1)(e) and 4(3)(b)-(e); and
- d) Other.'

Six selected a) and five selected b), each representing a mix of Member States from all three zones, with **Germany** declining to select an answer.

It is interesting that so many indicated that they require certainty as to the safety of a PPP in order to authorise it. Scientific certainty is impossible to achieve, no less so here, given persistent conditions of ignorance surrounding the potential harm arising from interactions between pesticides and the environment (Pretty, 2005). As such, as discussed in section IV.1, regulation may not seek zero risk, again on the basis that this is impossible to prove. However,

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<sup>252</sup> *Sweden v Commission (Paraquat)* (n 52).

the responses perhaps indicate six Member States pursuing a very high level of safety, beyond that endorsed by EU law in this area, through the application of a strong interpretation of the precautionary principle which pursues certainty of safety. As discussed in section IV.1, Member States are arguably entitled to seek certainty of safety in terms of reducing *known* (as opposed to hypothetical) risks to zero<sup>253</sup> (Lee, 2008, p.46) but may not pursue certainty of safety overall, as this is impossible to achieve, as indeed, one Member State noted in a comment. The meaning of ‘certainty’ may be open to different interpretations, including among the respondent Member States. It is also not possible to detect, on the basis of the available data, how the reported requirement for ‘certainty’ might be reflected in national authorisation decisions. A more in-depth and detailed study of the divergences between Member State application of the precautionary principle in practice was beyond the scope of the present research.

**Sweden**, in particular, demonstrates a nuanced understanding of the question of scientific uncertainty noting the need for political judgment. It comments that:

*‘In practice, the risk assessment methodology is based on statistical probabilities. The inherent uncertainties are not propagated in the step-wise procedure and therefore not expressed numerically in the final calculated risk ratio used for decision-making. Moreover, there are further uncertainties in [sic] that are not accounted for in the calculations. The interpretation of standard of proof is therefore ultimately a policy level issue, rather than a scientific.’*

In comments, three Member States note that they rely on the Uniform Principles here, one of whom selected answer a) and one (**Sweden**) answer b).<sup>254</sup> One (Central zone) Member State indicates that it uses the standard, established in *Sweden v Commission (Paraquat)*, for ‘compliance with the requirements for approval of an active substance [which] must be shown beyond a reasonable doubt’,<sup>255</sup> as it considers this ‘an appropriate reference point for PPP authorisation’. The fact, though, that six Member States indicate their standard of proof is ‘beyond a reasonable doubt’ perhaps indicates wider adherence to this decision, which, as discussed in section VI.1, may be in doubt. Again, however, the data do not allow conclusions to be drawn about how the requirement for ‘beyond a reasonable doubt’ may actually be reflected in national authorisation decisions.

The second question asked whether Member States produce and follow any internal guidance in applying the precautionary principle. Three Member States indicate that they apply the precautionary principle on a case-by-case basis. The other nine indicate they employ external guidance, with two specifying the Uniform Principles, three EFSA guidance, five Commission guidance and two Northern zone guidance. In the Central zone, the **CZSC secretariat** provides support to Member States by acting as a contact point for questions or forum for discussion

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<sup>253</sup> *Hahn* (n 66).

<sup>254</sup> The third, **Germany**, did not select an answer.

<sup>255</sup> See discussion in section IV.1.

and by distributing agreements and conclusions. The **NZSC secretariat** reports that it provides no specific guidance on the precautionary principle.

Although the Stakeholder does not believe that the precautionary principle is applied consistently across Member States, it reports that 'most competent authorities' apply it correctly in the sense that 'most apply the Uniform Principles, and therefore comply with the requirements of the PPPR'. It does believe, however, referring to politically contentious decisions, that some Member States reject applications in cases of 'clear and unequivocal' compliance with the Uniform Principles, inappropriately using the precautionary principle as a justification.

### 3.2 Summary and recommendations

There may be some inconsistent interpretation and application of the precautionary principle. Member States appear to interpret and apply the precautionary principle with differing levels of ambition, perhaps suggesting at least two different standards of proof in operation in the EU for the grant of a PPP authorisation. This is perhaps not surprising given that the law relating to the interpretation and application of the precautionary principle is not entirely clear.<sup>256</sup> While the Uniform Principles exist to ensure that evaluation and authorisation decisions implement the requirements of the Regulation, by 'all the Member States at a high level of protection of human and animal health and the environment',<sup>257</sup> the fact that two different Member States appear to derive different standards of proof from them may indicate still the potential for inconsistent interpretation and application here. Six Member States report they apply the standard of proof indicated by the Court in *Sweden v Commission (Paraquat)* in the context of active substance approval. However, given the uncertainty of the law in this area, it may not be entirely clear what the correct approach should be in the context of PPP authorisations. Finally, Member States appear to refer to multiple different sources of guidance which may further indicate a diversity of approaches.

#### Recommendations

The above analysis suggests inconsistent application of the precautionary principle within the EU in the context of PPP evaluation and authorisation. However, to understand truly the divergences between Member State application of the precautionary principle in practice, a systematic, qualitative and comparative review of authorisation decisions would be required. Such research would provide a stronger evidence base on which to pursue efforts to harmonise interpretation and application of the precautionary principle, including the following two recommendations.

**Member States** are encouraged to collaborate at zonal and inter-zonal level to decide upon a harmonised interpretation and method of application of the precautionary principle in

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<sup>256</sup> See discussion in section IV.1.

<sup>257</sup> Paragraph A.1 Uniform Principles (n 50).

the context of PPP evaluation and authorisation. In the interests of enhancing co-ordination and efficiency within the zones, as well as transparency, **Member States** should set these out in guidance and publish that guidance.

Perhaps more importantly, given that EU law relating to the precautionary principle may be unclear and therefore causing inconsistent application, the **Commission** is encouraged to develop (and publish) guidance to clarify, perhaps on the basis of such research as suggested above, how the precautionary principle should be interpreted and applied in the context of PPP evaluations and authorisations.

Both **Member States** and the **Commission** are encouraged, in drawing up such guidance, to consult with wider stakeholders and/or relevant PIGs with the aim of enhancing both the transparency and quality of the guidance.

## 4. Sustainability

### 4.1 Discussion

Member States were asked five questions on sustainability. One Member State appears to have misinterpreted these questions as relating to the substitution principle. These answers are therefore excluded as unreliable and the responses of the remaining 11 are presented.

Firstly, Member States were asked whether they take the principle of sustainability into account in their decision-making regarding the authorisation of PPPs (Q11). Seven Member States indicate that they do so 'with every application' and one indicates that it does so 'with most applications'. **Sweden** selected 'never'. It comments, in response to Q12 which asks about the basis on which Member States decide whether or not to take this principle into account, that '[t]he concept "Principle of sustainability" cannot be found in the Regulation'. I agree, as discussed in section IV.2.<sup>258</sup> One Member State comments that it is taken into account on the basis of internal expert discussions. The **Netherlands** comments that the ability to take sustainability into account is limited, noting that the Regulation 'does not provide the possibility to take into account socio-economic effects and to weight [sic] the environmental risks and benefits of the measures and plant protection products used in a crop system'. It notes further that it is running pilots to develop integrated pest management (IPM) systems, including '[a]uthorisation of applications fitting in an IPM system and the development of the needed risk assessment methodology'. The aim is to create a 'framework to stimulate a sustainable agricultural practice'. Results will be shared with the Commission, EFSA and other

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<sup>258</sup> It was argued, in this section, that 'sustainability' is not mentioned explicitly in the Regulation. It argued further that 'sustainability' should be interpreted to incorporate social, economic and environmental dimensions and the interests of future generations. This interpretation is not to be found in EU policy or legislation on PPPs. Instead, the SUD and policy interprets 'sustainability' to mean 'risk reduction' and pursues this goal. For more, see (Hamlyn, 2015) The Regulation also pursues this goal.

Member States. Two Member States did not answer Q11, including **Germany** which notes, in comments, that it applies the Uniform Principles and Commission guidance.

ZSC secretariats were also asked whether Member States in their zones take sustainability into account during evaluation. The **NZSC secretariat** reports that it is not aware of any Member States who do. All three referred to the SUD as the regime relevant to sustainability and pesticides. Two **zSC secretariats** comment that sustainable use of pesticides was outside the scope of the zonal system or beyond its remit to provide any guidance on sustainability. The **CZSC secretariat** feels that sustainability is taken into account in the assessment of efficacy ‘when reflecting the resistance situation in a certain [good agricultural practice]’, following the Uniform Principles. The **SZSC secretariat** feels that ‘sustainable use’ imposes no limits on authorisations. The responses reflect the nebulous nature of sustainability<sup>259</sup> and therefore the difficulty of assessing the extent to which Member States have regard to it during evaluation. Indeed, the **SZSC secretariat** queries what is meant by ‘sustainability’ and states that it is a national issue.

Neither Q11 nor Q12 were designed to gather an understanding, specifically, of the interaction of the Sustainable Use Directive with national zonal authorisation procedures. However, either in comments to Q11 or in response to Q12, three Member States refer to their National Action Plans (NAP)<sup>260</sup> and/or the EU’s SUD itself. The **Netherlands** expresses its opinion regarding the difficulties of implementing sustainability within the framework of the Regulation, noting that ‘[o]nly the resilience of the agricultural system is guaranteed by the assessment of non-target arthropods and plant and risk mitigation measures as is laid down in the uniform principles and the guidance documents’, ‘[t]he methodology to account for sustainability in the assessment is largely missing...’. In the context of an interpretation of sustainability as risk reduction, **Belgium** highlights the potential to review authorisations<sup>261</sup> and its monitoring programme of active substances in water and its power to modify or withdraw applications on the basis of the results. The comments of **zSC secretariats** discussed above imply that the SUD and PPPR are regarded as operating separately.

Despite the lack of provision for considering NAPs during authorisation decision-making, Recital 29 PPPR provides that Member States may impose ‘appropriate conditions’ on the use of PPPs having regard to the objectives of their NAPs. Q15 asks Member States how often they do this in order to gain an impression of the potential influence of the primary national instrument for achieving the sustainable use of pesticides in authorisation decision-making. While one Member State selected ‘never’, two selected ‘in some authorisations’ and five selected ‘in every authorisation’. There were no zone-specific trends. **Sweden** notes, in practice, this occurs in few cases. The **Netherlands** refers to the influence of, *inter alia*, its NAP on agricultural practice, which is taken into account in risk assessments of PPPs, demonstrating a means by which efforts to achieve sustainable use of pesticides surface during PPP

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<sup>259</sup> See section IV.2.

<sup>260</sup> Article 4 SUD (n 3).

<sup>261</sup> Article 44(1) PPPR.

authorisation decision-making. **Germany** comments that in all authorisations it ‘imposes labelling requirements and use restrictions according to the specific circumstances in Germany’, although it does not refer directly to the objectives of its NAP. One Southern zone Member State reports that it does not impose such conditions as they are seen as causing a ‘lack of harmonisation between authorisation procedures in the different MSs’.

Q13 asked Member States to indicate their interpretation of sustainability. The available answers were as follows, with answers a), b) and c) constituting interpretations of sustainability which could be found in the 2009 regulatory regime as a whole: a) reducing the risks of using PPPs; b) optimising the use of PPPs, i.e. increasing efficiency of use to maintain or improve the benefits of using PPPs while reducing their risks; c) reducing dependence on PPPs; and d) considering the social, economic and environmental implications, including for future generations, of authorising or not authorising the PPP. Two Member States decline to answer this question. **Sweden** specifies e) ‘a combination of the above’ and in a comment differentiates between the approach taken with individual applications and the overall policy behind risk assessment. The former requires maintaining a high level of protection and reducing the risk, pursuant to the Regulation. The latter requires a ‘balance between the benefits of using PPPs and the level of protection... [as] expressed in the protection goals for the risk assessment’. Most selected a) and/or b), as shown in figure 1. Two Member States (both Central zone) select both a) and b), two select a) and d) and one selects a), b) and c).

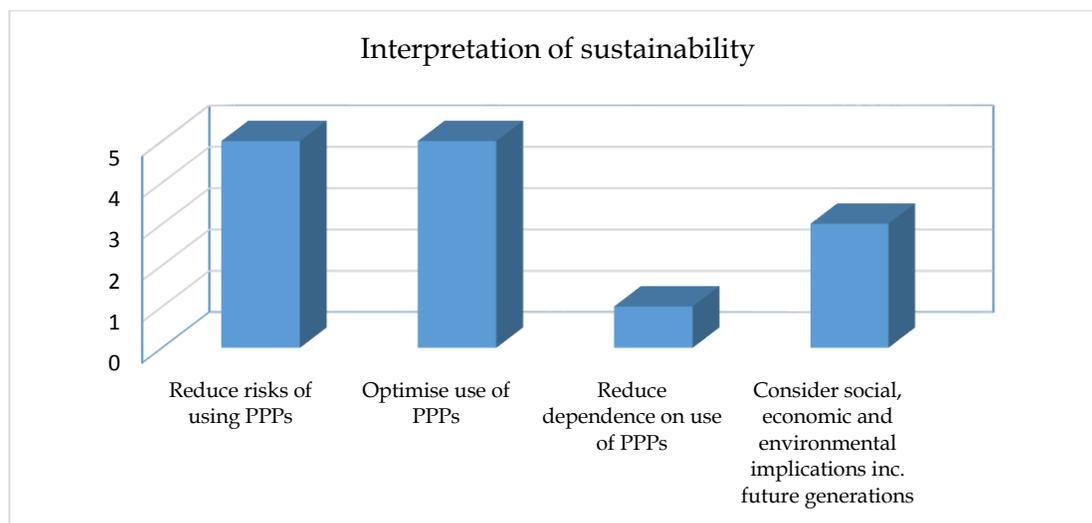


Figure 1: Interpretations of sustainability

It is significant that two Member States take social, economic and environmental implications, including for future generations, into account. As discussed in section IV.2, this interpretation of sustainability is not expressed in the SUD, nor in the Regulation. As the **Netherlands** forcefully argues:

*At the moment only the reduction of risk is possible within the framework of the Regulation. To realise a viable sustainable agricultural practice...the*

*interpretation of sustainability applied in...decision-making should also include social, economic and environmental implications, including implications for future generations.*

Q14 asked whether Member States follow any internal or external guidance when applying the principle of sustainability in order to apply it consistently. Two respondents report that they follow external guidance, three report they follow both internal and external guidance and four report they follow no guidance.<sup>262</sup>

The Stakeholder is of the opinion that all Member States take the principle of sustainability into account and apply it consistently. It understands the principle to be incorporated into the Uniform Principles and therefore CAs take the principle into account when they apply the Uniform Principles.

## **4.2 Summary and recommendations**

Although, again, the data are patchy, two tentative observations may be put forward. The first, as with the precautionary principle, has to do with consistency in interpretation and application of the 'principle of sustainability' both between and within Member States. Not every Member State takes sustainability into account in its authorisation decision-making and those that do, do not necessarily do so with every application and may not necessarily rely on guidance to ensure consistency in application. Moreover, responses from zSC secretariats suggest a belief that Member States are not *required* by the Regulation to take sustainability into account. In addition, Member States employ different interpretations of sustainability, potentially indicating varying levels of ambition in terms of the objectives they seek to achieve in implementing sustainability. These variations in practice may ultimately indicate an inconsistent basis for, and potential unpredictability in, decision-making across Member States, at least with respect to sustainability. In this respect, the **Netherlands'** comments that no methodology for taking sustainability into account during assessment exists, is pertinent. Without a methodology or clear guidance, potential for inconsistency is perhaps not surprising. However, the available data do not allow conclusions to be drawn regarding the extent to which these differing interpretations of sustainability or Member State decisions not to consider sustainability are reflected in national decision-making. As with the precautionary principle, a more in-depth study of national authorisation decisions would be required to understand their effect, if any.

Secondly, although the Regulation neither requires nor empowers Member States to consider their NAPs, the SUD or sustainability generally, when deciding whether or not to authorise a PPP, it appears that some Member States do so in practice. Furthermore, while Member States are entitled to have regard to the objectives of their NAPs when imposing 'appropriate conditions' on the use of PPPs, not all do so or do so all the time. This may suggest further inconsistencies in Member State decision-making practices in terms of the level of regard to sustainability during authorisation procedures.

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<sup>262</sup> This includes Sweden who indicated it does not apply the principle of sustainability.

## Recommendations

As with the precautionary principle, further empirical research is recommended to developed a greater understanding of the role sustainability (including its various interpretations) plays in PPP evaluation and authorisation. Such research should again involve a systematic, qualitative and comparative review of national authorisation decisions and would inform efforts to clarify the interpretation of sustainability and its role (if any) in decision-making, including the following recommendations.

The **Commission** is encouraged to develop and publish guidance clarifying whether Member States are required to take sustainability into account during evaluation and authorisation procedures. If Member States are so required, the **Commission** is further encouraged to clarify how sustainability is to be interpreted and applied in order to ensure consistent and predictable decision-making.

The Netherlands reported that it was working towards a framework for sustainable agriculture and that results of its experiments would be shared. The **Commission**, **EFSA** and other **Member States** are encouraged to review and consider seriously any findings or recommendations the Netherlands makes.

**Member States** are also encouraged to collaborate at zonal and inter-zonal level to decide upon a harmonised interpretation and method of application of sustainability in the context of PPP authorisation. In the interests of enhancing co-ordination and efficiency within the zones, as well as transparency, **Member States** should set these out in guidance and publish that guidance.

Both **Member States** and the **Commission** are encouraged, in drawing up such guidance, to consult with wider stakeholders including relevant public interest groups with the aim of enhancing both the transparency and quality of the guidance.

## 5. Substitution

### 5.1 Discussion

Member States were asked three questions on substitution and comparative assessment. Article 50(4) PPPR requires Member States to perform a comparative assessment of PPPs containing a candidate for substitution 'regularly and at the latest at renewal or amendment' of its authorisation (in addition to the requirement for comparative assessment during initial evaluation of an application<sup>263</sup>). Q16 asked how often CAs perform such a comparative assessment. One Member State's answer was unclear and is therefore not reported here. Of the remaining responses, ten Member States indicate comparative assessment is conducted at

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<sup>263</sup> Article 50(1) PPPR.

renewal and amendment, two of which also comment that it is also conducted for new authorisations. One Member State indicates comparative assessment is conducted at first authorisation and renewal. Member States may review an application at any time, in accordance with the provisions of Article 44 PPPR. This may lead to the withdrawal or amendment of an authorisation. The timing of amendments can therefore be unpredictable. However, without prejudice to Article 44, authorisations are granted for a maximum of one year 'from the date of expiry of the approval of the active substance' in the PPP 'and thereafter for as long as the active substances... are approved'.<sup>264</sup> Active substances are approved as candidates for substitution for a maximum of seven years.<sup>265</sup> This means that unless an authorisation is amended pursuant to Article 44, comparative assessments in the respondent Member States may be performed every seven or eight years, at most.

Q17 asked Member States to indicate the PPPs on which they conduct comparative assessments. All respondents selected 'PPPs containing active substances classified as candidates for substitution pursuant to Article 24(1) PPPR', as required by Article 50(1) PPPR. Only two Member States indicate a more ambitious substitution programme. **Sweden** indicates that it performs optional comparative assessments under Article 50(2) PPPR. **Belgium** referred to Article 29(1)(d) PPPR which provides that to be authorised the technical formulation of a PPP must be 'such that user exposure or other risks are limited as much as possible without compromising the functioning of the product'. It notes that it performs a kind of comparative assessment 'between formulation types containing the same active substance but for which efficacy/selectivity or effects on health or environment may differ due to co-formulants'. Commission guidance also recognises the presence of the concept of comparative assessment in this provision (Commission, 2014a, p.3).

Finally, Q18 asked whether Member States follow any internal or external guidance in order to deliver consistent results. All respondents indicate that they follow either external or both internal and external guidance with three referring to EU and EPPO guidance. The **Netherlands** reports use of its own manuals for comparative assessment which contain *inter alia* 'European guidance on comparative assessment and national guidance on assessment of practical and economic disadvantages'. One (Southern zone) Member State reports that it followed internal guidance which 'specifies national options on issues left as optional in the EU Guidance'. **Sweden** reports no guidance for comparative assessment under Article 50(2), which is therefore conducted on a case-by-case basis. The **CZSC secretariat** notes that Member States still have only limited experience with comparative assessment and the **NZSC secretariat** reports that it is beyond its remit to provide guidance on it.

The Stakeholder feels that some CAs are correctly implementing comparative assessment but does not know whether it is implemented consistently across CAs. It is, however, sceptical about the usefulness of comparative assessment for achieving the sustainable use of pesticides and risk reduction particularly, partly due to the high levels of safety PPPs must meet for

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<sup>264</sup> Article 32(1), second paragraph PPPR.

<sup>265</sup> Article 24(1) PPPR.

authorisation anyway. It indicates that industry, generally, holds this view. It doubts comparative assessment could be better implemented and regards it as 'mainly a political gesture to demonstrate the desire to reduce the use of pesticides' by which 'already under-resourced Competent Authorities are unnecessarily burdened'. The **CZSC secretariat** echoes these concerns, doubting its ability to enhance safety, reporting that comparative assessment had not yet led to the withdrawal of products and attributing to it a risk of increased resistance to the remaining active substances.

## 5.2 Summary and recommendations

The respondent Member States appear to exhibit greater consistency, with all or most conducting comparative assessment on the same occasions, on the same PPPs and following guidance to ensure consistency. The greater consistency here is perhaps not surprising given the greater clarity of the relevant provisions in the Regulation, despite the unsettled nature of the substitution principle in the literature, as discussed in section IV.3. At the same time, few respondent Member States implement a more ambitious interpretation of the substitution principle by, for example, exercising the power in Article 50(2) PPPR. However, it is perhaps wise to remember that this principle is still a relatively new addition to the regulatory toolbox and to view substitution therefore as a process of continuous development, rather than a single decision (Hansson, Molander and Rudén, 2011, p.456), evolving as guidance, assessment models etc. develop (Commission, 2014a, p.8).

### Recommendations

In order to encourage a more ambitious application of the substitution principle, the **Commission** is advised to develop or commission and publish guidance for conducting optional comparative assessment under Article 50(2) PPPR.

Substitution and comparative assessment are still novel and may have unintended consequences. Further research is therefore recommended to investigate the effects of these new provisions and whether substitution is in fact reducing risks from PPPs. Furthermore, given the novelty of these provisions, it may be wise to allow for a few more years of experience before embarking on such research.

Hanssen et al. have made recommendations for promoting substitution. These include increasing the availability of data about toxicity, chemical composition and technical functionality; developing green chemistry and providing helpdesk functions, for example technical help from experts (Hansson, Molander and Rudén, 2011, pp.457–458). The **Commission** and/or **Member States** may wish to consider investigating and developing one or more of these initiatives.

## VIII – Conclusion and recommendations

### 1. Conclusion

The scope of this research was broad. It generated new data in an area which is generally not well understood and about which there is little knowledge. Given this starting point, the need to break new ground and the breadth of the research questions, this report should be regarded as a first step towards understanding the various matters covered. However, many questions remain unanswered and, as implementation of the Regulation progresses and the zonal system evolves, new questions will arise. More, and more focused, research will be necessary to understand the current situation as well as new developments, perhaps once more experience has been gained with the zonal system, zonal evaluation and comparative assessment. The conclusions of this research are summarised here. Section VIII.2 summarises the recommendations.

While this research has not identified any deficiencies which are likely significantly to undermine the reliability of CA decisions-making, there are large parts of the zonal procedure and CA decision-making which could be improved. Overall, the dimension currently capable of the greatest and most immediate improvement relates to the transparency of CAs, particularly in terms of access to information. In the medium to longer term, it may be appropriate to review the Regulation and relevant guidance and policy with a view to establishing opportunities for wider participation in decision-making primarily for the contribution such activities can make to transparency and to countering the risk of regulatory capture. In addition, given the discussions above<sup>266</sup> regarding the diversity of interpretations and their context-dependency, consistency in interpretation and application of the precautionary principle and sustainability among Member States, and the ambition with which substitution is implemented, could also be improved, for example through clear guidance. Finally, as ever, greater resources – financial, technical, expert, personnel and greater remuneration in order to attract qualified staff may reduce information asymmetry, improve decision-making, both in terms of its quality and speed and boost the operation of the zonal system overall.

However, it should be remembered that there are tensions between the various values which the regulation and decision-making should support. Restricting the movement of regulator heads between industry and CAs may improve independence but could simultaneously hinder recruitment of those with the necessary expertise. Consultation may improve transparency but at the same time reduce the efficiency of evaluation and authorisation procedures and further burden CAs. Increased accountability to government for example, depending on how it is implemented, may reduce independence. As such, steps to improve one area need to be carefully researched and designed in order to avoid undermining progress in another area.

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<sup>266</sup> See sections IV.1, IV.2, VII.3 and VII.4.

### **1.1 Authorisation procedure and zonal system**

Zonal evaluation and national decision-making procedures are characterised by diversity. For example, Member States differ in terms of the institutional structure of their CAs, the type and extent of communications with applicants during evaluation and decision-making and the nature of the expert advice (binding or consultative) provided to decision-makers. Overall, very few trends within the zones may be identified. The zonal system is valued by Member States for the benefits it delivers, for example harmonisation, work-sharing and resolution of disagreements between CAs. However, it still faces significant challenges, especially in terms of improving harmonisation, sharing work fairly within the zones and further strengthening trust between the Member States. It is a new and complex system which warrants further research and continued monitoring in order to understand better its development and operation.

### **1.2 Independence**

There are varying levels of formal independence of respondent CAs from government. However, most respondent CAs have sole responsibility for their decisions. Lack of formal independence does not necessarily mean unreliable or unfair regulation.

There are also varying levels of independence from industry. However, few of the respondent Member States report restrictions on recruiting CA heads from industry or on employment in industry after their appointment. This may risk undermining their independence from industry. Increased transparency and/or PIGs may provide mechanisms by which to counter regulatory capture.

Most respondent CAs lose some formal autonomy due to their being funded by government. In addition, government control over salaries reduces autonomy further and restricts CA ability to recruit the required staff. However, most respondent CAs regard themselves as possessing sufficient resources (personnel, technical, financial) to fulfil their obligations under the Regulation.

Due to the lack of data concerning stakeholder and public views with respect to the fairness and reasonableness of CA decision-making, the extent to which it is trusted and how far the independence of individual CAs (or lack thereof) is regarded as a problem, it is not possible to determine whether strengthening the formal independence of CAs would improve the quality of its decision-making.

### **1.3 Transparency**

Levels of transparency among CAs are low, overall. This is so firstly, in terms of the availability of information about evaluation and authorisation procedures and secondly, in terms of access to the information on which decisions are based. Both of these are necessary to enable interested parties to gain an understanding of the procedural and informational basis of PPP authorisations.

Public participation in decision-making is important for improving transparency. Currently, the Regulation does not require or provide for such participation during evaluation and

authorisation procedures and comparative assessment. Furthermore, the zonal system itself acts as a barrier to participation due to the level at which zonal evaluation procedures are conducted; a level which is far removed from most citizens. Given this legal framework, it is not surprising that consultation activities in Member States are extremely limited, if conducted at all.

CAs are subject to differing levels of accountability to national governments and legislatures. Some Member States operate robust systems of peer review or auditing of decisions which should operate to improve the overall reliability of their decision-making. Increasing transparency could also improve accountability.

#### **1.4 Precaution, sustainability and substitution**

There is evidence of inconsistent interpretation and application of the precautionary principle and sustainability amongst Member States. Member States exhibit greater consistency in conducting comparative assessment but overall, levels of ambition are low. Comparative assessment is still a relatively new exercise but eventually ambition could be improved.

## **2. Recommendations**

### **2.1 Authorisation procedure and zonal system**

Further, longer-term (external) qualitative and quantitative empirical research is recommended to understand better the operation of the zonal system, the challenges each zone faces, how these may be overcome and the potential for improving evaluation and the overall authorisation process. Such research could identify further examples of best practice with a view to promoting sharing and policy learning among Member States. For example, it was unclear whether all Member States assign project managers to manage applications. Further research could investigate Member State experience with the use of project managers and whether, for example, they reduce the occurrence of delays.

**Member States** are encouraged to continue communicating and working together in their zones and to step-up activities designed to improve harmonisation of, for example, methods and models for evaluation and to achieve fairer work-sharing with the aim of strengthening trust between each other. **Chairs of zSCs/zSC secretariats** are encouraged to take particular responsibility for co-ordinating and pushing forward these activities. The **Southern zone**, particularly, could consider introducing guidelines or other measures both governing the timing of RR publication and to improve efficacy assessment within the zone.

Information about, and understanding of, the zonal system more generally could be improved in order to provide an evidence base for possible future action and support. The **Commission** is therefore advised to continue monitoring the zonal system, including stakeholder experiences of the zones, in order to keep track of its progress. The **Commission** and **zSCs** are also encouraged to consider whether it would be feasible and valuable for zSCs to report (for example, annually) to the Commission on progress in their zones. The Commission is encouraged to provide support, for example financial and administrative, for the production

of such reports to ensure their quality. In the interests of transparency, any such reports should be made publicly available.

## 2.2 Independence

It is recommended that further qualitative research is conducted. This research should target two specific enquiries. First, it should seek to understand how the zonal evaluation and national authorisation procedures of the CAs are perceived by all stakeholders, including applicants and the general public, and the extent (if at all) to which these procedures are viewed as fair and reasonable. Secondly, it should move beyond study of formal independence to investigate the existence (if any), in practice, of governmental influence on CA decision-making, for example through review of CA decisions and in-depth examination of interaction between CAs and government during decision-making. Such research may provide a stronger basis on which to make substantive recommendations.

The Regulation places no obligation on Member States to report their progress on the implementation of its provisions.<sup>267</sup> While acknowledging the difficulty of amending legislation, given the lack of information about CAs and the operation of the zonal system, the introduction of such a reporting requirement on Member States could provide valuable information and constitute a step towards filling this knowledge gap. The **EU institutions** are encouraged to consider such an amendment. In the interests of transparency, any such reports should be made publicly available.

Regulatory (particularly cultural) capture has been identified as a risk to CAs. However, further empirical research would be required to determine the extent (if at all) to which any CAs are, in practice, influenced or captured by industry. Such research should involve, *inter alia*, qualitative review of registration reports and decisions against information submitted by applicants and modes of interaction between CAs and industry to understand the nature and proximity of the relationship. Recent literature (for example, (Carpenter and Moss, 2014b)) proposes robust methodologies to conduct such research. Greater understanding would provide a stronger evidence base on which to make recommendations. However, pending such research, the following recommendations are made.

**Member States** are encouraged to review their national provisions regarding potential for commissioners/agency heads to have held positions in industry prior to their appointment to CAs and to accept employment in industry post-appointment. In order to reduce the risk of regulatory capture, **Member States** are encouraged, furthermore, to consider strengthening restrictions with respect to both.

**Member States** are also encouraged share best practice. For example, Member States may benefit from learning about France's experience with its charter on relations with interest

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<sup>267</sup> Such reporting requirements exist elsewhere. For example, Member States are required to report on implementation to the Commission every three years, under Article 31(4) European Parliament and Council Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms [2001] OJ L106/1.

groups (section VII.1.2) and the Netherlands' experience with its quality standards (section VII.1.4). If successful, Member States may wish to implement similar measures.

Involvement of public interest groups (PIGs) in regulatory decision-making was discussed in section II.1.2 as a mechanism for reducing the risk of regulatory capture. Again, further research would be required into, for example, their appropriateness, mechanisms for their support (including funding) and to identify potential candidates. PIGs could operate on a national level and, if the PIG itself transcends national boundaries, on a zonal or EU level too.

Research into the potential for the zonal system to act as a counterweight to external pressure was beyond the scope of this study. Further research may therefore be necessary to investigate this question. If this potential is real, **Member States** and the **Commission** should provide support at zonal and inter-zonal level for developing the networks required to ensure individual CAs can take full advantage of the zonal system as a means to maintain and enhance their independence.

**Member States** are encouraged to review the means by which CAs are funded and to consider introducing fees covering the costs of evaluation and authorisation, pursuant to Article 74(1) PPPR. However, while securing CA funding through fees levied on industry may promote independence from government, dependence on such fees may reduce independence from industry. A straightforward recommendation with regard to the benefits to CA independence of retaining such fees is therefore not possible. The further research, recommended above, into CA independence in practice from government and industry should generate greater understanding of the relative prevalence or risk of government influence or industry capture. Appropriate funding structures could be designed or adjusted in response to the identified risks.

While pressures on government budgets are acknowledged, given the need for expertise both to ensure the quality of evaluation and decision-making and to counter information asymmetry, **Member States** may wish to consider the following options. Firstly, review and, if appropriate reduction of, the application of constraints on civil service remuneration in order to promote recruitment and retention of the necessary expert staff. Secondly, the development or enhancement of in-house training programmes in order to cultivate sources of expertise other than from within industry, as a further means to counter asymmetric information and industry influence or capture.

### 2.3 Transparency

**Member States** are encouraged to review the amount of information available online about their evaluation and authorisation procedures from the perspective both of applicants and other stakeholders/general publics. It may also be helpful to review other CA websites with high levels of information as examples of good practice. The UK CA website, for example, contains substantial information. In order to enhance transparency with respect to these procedures, **Member States** are encouraged to provide clear and comprehensive information at least in their native language and ideally, eventually, in English.

**Member States** are encouraged to increase the publication, ideally online, of information on PPPs within the limits of the law, especially the following:

- Authorisation decisions
- Registration reports
- The information sources on which evaluation and authorisation are based. Ideally, this should include the conclusions of the zRMS's evaluation
- Any submissions (and responses thereto, if relevant) made during any consultation process

To this end, **Member States** are encouraged to step up discussions amongst themselves regarding the publication of registration reports and other information. These discussions may need to happen alongside the development of measures, for example guidelines or training, designed to improve the quality of registration reports in order to support this measure to enhance transparency.

It is acknowledged that CA resources are limited. However, where possible, publication of the above information in English<sup>268</sup> is encouraged for its potential to enhance access to information for a larger audience and to improve the quality of future applications. Increased public availability of such information would facilitate conduct of the research recommended in sections VII.1.5/VIII.2.2.

Stronger measures to improve access to information may be desirable. The **Commission** is therefore encouraged to consider the possibility of amending the Regulation to introduce a requirement that registration reports (at least) are made publicly available.

Although there is no legislative requirement, **Member States** are encouraged to consider ways to open up their national authorisation decision-making procedures to wider participation. Member States could experiment, for example, with providing opportunities to comment on dRRs during the commenting phase of zonal evaluation (described in section VI) and/or on draft authorisation decisions. Further upstream, wider participation in the definition of national data requirements could improve the transparency of CA decision-making. If opening up such elements of decision-making to stakeholders and the wider public generally is regarded as time-consuming and unmanageable, participation by a limited number of select PIGs could still improve transparency as well as contributing valuable expertise.

Again, although there is no legislative requirement to ensure participation during zonal evaluation procedures, **zonal steering committees** are encouraged to consider ways to enhance the openness of these procedures. While it may be difficult to reach citizens across the entire zone, a starting point may be to identify PIGs or individuals (for example, users, CSOs, university experts) within the zone who can contribute different knowledge and perspectives to the drafting of, for example, zonal guidance documents. Given that the zonal system is still in its early stages, opening up evaluation and decision-making procedures themselves should

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<sup>268</sup> Or another widely used EU language. The impact of the UK's departure from the EU may be a factor in choice of appropriate language.

be considered in the longer-term and may need to be implemented gradually and sensitively in order not to over-burden CAs. For example, a willing and capable **zRMS** could pilot a programme whereby a PIG participates in the evaluation of an application, following which the zRMS shares its experience with other Member States.

Stronger measures for improving transparency of the zonal authorisation procedure would come from the EU institutions themselves. **Commission** support for Member States wishing to open up their decision-making procedures could include administrative support and expertise, for example in identifying appropriate PIGs or other actors and designing appropriate participatory procedures and online platforms (such as CIRCABC) to facilitate wider participation and sharing of results and experiences between Member States. Longer-term, the **Commission** is encouraged to draw up guidelines (or similar, non-legislative instruments) for increasing the openness of zonal evaluation and authorisation procedures with particular regard to providing opportunities for wider participation.

The strongest measure for improving transparency through participation would be a legislative requirement. Again, in the longer-term, the **European Parliament, Council and Commission** are encouraged to review the provisions of the Regulation in light of the findings of this report and overall EU policy commitments to public consultation and participation (discussed in section III.3) and to consider the possibility of introducing a specific provision governing participation during the zonal evaluation and national decision-making procedures, including comparative assessment.<sup>269</sup>

Given the complex structure of the zonal system and limited resources of CAs, further research is recommended to identify and elaborate potential and feasible participatory mechanisms, including PIGs, consensus conferences, citizen juries etc. appropriate to the zonal system and capacity of CAs.

**Member States** who do not already do so are encouraged to produce annual reports as a step towards enhancing the transparency of their operations and thereby also their accountability. Such reports would need to contain information about the CA's operations and progress against its objectives of a sufficient quality and intelligibility to enable proper scrutiny by the relevant oversight institutions and the public.

**Member States** are also encouraged to establish internal and/or external procedures for scrutinising their decisions, for example annual audits of a sample of decisions, where these are not already in operation. There are already examples of good practice and Member States are encouraged to use already established zonal networks to share such practices.

## 2.4 Precaution, sustainability and substitution

The above analysis suggests inconsistent application of the precautionary principle within the EU in the context of PPP evaluation and authorisation. However, to understand truly the divergences between Member State application of the precautionary principle in practice, a

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<sup>269</sup> The benefits of wider participation in comparative assessment were discussed in section IV.3.

systematic, qualitative and comparative review of authorisation decisions would be required. Such research would provide a stronger evidence base on which to pursue efforts to harmonise interpretation and application of the precautionary principle, including the following two recommendations.

**Member States** are encouraged to collaborate at zonal and inter-zonal level to decide upon a harmonised interpretation and method of application of the precautionary principle in the context of PPP evaluation and authorisation. In the interests of enhancing co-ordination and efficiency within the zones, as well as transparency, **Member States** should set these out in guidance and publish that guidance.

Perhaps more importantly, given that EU law relating to the precautionary principle may be unclear and therefore causing inconsistent application, the **Commission** is encouraged to develop (and publish) guidance to clarify, perhaps on the basis of such research as suggested above, how the precautionary principle should be interpreted and applied in the context of PPP evaluations and authorisations.

Both **Member States** and the **Commission** are encouraged, in drawing up such guidance, to consult with wider stakeholders and/or relevant PIGs with the aim of enhancing both the transparency and quality of the guidance.

As with the precautionary principle, further empirical research is recommended to developed a greater understanding of the role sustainability (including its various interpretations) plays in PPP evaluation and authorisation. Such research should again involve a systematic, qualitative and comparative review of national authorisation decisions and would inform efforts to clarify the interpretation of sustainability and its role (if any) in decision-making, including the following recommendations.

The **Commission** is encouraged to develop and publish guidance clarifying whether Member States are required to take sustainability into account during evaluation and authorisation procedures. If Member States are so required, the **Commission** is further encouraged to clarify how sustainability is to be interpreted and applied in order to ensure consistent and predictable decision-making.

The Netherlands reported that it was working towards a framework for sustainable agriculture and that results of its experiments would be shared. The **Commission**, **EFSA** and other **Member States** are encouraged to review and consider seriously any findings or recommendations the Netherlands makes.

**Member States** are also encouraged to collaborate at zonal and inter-zonal level to decide upon a harmonised interpretation and method of application of sustainability in the context of PPP authorisation. In the interests of enhancing co-ordination and efficiency within the zones, as well as transparency, **Member States** should set these out in guidance and publish that guidance.

Both **Member States** and the **Commission** are encouraged, in drawing up such guidance, to consult with wider stakeholders including relevant public interest groups with the aim of enhancing both the transparency and quality of the guidance.

In order to encourage a more ambitious application of the substitution principle, the **Commission** is advised to develop or commission and publish guidance for conducting optional comparative assessment under Article 50(2) PPPR.

Substitution and comparative assessment are still novel and may have unintended consequences. Further research is therefore recommended to investigate the effects of these new provisions and whether substitution is in fact reducing risks from PPPs. Furthermore, given the novelty of these provisions, it may be wise to allow for a few more years of experience before embarking on such research.

