PESTICIDE STEERING NETWORK (PSN)
34th meeting

11th November 2025;12th November 2025
14.00-18.00 (CET)/ 09.00-13.00 (CET)
Minutes agreed on 1 December 2025

Location: EFSA - Parma (Meeting Room 00/07)/Webconference

Attendees:

- Network Participants:

Country	Member State Organisation
Austria	• AGES
Belgium	• FPS Health, Food Chain Safety and Environment
Czech Republic	• Central Institute for Supervising and Testing in Agriculture
Denmark	• Danish Environmental Protection Agency (DEPA)
Estonia	• Agriculture and Food Board
Finland	• Finnish Safety and Chemicals Agency (Tukes)
France	• ANSES
Germany	• Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL)
Greece	• Ministry of Rural Development and Food • Benaki Phytopathological Institute
Hungary	• National Food Chain Safety Office, Directorate of Plant Protection
Ireland	• Department of Agriculture, Food & the Marine
Latvia	• State Plant Protection Service
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	• The Administration for food safety, veterinary sector and plant protection • Kmetijski inštitut Slovenije
Spain	• INIA-CSIC
Sweden	• Swedish Food Agency • Swedish Chemicals Agency

- Observers:
  Federal Department of Home Affairs FDHA Federal Food Safety and Veterinary Office FSVO (Switzerland); Food and Veterinary Agency (Kosovo[1]); Food and Veterinary Agency of North Macedonia (North Macedonia); Republic of Türkiye Ministry of Agriculture and Forestry Directorate of Plant Protection Central Research Institute (Turkey).

- European Commission (DG SANTE; SANTE.E.4): WILLIAMS Mark

- Other EU Agencies representatives: ECHA: SIHVOLA Virve, MARCHETTO Flavio

- EFSA:
  Pesticide Peer Review Unit: TIRAMANI Manuela (Head of Unit), KARDASSI Dimitra (chair), HALLING Katrin (co-chair), AUTERI Domenica, BERNASCONI Giovanni, BLAZEVIC Marija, COLAS Mathilde, COLAGIORGI Angelo, ISTACE Frédérique, LEUSCHNER Renata, LOPEZ ROMANO Mariano, MAVRIOU Galini, RAMON Matthew, SILFVERLING Cecilia, STREISSL Franz, VERANI Alessia, VIANELLO Giorgia

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

  Risk Assessment Logistics Unit: POZZATTI Piera

[1] This designation is without prejudice to positions on status, and is in line with UNSCR 1244/1999 and the ICJ Opinion on the Kosovo declaration of independence.

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Switzerland.

2. Adoption of agenda

The agenda was adopted with two additional points proposed by Member States.

3. Brief introduction of Network participants and Observers

The meeting began with a round of introductions, allowing all Network members to briefly present themselves and their affiliations.

4. Presentation of the EFSA Guidelines for observers

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

5. Update on activities by the European Commission

The European Commission (EC), provided a comprehensive update on ongoing and upcoming activities related to Regulation 1107/2009 and associated pesticide and biocide legislation.

Key highlights included the adoption and implementation of Commission Regulation 2024/1487, which sets out data requirements and a work programme for safeners and synergists. The regulation entered into force in June 2024; a work programme containing 10 substances has been finalised – dossier submissions for those substances must be made by 19 June 2028. IUCLID functionality for applications for safeners and synergists is expected to be available in April 2026. The transitional period for products already on the market containing these substances extends until December 2030. The Commission is finalising targeted amendments to data requirements and uniform principles, reflecting new guidance documents — especially on bees, birds and mammals, and water treatment processes. These amendments aim to reinforce the use of non-animal methods and clarify exemptions for biological substances. The public consultation has closed, and a vote in the Standing Committee is anticipated soon, followed by scrutiny by the European Parliament and Council and a two-year transitional period.

On co-formulants, the EC described ongoing work to expand the EU list of unacceptable co-formulants, develop harmonised guidance, and establish a comprehensive database in collaboration with ECHA and EFSA. The database will facilitate assessments and harmonisation across Member States. The Commission also addressed new CLP hazard classes and their implications for classification and labelling, emphasising transitional

measures for substances and mixtures already on the market and the need for suppliers to ensure compliance.

The EC highlighted several priority areas such as the ongoing review of PFAS substances, and the food and feed safety simplification omnibus. The latter aims to streamline regulatory frameworks, reduce administrative burden, and facilitate faster market access for innovative substances. The EC is preparing an omnibus proposal and accompanying staff working document to justify proposed measures, with adoption targeted by the end of the year.

Belgium (BE) asked about the evaluation of co-formulants, specifically whether risk assessment should be conducted at the national or zonal level, and how harmonisation could be achieved. The EC responded that harmonisation is a priority, with guidance in development and a prioritisation exercise underway. The comprehensive database being developed by ECHA will support these efforts, and further guidance will be discussed with Member States once the database is available.

Denmark (DK) inquired about the guidance document for birds and mammals, particularly regarding the assignment of responsibility for the time-weighted average factor (FTWA). The EC clarified that the Member State receiving the first application would typically be responsible, but flexibility exists for other Member States to step in if needed. The process will be discussed further in the Post Approval Issues working group to ensure harmonisation and avoid duplication.

ECHA presenting on classification proposals and steps to be followed by the RMS

ECHA gave a presentation covering an outline of Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures[2] (the "CLP Regulation") and the related legal provisions applicable to the pesticides sector, both for pre- and post-Transparency regulation applications[3]. The presentation emphasized the specific procedures that Member State authorities should follow within the pertinent ECHA tools when submitting a proposal for harmonised classification (for an active substance) leading to an opinion from the ECHA Committee on Risk Assessment (RAC)[4]. Also, the nature and channels of communication were presented and discussed.

