PEST COMMITTEE MEETING OF 19 JUNE 2018

PUBLIC HEARING

EU AUTHORISATION PROCEDURE FOR PESTICIDES - COMMISSION APPROVAL OF ACTIVE SUBSTANCES

PREPARATORY QUESTIONS

Questions to all experts:

1. **In recent political and public debates, the presence of "data gaps" identified by EFSA have caused discussions about the validity of Commission approvals. However, data gaps do not necessarily mean that authorisation procedures cannot be positively concluded. Do you have recommendations on how to deal with data gaps in political and public communication so that they do not undermine the trust in the approval system?**

   The Commission is aware that sometimes the way in which technical issues are expressed in an EFSA Conclusion on the peer review of the pesticide risk assessment of a given active substance may be misinterpreted and therefore undermine trust in the system. One such example is the subchapter on "Data gaps": data gaps are identified by EFSA whenever data which, according to the data requirements, should have been submitted is missing.

   In these cases, EFSA further qualifies the importance of the gap for the outcome of the risk assessment (in the narrative of the conclusion, in the chapter "issues which could not be finalised" or "critical areas of concern").

   By contrast, some data gaps are of a more formal nature and without particular relevance for the outcome of the risk assessment.

   There are cases where the submission of a study "is not necessary owing to the nature of the product or its proposed uses, or it is not scientifically necessary". This is recognised in point 1.5 of the data requirements[1] which requests to submit an appropriate justification. This is the case for instance of naturally occurring substances with a low risk profile, such as pectin: applicants do not always submit studies on degradation but a justification why the study is missing, e.g. a statement that this is because the natural background of pectin in soil is expected to be higher than the additional input from the use of pectin as a pesticide.

   EFSA will record formal data gaps when no justification for not submitting the study is provided. This does not necessarily mean that the studies were necessary.

[1] 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, 3.4.2013, p.1.

Many data gaps do also not concern all uses supported by the applicant, but only a few. Such data gaps can then be addressed by applicants when submitting applications for authorisation for such uses and by Member States when evaluating the applications.

In summary, data gaps are considered by risk managers in the decision making phase. The Commission and EFSA are working on improving the way in which the outcome of the risk assessment is communicated through the EFSA conclusion.

2. **The SAM's High Level Group has been mandated to assess options for arbitration in case of diverging assessments by different competent authorities. In this regard, the biocidal products regulation has been mentioned as a possible positive example. Could you explain how arbitration is handled under the biocidal products regulation and how this is currently done for plant protection products? Are there other best practices that would be applicable to the PPP authorisation? In your opinion, would it make sense to extend arbitration also to scientific bodies other than competent authorities, particularly with a view to increase public trust in the soundness of the authorisation system?**

Regulation 178/2002 on General Food Law ('GFL Regulation')[2], which establishes EFSA, sets out a specific procedure for addressing diverging scientific opinions in its Article 30. Accordingly, EFSA exercises vigilance to identify at an early stage any potential source of divergence between its scientific opinions and the scientific opinions issued by other bodies carrying out similar tasks *i.e.* EU Agency, Commission Scientific Committee or a national scientific body. Where EFSA identifies a potential source of divergence, it contacts the interested body to ensure that all relevant data and information are shared. When a substantive divergence is actually identified, EFSA and the interested body have to cooperate to solve the divergence or to publish a joint document clarifying the scientific issues and uncertainties about the data. Where the divergence concerns a national scientific body, discussions take place in the context of the Advisory Forum of EFSA (Article 27 of the GFL Regulation), composed of all national risk assessment counterparts of EFSA and chaired by the latter[3].

More specifically, for active substances used in plant protection products, diverging views amongst Member States competent authorities or between Member States and EFSA on the assessment of active substances are addressed during the peer-review process, resolved as far as possible, and where this is not possible they are recorded in the peer-review documentation (Peer Review Report, EFSA conclusion). Where such divergences touch upon crucial elements for decision-making, the Commission can mandate EFSA to further discuss the issue and advise on the way ahead. For example, in relation to the assessment of genotoxicity, a fundamental aspect of safety

[2] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 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 (OJ L 31, 1.2.2002, p. 1).

[3] As reported in the Commission Staff Working Document, 'The REFIT Evaluation of the General Food Law (Regulation(EC) No 178/2002), SWD(2018)38, overall, EFSA's scientific outputs and especially scientific opinions have been accepted in a consensual way by both the mainstream scientific community and the national risk assessment bodies. Very few diverging opinions have emerged since the creation of EFSA and where this procedure has been applied, it has almost always delivered satisfactory conclusions. Indeed in the period 2003-2014, from a total of more than 4,500 EFSA scientific opinions, divergences of scientific opinions between EFSA and national assessment bodies have emerged only in 11 cases, seven of which were solved directly at the level of the Advisory Forum. Scientific divergences have only been confirmed in four cases, two of which concerned the same substance (for further information, see https://ec.europa.eu/food/sites/food/files/gfl_fitc_comm_staff_work_doc_2018_part1_en.pdf, p. 33).

assessments for all substances used in food and feed, following the emergence of divergent views between Member States and EFSA, the Commission mandated the Scientific Committee of EFSA to reconsider a number of key scientific aspects in this area. As a result of this mandate a scientific opinion was published to provide clarification and further guidance to risk assessors[4]. In other cases EFSA may itself mandate its Scientific Panels to look at specific issues - for example in 2012 EFSA asked its Panel on Plant Protection Products and their Residues (PPR Panel) to consider the developmental neurotoxicity potential of acetamiprid and imidacloprid. As regards divergences amongst Member States during the process for the authorisation of plant protection products, Regulation (EC) No 1107/2009 provides that all Member States of a zone shall be given the possibility to provide comments on the initial assessment of the zonal rapporteur. The legislation does not give the Commission a role in this process. Nevertheless, the Commission tries to facilitate the necessary discussion process between Member States by providing an IT infrastructure (an Interest Group on CIRCABC[5]) for exchanging documents during the discussion process within the zones and by hosting an Inter-Zonal Steering Group.

The Biocidal Products Regulation foresees a similar peer-review process organised by the European Chemicals Agency (ECHA) for resolving disagreements during the assessment of active substances, and, in addition, provides for a two-step mechanism to resolve disagreements as regards the mutual recognition of product authorisations by Member States. The BPR foresees two such processes: mutual recognition in sequence (mutual recognition of an authorisation that has already been granted in one Member State) and mutual recognition in parallel (the examination of the authorisation application for a product not yet authorised takes place jointly by several Member States). If the Member States do not agree on mutual recognition, the matter is referred to the so-called 'Coordination Group of Member States' that seeks to reach a harmonised position across the Member States. If the Member States fail to reach an agreement within 60 days, the matter is referred to the Commission which shall adopt a decision. The Commission may ask ECHA for an opinion on the scientific or technical aspects of the matter. The experience with the referral procedure shows that almost always (i.e. > 90% of the cases) the diverging matters are resolved by the Coordination Group, without the need for a Commission decision.

To resolve divergences of views between ECHA and other agencies, Article 95 of the REACH Regulation foresees that ECHA should identify early in the process "potential sources of conflict between its opinions and those of other bodies established under Community law, including Community Agencies, carrying out a similar task in relation to issues of common concern". In such cases, the Agency should contact the other body "in order to ensure that any relevant scientific or technical information is shared and to identify the scientific or technical points which are potentially contentious" and should try "to either to solve the conflict or submit a joint document to the Commission clarifying the scientific and/or technical points of conflict."

[4] https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2017.5113

[5] **CIRCABC** (Communication and Information Resource Centre for Administrations, Businesses and Citizens) is an application used to create collaborative workspaces where communities of users can work together over the web and share information and resources. CIRCABC will replace CIRCA (Communication and Information Resource Centre for Administrations), an **eGovernment application** supporting the online collaborative activities of the European Union's public administrations. http://ec.europa.eu/idabc/en/document/7400/5644.html

Lastly, ECHA and EFSA have agreed a Memorandum of Understanding[6] to ensure cooperation on issues of common interest including hazard and risk assessment, ensuring coherence in opinions prepared by the agencies, risk communication and IT practices and capacity building. The Memorandum also includes a common approach on managing conflicts of opinion and refers to existing Rules of Procedure that establish a mechanism for prevention of possible divergences of opinion.

3. **In the debate on the bee safety of neonicotinoids there has been an argument about the validity of the so-called "bee guidance document". Several stakeholders claimed that due to flaws in that guidance document the risk assessment was not reliable. However, the risk manager as well as politicians have to base their decisions on the scientific assessment of competent authorities as they are usually not qualified to judge the scientific quality themselves. Do you have recommendations on how to deal with disputed guidance documents in the future? Would some kind of an arbitration system be a possible solution here as well?**

Proper and independent risk management is not possible without a very good understanding for the scientific background on which risks are assessed. The separation of risk management and risk assessment is a separation of responsibilities to avoid conflicts of interest. It is not, however, a separation along technical qualifications.

The discussions between risk assessors and risk managers about the bee guidance document have mostly not been about the scientific part for the risk assessment (only a limited number of stakeholders were concerned about that), but about agreeing appropriate protection goals and the feasibility of the steps to be taken in the higher tiers[7] of the risk assessment.

The standard EFSA procedure for developing guidance documents foresees steps of consultation of experts and of the general public. It is of utmost importance that all relevant groups are aware of these consultations and are willing to contribute in time, in order to allow EFSA to consider their comments.

For instance, the guidance document for the implementation of the endocrine disruptors criteria[8] has been subject to several consultations: Member States and stakeholder experts were consulted twice (April-May 2017 and July-August 2017), a public consultation took place between December 2017 and January 2018 with about 2,000 comments received, a workshop with Member States and stakeholders on the guidance applicability (case-studies) took place in February 2018, and risk assessors and risk managers from the Biocidal Products and Plant Protection Products sectors were consulted in April and May 2018), respectively.

---

[6] https://www.efsa.europa.eu/sites/default/files/assets/mouecha.pdf

[7] A tiered risk assessment is done in several phases (tiers). In the first phase (tier), the screening-level assessment, basic tools (e.g. simple exposure calculations, default values, conservative assumptions) are used to conduct the assessment. Based on the results of the screening-level assessment the need for further refined risk assessment is considered. Higher tier assessments are based on a greater degree of realism and use more realistic exposure estimates, taking into account additional data to refine default worst case assumptions (e.g. results from field trials).

[8] http://www.efsa.europa.eu/en/efsajournal/pub/5311

The risk assessments – and the guidance used as basis for the risk assessments - need to provide all the accurate and precise evidence for the relevant risk management decisions that need to be done in a regulatory context. Because science is complex and often evolving, guidance documents need to evolve to remain fit for taking risk management decisions in the respective regulatory context.

Keeping guidance documents updated to science and "fit" for good regulatory decisions is not an easy task, in particular because the protection goals may vary depending on regions, particular circumstances, etc. As a consequence, these protection goals need to be further clarified by risk managers, in consultation with risk assessors, so that risk assessors know what the needs of risk managers are and can design fit-for-purpose guidance documents. This process of defining protection goals is important as the protection goals of an agro-ecosystem, an industry area, and a nature conservation area, or the situation in different geographical areas, are different and therefore the benchmarks for the corresponding risk assessments will vary.

The Commission intends to intensify the work on defining and agreeing specific protection goals for guidance documents in the area of pesticide use in the near future, in consultation with the risk assessors, the risk managers in the relevant Regulatory Committee, and all stakeholder groups.

