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REPORT

WORKSHOP 30 JUNE 2020

SECOND 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. Invitations were sent to the participants of the first workshop held on 6 March 2020 and the experts appointed by Member States who could not be present in the meeting in March 2020.

Due to travel restriction following the COVID-19 outbreak, the meeting was organised via WebEx. 22 Member States were present (absent: BG, CY, HU, MT and RO).

There were 4 participants from EFSA, 1 participant from ECHA and 4 participants from DG SANTE.

1. Welcome by Commission



Microsoft
PowerPoint Present:

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

The Commission summarised the relevant terms of reference in the EFSA mandate relating to the review of the specific protection goal for bees:

- To take into account **comments** from Member States and stakeholders
- To take into consideration **natural background mortality** of bees
- To **review the requirements for higher tier testing**, in particular by reconsidering the **magnitude of detectable effects** vs the statistical power and **validated population modelling** in light of realistic agro-environmental conditions
- To take into account planned and on-going discussions initiated by the Commission on defining **specific environmental protection goals** and review the risk assessment guidance based on the specific protection goals agreed during this process.

The last term of reference ensures a link with the horizontal project on 'Specific protection goals for the environmental risk assessment of plant protection products'. This project was initiated in 2018 and is based on a method proposed by EFSA in 2010 & 2016.

A workshop of the horizontal project in February 2020 focused on STEP 1 of EFSA method and confirmed that that the ES 'pollination' is potentially affected by the use of pesticides.



In the EFSA (2013), the SPU taken into account i.e. honey bees, bumble bees, and solitary bees were already indicated by the mandate i.e. the step 2 of the EFSA method was already given.. These SPUs are suggested to be taken over because they are consistent with the horizontal approach, as these bees

represent important SPUs for pollination and are within the focus of the mandate of the bee GD. However, biological differences between these bees exist; and data are still scarce for bumble bees and solitary bees.

Objective of this meeting

The workshop initiated the discussion on step 3 of the EFSA method, which is related to the definition of a specific protection goal per Service Providing Unit based on five interrelated dimensions: 1) Ecological entity; 2) Attribute; 3) Magnitude of the effect; 4) Temporal scale; 5) Spatial scale.

For this, EFSA proposes 4 approaches with different underlying scientific data and focus on either SPUs or the provision of the ecosystem services. The approaches would allow to review some or all dimensions of the SPG (step 3) pending on the feasibility within the current mandate.

Risk Managers were consulted on which is the most appropriate approach. In a further meeting, risk managers will be consulted to decide on the acceptable effect level within the selected approach together with the temporal and spatial scale of this effect.

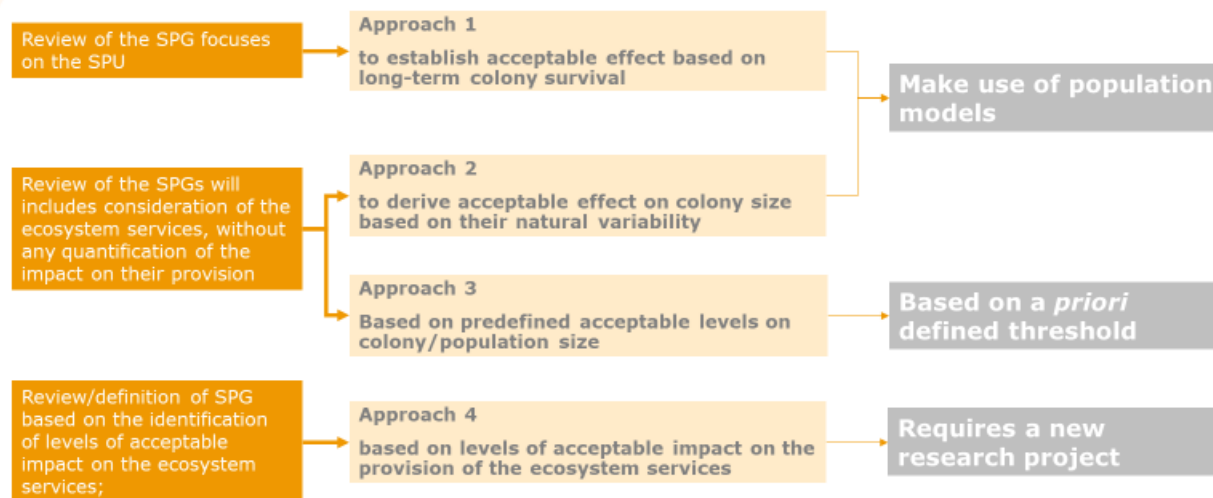
2. Presentation of the 4 approaches by EFSA



options for RM
consultation_30_6.p

EFSA explained the 4 approaches with the aid of graphs which were made for training purposes but do NOT contain real-life data. EFSA explained that the 4 approaches were developed on the basis of feedback by risk managers, that was put forwarded also during the first consultation on 6 March 2020 , preliminary results of the SPG project and state of the art of the EFSA (2013) .

Overview of the different approaches



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Approach 1 considers colony survival until next season or longer. This means that it will consider the review of some dimensions of the current SPGs e.g. *attribute* (survival instead of colony size effect) and *magnitude*. Model simulations will be used to establish colony maximum tolerable effects (MTEs). These simulations will be performed in selected scenarios covering different EU environmental conditions. In a second step Risk Managers provide feedback on whether the derived MTEs are considered acceptable.