The Netherlands (NL) indicated how to handle situations where an endpoint needed for classification is still under discussion in the peer review experts' meeting. ECHA advised that only endpoints explicitly assessed in the dossier can be open for consultation and discussed in RAC; if a hazard class is not proposed for classification due to inconclusive/lack of data, it can still be included in the harmonised classification and labelling (CLH) report and consultation may bring in new data.

EFSA and ECHA acknowledged that sometimes is not possible to fully align the timings of the peer review and the classification (CLH) processes, i.e. having the adopted RAC opinion available at the time of the MS experts' discussions. Notwithstanding, such cases are

[2] Regulation (EC) No 1272/2008 of the European Parliament and of the Council of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006. *OJ L 353, 31.12.2008, pp. 1–1355*

[3] Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the food chain and amending Regulations (EC) No 178/2002, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 2065/2003, (EC) No 1935/2004, (EC) No 1331/2008, (EC) No 1107/2009. *OJ L 231, 6.9.2019, pp. 1–28*

[4] https://echa.europa.eu/regulations/clp/harmonised-classification-and-labelling

becoming less frequent, as most of the peer review processes are now commence in parallel with the CLH process[5]. This enables the timely availability of the RAC opinion to inform the peer review process as needed. It was also reiterated that the two processes serve different purposes: ECHA's RAC focuses on hazard-based classification of chemicals, while Member States and EFSA conduct and peer review risk assessments for specific representative uses of active substances. It was acknowledged that discrepancies between the outcomes of these processes may occur, but efforts should be made to minimise them. To this end, EFSA emphasised the importance of coordination and continuous communication among all actors involved in both peer review and CLH processes.

Latvia (LV) requested clarification from ECHA on how to handle revisions in the CLH report following the requests during the accordance check, specifically whether changes should be highlighted/tracked or a clean version is sufficient.

ECHA indicated that a clean version is needed, since if the revised CLH report is in accordance, it will move directly to public consultation. However, still the dossier submitter (i.e. the Member State submitting the CLH report) may want to transmit to ECHA a clean and a marked version of the CLH report, especially when the dossier submitter may wish to clarify their responses to ECHA's comments.

It was indicated that when EFSA sends the requests for additional data to applicants, it is systematically required that the data submission is also transmitted to ECHA classification functional mailbox. Accordingly, ECHA has full access to these data upon their submission by applicants.

ECHA indicated that the use of these additional data to inform the CLH process is determined on a case-by-case basis. This depends mainly by two factors:

- The timing of the data submission - when the additional data becomes available to ECHA close to the adoption of the RAC opinion, it may be too late to take into consideration other new data.
- The relevance and criticality of the data - the potential impact of the new data on the proposed harmonised classification. If deemed necessary, the ECHA RAC Secretariat may decide to hold an *ad-hoc* consultation.

In summary, ECHA assesses both the timing and the importance of the new data for the hazard classes open for consultation in the CLH dossier before deciding whether it can be incorporated into the CLH process.

Austria (AT) requested an update from ECHA regarding long delays between the submission of an intention on the ECHA website made by a Member State to its publication in the Registry of Intentions (RoI); and asked whether this problem has been fixed. ECHA confirmed that the technical issues affecting the timely display of new submissions in the RoI have been resolved.

AT also asked whether in addition to Member States, also EFSA and ECHA may prepare and submit CLH proposals and to possibly consider this option in the ongoing food and feed safety simplification omnibus[6].

It was clarified that following the recent revision of the CLP Regulation, pursuant to article 37, the EC may indeed request ECHA or EFSA to prepare a proposal for harmonised classification and labelling (CLH report) of a substance or a group of substances. However,

[5] Legal obligation for substances falling under the post-Transparency Regulation as per Article 11(9) of Commission Implementing Regulation 2020/1740 setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation (EC) No 1107/2009 of the European Parliament and of the Council, and repealing Commission Implementing Regulation (EU) No 844/2012. *OJ L 392, 23.11.2020, pp. 20–31*

[6] https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/14824-Food-and-feed-safety-simplification-omnibus_en

such action requires a formal mandate from the Commission; currently, ECHA and EFSA do not proactively initiate CLH reports without this mandate.

EFSA Greece (EL) requested clarification regarding situations where, for example, the toxicological assessment of groundwater metabolites had to provisionally be concluded in the context of the peer review in lack of harmonised classification and/or RAC opinion(s). EL inquired whether it would be possible to put on hold the peer review process in order to await the proposal on harmonsied classification. EFSA and the EC clarified that the applicable legislation does not allow for the suspension or postponement of EFSA's peer review timelines to wait for a RAC opinion from ECHA. Nevertheless, both agencies make every effort to coordinate and align their processes and expert meetings as closely as possible. This proactive approach aims to minimise regulatory uncertainty and ensure that critical classification outcomes are available in time to inform the peer review process.

6. EFSA tool for targeted consultation - update

EFSA presented updates to the connect.EFSA platform, following feedback from the 32nd PSN meeting (October 2024), which highlighted usability issues - particularly the burden on single users to manually compile expert comments.

Between April and September 2025, EFSA conducted a business and technical analysis, resulting in several enhancements aimed at improving user-friendliness and transparency. Key changes include the introduction of two user roles:

- **Member States Experts**: Can input and submit comments internally.
- **Member States Coordinators**: Review and submit comments to EFSA, and may also add their own. The coordinator role is optional; if not appointed, experts may submit comments directly to EFSA.

Additional improvements include:

- A new field in the comment form to reference volume/chapter/page, aiding comment extraction.
- Visibility of comments across experts within and between Member States.

The updated tool was piloted in October 2025 with selected Member States, leading to final adjustments. The platform will go live at the end of November 2025. Member States are requested to submit expert/coordinator lists by 14 November 2025. Those with defined roles will use the new system; others will continue with the old one during a transitional phase. EFSA will provide training and a user guide.

Future developments include integrating applicant and EFSA comments and launching a satisfaction survey. Since October 2025, respondents are notified by email when relevant outputs become public.

DK asked clarification on whether the coordination role should be avoided if not used. EFSA clarified that Member States experts can submit comments directly to EFSA if no coordinator is appointed in a Member State.

