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## **REPORT**

### **WORKSHOP 6 MARCH 2020**

#### **FIRST CONSULTATION OF RISK MANAGERS ON THE REVIEW OF THE GUIDANCE ON THE RISK ASSESSMENT OF PLANT PROTECTION PRODUCTS FOR BEES**

The workshop was organised by DG SANTE Unit E4. Member States were invited to nominate 1 risk manager and 1 risk assessor. Nominations were received from 21 Member States. Due to travel restriction following the COVID-19 outbreak, only 17 Member States (BE, CZ, DK, DE, EE, IE, EL, ES, FR, HR, LV, HU, NL, AT, PL, SI and SK) were present physically during the workshop. BE, DK, DE, EE, IE, EL, FR, HR, LV, NL, AT, PL and SI were represented by a risk manager and a risk assessor. A second risk assessor from DE was present. ES and SK were only represented by a risk manager and HU only by a risk assessor. CZ and HR were represented by a member of their Permanent Representation.

The EFSA and ECHA were connected remotely via a video link. There were 6 participants from DG SANTE and 1 participant from DG ENV.

#### **Session 1. Welcome**

The Commission welcomed Member States and EFSA and recalled the reasons for this meeting.

In 2013 EFSA published a revised Guidance Document (GD) on risk assessment to bees. Since then, a clear majority of Member States have not accepted to implement the parts of the 2013 EFSA Bee GD (Bee GD) related to chronic risks and risks to other pollinators.

To brake this stalemate, the Commission proposed a partial implementation of the Bee GD with implementing the acute risk to honeybees unfortunately, the EP's Resolution of OCT 2019 prevents the Commission from adopting a draft regulation that would have allowed such a partial implementation of the Bee GD.

In parallel, the Commission mandated EFSA to review the Bee GD in March 2019. With this mandate EFSA is asked to take fully into account new scientific knowledge emerged since 2013. This will enable a comprehensive guidance with the most up-to-date methodologies for conducting risk assessments for bees leading to a higher level of protection.

This work has been initiated by EFSA and is progressing well. It is also very important that EFSA can timely finalise the mandate to review the Bee GD by March 2021.

The Commission has tasked EFSA to closely involve Member States experts and stakeholders in the process in order to ensure that all views are duly taken into account in order to enable a swift endorsement of the revised comprehensive guidance once finalised.

EFSA needs inputs from risk managers to be able to conclude the review. This workshop is the 1st meeting with risk managers and risk assessors of Member States to discuss some important issues. Other meetings will come in the next months.

The Commission explained the connection of the review of the EFSA BEE GD and the Specific Protection Goal (SPG) project. This SPG project is running independently but the Commission strives to keep consistency with the Bee GD review. Both projects are in parallel and related, but move at different speeds. SPGs for bees need to be decided by May but will move in the same spirit forward as the SPG project. In particular because there is wide recognition that pollination is a key Ecosystem Service, both for conservation and for agricultural production.

The Commission emphasized furthermore on the importance of finalising this mandate timely. It will therefore not be possible to extend discussions on the specific protection goals for bees beyond the May Standing Committee. Any delay beyond this date from risk managers' side would delay the finalisation of the EFSA mandate.

## **Session 2. Status Quo of the project on the review of the bee GD (EFSA, 2013)**

### Presentation by EFSA:



Status quo.PPTX

### Q&A

- I. MS: Why is nobody from Southern Member States in the working group? The selection is based on very academic criteria (e.g. publications) but regulatory experience would be also important and representation of all regulatory zones, in particular also the Southern zone which presents different agro-environmental conditions. EFSA should take care that all zones are represented.  
EFSA: Not only academia but also regulatory experience was considered; in fact in exceptionally high proportion for this WG. EFSA invited all Member States to send nominations and selection was made based on criteria in that call. EFSA did not receive applications from the Southern zone besides one from FR. The French candidate was included in the reserve list, appointed at the later stage and is now part of the WG. Agro-

environmental condition differences between zones are considered in different ways, including that EFSA encouraged Member States to provide input during the consultations.

- II. MS: We were only asked once to comment on the draft protocol for the background mortality. When did the second consultation took place?  
EFSA: There was only one consultation on background mortality. The first consultation was in general on the existing Bee GD.
- III. MS: which comments will be discussed in the April workshop?  
EFSA: First commenting round on the 2013 Bee GD was used for planning (establishing of a priority list). Based on that, a protocol was written on what and how parameters for Tier 1 will be revised. This protocol is subject of a written consultation and will be discussed in the April workshop.  
The third consultation will be launched on 20 March 2020 on the draft protocol outlining the preliminary considerations and planned methods for the revision of the Tier 1 risk assessment schemes of the Bee GD. This is a protocol by EFSA on how to perform the review of the Bee GD and is not linked to OECD protocols.
- IV. MS asked for a clarification on the next steps.  
EFSA: Protocol includes actions for drafting of the revised BEE GD (starts from June to October). Call for nomination to the April workshop (only for risk assessors): nominations to be sent in the next few days.
- V. MS: Sublethal effects and higher tier assessments should be included in the work  
EFSA: Currently the focus is on Tier 1 of the risk assessment. Sublethal effects and higher tier studies will be dealt with at a later stage.
- VI. MS: ToR 5 of the mandate is an important core point of the review as higher Tier was the key point for non agreement of Member States. Will there be a face to face meeting between EFSA and risk assessors of Member States on this issue or is a more specific consultation planned? Higher tier tests should be doable for GLP labs. Practicability should be kept in mind  
EFSA: At least a written procedure is possible for higher Tier. ToR 5 depends more on the review of the protection goal.  
The Commission encouraged Member States to take the opportunity given during the consultations and to make constructive comments including concrete potential solutions to points they identify as concerns.
- VII. MS: Will the protocol be endorsed by all Member States in order to avoid again late comments? Emphasizes need for endorsement of the protocol.  
EFSA: The scope of the April workshop is to understand the comments made during the written procedure. Finalisation will be the task of the working group. EFSA will publish everything (consultation, protocol) at the end of March 2021. The draft protocol may be shared with MSs.  
Comment was supported by 2 other MS.
- VIII. MS: Why is this workshop not planned for later in the process when all tiers are available?  
EFSA: We want early involvement on key points and in addition a consultation on the final draft will be held.  
COM: Early consultations are useful to avoid fundamental questions at the end. Important to perform the review step by step.
- IX. MS: draft protocol in which way to be published? Will it be revised afterwards?

EFSA: working group decision will be that what is the final protocol, no change afterwards, and then any deviation needs to be reported; not yet as a technical report (this would need e.g. proof reading). Protocol is EFSA plan to review the Bee GD, the Member States will use the revised GD not the protocol.

COM: The protocol should be fit for purpose. It could be envisaged to have a kind of formalisation at the ScoPAFF in May as it can have added value for EFSA if this milestone agreed. COM will reflect.

- X. MS: Would it be possible to make a mailing list available of people involved with regard to the communication on this project? Stated the importance to contact the right set of experts (risk managers and risk assessors). Approach on the Endocrine Disruptor Guidance Document (ED GD) could be used as an example.  
EFSA: Communications are sent to the pesticide steering network contact points. Any proposals to add colleagues should come from Member States.  
COM: We can forward communications to all people nominated to this workshop.
- XI. MS: If the protocol is endorsed, will it then not be possible anymore to comment on the final draft Bee GD?  
EFSA: There will be a public consultation on the final draft Bee GD.  
COM: Member States have thus to comment as well during the public consultation. There is a possibility to receive automatic notifications for these consultations.  
EFSA: A workshop will be held in November with Member States and stakeholders. During this workshop, MSs may be requested to present case studies based on the GD. This is an opportunity to give more detailed comments than during the public publication. The same working methodology was followed during the establishment of the ED GD.
- XII. MS: If agreement is asked on the protocol at the Standing Committee PAFF, a discussion in the national Parliament will be necessary.
- XIII. MS: EFSA's rules for protocols should be checked and applied to all protocols. Reference was made to a public consultation on sweetener- a good example for public consultation.
- XIV. MS: A workshop with Member States risk assessors is needed to conserve the practicability of the Bee GD.

### **Session 3. EFSA GD 2013: Exposure to bees and the Exposure Assessment Goal**

#### Presentation by EFSA:



ExposureRM.PPTX

#### Q&A

- I. MS: informed that it has concerns about the correct representation of Southern zone: e.g. if all the hives are in the mountains this will result in a different Gauss curve than the one assumed by EFSA. Therefore it would be interesting to define different environmental scenarios for distribution and exposure of bee colonies.
- II. MS: Agrees with previous comment. Exposure depends on agronomic scenarios. MS does not agree with one zone for seed coatings, also for this, different zones are needed.

- III. MS: Agrees with previous comments. How to translate this into Risk Management? Prefers different scenario over the 90<sup>th</sup> percentile approach as this is not appropriate for landscape management.

EFSA: Scenario's is something different than the 90<sup>th</sup> percentile for exposure. Even if 100 scenarios are developed, agreement on the use of the 90<sup>th</sup> percentile is needed. Within each scenario, there is a distribution of exposure and the question remains : which percentile do we want to protect?.

COM: stressed that the percentiles are statistical, and that for any statistical evaluation a decision on the boundaries is needed (statistics).

