# PESTICIDE STEERING NETWORK – IUCLID SUBGROUP
# 12th meeting

MEETING MINUTES
11-12 March 2024

**Location**: EFSA - Parma (Board Room)/Webconference

**Attendees**:

- Network Participants:

| Country | Member State 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 (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)<br>German Federal Institute for Risk Assessment (BfR) |
| Greece | Hellenic Ministry of Rural Develpment and Food<br>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 |
| 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**
  Federal Food Safety and Veterinary Office FSVO (Switzerland);
  Republic of TÜRKİYE Ministry of Agriculture and Forestry General Directorate of Food and Control (TURKEY)
- **European Commission**
  Domenico DESERIO
- **Other EU Agencies representatives**

European Chemicals Agency (ECHA)

- **Industry representatives**
  CropLife Europe (**CLE**), European Association of Regulatory consultants and Contract Research Laboratories (**EACL**), European Crop Care Association (**ECCA**), International Biocontrol Manufacturers Association (**IBMA**)
- **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, Laura PALTRINIERI, Bénédicte VAGENENDE

**IDATA**: Adrian CESAR RAZQUIN, Pier Lorenzo ROLANDO, Edoardo CARNESECCHI, Andrea GISSI

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

# 1. Welcome and apologies for absence

The Chair welcomed the participants and asked new EACL members to introduce themselves.

# 2. Adoption of agenda

The agenda was adopted without changes.

# 3. Action items from previous meetings and results of the feedback survey

EFSA briefed on the action items resulting from previous IUCLID PSN sub-group meetings. Actions "completed" and "in progress" were presented. EFSA invited members to actively contribute to open action items and reminded that an excel 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.

EFSA also presented the results of the 11th Meeting Feedback survey. Overall, the topics and the level of interaction were evaluated very good. Based on the feedback received, EFSA presented some proposals for improvement for the meeting, such as the organisation in two half days instead of one day also for the online meetings.

# 4. IUCLID Latest news and & updates

EFSA presented the latest news and updates on IUCLID.

A total of 11 meetings of the Virtual Tour with the Member States have been held so far covering AT, DK, GR, FR, NL, IT, ES, FI, DE, SI, and LV. Confidentiality request assessment has been added to the standard agenda in case the RMS has new AS dossiers.

The filtering configuration file is currently being aligned with IUCLID 6.9 and the Working Party on Filtering Rules will be consulted in writing before it is finalised.

Regarding the IUCLID Manuals, EFSA has started the systematic review of the Purpose fields within each Endpoint Study Record, with an example provided to show the difference between the current situation and the updated one. The IUCLID manuals are also being reviewed, with a call for suggestions on how they could be improved or made more user-friendly.

Regarding the management of a NAS dossier, EFSA highlighted that after a dossier is declared admissible the first step should be the confidentiality request assessment, which is the responsibility of the RMS. EFSA will inform the RMS upon publication of the dossier post-admissibility as this implies that the light check for personal data has passed and that the dossier version is stable for further assessment. The confidentiality assessment should be carried out before dossier evaluation begins, in accordance with the Practical Arrangements concerning confidentiality. Should the RMS for any reason carry out the confidentiality assessment in parallel to the

scientific evaluation, they should at least maintain a sequence when requesting dossier updates from the applicant, i.e. first request an update which covers only the aspects related to confidentiality assessment (which would then be the basis for the public consultation on the dossier, the outcome of which must be taken into consideration for the DAR) and only subsequently request a separate update to address any additional data requests.

Document J will be removed from IUCLID in May 2025 for chemical active substance dossiers, with no impact on previously submitted dossiers. For microorganisms' dossiers, the removal of Document J has been put on hold for the time being. EFSA has published the Mapping of Doc J elements to the fields in the IUCLID dossier, as well as ad-hoc instructions in the Applicants toolkit. A dedicated live Webinar is scheduled on 2 April 2025 to provide support to applicants.

EFSA held an ad-hoc Info session for RMS on 15 January, with over 60 attendees. The scope of the current phase was clarified, focusing on data entry and availability in the dossier. A dedicated Member States (MS) session will be held in June-July 2025 to ensure that the contents and format of the Confidential report are useful for compiling DAR Vol 4.