NL asked clarification on the need for the experts to specify on which section of the assessment report they will provide comments. EFSA clarified that this is not required, as all the experts can submit comments for all aspects of a dossier.

AT inquired about the go-live date and the impact on ongoing consultation. EFSA responded that the new system will be operational by the end of November 2025, with ongoing consultations considered. It was also clarified that for consultations closing after 13 December it is recommended to wait and use the new system.

7. Emergency authorisation protocols development

EFSA presented the development of protocols for evaluating emergency authorisations under Article 53 of the Regulation (EU) No 1107/2009. The presentation showed the objectives of the work, including the need for harmonisation across Member States and alignment with the Farm and Fork and Biodiversity strategies. For the protocol development, key principles highlighted were the focus on non-chemical methods, justification of the absence of alternatives, and avoidance of repeated authorisations for the same pest/crop combination.

Three different protocols were developed:

- Insecticides and acaricides (expected to be published in January 2026).
- Fungicides and bactericides (March 2026).
- Other substances such as herbicides and molluscicides (early 2027).

Additional outputs will include databases of non-chemical alternatives, case studies illustrating protocol application, and training activities scheduled for 2026 and 2027. The database already contains entries for insects and mites, fungi and oomycetes, with work ongoing for weeds and other pests.

In the discussion, it was clarified that only non-chemical measures were included as alternative measures, ranging from cultural practices to biological controls.

The EC recognised the importance of the work, highlighting its relevance for updating guidance and the practical value of the non-chemical alternatives database for Member States.

DK queried who participated in the work to develop these protocols. EFSA explained that the activity is outsourced to a consortium under EFSA coordination.

Finland (FI) asked about the target groups for upcoming training sessions. EFSA responded that participation will be open to Member State risk assessors, managers, and any other potentially stakeholder applying for emergency authorisations.

8. Feedback from Evaluating Member States on the timelines for assessing MRL applications and challenges in preparing the Evaluation Reports

EFSA presented an update on the lean initiatives on going for the MRL process, with a focus on the outcome of the survey with Member States run in 2025, to gather feedback on the challenges in preparing the Evaluation Reports.

The lean initiatives started in 2024 ended up in three main follow up actions, related to the creation of three new tools: 1) a scientific checklist for risk assessors, 2) a data requirement calculator, 3) a flowchart on processing studies (to identify when the need for new processing studies is triggered, based on the applicable data requirements). These tools have been piloted and discussed on the Interactive Pesticide Residue Platform (IPREP) and the related final versions are now ready to be published online, in form of appendices to the EFSA administrative guidance for pesticides applications, which will be updated at the beginning of 2026.

As regards the survey run with Member States, the investigation was launched following a reduction in the volume of Evaluation Reports' submissions over the last past years (after the transparency provisions' implementation). EFSA aimed to gather feedback on the main challenges faced at Member State's level. The inputs received could be clustered in 5 main areas: lack of resources/workload; administrative burden (especially related to Notification of Studies (NoS) and admissibility check steps); IUCLID/MRL report; increased complexity and

cross cutting issues with peer review; dossier quality/long lasting clock stops at Member State's level.

EFSA shared some first reflections to explore with Member States possible improvement actions, but also reminded Member States of services and activities that are already in place and can be helpful with these matters.

For example, EFSA reinforced the use of pre-admissibility teleconferences (TCs) and IUCLID virtual tours with Member States, to guide and support Member States with challenges related to IUCLID and the admissibility checks.

EFSA also reiterated the use of the services to applicants, as provided in the EFSA catalogue of services, to support applicants in the preparation of more complete dossiers and avoid long lasting clock stop issues later on. Services such as general pre-submission advice and clarification TCs with applicants (following additional data requests from EFSA) can be very helpful. Furthermore, the three new tools (scientific check list, DR calculator and flowchart on processing studies) that will be published along with the EFSA administrative guidance, are supposed to be very useful also for applicants, to double check the completeness of their dossiers prior to submission.

As regards the increased cross cutting issues with peer review, EFSA proposed to move the discussion on this topic on the IPREP platform, so to start elaborating with Member States some suggestions on how to treat parallel submission of studies through the MRL and peer review processes. Furthermore, EFSA anticipated that Member States can start considering the participation of EFSA in pre-submission meetings with applicants, where the presence of EFSA can be beneficial to discuss recurrent issues. EFSA already considered some topics that would be relevant for MRLs (representativeness of trials in honey, processing studies, toxicological data submitted to address previous peer review data gaps), but would like Member States to further explore and consider on which topics they would like EFSA to eventually participate.

Finally, EFSA reiterated the importance of staff exchanges and external mobility initiatives, also in this framework. Since they allow for improved knowledge sharing, talent development, and building competencies and joint strategies across the EU.

France (FR) asked whether the staff exchanges should be mutual or only Member States to EFSA (or vice versa). EFSA clarified that they can be in both directions, in parallel or not. Most of all, they should focus on addressing real needs and on building new competencies from both sides (EFSA/ Member States). So, they can also be short and very specific experiences. Member States were invited to reach out to EFSA if interested in such initiatives.

Sweden (SE) confirmed the feedback provided in the survey on the challenges related to cross cutting issues and parallel submission of studies under Peer Review/MRLs. SE mentioned they had practical cases in-house. EFSA noted this is a more frequent issue lately, and that further discussion should be taken forward, on the IPREP, especially with Member States who have practical experience of the issue, to start building clearer and more consistent approaches, when the same studies are submitted under peer review/MRLs.

9. Update on Interactive Pesticide Residue Platform (IPReP)

EFSA presented the scope of the Interactive Pesticide Residues Platform (IPReP), providing updates since the last PSN meeting and outlining ongoing activities. EFSA reported progress on LEAN topics including the development of flowcharts for processing studies under new and old data requirements, expected to be finalised by the end of 2025 with refinement planned for 2026. Additional topics under discussion include criteria for indoor versus outdoor residue

trials (suggested by Germany (DE)) and bridging residue trials for different formulation types (suggested by BE). EFSA mentioned training materials that were shared with Member States for the updated OECD storage stability guideline and for rotational crops.

