Outcome of the public consultation on the draft EFSA Scientific Committee Opinion on a systems-based approach to the environmental risk assessment of multiple stressors in honey bees

European Food Safety Authority (EFSA)

Abstract
The European Food Safety Authority (EFSA) carried out a public consultation to receive input from interested parties on the draft scientific opinion on a systems-based approach to the environmental risk assessment of multiple stressors in honey bees. This draft scientific opinion was prepared by the EFSA Scientific Committee, supported by a Working Group on the development of a holistic and integrated approach to the environmental risk assessment of multiple stressors in bees. The draft opinion was endorsed by the EFSA Scientific Committee for public consultation on 11 November 2020. The written public consultation was open from 07 January 2021 until 04 March 2021. EFSA received comments from 17 different interested parties. EFSA and its Scientific Committee wish to thank all stakeholders for their contributions to this work. The present report contains the comments received and details how they have been considered for the finalisation of the opinion. The final opinion was adopted at the Scientific Committee Plenary meeting on 14 April 2021 and will be published in the EFSA Journal.

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Key words: environmental risk assessment, systems-based approach, ApisRAM, modelling, monitoring, EU Bee Partnership platform, honey bee

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1. Introduction

1.1. Background and Terms of Reference as provided by the European Parliament

On 28 June 2018, the Coordinators of the ENVI committee endorsed a request for a scientific opinion by the European Food Safety Authority (EFSA) on the science behind the development of an integrated and holistic approach for the risk assessment of multiple stressors in managed honey bees (Apis mellifera).

This request was submitted in accordance with Article 29 of Regulation (EC) No 178/2002 on 'laying down the general principles and requirements of food law, setting up the European Food Safety Authority and laying down procedures in matters of food safety', which provides that the European Parliament may request the Authority to issue a scientific opinion on matters falling within the Authority's mission.

The request was introduced taking into account the world-wide importance of bees and pollinators, as 84% of plant species and 76% of Europe's food production depend on pollination by bees and this represents an estimated economic value of EUR14.2 billion a year. However, the health of honey bee colonies has been declining and there have been intensive scientific efforts to better understand the reasons for this decline, which may be related to intensive agriculture and pesticides use, poor bee nutrition, viruses and attacks by invasive species, as well as environmental changes and habitat loss.

The ENVI committee, therefore, considered it opportune for Parliament to request that EFSA deliver a scientific opinion on the science behind the development of an integrated and holistic approach for the risk assessment of multiple stressors in managed honey bees (Apis mellifera). The following issues have been identified for the development of a scientific opinion on the risk assessment of multiple stressors from both the in-hive environment and the surrounding landscape:

- The development of a methodology to take into account not only cumulative and synergistic effects of plant protection products (PPPs) but also include issues related to bees' genetic variety, bee pathogens, bee management practices and the colony environment (Term of Reference ToR 1).

- The assessment of acute and chronic effects of multiple stressors on honey bees including colony survival and sublethal effects (Term of Reference ToR 2).

- The work being developed by stakeholders to achieve harmonised data collection and sharing on bee health in EU and, by doing so, support the EU Bee Partnership initiative by providing guidance for harmonised data collection and evidence-based risk assessments (Term of Reference ToR 3).

- The work conducted by EFSA under its project MUST-B (EU efforts towards a holistic and integrated risk assessment approach of multiple stressors in bees) that integrates the work being developed in EFSA's various panels (Term of Reference ToR 4).

This scientific opinion, to be delivered by June 2021, should integrate efforts already conducted and propose a framework for risk assessment that can ensure the protection of managed honey bees in Europe.

1.2. Interpretation of the Terms of Reference

This scientific opinion presents ideas and concepts for consideration and future development. The document is not prescriptive, nor is it constrained by or aligned to specific EU legislation. Rather, the opinion seeks to present a framework, and supporting rationale, that is robust and forward thinking, while acknowledging that some detail will require further elaboration, which in part will be reliant on

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1 Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. OJ L 31, 1.2.2002, pp. 1–24.
new scientific discoveries. This scientific opinion is aligned to aspirations outlined in the EU Green Deal and the EFSA Strategy 2027 (EFSA, 2019a, b, c), presenting ideas and facilitating discussion, leading to practical solutions in this critical area of environmental risk assessment of multiple stressors in honey bees.

The first and second Terms of Reference (ToR 1 and ToR 2) refer to the development of a holistic and integrated risk assessment methodology taking into account various factors (i.e. ‘bee genetic diversity’, ‘beekeeping management practices’, ‘resource providing unit’) and stressors (‘chemical’ and ‘biological’) as well as various effect types (‘acute’, ‘chronic’, ‘sublethal’, ‘cumulative’, ‘synergistic’, ‘antagonistic’) on colony health status. For one colony, this would mean an adequate size, demographic structure and behaviour; an adequate production of bee products (both in relation to the annual life cycle of the colony and the geographical location); and provision of pollination services (see Section 3.2.2.1 of the scientific opinion). ToR 1 refers to ‘PPPs’ and ‘cumulative effects’. Clarifications on the definitions of those terms (i.e. ‘PPPs’ and ‘cumulative effects’) are provided in Appendix B. In their environment, bees are exposed to PPPs as well as other chemicals (e.g. biocides, veterinary products and contaminants), which are referred to in this scientific opinion as ‘multiple chemicals’ or ‘chemical stressors’. The term ‘cumulative effects’ is functionally synonymous to ‘cumulative impacts’ and frequently used in the area of environmental impact assessment under Annex IV of the Directive 2011/92/EU (see Appendix B of the scientific opinion for more details). In the context of this scientific opinion, which is focused on environmental risk assessment of multiple chemicals and stressors on honey bees, ‘cumulative effects’ refer to ‘combined effects from exposure to multiple chemicals’ at a given time (EFSA Scientific Committee, 2019) or to ‘combined effects from exposure to multiple chemicals and/or other multiple stressors’ at a single or multiple time points. For example, foragers might be exposed in time and space to several and different types of stressors, resulting in complex (non-linear) responses at the colony level.

To address these two Terms of Reference, an integrated and holistic approach is presented in Section 3.1 ‘A proposal for a systems-based approach to multiple stressors in honey bees’ of the scientific opinion. Findings from social research have informed the holistic approach by providing an understanding of the perspectives of the interested parties (e.g. beekeepers). This is further developed under Section 5.1 in which targeted research was conducted among beekeepers in EU to assess their understanding of the proposed approach, their needs and expectations in terms of data for managing their colonies, digital advancements and requirements for communication of applied research.

Furthermore, methodologies for risk assessment sought in ToR 1 and ToR 2 are addressed under Section 3.2 ‘the core components of the systems-based approach’ and some clarifications on the terminology used under these Terms of Reference are provided by the working group (Appendix B of the scientific opinion). The proposed approach is in line with the recommendations for actions made under the EU Green Deal (see Section 1.2.3 of the scientific opinion.) and is based on the work achieved under the auspice of the MUST-B project (see Section 1.2.1 of the scientific opinion.) and the knowledge gained on the risk assessment of combined exposure to multiple chemicals (EFSA Scientific Committee, 2019) applied to honey bee colonies (Spurgeon et al., 2016).

The third Term of Reference (ToR 3) refers to harmonised data collection and sharing among stakeholders as developed by the EUBP, which has the goal to improve data collection, management, sharing and communications to achieve a holistic assessment of bee health in EU and beyond (see Sections 1.2.1 and 1.2.2 of the scientific opinion). EFSA supports this initiative which is aligned to its mission to facilitate discussion among stakeholders, by providing guidance for harmonised data collection in the context of bee health assessment (Jacques et al., 2016, 2017; EFSA, 2017) and by promoting research in this field (EFSA, 2014a; EFSA and EC’s Directorate-General for Agriculture and Rural Development, 2016), with the support of developments under the research framework H2020. This Term of Reference (ToR 3) is addressed under Section 5.2 and supported by feedback obtained from members of the EUBP.

2 Directive 2011/92/EU of the European Parliament and of the Council of 13 December 2011 on the assessment of the effects of certain public and private projects on the environment Text with EEA relevance. OJ L 26, 28 January 2012, pp. 1–21.
The inclusion of the need to take into account beekeeping management practices in the Terms of Reference of the request (ToR 1), as well as the work being developed to achieve harmonised data collection (ToR 3), have prompted EFSA to bring social science skills to the interdisciplinary mix of expertise working together on this project. In line with EFSA’s social science roadmap, targeted social research was commissioned to provide an understanding of the perspectives of the interested parties and thus strengthen engagement and communication with target audiences.

The fourth Term of Reference (ToR 4) is on the inclusion of EFSA’s work on bee health through the MUST-B project. As highlighted in Section 1.2.1 and Table 1 of the scientific opinion, MUST-B is rooted in EFSA’s work, through the multidisciplinary Bee Task Force representing all Panels and Units involved in bee health (EFSA, 2012). This work is based on stakeholder engagement for a participative, inclusionary and integrated approach to environmental risk assessment, taking into account multiple chemical and biological stressors and combining modelling and monitoring strategies. This work might provide additional lines of evidence to risk assessors and may already have been implemented as part of the current predictive risk assessment that is under review through the EFSA Bee Guidance on the risk assessment of PPPs in bees (EFSA, in preparation). The main differences between this scientific opinion and the review of the bee Guidance in terms of requestor, legislative status, purpose, scope and timeframe is summarise in Figure 1.

Finally, a description of the terms in the mandate that require clarification to avoid any misinterpretation is presented in Appendix B. In addition, a glossary of the widely used terms and concepts in the multiple-stressor research (e.g. ‘multiple-stressor’, ‘cumulative effect’, ‘stressor interaction’, ‘additive’, ‘antagonist’) is provided by Orr et al. (2020).

1.3. Rationale for the public consultation and brief summary of the outcome

In line with EFSA’s policy on openness and transparency, and in order for EFSA to receive comments on its work from the scientific community and stakeholders, EFSA engages in public consultations on key issues. Accordingly, the draft opinion together with its annexes was released for public consultation from 07 January 2021 until 4 March 2021 by means of an electronical comment submission tool together with explanatory text on the EFSA website (See Appendix A). Comments were received from 17 interested parties from 8 countries (2 stakeholders did not make any comment). Table 1 provides an overview on the interested parties that have submitted comments through the electronic submission (3 uploaded an additional file in the online tool: 2 scientific papers: Requier et al. (2015) and Topping et al. (2021) cited in the list of references and a word document including a copy of the comments made by RIFCON GmbH (included in Table 2).
Table 1: Overview on stakeholders participating in the public consultation

| Stakeholder                                                                 | Category(a)                              | Country       |
|----------------------------------------------------------------------------|-------------------------------------------|---------------|
| Anses: French agency for food, environmental and occupational health and safety | National authority                        | France        |
| BeeLife                                                                    | Non-Governmental Organisation             | Belgium       |
| BeeSafe - Bee Health Consulting for Agriculture and Veterinary Medicine     | Private sector (e.g. industry, consultancy, etc.) | Germany       |
| Bonomo Roberta                                                             | Personal capacity                         | Italy         |
| Campbell Mike                                                              | Personal capacity                         | United Kingdom|
| Chetcuti Jordan(c)                                                         | Personal capacity                         | Ireland       |
| CIBE - International Confederation of European Beet Growers                | Farmers and primary producers             | Belgium       |
| Conelli Luigi(c)                                                           | Personal capacity                         | Italy         |
| CropLife Europe                                                            | Private sector (e.g. industry, consultancy, etc.) | Belgium       |
| Ctgb                                                                        | National authority                        | Netherlands   |
| deGraaf Dirk                                                               | Personal capacity                         | Belgium       |
| Lund University                                                            | University/public research institute      | Sweden        |
| Medrzycki Piotr                                                            | Personal capacity                         | Italy         |
| National Farmers' Union(d)                                                 | Non-Governmental Organisation             | United Kingdom|
| RIFCON GmbH                                                                | Private sector (e.g. industry, consultancy, etc.) | Germany       |
| Sweet Jeremy                                                               | Personal capacity                         | United Kingdom|
| Terre d’Abeilles                                                           | Non-Governmental Organisation             | France        |

(a): as specified by the commenter.
(b): a scientific paper (Topping et al., 2021) was sent by the interested party with no further comment. EFSA thanks the author for the material provided and for supporting the approach developed in the opinion.
(c): no comment was provided, and no material was sent.
(d): according to EFSA classification of stakeholder organisation, this interested party is registered as "Farmer and primary producers".

2. Data and Methodologies

The comments received were duly evaluated by the EFSA Scientific Committee MUSTB WG on the development of a holistic risk assessment of multiple stressors in honey bees. Wherever appropriate these comments were taken into account for finalisation of the draft opinion.

Table 2 provides a detailed list with all comments received from interested parties together with EFSA responses and explanations how the comments were considered for finalisation of the draft opinion. Some comments, especially those suggesting editorial changes, have been directly addressed in the text of the opinion, if they were considered appropriate.
Table 2: Stakeholder comments and EFSA responses

| Stakeholder            | Comment number | Chapter | Comment                                                                                                                                                                                                 | EFSA response |
|------------------------|----------------|---------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------|
| Roberta Bonomo         | 1              | General | San Rocco’s apiary is formed by 69 hives of *Apis mellifera ligustica*. It is located in Capraia Island (LI), one of the seven islands of the National Park of the Tuscanian Archipelago. The natural environment is typical of the Mediterranean climate so the availability of foraging resources for bees is very good and healthy. We are two beekeepers and scientists, degreed in Biology and Ecology. Our farm is biological certificated and we produce mostly honey, grape (not for wine) and fruits. In Capraia island (20 square km) the other agricultural activities are biological. Even the environment is very natural and there are not intensive activities around. Varroa mite is present and we observed DWV symptoms. We never had bee death or severe Varroa infestation. We do treatments with Oxalic acid twice a year, with the different techniques basing on the season period. If it could be useful for EFSA research purpose, we pleased to collect data and information on the environmental risk assessment. | EFSA thanks the stakeholder for sharing this information. For further inquiry on outsourcing activities led by EFSA, please check: https://www.efsa.europa.eu/it/engage |
| Campbell Mike          | 2              | General | If we have the capacity to recognise just how vital Bees (of all sorts) are in the pollination of our crops and much other flora on planet earth then surely we have the capacity to understand that acting to stop and reverse their current horrific declines is an absolute necessity. Failure to act leaves us morally bankrupt and well rather stupid. If you are over 50 years old you will if you open your eyes have observed the most dramatic decline in insect species. We must act now to stop and reverse this trend before our eco system collapses around us. We cannot let big chemicals business dictate issues of such global importance and must stand strong against economic strength. Time is running out. | EFSA thanks the stakeholder for sharing his view on insect decline. EFSA acknowledges such declines and has the mission to deliver the best scientific advice for risk managers to make informed decisions. |
| DeGraaf Dirk           | 3              | General | I am as a researcher involved in the Horizon 2020 funded project B-GOOD (coordinator). Within B-GOOD, we will contribute to the risk assessment process by developing measures of bee colony health that are better indicators for the resilience of the colony. This is, in my opinion, a robust and useful metric to assess impact. Furthermore, we extend EFSA’s ApisRAM model of honey bee colony to include further | EFSA thanks the stakeholder for sharing this information on B-GOOD. EFSA follows closely the progress of this work (EFSA is a member of the Steering Committee of B-GOOD). Synergies are promoted between |

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mechanisms and interactions, with particular focus on the complicated feedbacks between stressors and the bee responses that define bee colony dynamics. These projects are close to delivery of results. EFSA’s ApisRAM model will be ready in one year from now, and ongoing results from B-GOOD and PoshBee will start to flow between now and 2023. I am happy to see that EFSA’s recommendations are completely in line with the approaches outlined by these EC funded research projects.

| ANSES    | 4 | 2.0. The need for a holistic and integrated approach to the environmental risk assessment for honey bees: general comments |
|----------|---|-------------------------------------------------------------------------------------------------------------------|
| a.       |   | General comment 1: FR: The opinion is an innovative based-approach to what could be done for a multi-stress risk assessment of bees. It well reflects the state of the art and provides a valuable basis on how to improve the risk assessment to take into account multiple stressors. FR understand that some question remain unanswered at this step and that future opinion with the latest development and information would be necessary in order to implement such based-system approach. |
| b.       |   | General comment 2: FR: Extending this system-based approach to other species than honey bees would require the development of extended and harmonized monitoring network. |
|          |   | a. No action needed.                                                                                                                                                           |
|          |   | b. The WG agrees with this comment. There are ongoing initiatives (e.g. EC Pollinator Initiative and Member States’ monitoring schemes) in this field that would need to be considered when extending the approach to other species. |

| BeeLife  | 5 | 2.0. The need for a holistic and integrated approach to the environmental risk assessment for honey bees: general comments |
|----------|---|-------------------------------------------------------------------------------------------------------------------|
|          |   | The chronic impact of stressing factors like pesticides are not yet well covered by the opinion. A little bit more effort could be done in integrating these observations and foster the development of methodologies evaluating the impact of chronic exposure to pesticides. Furthermore, it would be key to integrate more comprehensively the sublethal effects of pesticides on bees and their potential integrations with other stressing factors. Epidemiological studies, integrating may stressing factors can help get a better picture of how fluctuating can be the observations in the field. Apart from that, this is a very good job. Thank you very much! |
|          |   | The modelling is seeking to account for both (chronic/sublethal) and the epidemiological monitoring would provide some answers; this is included in the systems-based approach. We take this into account and acknowledge the importance of such effects |

| CropLife | 6 | 2.0. The need for a holistic and integrated approach to the environmental risk assessment for honey bees: general comments |
|----------|---|-------------------------------------------------------------------------------------------------------------------|
|          |   | Comments on summary: (59-73) The modelling system seems to be selected so that to simulate effects of 1 or 2 chemicals and another stressor. For the approach to |
|          |   | We appreciate the comments made by the stakeholder on the summary & introduction, bringing further |
| Integrated approach to the environment al risk assessment for honey bees: general comments | be actually able to reflect potential monitoring results, the model should be able to simulate the effects of several other stressors together, in the hypothesis of exposure to chemicals is negligible or, as shown in previous monitoring studies, that the chemicals had no visible impact. Such system approach should not be built on the hypothesis that chemicals only have an effect on bees, or it won't be able to reflect part of the monitoring data.

