PESTICIDE STEERING NETWORK (PSN) 31st meeting

Location: Webconference

Attendees:

- Network Participants:

Country	Name
Austria	Klaus LEDER
Belgium	Wim HOOGHE
Czech Republic	Lucie VANOVA
Denmark	Alf AAGAARD
Estonia	Elise JOONAS
Finland	Heli ANTTILA
France	Suzanne PIERLOT
Germany	Eva GOCLIK
Greece	Agathi CHARISTOU Danae PITAROKILI
Hungary	Csilla NEMETH Ágnes STIER
Ireland	Aidan MOODY
Lithuania	Kristina VALIONIENE
Netherlands	Carla HUIZING
Norway	Anna MEHL
Poland	Pawel STRUCINSKI
Portugal	Bento CARVALHO
Slovak Republic	Marta GALUSOVA
Slovenia	Anja PALMAN MEHIKIC
Spain	Carmen LOPEZ GOTI
Sweden	Katarina LUNDBERG

- Observers:
  Expert name (Switzerland): Christoph GEISER

- European Commission/Other EU Agencies representatives:
  - Karin NIENSTEDT (DG SANTE)
  - Flavio MARCHETTO (European Chemicals Agency - ECHA)

- EFSA:

  Pesticide Peer Review Unit: Dimitra KARDASSI (Chair), Manuela TIRAMANI (Head of Unit), Chloé DE LENTDECKER, Mathilde COLAS, Angelo COLAGIORGI, Tunde Molnar, Renata LEUSCHNER, Anja FRIEL, Hermine REICH

  Environment, Plants & Ecotoxicology Unit: Rositsa SERAFIMOVA, Laura PADOVANI

  Front-Desk & Worforce Planning: Silvia MAZZEGA

  Risk Assessment Logistics Unit: Piera POZZATTI

1. Welcome and apologies for absence

The Chair welcomed the participants.
Apologies were received from Italy (Pasquale Cavallaro).

2. Adoption of agenda

The agenda was adopted with two points added under AOB.

The minutes were agreed by written procedure on 10 November 2023 and published on the EFSA website 16 November 2023.

3. Brief introduction of Network participants and Observers

The Chair indicated that around 100 observers had registered for the meeting, coming from all the major stakeholder groups (academia, industry, farmers, civil society etc).

4. Presentation of the EFSA Guidelines for observers

The meeting Chair presented the EFSA Guidelines for Observers, with specific attention to the code of conduct during the meeting.

For more details see slides presented during the meeting.

5. Debrief on the Observers feedback received from the 30th meeting of the PSN held on 20 October 2022, web-conference

Positive feedback was received on the topics addressed during the 30th Pesticide Steering Network meeting held on 20 October 2022.

The Head of Pesticides Peer Review Unit (Manuela Tiramani) highlighted that the project of piloting the attendance of Observers in the meetings of the Network has been concluded and positive feedback has been received over the last "open" meetings to Observers. Currently Networks are not open to Observers but the need of several stakeholders to see first-hand how EFSA works in this context has been considered beneficial by EFSA's Stakeholders. Of course, several areas of improvement have been identified and further internal discussion would be

needed to agree on the next steps. The feedback collected after the present meeting would also be important in terms of improving the interaction and ensuring meaningful discussions. Participants were invited to respond to the survey that will be circulated via email after the end of the meeting.

6. Update on the activities related the assessment of PPPs/co-formulants

The European Commission and EFSA provided an update on the activities related to the assessment of plant protection products (PPP)/co-formulants.

A quick update on the 2 workshops held in May and June 2023 was given.

The need for a thorough ecotoxicological assessment of each co-formulant added in the formulation has been questioned. Available studies performed with the formulation on non-target organisms are available for most cases as it is a data requirement, except for the aquatics, birds, and mammals. This lack of data to fully address the ecotoxicological risk assessment highlights the need for improved guidance and access to data. This is the purpose of the planned activities on the development of a European Union (EU) database and guidance document.

As part of the discussion, clarification was requested where in practice the assessment of the PPP and co-formulants should be included in the assessment report (currently left to the RMS' decision). Pending agreed approach, instructions regarding the PPP assessment are being addressed by following an interim approach e.g. assessment could be included in a (revised) Volume 4 of the Draft Assessment Report (DAR)/ Renewal Assessment Report (RAR). In case a co-formulant is a mixture, a separate Volume 4 may be created to differentiate the information submitted by the applicant with the one owned and submitted by the supplier.

It was noted that the concept of 'substance of concern' exists in biocides domain and is developed in an ECHA Guidance. It was clarified that co-formulant of concern and relevant co-formulant will be further defined in the guidance document. All available definitions already used across EU or national agencies (e.g., ECHA guidances), and existing guidances as well will be taken into consideration.

Finally, the challenge of identifying co-formulants, particularly for co-formulant mixtures with different CAS numbers, was raised. During the workshop, MS participants have emphasised the need to request specific data on the physico-chemical properties to accurately identify co-formulants. This issue is being considered in the development of the EU database and for the future guidance document.

Actions:

- A common database on co-formulants will be developed at EFSA level. This is one of the proposed actions at the May/June workshops and a consultation of Member States (e.g. PAI members, SCoPAFF members) on the requirements of content and design needed for the database is currently undertaken. MS support will be needed.
- At a longer term an online platform to facilitate sharing, access and re-use of information on chemicals from different EU Agencies/institutions will be developed. The EU-Common Data Platform on Chemicals will be hosted by ECHA and will contain building blocks from the Euroepan Agencies (ECHA, EFSA, EMA, EEA, EC). This project on development of EU common data platform on chemicals is however a long-term project.

7. Improvements in IUCLID (Microorganisms dossiers)

European Commission highlighted the importance - in the context of the farm to fork strategy - of having alternative plant protection products to replace traditional chemical pesticides. For this reason, many efforts were done in the past years to revise the regulatory framework for microbial pesticides, including to issue new data requirements, and it is therefore crucial to have an effective assessment of microbial substances. In the light of this, dedicated Commission communications[1] listing data protocols and guidances and different guidance documents (including explanatory notes) were developed and published, with the aim of facilitating the risk assessment of microbial pesticides. Also, European Commission reminded the importance for both the applicants and the evaluators to make sure that the tool for dossier submission and evaluation, i.e. IUCLID, is fit-for-purpose and in line with the new regulatory framework. In this context, an issue with the interpretation of the Appendix E of the EFSA administrative guidance for the submission of dossiers (EFSA, 2019[2]) that should be used for the presentation of studies in the assessment report was reported, underlining that a harmonized agreement on the interpretation can help to reduce the workload for competent authorities without effects on the risk assessment.