Hanssen et al. have made recommendations for promoting substitution. These include increasing the availability of data about toxicity, chemical composition and technical functionality; developing green chemistry and providing helpdesk functions, for example technical help from experts (Hansson, Molander and Rudén, 2011, pp.457–458). The **Commission** and/or **Member States** may wish to consider investigating and developing one or more of these initiatives.

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## **Annex IV**

# **Mapping the practices of scientific (risk assessment) evaluation of active substances used in plant protection products**

**Research paper  
by Dr. Dovilė Rimkutė**

### **Abstract**

The regulation of risks and hazards is highly differentiated and contested within the EU and beyond, i.e. risk assessors arrive at different scientific conclusions. This study, first, maps the practices of scientific (assessments) of active substances used in plant protection products: glyphosate, 2,4-D, bentazone and neonicotinoid pesticides. Second, the study aims to explain 'why scientific divergences have emerged' and whether the scientific differences between different risk assessors can be explained by differences in their institutional designs (mandates, procedures, formal working policies) and/or the technical/scientific quality standards followed in the risk assessment processes. To that end, this study draws on the analysis of primary documents, semi-structured interviews with the representatives of agencies, as well as an online stakeholders' survey.

The study has shown that several factors have contributed to the explanation relating to the main research question of this research paper: 'Why do risk assessors arrive at different conclusions?' The results from desk research and semi-structured interviews suggest that the diverging scientific conclusions on the studied substances have emerged because different risk assessors have engaged in different types of scientific evaluations (hazard identification versus risk assessment), which is an important explanatory factor explaining discrepancies in scientific conclusions. Furthermore, the following factors were identified as important causes explaining scientific divergences in scientific evaluations: agencies relied on different data sources to assess risks and hazards; they applied different scientific approaches (i.e., methodologies) to assess the collected data; they engaged in the different interpretations when weighing indefinite results.

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## Executive summary

Scientific risk assessments are devised to offer an analytical tool to assess scientific knowledge regarding potential hazards and risks to humans and the environment. The duties of regulatory agencies and bodies assigned with the hazard identification/risk assessment tasks are deemed to be a highly scientific activity, mainly entrenched in the technical use of scientific knowledge and technical data. However, the regulation of risks and hazards is highly differentiated and contested within the EU and beyond, i.e. risk assessors arrive at different scientific conclusions. This study contributes to the debate by, first, mapping the practices of scientific (risk assessment) evaluations of active substances used in plant protection products. Second, the study aims to explain ‘why scientific divergences have emerged’ and whether the scientific differences between different risk assessors can be explained by differences in (1) their institutional designs (mandates, procedures, formal working policies) and/or (2) the technical/scientific quality standards followed in the risk assessment processes. To that end, this study draws on the analysis of primary documents and publicly available information, semi-structured interviews with the representatives of (regulatory) agencies, as well as an online stakeholders’ survey to study the scientific/technical, procedural, performative and ethical aspects of the European Food Safety Authority’s (EFSA) work across a wide range of stakeholders and organisations (research community, national regulatory authorities, NGOs, industry, etc.).

This research paper has focussed on the following active substances: glyphosate (herbicide), 2,4-D (herbicide), bentazone (herbicide), neonicotinoids (insecticide). It has shown that the following scientific divergences have emerged between reputable risk assessors (for more information see Chapter 2):

- **Glyphosate:** The report released in 2015 by the International Agency for Research on Cancer (IARC), an agency linked with the World Health Organisation (WHO), classified glyphosate as ‘probably carcinogenic to humans’ (IARC, 2015). Other regulatory agencies and bodies reached the conclusion that glyphosate is unlikely to be genotoxic or to pose a carcinogenic threat to humans. Those regulators include: the German Federal Institute for Risk Assessment (BfR), the European Food Safety Agency (EFSA), the European Chemicals Agency (ECHA), the United States Environmental Protection Agency (US EPA), the New Zealand Ministry Environmental Protection Agency (NZ EPA), the Health Canada Department of National Public Health (PMRA), the Australian Pesticides and Veterinary Medicines Authority (APVMA) and the Joint FAO/WHO Meeting on Pesticide Residues (JMPR).
- **2,4-D:** The IARC has classified 2,4-D as ‘possibly carcinogenic to humans’, whereas other health and safety agencies worldwide and in the EU (including EFSA and the US EPA) do not currently consider 2,4-D to be a human carcinogen.
- **Neonicotinoids** (clothianidin, imidacloprid, thiamethoxam): EFSA reached the conclusion that the neonicotinoid pesticides cause an acute risk to bees (2013, 2018), while the American and Canadian regulatory authorities conclude that bees under fieldwork conditions are not exposed to the neonicotinoid pesticides to the extent which could cause an acute risk to them.

- **Bentazone:** Overall, agencies that have conducted hazard/risk assessments of bentazone agree on the core scientific conclusions regarding the risks caused by bentazone. National, EU-level and international risk assessors concluded that genotoxic, carcinogenic or neurotoxic effects are not produced by bentazone.

In Chapter 3, the study has assessed the institutional design of risk assessors and procedural mechanisms followed in the scientific assessments. The analysis has shown that different risk assessors possess different mandates which have different regulatory implications. The desk research and semi-structured interviews have indicated that the IARC is distinct from the risk assessors working in the regulatory context (e.g., BfR, EFSA, ECHA, US EPA). First, the IARC has a substantially different mandate and organisational mission. Second, the IARC and agencies working in the regulatory context have obligations to follow diverse procedures and rules in their scientific evaluation processes.

Chapter 4 has shown that several factors have contributed to the explanation relating to the main research question of this research paper: 'Why do risk assessors arrive at different conclusions?' The results from desk research and semi-structured interviews suggest that the diverging scientific conclusions on the studied substances have emerged because different risk assessors have engaged in different types of scientific evaluations (hazard identification *versus* risk assessment), which is an important explanatory factor explaining discrepancies in scientific conclusions. Furthermore, the following factors were identified as important causes explaining scientific divergences in scientific evaluations: (1) risk assessors relied on different data sources to assess hazards and risks and (2) they applied different scientific approaches (i.e., methodologies) to assess the collected data.

Finally, this research paper has drawn on an online stakeholders' survey to study the opinions of stakeholders about EFSA and its scientific risk assessments (see Chapter 5). The survey was filled in by 42 respondents, of which 55% were national competent authorities, industry/industry associations (15%), NGOs and advocacy groups (12%), research community (8%) and other groups. The survey results have shown that, overall, EFSA is a well-regarded organisation on various dimensions: technical/scientific, procedural, performative and ethical/moral. In particular, the scientific/technical aspects of EFSA's conduct are perceived positively by the stakeholders who have submitted their contributions to the survey. Furthermore, overall the respondents perceive EFSA as a credible regulatory body whose work is authoritative and free from the political influence. The survey indicated that overall EFSA is regarded as a transparent, trustworthy and independent organisation.

## List of abbreviations

<b>ACVM</b>	Agricultural Compounds and Veterinary Medicines
<b>ADI</b>	Acceptable Daily Intake
<b>AdoIs</b>	Annual Declaration of Interests
<b>AGRI</b>	European Parliament's Committee on Agriculture and Rural Development
<b>ANSES</b>	French Agency for Food, Environmental and Occupational Health Safety
<b>APVMA</b>	Australian Pesticides and Veterinary Medicines Authority
<b>ARfD</b>	Acute Reference Dose
<b>BASF</b>	Baden Aniline and Soda Factory
<b>BAuA</b>	German Federal Institute for Occupational Safety and Health
<b>BfR</b>	German Federal Institute for Risk Assessment
<b>BMEL</b>	German Federal Ministry of Food and Agriculture
<b>BMG</b>	German Federal Ministry of Health
<b>BMUB</b>	German Federal Minister for Environment, Nature Conservation, Building and Nuclear Safety
<b>BVL</b>	German Federal Office of Consumer Protection and Food Safety
<b>CAC</b>	Codex Alimentarius Commission
<b>CCPR</b>	Codex Committee on Pesticide Residues
<b>CLH</b>	Harmonised Classification and Labelling
<b>CLP</b>	Classification, Labelling and Packaging
<b>CMR</b>	Carcinogenicity, Mutagenicity, Reproductive Toxicity
<b>CoI</b>	Conflicts of Interest
<b>DFG</b>	German Research Foundation
<b>DG EPRS</b>	Directorate General for Parliamentary Research Service
<b>DGAL</b>	French Directorate General for Food
<b>DoI</b>	Declaration of Interests
<b>ECHA</b>	European Chemicals Agency
<b>ECPA</b>	European Crop Protection Association
<b>EFSA</b>	European Food Safety Authority
<b>ENVI</b>	European Parliament's Committee on Environment, Public Health and Food Safety
<b>EP</b>	European Parliament
<b>ESLC</b>	Evidence suggests lack of carcinogenicity
<b>EU</b>	European Union
<b>FAO</b>	Food and Agriculture Organization
<b>FIFRA</b>	Federal Insecticide, Fungicide, and Rodenticide Act
<b>FSCJ</b>	Food Safety Commission of Japan
<b>GAP</b>	Good Agricultural Practice
<b>GECU</b>	Emergency Collective Expert Assessment Group
<b>GHS</b>	United Nations' Globally Harmonised System
<b>GLP</b>	Good Laboratory Practice
<b>GM</b>	Genetically Modified
<b>GMO</b>	Genetically Modified Organisms
<b>HA</b>	Health Advisory
<b>HEAL</b>	Health and Environment Alliance

<b>HSNO</b>	Hazardous Substances and New Organisms
<b>IARC</b>	International Agency for Research on Cancer
<b>IESTI</b>	International estimated short-term intake (IESTI)
<b>INRA</b>	French National Institute for Agricultural Research
<b>IPCS</b>	International Programme on Chemical Safety
<b>JMPR</b>	Joint FAO/WHO Meeting on Pesticide Residues
<b>LOC</b>	Maximum Level of Concern
<b>LOEL</b>	Lowest Observed Effect Level
<b>MOE</b>	Margin of Exposure
<b>MPI</b>	Ministry for Primary Industries
<b>MRLs</b>	Maximum Residue Levels
<b>MSCA</b>	Member State Competent Authority
<b>NESTI</b>	National Estimated Short-Term Intake
<b>NOEC</b>	No Observable Effect Concentration
<b>NOEL</b>	No Observed Effect Level
<b>NRC</b>	National Research Council
<b>NTMDI</b>	National Theoretical maximum daily intake
<b>NZ EPA</b>	New Zealand Ministry Environmental Protection Agency
<b>OCSPP</b>	EPA's Office of Chemical Safety and Pollution Prevention
<b>ODoIs</b>	Oral Declarations of Interest
<b>OECD</b>	Organization for Economic Cooperation and Development
<b>OPP</b>	Office of Pesticide Programs
<b>PAN</b>	Europe Pesticide Action Network Europe
<b>PIC</b>	Prior Informed Consent
<b>PMRA</b>	Health Canada Department of National Public Health
<b>PPE</b>	Personal Protective Equipment
<b>PPP</b>	Plant Protection Products
<b>PPR</b>	Panel on Plant Protection Products and their Residues
<b>QMS</b>	Quality Management System
<b>RAC</b>	Committee for Risk Assessment
<b>RAR</b>	Renewal Assessment Report
<b>REACH</b>	Registration, Evaluation, Authorisation and Restriction of Chemicals
<b>RED</b>	Registration Eligibility Decision
<b>RfD</b>	Reference Dose
<b>RIVM</b>	National Institute for Public Health and the Environment
<b>RMS</b>	Rapporteur Member State
<b>RQs</b>	Risk Quotients
<b>SAB</b>	Science Advisory Board
<b>SAP</b>	Scientific Advisory Panel
<b>SDoIs</b>	Specific Declarations of Interest
<b>SDWA</b>	Safe Drinking Water Act
<b>UN</b>	United Nations
<b>US EPA</b>	United States Environmental Protection Agency
<b>WG</b>	Working Group
<b>WHO</b>	World Health Organisation
<b>WoE</b>	Weight of Evidence

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## Chapter 1

### I – Background

Scientific risk assessments are devised to offer an analytical means to assess scientific knowledge regarding potential hazards and risks to humans and the environment (Rimkutė, 2018). The duties of regulatory agencies assigned with risk assessment/hazard identification and classification tasks are deemed to be highly scientific activities, mainly entrenched in the technical use of scientific knowledge and technical data. However, the regulation of risks and hazards is highly differentiated and contested within the EU and beyond. Scholars analysing the practices of scientific risk assessments have observed that regulatory agencies' technical/scientific and procedural practices – i.e., the ways in which scientific knowledge is used in risk assessments – vary greatly (Bozzini, 2017; Peel 2010; Jasanoff 1995; Rothstein et al. 1999). The discussions between independent regulatory bodies become even more disputed when it comes to chemical, environmental or foodstuff policy-making (Lodge and Wegrich 2011; Lofstedt and Schlag 2016; Rimkutė 2015, 2016, 2018). For instance, independent regulatory agencies and bodies have taken a different scientific stance on pesticides, endocrine disruptors, air pollutants and genetically modified organisms.

More recently, heated debates emerged among national, EU and international regulators on different sides of the policy aisle on glyphosate where one group of risk assessors (working in non-regulatory environment) argues that the substance should be classified as 'probably carcinogenic' (the International Agency for Research on Cancer ([IARC, 2017c](#))), while another group of risk assessors (working in regulatory environment) argues that glyphosate is "unlikely to pose carcinogenic hazard" (e.g., [EFSA, 2015b](#); [ECHA, 2017c](#); [US EPA, 2016](#)). Similar contradictions can be observed regarding other active substances: 2,4-D (herbicide); neonicotinoids (insecticide): clothianidin, imidacloprid, thiamethoxam.

Given these scientific controversies, this research paper aims to assess the scientific and procedural aspects of risk assessments that have led to regulatory controversies (i.e., a lack of scientific consistency among independent regulatory agencies and bodies). More specifically, this research paper, firstly, aims to map (regulatory) agencies and bodies that conducted scientific evaluations of five active substances: glyphosate; 2,4-D; bentazone; neonicotinoid pesticides (more specifically, clothianidin, imidacloprid, thiamethoxam). It briefly introduces the scientific conclusions reached and outlines the core disagreements between risk assessors. Second, this research paper aims to explain why scientific disagreements in scientific evaluations have occurred. To that end, the paper reviews the institutional designs of key agencies that have produced scientific evaluations of the active substances of interest. Furthermore, the paper examines which technical, procedural and scientific methods the agencies used throughout the scientific assessments, as specified in the analytical framework of the paper.

## II – Analytical Framework

In this research paper, the risk assessors that have produced contradicting risk assessments are compared against the following criteria:

1. **The institutional design of risk assessors and procedural mechanisms followed in the scientific assessments:**
  - Formal mandate and accountability mechanisms;
  - Independence and transparency policies;
  - Selection of scientific experts: requirements for scientific experts (e.g., conflict of interest statements);
  - Procedures followed in the risk/hazard assessments;
  - Internal/external control mechanisms: quality standards followed in the risk assessments.
  
2. **The technical/scientific aspects of risk assessments:**
  - Scientific (quality) standards: the type of evidence used in the risk assessment (e.g., industry research, academic articles), data collection methods, scientific approaches followed to evaluate the collected data (e.g. Weight of Evidence (WoE) approach).

## III – Methodology: data collection methods and comparison strategy

This research paper follows the technical specifications for the assignment. As requested, the research paper maps the bodies (i.e., (regulatory) agencies and independent expertise centres) that have carried out scientific assessments of the following active substances: glyphosate; bentazone; 2,4-D; neonicotinoids: clothianidin, imidacloprid, thiamethoxam. These substances were selected based on the controversies they have raised in terms of scientific assessments, and hence public concerns.

This research paper aims to map the most relevant national, EU-level and international bodies that have arrived at similar/different scientific conclusions (compared with the European Food Safety Authority (EFSA)) and review (1) the institutional design of risk assessors and procedural mechanisms followed in the scientific assessments, as well as (2) the scientific aspects of risk assessments. To that end, the research paper relies on the following information sources:

**Primary documents:** The study extensively relies on publicly available documents such as founding regulations, formal mandates, corporate documents (e.g., annual reports, policy and strategy documents). Publicly available documents on the procedural aspects of the risk assessments such as: minutes of working group meetings; documents specifying procedures followed; press releases of agencies and bodies. Publicly available documents on the scientific aspects of risk assessments were retrieved from the scientific outputs.

**Semi-structured interviews:** the study draws on semi-structured interviews with representatives of the examined (regulatory) agencies and bodies. Semi-structured interviews were conducted to obtain in-depth information about the technical and procedural aspects of risk assessors' scientific outputs. Interviews were structured around a set of broad topics and general questions reflecting the analytical framework of the research paper.<sup>1</sup>

The interviews were collected between the 7<sup>th</sup> of December 2017 and the 6<sup>th</sup> of April 2018 (see Annex I: List of interviews) with scientists and managers from the following authorities: the European Food Safety Authority (EFSA); the European Chemicals Agency (ECHA); the German Federal Institute for risk assessment (BfR); the Federal Office of Consumer Protection and Food Safety (BVL); the French Agency for Food, Environmental and Occupational Health & Safety (ANSES); the Australian Pesticides and Veterinary Medicines Authority (APVMA); and the US Environmental Protection Agency (US EPA) (written responses were provided).<sup>2</sup>

The list and names of relevant interviewees were accessed through the publicly available sources of information. The Ex-post Evaluation Unit of EPRS provided help in establishing contact with the interviewees from national and EU agencies. The author emphasised that the participation in the interview programme is entirely voluntary: interviewees had the right to refuse to participate or to withdraw their participation without any consequences. All relevant information about the research and interview procedures were introduced before the interview started.

The researcher made sure that the research does not lead (either directly or indirectly) to a breach of agreed confidentiality and anonymity. No individual information and other personally identifiable information is used in the research paper (unless the interviewees noted that their personal names can be revealed). To maintain the anonymity of the interviewees' personal information, only partial information is provided, e.g. *Agency representative #1*.

The researcher asked permission to record the interview. If consent was given, the interviews were audio-recorded and transcribed. The interviewees were also able to choose not to be audio-recorded, in which case the researcher took notes and summarised what the interviewees communicated.

**Stakeholder Survey:** In addition to the desk research and semi-structured interviews, an online stakeholders' survey (entitled 'Study on the European Food Safety Authority and its risk assessment practices') was carried out from the 4<sup>th</sup> of January to the 23<sup>rd</sup> of February 2018 to collect opinions about the scientific risk assessment model established in the EU by Regulation (EC) 1107/2009 concerning the placing of plant protection products on the market. The questions explored the scientific, technical and procedural aspects of

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<sup>1</sup> The list of interview questions could be submitted upon request.

<sup>2</sup> It is of note that IARC and PMRA (Canada) were available to give an interview and/or submit a written contribution but after the closure of data collection (6 April).

European Food Safety Authority's (EFSA) work across a wide range of stakeholders and organisations (research community, national regulatory authorities, NGOs, industry, etc.). The survey was disseminated to 293 stakeholders, including national competent authorities, PPP manufacturers and industry organisations, associations of PPP users, farmers' associations, (human and animal) health and environment NGOs, consumer groups, and research community (e.g., academics). The list of potential respondents was collected from EFSA's website, i.e. EFSA publishes a list of organisations and individuals who attend its events (stakeholder consultations, conferences, other activities organised by EFSA). The survey received 42 responses (response rate: 15%). For more information, see Chapter 5.

**Data analysis:** the analytical framework (outlined in II – Analytical Framework) was used to assess the technical and procedural aspects of the contradicting risk assessments, as well as the institutional designs of agencies and bodies that have produced them. The comparison is organised as follows:

1. **Comparisons across risk assessors in terms of their institutional designs:** At this stage of the research project, formal mandate and accountability mechanisms, independence and transparency policies; policies specifying the selection of scientific experts criteria, requirements for scientific experts, procedures followed in the risk/hazard assessments, and internal/external control mechanisms are introduced and compared across the selected sample of agencies. The following agencies were covered in the analysis: (1) Relevant EU agencies (the European Food Safety Authority and the European Chemicals Agency) and national competent authorities (the German Federal Institute for Risk Assessment); (2) Most prominent international bodies (the International Agency for Research on Cancer); and (3) Agencies working outside the EU (the United States Environmental Protection Agency).

The selection of the aforementioned agencies for an in-depth analysis was motivated by the following. First, relevant EU agencies (EFSA and ECHA) were included in the analysis as they played an important role by providing the European Commission (the risk manager for approval of substances at EU level) with their scientific evaluations of active substances. Corresponding national authorities were also included in the analysis (e.g. the German (BfR)) as they issued the Renewal Assessment Report (RAR) on glyphosate on which EU agencies based their peer-reviews of pesticides. Last but not least, the IARC was selected as a case of an international regulatory body, and the US EPA as an independent regulatory agency functioning outside the EU. Furthermore, the US EPA is regarded as a typical case of the most relevant agencies operating outside the EU (i.e., Australian and Canadian regulatory agencies have comparable institutional designs to the American regulatory agencies). For more information on the case selection strategy and analysis, see Chapter 3.

2. **Comparisons of technical and scientific aspects of agencies** that have produced contradicting risk assessments. The same sample of agencies (EFSA, ECHA, BfR, IARC, US EPA) is covered in the comparison of scientific (quality) standards followed by agencies.

The core focus of comparison is on the glyphosate case. This focus has been selected due to the public interest in the issue, however, the interviewed representatives of regulatory authorities (e.g., EFSA, ECHA, BfR) confirmed that the same (or comparable) scientific practices were applied in evaluating other active substances (2,4-D; neonicotinoid pesticides; bentazone).

## Chapter 2

### I - Mapping regulatory agencies and their scientific conclusions

This chapter maps the bodies which have carried out scientific risk assessments of active substances, such as glyphosate, 2,4-D, bentazone and neonicotinoids. It reviews the most relevant national, supranational and international bodies that have assessed hazards/risks of the five active substances. The intended contribution of the mapping is, first, to identify which regulators conducted scientific evaluations of the active substance of interest. Second, the chapter aims to briefly discuss the scientific conclusions reached by different regulatory bodies.

#### Key findings

- **Glyphosate:** The report released in 2015 by the IARC, an agency linked with the World Health Organisation (WHO), classified glyphosate as ‘probably carcinogenic to humans’ (IARC, 2015). Other regulatory agencies and bodies reached the conclusion that glyphosate is unlikely to be genotoxic or to pose a carcinogenic threat to humans. Those regulators include: the German Federal Institute for Risk Assessment (BfR), the European Food Safety Authority (EFSA), the European Chemicals Agency (ECHA), the United States Environmental Protection Agency (US EPA), the New Zealand Ministry Environmental Protection Agency (NZ EPA), the Health Canada Department of National Public Health (PMRA), the Australian Pesticides and Veterinary Medicines Authority (APVMA) and the Joint FAO/WHO Meeting on Pesticide Residues (JMPR).
- **2,4-D:** The IARC arrived at the conclusion that 2,4-D should be classified as ‘possibly carcinogenic to humans’, whereas other health and safety agencies (including EFSA and the US EPA) do not currently consider 2,4-D to be a human carcinogen.
- **Bentazone:** EFSA and other agencies concluded that genotoxic, carcinogenic or neurotoxic effects are not produced by bentazone. However, EFSA, together with other regulatory agencies (e.g., US EPA), have identified several data gaps (in the mammalian toxicology area, in potential endocrine disrupting properties, risks to consumers etc.) which did not allow the finalisation of the risk assessment of bentazone.
- **Neonicotinoids:** In 2013 and 2018, EFSA reached the conclusion that the neonicotinoid pesticides (clothianidin, imidacloprid, thiamethoxam) cause an acute risk to honey bees, while the US EPA (and Canadian regulatory authorities) claimed that honeybees are not exposed to the neonicotinoid pesticides to the extent which could cause an acute risk to them.

## 1. Glyphosate

Glyphosate is one of the most widely used active substances, both worldwide and in the EU. The substance was discovered to be an herbicide by a Monsanto chemist in 1970. In 1974, glyphosate was introduced to market by Monsanto under the trade name Roundup. Glyphosate-based pesticides are utilised as herbicides in agriculture, horticulture, viticulture, silviculture, as well as garden maintenance (including home use). The primary use of this herbicide is aimed at combatting weeds (especially annual broadleaf weeds, grasses and woody plants) that compete with cultivated crops. The extensive use and public deliberation regarding glyphosate have stimulated societal concerns as well as a scientific controversy on the toxicity of glyphosate (Faria, 2015) beyond the scientific debate (Blaylock, 2015; Tarazona et al., 2017).

In the last 40 years, glyphosate has been assessed for safety by a multiplicity of national and international authorities, including the US EPA (1993), Australia (1996; 2016), WHO (1994), and the EU (2002; EFSA, 2015a; ECHA, 2017a), invariably giving an authorisation to glyphosate with some warnings about conditions for safe use. However, the debate surrounding the use of glyphosate in the European Union (EU) and beyond was initially sparked by the International Agency for Research on Cancer (IARC). On the 20<sup>th</sup> of March 2015, IARC published its scientific risk assessment classifying glyphosate as “probably carcinogenic” (IARC, 2017c). In parallel, risk regulators working at national, EU and international levels have carried out risk assessments of glyphosate to evaluate the (new) scientific data. The re-assessments were mainly carried out because the licence for the use of glyphosate was due to expire (e.g., in the EU, the due date was on the 30<sup>th</sup> of June 2016).

Regulatory agencies that possess (were given) a mandate to evaluate the risks of glyphosate have issued their evaluations of the active substance. The risk/hazard assessments were published by the regulatory agencies and bodies, such as the German Federal Institute for Risk Assessment (BfR), the French Agency for Food, Environmental and Occupational Health & Safety (ANSES), the European Food Safety Agency (EFSA), the European Chemicals Agency (ECHA), the United States Environmental Protection Agency (US EPA), the New Zealand Environmental Protection Agency (NZ EPA), the Health Canada Department of National Public Health (PMRA), the Australian Pesticides and Veterinary Medicines Authority (APVMA), the Food Safety Commission of Japan (FSCJ), and the Joint FAO/ WHO Meeting on Pesticide Residues (JMPR).

The agencies have come to different conclusions regarding the carcinogenic properties of glyphosate (see Table 1). The IARC concluded that glyphosate is “probably carcinogenic to humans” (IARC, 2017c), whereas other regulatory bodies including EFSA and ECHA agreed on the conclusion that glyphosate is unlikely to pose any carcinogenic hazard/risk to humans (ECHA, 2017a; EFSA, 2015a). ANSES stated that there is insufficient and inadequate analysis to produce any meaningful conclusion on the effects of glyphosate (ANSES, 2016b).

Table 1. Agencies' stance on the effects of glyphosate on human health

Glyphosate probably carcinogenic	Additional research must be conducted	Glyphosate poses no cancerous risk in humans
IARC	ANSES	BfR EFSA ECHA US EPA NZ EPA APVMA PMRA JMPR

In the remainder, the section reviews the regulatory authorities that have recently conducted scientific risk assessments of glyphosate, introduces the conclusions reached, and specifies the core scientific divergences between the IARC and other regulatory agencies. Furthermore, the section briefly discusses which risks of the active substance glyphosate were assessed by regulatory body and what the relevant agencies concluded.

### 1.1 Agencies concluding that glyphosate poses a carcinogenic hazard

#### International Agency for Research on Cancer (IARC)

An important actor in producing risk assessments for substances such as glyphosate is the International Agency for Research on Cancer (IARC). The IARC is a specialist branch of the World Health Organization (WHO). More specifically, they tackle issues in regard to cancer amongst the human population. Because of this, the focal point of their research on active substances takes the form of carcinogenic properties. Additionally, the IARC compiles any available information in a meta-analysis and then judges whether or not the substance poses a carcinogenic risk. The IARC does not claim whether or not the substance will directly cause cancer or not, but assesses the hazard and suggests, on a scale, how much of a carcinogenic risk the substance poses.

Specifically, when classifying an agent as carcinogenic, the IARC's scientific procedure is based on a table (see the table below and *Figure 1* and) in which both animal and human evidence are considered. A substance will only be classified as 'carcinogenic' (i.e., Group 1)<sup>3</sup> if there is sufficient evidence of it causing cancer in animals *and* humans (for more information please see: [IARC, 2006](#)). A substance will be classified as 'probably carcinogenic' (Group 2A) if there is limited evidence of carcinogenicity in humans *but* sufficient evidence of carcinogenicity in animals. An agent will be classified as 'possibly carcinogenic' (Group 2B) if there is inadequate evidence of carcinogenicity in humans *but* sufficient evidence of carcinogenicity in animals. Findings that fall outside of these areas

<sup>3</sup> which is the highest level of certainty compared to 'probably carcinogenic' (Group 2A) and 'possibly carcinogenic' (Group 2B).

are considered to be “not classifiable as to its carcinogenicity to humans” (Group 3). Group 4 refers to cases in which evidence suggests lack of carcinogenicity (ESLC) in both human and experimental animal studies.

The IARC scientific evaluation result in the classification of environmental factors in 5 groups:

- Group 1 - Carcinogenic to humans
- Group 2A - Probably carcinogenic to humans
- Group 2B - Possibly carcinogenic to humans
- Group 3 - Not classifiable as to its carcinogenicity to humans
- Group 4 - Probably not carcinogenic to humans

		EVIDENCE IN EXPERIMENTAL ANIMALS			
		<i>Sufficient</i>	<i>Limited</i>	<i>Inadequate</i>	<i>ESLC</i>
EVIDENCE IN HUMANS	<i>Sufficient</i>	Group 1 ( <i>carcinogenic to humans</i> )			
	<i>Limited</i>	Group 2A ( <i>probably carcinogenic</i> )	Group 2B ( <i>possibly carcinogenic</i> ) (exceptionally, Group 2A)		
	<i>Inadequate</i>	Group 2B ( <i>possibly carcinogenic</i> ) <small>“... it is biologically plausible that agents for which there is <i>sufficient</i> evidence of <i>carcinogenicity</i> in experimental animals also present a carcinogenic hazard to humans.”</small>	Group 3 ( <i>not classifiable</i> )		
	<i>ESLC</i>				Group 4

Figure 1. The logic behind the classification of environmental factors in 5 groups followed by the IARC

In the case of glyphosate, the IARC has undertaken extensive research and investigation on the impact that glyphosate has on human health. In 2014, an advisory group of 21 scientists from 13 countries and several government officials evaluated glyphosate. In March 2015, IARC classified glyphosate as ‘probably carcinogenic to humans’, placing it in Group 2A (IARC, 2017c).

The IARC has conducted a hazard-based and strength-of-evidence assessment of publicly available scientific information related to glyphosate. The study of the IARC scholars arrived at the conclusion for “limited” evidence of cancer in humans but “sufficient” evidence of cancer in animals. The IARC used case studies from the USA, Canada, and Sweden for their human evidence, whilst their animal evidence was derived from experiments conducted on laboratory animals (mice). Furthermore, the monograph concluded that glyphosate caused DNA and chromosomal damage in human cells and that

there was “strong” evidence for genotoxicity in chemical components like glyphosate (IARC, 2017c). See table below for more specific conclusions communicated by the IARC.

“There is strong evidence that glyphosate can operate through two key characteristics of known human carcinogens, and that these can be operative in humans. Specifically:

- There is strong evidence that exposure to glyphosate or glyphosate-based formulations is genotoxic based on studies in humans in vitro and studies in experimental animals. One study in several communities in individuals exposed to glyphosate-based formulations also found chromosomal damage in blood cells; in this study, markers of chromosomal damage (micronucleus formation) were significantly greater after exposure than before exposure in the same individuals.
- There is strong evidence that glyphosate, glyphosate-based formulations, and aminomethylphosphonic acid can act to induce oxidative stress based on studies in experimental animals, and in studies in humans in vitro. This mechanism has been challenged experimentally by administering antioxidants, which abrogated the effects of glyphosate on oxidative stress. Studies in aquatic species provide additional evidence for glyphosate-induced oxidative stress.” (IARC, 2017c, p. 78-79)

One can observe that the IARC was one of the first bodies to warn about the possibility of glyphosate leading to cancer. However, the IARC classifications do not have regulatory implications. The IARC clearly states that they do not measure the likelihood that cancer will occur as a result of exposure (i.e., they do not provide a risk assessment, rather they provide hazard classification). In this way, the IARC avoids any legal ramifications in their pursuit of classifying herbicides as carcinogenic. However, the hazard classification of the IARC has influenced regulators, policy/decision-makers and the public. The scientific conclusions of the IARC have significantly shaped the glyphosate debate in Europe and worldwide. For instance, the regulatory agencies and bodies that assessed the risks of glyphosate to humans and the environment, also concentrated on evaluating and reflecting on the scientific output on glyphosate published by the IARC in 2015. The glyphosate peer review process of EFSA, for example, was delayed as the European Commission gave an additional mandate to EFSA to assess the scientific output of the IARC (EFSA, 2015a; EFSA representative #2).

## **1.2 Agencies concluding that glyphosate is unlikely to pose a carcinogenic risk/hazard**

### Joint FAO/WHO Meeting on Pesticide Residues (JMPR)

The Joint FAO/WHO Meeting on Pesticide Residues (JMPR) is “an expert ad hoc body administered jointly by FAO and WHO” which has as its central mission “the purpose of harmonising the requirement and the risk assessment on the pesticide residues” (FAO, 2018). The JMPR has met annually since 1963 and continues to bring together multiple standpoints and scientific approaches of international scientists.

As in the case of the IARC, the JMPR only focussed on the carcinogenic properties of glyphosate. They explained this focus by stating: “There is a large body of literature regarding pesticide exposures and non-cancer outcomes (neurodevelopmental, neurodegenerative and reproductive outcomes, among other health outcomes), but the assessment of the epidemiological evidence on [...] glyphosate [...] was restricted to studies of cancer outcomes. This restriction was partly driven by feasibility reasons: a clinically relevant adverse effect size (or an acceptable level of risk) for a non-cancer outcome must be defined, and the methodologies for hazard identification and [characterisation] based on observational epidemiological findings of non-carcinogenic adverse effects are less well established than those for cancer” ([JMPR, 2016a](#), p. 4).

The WHO (through IARC) had already concluded that “glyphosate exposure could possibly lead to cancer” ([IARC, 2017c](#)). However, on the 9<sup>th</sup>–13<sup>th</sup> of May 2016, the JMPR, which gathered in Geneva, re-evaluated the risk assessment, which led to important conclusions. Regarding glyphosate specifically, the JMPR concluded that “glyphosate is unlikely to pose a carcinogenic risk to humans from exposure through the diet” ([JMPR, 2016a](#), p. 2). More specifically, the JMPR concluded as follows: (see table below).

**Summary Report from the May 2016 Joint FAO/WHO Meeting on Pesticide Residues (JMPR)**

“The overall weight of evidence indicates that administration of glyphosate and its formulation products at doses as high as 2000 mg/kg body weight by the oral route, the route most relevant to human dietary exposure, **was not associated with genotoxic effects in an overwhelming majority of studies conducted in mammals, a model considered to be appropriate for assessing genotoxic risks to humans**. The Meeting concluded that glyphosate is unlikely to be genotoxic at anticipated dietary exposures. [...] The Meeting concluded that glyphosate is not carcinogenic in rats but could not exclude the possibility that it is carcinogenic in mice at very high doses. In view of the absence of carcinogenic potential in rodents at human-relevant doses and the absence of genotoxicity by the oral route in mammals, and considering the epidemiological evidence from occupational exposures, the **Meeting concluded that glyphosate is unlikely to pose a carcinogenic risk to humans from exposure through the diet**. The Meeting reaffirmed the group ADI [Acceptable Daily Intake] for the sum of glyphosate and its metabolites of 0–1 mg/kg body weight on the basis of effects on the salivary gland. The Meeting concluded that it was not necessary to establish an ARfD [Acute Reference Dose] for glyphosate or its metabolites in view of its low acute toxicity.” ([JMPR, 2016b](#), p. 2)

[A joint expert taskforce](#) consisting of scientists from [the World Health Organization \(WHO\)](#), national authorities and universities pooled scientific capacities in May 2016 to review the information analysed by the IARC in order to evaluate and decide if there is a necessity to revise previous assessments on glyphosate undertaken by the Joint FAO/WHO Meeting on Pesticide Residues (or JMPR) in 2003, 2006 and 2011. The joint expert taskforce reached the conclusion that, while there was some evidence for a positive

association between occupational glyphosate exposure and non-Hodgkin lymphoma in several studies, the only reliable study (i.e., well-designed large cohort study) found no correlation at any exposure level ([JMPR, 2016a](#)). They concluded that the general weight-of-evidence suggests that glyphosate is not genotoxic in mammals. Furthermore, they indicated that, even at high doses, glyphosate is unlikely to be genotoxic to humans (at likely levels of dietary exposure). Finally, the JMPR arrived at the conclusion that glyphosate is unlikely to pose a carcinogenic risk to humans from exposure through the diet ([WHO, 2016](#)).

However, the JMPR only assessed the effects of glyphosate through dietary consumption, which poses certain limitations. Nevertheless, the JMPR does acknowledge that it is hard to extrapolate the results and the effects that glyphosate has on rodents to human beings ([JMPR, 2016a](#)). Based on these limitations, the JMPR has encouraged further risk assessments efforts as it understands the limitations the studies have.

#### *The German Federal Institute for Risk Assessment (BfR)*

In August 2014, glyphosate was re-evaluated by the Rapporteur Member State (RMS) Germany (the BfR in particular), as mandated by the European Commission and organised by the European Food Safety Authority (EFSA). In particular, the BfR made hazard identification and initial risk assessment of toxicology aspects (including carcinogenicity) of the substance. Please see the underlying procedure of the safety of pesticides assessments in the EU in the table below.

Under EU legislation (Regulation (EC) 1107/2009), pesticide active substances in plant protection products are approved in the EU only if it may be expected that their use will not have any harmful effects on human and animal health or the environment. The evaluation of both existing and new active substances follows a phased approach: “For each substance an initial draft assessment report (DAR) or renewal assessment report (RAR) is produced by a rapporteur Member State (RMS). Regarding applications for renewal of an approval, the Commission decides on the designation of a rapporteur Member State in consultation with all Member States and industry. The RMS’s risk assessment is peer reviewed by EFSA in cooperation with all Member States and other stakeholders. EFSA drafts a report (“Conclusion”) on the active substance. The EFSA Conclusion informs the European Commission in the approval process, the subsequent assessments of plant protection products (that will contain this active substance) done by the Member States, and the revision of maximum residue levels in food by EFSA. The European Commission decides whether or not to include the substance in the EU’s list of approved active substances. This determines whether the substance can be used in a plant protection product in the EU. EU Member States assess or re-assess the safety of plant protection products containing the active substance that are sold in their territory” (EFSA, 2015d, p. 3).

The German Federal Institute for Risk Assessment (BfR) concluded that glyphosate is “unlikely to pose a carcinogenic hazard to humans and the evidence does not support classification with regard to its carcinogenic potential” (EFSA, 2015g). They concentrated on the use of glyphosate as an herbicide on “emerged annual, perennial and biennial weeds” (EFSA, 2015g). The emphasis was put on the correct usage of the substance and no repetition of high dosages. Under these circumstances, glyphosate was evaluated by the BfR as safe for humans and animals and not being carcinogenic, leading to reproductive problems nor causing malformations.

The BfR’s scientific evaluation of the dossier on glyphosate in the Renewal Assessment Report (RAR) was forwarded to EFSA on the 20<sup>th</sup> of December 2013. After receiving the comments on the RAR, it was decided that EFSA should conduct an expert consultation in the areas of mammalian toxicology, residues, environmental fate and behaviour and ecotoxicology. EFSA was asked by the Commission to adopt scientific conclusions on whether the active substance glyphosate can be expected to meet the conditions provided for in Article 4 of Regulation (EC) No 1107/2009 of the European Parliament and the Council. To that end, on the 6<sup>th</sup> of August 2014, EFSA was mandated by the European Commission to provide the peer review of the active substance glyphosate (EFSA, 2015b, p. 2).

#### European Food Safety Authority (EFSA)

The assessment of glyphosate in the EU has taken three years, involving public sector scientific experts from EU agencies as well as national authorities in all 28 Member States (European Commission, 2016). The European Food Safety Authority (EFSA) has played an important role in the process.

