HOUSE KEEPING RULES

- You are **automatically connected** to the audio broadcast. One-way audio (**listen only** mode).
- The **event is in English. Questions** should be submitted **in English** via the **Q&A chat;**
- This event is **being recorded** and recordings will be published on EFSA's website
- After the event, attendees will receive a **link to a survey** to evaluate the EFSA's event & services

Presentation window
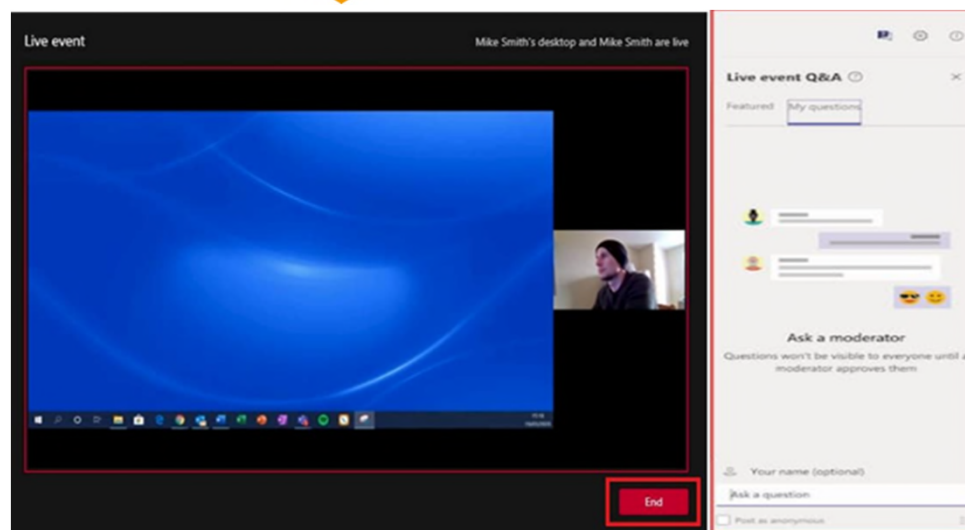
Q&A box: For any questions related to the topic or unexpected IT issues

2

AGENDA

First session
- Presentation on the specific protection goal
- Overview of the guidance document
- Chapter 5: Exposure

1st Q&A

Second session
- Chapter 6: Lower tier Hazard
- Chapter 7: Lower tier risk assessment
- Chapter 8: Time reinforce Toxicity (TRT)

Coffee break (11.30)

2nd Q&A

Third session
- Chapter 9: Scheme for sublethal effects
- Chapter 10: Higher tier studies

3rd Q&A

End of the info session

During the Q&A, we will answer to
- **Some questions received with the registration**
- **Selected questions from the chat**

Please submit your (short) questions in the Q&A CHAT at the end of each presentation!!
If possible, please tag, the speaker

NOTE: Questions will be only answered during the event

Bee guidance document:
setting of Specific Protection Goals and next steps.

European Commission
DG SANTE, Unit E4
Sofie Hofkens

EFSA,13 June 2023

Current status

- Status quo regarding the risk assessment for honeybees and other non-target arthropods is the 2002 Guidance Document on Terrestrial Ecotoxicology

- The 2013 Bee Guidance Document from EFSA was never fully endorsed by the majority of Member States in the Standing Committee on Plants, Animals, Food and Feed despite repeated efforts over several years.

- Commission mandated EFSA in March 2019 to review the 2013 Bee Guidance Document, taking into account scientific knowledge that has emerged since 2013. EFSA published a revised guidance for bees on 11 May 2023.

European Commission

Setting of SPG for honeybees

- Definition of Specific Protection Goals are key for a good Environmental Risk Assessment. Discussions with Member States started in 2020. Two information sessions with stakeholders were held in January and November 2021.

- Discussion was based on the EFSA technical report regarding the analysis of background variability of honeybee colony sizes.

- A majority of EU agriculture ministers supported a new specific protection goal for honeybees of 10% at the Agriculture and Fisheries Council meeting of 28 June 2021.

- This value of 10% should be understood as the <u>maximum</u> permitted level of honeybee colony size reduction following pesticide exposure and will be applied for the entire EU.

- This value is very ambitious compared to what is acceptable under the Guidance from 2002 and compared to the natural variability of colony size found by EFSA but verification via field studies is still technically feasible.

European Commission

Setting of SPGs for wild bees

- Discussion was based on the EFSA technical report regarding the analysis of the evidence to support the definition of SPGs for bumblebees and solitary bees.

- Absence of sufficiently robust evidence to set a specific protection goal for bumblebees and solitary bees.

- A majority of Member States indicated support for an undefined threshold approach for setting specific protection goals (SPGs) for both bumblebees and solitary bees

- The Commission therefore informed EFSA to continue the update of the Bee Guidance Document on the basis of an undefined threshold approach for bumble bees and solitary bees.

European Commission

Setting of SPGs for wild bees (II)

In practice, until further data becomes available and in case of potential exposure of bees, by default field studies on bumblebees and solitary bees will be required unless:

- the lower tier risk assessments for honeybees and non-target arthropods other than bees show no effects for the active substance, or

- semi-field (cage or tunnel studies) with bumblebees and solitary bees show absence of effects.

Furthermore, semi-field or field testing with bumblebees would also not be needed if laboratory studies according to OECD test methods No 246 and 247, show an LD_{50} > 100 µg active substance/bumblebee.

European Commission

How will the Bee Guidance Document be endorsed?

Two-step procedure involving Standing Committee PAFF:

1. Check and if needed update implementing regulations, in particular

   - Commission Regulation (EU) No 546/2011 as regards uniform principles for evaluation and authorisation of plant protection products

   - Commission Regulations (EU) No 283 and 284/2013 setting out the data requirements for active substances and plant protection products respectively

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

European Commission

Develop additional test guidelines: workplan

- **What ?** ➡️ Protocols for testing pesticides (chemicals and microbials) on pollinators - looking for concrete ways to support:

  - Development,
  - Validation and ringtesting,
  - And international agreement at OECD.

- **How ?** ➡️ Commission, together with the Member States, is currently establishing an inventory of available, under development and needed protocols to test the effects of pesticides on pollinators. This inventory will be used in a next step as a basis for a workplan.

European Commission

Latest news

Latest news is always available via the website of the European Commission

https://food.ec.europa.eu/plants/pesticides/protection-bees_en

Thank you

European Commission

OVERVIEW OF THE EFSA'S BEE GUIDANCE DOCUMENT

Domenica Auteri

efsa
EUROPEAN FOOD SAFETY AUTHORITY

BACKGROUND

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

European Food Safety Authority (EFSA).

Appendices of the guidance document:

- Appendix A   List of crop attractiveness (Excel spread sheet)
- Appendix B   Parameters for contact and dietary exposure (Excel spread sheet)
- Appendix C   Additional information for metabolite risk assessment

Annexes of the guidance document:

- Annex A   Guidance for refinement of residues dissipation – developed in common with the revised guidance document on risk assessment for birds and mammals (EFSA, 2023a)
- Annex B   Recommendations for field studies to refine exposure at higher tiers
- Annex C   Recommendations for higher tier effect studies.

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

In order to transparently document the science behind the revision of EFSA (2013a,b), the guidance is complemented by a stand-alone document referred to as supplementary document (EFSA, 2023b), which includes all the background information, data collection and analysis. This supplementary document includes an extended Appendix (i.e. Appendix A) on attractiveness of agricultural crops to bees, an Appendix on Selection of shortcut values for Tier 1 (i.e. Appendix B), and different annexes which were necessary in order to report highly complex topics.