Approach 2 considers the magnitude of the effect on colony size as acceptable when it remains in a range defined on the basis of the expected natural variability¹. It is assumed that any impact on the ES would then also be within the natural variability. This approach does not consider the full review of the current SPGs but will allow to redefine the *magnitude* dimension. Model simulations will be used to establish the natural variability of colony size i.e. the Normal Operating Range (NOR). These simulations will be performed in selected scenarios covering different EU environmental conditions. In a second step Risk Managers define which percentage of the NOR is to be used as a threshold for defining quantitatively the magnitude of acceptable effect for colony size reduction.

Both approaches 1 and 2 make use of population models. The EFSA Working Group for the review of the Bee Guidance Document considers the BEEHAVE model suitable for these exercises with regard to honeybees and considers it likely that the BumbleBEEHAVE can be used for bumblebees. The EFSA Working Group did not identify any suitable model for solitary bees.

Approach 3 is the approach taken in the EFSA Bee Guidance Document of 2013 and is based on predefined acceptable levels on colony/population size. It assumes that the provision of the ecosystem services is likely not impacted if the magnitude of the effect on colony/population size is negligible. The percentages of acceptable level is set at 7% in the EFSA 2013 Bee GD based on expert judgement

¹ Within this document, “natural variability” identifies variability between colonies in lack of a specific stressor, but still considering some influence of beekeeping.

considering the perception of beekeepers what is a negligible (i.e. undetectable) effect. Given the choice of a reasonable pre-defined threshold by risk managers, this approach can be applied to all bees (honeybees, bumble bees and solitary bees).

Approach 4 focusses on the levels of acceptable impact on the provision of the ecosystem services by bees. It links the specific protection goal with the ecosystem services provision. This approach requires scientific research on the possible link between the impact on the provision of the ecosystem services and the possible effects on its service providing units and is therefore not feasible within the timeline of the current mandate. If data is available, it can be applied to all bees (honeybees, bumble bees and solitary bees).

3. Overview of questions

During and after each presentation, participants were given the opportunity to ask questions. It was agreed at the workshop to collate and group the questions and answers in a separate section of the workshop report.

- *Q: Does the Ecosystem Service 'pollination' really cover the other Ecosystem Services for which bees are Service Providing Units?*

A: This assumption was already made in the 2013 Bee Guidance Document and is still considered valid. (Post meeting note: In the EFSA Opinion of 2012² it reported the following: *The protection goals for pollination service are more conservative compared to the specific protection goal for genetic resources, education and aesthetic values*).

Three of the four approaches provided do not focus on the Ecosystem Service in a quantitative way.

- *Q: Are other stressors considered in the simulation of approach 1? What are the environmental scenarios? Temporal scale needs to be defined.*

A: While any stressors may of course play a role in determining the colony dynamics, this approach does not consider any stressor in an explicit way. On the contrary, it focuses on a reduction of colony size (which could be in principle caused by one or multiple stressors) and the long-term effect of such reduction in terms of colony survival. Latitude is very likely to be the main driver in the scenario definition for approach 1. Spatial grouping of different regions will be done in a meaningful way by accounting for the outcome of the simulations.

- *Q: Is approach 1 considering honeybees as a superorganism? The model should better be run for several years. Is reduced fitness covered?*

A: Reduced fitness could in principle be modelled and the model can be run for several years. It is intended to increase the bee mortality rate, but this is just to define the maximum decrease in population size that the colony can sustain. In principle, the same exercise can be performed by reducing the queen ability to produce new eggs.

- *Q: Will different lengths of increased mortality be considered in approach 1?*

² EFSA Panel on Plant Protection Products and their Residues (PPR); Scientific Opinion on the science behind the development of a risk assessment of Plant Protection Products on bees (*Apis mellifera*, *Bombus* spp. and solitary bees). EFSA Journal 2012; 10(5) 2668. [275 pp.] doi:10.2903/j.efsa.2012.2668.

A: Length of mortality period and kind of mortality are decisions that still need to be taken once there is agreement on the approach. In the example in the presentation, the length of mortality corresponds with the length of flowering period. But also other periods are possible.

- *Q: Is the BEEHAVE model based on real data or is it mathematical? On what is the increased mortality based for approach 1?*

A: The model is mathematical because it works based on equations, and it is based on real data. The parametrization is well documented and was already evaluated by EFSA in 2015³. As always there are limitations which will be dealt with.

- *Q: Which approaches are feasible within the timelines of the mandate?*

A: Approaches 1, 2 and 3 are feasible within the current mandate according to EFSA, if the feedback from risk managers is timely given. According to the current planning⁴, to deliver the guidance on time, EFSA has to launch the public consultation of the final guidance in autumn 2020. The final agreed SPG are needed for finalising the guidance.

- *Q: Is the focus on the protection of the SPU?*

A: Approach 1 only focusses on the protection of the SPU. Also approaches 2 and 3 focus on protection of the SPU but these approaches allow for a certain non-quantifiable consideration of the Ecosystem Services. It is considered that a focus on the SPU ensures, in addition, protection of biodiversity by choosing umbrella species which are relevant and sensitive.

- *Q: Will the modelling for approach 2 use an operating range or 1 curve?*

A: The principle of approach 2 is to define normal operating ranges, i.e. the space delimited by the range of possible size for “control” (unstressed) colonies, at any time point. As such, the normal operating range is defined by the temporal curves of all colonies considered in the simulations.

- *Q: Resilience of healthy colonies depends on colony size. Will this be considered in approach 2? How will the colony size for field tests be considered?*

A: Resilience is not considered in approach 2, as the simulated colonies will not be exposed to any stressor, on the contrary, EFSA will focus on what is their natural variability under natural conditions. EFSA will also consider the size of the colonies used for field tests as a guiding principle for the simulations.

- *Q: Will different scenarios be used for the modelling? How many data from control fields is available to verify approach 2?*

A: Different scenarios will be simulated. EFSA will not manipulate any parameter in the model to simulate stress. EFSA wants to assess main different EU conditions and then to cluster them like north / central / south or even more than these 3 scenarios.