In August 2014, EFSA received a mandate from the European Commission asking to conduct the peer review of the active substance glyphosate. In April 2015, EFSA received a second mandate from the European Commission asking to consider the most recent conclusions by the IARC (2017c) regarding the conceivable carcinogenicity of glyphosate or glyphosate-containing plant protection products according to [Regulation \(EC\) No 1272/2008](#). To complete this additional task, EFSA asked the Commission for an extension of the overall deadline to the 30<sup>th</sup> of October 2015, to take into consideration the findings of the IARC as regards the potential carcinogenicity (EFSA, 2015b, p. 2).

In October 2015, EFSA, together with EU Member States, finalised the risk assessment and peer review that updated the scientific conclusions of the toxicity of glyphosate. The conclusions of EFSA were based on - and followed - the peer review results of the hazard identification and initial risk assessments conducted by the authority of the rapporteur Member State Germany, the German Federal Institute for Risk Assessment (BfR). The context of the peer review followed the requirements specified in the Commission [Regulation \(EU\) No 1141/2010](#) amended by Commission Implementing [Regulation \(EU\) No 380/2013](#) (EFSA, 2015b, p. 1).

Following the evaluation of BfR, in 2015, EFSA and EU Member States finalised the re-assessment of the toxicity of glyphosate (EFSA, 2015b). The re-assessment of the risks posed by glyphosate was part of the standard European Union pesticide renewal process. In line with Article 12 of Regulation (EC) No 1107/2009, EFSA carried out an assessment of glyphosate, considering the technical specifications provided by the applicants from Glyphosate Taskforce (EFSA, 2015e, p. 5). The risks of glyphosate were assessed in the following areas: mammalian toxicity; residues; environmental fate and behaviour; ecotoxicology (birds and mammals); and environmental compartments (soil, ground water, surface water and sediment, air).

EFSA assessed the risks of glyphosate to human health by relying on research in the areas of mammalian toxicology and ecotoxicology and, in contrast to the IARC evaluation, concluded that “glyphosate is unlikely to pose a carcinogenic hazard to humans and the evidence does not support classification with regard to its carcinogenic potential” (EFSA, 2015b, p. 2). EFSA also reached the conclusion that glyphosate is not classified as carcinogenic or toxic for reproduction (see table below).

#### **Glyphosate: EFSA updates toxicological profile**

“In contrast to the IARC evaluation, the EU peer review experts, with only one exception, concluded that glyphosate is unlikely to pose a carcinogenic hazard to humans and the evidence does not support classification with regard to its carcinogenic potential according to Regulation (EC) No 1272/2008 on classification, labelling and packaging (CLP Regulation). Glyphosate is not classified or proposed to be classified as carcinogenic or toxic for reproduction category 2 in accordance with the provisions of Regulation (EC) No 1272/2008 (harmonised classification supported by the present assessment), and therefore, the conditions of the interim provisions of Annex II, point 3.6.5 of Regulation (EC) No 1107/2009 concerning human health for the consideration of endocrine disrupting properties are not met.” (EFSA 2015b, p. 2-3)

Unlike the IARC and JMPR, EFSA assessed not only the cancer risks of glyphosate, but their scientific conclusions also included considerations for the following: residues; environmental fate and behaviour; and ecotoxicology (birds and mammals), that are briefly introduced below:

- Based on the existing information, EFSA proposed residue definitions for monitoring and risk assessment for plant and animal commodities. “These residue definitions were proposed considering the metabolism observed in conventional and in glyphosate-tolerant GM [Genetically Modified] plants. Based on the representative uses, that were limited to conventional crops only, chronic or acute risks for the consumers have not been identified” (EFSA 2015b, p. 3). Furthermore, EFSA made relevant conclusions and suggestions: “The toxicity of glyphosate needs to be redefined. An acute reference dose (ARfD) of 0.5 mg/kg of body weight has therefore been proposed, the first time such a safety measure has been introduced for glyphosate. EFSA will use this ARfD during its review of the maximum residue levels for glyphosate,

which will be carried out in cooperation with Member States in 2016. The acceptable operator exposure level (AOEL) has also been set at 0.1 mg/kg body weight per day and an acceptable daily intake (ADI) for consumers has been set in line with the ARfD at 0.5 mg/kg body weight per day” ([EFSA, 2015d](#), p. 1).

- Concerning the scientific conclusions on the fate and behaviour in the environment, EFSA concluded that further information is required to assess the “contamination route through run off (especially in situations where application to hard surfaces might occur) and subsequent surface water contamination and bank infiltration to groundwater” ([EFSA 2015b](#), p. 3).
- Concerning the scientific conclusions on ecotoxicology, EFSA concluded that “for aquatic organisms, the risk was considered low. The risk for bees, non-target arthropods, soil macro- and micro-organisms and biological methods for sewage treatment was considered low. The risk to non-target terrestrial plants was considered low, but only when mitigation measures are implemented” ([EFSA 2015b](#), p. 3).

More recently (September 2017), EFSA published one more risk assessment on glyphosate, in which it addressed the potential endocrine activity of glyphosate. The Authority’s assessment concluded that “the weight of evidence indicates that glyphosate does not have endocrine disrupting properties” (EFSA, 2017g, p.1).

The scientific conclusions of EFSA regarding mammalian toxicity, residues, environmental fate and behaviour, ecotoxicology (birds and mammals) and the potential endocrine activity of glyphosate were based on a risk-based approach, i.e. weight-of-evidence (WoE) assessment approach, meaning that EFSA considered a wide range of scientific evidence, including academic research as well as industry research. EFSA reached the conclusion that glyphosate does not cause cancer in humans and is unlikely to be genotoxic. 27 out of 28 EU Member State experts agreed with the EFSA-endorsed peer review of glyphosate (with the exception of Sweden which was in favour of another classification).

### European Chemicals Agency (ECHA)

ECHA is in charge of labelling and classifying substances and chemicals under [Regulation \(EC\) No 1272/2008](#). The Committee for Risk Assessment (RAC) is responsible for presenting information related to the attributed risk of chemicals and other substances for humans, animals and the environment. Their advice is directly forwarded to the European Commission. The approval of the use of glyphosate was about to expire in the EU and therefore a new assessment of the substance was needed in order to decide whether or not an extension of the licence to be given by the European Commission. This was done through harmonised classification and labelling within the EU.

In June 2016, the European Commission decided to prolong the registration of glyphosate in the EU for 18 months ([Regulation \(EU\) 2016/1056](#)). The extension was made to give time for the European Chemicals Agency (ECHA) to carry out an independent hazard

assessment of glyphosate. It is important to note that the assessment by RAC was only focussed on the potential danger caused by a substance and did not take into account the prevalence and exposure of humans and animals to the substance (this part was covered in the scientific output of EFSA): “The classification is based solely on the hazardous properties of the substance. It does not take into account the likelihood of exposure to the substance and therefore does not address the risks of exposure. The risks posed by exposure are considered, for example, when deciding whether to renew the approval of glyphosate as a pesticide in accordance with the EU’s Plant Protection Product Regulation (Regulation (EC) N° 1107/2009)” (ECHA, 2017b). This implies that both ECHA and the IARC conducted hazard assessment of glyphosate, while EFSA and other regulatory bodies discussed in this chapter focus on the risk assessment of glyphosate (see also EFSA, 2016e).

In March 2017, ECHA’s Committee for Risk Assessment (RAC) provided an additional *hazard classification* associated to toxicity results from prolonged or repeated exposure to glyphosate. The ECHA’s evaluation of glyphosate was carried out through public consultations. The Agency’s consultations involved a wide range of toxicological studies that may or may not have been published (ECHA, 2017b). In its scientific output, RAC concluded that there was not enough scientific evidence and information to confirm a carcinogenicity hazard classification of glyphosate. ECHA communicated that the existing scientific scholarship do not give sufficient confidence to the criteria to classify glyphosate as toxic for reproduction, as a carcinogen or mutagen under the CLP Regulation. However, in its classification of glyphosate, RAC published their results concluding that glyphosate causes (1) serious eye damage and (2) is toxic to aquatic life with long lasting effects. However, ECHA scientific opinion identified glyphosate as not carcinogenic to humans (ECHA, 2017b).

#### **Glyphosate not classified as a carcinogen by ECHA**

“ECHA’s Committee for Risk Assessment (RAC) agrees to maintain the current harmonised classification of glyphosate as a substance causing serious eye damage and being toxic to aquatic life with long-lasting effects. RAC concluded that the available scientific evidence did not meet the criteria to classify glyphosate as a carcinogen, as a mutagen or as toxic for reproduction” (ECHA, 2017b).

While the IARC assessed only the carcinogenic properties of glyphosate, the final evaluation of RAC and BAuA (the German Federal Institute for Occupational Safety and Health) was based on both: (1) Human Health Hazard Assessment and (2) Environmental hazard assessment (BAuA, 2016). Alongside its conclusions on the carcinogenic properties of glyphosate, RAC and BAuA arrived at the following conclusions regarding environmental hazard assessment: “Glyphosate fulfils the criteria for classification as Aquatic Chronic 2” (BAuA, 2016, p. 134). For more information on labelling and classifying substances and chemicals and the criteria for classification followed at the EU level, please see Regulation (EC) No 1272/2008.

*United States Environmental Protection Agency (US EPA)*

The United States Environmental Protection Agency (US EPA) was founded in 1970. Its mission is to “protect human health and the environment” (US [EPA, 2018d](#)). It provides assistance to the Legislative and the Executive Powers of the United States in framing policies that protect human health and the environment.

In September 2016, the US EPA re-assessed glyphosate (the carcinogenic effects glyphosate could have) as part of its Registration Review program (US [EPA, 2016](#)). In this particular scientific output (i.e., Glyphosate Issue Paper), the US EPA focussed on the evaluation of carcinogenic potential of glyphosate. The US EPA used a weight-of-evidence approach to re-assess the carcinogenicity of glyphosate. The EPA’s Office of Pesticide Programs concluded that glyphosate does not cause cancer. In “Glyphosate Issue Paper”, a 227-page peer review investigation which used more than 25 previous investigations (from 1975 onwards) on the potential effects of glyphosate, the US EPA concluded that “the available data [...] clearly do not support the descriptors ‘carcinogenic to humans’, ‘likely to be carcinogenic to humans’ or [the existence] of ‘inadequate information’” (US [EPA, 2016](#)).

**Glyphosate Issue Paper: Evaluation of Carcinogenic Potential**

“The available data at this time do not support a carcinogenic process for glyphosate. Overall, animal carcinogenicity and genotoxicity studies were remarkably consistent and did not demonstrate a clear association between glyphosate exposure and outcomes of interest related to carcinogenic potential. In epidemiological studies, there was no evidence of an association between glyphosate exposure and numerous cancer outcomes.” (US [EPA, 2016](#), p. 140)

In 2018, the US EPA will release its new risk assessment of glyphosate (US [EPA, 2017d](#)). However, the draft [human health risk assessment](#) and the [ecological risk assessment](#) are already available. As regards the human health risk assessment, the US EPA provided hazard characterisation, dietary (food and water) risk assessment, residential and non-occupational exposure and risk assessment, aggregate risk assessment, and occupational risk assessment. The US EPA states “The Agency’s assessment found no other meaningful risks to human health when the product is used according to the pesticide label” (US [EPA, 2017d](#)). The conclusion was drawn following the evaluation of dietary, residential/non-occupational, aggregate, and occupational exposures. In addition, the US EPA conducted “an in-depth review of the glyphosate cancer database, including data from epidemiological, animal carcinogenicity, and genotoxicity studies” (US [EPA, 2017d](#)).

In its ecological risk assessment, the US EPA found that there is a “potential for effects on birds, mammals, and terrestrial and aquatic plants” (US [EPA, 2017d](#)). For additional information, please see the conclusions of the US EPA of draft ecological risk assessment (2018c).

*Health Canada’s Pest Management Regulatory Agency (PMRA)*

The main objective of the PMRA when regulating pesticides is to protect the health of Canadians and the environment ([PMRA, 2017](#)). All pesticides need to be registered by the

PMRA. In April 2015, the PMRA re-assessed glyphosate as part of its standard regulatory procedure. The re-assessment concluded that glyphosate-containing products do not pose any risks to human health and the environment if they are used according to the directions on the label (PMRA, 2017) (see table below).

#### **Core conclusions of the PMRA's risks to human health and the environment**

##### **Health Considerations:**

- “Products containing glyphosate acid are unlikely to affect human health when used according to label directions.
- Residues in Food and Water: Dietary risks from food and water are not of concern.
- Risks in Residential and Other Non-Occupational Environments:
  - Non-occupational risks are not of concern when used according to label directions.
  - Non-occupational risks from bystander dermal exposure are not of concern.
- Occupational Risks from Handling Glyphosate:
  - Occupational risks to handlers are not of concern when used according to label directions.
  - Post application risks are not of concern for all uses.

##### **Environmental Considerations:**

- When used according to proposed label directions, glyphosate products do not pose an unacceptable risk to the environment. Labelled risk-reduction measures mitigate potential risks posed by glyphosate formulations to non-target plants and freshwater/marine/estuarine organisms.” ([PMRA, 2015](#))

In the re-examination, the PMRA assessed the risks for human health from glyphosate in the drinking water, food and occupational exposure, as well as the risks for the environment (PMRA, 2017). In the assessment, the PMRA looked at both the active ingredients and the formulated product. The assessment was performed on the basis of information from the producer of the product, as well as information found in scientific literature (PMRA, 2017).

#### **Proposed Re-evaluation Decision PRVD2015-01, Glyphosate**

“After a re-evaluation of the herbicide glyphosate, Health Canada’s Pest Management Regulatory Agency (PMRA), under the authority of the Pest Control Products Act and Regulations, is proposing continued registration of products containing glyphosate for sale and use in Canada.

An evaluation of available scientific information found that products containing glyphosate do not present unacceptable risks to human health or the environment when used according to the proposed label directions.” ([PMRA, 2015](#))

Canada has specified the MRLs for glyphosate for a wide range of products. Residues in all other agricultural commodities, including those approved for treatment in Canada but without a specific MRL, are regulated under Subsection B.15.002(1) of the Food and Drug Regulations, which says that residues should not exceed 0.1 ppm (PMRA, 2017). The final conclusion of the re-assessment is that glyphosate cannot be considered genotoxic and does not pose an extra risk for cancer in humans. Therefore, the PMRA has granted continued registration of products containing glyphosate with requirements of additional label updates to further protect human health and the environment; to comply with this decision the manufacturer needs to change labels within 24 months of the decision (PMRA, 2017).

In terms of environmental risk assessment of glyphosate, the PMRA concluded that “In the terrestrial environment the only area of risk concern identified from the available data was for terrestrial plants and therefore spray buffer zones are required to reduce exposure to sensitive terrestrial plants.

Glyphosate formulations pose a negligible risk to freshwater fish and amphibians, but may pose a risk to freshwater algae, freshwater plants, marine/estuarine invertebrates and marine fish if exposed to high enough concentrations. Hazard statements and mitigation measures (spray buffer zones) are required on product labels to protect aquatic organisms.” (PMRA, 2015)

When the PMRA conducts a risk assessment or – in the case of glyphosate – a pesticide re-evaluation, they consider the potential risks and the value of pesticide products to ensure they meet modern standards established to protect human health and the environment (PMRA, 2017). The risk assessment is based on data from registrants, published scientific reports, information from other regulatory agencies. After a science-based assessment, it has been decided by the PMRA that, when glyphosate is used according to the prescription, the products containing the product are not a concern to human health and the environment. The PMRA has set MRLs and these requirements are set at levels well below the amount that could pose a health concern (PMRA, 2017).

#### *Environmental Protection Authority of New Zealand (NZ EPA)*

Glyphosate is widely used in New Zealand, which is why the sale and use of glyphosate is regulated under the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997 and the Hazardous Substances and New Organisms (HSNO) Act 1996 (MPI, 2015). The ACVM Act makes sure that no agricultural compound can be used in New Zealand unless it is authorised by or under this Act (MPI, 2015). The Ministry for Primary Industries (MPI) has established thresholds and criteria for public health, trade, safety and security, and these criteria were established on the basis of international practices (MPI, 2015).

In August 2016, the Environmental Protection Authority of New Zealand (NZ EPA) completed an evaluation of the available evidence for carcinogenicity caused by exposure to glyphosate. The Authority concluded that glyphosate was unlikely to cause cancer in humans (NZ EPA, 2016) (see table below).

**Glyphosate Review**

“The review concluded that glyphosate is unlikely to be carcinogenic to humans or genotoxic (damaging to genetic material or DNA) and should not be classified as a mutagen or carcinogen under the HSNO Act.” ([NZ EPA, 2016](#))

The different risks that were tested are needed for the product registration under the ACVM Act ([MPI, 2018](#)). This means that a thorough scientific assessment of chemistry and manufacturing information, animal and plant safety, and residues in food was carried out. Furthermore, the NZ EPA also looked at the toxicity levels of glyphosate. In this case, MPI agrees with the JMPR, stating that, for glyphosate, there are very low toxicity levels, meaning that glyphosate does not form a risk on the basis of the ACVM act.

The MPI has adopted the same conclusion after careful review and its own review of the dietary risks of glyphosate to the New Zealand public ([MPI, 2018](#)). The MPI does not agree with the IARC’s view that glyphosate would be a risk to consumers and users. If used in line with the approved label directions, glyphosate complies with the New Zealand maximum residue limits and hence is not harmful to humans (MPI, 2018). Furthermore, the MPI emphasises that the toxicity and dietary risks of glyphosate have been reviewed by various other organisations, like the World Health Organization (WHO) and the Food and Agriculture Organization of the United Nations (FAO) who concluded that glyphosate is of very low toxicity.

*Australian Pesticides and Veterinary Medicines Authority (APVMA)*

The Australian Pesticides and Veterinary Medicines Authority (APVMA) was established in 1993 as a means by which agricultural and veterinary chemical products could be registered on a centralised system ([APVMA, 2017](#)). Any product that contains glyphosate needs to be registered for use in Australia; in order to be registered, all the products need to have been tested through a robust chemical risk assessment process to check that they are safe for use. A chemical risk assessment process means that both a hazard assessment and an exposure assessment have been conducted by the APVMA. These assessments are similar to the tests conducted in other countries: the APVMA uses a risk-based, weight-of-evidence assessment, which considers the full range of risk, like studies of cancer risks, minimisation of human exposure through instructions for use and safety directions (APVMA, 2017).

In 2016, the APVMA completed a “robust chemical risk assessment process”, concluding that “the use of glyphosate in Australia does not pose a cancer risk to humans” ([APVMA, 2017](#)). The review of glyphosate had two phases; the first identified which studies used in IARC’s initial report “should be reviewed in more detail”, whilst the second stage “involved a detailed assessment of those studies”. Generally speaking, the APVMA “uses a risk-based, weight-of-evidence assessment, which considers the full range of risks [...] and how human exposure can be minimised”. Furthermore, the APVMA’s assessment of glyphosate solely concentrated on “the potential of glyphosate alone to cause cancer”, as this was the IARC’s focus and the APVMA focussed on the aspects of glyphosate risks

assessed by the IARC. The APVMA assessed risks including studies of cancer risk through hazard assessment and exposure assessment, concluding that “products containing glyphosate are safe to use as per the label instructions” (APVMA, 2017). For more detailed conclusions, please consult the table below.

**Final regulatory position of the Australian Pesticides and Veterinary Medicines Authority (APVMA)**

- “exposure to glyphosate does not pose a carcinogenic or genotoxic risk to humans
- there is no scientific basis for revising the APVMA’s satisfaction that glyphosate or products containing glyphosate:
  - would not be an undue hazard to the safety of people exposed to it during its handling or people using anything containing its residues;
  - would not be likely to have an effect that is harmful to human beings;
  - would not be likely to have an unintended effect that is harmful to animals, plants or things or to the environment;
  - would be effective according to criteria determined by the APVMA by legislative instrument, and
  - would not unduly prejudice trade or commerce between Australia and places outside Australia.
- there are no scientific grounds for placing glyphosate and products containing glyphosate under formal reconsideration
- the APVMA will continue to maintain a close focus on any new assessment reports or studies that indicate that this position should be revised
- there are no scientific grounds for placing glyphosate and products containing glyphosate under formal reconsideration.” (APVMA, 2017, p. 9)

### 1.3 Agencies with inconclusive reports

*French Agency for Food, Environmental and Occupational Health Safety (ANSES)*

The assessment of glyphosate was conducted by the French Agency for Food, Environmental and Occupational Health Safety (ANSES) after several assessments were carried out at the European level when the substance needed a renewed approval. However, the assessment conflicted with the views of the IARC, who stated that glyphosate should be viewed as probably carcinogenic to humans (ANSES, 2015). In 2015, ANSES was asked by French authorities to conduct an expert appraisal on the basis of the monograph issued by the IARC (ANSES, 2016a). The expert appraisal was carried out by the French standard NF X 50-1104 (ANSES, 2016). Tasked with this request, the Emergency Collective Expert Assessment Group (GECU) included four experts on glyphosate and expertise in carcinogenicity, mutagenicity, and epidemiology (ANSES, 2016b). The request

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<sup>4</sup> Please read more about the French quality standards and commitments in the following link: <https://www.anses.fr/en/content/statement-anses-quality-policy-and-quality-commitment>

for expert appraisal was carried out by GECU and with the scientific participation of ANSES. GECU did not have the time to go through all the regulatory reports about glyphosate that had been published by either the BfR or the IARC. Thus, they concentrated on a select number of reports provided by ANSES (ANSES, 2015).

GECU analysed the reports in order to explain the different conclusions reached by the EU (EFSA and ECHA's RAC) versus the IARC on whether or not glyphosate can be considered carcinogenic (ANSES, 2016b). GECU suggested that the results of the epidemiological studies are not consistent: there have been cases where bias or lack of power could be identified. Furthermore, the epidemiological results are not consistent because exposure to glyphosate is not indicated clearly (ANSES, 2016b). ANSES stated that the data shows now that glyphosate has limited risks to humans and animals (ANSES, 2016b). It must be said that, due to the limited time available for the expert appraisal, GECU and ANSES could only focus on a limited amount of studies due to the high variety of publications available (ANSES, 2016b). They chose to focus on the research by the IARC and European renewal assessment reports. The evidence illustrates that the level of carcinogenicity can be considered too limited in humans to impose a strict classification. However, due to the limited level of evidence, the research should be reclassified (ANSES, 2016a).

ANSES stated that it cannot reclassify glyphosate due to the limitations of the research, which in its turn is due to the absence of a detailed analysis. Thus, ANSES based their conclusion on reviewing the research of peers. On the 12th of December 2015, ANSES concluded that glyphosate may need to be classified as a suspected human carcinogen and that ECHA should review their classification. As discussed above, in 2017, ECHA scientific opinion identified glyphosate as not carcinogenic to humans (ECHA, 2017).

## 2. 2,4-D

2,4-Dichlorophenoxyacetic acid (i.e., 2,4-D) is an extensively used herbicide that controls broadleaf weeds including: "a variety of field, fruit and vegetable crops, and turf, lawns, rights-of-way, aquatic sites and forestry sites" ([US EPA, 2017a](#)). 2,4-D is one of the oldest and most broadly accessible herbicides in the world: it has been commercially available since 1945 and is currently produced by many chemical companies because the patent on it has expired.

The section provides a summary of the scientific findings of relevant regulatory agencies concerning 2,4-D. The scientific conclusions of the IARC, EFSA and the US EPA are introduced and discussed in this section. The IARC has conducted a hazard classification of the herbicide 2,4-D and concluded that the substance should be classified as 'possibly carcinogenic to humans' (2B), whereas other independent agencies (including EFSA and the US EPA) conducted risk assessments of 2,4-D concluding that 2,4-D is unlikely to be a human carcinogen.

In a nutshell, the core agreements and disagreement between IARC and other regulators are the following. The IARC and regulatory bodies worldwide agree with the finding that there is "inadequate evidence" in humans. For instance, the following agencies mandated

with protecting human health have reached the same conclusion: The United States Environmental Protection Agency ([2007](#); [2012](#); [2014c](#)), the European Food Safety Authority ([2014a](#)), the World Health Organization ([1996](#); [2008](#)) and more than 90 other countries (according to IARC ([2016a](#))). These regulatory bodies and agencies have consistently concluded that the herbicide 2,4-D does not present a human cancer risk. This is in line with the conclusion of the IARC stating that epidemiological studies did not indicate strong or stable increases in risk of [non-Hodgkin's lymphoma] NHL or other cancers in relation to 2,4-D exposure ([IARC, 2016a](#)).

However, the IARC and other regulatory agencies disagree about the difference between hazard classification and risk assessment. The IARC have communicated that "the Monographs Programme identifies cancer hazards even when risks are very low at current exposure levels" ([IARC, 2016a](#)). On the contrary, the US EPA and other national and supranational regulatory bodies regard hazard classification as one step of a multiple-step process. To illustrate, in March 2016, the Health Canada's Pest Management Regulatory Agency (PMRA) issued a scientific evaluation of 2,4-D, in which the PMRA considered the IARC findings, and determined: "The IARC hazard classifications are not health risk assessments and the levels of human exposure, which determine the actual risk, are not taken into account in the IARC assessments." ([PMRA, 2016](#)). The IARC disagrees with such conclusions (the same disagreement applied in the glyphosate case).

In short, the relevant regulatory agencies have concluded that 2,4-D does not cause cancer in humans. The US EPA classified 2,4-D as 'not likely to be carcinogenic to humans' (US EPA, 2014). In 2008, the PMRA carried out a re-evaluation of 2,4-D and concluded that 2,4-D meets the health and safety standards of Canada. Furthermore, Canadian regulators emphasise that no other international regulatory body (except the IARC) regards 2,4-D to be a human carcinogen. The PMRA concluded that the herbicide "2,4-D does not increase the risk of cancer and can be used safely by homeowners, provided label directions are followed" ([Health Canada, 2009](#)). In 2015, following the peer review of the initial risk assessments carried out by the Rapporteur Member State Greece, for the pesticide active substance 2,4-D, EFSA reached the following conclusion: 2,4-D is unlikely to have a genotoxic potential or pose a carcinogenic risk to humans. EFSA could not identify any conclusive association can be established between exposure to phenoxy-herbicides (including 2,4-D acid) and human carcinogenicity ([EFSA, 2014a](#)).

The remainder of this section discusses the scientific findings of the three regulatory bodies - i.e., the IARC, EFSA, US EPA - in more detail.

#### **1.4 Agencies concluding that 2,4-D poses a carcinogenic hazard**

##### *The International Agency for Research on Cancer (IARC)*

As the IARC deals solely with cancer related hazard classification, this section is created to assess the hazards associated with 2,4-D in terms of carcinogenic properties.

The IARC reviewed the latest scientific literature and reached the conclusion that the herbicide 2,4-D should be classified as ‘possibly carcinogenic to humans’ (group 2B) ([IARC, 2017a](#)). Such a classification is one step below the more definitive “probably carcinogenic” category (e.g., the conclusion reached in the glyphosate case), however, two steps above the “probably *not* carcinogenic” category. The core justification for classifying 2,4-D as “possibly carcinogenic to humans” was the lack of data. The IARC stated that there is “inadequate evidence in humans and limited evidence in experimental animals” of relationship between 2,4-D and cancer ([IARC, 2015b](#), p. 1). Furthermore, the IARC concluded that epidemiological studies provided “strong evidence that 2,4-D induces oxidative stress [...] and moderate evidence that 2,4-D causes immunosuppression” ([IARC, 2015b](#), p. 1). However, the IARC found that there is not an association between leukaemia (blood cancer) and 2,4-D: “epidemiological studies did not find strong or consistent increases in risk of NHL (non-Hodgkin lymphoma) or other cancers in relation to 2,4-D exposure.” ([IARC, 2015b](#), p. 1, see also [IARC, 2017a](#)).

“The herbicide 2,4-D was classified as possibly carcinogenic to humans (Group 2B), based on inadequate evidence in humans and limited evidence in experimental animals. There is strong evidence that 2,4-D induces oxidative stress, a mechanism that can operate in humans, and moderate evidence that 2,4-D causes immunosuppression, based on in vivo and in vitro studies. However, epidemiological studies did not find strong or consistent increases in risk of NHL or other cancers in relation to 2,4-D exposure.” ([IARC, 2015b](#), p. 1)

### 1.5 Agencies concluding that 2,4-D is unlikely to pose a carcinogenic risk

#### European Food Safety Authority (EFSA)

2,4-D has been approved for usage in the EU by Commission implementing [Regulation \(EU\) No 540/2011](#). This regulation states that 2,4-D has been approved on the 1<sup>st</sup> of October 2002, with the date of expiration of approval being the 31<sup>st</sup> of December 2015. Therefore, renewal of the application was imminent.

Commission [Regulation \(EU\) No 1141/2010](#)<sup>5</sup> specifies the procedures for the renewal of the approval of active substances and establishes the list of those substances. 2,4-D is one of the substances listed in the Regulation. Following the relevant procedure, the Rapporteur Member State (Greece) and the co-Rapporteur Member State (Poland) provided their hazard identification on 2,4-D. Consequently, EFSA initiated the peer review in March 2013. EFSA was requested to issue “a conclusion on whether 2,4-D can be expected to meet the conditions provided for in Article 4 of Regulation (EC) No 1107/2009 of the European Parliament and of the Council” ([EFSA, 2014a](#), p. 5).

EFSA’s conclusion report summarises the outcomes of the peer reviews of the risk assessment on the active substance in relation to its typical uses as an herbicide on wheat,

<sup>5</sup> As amended by Commission Implementing Regulation (EU) No 380/2013.

barley, oat, rye triticale (cereals) and maize. In September 2014, EFSA made conclusions in regard to 2,4-D toxicity to mammals, the impact of residue left behind, 2,4-D environmental impacts and its potential ecotoxicological effects.

The overall conclusion from the evaluation is that plant protection products containing 2,4-D fulfil the safety requirements laid down in Regulation (EC) No 1107/2009 ([EFSA, 2014a](#)). The review has concluded that under the proposed conditions of use of 2,4-D there are no unacceptable effects on the environment. Furthermore, 2,4-D is not classified as a carcinogenic substance.

In its conclusion, EFSA notes that there is evidence of possibly adverse endocrine effects on the hormone system, which also might affect other organ systems. With regards to the ecotoxicological potential endocrine activity of 2,4-D, the scientific conclusion of EFSA does not identify specific concerns for fish and birds.

#### US Environmental Protection Agency (US EPA)

In 2005, the United States Environmental Protection Agency released a Registration Eligibility Decision (RED) on the chemical 2,4-D (US [EPA, 2005](#)). The RED included a comprehensive risk assessment (covering both human health risk and environmental risk); a risk management, reregistration, and tolerance re-assessment decision; and guidelines for registrants. The risk assessment was based on information from 1992 through 2000 for agriculture and 1993 through 1999 for non-agriculture risk. The studies used for assessment were based on the required target database supporting the use patterns of the currently registered products and additional information received from the 2,4-D Task Force II (comprised of leading industry actors such as Dow Chemical Company).

Action 4(g)(2)(A) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) calls for the US EPA to determine, after submission of relevant data concerning an active ingredient, whether or not products containing the active ingredient are eligible for re-registration. Based on a review of data and of public comments on the Agency's assessments for the active ingredient 2,4-D, the EPA claimed to have sufficient information on the human health and ecological effects of 2,4-D to make decisions as part of the tolerance re-assessment process under the Federal Food, Drug, and Cosmetic Act (FFDCA) and re-registration process under FIFRA (US [EPA, 2005](#)). To combat the numerous negative ecological conclusions of the assessment, the US EPA required the conception of plans to control spray drift, updated labelling, and a maximum turf rate of 1.5 lbs/Acre (down from 2 lbs/Acre). *The Agency has determined that 2,4-D containing products are eligible for re-registration provided that:* (1) current data gaps and confirmatory data needs are addressed; (2) the risk mitigation measures outlined in this document are adopted, and (2) label amendments are made to implement these measures. Under the mandate of this RED, 2,4-D was successfully re-registered and approved for both domestic and industrial use. There is not yet a date set for another assessment, however, the US EPA is obliged to re-evaluate all registered pesticides at least once every 15 years.

### 3. Bentazone

3-isopropyl-1H-2,1,3-benzothiadiazin-4(3H)-one 2,2-dioxide, more commonly known as bentazone, is a chemical used in pesticides and herbicides. Bentazone is used as a selective contact post-emergence herbicide which is absorbed through the leaves of target plants (Hartley and Kidd, 1983). Target plants are broadleaved weeds and sedges. Furthermore, bentazone is used for use on a variety of lentil crops (broad beans, field beans, runner beans, navy beans, combining peas, vining peas), as well as potatoes.

The section provides a summary of the scientific findings of relevant regulatory agencies and bodies concerning bentazone. The three agencies that have conducted risk assessments on bentazone and are covered in this section are EFSA, the US EPA and JMPR.

#### European Food Safety Authority (EFSA)

The active characteristics of bentazone were first managed by Commission Regulation (EU) No 1141/2010<sup>6</sup>, which characterises bentazone as a second-group of active substances. According to Article 16 of this Regulation, if mandated, EFSA needs to conclude if the active substance meets the conditions proposed in the above regulation, specifically in the areas of mammalian toxicology, residues, environmental fate and behaviour, and ecotoxicology. The risk assessment was initiated following the RAR (the Netherlands) for consultation of the Member States and the applicants BASF SE and AgriChem BV ([EFSA, 2015a](#), p. 2).

In 2015, EFSA issued its scientific opinion on bentazone. EFSA identified many data gaps and stated that the assessment could not be fully finalised. EFSA has identified data gaps in the following areas which are further explained below (for more detailed information, see ([EFSA, 2015a](#), p. 2)):

- An analytical method in terms of monitoring all the components of the residue definition in surface water;
- In the mammalian toxicology area;
- Potential endocrine disrupting properties;
- Risks to consumers;
- Toxicological data allowing to establish reference values for the metabolite 6-hydroxy-bentazone.

More specifically, EFSA stated that “in the area of identity, physical/chemical/technical properties and methods of analysis *a data gap was identified* for an analytical method for monitoring all the components of the residue definition in surface water” ([EFSA, 2015a](#), p. 2). Furthermore, *data gaps* were acknowledged in the mammalian toxicology area, which did not allow to “address the relevance of the individual impurities present in the technical specifications of both applicants” ([EFSA, 2015a](#), p. 2). As a result, EFSA proposed to classify

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<sup>6</sup> as amended by Commission Implementing Regulation (EU) No 380/2013

bentazone as toxic for reproduction category 2 in accordance with the provisions of Regulation (EC) No 1272/2008.

In addition, EFSA concluded that “an endocrine-mediated mode of action could not be ruled out regarding the critical effects observed in the developmental toxicity study in rats”, as *a data gap was identified* and therefore the assessment could not be completed (EFSA, 2015, p. 2). Furthermore, *a data gap* was also “identified for further toxicological data allowing to establish reference values for the metabolite 6-hydroxy-bentazone as it is included in the residue definition for risk assessment” (EFSA, 2015a, p. 2). In a similar vein, the consumer risk assessment is not completed because “the proposed residue definitions for risk assessment in plants and for enforcement in livestock are considered as provisional due to *the identified data gaps*” (EFSA, 2015a, p. 2).

Finally, the groundwater exposure assessment for bentazone could not be finalised by EFSA because *of the data gaps*. In addition, the National Institute for Public Health and the Environment (RIVM) (the Netherlands, Rapporteur Member State) reported to EFSA that residues of bentazone and other pesticides had been found in groundwater in concentrations above the drinking water threshold level (RIVM, 2015, p. 11), which led to questions on whether the regulations on these pesticides were strict enough. RIVM evaluated whether concentrations in groundwater under realistic worst-case conditions exceed the threshold limit in drinking water. The report found that bentazone failed to pass tests that are specific to the Netherlands. As a result, RIVM stated that “calculated annual average concentrations are minimally a factor of 20 above the criterion value” (RIVM, 2015, p. 70, for more information, please read the report issued by RIVM (2015)).

EFSA has concluded that there is *a high long-term* risk to mammals for the representative uses of bentazone applied to grass seed, grazing land and turf (EFSA, 2015a, p. 3). *A high acute and/or long-term* risk to birds and mammals was also concluded for several of the representative uses of bentazone. *A low* risk to all other groups of non-target organisms was concluded. However, according to EFSA, genotoxic, carcinogenic or neurotoxic effects are not produced by bentazone.

On the basis of the risk assessment of EFSA, in 2016, the European Commission suggested to renew the EU authorisation for bentazone herbicide until the 31<sup>st</sup> of January 2032 (its approval expired on the 30<sup>th</sup> of June 2017). However, at the same time, the Commission requested additional data confirming bentazone’s safety, as EFSA identified many data gaps which resulted in the unfinalised risk assessment.

#### United States Environmental Protection Agency (US EPA)

The United States Environmental Protection Agency, or the US EPA, initially began to inquire about the safety of bentazone (or products containing bentazone) in 1972. The chemical was issued a registration standard by the US EPA in 1985 – requiring cautionary labels (US EPA, 1994). More information and studies were needed, prompting the US EPA

to require registrants to generate and submit further data (US [EPA, 1994](#)). Using the new data, the US EPA released a reregistration eligibility decision known as an RED in 1994. This document contains a risk assessment based on all new data since the original registration in addition to extensive studies particularly in regard to oral consumption and carcinogenic effects. The contents of the RED on bentazone are summarised below.

In terms of human risk assessment, bentazone is considered slightly acutely toxic for both skin contact and ingestion (US [EPA, 1994](#)). Furthermore, it is classified as a “Group E” carcinogen, meaning that there is no evidence of the substance leading to cancer. Some development toxicity effects were, however, observed in rodent tests. As stated before, dietary risks associated with the presence of bentazone on crops are not considered of concern by the US EPA (this is backed-up by residue tests). Based on estimates of exposure, the US EPA also determined that a minimum PPE (personal protective equipment) is required for handling the substance. Overall, however, worker risks are considered low (US [EPA, 1994](#)).

In terms of environmental risk assessment, surface runoff and leaching through soil are considered the main routes of dissipation for bentazone (US [EPA, 1994](#)). The largest concern here is contamination of drinking water, which prompted the US EPA to set a lifetime Health Advisory (HA) of 20 parts per billion (ppb), which it will likely increase to 200 ppb. Despite this, bentazone is not officially regulated under the Safe Drinking Water Act (SDWA), meaning that no Maximum Contaminant Level has been set. Further risks were identified in regard to the reproductive health of birds, which, though acute/subacute, is not seen as a major concern. Usage restrictions of the substance are designed to mitigate this impact. No hazard has been identified for aquatic animals or honeybees. Overall, the US EPA concluded that the “use of bentazone as an herbicide will not pose a serious environmental threat” (US [EPA, 1994](#), p. 174).

In 1998, the EPA’s Integrated Risk Information System conducted another review on bentazone which ultimately confirmed the RED’s assessment (US [EPA, 1998](#)). In the following years, the US EPA revised its procedure concerning pesticide registration. Pesticides are to be reviewed every 15 years to ensure that the US EPA’s risk assessments are in compliance with contemporary scientific studies. This process began for bentazone in 2010 and is still ongoing as the US EPA has not yet released a final review decision. Several risk assessment studies conducted during this review process are, however, already available. Notably, a preliminary human health risk assessment on sodium bentazone conducted in 2014 as a part of the registration review. The results from this risk assessment are summarised below:

- Reaffirmation of “Group E” non-carcinogenic chemical classification. In other words, this assessment also rules out cancer risk (US EPA, 2014c).
- Human ingestion of bentazone occurs when pesticide residue is found in plants, livestock, and drinking water (US EPA, 2014c).
- The US EPA provides recommendations for tolerance level of bentazone residue in commodities. The recommended tolerance levels are nearly identical to those established in older studies (US EPA, 2014c).

- The US EPA provides similar toxicology assessment drawing from animal studies similar to those that were conducted in the RED. Newer studies are also included that provide similar results with increased accuracy. The conclusion is again that dietary intake effects are negligible considering residue amounts (US EPA, 2014c).
- The only significant point of departure is in regard to the maximum application rate for specific crops. The RED specified a maximum of 2 lbs ai/a while this particular risk assessment recommended between 1 and 1.5 lbs ai/a depending on the crop (US EPA, 2014c).
- Further studies were also done on the potential for spray-drift exposure, which was not provided in the RED (US EPA, 2014c).

