



Review of the Guidance Document for the risk assessment for bees

Supporting document for Risk Managers consultation on Specific Protection Goals for bees

22 June 2020
(Preliminary report)



Contents

1. Background	3
2. Possible approaches for reviewing the SPGs of EFSA (2013)	5
2.1. Approach 1 – to establish acceptable effect based on long-term colony survival.....	6
2.2. Approach 2 – to derive threshold of acceptable effect on colony size based on their natural variability.....	8
2.3. Approach 3 – based on predefined acceptable levels on colony/population size	10
2.4. Approach 4 – based on levels of acceptable impact on the provision of the ecosystem services.....	11
References	12
Appendix A - Exposure Assessment Goal (ExAG).....	13
Appendix B - Recovery option	14
Appendix C - Illustrative example of model simulation	14



1. Background

In 2013, EFSA has revised the risk assessment to bees following the European Commission request. In particular, EFSA has adopted:

- an EFSA Opinion on the science behind the risk assessment for bees (*Apis mellifera*, *Bombus* spp. and solitary bees) (EFSA PPR Panel, 2012);
- a Guidance Document for the risk assessment for bees (EFSA, 2013).

EFSA (2013) was never implemented in the regulatory context due to lack of consensus between MSs, even if it was used in some situations like the review of the neonicotinoids (EFSA, 2018).

In 2019 the Commission mandated EFSA to revise EFSA (2013). One of the terms of reference (ToR6) of this mandate is 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). The purpose of this terms of reference is to ensure consistency between the Commission project on SPGs, which is running in parallel, and the review of EFSA (2013).

The Commission project on SPG, initiated in 2019, has seen the involvement of stakeholders and MSs with the scope of achieving a common understanding on the ecosystem services (ES) and on the EFSA methods for defining SPGs (the opinion for SPG, EFSA, 2010 and the framework, EFSA, 2016). The EFSA methods and in particular the EFSA (2016) includes several steps:

Step 1 - Identification of the relevant Ecosystem Services potentially impaired by a stressor;

Step 2 - Identification of the relevant Service Providing Units (SPU);

Step 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.

Three workshops have been organised by the Commission (two in 2019 with Stakeholders and MSs separately, and one in February 2020, with Stakeholders and MSs together). Generally, stakeholders and MSs conveyed a rather positive opinion on the use of the EFSA framework for identifying SPGs (EFSA, 2016). Furthermore, they defined a preliminary list of the ecosystem services potentially impaired by pesticides, according to different pesticide use scenarios. The provision of pollination was widely recognised as a key ecosystem service, both for biodiversity conservation and for agricultural production.

In EFSA (2013), ecosystems services and SPGs were identified and discussed with risk managers, according to the methodology proposed by the EFSA opinion for SPG (EFSA, 2010). Therefore, the methodology and the process used by EFSA (2013) can be considered in line with the framework of EFSA (2010) and EFSA (2016) and therefore with the Commission project.

The ecosystems services identified in EFSA (2013) were **pollination, food and genetic resources provisioning, and cultural service**, in line with the preliminary results of the ongoing activity of the Commission. Furthermore, since the EFSA (2013) covers the bees, the second step of the EFSA method (i.e. identification of SPU for the above ecosystems services), can be considered already partially addressed. Other pollinators that are not covered by EFSA (2013) can be identified and covered by other future guidance. Finally, EFSA (2013) addressed the third step of the EFSA method, since the underlined scientific process of EFSA (2016) to identify the level of protection for the bees and the related dimensions (i.e. *Ecological Entities, Attribute, Magnitude, Temporal and Spatial scale*) was already carried out (see table 1).



Table 1. Overview of the SPGs as defined in EFSA (2013) in light with the steps described in the EFSA framework (EFSA, 2016).

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). 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><i>it is important to note that the above SPGs and in particular, the Magnitude of the effect (i.e. effect sizes) have been defined principally by reference to honey bee. In the case of other bees, the same magnitude has been used as surrogate to colony-level impacts (for other social bees, such as bumble bees) or to population sizes (solitary bees).</i></p>

Overall, based on the preliminary outcome of the ongoing Commission project, it seems that a full review (i.e. involving all steps) of the SPG of EFSA (2013) in accordance with EFSA (2016) may not be necessary and considered outside of the scope of this mandate. Nevertheless, the 2013's definitions of some of the five dimensions (i.e. of the Step 3) can be reviewed, in order to address the concerns raised by MSs around this topic.

Within such review, the risk managers should decide and indicate to the risk assessors what needs to be protected and to what extent. For example, it should be clearly defined if emphasis has to be given to the relevant SPUs, or to the provision of the ecosystem services, or to the definition of acceptable impact on the ecosystem services to be linked to the acceptable level of the effect for the relevant SPU.

This document presents a set of possible scientific approaches to support the risk managers on this decision-making process. For each of the approaches, the document illustrates the associated scientific method, the advantages, and the limitations.

As part of the SPG definition, risk managers should also consider providing input on the exposure assessment goal (i.e. the exposure level to be used in the risk assessment). This aspect is also briefly described in this document (see Appendix A), while a more in-depth consideration and description will be given when the approach for reviewing the SPGs will be agreed by the risk managers.



