PESTICIDE STEERING NETWORK (PSN) 32nd meeting

29th October 2024 - 30th October 2024
14.00-18.00 (CET)/ 09.00-13.00 (CET)
Minutes agreed on 21 November 2024

Location: EFSA - Parma (Meeting Room 07)/Webconference

Attendees:

- Network Participants:

Country	Organisation
Austria	AGES
Belgium	Federal Public Service Health, Food Chain Safety and Environment
Czech Republic	Central Institue for Supervising and Testing in Agriculture
Denmark	Danish EPA
Estonia	Agriculture and Food Board
Finland	Finnish Safety and Chemicals Agency (Tukes)
France	Anses
Germany	Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL)
Greece	Benaki Phytopathological Institute Hellenic Ministry of Rural Development & Food
Hungary	National Food Chain Safety Office; Directorate of Plant Protection and Oenology; Department of Plant Protection Product and Fertilizer Assessment
Ireland	Department of Agriculture, Food and the Marine (DAFM)
Latvia	State Plant Protection Service of Latvia
Lithuania	The State Plant Service under the Ministry of Agriculture
Malta	Malta Competition and Consumer Affairs Authority (MCCAA)
Netherlands	Ctgb
Norway	Norwegian Food Safety Authority
Poland	National Institute of Public Health NIH - National Research Institute
Portugal	DGAV
Slovak Republic	Central Control and Testing Institute in Agriculture
Slovenia	Administration for food saftey, veterinary sector and plant protection
Spain	INIA-CSIC
Sweden	Swedish Chemicals Agency

	Swedish Food Agency

- Observers:
  Federal Food Safety and Veterinary Office (Switzerland);

- European Commission/Other EU Agencies representatives:
  European Commission, European Chemical Agency (ECHA)

- EFSA:
  Pesticide Peer Review Unit: TIRAMANI Manuela (Head of Unit), KARDASSI Dimitra (chair), HALLING Katrin (co-chair), GINER SANTONJA Germán, COLAS Mathilde, COLAGIORGI Angelo, VIANELLO Giorgia, DE LENTDECKER Chloe, CAVALHEIRO Joao Filipe, CASTELLAN Irene, LEUSCHNER Renata, BERNASCONI Giovanni, VERANI Alessia, ISTACE Frédérique, LEUSCHNER Renata

  Environment, Plants & Ecotoxicology Unit: GOULIARMOU Varvara, IPPOLITO Alessio, KIENZLER Aude, RORTAIS Agnès

  Front-Desk & Workforce Planning: DE BERARDIS Sara, DELFINO Alessandro, MAZZEGA Silvia, GIAROLA Alessandra

  Risk Assessment Logistics Unit: POZZATTI Piera

1. Welcome and apologies for absence

The Chair welcomed the participants. No apologies were received.

2. Adoption of agenda

The agenda was adopted with one point added under Any Other Business (AOB).

3. Presentation of the EFSA Guidelines for observers

The rules governing observers' participation were presented. The registered observers for the meeting represent a range of major stakeholder groups including academia, industry, farmers and civil society etc.

4. Renewal of the Terms of Reference (ToR) of Pesticide Steering Network

The Chair informed that the Network Terms of Reference (ToRs) were due for revision, given that the last update was in 2021. The Chair informed the meeting that the updated ToRs had undergone a thorough consultation with Member States, the Advisory Forum and Commission services and all received comments have been thoroughly considered and addressed. Consequently, the ToRs are now deemed renewed and no further comments received during the meeting.

The updated ToRs have been published on the EFSA website[1]. The ToRs are scheduled for the next revision after 3 years in 2027.

5. Update on activities by the European Commission

The Commission provided an update on the activities related to legal requirements, guidances and feedback from decision making on active substances including feedback from the PAFF committee.

Q&A

BE inquired about the policy for centralising assessments already carried out for certain co-formulants in order to avoid duplication of work. In response, the Commission reiterated the existence of the negative list of unacceptable co-formulants i.e. Annex III to Regulation (EC) 1107/2009 and urged Member States (MSs) to notify any new unacceptable co-formulants as soon as possible, as Commission Regulation (EU) 2021/383 is currently being updated. Furthermore, the Commission is working on a positive list and on establishing a common repository for co-formulants.

In response to a question from AT regarding the new hazard classes, the Commission clarified that a CLH report submitted to ECHA will need to include notably the ED assessment for category 1 and 2 as of the applicability date set in the CLP Regulation. Although Regulation (EC) 1107/2009 does not explicitly define ED categories, the ED criteria defined under this regulation are equivalent to ED category one under the CLP Regulation. It was explained that it is intended that any active substance identified as an ED under Pesticide or Biocide regulation will be classified as ED category 1 under CLP via an omnibus process in due time, to avoid duplication of work.

The new hazard classes are applicable for new active substances applications submitted as from 1 of May 2025 onwards. Regarding the existing substances, the new hazard classes will be mandatory for existing substances as of **1 November 2026**, although they can be applied on a voluntary basis before the mandatory implementation date of 1 November 2026.

6. Practical implementation on the new act on safeners and synergist

EFSA anticipated the practical implementation of the new Commission Regulation (EU) 2024/1487 defining data requirements for the approval of safeners and synergists:

- Notification of Studies (NOS): applicants must notify studies, including details on alternative testing methods, in line with Article 32b(2) of the General Food Law. New domains for safeners and synergists will be added to Connect.EFSA for this purpose.
- Pre-Submission Advice (GPSA, RPSA): applicants can request general pre-submission advice (GPSA) in line with Article 32a(1) of the GFL and renewal pre-submission advice (RPSA) in line with Article 32c(1) of GFL from EFSA and Member States. Connect.EFSA will be updated to give the possibility to insert pre-submission activities in relation to applications for safeners and synergists.
- Regarding the list of MSs contact points involved in drafting GPSA and RPSA, new groups dedicated to safeners and synergists may be created to better manage the MSs contribution. MSs will be contacted for providing EFSA with the contacts to use.
- IUCLID submissions: dossiers for safeners and synergists will be submitted through IUCLID. A new table of contents is set to be implemented by December 2024, with a working context being developed for deployment in April 2025, leading to the first submissions expected in April 2026. To meet the data requirements of Commission

[1] https://www.efsa.europa.eu/sites/default/files/2023-09/terms-of-reference-pesticide-steering-network.pdf

Regulation (EU) 2024/1487 the IUCLID OHT on Efficacy is being improved to host data on efficacy trials.

Q&A

Concerns were raised on the impact of new IUCLID features on existing dossiers. DK is currently assessing an active substance that includes a safener, which requires evaluation by the RMS. The dossier was deemed admissible last year. Will the dossier format change with the new IUCLID features for safeners and synergists?