Since the scientific evaluation is only a preliminary health risk assessment to be used in the US EPA's registration review, it consists mostly of data. On the whole, it provides the US EPA with updated information that seems to imply that only a slight increase of caution might be appropriate. Consequently, the US EPA's stance – as reflected in their registration review decision – will likely be similar to the *status quo* established in the RED.

#### Joint FAO/WHO Meeting on Pesticide Residues (JMPR)

Bentazone was first assessed by the Joint FAO/WHO Meeting on Pesticide Residues (JMPR) in 1991, and then reviewed again in 1998; the most recent report in 2012 was the most updated risk assessment of bentazone in food. The Joint Meetings assess the hazard degree of bentazone in food, water, several grains, beans and animals, and arrive to the recommendation of dietary intake. In the 1991 meeting, the ADI was recommended to be 0–0.1 mg/kg bw on the basis of 9 mg/kg bw NOAEL per day. The level of acute toxicity in rats, guinea pigs and rabbits is characterised as low, and WHO has classified bentazone as slightly hazardous (JMPR, 1991). The 1998 report recommends a maximum residue level of 1 mg/kg for bentazone in dry peas, 0.1 mg/kg for bentazone in potatoes, 0.2 mg/kg for maize fodder, 0.07 to 1.14 mg/kg for alfalfa and 2 mg/kg for green alfalfa forage (JMPR, 1998). The ADI of 0–0.1 mg/kg bw is also reaffirmed in this meeting and the establishment for AfRD is ruled out.

Bentazone was reviewed again in 2012 as part of the periodic re-evaluation programme of the Codex Committee on Pesticide Residues ([JMPR, 2012](#)). The JMPR noted that since its last review in 2004, no relevant new studies have been produced. Furthermore, most of the studies do not fulfil with good laboratory practice (GLP) standards, as they were produced before implementation of GLP. The 2012 risk assessment was focussed on the effect of bentazone on rats and arrived at the conclusion that an ADI of 0–0.09 mg/kg bw derived from a NOAEL of 9 mg/kg bw per day change the effect on kidney and liver at 35 mg/kg bw per day (JMPR, 2012). The Meeting also concluded that bentazone is not teratogenic in rats or rabbits, and adverse health effect or poisoning symptoms are not identified in case of human exposure to bentazone (in manufacturing personnel and operators). However, it is reported that bentazone has potential impacts on foetuses, infants and children.

#### **4. Neonicotinoid pesticides: clothianidin, imidacloprid, thiamethoxam**

A suspicion that neonicotinoids were harmful to the environment first arose following the publication of the scientific articles published in the highly reputable scientific journal *Science*. Two teams of researchers (Henry et al. and Schneider et al.) concluded that “low levels of neonicotinoid pesticides can have significant effects on bee colonies” ([EFSA, 2012](#)). More specifically, Henry et al. suggested that “exposure of bees to sub-lethal doses of the active substance thiamethoxam causes a number of behavioural impairments in bees and, by altering their homing skills, may contribute to bee-colony weakening at a level likely to place the hive in a critical situation” ([ANSES, 2012](#), p.1). The scientific studies had prompted national and EU risk regulators to seek for the further scientific and technical explanations from their regulatory agencies (see Alemanno, 2013; Bozinni, 2017; Rimkutė, 2015).

On the 23<sup>rd</sup> of March 2012, ANSES received a request from the French Directorate General for Food (DGAL) for scientific and technical support. One month later (on the 31<sup>st</sup> May 2012), ANSES issued its scientific assessment and a recommendation stating that a review of neonicotinoids (thiamethoxam, clothianidin, etc.) should be conducted at the European Union level based on new scientific data from recent studies ([ANSES, 2012](#)). In this context, ANSES and EFSA worked together and engaged in a collaborative process to exchange data.

In a similar vein, following publication of the studies in 2012, the European Commission issued a formal request to EFSA to compare the actual exposure of bees to neonicotinoids with the exposure levels used in the published research ([European Commission, 2018a](#)). In addition, EFSA was asked to determine whether the results could be applied to other neonicotinoids used for seed treatment. More specifically, the European Commission’s mandate asked EFSA to evaluate the risks related to the use of clothianidin, imidacloprid and thiamethoxam as seed treatment or as granules, by exclusively focussing on:

- their acute and chronic effects on bee colony survival and development;
- their effects on bee larvae and bee behaviour;
- the risks posed by sub-lethal doses of the three substances.

This section maps the relevant regulatory agencies that provided risk assessments on neonicotinoid pesticides, focussing on the scientific outputs of EFSA, the US EPA) and the Canadian Pest Management Regulatory Agency (PMRA). The remainder of this section outlines which chemicals were analysed by the four agencies and provides an overview of the scientific conclusions reached.

### European Food Safety Authority (EFSA)

On the 16<sup>th</sup> of January 2013, EFSA published its conclusion on the peer review of the pesticide risk assessment for bees for the active substance clothianidin ([EFSA, 2013](#)), imidacloprid ([EFSA, 2013](#)), thiamethoxam ([EFSA, 2013](#)). EFSA scientific experts have identified a number of risks posed to bees by the three neonicotinoid insecticides ([EFSA, 2013](#)). However, most of the variables and types of risk were marked as ‘not finalised’. This

means that “there were no data, or insufficient data available to reach a conclusion / where there are no agreed risk assessment schemes available” (EFSA, 2013). The core scientific conclusions of EFSA are summarised in the table below.

“Where the risk assessments could be completed, EFSA, in cooperation with scientific experts from EU Member States, concluded the following for all three substances:

- Exposure from pollen and nectar: Only uses on crops not attractive to honey bees were considered acceptable.
- Exposure from dust: A risk to honey bees was indicated or could not be excluded, with some exceptions, such as use on sugar beet and crops planted in glasshouses, and for the use of some granules.
- Exposure from guttation: The only risk assessment that could be completed was for maize treated with thiamethoxam. In this case, field studies show an acute effect on honey bees exposed to the substance through guttation fluid.” (EFSA, 2013)

In 2013, following the risk assessments carried out by EFSA, the European Commission imposed restrictions on the use of clothianidin, imidacloprid and thiamethoxam (see [Regulation \(EU\) No 485/2013](#)). The Commission restricted the use of plant protection products and treated seeds containing three of these neonicotinoids to protect honeybees. The regulation “prohibits the use of these three neonicotinoids in bee-attractive crops (including maize, oilseed rape and sunflower) with the exception of uses in greenhouses, of treatment of some crops after flowering and of winter cereals” ([European Commission, 2018a](#)).

On the 28<sup>th</sup> of February 2018, EFSA has published its new scientific conclusions on the neonicotinoid pesticides (clothianidin, imidacloprid and thiamethoxam) that update those published in 2013 ([EFSA, 2018e](#)). In the new scientific assessment, the Pesticides Unit of EFSA carried out an extensive data collection exercise to collect all the scientific evidence published since the previous evaluations. In its new scientific conclusions, EFSA confirmed its key scientific conclusions of 2013, i.e. overall clothianidin ([EFSA, 2018j](#)), imidacloprid ([EFSA, 2018j](#)) and thiamethoxam ([EFSA, 2018j](#)) pose a risk to bees.

The literature reviews covered not only honeybees (as it was the case in 2013), but also included bumblebees and solitary bees. The core conclusion of the scientific evaluation was the assessed neonicotinoid pesticides (clothianidin, imidacloprid and thiamethoxam) pose high risks to honeybees, bumblebees and solitary bees: “The conclusions on risk varied according to factors such as the bee species, the intended use of the pesticide and the route of exposure (residues in bee pollen and nectar; dust drift during the sowing/application of the treated seeds; and water consumption). However, taken as a whole the conclusions confirm that neonicotinoids pose a risk to bees” ([EFSA, 2018j](#)). The head of EFSA’s Pesticides Unit, Dr. Jose Tarazona, noted: “There is variability in the conclusions, due to factors such as the bee species, the intended use of the pesticide and the route of exposure.

Some low risks have been identified, but overall the risk to the three types of bees we have assessed is confirmed” ([EFSA, 2018e](#)).

The most recent of EFSA’s conclusions were shared with the European Commission and Member States who are in charge of risk management, i.e., the considerations of potential amendments to the current restrictions on the use of these pesticides. By the time of completing this study, those considerations are on-going.

#### United States Environmental Protection Agency (US EPA)

Following suspicions that neonicotinoid pesticides caused harm to bees, in 2012, in partnership with the PMRA, the US EPA started investigating those chemicals.

In 2016, the US EPA conducted studies on the active substances clothianidin, imidacloprid, thiamethoxam and their effects on pollinators, ecology and human health ([US EPA, 2018e](#)). In its preliminary risk assessments, the US EPA concluded that the chemicals could pose risks to bees (Wagman et al, 2017),<sup>7</sup> but further research indicated that these risks occurred only under certain circumstances, as such, the agency concluded that neonicotinoids (clothianidin, imidacloprid, thiamethoxam) did not pose a direct threat to bees. The US EPA will finalise its findings in 2018.

#### Canadian Pest Management Regulatory Agency (PMRA)

In 2012 and 2013 following reports of “bee deaths linked to exposure to the dust created from planting corn and soy seeds treated with neonicotinoids” ([Health Canada, 2016](#)). The government of Canada introduced new rules in 2014, in order “to reduce dust when planting this type of treated seed” ([Health Canada, 2016](#)). The agency reports that, as a result of “these new requirements in place, the number of reported bee deaths from pesticide exposure has been reduced by up to 80%” ([Health Canada, 2016](#)).

For the past years, the PMRA has worked together with the US EPA to conduct risk assessments on neonicotinoid pesticides. The agency conducted risk assessments on the active substances imidacloprid, clothianidin, and thiamethoxam, focussing on their effects on human health, the environment and pollinators (and further a special review of aquatic risks) ([Health Canada, 2017b](#)). The PMRA has concluded that imidacloprid poses risks for aquatic environments; it is still finalising its reports on the other substances ([Health Canada, 2017a](#)). So far, the agency states that neonicotinoids (imidacloprid, clothianidin, and thiamethoxam) do not pose risks to human health or pollinators if used according to the limits established in the legislation.

Having discussed the general scientific conclusions, the section further goes in-depth in the conclusions reached by EFSA, the US EPA and PMRA per active substance, focussing on the several agencies’ findings regarding the three chemicals (clothianidin,

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<sup>7</sup> Wagman, M., Mroz, R., Blankinship, A. and M. Koper, C. (2017). Preliminary Bee Risk Assessment to Support the Registration Review of Clothianidin and Thiamethoxam. Washington D.C.

thiamethoxam, imidacloprid). *Table 2* and the following sub-sections provide an overview of these conclusions.

Table 2: Regulatory agencies and their risk assessments of neonicotinoids

Object of risk assessment	Regulatory agency	Scientific findings	Conclusion and suggestive policy output
Clothianidin	EFSA (2013)	Two studies were used to determine the 'no observable effect concentration' (NOEC) values, the highest dose on which there is no negative effect noticed. For clothianidin, this was expressed as $\geq 40 \mu\text{g a.s./kg diet}$ .	Risks were identified in most types of crops, including cereals, maize, oilseeds, and sunflowers. From the finalised risks, acute dust exposure risk is the most notable.
	US EPA	Combined preliminary risk assessment of clothianidin and thiamethoxam. The EPA examined the two substances' impact on bees in three tiers.	No acute, chronic, or short-term aggregate risk estimates of concern for the registered uses of clothianidin exist.
	PMRA	Clothianidin did not cause cancer in laboratory animals and is non-genotoxic.	Clothianidin is unlikely to affect humans' health when used according to label directions.
Imidacloprid	EFSA	EFSA noted a LD50, the doses at which 50% of subjects dies, of 81 ng/bee. The NOEC based on mortality is $< 2.5 \text{ ng/bee}$ , while an effect on habituation is reached at 0.1 ng/bee. Oral exposure levels are lower: LD50 at 3.7 ng/bee, NOEC at 1.2 ng/bee.	Risks were identified in most types of crops, including cereals, maize, oilseeds, and sunflowers. From the finalised risks, acute dust exposure risk is the most notable.

	US EPA	The threshold for imidacloprid in crops was '25 parts per billion'.	Crops below this level of 'nectar residue' do not pose risk.
	PMRA	A potential risk to bees was indicated for bee attractive crops associated with pre-bloom, during-bloom, and some post-bloom applications	Crops below this level of 'nectar residue' do not pose risk.
Thiamethoxam	EFSA	It is noted that, at 25 µg/kg sucrose solution, 2 out of 11 bees had not returned within 24 hours compared to 100% of the control bees	Acute risk for a number of crops from dust exposure was found. Risks stemming from maize and oilseed rape are labelled as acute.
	US EPA	MOEs were higher than identified concern (LOC 100)	No risk posed by the substance in any of the situations assessed
	PMRA	Some current uses of thiamethoxam are not expected to affect bees; however, there are some uses of thiamethoxam that may pose a risk of concern to bees	Mitigation measures are proposed to minimise potential exposure to bees, where necessary

### *Clothianidin*

EFSA utilised two studies to determine the no observable effect concentration (NOEC) values, the highest dose of which there is no negative effect noticed ([EFSA, 2013](#)). For clothianidin, this was expressed as  $\geq 40 \mu\text{g a.s./kg diet}$ . Although most of the results in the peer review research are "not [finalised]", risks were identified in most types of crops, including cereals, maize, oilseeds, and sunflowers. From the finalised risks, acute dust exposure risk is the most notable. Risks from nectar/pollen and guttation were largely "not [finalised]" either.

In its new scientific conclusions conducted in 2018, EFSA relied on extensive data which allowed the finalisation of the conclusions that were not completed in 2013. In the detailed and nuanced risk assessment of clothianidin, EFSA concluded that overall clothianidin

poses a high risk to honey bees and bumble bees across various seed treatments and across various tiers (EFSA, 2018j).

US EPA's final risk assessment on clothianidin is scheduled to be released in 2018. In its combined preliminary risk assessment of clothianidin and thiamethoxam, the US EPA examined the two substances' impact on bees in three tiers (US EPA, 2017).<sup>8</sup> In the first tier, it examined "risk quotient" to understand "acute and chronic risks" to individual bees. It concluded that risks for the bees existed in all uses ("foliar, soil and seed") in this tier. In the second tier, honey bee colonies were exposed to the "risks identified" in tier I. It concluded that similar level of risks also existed in this tier. In the third tier, there were "full field colony level studies" from "seed treatments". The effects in this tier were "transient or limited". In the US EPA's risk assessment of clothianidin's human health effects, the US EPA measured exposure through potential "dietary, food and drinking water" sources (US EPA, 2017e). For all three measures, the US EPA concluded that "no acute, chronic, or short-term aggregate risk estimates of concern for the registered uses of clothianidin exist" (US EPA, 2017).

The PMRA found that "clothianidin did not cause cancer in laboratory animals and is non-genotoxic", and as such "clothianidin is unlikely to affect humans' health when used according to label directions" (PMRA, 2013). The agency states that, if used according to the limits established in the country's legislation, the chemical is safe to use.

#### *Imidacloprid*

The acute and chronic toxicity of imidacloprid are determined on the basis of previous EFSA as well as INRA (the French National Institute for Agricultural Research) studies. In contact exposure, EFSA noted a LD50, the doses at which 50% of subjects dies, of 81 ng/bee (EFSA, 2013). The NOEC based on mortality is <2.5 ng/bee, while an effect on habituation is reached at 0.1 ng/bee. Oral exposure levels are lower: LD50 at 3.7 ng/bee, NOEC at 1.2 ng/bee.

Again, many of EFSA tests are marked as "not [finalised]". However, the acute risk from dust exposure for a range of crops is identified (EFSA, 2013). In its new scientific conclusions conducted in 2018, EFSA relied on an extensive data which allowed the finalisation of the conclusions that were not completed in 2013. In the detailed and comprehensive risk assessment of imidacloprid, EFSA concluded that, overall, imidacloprid poses a high risk to bees across various seed uses of the pesticide and across various tiers (EFSA, 2018j).

US EPA's final risk assessment on imidacloprid will be released in 2018. In its preliminary 'pollinator only' risk assessment in 2016, the agency examined the impact of imidacloprid on honey bees at individual and colony levels. It concluded that imidacloprid creates "risks" to their health (Cornell University, 2017). This risk, however, is determined by the "pollinating crops". The threshold for imidacloprid in crops was "25 parts per billion".

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<sup>8</sup>Preliminary Bee Risk Assessment to Support the Registration Review of Clothianidin and Thiamethoxam. (2017, June 15). Retrieved December 20, 2017 from <https://www.epa.gov/pesticides/epa-releases-four-neonicotinoid-risk-assessments> .

Crops below this level of “nectar residue” do not pose said risk. Citrus and cotton were identified as crops posing significant risks.

The PMRA found that with this active substance “a potential risk to bees was indicated for bee attractive crops associated with pre-bloom, during-bloom, and some post-bloom applications” (US [EPA and PMRA, 2013](#)).

### *Thiamethoxam*

In the scientific conclusions carried out in 2013, EFSA’s risk assessment of thiamethoxam was mostly not finalised. However, it was noted that, “at 25 µg/kg sucrose solution, 2 out of 11 bees had not returned within 24 hours compared to 100% of the control bees” ([EFSA, 2013](#)). Moreover, an acute risk for a number of crops from dust exposure was found. Risks stemming from maize and oilseed rape are labelled as acute. In 2018, EFSA have reached more conclusive results that allowed to conclude that overall thiamethoxam poses a high risk to bees ([EFSA, 2018j](#)).

In its draft human health risk assessment of thiamethoxam, the US EPA looked at the “dietary, residential and spray drift exposures” (US EPA, 2017).<sup>9</sup> The EPA concluded that there was no risk posed by the substance in any of these situations. In general, it concluded that “MOEs were higher than identified of concern (LOC 100)”.

The PMRA found that some current uses of thiamethoxam are not expected to affect bees; however, there are some uses of thiamethoxam that may pose a risk of concern to bees. As such, mitigation measures were proposed by the agency in December 2017 to minimise potential exposure to bees, where necessary ([Health Canada, 2017](#)).

## **II – Conclusion**

What are the key issues and controversies concerning glyphosate, 2,4-D, bentazone, and neonicotinoid pesticides? What are the scientific conclusions and regulatory decisions regarding the aforementioned pesticides?

Glyphosate is used as an herbicide in many agricultural sectors. It was discovered and patented by Monsanto but since its patent has expired it has been manufactured by many chemical companies. The active substance has been assessed multiple times by European Union (EU) agencies as well as other agencies worldwide. There have been ongoing debates about the effects of glyphosate on humans regarding carcinogenic, endocrine disruptive and fertility hazards. In March 2015, the International Agency for Research on Cancer (IARC) classified glyphosate as ‘probably carcinogenic to humans’ ([IARC, 2017d](#)). This was followed by a public and political debate about the labelling, classification and renewal of the glyphosate licence. The European Food Safety Authority (EFSA) conducted a risk assessment of glyphosate and concluded that “glyphosate is unlikely to pose a

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<sup>9</sup> Thiamethoxam. Draft Human Health Risk Assessment for Registration Review. (2017, December 5). Retrieved December 21, 2017 from <https://www.epa.gov/pollinator-protection/schedule-review-neonicotinoids-pesticides>;

carcinogenic hazard to humans and the evidence does not support classification with regard to its carcinogenic potential according to Regulation (EC) No 1272/2008” ([EFSA, 2015b](#), p. 1). The scientific evaluation of glyphosate risks (at EFSA level) was conducted together with and supported by 27 Member States (with an exception of Sweden). Furthermore, independent regulatory authorities worldwide working outside the EU have reached the same scientific conclusions as EFSA. Regulatory bodies that reached the same scientific conclusion as EFSA include independent risk assessors based in the US, Canada, Australia, and New Zealand; their scientific conclusion has been supported and endorsed by the Joint Food and Agriculture Organization of the United Nations – World Health Organisation Meeting on Pesticide Residues (JMPR). In a similar vein, in 2017, the Risk Assessment Committee (RAC) of the European Chemicals Agency (ECHA) concluded that a link between glyphosate and cancer in humans cannot be established (ECHA, 2017). In addition, ECHA’s scientific evaluation (based on their assessment of available information and existing scientific knowledge) was in line with EFSA and other national regulatory authorities’ conclusions: glyphosate should not be categorised as a substance that causes genetic damage (mutagen) or disrupts reproduction. In November 2017, a qualified majority supporting the proposal by the European Commission to renew the approval of glyphosate for a period of 5 years was reached by the Appeal Committee. On the 12<sup>th</sup> of December 2017, the Commission adopted the act to renew the approval of glyphosate for 5 years ([European Commission, 2018b](#)).

2,4-D is an herbicide that was developed in the 1940s and is now manufactured by many chemical companies because the patent on it has expired. It was the first widely deployed herbicide used to control broadleaf plants and woody plants in small grain, fruit, nut, vegetable crops, pastures, and rangeland. 2,4-D can be found in many weed-control products and is often mixed with other herbicides. In 2014, the European Food Safety Authority published a peer review of the pesticide risk assessment of the active substance 2,4-D, concluding that “based on the available data, no chronic or acute concerns were identified for the consumers” ([EFSA, 2014a](#), p. 1). EFSA and other regulatory agencies (e.g., US EPA, Canadian regulatory authorities) also do not consider 2,4-D to be a human carcinogen. On the contrary, in 2015, the IARC finalised a hazard classification of the herbicide 2,4-D and concluded that the substance should be classified as ‘possibly carcinogenic to humans’ ([IARC, 2017a](#)). In December 2015, the European Commission renewed the approval of 2,4-D as active substances for use in plant protection products.

3-isopropyl-1H-2,1,3-benzothiadiazin-4(3H)-one 2,2-dioxide, more commonly known as bentazone. Bentazone is manufactured by the BASF Corporation and its primary use is for large scale agriculture – particularly rice, beans, corn, and peppers. Concern for the use of this chemical is directed towards toxicity when it comes into contact with skin, potential harm from ingestion, and environmental concerns - mostly confined to groundwater. As an herbicide, bentazone has been subject to the review of many regulatory agencies or organisations dedicated to making risk assessments on its effects on human health and the environment. The European Commission had approved bentazone for use in the EU; however, the recent expiry of the authorisation in June 2017 prompted discussion in EU Member States as to whether extension should be warranted. EFSA and other agencies concluded that genotoxic, carcinogenic or neurotoxic effects are not produced by bentazone. However, EFSA together with other regulatory agencies in the EU have

identified several data gaps (in the mammalian toxicology area; in potential endocrine disrupting properties; risks to consumers; etc.) (EFSA, 2015a), which did not allow the finalisation of the risk assessment of bentazone. The European Commission has suggested to renew the EU authorisation of bentazone for the maximum period (until the 31<sup>st</sup> of January 2032). However, it requested further data confirming bentazone's safety. Similarly, the US Environmental Protection Agency (US EPA) has assumed the tasks of both assessing bentazone risks and directly regulating the substance in the United States. Currently, the US EPA is still conducting a risk assessment of bentazone, however, based on its preliminary scientific evaluations issued in 2014, it is highly likely that the licence of bentazone will be extended in the US.

Neonicotinoids are a new class of chemicals that are used as insecticides. Neonicotinoid pesticides target the central nervous system of insects, causing paralysis and death. They include imidacloprid, acetamiprid, clothianidin, dinotefuran, nithiazine, thiacloprid and thiamethoxam. Following the international controversy over potential links between neonicotinoids and the disappearance of bee colonies, several regulatory agencies have started to re-evaluate licensed neonicotinoids (imidacloprid, clothianidin, thiamethoxam) in their jurisdictions. In 2013, as per Commission mandate, EFSA conducted three peer reviews of the pesticide risk assessments of the active substances imidacloprid, clothianidin and thiamethoxam. EFSA reached the conclusion that the three neonicotinoid pesticides cause an acute risk to honey bees. Following the scientific conclusion of EFSA, the European Commission restricted the use of plant protection products containing three neonicotinoid active substances (i.e., clothianidin, imidacloprid and thiamethoxam) to protect European honeybees ([Regulation \(EU\) No 485/2013](#)). On the 28<sup>th</sup> of February 2018, EFSA updated its risk assessments of the three neonicotinoids – [clothianidin](#), [imidacloprid](#) and [thiamethoxam](#) – concluding that, overall, the assessed neonicotinoid pesticides cause a high risk to honeybees, bumblebees and solitary bees. On the contrary, the use of the neonicotinoid pesticides is not restricted in the US and Canada because their regulatory agencies have arrived at different scientific conclusions than EFSA. The US Environmental Protection Agency claimed that honeybees are not exposed to the neonicotinoid pesticides to the extent that could cause an acute risk to them. Currently, the US EPA is re-assessing the risks of neonicotinoid pesticides to bees.

## Chapter 3

### I – Comparisons of the institutional design of (regulatory) agencies and bodies

The previous chapter has shown that one substance can be given different assessments by various bodies. For example, in 2015, the International Agency for Research on Cancer (IARC) suggested the existence of a probable carcinogenic link to glyphosate in humans, while numerous regulatory agencies, such as the European Food Safety Agency (EFSA), the European Chemicals Agency (ECHA) and the United States Environmental Protection Agency (US EPA) have also conducted risk assessments and arrived at different scientific conclusions. In a similar vein, regulatory bodies disagree on the risks and hazards caused by the herbicide 2,4-D and neonicotinoid pesticides. To explain the different conclusions at which agencies have arrived, this chapter first reviews the institutional designs of risk assessors in terms of their:

- Formal mandate and accountability mechanisms
- Independence and transparency policies
- Selection of scientific experts
- Procedures followed in the scientific assessments
- Internal/external control mechanisms

The respective agencies' institutional designs are introduced and discussed in detail, and include:

- European Union agencies: The European Food Safety Authority (EFSA) and the European Chemicals Agency (ECHA)
- National agencies: The Federal Institute for Risk Assessment (BfR)
- International bodies: The International Agency for Research on Cancer (IARC)
- Agencies outside the EU: The United States Environmental Protection Agency (US EPA)

The decision to cover the aforementioned agencies was motivated by the following: the study focusses on (1) the agencies that have produced scientific assessments at the EU-level or assisted EU agencies (e.g., the German regulatory authorities), (2) the agencies that arrived at different scientific conclusions compared to the EU agencies (the IARC (in the case of glyphosate) and the US EPA (in the case of neonicotinoid pesticides: imidacloprid, clothianidin and thiamethoxam). Such a case selection strategy assures the representation of relevant (regulatory) agencies worldwide: while the IARC is as a case of international bodies, the US EPA is a typical case of most relevant regulatory agencies operating outside of the EU (i.e., Australian, New Zealand and Canadian regulatory agencies have comparable institutional designs to the US EPA).

## 1. European agencies: EU and national regulatory bodies

### European Food Safety Authority (EFSA)

#### *Mandate and accountability mechanisms*

Established in 2002 with the General Food Law ([Regulation \(EC\) 178/2002](#)), EFSA is the agency of the EU that provides independent scientific advice on food-related risks. EFSA is funded by the EU; however, it was created to work independently of the European legislative and executive institutions such as the European Commission, the Council, the European Parliament as well as Member States (Regulation (EC) 178/2002).

EFSA was created in the aftermath of major food crises in the late 1990s to ensure that robust and rigorous scientific advice and communication of risks are provided to EU institutions and Member States. As a result, the responsibility to deliver independent scientific outputs are regarded as one of the core pillars of EFSA day-to-day tasks as well as its overall mission. The General Food Law created a EU-level food safety system in which EFSA is exclusively in charge of the scientific aspects of food safety regulation, i.e. EFSA is responsible for risk assessments (science), whereas the European Commission together with other EU institutions take responsibility for risk management (i.e., policy). As the risk assessor, EFSA provides scientific opinions that lay the foundations for European legislation in the areas of plant protection, plant health, food and feed safety, nutrition and animal health and welfare. EFSA also has a duty to communicate its scientific findings to the public and interested stakeholders.

The Executive Director (currently Bernhard Url, appointed in 2014) and the Management Team are responsible for the day-to-day activities of EFSA ([EFSA, 2018g](#)). The Management Board of EFSA is mandated to act in the public interest. The Board has an important duty to ensure that EFSA operates efficiently and delivers its mandate in line with its founding regulations as well as takes into account the expectations of EU and Member State institutions, stakeholders and the public. The board consists of 15 members with wide-ranging expertise. It is important to note that the members of the board do not represent a Member State, government, organisation or particular sector. However, four members do represent the interests of consumers and other interests in the food industry. The European Commission is also represented. The board members are appointed by the Council of the European Union - in consultation with the European Parliament - based on a shortlist prepared by the Commission ensuing an open call for expressions of interest (see the General Food Law ([Regulation \(EC\) 178/2002](#))).

The key tasks of the board are (1) to guarantee appropriate accountability and financial management, (2) to ensure that EFSA's activities follow its mandate and missions, (3) to plan EFSA's budget and work programmes as well as monitor their implementation, and (4) to appoint the Executive Director and members of the Scientific Committee and the Scientific Panel.

*Independence policies*

Independence (alongside scientific excellence, openness, innovation, cooperation) is one of the key values of EFSA: “EFSA is committed to safeguarding the independence of its experts, methods and data from any undue external influence and to ensuring that it has the necessary mechanisms in place to achieve this” (EFSA, 2018m; see also Regulation (EC) No 178/2002). Assuring independence is one of the core aims of EFSA, given that it was created as part of a broader legislative reform designed to re-establishing the confidence of EU citizens in the ability of the EU to guarantee safety of the food supply (Alemanno, 2016; Alemanno and Gabbi, 2016; Rimkutė, 2016). EFSA communicates that its independence policies ensure the impartiality of the persons participating in EFSA’s operations. The founding regulation of EFSA (Regulation (EC) No 178/2002) and secondary legislation require legal, financial and regulatory independence. They aim at preventing conflicts of interests by requiring the concerned actors to declare all interests held by them. They consider financial investments from business actors impacted directly or indirectly by EFSA’s operations as one of the key sources of attention when it comes to potential conflicts of interests. EFSA has a system that is meant to prevent conflicts of interest of its external scientific experts and processes (see table below).<sup>10</sup>

“EFSA’s existing range of safeguards rests on a comprehensive system for avoiding conflicts of interest among its external scientific experts. These measures include:  
 A multi-layered scrutiny system of annual declarations of interest (ADoIs), specific declarations of interest (SDoIs) and oral declarations of interest (ODOIs). ADoIs are submitted by all members of EFSA’s Scientific Committee, Scientific Panels and Working Groups.  
 All DoIs are screened to identify potential conflicts related to an expert’s professional activities and financial interests.  
 A range of options is available to resolve conflicts e.g. the expert may be considered ineligible for membership or chairmanship of a panel, or can be asked to relinquish a position, or shares in a company.  
 Compliance checks are performed on a sample of DoIs twice a year by staff members not involved in the assessment and validation process.  
 Regular external audits are carried out by the European Court of Auditors, the Internal Audit Service of the European Commission, and external contractors.” (EFSA, 2017d).

EFSA communicates that it is committed to a “robust set of measures and working practices to safeguard the independence of its scientific work and avoid conflicts of interest” (EFSA, 2018i). However, the independence aspects of EFSA’s conduct are regarded as controversial by many stakeholders. EFSA is often accused of having too close

<sup>10</sup> Please see the following documents for further information: EFSA, [Decision of the Executive Director of the European Food Safety Authority on Competing Interest Management](#), 2017; EFSA, [EFSA’s Policy on Independence](#), 2017; EFSA, [Decision on Declarations of Interests](#), 2012; EFSA, [EFSA report to the European Parliament on the implementation of its Independence Policy 2007-2012, 2012](#); EFSA, [Decision concerning recovery orders related to staff missions, 2009](#); EFSA, [Guidelines on Gifts and Hospitality, 2012](#); EFSA, [Declarations of Interest, Accessed: March 14, 2018](#); EFSA, [Independent science, accessed: March 14, 2018](#)

ties with industry and serious conflicts of interest: “Over half of the 209 scientists sitting on the agency’s panels have direct or indirect ties with the industries they are meant to regulate. A much clearer and stricter independence policy needs to be set up and rigorously implemented to restore the Authority’s reputation and integrity” ([Horel and Corporate Europe Observatory, 2013](#), p. 1). Furthermore, more recently experts analysing EFSA’s conflict of interest practices have discovered that 46% of current scientific experts contributing to EFSA panels have a financial conflict of interests, according to the Corporate Europe Observatory ([Pigeon, 2017](#)). In addition, EFSA currently faces new independence-related allegations as experts analysing EFSA’s activities have noted that in the process of the renewal of the European Food Safety’s Authority’s Management Board, the candidates with conflicts of interests are being considered ([Corporate Europe Observatory, 2018b](#)).

EFSA receives criticism not only regarding the independence of its experts, but also the independence in its processes. In 2012, the European Court of Audits assessed policies and procedures for the management of conflict of interest situations for EFSA ([European Court of Audits, 2012a](#)).<sup>11</sup> The Court has discovered that EFSA does not managed the conflict of interest situations adequately. A number of deficiencies of varying degrees have been identified in EFSA policies and procedures as well as their implementation. Furthermore, in terms of the glyphosate risk assessment, the Corporate Europe Observatory ([2017a](#)) has published an investigatory article communicating that industry revised EFSA’s Glyphosate scientific assessment ahead of its publication: “Shortly before the agency [EFSA] revealed its 2015 safety assessment for the world’s most widely-used herbicide, industry representatives were asked to file redaction requests and were even able to edit the documents at the very last minute. EFSA argues this is normal practice” (Corporate Europe Observatory, [2017a](#)). This implies that EFSA faces serious criticism regarding its de facto independence.

In response to the allegations, EFSA reiterates that it (as well as other regulatory agencies worldwide) is dependent on scientific information (studies) provided by the applicants (companies). As a result, according to EFSA, it is assumed by some stakeholder groups that this by default leads to the conflict of interest. In its statement addressing stakeholder concerns related to the EU assessment of glyphosate EFSA explained: “In the EU regulatory system for pesticides, the burden of proof of safety lies with the company that seeks to place their products on the market. This system is common to many regulated industries in the EU, including medicines. In practical terms, this means that applicants are required to present a dossier containing a set of mandatory guideline studies and to carry out a literature review of scientific papers published in the last 10 years, among other requirements. It is the role of Member State and EFSA experts to verify the applicant’s proposals, which they do by evaluating the findings and raw data of the mandatory guideline studies and by appraising the studies in the open literature according to a set of uniform scientific principles. In this way, EU experts are able to reach their own conclusion about the safety of the active substance in question” ([EFSA, 2017e](#)).

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<sup>11</sup> Please see the report here: European Court of Audits ([2012b](#))

This statement was issued in the context of the ‘Monsanto papers’ that took place in the US, however also significantly influenced debates in the EU. In the EU context, the ‘Monsanto papers’ scandal refers to the Parliamentary hearing that took place on the 11th of October 2017 and was held by the European Parliament Committees ENVI and AGRI (for more information please access [the EP website](#)). In this context, EFSA and its stakeholders discussed pertinent issues regarding the EU regulatory system, the role of EFSA in it and lessons learned from the US. Furthermore, such issues as independence, transparency and the role of science in risk assessments were touched upon.<sup>12</sup> In this context, the European Commission requested EFSA to explain what impact the allegations about Monsanto ghost-writing scientific review articles had on the overall EU assessment of glyphosate. EFSA responded by stating that: “Following this investigation, EFSA can confirm that even if the allegations regarding ghost-writing proved to be true, there would be no impact on the overall assessment as presented in the EFSA Conclusion on glyphosate” (see [EFSA, 2017f](#), p.5). Furthermore, the European Parliament (the Environment (ENVI) and Agriculture (AGRI) Committees) organised a public hearing - “[The Monsanto papers and glyphosate](#)” - in which the issue of ‘Monsanto papers’ was addressed. The presentation of the representatives of agencies, scientific community and NGOs can be found on [the European Parliament’s website](#).

Overall, EFSA is responsive to the criticisms of its stakeholders regarding its independence-related weaknesses. To illustrate, EFSA has revised and improved its independence policies which resulted in the new Independence Policy ([EFSA, 2017c](#)). The document communicates that EFSA strives for “the impartiality of the persons participating in EFSA’s operations based on the reassurance provided by projects securing the neutrality of the methods and data the Authority uses” (EFSA, 2017, p. 4). In particular, EFSA puts strong emphasis on its commitment to handling the conflict of interests in a rigorous manner: “Given the importance that experts’ judgment has in EFSA’s work, this policy [focusses] on the Authority’s ability to ensure that professionals contributing to the work of EFSA perform their tasks in an impartial manner, without favour or discrimination. This presupposes, among other things, that these individuals are devoid of conflicts of interest (CoI) harmful to the Authority’s work. This policy also outlines how EFSA prevents the occurrence of CoI” ([EFSA, 2017c](#), p. 4). Furthermore, the most recent strategic document issued by EFSA emphasises that EFSA is committed to achieve the independence of its experts, methods and data from any external influence ([EFSA, 2016a](#)). See which novel aspects were integrated in the new independence policy in the table below.

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<sup>12</sup> In the US, the scandal refers to the following allegations: “the Monsanto Papers show the company’s [Monsanto’s] real, and rather troubling, approach to science and evidence. Revelations include confirmation that the company hardly tested the real-world toxicity of its products, actively avoided pursuing studies which might show unwelcome results, and ghostwrote the studies of supposedly independent scientists. The documents also show Monsanto systematically attacked scientists whose research threatened their profits, as aptly summarised in a 2001 email by a Monsanto executive” ([Corporate Europe Observatory, 2018](#)).

“The revised policy now includes:

A new definition of what constitutes a conflict of interest, which brings EFSA into line with the most recent rules adopted by the European Commission for its expert committees.

A comprehensive set of “cooling-off” rules: external experts will be automatically barred from joining EFSA’s scientific panels if in the preceding two years they have been employed by, acted as consultants to, or have offered scientific advice to organisations that work in areas covered by EFSA’s remit. The cooling-off rules also apply to experts who have received research funding from such organisations over the same period.

A requirement that experts declare the proportion of their annual earnings received from any organisation, body or company whose activities fall within EFSA’s areas of work. This information will be published and used as part of the DoI assessment.

Publication of the list of EFSA’s partner organisations, such as national and international authorities, universities or research institutes.

Member State experts who take part in peer review meetings to be subject to the same scrutiny and transparency measures as panel experts” ([EFSA, 2017d](#)).

EFSA strongly reiterates its commitment to the new independence policies and its attempts to strive for improvements in its actual independent practices. This is reflected in their public communication. Jaana Husu-Kallio, Chair of the Board, noted: “The next challenge is to implement the policy, to turn the words into action. We will do this by the end of 2017 so that the new rules can be used in the renewal process for our scientific panels, which begin new terms in 2018.” ([EFSA, 2017d](#)). However, a group of stakeholders who have scrutinised the changes in the new independence policy remain sceptical: “The new independence policy is a modest improvement compared to the previous one. It does not close the current policy’s main loopholes, however. As a consequence, the improvements brought by this new policy (ban on consultancy contracts for, scientific advice to and managerial positions with regulated companies and organisations funded by them), while real, remain limited” ([Corporate Europe Observatory, 2017c](#)).

#### *Transparency policies*

Transparency and openness are essential aspects of EFSA’s work and are integrated in its founding regulation (Regulation (EC) No 178/2002, articles 38 and 39) (see table below). EFSA emphasised that transparency (defined as “access to data, information and documents”) and openness (i.e., engagement with stakeholders) have been the underlying values for EFSA since its inception. EFSA communicates that “openness and transparency mean that EFSA is able to meet the legitimate need of stakeholders to understand the basis for risk assessment” ([EFSA, 2017d](#)). For this purpose, EFSA is committed to making its scientific opinions, the agendas and minutes of meetings and other key documents publicly available. Furthermore, more recently, EFSA started to broadcast important meetings and events through its website. In addition, EFSA regularly opens meetings of its Scientific Committee and Panels to observers.