2. Possible approaches for reviewing the SPGs of EFSA (2013)

The EFSA WG has analysed three different possible approaches which could be used for the review of some aspects of the Specific Protections Goals (SPGs) defined in the EFSA (2013):

- Approach 1 – to establish acceptable effect based on long-term colony survival;
- Approach 2 – to derive threshold of acceptable effect on colony size based on their natural variability;
- Approach 3 – Based on predefined acceptable levels on colony/population size;

The WG has, alternatively, identified a fourth approach, which could lead to review or a full redefinition of the current SPG:

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

The four approaches have very different underlining principles, particularly the approach 1 and 4 *versus* the approach 2 and 3.

In the case of the approach 1 the review of the SPGs will focus on services providing units (i.e. bees). In the case of the approaches 2 and 3 the review of the SPGs will include consideration of the ecosystem services, without any quantification of the impact on their provision. With the approach 4 it will be possible to identify a trade-off between the possible impact on the ecosystem services and the level of the effect on the services providing units (i.e. bees).

The operability and feasibility of the four approaches are very different:

- For the approaches 1 and 2 population model simulations would be used. In the case of the approach 2, those simulations, can be compared with some existing experimental field studies as supportive information.
- The approach 3 is based on a *priori* defined threshold and it reflects the current situation in EFSA (2013).
- The approach 4 would require a new research project and it cannot be considered feasible within the current mandate to review the EFSA (2013).

In relation to the approaches based on population models, it is important to note that for **honey bees** the WG decided to focus on BEEHAVE, considering that an evaluation of weaknesses and strengths of this model by EFSA is already available (EFSA, 2015). The BEEHAVE model simulates the hive population dynamics by considering environmental factors, such as weather conditions, distance to patches and food availability (pollen and nectar), that may influence foraging ability and infectious agents (the *Varroa* mite and two associated viruses) and other parameters that may impact the colony development (Becher *et al*, 2014). The EFSA (2015) has considered the model not suitable for pesticide risk assessment, primarily because it does not include a 'pesticide' module, i.e. the model was clearly not recommended to investigate effects of pesticide exposure under field conditions in its current status. However, the EFSA (2015) considered the model to address its original problem formulation (i.e. simulating population dynamic) and, for its original use, to be generally compliant with the criteria of the EFSA opinion on Good Modelling practices (EFSA, 2014). Furthermore, the EFSA (2015) has considered the model suitable for establishing first tier trigger values and reported clear recommendations on this aspect. Coherently with the above considerations, BEEHAVE is not considered in the present context as a risk assessment tool, but rather as a source of relevant information on the colony dynamics.

The WG will consider also the possibility to use for **bumble bees** the Bumble-BEEHAVE model that was recently published (Becher *et al*, 2018). According to the authors, the Bumble-BEEHAVE simulates in an agent-based approach the life cycle of bumblebees, foraging for nectar and pollen from a variety of plant species in a spatially explicit landscape. However, an EFSA evaluation (e.g. according to the EFSA, 2014) of this model is not available. In addition, experimental field data for bumble bees are very scarce.

The WG has considered two models for **solitary bees** available in the public literature (Ulbrich and Seidelmann, 2001; Everaars and Dormann; 2014). The WG concluded that the available models are not



suitable to properly describe population dynamics of solitary bees. One of the main drawbacks is the lack of an explicit death rate for adult bees, which would be needed to understand the population dynamic within the year. Therefore, it was acknowledged that no suitable models are available for **solitary bees** and available experimental field data are also very scarce for this group.

Therefore, in the context of the review of the SPGs, risk managers could consider following a pragmatic approach for solitary bees and perhaps for bumble bees.

2.1. Approach 1 – to establish acceptable effect based on long-term colony survival

This approach offers the opportunity to focus on the service providing units (SPUs) that have been identified based on the ecosystem services. This means that the level of protection defined by the SPG dimensions focus on the SPUs only. Therefore, any link between the effects on the SPUs and possible impact on the ecosystem services is not further considered.

This approach, which could be implemented within the current review of EFSA (2013), considers specifically the long-term survival of colony (i.e. viability). By following this approach, it would ensure that the colony will be alive in a long time period (e.g. survival of the colonies until the next year or longer). The magnitude of the effect would be assumed *acceptable* when the colony, after a period of increased mortality, will survive for the specified long-term period.

This approach focusses on '*colony survival*' instead of the '*colony size effect*', which is the current attribute of the EFSA (2013). It does not envisage a full review of the current SPGs, but a reconsideration of the *Attribute* and, consequently, of the *Magnitude*. In other words, by changing the attribute to long-term *colony survival* this may likely results in an increase of the current magnitude of acceptable effect. In addition, this approach implicitly considers to some extent the capability for the colonies to recover, although not necessarily to their original status.

If the risk managers decide to use this approach, it does not require to define any level of colony size reduction *a priori*, as survival is here considered as a dichotomous outcome (survive/not survive).

Process for the approach 1

This approach can be implemented by using population models with a proper parametrisation which can partially be informed by the collected data on background mortality (i.e. ToR2 of the mandate). The WG will use for this purpose the BEEHAVE model for honey bees. The WG will consider also the suitability of the Bumble bee BEEHAVE model. No population models are available for solitary bees.

The model will be used to simulate long-term colony survival and to establish maximum tolerable effects (MTEs) which are the 'safe levels' of colony size reduction, following a period of increased mortality, that do not lead to impairment of the colony survival. This is visualised in the Figure 1, which is an illustrative example not derived from an actual simulation.

