PESTICIDE STEERING NETWORK – IUCLID SUBGROUP
13th meeting

12 June 2025 09:30- 16:30
Minutes agreed on 02 July 2025

Location: Web conference

Attendees:

- Network Participants:

Country	Member State Organisation
Austria	Austrian Agency for Health and Food Safety (AGES)
Croatia	Croatian Agency for Agriculture and Food (HAPIH)
Czech Republic	Central Institute for Supervising and Testing in Agriculture (ÚKZÚZ)
Denmark	Danish Environmental Protection Agency (DEPA)
Estonia	Agriculture and Food Board
Finland	Finnish Safety and Chemicals Agency (Tukes)
France	French Agency for Food, Environmental and Occupational Health & Safety (ANSES)
Germany	Federal Office of Consumer Protection and Food Safety (BVL) German Federal Institute for Risk Assessment (BfR) Federal Environment Agency (UBA)
Greece	Hellenic Ministry of Rural Development and Food
Hungary	National Food Chain Safety Office (NEBIH)
Ireland	Pesticide Registration Division, Department of Agriculture, Food & the Marine
Italy	International Centre for Pesticides and Health Risk Prevention (ICPS)
Latvia	State Plant Protection Service of Latvia
Lithuania	The State Plant Service under the Ministry of Agriculture
Malta	Malta Competition and Consumers Affairs Authority (MCCAA)
Netherlands	Board for the Authorisation of Plant Protection Products and Biocides (CTGB)
Poland	Ministry of Agriculture and Rural Development, Merit Mark
Portugal	Directorate General of Food and Veterinary (DGAV)
Slovak Republic	Central Control and Testing Institute in Agriculture
Slovenia	The Administration of the Republic of Slovenia for Food Safety, Veterinary Sector and Plant Protection

Spain	Agencia Estatal Consejo Superior de Investigaciones Científicas (CSIC), Centro Nacional Instituto Nacional de Investigación y Tecnología Agraria y Alimentaria (INIA), Ministerio de Ciencia e Innovación
Sweden	Swedish Chemicals Agency

- Observers:
  Food Safety Agency (Bosnia and Herzegovina); Kosovo Food and Veterinary Agency (Kosovo); Ministry of Agriculture and Forestry (Turkey)

- European Commission:
  DG SANTE

- Other EU Agencies representatives:
  ECHA

- Industry representatives:
  EACL (ERM), EACL (Syntech Regulatory), EACL-Ramboll-SCC, Bayer, BASF SE / CLE, IBMA, CLE, ADAMA, European Crop Care Association (EUROFINS AGROSCIENCE SERVICES)

- EFSA:
  PREV SCARLATO Alessia Pia, TIRAMANI Manuela, COLAGIORGI Angelo, FERREIRA Lucien ,VERANI Alessia, KARDASSI Dimitra
  FDP : PALTRINIERI Laura, MACCHI Chiara, DELFINO Alessandro, MAZZEGA Silvia, GIAROLA Alessandra, Bénédicte VAGENENDE, BONDI Gabriele

  IDATA: CÉSAR RAZQUIN Adrián, ROLANDO Pier Lorenzo, CARNESECCHI Edoardo, GISSI Andrea

  LA: DE WILLIENCOURT Iris, HASLER Matthias, SCHENONE Silvia

1. Welcome and apologies for absence

The Chair welcomed the participants.
No Apologies were received.

2. Adoption of agenda

The agenda was adopted without changes.

3. Action items from previous meetings

EFSA presented the actions from previous meetings. Actions "completed", "in progress" or "not started" yet were presented. EFSA invited members to actively contribute to open action items and reminded that a summary file listing all action points collected within the IUCLID sub-group is available for consultation under the relevant Teams space of the sub-group. The file is regularly updated after each meeting with new action items (link only available to PSN IUCLID members).