It should be kept in mind that the available data of controls in field studies were not collected to validate BEEHAVE. Still it is expected that these data will be enough to verify the plausibility of the modelling outcome in approach 2. There will have been additional confounding factors in the control field studies which will be a limitation of this verification.

- *Q: What is the difference between approach 2 and approach 3?*

³ EFSA (European Food Safety Authority) PPR Panel (Panel on Plant Protection Products and their Residues), 2015. Statement on the suitability of the BEEHAVE model for its potential use in a regulatory context and for the risk assessment of multiple stressors in honeybees at the landscape level. EFSA Journal 2015;13(6):4125, 92 pp. doi:10.2903/j.efsa.2015.4125

A: Approach 3 sets thresholds in an arbitrary way as no scientific data is available to underpin what is negligible. In 2013, the experts based the 7 % mainly on perception of beekeepers on what is a negligible (i.e. undetectable) effect. The threshold of 7 % thus only reflects honey bees. It was applied in 2013 to bumble bees and solitary bees but this threshold was not underpinned by any real data. It was not an extrapolation but just an agreement to apply the 7% threshold also to bumblebees and solitary bees.

Approach 2 starts with modeling, which is science based, so starting point is here totally different compared to approach 3. Although also in approach 2 an arbitrary choice needs to be made of which percentage of the Normal Operating Range is considered acceptable. The definition of this range will be informed by actual data that will be verified, as far as possible, against real control field data. And the choice of the acceptable percentage can be based on statistical principles.

- *Q: How will the SPG be extrapolated to solitary bees if approach 1 or 2 will be followed?*
A: We are not in the position to provide any scientific basis for such extrapolation at the moment.
- *Q: With regard to approach 2, natural variability can be very wide. How will this influence the risk assessment?*
A: The risk assessment will be less strict if a larger natural variability is allowed by the risk managers. In other words, the strictness of the risk assessment will depend, in approach 2, from the selected percentile of the colony size variability that the risk manager will consider to set the threshold for unacceptable effects.
- *Q: Are there field studies planned to see what the magnitude of effect with approach 2 is in reality?*
A: No as this is not possible within the timeframe of the mandate to review the Bee guidance Document. However, there will be a verification of the modelling outcome against the available data of control groups in field studies to check the plausibility of the simulated variability.
- *Q: What is the influence of different honeybee races on approach 2?*
A: The BEEHAVE model is parametrized on publications and has a lot of input data. There is no intention to use one subspecies over another.
- *Q: Is the modelling for approach 2 under common beekeeping practices or is it for natural colonies?*
A: The approach is for managed colonies which were equalized at the start of the study. The idea is to reproduce as much as possible the conditions for the control colonies in effect field studies, as these are the reference tier for the risk assessment.
- *Q: Will the modelling be used for the risk assessment*
A: The beehave model is not proposed as a tool for risk assessment. It will be used to investigate the size variability in “control” colonies and to set the level for the maximal acceptable effects.
- *Q: How will acute mortality be dealt with?*
A: the Specific Protection Goal is set for a reference tier. This reference tier will be used to calibrate the lower tiers. The calibration exercise will use values for natural background mortality and will link acute mortality to the maximum allowed effect at the colony level.
- *One MS stressed the difference between honey bees and bumble bees/solitary bees. While the first are managed species (the term “natural variability” may need revision as the populations*

are managed), bumble bees and solitary bees are wild species. This MS wondered if it would not be appropriate to have different GD for these different groups.

- *Another MS stressed that Approach 3 is not transparent and can not be explained, and justifications can not be given to politicians and general public as regards the choices made.*
- *A third MS wondered if Approach 4 would be in line with the legal requirements.*

4. Outcome of the workshop

A Tour de table was held with the 22 Member States present during the workshop:

- 2 Member States preferred approach 1
- 15 Member States opted for approach 2
- 1 Member State opted for approach 2 for honey bees, and approach 3 for solitary bees.
- 4 Member States had a preference for approach 3, considered however Approach 3 and 2 quite similar and were therefore open to use the insights of Approach 2 to refine Approach 3. Approach 3 seems in particular feasible for solitary bees.

5. Further timeline

The Commission emphasized that the review of the Bee Guidance Document needs to be finalized in March 2021. Based on this, the next steps are:

- Standing Committee of 16/17 July 2020: new Tour de Table to confirm the preferred approach by MS. This will also give an opportunity to the 5 absent Member States to indicate their preference.
The 2 background documents from this workshop and the report of this workshop will be made available to the members of the Standing Committee for this discussion
- September 2020: Third workshop to discuss the SPG, in particular its dimensions (magnitude of effects, temporal and spatial scale) within the approach chosen and other open issues.