EFSA provides numerous engagement tools/activities, including general pre-submission advice, renewal pre-submission advice, pre-submission meetings, and pre-admissibility teleconferences. Support is also available during and after the peer review phase, with clarification teleconferences, applicant's technical hearings, and post-adoption teleconferences. Dedicated support is provided to SMEs on the use of IT tools, with Ask a Question, info sessions, and webinars also available.

EFSA invites PSN Members (both authorities and applicants) to keep them informed of issues related to IUCLID dossiers, including technical issues, dossier completeness and quality, and reports. This will enable EFSA to provide ad-hoc support and identify common problems.

**Q&A**

**NL** commented that it is not so easy to navigate within Ask a Question unless logged in as a registered user. **EFSA** replied that the options available to a requester have not been reduced lately and that the recommendation is always to submit questions as a registered user and not as a Guest. Users should use the Pesticides tag for any IUCLID related question.

**PT** asked how to contact EFSA in case of issues with IUCLID and exchanges with applicants on the topic. **EFSA** replied that if the issue is self-contained, Ask a Question should be used whereas if the issue emerges e.g. within an email string with many participants, EFSA-FDP should be added to the loop.

**ECCA** asked what will happen to the existing Doc J files for already submitted dossiers. **EFSA** replied that the document 'FLEXIBLE_RECORD.Manufacturer_EU_PPP' which contains the DocJ attachment will be moved to a "Legacy" section in order to still be available for consultation and editing if needed. A warning will be displayed on this document to ensure it is not unintentionally used by applicants who should no longer be using it. ECCA also asked how the structured Doc J data will be used by the MS for drafting the DAR/RAR and EFSA clarified that we will deliver a "Confidential report" which will extract the data

from the dedicated fields and compile a draft to be further elaborated by the MS as needed.

**DE (BfR)** commented that the proposed timing for removing Doc J in May is very tight and that there were still several open issues raised by some MS. **EFSA** clarified that the Doc J dismissal will continue as planned and that all efforts are being made to make sure that applicants can work with this change. The pending MS comments refer to the Confidential report which will be built by the summer, taking into consideration the comments received from MS so far and will be further shared in a dedicated session with MS to ensure alignment among all and that the final report is fit for purpose.

**DE (BfR)** also suggested that manuals might be easier to consult in Wiki format and **EFSA** committed to looking into this solution.

**CLE (BASF)** asked whether EFSA has considered publishing working examples or up-to-date test dossiers which could be used by companies for training and testing purposes? **EFSA** replied that such dossiers were made available for IUCLID 6.7 but that it is an effort (both in human resources and costs) to maintain them and EFSA was not aware of them being used particularly by external stakeholders. EFSA will brainstorm further internally also based on concrete examples of use cases for such dossiers.

**ECCA** further asked how confidentiality aspects will be managed for the legacy Doc J attachments and **EFSA** explained that the associated justification fields will be maintained and can be updated by applicants upon request.

**DE (BfR)** commented that the test dossiers are useful and necessary for testing the API access as well as migration and validation rules and that any software requires properly maintained test cases and **EFSA** took note.**Actions**

- **EFSA** to circulate a short survey on the use of IUCLID manuals and to collect concrete proposals for improvement. The survey will also cover the use of test dossiers.

# 5. IUCLID format planning and validation rules

### 5.a

The presentation aimed to discuss the upcoming IUCLID format release, scheduled for 26 May 2025, and the planned highlights for this release, including improvements to the user interface, simplification of editing fields in tables, and performance enhancements.

The presentation addressed the new features and improvements in the IUCLID format that were not presented in the previous PSN-IUCLID meeting such as the introduction of a new repeatable block 'Substance composition analysis' in the ‘Analytical profile of batches’ endpoint study record and a new repeatable table in the ‘Impurities’ document. Details can be consulted in the dedicated slides.

Additionally, EFSA clarified that IUCLID documents applicable to the old microbial data requirements can still be created and updated under the section ‘Previously used documents now obsolete, kept until April 2024’. This section will be renamed to ‘Documents applicable to the former data requirements’ as from IUCLID 6.9.

