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Introduction to ECHA's Guidance on the assessment of risks to bees from the use of biocides *(February 2024)*

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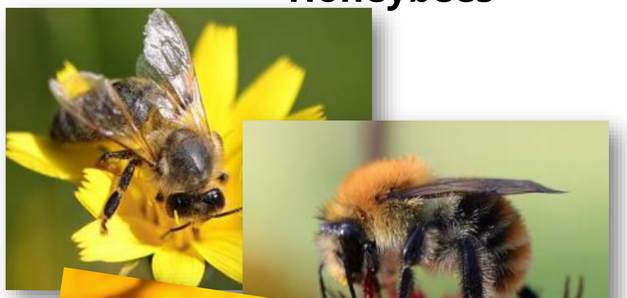
5th Biocides Industry Stakeholder Symposium - 29th May 2025

Why the concern with the risk assessment of pollinators?

Aim: reverse decline of pollinators to ensure…

sufficient protection of pollination ecosystem service

Bees



Honeybees

Bumble bees

Solitary bees

“Non-Bee Pollinators”

flies

Butterflies, moths

Wasps, sawflies

beetles

(adapted from ECHA webinar – Getting familiar with ECHA’s guidance to assess risks of biocides to bees)

Mandate to ECHA:

❖ In 2019, Commission mandated ECHA to:

- develop a guidance for assessing risks to arthropod pollinators (including bees)
- specify information required to enable a conclusion by evaluating authority

❖ ECHA was requested to take note of EFSA's guidance document:

- *Revised guidance on the risk assessment of plant protection products on bees (*Apis mellifera, Bombus spp*. and solitary bees)…*May 2023*


GUIDANCE

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

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European Food Safety Authority (EFSA)

Abstract

The European Commission asked EFSA to revise the risk assessment for honey bees, bumble bees and solitary bees. This guidance document describes how to perform risk assessment for bees from plant protection products, in accordance with Regulation (EU) 1107/2009. It is a revision of EFSA's previous guidance document, which was published in 2013. The guidance document outlines a tiered approach for exposure assessment in different scenarios, and tiers. It includes hazard characterisation and provides risk assessment methodology covering dietary and contact exposure. The document also provides recommendations for higher tier studies, risk from metabolites and plant protection products as mixtures.

Keywords: bees, pesticides, risk assessment, higher tier studies

Requestor: European Commission

Question number: EFSA-Q-2019-00308

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*https://pmc.ncbi.nlm.nih.gov/articles/PMC10173852/pdf/EFS2-21-e07989.pdf

European Commission

New biocide guidance.

Guidance on the assessment of risks to bees from the use of biocides (Feb 2024)*

- Quantitative risk assessment…
- Relevant application and uses…
- Relevant active substance and biocidal products…
- Toxicity studies required…

*https://echa.europa.eu/documents/10162/2324906/guidance_on_assessment_risks_to_bees_from_biocides_en.pdf

Bees: Specific Protection Goal (SPG)

- Protection of pollination ecosystem service providers – bee colony/population strength:
  - Under PPPs → threshold of 10% max reduction in colony/population size for honeybees.
  - Threshold for bumble bees and solitary bees not defined.

Environmental protection goal under BPR:
"impact on biodiversity and ecosystem"

SPG: Protection of pollination ecosystem service providers - Bee colony/population strength

Bee group	Maximum permitted level of colony/population size reduction
Honey bees	10 %
Bumble bees	Undefined
Solitary bees	Undefined

→ **Threshold used in quantitative risk assessment**

(from ECHA webinar – Getting familiar with ECHA's guidance to assess risks of biocides to bees)

Bee Guidance outline.