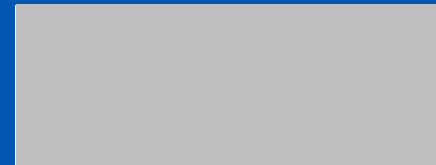


Review of the EFSA Bee Guidance

Second consultation of risk managers

Virtual Workshop with risk managers and risk assessors

30 June 2020



DG SANTE Unit E4

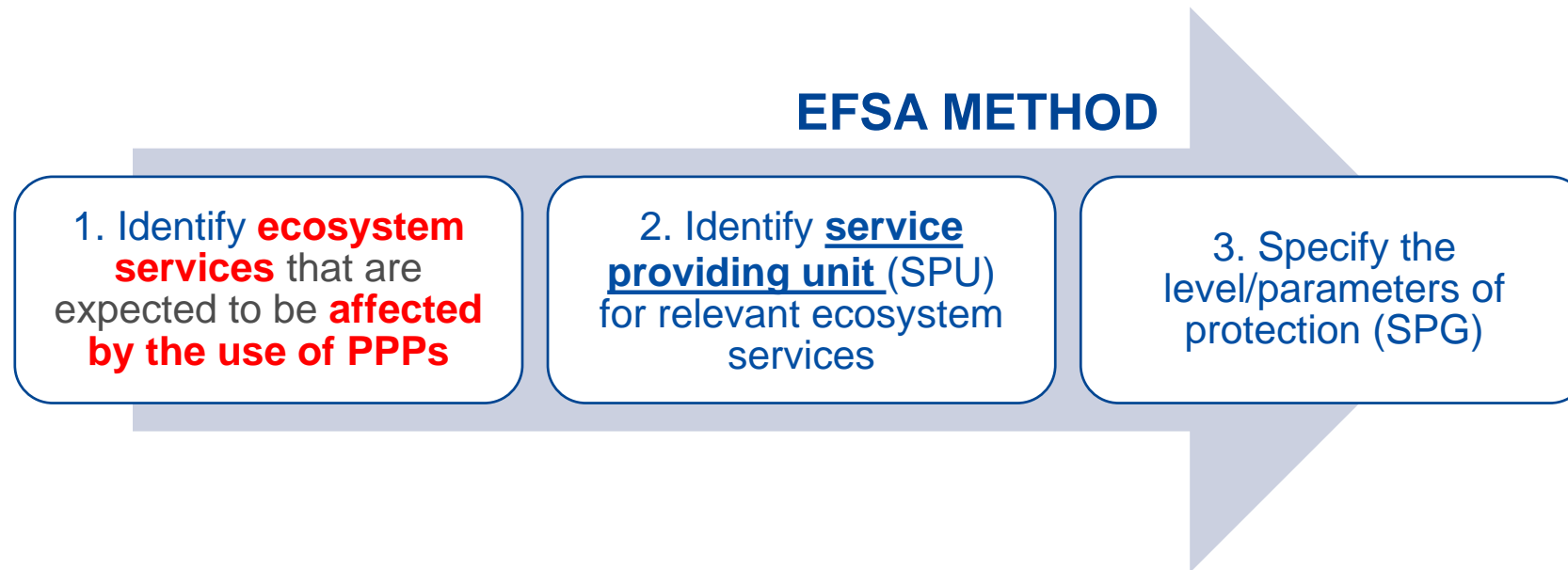
Mandate on the review of the Bee GD



- To take into account **comments from Member States and stakeholders**
- To take into consideration **natural background mortality of bees**
- To review the **requirements for higher tier testing**, in particular
 - magnitude of detectable effects vs the statistical power
 - validated population modelling in light of realistic agro-environmental conditions
- To take into account planned and on-going discussions initiated by the Commission on defining **specific environmental protection goals** and review the risk assessment guidance based on the specific protection goals agreed during this process.

Horizontal project on 'SPG for the ERA of PPPs'

- Initiated in 2018 and based on a method proposed by EFSA in 2010 & 2016



- Workshop in February 2020 focused on STEP 1 of EFSA method and confirmed that that the ES 'pollination' is potentially affected by the use of pesticides

Aligning bees and SPGs...

Steps in EFSA 2010/2016 to derive SPG	EFSA 2013	To be confirmed by risk managers 2020
Step 1 Definition of ES	<p>Pollination, food and genetic resources provisioning, and cultural service.</p> <p>A focus on pollination would cover the other ES identified in 2013 (food and genetic resources provisioning, and cultural service).</p>	The SPG project confirmed pollination as ES.
Step2 Selection of SPU	Honey bees, bumble bees and solitary bees	Based on EFSA's publications, honey bees, bumble bees and solitary bees are confirmed as Service Providing Units for the ecosystem service pollination.
Step3 Specific protection goal per SPU (five interrelated dimensions)	<p><u>Ecological Entities:</u> Colony/population</p> <p><u>Attribute:</u> Colony strength (honeybees, bumble bee), population abundance (solitary bees). Colony strength is defined operationally as the number of bees it contains (= colony size).</p> <p><u>Magnitude:</u> Negligible effect. It is such if statistically distinguishable from "small effects" The effect was considered negligible when the magnitude is below 7%.</p> <p><u>Temporal scale:</u> not defined i.e. any time</p> <p><u>Spatial scale:</u> edge of field</p> <p>it is important to note that the SPG, in particular, the Magnitude of the effect (i.e. effect sizes), have been defined principally by reference to honey bee colonies. In the case of other bees, the same magnitude has been extrapolated to colony-level impacts (for other social bees, such as bumble bees) or to population sizes (solitary bees).</p>	<p>Not yet defined, discussion to be initiated with the current risk manager consultation.</p> <p><i>Initiated today</i></p>

SPUs: main differences between honey bees, bumble bees and solitary bees



- Permanent nest, organised large colonies (up to 60,000), swarm
- Every bee hive has a queen, lives 2-5 yrs
- Queen lays up to 2000 eggs/day
- Worker bees take care for larvae
- Feed: nectar, pollen, water
- Colony hibernates when temperatures get below a threshold. Worker bees keep a certain temperature level inside hive – need honey for energy
- Produce honey – honey combs,
- Sting when aggressed – die afterwards



- Smaller colonies (120), do not swarm
- Mostly nesting underground,
- Have a queen
- Queen lays eggs, hatches them initially, then first workers take over
- Feed: nectar, use pollen to feed larvae
- Only queen hibernates, others die before autumn
- Produce a form of honey for feeding the colony, however do not make honey combs, concentrate or cap
- Sting if aggravated, do not die afterwards



