

PESTICIDE STEERING NETWORK – IUCLID SUBGROUP
11th meeting



21 November 2024
09:30-17:30

Minutes agreed on 11 December 2024

Location: Web conference

Attendees:

- Network Participants:

Country	Organisation
Austria	Austrian Agency for Health and Food Safety (AGES)
Belgium	Federal Public Service Health, Food Chain Safety and Environment
Croatia	Croatian Agency for Agriculture and Food
Czech Republic	Central Institute for Supervising and Testing in Agriculture (ÚKZÚZ), National Institute of Public Health
Denmark	Danish Environmental Protection Agency (DEPA)
Estonia	Agriculture and Food Board
Finland	Finnish Safety and Chemicals Agency
France	French Agency for Food, Environmental and Occupational Health & Safety (ANSES)
Germany	Federal Office for Consumer Protection and Food Safety (BVL), German Federal Institute for Risk Assessment (BfR)
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
Lithuania	The State Plant service under the Ministry of Agriculture
Malta	Malta Competition and Consumer Affairs Authority (MCCAA)
Netherlands	Board for the Authorisation of Plant Protection Products and Biocides (CTGB)
Norway	The Norwegian Food Safety Authority
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	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, Swedish Food Agency
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- **Observers:**

- Republic of Türkiye Ministry of Agriculture and Forestry
 - General Directorate of Food and Control (Turkey);
 - Agency of Food and Veterinary of Kosovo (Kosovo).

- **European Commission/Other EU Agencies representatives:**

- European Commission, European Chemicals Agency (ECHA)

- **Industry Representative:**

- International Biocontrol Manufacturers Association (IBMA), Crop Life Europe (CLE)

- **EFSA:**

- PREV: Alessia SCARLATO, Lucien FERREIRA DA COSTA, Angelo COLAGIORGI, Manuela TIRAMANI, Alessia VERANI, Dimitra KARDASSI, Giovanni BERNASCONI, Joao CAVALHEIRO

- FDP: Chiara MACCHI, Alessandro DELFINO, Alessandra GIAROLA, Silvia MAZZEGA, Lucrezia MERIGGI

- IDATA: Adrian CESAR RAZQUIN, Pierlorenzo ROLANDO, Edoardo CARNESECCHI, Andrea GISSI, Pierfranco FERRONATO

- LA: Iris DE WILLIENCOURT, Silvia SCHENONE, Matthias HASLER



1. Welcome and apologies for absence

The Chair welcomed the participants.

2. Adoption of agenda

The agenda was adopted with the following change:

Agenda Item 11 from BfR was not presented upon request from EFSA as considered to be out of scope based on the Terms of Reference of the IUCLID PSN sub-group. EFSA invited BfR to present the topic under the Advisory Group on DATA: <https://www.efsa.europa.eu/en/advisory-group-on-data>

Germany expressed objections to EFSA's decision to exclude the presentation from the discussion.

3. Action items from previous meetings

EFSA provided an update on the action items from previous meetings as detailed in the presentation. Actions "completed" and "in progress" were presented. The dismissal of three backlog files was also communicated, clarifying that the "[Ask a question service](#)" is available for support on IUCLID dossiers and related tools and that the ECHA backlog files should be used for providing input on general improvements to IUCLID. The update of the published Terms of Reference of the IUCLID PSN sub-group was announced (ToR available here: <https://www.efsa.europa.eu/sites/default/files/2023-10/terms-of-reference-iuclid-psn-subgroup.pdf>).

Q&A

- **FR** raised concerns that certain issues they had raised previously had not been taken into consideration and requested that these be reviewed before dismissing the backlog files. **EFSA** responded that all items listed in the Excel files had been addressed but committed to verifying the content of a specific Word file located in the dedicated folder. Following the meeting, EFSA contacted FR and addressed the outstanding points.

4. IUCLID Latest news and & updates

EFSA gave an update on the latest IUCLID support activities. It was announced that all IUCLID manuals (including the Basic substance) have been updated.