It was indeed proposed by some MSs to make a distinction between studies relied on to derive an endpoint (for which the full template according to Appendix E has to be used – e.g., including materials and methods) and studies which are used as supporting/supplemental/background information (e.g., '*Bacillus* is a spore forming bacterium') for which only the abstract, but not the material and methods is proposed to be included in the report. This aspect is especially relevant for biopesticides, as a dossier can contain many studies from public literature (journal papers) that might not be suitable to derive an endpoint.

EFSA clarified that the issue of the interpretation of the Appendix E of the EFSA administrative guidance will be further discussed under point 8, as this is not strictly related to IUCLID but it is relevant to many pre-transparency applications. In fact, the updated administrative guidance issued in 2021 (EFSA, 2021[3]) is applicable to post-transparency applications, for which information on the studies submitted as part of the dossier should be included in IUCLID using the dedicated IUCLID documents. A specific IUCLID tool, i.e. the report generator, is available to extract the information submitted in a dossier and to summarise it generating a report shaped on the Appendix E of EFSA 2019.

EFSA acknowledged that the report generator for the micro-organisms is currently not working as expected. In the light of this, a working party on micro-organisms was established in the framework of the IUCLID subgroup PSN in July 2023 with the aim of further revising the working context on micro-organisms and, among other activities, to refine the reports generated by the report generator, making them more fit-for-purpose so that they can be used as a basis for the

[1] Communication from the Commission concerning Part B of the Annex to Commission Regulation (EU) No 283/2013 setting out the data requirements for active substances in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market (Text with EEA relevance) 2023/C 202/03. OJ C 202, 9.6.2023, p. 14–24.
Communication from the Commission concerning Part B of the Annex to Commission Regulation (EU) No 284/2013 setting out the data requirements for plant protection products in accordance with Regulation (EC) No 1107/2009 of the European Parliament and of the Council concerning the placing of plant protection products on the market. OJ C 202, 9.6.2023, p. 2–13..

[2] 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

[3] European Food Safety Authority, 2021. Administrative guidance on submission of dossiers and assessment reports for the peer-review of pesticide active substances and on the maximum residue level (MRL) application procedure, *EFSA supporting publication* 2021: 18(3):EN-6464. 77 pp. doi:10.2903/sp.efsa.2021.EN-6464

draft of DAR/RARs. This working party is composed by competent authorities' experts, industry representatives and EFSA and European Commission staff.

It was also clarified that an up-to-date working context on micro-organisms in IUCLID is available as of May 2023, including new and revised documents and table of contents, that allows the applicants to submit data in line with the new regulatory framework.

Actions:

- Further discussions will be held with the aim of revising the working context on micro-organisms and, among other activities, refining the reports generated by the report generator, making them more fit-for-purpose so that they can be used as a basis for the draft of DAR/RARs.

8. Improvement in peer review

8.1. Feedback from peer review and completeness check, update of the Q&A on notification of studies (NoS)

EFSA provided feedback from the peer review and the completeness check of DAR/RAR. Several opportunities for improvement of the peer review process were highlighted. Issues with submitted revised assessment related to quality, timely submission and transparent inclusion of all evidence submitted in support of the (renewal) of the approval (including e.g. the outcome of the peer review meetings, studies submitted by the applicant etc) were raised. EFSA stressed that incomplete data set may have a significant impact on the assessment in case, e.g., of endocrine disruption (ED) for substances where the 2nd ED clock stop is no longer applicable. Of course this is not new and not specific to ED; the issue of incomplete data set applies to all endpoints and it is the applicant responsibility to address the data requirements as set by the legislation including the ED endpoints.

Possibilities for improvement before dossier/DAR/RAR submission and during the peer review process were mentioned. Notably, the opportunity of pre-submission meetings with the RMS (before submission of the dossier) and for specific/complex cases with RMS and EFSA (upon request by RMS) was highlighted. Indeed, these fora are appropriate to discuss the need of missing/generating additional data but it was reiterated that a pre-assessment of data is not the purpose, since that is the subject of the subsequent peer review. It was stressed that RMS may consider a dossier inadmissible if quality is limited. For IUCLID dossiers validation rules are used so if RMS spots recurrent parts of dossier incomplete, these should be shared with EFSA and thus the possibility of introducing new validation rules for dossiers at entry could be explored. In a nutshell, incomplete data set should be addressed at RMS level before submission of the DAR/RAR rather than leaving inconclusive assessment to be escalated to the peer review and finally to the decision-making phase. RMS should provide complete DAR/RAR, to allow a comprehensive assessment and an efficient peer review to be carried out, avoiding inconclusive outcomes and incomplete DAR/RAR to enter the peer review process.

EFSA mentioned recent cases where relevant compounds were not labelled properly and this was identified late in the peer review. MSs were requested to address the radiolabelling strategy and pay particular attention to the soil degradation experiments when they act as RMS.

Regarding the feedback from the completeness check, the importance of presenting a clear and accurate GAP table was reiterated. The GAP table is part of the list of endpoints and should be also presented in Level 1 of Volume 1 of the assessment report; it should not be repeated in other parts of the assessment report to avoid that different GAP tables are presented in different sections of the assessment report. It was stressed that according to the EFSA Administrative Guidance (2019, 2021) changing the GAP is not permitted during the ongoing peer review except

for providing clarifications or correction of errors. During completeness check, EFSA regularly requests the RMS to submit the latest GAP table contained in the D1 document to verify the alignment with the dossier. The latest GAP table template should be used[4].

The importance of presenting the individual studies using the relevant template available in the Appendix E of the EFSA Administrative Guidance, in the dossier by the applicant and in the assessment report by the RMS, was highlighted. The RMS should assess the individual studies for their acceptability and deviations to Test Guidelines and clearly present their view easily distinguishable from applicant's view. This applies also to non-guideline studies or scientific peer-reviewed publications and would allow a weight of evidence (WoE) approach and independent assessment to be made during the peer-review.

Finally, EFSA clarified that they are always available to further support MSs working on the peer review, in particular for complex issues and can support RMS during the completeness check or even during the admissibility process (for post-TR dossiers).

