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# DRAFT REPORT

on the implementation of the Plant Protection Products Regulation (EC) No 1107/2009
(2017/2128(INI))

Committee on the Environment, Public Health and Food Safety

Rapporteur: Pavel Poc

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## EXPLANATORY STATEMENT - SUMMARY OF FACTS AND FINDINGS

**General background and overview of evidence sources**

In May 2017, the Committee on the Environment, Public Health and Food Safety (ENVI) of the European Parliament requested to undertake an implementation report on Regulation (EC) 1107/2009 on the placing of plant protection products (PPPs) on the market, hereafter referred to as "the Regulation". This report is part of the implementation scrutiny program of the ENVI committee.

The Ex-Post Evaluation Unit (EVAL) of the Directorate for Impact Assessment and European Added Value (within Directorate-General for Parliamentary Research Services of the European Parliament, DG EPRS) provided expertise on the implementation of the Regulation. In order to prepare the required research evidence, a study aimed at evaluating the implementation of the Regulation was commissioned. The results were consolidated into a European Implementation Assessment (EIA) and officially published in April 2018[1].

The study was based on four interconnected research lines:

- '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';

- 'Assessing criteria and capacity for reliable and harmonised 'hazard identification' of active substances';

- 'Assessing Member States' capacity for reliable 'authorisation of PPPs', and its uniformity';

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

A comprehensive study on the impact of the Regulation had never been carried out before. The EIA gathered new data and findings and is the main source of information for this implementation report.

It should be noted that in November 2016 the Commission published a Roadmap on the REFIT[2] evaluation of the EU legislation on PPPs and pesticides residues, whose results are expected in early 2019.

The main purpose of both evaluations is to assess the implementation of Regulation (EC) 1107/2009. Although the scope of the Commission's evaluation is broader[3], the standard set of criteria for evaluation are, however, identical.

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[1] http://www.europarl.europa.eu/thinktank/en/document.html?reference=EPRS_STU(2018)615668

[2] https://ec.europa.eu/food/plant/pesticides/refit_en

[3] In particular, it covers Regulation (EC) 1107/2009 on placing of plant protection products on the market, which is in the focus of this implementation report, and Regulation (EC) No 396/2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin

Additionally, in February 2016 the European Ombudsman reached its conclusion in case 12/2013/MDC on the practices of the European Commission regarding the authorisation and placing on the market of PPPs.The Commission, in its risk manager role, has the duty to ensure that the active substances it approves are not harmful for human health, animal health, or the environment. The Ombudsman found that the Commission may be too lenient in its practices and might not be taking sufficient account of the precautionary principle.

There are also relevant judgements of the European Court of Justice and other relevant preliminary rulings that have been taken into consideration by the Rapporteur.

The recent controversy related to the renewal of the approval of the active substance glyphosate further highlighted that trust in the authorisation of PPPs in the EU has been seriously undermined. In October 2017 the Commission declared the European Citizens' Initiative (ECI) "Stop Glyphosate and protect people and the environment from toxic pesticides"[1] admissible. Over 1 million citizens called on 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".

Against this background in February 2018 the European Parliament decided to set up a special committee on the Union's authorisation procedure for pesticides (PEST) to analyse and assess, among other things, the authorisation procedure for pesticides in the Union, including the methodology used and its scientific quality, the procedure's independence from industry, and the transparency of the decision-making process and its outcomes

Furthermore in April 2018 as a follow-up to its reply to the ECI[2] the European Commission officially proposed a targeted revision of the General Food Law and published proposal for a Regulation on the transparency and sustainability of the EU risk assessment in the food chain[3], amending, among others, the Regulations whose implementation is discussed here.

This shows that evaluating a complex regulatory system to harmonise and monitor the placing of plant protection products on the EU internal market is high on the political agenda.

All the above mentioned facts have fed into the present report. The Rapporteur also takes into consideration other relevant studies and reports carried out by national authorities and stakeholders.

**The Regulation in the broader context of the EU pesticide policy**

In 2006, the European Commission adopted a thematic strategy on the sustainable use of pesticides in all Member States. As a follow-up, in 2006, the Commission published a proposal for a regulation repealing Directive 91/414/EEC. The final act (Regulation (EC) 1107/2009 which is in the focus here) was published in the Official Journal in 2009.