The annexes of the supplementary document are:

- Annex A   Preliminary considerations and planned methods for the revision of Tier 1 risk assessment schemes of EFSA's 2013 guidance
- Annex B   Outcome of the systematic literature review on food consumption
- Annex C   Outcome of the systematic literature review on the crop-specific sugar content in nectar
- Annex D   Relevance of the weeds in flower scenario for the treated field
- Annex E   Relevance of water scenario
- Annex F   Expert Knowledge Elicitation (EKE) to assess the attractiveness of crops for pollen collection of bees
- Annex G   Time-reinforced toxicity: concept and revised risk assessment scheme
- Annex H   Residue database data (Excel spread sheets)
- Annex I   Succeeding crops
- Annex J   Inter-species extrapolation data (Excel spread sheets)
- Annex K   Overview of sublethal effect testing on bees.

LOOKING BACK AND FORTH

EPPO, 2002

~ 1 page

EFSA, 2013

~300 pages

EFSA, 2023

74 documents
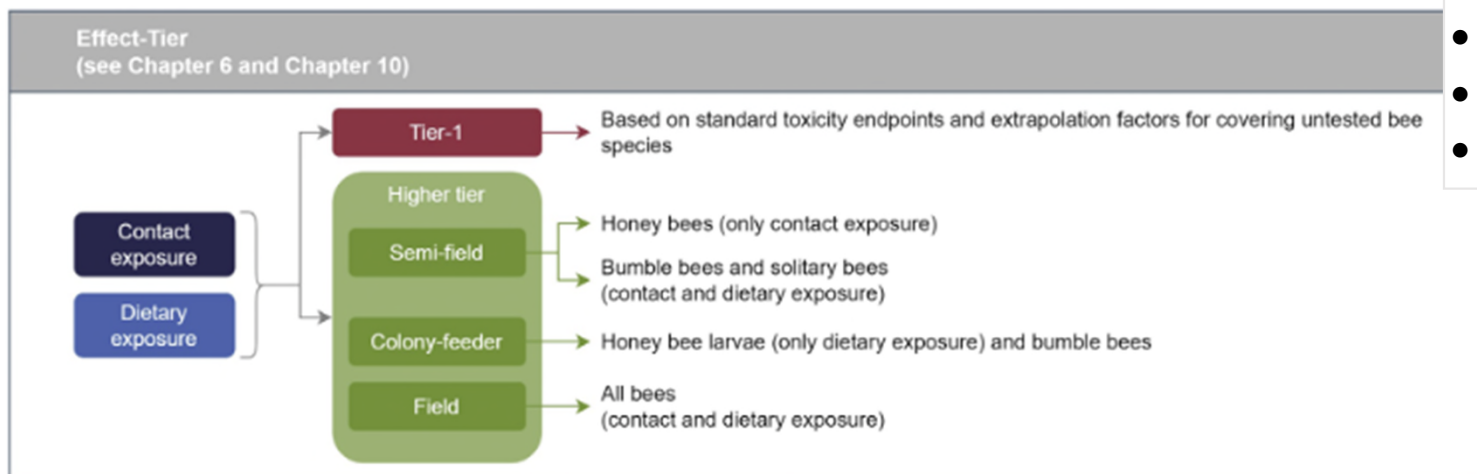>1600 pages
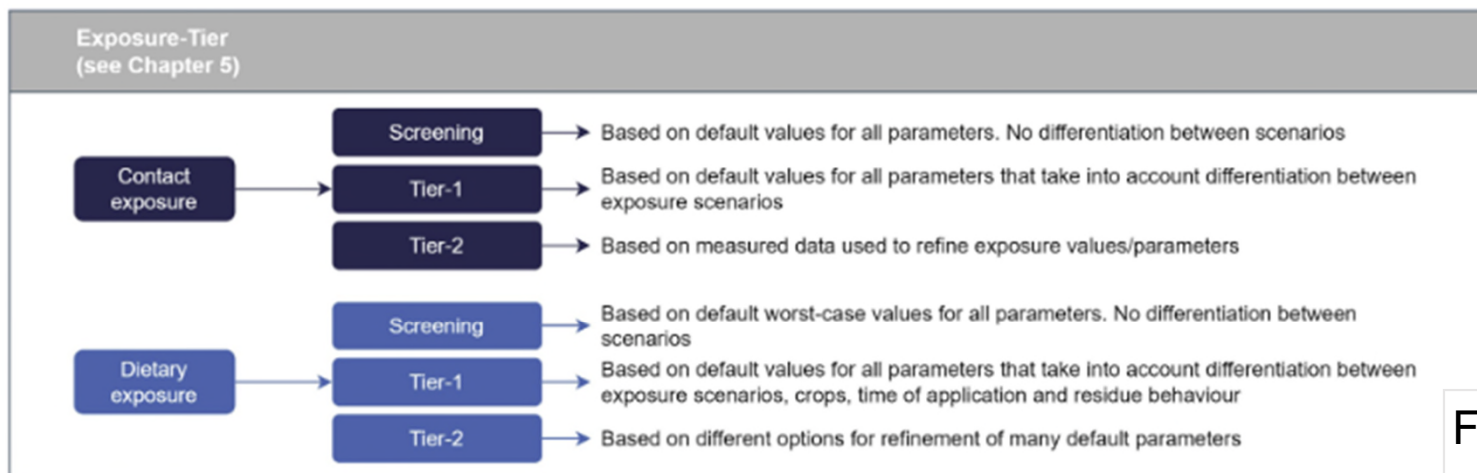
15
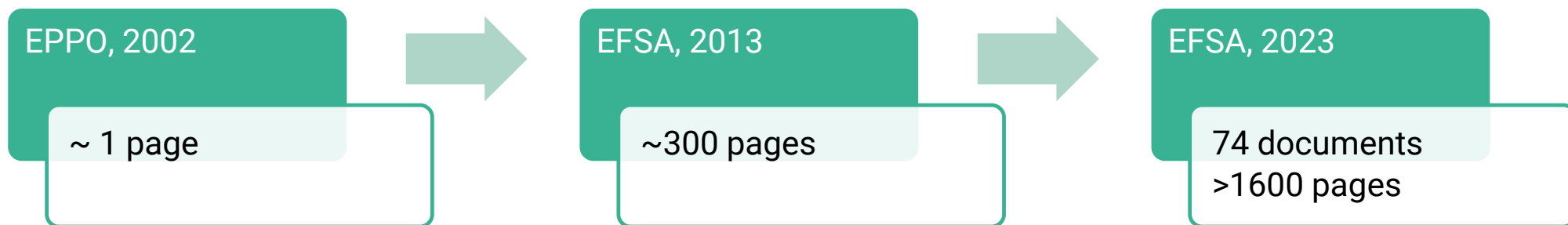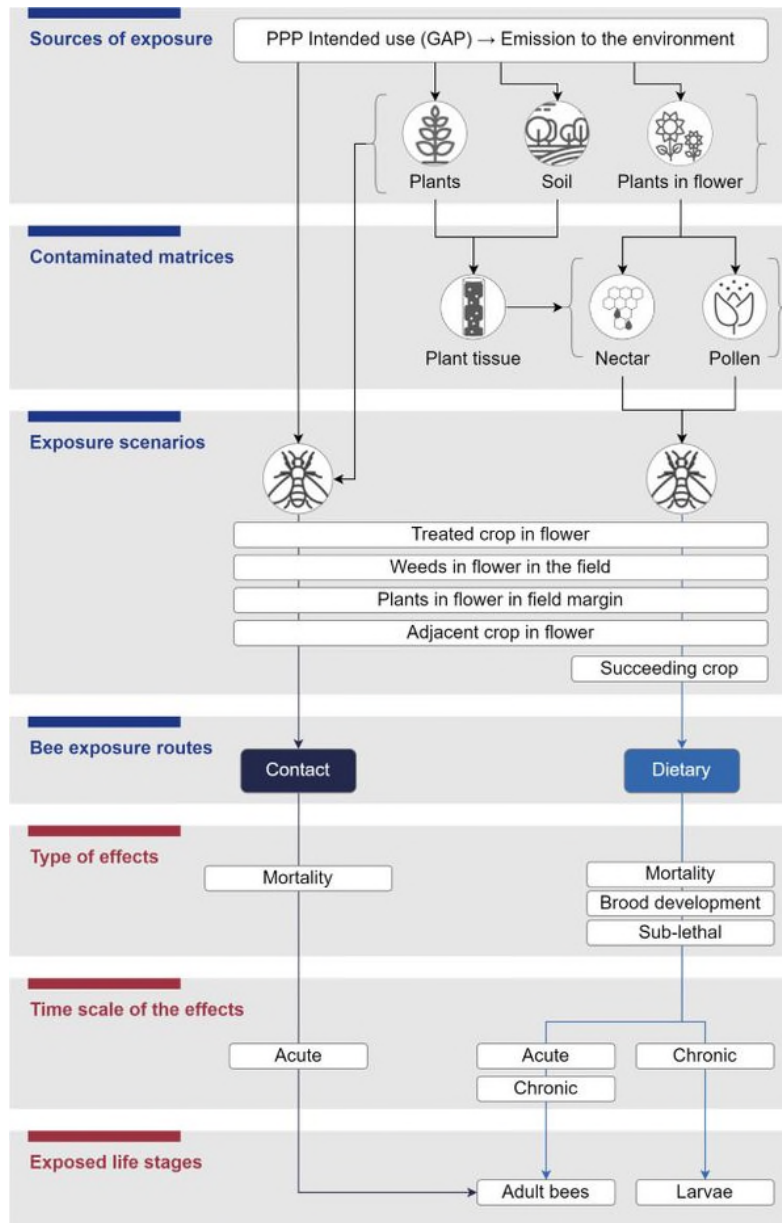
Chapter 1 - Introduction