- Ch 1: Introduction
- Ch 2: Scope
- Ch 3: Risk assessment scheme
- Ch 4: Problem formulation

  Scope & Problem formulation
- Ch 5: Exposure assessment
- Ch 6: Effects – lower tier
- Ch 7: Lower tier RA

  Methodology
- Ch 8: Time reinforced toxicity
- Ch 9: Sublethal effects

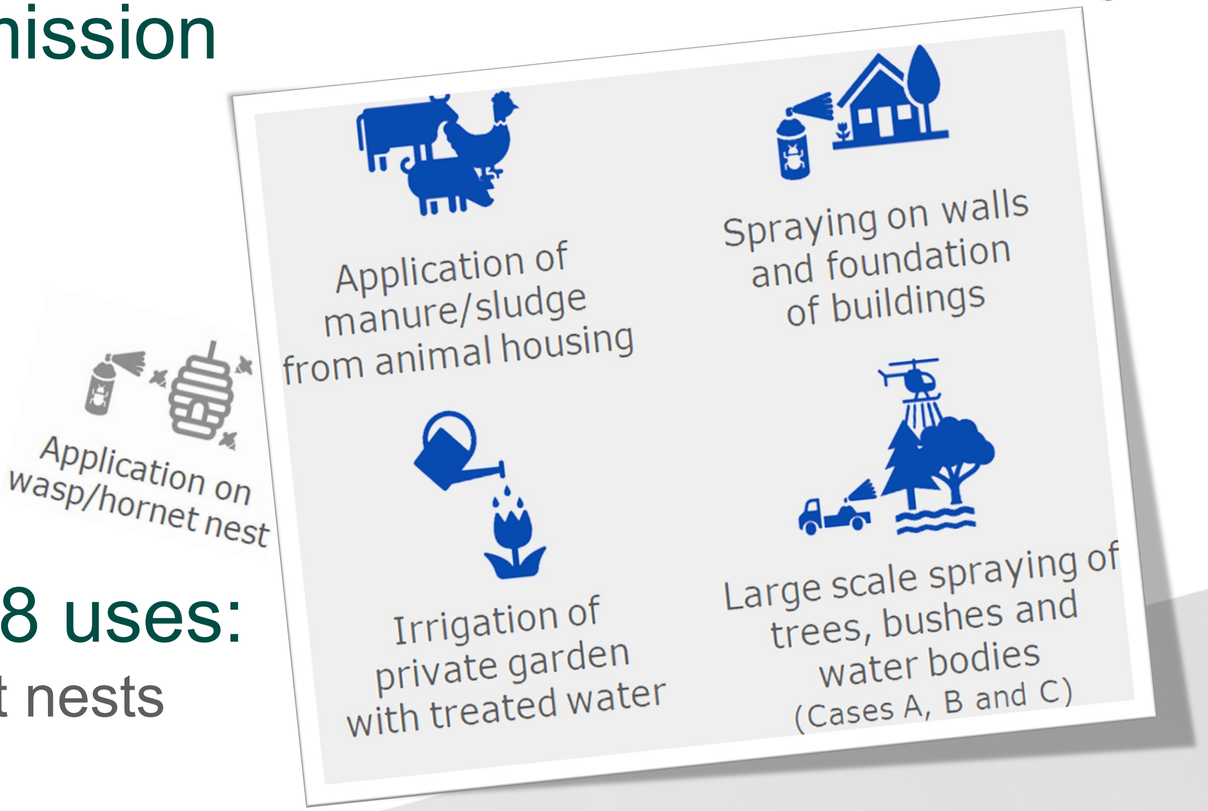
  New elements in bee risk assessment
- Ch 10: Higher tier RA
- Ch 11: Metabolites
- Ch 12: Mixtures (biocidal products)

  Specific schemes
- Ch 13: Risk mitigation measures and warning sentence*
- Ch 14: Conclusions
- Ch 15: Recommendations

(adapted from ECHA webinar – Getting familiar with ECHA's guidance to assess risks of biocides to bees)

Emission scenarios with exposure of bees.