During the discussion, NL pointed out that sometimes the outcome of the completeness check by EFSA is sent out in several iterations and they need to revise and resubmit the assessment reports after each request. This leads to potential delays and discouragement. NL requested that the outcome of the completeness check is communicated to the RMS only once. EFSA acknowledged that there have been some isolated cases where this was not possible but the aim is indeed to consolidate all requests to the RMS on a specific DAR/RAR in one e-mail only and then any follow up would be needed only to reiterate items already requested.

FR asked for clarifications on the MRL application form. EFSA clarified that for dossiers submitted under IUCLID, an MRL application form is not needed since this is embedded in the IUCLID dossier. The focus of the given presentation was on the pre transparency dossiers and thus on pre transparency DARs/RARs.

DE pointed out that it is desirable to provide an assessment report to EFSA without any outstanding issues, but that it is not always possible because during the evaluation there will always be issues that cannot be finalised even if an applicant can submit some information with the additional information request. EFSA reiterated that for the cases for which the 2nd ED clock-stop does not apply we might end up to the situation that the peer review will be inconclusive thus impacting substantially the decision-making process. EFSA invited MSs to try minimise the number of inconclusive issues, as much as possible, before the peer review starts in particular for the ED potential.

A discussion took place regarding the presentation of studies for microorganisms which are mainly scientific peer-reviewed publications. EFSA reiterated that the presentation of the scientific peer-reviewed publications should be carried out using the Appendix E of the EFSA Administrative Guidance and a full summary of the study should be done according to the OECD format. Often there is a selection made upfront on which studies coming from publication are presented, fulfilling the full Appendix E and which studies are not, perhaps because the RMS concludes these are only supportive. But as explained if the information is not fully completed then an independent assessment is not possible at the course of the peer review.

Actions:

- EFSA to consolidate as much as possible the requests sent to RMS with the outcome of the Completeness check. Follow-up requests would be needed only to reiterate items already requested to the RMS.

[4] https://food.ec.europa.eu/document/download/5a067575-40fa-4fb3-93f1-640d0a8a6984_en?filename=pesticides_ppp_app-proc_guide_doss_12592-2012.zip

- MSs to take stock of the discussion and improvements presented regarding the peer review and completeness check. RMS to take advantage of pre-submission meetings and consider avoiding inconclusive assessment to be escalated to the peer review and finally to the decision making phase.

8.2. Identification of insufficient dossier quality and exchange on the experiences with MS

DE informed that MSs were asked within the course of the SCoPAFF meeting in July 2023 by the European Commission not to accept dossiers of insufficient quality. It was highlighted that it is not always easy to determine the quality of a dossier, and in some cases IUCLID validation assistant (VA) is not able to identify all the shortcomings. In particular, it can be easily checked whether documents or justification are present in a dossier, but not the quality of these documents, and MSs sometimes become aware of such shortcomings only at later stages, e.g. during the evaluation.

DE presented a list of recurring shortcomings identified (at late stage) in some IUCLID dossiers, leading to delays in the evaluation, e.g. documents M and N submitted in a format that could not be edited (e.g. pictures, tables), some sections (e.g. materials and methods) of IUCLID documents summarising specific studies not compiled by the applicants.

Germany's view was also supported by other MSs.

European Commission highlighted the importance of not declaring dossier admissible in case they are not complete, even if they acknowledge that this is not always easy to check, e.g. in those cases where dossiers seem complete but then during the evaluation the situation, looking into detail, it appears to be differently.

EFSA informed that a letter was recently received by BVL reporting, among others, the same issues presented by Germany under this agenda point. In the reply to the letter, EFSA highlighted that it is important to acknowledge that IUCLID for pesticides has been in place for just over two years, being aware that there is still room for improvement. For this reason, EFSA continues its commitment to keep on working to make IUCLID more fit for purpose. To date over 150 Validation Assistant (VA) rules have been implemented to ensure that data meets the highest standards in line with applicable data requirements, and more will be developed in the future to strengthen the automated quality check of incoming applications. DE was invited to share any suggestions for improvement in the dedicated IUCLID backlog file, which would enable EFSA to identify any areas requiring immediate attention.

8.3. Assessment of common GW-metabolites

The issues with the assessment of common metabolites in the context of EU regulations were raised. The current procedures lack clarity and structure for timely assessment. As a solution, DE proposed to establish an overview table or database to easily identify common metabolites. In addition, it was also proposed to perform a series of steps upon identifying a common metabolite, including comparative assessment, scientific statement preparation, commenting by Member States/EFSA, technical report preparation and adoption in the SCoPAFF.

The need for access to data and harmonised guidelines to conduct hazard assessments was acknowledged. It was suggested to create a common repository of common groundwater metabolites accessible to all Member States which would be in line with the 'one substance one assessment' concept.

Pending development of a common data set, EFSA informed on the availability of the EFSA compilation of common metabolites (e.g., sulfonyl urea and pyrazole metabolites) available on the Data Management System that is accessible to Member States.

Action:

- European Commission questioned the legal basis to handle this issue within the peer review framework and suggested consulting the SCoPAFF members at the next PAFF meeting on this proposal. A mandate to EFSA, allowing applicants to submit data, might be an option.

8.4. Harmonisation of the EFSA peer review and the CLH procedure by ECHA

DE raised their concerns over misalignment encountered in the intake phase of the EFSA peer review and the ECHA CLH procedure, highlighting the importance of timely harmonization of the EFSA completeness check and ECHA accordance check as far as possible. They presented the practical example of sulcotrione where they received the results of the completeness check and accordance check by EFSA and ECHA, respectively, at a different point of time. Indeed, at the time point of responding to the EFSA completeness check feedback, DE was not aware that further amendments would be necessary following the accordance check by ECHA which was finalised only at a later stage, after the deadline set by EFSA for addressing the outstanding issues identified in the EFSA process. To avoid duplication of work, it was proposed that in future the deadlines in the intake phase were harmonised, so that the RAR can be amended only once in this procedural step.

It is recognised that close alignment during the intake phase among EFSA-ECHA is a crucial element to enable an efficient harmonisation from an early step onwards of the EFSA peer review and the ECHA CLH procedure. EFSA gave a short presentation on the work done in the alignment and outcomes achieved in the intake phase, including some recommendations for the MSs.

ECHA and EFSA developed since 2018 a general coordination mechanism with regular coordination meetings put in place at operational level, aiming to achieve alignment both in the intake phase and the peer-review and CLH processes for pesticide active substances.