4. **Regulation 1107/2009 specifies different maximum approval periods (first approval, renewal of approval, candidates for substitution, low-risk substances etc.) rather than clearly defining approval periods. This gives room for manoeuver to the risk manager. On the other hand the political decision on the approval period can also lead to confusion about the safety of a substance and undermine trust in the scientific assessment, if the risk manager decides for a shorter period than allowed according to the risk assessment classification. Would you say that the current system of maximum approval periods is fit for purpose, would you recommend any changes, particularly with a view to public perception?**

Providing different maximum approval periods for different groups of active substances (staggered according to the risk-profile established during their assessment, i.e. 15 years for low-risk substances, 10 years for normal active substances, 7 years for substances identified as candidates for substitution) is a useful tool, as it combines the periodic re-evaluation (and update) of active substance dossiers with an incentive for producers to invest in the development of innovative substances of lower risk.

An active substance shall be approved as a candidate for substitution pursuant to Article 24 of Regulation 1107/2009 when its hazard profile compares unfavourably to those of other substances having similar functions. A comparative assessment shall be performed by Member States when evaluating an application for authorisation for a plant protection product containing an active substance approved as a candidate for substitution.

Furthermore, for a limited number of substances the Commission decided for a shorter approval period instead of the standard periods on a case-by-case basis for special reasons identified during the assessment of the substance.

This approach strikes the right balance between predictability for the applicants and sufficient flexibility for risk managers to address special needs identified in the assessment of a substance.

Questions to the Commission:

Topic: Confirmatory information

14. Could you explain why there is no significant decrease in the number of substances approved through the confirmatory information derogation, despite the request of the Ombudsman?

The Commission has recently submitted a detailed report[9] to the Ombudsman on how it applies the provisions on confirmatory data foreseen in Article 6 (f) and point 22 of Annex II to Regulation (EC) No 1107/2009.

Article 6(f) allows to subject the approval of an active substance to the condition of "*submission of further confirmatory information to Member States, the Commission and the European Food Safety Authority), where new requirements are established during the evaluation process or as a result of new scientific and technical knowledge*". Furthermore, in exceptional cases, submission of confirmatory information may be also required in accordance with Annex II, point 2.2(b), in order to increase confidence in the decision to approve the substance. The report explains that the following three types of confirmatory information have been requested in approval or renewal Regulations:

(a) **Confirmation of the technical specification of the active substance**: In some cases, the confirmatory information is needed to link the technical specification of an active substance, i.e. its precise composition as manufactured in the past and used for the application dossier to more recent specifications of the substance as manufactured for use in pesticides. The reason is to demonstrate that there is no significant difference that may impact the risk assessment. This situation occurs because there is a considerable time lapse between the preparation of the dossier, for which material generated in a pilot production may be used, and manufacturing of the substance at commercial scale starts only after the approval. This situation relates to the development of technical knowledge in the production process and to the need to increase confidence in the decision.

(b) **Developments regarding the classification of a substance in accordance with Regulation (EC) No 1272/2008**: In some cases, a harmonised classification is adopted during the approval procedure, at a stage where the applicant is precluded from submitting new information. In cases where the classification does not lead to the fulfilment of the so-called cut-off criteria, a new classification may nevertheless trigger the requirement for additional data, for example additional studies on one or several metabolites of the substance. The request for confirmatory information follows in these cases from a new requirement established during the evaluation process and the Commission sets a clear deadline for the submission of the requested information.

[9] https://www.ombudsman.europa.eu/cases/correspondence.faces/en/93729/html.bookmark

(c) **The request for confirmatory information may also relate to new data to be generated in accordance with new guidance which did not yet exist when the application was submitted or even not at the time of conclusion of the evaluation process.** This is in accordance with Article 6(f) of Regulation (EC) No 1107/2009. It is about information that cannot yet be delivered at the moment of decision on approval or renewal of approval. If not requested under the confirmatory information procedure as a condition for the approval, the applicant would only need to provide such information in the context of the next renewal of the substance. The request for confirmatory information is thus a tool to obtain in a timely manner more data or studies that were not required at the time of submission of the application for approval or renewal of approval. A typical example is the request for information on the impact of water treatment processes on substances that may be formed in drinking water. Other requests related to the potential for endocrine disruption at a moment where neither concrete scientific criteria nor guidance were available so that the regulators could not specify the studies or tests to be performed – in such cases the deadline for submission of the confirmatory information is linked to the date of availability of an appropriate guidance document.

The Commission informed the Ombudsman that a total of 65 Regulations on approval or renewal of approval were adopted, to which the conditions set out in Regulation 1107/2009 applied in full, of which 24 contained requests for confirmatory information. Out of these 24 requests for confirmatory information, 8 concerned technical specifications. A number of additional decisions on approvals or renewal of approvals adopted since the Regulation became applicable, were based on dossiers still submitted under Directive 91/414/EEC. In accordance with the transitional measures set out in Article 80 of Regulation 1107/2009, decisions on the approval of these substances had to be taken in accordance with the provisions of the earlier Directive. Under that Directive the concept of confirmatory data was already used, but the situations in which confirmatory data could be asked for was not framed in the legislation, as it is now.

15. In 2013, the European Ombudsman was faced with the complaint on the derogations to approve pesticides even when the EFSA has not concluded that they are safe to use and when important data gaps still exist. These derogations have allowed for bans and discontinuation of use of numerous pesticides to be avoided, and have gradually become a standard procedure in DG SANTE. In 2016, the EC agreed on the conclusions by Ombudsman to change these practices. However, the Commission has not implemented the changes agreed in 2016 and thus is not able to demonstrate that the confirmatory data procedure is being used restrictively and that oversight of Member States' use of pesticides is improved. What are your justifications and explanations for not dealing with the problem?

The Commission considers that it applies the provisions on confirmatory data in accordance with the rules foreseen in Regulation 1107/2009 and has given a clear and detailed account on the use of confirmatory data requests under the Regulation to the Ombudsman in a report submitted in February 2018 (see also response to question 14). The NGO who complained to the Ombudsman in 2013 informed the Commission that it is dissatisfied by that report. The Commission has responded in May 2018 directly to the NGO concerned, providing further explanations and clarifications on all points raised by the NGO.

20. Can the Commission confirm how it and its relevant regulatory agencies have implemented proposals arising from decisions made by the Ombudsman that apply in the approval of an active substance under Regulation (EC) 1107/2009, in particular the decision regarding the Commission's use of the confirmatory data procedure dated 18 February 2016?

The Commission has recently submitted a detailed report to the Ombudsman on how it applies the provisions on confirmatory data foreseen in Article 6 (f) and point 2.2 of Annex II to Regulation (EC) No 1107/2009 – see the response to question 14 for further details. As set out in the report to the Ombudsman, EFSA is always involved in the assessment of the confirmatory information submitted by the applicant and conducts a peer review when necessary. A decision on whether a full peer review is warranted is taken by the Commission on a case-by-case basis following consultation of EFSA and Member States.

21. Does the Commission foresee any changes to the EU's pesticide authorisation process that will limit use of the confirmatory data procedure?

The Commission will continue to respect its commitment to recur to the request of confirmatory information in a restrictive manner as provided by the Regulation.

29. Why is the Commission using the "confirmatory information" procedure (article 6) for approvals, in cases where the legal conditions for this derogation are not applicable ("where new requirements are established during the evaluation process or as a result of new scientific and technical knowledge")?

The Commission considers that it fully respects the conditions set out in Regulation (EC) No 1107/2009 as set out in the response to question 14.

30. Examples of pesticides with carcinogenic metabolites, approved by Commission, are Thifensulfuron, Mesotrion, Metsulfuron, Iprovalixarb, among others. Can the Commission confirm use of confirmatory procedure in such cases?

Confirmatory information was requested in the Regulations renewing the approval of the substances iprovalicarb, thifensulfuron-methyl, iodosulfuron, mesotrione, metsulfuron-methyl, and Lambda-cyhalothrin in order to assess the potential hazardous properties of one or more of their metabolites. This became necessary as EFSA identified during the peer-review process potential hazardous properties of the active substance which were not known to the applicant before – and that were not even identified by the rapporteur Member State in the draft assessment report - and which triggered the need for generating additional information about some metabolites. This clearly falls under the scope of confirmatory information as set out in Regulation (EC) No 1107/2009.

Additionally, for some of the substances mentioned and for other cases, the metabolites for which additional data were requested are not expected to be present in groundwater or in crops (or expected to lead to exposure of humans and/or animals from other sources) in all pertinent use scenarios. Rather, the decision to request additional information was taken as a prudent measure to ensure that there was an EU harmonised conclusion on the relevance of metabolites to allow for consistent and harmonised evaluations of plant protection products by Member States. For example, in the case of iprovalicarb, the metabolite PMPA was confirmed to be relevant due to its acute toxicity but also had an incomplete dataset on genotoxicity. According to Regulation 1107/2009, a relevant metabolites shall not occur at levels above 0.1 μg/L in groundwater. The EFSA Conclusion indicated that the metabolite may occur above this threshold in

groundwater present in soils with a low clay content but it is still possible to use the substance (e.g. on other types of soil) such that groundwater contamination does not occur and this is reflected in the approval conditions which specify that Member States must pay particular attention to protection of groundwater if the substance is authorised in regions with low clay content in soil. Nevertheless, further data on genotoxicity was requested as confirmatory data to complete the assessment of this metabolite. Following the assessment of the submitted confirmatory information by the rapporteur Member State and a review by EFSA and other Member States, EFSA published a Technical Report which concluded that PMPA is unlikely to be genotoxic. The confirmatory information thus indeed confirmed that the approval criteria were fulfilled for the active substance.

31. Why does the Commission allow carcinogenic substances (in these cases pesticide metabolites) on the market, awaiting "confirmatory data", whereas the Regulation bans these, with only certain narrow exceptions where human exposure can be ensured to be negligible (the product is used in closed systems or in other conditions excluding contact with humans and where residues of the active substance, safener or synergist concerned on food and feed do not exceed the default value set in accordance with point (b) of Article 18(1) of Regulation (EC) No 396/2005).

The cut-off criteria in Regulation 1107/2009 apply to active substances and not to metabolites.

Metabolites must be fully assessed on a case by case basis depending on where they are predicted to occur and taking into account the level of exposure as well as their intrinsic properties. Information must be provided by applicants to determine their (eco)toxicological relevance. Metabolites that have a genotoxic or carcinogenic potential or are toxic for reproduction are relevant metabolites and according to Regulation 1107/2009 cannot be present above 0.1 μg/L in groundwater following use of a plant protection product. In such cases the approval or authorisation would not be possible. If present in crops or if operators or workers would be exposed to them, a full risk assessment must be undertaken to establish whether there would be any possible impact on human health – however, the Regulation does not contain the same rule for metabolites that are carcinogenic or toxic for reproduction as for active substances with such hazardous properties, i.e. that the active substances cannot be approved unless there is negligible exposure to them.

As explained in detail in the report to the Ombudsman (see response to question 14), confirmatory information was requested in situations where the suggestion that a stricter classification applies only appeared during the peer-review process or in the EFSA conclusions, i.e. no such classification existed prior to dossier submission and not even the rapporteur Member State considered it necessary. This is in particular relevant for the assessment of the toxicity of metabolites if EFSA concludes that the parent compound should be classified in a certain manner, so that the classification leads to "new" requirements which could not be foreseen by the applicant and are therefore one of the cases for requiring confirmatory information. For example an EFSA suggestion for classification of an active substance as carcinogenic category 2 may trigger these impacts.