- Single, do not swarm, mining species sometimes in nest formations
- No queen
- Each female constructs own nest in dry plants, underground, cavities
- Female lays 20-30 eggs
- Larvae feed on what was provided in egg cell, hibernate as pupae
- Feed: pollen, nectar, do not form a pollen basket like honey bees – fly, ore often- pollinate more often
- Do not produce honey
- Usually not aggressive, some have no sting

Review of the SPG for bees: 4 basic OPTIONS



The chosen option will define further work - Reference Tier

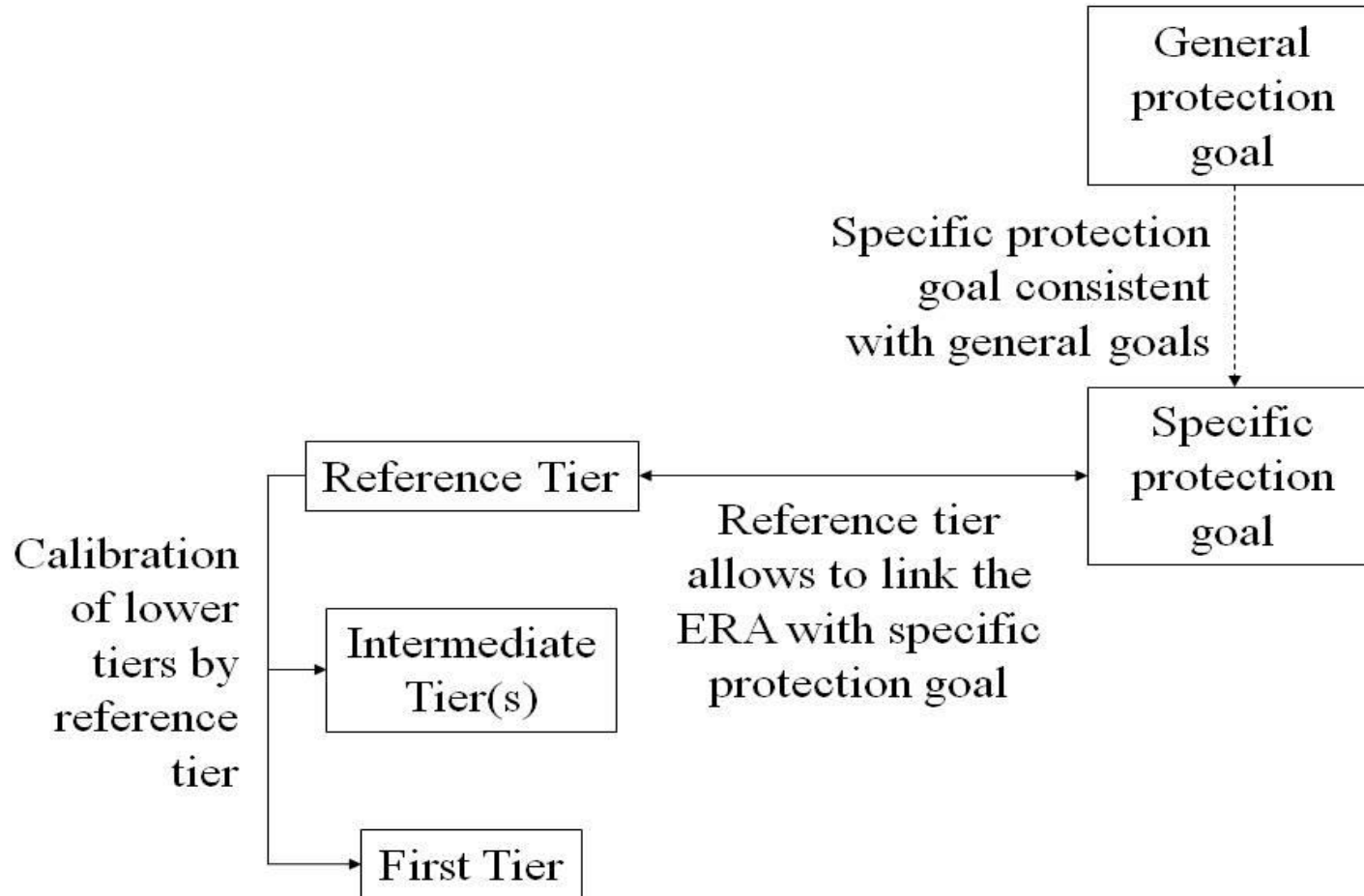


Figure 7, ERSA 2010

4 basic OPTIONS

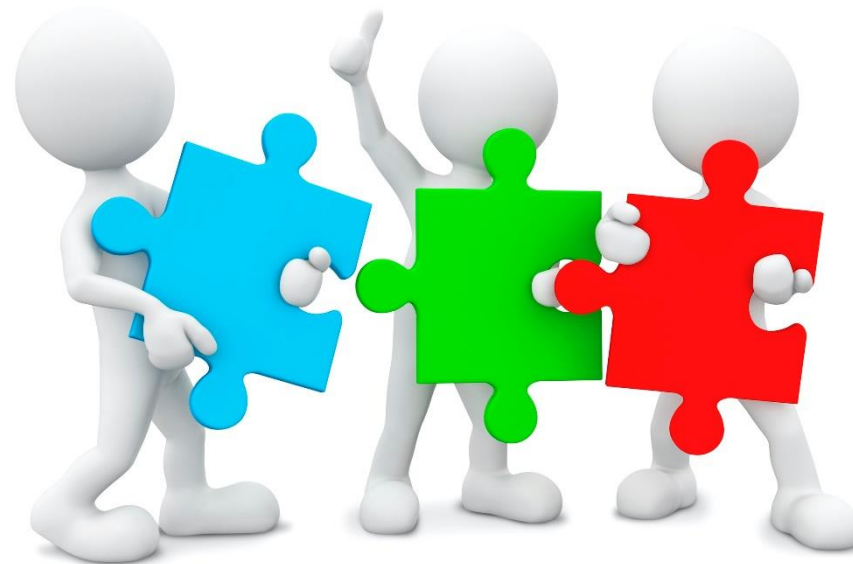
- EFSA proposes 4 approaches (different underlying scientific data and focus on SPUs or to the provision of the ecosystem services)
- Risk Managers need
 - 1st → to choose the most appropriate approach
 - 2nd → agreement on an (un)acceptable effect level, the temporal and spatial scale within the selected approach

