

N.B. Dit sjabloon aanhouden en geen verder opmaak (bullets oid) gebruiken. Elk vakje moet straks namelijk in de EFSA website worden geplakt in velden die eruit zien zoals in dit sjabloon weergegeven.

Please insert here your general comment on the document

General comments (4000 characters maximum)

The protocol gives detailed information on how to retrieve information and how to assess reliability and relevance of individual studies. This is very thorough and resembles the approaches known from the RIVM manual (Mensink et al. 2008: Manual for summarising and evaluating environmental aspects of plant protection products; RIVM report 601712004/2008), the Klimisch approach and the CRED approach (MOERMOND et al. 2016: CRED: CRITERIA FOR REPORTING AND EVALUATING ECOTOXICITY DATA. Environmental Toxicology and Chemistry, Vol. 35, No. 5, pp. 1297–1309, 2016). Regarding the aspects of integrating the outcomes the proposal is less developed. This is partly because it is not specified what functionalities of the ‘background mortality rate’ are anticipated: how will this information be used? Some comments are provided. These are the combined comments of Ctgb, RIVM (National Institute for Public Health and the Environment) and WUR (Wageningen University & Research).

Please insert here your specific comment on particular sections of the document

Specific comments

	Section	Page	Line No.	Comment
1	2.1.1	3		The section should also explain that the target population of the solitary bees is the population of individuals, whereas for the honey bees and bumble bees it is the colony (and neither the individuals nor the population of colonies). This connects directly to the protection goal. And since for different protection goals the exact level of protection (e.g. 5% effect), and the certainty with which this is achieved or determined (e.g. 95% certainty), may differ, this will also impact how to integrate all pieces of evidence (Chapter 4).
2	2.1.1	4	117	Leave out ‘taxonomic’. Taxonomic diversity is a trait of geographic areas or of ecosystems.
3	2.1.1	4	116-120	Some solitary bee species, e.g. <i>Osmia bicornis</i> and <i>O. cornuta</i> , are managed to be used for pollination. To align with the sections on the other bee groups, this should also be mentioned here.
4	2.1.2	4	123-125	The exclusion of the overwintering period for bumblebees means that survival of the queen during winter is not considered. This seems inconsistent with line 84 in section 2.1 and with line 123, since the queen is clearly an adult bee. More importantly, queen

				overwintering survival is an important parameter for bumblebees. It is recommended to include this in the literature search.
5	2.1.2	4	137, 146	Please specify the relationship between the EU biogeographic regions and the nine FOCUS groundwater locations
6	2.1.2	4	145-149	Please review where the daily data on temperature and precipitation were taken from. As far as we know AppDate is not the source for these data (probably meteo files of PELMO model for FOCUS groundwater scenarios?)
7	2.1.2	4	148	The weather data in appDate are from the previous century. More recent data are available in e.g. the Mars database. Please consider using those in view of climate change.
8	2.1.2	4	151-152	Please clarify what the exact procedure was. How were crops considered. Is the active period e.g. crop-dependent ?
9	2.1.2	5	158, Figure 1	The graph is not clear, e.g. is the admissibility area the red area, or the entire white box? What do the grey dots represent? And the grey areas outside the white box? And what is meant by average daily temperature/rain by month [this suggests the months are discernible, or the graph represents only one month e.g. March]: monthly average of daily temperature/rain ? Detail: Rainfall generally is expressed in mm, not cm. Please state also the conclusion on the admissibility area.
10	2.1.2	5	168	We suggest providing a quantitative criterion (e.g. at least x% of surface area within a radius of x km occupied by crops/orchards).
11	2.1.2	5	163-169	<p>Any background mortality found in agricultural landscapes is likely influenced by at least some exposure to plant protection products. By including only agricultural landscapes in your dataset, you exclude on forehand the 'real' natural mortality. While this may be the most relevant to assess the risk of an individual plant protection product in an agricultural landscape, it may underestimate the risk in a landscape-level assessment. If the latter comes into practice, the background mortality value should be re-assessed to include the entire landscape (including non-agricultural areas).</p> <p>Also, please consider that this guidance document will not only be used for large-scale agriculture, but also for home-and-garden use and for use in more urban areas such as parks and sports fields.</p>
12	2.1.3	5	175	Should the word <i>pesticides</i> not be replaced by <i>plant</i>