The new validation rules for IUCLID 6.9 were also presented, which include 11 new QLT warnings, 2 QLT updates, and 2 message updates.

The meeting concluded with an overview of the planned validation rules for the October IUCLID service release. Participants were invited to provide feedback on the proposed new validation rules.

Post-meeting note: Due to bugs identified in three of the proposed new validation rules for IUCLID 6.9, EFSA has decided to postpone their implementation to October 2025.

**Actions**

- **PSN-IUCLID members** to provide feedback on the new proposed validation rules for IUCLID 6.9 by 04 April 2025.
- **PSN-IUCLID members** to provide feedback on the new proposed validation rules for the October IUCLID release by 30 May 2025.

**5.b**

The IUCLID format changes screening exercise aims to ensure more transparency in the prioritization of format changes by EFSA. EFSA stated that the approach for prioritisation involves input from PSN IUCLID members such as industry, OECD IUCLID expert group members, and EFSA experts, as well as consideration of the IUCLID backlog items.

EFSA also mentioned that they have an ongoing contract with MetaPath developers, which will help improve the format of certain endpoint study records. Additionally, EFSA noted the need to automate the calculation in some fields, such as statistical indicators derived from a list of single values, and to extend the CSV import into IUCLID tables.

EFSA suggested that the list of format changes would be shared with PSN IUCLID members, and that they would revise the feedback; EFSA will then discuss about those items with ECHA while considering the possibility to establish a dedicated OECD working group or IUCLID PSN working party as needed.

**Actions**

- **EFSA** to share the list of format changes (as xlsx file) with PSN IUCLID members.
- **PSN IUCLID members** to provide their feedback on the list of format changes by 11 April 2025

## 6. IUCLID Report generator – Updates

EFSA presented an overview of the upcoming changes in IUCLID Report Generator.

The main topic discussed was the replacement of Document M reports with draft versions of the D(R)AR Vol3. EFSA explained that these changes aim to improve the reports by aligning them with official templates, clarify their intended use and reduce the administrative burden on applicants.

EFSA presented the main changes applicable to all reports, which include among other: i) the addition of evaluation boxes after each study, summary and data waiver,

ii) the revision of frontpages and tables of contents (including merging and splitting the contents of some former reports), iii) the addition of new administrative information and iv) the inclusion of literature references sorted by IUCLID section. Regarding literature references, EFSA highlighted two main limitations: i) literature searches will be available as a separate report and not directly included in each D(R)AR Vol3, and ii) the vertebrate study information (Yes/No) needs to be manually filled in by the RMS. In both cases, format changes might be needed in order to include such information directly in the reports. Moreover, in a few cases reports have been extensively reworked to produce the correspondent D(R)AR Vol3 versions (e.g., Identity and Physchem sections). EFSA also informed that these new templates will be published in Zenodo, along with supporting documentation, after the annual major release of IUCLID, and asked for feedback when using these reports (through Ask a Question service).

Additionally, EFSA presented the two tasking grants awarded to ICPS (Italy) in order to support the improvement and consolidation of reports generated with IUCLID Report Generator for i) the toxicology and ecotoxicology sections of chemical active substances and products, and ii) microbiological active substances. EFSA explained that ICPS (Italy) will review existing reports and propose improvements, including format change proposals, which will be then discussed and implemented.

EFSA also provided a full overview of all ongoing work with reports, including the development of new reports and the revision of existing ones, and the estimated deadlines for delivery

To conclude, EFSA presented an update on the MRL report, which can be used to prepare evaluation reports for MRL applications. EFSA explained that the MRL report can give good results if the IUCLID dossier is complete, and that some member states have already started using it. The more Member States start using the report, the more feedback can be gathered to further improve it. EFSA reminded that submitting parallel MRL application dossiers outside of IUCLID is not good practice, as it duplicates the work for both Member States and applicants.

**Q&A**

**CLE** suggested that vertebrate study information could be inferred from the OHT type and guideline fields in IUCLID. In case this would not be feasible, they proposed creating a dedicated field in the Literature Reference document. ECCA and EACL supported CLE's proposals, and suggested other alternatives such as the inclusion of a dedicated field in the ChangeLog or a new picklist value in the "Reference Type" field in the Literature Reference document.