CHAPTER 2 - SCOPE OF THE GD

- Provide guidance in the context of the evaluation of PPPs and their active substances under **Regulation (EC) 1107/2009**

- The focus is on **direct effects**; indirect effects are out of scope

- The focus is on **chemicals**, the Guidance does not cover the risk assessment for micro-organism and semio-chemicals

- The focus is technical mixture undergo authorisation under the 1107

CHAPTER 3 - OVERVIEW: TIERED APPROACH

Exposure-Tier (see Chapter 5)

Contact exposure
- **Screening** → Based on default values for all parameters. No differentiation between scenarios
- **Tier-1** → Based on default values for all parameters that take into account differentiation between exposure scenarios
- **Tier-2** → Based on measured data used to refine exposure values/parameters

Dietary exposure
- **Screening** → Based on default worst-case values for all parameters. No differentiation between scenarios
- **Tier-1** → Based on default values for all parameters that take into account differentiation between exposure scenarios, crops, time of application and residue behaviour
- **Tier-2** → Based on different options for refinement of many default parameters

Effect-Tier (see Chapter 6 and Chapter 10)

Contact exposure / Dietary exposure
- **Tier-1** → Based on standard toxicity endpoints and extrapolation factors for covering untested bee species

Higher tier
- **Semi-field** → Honey bees (only contact exposure)
- Bumble bees and solitary bees (contact and dietary exposure)
- **Colony-feeder** → Honey bee larvae (only dietary exposure) and bumble bees
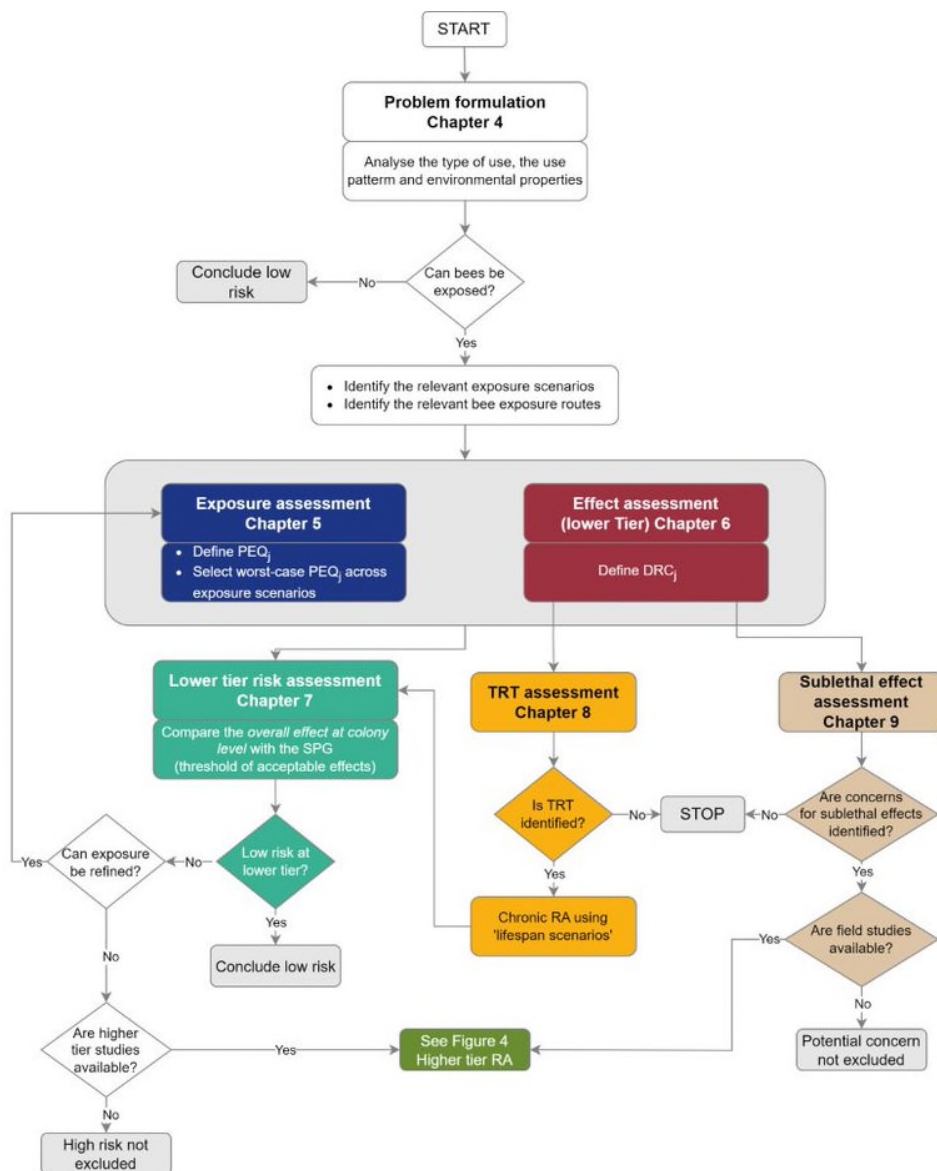- **Field** → All bees (contact and dietary exposure)