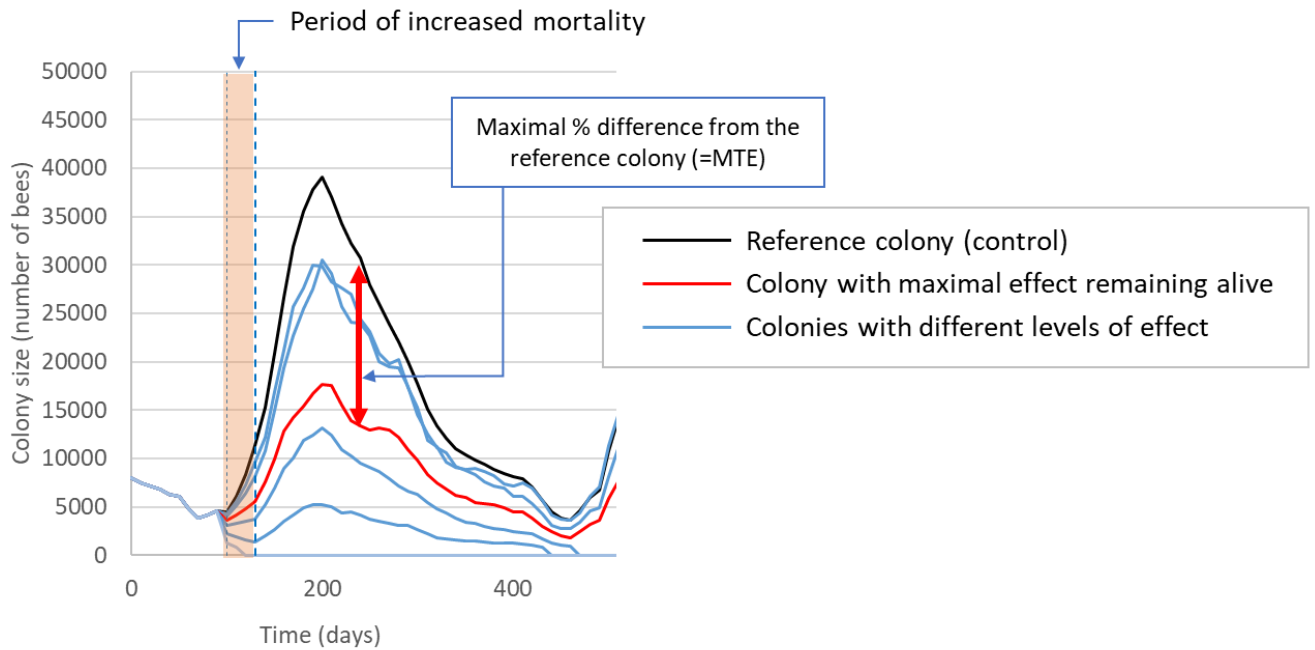


Figure 1: illustrative example (not derived from an actual simulation) showing long-term colony responses after a period of increase mortality

1. EFSA runs long-term model simulations to establish colony maximum tolerable effects (MTEs). The exercise will be repeated in selected scenarios, covering different EU environmental conditions.
2. Risk managers provide final feedback on the review of the SPG dimensions:
 - a. the *attribute* (survival);
 - b. the *magnitude* of effects, i.e. the established 'safe level' which is based on the MTEs and on
 - c. the exposure assessment goal (see Appendix A for further details)
3. EFSA revises the higher tier (reference tiers) requirements to detect the established 'safe level' (i.e. <MTEs) and to assess the exposure.
4. EFSA calibrates the lower tier risk assessment schemes by linking the established 'safe level' effects on colony to daily mortality levels. EFSA revises the trigger values for the lower tier risk assessments consistently with the agreed level of protection.

PROS	CONS
<p>Bio-ecology based: population models consider ecological factors</p> <p>Population modelling may ensure a certain level 'standardization' i.e. the variables are under the control of modeller.</p> <p>Feasible within the current timelines, if a decision by risk manager is communicated timely.</p>	<p>Possible alteration on the provision of the ecosystem services is not explicitly considered. No information on potential, transient effect (e.g. temporary reduction of pollination or honey production) due to the focus on the SPUs.</p> <p>Depends on model simulations for predicting long-term responses (conservative assumptions can be made).</p> <p>Only applicable for honey bees and maybe bumble bees, but not for solitary bees due to the lack of models.</p>



2.2. Approach 2 – to derive threshold of acceptable effect on colony size based on their natural variability

This approach assumes that the magnitude of the effect on colony size following the exposure of a pesticide is acceptable when it remains in a range defined on the basis of the expected natural variability. An explicit link between the effect on the service providing units (SPU) and the ecosystem service (ES) provision is not established, but it is assumed that any impact on the ES would also be within the natural variability.

This approach does not consider the full review of the current SPGs but will allow to redefine the acceptable level of the colony size reduction.

Process for the approach 2

The WG will use the BEEHAVE model to simulate the colony dynamics for honey bees. The WG will consider also the Bumble bee BEEHAVE model. No population models are available for solitary bees.

A parametrisation of BEEHAVE will consider the collected data on background mortality (i.e. ToR2 of the mandate). By running such model multiple times, it is possible to have an estimation of the expected natural (random) variability under perfectly equal conditions, i.e. the **normal operating range (NOR)** of a control colony.