The Regulation laid down rules for the authorisation of PPPs in commercial form and for their placing on the market, use and control within the EU. It laid down both rules for the approval

[1] http://ec.europa.eu/citizens-initiative/public/initiatives/successful/details/follow-up/2017/000002/en?lg=en

[2] http://ec.europa.eu/transparency/regdoc/rep/3/2017/EN/C-2017-8414-F1-EN-MAIN-PART-1.PDF

[3] https://ec.europa.eu/info/law/better-regulation/initiatives/com-2018-179_en

of active substances, safeners and synergists, which PPPs contain or consist of, and rules for adjuvants and co-formulants.

An important new element introduced by the Regulation were a number of strict cut-off criteria[1] for the approval of active substances at EU level. The criteria were introduced with the intention to ban the most toxic substances from the market. The introduction of cut-off criteria means that the approval process is governed by a hazard-based approach, which was not the case under Council Directive 91/414/EC.

The hazard-based approach was underpinned by another principle of EU environmental legislation: the precautionary principle. In particular, Member States shall not be prevented from applying the precautionary principle where there is scientific uncertainty as to the risks posed by the PPPs to human or animal health or the environment.

**Regulatory procedures for approval of active substances and authorisations of PPPs**

In the European Union, PPPs are subject to a dual approval process: active substances are approved at EU level, commercial PPPs are subsequently authorised at Member State level.

Three main instruments are at the core of the Regulation:

a) approval of active substances performed by national competent authorities, EFSA and the Commission together with Member States' experts (grouped in the Standing Committee on Plants, Animals, Food and Feed /PAFF Committee/)
b) authorisation of PPPs containing approved active substances
c) enforcement of regulatory decisions taken in frame of approvals and authorisations

The approval procedure consists of several stages:

1. Application for approval is submitted to an EU country called Rapporteur Member State (RMS);
2. RMS verifies if the application is admissible;
3. RMS prepares a draft assessment report;
4. EFSA issues its conclusions;
5. PAFF Committee votes on approval or non-approval;
6. Adoption by the Commission;
7. Publication of a Regulation in the EU Official Journal.

[1] 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. 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. (Bozzini 2018, Annex II to the EIA, p. 21)

A plant protection product usually contains more than one component. The active component against pests/plant diseases is called the “active substance”. PPPs contain at least one approved active substance, these may include micro-organisms, pheromones and botanical extracts.

The controls of the placing on the market of PPPs and their use are carried out by Member States.

**Main areas of concern**

The EIA published by EPRS identified a number of different concerns related to the implementation of the Regulation. In the draft report the Rapporteur focuses mainly on the aspects that have negative consequences for the achievement of health and environment objectives.

In particular, those include an increase in derogations granted under Article 53 without providing satisfactory justifications or the fact that a number of crucial aspects are not being sufficiently assessed (for example non-intentional mixtures and combination effects, environmental impact on biodiversity, pesticide degradation at low concentrations, developmental immunotoxicity and developmental neurotoxicity).

Although the Regulation brought about clear progress in terms of better protection of public health and the environment by introducing the hazard cut-off criteria, insufficient harmonization (e.g. ecotoxicology) hinders the evaluation of substances and hence the effective implementation in the relevant scientific areas.

The evaluation identified a number of concerns related to transparency.Particularly problematic is the unavailability of economically feasible and accessible alternatives, and the fact that good agricultural practice in the context of integrated pest management and increased use and availability of low-risk substances are not sufficiently promoted. It also appears that 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. Enforcement of the Regulation is problematic. There are indications of an increase of trade in illegal and counterfeit PPPs, which has been identified in recent years.

**Recommendations by the rapporteur**

The Rapporteur is convinced that further efforts on both EU and national level are needed to ensure effective implementation of the Regulation. Even though the objectives of the Regulation related to health and the environment are reported as relevant to the real needs, the evaluation showed that these two objectives are not being achieved in practice. This comes as a result from problems with the practical implementation of the three main instruments of the Regulation identified by the EPRS evaluation - (a) approval of substances, (b) authorisation of PPPs containing approved substances, and (c) enforcement of regulatory decisions taken in the framework of approvals and authorisations.

