Pesticide Action Network Europe

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Briefing: Pesticide Action Network Europe comments on the European Commission (DG Sante) overview report (2017-6250-MR) on the authorisation process of pesticides in Member States

Directorate General for Health and Food Safety (DG Sante) from the European Commission has published in 2017 an Overview report on audits carried out in EU Member States to evaluate the authorisation processes with regards to pesticides. Even though the report focusses on the processes, especially on the delays in the authorisation of pesticides, this report is very informative on a number of important issues taking place in Member States.

PAN Europe has analysed the report and presents the following comments.

1. Application fees (§3.1)

The placing on the market of PPPs generates important incomes to pesticide companies. Such products present an important amount of externalities to citizens: health costs for users and bystanders, water depollution costs, cost of loss of biodiversity (loss of pollination services for instance), etc. It is thus in our view not understandable that 4 out 7 member states do not collect fees from the applicants and that the other 3 do not update the fees to the actual cost.

Such fees should at least pay for the costs related to the public servants that deal with the applications plus that from the public servants that deal with the follow-up of the dossiers and the negative consequences of the uses of PPPs.

2. Pre-submission meetings (§3.2)

In principle, PAN Europe is opposed to so-called pre-submission meetings. The generation of data for the risk assessment of PPPs is handled by the applicant which we consider being a conflict of interest and a possibility of fraud. Providing to the applicants the possibility to directly meet competent authority's staff handling their dossiers pose a risk of influencing the final decision.

PAN Europe supports the provision of very clear guidance to the applicant on the necessary data and the form it should be provided to the competent authority. We support exchanges between competent authorities and applicants via a centralized and anonymous e-mail address to make it as neutral as possible and reduce possibilities to influence the final decision.

If a member state provides to an applicant the possibility to have pre-submission meetings, those should be open to the public and other stakeholders such as environmental NGOs, or some agriculture organisations (such as the organic farming groups which has an interest in, for instance, the authorisation of some more volatile pesticides that are contaminating their crops) should also have the possibility to have meetings with the competent authority to expose their views on the products in question.

3. Number of authorised products (§3.3.1)

According to the results of the audits, there is a great variation in the number of authorised active substances (a.s.) and products among Member States. This variation is not related to the size of the country (and thus the pedo-climatic variations within the country). For instance Luxembourg has more a.s. authorisations (241) than Germany (232) while France has 402! On the other hand, it is stunning to observe that Germany has 'only' 1432 authorised PPPs while France has nearly 3 times more (4100).

The audit unfortunately does not provide justifications for such important differences but in our view, the reasons underlying this situation should be determined. Is there a difference among Member States in the level of protection of human and animal health or the environment? Is this because more applications are being made in France because it is one of the countries in Europe that makes use of the most important quantities of pesticides, in part due to the intensive lobbying of pesticide companies and French agricultural cooperatives?

4. Specific national requirements

Overall, this report presents specific national requirements (6 out of 7 controlled member states) as a burden for meeting the deadline for the authorisation of the products. Even though the report does not state how to solve this problem, it should in our view be more explicit that member states should hire more staff (paid by the fees) to make sure that deadlines are met and not reduce specific national requirements. Specific national requirements permit to improve protection of human and animal health as well as the environment. They should thus be supported.

5. Guidance document at the time of application vs. latest scientific and technical knowledge

The aim of the pesticide regulation 1107/2009 is to provide a high level of protection for humans, animals and the environment. When, in the light of new scientific knowledge, there is evidence that an active substance might harm humans or the environment, it should be the duty of all member states to ask for more data to the applicant.

The example of the so-called 'Bee Guidance Document' shows that even though the most up to date scientific knowledge on the risk assessment of pesticides on bees was compiled

by EFSA in 2013, it was not taken note in the standing committee on phytopharmaceuticals for nearly 5 years. Fortunately, EFSA and many member states do implement it as the latest scientific knowledge. Were it not the case, the anterior guidance document, written in part by the pesticide industry, would still be made use of.

Finally, in our view, delays due to "latest scientific knowledge" should be seen as positive as they improve safety for health and the environment.

