

EFSA/COM Workshop on the revised Draft  
Guidance Document on the risk assessment of  
plant protection products on bees  
(*Apis mellifera*, *Bombus* spp. and solitary bees)

Joint presentation of the Central Zone

5 October 2022

The CZMS experts appreciate the concept GD and consider the science behind the document to be generally strong. Furthermore, a number of improvements and updates in risk assessment methodology are welcomed.



	TRT-Winter bees	RUD	Behavioral Effects	Mix Tox	Toxicity studies	LF Factor	Slope/energy budget/SV	Interspecies extrapolation factor/tiered approach	Statistical approach/ Unacceptable effects	Greenhouse assessment for BB	Accepting + uncertainty in non-apis bees
Austria	Key	Key		Key		Key	Key			Key	Key
Belgium	Key			Key		Key				Key	Key
Netherlands	Key			Key		Key		Key		Key	Key
Slovenia	Key			Key		Key		Key		Key	Key
Czech Republik	Key			Key		Key		Key		Key	Key
Poland	Key			Key		Key	Key	Key		Key	Key
Slovakia	Key					Key	Key	Key	Key	Key	
DE-UBA						Key			Key		Key
DE-JKI	Key	Key		Key			Key	Key	Key	Key	Key

**Legend**

- Key issue high priority
- Important, priority but not highest priority
- Important, but moderate priority
- No opinion

# (Key) points for which there was unanimity for responding CZMS

- ▶ Time Reinforced Toxicity (TRT)
- ▶ Landscape Factor (LF)
- ▶ Need for a greenhouse RA for BB
- ▶ Mixture toxicity methodology
- ▶ Workshop

# TRT: two key points

- 1) According to the current methodology (Section 8.1.1) it appears that a new chronic toxicity test (honey bee) at high doses/long duration (or an assumption of TRT i.e., Haber's constant of -2),—would have to be considered for all substances. The requirement to do the TRT assessment would put an undue burden upon low/non-toxic substances.
- 2) If TRT is indicated, the approach to conduct a risk assessment for winter bees to consider the overwintering period is quite severe and will cause a high level of overestimation. The exposure of winter bees to the same active substance over 182 days will not occur under realistic conditions depending on several factors, as discussed in Annex G.

# TRT Suggestion Point 1

- ▶ It is suggested to not require this assessment for substances which show no toxicity in bee (*Apis* and non-*Apis*) and potentially NTA tests (though these may be less informative for bees) and are not of concern for bioaccumulation.

# TRT Suggestion Point 2

- ▶ An alternative approach could be requiring studies to compare the sensitivity of summer bees to winter bees for the active substances with indications of TRT and apply the difference factors to the extrapolation for the whole life of summer bees.

# Landscape Factor (LF)

- 1) According to the current methodology (Section 5.3.7) it is possible to reduce the exposure by a percentage based on studies of the the type of pollen that is collected. However, as the risk assessment also covers weeds in and beside the treated field, it is not clear how this could be reliably measured... Would an assessment have to be done of the types of weeds present or potentially present?
- 2) Relating to the last question, it is unlikely that the results could thusly be extrapolated to areas other than the exact measured area.
- 3) The default of 0.99 seems less justified considering the data indicated that 1.0 was observed in field studies.



# LF: Suggestion

- 1) In line with other EFSA Guidance (i.e., PT in EFSA B&M 2009, 2022) the default value should be set to 1 for the first Tier.
- 2) Refinement should either be much more clarified as to feasibility and considerations of exposure via weeds/immediate off-field and extrapolation or disallowed.

# Greenhouse RA for BB

- The current draft does not provide a methodology/requirement for RA for BB in greenhouses
- Since BB are also managed pollinators (and vectors for microbial pesticides) in greenhouses, a specific RA for BB would be appreciated.

# Mixture toxicity

- ▶ ±7 of 8 responding CZMS considered this a key point, DE was split as to priority, one MS considered it important but not key
- ▶ Methodology is unnecessarily complex and it should be considered whether a toxic driver or other methodology could be adopted (or at least a very good tool to uniformly perform all calculations)
- ▶ Additional concern was noted as to accuracy/predictability

# Workshop

- ▶ Several points were considered by the CZMS to be important for harmonization and training, but not for revision or adjustment in the GD.
- ▶ It was therefore suggested to hold a workshop on these points, which will be listed at the end of the presentation.
- ▶ The idea of holding such a workshop was a unanimously agreed upon suggestion.

# Key points for which there was majority for responding CZMS

- ▶ non-*Apis* bee assessment
- ▶ Interspecies extrapolation/sensitivity analysis of tiered approach
- ▶ Mixing of castes in energy budget assessment

# Assessment of non-*Apis* bees

- ▶ “The perfect is the enemy of the good.” - Voltaire
- ▶ In order to implement an improved bee RA sooner rather than later, the majority of the CZMS (7/8) are willing to accept a higher level of uncertainty and extrapolation for non-*Apis* bees considering that European honey bees are extremely unique in ERA as they are:

# Assessment of non-*Apis* bees

- 1) Maintained by humans - there is a much larger basic knowledge base (i.e., more data) for honey bees than for any wild species;
- 2) Represented by only 1 species (*Apis mellifera*), which is unique amongst all organisms assessed in ERA.