EFSA provided a high-level update on the virtual tour of the Member States and clarified that, as has always been done until now, any issues raised or actions taken by EFSA arising from these meetings will be shared with the PSN IUCLID members.

General remarks were made regarding the use of the ERN and the importance of not changing it upon dossier resubmission unless agreed with EFSA. EFSA informed that new BRs will be in place as of April 2025 to help control this issue.

A new filtering rule was introduced for the Test Material (TM) Entity to cover the needs arising from the format includes changes proposed by EFSA (expanded list of categories for components with a confidentiality flag added to every entry of the TM composition table). The new filtering rules was slightly amended and endorsed by the Filtering Working Party on 13 November 2024 and will be deployed in April 2025.

Details were provided on the timeline and process for the dismissal of Document J for chemical active substance dossiers, set to occur in April 2025, and for microorganisms postponed to



April 2026. It was emphasized that this change would only affect new submissions post-release and that a new Manufacturer document would be delivered to cover fields currently missing in IUCLID. EFSA reminded Member States of the importance of no longer accepting new dossiers with a Doc J attachment (provided anywhere within the dossier) after April 2025.

The attendees were encouraged to check the mapping file which shows which IUCLID fields to use for each Document J elements. The file will soon be made available in the Applicants toolkit and broadly advertised. An info session will be held in December (for PSN members and their experts) to address any questions related to the mapping file. The report generator will be adapted in Q2 2025.

Q&A

- **NL (Ctgb)** asked to clarify which are the sample dossiers prepared by the contractor available on IUCLID Beta (testing environment). **EFSA** flagged firstly that not all test dossiers are necessarily always available in IUCLID Beta (e.g. the database is erased every time a new version is deployed) and that dossier names and datasets can be modified by any user therefore, any sample dossier could be different from the original version. The recommendation is to upload own test dossiers to Beta and rename them to ensure that other users do not edit them or to run a standalone version of IUCLID, download the dossiers published on Zenodo ([10.5281/zenodo.11471658](https://zenodo.org/record/11471658)) and master own data.

To support identification of the test dossiers, EFSA is reporting here below the test dossiers names:

- Basic active substance dossier (dossier name: "Substance A")
- Chemical Active substance (approval) dossier (dossier name: "EFSA Tender project: Representative product BC1 (active substance approval dossier)")
- Chemical Active substance (renewal) dossier – including MRL application (dossier name: "Case 3: Representative product BC1 (active substance approval + MRL dossier)")
- Microorganism (approval) dossier according to new data requirements (dossier name: "GREENB approval application")
- MRL dossier submitted AFTER the active substance approval/renewal (dossier name: "Case 1: MRL dossier submitted AFTER the active substance approval/renewal")
- MRL dossier submitted for a NOT APPROVED active substance (dossier name: "Case 2: MRL dossier submitted for a NOT APPROVED active substance")
- MRL dossier to delete maximum residue level(s) (dossier name: "Case 4: MRL dossier to delete maximum residue level(s)")
- **FR** asked whether the admissibility checklist to be used is the one annexed to the Administrative guidance and also asked for clarifications in relation to the new Manufacturer document in IUCLID and which type of information it will cover. Lastly, FR expressed their interest in attending the Info Session on Doc J if EFSA organises it. **EFSA** replied that the correct Admissibility checklist to refer to is indeed the one annexed to the administrative guidance and clarified the misunderstanding between the information provided by EFSA in relation to the new Manufacturer document in IUCLID, the mapping file for Doc J fields and the "Confidential report" to be provided with Report Generator, which will not be available before Q2 2025.
- **CLE** expressed their preference for migrating the existing Document J attachments and associated confidentiality justifications to the "Summary and Evaluation" of the dossier and also expressed the need for an Info session on Document J for applicants. CLE also mentioned the fact that applicants will require sufficient time to install the new IUCLID release so we need to ensure that there are no submission deadlines shortly after go-live of IUCLID 6.9 which would hinder them.



EFSA agrees to the need for an Info session open to applicants and aims to organise one early in 2025. The legal deadlines were checked and there are no submissions which would be impacted by go-live (meaning that applicants have time to adapt) and a NAS dossier can be submitted when ready.

