Vragen aan EFSA en antwoorden over de bijenkomst over het bijenrichtsnoer van 13 januari 2021 en het bijbehorende achtergronddocument.

(1) We kindly request that EFSA provide further advice regarding the choice of a threshold value on the basis of the modelling, particularly concerning the practical implementation and (field) measurement of the eventual protection goal.

Answer
EFSA is not in the position to provide further advice regarding the choice of a threshold concerning the practical implementation and field measurement of the protection goal. What EFSA can do (and has done) is to transparently reflect how field studies requirements will likely (see point 4) change to address different tolerable effects. Also, what EFSA can do (and has done) is to collect examples from literature/dossier to inform risk managers about what was possible to achieve in the past. Feasibility of larger field studies mainly entails considerations on availability of resources that EFSA cannot and should not estimate.

(2) Considering that the variability in the model is already lower than the variability in the field (Figure 4), we wonder whether there is a specific scientific reason to restrict the OR (i.e. to remove a percentage of the weakest hives from the analysis)? Could the EFSA please provide further explanation of the choice of the restricted ORs presented?

Answer
First of all, let us stress once again one aspect: the simulated variabilities are well in the range of the experimental variabilities observed in control field studies. It is however acknowledged that the median variability calculated across all field studies is generally higher than the variabilities simulated with BEEHAVE. The choice of removing a percentage of the weakest colonies or, in other word, to restrict the operating range, is entirely up to the risk managers, and will reflect the level of conservativism that the risk managers wish to have. This is because risk managers may decide that the strength of absolute weakest colony in the simulated "control" is not a suitable reference for setting the threshold for tolerable effect. What EFSA has done was to further inform this aspect by quantifying different potential tolerable effect thresholds on the basis of the fraction of colonies retained in the operating range. Furthermore, EFSA has provided a 'cap', over which risk managers should not go. This is represented by that 'one-third reduction' that was considered by experts in 2012 to lead to colonies not being viable anymore.

(3) EFSA points out that the largest studies have to be performed in larger areas (i.e. multiple different countries), which increases variability, using the example of a study performed with 90 hives. From this, we interpret that studies with 90 (or more) hives, would likely not have the same theoretical increase in power indicated in Table 4, due to increased variability based on largely differing environmental scenarios. Is it possible to indicate a "sweet spot" for number of hives that would be optimal without introducing higher variability due to the requirement of larger testing areas?

Answer
This is very appropriate comment/question. Indeed, the risk that using larger areas (i.e. across several countries) would cause an increase in variability compared to our estimation (and thus a decrease in power) is well possible. Unfortunately, at the moment, information

about variability among such large areas used for single studies (thus with homogeneous practices and experimental design) is limited to 2-3 studies. This makes any predictive estimation about a 'sweet spot' not so straightforward and quite uncertain. In fact, one could potentially carry out a study with a similar design (i.e. up to 10-11 replicate fields per treatment) while remaining in a more homogenous area. Just after the meeting, Spain submitted two literature studies where 3 to 10 replicate fields (over 3 years) were used in a much smaller area (central-south Spain). The practical limitation of this aspect regards mainly the possibility to access/use an appropriate number of fields in a certain area, which is not something that EFSA can estimate on a scientific basis.

(4) Could the EFSA address the possible variability in Table 4 more concretely? It is stated that several assumptions still should be discussed within the WG, but it is not directly stated which assumptions those might be, nor where these "preliminary" values stand within the possible range. Would it be possible to present a range of the possible power levels (as exemplified in the varying power analyses of Rolke, et. al. 2014)?

Answer

As correctly pointed out, the estimations in table 4 still need to be considered preliminary, as some of the assumptions are still to be discussed within the WG. However, the document already lists what these are:

a. variability in colony size - not just between colonies on the same field, but also between colonies in different fields. This can be further informed by some of the data we have already collected/generated for the sake of the exercise presented in the info session
b. type I error (alpha value)
c. type II error (beta value)

We envisage that more precise estimations can be presented in the future, but it is unlikely that those will present large difference compared the values currently presented in table 4.

(5) EFSA indicates that SPGs for bumble bees and solitary bees might be determined based on addition of a "safety factor" to the values for honey bees. We agree that the ecology of bumble bees and particularly solitary bees is not at all appropriately represented by the Behave model. However, <u>if</u> a safety factor is chosen in order to address non-apis bees, we would request that the EFSA update the toxicological sensitivity analysis based on the available toxicity data (which, while still limited for non-apis bees, is nevertheless likely larger than in 2011/12) to provide some indication as to species (population) sensitivity? We suggest that data for other solitary pollinating non-target arthropods might be included in the analysis for solitary bees, though these data are, of course, also likely limited.

Answer

It is clear that the exercise performed with BEEHAVE should be considered informative for honey bees only. Unfortunately, at the moment we cannot provide more scientific ground to the risk managers for setting SPGs. The application of uncertainty factors to the effect percentages identified for honey bees was suggested by the PPR Panel (2012) as a pragmatic solution for this lack of information. Concerning your request, please be informed that the WG is already updating the toxicological sensitivity analysis for bumble bees and solitary bees. The envisaged strategy for this is described in the methodological protocol for the revision of the EFSA Bee Guidance document which was shared, in its draft version, with Member States and stakeholders.