Objective for today

- **Understand each of the 4 approaches** for defining SPGs, in particular
 - **advantages and limitations**
 - The different underlying scientific data, the focus on SPU or ecosystem service.
- Select the preferred approach = **the basis for the future work**
 - this will have **implications** on the SPGs and the reference Tier for the risk assessment.
- Keep in mind that no suitable **models** for solitary bees and a “possible” model for humble bees. Consequently **extrapolation** from honey bees will still be necessary for **solitary bees** and possibly also for bumble bees.

Next Steps

- PAFF meeting on **16-17 of July 2020** → final endorsement of the approach
- discussion on the dimensions for the specific protection goal for bees within the chosen approach and on exposure goals will follow soon



inspired

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Risk Managers consultation on SPGs for bees

Trusted science for safe food

ToR6: to take into account planned and on-going discussions initiated by the Commission on defining specific environmental protection goals and review the risk assessment guidance based on the specific protection goals agreed during this process (ToR6).



To ensure consistency between the Commission project on SPGs, which is running in parallel, and the review of the EFSA (2013).

The Commission project on SPG, initiated in 2019, have seen the involvement of stakeholders and MSs with the scope to achieve a common understanding on the ecosystem services (ES) and on the EFSA method for defining SPGs (EFSA, 2016).



Rather positive opinion from stakeholders and MSs to use the EFSA framework for identifying SPGs (EFSA, 2016)

• Preliminary list of the ecosystem services

The EFSA opinion (2010) and EFSA guidance (2016) give a methodology for identify SPG which includes several steps:

1. Identification of the relevant **Ecosystem Services** potentially impaired
2. Identification of the relevant Service Providing Units (**SPU**)
3. Specification of the **level/parameters of protection** of the SPUs based on **five interrelated dimensions**:

1. Ecological entity;
2. Attribute;
3. Magnitude of the effect;
4. Temporal scale;
5. Spatial scale.



Dialogue
Risk assessors and Risk managers

SPGs were proposed based on Ecosystems Services (ES), in line with the EFSA, 2010 and the EFSA 2016.

EFSA (2010) and EFSA (2016)	EFSA 2013
<p>Step 1 Definition of ES</p>	<p>Pollination, food and genetic resources provisioning, and cultural service.</p>
<p>Step2 SPU</p>	<p>Honey bees, bumble bees and solitary bees</p>
<p>Step3 Specification of the level/parameters of protection of the SPUs based on five interrelated dimensions</p>	<p><u>Ecological Entities</u>: Colony/population</p> <p><u>Attribute</u>: Colony strength (honeybees, bumble bee), population abundance (solitary bees)</p> <p><u>Magnitude</u>: Negligible effect i.e. <7% colony/population size</p> <p><u>Temporal scale</u>: any time</p> <p><u>Spatial scale</u>: edge of field</p>

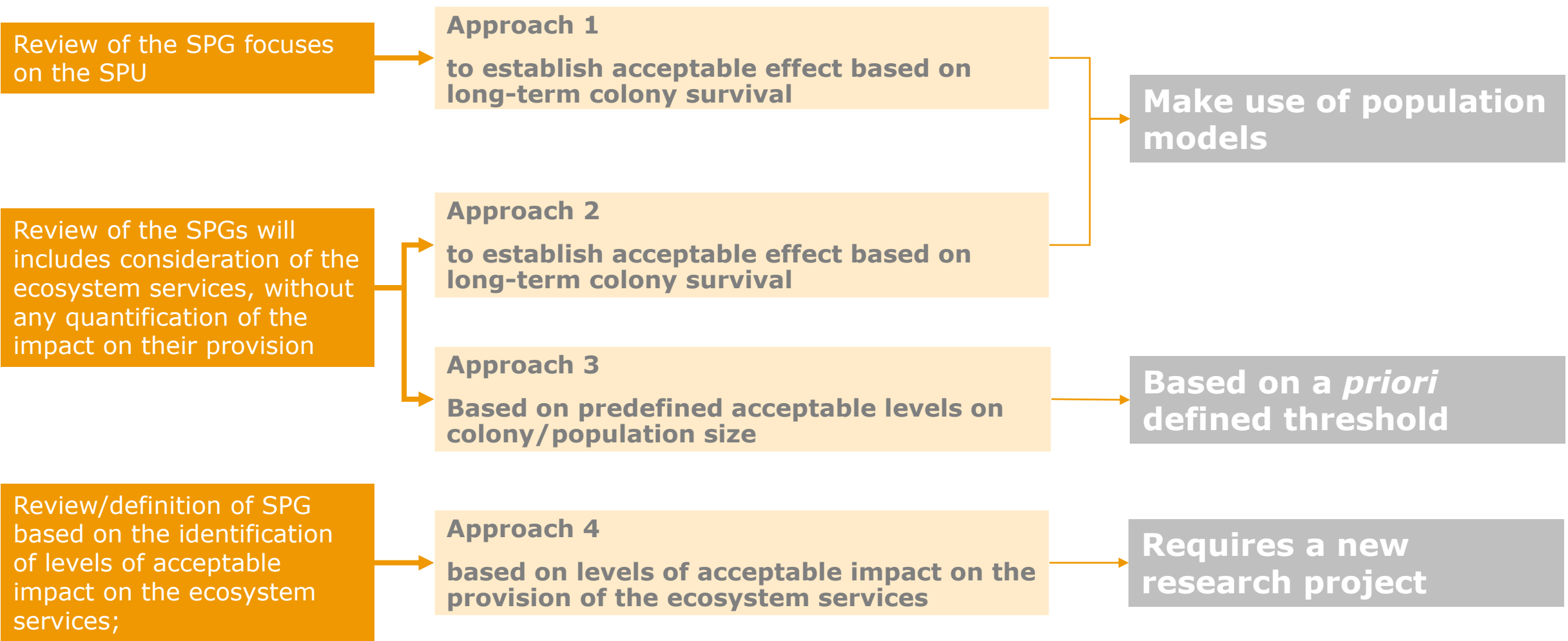
How to progress with the review of the EFSA, 2013?

