1.2 Expectations of risk assessors on the work of ICPPR in the context of a new regulation and a new guidance document

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Abstract

Concerns related to risk to honeybees due to exposure to plant protection products (PPP) have increased with time during the last years in public opinion. Based on these concerns, data requirements to address the risk for honeybees have been modified and completed in the latest regulation (Regulations 283/2013 [1] and 284/2013 [2]). Moreover, a new EFSA guidance document was developed in 2013 to address risks to honeybees, bumble bees and solitary bees [3]. Thank to scientific community, knowledge on effects of PPP on bees has also increased during the last few years, but the new data requirements refer to tests for which no guideline exist. The implementation of the EFSA guidance in the next future will also require additional testing to fulfil the requirements and address the risk for the species of concern. ICPPR has been ahead of many method developments related to risk assessment for bees. Its work in the framework of European risk assessment for PPP is still needed as scientific and specialized inputs are absolutely necessary to address new requirements and risk assessment schemes.

1. Context of risk assessment for bees and other pollinators in EU

The current available guidance document to conduct risk assessment of PPP for bees is the Sanco 10329/2002 [4]. It covers in-field oral and contact risks for sprayed products - expressed as HQ values-, higher tier risk assessment with semi-field and field studies, and mentions exposure to residues in pollen or nectar. However, no risk assessment scheme is proposed for this latest route of exposure.

Additionally, ICPPR working groups developed a risk assessment scheme for non-sprayed systemic compounds in 2010. It is presented in the EPPO Guideline 40-3 (2010), and addresses the risk assessment to bees (3/10 (3) Chapter 10 [5]), and side-effects on honey bees (1/170 (4) [6]).

Because concerns were raised after several accidents on bees due to exposure to dust during sowing of treated seeds, the DG Sanco decided to develop a guidance document for treated seeds (SANCO/10553/2012) [7]. This guidance is intended to provide for a harmonised implementation of the different provisions of Regulation (EC) No 1107/2009 [8], which are related to the treatment of seeds with plant protection products, and also to provide guidance for the performance of the risk assessment.

In this context, the scientific community agreed that there was a need for a new guidance, which could update the existing guidance document with current knowledge, and compile existing methodology in a consolidated document. It could use the available work done by international working groups such as ICPPR, and address the remaining questions such as risks for bumble bees and solitary bees raised in literature.

2. What does the new EFSA guidance cover?

A guidance document was developed by EFSA in 2013 to address risks to honeybees, bumblebees and solitary bees. It addresses the routes of exposure via contact for spray application or to dust during sowing of treated seeds, by consumption of nectar, pollen, honeydew, guttation droplets, and contaminated water. Several scenarios were developed to address the risk (1) in field: in the treated crop, in the following crops, via residues on flowering weeds; and (2) off-field: in adjacent crops and non-cultivated areas.

In the different scenarios, the following effects are assessed: acute oral and contact to adults, chronic oral to adults, toxicity to larvae, effects on hypopharyngeal glands, effects on colony strength, and behaviour (e.g. return to hive).

3. Difficulties when addressing the risk assessment as proposed in the new EFSA guidance

3.1 Test protocols

In order to cover all requirements of Regulations 283/2013 and 284/2013 and address the scenarios defined in the EFSA guidance, a number of tests are necessary. Some of them are immediately applicable as guidelines are available at international level, but for several data that are required to fill the scenarios in and conduct the risk assessment, no guideline is available (see Table 1). From a regulatory point of view, availability of validated and agreed guidelines is a guarantee of robust protocols, leading to repeatable and reproducible results. This is a key element for a common and harmonised risk assessment for all compounds within European countries. The lack of validated methods will lead to case by case decisions and acceptance or not by regulators of results issued from diverse protocols. The consequences of such a situation will be a disharmonised risk assessment conducted by different rapporteurs and/or for different compounds.

There is therefore a serious need for technical developments at international level to fulfil requirements, and ICPPR is one of the places where such work can be done.