EFSA also took the opportunity to remind participants of the key contact points for submitting IUCLID-related queries (the main one being the "Ask a Question" service) and emphasized the importance of completing the registration form in advance of the meeting to ensure a smooth process

Q&A

- **FR** asked clarifications on the correct channel that Member States should use in case they have IUCLID-related questions beyond the admissibility check phase. EFSA clarified that the Ask a Question service is the appropriate channel to submit IUCLID-related queries, including those that arise even once the admissibility check phase is completed.
- **IBMA** drew attention to an item in the ECHA backlog file that had not received follow-up action. ECHA explained that the file is regularly updated by members of the OECD expert panel and invited IBMA to contact them directly to discuss the specific item of interest and arrange for further follow-up. Additionally, EFSA noted that recent enhancements have been made to the monitoring of the backlog, aiming to improve its overall management.

Actions

- **IBMA** to contact ECHA for further follow up on the backlog item of interest

4. IUCLID Latest news and & updates

EFSA presented a general update on IUCLID, mentioning that 12 virtual tour meetings with Member States have been held so far, and the meetings will resume in September. EFSA announced that IUCLID 6.9 went live on 28 May 2025, with no issues or delays related to the migration of Cloud accounts. EFSA reported a minor migration issue related to Analytical methods, which is currently under investigation and will be fixed by the October release at the latest. EFSA explained that the manuals are being updated and will be published by the end of July at the latest, except for micro-organisms, which will be published in autumn. EFSA presented an updated Admissibility checklist to support both applicants and Member States in ensuring a complete and good-quality dossier and for carrying out the admissibility check, with clearer guidance on elements required during completeness check, use of IUCLID report generator, and enforced use of structured data reporting. The Checklist can be found in Appendix C to the '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 reminded the attendees about the need to process dossiers in 2021-2022 which have not yet been declared admissible, providing updated figures as of May 2025 and offering to support applicants and RMSs as relevant with this process. EFSA explained that a format change was included in IUCLID 6.9, giving the possibility to flag every individual item confidential within the test material entity, with the implementation of the amended filtering rule delayed to October 2025 therefore the confidentiality flag in the admin block of the associated endpoint study record must still be used for the time being. In relation to dismissal of Document J, EFSA informed attendees that a live webinar was held on 2 April, and material is available on the EFSA website, with a standalone support package available on the Applicants Toolkit. EFSA announced that it has started working on the "Confidential Report" to support the RMS in compiling the DAR Vol 4, with a draft report to be made available for testing and commenting before summer and a dedicated working group to convene indicatively in mid-September.

Q&A

- **ECCA** asked for clarifications concerning the Doc mapping file and asked that when the instructions are merged with the IUCLID manual a clear distinction is made between how to manage "legacy dossiers" which still have Doc J and how to manage newly submitted ones, for which all data must be structured. Clarity was also requested on management of confidentiality requests in the two different types of dossiers (pre- and post-Doc J dismissal) to ensure that applicants with old dossiers are not now asked to provide data/justify twice. ECCA also volunteered to join the testing and working party on the confidential report as the industry perspective should also be taken into account. Lastly, they requested further clarification on the migration of the analytical methods document. **EFSA** replied that the distinction between the Doc J instructions for maintaining old ones with Doc J and building new ones without Doc J will be maintained. EFSA will also support as needed if any doubts arise in relation to data entry and or confidentiality requests for the two types of dossiers. Concerning the work on the Confidential report, EFSA will launch an expression of interest to all PSN IUCLID members, and input from all is welcome. Concerning migration of analytical methods EFSA confirmed that no data have been lost and that the information is retained in the IUCLID dossier as an attachment. The recovery of the missing value is planned for the October release at the latest. EFSA invited Member States to reach out to EFSA if they are currently evaluating dossiers affected by this issue. EFSA will provide ad-hoc support to ensure that this does not delay the risk assessment process.
- **FR** asked how the expressions of interest for the testing and commenting of the Confidential report will be advertised? **EFSA** replied that the PSN IUCLID Teams channel will be used but that a dedicated email will also be sent.
- **PT** asked whether a previously submitted dossier which includes a Doc J must now drop the attachment and **EFSA** clarified that the dismissal only applies to chemical active substance dossiers newly submitted (i.e. submitted for the first time) after go-live of IUCLID 6.9.
- **DE** asked for reports of the virtual meetings with other MS for transparency reasons. **EFSA** will clarify and come back with a proposal.