Topic: Extension of approvals

16. **How does the Commission justify the fact that for almost every pesticide the current 10 years approval period is extended? And how does DG SANTE justify the extension for "hazard" pesticides (Flumioxazin 2,5 years; Linuron 4 years; propiconazole 4,5 years; Iprodion 5 years) while the contact of these substances with humans should be excluded according to Regulation 1107/2009?**

25. The 10 year approval period for an active substance can be extended by technical extension, taking the total period to over the 15 years limit given in Article 14 (2) of 1107/2009 (e.g. up to 16,5 years for Pymetrozine, Diquat). How many renewal decisions are preceded by technical extension of approval based on Article 17? How does the Commission justify these technical extensions? What are the primary reasons for these Article 17 extensions? What does the Commission do to ensure decisions are taken on time?

28. How does the Commission justify the extension for substances classified as "hazardous" (e.g. Flumioxazin 2,5 yrs, Linuron 4 yrs, Propiconazole 4,5 yrs, Iprodion 5 yrs) and how does it ensure that this extension is subject to "excluding contact with humans" (negligible exposure) according to Annex II of Regulation 1107/2009?

The three questions are closely related and are treated jointly. As explained by the Commission in its answer 35 to the questions sent prior to the meeting of the PEST Committee on 12 April, the process for reviewing the approval of an active substance according to Regulation (EC) No 1107/2009 should take three years. First, the applicant has to submit an application for renewal three years before the expiry of approval. The full dossier, containing all the studies and tests must be submitted 2.5 years before the expiry of approval to the rapporteur Member State (RMS). The RMS has 12 months to evaluate the substance, finalise the draft renewal assessment report and submit it to EFSA. EFSA then has 11 months in total to produce the conclusion on the peer review. The Commission should within 6 months from the publication of the EFSA Conclusion present a review report and a draft Regulation on the renewal or non-renewal of approval of the active substance to the Member States in the Standing Committee of Plants, Animals, Food and Feed for a vote.

However, Article 17 of Regulation (EC) No 1107/2009 states unequivocally that "w*here for reasons beyond the control of the applicant it appears that the approval is likely to expire before a decision has been taken on renewal, a decision shall be adopted in accordance with the regulatory procedure referred to in Article 79(3), postponing the expiry of the approval period for that applicant for a period sufficient to examine the application.*"

In the light of this provision and in order to ensure legal certainty, the decision-making has to be finalised before expiry of the approval of an active substance. Approvals cannot be left to expire when, for reasons beyond the control of the applicant, a decision on the renewal or non-renewal cannot be taken by the Commission before expiry of the approval of an active substance. Consequently, in such cases, the Commission is obliged to extend the approval periods for active substances until the renewal process is finalised.

Experience has shown that for practically all active substances, the evaluation of applications for renewal of approval is rarely or never concluded within the time period

foreseen by the Regulation. The Commission is concerned about these delays in the various steps for the evaluation of the dossiers submitted for the renewal of approval of active substances, which, are in general for reasons beyond the control of the applicant and, therefore, lead to the need to extend the approval of substances.

Delays occur mainly during the assessment by the RMS, but also during the EFSA peer review, or during the risk-management process. Each active substance is different and the evaluation processes for substances are delayed for different reasons. Member States report that increasingly complex assessments, the need for re-assessment of old studies, the size of the dossiers, resources, the alignment with the classification and labelling process under the CLP Regulation, and the absence of guidance for Article 4(7) and negligible exposure (this was the case for flumioxazin and pymetrozine) all contribute to delays of the evaluation process. The Commission has repeatedly reminded Member States in the Standing Committee of their obligations to respect the deadlines foreseen in Regulation (EC) No 1107/2009 for the evaluation of application dossiers. In addition, in February 2017, the Commission sent a letter to all Member States in delay with their evaluations, asking them to justify the delays and comply with the deadlines.

It should be noted that in the transition period from the earlier Directive 91/414/EEC to Regulation (EC) No 1107/2009, i.e., between 2009 and 2011, the Commission granted extensions of approvals for substances expiring before June 2014 in order to balance the workload for the evaluating authorities, but most importantly in order for the applicant to generate data to comply with the new data requirements that were eventually adopted in 2013. This was the case for flumioxazin, linuron, propiconazole, iprodione, diquat and pymetrozine. The new data requirements reflected the update in scientific and technical knowledge and provided for a more in-depth assessment of the active substances. Furthermore, Implementing Regulation 844/2012 setting out the provisions necessary for the implementation of the renewal procedure for active substances had to be adopted before the renewal process could start. The Commission considered that the benefits of awaiting the new data requirements and entering into force of the new renewal procedure and the resulting improved basis for evaluation of the safety of the substances outweighed the drawbacks of postponing the evaluation by a limited amount of time.

Where, during the evaluation of an application, Member States consider that additional information is required, they can request additional information and 'stop the clock' for the evaluation. Although for renewals of approval, recourse to this procedure can in theory not extend the period for examination and finalisation of the draft Assessment Report, in reality it does (this was the case for iprodione, propiconazole, linuron, diquat, pymetrozine). For the assessment of approvals of new active substances the timeline for producing the draft Assessment Report can be extended by 6 months. EFSA can also use a stop-the-clock procedure "where it considers that additional information from the applicant is necessary". This may cause a slight delay of the finalisation of the EFSA conclusion (this was the case for iprodione, propiconazole, diquat, pymetrozine and linuron).

In the decision-making phase, it has sometimes proved to be difficult for a decision to be taken shortly after the presentation of the draft review report and the draft Regulation (usually presented to the standing Committee within 6 months from the date of publication of the EFSA Conclusion). As the Commission shall endeavour to find solutions which command the widest possible support within the Committee – as require

by Article 3(4), 2nd subparagraph of Regulation (EC) No 182/2011[10], for difficult cases multiple rounds of discussions in the Standing Committee were sometimes required and, therefore, more time was needed in order to finalise the decision-making process (this was the case for pymetrozine and diquat).

27. Regulation 1107/2009 prohibits the use of active substances that are classified as carcinogenic, mutagenic or toxic for reproduction (Category 1A or 1B). However, the herbicides Flumioxazin and Glufosinate, both classified as toxic for reproduction (Cat. 1B), are still approved for use in the EU. How does DG SANTE explain this?

Active substances approved under the earlier Directive 91/414/EEC were deemed to have been approved under Regulation 1107/2009. The transitional provisions in the Regulation also set out that for those substances, including flumioxazin and glufosinate, the new approval criteria, including the "cut-off criteria" would be applicable at the time of renewal of the active substance - this intention of the co-legislators is explicitly reflected in Recital 10[11] of Regulation 1107/2009. As regards the specific case of flumioxazin, the decision-making process concerning the renewal of the approval of the substance is ongoing with a decision expected later in 2018 (as also outlined in the answer to question 16). As regards glufosinate, the applicant has withdrawn the application for renewal of approval of the active substance and the approval will expire on 31 July 2018.

11. Why are there delays between the assessment of EFSA and a decision at Commission level?

According to Regulation (EC) 1107/2009 and its implementing Regulations (844/2012 and 1141/2010) the Commission shall within 6 months after receiving the EFSA conclusion on the peer review of an active substance, present a draft review/renewal report and a draft Regulation to the Standing Committee on Plants, Animals, Food and Feed. The Commission is obliged to undertake a number of steps before it can present the draft review/renewal report and the draft Regulation to the Standing Committee, including a thorough analysis of the EFSA conclusion, the assessment report prepared by the Rapporteur Member State, consideration of other legitimate factors (where relevant), preparing the draft review/renewal report and allowing the applicant to submit comments, as well as preparing the draft Regulation and notifying it to the WTO under the TBT agreement.

Additional delays between the assessment of EFSA and a decision at Commission level may occur once the renewal/review report reaches the Standing Committee on Plants, Animals, Food and Feed and discussions with Member States start. These delays do not occur in all cases but for complex / sensitive cases multiple rounds of discussions in the Standing Committee are required before the decision-making process can be finalised.

[10] 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, (OJ L 55, 28.2.2011, p. 13–18).

[11] […] *In order to achieve the same level of protection in all Member States, the decision on acceptability or non-acceptability of such substances should be taken at Community level on the basis of harmonised criteria. These criteria should be applied for the first approval of an active substance under this Regulation. For active substances already approved, the criteria should be applied at the time of renewal or review of their approval.*

Topic: elements taken into account in the decision making

5. There are many concerns about glyphosate next to carcinogenicity, for example, concerns about the loss of farmland biodiversity, water contamination, soil health, dependence of farmers on few big corporations, superweeds etc. In your view, does the current legal framework for pesticides in the EU allow for the consideration of these broader societal issues in the authorization process?

Should the legislation be improved so that these broader concerns can be taken into account (see Prof. Dr. Hensel's statement in the session of 15 May that glyphosate is a proxy for bigger societal issues). Is the current framework focusing too narrow on safety issues (and right now even only on carcinogenicity), therefore placing too much responsibility on a scientific agency (EFSA)?

A comprehensive assessment of the potential hazard and risks of active substances and of the plant protection products that contain such substances forms an important element of the EU regulatory system for pesticides. Overall, the EU legislation on pesticides is broader than the **Regulation on placing on the market of plant protection products** (Regulation (EC) No 1107/2009), and other legal instruments apply as well.

The overall objective of Regulation 1107/2009 is to ensure a high level of protection of 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. This means that a safety assessment for human health but also for animals and other non-target organisms and the environment, including different compartments such as groundwater, must be conducted. A broad and comprehensive range of scientific aspects is considered in the risk assessment including in addition to considerations relevant for human health, for example, impacts on water quality and the impact on non-target species. Carcinogenicity is therefore not the only focus. The legislation makes it clear that safety must be demonstrated for a broad range of criteria before substances and products are placed on the market.

Furthermore, under the **Directive on Sustainable Use of Pesticides (SUD – Directive 128/2009/EC)** Member States have developed National Action Plans which set objectives and targets to reduce the risks and impacts of pesticide use to humans and the environment, requiring the use of integrated pest management (IPM) and alternative approaches to pesticides (see also Commission's report to the European Parliament and the Council 587/2017[12]). Among other measures, the SUD obliges Member States to prohibit or minimise the use of pesticides in areas used by the general public (e.g. parks, playgrounds) and protected areas as defined under the Water Framework Directive or the Habitats Directive (e.g. Natura 2000 areas).

Additional rules on pesticide use have been adopted in the context of other legislation. For example, guidance issued to implement the current **Habitats Directive**[13] recommends that no pesticides are applied in Natura 2000 areas. Under the current **Common Agricultural Policy (CAP),** the use of pesticides is banned in productive "ecological focus areas". Further, the new CAP-proposal published on 1 June 2018

[12] https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_sup_report-overview_en.pdf

[13] Council Directive 92/43/EEC of 21 May 1992 on the conservation of natural habitats and of wild fauna and flora; *OJ L 206, 22.7.1992, p. 7–50*

provides that Member States consider in their strategic plans a more sustainable use of pesticides, aiming to further reduce exposure to them. Member States will be evaluated as regards achieving this objective.

6. **The Commission as risk manager is, according to current EU law including case law of the CJEU (e.g. Case T-177/13 Test BioTech), not obliged to follow the EFSA opinion. As a politically accountable institution the Commission has discretion to consider minority opinions, but also consider other legitimate factors. Has the Commission done that in the process of authorizing glyphosate, and if so, which factors were considered and how?**

   The Commission proposed to renew the approval of glyphosate based on the extensive scientific and technical knowledge available, including the opinion by the European Chemicals Agency (ECHA) received on 15 June confirming that there is no justification to classify glyphosate as a carcinogen[14]. The criteria for approval as laid down in the EU legislation on pesticides were clearly satisfied and no concerns were raised in the EFSA Conclusion that precluded the renewal of approval.