When defining “acceptable effects” for pesticides, the focus is generally on any decrease compared to the mean value. Hence, the magnitude of the acceptable effect on the colony size can be defined by comparing the mean colony size with the lowest end of the NOR, both resulting from the model simulations. The ratio of these two figures would inform on the maximum % reduction of the average colony size caused by natural variability.

It should be noted that the NOR may consider the full variability range or it could be “restricted” by selecting a percentile of the variability distribution. The higher the restriction (i.e. closer to the mean colony size), the lower is the allowed reduction, and hence the stricter is the risk assessment. The selection of a given percentile of the variability distribution can somehow be interpreted as the probability of accepting “false positive”, i.e. to consider that a certain reduction of colony size is due to an external effect (e.g. exposure to a pesticide) while in reality it is only due to natural variability.

The whole concept is visualised in the Figure 2, which is an illustrative example not derived from an actual simulation. An illustrative example based on model simulation about how this approach might potentially be applied, is reported in the Appendix C of this document.

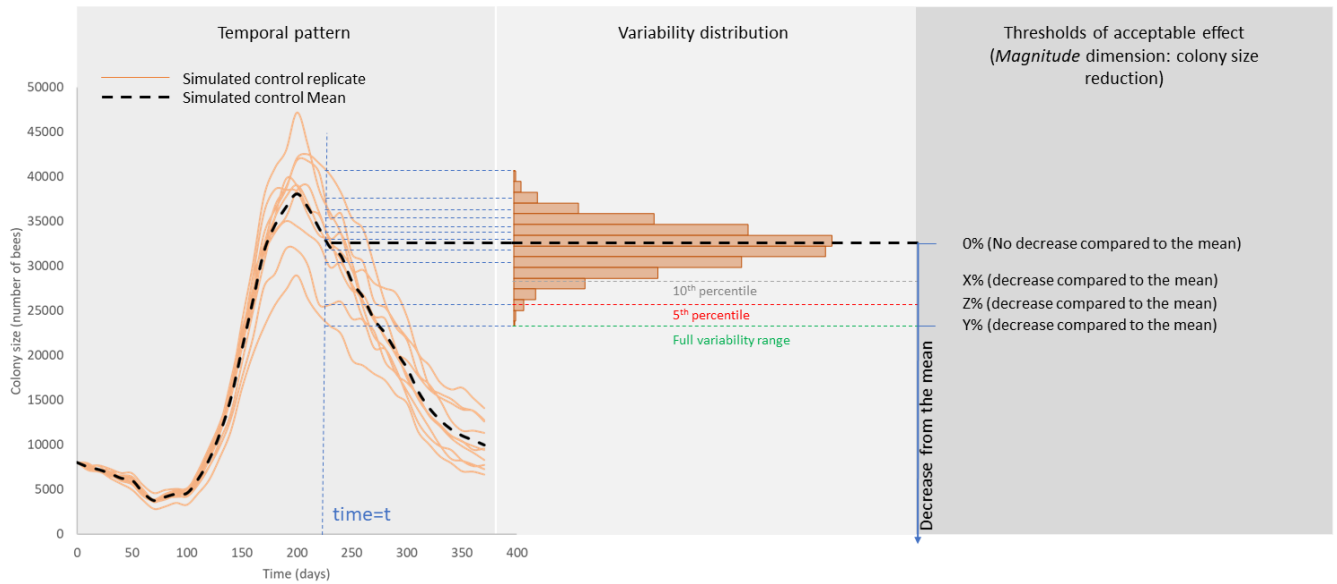


Figure 2: illustrative example (not derived from an actual simulation) showing the normal operating range (NOR) and possible selection of threshold of acceptable effects within the natural variability distribution

If the risk managers decide to use this approach, they will be consulted in a second step to provide input on the selection of the percentile of natural variability, which will determine the % of colony size reduction considered as acceptable. Risk managers decide on a percentile deviation from the simulated average colony size as relevant for defining the NOR. On this basis, model simulations are used to define the *magnitude* of the acceptable effect, expressed as % reduction of the colony size. Deviations larger than this threshold would be considered outside of the NOR and hence caused by an external agent such as the exposure to a pesticide (effect greater than negligible).

The approach is purely model-based. However, the simulated natural variability could be checked against the control variability observed in available field studies on bees. Although this cannot be considered as a true 'validation' of the model simulations, this comparison might provide some information on the potential uncertainties of this approach.

Within this approach:

- 1) EFSA runs "control" model simulation accounting for reasonable sources of uncertainty and variability, obtaining probability distributions of colony size. The exercise will be repeated in selected scenarios, covering different EU environmental conditions. EFSA checks the simulated natural variability against the control variability observed in available field studies on honey bees.
- 2) Risk managers are consulted on the basis of model simulations to define a percentile (level of restriction) of the natural variability distribution. The chosen percentile is translated into a % deviation from the mean colony size to be used as threshold for defining "acceptable" effects.
- 3) Risk managers provide final feedback on the review of the SPG dimensions:
 - a. the *magnitude* of effects, i.e. the threshold of acceptable effect which is based on the derived NOR;
 - and on
 - b. the exposure assessment goal (see Appendix A for further details)
- 4) EFSA revises the higher tier (reference tiers) requirements:
 - a. to detect the derived threshold of acceptable of effect and to assess the exposure;



- b. if indicated by the risk managers, the allowed time for recovery (see Appendix B for further details).
- 5) EFSA calibrates the lower tier risk assessment schemes by linking the threshold of “acceptable” effects on colony to daily mortality levels. EFSA revises the trigger values for the lower tier risk assessments consistently with the agreed level of protection.