5. IUCLID OECD activities and update on validation assistant rules

EFSA gave an update on the OECD IUCLID improvement activities and validation assistant rules for the next IUCLID October release. EFSA explained that the IUCLID improvement activities, which were identified by the OECD IUCLID User Group Expert Panel in 2022, focus on 1) user interface improvements, 2) reporting, 3) using the same dataset for multiple recipients, 4) data availability, and 5) picklist management. Specifically, updates were given for activities #1, #3 and #5 which are still in progress. In addition, EFSA informed the audience about the updates on validation assistant rules, including the feedback received from stakeholders and the scope of the next IUCLID October release. The latter includes new rules to strengthen the completeness of dossiers, improvements to existing validation assistant rules, and enhancements to the message display in the Validation Report to facilitate the identification of missing fields that trigger failures. EFSA

announced that the IUCLID May release introduced some bugs to the rules, which could not be fixed before the release, and a fix is already scheduled for the next IUCLID October release.

Q&A

- **EACL** inquired whether EFSA intends to convert any quality warnings into business rules in the upcoming October release or in future releases. **EFSA** has stated that no conversion will occur in October. It is anticipated that some quality warnings may be converted into business rules next year however, this has not yet been formally communicated and agreed upon bythe PSN-IUCLID.
- **ECCA** asked whether the improvement to the message display in the validation report apply to all rules. **EFSA** clarified that this improvement will, for the time being, apply only to the rule checking the GAP table. In the future, it may be extended to other rules if deemed necessary.

6. IUCLID Report generator – Updates

EFSA started with a recap of the work done for the MRL report in the last years and shared future steps with all IUCLID PSN Members. These include an extension of the testing phase with Member States Representatives till the end of July 2025, where all received comments impacting the general structure of the MRL report will be discussed and agreed with all other Member States prior implementation, while bugs and fixes will be implemented without further consultation. This process will ultimately lead to a consolidated version of the MRL report around November 2025 for endorsement at ScoPAFF level. EFSA clarified that the MRL report template can be used also in case the purpose of an application is to submit Art. 12 confirmatory data, with appropriate adjustments by Member States on the generated report. EFSA then described in detail the latest technical enhancements and fixes on the MRL report including: change of wording and instructions text; fixing of hyperlinks; molecular formulas with subscripts; traceability of information coming from summaries when merging sections; clearer structure of Toxicity studies of metabolites section; automatic integration of GAP table.

Replacement of Documents M with the corresponding draft versions of the D(R)ARs Vol3 (already anticipated during the 12th IUCLID PSN meeting) followed in EFSA presentation. This operation required different levels of adaptation based on each report's specificities. EFSA explained that the list of main changes for these reports includes the front page and table of contents, merging/splitting of some reports, addition of references relied on, and specific structural changes to align with DAR templates (e.g. Identity and Physchem sections). Brand new reports have also been introduced (e.g. 2 – List of References). In addition, EFSA reported on the way test material information will be displayed from now on in reports (no Annex anymore) and also proposed a strategy to make users aware of the presence of attachments linked to the dossier directly in generated reports, since only attachments of type image are currently included. This could be done by displaying name and format of attachments in reports, including hyperlink to redirect users to the relevant IUCLID document/attachment. EFSA informed attendees about the addition of relevant impurities data to all reports, which generated as an action point from discussions held during the 12th IUCLID PSN meeting. Data on relevant impurities will be displayed with the same structure/logic as studies on active substances and metabolites, with the appropriate indications to distinguish. EFSA clarified that publishing process via Zenodo of all report templates, including some mapping files for guidance where available, will be completed in the coming weeks.

EFSA presented an overall list of updates and ongoing work for the report generator, including statuses and estimated deadlines for each report. EFSA acknowledged the presence of bugs in a few reports in this year's IUCLID release: affected reports are already fixed and available in the Agency instance under the "Uploaded IUCLID reports" section (they can be easily found using the keyword 'FIXED' in the Report Generator search bar). Fixed and updated versions of the reports will also be made available on Zenodo for local download, and they can be reached through the EFSA's Toolkit.