- **DE** asked whether versioning can be added to the Admissibility checklist in order to facilitate use of the most up-to-date version. They also asked for conformation that Doc J dismissal would only apply to new submissions (not resubmissions) and confirmed their interest in the Info session, including participation of their Physchem experts.

EFSA agreed to DE's proposals and confirmed that dossiers which will be resubmitted after April 2025 will retain the existing Doc J attachment.

ACTIONS

- **EFSA** to consider organising an info session open to the public
- **EFSA** to consider adding versioning/dates to the admissibility checklist

5. IUCLID Report Generator

Updates on the Report Generator:

EFSA presented fixes and improvements to the Report Generator included in the October release (8.13.2) related to the generation of DOCX (Word) from HTML, the handling of rich-text errors, and the printing of dates from annotations. New reports were also presented including: i) final versions of the List of Data Waivers and Table of Analytical Methods (Appendix D), which are now available under the "Default" section as part of the October release (8.13.2); ii) reports on Physical and Chemical properties (which will substitute the current "Document M" by the April 2025 release) and the first section of the List of Endpoints (to be expanded in the future), both developed as part of Working Party on Physical and Chemical Properties and List of Endpoints between June and September 2024 and which can be found under the "Uploaded" section; and iii) the Appendix I for Microorganisms (overview table in support of the metabolite assessment according to SANCO/2020/12258) also available under the "Uploaded" section. EFSA welcomed feedback on any of these reports. Moreover, EFSA explained that a set of changes have been implemented for the MRL Application report, including the addition of commenting boxes and instructions for the EMS, to allow using the report as explained in the section below. Finally, other ongoing and planned work was presented as well as a proposal to rename the current reports intended to be used by MSs for evaluation in order to avoid the use of non-applicable nomenclature (i.e., SANCO/10181/2013 and /12545/2014) and to align with the structure/volumes of the DAR.

Q&A

- **FR** informed that they will soon provide feedback on the testing of the new PhysChem reports which they did not manage to perform during the working party due to lack of time. **EFSA** acknowledged the importance of this feedback and indicated that further input based on tests with real dossiers is welcome, and such feedback as well as any issues found should be communicated through the "Ask a question" service. In addition, they also expressed the need for clarity on whether the new report formats developed will be officially accepted by EFSA, emphasizing the desire to avoid redundant work. It was also reassured that EFSA is aware of the structure of these new reports and is involved in their revision, thus acceptance will not be an issue.
- **NL** asked for clarifications on which reports should be used when there are different versions in the "Default" and "Uploaded" sections. **EFSA** clarified that whenever there are changes in existing reports implemented before an official IUCLID release, the only option is to include such modified reports under the section "Uploaded", to then move



them to “Default” when the new IUCLID release is out. Therefore, if there are different versions of reports, the ones under “Uploaded” are always the most up to date and the ones to be used. Similarly, new reports remain in the “Uploaded” section until testing is finalised and a new release of IUCLID is out. In relation to this, it was brought to EFSA’s attention that the new report on the Appendix I for metabolites is not yet available in IUCLID Agency, and EFSA clarified that it will be soon uploaded. EFSA also committed to keep the lists of reports as clean as possible in order to facilitate the identification of the relevant reports.

- **FR and NL** raised concerns on the quality and completeness of some dossiers used for testing in the Beta instance. **EFSA** clarified that a number of reports were developed by a contractor and are of good quality, however some documents and fields might not be complete if they were introduced in later IUCLID updates. If needed, a clarification on which dossiers are better fitted for testing can be made via the IUCLID PSN Teams channel.
- **AT** raised some questions about the proposed renaming of reports and the discontinuation of the ‘Documents M’. **EFSA** explained that the ‘Document M’ reports will be renamed, and in most cases, improved or replaced with new versions that align with DAR volumes. The renaming will facilitate identification and consistency and make clearer that the intended use of the reports is for the Member States and not for applicants. Applicants can generate the reports in order to ensure that data has been entered properly in IUCLID, but should not attach them in the dossier. In addition, Austria raised a question about the List of Endpoints report coverage. EFSA confirmed that the report is being expanded to cover all sections and is expected to be complete by April 2025.