EFSA clarified that the new working context or table of content on safeners and synergists has no impact on existing dossiers that are under evaluation in another working context or table of content on 'EU_PPP for the approval or renewal of AS'. The implementation of safeners/synergists dossiers in IUCLID is a separate process which does not affect the on-going assessments and dossiers that are already declared admissible. For additional questions, please refer to the presentation given by Commission under point 5.

DE noted that Commission Regulation (EU) 2024/1487 foresees the submission only of summaries of publicly available literature, and enquired whether applicants should provide complete literature studies or only summaries in IUCLID.

The discussion highlighted the importance of having detailed data for risk assessment, also in the context of safeners and synergists. While summaries may be acceptable, the detailed study is ultimately needed for a thorough assessment. It was also recognised that this is an horizontal issue that affects not only safeners and synergists but also the wider discussion on how to evaluate the scientific peer-reviewed papers. The discussion raised awareness of the need to clarify the issue of the submission of complete literature studies and a follow-up on this issue will be pursued.

ACTIONS

- EFSA to follow up on the issue of requiring complete literature studies versus summaries of publicly available literature in IUCLID, and provide clarifications on the horizontal aspects, as well as in the context of safeners and synergists. However it is clear that if a study is deemed relevant, the risk assessors at RMS must have access to the complete study to assess it.

7. Risk assessment of microbial consortia

EFSA highlighted that Regulation (EU) 283/2013, as amended by Commission Regulation (EU) 2022/1439, introduced the possibility of approving active substances that are "qualitatively defined combination of strains as they occur naturally or by manufacture", i.e. microbial consortia. It was flagged that differently from other food areas, applications on microbial consortia for plant protection purposes represent a novelty, and as such, no guidance is available on their risk assessment. Discussion is ongoing at Biopesticides Working Group (BPWG) to agree on the relevance of data requirements for the whole consortium or for the single components (consorts). In fact, some data requirements will apply unequivocally to all members of a consortium (e.g. the lack of transferable relevant antimicrobial resistance genes in case of bacterial consorts), while for other data requirements it may be justified to exempt providing certain data for some components of the consortium.

EFSA provided also an update on the work ongoing to improve IUCLID in order to accommodate the submission of dossiers on microbial consortia, with the aim of having a minimum viable product ready soon and a full adaptation of the tool pending on the finalisation of the ongoing discussion on the risk assessment.

Q&A

PT asked clarification on whether the approval at EU level of a microbial consortium also applies/can be extrapolated to the individual consorts (strains/isolates in the consortium).

EFSA and the European Commission clarified that the approval is conducted at consortium level, therefore the individual consorts cannot be considered individually approved.

It was also clarified that a consortium can be created at product level formulating a PPP which contains several a.s. In this case, the individual components need to be approved separately.

SE asked clarification about possible advantages for having a mixture of microorganisms as one active substance from a regulatory perspective, as more effort and complexity might be expected for the assessment of dossiers on microbial consortia than for dossiers on single active substances.

EFSA clarified that, as reported in the explanatory notes[2], there may be advantages in having active substances that are consortia of microorganisms, such as increased efficiency in plant protection due to the use of a combination of strains. Concerning the risk assessment perspective, EFSA mentioned that similarly to the approach taken with botanicals, the new regulation could facilitate a faster way to carry out the peer review process, looking at one single compound instead of multiple ones. The European Commission added that, in some cases, it may not be possible to assess the individual strains as they are part of naturally occurring consortia that cannot be separated in single strains (e.g. in case of soil microbiome). The new regulatory framework aims to foster innovation and to facilitate the entry of new products into the EU market.

ES pointed out the need to reflect on how to deal with the assessment of the quantitative composition / proportion of the individual consorts in the microbial consortia.

The European Commission clarified that a characterisation of the consortium would be needed, e.g. defining the proportion of each consort in the a.s. AT also mentioned that all these aspects were considered and discussed in the course of the drafting of the new data requirements before their implementation.

8. Update on Interactive Pesticide Residue Platform (IPReP)

EFSA provided an update on the Interactive Pesticide Residue Platform (IPReP), giving particular attention to the recently approved Terms of References (ToR) and the next steps foreseen, e.g. additional scientific topics such as rotational crops (in the light of the recent publication of the EFSA Guidance), the ongoing internal trainings on the EFSA rotational crop guidance intended to be shared with MSs and a new initiative regarding a leaning exercise of the MRL assessments with the aim to streamline the process and to optimise the time needed to finalise assessments.

EFSA stated that since the last PSN, a Microsoft Teams IPReP workspace has been established, with two nominated residue experts from each MS (as nominated by MSs) to contribute to this activity. Terms of reference (ToRs) were established together with the first scientific topic "deriving residue definitions" and have been shared with MSs via the IPREP teams workspace. How to further develop the workspace on the topic 'deriving residue definitions' will be agreed once the OECD Guidance on the residue definitions will be published and further trainings will become available.

EFSA illustrated the dedicated Microsoft Teams IPReP workspace to the audience and highlighted the governance structure, i.e. that the IPReP is hosted in the Pesticides Peer Review Unit (PREV) of EFSA and managed by a governing board composed of the Head of Unit, residue team leaders, the residue lead scientist and an administrator. The governing board meets three/four times per year.

EFSA concluded the presentation by outlining the next steps foreseen for the IPReP, i.e.:

[2] Explanatory notes for the implementation of the data requirements on micro-organisms and plant protection products containing them in the framework of Reg. (EC) No 1107/2009. PAFF-PPL-October 2023-Doc.A.07.01 12 October 2023. https://food.ec.europa.eu/system/files/2023-10/pesticides_ppp_app-proc_guide_imp-data-req_micro-organisms-ppp_imp-reg-11072009.pdf

- Engagement on rotational crops: EFSA Guidance on rotational crops has been published (https://efsa.onlinelibrary.wiley.com/doi/full/10.2903/j.efsa.2023.8225) and training videos will be made available by the end of 2024. According to MSs' feedback, further trainings can be organized by EFSA. A workspace on the scientific topic 'rotational crops' is anticipated to be added to the IPREP workspace.

MRL application leaning exercise: EFSA referred to the PSN agenda item 13 that will be presented the second day (PSN agenda item 13 entitled 'lean exercise in MRL applications - how to reduce impact of clock-stop?') which aims to streamline the Article 10 assessment process and minimize the impact of clock-stops. In relation to this, IPREP could be used as a platform to interact with MSs on identified topics such as a 'scientific check lists', 'applicable data requirements' and on the need for 'nature and magnitude of processing studies'. EFSA invited the audience and MSs to propose any other topics MSs would like to tackle.