- IV. MS: is the exposure quantitative or qualitative?  
EFSA: daily max. concentration entering the hive ( $\mu\text{g}/\text{kg}$ )
- V. MS: Always look at max. field rate to apply. The 90<sup>th</sup> percentile can never be the worst case. It is calculated on exposure not on real trials, the 90<sup>th</sup> percentile scenario is too theoretical. No colonies can be lethally affected, therefore not the right perspective and need to protect all colonies. Real scenarios: Dust with seed treatment; field crop oilseed or taller crops as apples.
- VI. MS: agree with previous comment: we need to have a long discussion between Member States expert and EFSA. MS does not agree to protect all the hives (using the 100<sup>th</sup> percentile), but population (you can take hives away from the field as risk mitigation); Different scenarios should also include different environmental factors (reference to FOCUS scenarios was made, as an example).
- VII. MS: support previous comment. Aim should be to be as conservative in the 3 zones. However, SPG needs to be different in MS: natural death 7% in hives; 10 % is too much.
- VIII. MS: Is the revision of the exposure percentile within the mandate? For 10% the SPG might not be reached. What if several applications?  
EFSA: Risk assessment is done for the representative GAP: if one application, it is one, if it is more then more applications.
- IX. MS: Why not 95%?  
EFSA: The exposure percentile was explicitly agreed in 2013, now it is open again. With a higher percentile, the risk assessment would be more severe but more protective.
- X. MS: if it is 10%, all substances go to Tier 2 and 3

#### **Session 4. EFSA GD 2013: Specific Protection Goals and triggers values**

Presentation by EFSA:



SPG\_triggers\_RM.pptx

#### Q&A

- I. MS: What is the connection with the general SPG project?  
COM: There is link. During the general SPG project it became already apparent that the ecosystem service 'pollination' is affected by the use of pesticides. It is know that bees are

one of the SPUs for this ecosystem service. The review of the Bee GD is therefore going to speed up the SPG definition (step 3 of the EFSA method on SPGs) for bees. Now we have to look at the 5 dimensions for EFSA to finalise the review of the Bee GD. Priority needs to be given to bees and pollination. If, at a later stage, other additional species are identified as relevant for the ecosystem service 'pollination' than they could be covered by another GD. EFSA: SPG for bees is meant to protect all the 4 ecosystem services identified (pollination, food, genetic resources, cultural services), although the focus was on pollination. By protecting pollination the other services are protected as well as pollination is the worst case. Food was considered as well: if we protect colony strength than we have enough bees and then we have enough honey.

- II. MS: The author from the Khoury model is from Australia. There is no raw data behind and the model was tested with data from the US. EL considers the 7 % as unacceptable. In Greece, beekeepers yearly split 20% of colonies. EU decisions should be based on EU data and models. Pragmatic and realistic conditions are needed.

COM reminded that a revision of the natural background mortality was included in the mandate.

EFSA: the 7% colony reduction is not based on a model, but was derived by an expert group as the colony size reduction can be considered as negligible. The Khoury model was only used to derive the trigger values.

- III. MS: does the 2013 Bee GD addresses biodiversity?

EFSA: Biodiversity was considered to be covered by the ecosystem service 'genetic resources'.

- IV. MS: For the magnitude not only expert judgement but also publications on background mortality were considered. Population dynamics (colony growth and decline -> we need very precise measurement of the change of colony size): are there new development which allow to measure colony decline more precisely? Can we detect such effect? Did EFSA develop a new model?

EFSA: This concerns the requirement of field studies, which can go differently from the specific protection goal (SPG). SPG should be sufficient to ensure the ES protection. How it is implemented this is another layer. Best available field study was not able to show the level of sensitivity of 7% in the field.

Model development ApisRAM is ongoing but will not be finalised in time for this mandate (expected summer 2021). Therefore, this model cannot be incorporated in this review.

- V. MS: any validation happened in real life and this is for honeybees?

EFSA: Revision of the background mortality is ongoing. Parametrisation is based on open literature, assumption behind the model comes from real field measurements.

- VI. MS: Khoury model: first extrapolation with oilseed rape in spring for neonicotinoids did not match reality. Is there any revision of those factors? Acceptable mortality in OECD guidelines 203 and 204 is 10%.

- VII. MS: does not support the use of the Khoury model. The Bee GD is for the EU and uses science from non-EU people with very little experience on bees. Management of colonies should be considered (different in USA where pollination by honeybees is industrialised). 7% is not relevant; if industry to go to semi field and field, then they will not come as they protect global investment; In southern EU, Xylella is the biggest problem for which pesticides are needed or olive trees are lost.

- VIII. COM: for calculating the trigger values, should not the background mortality for foragers be considered as the Khoury models is also for forager mortality? What do we want to protect? This is biology, bee experts should explain what needs to be protected.  
EFSA: In agreement with the RMs, the lowest mortality figure found in literature was used as a conservative approach.
- IX. MS: 7% is the heart of the calculation and seems a black box. This value is strongly contested by some countries. On what is this figure based and will it be revised?  
EFSA: 7% based on expert judgement. This means that when a substance is approved, the colony size can be reduced to a maximum of 7% as this is considered as negligible against any possible impact of Ecosystem Services. Few data indicated 3,5% but 7% was indicated as reasonable. Linking this 7% to impact on Ecosystem Services is not feasible currently.
- X. COM: Why a linear dose response was used instead of the usual logarithmic scale?  
EFSA: The dose response relationship follows a sigmoid curve. As the linear dose response curve is above, it is always worst case.
- XI. MS: a linear dose response is too conservative. The most toxic substances will be privileged over low risk substances with this method.  
EFSA: we are aware of these criticisms (Khoury model, background mortality, linear dose model). Alternative approaches, if available, will be considered during the review. MS also want different scenarios for different zones, but the essential questions is it is not so much about the scenarios, it's the right percentile that we should agree on.
- XII. MS: support previous comment: using a linear curve does not make sense if only for conservatism. Is there enough data on background mortality for wild bees?  
EFSA: Screening of literature resulted in 11000 data on bee mortality of which 700 were withheld. These were further narrowed down, but the final number of data points are some hundreds. These are dominated by honeybees.
- XIII. MS: For field studies, it is required to 'standardise' your colonies by leaving the weakest and strongest out. To have 200 such comparable colonies you therefore actually need 500 colonies (only 2-3 apiculturists in MS have such number of colonies). Furthermore standardisation will disappear in a hive after six weeks.  
EFSA: This is to filter out all other variabilities (stressors) from the assessment so only the effect of the pesticide is tested.
- XIV. MS: The OECD chronic test is too short. Exposure period should be prolonged.

## **Session 5. Comments received by COM on SPGs for bees**

The Commission gave an overview of all comments it received during the past years on the 2013 EFSA Bee GD in relation to the Specific Protection Goal. The most important comments were already mentioned in previous sessions of this meeting, however this overview ensured that all comments from the past years are addressed.

## **Session 6. Next steps**

Commission presented the following example of a 1<sup>st</sup> draft of what would need to be agreed by May 2020 as input for EFSA:

<b>SPU</b>	<b>Honey bee (<i>Apis mellifera</i>)</b>	<b>Bumble bees</b>	<b>Solitary bees</b>
Ecological entity	Colony	colony	(meta)population
Attribute	strength	strenght	
Magnitude	...	...	
Spatial scale	Edge of the field...	...	
Temporal scale	...		
Degree of certainty			

A document will be prepared by the EFSA and COM outlining all the inputs needed from risk managers and the options available. Further discussion is foreseen in the Standing Committee PAFF of the 23 and 24 of March, 2020, with decisions expected to be taken around the time of the Standing Committee meeting of May 2020.



06/03/2020

# Status Quo of the project on the review of the bee GD (EFSA, 2013)



Interpretation  
of the ToRs and  
planning the  
tasks

Selection of  
stakeholders

- 17 applications received
- Based on the predefined criteria, 9 had been selected
- All the 9 organisations plus MSs are involved in all ad-hoc consultations

## 5. List of selected stakeholders

Name of Organisation	Stakeholder Category	Name of Expert
European Crop Protection Association (ECPA)	Business and food industry	Mark Miles
European Seed Association (ESA)	Business and food industry	Anne Alix
International Biocontrol Manufacturers Association (IBMA)	Business and food industry	Silvia Hinarejos
Pesticide Action Network (PAN) Europe	Environmental/health NGOs and advocacy groups	Martin Dermine
Pollinis*	Environmental/health NGOs and advocacy groups	Barbara Berardi Tadié
Beelife European Beekeeping Coordination	Environmental/health NGOs and advocacy groups	Noa Simon Delso
APIMONDIA*	Farmers and primary producers	Fani Hatjina
Copa and Cogeca	Farmers and primary producers	Chris Hartfield
International Confederation of European Beet Growers (C.I.B.E.)	Farmers and primary producers	Alexander Krick

\* Association is invited to register as EFSA stakeholder organisation.