PROS	CONS
<p>Bio-ecology based: population models consider ecological factors.</p> <p>Feasible within the current timelines if a decision by risk manager is communicated timely.</p> <p>Although possible alteration on the provision of the ecosystem services is not explicitly considered, it may be assumed likely not impacted as in the range of natural variability.</p> <p>The simulated natural variability could be checked against the control variability observed in some available field studies although this should not be regarded as a systematic validation.</p>	<p>Puts considerable trust in the model simulations for predicting colony dynamics (conservative assumptions can be made)</p> <p>Only applicable for honey bees and maybe bumble bees, due to the lack of models for solitary bees</p>

2.3. Approach 3 – based on predefined acceptable levels on colony/population size

This is the approach currently agreed and implemented in EFSA (2013), which assumes that the provision of the ecosystem services is likely not impacted, when the magnitude of the effect on colony/population size is *negligible* i.e. when, it is not possible to detect any difference in colony size at any time. In EFSA (2013), based on expert judgement, the effect was considered negligible when the magnitude is < 7%. This value was based on the consideration by the experts that beekeepers can only detect effects on their colonies of a magnitude of 7% and higher and on the available knowledge in 2013 on bee background mortality. This was considered a reasonable pre-defined level of acceptable effect to maintain the ecosystem services provision unaltered.

If the risk managers decide to use this approach, the threshold of the effects for colony/population size reduction needs to be reviewed. The decision could be to maintain the current threshold <7% or another value needs to be put forward. This choice will still be only driven by the perception of what is an acceptable reduction in colony/population size.

Process for the approach 3

- 1) Risk managers decide on the pre-defined acceptable level of impact on the colony/population size (magnitude of the effect) and on the exposure assessment goal (see Appendix A for further details);
- 2) EFSA revises the higher tier (reference tiers) requirements:
 - a. to detect the pre-defined acceptable level of effect and to assess the exposure;
 - b. if indicated by the risk managers, the allowed time for recovery (see Appendix B for further details).
- 3) EFSA calibrates the lower tier risk assessment schemes by linking the indicated threshold of “acceptable” effects on colony to daily mortality levels. EFSA revises the trigger values for the lower tier risk assessments consistently with the agreed level of protection.



PROS	CONS
<p>Although possible alteration on the provision of the ecosystem services is not explicitly considered, the provision can be assumed as not impacted by the pre-defined acceptable level of protection.</p> <p>Feasible within the current timelines if risk managers decide on the level of the effects (either to confirm the 7% or to indicate another %)</p> <p>It can be applicable for honey bees, bumble bees and solitary bees.</p>	<p>The definition SPG is not backed up by sound bio-ecological considerations.</p>

2.4. Approach 4 – based on levels of acceptable impact on the provision of the ecosystem services

This approach focusses on ecosystem services (not on SPU) and offers the opportunity 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. In the case of the bees, this approach would allow identifying the desired level of protection against the defined acceptable impact on the provision of the services.

This approach would require scientific developments to investigate the possible link between the impact on the provision of the ecosystem services and the possible effects of pesticides on the various services providing units. Therefore, it cannot be considered as part of this mandate.

Tentative process for the approach 4

This approach is ecosystem service based and can be performed only when sufficient scientific developments will be available. In such a case the tentative process could be as follows:

- 1) EFSA undertakes a new research project e.g. to obtain data to link ecosystem services provisioning with the level of protection of the SPU (e.g. colony/population size or more relevant attributes).
- 2) Risk managers decide on a pre-defined acceptable level of impact on the relevant ecosystem services (e.g. no more than X% loss of pollination provision).
- 3) EFSA perform the scientific process to define SPG dimensions allowing the ecosystem services to be maintained within the level defined by the risk managers.
- 4) Risk managers provide final feedback on the SPG dimensions, including the exposure assessment goal (see Appendix A for further details).
- 5) Higher tier requirements are adjusted to be compliant with the agreed SPG and the exposure assessment goal.
- 6) EFSA calibrates the lower tier risk assessment schemes consistently with the agreed SPG.

PROS	CONS
<p>Link between the level of protection of the SPU and the level of impact of the ecosystem services</p>	<p>High complexity.</p>



	Scientific data not currently available. It would require initiating a new big research project, likely with the support of the JRC and Academia.
--	---