The scientific process for defining the specific level of protection can be driven by the risk managers decision to:

- Focus on the protection of the identified SPU
- Consider the provision of ecosystems services

- **The approaches identified take into account these drivers.**
- **RM decision would allow the review of some aspects of the current agreed SPGs (i.e. Step 3)**

Overview of the different approaches

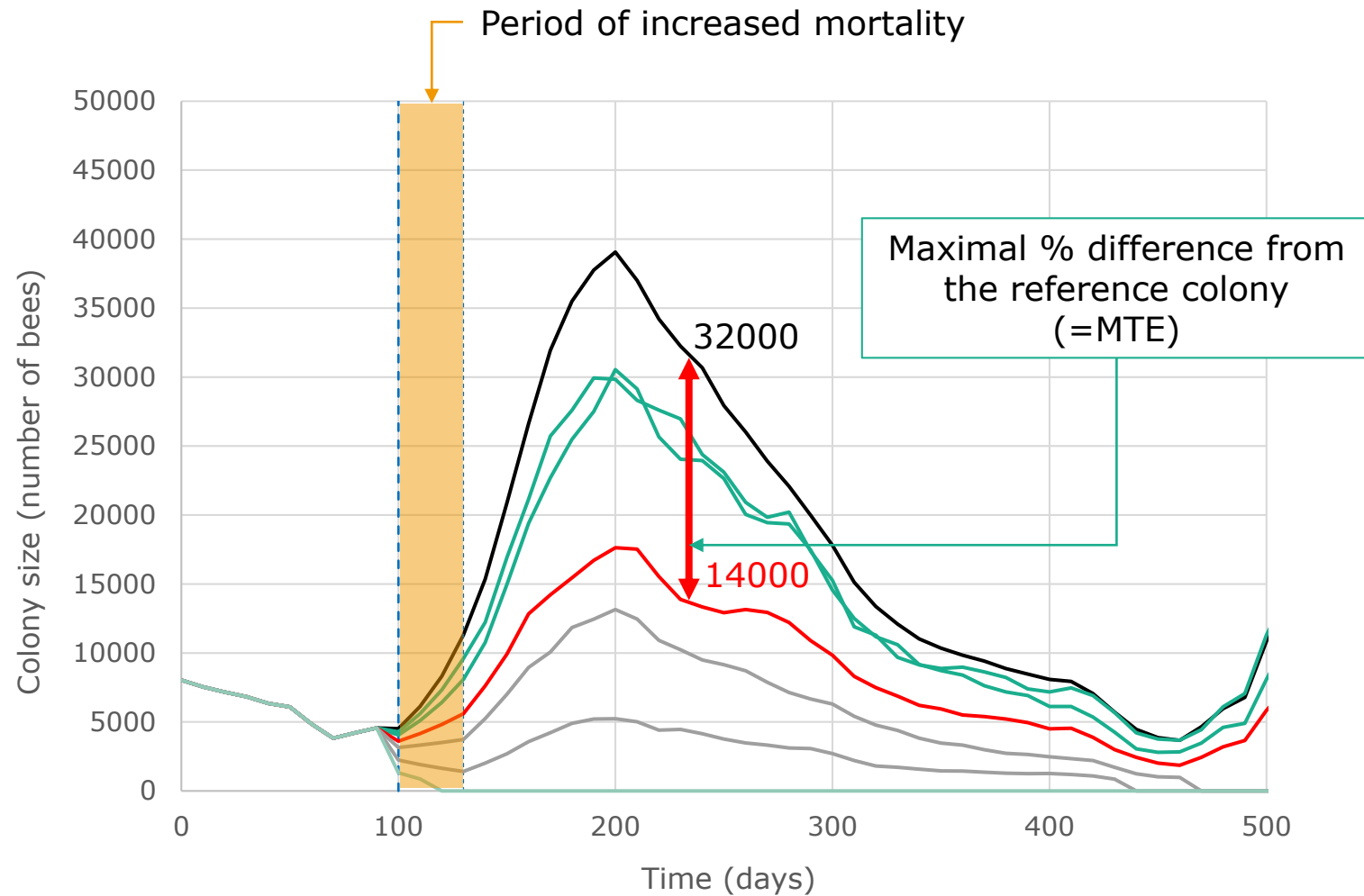


- Ecosystem Services are used to define the SPU. The definition of SPGs does not consider further any possible link between the effect on the SPU and the impact on the ecosystem services.
- The long-term survival of colony e.g. survival of the colonies until the next year or longer.
- Reconsideration of some dimensions of the current SPG e.g. **Attribute** (**survival** instead of **colony size** effect) and **Magnitude**.