Interpretation  
of the ToRs and  
planning the  
tasks

Selection of  
stakeholders

Selection of  
experts for the  
WG

# The scientific Working Group

Academia

- Pauline Adriaanse (WUR, PPR panel)
- Andres Arce (Imperial College London)
- James Cresswell (University of Exeter)
- Maj Rundlöf (Lund University)

MSS\*

- Daniela Jölli (AGES, AT)
- Dirk Süßenbach (UBA, DE)
- Brecht Ingels (FPS, BE)  
– invited hearing expert

EFSA

- Support: AMU Unit



\*On their own capacity

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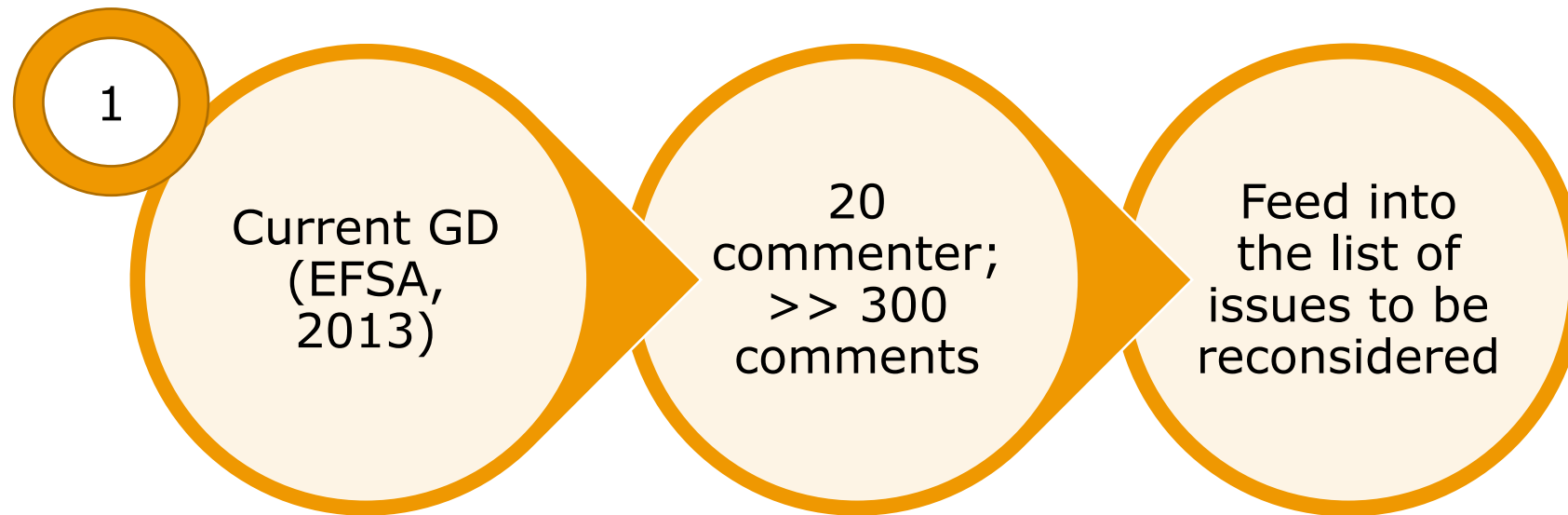
Interpretation  
of the ToRs and  
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Selection of  
stakeholders

Selection of  
experts for the  
WG

1<sup>st</sup> Stakeholder  
and MSs  
consultation

Update the  
planning





Development of  
the protocol for  
background  
mortality

2<sup>nd</sup> Stakeholder  
and MSs  
consultation



Development of the protocol for background mortality

2<sup>nd</sup> Stakeholder and MSs consultation

Screening of the publications for the background mortality

Discussion papers for reviewing Tier 1

Kick of the protocol for reviewing Tier 1

Two physical meetings in Parma and one TC

January  
2020

**Implementation of the protocol for ToR2 (bee mortality):**

- Full text screening
- Appraisal
- Data extraction
- Data analysis

**Development of the protocol for ToR3 and ToR4:**

- Formal EKE for the attractiveness to pollen and nectar
- Systematic literature review for food consumption
- Systematic literature review for the sugar content in nectar
- Update of the residue database
- Relevance of the water scenarios (inc. guttation)

2 WG meetings → TCs

Preparation of the workshop with Stakeholders and MSs

Launch of the Stakeholder and MS consultation on the protocol

Kick-off of Consultation of RM (ToR6) to get input on SPG

March  
2020

April  
2020

Workshop with Stakeholders and MSs

Finalization of the protocol for ToR3 and ToR4

2 WG meetings

June

**Implementation of the protocol for ToR3 and ToR4:**

- Perform the EKE for the attractiveness to pollen and nectar
- Systematic literature review for food consumption
- Systematic literature review for the sugar content in nectar
- Update of the residue database
- Relevance of guttation

**Implementation of the SPGs**  
Revision of the methodology for deriving the trigger values

Final outcome of RM consultation(ToR6)

Revise the higher tier studies requirements (ToR5)

2 WG meetings

Draft of the GD

Preparation of the workshop with Stakeholders and MSs

September  
2020

October  
2020

Public Consultation

Workshop with Stakeholders and MSs

Mid November

Finalization of the GD

2 WG meetings

March  
2021

## Implementation of the protocol for ToR2 (bee mortality):

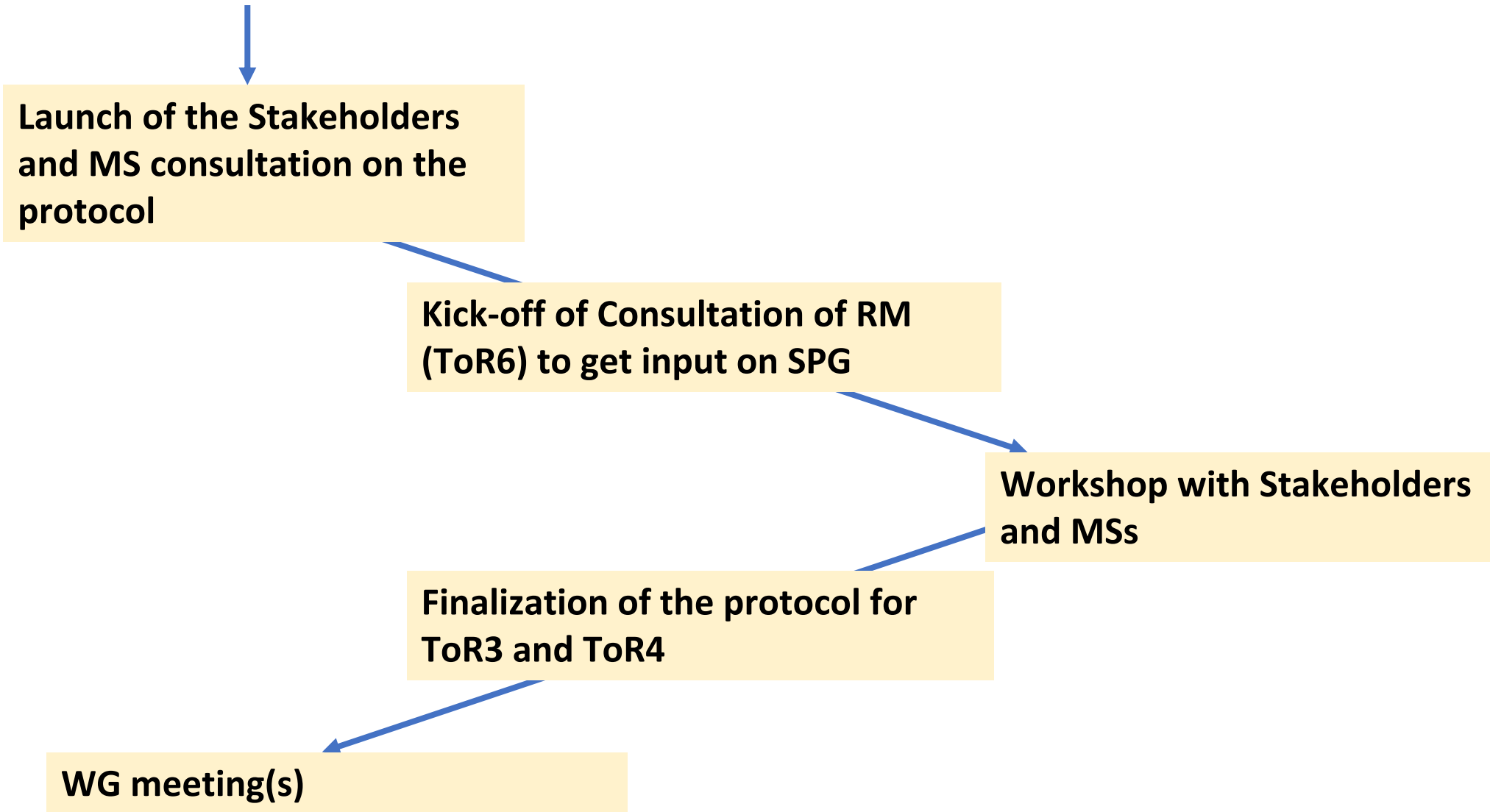
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2 WG meetings → TCs

Preparation of the workshop with Stakeholders and MSs



# Questions?



06/03/2020



# EFSA GD 2013: Exposure to bees and the Exposure Assessment Goal

Trusted science for safe food



## Honey bee



- single species
- eusocial living in large, perennial colonies
- sophisticated communicational channels to communicate the foraging site
- continuous larva rearing in the season (processed and unprocessed food)
- managed by the beekeepers

## Bumble bee



- 68 species in Europa
- eusocial living in smaller annual colonies
- no sophisticated communicational channels
- continuous larva rearing in the middle of the season (unprocessed food)
- wild, nests underground or in other protected sites above ground (e.g. tree cavities)

## Solitary bee



- > 1800 species in Europa
- non-social, no colonies
- no communicational channels
- many different ecological traits
- larvae are provisioned by unprocessed pollen and nectar
- wild, nests in protected places

