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?

   Du to my expertise, I will focus here on the procedures related to the effect of pesticides on soil organisms, and potential off site effects. There are severe data gaps with respect to

   - Ecotoxicological tests for soil organisms: the short term effects of a single active substance and/or pesticide formulation are tested on a limited amount of 5 species/groups out of more than 1 million species of organisms occurring in soils. Silva et al. (2018) detected in an European survey (testing less than 20% of the active substances currently approved for the EU markets) more than 160 different mixtures of pesticide residues in agricultural soils, with 83% of the samples containing pesticide residues. Related short and long term risk on soil organisms and community structure changes are unclear and not assessed, including shifts in the ratio between pathogens and beneficial organisms.

   - Pesticide residues attached to soil particles and transported by wind and water erosion will lead to off-site effects. In case of wind erosion this might lead to direct human exposure, especially if pesticides are attached to the long relevant dust fractions. This potential pesticide transport pathway is not accounted for in the EFSA risk assessment procedure.

   - Decay in soils is only tested for single compounds, not for mixtures or formulations.

   Adapting the test procedures to assess the short and long term effects of residue mixtures and formulations on the entire soil organism community (by DNA sequencing, metagenomics), and assessing the particulate transport of residues by wind erosion as an

important off site pathway in regions prone to wind erosion could help to minimize existing data gaps. This could lead to better insights in overarching effects of repeated and long-term use of pesticides on soil life, transport pathways of these compounds, and improved risk assessment for people and the environment. This is crucial to gain trust from the public about the approval system and safety of these products.

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?

To answer questions 2 and 3, I focus here on potential best practices and solutions:

I recommend that a certain number of independent scientific organisations conduct risk assessment tests based on state-of-the-art scientific knowledge and expertise, and financed through public money streams to guarantee independency from PPP producers. To arrange such, PPP producers should make available the required financial resources to the respective governmental institutions to enable this independent review and assessment of new PPPs by qualified scientific organisations.

In case of diverging assessments, the lowest value for risk assessment indices for environmental and/or human health should be selected for regulation purposes, in accordance with the precautionary principal. This simplifies the regulation and makes it much stronger: only PPPs are approved that evidently do not cause harm to the environment and humans. It can be expected that such a procedure will increase public trust in the authorization system.

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?

In addition to the existing monitoring programs for water and food, monitoring systems for mixtures of residues in soils and dust on European scale are required to detect PPP residues in the environment after their approval.
Actually, residues in soils are only calculated by EFSA as predicted environmental concentration (PEC), residues in dust are not at all assessed. The applied models for offsite transport focus on runoff, rough estimation of and leaching to the ground water.
We recommend to restart approval procedure if PPP residues are exceeding the maximal tolerable value in more than 10% of the analysed food, soil, water, dust samples. It is important to mention that maximal tolerable values for mixtures of residues still have to be defined for food, soil and dust.

Questions to Prof. Dr. Violette Geissen:

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

Reference or maximum levels in soils for no-longer approved and highly persistent and obsolete PPP, such as DDTs, HCHs, atrazine and dieldrin, are included into the legislation of some European countries. However, although a couple of these countries' regulations include admissible levels for unspecified "other pesticides", thresholds for approved, currently used active substances do not exist.

Concentrations/content of approved active substances in soil are interpreted based on their predicted environmental concentrations (PECs). PEC values are calculated by fate models (e.g., FOCUS-PEARL) and used in the review process of individual active substances. In the European Food Safety Authority (EFSA) conclusion report of an approved active substance, different PEC values are presented: the initial PEC of the active substance and of its major metabolites (immediately after pesticide application), the short and long term PECs (1–4 and 7–100 days after application, respectively), and, if applicable (substance or metabolites DT_{90}> 365 days; DT_{90}–time to reach 90% residue degradation), the background or plateau concentrations (after multi-year applications) as well as the PEC accumulated (PEC initial + plateau concentrations). PECs are calculated for the main crops to which the substance is applied, considering the highest application rates and the longest degradation times of the substances or metabolites in the field.

Current pesticide risk assessment relies on the comparison of toxicity exposure ratios (TERs) and trigger values. TERs are calculated for single residues by dividing ecotoxicologically relevant concentrations for indicator organisms by the residue's highest PEC (PEC initial or PEC accumulated). The ecotoxicologically relevant concentration is the LC_{50} (concentration resulting in the mortality of 50% of the exposed individuals), or the NOEC (highest No Observed Effect Concentration), in the case of acute/short-term toxicity or chronic/reproductive toxicity assessments, respectively. The in-soil indicator organisms are the earthworms *Eisenia fetida* and *E. andrei*, the springtails *Folsomia candida* and *F. fimetaria*, the mite *Hypoaspis aculeifer,* and nitrogen transformation microorganisms. TERs lower than 10 or 5, the trigger values for, respectively, acute and chronic exposures of earthworms and other soil macroorganisms, indicate an unacceptable risk for such organisms. The risk for soil microorganisms is not based on TERs but on the percentage of effect compared to a control; an effect above 25% after 100 days of exposure represents an unacceptable risk.