In this context, to improve alignment of the intake phase, ECHA and EFSA carried out the analysis of the legal constraints existing under the two legislations (PPP and CLP) and the practices in place to better streamline the process. It is recognised that Regulations (EC) No 1107/2009 and (EU) No 2020/1740 prescribe precise timelines for the circulation of the assessment report to the applicant and to the other Member States (1 month and 3 months respectively for new active substances (NAS)/renewals) while no such constraints exist under the CLH process.

In view of the above legally set timelines in the PPP process, a joint effort has been put in place among ECHA and EFSA to prioritise NAS and to align the processes for all other pesticides in general, as much as possible.

An analysis of the internal timelines implemented at ECHA and EFSA at the intake phase showed that:

- the ECHA accordance check, being a task of scientific nature to support the upcoming work by RAC, requires substantially longer time compared to the EFSA completeness check, not involving a scientific check;

- consequently, the time granted to the RMS for the revision of the AR/CLH report is considerably longer in the ECHA CLH process and is generally aligned for all CLH dossiers under ECHA's remit irrespective of the legislation;

- the time needed for the verification of the resubmitted AR/CLH report is generally aligned between EFSA-ECHA.

Overall, it was acknowledged that in view of the different nature of the accordance and completeness checks and the internal practices in each Agency, a full harmonisation and parallel accordance/completeness check in the intake phase cannot be achieved. Nevertheless, ECHA and

EFSA agreed on *ad-hoc* prioritisation of pesticide active substances, in particular for NAS to align the intake phase as much as possible.

It was highlighted that the RMS role remains crucial in various aspects, first of all in the concomitant submission of the AR/CLH report to both EFSA and ECHA and secondly in the time taken for the AR/CLH revision. It was noted that when two different Competent Authorities within the same MS are involved in the AR/CLH preparation, additional national coordination is needed to avoid further delays.

Overall, the following recommendations were made to the MSs:

- reinforcing the need to submit the AR/CLH report at the latest at same time to the two Agencies, or even to proceed with rather earlier submission to ECHA, accounting for the longer time needed for completing the accordance check in the CLH process;

- to consolidate the feedback from the EFSA completeness check and ECHA accordance check and resubmit the AR/CLH report to both Agencies at the same time: EFSA-ECHA will subsequently align the verification phase in preparation for the parallel public consultation;

- ensure alignment among the different competent authorities in the Member State responsible for the PPP/CLH processes.

Overall, the above recommendations were supported by the PSN. Although the proposal from Germany that ECHA and EFSA should send a consolidated feedback to the RMS covering both the ECHA and EFSA accordance check comments in one go does not appear to be feasible, MSs welcomed the approach to resubmit a consolidated version of the AR/CLH report to both Agencies at the same time, combining their feedback by addressing the comments from both the EFSA completeness check and ECHA accordance check.

Some questions were raised as regards practicalities linked to the CLH process.

It was clarified that under the PPP Regulation, applicants are expected to submit ALL available data (studies) and it would not be expected that a significant amount of additional studies would arise during the subsequent evaluations. For the aligned substances it is expected that the same data package is available for both the EFSA-ECHA processes with all relevant studies to be also reflected in Vol 2 of the RAR. In addition, to ensure having the same level of information at both processes, applicants are specifically requested to provide relevant data submitted additionally during the EFSA clock stop, also to ECHA to allow their consideration by RAC. This is also because in ECHA there is no formal clock stop possible for additional data request outside of the public consultation.

Clarification was also requested on who is responsible for notifying to ECHA a CLH submission intention (RoI) in case during a renewal of an active substance the outcome of the peer review indicates that an already existing harmonised classification needs to be changed, and whether there is a difference in the procedure depending on whether the RMS concluded on the need for change or EFSA (i.e. in the EFSA conclusion).

Indeed such cases may have occurred in the past in particular for substances where a parallel process with ECHA CLH did not take place, and a formal CLH report would deem to be necessary to follow up eventual classification proposals (or change in existing classifications) in line with the outcome of the EFSA peer review. Under the current CLP rules, the RMS can submit CLH proposals to ECHA. EFSA is not empowered under current rules to do so. It was recalled that, in the near future, the obligation for RMS to provide the CLH report to ECHA, at the latest at the time of the submission of the RAR for renewal to EFSA, will become more stringent (cf Article 11(9) of Regulation (EU) No 2020/1740), and therefore it is likely that the majority or almost all cases will run in parallel between EFSA-ECHA, making the need for harmonization to be more prominent, and also avoiding situations mentioned above. If no classification is proposed to be changed, the RMS should duly justify why no harmonised classification is warranted for hazard classes for which it considers that the criteria for classification set by Regulation (EC) No 1272/2008 are not fulfilled.

Actions:

MSs to follow the below suggestions in case of parallel AR/CLH report submission:

- Submit the AR/CLH report at the same time to the two Agencies, or rather proceed with an earlier submission to ECHA. Consolidate the feedback from EFSA and ECHA and resubmit the AR/CLH report to both Agencies at the same time. Ensure alignment among the different competent authorities in the Member State responsible for the PPP/CLH processes.

8.5. New way of handling targeted consultations

EFSA presented the new way for submitting comments on the full (confidential) version of the initial assessment report (DAR/RAR) prepared by the RMS (i.e. targeted consultation on DAR/RAR). Similarly to public consultations on DAR/RAR, MSs and other targeted stakeholders (e.g. applicant(s), ECHA, European Commission) will be invited to provide comments on the DAR/RAR via connect.EFSA, that is the external interface of Salesforce, the tool adopted by EFSA from March 2021 with the entry into force of the Transparency Regulation. The same tool is already used at EFSA level for targeted consultations in different other areas (e.g. genetically modified organisms and feed additives) for which approximately 140 targeted consultations were already launched, and more than 1000 comments received. The tool was further refined in the past months to increase the number of characters for each comment and to allow the submission of attachments.

It was clarified that access to the DAR/RAR will still be granted via DMS and that personal login to connect.EFSA is needed for accessing targeted consultation and for submitting comments. Differently from public consultations – where the comments are automatically published on openEFSA upon the closure of the consultation – the comments submitted in a targeted consultation will only be made publicly available at the end of the peer review process, as background documents of the EFSA conclusions. All the comments received will be collected automatically by the system in a file where they can be sorted e.g. per section, representing the starting point for the compilation of the reporting table.