As part of the discussion, NL indicated that residue colleagues prefer to have physical meetings occasionally, as these facilitate discussions more effectively than online formats. NL also requested clarification on the regulatory status of the decisions made following discussions in the IPReP channel. It was asked whether such decisions are documented in a guidance document or a technical report, to ensure that all Member States, including those not actively participating in the channel, are properly informed.

EFSA reported that the ongoing lean topic, related to the development of a flowchart outlining the requirements for processing studies, will be incorporated into the updated administrative guidance, which will be made available to both applicants and Member States.

Regarding the topic presented by BE about the criteria for bridging residue trials for different formulation types, EFSA explained that this had previously been discussed bilaterally and should now be brought to IPReP for broader discussion. Minutes will be prepared to inform all participants and allow everyone to provide input.

It was underlined that no developments will proceed directly from IPReP without the involvement of an official body such as PSN or PAFF. IPReP serves as an information, discussion and working platform, and this should follow clearly defined steps and ensure resource efficiency.

If certain topics are not best suited for discussion in IPReP, a general residue meeting can be used instead. The IPReP platform can also be used for the exchange of training materials. Soon, new material related to the updated rotational crops guidance will be shared.

Considerations of a future physical IPReP meeting can be included as an AOB item for the upcoming online IPReP meeting in November 2025.

DE proposed that, since experts appreciate the IPReP platform, a similar platform could be established for the section of toxicology.

EFSA welcomed the suggestion and noted that this aligns with the intended direction, depending on available resources.

EL agreed with DE and noted that Circabc already provides forums for discussions on toxicology, ecotoxicology, and physico-chemical topics. EL suggested that these activities could be further strengthened through EFSA’s coordination. EFSA will consider.

The EC acknowledged the significance of the many ongoing initiatives in the field. EC further stressed that it is essential for Member States to actively participate in the peer review meetings and encouraged greater involvement of Member State experts in peer review activities.

10. Replies to questions from Observers

Two questions were received from the public, all details are available in the related presentation.

11. Improvement in peer review

11.1 Upcoming peer review planning, data requirements vs. data gaps exercise, leaning activities

EFSA presented a comprehensive analysis of its conclusions (new active substances (NAS), renewals and basic substances) issued in the last 5 years. The analysis placed a particular focus on "biocontrol substances" which mainly encompass microorganisms, natural substances and basic substances. In addition to reviewing these conclusions, EFSA presented, figures and statistics on the on going peer review work and planning proposals for the next years. This information provided an overview of current activities and future directions in the peer review process. Lastly, EFSA shared the results of the analysis of 20 EFSA conclusions (chemicals a.s., NAS and renewals; January 2024 - June 2025) with the aim of mapping the requests of additional data (set during the peer review process) and the related data gaps in the conclusions. This mapping exercise served to identify clusters of recurring data gaps and, accordingly, informing on which specific areas "quality deficits" are identified in the dossiers. The results of this analysis are intended to inform and support the development tailored solutions for applicants and risk assessors with the aim of addressing these quality issues more effectively.

AT asked clarifications on:

- Which types of a.s. are falling under the category "natural substances".

EFSA indicated that active substances such as botanicals, semiochemicals are considered under this category that in turn is falling under the more general umbrella of "*biocontrol*".

- Does the average clock stop for renewals (over 600 days) include ED clock stops (which may be up to 30 months)?

EFSA indicated that the reported figure is an average of the last 5 years; some cases are much longer, especially those with ED clock stops.

DE requested whether "clock stop" means only requests for additional information, or also ED clock stops.

EFSA clarified that "clock stop" refers to the request of additional information to the applicant along the peer review process (1-month time of clock stop period for renewals and up to 3-months for NAS), as foreseen by legislation. These requests have been mapped in the analysis conducted by EFSA.

For certain active substances, those falling under Commission Implementing Regulation (EU) 844/2012, as amended by Commission Implementing Regulation (EU) 2018/1659, a "2nd ED clock stop may also be possible".

DE inquired EFSA if/which solutions are being considered to improve the recurring "gaps" identified in the dossiers, following the mapping exercise.

EFSA indicated that a main finding resulting from the mapping exercise highlights the environmental section -particularly ecotoxicology- as an area requiring further consideration, given the many recurring data gaps identified. Also, the overall results prompt risk assessors – Member States and EFSA - to a general reflection on how and why setting requests for additional information: *must have* VS *nice to have*. In this regard, it has been recalled that risk assessors shall request applicants all necessary information/studies to ensure compliance with the legal data requirements as stipulated in the legislation[7]. Early identification of data gaps is preferred to avoid delays in peer review.

Overall, to conclude:

- Need of working on new/enhanced system(s) to assist Member States in their assessments. This would also serve to enable a better alignment with the Member Statess while preparing the assessment reports and EFSA later during the commenting on it.

[7] Regulations (EU) No 283/2013 and No 284/2013

Possible options are being considered by EFSA (see agenda item 12.4 and May 2025 PSN[8]) and the topic has also been presented recently in the advisory forum[9].

- Need of focusing on the enviromental part to better understand the "root couse analysis" of the observed recurring gaps: intrinsic scientific complexity of certain endpoints or other issues?

DE pointed out that if additional information is requested during the preparation of the assessment report, meeting the deadlines for timely submitting the assessment report becomes difficult.

In this respect, the EC indicated that the legislation envisages the possibility for the RMS to request additional studies or information to the applicant while preparing the assessment report. For NAS, the additional period granted to the applicant to provide the additional information shall be of a maximum of 6 months. Without prejudice of what is stipulated in the legislation, when moving to real cases, it is acknowledged the difficulty of "balancing" the requests of additional information at the RMS level to get dossiers complete as much as possible and respecting the timings as set in the legislation.