Q&A

- **FR** asked if the endorsement of the MRL report will be discussed in the ScoPAFF Section Phytopharmaceutical "Legislation" or "Pesticide Residues". **EFSA** clarified that the aim is to endorse the MRL report in the ScoPAFF Section Phytopharmaceutical for Pesticide Residues.
- **DE (BfR)** asked about timeline of templates publishing in Zenodo (especially for MRL report). **EFSA** reassured that templates will be shared as soon as possible.
- **DE (BVL)** asked whether the vertebrate study information could be automatically included in the 2 – List of References report. **EFSA** clarified that given the current IUCLID format, this information cannot be automatically retrieved and included in the report. Nevertheless, discussion for a new format is ongoing and will be presented under agenda item 8.
- **DE (BVL)** asked if microorganism templates can be commented/proposed by other Member States before their implementation in IUCLID. **EFSA** clarified about the ongoing tasking grant with Italy (ICPS) to develop microorganisms report starting from templates shared by NL (Ctgb) and that there will be dedicated space/time for other Member States to provide feedback and test reports.
- **ECCA** asked for clarification on how to generate the enhanced MRL report with IUCLID local instances and on the timeline for all the new reports sharing. **EFSA** reiterated the message that updated templates to be used with IUCLID local instances will be published as soon as possible on Zenodo and that priority will be given to reports with acknowledged bugs (MRL, Residues, Ecotox) since all other reports are working as expected and are available by default with all new IUCLID installations. Links are published in EFSA's Toolkit.
- **ECCA** followed up with suggestions on attachments/hyperlinks in reports, since the approach proposed by EFSA may work when reports are generated and consumed with own IUCLID instances but it won't when dossiers/reports are shared among users. The insertion of attachments UUID codes (if possible) should be considered as a more sound and stable approach. **EFSA** acknowledged that hyperlinks may not work when sharing dossiers/reports among users and will consider the insertion of the UUID code of attachments if considered useful by IUCLID PSN members.
- **ECCA** asked for clarification on relevant impurities, since according to EFSA's presentation they should be reported in the impurity document to get their data in reports but at the same time they are also listed in the mixture composition document, thus creating some level of repetition in the dossier. **ECCA** suggested that report generator should be able to take the data from the mixture composition document. **EFSA** explained that for relevant impurities data to be included in reports, impurity dataset(s) should be linked at the level of the impurity document and with the type of impurity set to "relevant". It was also clarified that in both IUCLID documents only the link to impurity dataset(s) is requested thus having a minimum repetition of information.
- **ECCA** asked details on how the Vol1 report will be developed and if separated Vol1 for microorganisms will be available. **EFSA** clarified that work will start from the enhanced version of the CLH report prepared by ECHA and adapted to the specificities needed for the Vol1 of chemicals. For microorganism discussion and planning still need to start.
- **AT** asked if CLH report available with new IUCLID release will include the new classification classes on mobility and ED environment. **EFSA** will double check with **ECHA** and come back on this point.
- **AT** underlined that Member States are not encouraged by EFSA to put any hyperlink in the final D(R)AR to be published and asked if EFSA is expecting Member States to remove them in the process. **EFSA** clarified that hyperlinks have been added with the objective to facilitate evaluators' work when cross-checking/complementing information in reports with attachments or with data inserted in IUCLID documents directly. If hyperlinks are not considered useful by Member States they can be removed from the generated reports. EFSA asked AT to include their point of view in the ongoing testing phase for MRL report so that the topic could be further discussed with all Member States.
- **CLE (BASF)** shared its point of view on the removal of hyperlinks from generated reports since they won't work either for Member States when dealing with dossier updates (unless a new report is generated each time) either for the public once final D(R)ARs are published. **CLE (BASF)** asked why relevant impurities should be listed in the mixture composition document since the dedicated impurities document is available. **EFSA** clarified that relevant impurities listing in mixture composition document is a data requirement set by legislation.

Actions

- **Member States Representatives** to continue the testing phase for the MRL report until 31st of July 2025,
- **EFSA** to publish updated report templates on Zenodo (priority to MRL, Ecotox, Residues)

7. IUCLID Data Re-use

EFSA presented its strategy for IUCLID data reuse, which aims to exploit structured data in PPP IUCLID applications to speed up the risk assessment process. EFSA explained that it will produce dashboards with structured data across dossiers to facilitate data reuse, increasing consistency and efficiency of the process, and that the dashboards will be available to evaluators in EFSA and Member States. EFSA presented the progress made since the last meeting, including the development of a "Data product" – an IT solution to extract, manipulate and distribute data, and the use of IUCLID APIs to extract data from specific fields programmatically. EFSA informed the attendees about the target date for the first dashboards, which is set for H1 2026, and that the first use case will be a dashboard with metabolites to identify common metabolites and related studies across dossiers. EFSA explained that the work is on time to make available the first dashboards by H1 2026, and that functionalities to better search and exploit information in IUCLID attachments are also being considered. EFSA presented the plan to explore parallel solutions to extract data from IUCLID, including the use of ECHA Data extractor, which will be deployed by ECHA on PPP dossiers in EFSA Agency in June.