EFSA informed also that accounts for accessing the tool, as well distribution lists, were created in the past months, but they need to be further reviewed to make sure that all representatives are included. Once a targeted consultation will be launched, targeted users will receive an e-mail notification including the link to access the tool for submitting comments. EFSA RAL units will take care to create training materials and to organise an online training session for MSs representatives. In addition, applicants will be also informed and trained on the tool. The envisaged date for starting using the new way of commenting is Q1 2024, pending confirmation.

Some MSs asked for clarification about the possibility to provide comments in the same consultation using different accounts, e.g. each competent authorities' experts using its own account to submit comments. EFSA clarified that multiple accounts per country will be provided, nonetheless comments should be submitted by a single representative per each targeted consultation, as it is done in all the other areas in EFSA where the tool is used for the launch of targeted consultations. It was also clarified that it is not possible to create institutional accounts using functional mailboxes, but only personal accounts.

Actions:

- EFSA to organise the online training session for MSs representatives on the new way of handling targeted consultations in view of the envisaged date for starting the new way of commenting in Q1 2024. Similarly, applicants to be also informed and trained on the tool by EFSA.

9. Substance identity for chemical substance falling under the PPP Regulation-alignment with rules for identification and naming of substances under REACH and CLP

EFSA gave a presentation outlining a proposal aiming at alignment of the identity for chemical substances falling under the PPP Regulation with the rules for identification and naming of substances under REACH and CLP.

The alignment proposal is particularly fitting within the objectives of the EU Chemical Strategy for Sustainability (CSS), where the European Commission defined a series of actions among others:

- the 'one substance, one assessment' (1S1A) process which aims at improving efficiency and coherence of the safety assessment of chemicals across legislations;
- the development of a common open data platform on chemicals (EU-CDPC) to facilitate the sharing, access and re-use of information on chemicals coming from all sources.

In consideration of the above objectives, a common way for identifying and naming substances across EU is recognised as an essential step, which could potentially be achieved by the alignment to the existing ECHA Guidance for identification and naming of substances under REACH and CLP.

Since spring 2022, ECHA and EFSA decided to undertake a systematic substance identity (SID) check at the intake phase, undertaken by the ECHA SID team with support of EFSA PREV Physical chemical experts as needed, upon receipt of the AR/CLH report at EFSA and ECHA. The SID check has been put in place to ensure harmonization and consistency between the EFSA-ECHA naming convention for substances subject to assessment in the two processes. The experience gained so far proved to be helpful to clarify inconsistencies/issues on the name or identifiers used. However, the absence of current common agreed rules has resulted in EFSA to undertake a case-by-case internal verification of the names proposed by ECHA, while potential alignment to the rules of the ECHA SID Guidance, laying down the basic principles, would facilitate to bring forward a systematic procedure in handling cases in a consistent manner. Indeed, the ECHA guidance tackles already the naming for various substance types, including well defined substances with a clear qualitative and quantitative composition for both mono- and multi-constituent compounds, or for UVCB substances (i.e. Substances of Unknown or Variable Composition, complex reaction products or Biological materials) that could also be equally valid for pesticide active substances.

In fact, the principles of the ECHA SID Guidance are stemming from rules defined at sectorial level that are developed in the framework of the OECD and in collaboration with the relevant Industry Associations. According to current practice in place for substances falling under the remit of ECHA, the relevant Substance Identifiers (e.g. CAS/EC number and name, IUPAC name etc.) are laid down in each Regulation (e.g. CLP, REACH, BPR) while the alignment on the naming is ensured by the corresponding sectorial guidance documents making reference to the ECHA SID Guidance that can be adapted upon need in specific cases.

In view of the benefits of allowing consistency across different legislative frameworks and bringing forward a systematic procedure, it was proposed to advocate the ECHA SID Guidance as a tool for consideration for use also for chemical substances falling under the PPP Regulation. Indeed, the intention is to develop a procedure outlining best practice for substance identity for pesticide active substances, that as appropriate, follows the principles for identification and naming of chemical substances under CLP, aiming at harmonisation across the EU, involving EU Agencies and MSs. Ultimately, this would also be expected to facilitate the creation of the EU-CDPC and serve as an essential element for the foundation of the 1S1A project.

As next steps, the proposal for alignment to the ECHA SID Guidance is intended to be presented to the Pesticides Peer Review General Experts' meeting on physico-chemical properties, planned

to take place on 22-23 November 2023, for endorsement by the experts. If agreed, the alignment to the naming convention of the ECHA SID Guidance can subsequently be formally reflected in the appropriate Technical Guidance, similarly to what has been done for Biocides.

PSN members welcomed the proposal and the current practice put in place since spring 2022 to ensure harmonization and consistency between the EFSA-ECHA naming convention for substances subject to assessment under the two processes.

Some questions were raised as regard practicalities, in particular seeking some flexibility in the way of presenting the full names in the DAR/RAR volumes and filenames. Indeed, it was agreed that certain flexibility can be accepted balancing the number of identifiers and readability of documents (e.g. by presenting the chemical name in the cover pages while the ISO name appearing in the Volume 1 identity section). The approach can be agreed case by case, where relevant, during the completeness check phase.

Regarding identity of co-formulants, it was confirmed that PPP dossiers and assessment reports should generally follow the naming convention rules applicable under REACH, noting that for the PPP dossiers full identity characterisation, as far as technically possible, of all components of the co-formulants is requested (with a view to support the subsequent risk assessment). It was noted that this can be more stringent than the REACH rules in place that follow a major component approach.

As regards the current experience since spring 2022, EFSA confirmed that no discrepancy has been identified between EFSA-ECHA naming convention so far. As the way forward it was proposed to lay down a procedure for possible alignment at an earlier stage in the intake phase, potentially prior to submission of the DAR/RAR to EFSA. Indeed, early identification of potential discrepancies would be beneficial since by the time of submission of the DAR/RAR to EFSA, potential naming issues, if any, are expected to get resolved.

The question was also raised whether it could be feasible for including the correct identifiers already at the step of the Notification of Studies (NoS) check. Some limitations were acknowledged, especially as regards NAS where the exact name of the substance may not be known at an early stage and instead company development codes may be used in practice.

It was proposed that substance identity can be also a topic for pre-submission meetings.