Use of Report Generator in MRL Applications:

EFSA presented the idea of using the report generator to help EMS to prepare their evaluation report (ER) in the context of MRL applications, noting that some MS already make use of it (e.g. Slovenia; MRL application for acetamiprid in honey). The “MRL report” generated from IUCLID contains all the study summaries and the applicant’s conclusion in a structured format. It was noted that the structure of the MRL report is different from the ER template available on COM’s website, but the content is similar. EFSA confirmed that an MRL report hereby generated from IUCLID would already be accepted by EFSA and that it is even intended to replace the official ER template currently available on COM’s website for post-transparency applications. To this purpose, the discussion will be moved to the PAFF Committee, in order to set this transition in 2025. The most important point according to EFSA is to keep transparency and clearly identify what comes from the Applicant (data and conclusions) and what are the Assessment and Conclusions of the EMS. To this end, EFSA envisaged a document structure where for each section the EMS would have a dedicated box to provide their own conclusion below the Applicant’s summary.

EFSA highlighted that the MRL report can be generated for the first time at admissibility, to check the completeness of the dossier and to help to visualize the content of the dossier, but this step is not mandatory. The EMS is advised to generate the MRL report and start working on it, after the declaration of admissibility, when the dossier is more “stable. The EMS input shall ideally be reported in the boxes foreseen for EMS. EFSA pointed out that the IUCLID dossier should be cleaned and updated by the Applicant as reasonably possible, instead of being manually corrected by EMS in the evaluation report. This is to consolidate the IUCLID dataset as much as possible in view of future data reuse and for transparency reasons (consistency between data published in the dossier and reported in the ER). However, it was acknowledged that a perfect curation of the IUCLID dataset may sometime require too much time and back and forth between EMS and applicants. Therefore, after a minimum of dossier updates, the EMS may still be able to directly work on the ER and modify tables manually. This possibility needs to be adapted based on real cases reminding the principle that a clear distinction between applicant’s and EMS conclusion shall always be visible. The MSs were



invited to start using the report generator in order to be able to feed future discussions at the PAFF residue committee, based on practical experience.

Q&A

- **FR** expressed concerns about the suggestion of not being able to modify the text of the Report deriving from the Applicant's dossier as it would make the drafting more complex (with additional back and forth with applicants) and proposed to be more flexible in the way EMS work and update the MRL report (e.g. highlight text amended by EMS during the evaluation phase and being able to directly modify huge tables instead of duplicating them). **FR** also asked clarifications about the generation of the report during the admissibility phase.
EFSA welcomed the proposal from France of highlighting the modified text. Especially when mistakes are observed in the IUCLID dossier, and if different conclusions are reached by EMS in huge and complex endpoint tables, it would be easier for EMS to directly modify the tables generated from the Applicant. Therefore, specific indications in the instructions page of the MRL Report will be added by EFSA. On the generation of the report during admissibility, **EFSA** explained that this step is optional and was suggested because it could help the EMS to have an idea of the completeness of the dossier as submitted by the applicant.
- **BE** expressed concerns about the use of the MRL report generator for cases when the EMS acts directly as applicant. **EFSA** reminded that compiling the IUCLID dossier is mandatory in accordance with the transparency regulation requirements and that once the dossier is compiled, the automatic generation is more convenient.

6. Updates on confidentiality

EFSA provided an overview of the key elements of the confidentiality assessment workflow, steps and timelines - including in relation to additional data - applicable to approvals of new active substances ('NAS'), amendments to approval conditions ('AMEND'), renewals, and MRL, throughout the risk assessment life cycle, with a strict focus on the IUCLID dossier.

EFSA presented the two moments in time in which confidentiality requests are assessed in relation to the dossier: i. on the admissible dossier following the declaration of admissibility and ii. on the final dossier after the approval of the scientific output adopted by EFSA.