   In accordance with Article 13 of Regulation 1107/2009, the Commission took additional legitimate factors into account when setting the new period of approval. While a large amount of information on the active substance glyphosate already exists, additional information on glyphosate is being published at an exceptionally high rate compared to other active substances. Therefore possibilities of rapid future developments in science and technology had to be taken into account when deciding on the length of the approval period of glyphosate, also bearing in mind the fact that glyphosate is the most widely used herbicide in the Union.

   Moreover, there had been considerable debate on glyphosate in the public sphere. The European Parliament also adopted several Resolutions on the matter and the Commission paid close attention to the European Citizens' Initiative[15], calling specifically for a ban of glyphosate in one of its three aims. Therefore, the Commission proposed to set the new period of approval of glyphosate at 5 years instead of the maximum period of 15 years.

7. **Why does the Commission insist that it is obliged to follow EFSA's lead in the authorization procedure?**

   Regulation (EC) 1107/2009 and its subsidiary legislation require that the scientific conclusions of EFSA are taken into account in decision making. EFSA was created to take on the role as an independent scientific point of reference in risk assessment and under the General Food Law it is stated that the opinions of EFSA are relevant to inform risk management decisions. With regards to pesticide substances EFSA coordinates the peer review and therefore its Conclusions are the result of a comprehensive process that ensures full consideration of different scientific views and opinions and a thorough scrutiny of the assessment undertaken by the Rapporteur Member State. Therefore, the EFSA Conclusions provide the most objective basis for informing the Commission decisions. Nevertheless, the Commission agrees that it is not obliged to follow EFSA's views and can also diverge from the EFSA Conclusion if there are objective reasons to do so, and taking into account other legitimate factors and risk management considerations.

[14] https://echa.europa.eu/-/echa-s-opinion-on-classification-of-glyphosate-published
[15] http://ec.europa.eu/citizens-initiative/public/initiatives/successful/details/2017/000002

8. Is the Commission the right institution to consider other legitimate factors, and as such to take into account broader societal issues regarding pesticides as mentioned above?

The Commission's role is to implement correctly the legislation concerning plant protection products that has been adopted by the European Parliament and the Council.

Article 13 of this legislation specifically refers to other legitimate factors as a basis for a Regulation on the approval/renewal or non-approval/non-renewal of an active substance. It should be recalled that the decision-making process is a shared responsibility between the Commission and the Member States, who examine and vote on the Commission's proposed decisions in the Standing Committee on Plants, Animals, Food and Feed. In this role they also scrutinise the Commission's considerations of other legitimate factors.

In addition, the European Parliament has already adopted several Resolutions related to the decision-making on active substances (for example glyphosate and bentazone).

10. Is the Commission politically pressured to take a decision?

The Commission has a legal obligation to take decisions on applications for an approval/renewal of approval of an active substance under Regulation (EC) 1107/2009. Failure to do so could lead to Court proceedings launched by applicants.

22. Notwithstanding EFSA's scientific risk assessment, what other elements does the Commission take into account when coming forward with an authorisation or non-authorisation proposal for an active substance?

As stated in response to question 7, the EFSA Conclusion on an active substance forms the core basis for decision-making since it is the result of the comprehensive scientific evaluation and peer-review process. However, in addition to the EFSA Conclusion and its background documents, the Commission also considers the assessment report as prepared by the rapporteur Member State and co-rapporteur Member State, comments received by the applicant (on both the EFSA Conclusion and the draft review/renewal report) and also any other comments and correspondence submitted by other interested parties e.g. NGOs, growers associations, MEPs, citizens.

The Commission consults and discusses all draft proposals concerning approval or non-approval of active substances both internally amongst different services and with Member States. The comments and views of Member States also play a role in developing a final proposal and indeed decisions are the shared responsibility of the Commission and the Member States.

Topic: guidance documents

34. In accordance with its mandate, EFSA regularly updates its guidance documents. Please can you explain the process for updating guidance documents used by EFSA, and why there may be delays or other obstacles in this process? According to the Commission, what could be done to overcome these delays/obstacles? For example, where in the process is the updated guidance on soil organisms, and when can it be expected to be adopted? How about the guidance on bees, which has already been applied in the EFSA review of the three neonicotinoids? According to the Commission, are there other examples of updated guidance which are still waiting to be officially adopted? If so, what are they?

In its response to question 38 sent prior to the meeting of the PEST Committee on 12 April 2018, EFSA explained how guidance documents are drawn up and updated and in its response to question 58 of that same batch of questions and in its response to question 14 of the batch of questions sent to the Authority prior to the 7 June meeting of the PEST Committee, it addressed the update of the guidance on soil organisms.

EFSA has published a number of scientific opinions in the area of environmental risk assessment, compiling the state of science for different groups of organisms (non-target plants, non-target arthropods, soil organisms). These scientific opinions will serve as a starting point to update the corresponding guidance documents, from which some were developed before the creation of EFSA. EFSA has stressed in these opinions that protection goals need to be further defined by risk managers, and is waiting for input of the Commission in this aspect.

As already explained in the response to question 3, the Commission intends to intensify the work on defining protection goals in the area of pesticide use in the near future, in consultation with risk assessors, risk managers, and stakeholders. The Commission considers this process of defining protection goals important because the protection goals of an agroecosystem, an industry area, and a conservation area, or the situation in different geographical areas, are different and therefore the corresponding risk assessments will vary. Furthermore, the protection goals set in legislation often need to be further clarified by risk managers, in consultation with risk assessors, so that risk assessors know what the needs of risk managers are and can design fit-for-purpose guidance documents.

EFSA is also working on guidance documents which are related to the assessment of potential risks to humans, including operators (who apply pesticides), workers (who enter fields treated with pesticides), bystanders (people standing close to an area where pesticides are applied), and residents (people living close to areas where pesticides are applied). The guidance for bystanders and residents also includes assessing the risks to children. An update of this guidance document has been mandated to EFSA recently.

Further developments in the area are a guidance document on dermal absorption, which feeds into the assessment of exposure mentioned above. As regards consumers, guidance on residues and metabolites has been also recently developed by EFSA.

The Bee Guidance Document (Bee GD) was criticised by industry and some Member States, who consider that the approach used is too strict because of the protection goals chosen and the complexity in the higher tiers of the assessment. Many efforts were made to find a compromise, including a workshop and the definition of a stepwise implementation plan discussed with Member States experts (mostly risk managers but some risk assessors were present as well).The Commission remains determined to get the Bee GD endorsed as recently reaffirmed in the EU Pollinators Initiative[16].

Another guidance document waiting to be adopted is the EFSA guidance document on the residue definition for the assessment of the risk to consumers from residues in food (i.e. what the residue of a pesticide is if present on a food stuff) of 2017. Member States expressed strong concerns about the implementation of the Guidance Document and the additional resources needed. Industry also commented on the need of a transitional period. The Commission held a discussion in the Standing Committee and the majority of Member States agreed to better identify the impact of the guidance document before

[16] COM/2018/395 final, available at : https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1528213737113&uri=CELEX:52018DC0395 .

implementing it and requested training from EFSA in order to be able to implement the more complex definition.

35. **Guidance documents used by EFSA in pesticide risk assessments have to be approved by EU Member State representatives gathered in the SCoPAFF ("note-taking"). A recent report for the European Parliament's Research Service (EPRS) states that "this arrangement – guidelines voted by risk managers – is unique to the pesticides regulatory regime" (Bozzini, 2018, p. II-33). Is the Commission aware of any other areas in which EFSA guidance documents need to be approved by EU Member States? Why would the process be different for pesticides than other food safety related matters?**

Although Article 77 of Regulation 1107/2009 indeed foresees that the Commission may – "*in accordance with the advisory procedure referred to in Article 79(2), adopt or amend technical and other guidance documents such as explanatory notes or guidance documents on the content of the application concerning micro-organisms, pheromones and biological products, for the implementation of this Regulation*", , in practice guidance documents for risk assessment are not voted on, as implied by the report, but they are developed by EFSA (risk assessors) and after publication taken note of by consensus by the Member States in the Standing Committee on Plants, Animals, Food and Feed (risk managers). The Commission, Member States, and EFSA discuss and agree on an implementation date for the guidance document and add a reference so that the document can be more easily searched also through the Commission website. This is a direct continuation from the practice under the earlier Directive 91/414/EEC. It ensures that any new guidance document is applied by all Member States and EFSA from the same point in time and gives a clear indication to applicants as from which time dossier submissions will have to comply with the new standard.

However, it is indeed correct that such an approach is unique in the Pesticides Regulation, whereas in other areas, the development and adoption of scientific guidance documents is overseen by the relevant Agency which consults risk managers before finalising the guidance. This is the case for example for ECHA for REACH, CLP and the Biocidal Products Regulation[17].

Lately, efforts have been made in the context of the pesticides Regulation to consult risk managers before EFSA finalises a guidance document. This is the case with the last guidance document developed by EFSA and ECHA (implementation of endocrine disruptor criteria), where a formal consultation of risk managers was done before the guidance was finalised by the agencies on 7 June 2018.

Topic: Parliament Resolution on glyphosate

36. **In its Resolution of 13 April 2016, the European Parliament stated the following: "*whereas the draft implementing regulation does not, however, contain any legally binding risk mitigation measures, despite a high long-term risk found for almost all uses of glyphosate for non-target terrestrial vertebrates, including mammals and birds*;". The Commission failed to respond to this position in its formal response to the EP Resolution of 20 July 2016. Could the Commission justify why it did not adopt any restrictions/legally binding risk mitigation**

17 https://echa.europa.eu/documents/10162/13608/mb_63_2013_revision_consultation_procedure_guidance_en.pdf/f32a9a0f-fc05-4169-921e-f0c16dc51ae4

measures as part of the approval decision, despite the high environmental risks found by EFSA?

The response of the Commission to the specific points mentioned in Recital R of the above-mentioned European Parliament's Resolution was subsumed in its response to Point 1 of the Resolution, and in particular in the following paragraph:

"[…] Regulation (EC) No 1107/2009 provides for renewal of the approval of an active substance if the approval criteria are satisfied (Article 14(1)). The Commission considers that it is implementing the regulatory framework agreed by the co-legislators, and insofar is not exceeding its implementing powers."

In fact, the risk for non-target terrestrial vertebrates, including mammals and birds, was not identified as a critical concern in the EFSA Conclusion, because the assessment concluded for at least one of the representative uses that the risk was expected to be low. In line with Article 4(5) of Regulation 1107/2009, the approval criteria for an active substance shall be deemed to be satisfied where it has been established that at least one representative use fulfils those criteria. Refinements in the assessment of the other representative uses can be addressed by Member States in the context of the procedure for product authorisation.

Recognising that EFSA could not exclude a risk for non-target terrestrial vertebrates for some, but importantly not all, of the representative uses, the Commission adopted a specific provision in the approval conditions for glyphosate that Member States, when granting authorisations for glyphosate-containing plant protection products, must pay particular attention to the risk to terrestrial vertebrates.

As a consequence, Member States must assess the risks to terrestrial vertebrates when evaluating applications for authorisations for plant protection products at national level, based on suitable information that must be made available by applicants. Member States can only grant authorisations if the refinement of the assessment, e.g. through suitable higher-tier studies, allows to conclude a low risk for terrestrial vertebrates under the environmental circumstances prevailing on their territory.