Actions:

- The proposal for alignment to the ECHA SID Guidance to be presented to the Pesticides Peer Review General Experts' meeting on physico-chemical properties, planned to take place on 22-23 November 2023. If agreed, the alignment to the naming convention of the ECHA SID Guidance can subsequently be formally reflected in the appropriate Technical Guidance, similarly to what has been done for Biocides.

10. Feedback from MSs survey on an Interactive Pesticide Residue Exchange Platform (IPREP)

EFSA presented the Member States 2023 survey results on IPREP platform, concept previously introduced at the PSN held in October 2022. With an overall feedback of 32 replies, 21 MSs contributed to this survey, intended to identify and prioritise the needs of the MSs and to explore the scope, feasibility and usefulness of a future IPREP between MSs and EFSA for pesticide residues on issues that may arise from both interested parties. It has been highlighted that the intended interaction with Member States is dedicated to non-dossier specific advice only, with the aim to respect the principles of independency of MSs/EFSA RA.

The 50% of contributors supported the added value of establishing this new IPREP for MSs and EFSA collaboration; circa 47% supported the use of IPREP as a first step and, based on experience, followed by the identification of the possible need for regular meetings. Lower percentage of contributions supported the benefit of regular science meetings related to MRL

assessments (circa 38%) and of regular horizontal science meetings for pesticide residues. Circa 31% supported the sufficient adequacy of the existing collaboration channels (e.g. FMB, PSN).

For what concerns the tool intended to be used for the IPREP, 56% of contributors confirmed their current use of Microsoft Teams, that will be considered as possible tool of choice for ensuring the real-time collaboration, with the possibility to provide training to the users.

Regarding the relevant scientific areas for which a scientific exchange/discussion among MSs/EFSA is considered needed, the survey collected a broad list of proposal, e.g. consumer risk assessment, residue definitions for monitoring and risk assessment, analytical methods for monitoring and risk assessment.

As regards the possibility of establishing scientific expert groups with members coming from MSs (national experts) and EFSA (experts/contact points), circa 47% of contributors expressed their preference to join an established group at a later stage. Almost 70% supported the possibility of consulting a group composed of MS experts and EFSA via chat function and circa 87% supported the development of a transparent collection of discussed questions/answers in a searchable format (i.e. WIKI).

The presenter highlighted that EFSA has established a Teams workspace for the IPREP, currently populated with 179 experts reflecting the pesticide residue MSs contact list. The MSs will be contacted to nominate MSs contacts and/or express their intention to not be involved in the Teams workspace.

Actions:

- A notification will be sent to MSs contacts included in the platform. Experts to inform EFSA in case that they wish to nominate additional experts from their Organisation and/or they do not intend to be involved in the Teams workspace.

11. Scientific updates - Guidance Document updates

11.1. CATs – Critical appraisal tools in ecotoxicology project-call for expressions of interest

EFSA presented the call for nomination for the Critical appraisal tools (CATS) in ecotoxicology project, launched and evaluated in 2020 and which started in July 2021 lasting 1 year. In this project, EFSA was the contracting authority, with the PREV Ecotoxicology team involved in crucial revision steps, and the contractor was constituted by 4 agencies/organizations working in the risk assessment, i.e. RIVM (coordinator), WENR, ANSES, UBA. The aim of the project was to develop critical appraisal tools (CATs) for the evaluation of certain types of studies commonly used in ecotoxicological evaluation of active substances. EFSA highlighted the need behind launching this project, i.e. providing a structured approach to handle the coexistence of standard and not-standardized studies in the ecotoxicology section of pesticides dossiers for assessing studies' validity, increasing consistence among dossiers and ensuring transparent risk assessments.

The presenter introduced the CATs for 7 types of studies, i.e. modified exposure studies, mesocosms, honeybee brood test, extended laboratory studies, ages residue studies, field studies and supervised residue studies and related kinetics. Each excel-based CAT is accompanied by a handbook for guiding the criteria evaluation; furthermore, each CAT proposes a final classification of the study based on the reliability and the relevance and, if needed, the eventual experts' judgment could be reported and justified.

The aim of this call for nomination is to get ecotoxicology MSs experts in order to test these tools in the peer-review process before implementing them, in order to have external agreement with the MSs; the internal testing has been already performed with the contractors.

EFSA informed that the MSs feedback will be collected and discussed between EFSA and the nominated experts with the possibility to organize a general meeting for autumn 2024 for the final discussion and agreement. The call will be launched by the end of year 2023 via the EU Survey platform.

DK asked clarification whether this project would completely fit with the current guidelines, e.g. with the Guidance Document on the risk assessment for Birds and Mammals and the Guidance on the risk assessment of plant protection products on bees. EFSA confirmed the project is in line with the current guidelines.

AT asked clarification whether this project would be comparable to other evaluation criteria which are already available, like e.g. Klimisch criteria and whether they should be used in combination or individually. EFSA clarified that the CATs use the CRED approach (Criteria for Reporting and Evaluating Ecotoxicity Data), considered the closest to Ecotoxicology area.

Actions:

- The call for nomination will be launched by the end of the year aiming at getting ecotoxicology MSs experts in order to test the current CATs in the framework of the assessment of PPP. MSs feedback will be collected and discussed between EFSA and the nominated experts. A general meeting will be organized for autumn 2024 for a final discussion and agreement in order to get the final CATs for the use in the peer-review process.

11.2. Finalisation of the guidance document on rotational crops

EFSA presented the Guidance on the assessment of pesticide residue in rotational crops, which was prepared to complement the existing OECD and EU guidance documents on this topic, as they are not fully compatible and/or are not fully aligned with the EU data requirements, leaving room for interpretations.

This project started in 2020 with EFSA drafting a technical report; afterwards, in 2022 EFSA received a formal mandate from the European Commission with the aim to provide scientific and technical assistance to COM by preparing an EU Guidance Document fitting with the aforementioned purpose.

According to the mandate's terms of reference, the document should:

- describe the circumstances when the assessment is required,
- provide details on the design of rotational crop studies,
- develop guidance on the interpretation of the studies in view of performing the consumer risk assessment and also develop options on risk mitigation measures aimed at reducing the exposure.
- derive recommendations for the development of tools necessary to perform the assessment

The presenter introduced the process of preparing the guidance document, with internal discussions starting in 2020. A public consultation on the draft guidance document was launched in the first quarter of the year 2023; more than 200 comments on the guide have been submitted, which were incorporated in a revised version of the guidance document. The document has been approved on 4 August 2023 and its publication on EFSA Journal is imminent.

