

23 September 2020

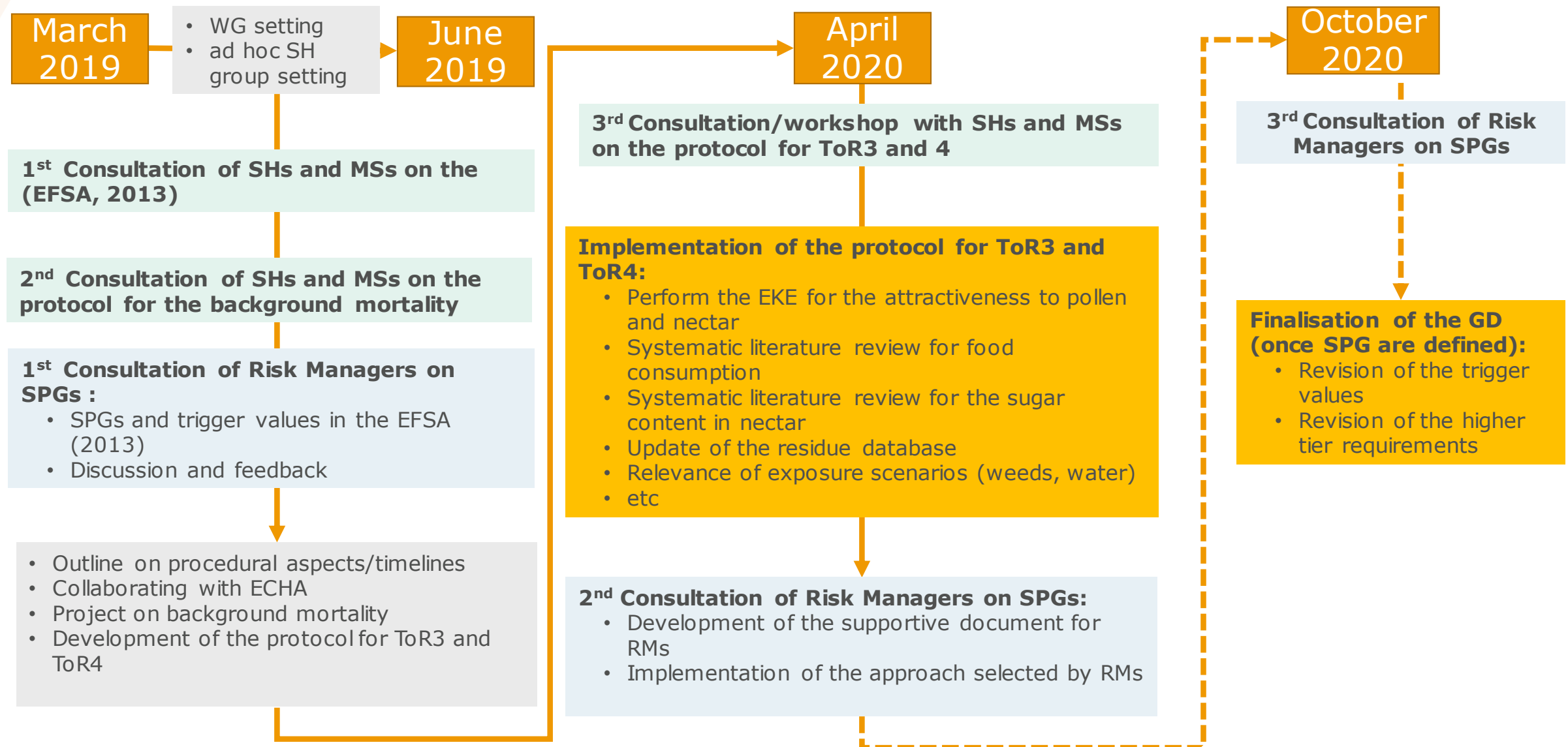
Status quo of the bee GD review

Trusted science for safe food

To present the state on:

- Progress of the review of the bee GD (i.e protocol implementation)
- Ongoing discussion on SPG setting by risk managers

Progress of the review of the bee GD: overview



Progress of the review of the bee GD: systematic sub-projects

- **Bee background mortality:**
 - About 11000 papers
 - Result published in the TR on the 28 July 2020
- **Systematic literature review for food consumption:**
 - Based on the problem formulation, 4 questions to answer for honey bees, solitary bees and bumble bees;
 - About 9000 papers;
 - Data evaluation/extraction/analysis in progress;
- **Systematic literature review for the sugar content in nectar of various crops:**
 - About 2000 papers;
 - Data evaluation/extraction/analysis in progress;
- **EKE for the attractiveness to pollen and nectar:**
 - Finally 6 experts have been selected (among c. 50) to be invited;
 - Experts indicated by the SH will also take part of this project
 - On tracks.
- **Systematic revision of the residue database**

Progress of the review of the bee GD: other aspects in progress...