**EFSA** agreed that in some cases, vertebrate information can be extracted from document types, but emphasized that this is not always reliable. EFSA supported implementing this approach where a clear logic exists but highlighted that a dedicated field might be needed to ensure consistent identification. The different options proposed will be discussed and assessed, and format changes will be proposed if needed.

**ECCA** raised additional questions on the maintenance of Documents M, how classification/non-classification information will be presented in DAR Vol 1, and how changes to the analytical methods format would affect the MRL report. They also

raised concerns about the continued request by Member States for Word documents in MRL applications despite available reports.

**EFSA** clarified that Documents M and DAR Volume 3 reports will not be maintained in parallel, and that DAR Volume 1 is still under discussion and work will proceed after the CLH release in May. Regarding the MRL report, EFSA explained that updated formats can only positively affect the report outputs, although some time is always needed between the format changes and the update of the reports. EFSA clearly stated that it does *not* support the practice of requesting parallel Word documents for MRL applications and instead encourages full use of the report generator.

**IBMA** raised two concerns regarding the naming convention for study titles that could potentially disclose confidential information (i.e. Authors names) and that templates for micro-organisms (based on CTGB formats) still need some level of revision.

**EFSA** clarified that there is a shared practice not to include author names in Endpoint Study record titles and that feedback on templates for micro-organisms will be shared with CTGB and ICPS to support improvements in templates for micro-organism dossiers.

**DE (BVL)** noted issues with the current RG MRL report. They advocated keeping its use optional and requested more time to test it on upcoming applications still at the admissibility stage, as at the recent SCoPAFF meeting also several other MS had reported issues (FR, BE, NL among others).

**EFSA** confirmed that use of the MRL report is currently optional but strongly encouraged. EFSA appreciated DE's willingness to test the tool and suggested using 2025 as a testing year (Germany (BVL), France, Austria, and Slovenia already volunteered to test the MRL report). An official endorsement of the report could come in September or December 2025. EFSA noted that while the RG MRL report still lacks some elements compared to the official current template, Member States can always add missing content in the generated output (what is important is the traceability of the information). EFSA invited all IUCLID PSN members to share outcomes of MRL report testing with colleagues involved in the PAFF meetings.

**AT** inquired about the deadlines for ICPS work on tox and ecotox reports, and asked whether EFSA will organize a working party afterwards as done previously for other reports. In addition, they asked about the official use of the new reports, considering that not all DAR sections are yet available (such as Vol1) and some are still under revision, and whether EFSA would accept the reports generated. They also questioned the use of commenting boxes for the RMS and asked for a clarification on the content of the reports regarding metabolite studies and lists of references.

**EFSA** clarified that all results from ICPS' work will be presented to the PSN in the upcoming meetings, and that the need or interest in a working party could be reassessed once results are available. EFSA explained that committing to a specific deadline for implementation of changes in reports is not yet possible, since it will depend on the volume of the requests. Regarding the format and use of reports, EFSA clarified that as of May 2025 the format of reports will already be aligned to the official D(R)AR Vol3 templates (for chemical substances), even if changes and improvements will continue, and confirmed that EFSA will accept such reports. EFSA

also stated that their aim is to have the missing reports (e.g., Vol1, LoE) ready as soon as possible so that they can also be used. As for the contents, it was clarified that reports for the Active Substance contain all studies provided in the active substance dataset and in any of the metabolites datasets in the dossier, while the reports for the Product contain studies from the representative product dataset from which the report is generated (for representative products in the section "1.4.5 Other representative products", the so-called 'sub-entity' reports need to be used). Following a direct question from EFSA, it was decided to also include studies on relevant impurities in the Active Substance reports. Finally, EFSA stressed once again that reports from report generator will be accepted provided that the dossier is of good quality and contains all the necessary information to perform a transparent risk assessment. They also proposed that, if deemed necessary, they could discuss with the European Commission the possibility of amending their webpage containing the official DAR templates in order to include clarifications on the reports.