				<i>protection substances/products?</i>
13	2.1.3	6	184	'...exposure to in-hive chemicals': please clarify that this concerns veterinary products (if that is indeed the intention).
14	2.1.3	6	185	<p>"Within this document, bee background mortality is generally intended in terms of rate (e.g. percentage mortality over a certain time period)."</p> <p>The focus should not be on the fact that it is expressed as a rate, but on what the parameters in this rate are. Do you intend to say the following?:</p> <p>"Within this document, bee background mortality is generally intended as the percentage mortality over a specified time period Δt (resulting in a rate: $x\%/time$). Percentage mortality is the number of dead adult bees / total number of adult bees in colony [Apis/Bombus] or population [solitary bees]".</p> <p>Check also lines 575-578 (here no time aspect is mentioned).</p> <p>This terminology should be clearly defined.</p>
15	2.1.3	7	186	<p>"Ideally, bee background mortality is expressed in terms of a daily rate (daily percentage mortality), in order to account for the dynamicity of colonies and populations."</p> <p>Could it be elucidated that the bee background mortality is expressed in daily percentage mortalities <i>for the time period investigated (i.e. noting a.o. the duration of that time period and other properties such as the dates)?</i> And that we are interested in knowing the (variability in) bee background mortalities for any time period during the active period (and for the dormancy period), everywhere in the EU?</p> <p>Small detail: "Dynamicity" is not a word (not present in dictionaries). It might be better to simply state that this is "in order to account for variation in colony and population dynamics", for clarity.</p>
16	2.1.3	7	233-235	This sentence currently implies an automatic rejection of all effect studies. Is this due to the expectation that all studies include such disturbance that they do not reliably predict 'normal' mortality? In which case, especially for older studies, it may not have been the case that frequent observations were done. Or do we misunderstand the reason for the consideration that

				<p>‘the available information will be unsuitable for the present purposes’? Please clarify.</p> <p>NB if indeed no effect studies are used for determining the background mortality, it is especially important that in the eventual evaluation of effect studies, the ‘natural background mortality’ is not considered, and only the control and the treatment in that particular study are compared. This could be added here to provide clarity especially for risk managers.</p>
17	2.1.3.	7	240-244	This is a strange formulation since mortality per generation determines the population development and its fitness. Background mortality should be estimated per generation and whether one, two or three generations per year occur does not matter as they are consecutive events that are linked.
18	2.1.3	7	246	In northern Europe bees have a winter rest, in southern Europe bees can have a summer rest. Both are periods without brood, but perhaps this sentence can be rephrased?
19	2.1.3	8	263-264	Please clarify ‘2) the colony cannot always be fully inspected without disrupting it’. Isn’t this exactly what we are trying to discover here? Or is the intention to explain why full inspection will normally not be done and that such data will therefore not be available?
20	2.1.3	9	Table 1 question 3b	‘Some species of solitary bees’: in principle information will be gathered for all species, right? So does ‘some’ reflect that only for some, information will be available? Please clarify.
21	3.1.1	14	Table 3, Landscape (just above 284)	Lines 168/169 make clear that only EU agricultural landscapes are considered relevant. Therefore it is somewhat confusing that here ‘All possible locations’ are included.
22	3.1.1	13	Table 3 Study design Out	Please explain why colony feeding studies are ‘out’ even if they have a field design.
23	3.1.1	13	Table 3 Population design In	Please provide the Latin name here. “European Honey bees” suggests that honey bees outside Europe are not considered, which is not true.
24	3.1.1	13	Table 3 Exposure In	It is noted that there is no clear definition of what is considered a level of stressor ‘comparable with the usual background level’. This could be improved, or should at least be discussed in detail by all study evaluators to ensure a consistent approach.
25	3.1.1	13	Table 3 Outcome Out	Please explain why the methods most often used for determining mortality (dead bee traps, linen sheets) are not considered acceptable for the current purpose.
26	3.1.1	14	Table 4, Population In	Is it the intention to pool the information for all bumblebee species?
27	3.1.1	14	Table 4,	Note that to date it is not possible to do any brood