The founding regulation of EFSA specifies in Article 38 as follows. EFSA should make public without delay, in particular:

- “(a) agendas and minutes of the Scientific Committee and Panels;
- (b) the opinions of the Scientific Committee and Panels immediately after adoption, including minority opinions (if any);
- (c) the information on which opinions are based;
- (d) the annual declarations of interest made by selected people participating in its work;
- (e) the results of its studies;
- (f) the annual report of its activities; and
- (g) requests from the European Commission, the European Parliament or a Member State for scientific opinions which have been refused or modified and the underlying justifications” (Regulation (EC) No 178/2002, p. 18-19).

EFSA organised several activities that were aimed to contribute to generating more transparent and open scientific assessments that would be in accordance with the recent discussion paper on transformation to an “Open EFSA” (EFSA, 2014b) in order to deliberate on how EFSA can achieve two strategic goals within the next five years: “(1) to improve the overall quality of available information and data used for its outputs and (2) to comply with normative and societal expectations of openness” (EFSA, 2015h, p. 3). Furthermore, it is evident from the public communication and activities of EFSA that it spends much effort to advance transparency related aspects of its day-to-day activities. This can be observed by the number and extent of activities dedicated to transparency related issues.<sup>13</sup>

However, when it comes to the day-to-day activities of EFSA, a group of stakeholders have pointed out that there is much room for improvement regarding the actual transparency practices of EFSA, as well as how the regulatory systems regarding pesticide peer reviews works. EFSA and the BfR were accused of serious transparency flaws in the scientific evaluation process. For instance, the scientific community expressed strong criticism towards EFSA: “we urge you [EFSA] and the European Commission to disregard the flawed EFSA finding on glyphosate in your formulation of glyphosate health and environmental policy for Europe and to call for a transparent, open and credible review of the scientific literature” (Portier et al. 2015, p. 2). In response to the criticism and an increased public interest in the glyphosate issue, the raw data that EFSA relied on in its risk assessment (i.e. all the genotoxicity and carcinogenicity studies used in the glyphosate assessment) has been published by EFSA, meaning that the conclusions could be

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<sup>13</sup> Please see the following EFSA documents for more information: [Implementing measures of transparency and confidentiality requirements](#); [Openness, transparency and confidentiality - general principles](#); [Decision concerning access to documents](#); [Mandate for a new policy on information access](#); [Editorial: Increasing robustness, transparency and openness of scientific assessments](#); [Outcome of the targeted consultation of the EFSA Journal editorial on increasing openness, robustness and transparency of scientific assessments](#).

independently scrutinised and reanalysed by the interested scientists (EFSA, 2016c). This led to more heated debates because Prof. Portier reanalysed the data released upon request and found that EFSA and ECHA omitted relevant data in their assessments: “eight instances where significant increases in tumor response following glyphosate exposure were not included in the assessment by either EFSA or ECHA. This suggests that the evaluations applied to the glyphosate data are scientifically flawed, and any decisions derived from these evaluations will fail to protect public health” (Portier, 2017, p. 1).

In the case of glyphosate, according to the interviewed EFSA representatives, EFSA did its utmost to meet the expectations and requests of information coming from various stakeholders (EFSA representative #2). For instance, EFSA emphasises that it “has gone to great lengths to be open and transparent about the EU assessment of glyphosate. It has published its final Conclusion and 6,000 pages of background documents, which include the comments and views of experts offered during the process as well as very detailed information about how EU experts appraised each and every study and how they evaluated the evidence” (EFSA, 2017e, p. 4-5). The published documents can be accessed on EFSA website (see [EFSA, 2015f](#)).

Furthermore, in response to Public Access to Document requests, EFSA has released the findings and raw data from all the genotoxicity and carcinogenicity studies that were tendered by industry regarding glyphosate. The Authority notes that “in doing so, EFSA rejected the vast majority of confidentiality claims submitted by industry and provided the requestors with enough information to allow full independent scrutiny of the EU assessment” (EFSA, 2017e, p. 5). EFSA marked that such transparency practices are highly exceptional: “As far as EFSA is aware, it is the first regulatory body anywhere in the world to release this amount of information related to pesticide risk assessments” (EFSA, 2017e, p. 5; see also [EFSA, 2016d](#)). However, transparency-related issues and accusations reoccur. To give an example, in 2013, two groups of stakeholders – ClientEarth and Pesticide Action Network Europe (PAN Europe) – accused EFSA for refusal to access to relevant documents (see more on the background to the dispute here: ([Judgement of the Court, 2015](#))). The court decided to annul the decision of EFSA of the 12<sup>th</sup> of December 2011.<sup>14</sup> This court case illustrates that stakeholders are concerned about EFSA’s transparency practices and it

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<sup>14</sup> “On 12 December 2011 EFSA adopted and informed ClientEarth and PAN Europe of a further decision on the application which they had submitted on 23 December 2010. EFSA stated that it had decided to ‘withdraw’, ‘annul’ and ‘replace’ its decision of 10 February 2011. In that further decision, EFSA granted ClientEarth and PAN Europe access to, inter alia, the individual comments of the PPR and PSC external experts on the draft guidance document. EFSA stated however that it had redacted the names of those experts, pursuant to Article 4(1)(b) of Regulation No 1049/2001 and EU legislation on the protection of personal data, in particular Regulation No 45/2001. EFSA stated in that regard that the disclosure of the names of those experts was a transfer of personal data, within the meaning of Article 8 of Regulation No 45/2001, and that the conditions for such a personal data transfer laid down in that article were not fulfilled in this case.” ([Judgement of the Court, 2015](#))

takes much time and effort for them to obtain information that they have the right to request.

The interviewed representative of EFSA, however, noted that to meet the concerns of the public and stakeholders in relation to glyphosate, EFSA spent much time and effort to release much information about the glyphosate risk assessment (i.e., content) as well as peer-review process followed by EFSA and Member States for the renewal of the approval of the pesticide active substance (i.e., procedures followed) (EFSA representative #2).

However, major concerns regarding EFSA transparency and independence remains prominent. For instance, the scientific conclusions and processes through which EFSA and the BfR conclusions were reached have received much criticisms from representatives of the scientific community. In particular, there were concerns about EFSA and the BfR transparency and independence practices that according to them are less advanced compared to the IARC which leads to the less credible scientific conclusions (see table below).

**Open letter: Review of the Carcinogenicity of Glyphosate by EFSA and BfR**

“We reviewed these two differing decisions on the human carcinogenicity of glyphosate and conclude that the IARC WG decision is by far the more credible. The IARC WG decision was reached relying on open and transparent procedures by independent scientists who completed thorough conflict-of-interest statements and were not affiliated or financially supported in any way by the chemical manufacturing industry. It is fully referenced and depends entirely on reports published in the open, peer-reviewed biomedical literature. It is part of a long tradition of deeply researched and highly credible reports on the carcinogenicity of hundreds of chemicals issued over the past four decades by IARC and used today by international agencies and regulatory bodies around the world as a basis for risk assessment, regulation and public health policy.

In contrast, the BfR decision is not credible because it is not supported by the evidence and it was not reached in an open and transparent manner.

Accordingly, we urge you and the European Commission to disregard the flawed EFSA finding on glyphosate in your formulation of glyphosate health and environmental policy for Europe and to call for a transparent, open and credible review of the scientific literature.” (Portier et al., 2015, p.2)

EFSA responded to the open letter by stating that it strongly disagrees with these accusations (EFSA, 2016b, see p. 3). EFSA outlined which transparency practices were followed and how open EFSA was regarding, in particular, the case of glyphosate.

Regardless of EFSA’s efforts to be transparent about procedures followed and studies used in the case of glyphosate scientific evaluation, various stakeholder groups have raised concerns about transparency of EFSA and EU risk assessment system. For instance, on the 6<sup>th</sup> of October 2017, the European Commission received the submission of ‘[Stop](#)

[Glyphosate](#) European Citizens' Initiative. More than 1 million EU citizens have requested the Commission "to propose to Member States a ban on glyphosate, to reform the pesticide approval procedure, and to set EU-wide mandatory reduction targets for pesticide use" (European Commission, 2017a). The initiative required the EU scientific evaluation of pesticides to be based exclusively on published studies: "The Commission must ensure that the scientific evaluation of pesticides for EU regulatory approval is only based on published scientific evidence, which is commissioned by competent public authorities instead of the pesticide industry. Regulatory studies should be published in full and open to scientific scrutiny. The potential for conflicts of interest should be eliminated, by disconnecting contracting laboratories' finances from the commissioning procedure, and by prohibiting pesticide producers from choosing which authority they charge and pay for the authorisation procedure." ([Corporate Europe Observatory, 2017d](#)).

The Commission adopted a communication the 12th of December 2017 setting out the actions it intends to take in response to the initiative. After considering the initiative, the Commission reached the following conclusions: (1) "there are neither scientific nor legal grounds to justify a ban of glyphosate, and the Commission will not make a legislative proposal", (2) the Commission plans "to come forward with a legislative proposal by May 2018 to enhance the transparency in scientific assessments and the quality and independence of the scientific studies that are the basis of the assessments carried out by the European Food Safety Authority (EFSA). The proposal will also cover other aspects, such as the governance of EFSA"; (3) the Commission intends to "focus on the implementation of the [Sustainable Use Directive](#), and will re-evaluate the situation, initially in a report to Council and the Parliament on the implementation of the Directive to be produced in 2019" ([European Commission, 2017b](#)).

On the 11<sup>th</sup> of April, the Commission issued a proposal on transparency and sustainability of the EU risk assessment model in the food chain ([European Commission, 2018b](#)). The proposal was a direct response to the [European Citizens Initiative on glyphosate](#). It stipulates to EU citizens' concerns regarding the scientific evaluations on glyphosate risks. To address these concerns, the Commission intends to strengthen the transparency in the risk assessment process. The Commission also intends to provide supplementary guarantees of reliability, objectivity and independence of the studies used by EFSA in risk assessments. Furthermore, the proposal communicates that the Commission is committed to "Better Regulation", i.e. "the need to improve the transparency in the EU decision-making cycle as well as the need to safeguard European Food Safety Authority ability to get access to a sufficiently high number of qualified and multidisciplinary scientific experts. An important element is also the need to reinforce the co-operation between EFSA and national scientific bodies, increasing Member States' involvement in EFSA's operation" ([European Commission, 2018b](#)).

#### *Selection of scientific experts*

EFSA states that "the knowledge, experience and decision-making of EFSA's scientific experts are at the heart of our work" ([EFSA, 2018l](#)). Authority's Scientific Panels of experts are responsible for the EFSA's scientific risk assessments, while the Scientific Committee has the task of assisting and supporting the work of the Panels on scientific issues. In particular, the committee concentrates on developing harmonised risk assessment

methodologies. EFSA staff are in charge of supporting the Scientific Panels and Scientific Committee in conducting EFSA's scientific work.

EFSA communicates that its Scientific Committees and Panels consist of independent scientific experts with a three-year mandate. The [Declarations of Interests and CVs](#) of the PPR (Panel on Plant Protection Products and their Residues) Panel Members (2015-2018) are publicly available. To elaborate, EFSA launches a call for expression of interest from experts who will be potentially engaged in the risk assessment process of the substance. Applications are considered from both the European Union (EU) and the rest of the world. EFSA selects experts for a Panel or the Committee based on selection criteria such as risk assessment experience and expertise in peer reviewing scientific work, with external evaluators ensuring the fairness of the selection process ([EFSA, 2017b](#)). All applicants must complete an Annual Declaration of Interests (ADoI), which is evaluated by EFSA for potential conflicts of interests. A second screening of ADoIs is also completed before nominated candidates are invited to their first meeting ([EFSA, 2017b](#)).

EFSA clearly specifies how scientific experts are selected and what the core selection criterion are.<sup>15</sup> In selecting its experts, EFSA pays attention to the following factors: (1) The expertise required (i.e., "specific scientific expertise and experience; additional expertise and potential contribution to a diverse range of scientific disciplines in the process of opinion development; and the overall mix of knowledge areas available to the Scientific Panel/ Committee to cover its foreseen needs" ([EFSA, 2017b](#), p. 6)); (2) Nationality balance among Member States; (3) Gender balance (among equally qualified candidates, preference shall be given to those belonging to the underrepresented gender). In addition, all scientific experts working for EFSA are required to sign declarations of interests, declarations of commitment, including a commitment to act independently (EFSA, 2017).

However, when it comes to the day-to-day activities of EFSA, some stakeholders note that there are several loopholes when it comes to the declarations of interests in the pesticide peer reviews processes and the representatives coming from the Member States: "80 per cent of national experts who took part in the peer review of the European Food Safety Authority's (EFSA) assessment have refused to be identified, making it impossible to know whether the authors of the EU risk assessment were independent from relevant economic and political interests, or in fact had conflicts of interest" ([Corporate Europe Observatory, 2017b](#)).

#### *Procedures*

In the EU, before a pesticide can be authorised for use, the safety of its active substance must be assessed. EFSA follows the following key steps in the process (see document: [who assesses pesticides in the EU](#); the table below summarises the formal procedure in accordance with Article 12 of Regulation (EC) No 1107/2009):

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<sup>15</sup> see [Decision of the Executive Director concerning the selection of members of the Scientific Committee the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work](#)

1. Application submitted: Application for approval of active substance submitted to an EU Rapporteur Member State (RMS);
2. Application verified: RMS verifies that the application is admissible;
3. Report prepared: RMS prepares a Draft Assessment Report or Renewal Assessment Report that includes a risk assessment
4. Peer review: RMS shares report with EFSA, Member States and the European Commission. EFSA begins review of RMS report
5. Member State consultation: EFSA organises consultation with experts from Member States
6. Public consultation: EFSA canvasses stakeholders and any other interested parties for views on the report
7. Additional information: EFSA requests additional information from the RMS if needed
8. Report updated: Assessment report is updated by the RMS
9. EFSA issues conclusions: EFSA holds final consultation with experts from 28 Member States before issuing its conclusions
10. Draft decision: Committee comprising representatives of Member States votes on draft decision proposed by European Commission
11. Substance approved/rejected: Commission decides whether to allow the active substance to be used in pesticides in the EU. Member States can then decide whether pesticide products containing the substance should be authorised for use in their countries. (Source: [EFSA, 2016f](#))

The interviewed EFSA representative emphasises an important role of Member States and their experts in the process of EFSA risk assessments: “What you see in the legislation concerning pesticides is that the first assessment is conducted by the rapporteur member state. EFSA’s responsibility is, in cooperation with all other EU Member States, to revise the assessment that has been conducted by the rapporteur member state, and then to publish the conclusions. The legislation states that EFSA should cooperate with the Member States but does not specify how this consultation should be done. We have elaborated a process we call the peer review, focussing on the review of the science. As you know, peer review is one of the key elements in scientific assessment, and we have implemented this peer review process for the assessment of the pesticides. The aim of the peer review process is to check the assessment that has been conducted by the rapporteur member state. So, the first assessment is conducted by the rapporteur member state, but then the idea is to check this.

This has two aims: Obviously, we want to make sure that the assessment is correct, and in all cases, we see significant improvements in the assessment; and also, to be sure on the consistency and coherence for the whole assessment on pesticides. It is important for industry, but also for citizens that the quality of the assessment does not depend on the expertise of one particular Member State. All assessments should be the same, independent of who is the rapporteur Member State; and we ensure this through the peer review process. It is conducted by scientists in EFSA, and scientists in all Member States; and it is conducted for different scientific disciplines. We have personal consultations, so we collect comments; we define the key elements to be discussed; we organise expert meetings – tele-meetings or physical meetings, depending on the number of questions to be discussed and

their complexity – and following all this, the rapporteur Member State modifies their assessment, including all the comments from experts from EFSA, and publish a conclusion with a final recommendation for the European Commission.” *EFSA representative #2*

In a nutshell, the EFSA conclusions on pesticides have a complex structure and are designed to assist the European Commission in its risk management decisions on the approval/renewal of approval of substances as well as Member States in the assessment and risk management decision on Plant Protection Products containing approved substances; furthermore, EFSA’s conclusion support the review of the Maximum Residue Levels (MRLs) of pesticides. Please consult the figures below (see Figure 2; Figure 3; Figure 4; Figure 5) to learn about the common procedures regarding the renewal of approval of active substances under Regulation EU 844/2012.

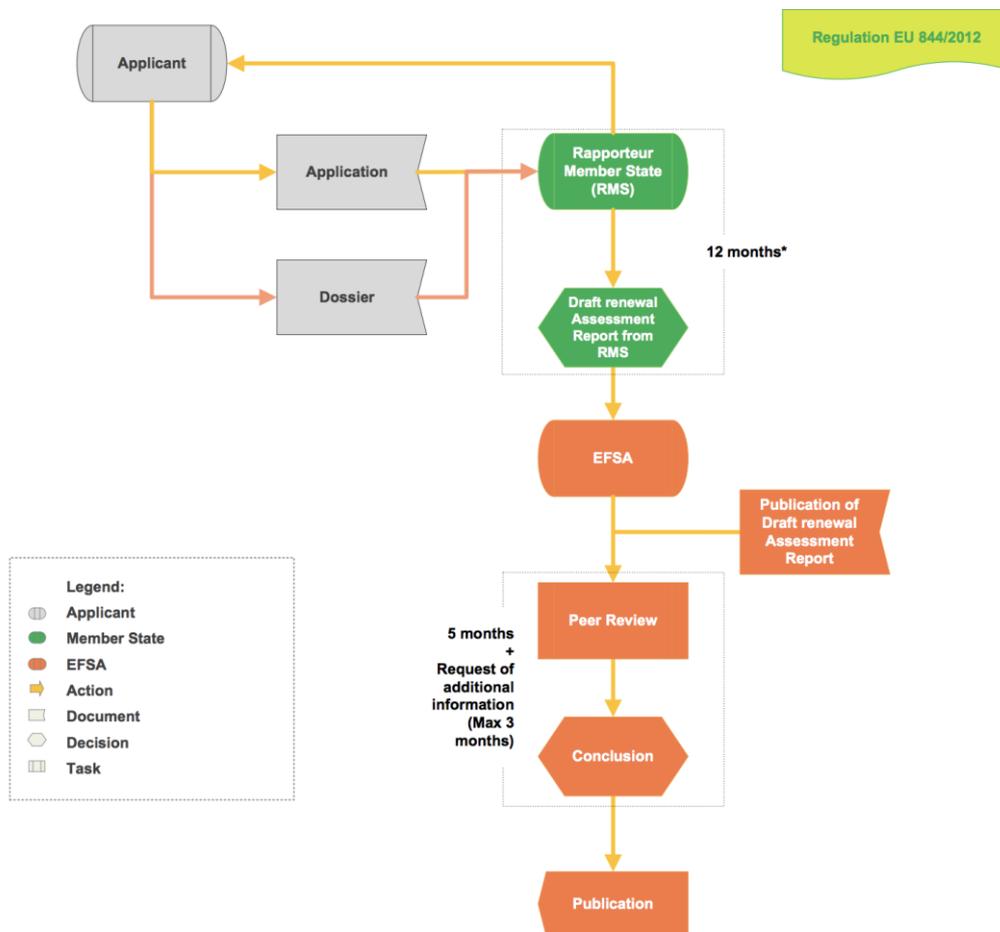


Figure 2. Renewal of approval under AIR programme: application procedure  
 Source: EFSA, [Applications helpdesk – Renewal of approval under AIR programme: application procedure](#)

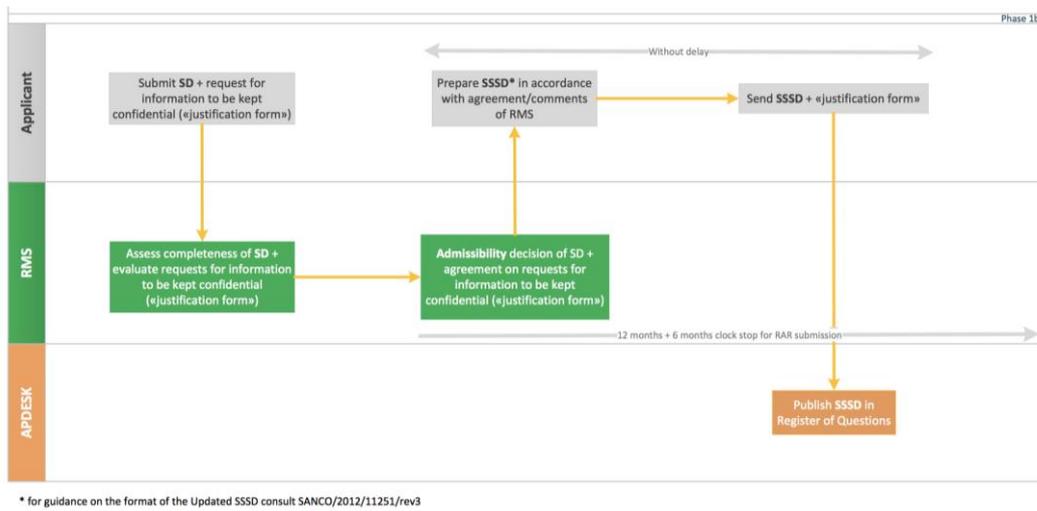


Figure 3. *Phase 2b Renewal of approval of active substances under Regulation EU 844/2012.* Source: EFSA

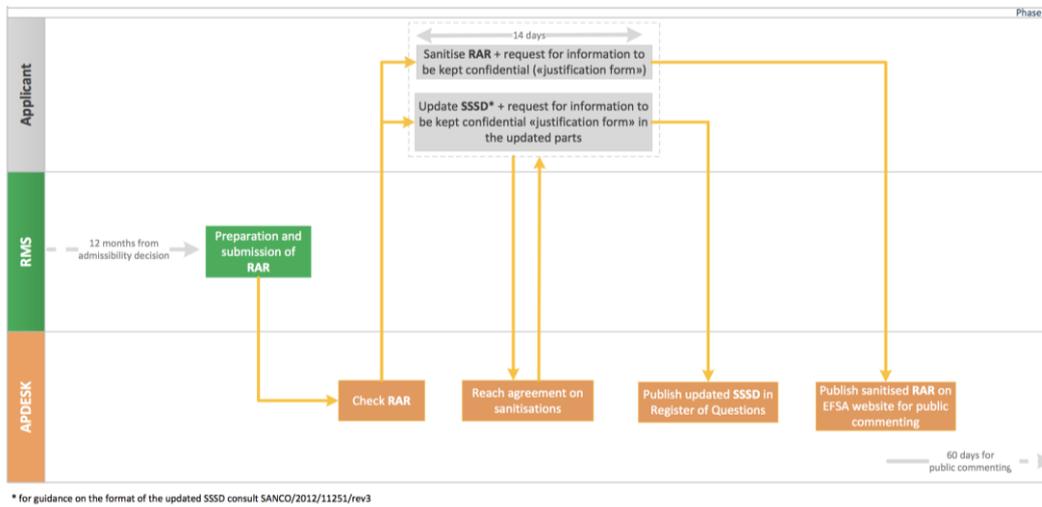


Figure 4. *Phase 2: RAR dispatch and call for comments.* Source: EFSA

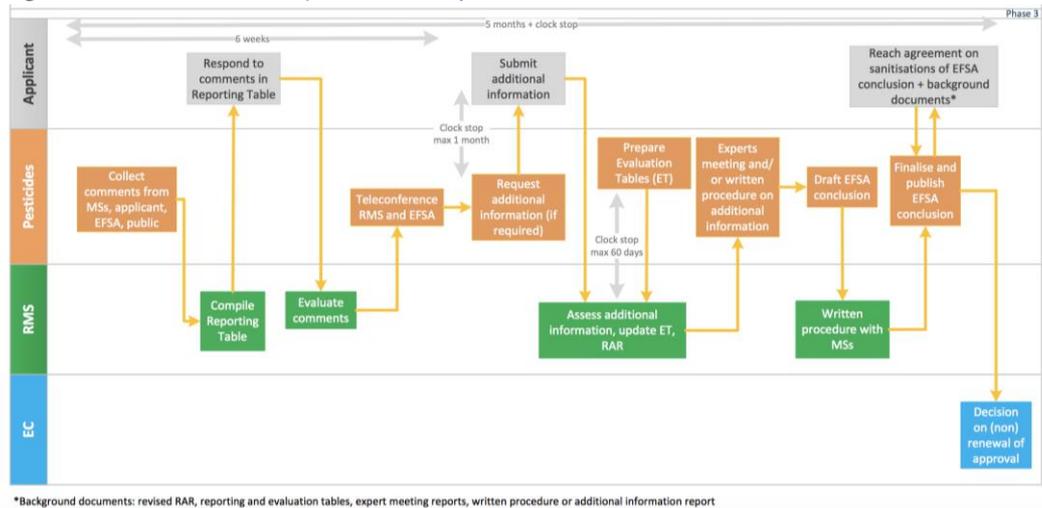


Figure 5. *Phase 3: EFSA Conclusions.* Source: EFSA

In the cases of glyphosate; 2,4-D; bentazone and neonicotinoid pesticides, EFSA followed all steps indicated above. The interviewed EFSA representative emphasised that EFSA is committed to following due processes specified in regulations defining EFSA tasks and responsibilities (EFSA representative #2).

#### *Internal/external control mechanisms*

In recent years, EFSA has worked on setting up and improving its Quality Management System (QMS) to guarantee a firm basis for scientific excellence, openness, independence, innovation and cooperation ([EFSA, 2017a](#)). QMS aims at guaranteeing that the quality of EFSA's scientific work is appropriately monitored and, when needed, strengthened: this contains self-review and customer feedback systems, which guarantees that scientific processes are developed consistently. Reviews and inspections are conducted by an internal auditor who reports to the EFSA's Management Board's Audit Committee, which, in turn, advises senior management on possible improvements to EFSA scientific work practices.

In terms of external evaluation, EFSA's Founding Regulation obligates EFSA to commission independent external evaluations of its activities and working practices. Relying on these evaluations, the Management Board makes suggestions on the future management plans and strategies of EFSA ([EFSA, 2018h](#)).

The analysis of primary documents and the interview with EFSA representative suggest that EFSA followed the standard procedures and policies in their glyphosate, 2,4-D, bentazone and neonicotinoid pesticides scientific evaluations. Even though EFSA received much criticism from various groups of stakeholders (and the European Court of Auditors) regarding its independence and transparency policies, it was responsive to this criticism by publicly defended its practices and altering its independence and transparency policies.

#### *European Chemicals Agency (ECHA)*

##### *Mandate and accountability mechanisms*

The European Chemicals Agency (ECHA) presents itself and its mandate as "the driving force among regulatory authorities in implementing the EU's ground-breaking chemicals legislation for the benefit of human health and the environment as well as for innovation and competitiveness" ([ECHA, 2018a](#)). ECHA core duties in terms of active substances are laid out in the Classification, Labelling and Packaging (CLP) Regulation ((EC) No 1272/2008) which is based on the United Nations' Globally Harmonised System (GHS). The regulation aims to guarantee a high level of protection of health and the environment and a free movement of substances, mixtures and articles.

The Management Board is the core governing body of ECHA ([ECHA, 2018e](#)). It has a supervisory role with general duty to manage (1) budgetary and planning matters; (2) the appointment of the Executive Director, (3) the members and the Chair of the Board of Appeal and the reporting of ECHA's activities to EU institutions. The Board consists of 28 members from Member States, six representatives of the European Commission, and two

representatives of the European Parliament. The key tasks of the board are to guarantee appropriate accountability.

#### *Independence policies*

Independence is one of the core values of ECHA: “We are independent from all external interests and impartial in our decision making. We consult members of the public openly before taking many of our decisions” ([ECHA, 2018h](#)). ECHA assures independence “by having transparent declarations of interest and taking measures to ensure that interests cannot have an impact on decision making in the Agency. In reality, that implies striking a delicate balance between having staff members with expertise and experience and, at the same time, strictly avoiding potential conflicts of interest” ([ECHA, 2018h](#)). According to ECHA’s policy<sup>16</sup>, a conflict of interest could occur in situations where the impartiality and objectivity of a decision is affected by the interest of an individual working in or with the Agency. As a result, personnel working for ECHA have to fill an annual declaration of interests. Furthermore, ECHA has a Conflicts of Interest Advisory Committee to support the Agency’s Executive Director in ensuring independence of decision making.

In the context of the glyphosate scientific evaluation, ECHA received criticism from the Greenpeace European Unit regarding the independence and transparency of the European Chemicals Agency’s Risk Assessment Committee (RAC). Stakeholders claimed that, in the case of glyphosate, “several members as well as the Chair of the Risk Assessment Committee appear to have a conflict of interest, according to ECHA’s own criteria. [...] By these standards, RAC members Slawomir Czerczak and Tiina Santonen appear to have conflicts of interest. Both are employed by public scientific institutes that also generate income from providing risk assessment consultancy services to the chemical industry” ([Riss, Greenpeace European Unit, 2017](#), p.1-2).

ECHA defended its commitment to independence by issuing an open response letter to the concerned stakeholders: “your fundamental concern is whether this could call into question the impartiality of the impending opinion on glyphosate. Our answer is absolutely not. The chair and two members have not declared an interest in the substance and we believe this to be correct. Furthermore, in the development of any RAC opinion – including glyphosate – there is a very small group of active RAC members who on the one hand, do the analysis and draft the opinion and on the other, act as peer reviewers. The members you cite have not been involved in the analysis of data on glyphosate, nor in the drafting of the opinion, nor in peer-reviewing it. Rather they are two from 53 scientists who will discuss the opinion thoroughly and aim to reach consensus on the classification of glyphosate. All of them are independent in their judgement, all of them nominated by their respective governments and all of them appointed by our Management Board to undertake this important role. As a matter of interest, we will be publishing the names of the rapporteurs after the opinion has been agreed – we do not do it before, precisely so as to protect them from any lobbying” (Geert Dancet 7 March 2017).

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<sup>16</sup> See ECHA’s procedures and policies on independence: [ECHA Policy for Managing potential Conflicts of Interest](#); [Guidance for filling in the declaration of interest](#); [Guidance for the prevention of potential conflicts of interest in ECHA networks and expert groups](#)

There were several exchanges of open letters between ECHA and the Greenpeace European Unit (see second letter of the Greenpeace European Unit (2017) and ECHA response (2017)). ECHA used this open exchange to emphasise its significant progress in its independence and transparency policies and practices. For instance, in 2012, the European Court of Audits issued a report on the management of conflict of interest in selected EU Agencies. The Court concluded: “The Court evaluated policies and procedures for the management of conflict of interest situations for four selected Agencies making vital decisions affecting the safety and health of consumers, namely the European Aviation Safety Agency (EASA), European Chemicals Agency (ECHA), European Food Safety Agency (EFSA) and the European Medicines Agency (EMA). The Court found that none of the selected Agencies adequately managed the conflict of interest situations. A number of shortcomings of varying degrees have been identified in Agency-specific policies and procedures as well as their implementation” (European Court of Audits, 2012a).<sup>17</sup> In its response letter to the Greenpeace European Unit, ECHA mentioned its progress in terms of criticism received from the European Court of Audits: “ECHA’s independence policy builds on international best practice, as reflected in guidelines from the Organisation for Economic Co-operation and Development and the European Commission. The common objective of these is to protect the independence of public bodies whilst enabling them to collaborate with the best available experts. The European Court of Auditors audited ECHA’s policy and procedures in 2015 and found that we had implemented all their recommendations from the 2012 special report on conflicts of interest. We are clearly in line with international best practice” (Geert Dancet 10 March 2017, p.1).

#### *Transparency policies*

Transparency is one of the core values of ECHA: “We are open and transparent in our actions and decision-making. We are easy to understand and to approach” (ECHA, 2018h). ECHA communicates that it aims to provide interested parties the opportunity to question, challenge and hold ECHA to account. ECHA’s approach to transparency relies on three main pillars: (1) clear and transparent procedures; (2) open decision making; (3) information available.<sup>18</sup>

Please see the discussion above (i.e. independence policies) regarding the criticism about ECHA’s transparency (and independence) policies and practices.

#### *Selection of scientific experts*

Within ECHA, the Committee for Risk Assessment (RAC) is responsible for providing scientific opinions on substances. Every Member State is allowed to nominate candidates for RAC. Those nominees are then made public on the ECHA website and appointed by the Management Board. Each Member State is allowed a maximum of two representatives per committee. At the moment, RAC has a total of 52 members (ECHA, 2015). The members of RAC are appointed for a three-year period. On their website, ECHA publishes all members of the committee including their [CV and a Declaration of Interest](#). The Declaration of Interest states prior research interests, employment, funding and sponsors

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<sup>17</sup> Please see the report here: European Court of Audits (2012b)

<sup>18</sup>For more information see: [ECHA, 2014](#)

of the members which helps ensuring transparency. It also reduces conflict of interests of the members, with the aim of ensuring an independent risk assessment by the Committee.

#### *Procedures*

Within ECHA, the Committee for Risk Assessment (RAC) is responsible for providing an opinion on substances that pose a potential risk to human health and the environment. The opinion of RAC is then forwarded to the European Commission. Their final opinion is based on the harmonised classification and labelling of substances (see Regulation ((EC) No 1272/2008)).<sup>19</sup>

The Classification, Labelling and Packaging (CLP) legislation is legally binding in all Member States and directly applicable to all industrial sectors. “It requires manufacturers, importers or downstream users of substances or mixtures to classify, label and package their hazardous chemicals appropriately before placing them on the market” (ECHA, 2018g). One of the main aims of CLP is to determine whether a substance exhibits the properties that lead to a hazardous classification.

CLP criteria sets general packaging standards to ensure the safe supply of hazardous substances and mixtures. “In addition to the communication of hazards through labelling requirements, CLP is also the basis for many legislative provisions on the risk management of chemicals” (ECHA, 2018g). See the table and Figure 6 for more detailed information on how the process of harmonised classification and labelling unfolds in the EU system.

#### **Harmonised classification and labelling (CLH)**

“Manufacturers, importers or downstream users have to (self)-classify and label hazardous substances and mixtures to ensure a high level of protection of human health and the environment.

For hazards of highest concern (carcinogenicity, mutagenicity, reproductive toxicity (CMR) and respiratory sensitisers) and for other substances on a case-by-case basis, classification and labelling should be harmonised throughout the EU to ensure an adequate risk management. This is done through harmonised classification and labelling (CLH).

Harmonised classifications are listed in Annex VI to the CLP Regulation and should be applied by all manufacturers, importers or downstream users of such substances and of mixtures containing such substances.

CLH can be proposed for substances without a current entry in Annex VI to CLP, or to those with an existing harmonised classification, which would need to be changed either due to availability of new information, new scientific or technical developments, changes in the classification criteria or based on the re-evaluation of existing data.

<sup>19</sup> The Classification, Labelling and Packaging (CLP) Regulation ((EC) No 1272/2008) relies on the United Nations’ Globally Harmonised System (GHS) and its aim is to guarantee a high level of protection of health and the environment, as well as the free movement of substances, mixtures and articles.

A Member State competent authority (MSCA), or a manufacturer, importer and downstream user of a substance can submit a CLH proposal to ECHA” (ECHA, 2018c).

ECHA can start the process of harmonised classification and labelling (CLH) when a Member State competent authority submits a proposal. The proposal must have sufficient evidence that the amount and usage of the substance is relevant to be assessed. In the case of glyphosate, the German agency – the Federal Institute for Occupational Safety and Health Federal Office for Chemicals (BAuA) – was the dossier submitter in May 2016 (ECHA, 2018c). Following this proposal, a 45-day long period begins during which a public consultation takes place. In the case of glyphosate, this period started on 2 June 2016 and ended on 18 July 2016 (ECHA, 2017). These consultations can be of any scientific nature regarding the classification proposal, as well as other potential risks associated with the substance. Following the end of the public consultation period, all non-confidential documents taken into account by ECHA were made available for the general public on the ECHA website. The dossier submitter then has the chance to respond to the submitted comments. Afterwards, RAC forms a draft opinion on the classification and labelling of the substance.

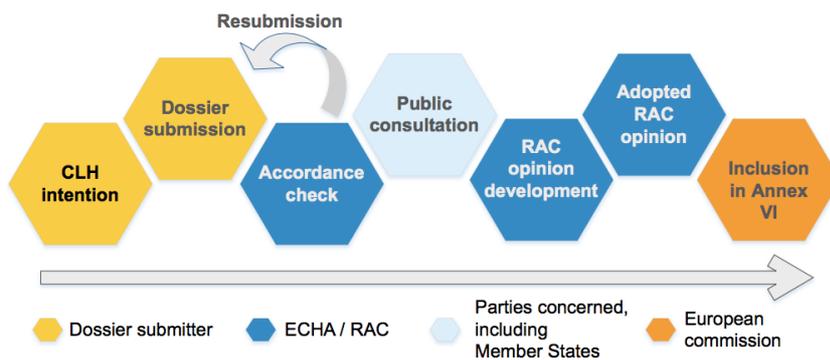


Figure 6. Steps of the harmonised classification and labelling (CLH) process

Table 3. Formation of final opinion by RAC

1	Day 1	Comments by the applicant on the draft opinion are distributed to RAC
2	Week 4	Draft of final RAC opinion
3	Weeks 4-6	Written comments and editing of final opinion
4	Week 6	Second revision period
5	Weeks 8-9	Discussion period, plenary and written editing building up the final opinion. Within the next 15 days, the secretariat will send out the final opinion of RAC and publication of all relevant documents.

Source: [ECHA, 2014](#)

The interviewed representative of ECHA further clarified how the steps of the harmonised classification and labelling (CLH) process unfold and how two EU agencies – EFSA and ECHA – interact and complement each other. The interviewed ECHA representative notes

that, normally, EFSA and ECHA work in parallel (especially when it comes to approval of new substances), however, at times the work of EFSA and ECHA follow each other, as clarified by the ECHA expert in the interview (see table below).

**ECHA representative #1**

“We [ECHA] are responsible for the regulation classification and labelling, where the agency provides an opinion on proposals for [harmonised] classification. This includes [harmonised] classification for pesticides. And that is where the two regulatory agencies [EFSA and ECHA] come together.

Now the process is as follows: The normal approval of pesticides’ active ingredients goes through the pesticide regulation [Regulation (EC) No 1107/2009]; it involves the Member States, it involves EFSA. As part of that dossier they also provide a view on the hazard of the substance, but at that point in time they do not take a formal view on hazard classification. Because that formal view falls under the CLP regulation. But what’s normally done is, as part of the dossiers which the Member States provide to EFSA, they also take a look at the hazard, because they need to know the hazard and the risk assessment. Therefore, very often at that point in time they already take a view on the hazard properties of the chemical; and we try to have a system where, preferably in parallel to the approval process under the pesticide regulation, the Member States also submit a dossier under the CLP regulation. So that the formal hazard classification is taken care of through that CLP process, in parallel to the risk assessment process under the pesticide regulation. We then provide an opinion on the classification which goes more or less in parallel to the risk assessment; and then the Commission can take its final view on the approval of the pesticide active ingredient knowing what the conclusion is of the hazard site in terms of classification. That’s the ideal situation.

Now what happens very often in practice is, because we very often deal with substances which are already on the market, where the process has not been followed perfectly in the past, very often the reports which the member states submit to EFSA, this practice of having a parallel report on the classification labelling process, is not always happening. Quite often, there are delays; in some cases, Member States do not even submit the dossier at all. Therefore, we sometimes have a problem in matching the two regulatory processes.”

Furthermore, the ECHA representative explained the process which unfolded in the case of glyphosate scientific evaluations:

**ECHA representative #1**

“In the case of glyphosate, it was indeed also the case that the Member States’ authorities – the German authorities – first submitted the dossier on the risk assessment for re-approval to EFSA. It went through the discussion in EFSA, and whilst it was more or less [finalised], the IARC opinion came in, which started the whole

discussion on the carcinogenicity of glyphosate. When that happened, the decision-making process in EFSA was already quite far advanced, but there was not yet a formal proposal for classification provided to us; the CLP process hadn't started yet. The political discussions then started in reaction to the IARC discussions. EFSA then had already indicated in its draft final conclusion document and risk assessment that they did not consider glyphosate to be carcinogenic; this was based on the proposal from the German authorities. This discussion was taken further to their expert groups, which also concluded that there was no problem with glyphosate. Nevertheless, when the Commission took note of all these discussions, and the political debate was becoming more intense, then the Commissioner indicated that he did not want only the EFSA opinion without having a formal view from ECHA on the hazard classification; because there would be only one body providing a formal opinion on the hazard classification. That is when the temporary re-approval of glyphosate took place last year, with a clear request to Germany to submit the classification proposal as quickly as possible; they did so over the summer last year. Then, the CLP process here at ECHA started. We were asked to provide an opinion as quickly as possible; of course, we needed to follow the whole process and hold public consultation. Then we started to work and provided the opinion earlier this year. The opinion went back to the Commission, which concluded on the basis of the proposal that the substance should be reapproved."