- **Population model simulation based:**
 - for honey bees BEEHAVE
 - for bumble bees Bumble bees BEEHAVE could be considered
 - for solitary bees, no suitable models
- **Applicable for honey bees and (Likely) for bumble bees only.**

Model simulations to establish colony **maximum tolerable effects (MTEs)**. Simulations will be performed in selected scenarios, covering different EU environmental conditions.

Illustrative example



MTE = 56%

Approach 2 – to establish acceptable effect based on long-term colony survival

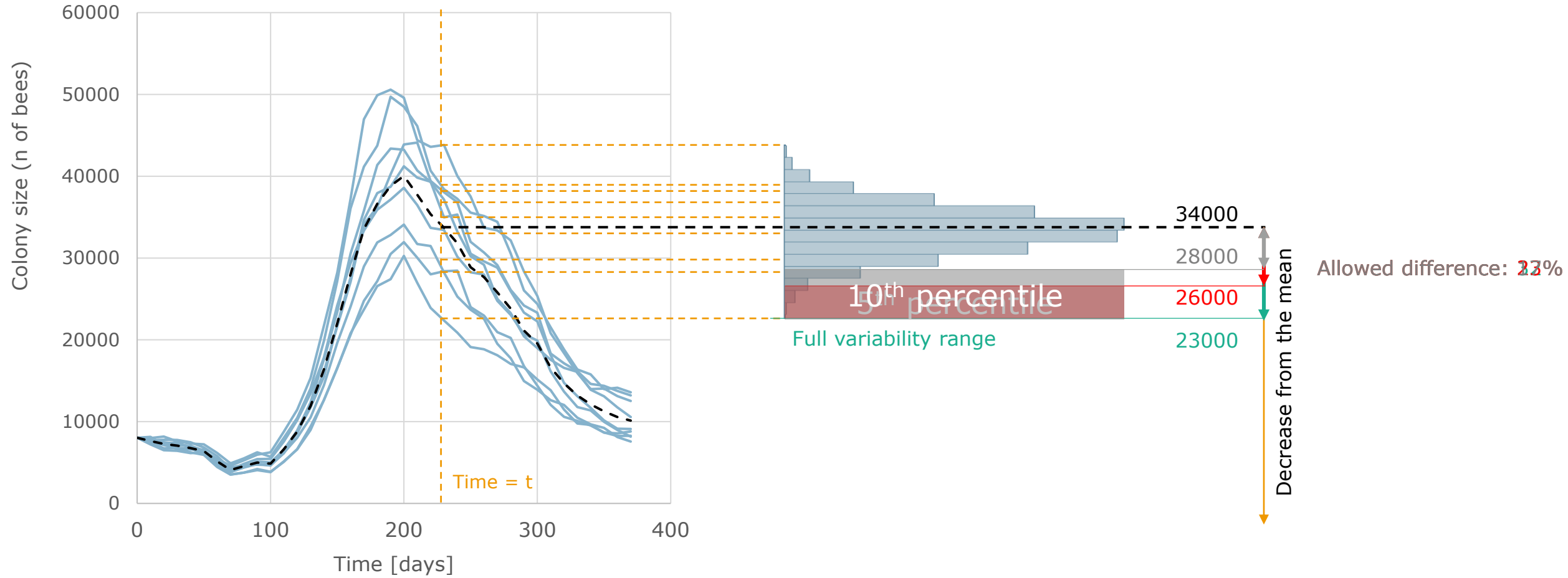
- The magnitude of the effect on colony size is acceptable when it remains in a range defined on the basis of the expected natural variability.
- It is assumed that any impact on the ES would also be within the natural variability.
- Does not consider the full review of the current SPGs but will allow to redefine the acceptable level of the colony size reduction (e.g. review of the **Magnitude** dimension).

- **Population model simulation based:**
 - **for honey bees BEEHAVE**
 - **for bumble bees Bumble bees BEEHAVE could be considered**
 - **for solitary bees: no suitable models**
- **Applicable for honey bees and (Likely) for bumble bees only.**

Model simulations to establish colony natural variability of colony size i.e. **Normal Operating Range (NOR)**.

Simulations will be performed in selected scenarios, covering different EU environmental conditions.

Illustrative example



- The provision of the ecosystem services is likely not impacted, when the magnitude of the effect on colony/population size is *negligible*.
- RMs define a % of acceptable effects, (e.g. in the current GD <7%) which are reasonable pre-defined threshold to maintain the ecosystem services provision likely unaltered

- **RM decision based.**
- **Applicable to all the bees (honey bees, bumble bees and solitary bees)**

Approach 4 - based on levels of acceptable impact on the provision of the ecosystem services

- To set the overall level of protection of the service providing units (SPU) to be fully consistent with the level of acceptable impact on the provision of the ecosystem services they deliver
- It requires scientific developments to investigate the possible link between the impact on the provision of the ecosystem services and the possible effects

- **Link between the SPG and the ES provisions.**
- **Applicable to all the bees (honey bees, bumble bees and solitary bees).**
- **Require to initiate a new project to get data to link ES and SPG**
- **RM decision based.**
- **Full revision of the SPG**

- RM to select one of the four approaches presented.
- For the approach 1,2:
 - EFSA run the simulations and would require final feedback to RM
- For the approach 3:
 - RM provide the pre-defined thresholds

As follow up of the approaches 1,2,3:

- EFSA revises the higher tier (reference tiers) requirements
- EFSA calibrates the lower tier risk assessment schemes
- For the approach 4
 - EFSA starts a new research project
 - RM defines acceptable levels of the impact on the ES
 - EFSA/RM run the dialogue to revise the SPG



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