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REPORT

WORKSHOP ON 17 FEBRUARY 2022 (14H-17H30)

REVIEW OF THE EFSA GUIDANCE ON THE RISK ASSESSMENT OF PLANT PROTECTION PRODUCTS ON BEES (*APIS MELLIFERA*, *BOMBUS* SPP. AND SOLITARY BEES) - SPECIFIC PROTECTION GOALS FOR BUMBLE BEES AND SOLITARY BEES

Following the invitation from DG SANTE Unit E4, risk managers and risk assessors from 23 Member States, Norway and Switzerland participated.

DG SANTE.E4 welcomed the participants and thanked the European Food Safety Authority (EFSA) for the publication on 28 January 2022 of the technical report with the analysis of the evidence to support the definition of Specific Protection Goals (SPG) for bumblebees and solitary bees¹.

This technical report formed the basis for the discussions and was summarised by DG SANTE.E4 in an opening presentation (see annex). The presentation highlighted the differences in biology and ecology of bumblebees and solitary bees versus honeybees, summarised the limited data available for bumblebees and solitary bees, described the most relevant parameters for bumblebees (e.g. colony weight) and solitary bees (those related to population abundance) and explained the two potential options, considered by EFSA, for defining Specific Protection Goals, i.e. an *a priori* defined threshold or an undefined threshold.

Experts from the Member States had the possibility to ask questions for clarification and were subsequently asked for their views on the way forward for the setting of specific protection goals for wild bees.

The results are indicated in the table below:

	BUMBLEBEES – COLONY WEIGHT	SOLITARY BEES – POPULATION ABUNDANCE
DEFINED THRESHOLD OPTION	Preferred by 17 out of 23 Member States. 15 of these Member States mentioned a value of 10%	Preferred by 6 out of 22 ² Member States. 3 Member States did not propose a value.

¹ <https://www.efsa.europa.eu/en/supporting/pub/en-7125>

² One Member State left the meeting early and did not participate in the discussion on solitary bees.

	<p>although many of them mentioned that the position is preliminary.</p> <p>1 Member State stressed that 10% is already very conservative and ensures a high margin of safety.</p> <p>1 Member State could not indicate a value.</p> <p>1 Member State preferred a value as close to 7% as possible.</p>	<p>1 Member State stated it should not be higher than 10 % while another Member State mentioned 7-10%.</p> <p>A third Member State indicated maybe 10% or higher.</p>
UNDEFINED THRESHOLD OPTION	<p>Preferred by 1 out of 23 Member States because there is not enough evidence available to support any value.</p> <p>This Member State indicated to be able to support a defined threshold of 7-10% if preferred by a majority of Member States in order not to delay the finalisation of the update of the Guidance Document.</p>	<p>Preferred by 13 out of 22 Member States.</p> <p>About 10 Member States preferred this option as a temporary solution because of the current lack of evidence which does not allow to set a defined threshold. Once more data is available, a defined threshold could be set. The need for ongoing scientific research was mentioned.</p> <p>One Member State indicated to be able to support a defined threshold, if this option is preferred by a majority of Member States, as close as possible to 7%.</p> <p>Several Member States mentioned that it is acceptable to have different approaches for bumblebees and solitary bees.</p>
NO POSITION YET	<p>5 Member States did not have a position yet.</p> <p>1 of these indicated to be ready to follow the majority in order not to hold up finalisation of the update of the Guidance Document.</p> <p>Another of these acknowledged the need to finalise the review of the Guidance Document.</p> <p>Two of these Member States pointed to the scarcity of data and</p>	<p>Three Member States did not have a position yet.</p> <p>One of these indicated to be ready to follow the majority in order not to hold up finalisation of the Guidance Document and will discuss internally if an undefined threshold is viable.</p> <p>Another of these did not support any of the options and considered that the review of the Guidance Document can currently not be finalised for solitary</p>

	the need to be precautionous.	bees due to lack of data. The third of these did not express any preference and stressed the importance of considering ecological differences.
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Next steps and closing

DG SANTE.E4 thanked all participants for the good exchange of views.