It is important to note that in the case of ECHA procedures followed in the glyphosate case, the ECHA representative confirmed that all standard procedures had been followed, however, as was the case with other agencies - e.g. EFSA and BfR - ECHA spent much time and effort to communicate its conclusions and procedures: "The process which we have followed for glyphosate is not unique in terms of which steps were taken. We have done 250 hazard classifications in the last decade, and we followed the normal process. The only point which was unique is that, given that there was so much political tension, we paid more attention to being very extensive in our communication. We wrote Q&As, we put a lot of information on our website, which is not normal for every case. We had enormous numbers of press questions and answers, which we did. We had a special session in December, in the Risk Assessment Committee, where we allowed all relevant parties to provide their views on the dossier - so the industry, the NGOs from different sides, and so on. So, we had a quite extensive session to make sure that everybody was heard properly, but formally, the process which we followed is the same as the process we follow everywhere; the [standardised] way of dealing with it, which you can find on our website. So that's not unique, but the uniqueness was in that we paid a lot more attention to serving everybody's questions and to be a hundred percent transparent about the process." ECHA representative #1

The representative of ECHA emphasised that one of the reasons why the scientific evaluations of the IARC and ECHA diverge - even though they had the same focus and scope - is that the two agencies followed different procedures: while ECHA is mandated to follow Regulation ((EC) No 1272/2008 in its hazard classification tasks, the IARC follows different evaluation criteria: "The IARC and ECHA focussed on the same aspects [they both conducted hazard classification of glyphosate]. The IARC is only focussed on hazard

identification and hazard classification, and we do the same under the CLP [Regulation ((EC) No 1272/2008)], because with the classification, you look at the available information on the substance, and whether it fulfils certain criteria for being carcinogenic, for instance. So, you have all these classes of hazards, which are indicated in Annex VI of the CLP. That is our task. We directly compare the information on the chemical to the criteria and then provide the view whether the substance should be classified or not. In essence, the IARC does the same, but they work on slightly different criteria; although I think they are not that different if you look at the wording. The main difference is probably what you're interested in, why we came to different conclusions." ECHA representative #1

This observation was reiterated by many (regulatory) agencies working at the Member State and EU levels. For instance, the German Federal Institute for Risk Assessment (BfR) has argued that the IARC has "no hazard classification" compatible with "CLP [EU] criteria" (BfR representative #3; BVL representatives #4; EFSA representative #2). It could be concluded, then, that ECHA (and EFSA, BfR) and the IARC use widely different classification criteria, which may alter the conclusions of the scientific evaluations.

To summarise, the desk research and semi-structured interviews suggest that one of the explanatory factors of why scientific divergences emerge between agencies (the IARC and ECHA) assessing hazards of pesticides is the different procedures and regulations followed in the scientific evaluation processes.

#### *Internal/external control mechanisms*

ECHA communicates that it is committed to providing "a service that meets the needs and expectations of its various stakeholders in a balanced and impartial way and in strict compliance with applicable legislation" ([ECHA, 2018d](#)). The Agency's integrative approach to internal quality management combine the European Commission's Internal Control Standards for effective management and the internationally recognised ISO 9001 standard for quality management systems. This approach assures good governance to obtain full stakeholder confidence and satisfaction. ECHA notes that "performing to excellent standards while meeting the requirements of our stakeholders and ensuring the consistent implementation of the REACH, CLP, Biocides and PIC Regulations" ([ECHA, 2018d](#)) is at the core of ECHA's Quality Policy.

In conclusion, the analysis of primary documents and the interview with the ECHA representative suggest that ECHA followed the standard procedures and policies in their glyphosate scientific evaluation. Even though ECHA received much criticism from various groups of stakeholders regarding its independence and transparency policies, it was responsive to this criticism by justifying or improving its practices.

#### *The Federal Institute for Risk Assessment (BfR)*

##### *Mandate and accountability mechanisms*

The BfR was established in November 2002 in order to assist consumer safety ([BfR, 2018b](#)). Their main focus lies in the assessment of associated health risks of foods, chemicals and

other products. Those assessments are then meant to assist federal ministries during decision making processes.

The BfR is in charge of consumer protection in Germany. Based on risk assessment, its purpose is to advise policy-makers in Germany and Europe and to contribute to national and international committee work. In order to contribute to the risk assessment, the BfR conducts risk assessments based on the focus points. Besides risk assessment, it plays a key role in risk communication in order for consumers to have a better understanding of associated risks of certain goods. In order to make decisions which are not influenced by political, economic or social factors, the institute is – as stated in its founding law – independent in its decisions (BfR, 2017b).

Focus of the BfR's work:

- Evaluation of health effects of biological and chemical substance security of foods
- Evaluation of health effects of chemicals, biocides, pesticides, food packaging, cosmetics, tobacco etc.
- Evaluation of health effects of GMO's
- Risk communication
- Development and validation of food supplements
- Methodology development/validation of national reference laboratories.

Source: ([BfR, 2017f](#))

The BfR supports and secures academic expertise through its independent research, which is financed purely through public funding ([BfR, 2018b](#)). The BfR does not receive funding from third parties, which is meant to reduce social influences and maintain political and economic independence neutrality: "All the activities of BfR are only financed by public sources. There is absolutely no funding from the industry, the BfR follows the rule of independent science which are published in publicly available several documents." BfR representative #3

The BfR is part of the Federal Ministry for Nutrition and Agriculture (BMEL) and its main function is to advise the Federal Government ([BfR, 2017h](#)). It directs the risk evaluation statement towards all public institutions which are in any way related to public health and consumer security such as federal and state ministries, authorities at state, province and municipality level, consumers' associations and other unions, NGO's, research institutions, national and international organisations, and media. The media consumer associations base their information on the BfR and play a key role in informing the general public ([BfR, 2017e](#)).

The BfR is the national centre for the communication between EFSA and all German institutions (various agencies) which are related to food and animal feeds safety, such as the Federal Ministry of Food and Agriculture (Bundesministerium für Ernährung und Landwirtschaft (BMEL)), the Federal Ministry of Health (Bundesministerium für Gesundheit (BMG)) as well as the Federal Ministry for Environment, Nature

Conservation, Building and Nuclear Safety (the Bundesministerium für Umwelt, Naturschutz, Bau und Reaktorsicherheit (BMUB))([BfR, 2017c](#)).

#### *Independence and transparency policies*

The BfR communicates that “transparency is a fundamental aspect of the work of the BfR which is essential for sound and trustworthy risk communication” ([BfR, 2017a](#)). Conflicts of interest must be recorded in writing. The members of scientific committees sign a declaration which is made publicly available by the BfR. Furthermore, “oral inquiries about topics dealt with by the committees which could conflict with the interests of the members are made at the start of every meeting and the results are recorded in the minutes” ([BfR, 2017a](#)). The minutes of the meetings that form the basis of the scientific opinions of the committees are also made available to the general public.

#### *Selection of scientific experts*

The BfR Committees: 16 committees<sup>20</sup> give external and independent input based on expert knowledge ([BfR, 2017b](#)). Their tasks are to advise the BfR in conceptual and methodological questions, as well as to contribute to the scientific work through independent research and evaluate those studies which are included in the risk evaluation. It increases the quantity and quality of research which is taken into consideration by the BfR. Additionally, in times of crisis, the consultation through those committees allows for quick advisory decisions. The experts of those committees have a purely advisory purpose and are not included in the final advisory decision, in order to insure an independent outcome. Please consult the table below to learn more about the appointment procedures followed at the BfR.

#### **Appointment procedure**

“Three appointment procedures have been carried out (2007, 2010, 2013) since the establishment of the BfR committees. Within the scope of a comprehensive and transparent appointment process, all of the experts interested in getting involved in a BfR committee are invited initially per public announcement to submit their applications. The appointing panel set up especially for this purpose then selects suitable candidates from the group of applicants. The appointing panel is made up of members of the BfR Scientific Advisory Board, the chairs of the German Research Foundation’s (DFG) Senate Committees for the Health Assessment of Food and of Substances and Resources in Agriculture, and a representative of the Senate of Federal Research Agencies.

<sup>20</sup> Consumer Products; Assessment of Intoxications; Biological Hazards; Nutrition, Dietetic Products, Novel Foods and Allergies; Exposure Assessment, and Exposure Standardisation; Feeds and Animal Nutrition; Genetically Modified Food and Feed; Hygiene; Contaminants and Other Undesirable Substances in the Food Chain; Cosmetics; Food additives, Flavourings and Processing Aids; Pesticides and their Residues; Pharmacologically Active Substances and Veterinary Medical Products; Risk Research and Risk Perception; Wine and Fruit Juice Analyses; Breast Feeding ([BfR, 2017](#))

The appointing panel nominated a total of 187 experts as BfR committee members for the period 2014 to 2017. They come from universities and other research institutions, national and regional authorities, trade and consumer associations, private laboratories and industry. Overall, roughly 50 of the experts come from universities and university clinics, including poison information centres, and non-university research institutions such as the Fraunhofer institutes, 34 % from authorities such as the federal research institutions and regional investigation offices and 16 % from enterprises and industrial associations. Around 12 % of the committee members do not work in Germany” ([BfR, 2017a](#)).

#### *Procedures*

See EFSA procedures discussed above, of which the BfR is a part of, acting as a Rapporteur Member State (RMS).

#### *Internal/external control mechanisms*

The BfR has been certified in accordance with Quality Standard DIN EN ISO 9001 since 2010 in all of its working areas: science, assessment, communication and administration. The BfR rigorously implements its Quality Management System and communicates that “Authorities, especially scientific institutions such as the BfR, must now also demonstrate that they comply with internationally recognised standards, and they must ensure such compliance by means of a functioning quality management system (QMsystem)” ([BfR, 2018a](#)).

#### **Quality policy of the BfR**

“With its quality management, the BfR pursues the following goals:

- Ensuring the best possible quality for scientific findings
- Focus on consumer protection
- Preserving scientific independence
- Ensuring economic service delivery
- Safety in the future through forward-looking planning and flexibility
- Critical assessment and monitoring of all research findings, before they are communicated to the public or a job initiator
- Use of confirmed data and verified and / or validated methods and models; the quality management of the BfR is based on the most stringent national and international standards
- Disclosure of limits and uncertainties of any research findings” ([BfR, 2018a](#)).

The analysis of primary documents and two interviews with the representatives from German regulatory authorities (BfR and BVL) suggest that the BfR strictly followed the standard procedures and policies in their glyphosate scientific evaluation (BfR representative #3; BVL representatives #4).

## 2. International Organisations

### The International Agency for Research on Cancer (IARC)

#### *Mandate, funding and accountability mechanisms*

The International Agency for Research on Cancer (IARC) is the specialised cancer Agency of the World Health Organization (WHO). It was created in 1965 by a resolution of the World Health Assembly. It is important to note that, even though the IARC is called an 'agency', its hazard classifications do not serve regulatory purposes.

The IARC has the main objective of promoting interdisciplinary and international collaboration in cancer research. The organisation brings together experts from various fields such as epidemiology, biostatistics and laboratory sciences to identify the causes of cancer, as well as its designing preventive measures ([IARC, 2018c](#)).

As a part of the United Nations (UN), the IARC has a complex governing body. According to the 2014 Agency Statute, the main governing body of the IARC is composed of the Governing Council, the Scientific Council and the Secretariat ([IARC, 2014b](#)). As a specialised agency of the World Health Organization (WHO), the IARC is UN-sponsored, meaning it "follows the general governing rules of the UN family" ([IARC, 2018d](#)). The Director-General of the WHO sits on the IARC's Governing Council, therefore, the IARC is directly accountable to its parent organisation. The IARC is also financially accountable to the WHO, most notably through the IARC and WHO Financial Regulations and Financial Rules.

The IARC's activities are funded through two main sources. One is statutory contributions, which are provided by the participating member states ([IARC, 2018a](#)). Other funding is provided by voluntary contributions. These contributions are derived from competitive grants, but also progress through direct contributions from funding agencies ranging from charities to government organisations. These voluntary contributions are allocated to specific programmes and projects, which often happen at the request from a certain donor or organisation. The IARC also receives donations from private individuals, however, the independence polities strictly regulate which individual contributions can be accepted and which ones must be declined. These individual contributions are part of the Agency's Undesignated Contributions account. The Governing Council allocates money to certain programs and projects from the Agency's Undesignated Contributions account.

#### *Transparency policies*

The IARC has implemented various policies in order to make its research as transparent as possible. In the Agency's Medium-Term Strategy for 2016-2020, the Governing Council highlights five key values that underpin IARC's actions: honesty, integrity, independence, courtesy and generosity ([IARC, 2015a](#)). Within this, the Agency states that transparency "is required of all public institutions, but honesty goes further" (IARC, 2015a). Therefore, the IARC sees its function in not only making information freely available, but also explaining this information, including "its caveats, complexities and subtleties" (IARC, 2015a). This, it is argued, will build a "greater degree of trust" in the Agency (IARC, 2015a).

In the Medium-Term Strategy for 2016-2020, the previous policy strategies regarding transparency are also touched upon; the Agency argues that these efforts have supported “the research Sections in implementing their activities” (IARC, 2015a). The same text also draws attention to further policy decisions, such as the implementation of “new tools for systematic review, [standardising] literature searches and creating databases of information on study designs and results” (IARC, 2015a). These policy decisions will serve to “increase transparency and efficiency in the Monographs” (IARC, 2015a).

#### *Independency policies*

The IARC has a specific code of scientific conduct. In this document, the IARC outlines that their mission is “to accomplish the work outlined in the Statute to the highest standards possible, both scientific and ethical; to become the leading international centre in research for cancer prevention and provide leadership to the international community engaged in research in cancer prevention and control worldwide” (IARC, 2008, p. 8). The IARC has composed numerous principles to ensure their code of scientific conduct. These are the principles as they are outlined in the scientific code of conduct (IARC, 2008): Integrity, transparency, impartiality, independence. The IARC emphasises that their independence allows them to provide reliable and authoritative assessments of the different aspects of cancer information.

#### *Selection of scientific experts*

The IARC currently has around 300 members of staff from over 50 different countries. According to the 2014 Statute of the Agency, “the staff of the Agency shall be appointed in a manner to be determined by agreement between the Director-General of the World Health Organization and the Director of the Agency” (IARC, 2014b, p. 13). Staff members (excluding the members of the SC) - principally scientists - are usually recruited from low- to medium-income countries and “geographical representation shall also be given full consideration” (WHO, 2013). This is because the IARC is interested in developing a new generation of scientists, especially in places with scarce health services. Moreover, applicants should fulfil the following criteria: (1) Applicants cannot be related to any actively working staff members employed by the IARC; (2) Candidates must be between 20 and 62 years old (IARC, 2013). Both the IARC and the World Health Organization are transparent with selection procedures. The appointment of directors and high-ranking staff can be found on the Agency’s webpage.

The IARC has strict policies in terms of who can be involved in the production of its scientific outputs (i.e., monographs). Scientific experts that have a clear conflict of interest are only allowed to participate in a limited capacity (IARC, 2014a). This is to assure public confidence. If this is the case, the scientific experts will not serve as the meeting chair or the subgroup chair, contribute to text that pertains to the description or analysis of scientific data, nor participate in any evaluations of such nature. Experts that fall under this category and pose a threat with their conflict of interest will only be invited to meetings in which they are necessary due to publishing relevant papers concerning the rates of cancer and all conflicting interests will be disclosed (IARC, 2014a).

For the IARC to assess any active substance, and in this case glyphosate and 2,4-D, the agents (not ‘active substances’, but *the formulations used in the real-world situations* such

as *Roundup produced by Monsanto*) must comply with two important criteria: (a) there is evidence of human exposure and (b) there is some evidence or suspicion of carcinogenicity (IARC, 2006). A special “Ad-hoc Advisory Group” is then convened to assess the existing literature and findings to then determine the appropriateness of studying and examining such an agent. In the case of glyphosate, the Advisory Group concluded that it was pertinent to study the agent in March 2015 (IARC, 2017d). In the case of 2,4-D, the Advisory Group concluded that it was pertinent to study the agent in August 2016.

#### *Procedures*

After the Ad-hoc Advisory Group has determined the appropriateness of studying a certain agent based on the existing literature, IARC starts setting up a Monograph. A Monograph is a document in which the Agency states the findings and conclusions on the carcinogenic effects of a certain agent. In assessing glyphosate and 2,4-D, at least five categories of participants were present at Monograph meetings. These are:

**The Working Group:** The tasks of this group included “[selecting] and [summarising] the data relevant for the evaluation of glyphosate” as well as the data on mechanisms of carcinogenesis. Working Group Members have generally “published significant research related to the carcinogenicity” (IARC, 2006) and are selected based on “(a) knowledge and experience and (b) absence of real or apparent conflicts of interests” (IARC, 2006). In the cases of glyphosate and 2,4-D, special consideration was given to demographic diversity. In the case of glyphosate, a Working Group of 17 experts from 11 countries met at the International Agency for Research on Cancer in March 2015 to review the available published scientific evidence and evaluate the carcinogenicity of glyphosate formulations. Pertaining specifically to 2,4-D research, in 2015, 26 experts from 13 different countries met to assess the carcinogenicity of the herbicide, 2,4-D.

**Invited Specialists:** These are selected to contribute unique knowledge and experience to the assessment of the active substance. In the case of glyphosate, only one specialist was invited: Christopher Portier. Dr. Portier is a scientist at the US National Center for Environmental Health and the US Agency for Toxic Substances. In the case of 2,4-D, no specialists were invited to consult on the investigation, and no forms of conflicting interests were reported by the Secretariat.

**Representatives of National and International Health Agencies:** These representatives are invited because their governments’ agencies sponsor the investigation programme. In the case of glyphosate, representatives from the Tunisian, American and French agencies were invited as these countries significantly contributed to the research on the agent. Representatives do not chair meetings, draft parts or enable actions at Monograph meetings. In the case of 2,4-D, representatives from the Brazilian, American and French agencies were invited.

**Observers with Relevant Scientific Credentials:** These observers are invited to stimulate the objectivity of the Monograph meeting. IARC prioritises participants with “constituencies from differing perspectives”. Observers have, however, limited responsibilities and may only participate in certain discussions. In the case of the

glyphosate Monograph meetings, observers from Denmark, France, England and Germany were invited to attend.

The IARC Secretariat: These are the scientists who are designated by IARC and have relevant expertise. The IARC secretariat “serve as rapporteurs and participate in all discussions” ([IARC, 2006](#)).

In addition to these five categories, all members who participate in the Monograph must complete a “WHO Declaration of Interests” in which they report their “financial interests, employment and consulting, and individual and institutional research support” ([IARC, 2016b](#)). Moreover, “it is not acceptable for Observers or third parties to contact other participants before a meeting or to lobby them at any time” ([IARC, 2016c](#))<sup>21</sup>.

The IARC tries to design a method that objectively studies the carcinogenic effect that active substances have, while simultaneously aiming to achieve a geographically representative group of assessment staff that includes different discourses into its research process.

To conclude, based on the analysis of publicly available documents and semi-structured interviews with the representatives of (regulatory) agencies (EFSA, ECHA, BfR), the IARC did not deviate from its procedures and policies when assessing glyphosate and 2,4-D hazards.

### **3. Regulatory agencies outside the EU**

#### *US Environmental Protection Agency (US EPA)*

##### *Mandate and accountability mechanisms*

The US EPA is the American regulatory agency dedicated to protecting human health and the environment ([US EPA, 2017a](#)). The US EPA is required to develop policies, aims at fair and effective policy enforcement, using quality information, engaging stakeholders, and consulting with global partners. In achieving its goal, the US EPA develops and enforces regulations, provides grants for research and projects, sponsors private sector partnerships, and educates people about the environment.

The EPA is classified as an independent regulatory agency, meaning it is given statutory grants from Congress to act autonomously in creating regulation for specific issues (the regulations the US EPA creates can become federal law directly) ([EPA, 2017a](#)). These statutes include, for example, the Clean Air Act, which grants the EPA the power to set a national air quality standard (US EPA, 2017a). Unlike most independent agencies in the EU, the US EPA differs in that it is headed by a single administrator who is appointed by the President and approved by the Senate. The administrator of the US EPA is present at cabinet meetings but does not officially belong to the cabinet – as the powers of the agency

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<sup>21</sup> A complete list of the participants on the glyphosate *Monograph* Meeting can be found [here](#).

are granted by congress (in the form of congressional statutes) and not by the executive branch. In fact, the administrator of the EPA is accountable to the Congress, though the President has the ability to fire them. Another way the Congress increases the agency's accountability is by requiring transparency – which it does by passing laws such as the Freedom of Information Act (EPA, 2017a).

Other notable congressional statutes regarding the EPA's powers can be found in the Atomic Energy Act, Clean Water Act, Endangered Species Act, Energy Policy Act, Federal Insecticide, Fungicide, and Rodenticide Act, Pesticide Registration Improvement Act, and the Pollution Prevention Act (EPA, 2017a).

#### *Independence and transparency policies*

The US EPA has four guiding principles in conducting risk assessments: transparency; clarity; consistency; and reasonableness. In terms of transparency, the US EPA states the [characterisation] should fully and explicitly disclose the risk assessment methods, default assumptions, logic, rationale, extrapolations, uncertainties, and overall strength of each step in the assessment ([EPA, 2014a](#)).

The US EPA, by definition, is an independent US government agency. Thus, it is subjected to [Title 2 of the Code of Federal Regulations](#), section 200.112, which mandates that the EPA comply with comprehensive audits designed to prevent conflicts of interest in their independent committees. Despite this commitment, the US EPA has struggled with independence issues: for example, the Flint Water Crisis was largely caused by a biased Scientific Advisory Board that favoured industry and economic efficiency over the health of individual (Volcovici, 2017). Currently, the US EPA is undergoing large-scale changes under the Trump Administration and its appointed head Scott Pruitt. Mr Pruitt, is claimed to be “politicising” the US EPA by removing scientific experts from many independent panels. Pruitt's critics – such as Tom Carper, top Democrat on the Senate Environment Committee – claim that Pruitt's decision was part of an EPA effort to “delegitimise the work of nonpartisan scientists” as part of a larger effort to transform the agency's purpose from protecting human and environmental health to promoting business interests (Volcovici, 2017).

There have been questions about the independence of the US EPA when it comes to their risk assessment of glyphosate. The US EPA was widely criticised as a result of their move to postpone the Scientific Advisory Panel advisory meeting because CropLife America (an industry trade group representing Monsanto and other pesticide companies) objected to one of the members on the panel ([Center for Biological Diversity, 2017](#)). The member that they objected to (Dr. Peter Infante, a researcher with the National Institute for Occupational Safety and Health) was subsequently removed from the panel after CropLife accused the scientist of bias (Center for Biological Diversity, 2017).

In addition to this, documents revealed in court showed that the chair of the US EPA's Cancer Assessment Review Committee on glyphosate was in regular contact with Monsanto, providing insider information that guided Monsanto's messaging (Center for Biological Diversity, 2017). Furthermore, the chair warned Monsanto that the IARC had found glyphosate to be a probable carcinogen months before the 2015 IARC Monograph on

glyphosate became public, which reportedly allowed the company to mount a public relations attack on the finding. A Monsanto executive emailed other company officials that they could hire academics to put their names on glyphosate research papers written by Monsanto, citing a previous instance where this was done (Center for Biological Diversity, 2017).

The US EPA has also received criticism by other agencies (such as the French ANSES) on the basis that the investigative mechanisms used were incomplete and inadequate ([ANSES, 2016b](#)). However, the 2017 US EPA Panel reaffirmed that the previous risk assessment of glyphosate had used a “sound, appropriate and acceptable approach” and that the US EPA “correctly addressed the issue” (US EPA, 2017). The 2017 US EPA Panel again concluded that there is “no reliable evidence of an association between glyphosate exposure [and cancer], even [considering] the possibility that some of the studies reviewed were subject to potential biases” (US EPA, 2017). That being said, the US EPA discredited arguments that claimed that certain risk-assessment procedures were subject to corporate interests that had induced bias into the research itself.

In their written responses to the questions of this study, the US EPA specified how those processes and criteria were applied to the case of glyphosate: the “EPA routinely completes independent scientific risk assessments and strives to achieve transparency in the risk assessment process and scientific outputs for all pesticide review cases. The same amount of consideration was given to glyphosate, however, EPA provided additional opportunities to solicit technical advice and feedback from independent experts and the public due to the high level of public interest. For instance, the evaluation of the human carcinogenic potential of glyphosate conducted by EPA was presented to the FIFRA SAP. As part of this process, all supporting documentation was publicly available, which included full study reports, the Agency’s individual study reviews (data evaluation records, or DERs), and the Agency’s issue paper detailing the process and decisions undertaken to reach the conclusions based on a weight-of-evidence approach. The transcript to the glyphosate FIFRA SAP meeting is also available.” US EPA representatives

#7

#### *Selection of scientific experts*

It is in the US EPA’s mandate to ensure its actions are based on strong scientific data, analyses, and interpretations ([US EPA, 2016](#)). The US EPA’s primary mechanism for doing so is the Science Advisory Board (SAB). The SAB is responsible for reviewing the quality and relevance of the information used to inform the EPA regulations. Additionally, the SAB reviews and influences the US EPA’s research programs and plans; provides scientific advice to the EPA administrators; and advises the agency on broad scientific matters (US EPA, 2016). The SAB works in tandem with the US EPA’s advisory committees: it oversees the formation of the committees (and panels) to ensure quality and balanced expertise; it advocates committee transparency; and it provides the committees with policy, technical, and administrative assistance (US EPA, 2016). Currently, the SAB is comprised of a mix of professors, public sector employees, and private sector experts, many of whom work for pharmaceutical companies (US EPA, 2017). It must be noted that the current head of the US EPA, Scott Pruitt, is pushing to exclude public sector employees/government grant recipients from the SAB (Northerly, 2017). If Pruitt’s proposal is passed, private sector

scientists (many of whom are at least partially funded by industry) will replace expert scientists that were previously selected by the US EPA (Northerly, 2017).

The SAB is a Federal Advisory Committee, and thus it is subject to the Ethics in Government Act of 1978. It is therefore required by law to be fairly balanced in terms of the points of view represented and the functions to be performed by the advisory committee, and in ensuring contemporaneous public access and public input into the advisory process (US [EPA, 2002](#)). Consequently, a complex process is involved in forming SAB Panels. When an agency brings an issue or a project to the SAB, the board first identifies the field(s) from which experts would most appropriately be selected. Following this preliminary step, actors such as the US EPA, the public, NGOs, and industry nominate potential panellists.

The next stage in the selection process is the formation of a Short List. Criteria for evaluating prospective Short List members include: expertise, knowledge, and experience; availability and willingness to serve; scientific credibility and impartiality; and skills working in committees and advisory panels (US [EPA, 2002](#)). All candidates must fill out a Confidential Financial Disclosure Form for Special Government Employees Serving on Federal Advisory Committees at the US Environmental Protection Agency in order to gauge their conflicts of interests. If a conflict is found, the expert is often removed from the selection process. In some cases, however, when a candidate panel member possesses special knowledge or skills, the SAB Staff Director can grant a waiver that will allow an individual to serve on a panel. In this event, the US EPA issues a public notice explaining the conflict of interest and justifying its choice. The SAB staff publicises the names and bio sketches of all Short List candidates. People are invited to provide the Board with information, analysis, and/or documentation regarding candidates – all of which is considered in the final panel selection. The final panel selection is executed by the SAB Staff Director, in consultation with SAB leadership. The criteria for this final selection are: helping the Board meet EPA's legal requirements; being transparent and open to public input, so that the public can understand and participate in the process; and helping the Board fulfil its mission (US EPA, 2002).

In their written responses to the questions of this study, the US EPA specified how those processes and criteria were applied to the case of glyphosate: "The glyphosate registration and registration review team is composed of more than two dozen staff with expertise in various disciplines, including toxicology, pharmacology, epidemiology, chemistry, biology, environmental fate, entomology, statistics, risk management, and communications. Like in all executive agencies, EPA employees are subject to the [employee standards of ethical conduct](#) issued by the US Office of Government Ethics. These standards provide specific assurances to help guarantee impartiality. EPA employees maintain a high level of ethical conduct to maintain the public trust.

Furthermore, members of FIFRA Scientific Advisory Panel are classified as "[special government employees](#)" and are similarly subject to [ethical screening and training](#) as required by the office of government ethics to ensure members do not have conflict of interest and can render impartial advice. For glyphosate, panel members were selected based on their knowledge of core expertise needed for the evaluation of the human

carcinogenic potential, such as epidemiology, animal bioassays, and genotoxicity.” US EPA representatives #7

#### *Procedures*

The US EPA has a standardised formula for assessing the risk of chemicals (including plant protection products). It divides risk into two categories: human health and ecological. The initial stage of risk assessment involves the collection of extensive data on the three key factors to risk: the quantity of the chemical that is/will be present in relevant environmental mediums (e.g. soil, air, water), how much exposure a person or ecological receptor makes/will make with the environmental mediums, and the inherent toxicity of the chemical ([EPA, 2017b](#)). The US EPA claims to recognise the impossibility of conducting a perfect risk assessment, and thus they pledge to openly present all of the uncertainty in their calculations and to provide a characterisation of the reliability of their estimates (EPA, 2017). While the general procedural steps described above apply to all of the US EPA approved chemicals, the process is often much more complicated, especially when there is limited understanding of a controversial substance.

In its responses, the US EPA emphasised that “EPA uses the same [standard risk assessment procedure](#) for all pesticides. Each step, in risk assessment (planning, hazard identification, dose-response assessment, exposure assessment, and risk characterisation), follows standard criteria” US EPA representatives #7

#### *Internal/external control mechanisms*

When conducting risk assessments, the US EPA must comply with statutory requirements and mandates set by Congress. These include the following (US [EPA, 2002](#)):

- (A) The substance of the information should be accurate, reliable and unbiased. This involves the use of: The best available science and supporting studies conducted in accordance with sound and objective scientific practices, including, when available, peer reviewed science and supporting studies and data collected by accepted methods or best available methods (if the reliability of the method and the nature of the decision justifies the use of the data).
- (B) The presentation of information on human health, safety, or environmental risks, consistent with the purpose of the information, should be comprehensive, informative, and understandable.

To conclude, the US EPA – in their written responses to the questions of this study – confirmed that they have followed all the formal procedures and policies in their scientific evaluations of glyphosate, 2,4-D, bentazone and neonicotinoid pesticides (US EPA representatives #7). Furthermore, the US EPA has emphasised that it is “confident in its risk assessment and its conclusion that glyphosate is not likely to be carcinogenic to humans. The EPA’s conclusion is consistent with other countries and regulatory authorities including the Canadian Pest Management Regulatory Agency, Australian Pesticide and Veterinary Medicines Authority, the European Food Safety Authority, the European Chemicals Agency, German Federal Institute for Occupational Safety and Health, The Joint FAO/WHO Meeting on Pesticide Residues, the New Zealand

Environmental Protection Authority, and Food Safety Commission of Japan.” US EPA representatives #7

## II – Conclusion

The chapter has assessed the formal mandate and accountability mechanisms, independence and transparency policies, scientific experts’ selection policies, procedures followed in the scientific assessments, internal/external control mechanisms of the five agencies: The European Food Safety Authority; the European Chemicals Agency; the German Federal Institute for Risk Assessment; the International Agency for Research on Cancer; and the United States Environmental Protection Agency. The empirical analysis of primary documents and the semi-structured interviews with agency representatives (i.e., EFSA, ECHA, BfR, BVL, ANSES, US EPA, APVMA) suggest that the agencies followed all the formal procedures and policies in their scientific evaluations of glyphosate, 2,4-D, bentazone and neonicotinoid pesticides (imidacloprid, clothianidin, thiamethoxam). However, stakeholders of the agencies (e.g., NGOs, scientific community) and institutions in charge of researching/monitoring agencies’ independence and transparency policies have expressed some concerns. In response to the criticism, in recent years, the agencies – especially, EFSA and ECHA – have worked to improve their independence and transparency policies and practices.

The analysis of primary documents and the semi-structured interviews have shown that the IARC is distinct from risk assessors working in the regulatory context (e.g., BfR, EFSA, ECHA, the US EPA). First, the IARC has a different mandate and organisational mission. Second, the IARC and other agencies (working in the regulatory context) follow diverse regulations and rules in their scientific evaluation processes.

### *Differences in mandates and accountability mechanisms*

The IARC does not directly contribute to national or international regulatory processes. The *Monographs* of the IARC provide scientific evaluations of cancer hazards based on a wide-ranging review of the relevant scientific literature, including open peer reviewed literature and industry-produced studies. Once finalised, IARC *Monographs* are considered as one of the most trustworthy and reliable scientific information on which national and international organisations may (if they choose so) rely and introduce protective measures in their national regulations, legislation, or public health intervention. However, it is important to note that it remains the discretion and responsibility of national governments to introduce corresponding regulations.

On the contrary, the risk assessments provided by agencies and bodies (e.g., EFSA, ECHA, BfR, the US EPA) working in the regulatory context carry different implications. They are designed to provide scientific advice that informs risk managers about possible risk management measures. As a result, risk assessments carried out by agencies working in the regulatory context are designed for different purposes: they have regulatory implications, i.e. based on agencies’ risk assessment, risk managers take regulatory

decisions (e.g. suggestions for bans, limitations and restrictions of certain uses of pesticides).

### *Differences in procedures*

There is substantial variation in how scientific assessment procedures are organised by the IARC and risk assessors working in the regulatory context. The analysis has revealed that the regulations and procedures followed by EFSA, ECHA and the US EPA are highly standardised and formalised (in particular, this is the case in the American regulatory system). As regards the EU, the processes are detailed in complex regulations (Regulation (EC) No 1107/2009 and relevant legal acts) and international and EU-level guidance documents (e.g. [guidance document](#) issued by EFSA on how the risks to bees should be assessed in the EU). Risk assessors working in the regulatory context have little room to manoeuvre and – as the desk research and the semi-structured interviews have shown – they strictly follow the required steps, rules and regulations in their scientific evaluation tasks.

In a similar vein, IARC *Monographs* are conducted according to the published and standardised procedures. However, the IARC, being not a regulatory body, does not have to follow the EU/US rules and regulations specifying scientific assessment procedures.

## Chapter 4

### I – Comparisons of scientific aspects of evaluations

This chapter reviews the scientific aspects of evaluations conducted by regulatory agencies and bodies. More specifically, it focusses on the following scientific (quality) standards: the type of evidence used in the evaluation (e.g., industry research, academic studies) and data collection methods and scientific approaches followed to evaluate the collected data (e.g., Weight of Evidence (WoE) approach).

As in the previous chapter, a sample of agencies that have conducted scientific assessments of the selected active substances are covered in this chapter. Those agencies (or bodies) include: (1) Relevant EU and EU Member State agencies (the European Food Safety Authority (EFSA), the Federal Institute for Risk Assessment (BfR), the European Chemicals Agency (ECHA)); (2) Relevant international bodies (the International Agency for Research on Cancer (IARC)); (3) Relevant agencies working outside the EU (the United States Environmental Protection Agency (US EPA)).

The core focus of the chapter is on the glyphosate case. This focus has been selected due to the public interest in the issue as well as the availability of information on this particular case, i.e. relevant agencies and bodies extensively used the case of glyphosate to illustrate various scientific aspects of their scientific evaluations. The interviewed representatives of regulatory authorities (e.g., ECHA representative #1; EFSA representative #2; BfR representative #3; BVL representatives #4; ANSES representatives #5; APVMA representatives #6; US EPA representatives #7) confirmed that the same (or comparable) scientific practices were applied in evaluating other active substances (2,4-D; neonicotinoid pesticides; bentazone).

In the remainder, the discussion on the scientific aspects of evaluations conducted by relevant agencies starts with the IARC and is followed by other agencies. This approach has been chosen to better illustrate the core differences between the IARC and other (regulatory) agencies, i.e. in the case of the glyphosate evaluation only the IARC arrived at different scientific conclusions, whereas other (regulatory) agencies concluded that glyphosate is unlikely to cause cancer in humans. For this reason, the scientific aspects of the IARC evaluation are compared to other agencies' practices.

#### 1. International Organisations

##### International Agency for Research on Cancer (IARC)

Before presenting the scientific aspects of the IARC evaluation of glyphosate, one important specificity of its scientific evaluation approach has to be noted. There is one crucial difference between the IARC and other agencies' scientific assessments. Regulatory agencies worldwide (including EFSA) test only so-called '*active substance*', whereas the IARC focusses on *the formulations used in the real-world situations*. This is the case

because the regulations and guidelines that (regulatory) agencies (e.g., EFSA) follow require agencies to respect this approach. Such an approach implies that (for glyphosate-based herbicides) only glyphosate is actually tested by regulatory agencies, not *formulations* such as *Roundup produced by Monsanto* (to which, for instance, farmers are actually exposed). This makes a difference in how data is assessed by agencies. For a more detailed discussion between the tests behind the *formulations* of glyphosate-based pesticides used in the real-world situations and the so-called *active substances* please see Bozzini (2017) and Corporate Europe Observatory (2018a).

The IARC was active and assertive in communicating the rigorousness of its procedures and scientific methods followed in its scientific evaluation of glyphosate (see table below).

“The IARC Monographs evaluation is based on the systematic assembly and review of all publicly available and pertinent studies, by independent experts, free from vested interests. It follows strict scientific criteria, and the classification system is [recognised] and used as a reference all around the world. This is because IARC evaluations are based on independent scientific review and rigorous criteria and procedures. To reach these conclusions, *IARC reviewed about 1000 studies*. Some of the studies looked at people exposed through their jobs, such as farmers. Others were experimental studies on cancer and cancer related effects in experimental systems” (IARC, 2017c).

IARC’s research on the effect that glyphosate (i.e., *formulations*) might have on human health was mainly based on the review of publicly available research. The evidence of the IARC Monograph Volume 112 on glyphosate was based on evidence from “reports that have been *published or accepted for publication in the openly available scientific literature*” and from “data from governmental reports that are publicly available” (IARC, 2017d). In the specific case of glyphosate, the type of evidence was mainly based on animal experimentation. For their conclusions, the IARC noted that previous investigations have shown that “glyphosate also can cause cancer in laboratory animals” (IARC, 2015). Based on the evidence, the IARC eventually concluded that there is “sufficient evidence of carcinogenicity in experimental animals” (IARC, 2015), which might also be the case in human beings.

The IARC was transparent in terms of the type and amount of data used in its scientific evaluation: “For the IARC Monograph on glyphosate, the total volume of publications and other information sources considered by the Working Group was about 1000 citations. All citations were then screened for relevance, following the principles in the Preamble to the IARC Monographs.

After this screening process, the Monograph sections on cancer epidemiology and cancer bioassays in laboratory animals cited every included study. The sections on exposure and mechanisms of carcinogenesis consider representative studies and therefore do not necessarily cite every identified study. Once published, the IARC Monograph on glyphosate cited 269 references” (IARC, 2017c).

This scientific information was identified through systematic literature searches, submissions succeeding the public call for data published on the IARC Monographs website, as well as requests to the US Environmental Protection Agency for public release of previously unpublished but relevant toxicological information. All retrieved studies were screened for relevance by experts following the principles of the IARC Monographs Preamble (see the table below).