No questions were raised by the audience for this agenda item.

9. Tools and options for engagement with applicants

EFSA (Front-Desk & Workforce Planning Unit) provided an overview of the available tools and options for engagement with applicants, as outlined in the EFSA's Catalogue of support initiatives during the life-cycle of applications for regulated products.

NL inquired whether it is possible to have a meeting between RMS/APPL/EFSA even when the dossier has already been submitted and the RMS is assessing it. EFSA clarified that in accordance with the indications provided in section 2.3. of the EFSA Administrative Guidance document, 2021, it is possible for RMS to request EFSA for advice during the assessment phase (participation of the applicant is not foreseen).

Lastly, EFSA and the European Commission encouraged MSs to make greater use of these tools, especially pre-submission advice and applicant hearings, notably for active substances with 'new' mode of action (e.g., RNA-based a.s). By engaging with applicants early in the process, MSs and EFSA can work together to ensure that dossiers are of high quality, leading to sound and robust risk assessments and peer reviews.

EFSA emphasised its commitment to providing advice to RMS/co-RMS at any stage of the assessment process. MSs were also invited to consider involvement of EFSA in RMS pre-submission meetings (i.e. pre-submission meetings organised by the RMS outside of the framework of Article 32a(1) of the GFL Regulation), as outlined in Section 2.2 of the EFSA Administrative Guidance document (2021). To facilitate this, it is essential that the RMS provides EFSA with a robust preliminary assessment of the pertinent data and clearly states the specific questions on which EFSA's advice is sought.

10. Update on reporting tables compilation. Questions by MSs on the commenting templates in Connect.EFSA

In response to concerns raised by DK and DE, EFSA clarified that the number of licenses for accessing Connect.EFSA can be increased from the current number of licences per Member States, however EFSA will closely monitor the actual use of these additional licenses. It was noted that functional mailboxes are not eligible for license granting. EFSA highlighted the distinction between accessing documents to be reviewed/commented and submitting comments via Connect.EFSA. For accessing the documents no license to Connect.EFSA is needed, instead authorised access to EFSA DMS is required. The license is only necessary to submit actual comments on the DAR/RAR via Connect.EFSA. In addition, EFSA clarified that even if two or more licenses are granted for each Member State, one license holder will not be able to see the comments inserted in Connect.EFSA

(either as draft or submitted) by another license holder from the same Member State. In cases where multiple users from the same Member State submit comments, all submitted comments will be attributed to the same Member State, regardless of the section or sub-section they were submitted for. This ensures that no comments are lost or overwritten.

With respect to accessing the documents to be reviewed/commented, EFSA clarified that the full DAR/RAR (incl. the confidential Vol. 4) is accessible to MSs via the EFSA DMS (no changes compared to the past) and the link for accessing it is included in the 'scope of the consultation' in Connect.EFSA. MSs having access to Connect.EFSA were invited to share the link with the MS experts involved in the peer review of the active substance under consultation. In addition, MSs were reminded not to access the public interface of Connect.EFSA, but to use the designated targeted consultation interface. This is simply to prevent that MS comments (incl. comments on the confidential Vol. 4 of the DAR/RAR) are submitted via the public channel since those comments are automatically disclosed in OpenEFSA at the closure of the public consultation.

EFSA has explicitly requested that MSs to refrain from submitting comments as attachments in Connect.EFSA or via e-mail. On this latter point, several MSs noted that, as long as comments are submitted to EFSA within the legal deadline, there is no legal base to reject comments that were not submitted via Connect.EFSA or even for instance as excel attachments in Connect.EFSA.

DE also noted that there are not enough fields/lines/rows for submitting comments in Connect.EFSA. The maximum number of comments that one MS can submit with one license on a given section (or sub-section) is 15 (fifteen). This is not ideal so either more fields/lines/rows are added by default, or the user should be allowed to add more fields/lines/rows, as needed. EFSA clarified that additional fields were recently added in many sub-sections of the consultations, and that adding more fields/lines/rows as a default option is technically feasible, having already been successfully implemented for consultations on microorganisms. The European Commission suggested checking the average number of comments submitted per section/sub-section, to prevent sections being overloaded with unnecessary, or underloaded with the necessary number of fields/lines/rows.

DE also noted that for microorganisms there is a mismatch between how the sections/sub-sections are named in Connect.EFSA and how they are named in the commenting template used by the applicants (and by some MSs to collect comments before including them in the tool). Alignment of the two should help assigning comments to the right section/sub-section in the tool. EFSA clarified that the commenting templates referred to by DE are appendices (namely C3 and C4) to the 2019 EFSA Administrative guidance on submission of dossiers and assessment reports[3]. EFSA acknowledges the benefit of aligning the structure of the templates with the table of contents of the targeted consultation on microbial active substances, similarly to what was recently done with the structure of the consultation that was adapted to the structure of the reporting table.

As part of the discussion, DE also noted that at the last 31st PSN meeting in 2023, it was announced that the RMS would have the option to generate the reporting table directly from the tool, yet this feature is not available. AT pointed out that without the feature to generate the reporting tables there is little or no added value in using Connect.EFSA for MSs. FR noted that Connect.EFSA appears to facilitate the work of EFSA, but not those of MSs mentioned issues with limited user access, lack of a 'mass upload' option, and time-consuming comment insertion. FI also mentioned the need to manually insert comments into a Word template after downloading them from Connect.EFSA. As a concluding remark, DE inquired whether EFSA and the applicants will also be invited to submit their comments via Connect.EFSA. Other MSs shared similar concerns.

EFSA clarified that Connect.EFSA is not only used for consultations in the pesticides area, but it is used for consultations across EFSA's remit. EFSA will investigate if there is a possibility to further develop the tool to meet the needs of MSs in the pesticides area. EFSA also clarified that it is not foreseen to expand the use of the tool to the applicants, in view of the high number of licences it would require. It was also noted that EFSA is already looking into ways to support the RMS in the

[3] European Food Safety Authority 2019. Administrative guidance on submission of dossiers and assessment reports for the peer-review of pesticide active substances, *EFSA supporting publication* 2019: 16(4): EN-1612. 49 pp. doi: 10.2903/sp.efsa.2019.EN-1612

generation of the reporting table by temporarily outsourcing this task to a contractor. The representative of the European Commission suggested looking into AI-driven (artificial intelligence) solutions.