Four risk cases:
- Acute-contact risk
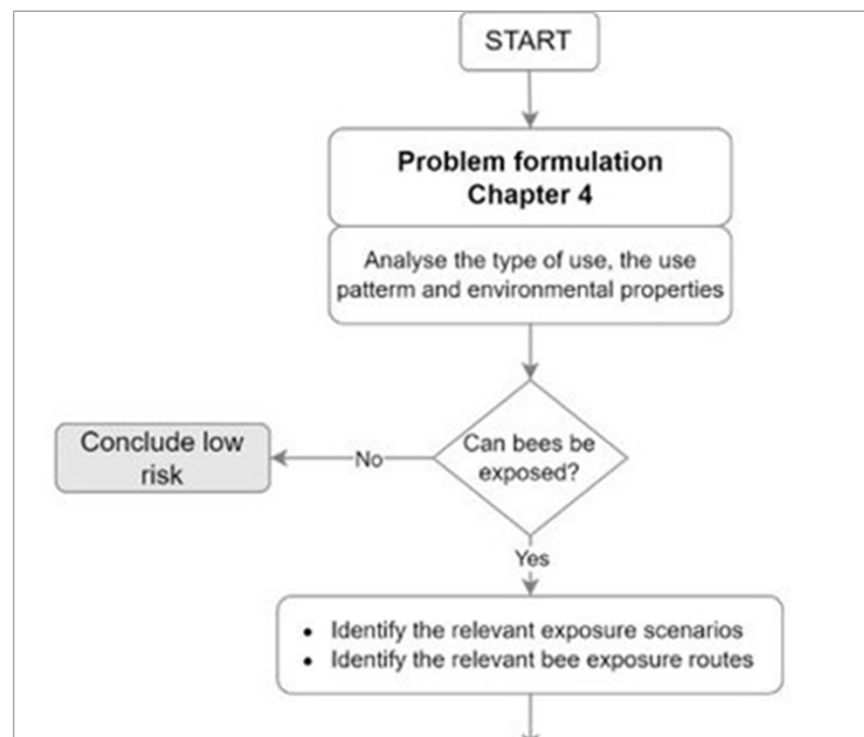- Acute-dietary risk
- Chronic-dietary risk
- Larvae-dietary risk

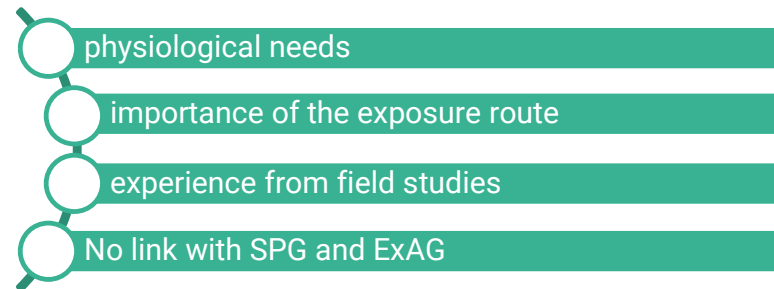# Chapter 3 - Overview: risk assessment scheme

CHAPTER 4 - DEFINITION OF PROBLEM FORMULATION

➢ **Better definition of the Problem formulation**

➢ **Consideration of exposure for several methods of application**

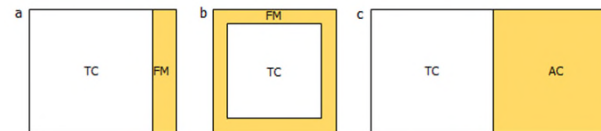➢ **Consideration of relevance of the scenarios**

➤No water scenarios

physiological needs

importance of the exposure route

experience from field studies

No link with SPG and ExAG

➤Crop attractivity revised (EKE)

➤Amendments for the off-field scenarios

➤Weed abundance taken into consideration

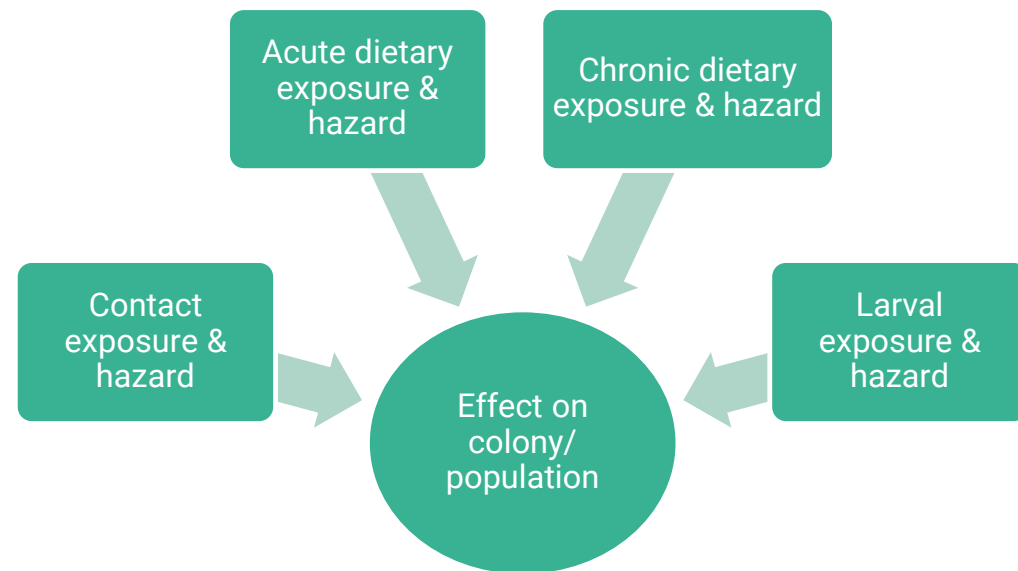➤Triggering the succeeding crop scenario
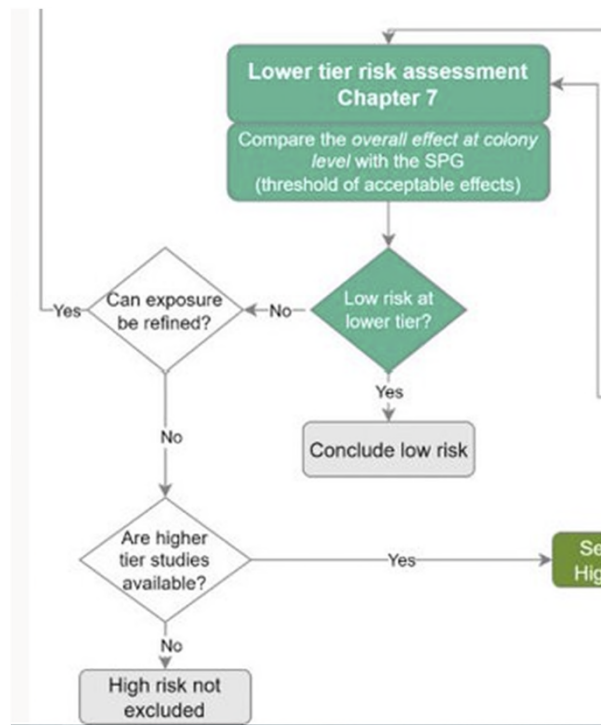
EXPOSURE/HAZARD DEFINITION
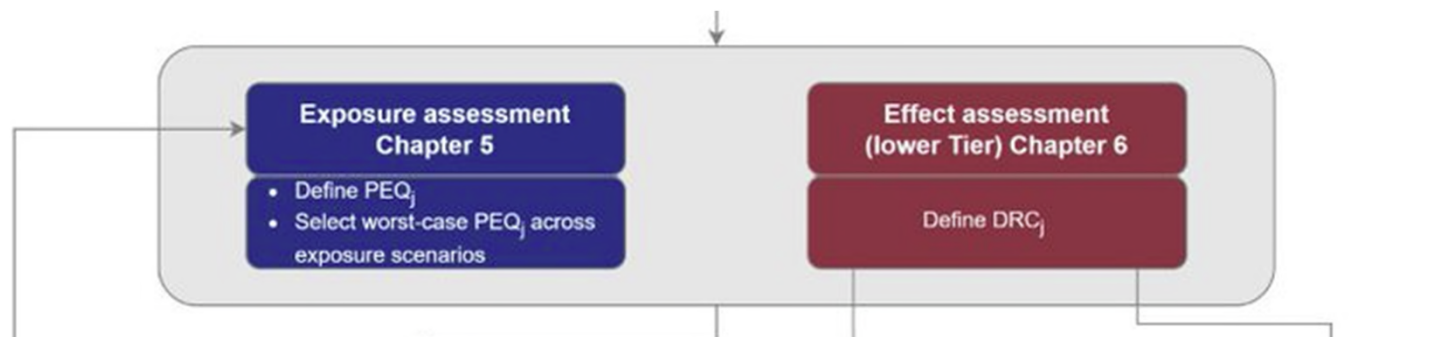
- Identify the more suitable exposure model
- Identify the worst-case PEQ for each of the 4 risk cases