(77-81) Additional data should also be collected on stressors such as pathogens, good resource and quality, habitat or climate so that to reflect the range of stressors that may affect bee health.

(9 -10) The ENVI Committee of EU Parliament requested a focus on the development of a methodology that takes into account multiple stressors including single or multiple chemicals...”. This ENVI mandate states multiple stressors "including" chemicals. Whereas this Opinion only focusses on chemical stressors in combination with other stressors and does not take into account the methodologies for non-chemical stressor combinations which can have a big impact on colony development.

(45-46) Reference again to need for "practical solutions" in the critical area of environmental risk assessment for multiple stressors. However, this analysis (which focusses on PPPs) leaves a big gap that needs addressing i.e., effects from multiple non-PPP stressors.

(82-86) No consideration is given as to how implementable such a Systems Based approach is within the 1107 PPP Regulatory Framework.

(112 -113) A "holistic and Systematic approach" should consider all the potential multiple stressor impacts and not just focus on the PPP interactions.

(124-126) The following statement "It is recommended that the systems-based approach reports relevant information in a manner that gives EU citizens a better understanding of the possible causes clarity, but these sections were not part of the sections to be commented by stakeholders. The summary reflects the content of the opinion in the subsequent sections that were open for commenting by stakeholders. If deemed necessary, EFSA will revise the summary according to the comments received in the other parts of the opinion.

Replies to comments on introduction:

a. The section 1.1 is the background provided by the European Parliament in its mandate to EFSA. We acknowledge that these estimates could be referenced as there are many references available with different figures (e.g. FAO refers to 75% of the world crops producing fruits and seeds that depend on pollinators, including bees; Potts et al. (2015) and IPBES (2016) refer to 84 % of crop species and 78 % of wild flower species depend, at least in part, on animal pollination. Gallai et al. (2009) refer to almost EUR 15 billion of the EU’s annual agricultural output is directly attributed to insect pollinators.
and underlying mechanisms of bee losses in Europe and world-wide." is misleading as it starts from the presumption that bee losses are primarily driven by PPPs in combination with other stressors. The holistic systematic approach being suggested completely misses the impact of non-PPP stressors either alone or in combination. Surely EU citizens deserve a better understanding of all potential causes of bee losses and not just those relating to PPPs and PPP interactions.

Comments on section 1 Introduction:

Section 1.1:

a. (144) "...76% of Europe's food production depend on pollination by bees..." Need to provide a citation. Grains and root crops represent a significant amount of agricultural production but do not rely on bees (other than seed production for root crops). Yields of other crops may be increased by bees, but would still be productive without bees.

Section 1.2.1:

b. (173-175) It should also be pointed out that the risk assessment is only performed for regulated products. There is no risk assessment for other stressors which constitutes a data gap and biases the tool development towards chemicals only.

c. (184-207) The projects mentioned reflect the focus on some stressors such as pesticides (PoshBee, Insignia). It would be useful to also include projects that have been looking at effects of other parameters.

d. (192) Please define 'omics - is this econ-omics, proteon-omics, metabol-omics?

e. (263) Please describe the validation status of the ApisRAM model. The uncertainties associated with the semi-field and field studies are covered in some amount of detail - a similar discussion should be included for models that are being developed. For example, there will be uncertainties with both the underlying datasets used in construction
| Terre d’Abeilles | 7 | 2.0. The need for a holistic and integrated approach to the environmental risk assessment for honey bees: general comments |
|-----------------|---|---------------------------------------------------------------------------------------------------|
|                 |   | The multifactorial approach to assess environmental risks for honey bees, developed in the Must-B program, is interesting and necessary. Complementary to the methodologies of the EFSA guidance document 2013, it seems to us however that the implementation of this system-based approach is not a priority, but a secondary one. Indeed, we ask for the application of the guidelines of the EFSA guidance document 2013, as soon as possible. EFSA and ANSES (European Union Reference Laboratory for Bee Health) have published a set of flagship risk assessment and risk management methodologies that would - if applied - ensure a high level of protection of bees and other pollinating insects against the acute, chronic, lethal and sublethal effects of pesticides. This is the | The comments and suggestions made by the stakeholders are relevant to the Guidance Document that is currently under revision by EFSA/Pesticides. Please raise this comment to the public consultation of the Bee GD. |

The model as well as with the assumptions and algorithms within the model.

f. (263-277) All citations for the ALMASS model are results of a single work group at Arhus University. We would expect if this model system is extensively used in pesticide risk assessment that also other Universities or research groups would have started to work with ALMASS in the past 17 years. In contrast the BEEHAVE model was picked up in the last 6 years by more than 9 research institutes, CROs or Universities (see line 922-934) in 6 countries. We can provide the reference citations on request.

Section 1.3:
g. (365-383) The ToR make clear the holistic character of the system approach to be developed and the role of all factors. This should be referred to and followed in developing the tools entering in the system approach later on. In particular in the later paragraphs where risk assessment is mentioned, it should be clarify that in relation to the interpretation of monitoring data, and their role in the system approach this refers to prospective risk assessment of the factors combined that happen to be involved in an observed effect.

international experts belonging to a variety of stakeholders (beekeepers, risk assessors, risk managers, scientists) & extensive literature reviews is planned in the near future.

f. ALMASS team is about 30 people from 11 countries. ALMASS team is a multi-country effort; see SESS/Aarhus website: https://projects.au.dk/sess/team-and-partners/
For examples of recent outputs see: https://doi.org/10.1016/j.scitotenv.2021.145746

g. In the terms of reference provided in the mandate of the European Parliament (see section 1.1), the focus is primarily on PPPs (in combination with other stressors).
2013 guidance document published by EFSA and the referral published by ANSES on 5 February 2019.
https://www.anses.fr/fr/content/protection-des-abeilles-
%E2%80%99anses-%C3%A9met-des-recommandationsafin-de-
renforcer-le-cadre

We consider the implementation of these methodologies to be of paramount importance. We categorically oppose a revision of the guidance document 2013 that would guarantee a lower level of protection for bees and other pollinators.

To ensure that their products comply with these new regulatory requirements, agrochemical companies must submit them to the corresponding tests. However, some evaluation tests likely to meet the standards recommended in the EFSA guidance document 2013 do not currently exist.

This is why, to get out of this impasse, we recommend duplicating, at the community level, the French pesticide/bee risk assessment tool, entitled "Groupe Méthodes Abeilles". Placed by the French Ministry of Agriculture under the aegis of the Commission des Essais Biologiques, this working group, set up in 2004, is responsible for defining, developing and drafting relevant test protocols for risk assessment, complementary to those already existing. Tests to identify all the deleterious effects of pesticides on bees and other pollinating insects: acute, chronic, lethal, sublethal, behavioural disorders...

Composition of the "Groupe Méthodes Abeilles":
Beekeeper(s)/apidologist(s) - Ecotoxicologists, from public and independent laboratories and firms - Test providers - Representative(s) of the Ministry of Agriculture and technical institutes - Representative(s) of ANSES

The experience of the French "Groupe Méthodes Abeilles" has shown the relevance and effectiveness of these risk assessment tests as they become available.

We request the support of EFSA for the following recommendations:
1/ To constitute, within the European Union, new "Bee Methods" groups, duplicated on the French model, in order to share the burden of elaborating the test protocols missing from the arsenal of risk assessment, according to the EFSA's 2013 guide-document, is one of our major recommendations to guarantee a high level of protection for bees and other pollinators.

2/ Submitting the new tests to inter-laboratory ring tests, which are mandatory before validation by the OECD, is the next phase. We propose that the financing of the ring-tests be taken in charge by the firms. The financing of these ring-tests should not be at the expense of the beekeeping sector.

| ANSES | 8 | 2.1. Environmental risk assessment of PPPs |
|-------|---|------------------------------------------|
|       |   | [2.1/p16/439+444] FR: The regulation is reported as "Regulation (EC) No 1107/2009" instead of Regulation (EC) No 1107/2009. | Amended |
### CropLife

| 9 | 2.1. Environmental risk assessment of PPPs |
|---|------------------------------------------|
|   | "Of all the areas in EFSA’s remit that could contribute to the EU Green Deal, advancing the environmental risk assessment of PPPs is expected to have the highest possible impact." Suggest adding rationale why this determination has been made a priori to the full analysis of multiple stressors. Multi-stressor analysis is very complex - all potential stressors should be listed, and a rationale given for ranking them in terms of potential importance at this point in the analysis. |

We respond first to the concern of a possible bias in the assessment towards PPPs. The European Parliament asked EFSA to deliver an opinion on the science behind the development of an integrated and holistic approach for the risk assessment of multiple stressors in managed honey bees. The terms of reference have specifically asked for methodology to account for the impact of multiple stressors, including plant protection products (PPPs), on colony health.

In response to the comment regarding the Green Deal, we note that there are multiple actions/measures proposed. However, the action/measure most closely aligned to EFSA’s remit relates to PPPs, specifically a "significant reduction in the use and risk of chemical pesticides by encouraging innovation for the development of safe and sustainable alternatives".

### National Farmers’ Union

| 10 | 2.1. Environmental risk assessment of PPPs |
|----|------------------------------------------|
|    | Line 475/476 - 'Of all the areas in EFSA’s remit that could contribute to the EU Green Deal, advancing the environmental risk assessment of PPPs is expected to have the highest possible impact'. This sentence, relatively near the beginning of this draft consultation, which is supposed to be assessing MULTIPLE stressors, makes clear there is a |

See reply provided to comment 9.
| | strong bias towards thinking that the main cause of honey bee health problems is PPPs. This does not help create a sense of stakeholder trust in this being an open and transparent process. |
| BeeSafe - Bee Health Consulting for Agriculture and Veterinary Medicine | 11 | 2.2.1. Overview | a. lines 492-497: It has to be considered also that beekeepers use multiple substances that may interfere with PPPs or are the same (tau-fluvalinate). The practices vary widely between different EU MS. If these substances are used both in agriculture and beekeeping, this has to be documented, at least.  

b. Lines 498-500: Beekeepers use synthetic acaricides often in illegal applications (homemade strips).  
c. Lines 507-509: The overwintering period is crucial for seeing the outcomes of chronic effects at the colony level. This is a bottleneck for honey bee colony survival. Small, statistically non-significant differences in autumn may lead to colony losses in winter. This may be true also for other bottlenecks in survival, like broodless periods in the hot summer months in Southern Europe.  
d. Lines 529-530: pre-existing conditions may not show clearly at a single assessment. There are several carry-over effects of pollen scarcity (Requier et al. 2016), for instance, that influence the colony development long-term.  

a. Agreed and amended with two new references: Lozano et al., 2019; Mullin et al., 2010.  
b. “Veterinary products” was added in this section (see reply to comment 11a).  
c. We thank the stakeholder for this good remark. The example provided was just illustrative with the choice of the active season to illustrate potential chronic effects on foragers and brood. We agree that the winter season is another season to consider to illustrate chronic effects and this was already shown on Figure 2 when illustrating the context of multiple stressors impacting the colony dynamics in space and time.  
d. Agreed and amended. |
Public consultation on systems-based approach for ERA applied to honey bees

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EFSA Supporting publication 2021 EN-6608

| CropLife | 12 | 2.2.1. Overview |
|----------|----|----------------|
| a. (488) Suggest using "accuracy" rather than "efficiency"? Isn't the primary goal to be accurate (rather than save time and other resources)? |
| b. (492) "The risk assessment... Does not take into account... Potential combined effects..." This is a critical gap in the modeling and systems approach being discussed but no methods are proposed to fill the gap. |
| c. (493) While it is correct that for a registration of an active substance that said active substance is in the focus of the EU evaluation. However, there are multiple examples when the representative formulation, which is also reviewed in the EU process is composed of different active substances with different modes of actions that will be assessed as part of the review process. Furthermore, during the registration of the formulated products data on formulations with multiple active substance are reviewed. Currently there is only limited evidence of synergistic interactions between different active substances, many of them relating to a combination of certain insecticidal and fungicidal modes of actions. Synergism of plant protection products is a rare case in ecotoxicological testing. Nevertheless, there are some examples in the literature describing situations where concentration addition is not able to explain the increase in toxicity (e.g. Pilling & Jepson 1993; Johnson et al. 2013, Thompson et al. 2014, Werneck et al. 2019). However, according to current empirical evidence, joint actions of active substance that indicate clear synergistic effects, are obviously exceptional situations and not at all the rule (cited from Frische et al. 2014 with reference to Altenburger et al. 2012; Kortenkamp et al. 2009). |
| d. Agree and amended. |
| e. Tosi et al (2018) shows a spatial and temporal trend of pesticide contamination and risk. This assessment was performed over the...
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Frische T., Matezki S., Wogram J. 2014: Environmental risk assessment of pesticide mixtures under regulation 1107/2009/EC: a regulatory review by the German Federal Environment Agency (UBA). J. Verbr. Lebensm. DOI

Johnson RM, Dahlgren L, Siegfried BD, Ellis MD (2013). Acaricide, Fungicide and Drug Interactions in Honey Bees (Apis mellifera). PLoS ONE 8(1)

Kortenkamp A, Faust M, Backhaus T (2009) State of the Art Report on Mixture toxicity. Report to the EU-Commission (Study Contract Number: 070307/2007/485103/ETU/D.1)

Pilling, E.D. and Jepson, P.C. (1993). Synergism between EBI fungicides and a pyrethroid insecticide in the honeybee (Apis mellifera). Pestic. Sci., 39: 293-297.

Thompson, H.M., Fryday, S.L., Harkin, S. et al. (2014). Potential impacts of synergism in honeybees (Apis mellifera) of exposure to neonicotinoids and sprayed fungicides in crops. Apidologie 45, 545–553.

Werneck, A., Frommberger, M., Forster, R. et al. (2019). Lethal effects of various tank mixtures including insecticides, fungicides and fertilizers on honey bees under laboratory, semi-field and field conditions. J Consum Prot Food Saf 14, 239–249.

d. (498) Suggest adding habitat, weather, and climate to this list.

e. (501-509) The publication by Tosi et al (2018) presents data on a total number of 18 active substances (out of 66 covered by the analytical method) which have been detected in pollen baskets collected from hives in Italy between March/April and September 2012 to 2014. In addition to the frequency of detections and maximum residue levels, which the focus by Tosi et al. and which were quite different for the different compounds detected, also the range of levels need to be considered (not only the maximum). These seem to be quite low for the majority of detections (looking at mean and especially median values). When comparing the reported maximum values for the fungicides, which would most likely also be applied during flowering, with the levels that are reported by Kyriakopoulou et al. (2017, EFSA Supporting publication 2017:EN-1303) where industry whole beekeeping season in 3 subsequent years, in a nation-wide monitoring survey. In that study, Figure 2 shows that, for example, specific locations are consistently exposed to multiple pesticides, which also lead to relatively high risk, over time. Thus, we report in the Opinion that "bees and their colonies can be continuously exposed to chemicals throughout the beekeeping season (Tosi et al., 2018)".

f. This is a valid point but is beyond the scope of this opinion (which is presenting ideas for further consideration and investigation). This specific point is currently being addressed under the revision of the Guidance Document by EFSA/Pesticides.

g. This aspect is beyond the scope of this opinion that is dealing with honey bees (not with native pollinators, nor on competition with those bees).

h. The systems-based approach seeks to resolve this issue using data that is available (from lab/field) and implemented in the model (i.e. translated from individual to colony level effects).
residue studies were reviewed, the values reported in Tosi et al. seem to indicate much lower exposure. The data by Tosi et al. indicate that dilution plays an important role under realistic field conditions which is not the case in the industry studies where a worst case scenario was followed that allowed no dilution.