Actions:

- MSs to request EFSA to allocate additional Connect.EFSA licences where needed. EFSA to monitor the actual use of the licenses.
- EFSA will investigate if there is a possibility to further develop EFSA.Connect to meet the needs of MSs in the pesticides area, and at the same time to find other ways to support the RMS in the generation of the reporting table.

11. Engagement possibilities-new open call for entrusting tasks

EFSA informed on the positive aspects of the ongoing framework partnership agreement GP/EFSA/PREV/2021/01 on entrusting pesticide tasks for art.36 organisations, and also what needs to be improved for the next call, mainly aiming at the wish to have more organisations applying to the call. EFSA is currently drafting a new call Entrusting tasks on pesticides falling within the mission of the PREV, PLANTS and FDP Units. The new call is expected to be launched in the beginning of 2025. EFSA would like to know how to make the new call as clear and effective as possible. An EU survey was made available for MSs to provide feedback by 15 November 2024.

No questions were raised by the audience for this agenda item.

Replies to questions from Observers

All replies to questions from Observers are reported in Annex II.

12. Improvement in peer review

12.1 Upcoming peer review planning, NAS dossiers in the pipeline, specific aspects for new biopesticides

This agenda item was presented without a power point presentation.

The Commission informed that the purpose of the agenda item was to raise awareness and necessary preparation from MSs and EFSA as regards new active substances (NAS) having innovative mode of action (MoA) that are currently already at RMS and are expected to enter the peer review process soon, and for which a specific risk assessment expertise will be needed. D A draft guidance is under preparation for viruses. The European Commission emphasised that innovative biopesticides are waited for and their access to the market should not be delayed unnecessarily as farmers need more tools for their boxes. To facilitate decision-making and not delay the process, risk assessors are reminded to avoid "nice to have" and focus on "need to know". This will enable managers to make informed decisions about the approval and use of these innovative biopesticides.

The pre-submission meetings and early involvement of EFSA should be used, in order to streamline the assessment of new biopesticides. Furthermore, the involvement of the applicants, as described under item 9, given their knowledge on the MoA is highly encouraged.

Q&A

In a question by EFSA whether there is any intention from the Commission to mandate EFSA to prepare guidance on how to handle RNAi pesticide dossiers, Commission clarifies that there is no intention to develop guidance at this stage, as it is considered that guidance can only be developed once there is a certain level of experience with the type of dossiers in question. The risk assessment process needs to be flexible and adaptable to the specific characteristics of the substance and this applies to other similar cases e.g. peptides.

SE raised the problem of resources to assess this kind of substances in the absence of guidance. The need to have guidance/guidelines was discussed as it would be difficult for RMSs to be left 'on their own'. It was noted that the same issues may be encountered in other frameworks. A possible mandate to EFSA to guide and support MSs was suggested. Commission responded that while there may not be specific guidance on RNAi active substances, there are existing data requirements and guidance documents that have to be used as a starting point and where RMS need to use as a reference for a first assessment, including also the provision in the Introduction. This scientific assessment from the RMS would then be peer reviewed. Other MSs supported the need to have guidance/guidelines as it would be difficult for RMSs to be left 'on their own'.

Some RMSs having already received dossiers for RNAi-based pesticides or expecting such dossiers, reacted and confirmed that pre-submission meetings were held, and a workshop was organized to discuss and exchange experiences. The MSs are discussing and working together to tackle the complexities of assessing these substances. According to the experience of one RMS, the main difficulty seemed to be in ecotoxicology field as the expected effects on non-target organisms are unknown and difficult to forecast. Tests on non-target organisms close to the targeted pests have been carried out but these may not be sufficient taking into account the mode of action of RNAi-based insecticides. Bioinformatics is used to assess the effects on ecotoxicity, but this approach is new and there are many unknowns. The specificity of the RNA-based insecticide is also unclear. Another aspect to be considered is the resistance development and the need to build a resistance management strategy. One RMS noted that the approvals in the US, that are freely available, may help to retrieve some useful information and indicated to have contacted Canada as well to share knowledge and experiences.

In conclusion, European Commission reiterated the need for *ad hoc* scientific risk assessment for these specific substances during the draft assessment and peer review.

12.2 Risk Assessment in peer review state of the art

EFSA provided an update on its ongoing activities related to peer review processes and mandates for specific substances. The presentation highlighted several positive developments, notably the active collaboration between EFSA and knowledgeable MSs on ED assessments, where some MSs work closely with EFSA, MSs taking the lead on certain risk assessment areas and contributing to the revision of guidance documents. Additionally, MSs are supporting EFSA on multiple projects via tasking grants, negotiated procedures, and through experts engaged under the Individual Scientific Advisors scheme. Looking ahead, areas for improvement were identified: the coordination with MSs of activities with ECHA (biocides, classification and labelling, coformulants), as well as increasing participation in peer review meetings, and optimising the timeliness of work steps and resources. As next steps, EFSA plans to gather MS feedback and proposed solutions through a survey. The outcome of the survey will be discussed at the next PSN meeting.

Q&A

The proposal to gather feedback through a survey received a positive response from MSs.

AT asked if the initiative to improve CLH assessment report by March 2025 included an updated Volume 1 format and when would it become available. EFSA clarified that a revised Volume 1 template, incorporating new hazard classes introduced by Commission Delegated Regulation 2023/707 of 19 December 2022 amending the CLP Regulation (EC) No 1272/2008, has been finalised. Subsequently, the revised template with the new hazard classes has been formally endorsed in March 2024 SCoPAFF meeting and published on the European Commission website (PDF format / ZIP format). Finally, the report generator for generating the combined CLH report/Volume 1 is under development with ECHA with the aim to have a first product available in 2025.

AT asked clarification on the meaning of a 'dossier not up to standard'. It was clarified that while a dossier may meet formal data requirements, it may not be sufficient for robust risk assessment. AT mentioned that some dossiers may be of better quality, but some may have a lot of waivers. RMS can't simply refuse dossiers because of problematic waivers. EFSA is interested in collecting MSs feedback on whether RMS may accept a dossier if it does not provide sufficient information or data to support a comprehensive risk assessment.

AT raised concerns about delays caused by the late submission of studies, particularly under NAS procedures. These studies may be conducted under other regulatory bodies (e.g. China, the USA or the UK) and are shared proactively by applicants (not requested by the RMS) for completeness. As a result, the RMS is obliged to take into consideration these studies, which can lead in delays in the assessment process. EFSA reiterated that it adheres to strict rules governing the submission of additional information, which must be provided within specific submission windows as outlined in the regulations.