- Identify the hazard endpoints for the 3 bee groups
- Identify dose response curves for each of the 4 risk cases

SPECIFIC CONSIDERATIONS

➤ New scheme for Time Reinforced Toxicity

Chapter 8

➤ New scheme for sublethal effects

Chapter 9

➤ New scheme for technical mixtures

Chapter 12

➤ New scheme for metabolites

Chapter 11

CHAPTER 10 - HIGHER TIER REQUIREMENTS

- **Existing protocols are considered as much as possible**

Field
• HB, BB, SB

Semi-field
• (HB), BB, SB

Colony feeder
• (HB), BB

- **Limited number of endpoints**
- **Link to the SPG**
- **New statistical requirements**

OTHERS

- Chapter 13 – Risk mitigation measures
- Chapter 14 – Conclusion (in relation to the terms of reference)
- Chapter 15 – Recommendations

Next steps

Calculator development

➢ Ongoing
➢ Web tool
➢ Available for the implementation of the GD

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CHAPTER 5: EXPOSURE

EXPOSURE ROUTES

contact

dietary

water

extrafloral nectaries

resin

honey dew

wax

soil/mud/leaves

EXPOSURE ROUTES

contact

acute exposure
during flowering

dietary

acute & chronic exposure
during & before flowering

Scenario		Contact exposure	Dietary exposure
Treated crop	In-field	✓	✓
Weeds	In-field	✓	✓ *
Field margin	Off-field	✓	✓
Adjacent crop	Off-field	-	✓
Succeeding crop	In-field, but later in time	-	✓

* Except seed treatment
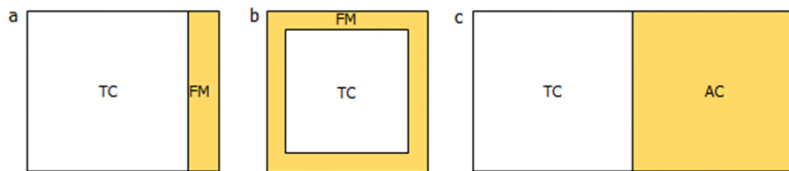
Spray application

Seed treatment

Granular application
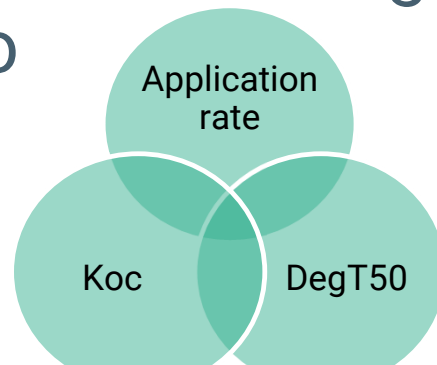
Table 3 gives some guidance for other application methods

➢ Amendments for the off-field scenarios

➢ Weed abundance taken into consideration

➢ Triggering the succeeding crop scenario

Application rate

Koc

DegT50

I am here!

32

Description of the exposure
(lower tiers)

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CONTACT EXPOSURE

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

Where:

PEQ_{co}: Predicted Exposure Quantity for contact exposure - μg/bee

AR: application rate – g/ha

EF_{co}:   exposure factor for contact exposure (-)

BSF: body surface factor - dm^2/bee

For Tier 1, PEQ_{co} can routinely be estimated for the 5th% small bumble bee and solitary bee species.

Category for the risk assessment	Representative species	Bsf (dm^2/bee)
Honey bee	Apis mellifera	0.0114
Bumble bee	5th percentile (by body surface) bumble bee species	0.0146
Solitary bee	5th percentile (by body surface) solitary bee species	0.00184