Despite the clear importance of PEC values on the risk assessment procedure, the validation of PECs in soil with field data from pesticide monitoring programs is still missing.

Possibilities for the improvement of the evaluation:

Mixtures of active substances, their metabolites and formulations should be tested to the soil biological community including DNA / RNA sequencing. This allows to estimate the real effects on soil life and the ration pathogens/beneficial organisms which is very important for soil health. NOEC should be based on these tests.

The evaluation should include as well long term effects (minimum 1 year) to test real chronic effects on changes in soil biological communities.

Laboratory and field studies should be used for these tests under different climatic conditions using different soil types. PPP are worldwide applied; therefore a realistic risk assessment is required for different conditions.

Substances adsorbed to soil particles are transported by wind and water erosion in regions prone to these threats. Field monitoring, including dust monitoring is necessary to address the actual situation. Procedures for flume experiments (water erosion) and wind tunnel experiments are needed and models should be developed to predict these off site effects on field scale.

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

The compost worms *Eisenia fetida* and *E. andrei* used for ecotoxicological tests (EFSA) are not very sensitive for Glyphosate and AMPA on the short term (14 days, 56 days).

However, the surface casting activity of the vertically burrowing earthworms (*Lumbricus terrestris*) almost ceased three weeks after glyphosate application. Furthermore, reproduction was reduced by 56% within three months after herbicide application (Berghausen et al. 2015). This example shows that the selection of the test species and the time frame of testing are crucial aspects for a proper risk assessment. Please, note also, that *Lumbricus terrestris* is evidently the most important earthworm species to keep soils healthy and alive.

7. 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

The aerial transport of residues from the fields of application is actually only assessed by modelling the drift originating from spraying. Transport of residues attached to soil particles by wind erosion is not at all assessed in the current procedure although it is shown that glyphosate is primarily attached to the finest, long-relevant, soil fraction of PM<10 um? (Bento et al. 2017).
National monitoring programs are needed to identify pesticide residues in soil dust transported by wind erosion, in particular in regions prone to wind erosion. Based on results gathered, predictive models can be developed. Wind tunnels can be used to test off site transport of substances.

8. 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?

Glyphosate inhibits the shikimate pathway that is present not only in plants but also in fungi and bacteria, rendering many taxa of microorganisms sensitive to glyphosate. However, not all organisms with the shikimate pathway are sensitive to glyphosate, depending on the class of EPSPS they produce: class I EPSPS is glyphosate sensitive and class II EPSPS is glyphosate-tolerant. Consequently, differences in sensitivity among microorganisms affect the microbial composition of various habitats harbouring glyphosate, including soil, plant surfaces and animal intestinal tracts (van Bruggen et al. 2018).

Minor differences in sensitivity of soil and rhizosphere microorganisms to glyphosate may result in important shifts in plant or animal pathogens. For example, the root pathogen *Fusarium sp*. is comparatively insensitive to glyphosate. Thus, glyphosate application may shift the balance in favour of pathogenic *Fusarium spp.* at the expense of antagonistic microorganisms, resulting in an increase of root pathogens. Increased root rot caused by pathogenic *Fusarium spp*. in glyphosate treated soil has been shown repeatedly, resulting in more frequent use and higher applications of fungicides. Similarly, the human and animal pathogen *Staphylococcus aureus* is insensitive to glyphosate and may become more dominant in glyphosate treated soil. Thus, the presence of glyphosate in soil could change the community compositions of bacteria and fungi, and in turn alter soil ecosystem functions and plant and animal health (van Bruggen et al. 2018).

9. 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?

   Yes, it is possible to create such standards. In the recent years specific methods are developed to detect rare microorganisms, shifts in microbial composition, and changes in metabolic functions. These techniques of sequencing of extracted DNA or RNA should be applied rigorously to assess the risk of (repeated) PPP applications on the soil community structure, both on the short and long term. Based on this assessment, maximal tolerable values for residues in soils can be determined, which in my opinion is urgently required.

10. 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?