NL mentioned the case when a pesticide active substance regulated in other areas than pesticides (e.g., as a food additive) data from REACH may be available. The inclusion of all REACH data in Volume 1 of the DAR/RAR can lead to delays as the applicant may not have access to all of the studies and data required by ECHA. Additionally, not all of the data may be relevant for the risk assessment. EFSA noted this issue, EFSA is engaged in ongoing discussions with ECHA to enhance collaboration and efficiency on those issues.

Finally, the Commission highlighted that delays in the peer review process were the main issue identified in the REFIT exercise. The Commission express willingness to support EFSA and MSs in addressing the issue of timeliness.

Actions

- EFSA will launch a survey to collect feedback on the issues related to peer review and propose potential solution measures as a first step. Aim is to prepare a workplan with actors and actions and possibly rediscuss in the next PSN. Following this, EFSA may pilot and implement the agreed-upon actions to improve the peer review process.

12.3 Feedback from peer review and completeness check, quality of assessments reports, delays

EFSA provided feedback from peer review and completeness check highlighting several key points. Firstly, EFSA reminded MSs to provide EFSA with updated information on the expected time of submission of the DAR and RAR, notifying EFSA even if there are no updates or changes since the last feedback. When uploading the DAR/RAR to EFSA's Document Management System, the RMS is also reminded to inform EFSA by sending an email to: FDP@efsa.europa.eu and pesticides.peerreview@efsa.europa.eu.

Regarding the completeness check, EFSA focused on the following topics:

CLH obligation: It was emphasised the obligation of submitting the CLH dossier to ECHA at the latest by the time of submission of the RAR to EFSA, as laid down in the legislation. The RMS shall

submit a proposal to ECHA to obtain an opinion on a harmonised classification of the active substance, covering at least the hazard classes listed in Art. 11(9) of Commission Implementing Regulation (EU) 2020/1740 and Commission Implementing Regulation (EU) 2020/103. If no changes are proposed to the current CLH, the RMS should contact ECHA and submit the Vol. 1/CLH report and other relevant RAR Volumes in support of the justification.

During the meeting it was clarified that the updated combined CLP/PPP template (Vol 1) with the new/revised sections consequent to the new hazard classes, has been formally endorsed in the March 2024 SCoPAFF meeting and has been published on SANTE guidelines webpage[4].

Report generator: EFSA mentioned that there is work ongoing with ECHA on the possibility to generate the CLH report/Vol.1 via report generator, but this is still under development.

GAP table: RMSs were reminded that lower risk GAPs (lower application rate or lower number of applications) should be considered in a more systematic way during the preparation of the initial DAR/RAR. This will ensure that the information is available at the beginning of the peer-review process and can be commented by all parties, instead of being submitted only after the clock stop.

It was also highlighted that the GAP table submitted in Vol.1 and LoEP should be in line and presented in the new format (should not be repeated in other parts of the DAR/RAR).

The GAP table submitted in the DAR/RAR should be consistent with the GAP in the dossier, specifically document D1 for pre-TR dossiers and IUCLID GAP from report generator for post-TR dossiers. Also it was recalled that changing the GAP is not permitted during the ongoing peer-review. During the completeness check, the RMS is asked to confirm that the GAP in the DAR/RAR is the latest version and was agreed with the Applicant.

For data gaps that were identified by EFSA in the framework of the MRL review according to Art. 12 of Regulation (EC) No 396/2005 and confirmed by the EC, the RMS is reminded to inform EFSA pesticides.mrl@efsa.europa.eu once the data requested have been submitted by the authorization holders and to indicate under which regulatory framework these are intended to be assessed.

Finally, EFSA informed on a lean approach to speed up the speed up the Completeness check phase and facilitate the revision work by the RMS. In particular, instead of listing in an email all deficiencies found during completeness check in the various DAR/RAR volumes, comments are included in track changes in the word version of the DAR/RAR submitted by the RMSs.

This approach was well-received by MSs.

Q&A

The NL asked about the confidentiality assessment of Vol. 1/CLH report, and it was clarified that this is shared with ECHA beforehand in cases of parallel CLH/PPP public consultations.

FR mentioned some cases where it was difficult to allocate comments in Vol. 1, as comments might be relevant to more than one team. It was suggested that FR will come back to EFSA with specific examples.

12.4 Presentation of studies used as supporting information in the assessment report

The NL presented a proposal on how to report the peer reviewed articles and/or other studies in the public domain (i.e. not proprietary studies conducted for regulatory purposes) available in the

[4] https://food.ec.europa.eu/document/download/ce98e221-65dc-4014-902b-d0d96a68b65a_en?filename=pesticides_ppp_app-proc_guide_doss_12592-2012.pdf
https://food.ec.europa.eu/document/download/5a067575-40fa-4fb3-93f1-640d0a8a6984_en?filename=pesticides_ppp_app-proc_guide_doss_12592-2012.zip

dossiers, especially the ones supporting the approval for microorganism a.s as largely relying upon literature studies, in the corresponding assessment reports.

The NL proposal is to have a full reporting and pertinent assessment of these studies, i.e. following Appendix E of the EFSA Administrative Guidance, only for those that are fulfilling specific endpoints (e.g. toxicity of metabolites). Conversely, for studies used only as supporting/supplemental/background information, only the abstracts should be reported without providing all the other information (e.g., material and methods).

Many MSs supported the proposal by NL (AT, SE, FI, FR, HU, ES, DK). BE welcomed the proposal as well, however it was pointed out that this approach may not be appropriate for the papers discussing the biological properties of microorganisms as this aspect, i.e. biological properties, is crucial for the risk assessment of microbial pesticides. Accordingly, it is important to have a thorough and proper assessment of such papers (the ones judged as relevant by the RMS) duly reflected in the assessment report to enable a meaningful peer review. EFSA concurred with this consideration, underlying that it is important to capture and well document (i.e. in a structured manner by following Appendix E) in the assessment report any possible pertinent/relevant lines of evidence, as well as the specific methodologies applied to get the outlined results, that might be available in the literature papers which by just quoting the abstract would not be possible to extract. On the same time, EFSA acknowledged the fact that if a reference available in the dossier is judged as being not relevant but just as a marginal supporting evidence, it may be likely just sufficient quoting the title of the concerned reference alongside a short indication of the possibly supporting information the reference may contain. Also, BE indicated whether the same approach for the literature/public studies might be followed for synthetic a.s. and not only for microbial pesticides. It was pointed out that indeed, in principle, the same approach may be followed also for chemical a.s, however it was recognised that for synthetic a.s. (especially new active substances), where the amount of public information/literature available is generally limited compared to microorganisms.