Through soil contamination

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

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

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

Pre-flowering contamination

$$PEQ_{di} = \frac{AR}{1000} EF_{di} PFF (SV_{po,be} + SV_{ne,be})$$

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

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

$$PCUD_{po,be} = function(RUD_{po}, n_{be}, i_{be}, DT50_{pl})$$

$$PCUD_{ne,be} = function(RUD_{ne}, n_{be}, i_{be}, DT50_{pl})$$

During flowering contamination

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

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

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

$$PCUD_{po,du} = function(RUD_{po}, n_{du}, i_{du}, DT50_{po}, w)$$

$$PCUD_{ne,du} = function(RUD_{ne}, n_{du}, i_{du}, DT50_{ne}, w)$$

19 parameters make up the 3 mathematical models

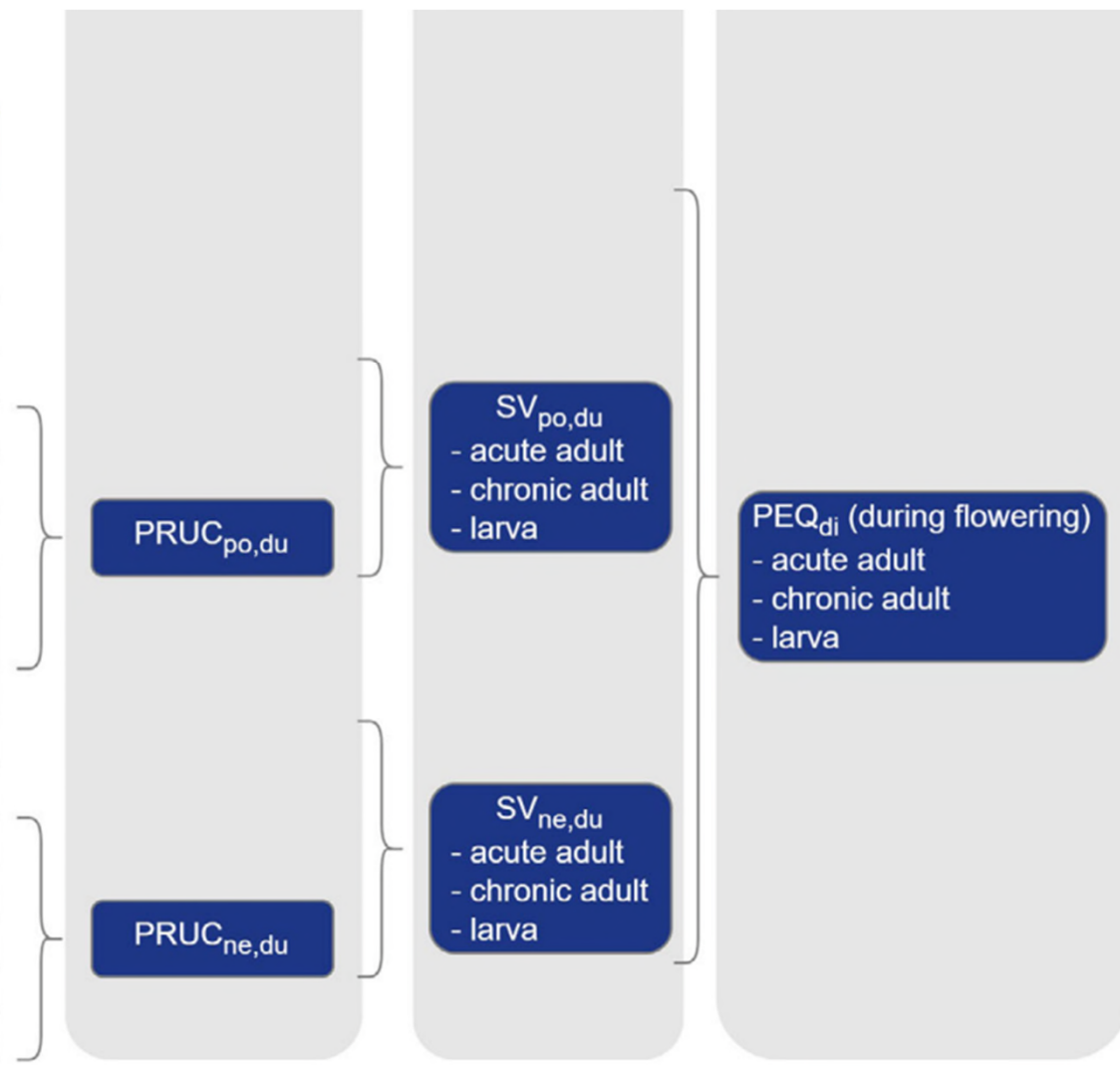| Parameter	Definition	Unit
AR	Application rate	g/ha
EF_{di}	Exposure factor for dietary exposure	- (unitless)
PFF	Pre-Flowering Factor	- (unitless)
$SV_{po,be}$	Shortcut value for pollen for before flowering situations	µg/bee or µg/bee/day or µg/larva/developmental period
$SV_{ne,be}$	shortcut value for nectar for before flowering situations	µg/bee or µg/bee/day or µg/larva/developmental period
$SV_{po,du}$	shortcut value for pollen for during-flowering situations	µg/bee or µg/bee/day or µg/larva/developmental period
$SV_{ne,du}$	shortcut value for nectar for during-flowering situations	µg/bee or µg/bee/day or µg/larva/developmental period
$SV_{po,so}$	Shortcut value for pollen for situations for contamination from soil	µg/bee or µg/bee/day or µg/larva/developmental period
$SV_{ne,so}$	Shortcut value for nectar for situations for contamination from soil	µg/bee or µg/bee/day or µg/larva/developmental period
CMP_{po}	pollen consumption	mg/bee or mg/bee/day or mg/larva/developmental period
CMP_{su}	sugar consumption	mg/bee or mg/bee/day or mg/larva/developmental period
SN	sugar content of the nectar	kg/kg (i.e., -)
LF_{po}	landscape factor for pollen	- (unitless)
LF_{ne}	landscape factor for nectar	- (unitless)
$PCUD_{po,be}$	Predicted Concentration per Unit Dose in pollen from before flowering application	mg/kg
$PCUD_{ne,be}$	Predicted Concentration per Unit Dose in nectar from before flowering application	mg/kg
$PCUD_{po,du}$	Predicted Concentration per Unit Dose in pollen from during-flowering application	mg/kg
$PCUD_{ne,du}$	Predicted Concentration per Unit Dose in nectar from during-flowering application	mg/kg
RUD_{po}	Residue per Unit Dose in pollen	mg/kg
RUD_{ne}	Residue per Unit Dose in nectar	mg/kg
$DT50_{po}$	half-life in pollen; the time within which the concentration in pollen is reduced by 50 percent	day
$DT50_{ne}$	half-life in nectar; time within which the concentration in nectar is reduced by 50 percent	day
$DT50_{pl}$	half-life in plant matrices; the time within which the concentration in crop/plant matrixes is reduced by 50 percent	day
n_{be}	number of applications before flowering	- (unitless)
n_{du}	number of applications during flowering	- (unitless)
i_{be}	interval between multiple applications performed before flowering	day
i_{du}	interval between multiple applications performed during flowering	day
w	time window for deriving time-weighted average concentrations for chronic exposure	day
PEC_{pw}	Predicted Environmental Concentration in pore water	mg/L = mg/kg

THE RELEVANCE OF THE DIETARY MODELS

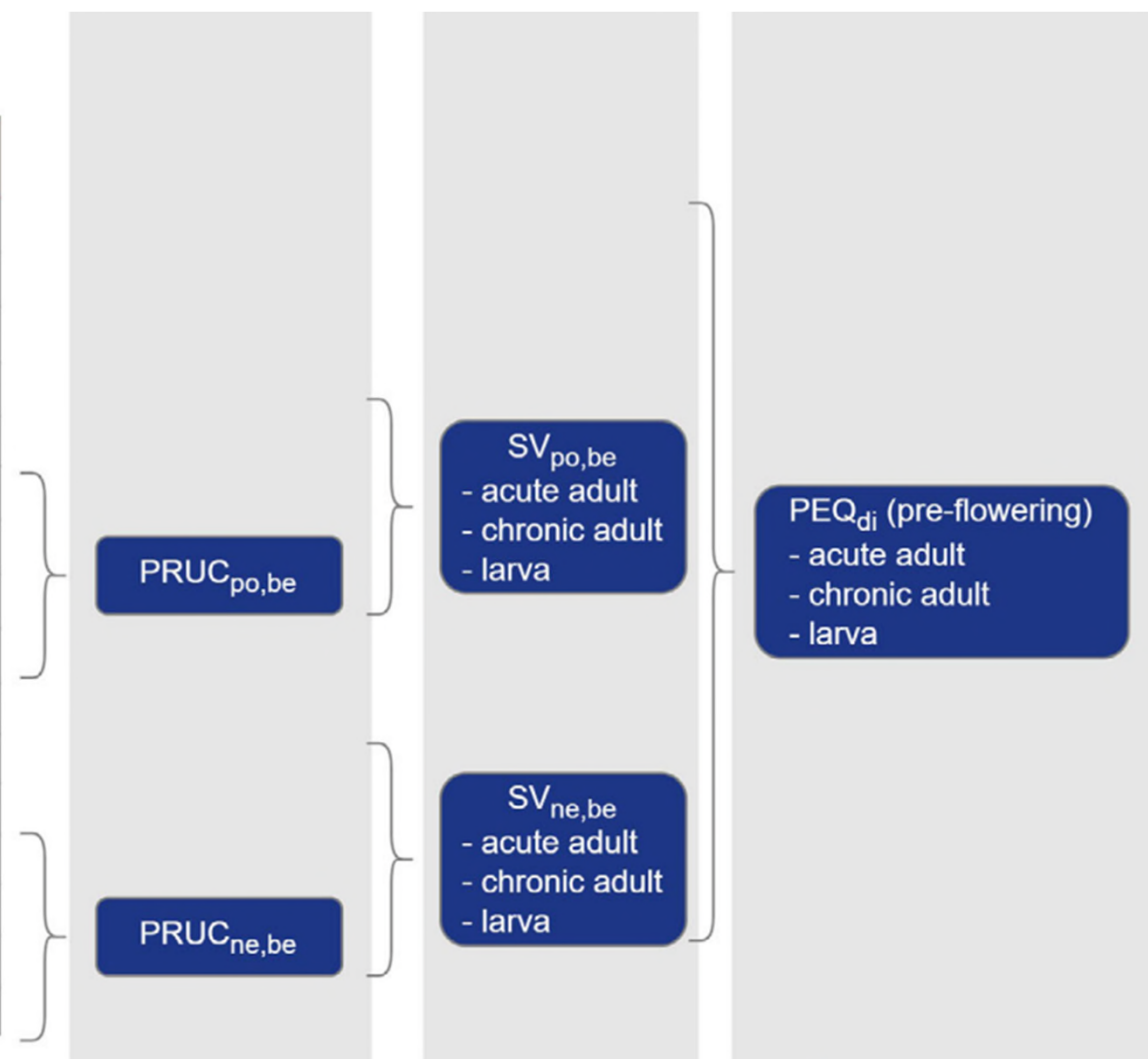| PPP application	Exposure scenario				
	treated crop	weeds in the field	field margin	adjacent crop	succeeding crop
BBCH < 10, 'bare soil' situation	through-soil contamination	through-soil contamination			
BBCH < 10, presence of emerged weeds not excluded	through-soil contamination	during-flowering contamination	during-flowering contamination	during-flowering contamination	through-soil contamination
BBCH 10-59	pre-flowering contamination				
BBCH 60-69	during-flowering contamination				
BBCH ≥ 70	Not relevant				