6. Pre-1993 PPPs (§3.3.4)

Three out of 7 member states still have pesticides (9 to 33% of the total number) that were not re-evaluated since the establishment of the uniform principles (established under directive 91/414, applied since 1993). This situation is unacceptable and should not be tolerated by the European Commission. More than 14 years delay in the re-evaluation of a PPP is not justifiable and member states should simply suspend the authorisation of such PPPs until the evaluation is completed.

PAN Europe would like to emphasize the conclusion of this paragraph: *'Delays in reviewing PPP authorisations after the re-assessments of a.s. undermine the implementation of EU standards*'. Should be also highlighted that this situation already takes place at EU-level: the reviewing of the active substances is often postponed by several years. To this delay must be added the delay from Member States. This might reach up to 10 years delay in total, from a.s. review to PPP review.

7. Mutual recognition (§3.3.5)

We disagree with the interpretation of the statistics. In 56% the conclusions of the re-evaluation of the application by Member States in cases of mutual recognition lead to similar conclusions to that of the origin Member State.

In 44% of the case, i.e. nearly half the cases, the conclusions lead to a different authorisation:

- 27%: there are differences in risk mitigation measures. The report presents this figure as being a cosmetic modification but mitigation measures play an important role in the protection of citizens and the environment.
- (e.g. buffer zones to avoid contamination of rivers and lakes).
- 6% of the PPPs are simply refused which raises questions on the reason that the produc was approved in at least one other member state (especially if it is due to data gaps)

The conclusion of this paragraph is very worrying: when a PPP is rejected, similar PPPs from the market are not suspended and re-evaluated. An identical unjustifiable situation prevails for generic products (conclusion of §3.3.6). This situation must take an end and regulation 1107/2009 must be improved accordingly.

8. Parallel trade permit (§3.3.1 and §3.3.7)

45 days in our view do not seem enough as there is no reason to give 120 days to member states to carry out the MR while only 45 days for PTP. In both cases the products will be used on the territory from the MS so it should be evaluated the same way! Further, this rule takes for granted that two plant protection products containing the same concentration of a.s. present the same risk characteristics. This is untrue: co-formulants, impurities are never the same, from one formulation to the other. Therefore, each PPP should undergo a separate and detailed analysis based on their toxicity and ecotoxicity profile. This fast-track procedure should not exist.

9. Emergency authorisations (§3.3.8)

If a PPP has not been thoroughly evaluated for one representative use and no approval has been granted by the European Commission, no emergency authorisation should be granted either as the safety of humans and the environment is not minimally guaranteed.

The constant increase in the provision of derogation is on our view unacceptable. The report does not indicate that it is not only for minor uses that derogations are provided. The audited Member States also provide derogations for substances that were restricted or banned because of their toxicity to humans or the environment (e.g. neonicotinoids or fipronil).

PAN Europe disagrees with the justification of '*absence of effective and economically viable alternatives*'. Alternatives may sometimes be more expensive but once they are broadly used (i.e. if no derogation is provided to the old substances), economy of scale leads to price reduction. Further, the emergency authorisations dossiers often present only chemical alternatives while non-chemical alternatives (often a simple crop rotation) might be cheaper. The report does not mention unfortunately that there is very little effort from the public authorities to avoid providing emergency authorisations by developing non-chemical techniques (in line with the Sustainable Use of Pesticides Directive 128/2009/EC) to the benefit of operators, bystanders and the environment.

10. Overall conclusion

This reports unfortunately focusses on the negative consequences of delays. PAN Europe acknowledges that for the industry, it is important that competent authorities meet deadlines but for the general public, deadlines should not prevail on human health and the environment. Delays should thus not be seen as negative when it comes to safety of the used products.

A solution for reducing delays would be to increase staff and that costs related to the evaluation of dossiers to be charged to the applicants, depending on the amount of time

necessary for evaluating dossiers. This would also be in line with the ‘polluter pays’ principle.

PAN Europe supports the use of the most up to date scientific knowledge on pesticide risk assessment. We acknowledge that this might increase delays in the provision of a.s and PPPs authorisations but it constitutes the most logical way to provide citizens and the environment the highest level of protection foreseen in regulation 1107/2009.