Welcome

Webinar: Getting familiar with ECHA's guidance to assess risks of biocides to bees

5 March 2024

Adam Elwan
Communications
European Chemicals Agency

What you can expect today

→ Understand when to assess risks of biocides to bees

→ Learn about the methodology and decision schemes followed in the risk assessment

→ Get answers to your questions

Live Q&A

- → Join Q&A at: slido.com
  Event code: # **echabees**
- → Send questions throughout the event until 13:00 (EET, GMT +2)
- → Question for a specific speaker? Indicate when sending your question
- → Only questions within scope
- → Question not answered? Refer to published Q&A

Questions after the webinar?
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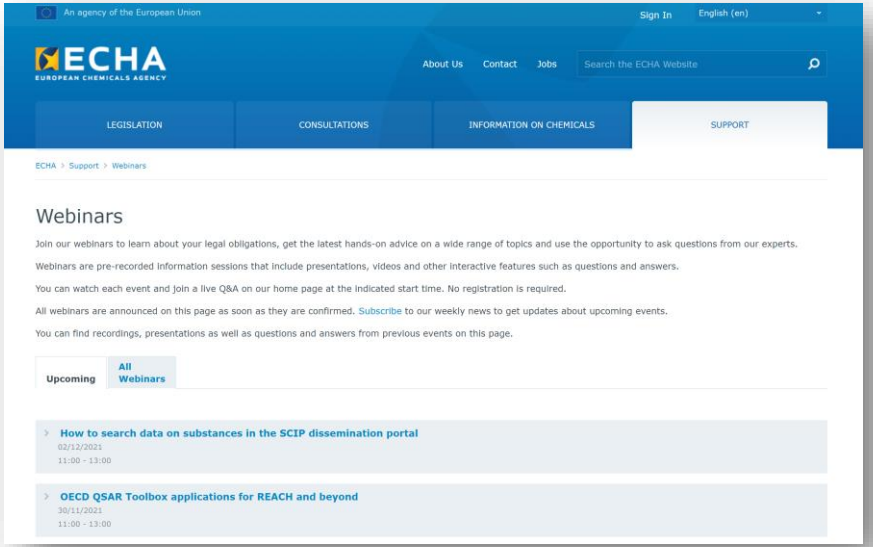
Material available

→ Video recording
→ Presentations
→ Q&A (soon after the event)



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Programme

Time	Topic	Speaker
11:00	Welcome	Adam Elwan, ECHA
11:05	Introducing the guidance	Jaana Laitinen, ECHA
11:15	Scope and risk assessment scheme	Tenzing Gyalpo,Swiss Federal Office for the Environment (FOEN)
11:25	Exposure assessment	Adriana Lipkova, ECHA
11:40	Information requirements and lower tier assessment	Petra Kunz, Swiss Federal Office for the Environment (FOEN)
11:55	Time reinforced toxicity and sublethal effects	Maria a Marca, Swiss Federal Office for the Environment (FOEN)
12:10	Approach for metabolites and mixtures	Ella Laakkonen, ECHA
12:20	Conclusions	Ella Laakkonen, ECHA
12:25	Introduction to Q&A	Adam Elwan, ECHA
12:30 – 13:00	Live Q&A	

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Introducing the guidance

Webinar: Getting familiar with ECHA's guidance to assess risks of biocides to bees

5 March 2024

Jaana LAITINEN
European Chemicals Agency

Why risk assessment of pollinators?

Aim: *reverse decline of pollinators - ensure sufficient protection of pollination ecosystem service*

Bees

Honey bees

Bumble bees

Solitary bees

"Non-bee pollinators"

Flies

Moths and butterflies

Wasps, sawflies

Beetles

Pictures: Nancy Ludwig and Christian Kantner

Current/previous biocide guidance

Guidance on BPR: Vol IV Environment Parts B+C (2017)*

Risk assessment and data requirements for pollinators

- ...*no method available for biocides*
- …*qualitative risk assessment if data available*
- …*data required on large scale-outdoor applications, or, substances with known toxicity to bees*

How to perform quantitative assessment?

Relevant application types and uses?

Relevant active substances and biocidal products?

Toxicity studies required?

*https://echa.europa.eu/guidance-documents/guidance-on-biocides-legislation

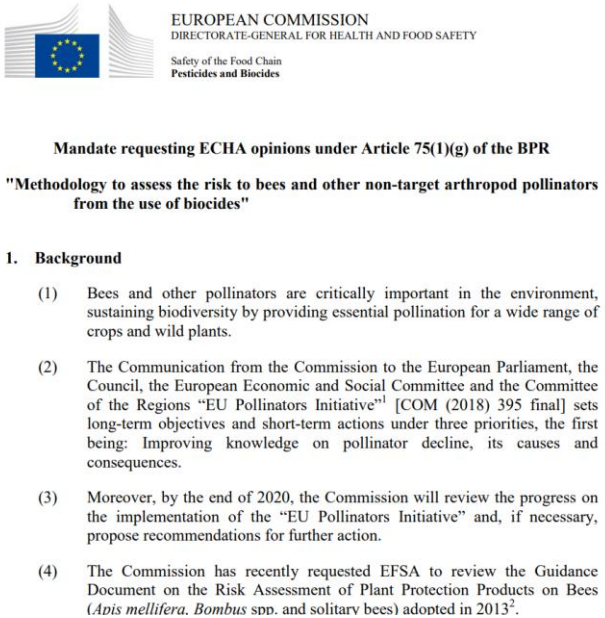
Mandate to ECHA

In 2019, Commission mandated ECHA* to

1) develop a guidance for assessing risks to **arthropod pollinators** (**including bees**)

2) specify **information required** to enable a conclusion by evaluating authority

*https://echa.europa.eu/regulations/biocidal-products-regulation/approval-of-active-substances/opinions-on-article-75-1-g



EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Safety of the Food Chain
Pesticides and Biocides

Mandate requesting ECHA opinions under Article 75(1)(g) of the BPR

"Methodology to assess the risk to bees and other non-target arthropod pollinators from the use of biocides"

1. Background

(1) Bees and other pollinators are critically important in the environment, sustaining biodiversity by providing essential pollination for a wide range of crops and wild plants.

(2) The Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions "EU Pollinators Initiative"[1] [COM (2018) 395 final] sets long-term objectives and short-term actions under three priorities, the first being: Improving knowledge on pollinator decline, its causes and consequences.

(3) Moreover, by the end of 2020, the Commission will review the progress on the implementation of the "EU Pollinators Initiative" and, if necessary, propose recommendations for further action.

(4) The Commission has recently requested EFSA to review the Guidance Document on the Risk Assessment of Plant Protection Products on Bees (*Apis mellifera, Bombus* spp. and solitary bees) adopted in 2013[2].

Bees: Risk assessment methodology

ECHA was requested to take into account EFSA's guidance document:

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

↳ Guidance for biocides uses methodology outlined in EFSA guidance

* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC10173852/#efs27989-sec-1004

Bees: Specific Protection Goal (SPG)

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

Bees: Guidance outline (1/2)

- 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

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Bees: Guidance outline (2/2)

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

New elements in bee risk assessment

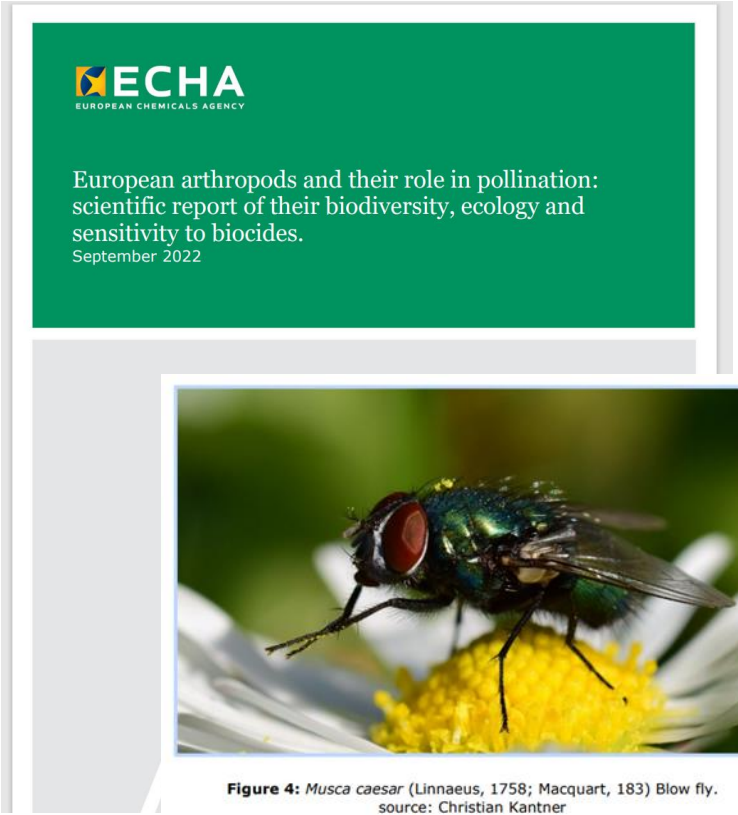
- Ch 10: Higher tier RA
- Ch 11: Metabolites
- Ch 12: Mixtures (biocidal products)

Specific schemes

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

*CA-Dec20-Doc.4.1: https://circabc.europa.eu/ui/group/e947a950-8032-4df9-a3f0-f61eefd3d81b/library/5e6cf719-8286-4cbf-9b1e-f01eade08bb7/details