EFSA presented the table of content of the Guidance Document with quick overview of the main sections.

It has been highlighted that, despite this guidance document was intended to give pragmatic advice for future assessments, the proposed approach needs to be further refined based on experience gained. For this reason, at the end of the guidance document, EFSA has included 20 recommendations (procedural and scientific) inviting MSs experts and risk managers to

discuss/prioritize them for follow up actions for further refine the risk assessment approach for rotational crops.

11.3. Finalisation of the guidance document on water treatment

EFSA informed participants on the new guidance document on water treatment that was jointly developed by EFSA and ECHA following a mandate from the European Commission. The need for a guidance document to address the effect of water treatment processes on the nature of residues present in surface water and/or groundwater, was identified in some EFSA Conclusions where the overall consumer risk assessment could not be finalised as the nature of the residues from drinking water intake was not known. The aim of the guidance is to enable the identification of public health concerns from exposure to harmful compounds generated during water treatment processes for the production of drinking water in the EU. In terms of water treatment processes, it was clarified that the new guidance focuses on pre-treatment (filtering) and disinfection processes. Upon developing the guidance, the objective was to use all available information and build on existing methodologies rather than developing something completely new. The novelty of the guidance, in terms of PPP, is the introduction of dilution factors for small ditches and streams adjacent to treated fields. The use of dilution factors (as such) is not new, yet the actual dilution factor values proposed in the guidance for estimating exposure to residues are new. Once exposure to residues is known then the next step in the methodology is a stepwise approach to identify the transformation products from water treatment processes. Only if data from literature or modelling is not available should lab scale experiments be performed to predict transformation products. Once the transformation products are identified a tiered risk assessment approach shall be followed. The guidance document was finalised in August 2023 and an implementation plan for its use is yet to be established by the European Commission.

As part of the discussion a question was raised whether confirmatory data requested in several approval regulations will have to be addressed/assessed within 2 years from the entry into force of the guidance. The representative from the European Commission clarified that they are already investigating for how many active substances this case is still valid for. Apparently, in some cases, this requirement will be superseded as the renewal of the active substance has already started or will start within the next 2 years. An overview (including deadlines) will be presented by the European Commission in one of the upcoming SCoPAFF meetings.

12. Observers

See Annex I

13. Replies to questions from Observers

See Annex II

14. Any Other Business

1. Call for MS nomination to take part to the network workshop in Wageningen planned in April 2024.

   EFSA gave an outline of the Framework Partnership Agreement (FPA) between EFSA and WUR (University & Research of Wageningen). The present FPA is a 4-year project (2021-2024) and its objective is the development of concepts and methods for the assessment of exposure of non-target terrestrial organisms to PPPs. It consists of two agreements: first one covering 2021-2022 issued two external scientific reports on i) dealing with the

development of exposure assessment goals and ii) characterization of off-field exposure to pesticide applications, focusing on spray drift deposition; the second one (running in 2023-2024) is covering the development of the necessary EU-harmonised and validated assessment methodologies for the characterization of off-field exposure in agricultural landscape. In this regard, a dedicated Pesticide Steering Network Workshop on spray drift models and comparison to measured deposition data for arable crops will take place in Wageningen on 15-16 April 2024. The aim of the workshop is to present the project's findings to stakeholders (Member States, Academia, agrochemical industry representatives, consulting companies, and others) and collect their feedbacks; share experiences and current practices for spray drift depositions assessment for regulatory ERA of NTTOs and discuss specific technical and scientific issues with the purpose of laying down the groundwork and preparing the way for (near) future work on development/revision of GDs on NTTOs.
It was flagged by MSs (DK) the importance of also having the ecotoxicology expertise on board and feeding this project/workshop. This aspect was fully acknowledged however EFSA explained that, due to the limited capability of the venue, MS nominations for joining the present workshop are limited to only one expert and preferably with environmental fate expertise as the workshop focus is on the exposure characterisation part.

2. Call for volunteers from MS and applicants for testing a new tool related to MetaPath

   EFSA is seeking volunteers from MS and applicants MSs for testing a new tool related to MetaPath (the MSS Aggregator that allows the automatic generation of Appendix G, metabolism data from xml files received through IUCLID applications) in order to enable EFSA to receive feedback on it from different stakeholders before a broad release of the tool.
   MSs/applicants were invited to volunteer for testing the new tool related to MetaPath.
   Greece, the Netherlands and CLE indicated their availability after the meeting. Germany and Belgium are exploring if they could join the initiative.

15. Next meeting

EFSA informed that next PSN meeting could be envisaged in 6-month time (spring 2024), to be confirmed based on the needs/issues possibly raised in the coming months.

ANNEX I

List of registered observers

Last Name	First Name	Name of employer	Affiliation
ALBERTI	Ilaria	CREA CI	University/public research institute
ANSEDE	Emma	Nichino Europe Co., Ltd.	Private sector
AZIMONTI	Giovanna	ASST Fatebenefratelli Sacco	Other - International Centre for pesticides and health risk prevention - ICPS
BALLABIO	Erika	ASST Fatebenefratelli Sacco	Other - International Centre for pesticides and health risk prevention - ICPS
BIBARS-REITER	René	Fine Agrochemicals Ltd	Private sector
BOURGOIN	Marjorie Bourgoin	Fine Agrochemicals Ltd.	Private sector
BRAMBILLA	Gianfranco	Istituto Superiore di Sanità	University/public research institute
BRUNNER	Stephan	Bayer	Private sector
ČAPKOVÁ	Katarína	National Institute of Public Health	National authority
CASSAR	Mark Anthony	Malta Competition and Consumer Affairs Authority (MCCAA), Technical Regulations Division (TRD)	National authority
CERNOCH	Marek	National Institute of Public Health	National authority
CHRISTIAN	Isabelle	Bayer	Private sector
COGALNICEANU	Elena	EAS Strategies	Private sector
COLLARILE	Magda	International Centre for pesticides and health risk prevention - ICPS	Other - Italian Ministry of Health (National competent authority)
CORONA	Daniela	Luiss University	University/public research institute
DELGADO CARTAY	Maria Dolores	Syngenta	Private sector
DOBICZEK	Maria	Synthos Agro Sp. z o.o.	Private sector
ELBASSUNY	Malak	National Food Safety Authority of	National authority