37. In its Resolution of 13 April 2016, the European Parliament stated the following: "*whereas use of the non-selective herbicide glyphosate kills not only unwanted weeds, but all plants, as well as algae, bacteria and fungi, thereby having an unacceptable impact on biodiversity and the ecosystem; whereas as such, glyphosate fails to comply with point (e)(iii) of Article 4(3) of Regulation (EC) No 1107/2009*". The Commission failed to respond to this position in its formal response to the EP Resolution of 20 July 2016. Could the Commission justify why it considers that glyphosate complies with the approval criterion in point (e)(iii) of Article 4(3) of Regulation 1107/2009?

The response of the Commission to the specific points mentioned in Recital R of the European Parliament's Resolution was subsumed in its response to Point 1 of the Resolution, and in particular in the following paragraph:

"[…] Regulation (EC) No 1107/2009 provides for renewal of the approval of an active substance if the approval criteria are satisfied (Article 14(1)). The Commission considers that it is implementing the regulatory framework agreed by the co-legislators, and insofar is not exceeding its implementing powers."

The assessment of the impact on biodiversity and the ecosystem of extensively used herbicides including but not limited to glyphosate was discussed at one of the meetings of Member States experts organised by EFSA in the context of the peer-review. Such an assessment requires consideration of indirect effects on non-target organisms via trophic interaction, which is dependent on the specific landscape setting, including the availability of alternative food habitats for farmland species and the spatial and temporal intensity of use of herbicidal or insecticidal plant protection products at this landscape. While, following their exchange of views, the experts considered this as an important risk management issue, it was not identified as a critical area of concern in the EFSA Conclusion.

It must be noted that indirect effects on non-target organisms via trophic interaction are inherently and inevitably linked with the intended effects of herbicides, i.e. eliminating other plants competing with the crop to be protected, and are not specific to glyphosate. Moreover, the efficacious application of non-chemical alternatives to herbicide use, such as mechanical weeding, ultimately leads to the same effects.

Nevertheless, recognising that risk assessors considered this as an important risk management issue, the Commission adopted, as part of the Regulation renewing the approval of glyphosate in 2017 a specific provision in the approval conditions for glyphosate that Member States, when granting authorisations for glyphosate-containing plant protection products, must pay particular attention to the risk to diversity and abundance of non-target terrestrial arthropods and vertebrates via trophic interactions.

As a consequence, Member States must assess the risks to diversity and abundance of non-target terrestrial arthropods and vertebrates via trophic interactions when evaluating applications for authorisations for plant protection products at national level, based on suitable information that must be made available by applicants. Based on the results of their assessments, when found necessary, Member States must then impose mandatory risk mitigation measures (such as obligation to keep vegetated buffer strips/no-spray zones, limitation to treatment of alternate rows only in orchards and vineyards) in the authorisation conditions that reflect the realities and possibilities under the environmental circumstances prevailing on their territory.

Topic: Application of the cut-off criteria

26. According to Regulation 1107/2009, an active substance, safener or synergists shall only be approved if it is not, or has not to be, classified as CMR 1A or 1B, subject to two possible narrow derogations. How many substances have not been approved based on these criteria since the date of application of 1107/2009? How many have been approved subject to a derogation?

Several decisions have been taken not approving active substances that are classified or are proposed to be classified as carcinogenic, mutagenic or toxic for reproduction (CMR) category 1A or 1B.

- Amitrole: EFSA considered that the substance should be classified as toxic for reproduction category 1B (R1B)
- Linuron: harmonised classification as toxic for reproduction category 1B (R1B)

– Iprodione: EFSA considered that the substance should be classified as carcinogenic category 1B (C1B)

In other cases applications for renewal have not been submitted for substances with such hazard classification e.g. warfarin (classified as toxic for reproduction category 1A). In those cases the approval of the substance expired without any prolongation.

There has not yet been any approval or renewal or approval under the provisions of negligible exposure or in accordance with the derogation in Article 4.7 (serious danger to plant health) to the Regulation.

Topic: Independence of EFSA

12. What is your opinion on the fact that experts in EFSA working groups can work on projects which may place them in a position of conflict of interest? Public confidence in EFSA is undermined by many controversial cases, including issues with pesticides' authorisation procedure.

EFSA has a well refined policy on independence, which was revised in 2017. Experts of the Scientific Panels / Committees as well as those of Working Groups, all participants to pesticides peer-review meetings or to meetings where EFSA's scientific outputs are developed need to make a declaration of interest. All declarations are screened to identify potential conflict. EFSA publishes all annual declaration of interests on its website. For further information on this issue, the Commission would like to refer to the response by EFSA to question 45 sent prior to the meeting of the PEST Committee on 12 April.

18. Could the Commission elaborate the consequences for the independence of the risk assessment if EFSA would be exclusively responsible for both commissioning required studies for the authorisation procedure and for carrying out the risk assessment? Could that lead to a higher direct exposure of EFSA to the applicant as well as to a less stringent peer-review of the assessment of the application?

The Commission would like to refer to the response to question 64 sent by the PEST Committee prior to the meeting on 12 April.

Topic: levels of risks accepted

13. When approving active substances, in many cases the Commission does not verify that the necessary precaution is taken and the restrictions or instructions, envisaged by the Commission's approvals of use of active substances, are complied with. Could you elaborate on this? How can you justify the practice of approving the safe use of an active substance before getting all of the data necessary to support that decision?

The comprehensive evaluation of an active substance identifies any potential risks and concerns that may arise from use of the active substance and of at least one formulated

products and also identifies any data gaps relevant for the representative uses assessed. Occasionally indications of possible uncertainties beyond the uses assessed and for other product formulations may also be identified during the scientific evaluation (e.g. for uses in certain soil types, given the properties of the substance, there could be different impacts on groundwater).

The Commission carefully considers the EFSA conclusions and in case where a concern is identified but where this is not relevant for all uses assessed or where it is necessary to include risk mitigation measures to ensure safe use, the approval conditions highlight the issue. For example, in case a risk to aquatic organisms was identified for use on one crop but not others the approval conditions would include an obligation for Member States to pay particular attention to the risk to aquatic organisms when considering applications for product authorisations. The purpose of including such conditions in the approval is to signal specific areas to Member States that are particularly important to be examined to ensure that plant protection products containing the substance do not pose any harmful effects on human and animal health and the environment.

As set out in the Regulation, the authorisation of plant protection products is the responsibility of Member States in line with the principle of subsidiarity. Member States must carry out assessments taking into account the agronomic, climatic and environmental conditions relevant for their territories and taking into account any restrictions or conditions of use that are imposed in the approval of the active substance concerned.

With regards to data gaps, as also explained in the response to the first question, in many cases data gaps identified are only relevant for a specific use, formulation or under certain conditions. These gaps can be filled by applicants before submitting applications for product authorisation (i.e. post approval). For example there may be the need for further residues trials in tomatoes but the residues package for uses on apples, grapes and maize were acceptable. In other cases, depending on the type of data gap, a requirement to submit confirmatory information may be included in the approval at EU level – please refer to the response to question 14 for further details as to when use of confirmatory information may be employed. If a data gap is such that it impacts all uses and does not enable to conclude that the approval criteria are satisfied, then EFSA identifies a critical area of concern and the Commission does not propose to approve the substance unless a particular restriction can be imposed as a condition to ensure that the identified risk or concern can be mitigated.

The Commission does not have the resources to inspect the compliance of individual national authorisations with the terms of the EU approval Regulations. Instead, the Commission follows a more strategic approach by performing a survey and audits in order to verify the functioning of the national system of authorisations of plant protection products (PPPs) in Member States. Furthermore, the Commission is working on developing an EU database to record information on authorisations, the Plant Protection Products Application Management System (PPPAMS). This will enable all stakeholders, not only the Commission, to have better access to authorisations so that if there is a need to follow up any particular element related to a substance approval this can be achieved more easily.

17. Can the Commissioner explain how decisions are taken by his services on the evaluation of active substances and the fact that the Commission sometimes departs from EFSA opinions on the dangerousness of certain pesticides, in

particular for aquatic organisms (cases of bendivindiflupyr and Oxyfluorfen) or for birds (case of Epoxiconazole)?

When taking decisions on active substances (first time approvals or renewals of approval), the Commission applies the criteria established by Regulation (EC) 1107/2009. It is important to recall that Member States represented in the Standing Committee on Plants, Animals, Food and Feed play a crucial role in these processes. The decision-making is a joint responsibility of the Commission and Member States acting as risk managers.

After receiving an EFSA conclusion, the Commission invites the applicant to comment on it. Then the Commission analyses the EFSA conclusion including its background documents, the draft/renewal assessment report of the RMS, and comments from the applicant and drafts a renewal/review report in which it indicates whether the substance can be expected to meet the approval criteria or not, and in case approval is proposed indicates any conditions or restrictions that are necessary. The Commission then sends the draft renewal/review report to the applicant for comments and makes available to Member States the draft renewal/review report and draft Regulation and the comments from the applicant on this report, so that a discussion between risk managers can take place at the Standing Committee. Based on comments received from Member States – in particular also on whether they consider that the approval criteria in the Regulation can be met (and under which conditions) - the Commission may amend the draft documents (Regulation and/or renewal/review report) and submits the renewal/non-renewal/approval/non approval draft Regulation to an interservice consultation so that all relevant services of the Commission can submit their comments. Thereafter the Commission finalises the draft Regulation and submits it to the Standing Committee for a vote.

In the cases of benzovindiflupyr, oxyfluorfen and epoxiconazole, considering the results of the risk assessment for each substance and following discussions with Member States, their approval/renewal of approval was granted/maintained with restrictions and accompanied with the obligation for Member States to apply mitigation measures identified as appropriate to reduce the level of risks.

Risk to environment:

32. **From several pesticides, EFSA conclusions found high risks for aquatic organisms (bendivindiflupyr), high risk for herbivourous mammals (Picolinafen), high risk for aquatic organisms (L-cyhalothrin), high risk for aquatic organisms (Oxyfluorfen), a high risk for birds (Epoxiconazole), a high risk for herbivorous mammals (Flumetralin) etc. The Commission, however, considered in its "Review report" on the approval, that the risks are acceptable, without providing any further data or scientific argumentation. Has there been any decision where a substance has not been approved due to unacceptable risk to the environment? Under what conditions would the Commission consider a risk unacceptable? Does the Commission have any consistent criteria, or is the decision made at its discretion?**

In cases where the comprehensive scientific evaluation conducted by the RMS and EFSA indicates risks (according to the established risk assessment methodology and protection goals) that cannot be resolved or mitigated through further refinement of the

assessment or appropriate mitigation measures, the Commission proposes not to renew the approval. As explained in the response to question 17, the Commission discusses its initial assessment with the Member States in the Standing Committee on Plants, Animals, Food and Feed, who might bring forward further information as regards possible risk mitigation measures or refinement of the risk assessment that were not taken into account by EFSA.

The Commission confirms that substances have not been approved due to unacceptable risk to the environment. For example, the approval of isoproturon was not renewed due to the expected contamination of groundwater by relevant metabolites of the active substance and the substance beta-cypermethrin was not approved due to risks to aquatic organisms, bees and non-target arthropods.

For benzovindiflupyr, oxyfluorfen and epoxiconazole, please refer to the response to question 17.

In the case of lambda-cyhalothrin, the EFSA conclusions published in March 2015 identified a high risk to aquatic organisms based on the interpretation of the dataset carried out by the rapporteur Member State Sweden but Member States considered that mitigation measures at national level were possible and the approval of lambda-cyhalothrin was eventually renewed for 7 years as a candidate for substitution.