# Application methods

Spray application



Liquid formulations

Seed treatment



Granular application



Broadcast

Soil incorporated

Solid formulations

# Routes of exposure

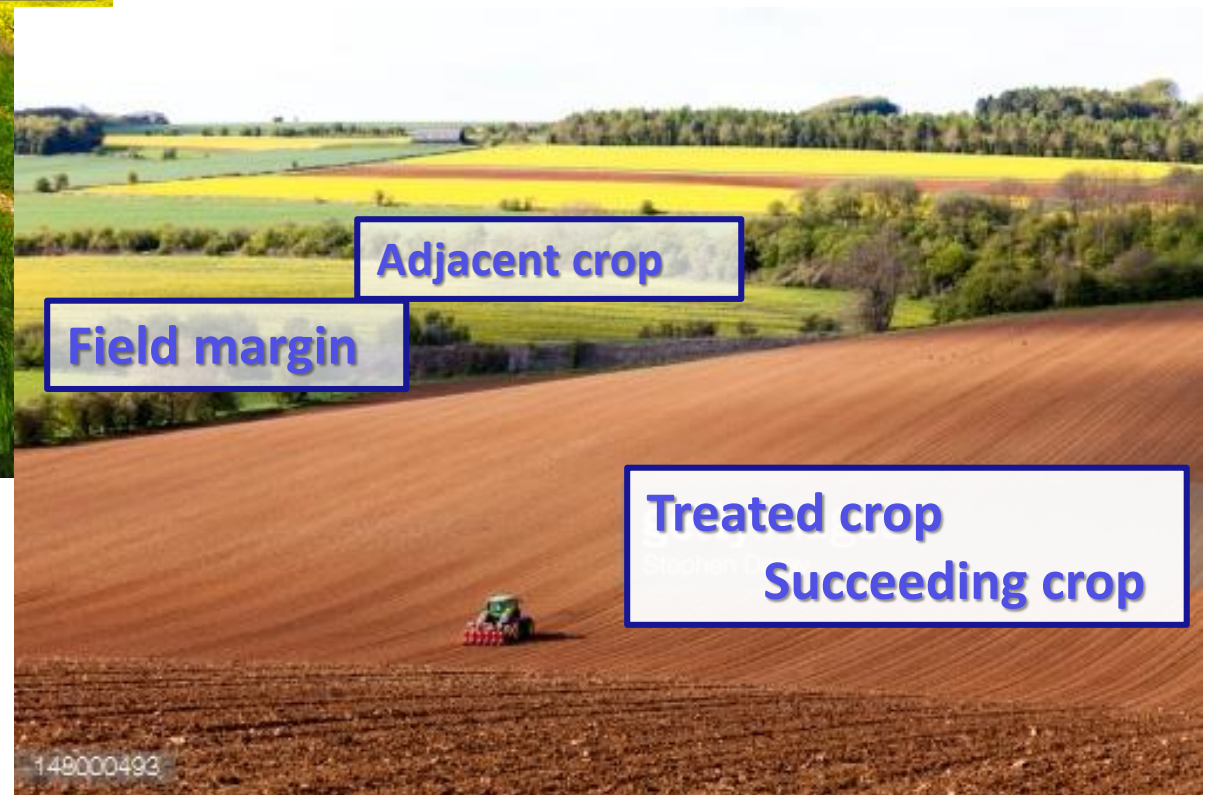
- Exposure via contact  
(i.e. overspray, spray drift, dust drift)
- Consumption of pollen
- Consumption of nectar
- Consumption of water  
(guttation fluid, surface water  
and puddles)
- Risk from plant metabolites



# Exposure scenarios



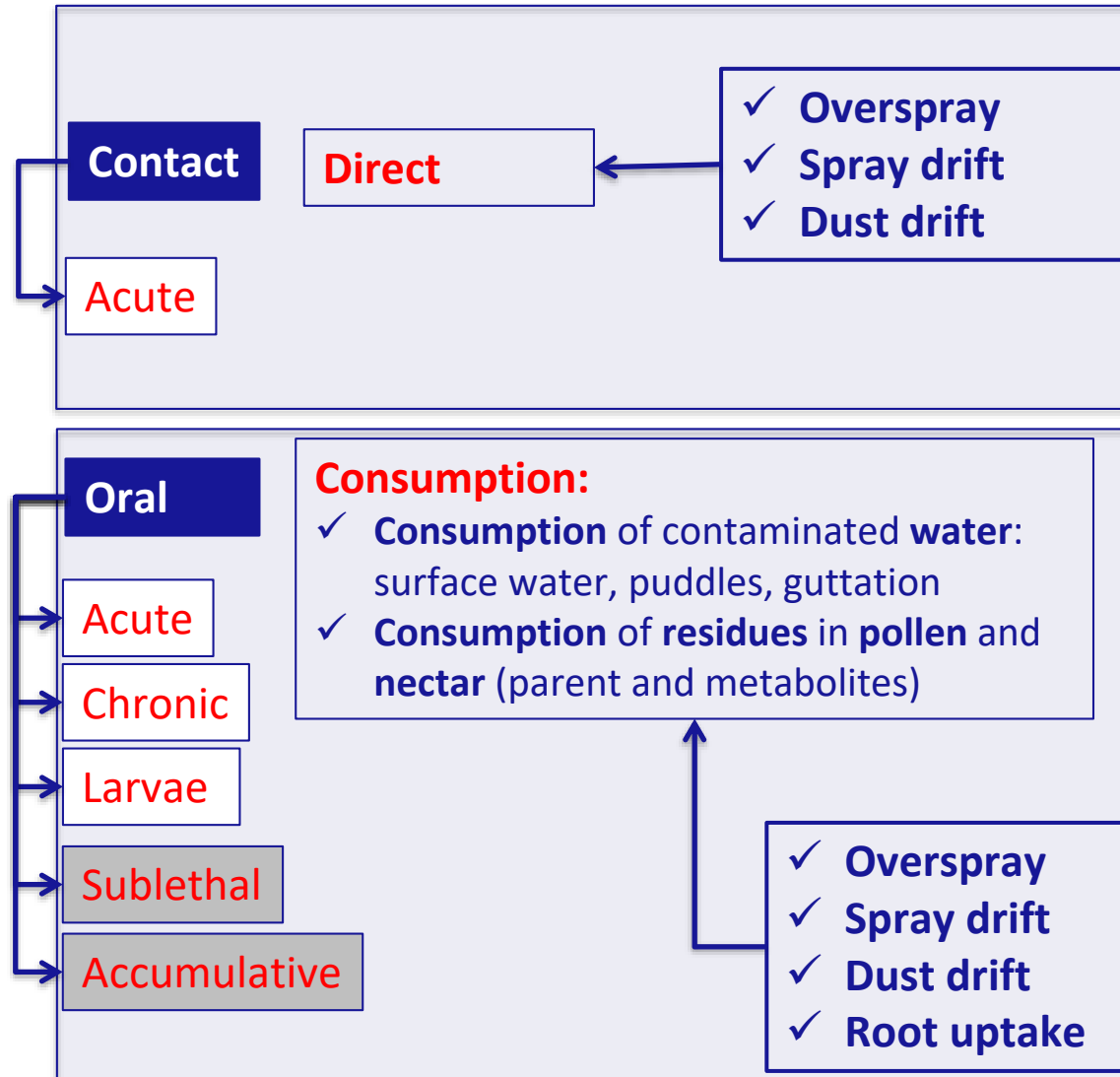
**Spray application,  
granules broadcast**



**Seed treatment,  
granules incorporated**

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

\* Except seed treatment, granules incorporated



“...the proposed goal of the exposure assessment is to provide concentrations corresponding to a 90<sup>th</sup> percentile worst case for the hives at the edges of treated fields in the area of use, in the context of registration at EU level.”

“...the proposed goal of the exposure assessment is to provide concentrations corresponding to a 90<sup>th</sup> percentile worst case for the hives at the edges of treated fields in the area of use, in the context of registration at EU level.”

What level of exposure?



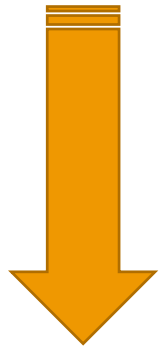
“...the proposed goal of the exposure assessment is to provide concentrations corresponding to a 90<sup>th</sup> percentile worst case for the hives at the edges of treated fields in the area of use, in the context of registration at EU level.”

What level of exposure?  
For which population?

“...the proposed goal of the exposure assessment is to provide concentrations corresponding to a 90<sup>th</sup> percentile worst case for the hives at the edges of treated fields in the area of use, in the context of registration at EU level.”

What level of exposure?  
For which population?  
What spatial scale?

“...the proposed goal of the exposure assessment is to provide concentrations corresponding to a 90<sup>th</sup> percentile worst case for the hives at the edges of treated fields in the area of use, in the context of registration at EU level.”



- Whole EU e.g. for seed treatment
- Regulatory zone (NEU, CEU, SEU)
- The definition could be applicable also for other spatial scales e.g. country, region, etc.

What level of exposure?  
For which population?  
What spatial scale?

## What concentrations?

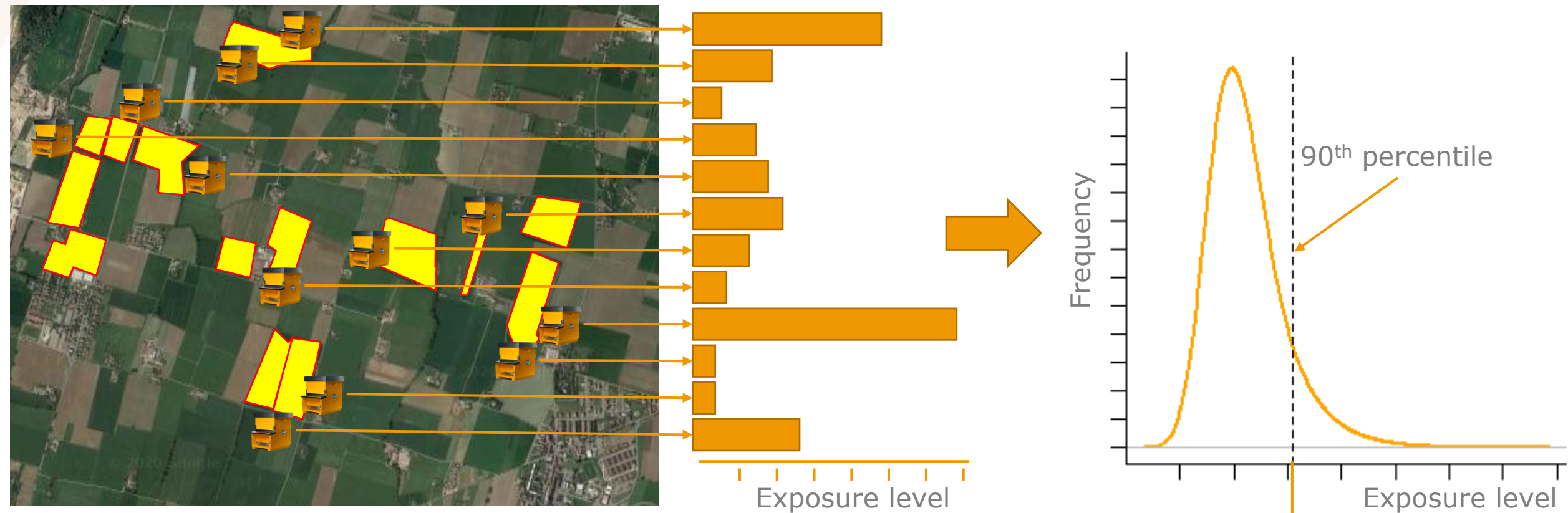
The current agreed exposure assessment goal is focuses on the residue entering in the hive.