- **Inter-species sensitivity analysis** based on a systematically consideration of the available data;
- **Analysis of dose-response** (extensive review) useful for:
 - Extrapolation factors
 - Endpoints definition
 - Trigger values
- Review of the **weed/water/succeeding crop scenarios**;
- Revision of the **higher tier requirements** (pending on the SPG definition);
- Definition of **default parameters** included in the **oral exposure model**;
- **Mixture** toxicity and risk assessment;
- Risk assessment **metabolites**
- Consideration of **sublethal** effect, **accumulative** effect, recommendations for exposure refinement.

Progress of the review of the bee GD: aspects to be reviewed after the SPG setting

- **Revision of the higher tier requirements** (reference tiers):
 - to detect the derived threshold of acceptable of effect and to assess the exposure;

- **Revision of the methodology for the trigger values:**
 - to calibrate the lower tier risk assessment schemes by linking the threshold of 'acceptable' effects on colony to daily mortality levels.
 - to revise the trigger values for the lower tier risk assessments consistently with the agreed level of protection.

ToR

*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.***



To ensure consistency between the Commission project on SPGs and the review of the EFSA (2013).

The Commission project on SPG has 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

EFSA methods vs EFSA 2013

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
Step 1 Definition of ES	Pollination, food and genetic resources provisioning, and cultural service.
Step2 SPU	Honey bees, bumble bees and solitary bees
Step3 Specification of the level/parameters of protection of the SPUs based on five interrelated dimensions	<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>

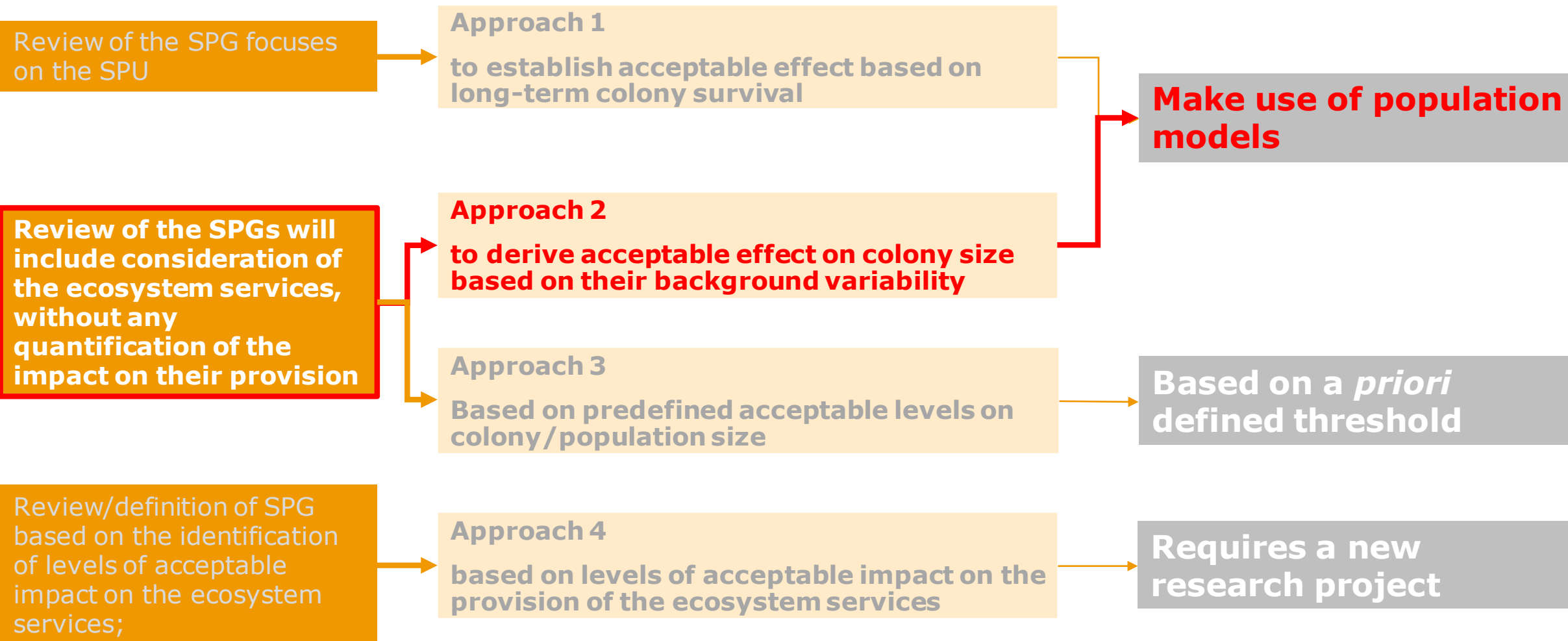
How to progress with the review of the EFSA, 2013?

To support the decision-making process EFSA identified four approaches (discussed in a workshop organised by SANTE on **30 June**).