References

- Becher MA, Grimm V, Thorbek P, Horn J, Kennedy PJ, Osborne JL. 2014. BEEHAVE: A systems model of honeybee colony dynamics and foraging to explore multifactorial causes of colony failure. *J Appl Ecol* 51:470–482.
- Becher, M. A., Twiston-Davies, G., Penny, T. D., Goulson, D., Rotheray, E. L., Osborne, J. L. (2018) Bumble-BEEHAVE: a systems model for exploring multifactorial causes of bumblebee decline at individual, colony, population and community level. *J Appl Ecol*
- EFSA Panel on Plant Protection Products and their Residues (PPR), 2010. Scientific Opinion on the development of specific protection goal options for environmental risk assessment of pesticides, in particular in relation to the revision of the Guidance Documents on Aquatic and Terrestrial Ecotoxicology (SANCO/3268/2001 and SANCO/10329/2002). *EFSA Journal*, 8(10):1821, 55 pp.
- EFSA Panel on Plant Protection Products and their Residues (PPR), 2012. 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*, 10(5), 2668, 275 pp.
- EFSA Scientific Committee, 2016. Guidance to develop specific protection goals options for environmental risk assessment at EFSA, in relation to biodiversity and ecosystem services. *EFSA Journal* 2016;14(6):4499, 50 pp.
- EFSA, 2013. EFSA Guidance Document on the risk assessment of plant protection products on bees (*Apis mellifera*, *Bombus* spp. and solitary bees). *EFSA Journal*, 11(7), 3295, 268 pp.
- European Food Safety Authority. 2014. Scientific opinion on good modelling practice in the context of mechanistic effect models for risk assessment of plant protection products. *EFSA J* 12:3589.
- EFSA, 2015. EFSA Guidance Document for predicting environmental concentrations of active substances of plant protection products and transformation products of these active substances in soil. *EFSA Journal* 2015;13(4):4093, 102 pp
- EFSA, 2018. Evaluation of the data on clothianidin, imidacloprid and thiamethoxam for the updated risk assessment to bees for seed treatments and granules in the EU. *EFSA supporting publication* 2018:EN-1378.
- European Food Safety Authority. 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 J* 13:4125.
- EVERAARS, J. & DORMANN, C. 2014. Simulation of Solitary (non-*Apis*) Bees Competing for Pollen. In: J, D. (ed.) *In Silico Bees*. CRC Press.
- FOCUS, 2000. FOCUS groundwater scenarios in the EU review of active substances. Report of the FOCUS Groundwater Scenarios Workgroup, EC Document Reference Sanco/321/2000 rev.2, 202pp.
- FOCUS, 2001. FOCUS Surface Water Scenarios in the EU Evaluation Process under 91/414/EEC. Report of the FOCUS Working Group on Surface Water Scenarios, EC Document Reference SANCO/4802/2001-rev.2. 245 pp.
- ULBRICH, K. & SEIDELMANN, K. 2001. Modeling population dynamics of solitary bees in relation to habitat quality. *Web Ecol.*, 2, 57-64.



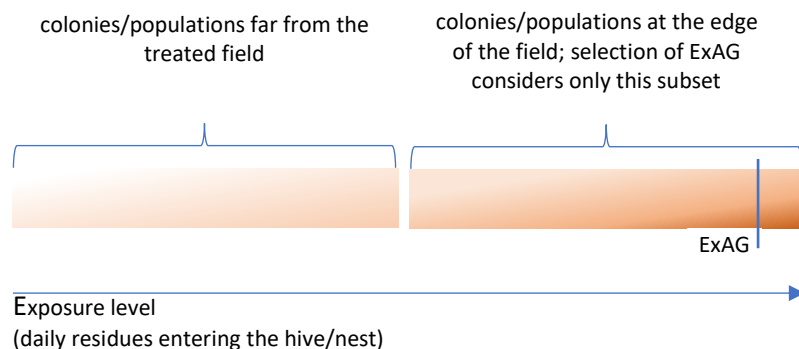
Appendix A - Exposure Assessment Goal (ExAG)

The Exposure Assessment Goal (ExAG) specifies exactly how (i.e. where, when, for how long and how strict) the exposure estimation should be. This could be considered as a further dimension that needs to be specified within the definition of the SPGs. As the protection goal focuses on bee colony/population, the ExAG also consider hive/nests in which bee colony/population live as the relevant spatial unit.

Within EFSA (2013), the relevant exposure level consists of the daily residues entering the hive/nest. Due to bee foraging strategy, these residues tend to be higher in hive/nests closer to the treated field(s). Bees living in hives/nests located far from the treated field(s) (e.g. in the mountain areas or in an apiary far from intensive agricultural areas) will get less exposed than the ones close to the treated field(s).

In EFSA (2013), since the identified spatial scale is the *edge of field*, the ExAG considered uniquely the hives/nests that are located at the edge of the field, i.e. those that get most exposed among the ones in the area of use of the pesticide under evaluation. As such, the rest of colonies/populations living in the remaining hive/nests are automatically protected. While in principle the ExAG could explicitly include all bee population/colonies (also the ones far from the treated fields), this has severe limitations in its practical implementation. As already clarified, the level of exposure is heavily influenced by the distance between the hive/nest and the treated field(s). Since the actual location of all bee population/colonies in Europe relative to agricultural crops is unknown (and likely not constant in time), this approach has limited possibility to be effectively used in the risk assessment.

Colonies/populations at the edge of the treated field(s) will experience different levels of exposure (i.e. different daily level of residues entering the hive/nest). Variability in the daily residues entering the hive may be due to temporal differences (e.g. the same hive/nest may experience different exposure level in early in spring or during summer) or due to spatial differences (e.g. different hives/nests placed at different locations in the area of use of the pesticide). These different levels of daily exposure can be ranked between 0 and 100, i.e. the percentile of the daily exposure distribution. The concept is illustrated in this figure below.