## Why 90<sup>th</sup> %-tile?

It has some tradition in the regulatory area;

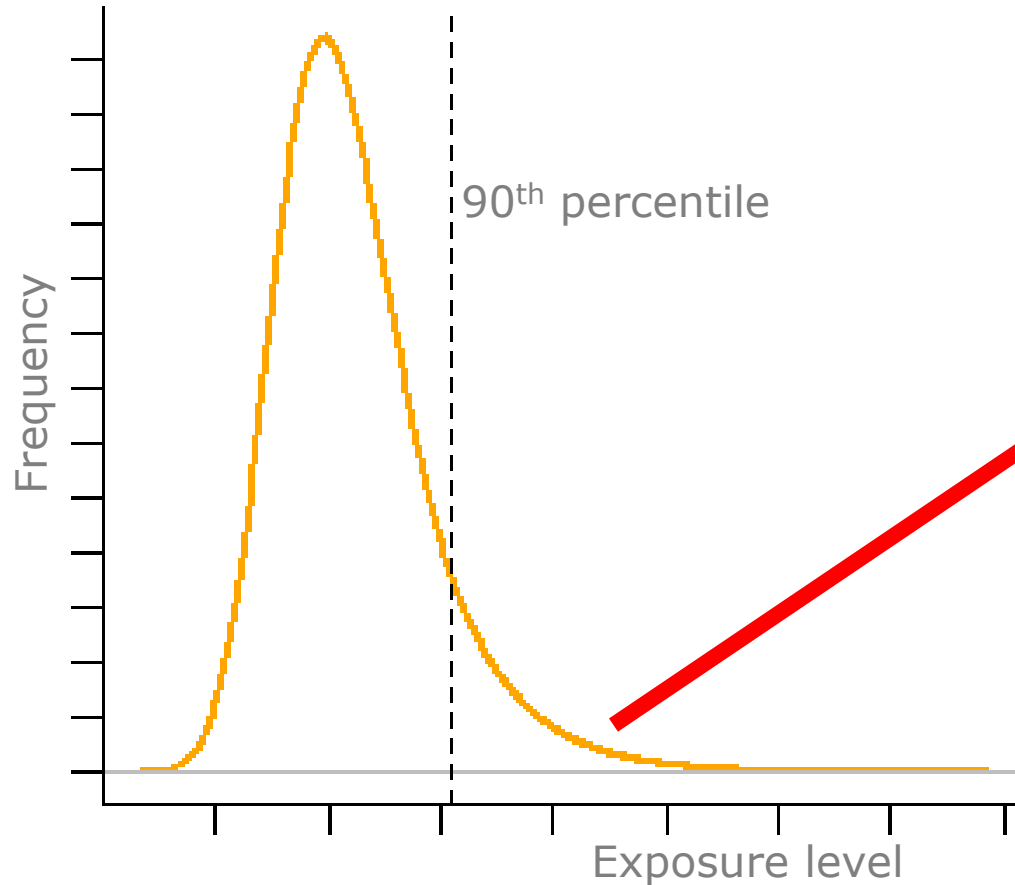
e.g.: the FOCUS GW scenarios intend to assess the 90<sup>th</sup> percentile of the pore water concentration leaching at one meters depth

# What this 90<sup>th</sup> percentile mean exactly



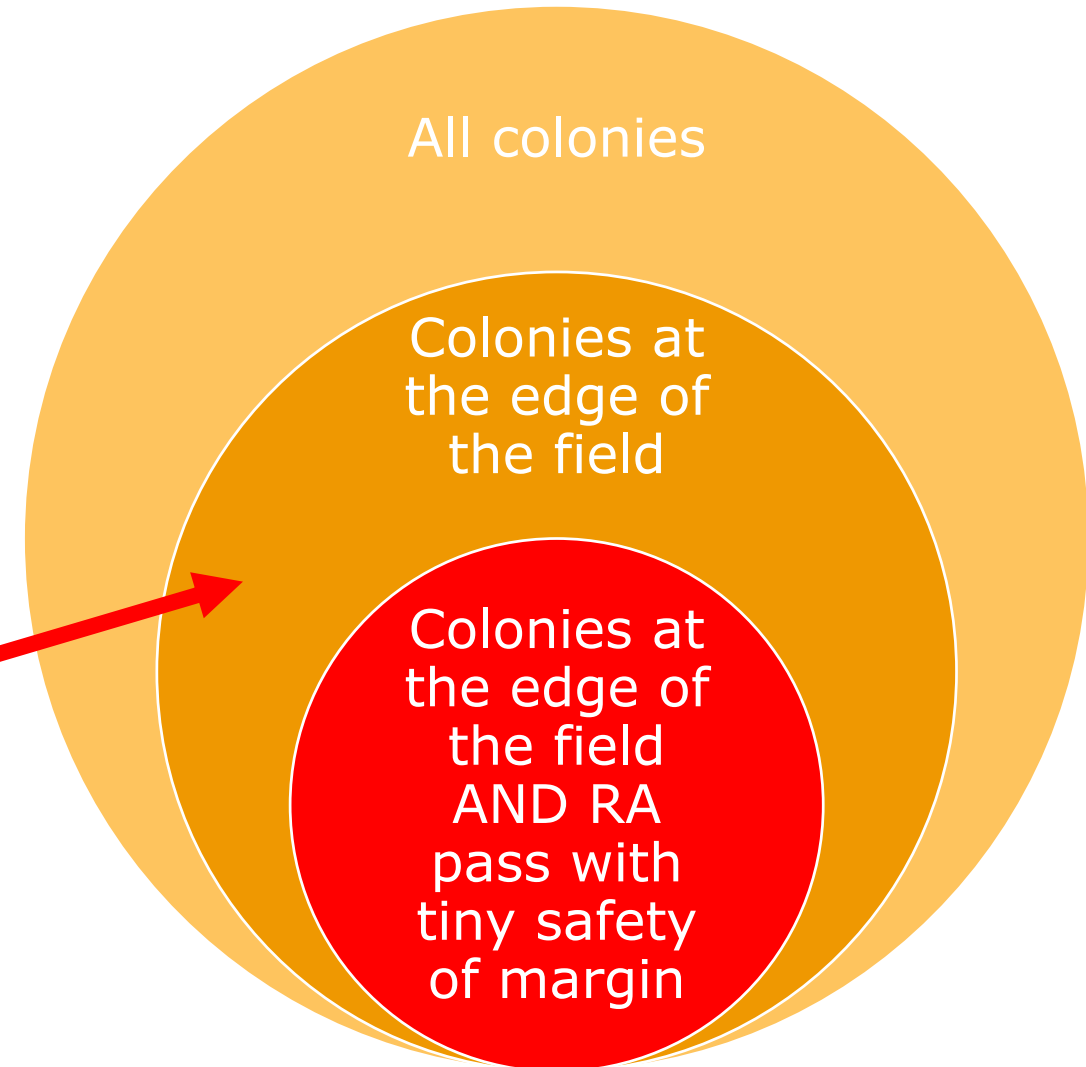
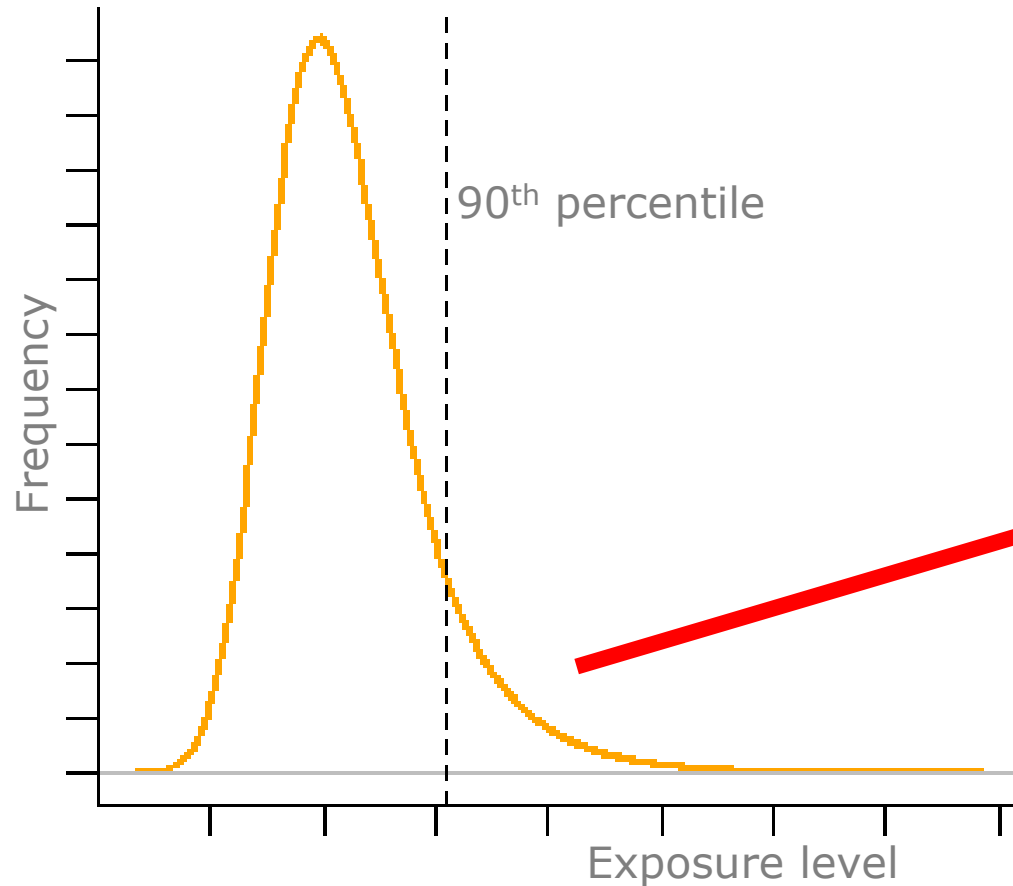
Exposure Assessment goal for the area of use  
(= exposure at which the assessment should be performed)