Overall, EFSA remarked that any unresolved issue/gap at the level of the RMS assessment is then carried forward into the peer review process, which is considered suboptimal. Accordingly, Member States are strongly encouraged to proactively identify and possibly address all data needs/gaps as early as possible, ideally during the dossier admissibility phase, before the formal timing for preparing the assessment report begins.

Portugal (PT) raised issue of "misalignment" between what is required by legislation for renewals to applicants (a *supplementary* dossier) and what EFSA requests to the RMS (a *full* assessment report).

The EC acknowledged that this approach for renewals, i.e. applicants to provide a supplementary dossier, has led to different interpretations and was not fully optimal. In this regard, it has been recalled that in the "new" renewal regulation[10] this concept of "supplementary" dossier is no longer there. The paradigm has changed, and full IUCLID dossiers are requested also for renewals.

Moreover, the EC also reminded that in January 2024 the Standing Committee on Plants, Animals, Food and Feed (SCOPAFF) adopted a guidance on problem formulation for environmental risk assessment in the context of Regulation (EC) No 1107/2009[11]. Such guidance is aimed at assisting applicants in deciding possible data waivers, especially in the environmental part, as foreseen by legislation (i.e. point 1.5 of the Introduction of the Annexes of Regulations (EU) No 283/2013 and No 284/2013). Linked to this, it was also recalled that under the on-going targeted revision of the data requirements regulations, the text of point 1.5 has been further elaborated to reinforce that, under specific circumstances, certain data requirements may be waived.

The EC expressed appreciation on this "data requirements vs data gaps" exercise carried out by EFSA and expressed its willingness of being part of the conversation to support EFSA/ Member States in further developing this activity.

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[8] See presentation "SOPRA PSN May 2025" available at: https://www.efsa.europa.eu/en/events/33rd-pesticide-steering-network-meeting

[9] https://www.efsa.europa.eu/en/events/95th-advisory-forum-meeting

[10] Commission Implementing Regulation (EU) 2020/1740 repealing Commission Implementing Regulation (EU) No 844/2012. *OJ L 392, , pp. 20–31*

[11] https://food.ec.europa.eu/document/download/c4d6b7df-b7f9-4b3b-8ce5-b823ccdcf98c_en?filename=pesticides_ppp_app-proc_guide_horiz_problem-formulation-era.pdf&prefLang=hu

With reference to the Member States consultation on the draft EFSA technical reports for basic substances (step introduced for Post-Transparency applications), DE indicated that 1-week time is often too short to enable the Member States commenting and asked whether it would be possible to extend it up to 2-weeks as for standard peer review processes.

EFSA replied that this proposal can be considered for the next Member States consultations as this is an internal deadline.

DE asked if there is an official commenting period for minutes of expert meetings. EFSA explained that the current approach involves adopting the minutes during the meeting, with just minor editorial revisions made afterwards. Should significant revisions be necessary, a written procedure typically follows, involving the Member States experts who attended the meeting, to obtain agreement on the minutes.

11.2 Feedback from Completeness Check and leaning exercise Outcome of the Pilot on SID and implementation plan

EFSA (Front-Desk and Workforce Planning (FDP) Unit), delivered a presentation focusing on the following three topics: i) update of planning tables; ii) completeness check of Draft Assessment Report (DAR)/Renewal Assessment Report (RAR); and iii) feedback from the Substance Identification (SID) Pilot Project.

With respect to the planning tables, the timely update of these tables by the respective Member States was emphasised as it helps prioritising substances both for the initiation of the peer-review process and confidentiality assessments. It will also ensure alignment of the CLH and peer-review processes when the two processes are running in parallel. In terms of completeness check, members of the PSN were reminded that the Good Agricultural Practice (GAP) table in Vol. 1 of the DAR/RAR should be identical with the GAP table in the List of End Points (LoEPs), and should also be in line with the GAP table in Document D1 (for pre-Transparency Regulation (TR) dossiers) and IUCLID GAP (for post-TR dossiers). During the completeness check, the RMS is asked to confirm that the GAP in the DAR/RAR is the latest version and if it was agreed with the applicant. Changing the GAP during the ongoing peer-review, apart from correction of factual errors, is not permitted. Members of the PSN were also reminded that:

i) literature search should be presented in line with the applicable template;
ii) for presenting analytical methods, the 'Overview table for analytical methods used for risk assessment' should be included in Vol. 3 CA B5 and 3 CP B5 of the DAR/RAR;
iii) representativeness of batches in mammalian toxicology and ecotoxicology studies should be presented in Vol. 4, section C.1.4. of the DAR/RAR, along with the RMS conclusion also in Vol. 4;
iv) the list of metabolites should be included in Vol. 1 of the DAR/RAR;
v) relevant Excel files (e.g. BfR template for the assessment of *in vitro* dermal absorption studies) should be submitted together with the DAR/RAR volumes.

As for the completeness check of post-TR DARs/RARs, reference was made to the 12th meeting of the PSN IUCLID sub-group, held on 11-12 March 2025[12]. EFSA reminded that full alignment needs to be ensured at the completeness check stage among post-TR DAR/RAR and the corresponding IUCLID dossier in relation to three elements: the GAP table, the table

[12] https://www.efsa.europa.eu/en/events/12th-meeting-pesticide-steering-network-iuclid-sub-group

of Substances and Metabolites and the Table Overview of the analytical methods. The RMS is recommended to make full use of the IUCLID Report Generator functionality.

In relation to the SID Pilot Project, members of the PSN were informed that out of the 10 substances selected for the pilot project, for 3 of them the naming has already been agreed. For the remaining substances work is still ongoing. Based on the results achieved so far, the pilot project demonstrated the feasibility of introducing the substance identity check at dossier level and the applicability of the 'Guidance on substance identification and naming under CLP' for substance identification and naming to pesticide active substances. The systematic implementation of the SID check will ensure the substance's name is agreed before the peer-review starts.