In the case of flumetralin and picolinafen it was considered that further refinement options and provision of higher tier data could be considered by Member States when carrying out assessments of applications for authorisation of plant protection products.

On Member State risk management:

38. According to Article 6 of Regulation 1107/2009, the approval of an active substance may be subject to conditions and restrictions. Such restrictions at the level of the approval have been adopted inter alia for glufosinate, a total herbicide like glyphosate, as well as in the context of the approval decisions of three neonicotinoids. However, for glyphosate, the Commission refused to take such measures at the level of the active substance, and instead passed risk management decisions on to Member States in the context of glyphosate-based product authorisations. Why did the Commission decide to adopt restrictions at the level of the active substances for e.g. glufosinate and three neonicotinoids, but not for glyphosate? In light of the various high risks found for glyphosate, does the Commission consider it appropriate to pass on the responsibility for risk mitigation measures to Member States? Does the Commission control the implementation of such risk mitigation measures in any way?

Regulation (EC) No 1107/2009 provides that an approval may be subject to conditions or restrictions. In determining whether such measures are required, the Commission considers the outcome of the scientific evaluation of the active substance conducted by the Member States and EFSA. In cases where the assessment highlights a potential risk for all uses examined, a particular use restriction may be considered appropriate if the assessment shows that such a measure leads to a safe use being demonstrated (in cases where there are no options available to ensure safe use a non-approval would be proposed).

This was the case for glufosinate and the neonicotinoids where the risk to mammals and non-target arthropods and to bees, respectively, could only be managed by imposing a restriction of use at EU level since there was no evidence to demonstrate a safe use without the particular restriction. For glufosinate a restriction to the rate of application was added to the approval (maximum rate of 750 g per hectare per application with a maximum of two applications per year) whilst for the neonicotinoid substances a restriction to use in permanent glasshouses for the full life cycle of the crop was imposed. In other cases, there may be concerns identified for some particular uses or under certain conditions of use (e.g. when used in certain soil types or at a particular stage of crop growth) but not for all uses in all parts of the EU. In these cases, and in line with the principle of subsidiarity, it is considered appropriate that Member States can assess each product taking into account the agronomic, climatic and environmental conditions relevant for their territories. In fact, it may be that a given product can be authorised in one Member State but not in another due to the specific agricultural practices or environmental conditions (e.g. soil type, rainfall).

For glyphosate no unacceptable risks were identified for consumers, for operators (taking into account easily acceptable personal protective equipment for hand held application such as gloves), workers, bystanders or residents nor for groundwater. In relation to non-target organisms no risks were identified for at least one representative use taking into account use of mitigation measures in the case of non-target terrestrial plants. In the case of herbivorous mammals and insectivorous birds a data gap was identified to further address the risk for some uses but a critical concern was not identified by EFSA because the assessment concluded that for at least one of the representative uses the risk was expected to be low. Therefore it was not appropriate to set any EU level restrictions in the approval condition, while, however, obliging Member States to pay particular attention to assessing these potential risks when evaluating applications for authorisation of plant protection products.

With regards to the question about leaving the responsibility for deciding risk mitigation measures to the Member States, it must be recalled that the representative use(s) of an active substance assessed at EU level during the procedure for the approval of an active substance may be different to the uses for which companies eventually apply in the Member States. For example, the representative use of a substance may be on maize but the authorisation in a Member State could be for potatoes. And even for the same crop, use conditions can be very different as the agricultural practices, climatic, soil and meteorological conditions may differ considerably between Member States: e.g. grapes can be produced from vertically growing (Germany, France), horizontally growing (Portugal, Austria) or creeping (Greece, Canary Islands) vines. The risk mitigation measures which will be imposed by the Member State as a result of its assessment are thus specific to the uses envisaged at national level.

In addition, the technical risk mitigation measures available in different regions of Europe differ widely depending on the level of technology available to farmers and their capacities for investment. For example, in Germany the authorities can impose the use of specific nozzles which will significantly reduce spray drift instead of taking recourse to non-spray buffer zones. However, this kind of specific nozzles may not be available in other Member States, where buffer zones would be adequate risk mitigation measures. It is therefore not appropriate to limit mitigation measures in an EU approval of an active substance as this would prevent the use of additional methods and techniques, including new innovative technology that may be developed after the time of an EU assessment.

The last part of the question has already been replied to under question 13.

Topic: Article 21 – early review

On calls for re-evaluation:

33. It usually takes a long time before the adverse effects of a pesticide are fully established, after it had initially been found reasonably safe (e.g. neonicotinoids). What criteria are used by the Commission when asking EFSA to re-evaluate whether an approved active substance still meets the approval criteria (Articles 21, 69 of Regulation 1107/2009)? Please also provide an explanation of the internal procedures followed within the Commission and the objective criteria applied in this process. What, if any, external stakeholders are involved in the process? In how many cases have the approval conditions been amended based on Article 21 or 69 of Regulation 1107/2009?

The Commission regularly receives information from different stakeholders, including applicants and NGOs, that active substances may no longer fulfil the criteria for approval set in Regulation (EC) No 1107/2009. Whenever the Commission receives substantial information it requests EFSA to verify the merits from a scientific point of view. In addition, that information is shared with experts from Member States and referred to the Standing Committee on Plants, Animals, Food and Feed for further discussion.

In a number of cases the Commission has used the provisions of Article 21 to restrict existing approvals as information became available indicating that the substance may no longer fulfil the approval criteria of the Regulation for some or all uses. This was recently the case for clothianidin, imidacloprid, thiamethoxam, fipronil, diflubenzuron and chlorpyriphos. In all the aforementioned cases the process was either triggered by new elements identified by EFSA or on the initiative of the Commission based on information received from stakeholders.

Topic: REFIT + GFL proposal

19. The Commission is close to completing its evaluation and fitness check on Regulation (EC) No 1107/2009 and Regulation (EC) No 396/2005, to ensure that both pieces of legislation remain fit for purpose. This assessment includes a three-month open public consultation which closed in February 2018. Can the Commission now inform the PEST committee about its preliminary findings? In particular, can the Commission confirm whether any new measures, both legislative and non-legislative, will be considered and if so, when can we expect these proposals to be published?

As explained in the answers submitted to the Commission prior to the 12 April meeting of the PEST Committee, the public consultation opened on 13 November 2017 and closed on 12 February 2018. 9879 responses were submitted, including 32 duplicates that were removed, resulting in 9847 responses that will be subject to analysis. A factual summary report is available online on the Commission's website[18] .

[18] https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_refit_eval_factual-sum-report-opc.pdf

The public consultation is one part of the data collection for an external study commissioned by DG Health and Food Safety in order to collect evidence for supporting the REFIT evaluation of the EU legislation on plant protection products and pesticide residues. The external study is expected to be finalised in the summer of 2018. The Commission services will take into consideration the outcome of the study and all the positions expressed during the consultations but also the report from the PEST Committee, the report from the European Parliament Research Service prepared for the ENVI Committee and the Parliament's own-initiative report that it being prepared, as well as the findings of the Commission's audits in the Member States and the opinion of Scientific Advice Mechanism (SAM), and then draft a Staff Working Document summarising the findings of the evaluation which is expected to be finalised in the first half of 2019.

It is premature to identify specific measures before the finalisation of the evaluation which will provide a solid evidence-base for an appropriate course of action, other than the specific amendments to the General Food Law[19], in relation to the transparency and sustainability of the EU risk assessment in the food chain, that the Commission proposed on 11 April 2018

24. Can the Commission explain how the conclusions drawn in the roadmap and open consultation have been considered in the preparation of the General Food Law proposal? These include, but are not limited to, provisions granting earlier access to industry studies in the risk assessment process, new guidance on what information from industry studies can be claimed as confidential, the introduction of a verification process on the quality of industry studies as regards compliance with relevant standards, and further involvement of Member State authorities in EFSA's activities.

The following key messages arising from the different consultations were taken into account when preparing the Commission's proposal:

- The earlier the access to industry studies in the risk assessment process, the greater its impact on transparency.
- Safeguarding confidentiality and intellectual property rights is fundamental in order to avoid hampering innovation and competitiveness.
- Details on what information from industry studies can be claimed as confidential need to be clear, and the related claims must be thoroughly assessed.
- Need for proportionate verification processes on the quality of industry studies as regards compliance with relevant standards.
- Potential value of EFSA's pre-submission advice to industry applicants while fully respecting the independence of scientific processes.
- Capacity for more public resources to finance studies on food safety.
- Need to tackle potential negative impacts of consultations on studies submitted on the length of the assessment processes. Need to ensure the protection of confidential data and personal data.
- Risk communication on food safety can be further strengthened by improving coordination and involving relevant stakeholders.

[19] https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1523604766591&uri=COM:2018:179:FIN

- Further involvement of Member States authorities in EFSA's activities must continue to ensure the separation between risk assessment and risk management.
- Scientific independence and excellence of experts are cornerstones of the EU risk assessment system.
- Adequate incentives are needed in order to ensure that EFSA obtains the expertise it needs from Member States.

The results of all consultation activities are summarised in the synopsis report and the explanatory memorandum to the proposal.[20]

Topic: Low risk substances

9. In light of (1) the nearly unanimously adopted European Parliament Resolution 2016/2903 of 15 February 2017 calling for fast-track market access for low-risk biological active substances and products, (2) the AGRIFISH Council Conclusions on Integrated Pest Management of June 2016 and (3) the Scientific Advice Mechanism High Level Group recommendations of April 2018, how does the European Commission plan to address the unintentional implications of Ombudsman O'Reilly's February 2016 call for preventing the presence of data gaps and a need for confirmatory data when applied to low-risk biological pesticides, when these data gaps are in fact created by the inappropriateness of the data requirements and regulatory process?

Indeed, these gaps occur largely because the data requirements and regulatory process are designed for chemical plant protection products (PPPs) assessment and management and are ill-fitting for low-risk biological PPPs. The shortcomings of the PPPs legislation and data requirements have been confirmed for micro-organisms as a criticism by stakeholders and competent authorities at EU and MS level in the "Draft Study supporting the REFIT Evaluation on plant protection products and pesticides regulation" report prepared for DG SANTE in the review of Regulations (EC) No 1107/2009 and 396/2005. How does the European Commission plan to insulate these low-risk biological PPPs from escalating requirements for chemical PPPs and bring them to the market more quickly as called for by all the above parties, and thus how does it plan to support the innovative SMEs developing biological low-risk pesticides?

Data gaps found in the assessment of potentially low risk biological pesticides are not necessarily created by inappropriateness of data requirements and the regulatory process. There are already specific data requirements for micro-organisms adopted at EU level that include requirements for highly-topical and important issues such as pathogenicity, infectivity, toxins production and antimicrobial resistance, however, these are not always fully addressed in the dossiers submitted. Nevertheless, the Commission recognises the need to review the data requirements for such active substances to adapt them to scientific progress. The Commission has initiated discussions at expert level with Member States, EFSA and stakeholders on the future review of data requirements for micro-organisms, in particular considering the progress in genetic methodologies testing.

[20] https://ec.europa.eu/food/sites/food/files/gfl_transparency_comm_proposal_synopsis_20180410_en.pdf

Furthermore, the Scientific Advice Mechanism High Level Group recommendations include a consideration on biological control agents "which should not automatically be classed as "low-risk" and call to secure and strengthen the scientific knowledge and capacity in risk assessment to keep pace with the increasing shift to biological control.