Continuation of section 2.2.1:
f. (501-509) The 10 day toxicity study according to OECD 245 is a highly standardised study design which has been validated in a thorough ring-testing exercise. Keeping short-lived summer bees in such artificial conditions for a longer period of time increases the risk of "cage effects" and potentially mistaking substance effects with effects of natural senescence. Such ageing effects were most likely also occurring in the study by Simon-Delso et al 2018, where a laboratory study was conducted exposing bees over 30 days to constant high concentrations of a formulated product (not active substance) which even at the lowest rate were far above maximally observed residue levels for the active substance in bee matrices.

g. (529) One thing missing from this section is the potential effect of managed honeybee foragers coming from "white box colonies" competing for resources (pollen/nectar) with native pollinators along with possibly being a source of diseases or parasites.

h. (512-515) Sublethal/behavioral effects are also check for, in a qualitative way, in standard regulatory studies. It is quite difficult though to do this in a quantitative way which is why there are many creative approaches available to address this topic, as also presented in lines 643-654 of this document. It still remains questionable, if the effects observed in such studies really translate into a field environment and if the exposure levels chosen to elicit an effect are at all field realistic/would have also been detected in the standard studies necessary for registration at the same dose levels.

i. (510-511, 518-523) The key question is not whether the selected species is more sensitive than all others but rather whether the outcome of the risk assessment is protective of the wider range of
species whilst allowing differentiation between uses of low risk and those requiring further refinement (and methodology to enable this to be reliably and reproducibly undertaken). Honeybee tier 1 contact risk assessment has been demonstrated as protective of other bee species across EFSA, USEPA and EPPO schemes; the generation of toxicity data for additional bee species shows no additional benefit over the use of the honeybee data in the tier 1 risk assessments (which include worst-case exposure estimates) for insecticides (Thompson and Pamminger 2019 DOI 10.1002/ps.5494)

j. (598-500) The risk assessments of regulated chemical products need to be conducted in the context of both “one Substance” and multiple stressors such as non-regulated chemicals, biological agents and beekeeping 500 management practices, this to be suitable for decision making relative to the substance and additional considerations, which do not fall in the remit of product approval, for multiple stressors that requires risk management.

k. (510-511) 4) There is a requirement for evidence regarding species-specific traits in relation to chemical toxicity and sensitivity to other stressors, in particular for surrogate species used to cover all untested species.
### 2.2.1. Overview

**a. Line 486** - The draft Scientific Opinion repeatedly refers to there being declines in honey bees. To defend this position there is often reference to overwintering losses of honeybees, which have reached concerning levels. However, the fact is the latest data (https://ec.europa.eu/info/sites/info/files/food-farming-fisheries/animals_and_animal_products/documents/market-presentation-honey_autumn2020_en.pdf) shows there are over 18 million honey bee hives in the EU, and this number has been steadily increasing for at least the last 15 years. How does this represent a decline in honey bees? Please can EFSA state all the available evidence regarding numbers of bees and declines, and not just the evidence that supports the populist view of 'Insectageddon'.

**b. Lines 489-491** - There are other fundamental key issues related to bee health risk assessment of multiple chemicals and stressors that need to be addressed that are not mentioned here. These include:
- Recovery: once exposure of honey bees stops, to what extent do they recover?
- Exposure: there remains relatively little residue data demonstrating the actual extent to which honey bees are exposed in real-world scenarios.
- Extent to which honey bees forage in treated crops: again there is a lack of understanding about the extent to which honey bees are foraging within treated crops and in turn the extent of exposure.

c. There is extensive evidence and data available about the toxic effects of various chemical stressors, but this data fails to inform policy makers about the environmentally relevant doses or the impacts at the population level.

d. If this process is to be successful in taking a true systems-based approach to the environmental risk assessment of multiple stressors in honey bees, it must move beyond the toxicology, which is relatively well understood, and gain a much better understanding of the ecology involved.

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**National Farmers' Union**

**13**

**2.2.1. Overview**

**a.** This total number of colonies in Europe must be clearly defined, since it groups together colonies of very different nature:
- i) colonies of normal size and producing honey
- ii) weak colonies (insufficient population size), and therefore not producing honey. This reduction in their size may be, for example the consequence of pathology or intoxication by pesticides
- iii) sparsely populated (and unproductive) colonies resulting from the division of a strong colony by a beekeeper, with a double objective: a) to obtain a new colony to replace a dead colony, b) to increase the number of its productive hives to compensate for the decrease in the quantities of honey per hive, in order to obtain the same quantity of honey collected previously.

Honey production is a key part of bee rearing, which allows the beekeeper activity to be maintained, as is the case for all other categories of breeders. This is why this point should be taken into account when counting bee colonies in Europe (see also comment 34).

Beekeepers can restock their apiaries, especially when experiencing colony losses. The restocking of colonies does not imply that the honey bee population is
|   |   | e. Lines 498-500 - This ‘multiple stressor’ approach still comes across as heavily biased against chemicals. Where will it factor in habitat loss, the impact of poor bee nutrition, honey bee pests, viruses and other diseases, attacks by invasive species, as well as environmental changes caused by changes in weather patterns and climate? It must be made clear where these stressors are factored into this process. Otherwise how can this be considered a genuine systems-based approach to assessing multiple stressors? | healthy. Instead, there is a current honey production crisis, and productive honey bee colonies are decreasing. In general, also, there is an agreement of the colony health decline. This was clarified in multiple parts of the opinion. |
| b. We agree that more data on the recovery (and resilience) of the colonies, exposure, and toxicity of pesticides are needed. We have amended the text accordingly (see new bullet point No 10) |   |   |
| c. We agree that a more efficient communication with policy makers about the environmentally relevant levels and the impacts on honey bees would be valuable. However, it is not under the scope of this chapter that is focused on the description of the scientific issues related to bee health risk assessment. |   |   |
| d. We agree that more data on both ecology and toxicology (for interactions between stressors) is needed. |   |   |
| e. The systems-based approach will assess the effects of PPPs in combination with other factors/stressors such as those listed by the National Farmer’s Union. It |   |   |
will also be possible to assess those factors independently or in interactions.
| RIFCON GmbH | 14 | 2.2.1. Overview | Overall, in this section we intend to present the challenges relating to bee health risk assessment of multiple chemicals and stressors that need to be addressed. |
|-------------|----|----------------|-----------------------------------------------------------------------------------------------------------------------------------|
|             |    | Point 1: agree | Point 1. No action required                                                                                                     |
|             |    | Point 2: agree, but it is regarded very difficult for beekeeping management practices as this cannot be standardised.           |
|             |    | Point 3: agree; but a longer worst-case exposure period of a chemical/formulation by more than 10 days is very unlikely; a 10-day exposure period with respect to the function (i.e. life span) of a worker bee as a forager bee during the honey flow period seems to be sufficiently worst-case. |
|             |    | Point 4: like for all other areas of ecotoxicology the use of representative species should cover main taxa/guilds. Surrogate species can never cover all untested species as each species is unique with its own life history, ecology (habitat requirements), distribution etc.; for bees in Europe this would mean to cover about 2000 solitary bees! |
|             |    | Point 5: very difficult to cover as bees show a high plasticity regarding behaviour and how should these look like on the colony level? We regard this possible for only a few categories (e.g. bees which display a moribund behaviour); How to setup a model if a lack of knowledge exists? |
|             |    | Point 7: regarded as almost impossible to assess |
|             |    | Point 8: agree, but taking into account the enormous diversity of landscapes throughout Europe and the use by man (incl. PPP) it is regarded difficult to derive concrete scenarios from this |
|             |    | Point 3. Honey bees are exposed to pesticides beyond 10 days through multiple exposure modes, inside or outside the hive – see Tosi et al. 2018 & Tosi et al. in revision in Comm Biol. (added). |
|             |    | Point 4. We agreed and this was recently highlighted in the literature (Topping et al., 2021). We amended the section. |
|             |    | Point 5. We agree with the difficulties. Nevertheless, some sublethal effects like the homing failure, has rather obvious link to the colony. The feedback to the colony |
| ANSES | 15 | 2.2.2. Current challenges to honey bee health risk assessment | The co-exposure of honeybee colonies with multiple PPP is the result of the complexity of landscapes, but also of the succession of crops on the same plot, taking into account the persistence of PPP in the environment. With the complexity of landscape implies to consider the mobility of PPP in the environment, especially by surface water. Also, American foulbrood (AFB) is not mentioned in the list of biological agents. |
| | | | Co-occurrence/exposure of PPPs is first mentioned under 2.1 and therefore this point was added in this section. However, we would like to remind that co-exposure is not only linked to the complexity of the landscape, but also to the foraging range of the bees (and therefore covering a large area) and also from accumulation in bee matrices (pollen/beebread, nectar/honey and wax). |
| CIBE  | 16 | 2.2.2. Current challenges to honey bee health risk assessment | a. The statement on page 22 (lines 688 to 692) "PPPs can contaminate the air (i.e. through spray treatments or dust emissions caused by seed treatments), the food (i.e. nectar, honeydew, pollen, water), and other materials (i.e. resin, guttation water, water collected for thermoregulation purposes) to which bees are exposed in the environment, as well as within their nest (i.e. wax, propolis, honey, beebread)." is in our view misleading, as it puts dust emissions caused by seed treatments on a par with spray treatments. Dust emissions are not caused by seed treatments per se, but by the sowing/drilling/seeding of treated seed. This ignores the fact that dust emissions by sowing/drilling/seeding of treated seed are in good agricultural practice kept to a minimum by using appropriate sowing equipment (mechanical seeders or pneumatic seeders with dust deflectors).

b. Similarly, no account is taken of the fact that guttation water is not equally relevant to all arable crops. For example, sugar beet is a low guttation crop with few and small droplets, and then only at high humidity level (>90%); due to this comparative rareness of crop guttation in sugar beet, exposure to residues of plant protection product active substances from guttation seems to be unlikely because guttation droplets from sugar beet are very unlikely to serve as a preferred source for water foraging insects (including bees). | AFB and EFB were added to the list of biological agents.

a. Agreed and amended: for simplicity, i.e. to remain short and concise "dust emissions caused by seed treatments" was removed from the examples.

b. Agreed and amended. |
| --- | --- | --- | --- |
| CropLife | 17 | 2.2.2. Current challenges to honey bee health risk assessment | Section 2.2.2:

a. (566-569) This section only mentions crops - but the "complexity of landscapes" includes more than just crops but also field edges, roadside areas, unplantable areas (ditchbanks, streambanks), urban/suburban lands, etc. If the "complexity" is limited to just crops then the assessment will be incomplete and likely misleading.

Section 2.2.2.1:

b. (Figure 2) We believe that there needs to be a clear understanding that the average colony requires a lot of care by the beekeeper in a. Agreed and amended

b. Agreed and amended in the legend of Figure 2; the text accompanying the Figure is about the mechanisms of looping effects within the colony – not about the description of the different possible colony size per se).

c. There are many factors influencing egg-laying and the |
order to develop as shown in Fig. 2 A. Without e.g. a proper Varroa control and treatment there will not be a lot of a colony left. Please consider adding an overview of best management practices which will be necessary for an "average" colony development.

c. (583) Suggest also including weather and seasonality in the list of factors that will affect egg laying.

d. (629) While the neonicotinoid pesticides is one example of potential effects that might occur under certain circumstances. Suggest that for the sake of completeness, other examples also be provided. Drought, restricted food sources, weather (hot or cold or periods of rain), disease/parasites, can also affect hive function and should be a part of this discussion.

e. (650) While the pesticide examples are important, other factors should also be listed that might have sublethal effects on colony health. Drought, restricted food sources, weather (hot or cold or periods of rain), disease/parasites, can also affect hive function and should be a part of this discussion.

f. (687) Unclear how "[the process of] seed dressing" "granules" or "soil drenching" are significant sources of exposure.

The purpose of this section is not to describe exhaustively the factors influencing egg-laying (that are largely described under the HEALTHY-B opinion that is used in this opinion).

d. We added an example with Varroa and a reference and made a slight editorial change to clarify that the example provided is just one example among many others (as correctly highlighted by the stakeholder).

e. We acknowledge the importance of other factors as mentioned by CropLife, while also recognizing that sublethal effects are mostly studied in the area of chemicals/neonicotinoids. We amended the text and added new references (Thompson, 2012 & ANSES, 2015) to reflect on this.

f. There is a significant exposure from these processes because of the systemic property of the pesticides that is taken up from the roots and dispersed all through the tissue of the plants including pollen/nectar.

a. We are not saying that the honey bees are "special". Under 2.2.2, we highlight the complexity of the honey bees, including their relation to the landscape. Each of these have
### National Farmers' Union

2.2.2. **Current challenges to honey bee health risk assessment**

|   |   |   |
|---|---|---|
| 19 | a. **Lines 566-569** - There is more to landscapes than just agricultural land, and these other landscape types need to be factored in. | a. **Agreed and amended.** In addition, more information is provided on landscape characteristics in section 2.2.2.2. |
|   | b. **Lines 583-584** - Egg laying and brood survival will also be affected by weather, temperature and other factors which need to be considered here. | b. **This was already factored in with the sentence “the dynamics of honey bee colonies is influenced by a range of factors”.** However, it is further clarified in the paragraph. |
|   | c. **Lines 628-629** - 'Stressors that do not lead to direct mortality of individual bees can still substantially and adversely affect colony health' - the ONLY example given here is neonicotinoid pesticides. Again, this biased approach, given no other examples, does not fill stakeholders with confidence that this is a true 'multiple stressor' approach. The toxicology of many chemicals is already well understood - but the purpose of this work is to surely elevate the science and evidence beyond that to better understand the real-life ecology and environmental relevance of these factors in terms of impacts at the population level. | c. **Another example taken from bee biological agents was added with a reference.** |
|   | d. **Line 783** - Again, there is more to the landscape than cropped areas. This needs to consider non-cropped areas and non-agricultural land. | d. **Agreed and amended.** |

### RIFCON GmbH

2.2.2. **Current challenges to honey bee health risk assessment**

|   |   |   |
|---|---|---|
| 20 | a. Fully agree, but what does this (i.e. 80 km² foraging area) mean in practice? Farmers should organise their spray activities because of multiple stressor (mixed tox)? How should this be transferred in field studies? | a. **This paragraph describes the current challenges, which are then specifically addressed in the following parts of the opinion.** This specific statement related to honey bee biology that highlights the |
|   | **Chapter 2.2.2.1. The complexity of a honey bee colony** |   |
### From individuals to colony effects

b. As a key driver the infestation level of a colony with Varroa has been several times proved to be the key factor for winter colony losses. And already in 2004 GENERSCHE has shown that viruses are not a relevant factor when a colony dies. Honey bee colonies have evolved over the past several 10 000 years to very flexible super organisms where the loss of forager bees due to e.g. sudden weather changes etc. can be compensated by flexible and adaptive changes within a colony. The described problem of chilling and thus death of a colony has been shown to be a problem if the level of Varroa infestation it too high and/or the size of the colony before hibernation. If a colony is too small (e.g. below approx. 5000 bees) or too many bees die during winter (approx. 30% of a decrease of the colony strength is very normal) a sufficient thermoregulation is not possible any more and the probability of a colony loss is increased. So, in our opinion colony loss due to “chilling” is not regarded as a PPP related topic.

c. Importance of sublethal effects for bee colony health

Although there are several studies which describe several effects caused by PPP in the lab or under lab-like conditions, there is no proof or an observation in field studies or monitorings that such effects would really lead to increased colony losses.

d. Line 674: What about costs of such experiments? If realistic measurements are available, what is the benefit of modelling, which will generate additional costs.

e. Multiple routes of exposures to chemicals

Regarding the exposure routes, we think that it would be useful to distinguish major exposure routes and less important (negligible) routes as the level of exposure is low(er) or less significant (see outcome of the EPA exposure workshop in January 2017).

f. The genetic diversity of honey bees

Subspecies and a considerable number of colonies would need to be tested: In combination with more realistic experiments (Line 674, complexity of assessing risks for honey bees. This is the reason why a novel approach using experimental studies, monitoring, and modelling is suggested.

b. We amended the opinion, that now reports

“A hypothetical and explanatory scenario was made to describe the possible complex mechanisms from the individual to colony level behind such mortalities (Figure 2). The example used the context of exposure to multiple stressors and included a failure in thermoregulation (Figure 2).” This is an example on a possible way for multiple stressors interaction within a superorganism system. This paragraph aims at underlining that colony loss is not caused by “chilling” alone, instead there is a complex interaction among different factors that can lead to the loss of the colony.

c. Sublethal effects from a chemical has the potential to increase risk to the health of an organism. There are three reasons for considering sublethal effects in the current work: (1) this opinion aims to protect honey bee health, (2) the term of reference specifically require the assessment of sublethal effects, and (3) regulation 1109/2009
| Comment | Section | Details |
|---------|---------|---------|
| | Chapter 2.2.2.2 | The complexity of the environment of a honey bee colony |
| | g. | Line 756ff: landscape structure is a complex confounding variable. Agree, but landscape structure is not fixed. Crop rotations can change, structure can change because of sealing of land etc. How to implement it in the risk assessment? Keyword: Scenarios. Does this aspect have an influence on "Tier 1" landscapes. |
| | h. | Line 784ff: Climate and weather are crucial parameters...: Substances will usually register for 10 years. What about climate effects? |
| | i. | Line 748 – 816: We all know that it is a complex systems and stressors and their combinations are almost infinite. The aim of the risk assessment cannot be to check all stressor combinations. |
| | j. | List of biological agents: Vespa velutina is an insect predator but their prey on honey bee colonies strongly depends on the regions. Additionally, especially weak honey bee colonies might be predated by V. velutina whereas strong ones not; moreover, V. velutina is frequently distributed in Southern countries (Portugal, Spain, parts of France) but rarely occurs in Central Europe. We think that it is commonly agreed, that the influence of the beekeepers activity has the greatest influence on the colony health and thus on the survival of the colonies. Additionally, there is no common understanding what "good beekeeping practice" means. In fact beekeeping does not base on fixed methods and actions but can vary very much. And due to the plasticity of the colonies, they can compensate less optimal actions (see above). |
| | f. | These are considerations that will need further thoughts when considering the application of the approach (see new last recommendation added in the opinion). |
| | g. | The details of this would be part of a future risk assessment scheme yet to be worked out. However, the concept is likely to build on the use of multiple landscapes for |
| CropLife | 21 | 2.2.2.2. the complexity of the environment | a. (773) "...given the variability of both climate and land use..." suggest also including weather which is better connected with short-term variability than "climate." |
|----------|----|--------------------------------------------|----------------------------------------------------------------------------------|
|          |    | a. Agreed and amended.                     | a. Agreed and amended.                                                             |

h. In the opinion, the impact of climate (and weather) was mentioned on several occasions but more explicitly right from section 2.2.1 on the overview of the environmental risk assessment (under issue 2) by adding the new sentence “and potentially impacted by habitat, weather and climate”.

i. We agree. The modelling approach would indicate the most critical combinations influencing the population dynamics and to include in the risk assessment.

j. Regarding the impact of V. velutina on honey bees, we agree it is variable (it also depends on the defensive strategies and subspecies type), but the objective of this section is to list the main biological agents, not the impacts. Regarding the importance of the beekeeper, we acknowledge that this is very important. Under figure 2 (legend), for the maintenance of a good colony size to fight properly stressors, we added the sentence “good beekeeping practices”.