- Criteria to identify relevant emission scenarios:
  - Outdoor use/release
  - Release pathway/application type
  - Release scale of certain magnitude (e.g., spray or manure application)
  - Insecticidal mode of action



- Focus on product type (PT) 18 uses:
  - Baits and applications to wasp/hornet nests are not currently assessed.

Relevant sources of exposure from the use of biocides (Product Type 18) (from ECHA webinar – Getting familiar with ECHA's guidance to assess risks of biocides to bees)

Information requirements for effect assessment:

❖ Information requirements for active substances and biocidal products:

- BPR Annex II (active substance): for honeybees (9.5.1); for bumble bees, solitary bees and other arthropods (9.5.2)
- BPR Annex III (biocidal product): (9.3) - toxicity tests related to a certain exposure pathway should be included.
- Bee studies should in general be provided if:
  - active substance has insecticidal mode of action **and**
  - there is relevant exposure of the biocidal product to bees (→ chapter 2 and 5)

❖ Mandatory requirement: data on honeybees:

- Data on bumble bees and solitary bees may be requested if relevant for the assessment.

Currently available test guidelines.

Test type	Test guideline		
	Honey bees 	Bumble bees 	Solitary bees 
Acute oral toxicity	OECD 213	OECD 247	b
Acute contact toxicity	OECD 214	OECD 246	c
Chronic oral toxicity	OECD 245	a	d
Toxicity to larvae	OECD 239	Standard test methods not yet available	e

Standard test methods not yet available

a) Proposal for a test protocol available for *Bombus* species (Exeler et al., 2019).
b) Draft version available for *Osmia* species (Roessink et al., 2019).
c) Draft version available for *Osmia* species (Roessink et al., 2017).
d) Proposal for a test protocol available for *Osmia* species (Azpiazu et al., 2022).
e) Proposal for a test protocol available for two *Osmia* species (Claus et al., 2021).

❖ Tests considered:

- Std. test guidelines (e.g., OECD).
- Existing protocols (pending validation and adoption as new test guideline).
- Rel. info. from public lit. and non-guideline studies.

Data requirements for active substances and biocidal products with insecticidal mode of action.

Tier 1 study type	Study with active substance	Study with formulation (biocidal product) required?	
		Formulation with 1 a.s.	Formulation with 2 or more a.s. with insecticidal MoA
Acute oral, adults	yes	Yes	yes
Acute contact, adults	yes	Yes	yes
Chronic oral, adults	Yes	Pending on comparison between acute studies	yes
Toxicity to larvae	Yes		yes

$\frac{LD_{50,acute\,(a.s.)}}{LD_{50,acute\,(b.p.)}} \leq 3$ … no further data on biocidal product needed

Tests with biocidal product necessary, if… $\frac{LD_{50,acute\,(a.s.)}}{LD_{50,acute\,(b.p.)}} > 3$