In relation to negative impacts on public health and the environment, the Rapporteur considers several aspects of the implementation particularly problematic. These include: misuse of the emergency authorisation procedure, evidenced by an increased number of derogations granted under Article 53, frequent use of the confirmatory data procedure, compatibility of the Regulation with the precautionary principle, incomplete harmonisation of data requirements and methodologies used in some scientific fields used for the evaluation of substances against the cut-off criteria.

The Rapporteur welcomes the recent proposal of the Commission on transparency and sustainability of the EU risk assessment model covering among others PPPs, whilst noting, however, that some of the crucial aspects of the regulatory decision making process are not sufficiently addressed by this proposal and in particular the risk management stage performed by the PAFF Committee in the context of approval of active substances. Increased transparency is also needed as regards aspects of the authorisation by the Member States' competent authorities.

Additionally, effective implementation cannot be achieved without better harmonisation with EU policies and without increased incentives to promote alternative solutions.

The available evidence shows that enforcement of regulatory decisions under the Regulation is insufficient and that better controls at national level are needed.

## MOTION FOR A EUROPEAN PARLIAMENT RESOLUTION

**on the implementation of the Plant Protection Products Regulation (EC) No 1107/2009 (2017/2128(INI))**

*The European Parliament,*

– having regard to 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[1],

– having regard to 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[2],

– having regard to 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[3],

– having regard to 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[4],

– having regard to its resolution of 24 October 2017 on the draft Commission implementing regulation renewing the approval of the active substance glyphosate 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, and amending the Annex to Implementing Regulation (EU) No 540/2011[5],

– having regard to its resolution of 15 February 2017 on low-risk pesticides of biological origin[6],

– having regard to the decision of the European Ombudsman of 18 February 2016 in Case 12/2013/MDC on the practices of the Commission regarding the authorisation and placing on the market of plant protection products (pesticides)[7],

– having regard to the European Implementation Assessment on Regulation (EC) 1107/2009 on the placing of plant protection products on the market and its relevant Annexes published by the European Parliamentary Research Service (DG EPRS)[8] in April 2018,

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[1] OJ L 309, 24.11.2009, p. 1.
[2] OJ L 70, 16.03.2005, p. 1.
[3] OJ L 353, 31.12.2008, P. 1.
[4] OJ, L 309, 24.11.2009, p. 71.
[5] Texts adopted, P8_TA(2017)0395.
[6] Texts adopted, P8_TA(2017)0042.
[7] https://www.ombudsman.europa.eu/en/cases/decision.faces;jsessionid=414F07CA7B69C35675EE16710B5AB5AC
[8] http://www.europarl.europa.eu/RegData/etudes/STUD/2018/615668/EPRS_STU(2018)615668_EN.pdf

– having regard to the judgments of the Court of Justice of the European Union of 23 November 2016 in Cases C-673/13 P Commission v Stichting Greenpeace Nederland and PAN Europe and C-442/14 Bayer CropScience and Stichting De Bijenstichting v College voor de toelating van gewasbeschermingsmiddelen en biociden,

– having regard to the Commission proposal for a Regulation of the European Parliament and the Council of 11 April 2018 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][1],

– having regard to Rule 52 of its Rules of Procedure, as well as Article 1(1)(e) of, and Annex 3 to, the decision of the Conference of Presidents of 12 December 2002 on the procedure for granting authorisation to draw up own-initiative reports,

– having regard to the report of the Committee on the Environment, Public Health and Food Safety and the opinion of the Committee on Agriculture and Rural Development (A8-0000/2018),

A. whereas the evaluation of the implementation of the Regulation revealed that the health and environmental protection objectives are not being achieved;

B. whereas the implementation of the Regulation is not in line with related EU policies, including in the field of pesticides;

C. whereas the available evidence shows that the practical implementation of the three main instruments of the Regulation – approvals, authorisations and enforcement of regulatory decisions – is unsatisfactory and does not ensure the fulfilment of the purpose of the Regulation;

D. whereas there are concerns associated with the evaluation approach, as established by law, in particular as regards who should produce the evidence for evaluations and the hazard-based approach;

E. whereas there are concerns associated with the practical implementation of the established evaluation approach; whereas in particular there are major concerns associated with the incomplete harmonisation of data requirements and methodologies used in some scientific fields that may hinder the evaluation process and thus may lead to direct negative effects on public health and the environment;

F. whereas the performance of national competent authorities was found to be a major factor influencing the evaluation of active substances; whereas there are substantial differences among Member States as regards available expertise and staff; whereas the

[1] COM(2018)0179.