Defining a percentile from the exposure level for colonies/populations at the edge of the treated field for use in the risk assessment is a task for the risk managers. By selecting this target percentile, risk managers indicate how conservative the exposure estimate should be and which fraction of the spatio-temporal exposure distribution should be covered by the risk assessment. The higher the percentile, the more conservative the exposure and the resulting risk assessment. The selected percentile will have an impact on the default exposure estimations in the lower tiers, as well as on the requirements that will be set for the higher tier tests.

For bees, no final decision was taken by RMs in the context of the EFSA (2013), therefore the proposed exposure value was set at the 90th percentile of the spatio-temporal exposure distribution. The selection of the 90th percentile as target exposure is commonly used in other areas of the environmental risk



assessment, e.g. for the EU FOCUS surface water (FOCUS, 2001) as well as groundwater scenarios (FOCUS, 2000), and for soil (EFSA, 2015).

It is noted that the selection of e.g. the 90th percentile value would not mean that 10% of the colonies/populations would automatically be exposed to residue levels causing unacceptable effects. This is still depending on the specific risk characterisation and, in particular, on the severity of the exposure (i.e. how much higher than the ExAG the exposure is), the toxicological profile of a specific active substance and the margin of safety originating from the specific risk assessment.

Appendix B - Recovery option

In both approach 2 and approach 3 described in the main document, the risk managers are requested to define a level of protection which would reflect that a *magnitude* of the effect on colony size reduction that does not include a *temporal scale*, since any possible effect following the exposure to a pesticide should remain at level indicated as acceptable at any time.

In reality, transient effects (i.e. greater than negligible) caused by exposure limited in time can be compensated because of the capacity of colonies to recover. Therefore, within the approach 2 and 3 it may be possible to define a Maximum Acceptable Time (MAT) for a colony/population affected by the exposure to a pesticide to recover their size at the acceptable levels defined within these approaches. In other words, once the level of protection is defined (i.e. threshold of acceptable colony size reduction), risk managers could decide, as additional option, to set a temporal scale in which the colony will recover to the defined level of protection. This would then be translated into the higher tier risk assessment.

It should be noted that the recovery cannot be implemented for the lower tier risk assessment and, if considered as part of the SPG definition, will not have an impact on the calculation of the trigger values. The calibration of the lower tiers would anyway be based on the 'threshold of *acceptable*' effect as identified according to approach 2 and 3. However, the introduction of this option would have a consequence on the higher tier requirements, which would be adjusted to allow the analysis of the recovery time. This process presents similarity with the one currently in place for the risk assessment of aquatic organisms.

Appendix C - Illustrative example of model simulation

A.1. Introduction

The present appendix reports an illustrative example about how approach 2 might potentially be applied, by using BEEHAVE, to derive the magnitude of effects for the SPG determination.

It should be clear that this is just an example of the first steps of the approach, obtained with preliminary simulations. The values reported should not be considered as the EFSA proposal for the quantification of the colony size variability to be used for the actual SPG determination.

A set of example runs with BEEHAVE were performed to demonstrate how normal operating ranges look like, and how model parameter choices and scenario settings can influence those.

For the present application, the scenarios are mainly based on the following determinants:

- Weather data
- Food availability



A.2. Scenario definition

A.2.1. Weather data

A set of specific weather scenarios available from the original model publication (Becher et al. 2014) was chosen, based either on real local weather or on completely artificial data. Real data were available for several years for one location in the UK (Rothamsted, 2009-2011) and from Germany (Berlin, 2000-2006). Artificial weather data leading to bell shapes curve of seasonal foraging period are reported under the name 'HoPoMo_Season'.

A.2.2. Food availability

BEEHAVE allows to read in food flow data of available flower patches for 365 days, defining the food availability of each flower patch on each day of one year. The standard model comes with two different time series: **generic** and **landscape**. The **generic** food flow scenario quantifies nectar and pollen availability for a simplified landscape with only 4 patch types. The **landscape** scenario integrates the locations and sizes of real patches of forage into the model run from a landscape map of the area around Rothamsted (UK), and includes seasonal food flow and varying flower handling times for nectar and pollen foraging. This gives a more realistic foraging landscape for the bees.

A.2.3. Other parameters

The remaining model settings were left with the default parameterisation.

A.3. Simulations

Simulations were run by combining the three weather sets with the two food availability conditions, originating six different scenarios. Each set of simulations (i.e. for each scenario) 500 runs were performed under perfectly equal conditions, so that the variability observed in the output is only due to the stochasticity intrinsic to the model. The only output reported in this appendix is the colony size (i.e. number of adult bees) in each day of the simulation period. Simulations were run for three years in order to show also the variability caused by different weather in the same area.



A.4. Results of the preliminary simulations

The results of these preliminary simulations show the importance played by the scenarios, both in terms of weather and of food availability, with more realistic and complex scenarios resulting in higher predicted variability. The simulations show clearly that the lower end of the colony size distribution is rather unstable in time, even during the 1st year, with up to 40% decrease compared to the mean in the simple scenarios, and up to 80% in the most complex ones. This means that basing the SPG on the full range of the simulated variability is likely to result in very high effect thresholds. Consideration of low percentiles of the variability distributions will result in more conservative and more stable values, which are nonetheless capturing a large fraction of the expected variability. In all scenarios all simulated colonies survived the first year, whereas in the most complex scenarios some died in the second and third year. In this situation, accounting for the entire range of variability translates into a 100% difference from the mean.