The scientific process for defining the specific level of protection is driven by the risk managers decision on **what** to protect and to **which** extent.

- The approaches reflected:
 - The feedback from MSs and SH over the last 7 years
 - The preliminary results of the wider SPG project
 - The EFSA (2013)

Overview of the different approaches



- The magnitude of the effect on colony size is acceptable when it remains in a range defined on the basis of the expected background variability -**Normal Operating Range (NOR)**;
- It is assumed that any impact on the ES would also be within the background 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).

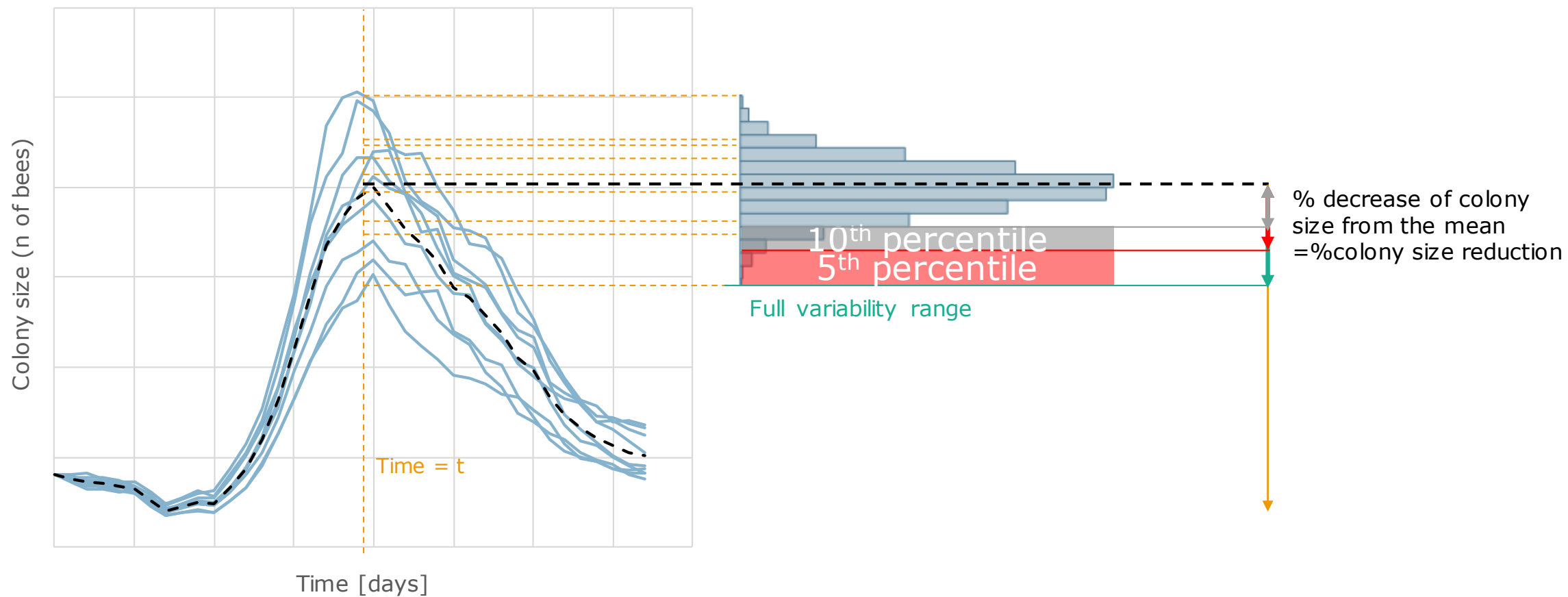
- Population model selected: **BEEHAVE** for honey bees;
- No model evaluated by EFSA for bumble bees;
- No suitable models for solitary bees:

Why?

- BEEHAVE was evaluated by EFSA in 2015;
- Main limitation (i.e. lack of PPP module) not relevant for this purpose;
- Other limitations addressed in the implementation of the approach#2;
- ApisRAM and data for using it as in the approach#2 not yet available.

- Simulations performed in different scenarios, covering different EU environmental conditions.

Approach 2 – illustrative example



Regarding the overall progress:

- Due to the complexity of the project and the uncertainties caused by the COVID-19, the current tentative planning will be revised if needed, to reflect the status of the ongoing work.

Regarding the SPG setting:

- Overall, EFSA reviewed the scientific ground to support the decision-making on SPG because of a specific need and request of RMs. This was presented in a report, published on the 28 of July.
- EFSA, for this review, considered the preliminary results of the EC activities on SPG and the RMs feedback, in line with the mandate;
- EFSA is implementing the Approach#2 selected by RMs. A second preliminary report will be issued to RMs for the next consultation; the report will be published on the EFSA website, SHs *ad hoc* group will be pre-notified;
- The SPG setting remains a RMs responsibility.



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