...given the variability of both climate and land use... suggest also including weather which is better connected with short-term variability than "climate."
Public consultation on systems-based approach for ERA applied to honey bees

|   | of a honey bee |
|---|---------------|
| b. | (778) Suggest defining biodiversity as "native pollinator biodiversity" - don't want this "biodiversity" to be confused with the honeybee subspecies diversity discussed above. |
| c. | (783) Since this section is discussing the broader landscape, I would expand "field and crops" to also include "non-crop areas". |
| d. | (793-796) There has to be a lot of research on Varroa since 2008 which is worth considering in when addressing such an important stressors for honey bee colonies. For example Wegener et al (2016) showed a clear correlation between mite fall in summer/autumn and colony collapse in winter. So regardless of the interactions between mites and viruses, the level of mite infestation is an important indicator for colony survival and much easier to detect than virus prevalence. Furthermore the feeding behavior of the mites is now better understood (Ramsay et al. 2019). Apparently Varroa feeds on the fat body of honey bees, "a tissue integral to proper immune function, pesticide detoxification, overwinter survival, and several other essential processes in healthy bees". |
| e. | (815) Suggest adding non-crop land-use to the list of "stressors of anthropogenic origin" - building houses, roads, or even manicured parklands, etc. will also be stressful. In addition, certain types of suburban or industrial land uses can affect the level and types of... |

J. Wegener, H. Ruhnke, K. Scheller, S. Mispagel, U. Knollmann, G. Kamp, K. Bienefeld, Pathogenesis of varroosis at the level of the honey bee (Apis mellifera) colony, Journal of Insect Physiology, Volumes 91–92, 2016, Pages 1-9, https://doi.org/10.1016/j.jinsphys.2016.06.004.

Ramsey, S. D.; Ochoa, R.; Bauchan, G.; Gulbronson, C.; Mowery, J. D.; Cohen, A.; Lim, D.; Joklik, J.; Cicero, J. M.; Ellis, J. D.; Hawthorne, D. & vanEngelsdorp, D. Varroa destructor feeds primarily on honey bee fat body tissue and not hemolymph Proceedings of the National Academy of Sciences, National Academy of Sciences, 2019, 116, 1792-1801, DOI 10.1073/pnas.1818371116

e. Agree and amended.

d. Thank you for these interesting references, but the purpose of this paragraph is to introduce the biological agents (macroparasites) present in honey colonies and this is why we used the reference of OIE.

e. Under "other stressors", we just added some examples. We did not intend to be exhaustive.
| Name: BeeSafe - Bee Health Consulting for Agriculture and Veterinary Medicine | 22 | 3.0. A systems-based approach of multiple stressors in honey bee colonies: general comments | a. Considering that this scientific opinion goes for a systems-based approach and also discusses the complexity of the superorganism honey bee colony, this isn't reflected in the proposed methods. In addition to the “snapshots” of the assessments, the overall temporal development and the most important bottlenecks for this development aren't considered. Overwintering, for instance, is one of these bottlenecks, as well as an estivation phase in the hottest regions in Southern member states.  
   b. In addition, the methods partly lack practicability or, in case of colony strength, even mean a severe disturbance and risk for the colonies (see more detailed comments in section 3.2.2) | a. Figure 3 provides an overview. The concept is to model the full life cycle of the colony (not only the active season but also winter). The systems-based approach relies on a monitoring and modelling system that are placed across different EU regions. The monitoring frequency can cover winter and the model can assess data from this period as data from the active season, under different climates and regions in EU.  
   b. see answer to detailed comments in section 3.2.2. |
| --- | --- | --- | --- | --- |
| Name: Medrzycki Piotr | 23 | 3.0. A systems-based approach of multiple stressors in honey bee colonies: general comments | The idea of modelling the development of an organism (e.g. a honey bee colony) is a good idea. If we had a reliable model, we could feed it with all the possible input data, both those related to the organism’s status and those related to the external conditions. The model would then forecast the development of the organism. If then the real development showed to be different (reduced) compared to the one proposed by the model, this would mean that an unpredicted external factor (e.g. pesticide exposure) intervened and impacted negatively the development. A precisely working model could also predict the effects of any external factor (like pesticide exposure) on the organism’s life. Unfortunately, this approach cannot work in case of a honey bee colony as a model organism. It would be theoretically possible if it was possible to assess all the external and internal input data with a sufficient precision. Nevertheless, it is impossible to assess neither of the two groups because:  
   1. The assessment of the external data in a precise and complete way means the precise sampling of the area of at least 1,000 hectares around the hive, i.e. the range of interest of one honey bee colony (but probably this range would not be sufficient). Sampled data are | It is correct to say that modelling a honey bee colony with all the complexity of its dynamics, its environment and its response to the different stressors is challenging. However, there have been substantial progress made from different areas (modelling/data collection) and each of these is contributing to the current proposal. Higher tier testing to collect the appropriate data for risk assessment is also challenging given the complexity of the measurements and the variability and underlying uncertainties. Therefore, further developments are needed. However, the systems-based approach relies also on more robust |
intended as: food availability (quantity and quality separately per each plot characterised by its distance and direction from the hive); potential sources of pathogens and predators; sources of pollution; weather, mainly temperature and insolation, not only at the hive site, but on each plot where food availability was defined; all the other parameters of this area around the hive. The difference between a free-flying honey bee colony and a caged guinea pig, for this aspect, lays in the different extension of the area of activity (hundreds of hectares vs a few square cm) and the homogeneity of this area.  
2. Similarly, it is almost impossible to sample the entire colony with all its components, including not only the dimension of each age cohort of the adult bees and brood, but also the quantity and quality of the stored pollen and honey (including nutritional quality, residues etc), the pathogens etc. And it seems that in case of a honey bee colony the butterfly effect plays an important role: negligible differences in stored provisions may play a crucial role in the forager recruitment and, during long time, in the hive destiny. In the same way, differences in external factors like temperature (in different points of the territory around) food availability and distance from the hive, may play a very important role in defining the food collection, flight intensity and thus the hive destiny.  
One of the most important parameters necessary in order to elaborate the colony development is the caloric balance. This depends both on the external temperature, colony parameters (strength, stores etc) but also on the hive structure, i.e. mainly the thermal features of the material the hive components are made of. I haven't seen this parameter to be considered in the proposal. Summarising, I consider impossible any calculation of the colony conditions and external factors with a precision level sufficiently high to avoid the butterfly effect. Thus, I think that the ambition to build a working model of a honey bee colony, characterised by enough reliability to make it usable in ecotoxicology, cannot be satisfied and therefore in my opinion this approach has no future. I think that the only valid alternative to this approach is the adoption of the higher tier tests proposed by EFSA in the "Guidance on the risk assessment of plant protection products on bees" (EFSA, 2013). It is obvious that this data coming from lab testing (and eventually some specific field tests such as homing behaviour).
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| ANSES | 24 | 3.1. A proposed systems-based approach | a. [3.1/p26/862-872]: FR: The chemical residue data in pollen should come with palynological data, that would allow to link the contamination of pollen samples by PPP with the agricultural resources foraged by honeybees, and finally with PPP uses behind the contamination.  

b. [3.1/p26/873-878]: FR: Landscape data should include the localization of farms around beehives to assess the exposure of honeybee’s colonies by veterinary product. Pastures, receiving cattle faeces contaminated with antiparasitic products, should be known. | a. Agreed and amended. This is a requirement that MUST-B asked for when conducting the field data collection for the calibration of ApisRAM (Dupont et al., 2021) and this was also clarified in the sentence.  
b. This was clarified in the text. |
| --- | --- | --- | --- | --- |
| CIBE | 25 | 3.1. A proposed systems-based approach | Lines 848 to 852 on page 25 indicate that the modelling component, which is constructed based on a fundamental understanding of the science base of the organism in its environment, “includes estimating the landscape-specific use of agrochemical-treated crops by foragers, which depends on the dispersion and richness of flowers in the region, and of the impact of the prevailing stressors in the region, including both biologicals (such as infectious agents) and chemical stressors (e.g. several applications of PPPs in time and space) including cumulative and synergistic effects.” This is in our view unbalanced as it mentions “use of agro-chemical treated crops by foragers” without any consideration of the fact that some crops (notably sugar beet) are rarely (if ever) visited by honey bee foragers (or indeed by bumble bee or solitary bee foragers). | Agreed and amended. |
| CropLife | 26 | 3.1. A proposed systems-based approach | a. (831) The monitoring box should also include stressors such as varroa mites, etc. In theory, "Landscape" would include weather monitoring but it would be better if "weather" was a separate line because it will have a significant effect on colony health.  
b. (860) Colony data should include varroa mites and diseases (maybe this is what is meant by "biological agents"?). | a. We agree and added as suggested biological agents and weather in figure 3.  
b. Yes this is what is meant by "biological agents" as referred in section 3.2.2.2.1. |
| Lund University | 27 | 3.1. A proposed systems-based approach | a. A specific point on P25 L847-856: it is stated that “The modelling component is constructed based on a fundamental understanding of | a. We agree and have amended the text accordingly. Well-designed |
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The science base of the organism in its environment (ecology, demography, physiology, behaviour and toxicology). This science base appears to be assumed to exist, but will to a large extent come from previous and future well-designed experiments and field studies rather than monitoring. This should be explicitly highlighted in conceptualization of the system-based approach (figure 3).

b. See also the comments on sections 4.3. Risk assessment, risk management and the broader society and 6. Gaps and opportunities for implementation.

| ANSES | 28 | 3.2.1. Modelling |
|-------|----|-----------------|
| a. [3.2.1.1/p27/ 909-910]: FR: A scheme of the overview for the ApisRAM model structure would be welcome to support the description of several modules and visualize relevant interactions. |
| b. [3.2.1.3/p30/1041]: FR: There is no reference for the acronym CAG (Cumulative Assessment Group). |
| c. [3.2.1.5/p31/1107]: FR: The authors indicate that the estimated mean ratio approach (EMR) is limited to binary stressors. Could the authors specify if there is room for the toxicity estimation of mixtures with more than two chemicals and if this is/can be implemented in ApisRAM? |
| d. [3.2.1.5/p32/1147]: FR: The rationale for taking into account multiple stressors is additive, and there is a very high diversity of substances found in the environment. The model should aggregate stressors by functional (toxic) groups. This will help highlighting dose-effect responses from similar substances, which would individually go undetected. It would also make substance pools comparable between agricultural regions. Suggested sentence: “Substances of a similar mode of action could be taken into account cumulatively in the model, as a compound stressor. It would improve the detection of dose-effect links and allow for comparing between agricultural regions.” |
| e. [3.2.1.5/p32/1163] FR: While the authors propose a default dose addition assumption when simulating combined toxicity of chemicals with toxic units (TU), the study by Carnesecchi et al. 2019 cited earlier experiments and studies, conducted in the laboratory and in the field, have and will continue to play a critical role in this regard. |
| b. Addressed under the specific comment/sections. |

A figure (5) was added to describe the timeline of the development of ApisRAM including the various calibration/testing phases and versions of the model.

b. Noted and amended with a new reference (EFSA PPR Panel, 2013).

c. The EMR is not limited to binary mixtures and can be applied to more complex ones pending toxicity data for these mixtures are available. Implementation in ApisRAM will require a number of careful considerations, including body burden of individual chemicals and their mode of action. This can be considered for future implementation.

d. Noted and included in the opinion.

e. We state that in the absence of other information dose addition will be assumed, a default in the absence of knowledge. If other
demonstrated that interaction effects of PPP on bees is mainly synergistic (72% of the interaction investigated). Could the authors describe how representative these plant protection products are compared to those commonly use in EU? Despite there may be situations where the default dose addition assumption would not cover potential synergism, this could be partly covered by the systematic request of tests performed with the products. Moreover, monitoring data (monitored colonies, residues...) could provide in hindsight valuable information to identify potential situation where synergism would occur. Could the authors share their point of view on this situation?

In order to assess the combined toxicity of all PPPs commonly used in the EU, it would require a thorough analysis that is relevant, but beyond the scope of this scientific opinion which focuses on the conceptual framework for the systems-based approach.

| CropLife | 29 | 3.2.1. Modelling |
|----------|----|------------------|
| Section 3.2.1.1: |
| a. (896) When discussing models it is important to indicate which version is being used and also the validation status of each model. Models should undergo a rigorous (and transparent) validation process prior to being used in this project. In addition, the model code should be publicly available. Strongly recommend adding a model validation subsection. |
| b. (935) Please include a sub-section on the validation status for ApisRAM. Models should undergo a rigorous (and transparent) validation process prior to being used in this project. For example, under what climate conditions has the model been validated using monitoring data? Under what landscape structure conditions has the model been validated? Has the model been validated for long (multi-year) periods of time and found to accurately predict colony behavior? In addition, the model code should be publicly available. |
| c. (935) The development of ApisRAM should follow the EFSA SO on Good modelling Practice and be documented accordingly. The current document does not fulfil these criteria. Is that planned and if yes, when will the documentation according to EFSA SO on GmP be available? EFSA. 2014. Scientific opinion on good modelling practice in interactions are known, then these will be included. In order to assess the combined toxicity of all PPPs commonly used in the EU, it would require a thorough analysis that is relevant, but beyond the scope of this scientific opinion which focuses on the conceptual framework for the systems-based approach. |
| d. | Who are the end users for ApisRAM? Is it planned that the model be used beyond the lab and network of model developers? Given the model complexity and dependence on many data sources as described in this section, there will be a need for appropriate training for users. Is any such training planned and within scope of the development and application of ApisRAM? |
|---|---|
| e. (1026) | How will the multiple stressor model that is proposed for ApisRAM be validated? |
| f. (1031) | The TU approach is based on the assumption that the toxicants act via the same mode of action. For ApisRAM it seems that the proposal is to apply the TU approach to predict the combined effects of chemical and non-chemical stress. However non-chemical stress clearly acts via modes of action different to chemicals and therefore one of the assumptions of the TU concept is violated. Which other concepts have been considered? There are alternatives in the scientific literature (e.g. Goussen B, et al. 2020. Bioenergetics modelling to analyse and predict the joint effects of multiple stressors: Meta-analysis and model corroboration. Sci Total Environ. 749:141509.) |
| g. | How will EFSA assure that ApisRam indeed is the best model for the purpose? There are other models available with a long track record and more comprehensive validation (e.g. BEEHAVE REFS). It would be prudent to test whether ApisRam gives more accurate predictions than other available models before it is made the model of choice. |
| h. | For a regulatory model it is essential that links between effects and exposure are transparent and can be parameterised with standard and common ecotox studies that have agreed protocols (e.g. OECD protocols). While there is mention on the types of effects ApisRam will represent, there is very limited information on how ApisRam will represent exposure in the landscape and the hive and how that is then This will of course be published when it is complete. |
| d. | ApisRAM is designed as a tool supporting risk assessment of PPP in the context of multiple stressors. It is likely that ApisRAM itself will not be a tool for regulators due to its complexity. Further work will be needed to develop a user-friendly interface to be used by risk managers/assessors. |
| e. | ApisRAM is being calibrated and tested using highly detailed data collected in the field by EFSA and two large H2020 projects (B-GOOD; PoshBee). Other data sources (literature, expert knowledge) will also support this calibration exercise. |
| f. | Within ApisRAM the individual effects of each stressor will be taken into account as they effect different parts of the bee-vitality model. The TU approach is used to combine external stressors, and those that have the same effects will be combined. |
| g. | The “validation” of ApisRAM is ongoing and based on more comprehensive data than BEEHAVE. After first release, it will be tested initially through expert knowledge elicitation, and later iteratively against the data from the sentinel |
translated into effects; transparent and comprehensive documentation of this is needed before any regulatory use.

i. It is stated that ApisRam will be continuously improved, yet there is no information on version control. So this appear to be more of an academic than a regulatory approach. More detail on how version control will be managed would be welcomed.

j. (1008-1010) Is the ALMASS pesticide module a mechanistic or empirical model? If it is an empirical model based on data from farmers in Denmark from 2000 which is two decades ago, does this reflect the current agricultural practice in Europe? The environmental fate processes in ALMASS are very simplistic and need further improvement to be useable in environmental risk assessment. Are there benchmarks available how this fate module in ALMASS compare to fate models currently used in standard risk assessment for drift, soil and surface water?

k. (1014) Only two pesticides can be simulated, or one pesticide with one metabolite.

l. (1046-1050) The effect model is simplified to a simple threshold response, so a binary response above or below the threshold. This is currently far away from state of the art. Current effect modules include in the most simple form either a dose-response relationship or to take up effects from time variable exposure a toxicokinetic-toxicodynamic model as an ecotoxicological unit. EFSA has published both of these ecotoxicological modelling approaches for honey bees so we do not understand this major simplification which result in high uncertain model outputs.

m. (1063) As discussed earlier in the document, there are numerous factors in addition to pesticides that may have sublethal effects. This section should also discuss the effects of nutrition, parasites, diseases, etc. and how they will be incorporated into the model.