At both stages, EFSA is in charge of assessing the confidentiality requests for renewals and MRL, while Rapporteur Member States (RMS) do so for NAS and AMEND, each within a deadline of 10 calendar weeks from admissibility.

The RMS can consult EFSA on its draft confidentiality decision, with a deadline of 4 calendar weeks from admissibility, and EFSA provides comments on the draft decision within 10 working days. The RMS then shares the draft decision with the applicant with a commenting period of 10 working days before issuing the final decision.

EFSA emphasized that the implementation of the final decision by the applicant is crucial in ensuring that the confidentiality requests are properly addressed, both when it is EFSA or the RMS in charge of the confidentiality assessment.

Moreover, with regard to additional data, EFSA highlighted that the confidentiality requests on all updates and all additional data submitted by the applicant in response to requests from the Member State or EFSA during the risk assessment **must be addressed via one single confidentiality decision** on all additional data in the final dossier. This second confidentiality assessment is initiated, upon notification of the adoption of the EFSA scientific output.



Q&A:

- **AT** asked if the second moment in time in which the confidentiality assessment takes place with regard to the final dossiers starts when MS get notified of the publication of the scientific output or when there is the official publication in the database (Wiley). **EFSA** clarified that the second confidentiality assessment starts from the moment when MS and all interested actors are notified via e-mail of the adoption of EFSA's scientific output by EFSA's Risk Assessment Logistic Unit.
- **PL** asked if there is the possibility to get support from EFSA on the preparation of the decision for the confidentiality assessment for NAS/AMEND as well as a contact point to reach. **EFSA** proposed to get in touch and circulate some support materials and reminded that MS are not bound by any specific format as concerns the confidentiality decision, as long as the decision is explicit and in writing.
- **CLE** shared concerns on the timelines indicated in the Practical Arrangements, which can be challenging for applicants, especially during the commenting stage, and asked if those timelines are envisaged to change in the future. **EFSA** reminded that those are legal deadlines and that there are several opportunities for the applicant and RMS/EFSA to interact on confidentiality before the draft decision stage and to therefore improve compliance of the confidentiality requests. While **EFSA** takes good note of the feedback, it was suggested that matters such as legal deadlines should be better discussed in less technical fora and involve the EC. **EFSA** recalled its commitment to facilitating the work of applicants and improving the efficiency, notably regarding possible IT issues.
- **EL** asked if, in the event when the request for clarification is not correctly addressed, the RMS can ask the applicant to update the dossier a second time. **EFSA** confirmed that there is the possibility to ask for several resubmissions, however, always within a reasonable deadline. This also applies when it comes to RMS requests to have the applicant implement their confidentiality decision.
- **EL** asked whether RMS are informed of the final decision when EFSA performs the confidentiality assessment for renewals. **EFSA** confirmed that after finalising a confidentiality assessment and following the implementation of a decision, all interested parties are informed. The Risk Assessment Logistic Unit notifies RMS and EC about the decision before the public consultation is launched. **EL** asked whether RMS are informed regarding the result of the public consultation. **EFSA** responded that MS are notified at the end of the public consultation which, for renewals, is after the legal deadline of 6 weeks. Regarding the results of the public consultation, EFSA confirmed that an official notification is normally sent to RMS.
- **FR** acknowledges that EFSA has gained an expertise on the confidentiality assessment, while it still represents a heavy workload for RMS. **EFSA** confirmed its availability for support and sharing recommendations, guidance and lessons-learned.

ACTIONS

- **EFSA** to share with **PL** and any other interested MS the confidentiality functional mailbox to contact EFSA to get support with the confidentiality assessment and a decision template for NAS/AMEND.

7. IUCLID Data re-use



EFSA started highlighting that structured data in IUCLID offer an opportunity to enhance the speed of scientific assessments under EFSA's remit. It was noted that pesticide data and curated endpoints are now in IUCLID format and there are plans to expand IUCLID to other food areas too.

The current IUCLID data reuse was discussed, which is mainly limited to visualizing data in IUCLID and generating predefined reports from individual dossiers using IUCLID report generator. The need to reduce manual work for answering business questions was also highlighted.