The Commission has been and is continuously working, also at OECD level, to elaborate comprehensive guidance for the specific assessment of biological active substances to achieve both, a simplification of the process and a high level of protection (e.g. Guidance on Botanical active substances used in plant protection products[21], on Semiochemical active substances and plant protection products[22]).

In addition, in order to accelerate procedures to bring low-risk products on the market, the Commission has worked with Member States to identify short and long term actions to be put in place to achieve such target. A plan including 40 actions[23] was endorsed by the AGRI-FISH Council of June 2016. Among the actions which were identified to facilitate the entry into the market of such products: the allocation of focused resources, provision of advice in dossier preparation, pre-submission meetings and reduction of fees, but also the submission of high quality and complete dossiers by applicants. In January 2018 the Commission Services finalised a progress report[24] which recognises that certain improvements have been made but that not all actions included in that focused plan have been fully addressed. All actions identified for the Commission are either in progress, close to finalisation or finalised. In particular, updated criteria to identify low-risk active substances have been adopted in August 2017[25], a Commission Communication concerning a list of potentially low-risk active substances is currently under translation and will be adopted soon, the guidance on zonal evaluation[26] has been amended to include a harmonised procedure for low-risk plant protection products in view of future increased workload resulting from higher number of low-risk active substances approved, and work is ongoing for guidance documents on the implementation of the new low risk criteria and on secondary metabolites. An expert working group on basic substances has been reconvened and a new revision of the working document regarding procedure for application is under development. The ongoing REFIT evaluation of the pesticides legislation will also examine the functioning of the provisions on low-risk substances, and whether they are meeting their objectives.

To support innovative SMEs to develop biological low-risk products, the Commission has identified relevant areas of research already under the FP7 and Horizon 2020 programmes and several projects have already or could be financially supported, the most recent ones being: BIOCOMES (9 million Euros), "Integrated health approaches and alternatives to pesticide use" (15 million Euros), "Stepping up Integrated pest management" (5 millions). The SME instrument and fast track innovation under the European Innovation Council Pilot of Horizon 2020 to support measures for bottom-up innovations can also be used.

Furthermore, under the European Innovation Partnership (EIP) support with funding opportunities is ensured to the implementation of policy measures at national and

[21] http://www.oecd.org/officialdocuments/publicdisplaydocumentpdf/?cote=env/jm/mono(2017)6&doclanguage=en
[22] https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_ppp_app-proc_guide_doss_semiochemicals-201605.pdf
[23] http://data.consilium.europa.eu/doc/document/ST-10041-2016-ADD-1/en/pdf
[24] https://ec.europa.eu/food/sites/food/files/safety/docs/adv-grp_plenary_20180427_pres_09a.pdf
[25] Commission Regulation (EU) 2017/1432 concerning the placing of plant protection products on the market as regards the criteria for the approval of low-risk active substances. OJ L 205, 8.8.2017, p. 59
[26] https://ec.europa.eu/food/sites/food/files/plant/docs/pesticides_ppp_app-proc_guide_mut-rec_en.pdf

regional level to strengthen interactive innovative formats such as thematic networks and close the research and innovation divide. Through the Enterprise Europe Network and Intellectual property rights helpdesk, small companies can also get advice for business opportunities.

Topic: other miscellaneous matters:

23. Can the Commission explain the difference between ECHA's process for the classification of active substances and the EFSA risk assessment for plant protection active substances?

As explained by ECHA and EFSA in theirs responses to the questions in the context of the meeting of the PEST Committee on 7 June 2018, both agencies work within the remit of the mandates given to them by their establishing Regulations, namely 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) and establishing a European Chemicals Agency, and Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 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.

ECHA and in particular its Risk Assessment Committee (RAC) is in charge of the process of harmonised classification and labelling (CLH) of substances. Regulation (EC) No 1272/2008 (the CLP Regulation) regulates the way in which substances are classified and labelled in the EU, i.e. based on their intrinsic hazardous properties, e.g. toxic substances, flammable substances, carcinogenic substances, etc.

EFSA on the other hand is responsible for the risk assessment of pesticide active substances. The risk assessment needs to take into account the hazardous properties of the substance as well as exposure to the substances. Hence hazard identification is also relevant for EFSA's work and the hazard identification is conducted according to the criteria in the CLP Regulation.

39. **The aforementioned report for the European Parliament's Research Service (EPRS) states that "it is generally recognised that the number of active substances that are available is substantially decreasing" (Bozzini, 2018, p. II-27). However, a draft study supporting the REFIT evaluation of the EU PPP legislation, which was leaked to Politico, states that "the total number of available active substances did not significantly change since the entry into force of Regulation 1107/2009". Information provided to the PEST Committee by ECPA appears to support this analysis. ECPA said that, further to applications submitted since June 2011, the EU approved 12 new active substances whereas 2 were not approved; it also renewed the approvals of 32 active substances whereas 8 approvals were not renewed. Could you give an overview of the number of active substances available in the EU each year since Regulation 1107/2009 came into force in June 2011? In addition, could you give an overview of how many decisions were taken to approve / renew EU approvals as opposed to not approve / not renew EU approvals of active substances?**

The number of active substances approved for each year since 2011 are reported in the table below:

Approved substances			
Year	**Actives**	**Basics**	**TOTAL**
2011	427		427
2012	432		432
2013	443		443
2014	464	3	467
2015	474	9	483
2016	478	12	490
2017	476	18	494
2018	474	19	493

It is correct that the overall number of active (and basic) substances approved has remained relatively stable since 2015. From 2011 to 2015, the overall number increased, primarily due to the approval of a considerable number of new active substances for which applications had still been submitted under the earlier Directive 91/414/EEC, as already mentioned in the response to question 1 that the PEST Committee sent prior to its meeting on 12 April 2018.

The table below presents a detailed overview of the number of Decisions taken by the Commission to approve / renew the approval or not to approve / not renew the approval of active substances or basic substances.

One single decision may relate to more than one active substance (e.g. the active substance 'copper compounds' comprises 5 distinct chemical substances).

The 14 non-approval Decisions include decisions not to renew an approval after an evaluation but also some substances for which no application for renewal of approval was submitted as, in such cases, the Commission initially adopted decisions to withdraw the approval of the substances. In recent years however, the practice changed: no non-renewal decisions were adopted and the approval of the substance expired at the date set in the earlier approval decision.

Decisions taken in the Standing Committee							
	Approvals	**Non-approvals**	**Renewals**	**Non-renewals**	**Withdrawals**	**Basic approvals**	**Basic non-approvals**
2011	5	4	7				
2012	11	1					
2013	39	2			2		
2014	12		1		1	3	
2015	11	1	11		2	6	5
2016	7	1	6	4		3	2
2017	5	4	15	3	3	6	3
2018	1	1	8	1		1	
TOTAL	**91**	**14**	**48**	**8**	**8**	**19**	**10**

40. In relation to a question on Diquat, DG SANTE told the PEST Committee earlier that it needed to follow procedures to be able to stand up its decisions in Court. DG SANTE emphasised that it often "harvested" legal challenges when it restricted or banned the use of active substances. Could you elaborate on the Commission's track record in Court? How often are restrictions, non-approvals or non-renewals contested? And how often does the industry win these cases?

The Commission draws attention to the fact that the Court is not only seized against Implementing Regulations that do not approve / not renew the approval of active substances but also where the approval conditions are restricted following a review or following the evaluation of confirmatory data that were required in the earlier approval. Furthermore, there are also cases brought by industry against the inclusion of active substances in the list of candidates for substitution[27]. Action, by industry, is also brought against EFSA decisions, for example regarding the disclosure of information in its conclusion. In accordance with the Court rules the Commission can request to be granted leave to intervene on behalf of EFSA[28].

The table below provides a detailed overview of the Court cases inquired about in this question. As regards the question on the success rate, it is too early to provide a response, as most of the cases are still pending and it is not possible to confirm a

[27] **Cases T-296/15 and T-310/15**: Request by companies to annul the listing of **copper compounds** and **metalaxyl** as candidates for substitution in Regulation 2015/408. The Court of Justice rejected the appeals brought and declared the actions inadmissible.

[28] T-**621/17**: Taminco and Arysta vs EFSA: Active substance **thiram** - Action for the annulment of the decision of the European Food Safety Authority of 18 July 2017, notified to the applicants on 20 July 2017, on the assessment of the confidentiality claims made in relation to the application for renewal of the approval process - regarding a classification of thiram in accordance with Regulation 1272/2008 on classification and labelling of chemicals
T-725/15: Chemtura vs EFSA: Active substance **diflubenzuron:** annul the European Food Safety Authority ('EFSA') Decision of 10 December 2015 concerning the publication of certain parts of the EFSA Conclusion on the Peer Review on the review of the approval of the active substance diflubenzuron regarding the metabolite PCA in respect of which the applicant claimed confidentiality

"trend": the Commission's Decisions stood in the two cases lodged in 2013 concerning the restrictions for three neonicotinoids, as well as the inclusion of copper compounds and metalaxyl in the list of candidates for substitution lodged in 2015 (the latter being inadmissible). One case was withdrawn by industry. The Commission lost the fipronil case, brought in 2013, recently (17 May 2018) – for the part pertaining to the review of the approval conditions for fipronil.

Procedural rights (including the right to be heard, the right of defence, the right regarding the protection of legitimate expectations) are core arguments used by the industry when challenging Commission regulations (see the neonicotinoid cases) and warrant that the Commission ensures full procedural compliance, to lower the risk of losing in Court or to be exposed to financial damages claims.

Stakeholders other than from the industry have also lodged Court proceedings against Commission Decisions approving or renewing the approval of active substances: 2 cases were brought in 2018 against the Commission Implementing Regulation renewing the approval of glyphosate (Brussels Capital Region and an Italian NGO). The approval of sulfoxaflor was challenged in 2015 (PAN) but the action was declared inadmissible by the Court.

NGOs also bring cases against confidentiality decisions of EFSA and the Commission under the Access to Document rules as well as cases against the refusal to carry out an internal review under the Aarhus Convention.

YEAR	REFERENCE	Parties	Active Substance	SUBJECT	Pending/outcome
2018	T-393/18	Mellifera e.V. vs. Commission	Internal Review Aarhus Regulation: Glyphosate	Annul Commission decision to not carry out an internal review of Commission Implementing Regulation (EU) No 2017/2324 on the renewal of approval of the active substance glyphosate	Pending
2018	C-115/18 (suspended until a judgment is rendered in case C-616/17 which concerns nearly identical issues)	n/a Reference for preliminary ruling	n/a (indirect: Glyphosate – national criminal proceedings against individuals destroying glyphosate containing products in stores)	Validity of Regulation (EC) No 1107/2009 in the light of the precautionary principle	Pending
2018	T-25/18	Pesticide Action Network Europe (PAN Europe) vs Commission	n/a	Annul Commission decision C(2017) 7604 final of 9 November 2017, partially refusing to grant the applicant access to documents relating to the drafting of Delegated Regulations on scientific criteria for the assessment of endocrine disrupting substances	Pending
2018	T-178/18	Région de Bruxelles-Capitale v Commission	Glyphosate	Annul Commission Implementing Regulation (EU) 2017/2324 renewing the approval of the active substance glyphosate	Pending

YEAR	REFERENCE	Parties	Active Substance	SUBJECT	Pending/outcome
2018	T-125/18	Associazione - GranoSalus vs Commission	Glyphosate	Annul Commission Implementing Regulation (EU) 2017/2324 renewing the approval of the active substance glyphosate	Pending
2018	Case T-67/18	PROBELTE S.A. vs Commission	8-hydroxyquinoline	Annul Commission Implementing Regulation 2017/2065 **confirming the conditions of approval** of the active substance 8-hydroxyquinoline, as set out in Implementing Regulation 540/2011 and modifying Implementing Regulation 2015/408 as **regards the inclusion of the active substance 8-hydroxyquinoline in the list of candidates for substitution** (The applicant had applied for an amendment of the approval - to lift the restrictions to greenhouse applications)	Pending
2017	C-616/17	n/a: Reference for preliminary ruling	n/a (indirect: Glyphosate – national criminal proceedings against individuals destroying glyphosate containing products in stores)	Validity of Regulation (EC) No 1107/2009 in the light of the precautionary principle	Pending
2017	T-719/17	DuPont & FMC vs	flupyrsulfuron-methyl	Annul Commission Implementing Regulation 2017/1496 of concerning **the**	The main application is still pending.