Non-bee pollinators (NBP)



ECHA Scientific publication (2022)*

- Due to identified data gaps, not possible to propose risk assessment scheme
- Future update of BPR Vol IV Part B+C: NBPs to be covered under non-target terrestrial arthropods assessment

*https://echa.europa.eu/documents/10162/17231/nbp_report_en.pdf/7ea8718e-2d64-141e-9f23-3c9207dcd824?t=1662372417706

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Scope and risk assessment scheme

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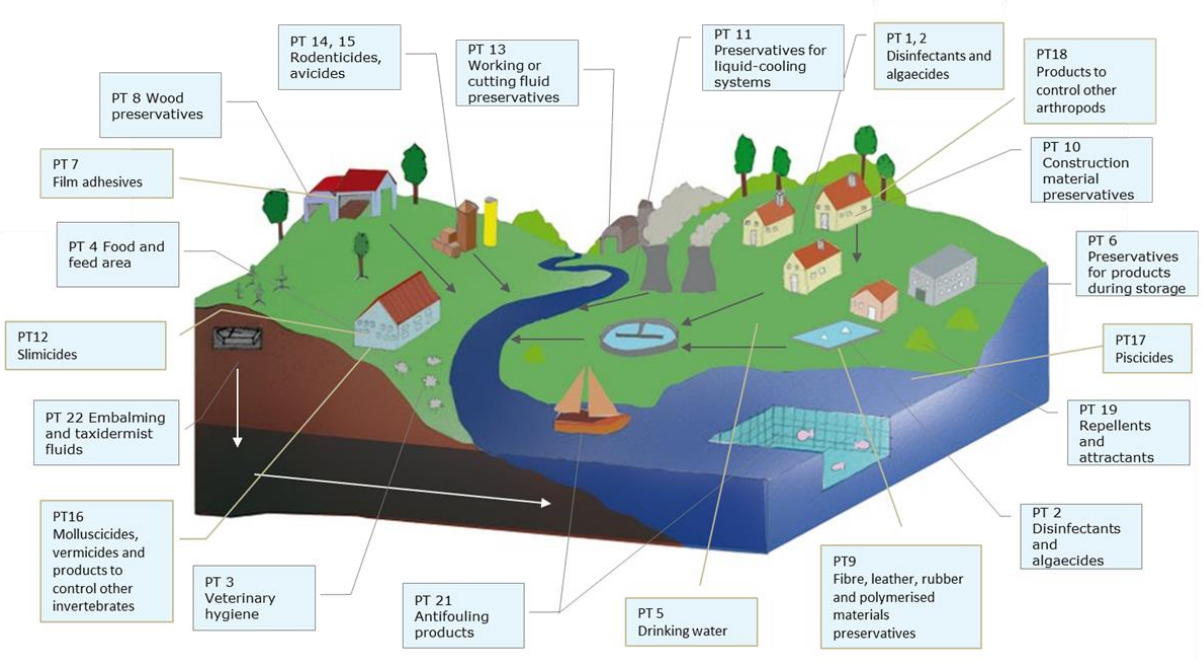
Tenzing GYALPO
Swiss Federal Office for Environment (FOEN)

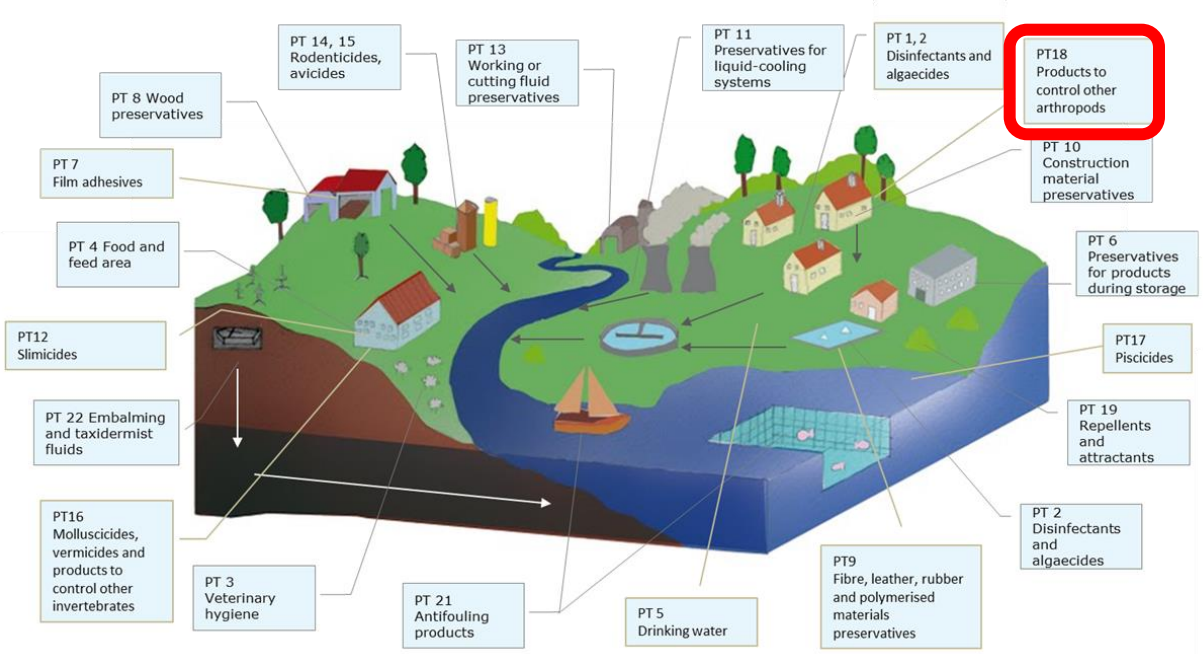
Emission scenarios with exposure of bees



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

Emission scenarios with exposure of bees



Criteria to identify relevant emission scenarios

- → Outdoor use/release
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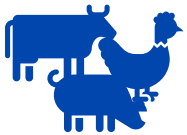
Focus on product type (PT) 18 uses

Sources of exposure



Application of manure/sludge from animal housing

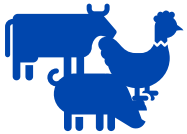
Spraying on walls and foundation of buildings

Irrigation of private garden with treated water

Large scale spraying of trees, bushes and water bodies
(Cases A, B and C)

Focus on product type (PT) 18 uses

Sources of exposure



Application of manure/sludge from animal housing

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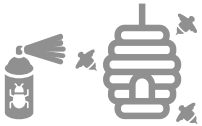
Not assessed for the moment:

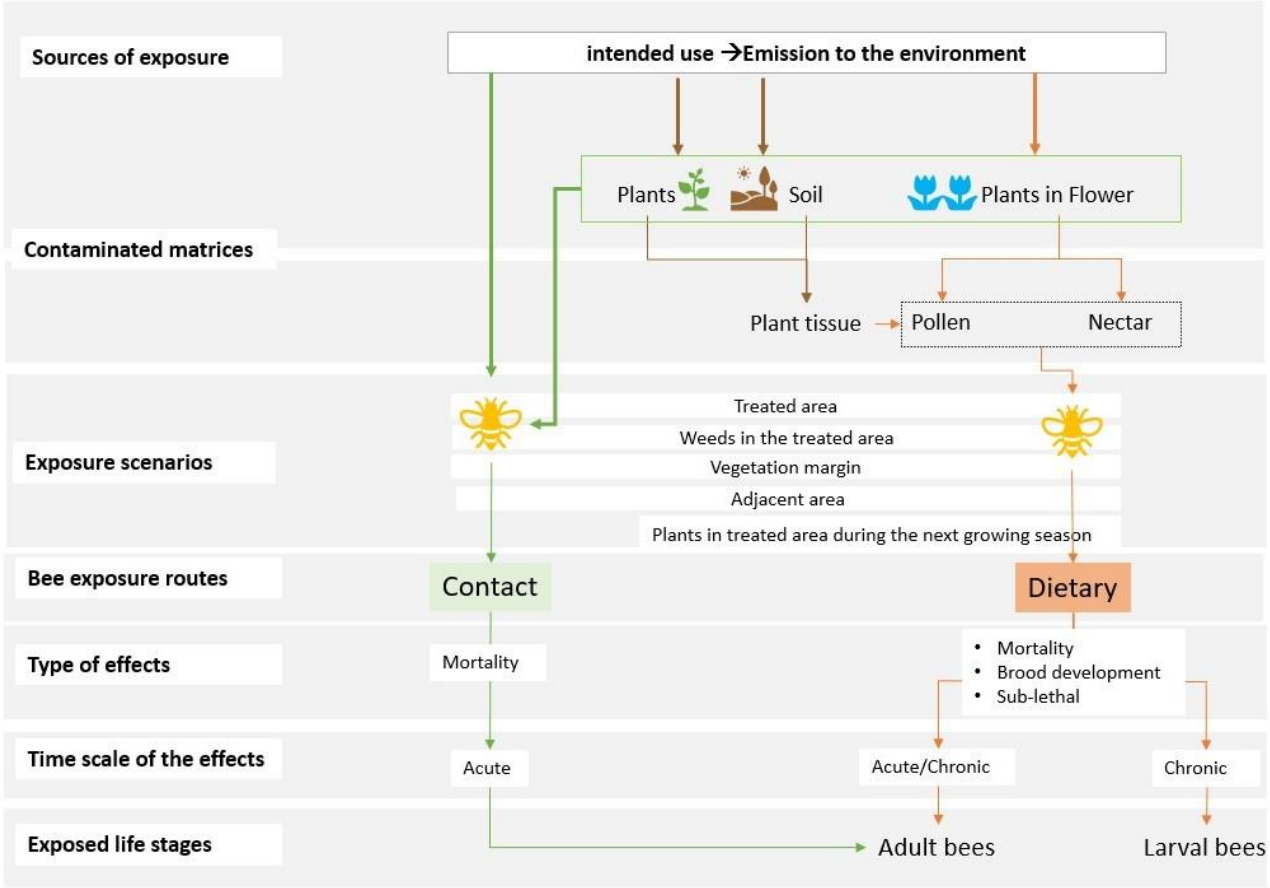
Bait and spot applications on terraces



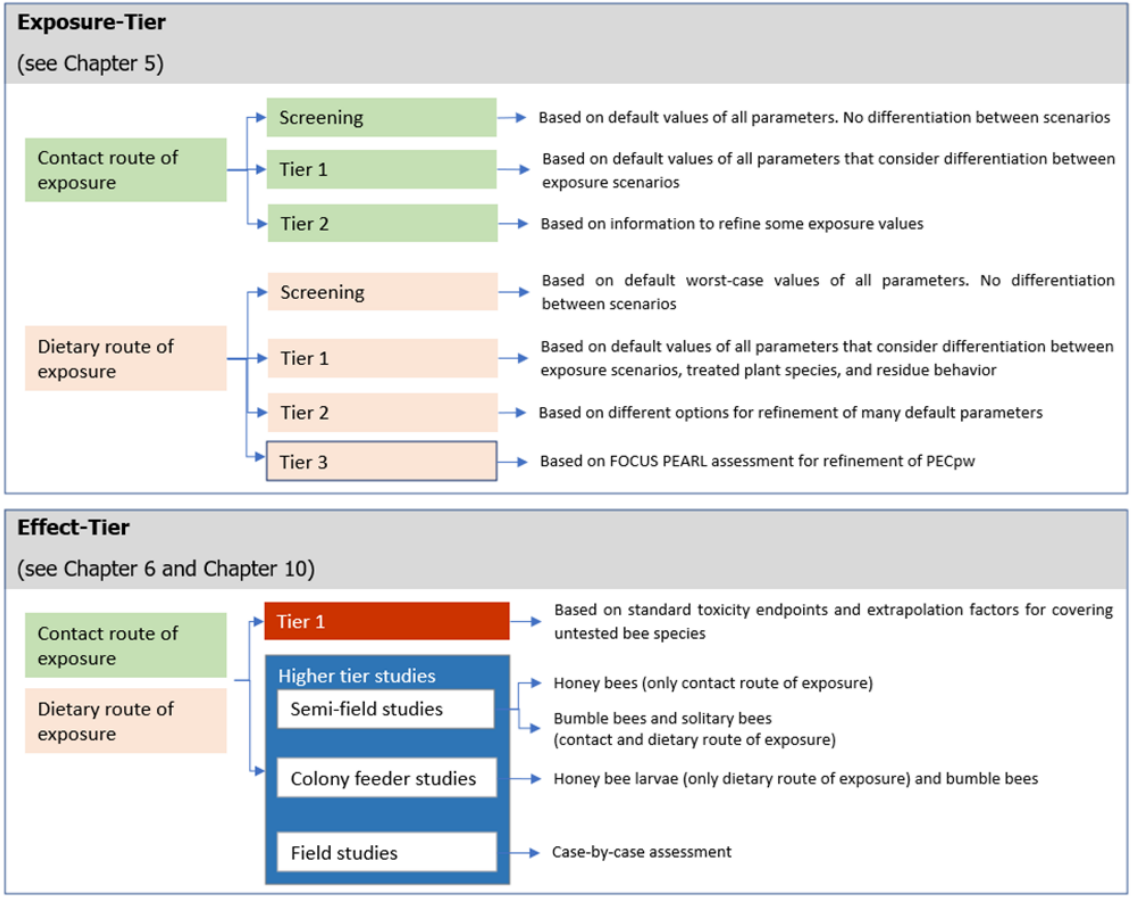
Application on wasp/hornet nest

Direct consumption of baits

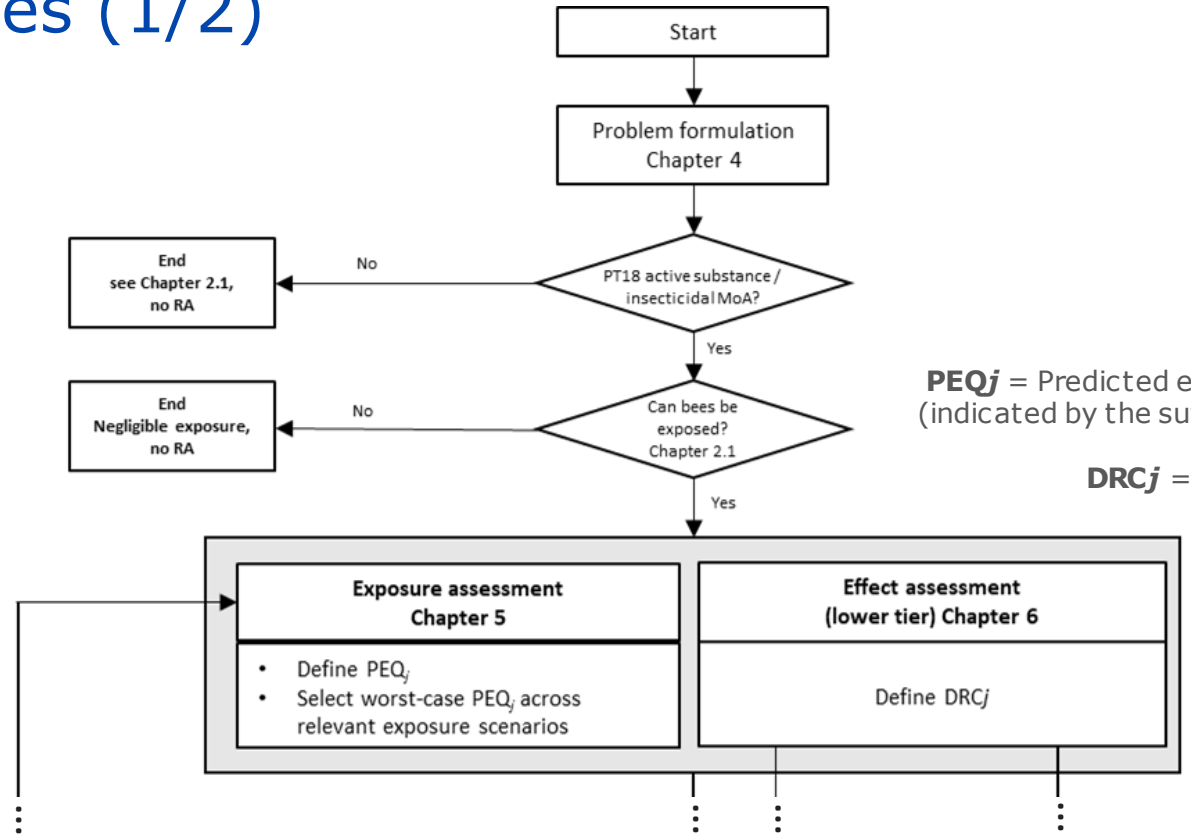
Overview of biocide exposure to bees



Tiered approach for exposure and effect

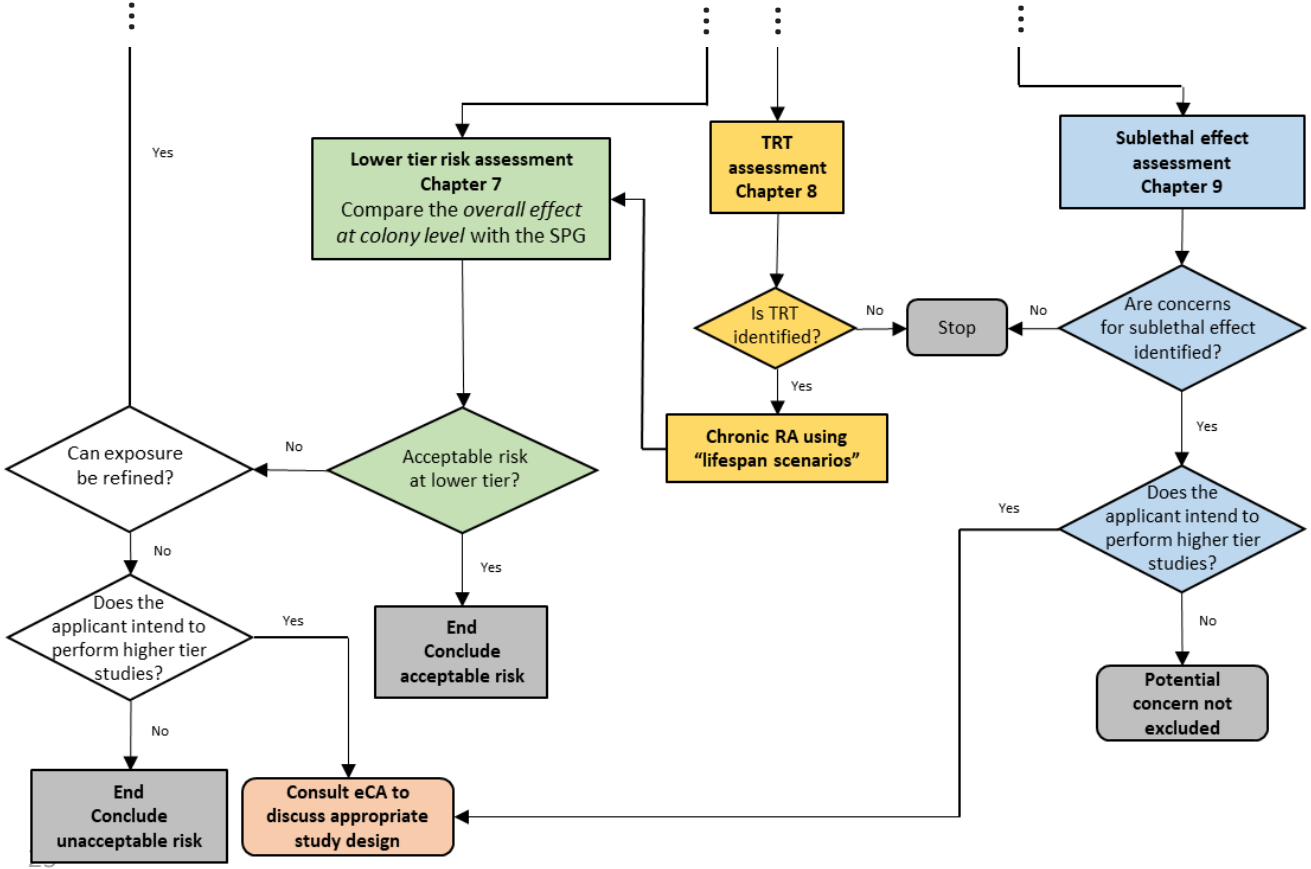


Risk assessment scheme for honey bees (1/2)



HB = honey bees
MoA = mode of action
RA = risk assessment
PEQ*j* = Predicted exposure quantity for the four risk cases (indicated by the suffix *j*, i.e., acute-contact, acute-dietary, chronic-dietary and larvae-dietary)
DRC*j* = dose-response curve for the risk case *j*

Risk assessment scheme for honey bees (2/2)



Note that a risk assessment for metabolites (Chapter 11) and for mixtures (Chapter 12) need to be conducted, where relevant. For higher tier risk assessment, see Chapter 10

TRT = time reinforced toxicity (only relevant for honey bees)
SPG = specific protection goal
eCA = evaluating competent authority

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Exposure assessment

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5 March 2024

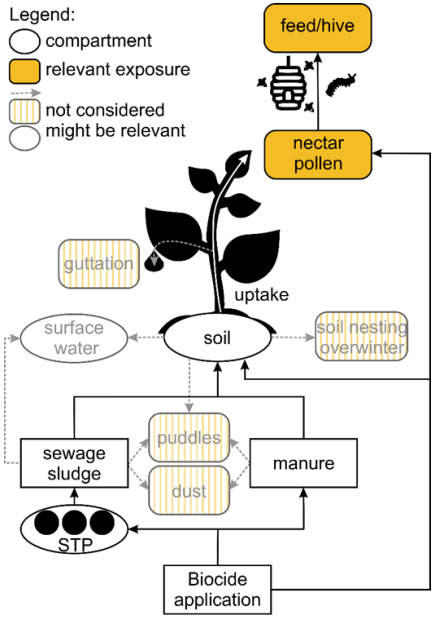
Adriana LIPKOVA
European Chemicals Agency
Ricardo SCHÖPS
German Environment Agency (UBA)

Exposure assessment

- Two main routes of exposure: dietary and contact

- Relevant exposure assessment models:

Dietary		Contact
above-soil model	through-soil model	contact model
during flowering - direct contamination of pollen/nectar	residue uptake from soil	through physical contact between bees and biocide



Mathematical models - dietary exposure

- Calculation of Predicted Exposure Quantity due to dietary exposure (PEQ_{di})

Above-soil model

$$PEQ_{di} = \frac{AR}{1000} \times EF_{di} \times \left(SV_{po,du} + SV_{ne,du}\right)$$

$$SV_{po,du} = \frac{1}{1000} \times LF_{po} \times PCUD_{po,du} \times CMP_{po}$$

$$SV_{ne,du} = \frac{1}{1000} \times LF_{ne} \times PCUD_{ne,du} \times \frac{CMP_{su}}{SN}$$

Through-soil model

$$PEQ_{di} = SV_{po,\mathrm{soil}} + SV_{ne,soil}$$