DG SANTE.E4 will reflect internally on the most appropriate way forward and announced that it intends to continue the discussion in the Standing Committee Plants, Animals Food and Feed at its next meeting on 30/31 March 2022.

Annex:









Review of the EFSA Guidance on the risk assessment of plant protection products on bees (*Apis mellifera*, *Bombus* spp. and solitary bees)

Setting a specific protection goal for bumble bees and solitary bees

SANTE E4 Pesticides - Legislation

Wild bees vs honey bees



Bumble bee	Solitary bee	Honey bee
 	 	
<ul style="list-style-type: none">• 68 species in EU in the same genus (<i>Bombus</i>)• Small annual colonies (with limited structure)• One egg-laying queen that overwinters• Mostly wild• Limited food storage in the nest	<ul style="list-style-type: none">• ~ 1900 species in Europe• No colonies (not eusocial), tax. diverse• All females lay eggs• Mostly wild• Provision nests only once	<ul style="list-style-type: none">• One species only in Europe (<i>Apis mellifera</i>)• Large perennial colonies (Highly structured)• One egg-laying queen• Mostly managed• Nests contains large reserves of food

VS

Dimension of the Specific Protection Goal

- Table 1: Specific Protection Goals as implemented in EFSA (2013)

Dimensions	Bumble bees	Solitary bees
Ecological Entities	Colony	Population
Attribute	Colony strength	Population abundance
Magnitude	Negligible effect (percentage of colony size reduction as for honey bees)	Negligible effect (percentage of population abundance reduction as for honey bees)
Temporal scale	Not relevant i.e. any time	Not relevant i.e. any time
Spatial scale	Edge of field	Edge of field



Other existing SPG approaches

- Non-target arthropods:
 - EFSA PPR Panel (2015b) scaling magnitude based on expert judgement (considering typical dose–response such as . EC10, EC50) and not based on data. Proposed options are not yet discussed with risk managers.
 - Terrestrial guidance document (2002): general protection goal: for higher tier case-by-case decision
- Aquatic organisms:
 - Minimal Detectable Difference (MDD) concept



Can the same approach as for the honeybee SPG be used?

- The normal operating range (NOR) provides an indication of the range of typical 'natural variability' that can be used as a baseline to understand what magnitude of effects can be tolerated following exposure to a pesticide.
- For honeybees, the NOR was defined by simulating the background variability of honey bee colony strength. The magnitude of acceptable effect expressed maximum colony size reduction was defined by the relative difference between the mean colony size and the lower limit of the operating range.
- The used methodology for honeybees cannot be directly transferred to bumble bees and solitary bees, due to their different biology and ecology
- However in principle, it may be possible to apply a similar concept by using a combination of mechanistic modelling and data from field studies.



Biology of bumble bees



- Bumble bees belong to the genus *Bombus* (68 species in Europe). Mostly wild.
- Small annual colonies with a single egg-laying queen responsible to establish colony in spring. Only the new queens hibernate during the winter.
- Nests above or below ground, include wax but limited structure.
- Workers switch between in-hive tasks and foraging.
- Colonies store only enough food to allow the colony to persist through short periods of poor weather.
- Visit a wide range of flowers.



Models for bumble bees

- EFSA identified 9 potentially useful models: 7 on bumble bees and 2 on both bumble and solitary bees
- These should be evaluated according to the 2014 EFSA good modelling practices opinion (not feasible within timeframe mandate)
- Models must cover the numerous different species to incorporate species-specific ecological processes
- Identified models thus require further in-depth analysis and consideration before they can be used
- But models are a powerful tool for the future!