Section 3.2.1.5:

hives. Text amended to make this clear.

h. The full ApisRAM model will be published including these details which will cover these aspects.

i. Version control will be implemented in any regulatory version of the model at the time that it is taken into use.

j. It is a mechanistic model and is not based on Danish farmers, except when used in Denmark, and takes current agricultural practices into account through the CAP subsidy information.

Fate processes follow standard models, they are applied at a high resolution and over a broad area. Unlike point fate models this is a spatial model and as such are computationally complex.

k. The “two pesticides” limit was based on the original specification for ApisRAM from EFSA (2016b). This limit can be lifted at the cost of reducing the complexity of the fate models, in this case to remove dynamically simulated drift. This will be one of the decisions taken when a regulatory implementation is defined.
n. (1149) "...as well as other stressors to make a dynamic multiple-stressor risk assessment..." Suggest adding examples of other stressors...as well as other stressors (biological, landscape, etc.) to make a dynamic multiple-stressor risk assessment..."

o. (1163) "Therefore it is proposed to simulate combined toxicity..." This should follow a validation step using data from a variety of potential stressor scenarios.

p. (1168) Suggest adding a discussion to each point on the likely potential effect of each "development" on the accuracy of the model. Also include how the model would be validated for each of these components.

q. (1051) Proboscis Extension Reflex (PER) is not a reliable an endpoint and there are no internationally recognised test guidelines for this or any other sub-lethal endpoint. Furthermore, no link between this endpoint and adverse effects at the colony level have been established. Typically, bees recover quickly when the chemical stressor has been removed.

r. (1067-1068) How will the dose for the queen be calculated? How will the reduction of reproduction be related to the dose, is there any data available that pesticides reduce queen reproductive rates? Published data on queen exposure has shown that due to being fed Royal Jelly it is negligible.

s. (1086) The proposed mixtox approach sounds like a very static one, whereas the reality in the field is much more complex. Different actives distribute and degrade differently which would need to be taken into account for a realistic simulation of mixtox effects.

t. (1134-1135) Here and also in other parts of the document (e.g. dose calculation for the queen) in hive exposure is mentioned, but nowhere it is described how this in hive exposure is calculated. Since a realistic in hive exposure of in hive bees, larvae and queens are essential to

l. This is just a simple statement of fact – often this dose-response information is not available. If available it can be included. ApisRAM default assumes a dynamic body burden model if there is data to support this.

m. Nutrition, parasites and diseases are all included in the model in detail.

Diseases will not be part of version 1.0 but will be implemented later: see new Figure 5 added to the opinion.

n. Agreed and amended.

o. ApisRAM colony behaviour will be validated first.

p. At this point it is not possible to comment on the additional accuracy provided by the consecutive model versions/modules. The contribution to reducing uncertainty within the model will be documented for each version. This information will be published when available (see new added Figure 5).

q. PER has been identified as a reliable endpoint in a number of scientific published studies.
simulate a realistic effect patterns of pesticides we hope that for this important part there is put as much efforts than for the temperature regulation. Will this in hive exposure model be generic or would it need compound specific input? In the latter case what input would be required to simulate the exposure in the hive?

u. (1150-1151) This approach would assume that application, fate and degradation would result in the same exposure for all these chemicals. Especially if we are talking about pesticides, biocides and veterinary compounds it is already clear that this assumption does not hold true and therefore the proposed approached cannot be used in the described context. For many pesticides (e.g. herbicides and fungicides) toxicity values are unbound endpoints (i.e. no effects at >100 ug a.i./bee) how can these be accounted for in the model?

v. (1161-1164) In line 1046-1055 it is explained that the effect model will be based on a simple threshold function since dose-response relationships are not available. Here now the LD50 is stated, which seems a little bit contradictionary. So for us it is now unclear how effects will be simulated. A dose-response relationship is characterised by the LD50 and the slope. Especially at lower doses the slope of a dose-response relationship might be very important to simulate the effects realistically.

w. (1188-1192) This dynamic approaches for biological agents, especially varroa, are already available (Becher et al. 2014). We suggest using these approaches instead of developing something new. The advantage would be that these approaches were already evaluated by EFSA and the improvements needed are clearly defined in EFSA 2015.

x. (1193-1197 and 1210-1215) We are not sure how this paragraph should be understood. However, it has been proven previously that dynamic of food quality and food quantity in a landscape context is the main driver of colony dynamics. If ApisRam is currently not able to provide this landscape context a realistic simulation of bee hives is very unlikely. In addition, the resilience of the beehive depends on the An international Guideline for this endpoint and other sublethal endpoints should be developed. If a sublethal effect can be demonstrated, this is part of the multiple stressors environment that a colony is subjected to and therefore it should be included in the systems-based approach.

r. Within colonies, the dynamics of the pesticides will be modelled (see newly added Figure 5 for the timeline of ApisRAM). There is data showing the queens can be affected by pesticides (Wu-Smart & Spivak, 2016; Martin et al., 2018; Chaimanee et al., 2016; Dai et al., 2010) and therefore this option is included in the model. These new references were added in the opinion.

s. The proposed mixtox approach applies tiered principles. The first tier to address combined toxicity in bees would use lab data. When data are available from field studies, the mixtox approach can be applied at a higher level of biological organisation (individual to colony level) and take into account the fate of the chemicals in the environment prior to the combined toxicity evaluation.

t. This is part of the full ApisRAM formal model version 1.0, which will
food dynamics in the landscape and therefore also the response of the beehive to multiple stressors. Without such dynamic landscape context for food sources all the proposed modelling would be arbitrary number crunching, but no realistic simulations as was the aim of the system approach.

y. (1210-1215) The EFSA SO about BEEHAVE had, beside minor technical details, three major concerns. 1) No specific ecotoxicological module to simulate exposure in the hive and resulting effects; 2) No module to simulate the dynamics of beehives in different landscapes; 3) need for further validation. As far as we have understood from the current text, we are now 5 years later and none of this three major deficiencies were addressed by the new model approach ApisRam. This is astonishing, because this was the major aim of the EFSA call which resulted in the development of ApisRam.

be published early 2022 (see new added Figure 5). ApisRAM will provide a mean to estimate exposure in bees by dynamically modelling pesticides in the colony/hive.

u. This is indeed a complex problem and it will have to be addressed in the future through using multi parametric modelling including physico-chemical and toxicity properties of chemicals to be assessed. The solution will need to balance computational resources, sensitivity analysis, data availability and realism.

v. Agreed, this is why we say that this will be used if/when available. The TU approach is then applied for compounds with similar effects after body-burden is calculated.

w. This option was considered previously and not found to be feasible.

x. The statement about ApisRAM is incorrect. One of the major constraints of BEEHAVE is the lack of dynamic landscapes, both in terms of agricultural use and floral resources. These constraints have been addressed in ApisRAM to cover each of the points you raise.
| Ctgb | 30 | 3.2.1. Modelling | 
|------|----|----------------|
| a. 3.2.1.1 L909: Is this statement not a bit too broad? It should likely not be so broadly stated as "regulatory contexts" in the first sentence of line 909, since the evaluation referred specifically to the risk assessment for pesticides and not to all regulatory contexts. |
| b. 3.2.1.2 L990-996: In L996 it is stated that "biological agent stressors affect the bee immune system strength, which interacts with the vitality." Since it was stated in line 992 that the vitality comprises immunocompetence status, it is unclear how it could interact with vitality. These two paragraphs should better explain the core model assumptions about the mechanism of stressors interactions and effects. |
| c. 3.2.1.2 Have ALMASS and/or ApisRAM been evaluated for appropriateness for use in the given context? Or is this planned for the future? This is not immediately visible in Table 3, as only "evaluation by stakeholders" is stated, but it is unclear what is meant by that as to which stakeholders and what type of evaluation is planned. |

y. BEEHAVE has three main deficiencies, these are as stated the lack of dynamic landscapes including ecotoxicological module and hive effects, but also the lack of realism and interactions between stressors, the over-simplified in-hive representation of bees (as cohorts), and the very simplified foraging module based on BeeScout, the need for better validation. All of these deficiencies are addressed in the development of ApisRAM. This was further clarified under section 3.2.1.1. See the timeline figure 5.

a. Amended.

b. It is stated that vitality comprised of immunocompetence and a daily mortality probability so biological agents and other stressors affect vitality directly. Sentence amended to make this clear.

c. This evaluation is ongoing.

d. Amended to make clear this is both survival and sub-lethal.

e. Noted and amended.

f. This is a model construct not a parameter. Vitality itself is not measured but is a way to combine multiple stressors. Hence input data would be e.g. dose response curves.
| National Farmers' Union | 31 | 3.2.1. Modelling | Lines 1148-1150 - As stated previously, to make this a genuine dynamic multiple stressor approach it needs to factor in other stressors such as habitat loss, the impact of poor bee nutrition, honey bee pests, viruses and other diseases, attacks by invasive species, as well as environmental changes caused by changes in weather patterns and climate. | This is very much the idea behind ApisRAM. |
| RIFCON GmbH | 32 | 3.2.1. Modelling | Chapter 3.2.1.1. Introduction |
| | | | a. Line 903ff: One remaining criticism of BEEHAVE seems to be the implementation in NETLOGO. This might be a limitation depending on how the model needs to be expanded or changed. However, it is important to distinguish between a model and its implementation. Therefore, it should not be a major reason to reject the model directly because the programming language does not seem to be ideal. |
| | | | a. BEEHAVE is a much simpler model than ApisRAM, which is imposed by the choice of language (i.e. NetLogo in Beehave versus C++ in ApisRAM). The rejection of the model is due to overly simple approach and lack of proper integration of multiple stressors. |
b. Line 933: The comment needs clarification, as it would in general not be impossible to implement the concept of superorganisms in NETLOGO.

c. Chapter 3.2.1.2. An agent-based simulation for honey bee colonies: ApisRAM
Having an individual based model running partly on a 10 minute and partly on an hourly time steps and a spatial (explicit?) representation within the hive and the landscape (simulated on a 1m^2 cell size in ALMaSS) sounds like a rather complex model that would likely have a very long simulation time. This could particularly be a problem, on the one hand for (project-specific) model (sensitivity and uncertainty) analyses that might be required for use in ERA and, on the other hand, to allow the simulation of relevant scenarios with a sufficient number of replicates that are required for a stochastic simulation model. Here it would be important to have more information on relevant model characteristics, including run time, uncertainties involved with the different model components, or usual stochastic variability in model output. Another question is whether such high-resolution data are available for all regulatory zones and member states. In general, as uncertainties usually increase fast with increasing model complexity and as the model should be as parsimonious as possible for its purpose, the need for such a large model complexity (huge number of input parameters, very small-scale resolution in space and time) in ApisRAM needs to be discussed and justified.

d. Line 960: ED = Environmental drivers: I would prefer another abbreviation because ED is already used in the PPP risk assessment (Endocrine Disruptor).

e. Line 995ff: vitality: many stressors can have a negative impact on the bee vitality (e.g. temperature, food limitation etc.). Detailed scenarios are necessary for the PPP risk assessment, otherwise the detailed effect of the toxicant is unclear. Moreover, in the PPP RA the applicant has to assume that the beekeeper take care of the bee hive adequately (for instance treatment against Varroa). Moreover, ‘vitality’

b. As stated in the opinion, this could not be used to represent the complexity of the system. This is correct. Additional clarifications were provided.

c. These issues will be considered when the full ApisRAM model is available. It would be premature to open this discussion before then.

d. We prefer not to amend. This abbreviation (RPU-ED) was already used in a previous published output referring to the design of the model specifications (see EFSA, 2016b) and therefore should not be changed. The abbreviation is described in the glossary so it is not mixed with endocrine disruptors (which is not the topic of this opinion).

e. Vitality is not a measured parameter, it is the result of multiple interacting rates, exactly including the factors mentioned. There are ongoing detailed studies designed to evaluate this model component (H2020 B-GOOD & PoshBee).

f. The details of any future risk assessment scheme as well as the data requirements will need to be defined.
(e.g. immune-competence) as a parameter/endpoint is usually not known for pesticides, diseases, pests, temperature, nutrition etc., as it is not measured in experiments for bees. Where should these data come from? And how would it be linked to free flying colonies? Are there any studies planned on this? An internationally validated method is needed for this.

f. Line 1013: multiple stressors: How to include multiple stressors in practice?
The new model approach will require new experimental data. The PPP reregistration window is usually 10 years, so that uniform modelling input data for PPPs are not available in the near future.

g. The combination of multiple stressors will end up in a variety of runs. In combination with long simulation times for higher tier solutions, this seems a technical bottleneck.

Chapter 3.2.1.3. Integration of multiple-stressor effects on individual bees in ApisRAM

h. Line 1032: As a starting point, the default assumption of dose addition...: When should ApisRAM be used in the PPP risk assessment. Is there a tiered approach in the next bee guidance or should ApisRAM always be involved? If a tiered approach is chosen, how to guarantee that the addition of all effects will not end up in an overly conservative worst-case situation? (see also ‘Major question’ at the beginning of the commenting)

i. Figure 4: Data on ‘vitality’ (e.g. immune-competence) is usually not known as it is not measured in experiments for bees. Where should these data come from?

Chapter 3.2.1.5. Future development of ApisRAM

j. Line 1086: exposure to multiple chemicals...: There is no digital database available for plant protection product endpoints. All data are g. It would be a technical bottleneck if ApisRAM had to be parameterised and run in each case. However, it is unlikely that the model will be used in this way.

h. A new figure (Figure 5) was added to describe the timeline related to the development of ApisRAM until it can be used for the risk assessment of PPPs. The use of the model in the revised Bee Guidance (that is not yet published) or a tiered approach is out of the scope of this opinion.

i) See answer provided to comment 32.e.

j. It is agreed that currently there is no comprehensive digital database for plant protection product endpoints. Nevertheless, the data exist. Digital database will be available in the future (the EU system is currently going through significant development in relation to the transparency regulation that will result in digital databases for pesticides). EFSA’s OpenFoodTox provides all reference points used by EFSA since EFSA’s creation. It includes acute hazard endpoints for bees (LC50) computed from EFSA conclusions on plant protection products. RP from OpenFoodTox can be downloaded under this link:
only available as pdf (e.g. EFSA conclusion or EU review reports). So how to setup a database for all possible chemicals?

k. Line 1128: inappropriate beekeeping management practices: Similar to good agricultural practices, a PPP risk assessment assumes that beekeepers are doing their job properly.

l. Line 1144: An alternative method is to quantify the relative impact of each stressor on mortality or sublethal effects...: How to do this in practice?

m. Line 1172: ... using a modular approach, for subsequent model expansion...: EFSA has to give detailed guidance how to setup and run the respective model version. It seems that the number and choices of model settings is infinite. EFSA should predefine scenarios.

https://zenodo.org/record/3693783#.YFIdXp1KheU. In addition, a full description of the database is available under this link: https://www.sciencedirect.com/science/article/pii/S0160412020322480. For other endpoints and chemicals in bees, this data will need to be collected from the literature.

k. Noted and removed.

l. The alternative method to quantify the relative impact of each stressor on mortality or sublethal effects can be put in practice using mortality data or “Toxic Unit” as a common metric for adverse effects (i.e. a hazard metric). This was amended in the opinion. However, such data for each stressor are currently limited. When they become increasingly available, the relative contribution to mortality of each stressor can then be quantified.

m. Modular expansion refers to the further development of the models in the future and is not related to specific model settings.

| ANSES | 33 | 3.2.2. Monitoring |
|-------|----|------------------|
| a. [3.2.2.1]: FR: The document deals with neither the size of sentinel beehives network, nor the environment where beehives should be deployed. Indeed, the sentinel concept implies the early detection of PPP in the honeybee environment. Sentinel beehives should therefore be deployed in situation favoring the exposure of honeybees to PPP. And the network must be large enough to cover a wide panel of | a. We agree with ANSES this is a valid comment that needs to be discussed for implementation of the approach and this was added to the opinion. This issue is complex and would need careful considerations. However, this discussion goes |
agricultural contexts to be representative of the diversity of agricultural situations in Europe.

b. [3.2.2.1/p34/ 1265]: FR: This sentence is a tautology. Suggested sentence: “Infectious and parasitic diseases are defined as bees displaying clinical symptoms (as opposed to being healthy carriers of potentially pathogenic microbes”).

c. [3.2.2.2/p35/ 1310]: FR: Given the tremendous heterogeneity of substances to which the bees are exposed (not to mention dangerous metabolites), it seems important to explain here which strategy of multi-residual analysis will be used. From table 3 p.50, it can be understood that an “omics” approach is underway in the PoshBee program (expected output 2023). FR suggests adding the following sentence at the end of this paragraph “There is a technical challenge to have tools for high-throughput, low detection threshold and multiresidual analysis. Such a tool is under development in the PoshBee program through an “omics” approach.”

d. [3.2.2.2/p35/ 1315]: FR: Could the authors detail a little bit more what kind of chemicals they recommend to monitor in the residues (e.g. only plant protection products on the EU market, old plant protection products, pharmaceutical chemicals, metals...). Would a priority list be a useful tool?