$$SV_{po,\mathrm{soil}} = \frac{1}{1000} \times LF_{po} \times PEC_{pw} \times CMP_{po}$$

$$SV_{ne,soil} = \frac{1}{1000} \times LF_{ne} \times PEC_{pw} \times \frac{CMP_{su}}{SN}$$

Mathematical models - dietary exposure

LF	Landscape dilution factor for pollen (LF_{po}) and nectar (LF_{ne}) (-)
PCUD	Predicted Concentration per Unit Dose in pollen ($PCUD_{po,du}$) and nectar (PCUDne,du) from during flowering application (mg/kg)
CMP	Consumption of sugar (CMP_{su}) or pollen (CMP_{po}) (mg/bee or mg/bee/day or mg/larva/developmental period)
SN	Sugar content in nectar expressed as mass/mass (e.g., kg/kg)
PEC_{pw}	Predicted Environmental Concentration in pore water (mg/kg ≙ mg/L)

soil model

$_{,soil} + SV_{ne,soil}$

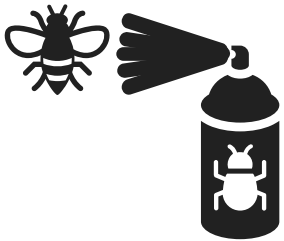
AR	Application rate (g/ha)
Ef_{di}	Exposure factor for dietary exposure (-)
SV	Shortcut value (µg/bee or µg/bee/day or µg/larva/developmental period)

Mathematical model - contact exposure

- Calculation of Predicted Exposure Quantity for contact exposure (PEQ_{co})

Contact model

$$PEQ_{co} = AR \times EF_{co} \times BSF$$



EF_{co}	Exposure factor for contact exposure (-)
BSF	Body surface factor (dm^2/bee)

Mathematical model – screening step

- Calculation of Predicted Exposure Quantity due to dietary exposure (PEQ_{di})

Dietary model

$$PEQ_{di} = \frac{AR}{1000} \times n \times B$$

n	number of applications (to soil)
constant B	

- Calculation of Predicted Exposure Quantity for contact exposure (PEQ_{co})

Contact model

$$PEQ_{co} = AR \times BSF$$

Sources of exposure

Application of manure/sludge from animal housing

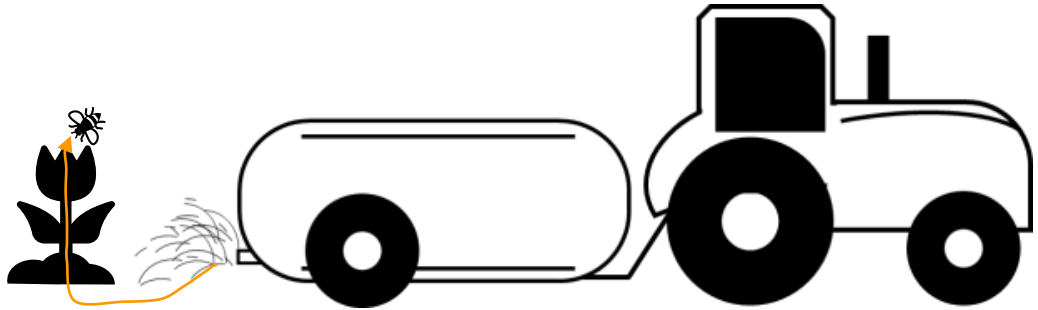
Spraying on walls and foundation of buildings

Irrigation of private gardens with treated water

Large scale spraying of trees, bushes and water bodies– Cases A, B and C

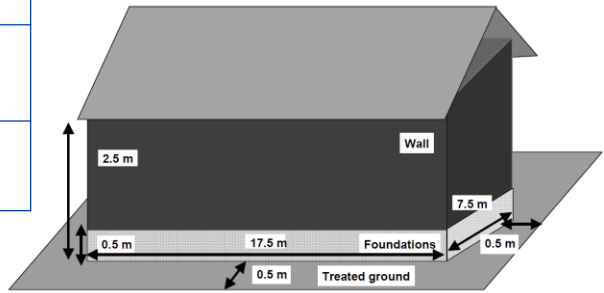
Application of manure/sludge

Use	Application in stables and manure storage systems
ESD	ESD PT 18 (2006) for Insecticides for Stables and Manure Storage Systems
Exposure route	Dietary intake (through soil only)
Exposure scenario	Treated area

