PEST COMMITTEE MEETING OF 19 JUNE 2018

PUBLIC HEARING

EU AUTHORISATION PROCEDURE FOR PESTICIDES - COMMISSION APPROVAL OF ACTIVE SUBSTANCES

PREPARATORY QUESTIONS

In the context of the PEST Committee meeting of 19 June, an exchange of views will take place to give Members an insight into the approval of active substances by the European Commission.

To prepare for this exchange of views, political groups have submitted the following questions. These questions, which address many of the topics at stake, should be answered in writing beforehand.

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?

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?

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?

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?

Questions to the European Commission:

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)?

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?

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

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?

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?

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

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

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.

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?

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?

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?

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?

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)?

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?

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?

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?

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

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?

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?

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.

On technical extensions:

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?

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?

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?

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" (negligable exposure) according to Annex II of Regulation 1107/2009?

On confirmatory procedure:

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").

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?

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).

On unacceptable 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?

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?

On 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?

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?

On response to the Parliament Resolution:

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

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?

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?

On other miscellaneous matters:

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?

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?

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?

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?

Questions to the OECD:

43. Could you explain the concept of Good Laboratory Practice (GLP) and the GLP Guidelines? Particularly, how is GLP certified, who can apply for a GLP certification, how is the compliance with the principles of GLP audited?

44. How important is compliance with the OECD Principles of Good Laboratory Practice (GLP) when ensuring that studies are of sufficient scientific quality for consideration within the approval process?

45. Can you explain how the OECD works together with the Commission to ensure that the EU's testing protocols are fully aligned with its test guidelines?

46. Could you explain to what extend the authorisation procedure for PPPs under Regulation 1107/2009 follows available relevant OECD guidance? Compared to other international authorisation procedures, how would you evaluate the performance of the European authorisation system, particularly with a view to scientific soundness of risk assessments as well as of authorisations granted?

Questions to the Ombudsman:

47. What is your opinion on the fact that the Commission did not implement the changes, agreed two years ago, to the derogations from the pesticide approval procedures and the confirmatory data procedure?

48. What is your opinion on the changes in the General Food Law recently proposed by the EC? Does the proposal address all problems with authorization and placing on the market of PPPs?

49. In your investigation following the complaint of Pesticide Action Network Europe, did you find that Commission uses the procedure of 'confirmatory information' according to Article 6(f) of 107/2009 restrictively and in exceptional cases? (i.e. only in duly justified cases strictly corresponding to the conditions specified by the legislation and where there is no risk that the conclusion on the safety of the active substance could be flawed). Were the decisions underpinned by the precautionary principle, as the regulation requires?

50. Did you find cases where the Commission asked for additional information relevant to the data requirement of a pesticide active substance, after granting its approvals? Are pesticide active substances with incomplete dossiers granted approvals? How many?

51. According to you, when the confirmatory information is received, is it assessed by DG SANTE as thoroughly as any other data in the original dossier?

52. In your opinion, is there a concern that some of the pesticide active ingredients that have been approved (or their metabolites) may cause adverse effects on human, animals or the environment as they have not been fully assessed?

53. According to you, how can EFSA address public concerns that it relies too much on data provided by applicants for authorisations when carrying out the risk assessment of their substances?

54. According to you, what can EFSA do to guarantee the independence of its staff and the experts on which it relies to carry out its work in the context of risk assessments?

55. According to you, is EFSA's risk assessment process sufficiently transparent?

56. According to you, is EFSA doing enough to engage with the public and relevant stakeholders?

57. According to you, how could EFSA do more to ensure that the often complex assessments it carries out can be understood by the public, given the direct relevance for public health?

58. Is the Ombudsman satisfied with the conduct and follow up actions taken in connection with any cases, either outstanding or resolved, involving the Commission and the relevant regulatory agencies as regards EU pesticides approvals?

Questions to Prof. Dr. Violette Geissen:

59. Please explain how active substances/pesticides are evaluated for their impacts on soil health/organisms? How could this evaluation be improved?

60. The EFSA conclusion says that glyphosate and its metabolite AMPA cause low risk for earthworms. Would you agree with this conclusion?

61. Please explain how the possible health and environmental impacts of active substances/pesticides being carried by the wind from crops are evaluated in the current process? How could this evaluation be improved?

62. In your research, you have found that 42% of the soils examined contained AMPA residues, whereas glyphosate was present in 21%. Do you consider that these residue levels are cause for concern? What are the possible impacts for the environment? What are the possible impacts for health?

63. Your study has shown that 45% of agricultural land in Europe contains glyphosate and AMPA, the most stable degradation product of glyphosate. The presence and concentrations of AMPA were higher than that of glyphosate, with some measurements as high as 2 mg per kilogram of soil. (There is no official standard for soil. For drinking water the standard is a maximum of 0.1µg per litre.) According to you: "*This leads to the conclusion that the European Commission also needs to set standards for glyphosate and AMPA in soil and surface water as quickly as possible. The potential negative effects on soil biodiversity, aquatic life and people after being exposed to these substances are manifold. Considering the high levels of traces of glyphosate we found in soil across Europe, it is not prudent to extend the approval of glyphosate.*" Would it technically/scientifically be possible to create such standards and control and apply those?

64. According to DG SANTE, the levels of glyphosate and AMPA in soils, which you found in your research, had been "*considered during the EU review of glyphosate*". Moreover, "*the risk assessment carried out for soil microorganisms, as reported in the EFSA Conclusion, was based on levels considerably higher than the maximum value reported in the study by JRC and Wageningen University*" (see minutes of SCoPAFF meeting of 27 October 2017). Do you agree with that statement? Do you consider that the data would have changed the outcome of EFSA's exposure assessment?

65. In autumn 2017, you stated that "*Considering the high levels of traces of glyphosate we found in soil across Europe, it is not prudent to extend the approval of glyphosate*." Why?

66. Following the results of your research, do you consider that the use of glyphosate-based products is adequately regulated in Europe?

67. What would you propose to regulators to improve environmental risk assessment of pesticides?

68. What other improvements or changes do you think should be made to the current evaluation/authorisation procedures (for both active substances and product formulations)?

69. As legislators, we often hear that farmers loose too much productivity and cannot produce efficiently without pesticides and especially glyphosate. What would be your reply to that statement?

70. Your study highlights a comparison between safe levels for drinking water and possible concentrations found in surface water. Can you explain the difference in the conclusions reached by your study and those reached by the WHO, who have reported in their Guidelines for Drinking Water Quality that "*establishing a formal guideline value for glyphosate and aminomethylphosphonic acid (AMPA) is not deemed necessary*"? Furthermore, do you agree that residue levels are matters that can be addressed independent of any active substance approval process, through measures controlling the use of products within which active substances are found?

71. During the PEST committee hearing on 15 May 2018, the Julius Kühn-Institute (JKI) drew attention to the negative environmental consequences of an overuse of copper sulfate in organic agriculture. Can you tell us what alternatives are available in conventional and organic agriculture in order to replace copper-based fungicides?

72. What do you consider to be the major challenges in the discovery and use of low-risk substances and biological agents for crop protection?