The vision for IUCLID data reuse was articulated, with a focus on setting up a data analytics service that would facilitate the identification and use of information in IUCLID dossiers across the whole database, thereby increasing the efficiency of risk assessments, starting with pesticides.

The strategy for achieving this vision was outlined, including the production of dashboards from data in EFSA Agency IUCLID instance and from other related systems. The service's availability to EFSA evaluators and Member States was emphasized.

Several use cases were presented to illustrate the potential benefits of the data reuse strategy, including the easier identification of studies across dossiers and the identification of substances with certain properties.

The roadmap for IUCLID data reuse was shared, detailing the conceptualization of dashboards, mock-up dashboards with test data, and the extraction of data from the EFSA Agency IUCLID instance. The timeline for structured and unstructured data reuse was discussed, highlighting the development of IT tools as a determining factor for the overall timing. The first dashboards are expected in production at the beginning of 2026.

An example of a metabolites dashboard was provided to demonstrate the practical application of the envisioned data reuse strategy. The dashboard would enable users to search for specific metabolites across dossiers and access endpoint data related to those metabolites.

Q&A

- **DE (BfR)** expressed concerns on the use of Copilot on confidential data. **EFSA** replied that it will take into account the presence of confidential data and will use CoPilot or other AI tools in accordance with the Commission Guidelines and internal guidelines on the use of AI.
- **DE (BfR)** also asked whether the work will be done internally in EFSA or contracted? **EFSA** clarified that the work to extract IUCLID data is contracted whereas the creation of dashboards will be done mainly by a team of EFSA staff.
- **DE (BfR)** asked whether Member States can be involved. and if they will be able to replicate what EFSA is doing. **EFSA** replied that Member States will be involved for designing the dashboards. The data extraction part will stay in EFSA, but technically it will be possible to allow MSs to design their own dashboards.
- **DE (BfR)** expressed interest in being involved in this project and made a remark on making the IUCLID data FAIR and made a reference to a PARC project on this. **EFSA** replied that there is already a bilateral communication channel open on data reuse and further communication is planned.

8. IUCLID format - Updates and planning

Presentation 8a

EFSA presented the latest IUCLID format changes in view of April 2025 IUCLID release. The OECD consultation on the IUCLID format (OECD, CORE, DOMAIN) was closed on 1 Nov.

EFSA presented the results of the work of the working party on OHT 85-5 and 85-9 (established in 2024) which include the update of four documents, and the addition of FoodEx2 codes for RAC and feed items in RAC.



The prioritisation of IUCLID format changes in view of April 2026 release has started and it will consider input from PSN members (industry, MSs) as well as EFSA experts.

Presentation 8b

EFSA walked the group through the process of the EU_PPP format changes, for which EFSA is responsible, and introduced the changes proposed for the next IUCLID release of April 2025. New documents were also presented including 'Microorganisms defining consortium', 'Spectra' and 'Manufacturer document'.

EFSA also provided an update on the migration of data from the EU PPP Summaries and presented the outcome of the consultation with industry representatives. The consultation with Industry resulted in the decision to keep the obsolete EU PPP summaries and not to migrate data until the harmonised endpoint summaries are more aligned with EU PPP needs. An exception will be made for the data from the "Carcinogenicity" summary that will be migrated to the OECD summaries for Repeated Dose Toxicity and Carcinogenicity. EFSA also informed that, upon request from Industry, the 'Obsolete' sections will be renamed to 'Legacy PPP Endpoint summaries' in the next IUCLID major release.

EFSA also presented the status of the implementation in IUCLID of the new act on safeners and synergists (COMMISSION REGULATION (EU) 2024/1487) and informed that a new dedicated working context is being prepared and will be deployed in IUCLID in April 2025.