YEAR	REFERENCE	Parties	Active Substance	SUBJECT	Pending/outcome
		Commission		**non-renewal** of approval of the active substance DPX KE 459 (flupyrsulfuron-methyl)	The application for interim measures was rejected by Order of President of the General Court on 22 June 2018.
2017	T-476/17	Arysta vs Commission	diflubenzuron	Annul Commission Implementing Regulation 2017/855 **as regards the conditions of approval of the active substance diflubenzuron** (restriction to greenhouse uses) – based on the assessment of confirmatory information required in the earlier approval	The main application is still pending. The application for interim measures was rejected by Order of President of the General Court on 22 June 2018.
2017	T-12/17	Mellifera e.V. vs Commission	Internal review (Aarhus Convention) - glyphosate	Annul Commission Decision Ares (2016) 6306335 of 8 November 2016 order the Commission to adopt a new decision on the merits of the applicant's request for internal review of Implementing Regulation (EU) 2016/1056 on the extension of authorisation for glyphosate	Pending
2016	T-476/16	Adama vs Commission	isoproturon	Annul Commission Implementing Regulation 2016/872 concerning the **non-renewal** of approval of the active substance isoproturon	No decision - Action withdrawn by the applicant
2015	T-746/15	BIOFA vs Commission	sodium hydrogen carbonate	Annul Commission Implementing Regulation (EU) 2015/2069 approving the basic substance sodium hydrogen carbonate Note: the annulment was not about Article 4 approval criteria but regarding	Action dismissed as inadmissible (Order of the General Court of 9 November 2016)

YEAR	REFERENCE	Parties	Active Substance	SUBJECT	Pending/outcome
				the **use of data** for approving sodium hydrogen carbonate as a basic substance	
2015	T-600/15	Pesticide Action Network Europe (PAN Europe) and Others vs Commission	sulfoxaflor	Action for annulment of Implementing Regulation No 2015/1295, approving the active substance sulfoxaflor	Action was dismissed as inadmissible – Order of the General Court of 28 September 2016
2015	T-310/15 Appeal C-384/16 P	European Union Copper Task Force vs Commission	copper compounds	Partial annulment of Commission Implementing Regulation (EU) 2015/408 establishing a list of candidates for substitution – for copper compounds	The Appeal brought by the Taskforce was dismissed. (Judgment of the Court of 13 March 2018) The application was judged inadmissible (Article 263 (4) TFEU)
2015	T-296/15 and appeal C-244/16 P	Industrias Químicas del Vallés vs Commission	metalaxyl	Partial annulment of Commission Implementing Regulation (EU) 2015/408 establishing a list of candidates for substitution – for metalaxyl	The Appeal brought by the company was dismissed. (Judgment of the Court of 13 March 2018) The application was judged inadmissible (Article 263 (4) TFEU)
2014	C-442/14	n/a: reference	Several plant	National Court case (NL) – Bayer	Judgment of the Court 23

YEAR	REFERENCE	Parties	Active Substance	SUBJECT	Pending/outcome
		for preliminary ruling	protection and biocidal products	CropScience SA-NV Stichting De Bijenstichtig vs College voor de toelating van gewasbeschermingsmiddelen en biociden: Interpretation of Directive 2003/4/EC of the European Parliament and of the Council of 28 January 2003 on public access to environmental information – concept of emissions into the environment; overriding public interest: Underlying national case - request to the Netherlands authority responsible for authorising the marketing of plant protection products and biocidal products (the College voor de toelating van gewasbeschermingsmiddelen en biociden, CTB) for disclosure of 84 documents concerning marketing authorisations issued by that authority for certain plant protection products and biocides.	November 2016 Wide interpretation of the expression "information on emissions into the environment" by the Court
2013	T-671/13	Pesticide Action Network Europe (PAN Europe) (and Syndicat agricole Confédération	clothianidin, thiamethoxam and imidacloprid	Annul the Commission decision of 9 October 2013 in which the Commission declared inadmissible the request for internal review of Implementing Regulation (EU) No 485/2013 of 24 May 2013 amending Implementing Regulation (EU) No 540/2011, as regards the conditions of approval of the active	Action withdrawn in 2015 by the applicant

YEAR	REFERENCE	Parties	Active Substance	SUBJECT	Pending/outcome
		paysanne vs Commission		substances clothianidin, thiamethoxam and imidacloprid	
2013	T-578/13	Luxembourg Pamol (Cyprus) and Luxembourg Industries vs Commission	Potassium Phosphonates (case still governed by Directive 91/414/EC)	Annulment of EFSA Decision of 8 October 2013 concerning the publication of certain parts of the Peer Review Report and Final Addendum on Potassium Phosphonates in respect of which the Applicants claimed confidentiality pursuant to Council Directive 91/414/EEC1 and Commission Regulation (EU) No 188/2011	Judgment of the General Court of 3 June 2015: Action dismissed as inadmissible
2013	T-584/13	BASF AGRO vs Commission	fipronil	Annul Commission Implementing Regulation 781/2013 amending the conditions of approval for fipronil and the sale and use of treated seeds	Judgment of the General Court of 17 May 2018: • Commission decision partially annulled (amendment of conditions of approval of the active substance) • Action on sale and use of treated seeds dismissed (inadmissible)
2013	Joined casesT-429/13 and T-451/13	Bayer CropScience and Syngenta Crop	neonicotinoids	Annul Commission Implementing Regulation 485/2013 amending the conditions of approval for imidacloprid, chlothianidin and thiametoxam	Judgment of the General Court of 17 May 2018: The action was

YEAR	REFERENCE	Parties	Active Substance	SUBJECT	Pending/outcome
		protection vs Commission		(neonicotinoids) and the sale and use of treated seeds	dismissed.
2011	T-545/11 Appeal C-673/13 P T-545/11 RENV	Stichting Greenpeace Nederland and PAN Europe vs Commission	Access to documents - glyphosate	Declare that the Commission's decision of 10 August 2011 is in violation of the Aarhus Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters, Regulation (EC) No 1049/20012 and Regulation (EC) No 1367/2006 (see also C-442/14 on substance)	Judgment of 23 November 2016 on the Commission's appeal: Judgment of the General Court of 8 June 2013 was set aside and case referred back to the General Court where the case is still pending (hearing took place in March 2018). The criteria developed in the appeal judgment have now to be applied to the specific situation underlying the case.
2011	T-362/11	Stichting Greenpeace Nederland, Pesticide Action Network Europe (PAN Europe) vs Commission	Glyphosate (still under Directive 91/414 regime)	Action for annulment of the Commission’s decision of 6 May 2011, refusing to grant the applicants full access to certain documents concerning the first authorisation to place the active substance glyphosate on the market under Council Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market	Case withdrawn in 2012 by the applicant

YEAR	REFERENCE	Parties	Active Substance	SUBJECT	Pending/outcome
2011	T-232/11	Stichting Greenpeace Nederland, Pesticide Action Network Europe (PAN Europe) vs Commission	glyphosate	Internal review and access to documents	Case withdrawn in 2015 by the applicant.

41. Are the interpretations, assessments and Klimisch ratings of the published studies on genotoxicity, described in the chapter "B.6.4.8 Published data (released since 2000)", meant to be the interpretations, assessments and Klimisch ratings of the RMS? order to require a better separation of applicant vs RMS opinions?

The Commission assumes that the questions is referring to the Renewal Assessment Report for glyphosate and answers the question on that basis. It is the understanding of the Commission that the Klimisch evaluations for each study come from the rapporteur Member States, following the guidance of EFSA with regards to evaluating data. The general introduction to Section B.6.4.8 i.e. B.6.4.8.1 and 6.4.8.2 describes the review of published data since 2000 and the way in which data has been systematically considered in the section and incorporated into the review. The section must be considered in its entirety to understand how the review of the articles at the end of the section fit into the overall assessment. The final paragraph of section '6.4.8.11- Genotoxicity weight of evidence' states "*Scientific publications contrary to these regulatory reviews should be evaluated using a weight of evidence approach with consideration for reliability of the assay used and data quality presented*" and the relevant studies are then detailed with abstracts (clearly indicated as coming directly from the articles) and the Klimisch evaluation which in this context is clearly coming from the rapporteur Member State and flows from the weight of evidence assessment.

42. The description and evaluation of the published studies on the genotoxicity of glyphosate, described in Volume 3, Annex B, Chapter B.6.4.8 "Published data (released since 2000)" of the Renewal Assessment Report (RAR) for glyphosate, is remarkably similar to the literature review presented by the GTF in its application dossier under Section IIA 5.10.4 "Literature Review of Genotoxicity Publications". In fact, the description and evaluation of the studies appears to be identical between the RAR and the application dossier. There appears to be no difference between the opinions of the RMS and the applicants. DG SANTE has issued a "Template to be used for Assessment Reports". This document includes "general guidance on the content of Volume 3 - Annex B" saying that: "For each individual study, comments and conclusions of the RMS should be clearly identified and separated from the conclusions of the study author or applicant. It should be clearly indicated whether the RMS's conclusion deviates from the conclusion of the applicant or the study author." Would DG SANTE argue that the presentation of the published studies in Chapter B.6.4.8 of the RAR for glyphosate is in line with its "Template to be used for Assessment Reports"? Does DG SANTE consider to adapt its Template in order to require a better separation of applicant vs RMS opinions?

The Template for Assessment Reports is designed to ensure consistency in how evaluations are presented but Member States are not obliged to follow the templates. The guidance as quoted in the question should be followed as a default, but if there are specific reasons for Member States to use a different approach and this is explained clearly then such an approach can also be used.

Moreover, according to the Commission template and guidance, a distinction is made between the assessment of the studies and articles identified in the literature search.

Studies and articles considered irrelevant or unreliable do not require study-by-study consideration whereas those considered relevant and reliable should be integrated in the Assessment Report and assessed in the standard way: i.e., for each study, the applicant's and rapporteur Member States' views are described and then results are integrated into the risk assessment.

For glyphosate, the rapporteur Member State carried out an overall assessment of the data and used a weight of evidence approach taking into account information on each endpoint for genotoxicity (gene mutation, chromosome effects, DNA damage and other endpoints) and also looked at studies on human and environmental effects as well as other elements related to genotoxicity, including for the major metabolite AMPA and for POE tallowamine (one of the coformulants used in formulations). Certain studies that were considered relevant were individually reported in the weight of evidence section (B.6.4.8.11) with the Klimisch scores being given by the RMS (See also the reply to question 41). Therefore, the Commission considers that the assessment is in line with the template.

Nevertheless, the Commission considers it important that assessments are transparent and will therefore consider whether the existing guidance and template should be updated, in particular to differentiate clearly what comes from an applicant and what comes from the rapporteur Member State.