AT wanted to know the legal basis for EFSA requesting changes to the RMS during the completeness check phase. EFSA responded that while there is no legal basis for such, Appendix A (i.e. the completeness checklist for assessment reports) of the applicable EFSA Administrative Guidance Document[13] was discussed and endorsed by the Standing Committee on Plants, Animals, Food and Feed (PAFF Committee) of the European Commission in March 2019. The completeness check was introduced as a best practice to ensure that the assessment report contains all necessary information, is complete, and does not include ambiguities in the data on which the risk assessment is based.

BE and DE wanted to know if the systematic check by EFSA, to verify alignment among the post-TR DAR/RAR and the IUCLID dossier, forms part of a standard check, or if it was implemented to mitigate increasing instances of such discrepancies for example in the GAP tables of the same DAR/RAR. EFSA explained that a full (100%) completeness check of the IUCLID dossier vs the DAR/RAR cannot be undertaken, therefore the focus is on the following 3 elements which need to be matching: i) GAP table; ii) metabolites; and ii) analytical methods.

DE and SE added that if the applicant is requested to update the dossier, it will result in delays in the peer-review. While updating the GAP table would not be very time consuming, updating the other sections of the dossier may take longer for the applicant to complete. EFSA responded that at the time of the call for removal of confidential information from the DAR/RAR, the applicant can still update the dossier. SE added that some aspects cannot be fully aligned as it depends on the assessment of the RMS (e.g. % of metabolites in various matrices).

PT raised the question on how to proceed in cases where the GAP table cannot be fully supported, and it would need to be adjusted. Even if the RMS goes back to the applicant, the applicant may not agree to change the GAP table. EFSA responded that in these specific cases EFSA should be informed. PT noted that the SID Pilot Project did not include substances with variants and wanted to know whether this was intentional or not, and if a variant is approved at the time of the renewal, whether it would have any implications for products already on the market (this second point from Portugal was also supported by Spain). EFSA responded that it is only by chance that substances with variants were not included in the 10 substances selected for the pilot project. The EC responded that approval of a new active substance variant can indeed have implications for products already approved and on the market with another variant of the same active substance. The renewal assessment should define which variant (or variants) are assessed and if bridging of studies between the approved variant and the new variant can be made or not.

11.3 RMS role in literature search checks

[13] https://www.efsa.europa.eu/en/supporting/pub/en-6464

NL presented the current RMS' approach in checking the scientific peer-review open literature provided by the Applicant in accordance with the EFSA guidance document on "Submission of scientific peer-reviewed open literature for the approval of pesticide active substance under Regulation (EC) No1107/2009" (EFSA, 2011), which is a provision defined by Article 8(5) of Regulation (EC) No 1107/2009. The speaker raised some questions related to literature search requirements and common RMSs' approaches; responses and shared practices have been provided by some Member States, EFSA and European Commission representatives.

- **Role of RMS in rapid assessment of summary records:** NL asked whether RMSs are required to check the rapid assessment of the literature search study records or if this is solely the applicant's responsibility. BE shared that while formal checks are performed, they also conduct their own literature searches to identify missed relevant studies.
- **Literature search by RMS after dossier submission:** NL highlighted the current issue in having peer-reviewed literature searches (covering the last 10 years prior the dossier submission) sometimes outdated due to delays in the start of the peer review process after the dossier submission. Feedback was requested about the current RMSs' practice on this point.
  BE confirmed they conduct their own literature searches to identify missed studies scientifically relevant. EL highlighted that due to the delays in the Assessment Report finalisation, the availability of new articles published after the 10-years period may be an issue during the preparation of the Assessment Report, specifically for active substances that are not conventional chemicals. Their practice does not foresee repeating the literature search for all endpoints but conducting a literature search on a case-by-case basis.

- **New public literature: only adverse data?:** NL inquired about the process when new adverse studies are published after the dossier submission.
  EFSA and EC clarified that, Regulation 1107/2009 requires a 10-year literature search before submission and does not specify requirements for new literature published afterward. Article 56 allows for the inclusion of new adverse data at any stage, and applicants must notify authorities if new information affects approval criteria. While routine updated literature searches are not required by the current legal framework, any new studies showing adverse effects, and possibly undermining the compliance to approval criteria, should be integrated in the Assessment Report on a case-by-case basis.
  PT asked whether EFSA is performing routine checks on possible new (adverse) studies available in literature. EFSA clarified that routine checks for new literature studies, including those showing possible adverse effects, are not standard practice in EFSA, but are conducted when specific concerns arise.

11.4 Support to applicants and Administrative guidance update

EFSA presented the following two proposals to be consulted and for future endorsement in the Administrative guidance update:

- Reinforcing pre-submission activities
- Meeting between RMS/ Evaluating Member State (EMS) and an applicant with possible participation of EFSA during risk assessment

In addition, EFSA proposed that, when an update of the administrative guidance is needed, Member States and EC are consulted via PSN, without the need for discussion at the Standing Committee on Plants, Animals, Food and Feed (PAFF Committee). The reason for this is that updates are frequently needed, and the current workflow delays their publication. This proposal will also be consulted.

Regarding the proposal to reinforce pre-submission activities, EFSA clarified that EFSA's participation in these activities will aim to simplify the administrative process and effectively support the RMS.

The EC clarified that the administrative guidance is not legally binding, as it aims to make sure that the results of the assessment are fit for purpose.

Regarding the simplified procedure to update the administrative guidance, EC and EFSA clarified that the proposal is intended to publish routine and technical updates. For major updates of the guidance, the PAFF may also be consulted.

AT and PT expressed doubts about EFSA's proposal, while SE supported the EFSA proposal. FR suggested that PSN could define what is a major update of the guidance.

Regarding the proposal for a meeting between RMS/EFSA/applicant during the risk assessment phase, EFSA clarified that the applicant would participate only during a dedicated hearing slot. During this time, the applicant may respond only to questions that have been identified in advance of the meeting. The applicant will not be present for the remainder of the meeting. This approach aims to streamline the peer review process, enhance the quality of EFSA's conclusions, and help reduce data gaps.