# What about the 10%-tile?



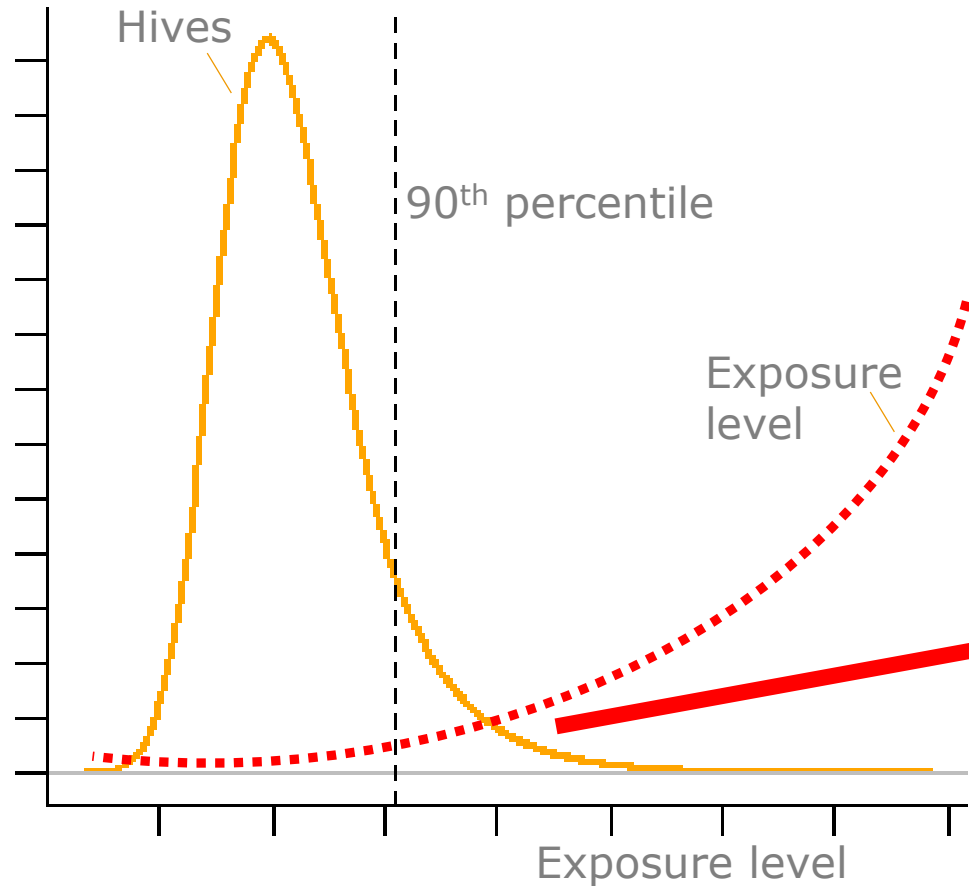
Does it mean that 10% of the colonies/populations will encounter an exposure level which triggers a large effects?

# What about the 10%-tile?



The same applies for solitary bees; they do not have colonies, but populations

# What about the 10%-tile?



Even this (sub)population will encounter different levels of exposure triggering different levels of effects from small to large

Colonies at the edge of the field AND RA pass with tiny safety of margin

The same applies for solitary bees; they do not have colonies, but populations



Questions?



06/03/2020



# EFSA GD 2013: Specific Protection Goals and triggers values

Trusted science for safe food

## Ecosystems services

(EFSA SPG opinion, 2010  
EFSA GD, 2016).

The ecosystems services that may be impacted following the exposure of bees to pesticides are:

**Pollination, food, genetic resources, cultural service**

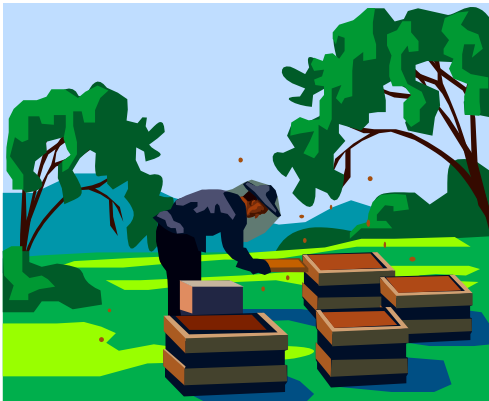
<b>Service Providing Unit (SPU)</b>	Honey bees, bumble bees and solitary bees.  Other pollinators are not covered, not part of the mandate.
<b>Ecological entities</b>	Colony (honeybees, bumble bee*), population (solitary bees)
<b>Attribute</b>	Colony strength (honey bees, bumble bee), population abundance (solitary bees)
<b>Magnitude</b>	Negligible effect i.e. <7% colony reduction  The colony size reduction of the exposed colonies should be no more than 7% smaller than the control colonies at any time.
<b>Spatial scale</b>	Edge of field*
<b>Temporal scale of protection</b>	At any time
<b>Degree of certainty</b>	not defined (to explain)

\*questionable for BB/SB

# Attribute to protect and magnitude (HB)

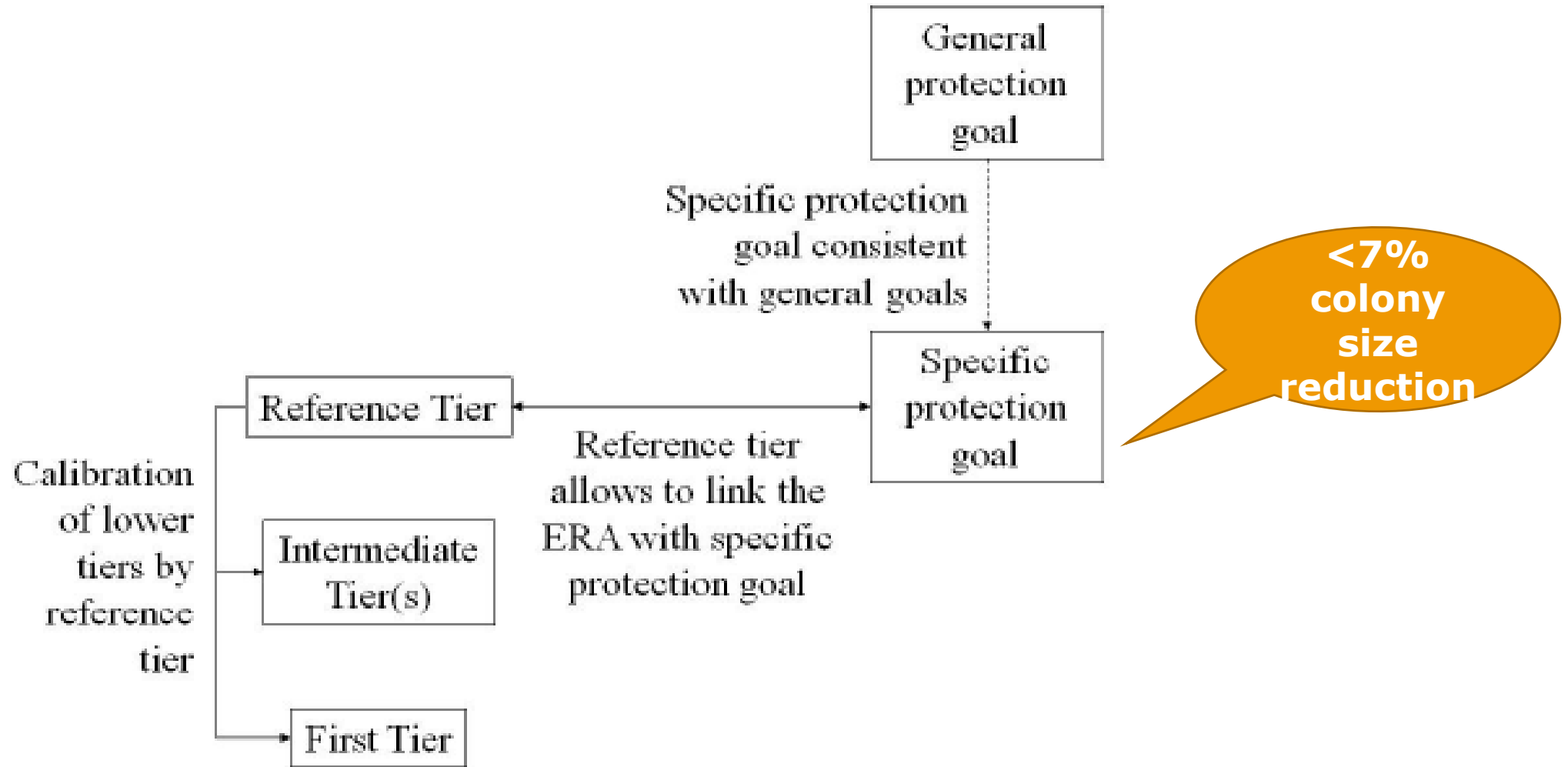
The viability of each colony, the pollination services it provides, and its yield of hive products all depend on the colony's strength.