8. IUCLID format changes

EFSA presented an update on the IUCLID format changes, which include changes to accommodate safeners and synergists data requirements, and the addition of new endpoint study records, such as the MetabolismInLivestock and MetabolismInCrops records. EFSA explained that the IUCLID 6 v9.0.1 release took place on 26th of May, and an ECHA IUCLID webinar was held on 28th of May to introduce the new version and provide an overview of the format changes. EFSA presented the results of the IUCLID format changes screening exercise, which identified prioritised format changes for the IUCLID 2026 and 2027 releases (Format changes planning PSN IUCLID June2025.xlsx). EFSA informed the attendees about the kick-off meeting of the IUCLID PSN working party on metabolism studies (i.e. OHT 85-2, 85-3 and 58), which took place on 22nd of May, and the list of prioritised format changes, which is available to PSN IUCLID members. EFSA explained that additional format changes will be considered following the analysis of the IUCLID backlog file in Q3 2025, and that the PSN IUCLID members are encouraged to report new format changes requests in the IUCLID backlog file. EFSA presented the take-home messages, which include the need for PSN IUCLID members to report new format change requests and to discuss and assess prioritization of format changes in agreement with ECHA.

Q&A

- **CLE** asked whether endpoint summaries on e-fate (c.f. OHT 29 S, OHT 30 S) were considered in prioritisation exercise. **EFSA** confirmed that the aforementioned documents are considered.
- **DE** asked where the latest available OECD documents can be found and which are the upcoming deadlines for providing comments to ongoing revised documents. **EFSA** clarified that all IUCLID documents including OECD documents (i.e. OHTs and their summaries) are available on ECHA IUCLID website (i.e. IUCLID format) and OECD website. Similarly, EFSA clarified that comments to the OHT 85-2, 85-3 and 58 shall be provided via the dedicated IUCLID PSN working party in July 2025.

9. Updates on confidentiality

EFSA presented the latest update to the User Guide on Confidentiality published in April 2025, which now features a stronger focus on confidentiality-related issues both with regard to the submission and processing of confidentiality requests. EFSA explained that the User Guide has been comprehensively restructured and now includes a revised and simplified explanation of the main confidentiality requirements and recommendations for applicants on how to submit proper confidentiality claims. EFSA highlighted the updates to Section A, which includes an updated glossary of key confidentiality terms related to the application of the Transparency Regulation and a clearer definition of each step of the confidentiality decision-making process, including the implementation of confidentiality decisions and the importance and timing of proactive publication. In Section C of the User Guide, which concerns submissions to IUCLID, a clearer distinction was made between the IT requirements arising from the tool and the legal requirements. EFSA explained that the revamped Section C now includes updated templates for justifications and a list of examples of elements for which confidentiality can be requested in the PPP sector, as well as some guidance for the RMS on the handling of confidentiality requests related to NAS/AMEND application dossiers under Article 7(3) of the PPP Regulation.
Finally, and also related to NAS/AMEND application dossiers under Article 7(3) of the PPP Regulation EFSA presented the newly defined approach and modalities for the exchange of confidentiality-related documents between EFSA and the RMSs, which foresees the use of a dedicated folder in the RMS dropbox for each case.

Q&A

DE and **CLE** shared their appreciation of the updates made to the User Guide.

10. Feedback from Industry Representatives

EACL

EACL presented feedback on the IUCLID format, specifically on the format changes for microorganisms, highlighting need for change for the biological properties document. EACL explained that the current structure does not allow for optimal data insertion, providing specific examples. EACL presented the proposed solutions explaining that the proposed solutions aim to simplify the entry of endpoint study records and improve the overall structure of the IUCLID format for microorganisms. EACL presented the need for interim solutions, in case the format change will take several months, and asked if any interim solutions are proposed by EFSA. Other issues coming with the new format changes were also presented (namely errors in generating the MRL Report and missing fields in the fate section).