DE raised that, at OECD level, is being developed a new OHT for presenting the research data/literature study results and asked whether this new template will be implemented in IUCLID. In reply to DE, it was confirmed that EFSA is involved in this OECD activity, however the timeline for the implementation of the new template in IUCLID is currently pending further discussion with US-EPA and ECHA.

Overall, it was acknowledged that there is a valid room for accepting the NL proposal as clearly in the dossiers there might be available a number of more or less relevant literature papers and accordingly a different approach can be taken for their assessment and presenting their results to avoid unnecessary burden and in the interest of efficiency and timeliness of the overall peer review process.

Actions:

- EFSA will reach out NL to elaborate on this proposal in more concrete terms. This may ultimately lead to incorporating the proposal into the EFSA Administrative Guidance document.

13. Lean exercise in MRL applications - how to reduce impact of clock-stop?

EFSA presented the approach and outcomes (incl. recommendations) of the Lean exercise that was undertaken by EFSA in the field of MRL applications. The objective of the agenda item was to receive feedback from the PSN on the following 3 (three) recommendations put forward for piloting, and to seek for volunteers from MSs for the piloting phase:

1) harmonise scientific check at Member State level by developing a scientific checklist and to test it with Member States;

2) gather more details from MSs when additional data requirement is set by the EMS during the intake phase, as well as to test the flow charts (yet to be developed by EFSA) on clarifying data requirements and on trigger values for new Nature of Residues / Magnitude of Residues studies in the context of processed commodities;
3) gather feedback from MSs on the usage of the MRL report generator feature of IUCLID.

As part of the discussion, France noted that they would be interested in contributing to the development of the checklist, yet how far the scientific acceptability should go is still to be agreed. EFSA clarified that the intention is to launch a dedicated survey with the involvement of MSs (towards end 2024) to gather further feedback on the planned pilots, and to collect additional ideas from Member States. In addition, EFSA informed the PSN that the Interactive Pesticide Residue Exchange Platform (IPREP) will be used as forum for follow-up and piloting. Last, but not least, EFSA encouraged all MSs to start using the MRL report generator feature of IUCLID as the optimisation of this feature is now at an advanced stage.

Actions:

- EFSA to launch a dedicated survey on the proposed pilot projects and to collect feedback and additional ideas from MSsin the framework of MRL applications towards end 2024.
- MSs to express interest in the presented pilot projects that will be kicked-off in 2025 and performed via IPREP.
- MSs to start using the MRL report generator feature of IUCLID as the optimisation of this feature is now at an advanced stage.

14. Scientific updates - Guidance Document updates

14.1 EFSA OPEX model. Issues encountered by MSs and possible solutions.

The NL presented issues encountered by their mammalian toxicology team with the use of the new online tool of the EFSA OPEX guidance, considered by the Dutch competent authority Ctgb as less transparent and more rigid.

Examples of these issues were shared with the audience in relation to:

- Worker exposure: There is a possibility to calculate the re-entry period for a safe use. However, only the number of days is presented, not the associated exposure. If there is no acceptable exposure (AOEL >100%), the exact exposure is not indicated while it would be needed to perform combined exposure calculations.
- Residents and bystanders exposure: It is not possible to check the mean exposure values for the individual exposure pathways, and therefore to refine the exposure estimates by excluding specific exposure pathways. Only the 75 percentile is presented.
- MAF (Margin of Acceptance Factor) : MAF cannot be set up manually or adapted.
- It is not possible to choose your own combinations of PPE: The NL highlighted that some PPEs are not accepted in some MSs, so it would be relevant to choose the specific combination applicable.

The NL asked the audience if other MSs experienced the same issues or might have additional one and opened the floor for discussion.

Q&A

EFSA informed that most of those cited issues will be addressed and solved in an updated version of the OPEX calculator (soon available):

- For the worker: there will be the possibility to choose a specific re-entry interval and the user will obtain the corresponding exposure estimates in the results.
- For residents: the mean values for the different exposure pathways will also appear in the results (in the report) for completeness.
- MAF: it cannot be set up manually but it is calculated online in the tool on the basis of the DT50, of the number of applications and the application interval; the calculation is the one reported in the GD.
- PPE combinations: in the updated calculator, it will be possible for the user to choose specific PPE combinations as available for the use under consideration.

DK informed that they will forward to EFSA specific feedback from the toxicology team on this regard.

NO raised a few points as regards to:

- Use of dermal absorption data when the testing is done with another formulation type than in the GAP: Norway highlighted that the recalculation in the model results in a dermal absorption > 50% (default value) and seek confirmation on the correcteness of the result.
- Use of drift reducing nozzles: some NGOs wonder whether this should be always used in all areas or if it can be used only on part of the area.

To reply to NO, EFSA clarified that the current version of the OPEX tool only applies the highest default value of dermal absorption as max value in case of prorata correction, while the updated version of the OPEX tool will include some more entries for the dermal absorption so the correct default value can be chosen according to the type of formulation.

Furthermore, as regards to drift reducing nozzles, ESFA confirmed that it is a default reduction factor and currently data are not available to EFSA to refine it for application on limited areas.

The Commission highlighted that the reduction of drift is very important from a risk management point of view to take decisions and asked if EFSA is considering the Compendium endorsed in May 2024.

EFSA replied that after the stakeholders' workshop held in 2022, EFSA had opened the submission of data by applicants and studies including drift reduction systems are under assessment for a possible derivation of additional drift reduction values.

14.2 Updates on PERA projects

• EESE - EU Environmental Scenarios for ERA of non-target organisms

EFSA presented an overview of the "EESE" project (EU Environmental Scenarios for ERA of non-target organisms), which aims to develop a system-based approach for environmental risk assessment of pesticides. The project has four objectives:

Characterize the landscape and identify representative locations for higher-resolution mapping.

Study the biology and ecology of species in field and semi-field conditions.

Develop environmental scenarios for risk assessment.

Analyse the state-of-the-art of food web and ecological interaction models.

The project will last four years and has already started to produce preliminary results, including the stratification of Europe into 240 strata based on land cover classes, environmental zones, and soil materials. The consortium will map 1000 quadrants of 2x2 kilometers with high resolution and collect primary data on habitat types, biological communities, and vegetation structure for 60 of those.

- **PERA FPA- Advancing the ERA of Plant Protection Products towards a system-based approach**

The PERA Framework Partnership Agreement (FPA) Project is a contract framework that covers four areas of work:

- Advance the characterization of exposure to non-target organisms.
- Investigate the hazard to non-target organisms.
- Investigate the use of mechanistic effect models for environmental risk assessment.
- Explore the integration and interconnection of data for risk assessment.