In the actual procedure only 5 species (groups) of soil organisms are tested for single active substances, nor for mixtures neither for formulations. The no observed environmental concentrations (NOECs) used by EFSA do not represent real conditions in soils, for instance the overarching effects of repeated PPP applications on community shifts, the ratio between pathogens versus beneficial organisms, or the reduction of soil biodiversity are not considered and assessed. The current EFSA approach is based on a procedure developed long ago, and urgently needs revision to properly assess the integrated effects of long-term use of PPPs on soil biota and communities.. To date, DNA and RNA sequencing make it possible to unravel cause-effect relations between PPPs applications and their cumulative effects upon the entire soil biological community, especially with regard to complex pesticide residue mixtures, not accounted for in current EFSA procedures or legislation...

11. 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?

    Based on the precautionary principal, we emphasise that there are strong and convincing indications that glyphosate affects the soil biological community, and might cause unknown risks for human exposure by inhalation by wind erosion. Since these risks are not assessed by the actual regulation we follow the precautionary principal.

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

    Unfortunately, the current regulations are not appropriate to estimate and./or assess the integrated effects of repeated and long-term use of PPPs. To specify, we recently investigated the same soil samples further to determine the residues of 74 other regularly used PPPs. Results are rather shocking: 83% of our samples contained pesticide residues, the majority (56%) contained mixtures of pesticide residues. Across our samples, 166 different pesticide mixtures were detected, up to 13 different compounds per sample. This clearly indicates that the use of glyphosate-based products is indeed not adequately regulated, however, it is not limited to these particular products alone, our results clearly show that this is the case for the entire spectrum of PPPs currently available on the market in the European Union. Without a proper procedure to assess the effects of pesticide residue mixtures, which are the rule rather than the exception in European agricultural soils, soil life might be unnecessary threatened and affected. I strongly recommend to reflect on the unknown risk of these mixtures and recommend to apply the precautionary principal in case of doubts and unknown risks. In addition, it might be worthwhile to implement the Polluter Pays Principle to this particular work field also.

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

Actually, there are more than 2000 pesticides with 500 active substances approved on the European market. For the soil environment I propose, as mentioned before (question 1), to adapt the test procedures in order to assess the short and long term effects of residue mixtures and formulations on the soil organism community (DNA, RNA sequencing). Furthermore, particulate transport of pesticide residues by wind and water erosion deserves more adequate attention also.

In addition, PECs (predicted environmental concentrations) should be validated by field data from regular monitoring.

Furthermore, specific organisms potentially sensitive to specific modes of action of the PPPs could be included into the approval procedure.

Please find more details in the answer of question 5.

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

I recommend the validation of the outcomes of the modelling data for off site transport and the calculations of the PEC and include effects of mixtures of residues and formulations on soil community structures into the assessment of NOECs. These tests should be carried out by a certain number of independent organizations with public money. The lowest risk value identified should be automatically be taken into consideration for maximum tolerable value.

Maximum tolerable values for residue mixtures from banned and approved substances in soils, dust and eroded sediment should be included into national – EU legislations. In case of exceeding the maximal tolerable values remediation is required. Remediation techniques on large scale should be developed by the PPP producing industry.

14. 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?

Farming practices in Europe is mainly based on high input and high yields, 30% of the produced food however, is wasted. Drinking water companies have high costs to clean the surface or groundwater from fertilizer and pesticide residues.

Actually, pesticide application is carried out as 60 years ago, spraying the whole field to eliminate weeds or pests that occur in a specific spatial distribution. Nowadays, advanced techniques as precision farming and robotica can be used for exact monitoring e.g. by infrared and elimination of the weeds/pests in an early stage. This can be done mechanically (weed control) with robotica or punctual spraying and not distributing pesticides over the whole field. Furthermore, crop varieties resistant to pests and crop diversification should be more taken into account to avoid pests. Governments could easily establish programs to promote modern techniques of food production.

Subsidies for farmers not applying herbicides and minimize insecticide and fungicide application applying modern farming techniques and minimizing food waste will accelerate the process of transforming EU farming systems to sustainable farming.

15. 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?

    Maximal tolerable values for mixtures of residues in soils are urgently required and as well maximal loads for off site export. Controlling the use of PPP applications by farmers is not feasible and the hotspots in some regions show that although the application guidelines exist, farmers do not always follow the rules.

16. 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?

    Due to my knowledge, actually there are no products on the market to replace copper-based fungicides, however, there is a lot of research ongoing. The best alternative actually is the use of pest resistant varieties and promote them.

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

    Crop protection is an integral concept consisting in crop diversification, cultivation of resistant crop varieties, increasing soil health by avoiding soil threats, reasonable fertilization, addition of organic amendments etc. In this way a stabile state will be reached in the whole cropping system and biological agents can be applied to support crop protection. Early warning systems are very helpful to avoid pests.

    In greenhouses biological agents are applied with great success already many years. They can be as well successful developed and applied on open fields but this requires means for development. However, their environmental and human health effects should be tested following the same regulations as for other PPPs.