BBCH 60 - 69 (during flowering)

Parameter	Source of parameter value
AR	GAP table
EF_{di}	Tier-1 or Tier-2
LF_{po}	Tier-1 or Tier-2
CMP_{po}	Tier-1
RUD_{po}	Tier-1 or Tier-2
n_{du}	GAP table
i_{du}	GAP table
$DT50_{po}$	Tier-1 or Tier-2
w	Tier-1
LF_{ne}	Tier-1 or Tier-2
CMP_{su}	Tier-1 or Tier-2
SN	Tier-1 or Tier-2
RUD_{ne}	Tier-1 or Tier-2
n_{du}	GAP table
i_{du}	GAP table
$DT50_{ne}$	Tier-1 or Tier-2
w	Tier-1

$PRUC_{po,du}$

$PRUC_{ne,du}$

$SV_{po,du}$
- acute adult
- chronic adult
- larva

$SV_{ne,du}$
- acute adult
- chronic adult
- larva

PEQ_{di} (during flowering)
- acute adult
- chronic adult
- larva

BBCH 10 - 59 (pre-flowering)

Parameter	Source of parameter value
AR	GAP table
EF_{di}	Tier-1 or Tier-2
PFF	Tier-1 or Tier-2
LF_{po}	Tier-1 or Tier-2
CMP_{po}	Tier-1
RUD_{po}	Tier-1 or Tier-2
n_{be}	GAP table
i_{be}	GAP table
$DT50_{pnt}$	Tier-1 or Tier-2
LF_{ne}	Tier-1 or Tier-2
CMP_{su}	Tier-1 or Tier-2
SN	Tier-1 or Tier-2
RUD_{ne}	Tier-1 or Tier-2
n_{be}	GAP table
i_{be}	GAP table
$DT50_{pnt}$	Tier-1 or Tier-2

$PRUC_{po,be}$

$PRUC_{ne,be}$

$SV_{po,be}$
- acute adult
- chronic adult
- larva

$SV_{ne,be}$
- acute adult
- chronic adult
- larva

PEQ_{di} (pre-flowering)
- acute adult
- chronic adult
- larva

BBCH < 10 (through soil)

Parameter	Source of parameter value
LF_{po}	Tier-1 or Tier-2
PEC_{pw}	Tier-1 or Tier-2
CMP_{po}	Tier-1
LF_{ne}	Tier-1 or Tier-2
PEC_{pw}	Tier-1 or Tier-2
CMP_{su}	Tier-1
SN	Tier-1 or Tier-2

$SV_{po,so}$
- acute adult
- chronic adult
- larva

$SV_{ne,so}$
- acute adult
- chronic adult
- larva

PEQ_{di} to be calculated for each relevant scenario

PEQ_{di} = 0 if no application is intended in the BBCH interval

PEQ_{di} (through soil)
- acute adult
- chronic adult
- larva

Select GAP-specific PEQ_{di} as the highest obtained across scenarios
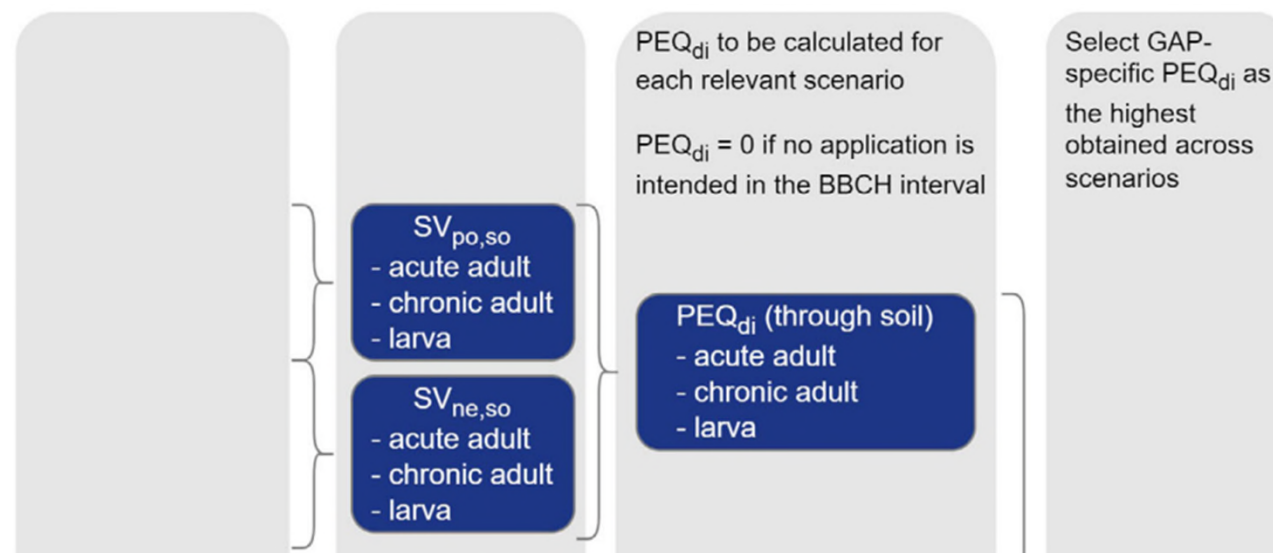
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BRAND NEW PARAMETERS