Q&A

- **CLE** asked whether, if claimed confidentiality confidential, the SITE information will be filtered even if no confidentiality flag is set for relevant impurity in the 'Impurity' document. **EFSA** replied that would need to double check the filtering rules and will get back to CLE. Having checked, EFSA confirms that the SITE information will be removed from the dossier if it is claimed confidential within the SITE Entity.
- **AT** informed that a new active substance application on microbial consortium will be submitted to EFSA and sought recommendations from EFSA on whether it is better to request the applicant to submit the application once the new document 'Microorganisms defining consortium' enters into force in April 2025. **EFSA** clarified that the current setting of IUCLID allows to report the consortium as active substance in the main formulation but does not allow to report data on the single strains defining the consortium. If the latter is required EFSA recommends waiting until the new IUCLID release is deployed in April 2025.

9. IUCLID life cycle management and validation rules

EFSA provided an update on the new and updated validation assistant (VA) rules introduced with the latest IUCLID service release of November. Details are published on [Zenodo](#). In addition, a new rule for the submission portal was presented. This new rule will be in place as of April 2025 to ensure consistency of the European Reference Number (ERN) across resubmissions and will be applicable only to EU_PPP Active substance and Microorganism working contexts.

To speed up the risk assessment of pesticide applications, EFSA informed the group about its plan to develop more VA rules, which would strengthen the completeness of dossiers and would reduce reiterations with applicants during the risk assessment phase. EFSA also invited risk assessors to share insight from the assessment of IUCLID dossiers e.g. most common additional data requests, data gaps, and other relevant observations that can be translated into new VA rules. This could be achieved for instance by keeping EFSA (fdp@efsa.europa.eu) in the loop in exchanges with applicants.

Lastly, EFSA presented the outcome of a joint EFSA-ECHA assessment on the main areas of concerns raised by Industry on the management of PPP dossiers which over time presents some specific issues on the need for version control and lifecycle management in IUCLID.



These main areas of concern are the following 1) IUCLID format changes and associated data migration, 2) Reuse of the active substance dataset across different/parallel regulatory processes and 3) Newly introduced validation assistant rules. Some potential ways forward were proposed by EFSA to address some of the issues e.g. proposal to temporarily stop/slow down on the systematic conversion of Quality warnings into Business Rules to minimize the impact on dossiers that are already in the risk assessment phase. In this context EFSA proposed a default period of 2 years from the implementation of the QLT to allow applicants to familiarise and adapt before converting the QLT into BR.

Q&A

- **CLE** emphasised that although the issue on reusing the same active substance dataset across different/parallel regulatory processes is at the moment related to PPP process only, it may become relevant in the future in the context of the one substance one assessment.

10. Feedback from Industry representatives

IBMA

IBMA underlined the importance of having in IUCLID the necessary documents/fields for the assessment of the biological properties and the mode of action of a micro-organism active substance. It was flagged that the current document for reporting biological properties does not mirror the structure of the Data Requirements. In addition, , IBMA flagged the need to extend the picklist of the unit measures for microorganisms to include all case scenarios (such as occlusion bodies) and not to receive errors from the validation assistant when a unit different from 'CFU' is selected for reporting the concentration of the active substance. As a final comment, IBMA presented an example of a completed flexible summary metabolites document.

Q&A

- **EFSA** replied that since the document for reporting information on the biological properties of the microorganism is shared with other regulatory domains, it was not possible to customise it further towards the PPP needs. EFSA acknowledges the importance of the biological properties for the risk assessment of microbial active substances, therefore, in order to guide applicants while preparing a IUCLID dossier, a clear mapping of the specific data requirements to the sections of the biological properties document has been included both in the dedicated IUCLID manual and in the crosswalks, both available on EFSA Knowledge Junction. As for the unit measure, EFSA committed to expand the picklist to accommodate m.o. needs. The validation rule mentioned in the presentation was deactivated following feedback from IBMA.

CLE

CLE informed the group that discussions on OHT 85-5 and OHT 85-9 would be postponed due to an ad-hoc meeting organised by EFSA the following week. With regard to OHT 58, OHT 85-2, and OHT 85-3 (metabolism Studies), it was noted that the current practice of submitting metabolism data via attachments to the relevant IUCLID section is no longer suitable and that a revision of the IUCLID document is urgently needed to simplify the compilation and submission of information. Revised versions of OHTs 58, 85-2, and 85-3 were provided by OECD in October 2024, and CLE had provided comments. CLE emphasized the importance of developing suitable OHTs before further developing interfaces to ensure a streamlined and efficient process.