“This screening process excluded any retrieved studies that did not provide data on glyphosate (about 80 studies) or that were not relevant to the cancer hazard evaluation (comprising about 450 studies, primarily identified through comprehensive searches for mechanistic evidence, that did not report pertinent toxicological information). Consistent with the Monographs Preamble, reviews and commentaries concerning cancer epidemiology and cancer bioassays (about 30 articles) were also excluded at this stage. Following this screening process, the Monograph sections on cancer epidemiology and cancer bioassays cited every study that provided primary data. The sections on exposure and cancer mechanisms consider representative studies to give a concise description of the relevant data and issues and thus these sections do not cite every identified study. Once published, the IARC monograph on glyphosate cited 269 references.” (Deutscher Bundestag, 2015, p.2)

However, authorities that have analysed the scientific output (for instance, Deutscher Bundestag, 2015) argue that the volume of cited references may not be indicative of the comprehensiveness of an assessment: “For instance, the IARC Monograph on glyphosate cites only the study by Séralini et al. re-published in 2014, but not a further 18 related articles cited in the BfR report – comprising the now retracted original article from 2012 and commentaries thereon (15 letters to the editor, a response from the authors, and an EFSA review of the study). About 25 more reviews and government opinions cited by the BfR are not included in the IARC Monograph, which instead cites the original publications (in the sections on epidemiology and cancer bioassays, as noted above); in the sections on exposure and cancer mechanisms, preference can sometimes be given to balanced reviews in place of numerous citations. Finally, because the Monograph includes only those data relevant to cancer hazard evaluation, some 30 studies concerning non cancer adverse effects (e.g., teratogenicity, lethality) that are included in the BfR document are not cited by the Monograph.” (Deutscher Bundestag, 2015, p. 3)

The method used for the IARC’s risk assessment was that of a systematic review. What this entails is that the IARC would compile different results and discussions used as well as risk assessments that have already been conducted by other individual agencies (e.g., US EPA). The collection of the data was reviewed by a group of interdisciplinary working group members consisting of scientific experts which then analyse and review the studies that are already published and used in the monographs. They then evaluated the strength of the evidence and determined whether or not *the formulation of glyphosate* poses a carcinogenic hazard. Each monograph produced by the IARC collects and reviews pertinent studies and bioassays conducted on experimental animals and these are judged as to whether or not they are inadequate or irrelevant. The working group of experts decides whether or not data should be cited in regard to its relevance. To reiterate the

transparency of the agency, “only reports that have been published or accepted for publication in the openly available scientific literature are reviewed” ([IARC, 2006](#)).

As it becomes evident from the discussion on the type of evidence used and data collection methods, the IARC puts a strong emphasis on the public nature of the data on which their evaluations are conducted. Furthermore, they highlight the fact that their goal is to rely on independent data (which means that the IARC might exclude industry data if they consider it as not meeting their criteria): “In the interests of transparency, [the] IARC evaluations rely only on *data that are in the public domain* and available for independent scientific review. The IARC Working Group's evaluation of glyphosate included any industry studies that met these criteria. However, they did not include data from summary tables in online supplements to published articles, which did *not provide enough detail for independent assessment. This was the case with some of the industry studies of cancer in experimental animals*” ([IARC, 2017c](#)).

The data collection the IARC uses in its monographs is largely based on publicly available studies. As mentioned in Chapter 3, the Working Group of each Monograph tries to encompass a wide range of scientific investigations that also cover a wide range of conclusions. However, there has been criticism regarding how the IARC collects its data. In a Reuters article published in 2017, the news agency stated that the IARC “edited out “non-carcinogenic” findings” ([Reuters, 2017](#)) and that the agency “dismissed and edited findings from a draft of its review of the weedkiller glyphosate that were at odds with its final conclusion that the chemical probably causes cancer” (Reuters, 2017). Moreover, Reuters also noted that the IARC would not give any explanation and “won’t say who made the changes or why” (Reuters, 2017). The accusations were serious and put the IARC’s scientific and evidentiary procedures in a position of great doubt. As a response to the Reuters article, the IARC stated that the article is “ambiguous” and that it does not say “who is alleged to have “edited out “non-carcinogenic” findings”” ([IARC, 2017b](#)). The IARC moreover stated that the conclusions on glyphosate are the “result of scientific deliberations of Working Groups of independent scientists, free from conflicts of interest” (IARC, 2017). The IARC highlighted that its scientific procedures are very transparent in comparison to their counterpart risk-assessment agencies. The debate is likely to go on, but the IARC has claimed that its scientific, technical and evidentiary procedures (and especially data collection procedures), are transparent and free from any possible interfering bias.

In terms of scientific method used to assess the collected data, the IARC uses the “strength of evidence” or “degree of evidence” approach. It is important to note that IARC’s “strength of evidence” approach has a more general meaning than the “strength of evidence” as defined under the procedures used by ECHA, EFSA and other regulatory agencies for evaluation of carcinogenic hazard. In other words, as emphasised by the APVMA (Australian Pesticides and Veterinary Medicines Authority), regulators (the APVMA is referring to EFSA, ECHA, US EPA, NZ EPA) do not use strength-of-evidence assessments in their scientific evaluations: they apply the ‘weight of evidence’ approach (APVMA representatives #6). The APVMA explains the core difference between ‘weight-of-evidence assessment’ and ‘strength-of-evidence assessment’ (see table below).

**“In a weight-of-evidence assessment**, relevant observations are validated because they are reproduced independently by different investigators/researchers. A weight of evidence assessment considers both the numbers of studies reporting a particular conclusion and the quality of the study design and data evaluation.

**A strength-of-evidence assessment** can be based on a single study, even if the study protocol has limitations or does not comply with internationally accepted regulatory protocols, or if the results are not consistent with observations made in other well-designed studies.” (APVMA, 2017)

Furthermore, it is important to note that the IARC conducted a hazard classification (not a risk assessment). Regulatory agencies regard this as one of the key explanations why differences between the IARC and other agencies (e.g., EFSA, US EPA, APVMA) emerged.

For instance, consistent with agencies in other countries, EFSA uses a risk-based, weight-of-evidence assessment, which evaluates the full range of risks—including studies of cancer risks—and the extent to which human beings are exposed to the active substance. While a hazard-based assessment takes into account only whether an adverse effect could occur but does not consider whether it is likely to occur when used in real-life situations. To that end, agencies working in the regulatory context regard the hazard-based assessment as the first step in determining whether a pesticide poses a risk. A risk-based assessment is built upon the hazard-based assessment by defining the “likelihood and extent to which the adverse outcome will occur if the product is used according to the instructions on the approved product label” (APVMA, 2017). Please see the table below for further clarifications.

“Chemical risk assessment = hazard assessment + exposure assessment

**Hazard assessment:** an assessment of the data related to the intrinsic toxicity potential of an active constituent and/or formulated product

**Exposure assessment [risk assessment]:** an assessment of the likely exposure of humans and environmental organisms that takes into account how the chemical product is to be used, the type and formulation of the product, and the crops or animals to be treated” (APVMA, 2017)

It is important to note that the IARC hazard-based assessment of glyphosate can be best compared with the ECHA’s scientific evaluation because ECHA has also conducted a hazard-based assessment, whereas other agencies (e.g., EFSA, US EPA) have engaged in the risk-based assessment. As a result, the following section starts with the discussion on the scientific aspects of ECHA evaluation before turning to the comparisons between the IARC and other risk assessors (EFSA, BfR and US EPA).

## 2. European agencies: EU and national regulatory bodies

### European Chemicals Agency (ECHA)

ECHA bases its scientific assessment on the evaluation of studies which concern the hazards that are associated with a certain substance. In general, their assessments are triggered by the proposal of a dossier submitted for the labelling and classification of a substance (see the Classification, Labelling and Packaging (CLP) Regulation ((EC) No 1272/2008), which – in the case of glyphosate – was Germany. Once the proposal is submitted, a 45-day period of public consultation begins. This started in May 2016 and ended in June 2016 ([ECHA, 2018b](#)). The information submitted during the public consultation period can include any hazards regarding the substance. RAC can invite speakers of the general public, industry and other stakeholders to present their evidence concerning a certain substance. All submitters are requested to submit a version of their documents which includes no confidential information. The dossier submitter now has the option to react to the comments, which were provided during public consultation.

Besides the public consultation, RAC's opinion is formed through the assessment of studies chosen through a literature review by RAC. All of the included studies must follow the Good Laboratory Practice standards. In the case of glyphosate, a total of 12 studies which addressed the carcinogenic potential of glyphosate were included. Those studies were all long-term animal studies. In addition, epidemiological studies following cohort and cross-sectional designs were included. In the case of glyphosate, a total number of 347 studies were evaluated before the final opinion was formed ([ECHA, 2016](#)). The weight-of-evidence approach was followed to evaluate the compiled data.

The assessment of the associated hazard of glyphosate can be found in the harmonised classification and labelling (CLH) report (see [ECHA, 2016](#)). It provides a summary of all included studies and the classification and labelling of glyphosate. The studies are divided into human health hazard assessment and environmental hazard assessment. These two sub-classifications of the assessment are further broken down into 10 sub-categories (toxicokinetics, acute toxicity, specific target organ toxicity-single exposure, irritation, corrosivity, sensation, specific organ toxicity-repeated exposure, germ cell mutation, carcinogenicity, toxicity for reproduction) for the human health hazards and four sub-categories (degradation, environmental disruption, aquatic bioaccumulation, aquatic toxicity) that focus on environmental hazards. Furthermore, third parties can be invited by RAC to present their opinion.

In the case of glyphosate, a large number of studies was taken into consideration regarding carcinogenic properties of the substance, as this was the key concern and media focus. 12 long-term animal studies were assessed, which is ten more than in a usual evaluation. 11 of those studies took place under good laboratory practice (GLP) and further EU standards. According to ECHA, this ensures high confidence and reliability of the results, and therefore ultimately a better evaluation. In addition, a range of epidemiological studies were evaluated, including case control and cohort studies. The final evaluation by RAC is founded on the evaluation of glyphosate, which in turn is based on: (1) substance

classification for physico-chemical properties; (2) human health hazard assessment; and (3) environmental hazard assessment ([BAuA, 2015](#)). For glyphosate, over 300 documents were taken into account.

Furthermore, ECHA allowed stakeholders to give presentations to RAC in order to present their findings and opinions, which were then taken into consideration ([ECHA, 2018b](#)). One key criterion for a stakeholder to be included is the provision of the registration number in the European Union Transparency Register to ECHA ([ECHA, 2018a](#)). In December 2016, presentations by the German Federal Institute on Occupational Safety and Health (BAuA), EFSA, IARC, FAO and WHO, Glyphosate Task Force, and representatives of the Health and Environment Alliance (HEAL) took place in Helsinki (ECHA, 2016). The inclusion of third parties insures a broad range of assessed data and thus forms a control mechanism. All data coming from third parties – and taken into account when forming the final decision – are later published on the ECHA website, and all third parties are requested to provide a censored version for such publication purposes. The interviewed ECHA representative notes that this is one of the differences of how the IARC and ECHA (together with other EU agencies) work: “The IARC works really behind closed doors with regards to their monographs. Nobody can actually follow the process which is taking place there. It has been their decision to only have discussions with scientists, without any presence and therefore without any potential influence of stakeholders. And I think from our side, we claim that *our scientists are perfectly able to discuss in front of NGOs and industry*. In the end, we take a decision based on the scientific facts, but we do not mind doing so in front of the stakeholders.” ECHA representative #1

In March 2017, RAC ended their evaluation that concluded that “the available scientific evidence did not meet the criteria to classify glyphosate as a carcinogen, as a mutagen or as toxic for reproduction” ([ECHA, 2017b](#)). This conclusion was in contradiction to the IARC scientific evaluation. The interviewed ECHA representative suggested that one of the reasons why scientific divergences between the two agencies have occurred is related to the differences in data sources on which they relied. The interviewee noted that ECHA had access to a wide set of data and research:

“The main difference [between the IARC and ECHA] is that in addition to information that is completely publicly available, we also take information into account which has been presented by industry. *That is part of the normal procedure. Therefore, we have access to a greater number of studies than the IARC has been using, and we have access to all the details behind those studies.* There is a huge amount of studies available on carcinogenicity, and the committee (RAC) has access to all underlying information, all the statistics behind it, all the details. And that is *not exactly the same as what has been happening within the IARC.* That is probably one of the reasons why the final conclusion – which, again, is a so-called weight-of-evidence conclusion – and the consensus by the members of the committee was that although some evidence in the studies indicated certain effects by the substance, the substance does not fulfil the criteria for classification.” ECHA representative #1

Furthermore, the representative of ECHA clarified one important aspect that is usually misunderstood in the public debates. Namely, the IARC also draws on the industry data (not only academic studies), however, not all industry data is available to the IARC: “it’s

not that we have one dataset and the IARC has another. There was a lot of overlap between the information used by both agencies. However, not all details on some studies were available to the IARC. Therefore, they could not take those studies into account, because their criterion is that studies need to be fully publicly available. And that has not been the case for all studies; *but it's incorrect to say that we only look at industry data and they only look at publicly available data. We also look at all publicly available data; in that sense, we probably have a wider database than the IARC has.*" ECHA representative #1

To summarise, the core reasons for the scientific divergences between the IARC and ECHA hazard-based assessments – as illustrated by the publicly available document analysis and semi-structured interviews – is that (1) ECHA as an agency working in a regulatory context had access to data sets provided by the industry, whereas the IARC assessed only publicly available data (including industry provided data that is available in the public domain), and (2) the two agencies followed different scientific criteria in their scientific evaluation: the IARC followed the strength of evidence approach, whereas ECHA relied on the weight of evidence approach.

#### European Food Safety Authority (EFSA) and the German Federal Institute for Risk Assessment (BfR)

The scientific aspects of the evaluation provided by the BfR and EFSA are discussed together because - as explained in Chapter 3 on 'European agencies: EU and national regulatory bodies' - the BfR was a Rapporteur Member State in the case of glyphosate. The BfR provided EFSA with a Renewal Assessment Report (RAR) upon which EFSA based its peer review concerning the renewal of the approval of the pesticide active substance glyphosate.

The BfR based its scientific output on the evaluation of evidence on the hazardousness of glyphosate. The BfR then produced a scientific evaluation regarding the attributed risks. The BfR assessed all studies cited by the applicant in the submitted dossier. In 2015, the BfR issued a Renewal Assessment Report (RAR) which entailed the re-assessment of the opinion on glyphosate ([BfR, 2017d](#)). This opinion was then forwarded to EFSA. The re-assessment of glyphosate was attached as an addendum to the RAR.

Independently from the studies included in the industry submitted dossier, research was carried out by BfR which concentrated on the effects of glyphosate on livestock – particularly cows (Riede et al., 2016). Further studies contributing to the assessment of glyphosate were carried out by the Friedrich-Löffler-Institut and the TiHo Hannover (Von Soosten et al., 2016). The BfR emphasised in the RAR that all studies that are to be assessed (using WoE approach) and included in the formation of an official opinion have to follow the guidelines of good laboratory practice (GLP). This is to ensure high standards and quality outcomes of research worldwide.

A review of all relevant studies for the assessment of glyphosate was also carried out. According to the BfR, especially in cases raising issues of carcinogenicity, genotoxicity and endocrine disruptive substances, the literature review and the inclusion of a broad

spectrum of studies were particularly important in order to ensure an accurate assessment ([BfR, 2017d](#)). Another part of the assessment was the evaluation of the opinion of Member States through a peer review assessment of their studies and public consultation. Only after the comments of Member States were included in the report was the opinion forwarded to EFSA.

Following the requirements of Regulation (EC) No 1107/2009, EFSA provided its assessment of the active substance primarily based on Germany's (BfR) initial evaluation of hazards and risks. The EFSA-led review considered "a large body of evidence, including the IARC report"; as well as "the original studies submitted by the applicants in line with the legal requirements", "all available and published studies were considered" ([EFSA, 2015e](#)). The EFSA-coordinated German evaluation examined more than 150 new toxicology studies (compared to its earlier assessments) and re-assessed almost 300 existing toxicological studies. EFSA also considered around 900 scientific publications and reviewed more than 200 of them in detail.

Although the EU assessment did not include a number of epidemiological studies that were included in the IARC's monograph, these studies were later added to the EU dossier, meaning that, in total, "EFSA assessed more evidence including additional key studies that were not considered by IARC" ([EFSA, 2015e](#), p.1). Thus, to summarise, EFSA's assessment was based on original studies: "mandatory regulatory Good Laboratory Practice (GLP) studies, other relevant studies and the outcome of the search of peer-reviewed scientific studies published within the last 10 years before the submission of the dossier" ([EFSA, 2015e](#), p.1). Also, the peer-review included "a public consultation... and several commenting phases by EFSA scientists and MSs experts, the possibility for requiring additional information from the applicants, and a set of experts' meetings covering different scientific areas" ([EFSA, 2015e](#) p.1).

Furthermore, the interviewed representative of EFSA emphasised that the claims that EFSA draws on industry research, whereas the IARC relies on academic studies is not true, i.e. the IARC also based their hazard-based assessment on industry produced data. The interviewee emphasised that EFSA draws on multiple sources of evidence including both publicly available and submitted by the industry:

"First, in our assessment we both have industry-sponsored studies, as well as the review of the scientific literature. That is mandatory because of the regulation. In the case of glyphosate, we have huge amounts of scientific literature that was first reviewed by industry, because the regulation requires them to do so. Afterwards, it was re-assessed by Germany and then by EFSA and all the other Member States during the process. More importantly, there are no valid studies on glyphosate's carcinogenicity, other than the ones that have been sponsored by industry. So, when people say that the IARC's assessment is based on the scientific literature, IARC's assessment on the carcinogenic effects on animals – which is the key issue – *is based on studies sponsored by industry*. The difference is that we received the full studies, just as all other regulatory agencies, and the IARC did not receive the full studies, but only the summaries of those studies which had previously been used in regulatory assessments, including EFSA's in some cases.

In the case of glyphosate, the IARC used studies used by the US EPA, and a secondary group of the WHO called the JMPR, the Joint Meeting on Pesticide Residues. What is important is that, *based on the same studies, the US EPA and the JMPR have concluded that glyphosate was not carcinogenic in animals*. Both groups, after the IARC assessment, have revised their assessments, and have again concluded that glyphosate is not carcinogenic in animals. So, *there is a lot of misinformation: the IARC used public information, but also used public summaries of industry-sponsored studies*. There is no other available information: There were only two other studies on glyphosate's carcinogenicity that were published, and both the IARC and EFSA concluded that these studies were not sufficiently valid. Therefore, all available information on glyphosate's carcinogenicity comes from studies sponsored by industry" *EFSA representative #2*

In the scientific evaluation conducted by EFSA, over 100 studies plus additional studies encountered during the commenting period and the public consultation regarding genotoxicity were included in the revised RAR (Renewal Assessment Report) ([EFSA, 2015e](#)). EFSA considered a weight of evidence approach, "taking into account the quality and reliability of all available data", hence concluding that "glyphosate is unlikely to be genotoxic *in vivo*" ([EFSA, 2015e](#)). Furthermore, it is important to reiterate that "unpublished [mainly industry] studies that were the core basis of the peer review evaluation [of EFSA] were not available to the IARC experts as reported in the IARC monograph 112 on glyphosate" ([EFSA, 2015e](#), p. 3). For example, out of the nine long-term rat studies EFSA examined, three of these "were not evaluated by the IARC experts" ([EFSA, 2015d](#), p. 3).

The method of data collection employed by EFSA was to gather all available evidence, evaluate it accordingly and then use a weight of evidence (WoE) approach to draw conclusions. EFSA defines 'weight of evidence assessment' as "a process in which evidence is integrated to determine the relative support for possible answers to a question" ([EFSA, 2017g](#), p. 1) The WoE approach comprises of three basic steps: "(1) assembling the evidence into lines of evidence of similar type, (2) weighing the evidence, (3) integrating the evidence" ([EFSA, 2017g](#), p. 1).

Regardless of the vast evidence and rigorous scientific methods used to assess the data, EFSA and the BfR were challenged by a group of scientists. The scientific conclusions of the BfR and EFSA were heavily scrutinised. An open letter by 96 independent scientists working in academia and governmental agencies was published and arguing that the BfR "differed from standard scientific practices in order to reach their conclusions" ([Portier et al., 2015](#), p. 5). For example, the BfR used confidential data in its research, meaning that it is impossible for an objective third-party to review the conclusions with scientific confidence ([Portier et al., 2015](#)). In addition to this, the scientists claimed that the BfR conclusions lacked citations for references, a list of authors or contributors, and an acknowledgement of conflicts of interests. In response to the accusations, on the 20th of September 2017, the BfR publicly rejected accusations of plagiarism, after a number of accusations through media organisations within Germany ([BfR, 2017g](#)). According to the BfR, it is usual that risk assessment agencies include original submitted information in their final report if those are of high significance for the final opinion. The accusations concentrated on the literary rights of the published information and summaries, as well as

literature reviews which were published to inform the public and communicate the risks associated with glyphosate.

In addition, in response to many public allegations and controversy, EFSA and BfR scholars<sup>22</sup> have published an open access article explaining why scientific differences between the IARC and other agencies including EFSA, BfR, ECHA have emerged. In a nutshell, Tarazona et al. (2017) argue that the scientific divergences between the IARC and EFSA have emerged because they have engaged in different types of scientific evaluations (hazard classification *versus* risk assessment), which is an important factor explaining discrepancies in scientific conclusions. Furthermore, the following factors were also identified as important causes explaining scientific divergences in the two scientific evaluations: (1) agencies relied on different data sources to assess risks; (2) they applied different scientific approaches (i.e., methodologies) to assess the collected data; and (3) they engage in different interpretations when weighing indefinite results. See the summary of the core differences in Table 4.

Table 4 Comparison of IARC and EU regulatory assessments roles, data sources and methodological elements

Issue	IARC	EU evaluators working in regulatory environment
Role	Hazard based identification  No regulatory power	Scientific assessment covering hazard identification (classification), hazard characterisation (setting toxicological reference values), exposure assessment, and risk characterisation.  Formal support for decision making
Data sources	Review of published information.  Summaries of industry sponsored studies used as secondary source if obtained from regulatory agency reports	Full set of mandatory (OECD guidelines) GLP studies and epidemiological data  Review of scientific peer-review publications, last 10 years  Information collected through a public consultation
Methods	IARC developed methodology, described in the “preamble”.	For chemical pesticides, hazard identification based on UN GHS criteria  Detailed guidance from ECHA available

Source: adapted from Tarazona et al. (2017)

<sup>22</sup> Jose V. Tarazona, Daniele Court-Marques, Manuela Tiramani, Hermine Reich, Rudolf Pfeil, Frederique Istace, and Federica Crivellente

*Different types of scientific evaluations (hazard classification versus risk assessment)*

The differences between the IARC and other regulatory bodies occur due to the differences between hazard and risk assessments. The hazard assessment provided by the IARC indicates “the strength of the evidence that a substance or agent causes cancer” ([IARC, 2015](#), p.3). The Monographs of the IARC identify *cancer hazards*, i.e. the potential for the exposure to cause cancer. However, it is important to note that, according to the interviewed representatives of agencies, hazard identifications *do not imply the level of risk related with actual exposure* (ECHA representative #1; EFSA representative #2; BfR representative #3; BVL representatives #4; ANSES representatives #5; APVMA representatives #6; US EPA representatives #7). For instance, the cancer risk associated with specific active substances assigned the same carcinogenicity classification may be very different. The difference depends on factors such as the type and extent of exposure and the strength of the effect of the substance: “While the hazard potential is intrinsic and, therefore, expected to be equivalent in all evaluations, the risk is related to the use of the substance – which is defined as the likelihood and magnitude of adverse effects – and strongly depends on the patterns and conditions of use” ([Tarazona et al., 2017](#)).

The IARC Monographs assess cancer hazards, but do not evaluate the risks related with exposure. A specific active substance is regarded as a cancer hazard if it is able to cause cancer under some circumstances. On the contrary, risk assessments measure the likelihood that cancer will occur, given the level of exposure to the active substance. As a result, according to regulatory bodies (such as EFSA, US EPA) the distinction between hazard and risk assessments is crucial. For instance, the IARC Monographs may identify cancer hazards even when risks to consumers are very low at the exposure levels they face. As a result, EFSA together with other regulatory scientists (US EPA, Canadian, Australian authorities) argue that “IARC assessments do not include recommendations regarding regulatory or legislative decisions; they are scientific evaluations informing regulatory assessments” ([Tarazona et al., 2017](#)).

However, it is important to note that the IARC disagrees with this reasoning, which is provided by the risk assessors working in the regulatory context (EFSA, US EPA). The IARC states that “the Monographs Programme identifies cancer hazards even when risks are very low at current exposure levels” ([IARC, 2016a](#)). In other words, the IARC argues that the differences in scientific conclusions occur not due to the differences between hazard classification and risk assessment practices, but other factors (e.g., data sources, scientific criteria followed in the evaluations).

*Different data sources: publicly available independent studies versus regulatory science*

Tarazona et al. ([2017](#)) argue that the core differences between the scientific conclusions of the IARC and other regulatory (EFSA, ECHA, US EPA) agencies and bodies have occurred because the risk assessors have drawn their scientific conclusions on different sources of data. In its scientific evaluations, the IARC relies not on ‘regulatory science’, but on publicly available data. The IARC “systematically assembles and evaluates all relevant

evidence available in the public domain for independent scientific review” (IARC, 2018); this included among others open peer reviewed literature and publicly available industry-produced studies. On the contrary, agencies operating in the regulatory context (such as EFSA, ECHA, US EPA) often rely on so-called ‘regulatory science’ that includes industry provided data as well as open scientific peer-reviewed literature. The reliance on industry data is a common approach followed by national, international and EU regulatory agencies and bodies. This is the case because companies producing pesticides are legally obliged to provide data to regulatory agencies on the toxicity (including carcinogenicity) of their products. Industry data production have to follow the strict Good Laboratory Practices (GLP). Such a system is deemed to ensure the reliability and validity of the data provided by industry. It is important to note that data delivered by industry is regarded a crucial element of the ‘regulatory science’ on which scientific assessments of active substances are based. The industry data are not available in the public domain due to confidentiality rules.

The interviewed representative of EFSA reiterated that one of the key reasons for differences between the IARC and other regulatory agencies was data availability: “Clearly, we have a much higher amount of information than the amount used by the IARC. Even more importantly, our experts have access to the full study reports, and IARC’s experts did not have access. They only have access to summaries of the key studies, so that’s a different kind of information.” *EFSA representative #2*

#### *Scientific criteria followed in the scientific evaluation*

According to Tarazona et al. (2017), methodological differences in the scientific evaluations of the available evidence have been identified. The IARC developed its own methodology as introduced and explained in its “preamble” (Please see Figure 1 more detailed explanations and illustrations). On the contrary, risk assessors working in the regulatory context are constrained by the internationally or EU-level defined methodologies and guidelines that they have to follow in assessing risk. In the EU context, those include hazard identification methods based on the UN GHS criteria, as well as detailed guidance from ECHA, as clarified by the EFSA representative in the interview: “What we are using as methodology to assess carcinogenicity is what was discussed in the United Nations; there is what is called the Globally Harmonized Classification and Labelling of Chemicals. This has been implemented in the EU through the CLP regulation, the regulation on classification and labelling. EFSA is using that assessment, in line with guidelines produced by ECHA. So, for the carcinogenicity, we use criteria that are in line with those provided in the Globally Harmonized Classification and Labelling of Chemicals; and we use the ECHA guidelines. The IARC is using a different methodological approach, and maybe that may explain some of the difference.” *EFSA representative #2*

#### *Different interpretations when weighing indefinite results*

The IARC and risk assessors working in the regulatory context have interpreted studies in different ways. For instance, the same weak evidence in humans for the carcinogenicity of glyphosate was interpreted in different ways by the IARC and EFSA: “The IARC considered the association between exposure to glyphosate and non-Hodgkin lymphoma as “limited evidence in humans”, while in the EU assessment, most experts considered the

evidence as “very limited” and insufficient for triggering the classification” ([Tarazona et al. 2017](#), p. 2738). The variance in the interpretation between the IARC and the EU is mainly caused by the fact that the IARC considered that “glyphosate is carcinogenic in animals, and concluded that strong evidence for two mechanisms, genotoxicity and oxidative stress, supported the plausibility of the weak association in humans” ([Tarazona et al. 2017](#), p. 2738, see also [Williams et al. 2016](#); [Portier et al. 2016](#) for an alternative explanation for scientific divergences).

However, the representatives of the scientific community, in turn, criticised EFSA and BfR regarding their interpretation of the selected studies that, according to Portier et al. (2015), have led to the omission of studies when assessing the risks of glyphosate (see table below).

**Open letter: Review of the Carcinogenicity of Glyphosate by EFSA and BfR**

In their RAR, BfR concluded (Vol. 1, p. 160) “classification and labelling for carcinogenesis is not warranted” and “glyphosate is devoid of genotoxic potential”.

- BfR agreed with the IARC on limited evidence in humans but then dismissed the association as “insufficiently consistent” with no justification.
- Using an inappropriate historical control dataset in an incorrect manner and ignoring established OECD guidelines cited in their report, BfR dismissed evidence of renal tumors in 3 mouse studies, hemangiosarcoma in 2 mouse studies and malignant lymphoma in 2 mouse studies. Thus, BfR incorrectly discarded all of the glyphosate-induced carcinogenic findings in animals as chance occurrences.
- The BfR ignored important laboratory and human evidence of genotoxicity.
- The BfR confirmed that glyphosate induces oxidative stress and dismissed this finding for lack of any other finding because they had dismissed all of the other evidence ([Portier et al. 2015](#), p. 7).

To conclude, this study has found that scientific divergences between the IARC and EFSA have emerged because of the following reasons: (1) the IARC and EFSA engaged in different types of scientific evaluations (hazard classification *versus* risk assessment); (2) agencies relied on different data sources to assess risks; (3) they applied different scientific approaches (i.e., methodologies) to assess the collected data; (4) they engage in different interpretations when weighing indefinite results.

### 3. Regulatory agencies outside the EU

#### United States Environmental Protection Agency (US EPA)

The US EPA has obtained its data through several ways: an open literature search; studies that are submitted to the agency; and the evaluation of relevant studies. Data was collected by searching the open literature and other publicly available sources (e.g., recent internal reviews, evaluations by other organisations) (EPA, 2016). Furthermore, internal databases were also searched for industry submitted studies conducted according to the Organization for Economic Cooperation and Development (OECD) test guidelines,

OCSPP<sup>23</sup> – harmonised test guidelines, and other pesticide test guidelines (Office of Pesticide Programs (OPP) guidelines) (US EPA, 2016). Furthermore, the agency has been encouraged by the National Academy of Sciences National Research Council (NRC) to move towards systematic review processes to enhance the transparency of scientific literature reviews that support chemical-specific risk assessments to inform regulatory decision-making (US EPA, 2016). In the written response to the questions of this study, the US EPA emphasised: “The Agency strives to use high-quality studies when evaluating pesticide chemicals and considers a broad set of data during this process. This includes registrant generated studies, typically using OECD test guidelines, required under FIFRA, as well as peer-reviewed scientific journals and other sources, such as other governments and academia. All studies are thoroughly reviewed to ensure appropriate conduct and methodologies are [utilised] and that sufficient data and details are provided. This ensures that decisions are informed by the best science available” US EPA representatives #7

As part of the evaluation of the human carcinogenic potential of glyphosate, the literature review described here uses concepts consistent with fit-for-purpose systematic reviews, such as detailed tracking of search terms and which literature have been included or excluded (EPA, 2016). To obtain literature, OPP worked with US EPA librarians to conduct searches in PubMed, Web of Science, and Science Direct (EPA, 2016).

For all pesticides, there are toxicology data requirements that must be submitted by industry to the agency for registration; these studies, defined under the 40 CFR Part 158 Toxicology Data Requirements, provide information on a wide range of adverse health outcomes, routes of exposure, exposure durations, species, and life stages (US EPA, 2016). They typically follow OECD, OCSPP, or OPP accepted protocols and guidelines, which ease comparisons across studies and chemicals (US EPA, 2016). The toxicological databases for glyphosate were reviewed and all relevant animal, genotoxicity, and metabolism studies were collected for consideration (US EPA, 2016). Studies submitted to the agency are evaluated based on OECD, OCSPP, or OPP test guideline requirements to determine whether studies are acceptable for use in risk assessment (US EPA, 2016).

To ensure the quality of the risk assessments that the US EPA conducts, the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) Scientific Advisory Panel (SAP) is augmented by other experts that come from the following organisations, namely the Food Quality Protection Act Science Review Board. They also assist in reviews, as well as discussing and peer reviewing the work of the agency (US EPA, 2016).

The US EPA’s Office of Chemical Safety and Pollution Prevention (OCSPP) is currently developing systematic review policies and procedures that are part of the scientific guidelines (EPA, 2018). This means that OCSPP employs “fit for purpose” systematic reviews that rely on standard methods for collecting, evaluating, and integrating the scientific data supporting the agency’s decisions (US EPA, 2016). They chose this particular concept because it implies that a particular activity or method is suitable for its intended use (US EPA, 2016). As a result, in this definition there is no ‘one size fits all’ and thus

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<sup>23</sup> EPA’s Office of Chemical Safety and Pollution Prevention (OCSPP)

flexibility is allowed (US EPA, 2016). However, it is important that, according to the US EPA, with this flexibility, there is transparency of documented processes, including the importance of transparency and clarity in approaches to data collection, evaluation, and integration (US EPA, 2016, US EPA representatives #7).

The US EPA uses a weight-of-evidence (WoE) approach when integrating data from multiple sources to take quality, consistency, relevancy, coherence biological plausibility, and uncertainty into account. Application of WoE analysis is an integrative and interpretive process routinely used by EPA and outlined in its [risk assessment guidelines](#).

The representatives of the US EPA noted, in their written responses to the question of this study, "EPA's risk assessment for glyphosate was conducted independently of any other [organisation] and the IARC decision did not influence EPA's conclusions. EPA's cancer classification for glyphosate is based on a weight-of-evidence evaluation in accordance with the Agency's 2005 Guideline for Carcinogen Risk Assessment. The dataset considered by EPA included studies submitted for registration of glyphosate, as well as studies identified in the open literature as part of a systematic review. EPA also incorporated data that were not previously available into its evaluation." US EPA representatives #7

Furthermore, as other (regulatory) agencies assessed and interviewed in this study, the US EPA emphasised the core differences between their and IARC's scientific assessment, i.e. the IARC and the US EPA have relied on different data sets because not all information was available to the IARC. "The IARC only considers data that have been published or accepted for publication in the openly available scientific literature. As a result, IARC only considered a subset of the studies included in [the] EPA's evaluation. [The] EPA also did not use some studies that IARC incorporated into their evaluation because [the] EPA did not believe the studies were appropriate for determining the human carcinogenic potential of glyphosate. For example, genotoxicity studies conducted in non-mammalian species (i.e., worms, fish, reptiles, plants) were excluded from the EPA's evaluation because they were not considered relevant for informing the genotoxic risk in humans." US EPA representatives #7

To conclude, the primary document analysis and interview data suggest that scientific divergences between the IARC and the US EPA have emerged because of the following reasons: agencies relied on different data sources to assess risks; they applied different scientific approaches (i.e., methodologies) to assess the collected data; and they engage in different interpretations when weighing indefinite results.

## **II – Conclusion**

The chapter has assessed the scientific aspects of evaluations produced by the International Agency for Research on Cancer; the European Food Safety Authority (together with the German Federal Institute for Risk Assessment); the European Chemicals Agency; and the United States Environmental Protection Agency. It has shown that several factors have contributed to the explanation relating to the main research question of this research paper: Why do risk assessors arrive at different conclusions?

The empirical analysis of primary documents and the semi-structured interviews have indicated that the scientific divergences between the IARC and other agencies (e.g., EFSA, ECHA, the US EPA) have emerged because they have engaged in different types of scientific evaluations (hazard classification *versus* risk assessment). Furthermore, the following factors were also identified as important causes explaining scientific divergences in the evaluations: agencies relied on different data sources to assess risks and hazards; they applied different scientific approaches (i.e., methodologies) to assess the collected data; and they engaged in the different interpretations when weighing indefinite results.

First, the differences between the IARC and other agencies (e.g., EFSA, ECHA, US EPA) occur due to the differences between hazard-based assessments and risk-based assessments. The *Monographs* of the IARC identify *cancer hazards*, i.e. the potential for the exposure to cause cancer. The scientific assessments of agencies are based on the risk evaluation, i.e. the likelihood and magnitude of adverse effects (which depend on the patterns and conditions of substance use). In other words, risk assessments measure the likelihood that cancer will occur, given the level of exposure to the active substance. As a result, according to regulatory bodies (such as EFSA and the US EPA) the distinction between hazard-based assessments and risk-based assessments is crucial. For instance, the IARC *Monographs* may identify cancer hazards, even when risks to consumers are very low at the exposure levels they face. EFSA, together with other regulatory scientists (American, Canadian and Australian authorities), argue that the IARC assessments do not include recommendations regarding regulatory decisions: rather, they are scientific evaluations informing regulatory assessments.

Second, one of the core differences between the scientific conclusions of the IARC and other agencies (e.g., EFSA, ECHA, the US EPA) have occurred because the risk assessors have drawn their scientific conclusions based on different sources of data. In its scientific evaluations, the IARC relies on publicly available data. The IARC systematically evaluates evidence that is available in the public domain (which includes - among others - open peer reviewed literature and publicly available industry-produced studies). On the contrary, agencies operating in the regulatory context (such as EFSA, ECHA, the US EPA) often rely on so-called 'regulatory science', which includes industry-provided data (not always available publicly), as well as open scientific peer reviewed literature. In other words, agencies such as EFSA, ECHA and the US EPA rely on publicly available data as well as confidential data provided by applicants (industry).

Third, methodological differences in the scientific evaluations of the available evidence have been identified between the IARC and other agencies (EFSA, ECHA, the US EPA). The IARC relied on a different methodology - defined and explained in its "preamble" - than other agencies. Risk assessors working in the regulatory context (EFSA, ECHA, the US EPA) are constrained by the internationally or EU defined methodologies and guidelines.

Fourth, there are some differences in how the IARC and other agencies (EFSA, ECHA, the US EPA) interpret studies when weighing indefinite results. That is, the IARC and risk assessors working in the regulatory context have interpreted studies in different ways. For instance, the same weak evidence in humans for the carcinogenicity of glyphosate was

inferred in different ways by the IARC and (regulatory) agencies. To illustrate, the IARC considered the association between exposure to glyphosate and non-Hodgkin lymphoma as “limited evidence in humans”, whereas, for instance, in the EU assessment, most experts considered the evidence as “very limited” and insufficient for triggering the classification.

## Chapter 5

### I – Stakeholder Survey: Study on the European Food Safety Authority and its risk assessment practices

In addition to the desk research and semi-structured interviews, an online stakeholders' survey (entitled 'Study on the European Food Safety Authority and its risk assessment practices') was carried out from the 4th of January to the 23rd of February 2018 to collect opinions about the scientific risk assessment model established in the EU by Regulation (EC) 1107/2009 concerning the placing of plant protection products on the market. The questions explore scientific/technical, procedural, performative and ethical aspects of European Food Safety Authority's (EFSA) work on risk assessment in the field of pesticides used in plant protection products.

The survey was sent to a wide range of stakeholders and organisations (research community, national regulatory authorities, NGOs, industry, etc.). It was disseminated to 293 stakeholders, including national competent authorities, PPP manufacturers and industry organisations, health/environment NGOs and consumer groups, and research community (e.g., academics), associations of PPP users, farmers' associations. The list of potential respondents was collected on EFSA's website, i.e. EFSA publishes a list of organisations and individuals who attend its events (stakeholder consultations, conferences, other activities organised by EFSA). The survey received 42 fully completed responses (response rate: 15%) plus 25 responses that were not fully completed (response rate: 23%).

The questions of the survey were developed by Dr Dovilė Rimkutė and Dr Madalina Busuioc, Leiden University, Institute of Public Administration. The questions are theoretically motivated and draw on the organisational reputation literature (see Carpenter, 2010).

#### 1. Distribution of the survey respondents

The largest group of respondents who filled in the questionnaire is national competent authorities (55% of all received responses), followed by industry/industry associations (15%) and NGOs and advocacy groups (12%), research community (8%) (see Figure 7). Regarding the highest education level achieved of the respondents, around 49% of the respondents have a doctoral degree, 27% master's degree and 2% bachelor's degree, while the remaining respondent have high school diploma, vocational or other qualifications. In terms of gender representation, 56% males and 44% females submitted their answers to the online survey. Representatives from the following countries took part in the survey: Italy, Denmark, Spain, Austria, Malta, Greece, Belgium, The Netherlands, Germany, Sweden, Finland, Lithuania, France, the UK, Canada, Slovenia, Norway, Croatia, Ireland.

