Brussels, 6th July 2022

Object: definition of the level of Specific Protection Goals and risk assessment of pesticide effects on bumble bees and solitary bees

Dear Commisioner Kyriakides, Dear Commissioner Sinkevičius,

As representatives of different civil society organisations and stakeholders of the EFSA working group on the revision of the Bee Guidance Document, we would like to express our concern about the ongoing discussions around setting a risk assessment strategy for wild bees.

We would like to remind you of the activities and engagement of the European Commission for pollinator protection via the EU Pollinators Initiative, the first-ever EU framework to tackle the decline of wild pollinators. Thanks to the Initiative, there has been good progress in raising awareness of the problem, but no sufficient action to stop or even slow down the downfall of pollinator populations.

In this context, we urge you to have ambitious Specific Protection Goals (SPGs) for wild pollinators to achieve coherence with the Green Deal aims, Farm To Fork, Biodiversity and Chemicals Strategies.

SPGs

For honey bees, EU Member States opted for an SPG of 10% as the maximum threshold of colony reduction. However, this threshold has already been contested by beekeepers, civil society[1] and scientists[2].

We would like to stress the importance of having more protective SPGs for wild bees, as several ecological factors could influence the vulnerability of bumble bees and solitary bees to pesticides compared with honey bees:

- Scientific evidence shows that wild bees have a high variability of sensitivity when compared to *A. mellifera*, with certain species being more sensitive to pesticides (Arena and Sgolastra 2014)[3], while bumble bees have lower social resilience due to the small size of their colonies and solitary bees have none (Straub *et al*. 2015)[4];

[1] https://www.bee-life.eu/post/civil-society-urges-the-european-council-to-secure-highest-protection-of-bees-and-pollinators

[2] https://scienceforbees.org

[3] Arena, M., & Sgolastra, F. (2014). A meta-analysis comparing the sensitivity of bees to pesticides. *Ecotoxicology*, *23*(3), 324–334.

[4] Straub, L., Williams, G. R., Pettis, J., Fries, I., & Neumann, P. (2015). Superorganism resilience: Eusociality and susceptibility of ecosystem service providing insects to stressors. *Current Opinion in Insect Science*, *12*, 109–112.

- The bumble bee and solitary bee tested species are meant to be representative of some 1,900 other species, some of which are likely to be more vulnerable than the tested species (*Bombus terrestris* and *Osmia bicornis*);
- The loss of wild pollinators cannot be compensated for by human intervention, as is partly the case with honey bees (which, however, represents a cost of production for beekeepers);
- Bumble bee and solitary bee nests located in the field may be exposed to pesticides, e.g. via direct exposure of larvae and adults to soil residues (many wild bees are soil-nesting insects). However, this route of exposure is currently not considered in the risk assessment.

For all these reasons, it is of paramount importance that a conservative approach for the SPGs setting within Regulation (EC) No 1107/2009 should be warranted for wild bees, as also recommended by EFSA in its 2012 opinion (EFSA PPR Panel, 2012) and its 2022 supporting publication for the definition of SPGs for wild bees.

In its supporting publication, EFSA considers that there are two potential options for defining the SPGs: (1) an *a priori* defined threshold option; and (2) an undefined threshold option, highlighting that any decision relying on the current knowledge may require revision in the future when new data and tools become available.

In our view, **the level of protection of wild bees should be defined as an *a priori* threshold** constituting the level of harm we accept to be observed between the treated crop and the pesticide-free control crop (which will automatically include background mortality). Using an undefined threshold would block us in an unharmonised situation where "expert judgment" will be used and where the quality of the risk assessment will be highly variable between the Rapporteur Member States. For example, neonicotinoids were approved under "expert judgment", even though semi-field tests already showed harm to bees. Still they were accepted. A cut-off must be set to carry out a proper risk assessment and take the best possible informed decisions.

Furthermore, it must be stressed that in the framework of the undefined threshold option, as it is currently applied for aquatic ecotoxicology, conclusions on the acceptability of risk are largely drawn from statistical analysis of ecotoxicological study results. This statistical significance is evaluated through the minimal detectable difference (MDD) concept. However, recent studies (Duquesne *et al*. 2020; Mair *et al*. 2020)[5] point out the low power control of the current approach for MDD calculation, potentially leading to false negatives (type II errors). More specifically, these studies demonstrated that the current approach for MDD calculation allows detecting significant effects with only 50% certainty (and consequently a 50% probability of not finding significant effects, which, however, exist). This conflicts with the fundamental regulatory aim of avoiding overlooking considerable effects and resulting risks. Type II errors are highly relevant in ecotoxicology, particularly in the context of ERA of PPP, since they may lead to unacceptable impacts on the ecosystems (Duquesne *et al*. 2020).

Some risk managers are claiming that it is difficult to determine SPGs for wild bees today because of a lack of data. However, precisely because of such a lack of data, we need to apply the precautionary principle and fix an ambitious protection goal of a 3% maximum loss of colonies/populations to halt pollinators' decline and to allow them to re-develop, rather than an undefined threshold which currently leads to detect significant effects with only 50% certainty.

Such an *a priori* defined threshold option of 3% is feasible, considering that the biology of bumble and solitary bees allows many more colonies/cocoons at the edge of treated fields, thus increasing statistical robustness.

Ideally, we would propose a 0% loss of colonies/populations provoked by pesticide application, but we acknowledge the need to offer workable technical alternatives. Nevertheless, the collapse of insect populations deserves a high level of ambition.

[5] Duquesne S, Alalouni U, Gräff T, Frische T, Pieper S, Egerer S, Gergs R and Wogram J. (2020). Better define beta-optimizing MDD (minimum detectable difference) when interpreting treatment-related effects of pesticides in semi-field and field studies. *Environmental Science and Pollution Research International,* 27(8), 8814–8821.
Mair MM, Kattwinkel M, Jakoby O and Hartig F. (2020). The minimum detectable difference (MDD) concept for establishing trust in nonsignificant results: A critical review. *Environmental Toxicology and Chemistry*, 39(11).

Risk assessment procedure

Both the EFSA Scientific opinion (2012) and the available scientific literature stress the importance of testing wild bees, as honey bees are not a good proxy for these species. The 2013 EFSA Bee Guidance Document provided protocols to this end. A test guideline for bumble bees' oral acute toxicity (OECD 247) has been available since 2017. A test protocol for acute contact toxicity for solitary bees is at the final stage of validation, and several semi-field and field studies have been conducted (also for regulatory purposes), both on bumble and solitary bees. Protocols are thus available and must be used, as decision-making should also be done based on toxicity to wild bees.

We would like to inform you that some semi-field/field test protocols currently employed for honey bees have never been ring-tested. Therefore, the fact that some protocols present only in the validation process is not a good reason not to implement them. We can only regret the passivity of the European institutions and national governments about investing to accelerate protocol improvement. To date, the largest investments in protocol validation and standardisation are put in private hands, despite this situation being well known by authorities since 2013.

For these reasons, we, the co-signing organisations, request the European Commission and the Member States to set the threshold of SPGs for wild bees at 3%. This value should be used to set trigger values for decision-making and included in EU Regulation 546/2011. Only in doing so can we acknowledge a clear intent to achieve the Green Deal objectives.

Best regards,

Jeff Pettis & Fani Hatjina, Apimondia

Francesco C. Panella, BeeLife European Beekeeping Coordination

Martin Dermine, PAN Europe

Nicolas Laarman, POLLINIS

Contact: Martin Dermine, martin@pan-europe.info, +32 2 318 62 55