# Assessment of non-*Apis* bees

Where are we?  
Ecotoxicity assessment

"Umbrella"	# of European Species
Mammals	270
Birds	540
Amphibians*	85
Reptiles*	151
Fish (freshwater)	531
Aquatic invertebrates	>1000
Vascular plants	9875
Bees	±2000*
Other arthropods	Many thousands
Soil organisms	Many thousands



ctgb

\*Amphibians and reptiles are currently "represented" by birds and mammals

\* The vast majority of which are solitary bees



# Assessment of non-*Apis* bees

- It is unlikely that a similar level of quantitative data will be available for non-*Apis* bees, thus the majority of CZMS generally agree with the extrapolations and higher uncertainties in the non-*Apis* assessment (considering specific points to be addressed, as noted previously).
- It is suggested that the non-*Apis* bee risk assessment could be reconsidered/updated/adjusted when the NTA GD is updated (i.e., considering the pollinator assessment to be implemented there).
- One responding MS (Slovenia) and JKI-DE consider the underlying data for the assessment of non-*Apis* bee species as currently insufficient.

# Tiered approach/sensitivity analysis

- ▶ 5 of 8 responding CZMS considered this a key point, one MS considered it moderately important
- ▶ Majority CZMS: Do high extrapolation factors (e.g., for solitary bees) on the effect assessment endpoint in combination with limit dosing result in a break-down of the tiered approach (i.e., too conservative for non/low-toxic substances)?
- ▶ Minority CZMS (BE, UBA-DE): Considering other assumptions (i.e., default slope of effect curve and internal exposure assumptions) and the sensitivity analysis performed by the WG (Supplementary document 7.1.5), this will not be an issue.

# Tiered approach/sensitivity analysis

- ▶ The sensitivity analysis performed by the WG is greatly appreciated however (a) HB endpoints were used (no other option), (b) the analysis is performed for only the crop scenario, and (c) some lower-risk substances were not reported.
- ▶ Suggestion to perform sensitivity analysis of the risk assessment to determine whether a tiered approach is achieved also for non-crop scenarios and specifically low-risk substances

# Mixing of castes in EB (SVs)

- A majority (5/8) of responding CZMS were concerned about mixing of worker castes with the reproductive caste in the sugar consumption/weight slope value (critical for SVs). If the different species are mixed for an overall model slope we propose either:
  - 1) “species” as a random factor in the model (so far we believe only “study” was accounted for as a random factor); or
  - 2) A single species should be used. Since the honeybee dataset is the most complete this would be the most appropriate to use (resulting in a slope value (upper bound) of 0.11).

# Other key points raised by individual or minority CZMS

- ▶ RUDs (JKI-DE, AT = key; important but lower prio for other MS): The differences of RUDs for pollen and nectar after sideward and downward application are very large. The referenced publication (Kyriakopoulou et al., 2017) stated there was no data to assess this. No information is given if new data is available or if the RUDs are based on extrapolation. The 90th percentile value of the distributions of RUDs (mg/kg) indicated that the RUD will be higher after sideward application by only a factor of 1.6 for pollen and 0.8 for nectar. Otherwise, in the version of the EFSA Bee Guidance Document (2013) the given values for pollen were higher by a factor of 11 after downward application compared to sideward application and for nectar higher by a factor of 2 for sideward application.

▶ Sensitivity of wild bees as regards detoxification enzymes (point to be specifically addressed) - SK, SI, JKI - see also considerations of non-*Apis* bee assessment and extrapolation in previous slides.

# Other key points raised by individual or minority CZMS - SK

- ▶ Calculating the lifespan dose-response (LDD50 and slope) - does the lifespan of 27 days not underestimate the risk to HBs? Drones are also chronically exposed...
- ▶ Risk assessment for winter bees - only honey is included but pollen may also be exposed and stored for winter
- ▶ Risk assessment for winter bees - larvae may be present/exposed in the winter
- ▶ Sublethal effects on honey bees in risk assessment - other parameters than foraging behaviour can influence overall colony health; see e.g., Weidenmüller et al. (2022); DOI: [10.1126/science.abf7482](https://doi.org/10.1126/science.abf7482)
- ▶ General - Potential risk from miticides (containing pyrethroids and licenced in EU) is absolutely absent in RA scheme (e.g., TRT and / or sublethal effects) or at least some short paragraph describing this issue.

# Points to be discussed/ harmonized in a workshop

- ▶ Statistical methods: When is a study in non-*Apis* bees acceptable (i.e., what level of effect should be considered an unacceptable effect)?
- ▶ Other aspects of effects on non-*Apis* bees, e.g., Should recovery be considered?
- ▶ Behavioural effects: Further agreements on what level of effect and types of effects are linked to effects on population
- ▶ Toxicity studies: What to do when it is not possible to determine an LD(D)50?





Questions are welcome!