Available field studies for bumble bees

- Can colonies grow strong enough to provide pollination services AND produce new queens to be able to establish new colonies the following season?
- Endpoints considered: number of workers, number of adults and colony weight
- Variability for colony weight comparable to variability for honeybee colony strength

	Bumble bees
Species	Data available only on <i>B. terrestris</i>
Available data	Field data: 7 field studies (33 fields overall, 2–25 replicate colonies/field)
Colony size CV	CV workers : 0–135% CV adults : 0–95% (n workers ≠ n adults)
Colony weight CV	CV: 5–60% (versus CV 0–50% honeybee colony strength)



Overview for bumblebees

acceptable percentage value of size reduction specific for bumble bee colonies

Lines of evidence	Defined Threshold	Undefined threshold
	Bumble bees	
Biology and Ecology	Biology and ecology cannot be fully covered in the risk assessment due to lack of data. Bumble bees and solitary bees have different biology and ecology. Extrapolation factors between species (e.g. from honey bees to bumble bees and solitary bees) based on some aspects of their biology can be considered in the risk assessment	
Background variability	Comprehensive data on NOR not available. Available data may support a threshold as agreed for honey bees or any other threshold in that range.	Not applicable
Impact for lower tier risk assessment	Risk assessment schemes will be developed to be compliant with the defined threshold. It will result in more harmonisation and less complexity as a similar risk assessment among honey bees, bumble and solitary bees will be implemented	It will require definition of assessment factors (trigger values) that may reduce the effectiveness of the lower tier risk assessment. It will lead to less harmonisation and more complexity due to the implementation of different risk assessment schemes among honey bees, bumble bees and solitary bees
Requirements for field studies vs power of available field studies	Available studies indicate feasibility to detect ~ 10% (based on colony weight)	Case-by-case. In the future, a definition of MDD or CI values may support more harmonised evaluation.



Biology of solitary bees



- Taxonomically diverse (in EU approx. 1900 species)
- No colonies, no worker caste, only males and females
- Most specialised in collecting pollen from one genus or one family of plants
- Vary considerably in size, appearance and use a wide variety of nesting substrates
- Most have one generation of offspring per year. All females lay eggs.
- Produce a relatively small (approx. 10) number of offspring per female.



Models for solitary bees

- EFSA identified 3 potentially useful models: 1 on solitary bees and 2 on both bumble and solitary bees
- These should be evaluated according to the 2014 EFSA good modelling practices opinion (not feasible within timeframe mandate)
- Models must cover the numerous different species to incorporate species-specific ecological processes
- Identified models thus require further in-depth analysis and consideration before they can be used
- But models are a powerful tool for the future!



Available field studies for solitary bees

- Can the (starting) population replace itself?
- Endpoints considered: number of females emerged in the next generation per number of females emerged in the starting population, number of female cocoons per introduced female cocoon, number of cocoons (both sexes) per introduced female cocoon and number of brood cells per introduced female cocoon.

Solitary bees	
Species	Data available only on <i>O. bicornis</i>
Available data	Field data: 8 field studies (35 fields overall, 1 population/field)
Colony size CV	Not relevant
Colony weight CV	Not relevant



Overview for solitary bees

acceptable percentage value of size reduction specific for solitary bee population abundance

Lines of evidence	Defined threshold	Undefined threshold
	Solitary bees	
Biology and Ecology	Biology and ecology cannot be fully covered in the risk assessment due to lack of data. Bumble bees and solitary bees have different biology and ecology. Extrapolation factors between species (e.g. from honey bees to bumble bees and solitary bees) based on some aspects of their biology can be considered in the risk assessment.	
Background variability	Comprehensive data on NOR not available. Available data give inconclusive results	Not applicable
Impact for lower tier risk assessment	Risk assessment schemes will be developed to be compliant with the defined threshold. It will result in more harmonisation and less complexity as a similar risk assessment among honey bees, bumble and solitary bees will be implemented	It will require definition of assessment factors (trigger values) that may reduce the effectiveness of the lower tier risk assessment. It will lead to less harmonisation and more complexity due to the implementation of different risk assessment schemes among honey bees, bumble bees and solitary bees
Requirements for field studies vs power of available field studies	Not possible to give indication based on the available data (the studies for which a power analysis is available indicate that 10% may not be feasible with the current design)	Case-by-case. In the future, a definition of MDD or CI values may support more harmonised evaluation.



Thank you



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