**BeeSafe - Bee Health Consulting for Agriculture and Veterinary Medicine**

| 34 | 3.2.2. Monitoring | a. Lines 1232-1234: These points are more from a beekeeper's perspective than relevant for colony health. Honey production, e.g., is forced by beekeepers also by transporting colonies at different places. In addition, depending on the development of beekeeping practices in different MS, what is adequate even under similar conditions may be considered very different. The adequate provision of pollination services is also from the beekeeper's perspective. For the colony, adequate provision with pollen is more important and this is independent of crop pollination services. The pollination services don't depend only on honey bees. The pollinator community may vary substantially in different regions, also depending on the surrounding landscape. Insufficient pollination services, therefore, may not necessarily say something about honey bee health. |
| b. Agreed and amended. |
| c. Agreed and amended. |
| d. Here, the goal is not to provide recommendations on how to prioritise among chemicals, as this would need also to take into account other parameters that are beyond the scope of this opinion. Therefore, in the opinion we present one possible approach to prioritisation based on cost but accept that other prioritisation approaches could be used taking into account stakeholders needs and research development. |
| a. These are the conclusions from the ESFA opinion on healthy-B (EFSA AHAW, 2016). The points from a beekeeper's perspective and relevant for colony health are closely related and cannot be separated. i) The honey production is obviously essential for bees, for their survival and the development of their colony, but it is also essential for professional beekeepers to ensure their income, and even for hobbyist beekeepers for their motivation (and...). |
**b. Lines 1241-1244:** the number of queen cells ("queen brood") doesn't say much about the colony health. In some MS, honey bees have been selected for low swarm tendency (e.g. Germany, Austria, Italy), while in others this didn't happen as much (e.g. Spain). The latter will produce much more swarm cells being at similar overall health conditions than selected colonies. On the other hand, the type of queen cell is a better indicator: Swarm cells indicate the natural behaviour of honey bees and are a sign of "adequate development", while replacement cells indicate the loss or supersedeure of the queen. Finally, drone brood is also an important indicator for colony health: in the swarming season, healthy colonies produce preferentially drone brood. On the other hand, drone brood in worker cells indicate an old queen or laying workers. More than the absolute numbers, the proportion of brood types and the development over time are a more accurate indicator for bee health.

**c. Lines 1284-1288:** Colony size - Weighing colonies this way is a severe disturbance of the colony and doesn't give an accurate picture of the number of bees in a colony. The average weight of a worker bee is around 100 mg, however, it's highly variable depending on the age, activity (foraging, storing provisions etc.) and other factors. In several monitoring or selection projects, sample audits gave weights per bee between 90-120 mg. So the apparently "exact" number of weight is a very illusionary one. More important, however, is the extreme disturbance of the colony: - shaking off all bees from the combs irritates the bees causing aggressive behaviour. - the queen may get lost during the procedure - it's time-consuming which increases the risk of aggressive behaviour - there is increased risk of robbing due to the length of the procedure. Instead, the Liebefeld method is well established in the scientific community. Many beekeepers and CROs are trained in the method which results in much more telling data on the number of bees, brood cells, and stores. It's also included in the COLOSS Bee Book (Standard methods in honey bee research their pleasure) to breed honeybee colonies.

**ii) The same goes for collecting pollen, which is obviously essential for bees for their development, but also for the environment in general (pollination of wild flowers), and for certain crops which must be pollinated by insects.**

**b and c. Thank you for this detailed analysis of the paragraph 3.2.2.1 (Sentinel beehives). As stated above in our answer to comment 34a, these are the conclusions from the ESFA opinion on healthy-B (EFSA AHAW, 2016). However, this is a valid comment that needs to be discussed for implementation of the approach with all involved stakeholders at EU level (e.g. EC, EP, MS, EU agencies, etc.).**

**d. We agree with this comment. See answer above for future implementations.**
https://www.tandfonline.com/doi/pdf/10.3896/IBRA.1.52.1.03?needAccess=true&).
Both factors, the inaccuracy of measurements through weighing and the extreme disturbance of the colonies makes this method completely inappropriate for measuring colony strength and not practicable.

d. Lines 1345-1353: the density of sentinel hives must be adjusted to the structure of the surrounding landscape to not interfere with existing apiaries and the wild pollinator community.

| CropLife | 35 | 3.2.2. Monitoring | Section 3.2.2.1: |
|----------|----|------------------|------------------|
| a. Two subsections are missing from this discussion (1) how to select appropriate locations for sentinel hives and (2) the number and spacing of hives needed to provide statistically and biologically meaningful data. Information to complete these two subsections will include simulation modeling, field studies of several location and spacing designs to test model results at various locations, and then detailed statistical analysis of the field results. Without a significant effort in understanding the uncertainties associated with the different sentinel beehive deployment strategies this effort is unlikely to provide meaningful data to regulators. |
| b. (1282) “Good photography skills...” Need to develop methods (SOPs) and training to assure that the robustness of this step is not dependent on the “skills” of the operator. |
| c. (1284) Colony size determination via complete removal of the bees from the hive is incredibly stressful to the colony and should be avoided. Also, need to correct for the amount of bee products (wax, honey, pollen) in the hive if measuring the weight of the colony over time. |
| d. (1289) Measurement of honey production and food stores is incredibly stressful to the colony. The effects of this stressor will need to be taken into account when validating any model that is used in the risk assessment. |

a. This is a valid comment that needs to be discussed for implementation of the approach with all involved stakeholders at EU level (e.g. EC, EP, MS, EU agencies, etc.). This was acknowledged in the opinion. The detailed and technical information related to “the simulation modelling, field studies of several locations and spacing designs to test model results at various locations, and then detailed statistical analysis of the field results” is beyond the scope of this opinion.

b. We agree, this is an approach we developed under the EFSA field data collection conducted in Denmark and Portugal for the calibration of the model. The equipment used is key in delivering the required level of accuracy of the photos needed (Dupont et al., 2021). We amended the opinion accordingly.

c & d. we acknowledged that such practices are invasive and added a
Behavioral patterns on combs can be affected by factors such as time of day and weather. Need to include ways to account for this source of variability when collecting data.

Section 3.2.2.2:

f. (1306 - onwards) Recommendations on sampling are focused on PPP. Specific recommendations for other chemicals should be included as it could help prioritize the matrices to be analysed.

g. (1322) It is unclear what the "a" "b" "c" at the end of each line in this section represent.

Section 3.2.2.3:

h. (1346) "The 'structure' includes data on land use (crop and forestry practices)...." The structure also includes any other land use including urban/suburban structures and land use, roads, etc. This paragraph should be expanded to include all potential land uses that might directly or indirectly affect colonies within a specified radius around the colony.

i. (1354) Landscape dynamics not only includes crops, but should also include all non-crop activities.

j. (1364) "For all time-varying parameters, hourly data are needed." Hourly data are only needed for a few key parameters - mostly associated with weather. Parameters such as planting, application, harvesting, crop type, etc. do not need hourly data.

k. (1345-1353) What seems to be missing here is flowering weeds in the off-crop area. If this is not represent the nectar and pollen dynamic in the landscape seems to be wrong which would result in a wrong colony dynamic. In addition, non-inclusion of flowering weeds in the off-crop area would make drift assessment impossible.

Note on this. In the field data collection conducted in Denmark and Portugal, we reduced the frequency of such observations (to allow recovery by the colony). Some authors conduct such experiments and did not find any impacts on the colony (see Odoux et al., 2014 and Requier et al., 2015) that were added to the list of references.

e. Agreed and amended.

f & g. Here, the goal is not to provide recommendations on how to prioritise among chemicals, as this would need also to take into account other parameters that are beyond the scope of this opinion. Therefore, in the opinion we present one possible approach to prioritisation based on cost but accept that other prioritisation approaches could be used taking into account stakeholders needs and research development.

"a", "b", "c" rating relates to the objective of assessment made (i.e. for bee health, model calibration, early warning signals and respectively) in relation to the matrices sampled and analysed.

h. The "urban/suburban structures and land use, roads, etc." is comprised under "landscape
### 3.2.2. Monitoring

| RIFCON GmbH | 36 | a. Five colony attributes that should be analysed when assessing the health status of a honey bee colony: |
|-------------|----|--------------------------------------------------------------------------------------------------|
|             |    | 1) Queen presence and performance: not agree as this attribute strongly depends on the queen's age, the genetic breeding line, the race, the region of the colony etc. |
|             |    | 2) Brood demography and colony size: not agree, as it strongly depends on bee race, breeding line, time point when it is measured, bee keeping practice, Varroa infestation level etc.; moreover, it is very elaborate to monitor this in short time intervals, disturbs the colony and always bears the risk to injure the queen, as all bees have to be removed from the combs to assess the brood proportions (i.e. eggs, larvae, pupae) |
|             |    | 3) Behaviour and physiology: not agree, as the ability and degree of thermoregulation strongly depends on the colony size and thus on beekeeping practice, including Varroa control; foraging activity does not necessarily mean behaviour - in fact, colonies can display a high activity even when they are queen less (in fact this is sometimes used by beekeepers to optimise honey production); it has first to be agreed on what “abnormal behaviour” means for worker bees, the queen and the drones; moreover it would need a continuous monitoring that |
|             |    | structure and management/land cover”. We included some more examples to clarify this. However, we disagree to expand more adding “all potential land uses that might directly or indirectly affect colonies” as this is not the scope here. |
|             |    | i. Agreed and amended within section on both “landscape structure and management” & “dynamics”. |
|             |    | j. Agreed and amended. |
|             |    | k. Agreed and amended (see answer to comment 35i). |

a & b. We thank RIFCON GmbH for sharing their views on the usefulness of the attributes/variables/tools that should be analysed when assessing the health status of a honey bee colony. These were extensively discussed with stakeholders in a workshop organised by EFSA in 2016 (https://www.efsa.europa.eu/fr/events/event/160413; EFSA, 2016a) prior to the publication of the EFSA opinion reporting on these attributes (EFSA AHAW, 2016). Note that B-GOOD H2020 project will determine a set of attributes/indicators to assess the health status of a honey bee colony in a standardised way. This project is due in May 2023 (see Table 3).
would then be invasive for the colony to check the behaviour of the queens and drones

4) In-hive products: agree, as this is regarded as the only relevant parameter, which is additionally regarded as a SPG in the EFSA Bee GD.

5) Disease, infection and infestation: agree, but it depends on the beekeepers’ practise and the weather conditions. Additionally, it depends on the colony density in a region. Finally, many colonies inhabit a set of naturally occurring micro-organisms, which would not come to a clinical outbreak and which would not mean that they are of any problems for the colonies.

b. Variables and tools to assess bee health status (EFSA AHAW Panel, 2016)

1) Foraging activity: There is a long history to try to measure the foraging activity, but in fact until today no GLP-validated tool is available to do so. Moreover, such tools measure activity in general as they cannot differentiate whether bees just fly out and in again or are really flying out to/coming back from foraging trips

2) Foragers mortality: see comments above; current techniques do not provide such data

3) Brood development/colony size: see comments above

4) Honey production and food stores: agree

5) Infectious agents: see comments above

6) Abnormal behaviour: see comments above; moreover, it is always mentioned that the abnormal behaviour “may result from many potential causes and might indicate a problem on the colony level”. So, obviously there is no or an unclear link between these factors

One main open point is that there are no real controls foreseen to indicate what is “normal”, e.g. normal development without certain stressors. Thus, we propose to include control groups into the monitoring phase.

c. Chapter 3.2.2.3. The landscape, including around sentinel beehives

General comment: It seems that the model requires a huge variety of different kind of input data. How is the model meant to be used in ERA? Will specific scenarios for (relevant) combinations of the various

| The objective of this draft opinion is to describe these attributes/variables/tools for the systems-based approach. Should the approach be considered for application/implementation, this information could be re-discussed with stakeholders, including RIFCON. | c. The final use of the model in ERA will be determined when a risk assessment scheme for the systems approach is finalised. It is likely that this will use a time series of weather data for previous years, together with local context from a range of locations to create representative scenarios. Hourly data are specifically for weather data, which is generally available. |
| ANSES | 37 | 4.1. Beekeeping and farming |
| --- | --- | --- |
|  | 4.1/p37/1384: FR: There is an ambition to develop an early warning system based on this monitoring/modelling approach. While this network is powerful for risk assessment, its adequation is questionable, i.e. neither toxicovigilance nor epidemiovigilance. Indeed, the number of beehives that are monitored is very small compared to the overall population of apiaries in Europe. The network would be insufficiently sensitive to detect emergent health incidents, that are by definition rare. Furthermore, the delay between gathering the data and having them available for the investigation of an incident in the sentinel hives would be too long. Rather, early warning systems are based on documenting and investigating incidents (event-based surveillance), by specifically trained veterinarians, with a standardized protocol of clinical observations and rapid response biological and chemical laboratory analyses. The difference should be discussed with beekeepers, so they will not be disappointed with the system. Nevertheless, the monitoring and modeling network can be very useful as a reference, to inform the investigators of case-clusters about the regional history of exposure and life conditions. Combining the information from monitoring/modeling in sentinel hives with cases in the broader population could help to interpret the findings of the early warning system. Suggested sentence: “be a reference of regional exposure and life conditions, to help with the investigations of cases that can happen in the general population of apiaries.” Or, the sentinel beehives may be considered as tools to be useful for the post-authorization process, bringing useful information concerning exposure to PPPs and related health status of colonies. | We agree about the concerns raised and amended the text accordingly to state “contributing to” rather than “developing” an early warning system. |
### Roberta Bonomo

**38** 4.1. Beekeeping and farming

Today it is possible to monitor the health of bee colonies in a non-invasive way with various commercial devices available on the market but all this data must carry out a comparative scientific study of their reliability. These monitoring data will inform farmers about the health of local bee colonies, providing ongoing assurance of good farming practice or early warning when bee health is being adversely impacted. It will be possible to conduct ongoing regional, national and EU-level surveillance of honey bee colony health. The sentinel hive data can contribute to a broader network of data collection conducted by individual participating beekeepers, for the broader benefit of the industry. The systems-based approach will also contribute to ongoing research on honey bee colony health.

Scientific studies on the quality and reliability of the tools used for bee monitoring are needed, as reported in sections 3.2.2.1 and 7.2 and Appendix D. In the meantime, new projects (e.g. B-GOOD) are being developed to compare tools for risk assessment purposes.