The project has already started work on areas 1 and 2, and plans to start work on areas 3 and 4 in the second quarter of 2025. PERA - Develop a stepwise approach for a fit for purpose risk assessment for low-concern active substances and uses

Finally, there was an update on PERA project related to the development of a risk assessment approach for active substances of low concern. The project has two main goals:

To support the identification of situations where some or all data may not be required due to the nature of the active substance or its proposed uses.

To develop a stepwise approach for a fit-for-purpose risk assessment for low-concern active substances and uses.

The project is a framework agreement and is being carried out by a consortium of universities and research institutions. The scope of the project includes active substances that are potentially of low concern, such as botanicals, semiochemicals, and biological materials. The project aims to develop harmonized and science-based criteria for justifying the non-submission of guideline studies, investigate the potential use of alternative methods, and develop a fit-for-purpose approach for exposure and hazard assessment.

The project is an 18-month project that started early this year and will end in July next year. A draft approach was submitted in October and is currently being reviewed. The consortium is proposing an approach similar to the tiered approach used in some risk assessment fields.

A workshop will be organized in January 2025 to discuss the plan and get input from stakeholders. The approach will be finalised based on the input from the workshop.

A call for nomination was published 2 weeks ago and will be closed on November 8. The nomination is for stakeholders to participate in the workshop and provide input on the approach.

Q&A

A question was raised regarding the call for nominations. It was clarified that both risk assessors and risk managers will be invited to the workshop based on availability. For the time being the workshop is currently scheduled as physical meeting to increase active participation, and no online participation is foreseen.

14.3 Updates on the mandates for GD revision and indirect effects

EFSA updated on the status of two ongoing mandates:

- Request to EFSA to review the Guidance Document on Terrestrial Ecotoxicology on plant protection products (PPPs) (i.e. on non-target arthropods (NTAs), non-target terrestrial plants (NTTPs) and in-soil organisms).
- Request to EFSA to develop a guidance to assess potential indirect effects on biodiversity via trophic interactions under agro-environmental conditions.

No questions were raised by the audience for this agenda item.

Observers

See Annex I

Replies to question from Observers

See Annex II

Any other Business

EFSA advised applicants to avoid changing the PPP composition, where possible, during EFSA's peer review process.

AT asked whether PPP composition should be changed when a co-formulant is identified as unacceptable in Annex III of Regulation (EC) No 1107/2009 during peer review. EFSA clarified that in cases where a co-formulant is identified as unacceptable in Annex III of Regulation (EC) No 1107/2009 during peer review, EFSA will document this in its conclusions for risk managers' consideration. Alternative PPP compositions may be reported in the assessment reports. It was noted that changes in formulation may influence toxicological outcomes and complicate the assessment. Submission of data performed with the updated PPP compositions may be necessary, especially for areas like ecotoxicology.

It was noted that the guidance on PPP composition changes is under revision and may improve consistency. EFSA is considering a pragmatic approach to facilitate this process.

-Date for next meeting

EFSA informed that next physical PSN meeting could be envisaged in one year time (e.g. October 2025) while a Teleconference (TC) may be organized in spring 2025. The exact timeslots will be confirmed and communicated as soon as possible.

Conclusions

The chair concluded the meeting by summarising the main points discussed and the action points agreed upon. There are several action points, including collecting feedback on the proposal for improvement in the peer review, preparing a work plan for the different actions and actors involved, liaising with the Netherlands on the presentation of studies, launching a dedicated survey on the proposed pilot projects and to collect feedback and additional in the framework of MRL applications etc.

It was also mentioned that a satisfaction survey will be launched to gather feedback from the participants. The chair thanked all participants and presenters for their contributions and active participation in the meeting.

ANNEX I

List of registered observers

Last name	First Name	Name of employer	Affiliation
BICI	Ismet	Ministry of Agriculture and Rural Development	National authority
HEYLEN	Kevin	CropLife Europe	Other
PADOVANI	Alexandre	FMC Corporation	Private sector
TRAVNICKOVA	Zdenka	National Institute of Public Health	National authority
POLACKOVA	Sona	National Institute of Public Health	National authority
SUMBEROVA'	Hana	National Institute of Public Health CZ	National authority
NOVAKOVA	Nadezda	Central Institute for Supervising and Testing in Agriculture	National authority
NINGA	Ederina	DTU-Food	University/public research institute
LOZANO	Anthony	Sumitomo Chemical Agro Europe	Private sector
ROONI	Uku	Sumitomo Chemical	Private sector
PLAK	Sylvia	Sumitomo Chemical Agro Europe	Private sector
YAMADA	Ohri	ANSES (French Agency for Food, Environmental and Occupational Health and Safety)	National authority
HAMADEH	Inga	Corteva Agriscience	Private sector
THUMUS	Regine	Corteva	Private sector
DATTA	Gopal Krishna	Bayer AG	Private sector
WIETHOFF	Juergen	ADAMA Deutschland GmbH	Other
GREBEL-KOEHLER	Dörthe	Bayer AG	Private sector
REINEKE	Anne-Kirsten	Bayer AG	Private sector
BOIE	Christiane	Bayer AG	Private sector
STRUPP	Christian	Gowan Crop Protection Ltd	Private sector
MATTEINI	Paolo	Paolo Matteini	Private sector
BETT	Dominic	Pest Control products Board Kenya	National authority
BOAHENE	Nana	Norwegian Scientific Committee for Food and Environment (VKM)	EFSA Panel/WG/Network
SCHILLER	Marta	Sumitomo Chemical Agro Europe	Private sector
ANSEDE	Emma	Nichino Europe Co., Ltd.	Private sector
BADAWY	Mohamed	Corteva Agriscience	International organisation

WAKE	Christel	Corteva Agriscience	Private sector
ALIX	Anne	Corteva Agriscience	Private sector
JENKINS	Emma	Corteva Agriscience	Private sector
TOMUSANGE	Joseph	Corteva Agriscience UK Ltd.	Private sector
HALEY	Alasdair	Corteva Agriscience	Private sector
SALOMONSEN	Annette	ADAMA	Private sector
MARSHALL	Gareth	TSG Consulting Ltd	Private sector
WHYTE	Andrew	ADAMA	Private sector
CAMACHO-RAMOS	Iris	Keller and Heckman	Private sector

ANNEX II

List of questions from observers and answers

Questions received upon registration as well as questions posed during the meeting were answered as follows :