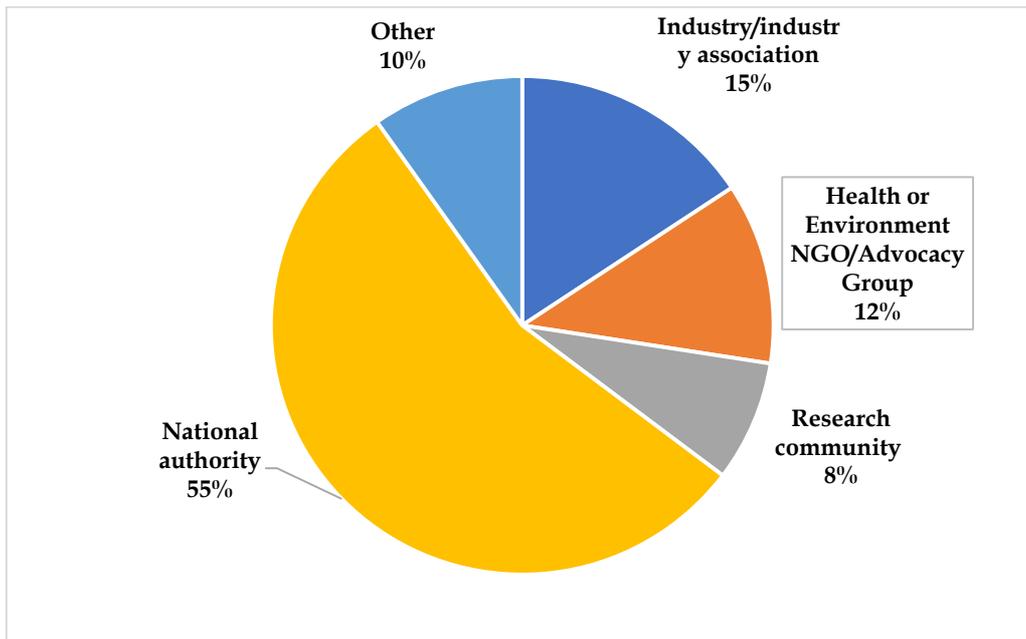


Figure 7. Distribution of the survey respondents

Figure 8 illustrates that the stakeholders that have filled in the questionnaire interact with EFSA mostly on a weekly (29%) or monthly (27%) basis.

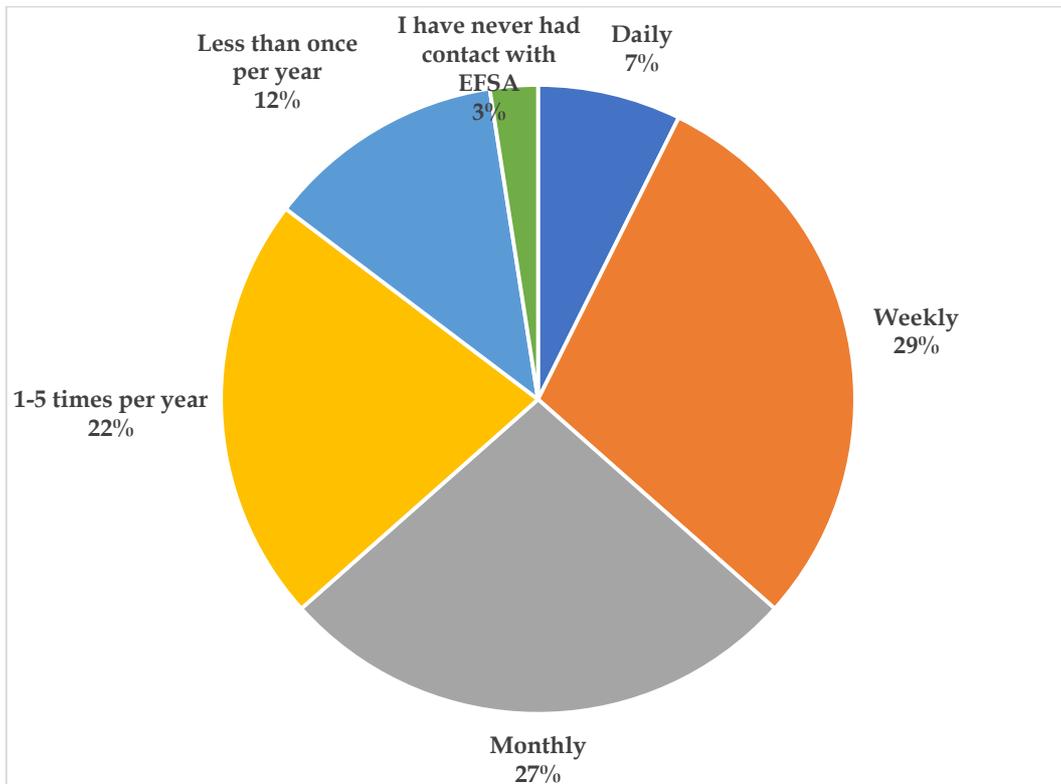


Figure 8. Stakeholders' interaction with EFSA

## 2. Survey results

The questionnaire consisted of 18 statements in which the respondents were asked to indicate the extent to which they agree or disagree (7-point Likert scale), with the statements regarding EFSA and its scientific work. The survey questions aimed to cover five different aspects of the day-to-day activities of the European Food Safety Authority. For this purpose, the questionnaire included from three to five statements asking respondents to express their opinions regarding the activities of EFSA in the following categories:

- Technical/scientific conduct of EFSA: Does EFSA follow rigorous scientific standards in its activities?
- Performative aspects of EFSA's work: Does EFSA deliver effectively on its mandate?
- Procedural aspects of EFSA's work: Does EFSA follow due processes?
- Moral/ethical aspects of EFSA's work: Does EFSA protect in the public interest? Is EFSA an inclusive and transparent organisation?
- Overall credibility of EFSA's scientific work: Are the scientific outputs of EFSA authoritative? Is EFSA free from political influence?

In the remainder of this section the results of the survey are briefly introduced and discussed.

*See Figure 9:* The survey aimed at capturing the perceptions of stakeholders regarding the scientific and technical conduct of EFSA (see Figure 9). The statements measuring the technical character of EFSA's work included: (1) EFSA delivers scientific outputs that are of high methodological quality; (2) EFSA provides high-quality scientific advice; and (3) EFSA applies rigorous evidence selection criteria in its scientific outputs. In general, the respondents are rather positive about EFSA's scientific conduct. 74% of the respondents agree in various degrees (i.e., strongly agree/agree/somewhat agree) with the statement that EFSA delivers scientific outputs that are of high methodological quality. 67% agree that EFSA provides high-quality scientific advice and 26% of the respondents strongly agree with the statement. It is important to note that this particular statement has received the highest support from the respondents (one third strongly agree with the statement) implying that the respondents are quite positive about the quality of scientific advice that EFSA provides to EU institutions and Member States. When it comes to the claim 'EFSA applies rigorous evidence selection criteria in its scientific outputs', 70% agree with the statement, while only 17% disagree (i.e., strongly disagree/disagree/somewhat disagree). This, in turn, indicates that the respondents are convinced and satisfied with the evidence selection practices followed by EFSA in its scientific work. In summary, the survey results overall indicate that, on average, the stakeholders of EFSA tend to have very positive perceptions of EFSA scientific/technical performance.

The respondents were also provided with the opportunity to comment on EFSA's day-to-day activities. In general, the respondents are very positive when it comes to the scientific conduct of EFSA, as illustrated in the following quote: "EFSA operates in a field with

diverse interests. Thanks to the independent scientific approach of their work EFSA is a very reliable organisation. We are impressed by their results” (Survey comment: *Representative of a national authority*).<sup>24</sup>

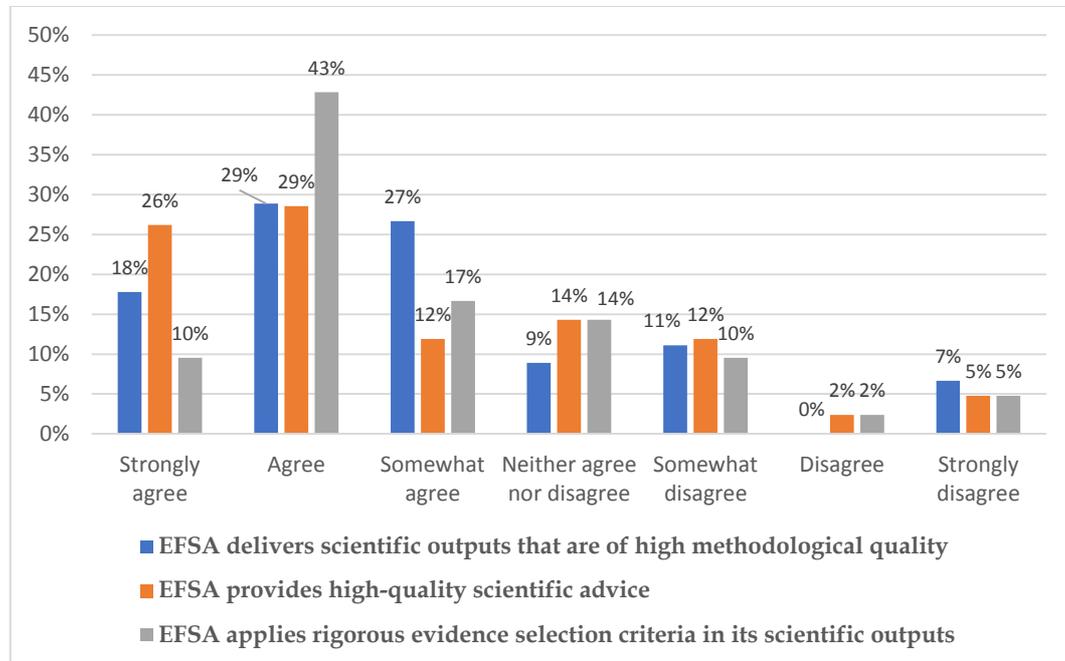


Figure 9. Opinions of the scientific/technical conduct of EFSA

See Figure 10: The survey included a question on the independence of EFSA’s experts, methods and data (‘EFSA is committed to safeguarding the independence of its experts, methods and data’). Figure 10 indicates that 80% of the stakeholders who filled in the questionnaire are of the opinion that EFSA is an independent organisation, i.e. they agree with the statement on various degrees (i.e., strongly agree / agree / somewhat agree). Whereas only 9% somewhat disagree / disagree / strongly disagree with the statement. This finding is quite surprising because the desk research revealed that EFSA receives much criticism regarding its independence policies and practices. However, according to the survey results, EFSA is regarded very positively among the group of stakeholders that contributed to this survey.

On the other hand, an industry representative expressed some concerns regarding too stringent independence policies of EFSA: “strict independence policy is a blocker to the exchange of a comprehensive scientific and practical knowledge with directly involved stakeholders. We would support an adaptation of this policy to include more scientific inputs from stakeholders with a particular interest (e.g. Industry, NGOs) in a fully declared, visible and public way” (Survey comment: *industry/industry association representative*).<sup>25</sup>

<sup>24</sup> Respondents had an opportunity to provide their comments to the survey questions.

<sup>25</sup> Respondents had an opportunity to provide their comments to the survey questions.

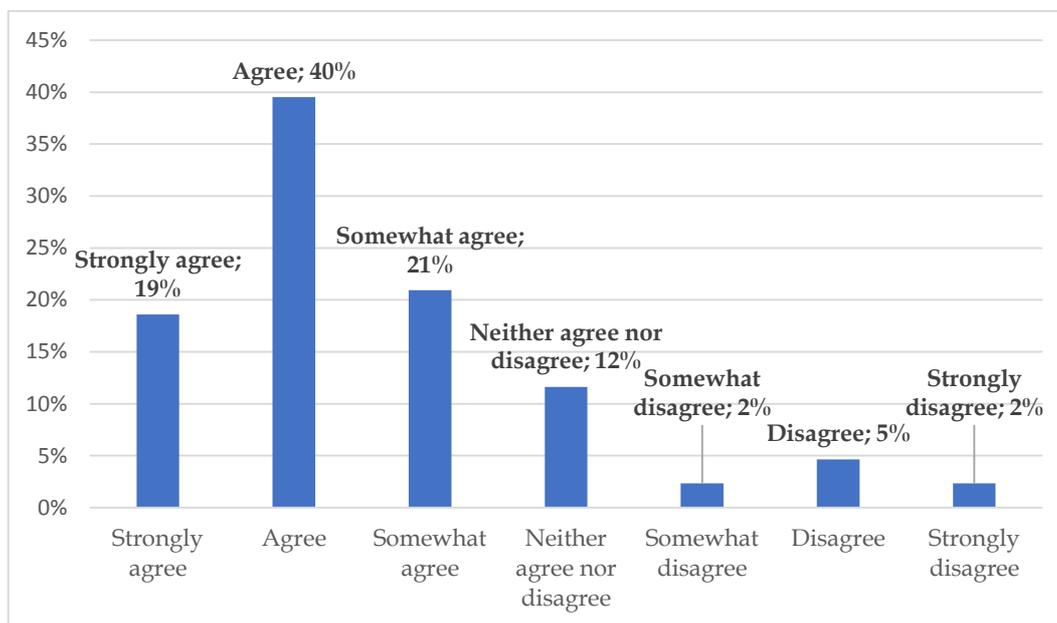


Figure 10. Perceptions about the independence of EFSA regarding its experts, methods and data

See Figure 11: Alongside the technical and scientific conduct of EFSA, the survey included questions measuring the perceptions of stakeholders regarding EFSA's organisational performance and effectiveness (see Figure 11): (1) EFSA is able to attain goals that are relevant to the organisation/stakeholder group that you belong to; (2) EFSA is capable of taking effective action in the pursuit of its core responsibilities; and (3) EFSA delivers effectively on its mandate. While the vast majority (65% - 69%) of the respondents to various degrees agree (i.e., strongly agree/agree/somewhat agree) that EFSA is able to deliver effectively in line with its mandate and core responsibilities, 14% - 19% do not believe that EFSA is an effective organisation. The vast majority of those who participated in the survey (77%) are satisfied with how EFSA attains goals that are relevant to the organisation/stakeholder group they belong to. In short, the respondents are, on average, positive regarding the performative aspects (i.e., effectiveness, ability to deliver outputs) of EFSA's conduct. However, it is important to note that 21% of the survey participants could not make up their mind (neither agreed nor disagreed) about the capability of EFSA to take effective action. This implies that the respondents found it difficult to decide if EFSA can be regarded as an assertive organisation that can take effective action in line with its mandate. The respondents of the survey suggested some reflections on this aspect of EFSA conduct: "The big problem in the regulation 1107/2009 is not the part of risk assessment, but the risk management and the enforcement of the regulation, which is not in the hands of EFSA but in the hands of the Commission and Member States. The regulatory framework we have could be improved. The problem is that the law is not enforced. Once

the risk has been assessed and determined, risk managers forget their responsibility to manage risks properly” (Survey comment: *NGO representative*).<sup>26</sup>

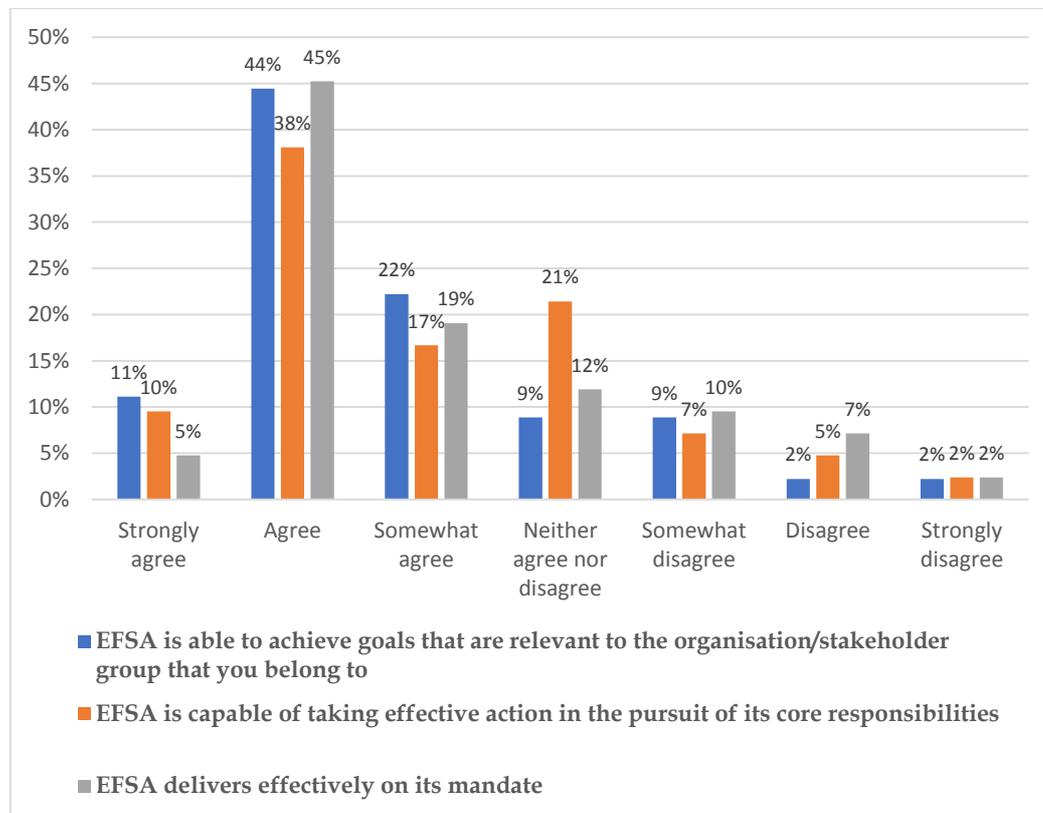


Figure 11. Opinions of the performative aspects of EFSA’s work

See Figure 12: The survey included a set of questions that aims to assess the perceptions of stakeholders regarding the procedural aspects of EFSA’s scientific work (see Figure 12). The statements measuring how well EFSA is capable to adhere to the proper procedures and rules include: (1) EFSA follows due process in its scientific work; (2) EFSA follows proper procedures in carrying out its scientific tasks; (3) EFSA includes legitimate stakeholders in its activities. 69% percent to various degrees agree (i.e., strongly agree / agree / somewhat agree) that EFSA follows due process in its scientific work, 73% agree with a very similar statement stating that EFSA follows proper procedures in carrying out its scientific tasks, 65% believe that EFSA is an inclusive organisation. In general, EFSA scores highly on the procedural dimension, however, 19% were hesitant (neither agreed nor disagreed) about the ability of EFSA to include stakeholders in its day-to-day activities.

<sup>26</sup> Respondents had an opportunity to provide their comments to the survey questions.

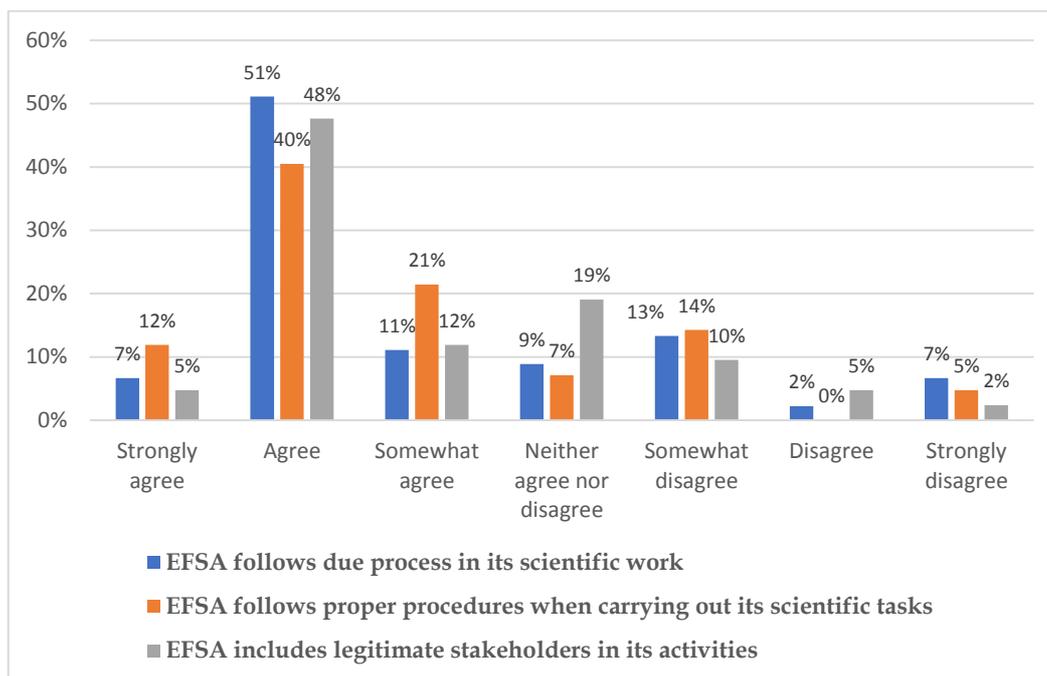


Figure 12. Opinions of the procedural aspects of EFSA's work

See Figure 13: The other group of questions aimed to assess the opinion of stakeholders regarding the moral and ethical aspects of EFSA work (see Figure 13). The moral/ethical dimension included the following statements: (1) EFSA is committed to transparency in its work; (2) EFSA is considerate towards the interests of the stakeholder group/organisation you belong to; (3) EFSA follows ethical standards in its work; and (4) EFSA protects the public interest. The desk research has indicated that EFSA received much criticism regarding its transparency practices, especially, in the context of the glyphosate case. However, the survey results indicate that the vast majority of the respondents (74%) on various degrees agree (i.e., strongly agree / agree / somewhat agree) that EFSA is a transparent organisation, whereas only 14% disagree with the statement. In a similar vein, the majority considers EFSA as an organisation that follows ethical standards (71%) and protects public interest (66%). However, EFSA received less support from the stakeholders when it comes to the statement claiming that EFSA is considerate towards the interests of the stakeholder group/organisation the respondents belong to (57% agree, whereas 33% feel that EFSA does not address their interests).

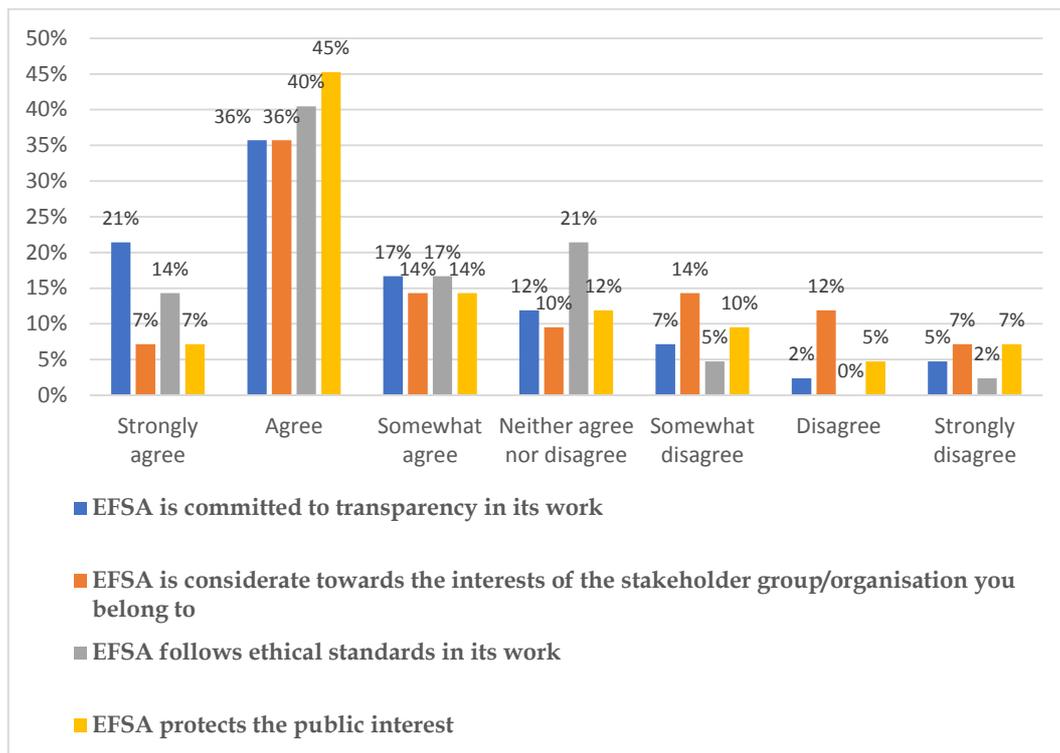


Figure 13. Opinions of EFSA moral/ethical aspects of EFSA's activities

See Figure 14: In addition to organisational reputation questions aimed at measuring scientific-technical, performative, procedural and moral aspects of EFSA scientific work, the survey also included questions that aimed to measure the credibility of EFSA (see Figure 14). Those statements included: (1) EFSA deploys consistent and predictable criteria in its scientific outputs; (2) EFSA is guided by technical as opposed to political considerations; (3) EFSA's scientific outputs are authoritative; and (4) EFSA's scientific outputs are free from political influence. Overall, EFSA is perceived as a credible organisation. The majority to various degrees agree (i.e., strongly agree / agree / somewhat agree) with the first (78%), the third statements (76%), whereas the statements claiming that EFSA is guided by technical as opposed to political considerations (67%), and the statement that EFSA's scientific outputs are free from political influence (60%) receive slightly less support from the respondents. This indicates that the respondents, to some extent, refer to the issues related to the independence of EFSA from political influence. However, they regard EFSA as an authoritative and predictable organisation. This result is not unexpected, given that the majority of the respondents (i.e., 55%) consists of the representatives of competent national authorities that work and cooperate with EFSA closely in their day-to-day activities.

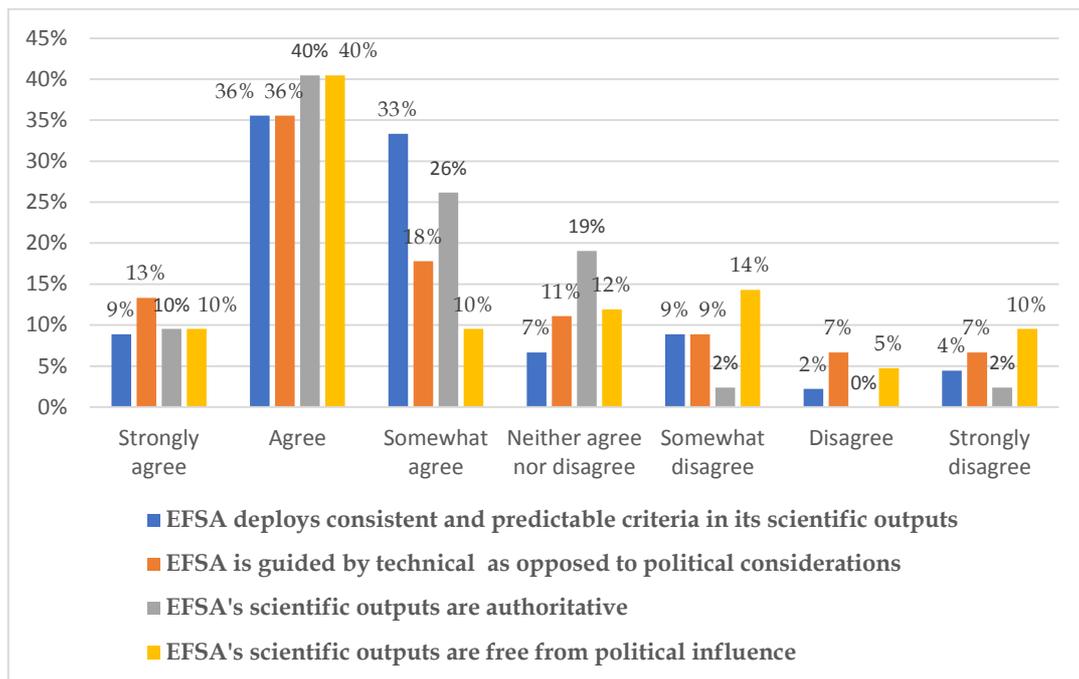


Figure 14. Credibility of EFSA

See Figure 15: The survey included a couple of questions regarding the expectations of the respondents (see Figure 15). The respondents were asked whether pesticides should be more strictly regulated in the EU (36% agree versus 29% disagree); whether the precautionary principle should be applied more often in the EU (41% agree versus 26% disagree); whether EFSA should show greater considerations for the societal implications in their scientific work (46% agree versus 24% disagree); whether EFSA should show greater considerations for the economic implications in their scientific work (38% agree versus 22% disagree); whether EFSA should be involved in risk management (28% agree versus 43% disagree). There is one clear pattern in the answers regarding the expectations of the respondents about the EU pesticides regulation practices, i.e. a considerable amount of the respondents neither agree nor disagree with the above-mentioned statements, which suggests that the respondents tend to be satisfied with the current situation (they prefer *status quo*).

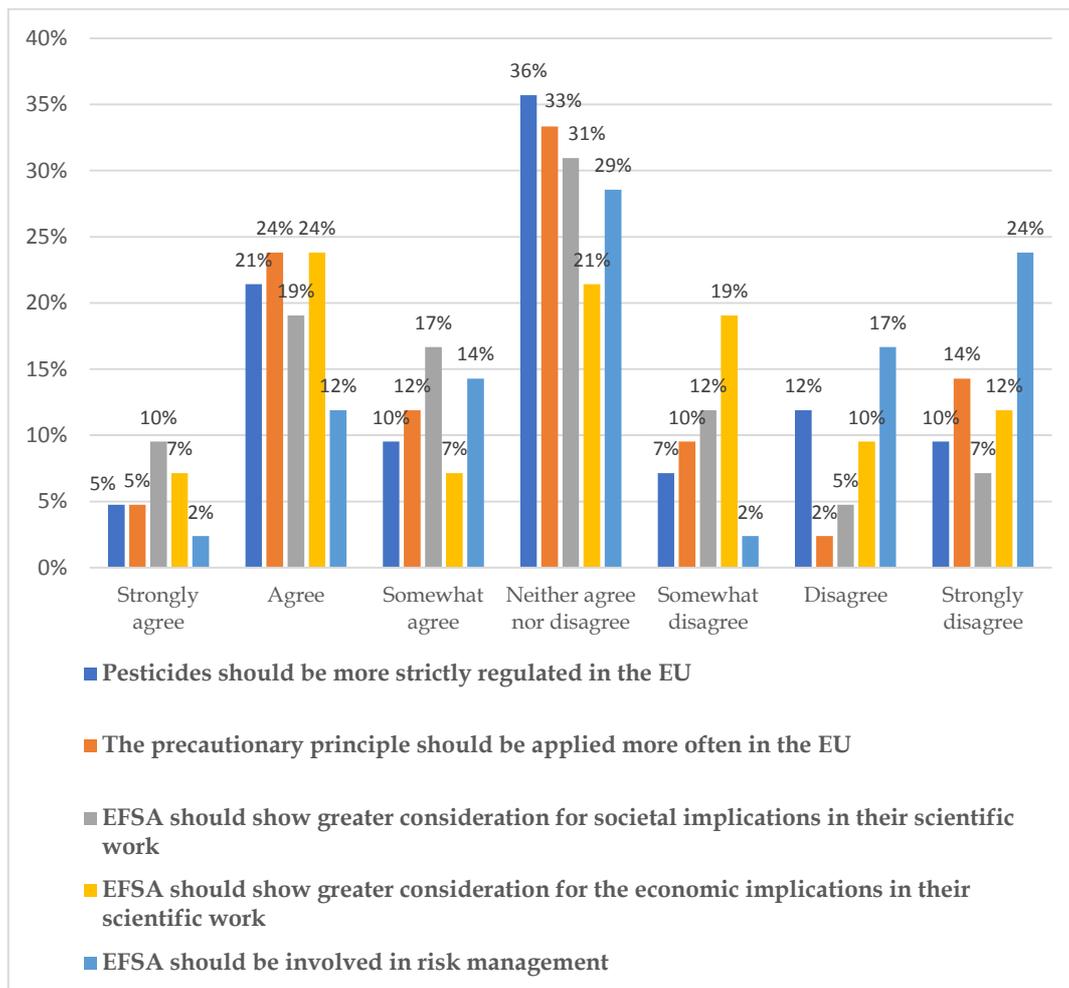


Figure 15. Expectations about pesticides regulation, precautionary principle, societal and economic impact

See Figure 16: The survey included a question on trust in EU/national institutions and agencies (see Figure 16). With this question, the researchers intended to analyse where EFSA stands in terms of trust compared to other national and EU institutions. EFSA is regarded as the most trusted institutions in the context of the organisations included in the survey (e.g. the European Commission, European Parliament). 73% of the respondents trust EFSA in various degrees (trust very much / trust / trust somewhat). In general, the respondents expressed their trust to EU agencies (72%), whereas they are less positive about the European Commission (55% replied that they trust the Commission), the European Parliament (43%), the Council of the European Union (42%).

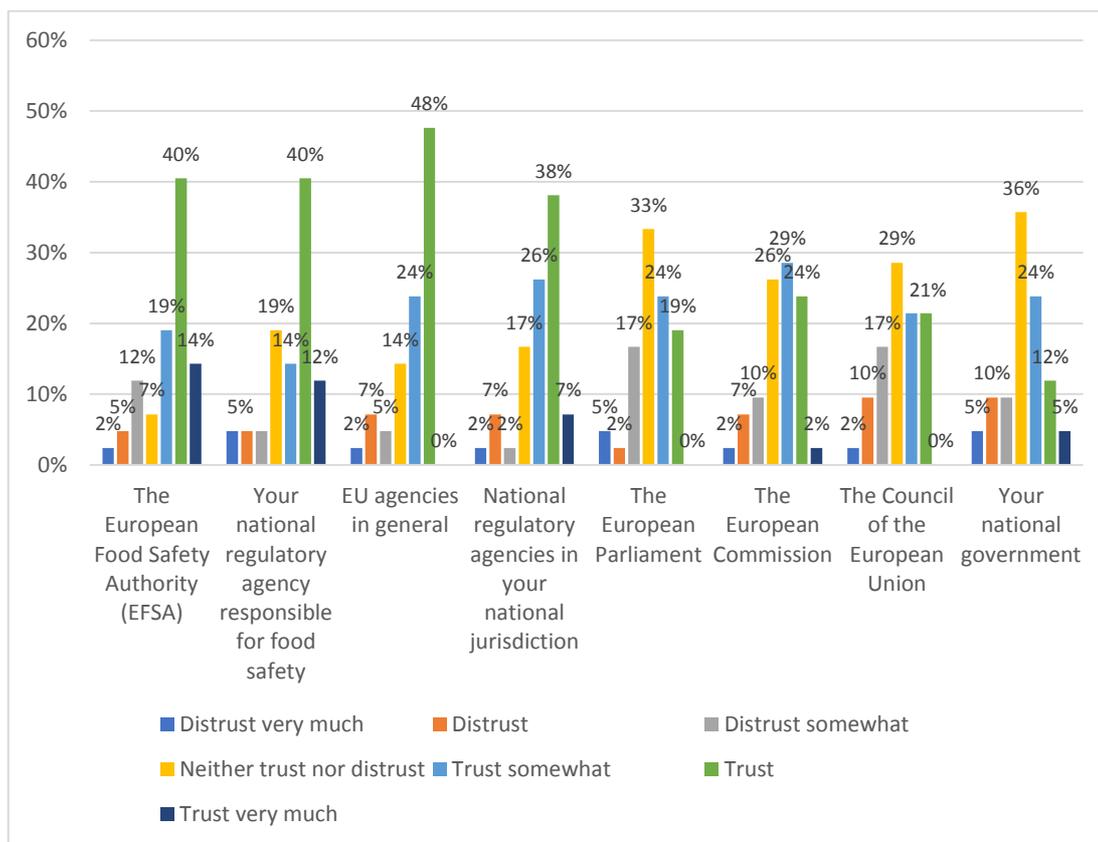


Figure 16. Trust in EU/national agencies and institutions

## II – Conclusion

In order to complement the information obtained from primary document analysis and semi-structured interviews, an online stakeholders’ survey was carried out to learn about stakeholders’ perceptions of the scientific risk assessment model established in the EU by Regulation (EC) 1107/2009 concerning the placing of plant protection products on the market. In particular, the questions of the online survey explored the scientific/technical, procedural, performative and ethical aspects of European Food Safety Authority’s (EFSA) work on risk assessments in the field of pesticides used in plant protection products.

The survey was sent to a wide range of stakeholders and organisations (research community, national regulatory authorities, NGOs, industry, etc.). It was disseminated to 293 stakeholders: including national competent authorities, health/environment NGOs and consumer groups, research community (e.g., academics), etc. The survey received 42 fully completed responses (response rate: 15%). The largest group of respondents who filled in the questionnaire is national competent authorities (55%), followed by industry/industry associations (15%) and NGOs and advocacy groups (12%), research community (8%).

The questionnaire consisted of 18 statements in which the respondents were asked to indicate the extent to which they agree or disagree (7-point Likert scale) with the statements regarding EFSA and its scientific work. The survey questions aimed to cover five different aspects of the day-to-day activities of the European Food Safety Authority: (1) technical/scientific conduct of EFSA; (2) Performative aspects of EFSA's work; (3) Procedural aspects of EFSA's work; (4) Moral/ethical aspects of EFSA's work; and (5) Overall credibility of EFSA's scientific work.

The survey results indicate that EFSA is a well-regarded organisation on various dimensions: technical/scientific, procedural, performative and ethical/moral. In particular, the scientific/technical aspects of its daily conduct are perceived rather positively by the stakeholders who have submitted their contributions to the survey. Furthermore, the respondents perceive EFSA as a credible agency whose work is authoritative and free from the political influence. The survey indicated that EFSA is regarded as a transparent, trustworthy and independent organisation.

However, the results of this survey have to be interpreted carefully. First, there might be a self-selection bias, e.g. only stakeholders that are positive about EFSA filled in the questionnaire. Second, even though the researchers of this study attempted to be as exhaustive as possible and send the questionnaire to an extensive list of EFSA stakeholders, an exhaustive list of stakeholders does not exist. For this reason, only a small sample of stakeholders was surveyed. Furthermore, as the population of stakeholders is not known, it is difficult to assess how representative the surveyed sample is to the actual population of EFSA stakeholders. Third, the majority (55%) of those who filled in the questionnaire consists of the representatives of competent national authorities. As a result, one might expect opinions that are skewed towards more positive perceptions about EFSA and its scientific work. Fourth, as the survey received only 42 responses, it is difficult to capture statistically significant differences between various stakeholder groups (competent authorities, health/environment NGOs and consumer groups, research community, industry and industry associations).

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## Annex I: List of interviews

Table 5. List of interviews

Number/reference in the text	Interviewee	Date	Duration of the interview
1. ECHA representative #1	Representative of ECHA (1 interviewee)	07/12/2018	01:07:22
2. EFSA representative #2	Representative of EFSA (1 interviewee)	19/02/2018	01:02:45
3. BfR representative #3	Representative of BfR (German competent authority) (1 interviewee)	27/02/2018	01:24:41
4. BVL representatives #4	Representative of BVL (German competent authority) (3 interviewees)	28/02/2018	00:51:35
5. ANSES representatives #5	Representatives of ANSES (4 interviewees)	20/03/2018	01:06:57
6. APVMA representatives #6	Representatives of APVMA (Australian regulatory authority) (3 interviewees)	27/03/2018	00:45:00
7. US EPA representatives #7	Representative of US EPA	06/04/2018	Written responses







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Regulation (EC) 1107/2009 lays down the main instruments for placing effective plant protection products (using pesticide substances) on the market that are safe for humans, animals and the environment, while at the same time ensuring effective functioning of the internal market and improved agricultural production.

This European Implementation Assessment found that the above objectives, while largely relevant to real needs, are not being achieved in practice. In particular, implementation of the main instruments of the regulation – substance approval, plant protection products authorisation and enforcement of the regulatory decisions taken in the frame of the approvals and authorisations, is problematic, which also affect other related EU policies.

Nevertheless, despite the implementation challenges observed, stakeholders – including national competent authorities, health/environment NGOs, manufacturers of substances and plant protection products and their users (farmers) – agree that the EU is the appropriate level at which regulatory action in the field of pesticides (used in plant protection products) should continue to take place.

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