12. Feedback on French phytopharmacovigilance

France (ANSES) presented its national phytopharmacovigilance (PPV) system, which monitors adverse effects of plant protection products (PPP) post-authorisation through data collected from multiple networks. The system, legally established in 2014 and funded via a tax on PPP sales, produces fact sheets and identifies alerts for active substances. An example of data use was provided showing discrepancies in monitoring data for the active substance folpet, where no monitoring data were identified in the assessment report, but such data were available in France. Another example on the usefulness of the system was presented demonstrating health-related alerts based on associations between prenatal, occupational or domestic exposures and health effects, using collective expertise from Inserm (French Institute of Health and Medical Research).

The PestiRiv study was also presented, showing higher pesticide exposure in wine-growing areas and during treatment period and identifying factors influencing pesticide exposure. The presenter emphasised openness to further collaboration and harmonisation at EU level, noting the uniqueness of the PPV system and its potential contribution to regulatory processes. Questions were raised on when and how national monitoring and alert data could be shared to support EU-level risk assessments.

DE suggested possible sharing during the early IUCLID dossier commenting phase.

FR welcomed the idea, noting it would allow early integration into the assessment process.

BE inquired about the electronic registration of PPP use as potential source of information.

The presenter replied that they strongly support the idea, noting that precise use data is essential for interpreting monitoring results. In fact, France is compiling examples to demonstrate the added value and has consulted Member States focal points on existing national registers.

DK raised concerns about the representativeness of monitoring data in risk assessment.

It was emphasised the need for contextual information to interpret exceedances, especially when substances are used outside PPP contexts. This links back to the need to have more precise data on the use of PPP to make good interpretation of the results.

DE requested possibility to access to published data.

The presenter confirmed that all PPV data are open and available on the French national website, and links will be shared.

The presenter provided the following links after the meeting:

Report with a review of 10 years of activities of French phytopharmacovigilance:

- https://www.anses.fr/en/content/phytopharmacovigilance-marking-10-years-only-scheme-its-kind-europe
- https://www.anses.fr/system/files/PPV2024-VIG-0150-RA-EN.pdf

Analysis of Inserm's collective expert review on health effects of pesticides:

https://www.anses.fr/en/content/analysis-results-inserms-collective-expert-review-health-effects-pesticides

PestiRiv study:

https://www.anses.fr/en/content/pestiriv-study-exposure-pesticides-people-living-wine-growing-areas

French monitoring data openly available:

- **Groundwater:** https://ades.eaufrance.fr/
- **Surface Water:** https://naiades.eaufrance.fr/
- **Drinking Water:** https://www.data.gouv.fr/datasets/resultats-du-controle-sanitaire-de-leau-du-robinet/
- **Outdoor Air:** https://www.data.gouv.fr/datasets/base-de-donnee-de-surveillance-de-pesticides-dans-l-air-par-les-aasqa-a-partir-de-2002

13. Scientific updates - Guidance Document update

13.1 Update on ERA (PERA and WG)

EFSA presented the PERA multiannual plan and ERA Working Group activities. The presentation covered the objectives of the PERA project including its four focus areas: exposure, hazards, models and tools, and the development of a common platform for environmental risk assessment (ERA). EFSA also outlined the EESE project for EU environmental scenarios. Additional topics including a stepwise approach for risk assessment of low-concern plant protection products, progress on revising terrestrial guidance, and methodologies for assessing indirect effects on biodiversity were also presented. Key timelines for public consultations and finalisation of guidance documents were shared.

During the discussion, DK requested clarification on the timing of the definition of specific protection goals.

EFSA clarified that the specific protection goals will be defined by risk managers, and EFSA has been requested to support this decision-making process. This decision should take place before the finalisation of the guidance document, as the risk assessment scheme will be developed according to the defined protection goals.

DK noted that modelling appears to be a significant component of the PERA project and asked whether EFSA intends to maintain these modelling activities or whether industry will also be able to contribute.

EFSA mentioned that this relates to Area 3 of the PERA project, which includes an agreement with the beneficiary for the engagement of relevant stakeholders. EFSA noted that a workshop is planned, and the relevant stakeholder categories will need to be defined. These should include academia, Member States and industry, as all have relevant expertise. The aim of this workshop will be to develop a protocol for model evaluation which will support the development of a repository for model assessment.

13.2 Updated version of the OPEX online calculator for non-dietary exposure assessment

EFSA presented an update on the OPEX calculator for non-dietary exposure to plant protection products. The update includes corrections to calculated values, improved flexibility, and the ability to generate ad hoc reports. EFSA also outlined the ongoing OPEX project which involves data collection and analysis for seed treatment, resident exposure and worker exposure. Key challenges raised by Member States were discussed, including approaches for low application rates, interpretation of DFR/DT50 studies and harmonisation of non-professional use scenarios.

During the discussion, AT asked whether the topic would also be presented at the General Meeting on Mammalian Toxicology (13–14 November). EFSA confirmed that the upgrade will be presented during the meeting.

Replies to questions from Observer

Two questions were received from the public, all details are available in the related presentation.

Any Other Business:

1) EFSA repository on co-formulants

EFSA presented co-formulants repository which was published on the EFSA website on 23 September 2025.
Co-formulants repository contains publicly available data on co-formulants reported in dossiers that were submitted to EFSA since January 2019 to September 2025. The repository was created to facilitate formulation's assessment and to avoid the duplication of work for Member States and EFSA.
EFSA explained that repository is recommended as a tool to support formulation assessment, but it is not mandatory for regulatory decision making.

Public version is available on the EFSA website:
https://www.efsa.europa.eu/en/topics/topic/chemical-mixtures#latest
Confidential version is available on EFSA Document Management System (DMS) to Member States and ECHA.
EFSA pointed out that if any mistakes are identified in co-formulant repository to contact pesticides.peerreview@efsa.europa.eu and an updated version of the repository will be published where necessary.