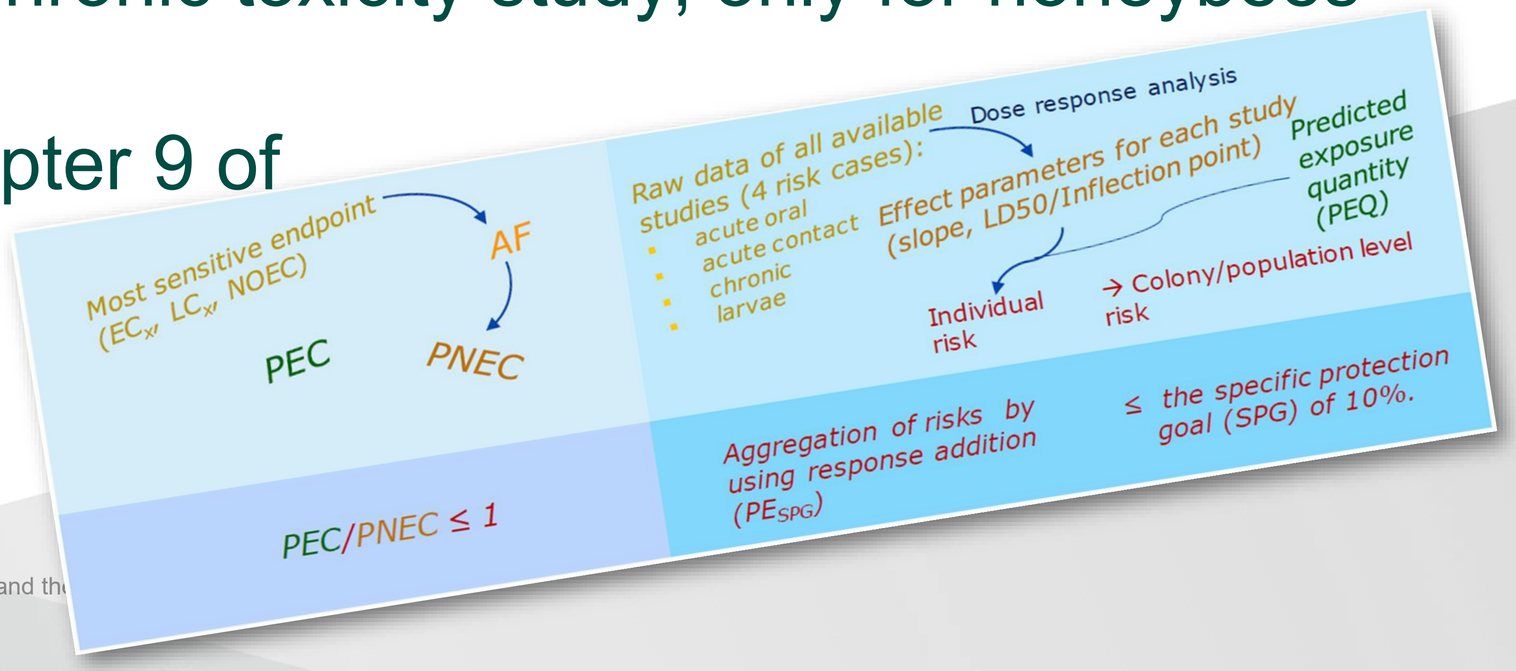
Tests with biocidal product - data on mixture toxicity always required

New Risk Assessment for Bees.

- Traditional risk assessment for biocides – uses the PNEC
  - New risk assessment → similar to guidance for plant protection products
  - Different bee exposure pathways evaluated → biocide risk assessment.

- Time reinforced toxicity (Chapter 8 of ECHA Bee Guidance) → data from std. 10-day chronic toxicity study, only for honeybees

- Sub-lethal effects (Chapter 9 of ECHA Bee Guidance)



Approach for Metabolites and Mixtures.

❖ Risk assessment needed for metabolites:

- Metabolites a concern when found in plant materials (pollen, nectar, other plant matrices attractive to bees).
- Exposure to bees → risk assessment triggered → measured metabolite data in relevant matrices may be required.

❖ Mixture assessment for honeybees:

- Only ≥ 2 active substances with an insecticidal Mode of Action (MoA) present in a product.

Summary:

- ECHA bee guidance developed by considering guidance for PPPs – with biocide specific adaptations.
- ECHA bee guidance applicable for sources of emissions belonging to product type 18 uses.
- Assessment currently only for honeybees (no agreed specific protection goals (SPGs) for bumble/solitary bees).
- Sublethal effects and time-reinforced toxicity assessments new elements for biocides.
- Risk needs to comply with SPGs, no PEC/PNEC risk ratio.

Implications:

- for **bees**: new data requirements and new risk assessment methodology in the biocide assessment.
- a calculator tool to be provided,
- more consistent and robust assessment of risks to bees,
- better protection of pollinators.
- for **non-bee pollinators**: further research needed to define a method for quantitative risk assessment

Conclusion:

- The new guidance will apply to **active substance approval and biocidal product authorisations** for which applications are submitted on or after 1 February 2026.