Position paper on the development of a risk assessment of pesticides on bumblebees and solitary bees

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Introduction

While the collapse of biodiversity is not questionable anymore and, particularly, that of insects, the pace of improving the situation at the pesticide regulatory level is extremely slow. The revision of existing guidance documents and the development of new ones are lengthy processes that do not correspond to the urgency of the environmental situation. At least ten years will have passed since the EFSA published its Scientific Opinion on the Science behind the Risk Assessment of Plant Protection Products on Bees[1] in 2012, and the Member States finally (and hopefully) approve an EU Bee Guidance Document.

Wild pollinators play a crucial role in the pollination of our crops. Indeed, a diversity of pollinators are necessary to ensure efficient pollination services. Science has shown that higher pollinator diversity leads to increased yields, fruit weight and quality, and higher resistance to pests. Furthermore, a majority of wild plant species rely on wild pollinators' pollination to reproduce.

In 2013, the European Food Safety Authority developed a Guidance document on the risk assessment of pesticides on honeybees, bumble bees and solitary bees. At the time, the available scientific knowledge allowed to broadly develop a guidance document for honeybees only, while some protocols were suggested for wild bees.

In 2021, the breadth of scientific knowledge has considerably increased as the scientific community has increased its research and knowledge on bumblebees and a series of wild bee species. Projects, including some funded by the European Commission, have developed methodologies to assess the toxicity of pesticides on wild bees. Furthermore, regulatory laboratories and industries have made their own experience on using wild bees as test species.

Methodologies now exist to assess the toxicity of pesticides on bumblebees and solitary bees. Some of them are already available as test guidelines by OECD, and the validation continues for toxicity testing in solitary bees[2]. While the knowledge on the biology of wild bees remains less developed than that of honeybees, wild bees present significant advantages for risk assessment. Therefore, the risk assessment of pesticides on wild bees should rapidly be implemented in the EU regulatory framework. Indeed, they can compensate for weaknesses from the honeybee risk assessment.

Furthermore, the setting of protection goals for the protection of wild pollinators must be carried out in a scientifically-sound manner. According to the information shared recently by the European Commission and the EFSA, we are concerned that the basis of the decision of EU risk managers might be based on a flawed approach.

1 EFSA, Scientific Opinion on the science behind the development of a risk assessment of Plant Protection Products on bees

2 OECD https://www.oecd.org/chemicalsafety/pesticides-biocides/work-related-beespollinators.htm

Setting protection goals

For honeybees, risk managers decided to express the level of protection in terms of variation in colony size based on modelling the background variability. The background variability was established using a model calibrated with data provided from regulatory tests, using artificial colonies (smaller and homogeneous size, different structure than typical field colonies, etc.) in environments containing high loads of pesticides, including control fields. This approach has been named "Approach 2", based on a previous EFSA communication to EU risk managers. However, as mentioned in prior communications to risk assessors and managers, PAN Europe and BeeLife consider this approach wholly disconnected from the reality, and inappropriate.

Over the past year, the Member States and the European Commission have mentioned that "Approach 3" would be considered for the risk assessment of pesticides on wild bees.

During a presentation from the European Commission and EFSA to stakeholders on 23 November, new field data on the variability in the development or reproduction of bumblebees and solitary bees were presented. We are very surprised that the EFSA keeps carrying out research on variability. Firstly because this does not correspond to Approach 3. Second, because discussing the Specific Protection Goals in terms of variability (i.e., the maximum variability in the development of bumblebees or solitary bees' populations acceptable to be caused by one pesticide active ingredient) does not make much sense as detailed below. In doing so, EFSA and the Commission are leading the debate towards a dead-end resulting either in decisions based once again on flawed and useless calculations or simply postponing the debate for another few years, delaying even longer the protection of wild pollinators.

Approach 3, as exposed by EFSA, sets a level of harm that is deemed acceptable by risk managers. This level of harm is obtained by comparing a set of test units (micro-colonies in the case of bumblebees and cocoons in the case of solitary bees) and control units. The biological variability between colonies will automatically be included in the compared groups, which happens in any test, including laboratory tests.

We, therefore, consider that the preparatory work carried out by EFSA and the Commission is inadequate and will lead to new complex and delayed discussions with risk managers.

Furthermore, while the Member States decide on the thresholds for concern (SPGs), the precautionary principle should involve an acceptance threshold of 0%, which can be adapted as soon as more data is available. Indeed, the European Red list of bees[3] identified that 14% of EU wild bees are threatened but for 55% of the species, knowledge is lacking. The Biodiversity Strategy for 2030[4] of the European Commission aims at restoring biodiversity. Finally, the pesticide regulation 1107/2009/EC ensures a 'high level of protection' to the environment. All this together clearly shows risk managers need to tend towards a 0% harm to wild bees. In order to be as close as possible to this goal, and in order to ensure a sufficient statistical power for regulatory tests, we consider that risk managers should ensure that regulatory tests are sufficiently statistically robust to measure a 3% difference between test and control fields trials.