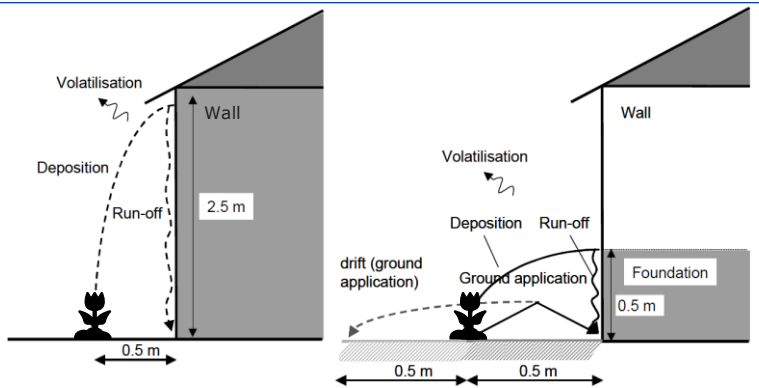


Spraying on walls and foundation

Use	Wall/foundation spray application on residential and non-residential buildings
ESD	ESD PT 18 (2008) for household and professional uses, revised ESD PT18 (ongoing)
Exposure route	Dietary intake (above and through soil) and contact
Exposure scenario	Vegetation margin



From ESD PT18 for household and professional uses ENV/JM/MONO(2008)14



From ESD PT18 for household and professional uses ENV/JM/MONO(2008)14

Irrigation of private gardens

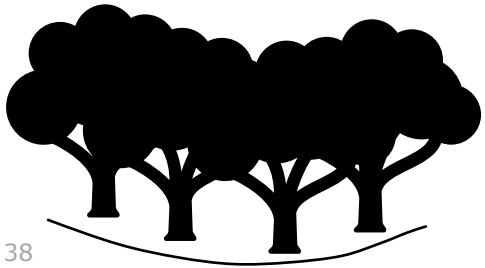
Use	Irrigation of private gardens with treated water
ESD	TAB entry ENV 205 (ECHA, October 2022)
Exposure route	Dietary intake (above and through soil) and contact
Exposure scenario	Treated area

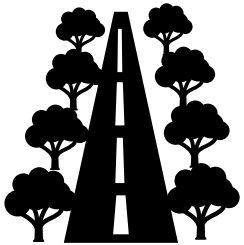
Large scale spraying

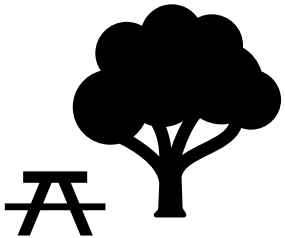
Case A	Large scale spraying of specific species of trees
Case B	Large scale spraying of mixed species of trees and bushes
Case C	Large scale spraying of natural water bodies

Large scale spraying – Cases A

Use	Case A: Large scale spraying of specific species of trees
ESD	TAB entry ENV 248 (ECHA, October 2022)
Exposure route	Dietary intake (above and through soil) and contact
Exposure scenario	Treated area, Weeds in the treated area, Vegetation margin, Plants in treated area during the next growing season





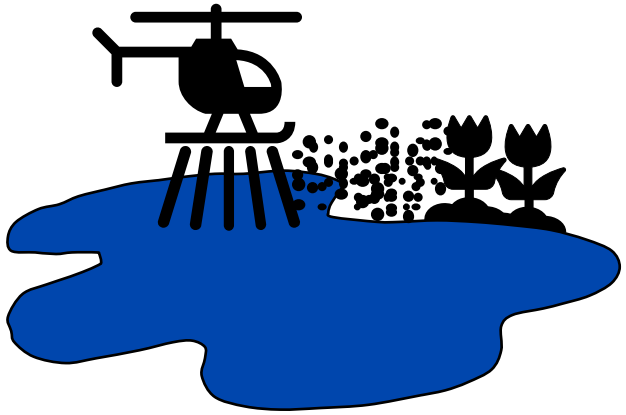


Large scale spraying – Cases B

Use	Case B: Large scale spraying of mixed species of trees and bushes
ESD	TAB entry ENV 248 (ECHA, October 2022)
Exposure route	Dietary intake (above and through soil) and contact
Exposure scenario	Treated area, Weeds in the treated area, Vegetation margin, Plants in treated area during the next growing season

Large scale spraying – Cases C

Use	Case C: Large scale spraying of natural water bodies
ESD	for household and professional uses, plant protection products MED-RICE scenario
Exposure route	Dietary intake (above soil) and contact
Exposure scenario	Vegetation margin



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Information requirements and lower tier assessment

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5 March 2024

Petra Kunz
Swiss Federal Office for Environment (FOEN)

Short overview on how to do:

- Effect assessments in lower tiers (Chapter 6)
- Lower tier Risk Assessment (Chapter 7)

Information requirements for effect assessment

- Information requiremens for active substances and biocidal products
  - BPR Annex II (active substance): For honey bees (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 honey bees**

⇢ 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

- Standard test guidelines (e.g. OECD TG)
- Existing protocols (pending validadion and adoption as new test guideline)
- Relevant information from public literature 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

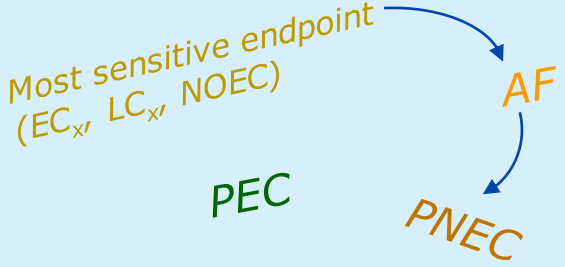
$\frac{LD_{50,acute\,(a.s.)}}{LD_{50,acute\,(b.p.)}} \leq 3$ … no further data on biocidal product needed

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

Paradigm change for bee effect and risk assessment

Traditional risk assessment - Biocides



PEC/PNEC ≤ 1

New risk assessment for Bees

Raw data of all available studies (4 risk cases):

- *acute oral*
- *acute contact*
- *chronic*
- *larvae*

Dose response analysis

Effect parameters for each study (slope, LD50/Inflection point)

Predicted exposure quantity (PEQ)

Individual risk

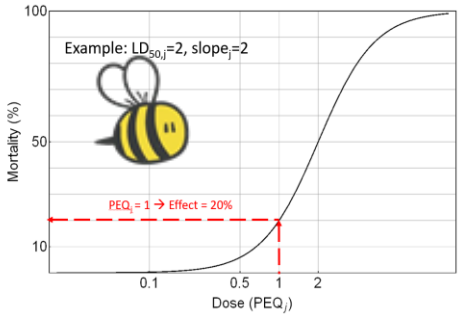
→ Colony/population level risk

Aggregation of risks by using response addition (PE_{SPG})

≤ the specific protection goal (SPG) of 10%.

Procedure for lower tier risk assessement

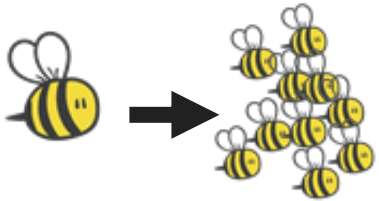
1. Individual level effect calculation



Quantification of effects for four risk cases based on:

- Standard laboratory studies (acute oral, acute contact, chronic & larvae)
- Standard exposure estimates

2. Extrapolation individual → Colony/population



Extrapolation of individual level effects to colony/population level effects for each risk case

3. Aggregation of all risk cases at colony/ population level

PE_{SPG}: *predicted effect at specific protection goal level (colony level)*

Combination of effects for all risk cases into a single predicted effect at colony/population level

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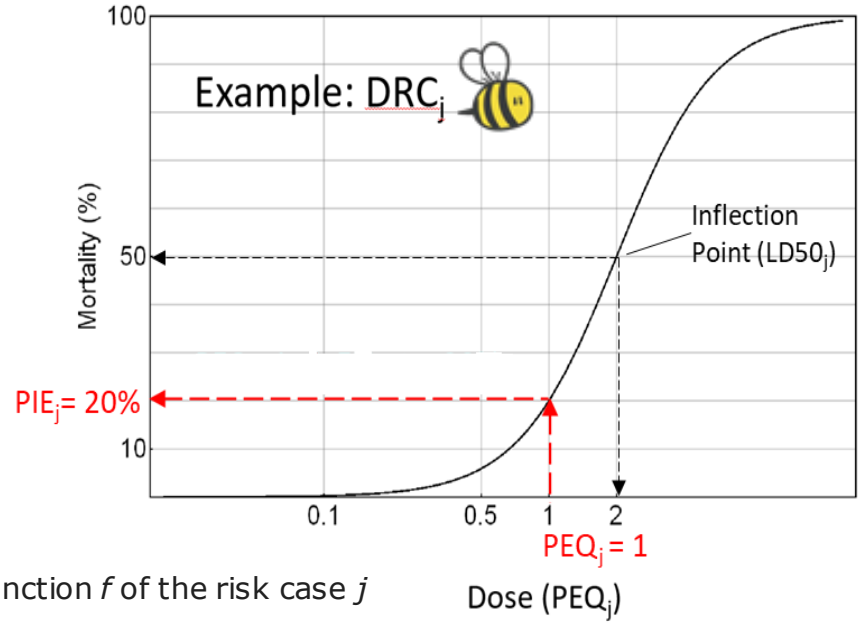
Step 1: Effects at individual levels

