

Increased Pollinator testing demands: What we know by now from the rush

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Introduction

With the European Food Safety Authority (EFSA) Guidance Document on the risk assessment of plant protection products on bees (2013), a number of changes and impacts on assessing the potential risk for pollinators has moved into focus. While some of the newly requested test setups and endpoints have undergone development and in some cases multiple ring-test phases, other designs still phase lack of data or time to develop the methodology properly. However, are these additional data sets indeed helpful and increase the safety of the given compounds, or is it just a tick the box procedure without a serious use for risk assessment?



Figure 1: Honey bee larvae



Figure 2: Honey bee



Figure 3: Bumble bee

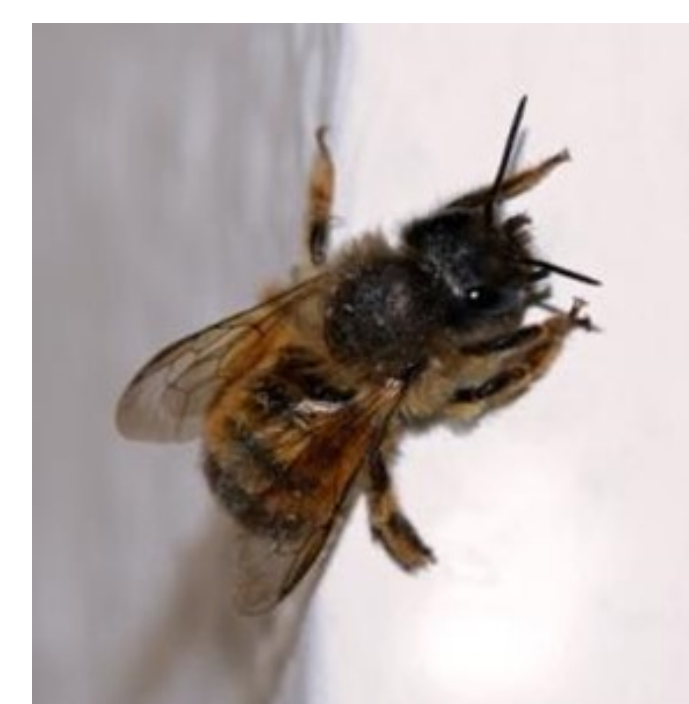


Figure 4: Solitary bee



Figure 5: Semi-field setup



Figure 6: Comb from a honey bee colony

Regulatory Background/Authority Aspects: Risk Assessment for Pollinators

The EFSA Guidance document on pollinator risk assessment is proposed to enlarge the focus from testing the honey bee as the only representative for pollinators in a limited number of exposure scenarios. Now a plenty of exposure scenarios is recognized and several additional species are included (Table 1, Figures 1-5).

However, the EFSA GD is still not adopted, public consultation revealed several concerns:

- Trigger values and safety factors are very conservative.
- Protection goals and field studies specification are hard to meet.
- Recommendations from previous guidances (SANCO, EPPO) are ignored.
- Testing requirements are partly not included in official EC documents.
- EFSA GD (2013) is very complex (species, methods, exposure)
- Important test systems are missing or inconclusive (e.g. honey bee hypopharyngeal gland test, cumulative toxicity, exposure via guttation).
- Testing at the Lowest Tier requires 14 studies; however, for many products honey bee is the most sensitive species in comparison to bumble bees (Table 2), and solitary bees are considered also to be less sensitive regarding the limited number of tests (data not shown).

Outcome & Future Perspectives

- EU Commission postponed finalization of EFSA guidance for two more years, but also clearly mandates EFSA to revise the current document before finalization in 2021.
- Third round of public consultation is currently running.
- All new and recently developed tests will be included from 2021 on as mandatory parts for honey bees, bumble bees, solitary bees in the revised GD.
- More parts to be developed are clearly addressed:
 - **Chronic oral toxicity with bumble bees.**
 - **Larval toxicity with bumble bees.**
 - **Accumulative toxicity risk assessment in bumble bees.**
 - **Field tests with bumble bees.**
 - **Chronic oral toxicity with solitary bees.**
 - **Larval toxicity with solitary bees.**
 - **Accumulative toxicity risk assessment in solitary bees.**
- In addition, new residue relevant data are requested from 2020 on (Maximum Residue Levels in Honey, Figure 6).