Q&A



- **EFSA** thanked CLE for the presentation and addressed the topic of OHTs on metabolism studies. EFSA clarified that significant work had been done in collaboration with ANSES over the past two years to ensure that MetaPath composers align with IUCLID. As a result, EFSA shared concerns about making substantial modifications to the OHTs again. It was suggested that the topic be discussed further at the OECD MetaPath User Group (MUG) meeting. It may still be possible to work on OHT 85-2, 85-3 and 58 improvements provided this is not dramatically affecting the on-going work on the IUCLID and MetaPath connectivity. To this end, EFSA would like to receive more detailed proposals from CLE regarding the alternative to nested tables. An analysis will be performed with the developers to see how the user aspect of these OHTs can be improved without affecting the backend structure of the document and their interoperability with MetaPath.
- **DE (BfR)** asked clarifications about the method CLE used to import data in IUCLID. **CLE** clarified that the "Information integration Platform" was used.

ACTIONS

- **Member States** to share insight from the assessment of IUCLID dossiers e.g. most common additional data requests, data gaps, and other relevant observations that can be translated into new VA rules.

11. Feedback from Member States representatives

NL (CTGB)

The objective of the EFSA – CTGB framework partnership was discussed, focusing on support in all pre- and post-submission activities related to the intake of pesticide dossiers, further development of dossier completeness checks, Notification of Studies (NoS), light check on confidential/personal data in IUCLID dossiers.

Future activities were outlined, including providing feedback and support during the completeness check of DAR/RAR, reviewing the CLH report and generating a corresponding report on Section 1 of the DAR/RAR Vol. 1, as well as offering feedback on newly introduced templates for Doc M CA, CP Physical and Chemical properties, and the List of Endpoints. Additionally, feedback on the report Appendix 1 for the assessment of secondary metabolites was also listed.

Q&A

- **EFSA** thanked CTGB and invited all MSs to embark on this collaboration with EFSA when possibility of new partnership will be available.

FR (ANSES)

France (FR) reported that during the assessment of MRL applications, they need to send a systematic request for additional information to applicants regarding analytical methods, especially when additional residue trials and/or other residue studies are required. It was noted that while IUCLID may be correctly prepared for the initial dossier, this is not always obvious when new studies are added, therefore listed some points requiring attention from applicants.

The removal of Document J was discussed. EFSA was requested to clarify and involve MS urgently in testing, and to confirm whether the proposed info session will include a commenting phase.



Report Generator for MRL Applications: The preparation of the "application report" was discussed, and it was noted that the Evaluation Report (ER) automatically generated by IUCLID does not correspond to the ER template currently available.

Q&A

- **EFSA** replied that the info session will soon be organised and encouraged members to familiarise with the mapping file that was provided so as to have an idea of which information will be included in the report. EFSA also clarified that the report generator work cannot be carried out now, nor can a demo be provided, because not all fields are available in IUCLID yet. At this moment in time the consultation is focussed on ensuring that all data are captured correctly in the dossier and the next phase will focus on designing the report.
- **FR** also asked EFSA to provide references of MRL applications using the ER generator and to confirm acceptance of ER generated automatically by IUCLID. **EFSA** announced that the ER template is ready and has already been used by some MS, therefore EFSA confirmed that the ER as generated automatically by IUCLID will be accepted.
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12. Any Other Business

Planned dates for 2025 meetings were shared.

DE requested further clarification on whether studies initially notified for an MRL application could also be used for the risk assessment of a renewal application, even if they were not specifically notified for the renewal.

CLE requested EFSA to include the reply to the question raised by DE in an updated version of the 'Questions and Answers on EFSA Practical Arrangements'

EFSA clarified that studies notified in the context of an application can be used for the risk assessment of another application submitted by the same applicant. In such cases the study must be included in both IUCLID applications. In Connect.EFSA, the studies must be notified only once, as explained in section 3.3 of the [User guide on pre-application ID](#).