- Calculation of predicted individual level effect (PIE)
- Using realistic worst-case exposure (PEQ, predicted ecotoxicologically relevant exposure quantity)

$$PIE_j = f(LD_{50,j}, slope_j, PEQ_j)$$

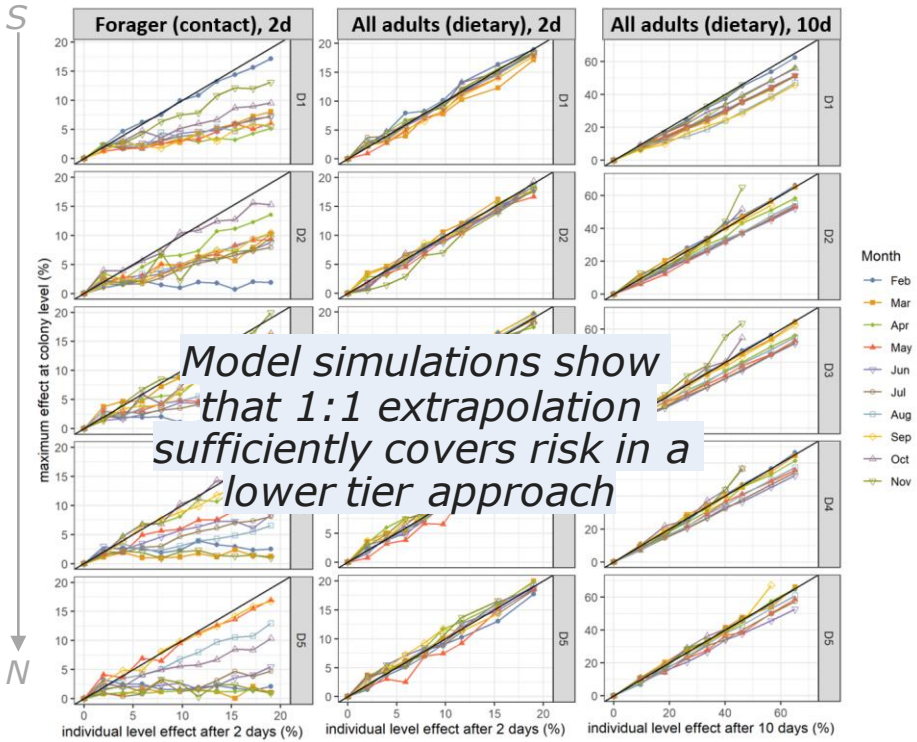


PIE_j : predicted individual level effect for the risk case j

$LD_{50,j}$, $slope_j$: parameters of log-logistic dose-response function f of the risk case j

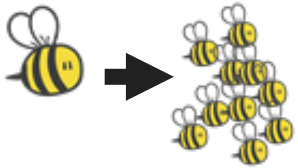
PEQ_j : relevant exposure quantity for the risk case j

Step 2: From individual to colony level effects



Model simulations show that 1:1 extrapolation sufficiently covers risk in a lower tier approach

Extrapolation of additional mortality from individual to colony level for **forager bees by contact exposure**, and **all adult bees by dietary exposure** for locations from southern (D1) to northern (D5) Europe. Average values from 100 replicate simulations.



- To make lower tier risk assessment compliant with the SPG
- Extrapolated from individual to higher levels of biological organisation (colony/population)

$$PCE_j = PIE_j$$

$$1 : 1$$

For contact (acute), and dietary exposure (acute, chronic, larvae).

PCE_j : *predicted colony level effect* for risk case *j*.

PIE_j: *predicted individual level effect* for risk case *j*.

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Step 3: Combination of effects at colony level → response addition

- Rationale: Under real world conditions effects are adding up at colony levels, where SPG is set
- Adding responses to biocide exposure can be mathematically expressed by using model of response addition (Bliss, 1939):

PE_{SPG}:
predicted effect at colony level (% in colony size reduction)

4 risk cases:
- *acute oral*
- *acute contact*
- *chronic*
- *larvae*

$$PE_{SPG} = 100 \cdot \left(1 - \prod_{i=1}^{n} \left(1 - PCE_j\right)\right)$$

PE_{SPG} has maximum of 100%

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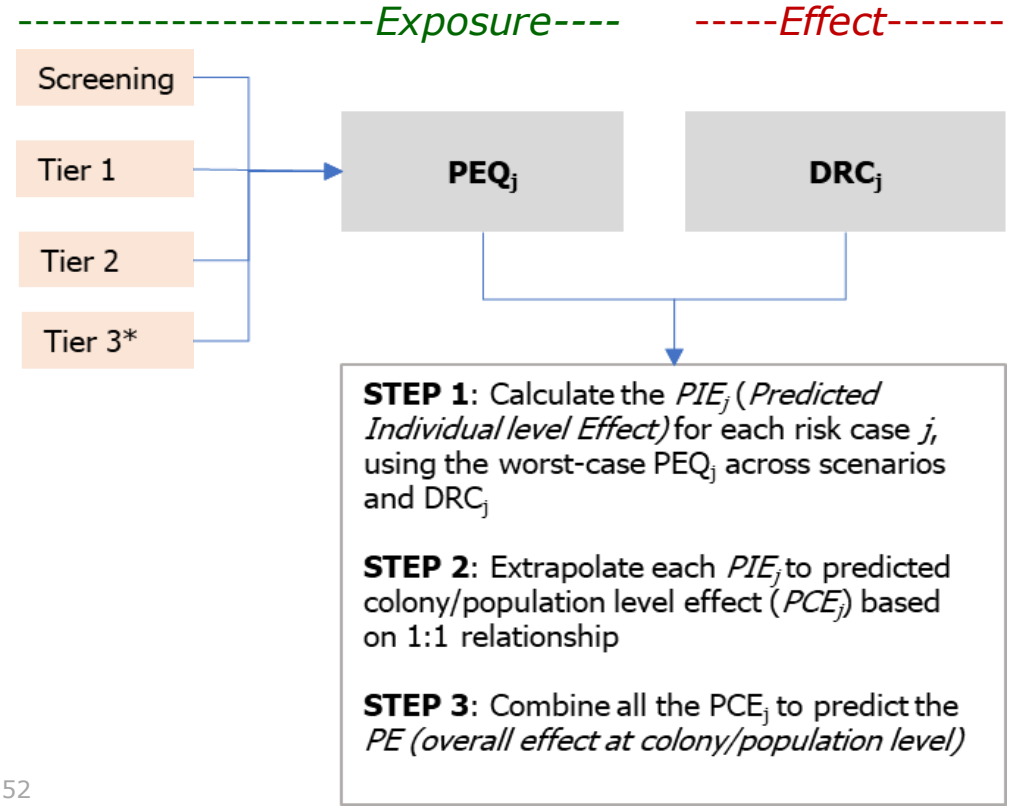
Combined risk assessment in tiered approach



STEP 4: Compare overall effect at colony level PE_{SPG} with SPG (≤10% for honey bees)

Example of lower tier risk assessment

Honey bees - Tier-1 exposure (Dietary model for through soil contamination and contact)				
	Risk cases			
	Dietary			Contact
	Acute (da)	Chronic (dc)	Larvae (dl)	Acute (ca)
Exposure: PEQ_j [µg/bee]	$PEQ_{da} = 0.265$	$PEQ_{dc} = 0.250$	$PEQ_{dl} = 0.272$	$PEQ_{ca} = 0$
Effect parameters (DRCj): **Mod:** Dose-response model **e:** LD50/IP [µg/bee] **b:** Slope	DRCda Mod: log-logistic e = 7 b = 1.84	DRCdc Mod: log-logistic e = 9 b = 1.67	DRCdl Mod: log-logistic e = 0.7 b = 2.24	DRCca Mod: log-logistic e = 15 b = 2.23
Step 1: Predicted individual level effect (PIE)	$PIE_{da} = 0.24\%$	$PIE_{dc} = 0.25\%$	$PIE_{dl} = 10.74\%$	$PIE_{ca} = 0.0\%$
Step 2: Predicted colony level effect (PCE)	$PCE_{da} = 0.24\%$	$PCE_{dc} = 0.25\%$	**$PCE_{dl} = 10.74\%$**	$PCE_{ca} = 0.0\%$
Step 3: combination of effects at colony level	$PE_{SPG} = 100 \cdot (1-(1-PCE_{da}/100) \cdot (1-PCE_{dc}/100) \cdot (1-PCE_{dl}/100) \cdot (1-PCEc_{ca}/100))$ $= 100 \cdot (1-(1-0.0024) \cdot (1-0.0025) \cdot (1-0.1074) \cdot (1-0))$ $=$ **11.18%**			
PE_{SPG} i.e., ≤ 10%	**No → unacceptable risk identified**			

Through soil model: Uptake of the a.s. by plant roots, therefore no contact exposure

Further refinement of the PEQj for the dietary model for through soil contamination

Thank you

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Time reinforced toxicity (TRT) and sublethal effects

Webinar: Getting familiar with ECHA's guidance to assess risks of biocides to bees

5 March 2024

Maria a Marca
Swiss Federal Office for the Environment (FOEN)

Time Reinforced Toxicity (TRT)
Concept and issue

Potential of active substances to show increasing toxic effects due to long-term exposure to low doses