### CropLife

**39** 4.1. Beekeeping and farming

| a. (1379 - onwards) these benefits to the beekeeper will only be possible if the system actually allows to account for all stressors in a fair way. In addition, details on the data collection, process and communication would help to illustrate the direct benefit to end users. |
| b. (1388) The information from the systems approach will also provide the benefit of understanding the effects of land-use changes that could affect honeybee and natural pollinator habitats. |

| a. The systems-based approach aims at considering all stressors that affect honey bee colonies. As outlined in section 4.2, research activities will be needed to assess the relative importance of each stressor in the context of multiple stressors. It is beyond the scope of this opinion to provide details on the data collection process and communication. Nonetheless, an early discussion on these important issues is presented in section 6.2.2 and is further highlighted in section 7. |
| b. This issue is addressed in various parts of the opinion, including section 2.2.2.2 and 5.2. |

### CropLife

**40** 4.2. Research development

| a. (1405) "...given the emphasis on data quality..." Suggest adding a subsection dealing with the criteria associated with determining if data are of sufficient quality for use in the model and decision making. |
| a. This sentence relates to the focus on data quality and harmonisation, which will be improved by data collection through standard protocols in the sentinel hives. |

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### ANSES

| Page | 4.3. Risk assessment, risk management and the broader society |
|------|-------------------------------------------------------------|
| 41   | b. [4.3/p38/1439]: FR: The current risk assessment tier approach would typically start with an unrealistic but conservative first tier to go stepwise to a more realistic (but still worst case) higher tier if unacceptable risk were identified in previous steps. It seems that the approach proposed by the authors is a stepwise approach, which would start with the risk assessment of a single substance to end with the risk assessment of mixture. An acceptable risk could be concluded for the first step (RA of a single substance) but with additional steps, unacceptable risk might arise (by taking into account multiple effect, indirect effect or other stressors...). Could the authors underline if their proposed risk assessment should be done completely and not in a stepwise approach in order to avoid not identifying potential unacceptable risks. |
|      | a. The scope of this opinion is to propose a systems-based approach, of which the model is a fundamental part. The specific use of the model for regulatory purposes is beyond the scope of this opinion. |

### CIBE

| Page | 4.3. Risk assessment, risk management and the broader society |
|------|-------------------------------------------------------------|
| 42   | a. [4.3/p39/1486]: FR: Could the authors specify by which level do they mean “local”, the 10km*10km area resolution of ALMaSS, the agricultural field or the hive? |
|      | b. The scope of this opinion is to propose a systems-based approach for the future. In 4.3, we have proposed potential applications and benefits. However, the implications of this approach for legislation and risk management, as suggested here, are beyond the scope of the current opinion. |

### CropLife

| Page | 4.3. Risk assessment, risk management and the broader society |
|------|-------------------------------------------------------------|
| 43   | a. (1425 - onwards) There is a need for a reflection on the actual added value in the decision making system for PPP: part of it is of importance to judge on the basis of the effect of a PPP to bee health and part of this is important from a risk management point perspective where other stressors may influence the outcome of the risk assessment. The assumption that a PPP may be approved where no other stressor is having an impact may in effect be obsolete and hide |
|      | b. The impact of environmental parameters..." suggest including pollen and nectar sources and changes in crop selection in the list of environmental parameters. |
|      | a. The scope of this opinion is to propose a systems-based approach for the future, including potential applications and benefits for risk management (4.3). The approach has been developed to consider the multiple stressors that impact colony |

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| Ctgb  | 44 | 4.3. Risk assessment, risk management and the L1434-1436: It would be good to emphasize which model features will be evaluated with those data. |
|-------|----|---------------------------------------------------------------------------------------------------------------------------------|

the lack of action on those stressors to start with. Actions are actually increasingly needed on those factors.

b. (1432-1434) We completely agree. However, what is important the ecological scenario of the model needs to be different. Whereas for the predictive modelling the landscape should reflect a realist worst-case (EFSA SO Good modelling, 2014) for post marketing monitoring the landscape needs to be as realistic as possible. If a model will be used in this context it is important that it is able to behave correctly in these two different worlds. In addition, also the input will be different, for the predictive modelling the model needs to be able to simulate with the standard data package as input. In contrast for the post-exposure phase it is important the model is able to take all available data into account and can place them into the overall context.

c. (1486-1492) This approach would need major changes in the registration of pesticides and in the regulation of agricultural practice on Eu as well as on MS level, including a completely new label language.

health, including PPPs. As suggested by CropLife, each of these stressors, including non-PPPs, have the potential to impact colony health. In response, we have modified the text to read: “The systems-based approach could be used to evaluate and prioritise potential mitigation measures ... to reduce risks from pesticide exposure and from other stressors.”

b. The proposed approach will allow PPP exposure, hazard and risk in the context of multiple stressors to be assessed in an ongoing way across different spatial scales in Europe. This offers the potential for both pre- and post-marketing assessment, potentially using different scenarios as suggested. The suggestions are very useful, however, implications for risk management are beyond the scope of this opinion.

c. The scope of this opinion is to propose a systems-based approach for the future. The immediate legislative implications of this approach are beyond the scope of this opinion.

The full ApisRAM model will be published in due course including details that will cover these aspects (new added Figure 5 & new text referring to the figure).
Lund University  45  4.3. Risk assessment, risk management and the broader society

I fully support a system-based approach to environmental risk assessment (ERA). However, there are drawbacks in relying predominantly on monitoring, which is a form of observational study, as the complement to modelling in ERA of plant protection products (PPPs) for bees. Instead it would be important to also include more specifically designed and experimental field studies. This is because it is important to select the study approach based on the question under exploration and not all questions can, with confidence, be explored with either observational or experimental (or even modelling) approaches.

For example, if exploring the potential causes of a specific condition in a bee colony is the focus of the study, a case control type of observational study may be most appropriate. If the focus is on how a particular condition develop over time in a honey bee colony, a cohort type of observational study may be most appropriate. The latter may be appropriate for tracking temporal variation in exposure to PPPs in bees, but is less appropriate for tracking effects on honey bee colonies of such exposure to either single or multiple PPPs. This is because it is impossible to exclude the confounding with other factors such as covariation among use of different agrochemicals (e.g. PPPs and fertilizers) or that use of PPP are related to specific crops and vary in intensity with the crops grown, creating a covariation between PPP use (and exposure) and landscape context. Such confounding biases can to a larger extent be excluded in experimental studies. In experimental field studies, it is thus easier to confidently link PPP use to potential effects on honey bee colonies. This is a requirement in ERA of PPPs for bees.

The two study approaches are however complementary, with support for that experimental studies provide insights on casual relationships over shorter time scales, while observational studies (such as monitoring) may provide understanding of longer-term trends over centuries and beyond.

We agree and have amended the text accordingly to read “Knowledge gained from well-designed experiments and studies, conducted in the laboratory and in the field, have played and will continue to play a critical role in this regard.”
| CropLife | 46 | 5.0. Societal perspectives from stakeholders in the area of bee health: general comments |
|----------|----|---------------------------------------------------------------------|
|          |    | Seeing how pesticides are singled out throughout the whole document, this section demonstrates how little has been done to actively look at other stressors affecting bee health. Other environmental contaminants, role of practices are not investigated. Not even outreach to relevant stakeholders seems to have been done (e.g. what about farmers views, not only from their input use but also from the landscape management side). |

We respond first to the concern of a possible bias in the assessment towards PPPs. The European Parliament asked EFSA to deliver an opinion on the science behind the development of an integrated and holistic approach for the risk assessment of multiple stressors in managed honey bees. The terms of reference have specifically asked for methodology to account for the impact of multiple stressors, including plant protection products (PPPs), on colony health. With regards to farmer participation, please note that the societal perspectives were explored through beekeeper focus groups and EU Bee Partnership interviews. Farmers and their representative organisations were indeed represented under the latter. The Outlook 2 of the partnership analysis also includes further reflection on addition of partners from agricultural sector. Although the representation was...
| CtgB | 47 | 5.0. Societal perspectives from stakeholders in the area of bee health: general comments | The section indicates many interesting ways to involve the public and beekeepers, but does not give any concrete ways in which this will be employed into the "systems approach". Could you please provide more clarity on how the information gather through the "citizen science" is intended to be utilized? | Findings from the beekeeper focus groups should inform the potential implementation of this approach, specifically in the areas of data sharing, use of digital tools and further research needed. On the other hand, EU Bee Partnership interviews provided several “outlooks” for the future development and sustainability of the partnership, some of which are mentioned under the recommendations of the report as well. We note this is not “citizen science” as such but targeted social research providing stakeholder perspective into the proposed approach. |
| National Farmers' Union | 48 | 5.0. Societal perspectives from stakeholders in the area of bee health: general comments | It is disappointing here not to see any evidence that there has been a clear exchange with farmers on the proposed systems-based approach. | With regards to farmer participation, please note that the societal perspectives were explored through beekeeper focus groups and EU Bee Partnership interviews. Farmers and their representative organisations were indeed represented under the latter. The Outlook 2 of the partnership analysis also includes further refection on addition of |
| CIBE | 49 | 5.1.3. Specific feedback | On page 40 (lines 1561 to 1562), it is stated that “Beekeepers argued that, in some cases, non-compliance can even occur through national derogations for using EU-level banned neonicotinoids.” In our view, the beekeepers’ argument that non-compliance (presumably with the regulatory system) can occur through national derogations is not valid, because national derogations (be they for EU-level banned/restricted neonicotinoids or for other EU-level banned/restricted active substances) are provided for in the regulatory system (Article 53 of 1107/209). Therefore, one cannot claim that national derogations constitute non-compliance or are the cause for non-compliance. We acknowledge the regulation but note that the reference to non-compliance in the document is a quotation from the focus group. We made this clear in the document. |
| CropLife | 50 | 5.1.3. Specific feedback | Section 5.1.3.1:
   a. While this section reflects only the views of the selected people in the focus groups it would have been good to consult other stakeholders as many elements could be challenged or rebutted.
   b. (1559-1560) Reference is made to a perception of beekeepers that sub-optimal testing procedures for honeybees exist. An ACTION should be taken to inform Beekeepers of the bee testing that is required to register a product in EU which is probably much more comprehensive than they realise.
   c. (1561-1562) Use of National Derogations for emergency use should not be described as "non-compliance".
   d. (1565) Again an action is required to inform Beekeepers that Long term chronic testing is required for both adult and larval honeybees. What can we say about sub-lethal effects?  
   a. We agree. The study included two components to gather stakeholder perspectives – focus groups with beekeepers and targeted interviews with representatives of the EU Bee Partnership. It can be further expanded as needed (see also answer to comment 46).
   b. Targeted communication to stakeholders can indeed be a resulting recommendation from social research. We included this in the recommendations of the report.
   c. See answer to comment 49. |
**Public consultation on systems-based approach for ERA applied to honey bees**

| Lund University | 51 | 6.0. Gaps and opportunities for implementation: general comments | I fully support a system-based approach to environmental risk assessment (ERA). However, there are drawbacks in relying predominantly on monitoring, which is a form of observational study, as the complement to modelling in ERA of plant protection products (PPPs) for bees. Instead it would be important to also include more specifically designed and experimental field studies. This is because it is important to select the study approach based on the question under investigation. | See answer provided to comment 45. |

| | | | e. (1566-1567) An action is needed to inform beekeepers that the laboratory experiments are conducted under the worst case exposure conditions where no escape of bee is possible. Also, if historical contamination is present then a field study would also take into account such contamination. | d. See point b above. |
| | | | f. (1573-1577) Interesting to see that the specific actions Beekeepers ask for do not relate in any way to pesticide products. Which again reinforces the need for a more holistic view and action rather than the focus on PPPs in this document. | e. See point b above. |

Section 5.1.3.2:

| | | | g. (1605) "... Unclear if... Monitoring initiatives... Over the last 20 years would be used or not." A key part of this systems project will be validating model. If these previously acquired data are not used, then this document should lay out a multi-year strategy to acquire data to design and validate the approach that will be finally implemented. |
| | | | h. (1610) "anonymity should be a choice left open to those willing to share data." Data without links to location and timing should not be used in the system. All data should be of high quality and traceable. |

Section 5.1.3.4:

| | | | i. (1628-1642) The research calls from Beekeepers one again indicate that much research is needed on the non-Pesticide factors again indicating that a wider focus is needed that just focusing on PPPs. |
| | | | f. Indeed, beekeepers were prompted to discuss the current regulatory system in the first part of the focus groups but not to seek specific actions in relation to pesticide products. Regarding multiple stressors, see answer to comment 46. |
| | | | g. This section relates to the views of the beekeepers from the focus group. Technical issues related to monitoring and model validation are presented in section 3.2 and in the added figure on timeline (Figure 5). |
| | | | h. This represents the beekeepers’ views to be considered when defining data sharing protocol in the system. |
| | | | i. Indeed, these are needs to be considered for future research, as they were deemed most important by the beekeepers. |

See answer provided to comment 46.
exploration and not all questions can, with confidence, be explored with either observational or experimental (or even modelling) approaches.

For example, if exploring the potential causes of a specific condition in a bee colony is the focus of the study, a case control type of observational study may be most appropriate. If the focus is on how a particular condition develop over time in a honey bee colony, a cohort type of observational study may be most appropriate. The latter may be appropriate for tracking temporal variation in exposure to PPPs in bees, but is less appropriate for tracking effects on honey bee colonies of such exposure to either single or multiple PPPs. This is because it is impossible to exclude the confounding with other factors such as covariation among use of different agrochemicals (e.g. PPPs and fertilizers) or that use of PPP are related to specific crops and vary in intensity with the crops grown, creating a covariation between PPP use (and exposure) and landscape context. Such confounding biases can to a larger extent be excluded in experimental studies. In experimental field studies, it is thus easier to confidently link PPP use to potential effects on honey bee colonies. This is a requirement in ERA of PPPs for bees.

The two study approaches are however complementary, with support for that experimental studies provide insights on casual relationships over shorter time scales, while observational studies (such as monitoring) may provide understanding of longer-term trends over centuries and beyond.

Some relevant literature on the subject:
Christie, A.P. et al. 2019. Simple study designs in ecology produce inaccurate estimates of biodiversity responses. Journal of Applied Ecology 56: 2742-2754 (doi: 10.1111/1365-2664.13499).
Shaffer, T.L. & Johnson, D.H. 2008. Ways of learning: Observational studies versus experiments. The Journal of Wildlife Management 72: 4-13.
Yuan, Z.Y. et al. 2017. Experimental and observational studies find contrasting responses of soil nutrients to climate change. eLife 6:e23255 (doi: 10.7554/eLife.23255).

| Ctb | 52 | 6.1. Environmental risk assessment of multiple chemicals |
|-----|----|----------------------------------------------------------|
| It is stated that toxicity data with multiple chemicals is needed, particularly chronic but also acute data, and in addition more sub-lethal endpoints. It is not further discussed how the various combinations would be prioritized and tested, or is an indication given of which sub-lethal endpoints would be considered relevant. Please explain how this point further and give more detail about the types of combinations that should be tested (i.e. how many and which substances) as well as whether current test methodologies would be acceptable to develop this data (which)? Is it the case that new methods would have to be developed? |

| Ctb | 52 | 6.1. Environmental risk assessment of multiple chemicals |
|-----|----|----------------------------------------------------------|
| This scientific opinion provides a conceptual framework using a systems approach for the risk assessment of multiple stressors in bees. Prioritisation of specific types of combinations, substances and specific endpoints (acute, chronic and sub-lethal) and testing methodologies are beyond the scope of this scientific opinion. Testing methodologies are addressed in the bee guidance document which is under preparation. In general, prioritisation should be performed taking into account use of chemicals including PPPs, results from monitoring studies, the likelihood of co-occurrence in hives, pollen and bee bread, their potency (toxicity) in the laboratory and in the field. This should be considered on a case-by-case basis. |

| CropLife | 53 | 6.1. Environmental risk assessment of multiple chemicals |
|----------------|----|----------------------------------------------------------|
| (1784) (ii) multiple stressors. Need to be able to dynamically model the complex interactions between chemical and non-chemical stressors, but also between the chemical stressors and the non-chemical stressors themselves. Alternate wording might be "A unifying approach is needed to dynamically model the complex interactions between a complex array of chemical and non-chemical stressors. |

(1784) All of these steps must be appropriately validated. |

(1798) Suggest that "data on combined effects..." should be "data on combined exposure and effects...".

| CropLife | 53 | 6.1. Environmental risk assessment of multiple chemicals |
|----------------|----|----------------------------------------------------------|
| Noted and amended (see ii in table 2). |

Agreed. |

Agreed and amended.
(1808) Suggest that "...as well as in silico models..." be ".. As well as validated in silico models...".  
Agreed and amended.

(1813) Suggest "It is recommended to test the methods and models developed under item 2) (immediately above) within the ApisRAM model and other available models using case studies" should be "It is recommended that specific case studies be used to test and validate the ApisRAM model and other available models." Until ApisRAM is fully validated, it should not be used to test other methods and models.  
Agreed and amended.

Ctgb 54 6.2. The systems-based approach  
This section indicates the many pros of using ApisRAM, but finally notes that there are many obstacles that must be overcome in order to use it and that a huge amount of data is required in order to parameterize and (regularly) update it. It is then stated that field and laboratory studies should not be abandoned. Is this referring to the "status quo" methodologies, including the existing risk assessment? Laboratory (and sometimes field) studies are a piece of the overall risk assessment framework, but do not constitute it wholly.  
This was based on the need for a transition; however, we also refer to the continual need to update and improve the tools and of course to validate our predictions. As such targeted experimental studies will continue to be invaluable.

ANSES 55 6.2.1. Modelling and monitoring  
[6.2.1/p46/1836 and 1849]: FR: While models tend to be a representation of the environment as realistic as possible, uncertainties are inherent to models. Certainties (i.e. confidence interval...) are key to contextualize the model output. Could the authors develop a little bit more for the readers not familiar with models on the importance of uncertainties intervals?  
Some explanatory text has been added.