Setting Specific Protection Goals is a political decision. Indeed, the EFSA and other risk assessment agencies are not capable of advising on SPGs as it is impossible to take into account the impact of the combination of pesticides bees are exposed to, the interactions with climate change as well as food scarcity. Such a figure (3%) is more easily attainable as regulatory experiments with wild bees allow for higher statistical robustness. Furthermore, a low threshold would partly compensate for the numerous endpoints that are not included into the current risk assessment: cumulative exposure, simultaneously and over time exposure, interactions between pesticides and pathogens or other

[3] https://www.iucn.org/content/european-red-list-bees
[4] https://ec.europa.eu/environment/strategy/biodiversity-strategy-2030_en

stressing factors, species of wild bees that might have a higher sensitivity to the tested pesticides, etc.

Improving the protection of pollinators through wild bees' risk assessment

Field tests carried out with honeybees present a series of weaknesses. For instance, showing a small toxicity effect is complex as it requires the multiplication of plots with high numbers of colonies. Furthermore, these colonies will be put in different environments, which will lead to results challenging to compare and more variable. Finally, the colonies used are not typical honeybee colonies: they are smaller, standardized and do not reflect the normal biology/exposure. Indeed, productive colonies have many foragers that will then be exposed and expose the colonies to higher quantities of pesticide residues in the tested group. On the other hand, smaller, regulatory colonies have proportionally fewer foragers, leading to a situation where toxic effects at the field level might be missed. All this involves that field trials are not so representative of the real situation that honeybee colonies experience once pesticides are authorised and used.

Bumblebee micro-colonies are naturally composed of a small number of individuals and can be grown in boxes. Furthermore, by foraging close to their nests, such species present an increased probability to be exposed to the tested pesticide, which is different to honeybees who forage up to several kilometres from the hive.

Contrary to honeybees, it is possible to place many bumble bee micro-colonies or solitary bee cocoons in one location and even in the middle of the fields. These species have smaller requirements, compared to honeybees, in terms of quantities of nectar and pollen. Therefore, contrary to honeybees, increasing the number of colonies for statistical purpose will not lead to an exaggerated competition between colonies and lead to better statistical results.

Laboratory results readily available

Since 2018, applicants have been required to provide results from laboratory tests for bumblebees. However, the lack of a risk assessment guidance document with clear thresholds prevents risk assessors from providing clear indications to risk managers. By rapidly fixing protection goals and finalizing the bumblebee and solitary guidance document, risk assessors would finally receive the tools to interpret the laboratory results regarding bumblebees and solitary bees correctly.

Making field control groups real control groups… or modifying the reference tier

As highlighted by the pesticide industry itself during the above-mentioned meeting, control fields are also treated fields: they are not treated with the tested product but as they are managed in a 'conventional way', the health of the control crops is also carried out through spraying with synthetic pesticides. The explanation provided by the CropLife Europe representative during this meeting cannot remain unheard.

Indeed, regulatory science is based on comparing exposed and unexposed organisms. The tiered approach gives the final word to field tests. They are the reference tier for decision making. Two possible consequences should follow the statement from CropLife Europe.

Firstly, the guidance documents on honeybees, bumble bees or solitary bees must clearly state that control fields should remain untreated and be grown on pesticide-untreated parcels over the previous five years to avoid pesticide residues in soils. Should this not be the case, soil residue analyses need to be provided to prove the absence of contamination of control fields. Therefore, we contest CropLife Europe's statement claiming the impossibility of growing bee-attractive control fields without pesticides. Indeed, were the laboratories conducting their fields under pesticide-free agroecological practices, this would be certainly possible. A change in practices (using resistant varieties, reducing sawing densities, using crop rotation, maintaining healthy soils, etc.) is certainly needed. We consider

that the statement from CropLife Europe is unacceptable and should lead to a quick reaction on behalf of risk managers.

Furthermore, test fields should be treated only with the tested product. No other pesticide product should be applied to the tested field. Non-chemical alternatives must be used. Finally, as previously mentioned, the tested field should be grown on a pesticide-untreated lot in the last five years. Otherwise, interactions could occur between the tested substance and other pesticide residues present in the crops' pollen and nectar and modify the test results.

In the meeting with stakeholders, EFSA and the Commission stated again that the baseline for defining a non-exposed environment should be the agricultural environment. Once more, we would like to stress how much we are opposed to this approach as bees in agricultural landscapes are exposed, simultaneously or consecutively, to dozens of pesticides. This approach is unscientific and must be reformed immediately.

If risk managers refuse to impose pesticide-free control fields grown in pesticide-free soils because they consider it impossible, the reference tier must be changed. Laboratory tests should thus become the reference tier for decision making. It would certainly simplify the risk assessment/management and increase the reliability of the whole process as all parameters would be better controlled.

Conclusion

PAN Europe and BeeLife wish to reiterate that there is no necessity further to postpone the protection of wild pollinators against pesticides. Protocols are available, and the industry is prepared. Delaying the discussions with debates on variability or other irrelevant topics, has no sense. Risk managers can quickly determine a protection goal.

Before the critical decline of biodiversity and because the current risk assessment is still not considering combined and consecutive exposures to pesticides, we ask EU risk managers to fix a maximum of 3% decline in the measured endpoints. Indeed, the precautionary principle should foster a decision aiming at being as close as possible to 0% damage.

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Pesticide Action Network Europe (PAN Europe) was founded in 1987 and brings together consumer, public health, environmental organisations, and women's groups from across Europe. PAN Europe is part of the global network PAN International working to minimise the negative effects and replace the use of harmful pesticides with ecologically sound alternatives.