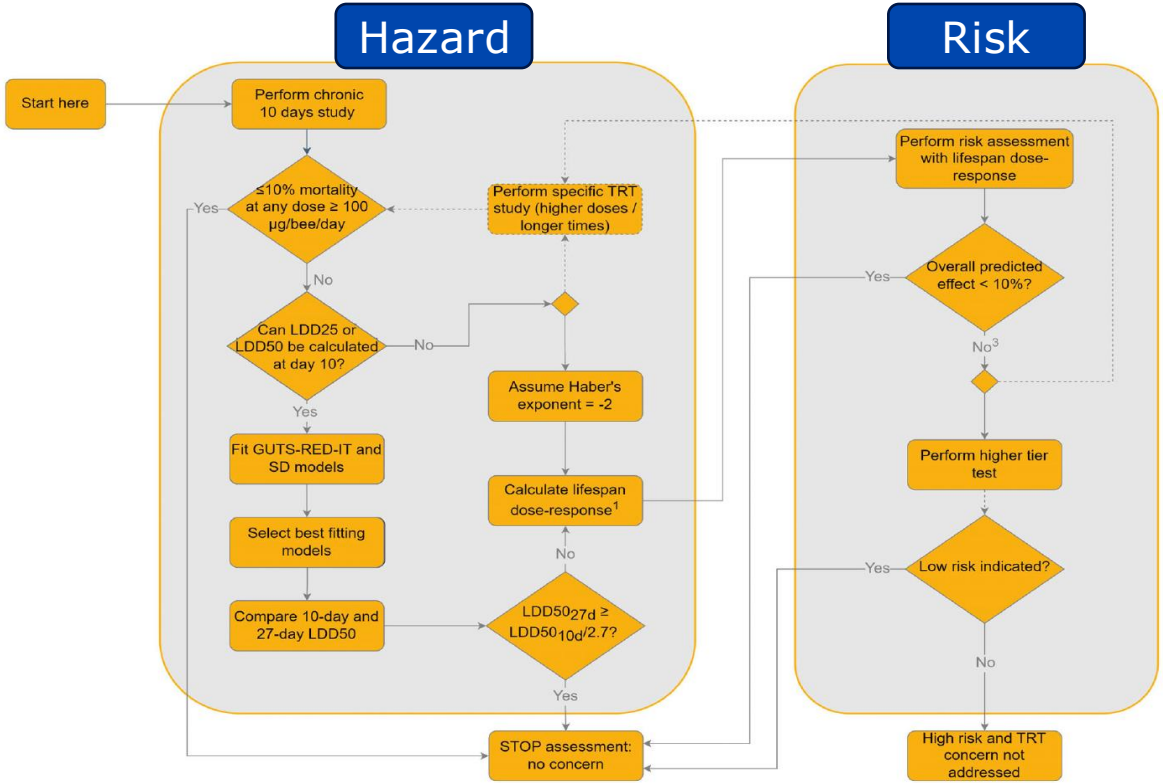
- Standard chronic toxicity test for 10 days for honey-bee (OECD 245)
- Standard effect assessment (chapter 6) -> toxicity dependent on dose
- TRT properties -> toxicity dependent on exposure time

➢ toxicity based on 10-day study could be underestimated if time reinforced toxicity properties identified

Time Reinforced Toxicity (TRT)
Relevance for biocides

- Possibility for bees to be exposed to low doses of biocides over a long period
- Properties and mode of action of biocidal active substances
- Time reinforced toxicity assessment of EFSA bee guidance

Time Reinforced Toxicity (TRT)
Assessment scheme



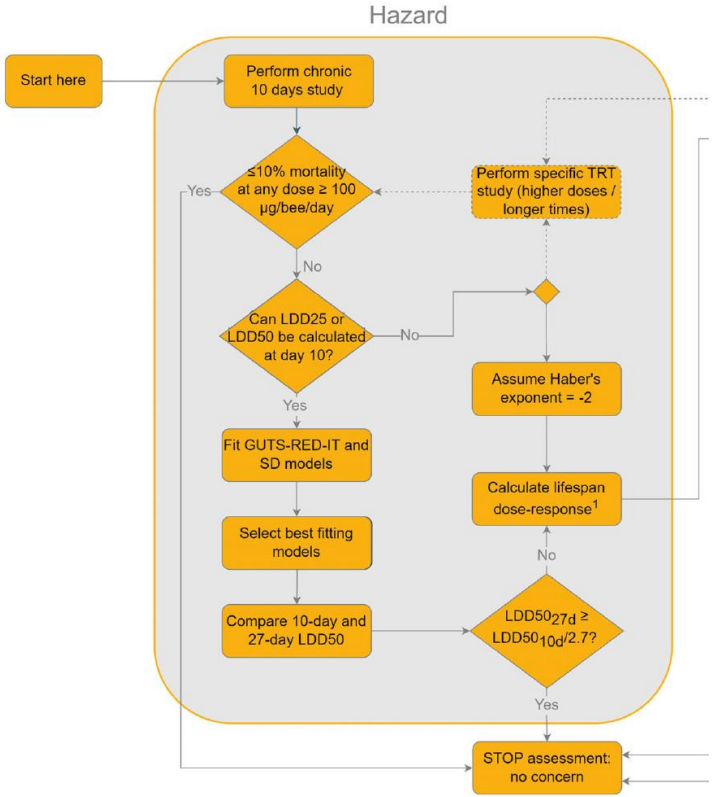
Chapter 8, Figure 14

How to test time reinforced toxicity?

- Use of data from standard 10-day chronic toxicity study
- Only for honey-bees

Time Reinforced Toxicity (TRT)
Hazard assessment

Does evaluated substance show time reinforced toxicity properties?



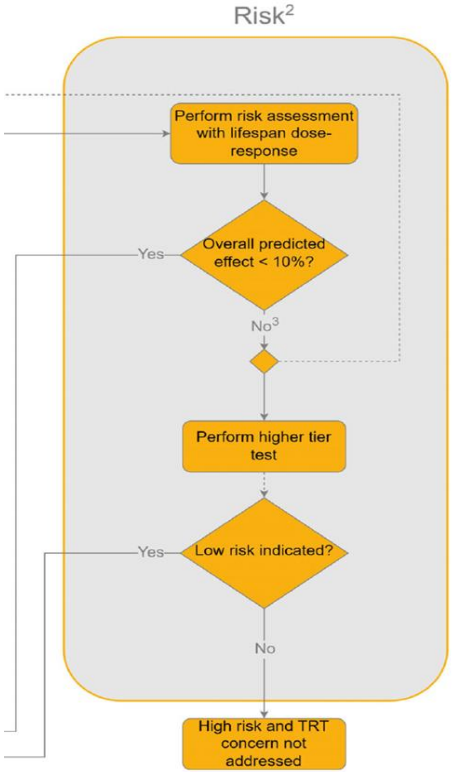
- Step 1: TRT assessment necessary?
- Step 2: Observed mortality high enough to fit GUTS model?
- Step 3: GUTS model fitting
- Step 4: Compare 10-day and 27-day LDD50

-> calculation of lifespan dose response for risk assessment

GUTS = General Unified Threshold model of Survival
LDD = Lethal Dietary Dose

Time Reinforced Toxicity (TRT)
Risk assessment

TRT properties shown in hazard assessment part.



- Summer bee scenario – lifespan of 27 days
- Winter bee scenario – lifespan of 182 days

-> Lifespan dose-response obtained from TRT assessment substitutes 10-days dose-response obtained directly from chronic testing with honey-bees

Sublethal effects
Definition

- Biological, physiological, demographic or behavioural effects on an individual or population that **survives** exposure to a substance at a lethal or sublethal concentration
- **Note**: Sublethal effects not directly linked to specific protection goal honey-bees of ≤ 10% reduction in colony strength (based on **mortality** endpoints)

Sublethal effects
Relevance for biocides

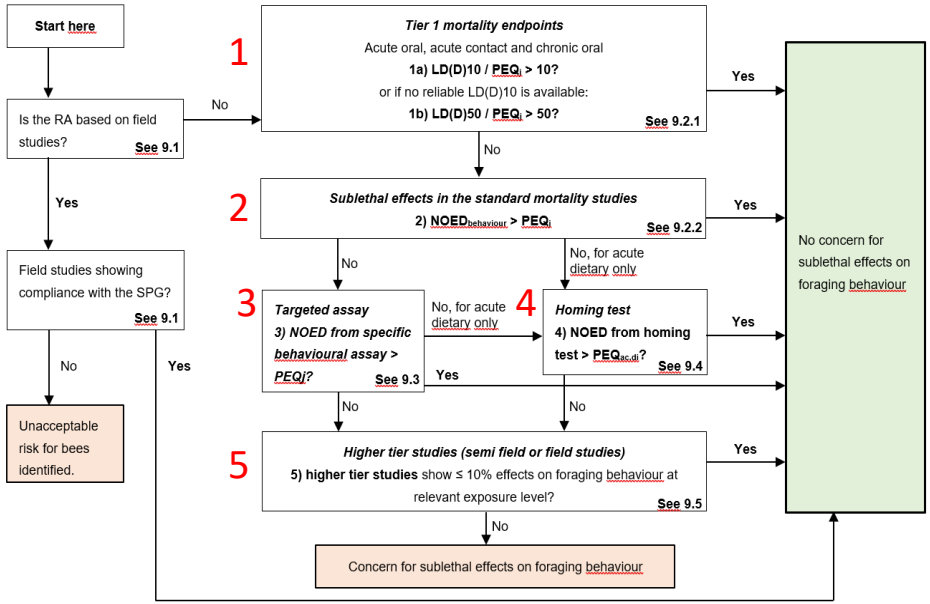
- Sublethal effects may affect, among others, life span, development, population growth, fertility and behaviour, such as feeding or foraging behaviour
- Concern: real effect to bees underestimated because sublethal effects may also impair colony strength

Sublethal effects
Endpoints

- Adverse sublethal effects – Annex K of EFSA bee guidance
- Focus on effects on foraging behaviour
- Standard toxicity test with honey-bees