CropLife 56 6.2.1. Modelling and monitoring  
a. (1839) "ApisRAM... There is a risk that it may not forecast the impacts of multiple stressors on hives to the degree of accuracy required for regulatory use." ApisRAM should not be used for regulatory purposes until it is fully validated across a full range of environmental scenarios.  
b. (1839-1858) As far as ApisRam is designed currently we agree that there is a high risk that the aim to have a model ready for honey bee risk assessment might be missed. It is recommended to look back into the key issues in bee modelling which were layed out by EFSA in 2015 and focus to solve them first before increasing the complexity further. However, if the model is setup in the right way it reflects the current state of knowledge and can help in an interactive way to improve the knowledge until the target is reached. CLE would be happy to contribute to the process to make this a success story.  
a. It is not the intention to use ApisRAM without calibration and testing to ensure that is accurate enough.  
b. Thank you we intend to use ApisRAM in the way you describe.  
c. There is a large difference between the way BEEHAVE implements these factors and the way they are implemented in ApisRAM. BEEHAVE including its recent additions is a much simpler approach lacking dynamics of
| RIFCON GmbH | 67 | General comments. |
|-------------|----|------------------|
|             |    | c. (1823-1828) Just for clarification BEEHAVE also takes localised landscape as input, there is also nowadays a user friendly add-on available to create these landscapes the BeeMap model and it was proven that with this spatial explicit landscapes including dynamic nectar and pollen availability the BEEHAVE model is able to predict beehive dynamics with high precision (Agatz et al. 2019). For ApisRam this feature seems to be missing (line 1193-1197 and 1210-1215) also for toxicant and pathogens ApisRam seems to miss the relevant dynamic features (see line 1008-1010, 1188-1192). Since there is no toxicokinetic-toxicodynamic component in ApisRam and the in hive fate model seems not to be readily implemented we would question that ApisRam in its current state is able to handle chronic effects. Therefore, this paragraph is factual wrong and should be removed from the document. |
|             |    | a. A new figure (Figure 5) was added to describe the timeline related to the development of ApisRAM until it can be used for the risk assessment of PPPs. The use of the model in the revised Bee Guidance (that is not yet published) or a tiered approach is out of the scope of this opinion. |
|             |    | b. All models used for prospective risk assessment are extrapolations and could be wrong. ApisRAM uses mechanisms and not statistical distributions which confer better predictive ability within its domain of applicability. |
| CropLife   | 58 | 6.2.2. Data flows into the systems-based approach |
|            |    | a. (1913) Suggest that this paragraph should also include the need to validate any models. |
|            |    | b. (1941) Table 3 - since a critical part of this project is to simulate the effects of multiple stressors, the Modelling section of the table should landscape and missing the critical interactions between stressors, behaviour and bee health. These aspects are more fully implemented in ApisRAM as stated. |
|            |    | a. The need to validate the model is addressed in several parts of the opinion, including the previous sections 3.1 & 6.1, Table 1 and Figure 5. |
indicate tasks associated with simulation of exposure and effects from multiple chemical and non-chemical stressors.

c. (1941) Table 3 - A critical part of monitoring will be to design the sentinel beehive network - understanding the optimal locational criteria, spacing, sampling, etc. will be critical to acquiring solid monitoring data. This section of the table should include a "sentinel beehive network" design and testing phase.

| RIFCON GmbH | 59 | 6.2.2. Data flows into the systems-based approach |
|-------------|----|-----------------------------------------------|
|             |    | Line 1859: Data flows: Data collection of all available data in an adequate format is one of the biggest challenges. When will be ApisRAM ready for risk assessment? The new bee guideline should be available this year. It seems that ApisRAM can't/Will not play a role in this guidance? |
|            | 60 | 7.0. Conclusions and Recommendations: general comments |
| RIFCON GmbH |    | General comment: |
|             |    | a. For us it is not clear, how ApisRAM will be implemented in the current risk assessment. As a higher tier refinement? If the model is meant to be used in ERA detailed guidance is required on where and especially how it is to be applied. Additionally, a model documentation according to EFSA PPR (2014, GMP) (e.g. TRACE or similar document) and a GMP summary need to be provided. It needs to be shown that the complexity of the model allows a proper validation according to EFSA GMP (e.g. in terms of sensitivity and uncertainty analysis). |
|             |    | Specific comments: |
|             |    | b. Table 1, year 2021, 6th point (page 11): A manual is mentioned at the end of the sentence only. Is there also a technical document according to GMP guidance (e.g. TRACE document) |
|             |    | c. Figure 1, Timeframe (page 15): "For future consideration as framework for ...." Is it clear when to use the model? To be used at Tier 3 or Always etc.? |
|             |    | The question related to the bee guidance and the role of ApisRAM in this work is beyond the scope of this opinion. |
|             |    | a. The scope of this opinion is to propose a systems-based approach, in which the model is a fundamental part. The specific use of the model for regulatory purposes is beyond the scope of this opinion. |
|             |    | b. The manual refers to the use of ApisRAM. The formal model containing all codes, parameters, references used will also be published. The development of the model reflects the approach of the GMP opinion published by EFSA in 2014. |
|             |    | c. Figure 1 does not consider the model solely but the systems-based approach. The use of this approach, |
| National Farmers' Union | 61 | 7.1. Conclusions | To make this a genuine dynamic multiple stressor approach it needs to factor in other stressors beyond PPPs and chemicals, such as habitat loss, the impact of poor bee nutrition, honey bee pests, viruses and other diseases, attacks by invasive species, as well as environmental changes caused by changes in weather patterns and climate. | The various stressors mentioned in the opinion potentially affecting honey bees were considered and included in the systems-based approach and would be included in the analysis (by a network of sentinel hives located in various specific regions having different conditions regarding their environment/weather/climate/infectious agents/invasive species, etc. that would also be described for further analysis within the system). |
|------------------------|----|-----------------|---|---|
| CropLife               | 62 | 7.1. Conclusions | a. (1963-1970) There is a need for a reflection on the actual added value in the decision making system for PPP: part of it is of importance to judge on the basis of the effect of a PPP to bee health and part of this is important from a risk management point perspective where other stressors may influence the outcome of the risk assessment. The assumption that a PPP may be approved where no other stressor is having an impact may in effect be obsolete and hide the lack of action on those stressors to start with. Actions are actually increasingly needed on those factors. | a. This opinion is a reflection document and provides ideas/concepts for further discussion. The point raised by the stakeholder is important. Policy makers and risk managers can make the requested implementations if deemed relevant. b. We agree and amended. |
b. (1848) Why the compete focus on PPPs plus other stressors and no focus on other (no PPP) stressors combinations which can also have big impacts on colonies eg food availability & Pest & disease for example.

c. (1952) No consideration is given as to the regulatory implementation of the systems-based approach that is being proposed i.e., how practicable or implementable this is within the existing 1107 PPP Regulatory Framework.

d. (1967) Consideration is needed as to the practicality for Regulatory Authorities to take into account all potential PPP mixture exposures as well as other potential non-regulated stressors in the evaluation of PPPs, as these will vary hugely in time and location. Also, how can mitigating actions taken by stakeholders eg bee keepers and farmers to improve the impact of other non-regulated stressors, be taken into account in the PPP risk assessment.

e. (1971) Similar to above comment no consideration is given as to how implementable such a Systems Based approach is within the 1107 PPP Regulatory Framework.

f. (1972) Why are we restricting the use of models to ApisRAM when ApisRAM suffers from the potential weaknesses identified by EFSA for the more widely used and researched honeybee colony model BEEHAVE i.e., lack of validation and a PPP Ecotox Module?

c. The scope of this opinion is to propose a systems-based approach for the future. The immediate legislative implications of this approach are beyond the scope of this opinion.

d & e. see answer to comment 62.a.

f. The statement is incorrect. The ecotox module is included in ApisRAM, but the model is not yet finalised. It is planned that the model will be calibrated with data from various EU regions (not only from ESFA field data collection conducted in Portugal and Denmark).

| RIFCON GmbH | 63 | 7.1. Conclusions | General remark: Such an approach can be very helpful for beekeepers to plan strategies. However, the lack of uniform data, lack of testing the (incomplete) model and missing guidance how to evaluate multiple stressors, makes this approach hardly usable for the current evaluation procedure of plant protection products. | The scope of this opinion is to propose a systems-based approach to benefit different stakeholders such as beekeepers, citizens, scientists, risk assessors and risk managers. This opinion is a reflection document and provides ideas/concepts for further discussion. |
| Name            | Page | Section | Recommendation | Summary |
|-----------------|------|---------|----------------|---------|
| Campbell Mike   | 64   | 7.1. Conclusions | Act now | The specific use of the approach for regulatory purposes is beyond the scope of this opinion. |
|                 | 65   | 7.2. Recommendations | Act now | The scope of this opinion, which is under the remit of EFSA, is to provide scientific evidence for risk managers and policy makers to make informed decisions (for action). |
| CropLife        | 66   | 7.2. Recommendations | a. (1991-1996) The system should actually be more ambitious and be used to predict survival chances of colonies exposed to all sorts of stressors, not focusing on chemicals only. This way it would actually reflect the situation encountered by pollinators. b. (1995) Surely a Systems based approach should also have the intent to propose solutions for the non-PPP stressors and not just focus on the PPP risk assessment approach. c. (1996) Need to add that if such a Systems based approach is to be adopted it will need to be calibrated to get the right balance of providing farmers with PPP tools and protecting pollinators. Thus, an impact assessment on PPP registration will be needed. d. (2000) There is a need to acknowledge the data and knowledge gaps that currently exist and need to be filled before this systems approach can be broadened to other bees and other non-target organisms. e. (2005) We support that risk assessment methodologies should be extended to include stakeholder views, and this should include Industry and Farmers views on practicality and impact. f. (2013) CropLife Europe support the recommendation that data quality is important, and that guidance is needed. This is particularly... | Same answer as for comment 64. |

The specific use of the approach for regulatory purposes is beyond the scope of this opinion. The scope of this opinion, which is under the remit of EFSA, is to provide scientific evidence for risk managers and policy makers to make informed decisions (for action).
true for scientific research papers where quality varies considerably in comparison to PPP registrant studies which must comply to GLP and Internationally accepted Test Guidelines.

g. (2020) "...ApisRAM needs... Testing with accurate data...." Agree with the need for accurate data but suggest that the appropriate word is "validation" rather than testing. Validation is a step by step pre-designed approach to make sure that the model is functioning correctly and producing valid results.

h. (2029) Is this Systems based approach also intended to be a communication tool to general public? May be some clarification is needed of the intended users and purpose of this new system-based approach?

i. (2029-2031) The holistic systematic approach being suggested completely misses the impact of non-PPP stressors either alone or in combination. Surely EU citizens deserve a better understanding of all potential causes on bee losses and not just those relating to PPPs and PPP interactions.

c. We agree, should it be adopted.

d. This is a point we have made quite clearly on several occasions in the opinion and, in particular, in section 6.

e. This is the objective of the EU Bee Partnership, whose members were interviewed, and views included in this opinion.

f. We agree that data quality is key. Under the field data collection project conducted by ESFA to calibrate ApisRAM, data models were established to ensure standardised and harmonised data collection. Hopefully this experience can be used for other similar initiatives and should be widely promoted to enhance interoperable data collection/sharing (the mission of the EU Bee Partnership).

g. Testing and mechanistic validation will take place after the model is calibrated against the data collected under the different projects. These steps will be informed by expert knowledge, i.e. to determine the biological relevance of the model (to fit the observed patterns).

h. The system-based approach is designed to respond to various
stakeholders needs (listed in detail in section 4), including citizens (see section 4.3). The approach can also be used as a communication tool, as outlined: "For citizens, a systems-based approach may provide a means to explain the complexity of the system, including a better understanding of the impact of PPP application given the presence of multiple stressors."

i. This statement is incorrect. The model considers both PPP and non-PPP components, and could be used to assess the effects of non-PPP interactions alone.

| National Farmers' Union | 67 | 7.2. Recommendations |
|------------------------|----|---------------------|
| a. Line 2004-2006 - the NFU supports that proposal that 'EFSA risk assessment methodologies should be extended to include stakeholder views when relevant, contributing to the building of trust in the science underpinning the risk analysis process in the EU', and that this should include farmers and their representative organisations. |
| b. Line 2029 -2031 - We agree 'The systems-based approach should report relevant information in a manner that will allow EU citizens a better understanding of the causes and of underlying mechanisms of bee losses, both in EU and worldwide' but feel this Scientific Opinion does not yet achieve this as it is too biased against PPPs. |
| a. Farmers and their representative organisations are represented within the EU Bee Partnership. Although the number of organisations limited a similar cooperative approach could easily be transferred to larger groups. |
| b. This statement is incorrect. The approach is holistic and considers all stressors which will contribute to a better understanding of the causes and of underlying mechanisms of bee losses. |


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Abbreviations

AFB  American foulbrood
AHAW  EFSA Panel of Animal Health and Animal Welfare
a.i.  Active ingredient
ALMaSS  An Animal, Landscape and Man Simulation System
ApisRAM  An Agent-based simulation for honey bee colony
BEEHAVE  Model to simulate the development of a honey bee colony and its nectar and pollen foraging behaviour in different landscapes
B-GOOD  Giving Beekeeping Guidance by Computational-Decision Making
BMP  Beekeeping Management Practice
C++  Programming language
EC  European Commission
ED  Environmental Drivers module
EFSA  European Food Safety Authority
EMR  Estimated Mean Ratio
EP  European Parliament
ERA  Environmental Risk Assessment
EU  Europe
EUBP  European Bee Partnership
HEALTHY-B  EFSA project on Assessing the health status of managed honey bee colonies (HEALTHY-B): a toolbox to facilitate harmonised data collection
HIS  Health Status Index
LD50  Median Lethal Dose
MIXTOX  EFSA Guidance on ‘Guidance on harmonised methodologies for human health, animal health and ecological risk assessment of combined exposure to multiple chemicals’
MS  Member State(s)
MUST-B  EFSA project on ‘EU efforts towards a holistic and integrated risk assessment approach of multiple stressors in bees’
OIE  Office International des Epizooties
PER  Proboscis Extension Reflex
PoshBee  Pan-European assessment, monitoring and mitigation of stressors on the health of bees
PPP  Plant Protection Product
PPR  EFSA Panel of Plant Protection Products and their Residues
OECD  The Organisation for Economic Co-operation and Development
RPU  Resource Providing Unit
SOP  Standard Operating Procedure
SPG  Specific Protection Goal
ToR  Term of Reference
TU  Toxic unit
Appendix A – Explanatory text on the EFSA website for the public consultation

EFSA’s Scientific Committee has launched an open consultation on its draft EFSA Scientific Committee Opinion on a systems-based approach to the environmental risk assessment of multiple stressors in honey bees. The scientific opinion is aligned to aspirations outlined in the EU Green Deal and the EFSA Strategy 2027, presenting opportunities and ideas facilitating discussion to advance environmental risk assessment of multiple stressors in honey bees. For this purpose, a holistic approach, based on monitoring and modelling strategies, is presented. This approach could substantially contribute to future development of environmental risk assessments of multiple stressors at larger spatial and temporal scales. The monitoring would rely on a network of sentinel hives placed across representative climatic zones and landscapes in the EU and connected to a platform for data storage and analysis. The modelling system, ApisRAM, which simulates a honey bee colony as accurately as possible would rely on data from the monitoring system, i.e. from the bee colonies and their environment. The model would be continuously informed by new scientific knowledge from research. It will be a supportive tool for beekeeping, farming, research, risk assessment and risk management, and it will benefit the wider society. Finally, gaps related to environmental risk assessment are highlighted. They will need to be filled to enable the systems-based approach to be fully implemented.

Interested parties are invited to submit written comments by 04/03/2021 (new deadline). Please use the electronic template provided to submit comments and refer to the line and page numbers. To submit additional data to support your comments or files, there is an upload function available in the tool (for a maximum size of 1Mb file). Otherwise you can also contact specific unit’s functional mailbox SCER.PublicConsult.10@efsa.europa.eu.

Please note that comments will not be considered if they:

- are submitted after the closing date of the consultation
- are presented in any form other than what is provided for in the instructions and template
- are not related to the contents of the document
- contain complaints against institutions, personal accusations, irrelevant or offensive statements or material
- are related to policy or risk management aspects, which are out of the scope of EFSA’s activity.

EFSA will assess all comments which are submitted in line with the criteria above. The comments will be further considered by the relevant EFSA Panel and taken into consideration if found to be relevant.

Copyright-cleared contributions

Persons or organizations participating in a Public Consultation of EFSA are responsible for ensuring that they hold all the rights necessary for their submissions and consequent publication by EFSA. Comments should inter alia be copyright cleared taking into account EFSA’s transparency policy and practice to publish all submissions. In case the submission reproduces third-party content in the form of charts, graphs or images, the required prior permissions of the right holder(s) should have been obtained by the PC respondent.

Publication of contributions

Contributions will be published and may be re-used by EFSA in a different context. It should be noted that contributions submitted by individuals in a personal capacity will be published as such, indicating the author’s first and family name, unless a substantial justification for protection is provided by the respondent. Contributions submitted on behalf of an organisation are also made publicly available and attributed to the organization in question. Submit comments by 4 March 2021.

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