			Outcome In	assessment in alive bumblebee colonies due to the internal structure of the colony and the sensitivity of the larvae. Up to date brood assessment can only be done by destructive sampling or using artificial mini-colonies in lab settings (sisters that produce males only).
28	3.1.1	15	Table 4, Landscape (just above 287)	Lines 168/169 make clear that only EU agricultural landscapes are considered relevant. Therefore it is somewhat confusing that here 'All possible locations' are included.
29	3.1.1	15	Table 5, Outcome In	What exactly is done during 'monitoring the population'?
30	3.1.1	16	Table 5, Landscape (just above 289)	Lines 168/169 make clear that only EU agricultural landscapes are considered relevant. Therefore it is somewhat confusing that here 'All possible locations' are included.
31	3.1.6	19	407-456	Networks for beekeepers (at least for honeybees) are already in place via COLOSS and possibly other networks and it seems more efficient to directly contact them.
32	3.1.6	19	491-503	The protocol proposes to ask beekeepers which numbers of bees they lose from management practice. We question this approach. We know of a beekeeper who had a bee-counter at his hive entrance. This counter showed that sometimes thousands of bees were lost after certain practice, although only few dead bees were seen. Of course, this is only anecdotal evidence. However, it emphasizes the need to investigate this in a structural and methodological way. Asking beekeepers will likely not yield reliable results, as most bees lost from practices remain "unseen".
33	3.1.6	21	496	Please note that the size of a honey bee colony varies during the year. A colony consists about 7,000 individuals in spring to 20,000-30,000 bees in summer, decreasing in size in autumn (Van der Steen: The Foraging Honey Bee, The British Bee Journal, February 2015). Thus, the season is an important factor to consider. See also WUR report 606 (5.1.2.e Woo 2015) for a good review on honeybee biology and foraging behaviour (in Dutch).
34	3.2	23	Table 8 Study conditions: weather	Adverse foraging weather during a study is taken as a reason to consider the study data less reliable. Is this based on the pre-assumption that mortality is higher under good foraging conditions? Would this not be a bias? Adverse foraging conditions also reflect reality.
35	3.2	24	Table 8 Test organisms stressors	It is noted that there is no clear definition of what is considered an 'unrealistic prevalence' of a disease. This could be improved, or should at least be discussed in detail by all study evaluators to ensure a consistent approach.
36	3.2	30	Table 9	Please consider that this guidance document will not

			Study conditions: agricultural landscape	only be used for large-scale agriculture, but also for home-and-garden use and for use in more urban areas such as parks and sports fields.
37	3.2	31	Table 9 Study conditions: beekeeping practices	To ensure consistency in the evaluation, it would be good to refer to a standard for beekeeping (e.g. some handbook).
38	3.2.1	35	Table 13	Please consider renaming 'Tier', as this has a different meaning in the ecotox risk assessment.
39	3.2.1	36	Table below line 567	What is the meaning of 'Refid'?
40	4	36	573	Here and/or in the Introduction, it would be useful to have an overview of how background mortality will be used for assessments. For example: Will the data be used to define performance criteria for control groups? Will the data be used to determine how a field study should be designed (number of controls, number of replicates)? Will the data be used to determine how much 'extra' effect (of a bee keeping practice, of a treatment) could be deemed acceptable? This will also impact differently on Apis/Bombus (impact on colony strength) compared to solitary bees (impact on species biodiversity). Results from numerous Apis studies may be generalized for all Apis colonies, whereas results for some solitary bees may not be transferable to all solitary bees. And for cage studies there will be different values than for field studies.
41	4.1	36	575-576	<p>"also other endpoint such as longevity" : not clear how this fits in this sentence.</p> <p>Here a 'new' definition of mortality is given, compared to the introductory chapters. Can this be aligned? Clearly, the daily percentage mortality over the total foraging period will be the same for every colony, when based on the number of dead bees versus the total number (since all adults present at any time during the active period will have died at the end). What is of interest, is to know what the range of rates on a daily (or weekly) basis can be during this entire active period. And when there are considerable differences, e.g. between colonies or over time, if driving factors can be identified, relevant for testing and/or assessment (e.g. region, month, species, beekeeping practices). Agreed that it depends on the "granularity of the information retrieve and type of data". But how the outcomes will be used in the end also determines how much data / precision is needed, which affects the appraisal of all outcomes.</p>