Sublethal effects
Strategy and data requirements

Based on EFSA bee guidance strategy



Chapter 9, Figure 15

- **Step 1**: Screening step (OECD 213/214, OECD 245)
- **Step 2**: Use behavioural data from OECD 213/214, OECD 245
- **Step 3**: Use behavioural data from targeted assays
- **Step 4**: Specific standard field studies (e.g. homing flight study)
- **Step 5**: Higher tier studies

Sublethal effects
Outcome

Conclusion of sublethal effect assessment:

"concern for sublethal effects indicated" → Potential regulatory consequences*

or,

"no concern for sublethal effects indicated" → End of assessment

*on-going discussion at competent authority level

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Approach for metabolites and mixtures

Webinar: Getting familiar with ECHA's guidance to assess risks of biocides to bees

5 March 2024

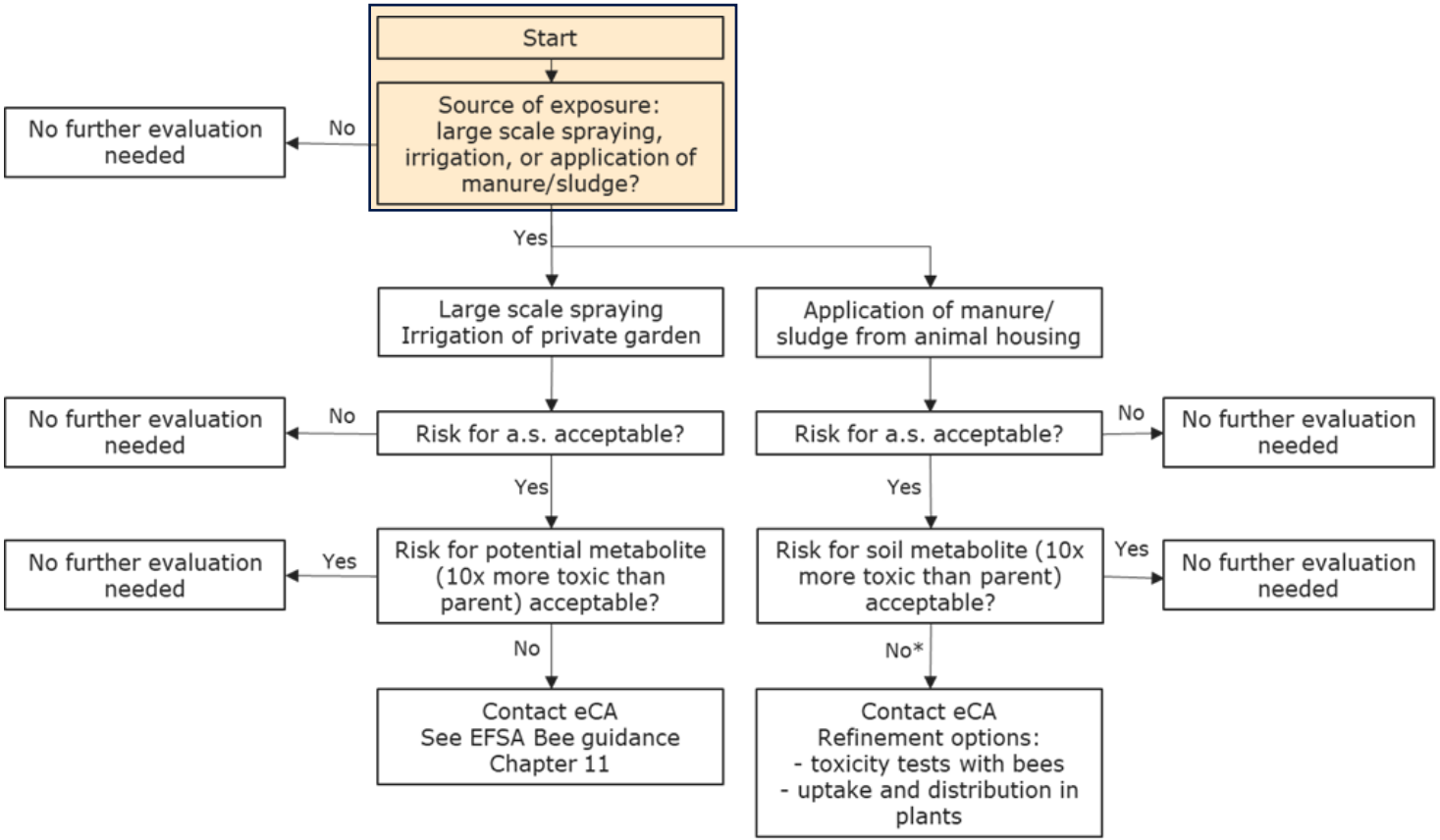
Ella LAAKKONEN
European Chemicals Agency

Metabolite assessment

- Starting point
  - Risk assessment required for active substances + 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

- Stepwise approach per source of exposure, risk assessment for active substances often covers metabolites

Metabolite assessment decision tree

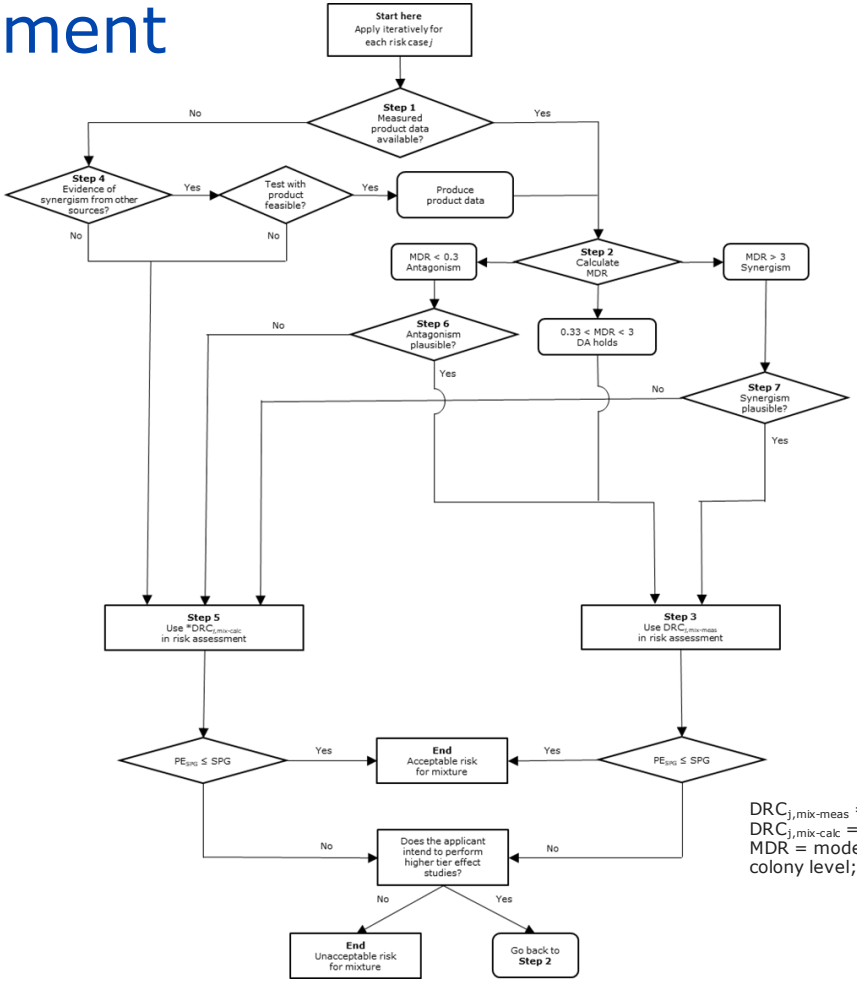


Mixture assessment for honey bees

- Only if two or more active substances with an insecticidal Mode of Action (MoA) present in a product
- Risk assessment **not** triggered if an active substance with non-insecticidal MoA is part of a biocidal product, e.g., when active substance is a co-formulant
- Novel approach for mixtures in line with EFSA method but simplified for biocides
- Risk estimated using **measured mixture** toxicity (unless technically not feasible)

Mixture assessment

- Flowchart illustrating the risk assessment scheme for mixtures



$DRC_{j,mix\text{-}meas}$ = measured dose-response curve for risk case j, $DRC_{j,mix\text{-}calc}$ = calculated dose-response curve for risk case j, MDR = model deviation ratio; PE = overall predicted effect at colony level; SPG = specific protection goal.

Summary and recommendations for future

Webinar: Getting familiar with ECHA's guidance to assess risks of biocides to bees

5 March 2024

Ella LAAKKONEN
European Chemicals Agency

Summary

- ECHA bee guidance developed by considering guidance for plant protection products (PPP) – with biocide specific adaptations
- ECHA bee guidance applicable for sources of emissions belonging to **product type 18** uses
- Assessment currently only for honey bees (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

Needs for future research and development

- Information needed on ecology and sensitivity of non-bee pollinators and generation of standard test guidelines
- To consider inclusion of potentially important matrices/exposure routes/life stages
- Test guidelines for bumble bees and solitary bees
- Experience with higher tier studies needed for biocides

Implications and next steps

- **For bees**: new data requirements and new risk assessment methodology in the biocide assessment

  → new skills required from industry and authorities – 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

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Conclusions

Webinar: Getting familiar with ECHA's guidance to assess risks of biocides to bees

5 March 2024

Adam Elwan
Communications
European Chemicals Agency

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