➢ **LF**

➢ **PFF**

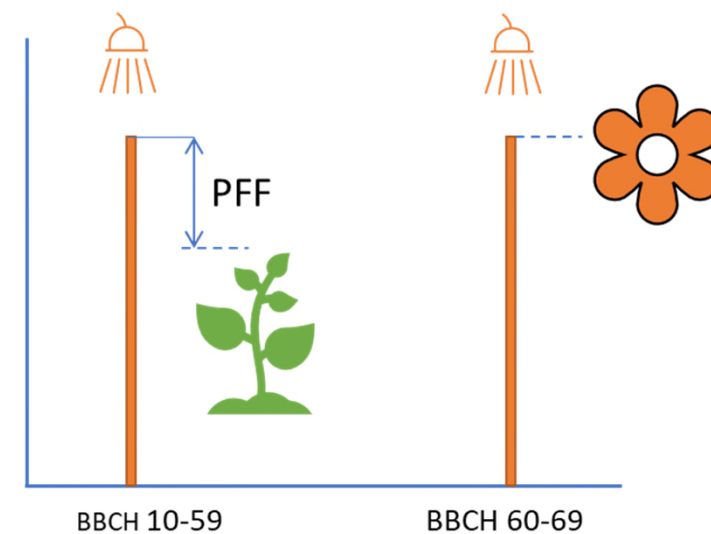➢ **PECpw**

41
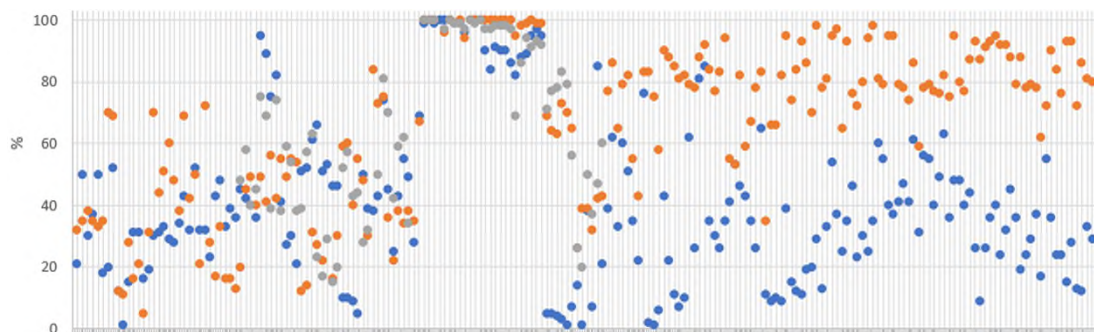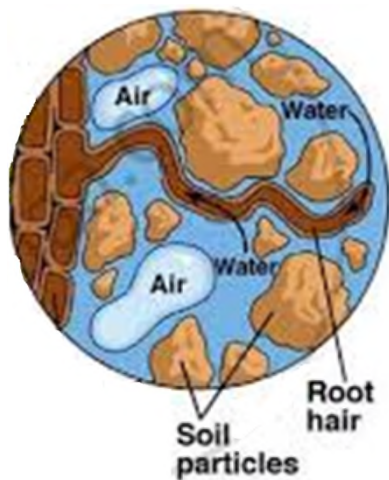
Refinement options (Tier 2)

CONTACT EXPOSURE

- EF$_{CO}$ parameter might be refined with crops/situations specific data

- PEQ$_{CO}$ itself might be refined in exposure field studies; the chemical washed-off from the surface of the bees has to be analytically determined (see Annex B).

DIETARY EXPOSURE

- Pore water concentration (PECpw)
- EFdi parameter
- Residue levels in pollen/nectar measured in exposure field studies (RUD)
- Residue decline in pollen/nectar or plant matrixes measured in exposure field studies (DT50)
- Landscape effect on the food collection (LF)
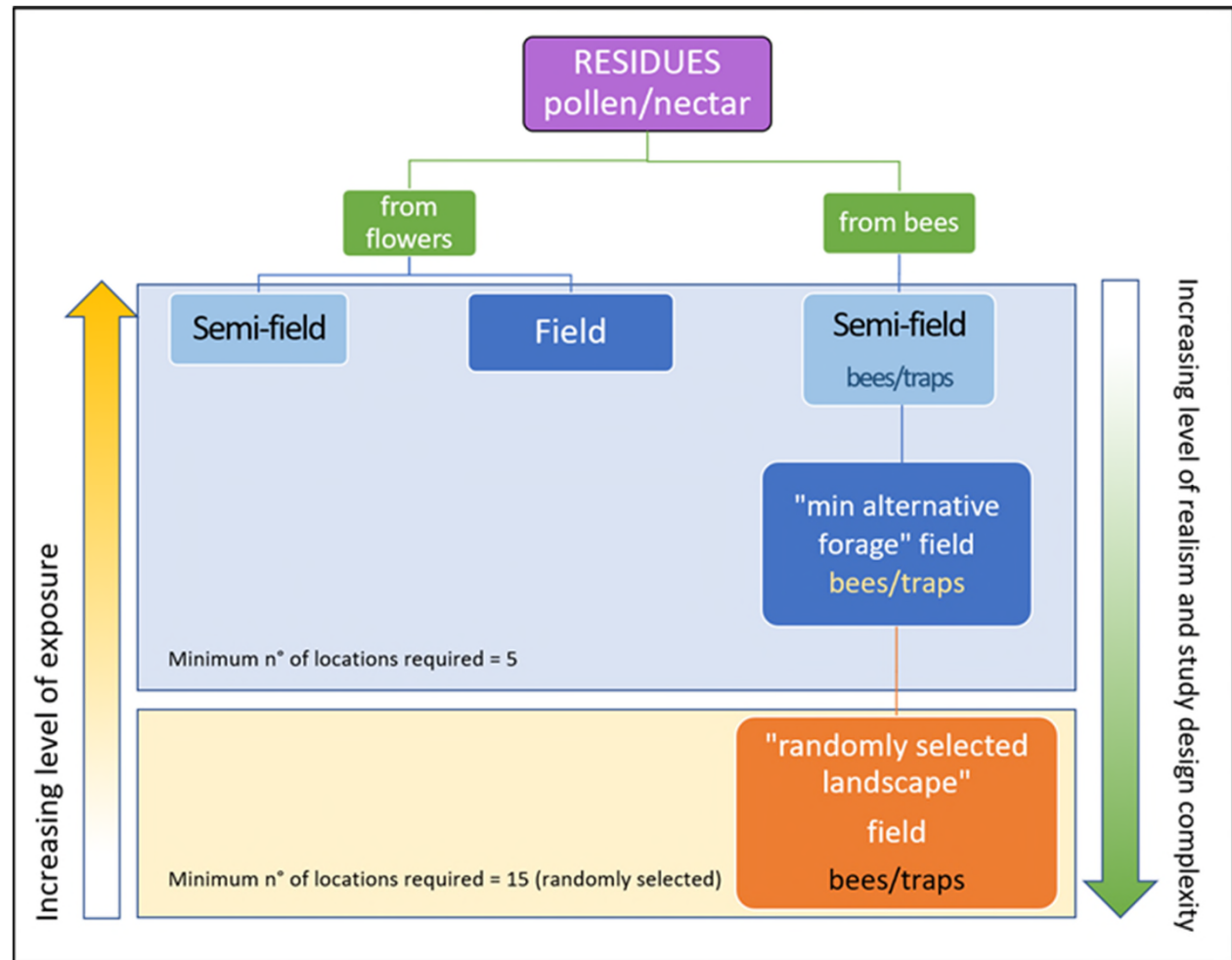- Sugar content of the nectar (SN)

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EXPOSURE FIELD STUDIES

Benchmarking the residue level in pollen and nectar in field conditions

Aim: encompass the 90%-tile worst case residue level in pollen and nectar (realistic worst-case concentrations)

FIRST Q&A

THE SESSION WILL START AGAIN AT 11.45

Thank you for attending our event!

- The recording of today's event will be available on the EFSA website in few days

- Please take few minutes to fill out the evaluation survey that you will receive after the event. Your feedback is essential to improve our future events