Table 1 Level of availability of test protocols

Test design	Honeybees	Bumblebees	Solitary bees
Acute oral toxicity to adults	OECD GL 213 [9]	ICPPR ring test	**No validated method**
Acute contact toxicity to adults	OECD GL 214 [10]	ICPPR ring test	**No validated method**
Chronic adults	Draft OECD GL	**No validated method**	**No validated method**
Larvae	OECD GL 237 [11]	**No validated method**	**No validated method**
HPG	**No validated method**	-	-
Semi-Field	Available	Under dev.	**No validated method**
Field	Available but feasible with new standards?	**No validated method**	**No validated method**

3.2 Data for risk refinement

The EFSA guidance document is based on a tiered approach. The first tier is therefore based on worst case assumptions, as in all other guidance documents. However, due to lack of data when the guidance was developed, exposure to residues is based on very conservative assumptions that might lead to failure at tier one level for many compounds.

Refinement is possible with additional data such as measured residues in nectar and pollen, or sugar content of crop nectar. However, generating field trials in order to provide such data needs time, especially if data have to be generated for a high number of compounds and crops. How could risk assessment be conducted if it fails at the first tier for too many compounds, and if these data are not available on time? It will be a real challenge for risk assessors and decision makers if no conclusion can be drawn due to lack of data.

3.3 Feasibility of field studies

Field studies that could be generated will have to deal with the protection goals of 7% effects on bee colonies set by risk managers at EU level. The statistical power of these studies should be high

enough to demonstrate effects below 7%. It implies a number of replicates in terms of tested and control fields, and hives per field. Moreover, in order to have comparable results, all treated and control fields should be placed in similar landscapes. Fields should also be separated by a distance large enough to avoid cross exposure. At last, exposure in treated fields should represent the 90th percentile of the expected exposure based on residue trials.

According to the protection goals set at EU level, these parameters are relevant. But are these field studies really feasible, especially in terms of number of fields and bee hives? Moreover, due to the high level of conservatism of the first tier, field studies might be needed for a high number of compounds.

3.4 Uniform principles

The new triggers presented in the guidance for tier 1 risk assessment are different from the ones currently defined in regulation 546/2011 [12]. If tier 1 risk assessment conducted according to the guidance identifies unacceptable risk and concludes to a need for refinement, when HQ values meet the trigger currently values defined in the regulation, risk assessors and decision makers will face a regulatory dilemma. There is therefore a need for harmonisation of trigger values and/or revision of the uniform principles.

4 What can a group such as ICPPR bring to risk assessors?

ICPPR working groups can help in the development of test protocols with bumblebees and solitary bees together with OECD, for laboratory, semi-field and field tests. They are also welcome to provide proposals for field tests with honeybees.

Effects on hypopharyngeal glands are required in the EFSA guidance. However, there is a need for research on ecological relevance of effects on HPGs and information on how to interpret the obtained results and extrapolate to effects on bee colonies.

The ICPPR Working Group could also make proposals based on scientific knowledge and data for refinement of default parameters (exposure values as well as trigger values) in order to help EFSA to provide a true screening / tier 1 risk assessment in the guidance document.

5 Conclusion

There is an important need for protocol developments in laboratory conditions as well as solution proposals for field studies. There is also a need for an update of the screening and first tier steps based on a realistic database that was missing when the EFSA guidance was developed. ICPPR is one of the places where such data and protocols can be provided and shared.

Attunement of work between risk assessors and working groups such as ICPPR is therefore of major importance if we want to provide robust risk assessment based on constantly updated scientific knowledge.

6 References

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8. Commission Regulation (EU) No 546/2011 of 10 June 2011 implementing Regulation (EC) No 1107/2009 of the European Parliament and of the Council as regards uniform principles for evaluation and authorisation of plant protection products, Official Journal of the European Union, 11.6.2011

9. OECD guidelines for the testing of chemicals, 213. Honeybees, Acute Oral Toxicity Test, 1998

10. OECD guidelines for the testing of chemicals, 214. Honeybees, Acute Contact Toxicity Test, 1998

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