Number	Question	Answer
Q.1 Kevin Heylen (CropLife Europe)	Question related to item 6: Practical implementation on the new act on safeners and synergist: 1) Could you clarify plans to refine the definition of a "synergist" to avoid the inadvertent inclusion of certain co-formulants? Our understanding is that synergists enhance the properties of active ingredients through a metabolic action, while some co-formulants may merely facilitate uptake e.g. through physico-chemical processes. a. How will COM ensure co-formulants in authorized products aren't retroactively classified as unregistered synergists, leading to compliance issues? b. Can you clarify the process for distinguishing synergists from certain co-formulants (substances that may simply facilitate uptake e.g. certain solvents)?	1) The Commission needs to reflect on this question together with all stakeholders. In the meantime, in case of doubt, it is suggested that substances that may be considered as synergists should be notified so that they can be assessed and potentially included in the work programme. Commission invited CLE to send the detailed question to the European Commission's functional mailbox for safeners and synergists, which is published on their website (sante-secteur-ppp@ec.europa.eu). Check also the reply in Q.9.
Q.2 Dörthe Grebel-Koehler (Bayer AG)	As dual regulation of safeners & synergists under both REACH and 1107/2009 seems undesirable, could you please clarify how this is intended to be corrected and indicate the connected timeline?	The Commission indicated that safeness and synergists will need to be approved under Regulation 1107/2009. The Commission will have a work programme to check the safeness and synergists that are on the market. New safeness and synergies can be applied for at any time. Studies available for other purposes can be used, but an application needs to be done and an approval needs to be obtained under Regulation 1107/2009. It is not uncommon that a substance is subject to different regulations e.g. pesticides and biocides.

Q.3 Emma Ansede (Nichino Europe Co., Ltd)	Coformulants: what is the procedure to follow by the MS/EFSA in case one co-formulant, currently used in a registered PPP, is suddenly auto-classified as CMR cat 1?	The Commission indicated that there are two routes: either a Member State initiates a dossier for a harmonized classification on the CMR under CLP, and this may lead to inclusion in Annex III of Reg 1107/2009 as unacceptable co-formulant (Regulation 2021/383) or MSs decide to launch a notification process on the Criterion 10. In this case, the process involves a peer review by EFSA and ECHA. More information on the criteria and procedure to amend Annex III is outlined in Regulation 2023/574.
Q.4 Dörthe Grebel-Koehler (Bayer AG)	Concerning the New Hazard Classes: Can you please explain the relevance of respective Hazard Classes and respective categories for 1107/2009 decision making?	The Commission replied that the new hazard classes and categories are relevant, but some do not change, such as CMR. The new CLP ED hazard classes have no regulatory consequence for PPPs, because ED category 1 is equivalent to the PPP ED. The persistency hazard classes will need to be updated in Annex II of Regulation 1107/2009 in the near future.
Q.5 Christian Strupp (Gowan Crop Protection Ltd)	Question related to COM presentation "difficulties in decision making at the end of the process": It has been a recurring issue that disagreements on metabolite grouping for testing arise at peer review, i.e. a time when no more date can be generated. Applicants typically discuss grouping proposals with the eMS/RMS and frequently also receive feedback, i.e. feel that their grouping strategy is endorsed, but are then facing critical concerns if the grouping is not agreed at peer review. Reasons for disagreement are frequently differing interpretations by individual experts what can and what cannot be grouped rather than specific safety concerns based on data. What can applicants do to ensure EFSA will be satisfied with the data agreed upon between applicant and RMS?	EFSA confirmed that metabolite grouping is a topic under detailed discussion among experts, focusing on harmonising grouping practices. An OECD draft guidance document on residue definition, currently under consultation, is expected to clarify grouping methods and is anticipated for publication by 2025. The guidance will facilitate a more consistent approach to grouping.

	Gowan Crop Protection Ltd also reiterated that grouping of metabolites is a recurring source of delays and additional vertebrate data requirements in numerous re-registration and MRL applications. As these disagreements are unforeseeable and happen late in the process, there is no possibility for better quality dossier submission.	
Q.6 Mohamed Badawy (Corteva Agriscience)	CLE open source Calculator provides the information on the exposure at the specific re-entry interval that pass the risk assessment and open for modification and adaption. can we use this model that is a replicate of OPEX online tool until EFSA resolve this?	No, unfortunately this CLE calculator has not been checked and validated at EU level. Please note the updated EFSA calculator will be available beginning 2025.
Q.7 Emma Ansede (Nichino Europe Co., Ltd.)	Multiple universities and nozzle machinery companies are generating drift reduction values. Is ad-hoc submission data the only way? why not organizing a call to have that data evaluated centrally?	Raw data that stakeholders wish to submit are collected at EFSA level. Further evaluation and analysis of these data (also including considerations of their relevance and reliability) could be organized at a later stage. Currently, analysis of data submitted to EFSA in relationship with other aspects of non-dietary exposure is already ongoing. European Commission indicated the Compendium. The centralization of data collection to be then used in the EFSA calculator was mentioned. Commission is reflecting as regards the next steps and maybe to mandate EFSA. EFSA emphasised the importance of receiving raw data from stakeholders which can enhance guidance and improve risk assessments. Stakeholders are encouraged to approach EFSA regarding data submissions. It was noted, however, that a call for data related to the OPEX guidance document was organized in 2022 to collect information and facilitate future planning. Submitting data during the call for data procedure is essential for EFSA to better anticipate available data and minimise the need to reopen assessments.

Q.8 Ohri Yamada (ANSES)	How come EFSA's assessment for some active substances (e.g. folpet and partly for S-metolachlor) conclude for monitoring data that there are no data whereas there are public monitoring data available in France?	EFSA assessments for the peer review of active substances use the environmental monitoring data that has been included in the dossier and DAR /RAR. If available environmental monitoring data are not included in the dossier, so not assessed in the RAR version provided for the Member State / public consultation, then this consultation is the opportunity to identify this. Then a further information request will be made to the applicant to add this available monitoring data to the dossier and then it will be assessed in the RAR and included in the peer review and EFSA conclusion on the substance.
Q.9 Kevin Heylen (CropLife Europe) Oral question	CLE expressed concerns about the potentially broad interpretation of the terms 'synergists' and 'safeners.' Specifically, there is a risk that any co-formulant enhancing the uptake of an active substance could fall under the definition of a synergist. This broad interpretation may place certain co-formulants under additional regulatory requirements if classified as synergists. How does DG SANTE intend to maintain a clear distinction between co-formulants and synergists?	Commission invited CLE to send the detailed question to the European Commission's functional mailbox for safeners and synergists, which is published on their website (sante-secteur-ppp@ec.europa.eu). It was also advised to applicants to notify the substance in question as 'synergist' or 'safener' if there is uncertainty on the correct classification or if there are doubts on the classification as a synergist or co-formulant. If the interpretation is wide and the substance is not notified, it may not be added to the list unless a new dossier is submitted.