Table 1: Current situation on available guidelines for Pollinator testing

Laboratory Test	Honey bees	Bumble bees	Solitary bees
8.3.1.1.1. Acute oral toxicity	OECD 213	OECD 246	Ringtest ongoing
8.3.1.1.2. Acute contact toxicity	OECD 214	OECD 247	Draft OECD guideline
8.3.1.2. Chronic toxicity to bees	OECD 245	Ringtest phase started	No validated methods
8.3.1.3. Effects on honeybee development and other honeybee life stages	OECD 237	Basic R & D started	Currently technically not possible
8.3.1.4. Sub-lethal effects	Draft OECD proposal		
	Development started < 5 years	Development / Evaluation not started > 5 years	Development / Evaluation started, first results promising > 3 years

Table 2: Examples from testing several pollinator species in the laboratory

Test item	Species	Acute oral	Acute contact	Chronic	Unit
		LD ₅₀	LD ₅₀	LD ₅₀	
Insecticide A	Honey bee adult	0.130	0.044	-	µg a.i./bee
	Bumble bee adult	0.283	0.776	-	µg a.i./bumble bee
Product A with 4 Herbicides	Honey bee adult	-	-	182	µg product/bee/day
	Honey bee larvae	-	-	258	µg product/larva
Insecticide B	Bumble bee adult	> 802	> 2500	-	µg product/bee/day
	Honey bee adult	> 86	> 100	> 175	µg a.i./bee
Fungicide A	Honey bee adult	-	-	65	µg a.i./bee/day
	Bumble bee adult	> 402	> 705	-	µg a.i./bumble bee
Product B with 2 Fungicides	Honey bee larvae	-	-	500	µg a.i./larva
	Bumble bee adult	> 1070	> 505	-	µg a.i./bumble bee
Product C with 2 Fungicides	Honey bee larvae	-	-	36	µg product/larva
	Bumble bee adult	> 1290	> 1183	-	µg product/bee/day
Product D with 2 Herbicides	Honey bee larvae	1736.0	> 220	-	µg product/larva
	Bumble bee adult	-	-	> 535	µg product/bee/day
Product E with 2 Fungicides	Honey bee larvae	-	-	135	µg product/larva
	Bumble bee adult	> 1727	> 2000	-	µg product/bee/day
Product F with 1 Insecticide	Honey bee larvae	12.0	-	-	µg product/bee/day
	Bumble bee adult	> 2540	> 2994	-	µg product/larva
Fungicide B	Honey bee larvae	0.05	1.64	-	µg a.i./larva
	Bumble bee adult	> 9.30	> 5.0	-	µg a.i./bumble bee
Product F with 1 Herbicide	Solitary bee adult	> 9.30	> 5.0	-	µg a.i./solitary bee
	Honey bee larvae	-	-	12	µg a.i./larva
Herbicide A	Bumble bee adult	> 96	> 100	-	µg a.i./bee/day
	Honey bee larvae	-	-	8.8	µg a.i./larva
	Honey bee larvae	-	-	3.0	µg a.i./larva
	Bumble bee adult	> 45	> 100	-	µg a.i./bumble bee
	Honey bee larvae	-	-	> 33	µg product/larva
	Bumble bee adult	> 101	> 94	-	µg product/bee/day

Conclusion:

- Based on available results and data, additional testing with bumble bees and solitary bees is adding additional and useful information, but will not result in change of risk assessment for many cases.
- Honey bees seem to be still the most sensitive species among the three and across different classes of plant protection products.
- However, species-specific exposure routes for bumble bees and solitary bees should be taken in consideration.
- Further refinement and even more new and yet undeveloped test systems will need years of development and take time to be integrated in current risk assessment scheme.

Sources

EFSA 2013, European Food Safety Authority, Guidance Document on the risk assessment of plant protection products on bees (*Apis mellifera*, *Bombus spp.* and solitary bees), EFSA Journal 2013;11(7);3295.

Acknowledgement

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