2) How Member States are handling their legacy Caddy xml

EFSA raised questions to the Member States about handling legacy Caddy xml file, with Caddy software no longer compiling to EFSA security standards. EFSA explained that their IT colleagues identified a new tool developed by the industry association which is aiming to replace caddy xml while maintaining all its functionality.

Several Member States reported using various workarounds, such as compatibility modes in browsers or e-submission viewers provided by Crop Life Europe but noted concerns about security compliance.

EFSA asked all Member States to report back to EFSA on how they are currently managing legacy Caddy xml files.

3) AOB from BE

BE raised the following question regarding the issue of confidential information:

"The current PSN agenda does not include any items on maintaining Vol. 4 and generating the confidentiality report using IUCLID, which is intended to be used in the preparation of Vol. 4. MS BE understanding is that this confidential report should be a kind of replacement for Doc. J, which should contain all the information necessary for the preparation of Vol. 4.

While one may indeed question the reason for removing Doc. J in favour of encoding confidential data in different sections of IUCLID, while still maintaining Vol. 4 rather than reporting this data differently across the various sections (probably mainly in sections B1), we find that Vol. 4 has the advantage of bringing all this confidential data together in one place. This still seems to us to be more readable than information scattered throughout different parts. During the EFSA information session, as far as we can remember, we did not notice any Member States opposed to retaining Vol. 4, but rather expressing concern about the quality of the confidentiality report that will be generated by IUCLID (will it contain all the information required for the various sections of Vol. 4?).

The problem is that currently, in the absence of Doc. J (as is the case for dossiers submitted under the new version of IUCLID) and without the possibility of generating the confidentiality report via IUCLID, the preparation of Vol. 4 can be difficult and very time-consuming (this is what we experienced with a NAS). Are other Member States also encountering this problem?

There is a working group on the quality of the confidentiality report that Phys-chem experts of BE were unable to join. Perhaps it would be interesting to ask for initial feedback on this working group and the progress made on generating the confidentiality report?

If the report generator report is sufficiently efficient (and produces a Conf Info report («doc J») including all various sections of conf. info) for optimal and rapid transfer in the form of Vol. 4, the impact would be low. However, during the 'transitional' period (absence of Doc. J and confidentiality report) and in case Doc. J would not be obtained from the notifier(s), this is much less clear."

EFSA explained that document J has been dismissed for new submissions for chemical active substances (both NAS, and AIR) after IUCLID5 v9 release (May 2025), so applicants need to provide this information in the appropriate sections/documents in IUCLID.

EFSA produced after the summer a first draft of an automatic report using Report Generator called "4 - Confidential Information" that extracts the relevant pieces from IUCLID and that MS will be able to use to draft their Volume 4

A call for volunteers was launched to set up a WP to discuss and test this new report with MS and Industry, and to propose amendments if necessary (but Belgium did not nominate any experts to take part in this activity).

The WP kick-off was on October 1st, and a second meeting will be held next Friday 14th.

An update on the activity of the WP was already given at the latest IUCLID PSN meeting, which took place last week on Nov 4th. Belgium participates in this meeting.

4) AOB from DE

DE raised question regarding the status and next steps for the guidance document on technical equivalence.

- The EC noted that the guidance document on technical equivalence had been discussed about a year ago, but since then, there had been no further updates from the Member States working on it.
- During the meeting it has been clarified which Member States was actually leading the work.
- NL and FR (NL as leading Member State) were identified as the countries currently finalising the document. France reported that the last meeting between FR and NL was scheduled for November 2025, and after that, the document would be nearly finished and then sent to the EC for Member States and stakeholder consultation.
- The EC confirmed that once a final draft is available, the Member States and EFSA would need to be consulted before launching a broader consultation.

Conclusions

The meeting concluded with expressions of appreciation for the active participation and constructive engagement of all Member States, observers, and EFSA colleagues. The Chair acknowledged the fruitful and substantial discussions, which, although they extended the meeting slightly beyond the scheduled time, reflected the value and depth of the exchanges.

Looking ahead, participants were informed that the dates for the next meetings are yet to be confirmed, but the intention is to continue with a mix of online and in-person sessions in 2026.

The Chair thanked everyone for their contributions, the meeting was then formally closed.

ANNEX I

List of registered observers

Last name	First Name	Name of employer	Affiliation
ATIS	Abdullah Emre	Plant Protection Central Research Institute (TÜRKİYE)	University/public research institute
REINEKE	Anne-Kirsten	Bayer AG	Private sector

MOODLEY	Catherine	Corteva	Private sector
ARENAS	Celia	Bloom&Wild	Private sector
DONAT	Christina	e-nema GmbH	Private sector
TENA	David	Eurofins Agrosciencie Regulatory	Private sector
ATHANASIOI	Dionysia	EFSA	EFSA staff
GREBEL-KOEHLER	Dörthe	Bayer AG	Private sector
FELKERS	Edgars	Bayer AG	Private sector
LOLOU	Evangelia	Albaugh	Private sector
ŠUMBEROVÁ	Hana	National Institute of Public Health CZ	National authority
CHEREDNYCHENKO	Hanna	Alfa Smart Agro	Private sector
GOTTWALD	Indra	EBRC Consulting GmbH	Other
VON EBEN-BRUNNEN	Jana	EBRC Consulting GmbH	Other
GIAKI	Katerina	Technical University of Denmark	University/public research institute
MARKAKIS	Kostas	European Crop Care Association	Private sector
RUBBIANI	Maristella	Rud Pedersen	Private sector
GÓRAK	Monika	Synthos AGRO Sp. z o.o.	Private sector
POLACKOVA	Sona	National Institute of Public Health	National authority
GRIFF	Tamas	Pannon Analitika Kft	Private sector
RENEHAN	Tess	PETA Science Consortium International e.V.	NGO