		Egypt	
ELFIKY	Hossam	Alofoq Company for Export, Import and Trading	Private sector
FALCIGNO	Pasquale	BASF Schweiz AG	Private sector
FERRANTE	Maria Carmela	University of Naples Federico II	University/public research institute
GINER	Marta	Devreg Consulta	Private sector
GORAK	Monika	Synthos Agro Sp. z o.o.	Private sector
GRIFF	Tamás	Pannon Analitika Kft. (Ltd.)	Private sector
HAM	Donna	LKC Switzerland Ltd.	Consultant
HEYLEN	Kevin	CropLife Europe	Private sector
HORVAT	Jasna	BASF	Private sector
IGLESIAS	Esther	Barclay Chemicals	Private sector
IVANOV	Konstantin	Corteva Agriscience	Private sector
KIPKOECH	Carolyne	Federal Institute for Risk Assessment	National authority
LOZANO	Anthony	Sumitomo Chemical Agro Europe	Private sector
LUPI	Daniela	Università degli Studi di Milano	University/public research institute
MACCHIAROLA	Ines	mediterraneaonline	Press/media
MARCHAL	Benoit	Knoell France SAS	Private sector
MAYA	Carolina	Sfifruit	Private sector
MEDRZYCKI	Piotr	Council for Agricultural Research and Economics	University/public research institute
MUELLER	Dennis	Bayer AG	Private sector
NAWROT	Iwona	Synthos Agro	Private sector
NHOATO	Andréa	FMC	Private sector
PAINA	Andrea	ISPRA	University/public research institute
PETERSEN	Annika	DTU and Danish EPA	University/public research institute
PUKLJAK	Ivana	Croatian National Institute of Public Health	National authority
RAMIREZ	Kelvin	LKC Switzerland Ltd.	Private sector
RENAHAN	Tess	PETA Science Consortium International e.V.	NGO
RICHTER	Monika	BASF SE	Private sector
RIVA	Cristian	International Centre for Pesticides and Health RiskPrevention (ICPS)	Other - National authority
SABROE	Lykke	Novozymes	Private sector

SCHNITZLER	Frauke	Knoell Germany GmbH	Other - Consultant
SGOURI	Vassilia	Bayer SAS, Crospcience dpt	Private sector
SIMON	Noa	BeeLife	NGO
SKÁCEL	Petr	National Institute of Public Health, Centre of Occupational Health	National authority
STANDAERT	Karlien	Eastman	Private sector
STIENON	Sarah	ISK Biosciences Europe NV	Private sector
ŠUMBEROVÁ	Hana	National Institute of Public Health	National authority
SZLENDAK	Joanna	Synthos Agro Sp. z o. o.	Private sector
TAGNI	Federica	ASST Fatabenefratelli Sacco	Other - International Centre for pesticides and health risk prevention - ICPS
TAIT	Sasha	Food Standards Australia New Zealand	National authority
TOMUSANGE	Joseph	Corteva Agriscience UK Ltd.	Private sector
WHEALS	Ian	Syngenta Crop Protection AG	Private sector
WIDENFALK	Anneli	Swedish Food Agency	National authority
ZENZ	Nikolaus	Syngenta Crop Protection AG	Private sector
ZUSKOVA	Eva	National Institute of Public Health	National authority

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 – Crop Life Europe	'Item 6: CLE did not take part in the workshop discussions on co-formulants and no EU decision on changed co-formulant templates seems to be available, yet we recently reported to the EU COM on recent MS divergences already following these workshops, namely in requesting additional co-formulant data in representative formulations as part of the ai registration process. For CLE, a consolidated and timely communicated approach is key, with respect to the one-substance one-assessment concept (including if similar information would also need to be provided for co-formulants at product level). Is there clarity on which information or data will be requested for co-formulants in crop protection products, and when would applicants	During the June workshop the participants discussed in length several aspects related to the assessment of active substance and formulation. The current focus of EFSA is the formulation for representative uses (EFSA has no role in the assessment of the formulations at national level). As reported in the session this morning, several aspects are under development, including a Guidance Document to support the risk assessors and the applicants alongside the creation of a local database for collecting co-formulants information with the ultimate goal to integrate this in the EU chemical data platform (in turn under development in the context of the 1 substance 1 assessment policy objective). All the details of the June workshop can be found at the following link: https://www.efsa.europa.eu/en/events/technical-workshop-risk-assessment-plant-protection-products The present topic is in an 'evolving' status and following the June workshop, discussions continued in the forum of the PAI WG meeting in September. Moreover, a mandate was sent to EFSA to complement

	be informed?'	the information contained in the technical report published in the summer 2022, and an upcoming dedicated session during the ZAPID workshop which will be held in Dec 2023. EFSA is committed to involve the stakeholders in all the relevant steps of this activity, through engagement measures such as public consultations and info sessions. The EC dedicated website will include all the necessary information to follow the developments, as well as the EFSA website for the specific actions undertaken at our level.
Q.2 Ms Frauke Schnitzler from knoell Germany GmbH	When will it be possible to generate CLH dossiers from a IUCLID dataset? Are there already detailed plans?	CLH dossiers can already be created using the corresponding context in IUCLID, and submitted as i6z If referring to the CLH report, a call for tender was launched earlier this year by ECHA to develop the Freemarker templates in order to generate automatically the report from a dossier using Report Generator – if awarded, this contract will run through next year.
Q. 3 Emma Ansede Nichino Europe Co., Ltd. (UK)	If possible I would like to ask if the RMM document gets endorsed in December SCoPAFF, will it become liable to MSs and applicants?	European Commission indicated that the RMM document is still being consulted and will be endorsed as soon as possible by SCoPAFF. Regarding liability, as any guidance is not liable to MSs/applicants but surely it can be referred to. In addition, the European Commission noted that this document on RMM might be taken into account also in the context of the dedicated PSN Workshop on spray drift models and comparison to measured deposition data for arable crops (see AOB n.1)
Q.4 Kevin HEYLEN – Crop Life Europe	Use of the EFSA draft guidance document on rotation crops VS the existing OECD TGs.	EFSA indicated that the present EFSA guidance document is not meant to replace the existing OECD TGs but it is aimed at better integrating them and basically at designing a process that can work for the European context. The methodology suggested in the guidance document is an important step forward to develop a common understanding and a consistent assessment approach, but it is acknowledged that further experience needs to be gained.