Regulation and relevant supporting legal requirements are not uniformly implemented across Member States with relevant health and environment implications;

G. whereas transparency in all stages of the approval procedure is insufficient and leads to negative effects on health and the environment and provokes public mistrust in the system regulating pesticide substances; whereas the transparency of the authorisation related activities of competent authorities is also unsatisfactory;

H. whereas authorisations of plant protection products, which take place exclusively at national level, often face delays in risk management decisions; whereas in consequence this leads in some cases to an increase of authorisations granted by Member States under derogation, making use of Article 53 of the Regulation; whereas there are cases where such derogations are used against the initial intention of the legislator;

I. whereas the available evidence shows that this piece of EU-level regulation enhances and adds value to national efforts and actions;

***Main conclusions***

1. Considers that the EU is the appropriate level at which regulatory action in the field of pesticides should continue to take place;

2. Is concerned by the fact that the Regulation has not been effectively implemented and that as a result its objectives are not being achieved in practice;

3. Notes that the objectives and instruments of the Regulation and its implementation are not in line with EU policies in the fields of agriculture, food security, climate change, sustainable use of pesticides and maximum residue levels of pesticides in food and feed;

4. Is concerned by the steadily increasing use and identified cases of misuse of emergency authorisations granted under Article 53;

5. Is concerned that the incomplete harmonisation of data and testing requirements in some scientific fields may lead to direct negative effects on health, the environment and agricultural production;

6. Regrets the limited public availability of information on the evaluation and authorisation procedure, as well as the limited access to information; regrets that the level of transparency of the rapporteur Member States is low (acting in the framework of the approval procedure), that accessibility and user friendliness of information at the European Food Safety Authority (EFSA) stage is problematic, and that transparency at the risk management stage seems to be lacking and is also considered problematic by stakeholders;

7. Is concerned that, in some cases, the PPPs available on the market and their application by users do not necessarily comply with the relevant authorisation conditions as regards their composition and usage;

8. Emphasises that the Regulation should better reflect the need to promote agricultural practices based on integrated pest management, including by stimulating the

development of low-risk substances;

9. Highlights that many authorised PPPs have not been evaluated against EU standards for more than 15 years;

10. Is concerned that the harmonisation of guidelines in fields like ecotoxicology or environmental fate and behaviour is not yet complete;

11. Stresses that missing or incomplete guidelines are serious shortcomings that have negative consequences for the implementation of the Regulation and hence for the achievement of its objectives;

12. Highlights that available guidance documents are not always legally binding, which creates regulatory uncertainty for the applicants and brings into question the results of the evaluations carried out in the framework of the approval procedures;

***Recommendations***

13. Calls on the Commission and the Member States to ensure effective implementation of the Regulation as regards their specific roles in the approval and authorisation procedures;

14. Calls on the Commission and the Member States to acknowledge that health and environmental protection objectives should take priority over the objective of improving plant protection;

15. Calls on the Commission and the Member States to ensure full and uniform application of the hazard cut-off criteria, following existing harmonised guidance, and to make sure that substances are assessed for their risk only if there is evidence that they do not present hazardous (cut-off) properties, as required by the Regulation;

16. Calls on the Commission and the Member States when acting as risk managers in the approval and authorisation procedures, to duly apply the precautionary principle and to pay particular attention to the protection of vulnerable groups of the population, including pregnant women, infants and children;

17. Calls on the Member States to limit the authorisations granted under derogations using Article 53 of the Regulation;

18. Calls on the Commission to finalise methods to determine whether certain derogations should be applied, in particular as regards ‘negligible exposure’ or ‘serious danger to plant health’;

19. Calls on the Commission to limit the use of the confirmatory data procedure;

20. Calls on the Commission and the Member States to increase the overall transparency of the procedures;

21. Calls on the Commission and the Member States to ensure better coherence of the Regulation and its implementation with related EU legislation and policies, in particular with the Sustainable Use of Pesticides Directive;

22. Call on the Member States to ensure effective enforcement of the Regulation especially as regards controls of the plant protection products marketed in the EU, regardless of whether they have been produced in the EU or imported from third countries;

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23. Instructs its President to forward this resolution to the Council and the Commission.