Therefore special focus on impacts on colony strength.



Effect	Magnitude (reduction in colony size)
Large	>35%
Medium	15 % to 35%
Small	7% to 15%
Negligible	3.5 % to 7%

Based on expert judgement



# Q&A

# SPGs and calibration of lower risk assessments

## Ecosystem services to be protected:

1. Pollination
2. Food production (hive products)
3. Genetic resources and cultural services (education, aesthetic, recreation)

## SPG:

<7% reduction on colony size

## Khoury Model:

To predict the **increase of the daily forager mortality** with respect to the model background mortality which still cause <7% colony reduction

Step 1

## Mortality over 2 days (acute test):

Increase in the background mortality level of a factor of **3**

## Mortality over 10 days (chronic test):

Increase in the background mortality level of a factor of **1.27**

Step 2

Real background mortality: e.g 5.3%

$$5.3 \times (3-1)$$

$$5.3 \times (1.27-1)$$

'acceptable' mortality: 10.6%

'acceptable' mortality: 1.43%

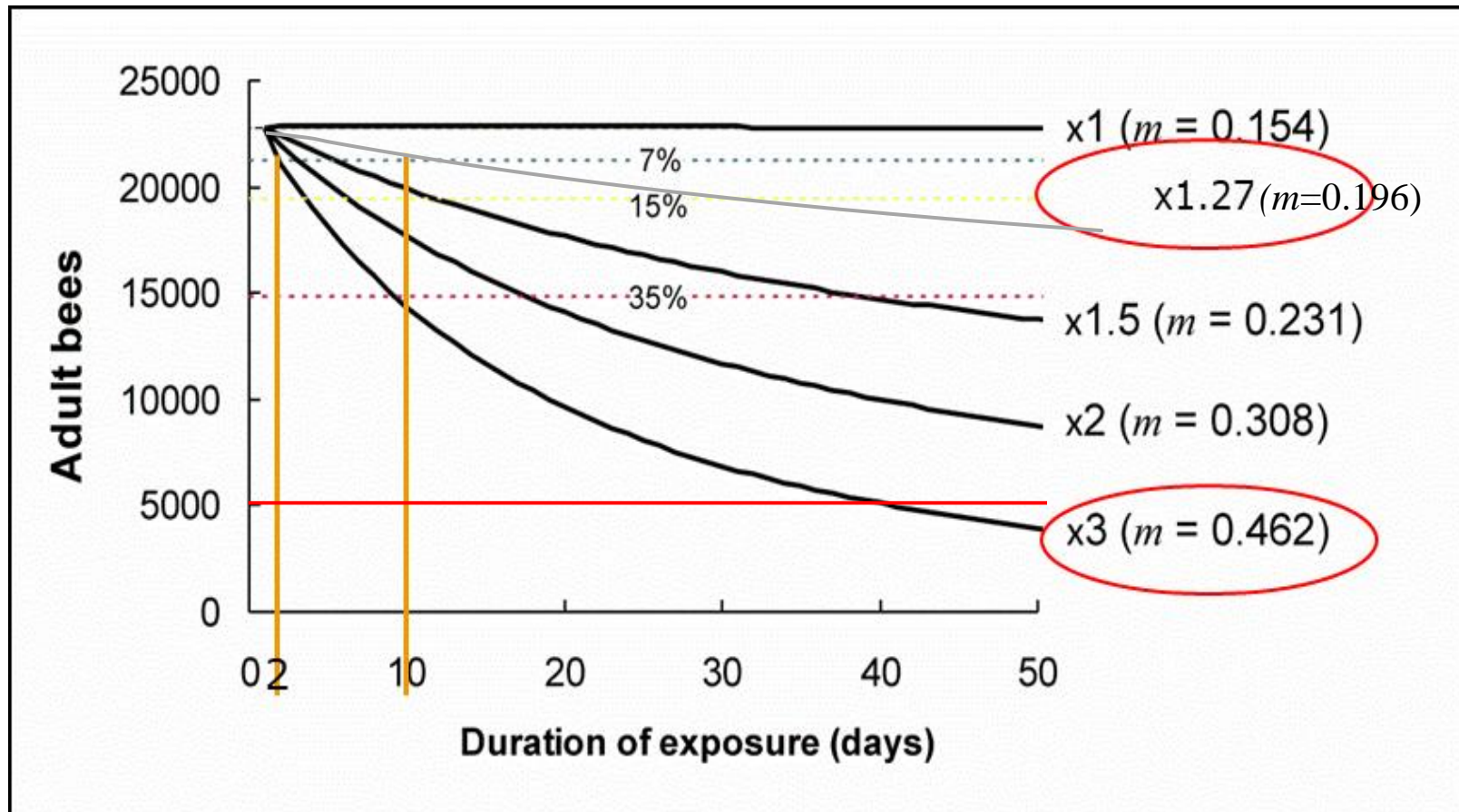
## Triggers:

Dose-response model linking 'acceptable mortality' and standard 50% mortality endpoint (LD50, LDD50)

Step 3

# STEP 1 - SPGs: Khoury Model

The model of Khoury et al. (2011) is focused on the effects of lifespan and mortality rates of forager bees on colony growth. It allows to link the colony size and the daily background forage mortality (assumed in the model to be 15.4%).

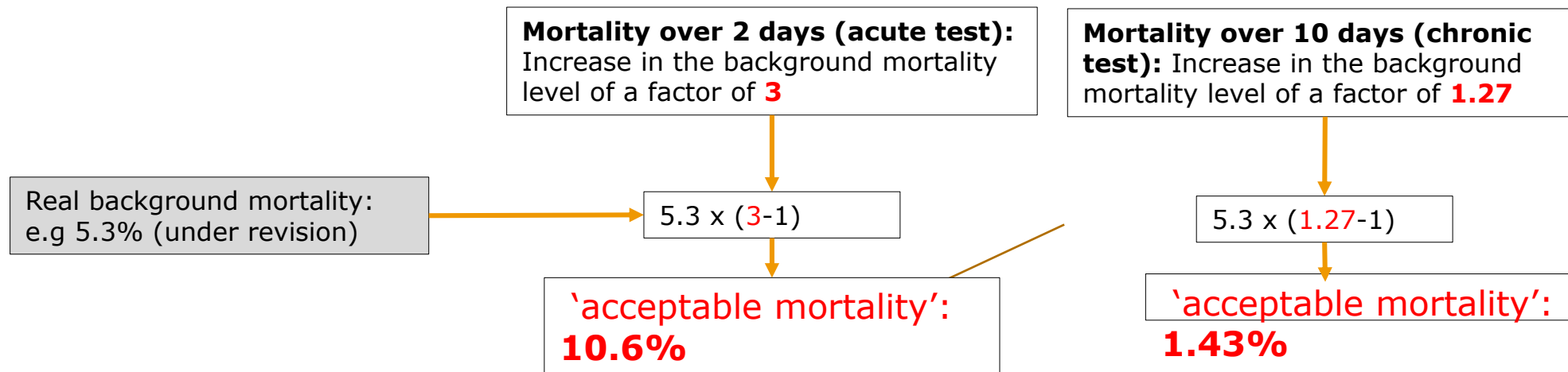


Multiple of background mortality of forager bees	Negligible effect Reduction of colony size by $\leq 7\%$
$\times 1.5$ ( $m = 0.231$ )	6 days
$\times 2$ ( $m = 0.308$ )	3 days
$\times 3$ ( $m = 0.462$ )	2 days



# STEP 2 - Mortality rates that meet the SPG

The increments of the background mortality are used to calculate the 'acceptable mortality' (=max mortality rate that meets the SPG).