The results also show a very clear seasonality, with lower % variability when the colonies get to their maximum size in summer, while the maximal variability is observed in spring when the colonies start growing in size.

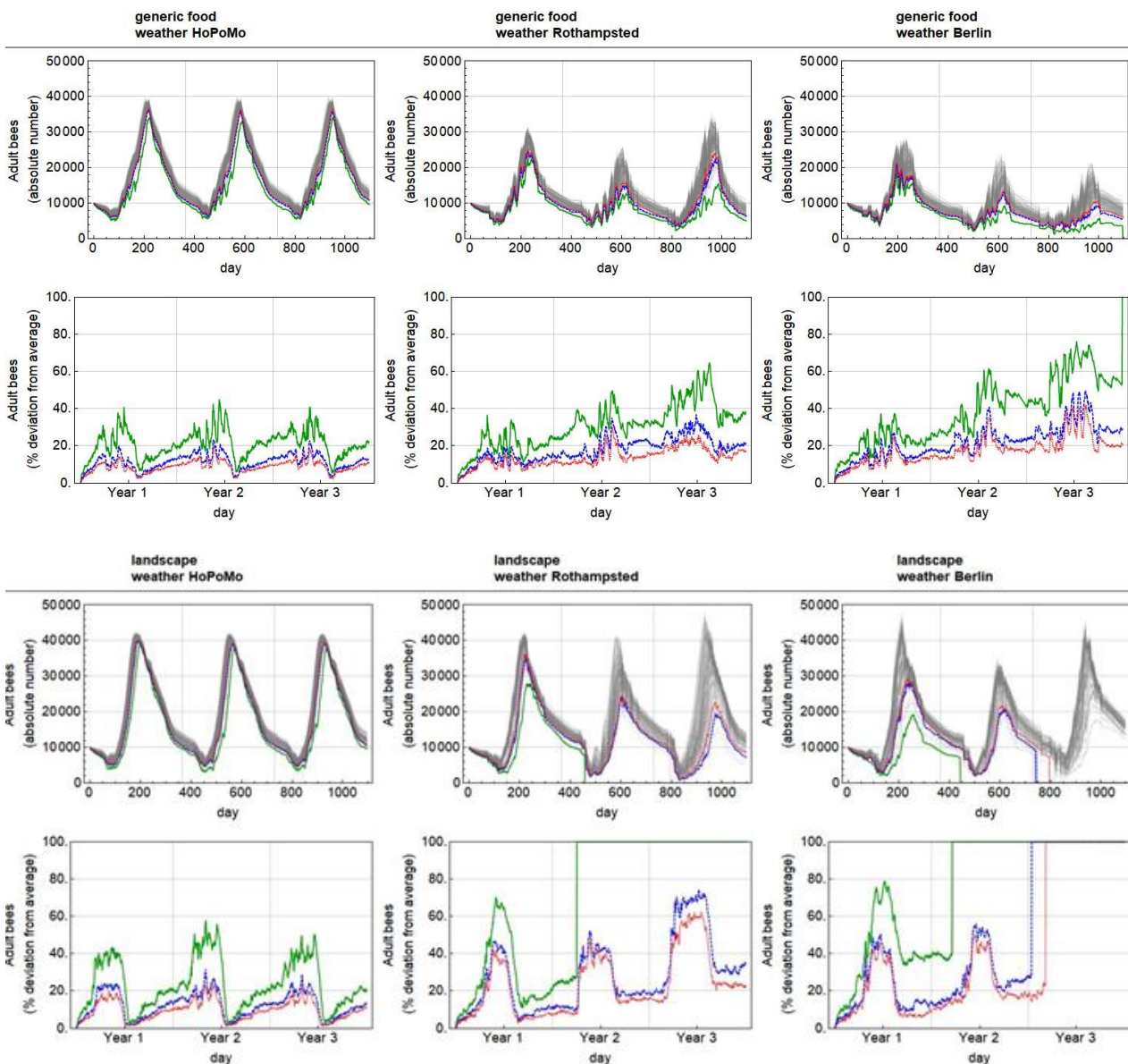


Figure 3: Results of the preliminary simulations with BEEHAVE for six scenarios. The upper plots report the dynamic of the colony size in time (3 years). Each grey line is a simulation run (i.e. the grey area is composed by 500 close lines). The green lines represent the maximum lower colony size values at any time point, the blue lines represent the 5th percentile, and the red lines represent the 10th percentile. The lower plots report the % deviation from the mean, in time, for the lower colony size, the 5th, and the 10th percentiles.

A.5. Outlook

If this option is selected by the risk managers as the favourite one to proceed in the definition of the SPG, the WG will consider:

- Whether it is possible to extend the scenarios currently available in order to better reflect the conditions of the three regulatory areas.
- Whether the current standard parametrisation needs to be amended/fine-tuned, or whether this is sufficiently fit-for-purpose for the present exercise. The recommendations already drafted by EFSA on BEEHAVE evaluation (EFSA, 2015) will be taken into account, considering that the aim of this model application is completely different to the focus of the former evaluation, which was assessing the suitability of BEEHAVE for risk assessment.
- Whether 1-year simulations (instead of multiple years) will better target the current scope, which is assessing variability under exactly equal conditions in order to define a threshold of acceptable effects.
- Whether different thresholds could be derived from different periods of the year, in order to explicitly target seasonal differences.