Q&A

Regarding the need for improvement of the format of the microorganisms working context, **EFSA** thanked EACL for the feedback and confirmed that similar concerns are being raised and addressed through the ongoing tasking grant on report generator with Italy (ICPS). The proposals submitted by EACL will be thoroughly discussed within the framework of this project, and the resulting outcomes will be presented at the next IUCLID PSN meeting scheduled for the fall.

With regards to the issue with the Report Generator highlighted in the presentation, **EFSA** announced that the bug has been resolved in the latest IUCLID release. On the missing fields in the fate document, EFSA took note and will discuss with ECHA the feasibility of the proposed format change

The need for improvement of the Biological Properties document was echoed by **ECCA** and **IBMA**, who highlighted the importance of updating this document to better support its intended purpose.

IBMA

IBMA presented the current status of IUCLID for biopesticides, highlighting the need for improved validation rules and the importance of having a clear and consistent format for data entry. IBMA explained that the current IUCLID format is not always appropriate for microbial active substances, and that there is a need for specific guidance on how to enter data. It was also highlighted the need for updates to the report generator for biopesticides dossiers, providing specific examples,

such as misalignments between the IUCLID table of content and the template reports. Also, IBMA reported issues related to the data protection field in certain documents.

Q&A

On the non-alignment between the IUCLID Table of Content and the current template Reports available for microorganisms **EFSA** thanked IBMA for the feedback and confirmed that work is already ongoing to address this issue within the tasking grant with Italy (ICPS). It was also communicated that IBMA's feedback will be taken into consideration and further discussion will be held with IUCLID PSN members during the implementation phase.

On validation rules, **EFSA** clarified that the rules currently in place were discussed and agreed during the working party on microorganisms but welcomed the possibility for further improvement. On the specific issue raised on the data protection field, it was explained that if no data protection is claimed, it's sufficient to leave the field empty.

CLE

CLE presented its feedback on the IUCLID 6.9 changes, highlighting the positive aspects of the new version, including the enhancements to the residue documents OHTs 85-5 and 85-9. The revised OHTs have been improved, resulting in a significant reduction in nesting, the inclusion of tables, and a direct linkage between in-life data and results. This makes it easier for applicants to prepare and submit their dossiers. However, CLE also emphasized the need for alignment between new requirements, new guidance, and the IUCLID format. It stressed the importance of reaching an agreement on suitable implementation and transition periods, taking into account the availability of data in a suitable format. The management of the dismissal of document J was cited as a positive example of how to effectively manage impactful changes to IUCLID. Nevertheless, CLE raised concerns about the migration issues with IUCLID 6.9, including data losses in OHTs 87 and 85-5, which require prompt attention to prevent disruption to the evaluation process.

Q&A

EFSA thanked CLE for the positive feedback on the management of Doc. J dismissal. Regarding the alignment between new guidance and IUCLID format, EFSA welcomed input from Industry perspective and acknowledged the need for alignment and potential transitional period for implementation. With regard to the new data formats, **EFSA** acknowledged that applicants would require time to familiarize themselves with and compile information in the new format. Consequently, applicants are not expected to comply with the new requirements immediately following the release. EFSA also encouraged MSCAs to take this into consideration when requesting resubmissions from applicants. EFSA also reminded the role of the OECD secretariat in managing the changes to the OECD documents.

Regarding validation rules, it was noted that new rules are typically not applied to newly introduced formats, as a buffer period is generally provided for their implementation.

Regarding the migration issue, **EFSA** clarified that data is retained in IUCLID and that the issue will be fixed with the IUCLID October release.

ECCA asked for updates on the changes needed in the dossier header to accommodate the requirements for task forces. EFSA replied that this improvement is still being assessed and more information will be given at the next IUCLID PSN.

Actions

- **EFSA** to consider input from IBMA to improve Report Generator templates for microorganisms currently under enhancement

11. Any Other Business

No AoB was discussed. It was announced that next IUCLID PSN meeting will be held online in October or November 2025. A poll will be circulated to identify best date for the meeting.