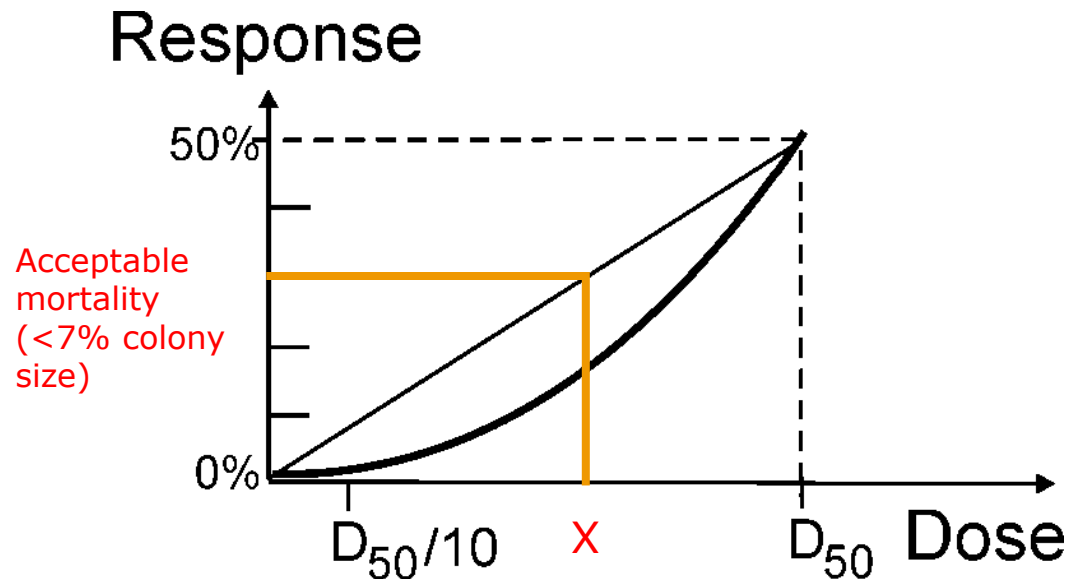


The treatment mortality in the laboratory studies is already corrected for background mortality observed in the controls. Hence it is necessary to reduce the factor of increase in mortality by 1 to derive the 'acceptable mortality'

# Q&A

# STEP 3 - Calculation of the Trigger values

## Linear Dose-response relationship



- mortality = 50% at exposure = LD50
- $\text{mortality} = \text{exposure} * 50/\text{LD50}$

When mortality = 'acceptable mortality' and exposure = X, then:

- 'acceptable mortality' =  $X * 50/\text{LD50}$

and rearrangement yields

- $X = \text{'acceptable mortality'} * \text{LD50}/50$ .

T (trigger value for the TER) is

- $\text{TER Trigger (T)} = \text{LD50}/\text{exposure (X)}$ .

by substituting exposure =  $X = (\text{acceptable mortality} * \text{LD50}/50)$  it gives

- $\text{TER trigger (T)} = \text{LD50}/(\text{'acceptable mortality'} * \text{LD50}/50)$

and algebraic simplification gives

- $T \text{ (ETR trigger)} = \text{acceptable mortality}/50$

# Triggers (oral exposure)

**Triggers:**

Dose-response model linking 'acceptable mortality' and standard 50% mortality endpoint (LD50, LDD50)

$$T \text{ (trigger)} = \text{acceptable mortality} / 50$$

	Honey bees	Bumble bees	Solitary bees
Daily background mortality (%)	5.3	4.4	5
Lowest mortality from literature			
Increase mortality factor	<b>3 (acute)</b> <b>1.27 (chronic)</b>	<b>3 (acute)</b> <b>1.27 (chronic)</b>	<b>3 (acute)</b> <b>1.27 (chronic)</b>
'acceptable mortality'	(3-1)×5.3 = 10.6 (acute) (1.27-1)×5.3 = 1.43 (chronic)	(3-1)×4.4 = 8.8 (acute) (1.27-1)×4.4=1.19 (chronic)	(3-1)×5= 10 (acute) (1.27-1)×5 = 1.35 (chronic)
ETR Trigger HB	T=10.6/50= <b>0.2 (acute)</b> T=1.43/50= <b>0.03 (chronic)</b>	T=8.8/50= 0.18 (acute) T=1.19/50= 0.024 (chronic)	T=10/50= 0.2 (acute) T=1.35/50= 0.027 (chronic)
ETR Triggers BB and SB with additional AF 5	-	<b>0.036 (acute)</b> <b>0.0048 (chronic)</b>	<b>0.04 (acute)</b> <b>0.0054 (chronic)</b>

# Triggers (contact exposure/Larvae)

## Contact

	Honey bees	Bumble bees	Solitary bees
Daily background mortality (Lowest observed mortality)	5.3	4.4	5
I	3	3	3
Max. increment	$2 \times 5.3 = 10.6$	$2 \times 4.4 = 8.8$	$2 \times 5 = 10$
HQ trigger = 4 × acceptable mortality (downwards spray)	42.4	7*	8*
HQ trigger (upwards and sideward spray) = 8 × acceptable mortality	84.8	14*	16*

\*An additional assessment factor of 5 is suggested to account for higher susceptibility of forager losses in bumble bees and uncertainties related to differences in species sensitivity distribution in solitary bees.

## Larvae

- ✓ Effect on larvae cannot be linked directly to the colony size so RA based on NOEC
- ✓ Based on a qualitative uncertainty analysis, an Assessment Factor of 5 (**ETR Trigger = 0.2**) was proposed to cover e.g. lab to field, inter species variability

- The trigger values were calculated by considering the SPG, the 'real' daily background mortality rates from literature and 'increase of forager mortalities' which is acceptable for a colony size reduction  $< 7\%$  - SPG.
- The trigger values for bumblebees and solitary bees were calculated by using the 'increase of forager mortalities' of honeybees, and therefore assuming the same SPG i.e.  $< 7\%$  colony size reduction. An additional AF of 5 was applied.
- The trigger values for contact exposure took in consideration the same figures as for the oral and literature data on measurement of deposit on individual bees;
- The trigger value for larvae was decided based on qualitative uncertainty analysis (AF of 5 which gives an ETR trigger of 0.2)

# Q&A

**Aim:** being able to detect an effect equal to the magnitude of effect included in the SPGs with the sufficient level of confidence.

Elements to consider:

- **Effect size** (i.e. 7% for colony strength, 50% increase of forager daily mortality)
- Required level of **confidence**
- Required level of **power**
- **Variability between colonies** on the same field
- **Variability between colonies** on different **fields**

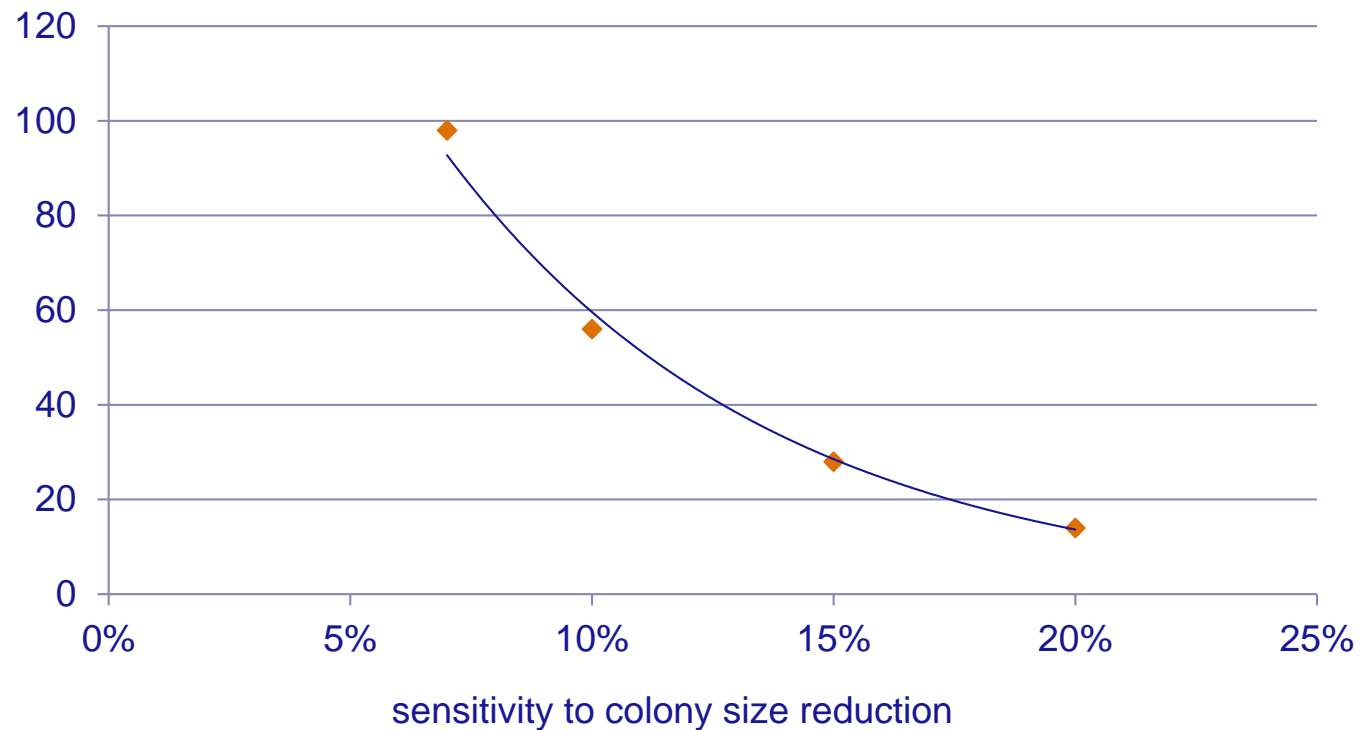
EFSA (2013) provided two examples of calculation of the necessary replication by assuming a **CV** between colonies = **15%** and between fields = **5%**, and assuming 7 hives per field.

- For **colony strength**: 14 fields (=98 colonies) for each treatment and the control
- For **forager mortality**: 2 fields (=14 colonies) for each treatment and the control



The design ('size') of a study should be such that it is able to identify negligible effects (i.e. 7%).

**Number of pairs of colonies needed based on an example given in the GD (7 hives/field)**



Altogether, required plot size, distance between control and treatment, the duration, and the number of replicates makes the experimental design significantly more challenge than the setup used before EFSA 2013

While most elements are fixed, there are ways for limiting the number of replicates and hence to limit the setup complexity.

- **Reduce variance in the outcome variable** by:
  - Reducing the initial variability (colonies as similar as possible, allocated randomly to the control and the treatment)
  - Minimise noise in the measurements by adopting more accurate measurement techniques
- **Accept a higher Type I error**

# Q&A



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