**DE (BfR)** expressed appreciation for EFSA's clear RG roadmap regarding reports in EFSA's presentation for this agenda point. DE also asked for an overview, that is in a clear place (not scattered across presentations) and for all project areas (a project roadmap). Regarding the annotation feature, DE raised concerns about the use of the annotation feature in reports. They explained that when they tested it in the past as requested by EFSA they reported several issues (e.g. possibility of modification by other users and unclear behavior when moving annotations form one dossier version to another) that could lead to inconsistencies in the reports if this functionality is used. They also asked to clearly reflect this in the guidance document. Also just processing the contents from the annotation to e.g. the MRL report can be seen as endorsement of the annotation feature; thus this functionality should be removed until the annotation feature is officially endorsed for usage. Having a function on a voluntary basis will lead to even further inconsistencies in user behavior and thus report formats.

**EFSA** thanked DE for the feedback and clarified that the annotation tool is currently only applicable for MRL reports (i.e. the content of annotations is not displayed in any other report) and on a voluntary basis. Furthermore, versioning is in principle supported since the "last modified" information is clearly displayed in reports. Issues with the functionality were openly reported and discussed in previous meetings. It was also clarified that annotations are never published together with the public version of the dossier. From EFSA's perspective, the annotation tool is optional and intended as an alternative to commenting at the end of each study, summary, or data waiver, and some Member States have already used it. EFSA will nevertheless consider amending the text of the instructions page and continuing the discussion on Annotations based on the feedback received from MSs during the testing phase of the MRL Report.

**Actions**

- **EFSA** to add studies of relevant impurities (if any) to D(R)AR Vol3 reports
- **EFSA** to discuss options to include information on Vertebrate study Y/N in the lists of references. A final solution will be taken based on the feedback from members.

## 7. IUCLID Data Re-use

EFSA gave an update on the progress on the implementation of its strategy for IUCLID data reuse, which was presented at the last PSN IUCLID meeting in November 2024. The strategy aims to exploit structured data in PPP IUCLID applications to speed up the risk assessment process. This strategy includes producing dashboards with structured data across dossiers to facilitate data reuse, thus increasing consistency and efficiency of the risk assessment process, with the first dashboards expected to be available in the first half of 2026.

Since the last meeting, EFSA has been exploring three options to extract data from IUCLID dossiers: building its own "Data product", using IUCLID APIs, and using ECHA's data extractor. A pilot with Germany has started to test the use of IUCLID APIs, and ECHA is working on deploying its data extractor tool on EFSA's agency.

Furthermore, EFSA presented that once the data are extracted from IUCLID, its IDATA unit will produce and give access to EFSA and Member States to dashboards containing IUCLID data across dossiers. The first dashboards have been conceptualised in collaboration with EFSA's PREV unit, and Member States will be involved in the design of the dashboards when the data become available.

EFSA also presented an example of a metabolites dashboard, which will allow users to search for dossiers that include a specific metabolite using chemical identifiers available in IUCLID dossiers. This dashboard will return the dossiers that match the search results and provide links to endpoint study records.

EFSA's presentation highlighted that it has prioritised IUCLID data reuse activities to support internal processes and Member States performing risk assessment. The first step for data reuse is the extraction of IUCLID data, which can then be used to populate dashboards. EFSA is exploring all options to extract data from IUCLID with a clear long-term preference for building its own Data Products (IT tools).

**Q&A**

**DE (BfR)** expressed appreciation for the work of EFSA in the data reuse area as it will ease access to data in IUCLID.

**ECCA** asked whether the dashboards will be made available also to the general public. **EFSA** clarified that the dashboards will operate on confidential data and their availability will be limited to users with access to the EFSA Agency IUCLID instance (i.e. EFSA and Member States). In future, EFSA may work on dashboards based on sanitized dossiers. In this case, the dashboards could be made publicly available.

**Actions**

- **EFSA** to provide further updates on IUCLID data reuse at the next PSN meeting.

## 9. Feedback from Industry Representatives

**IBMA**

IBMA presented issues related to the use of IUCLID for microbial active substances, highlighting problems with Member States intake, completeness checks, and the location of studies within the tool. They noted that applicants are often still required to submit summary documents outside IUCLID, in addition to IUCLID dossiers, and that updates to both are requested during the evaluation process, resulting in duplicated effort from applicants.

IBMA also raised concerns about the management of the confidentiality process in IUCLID, citing lengthy update processes and inconsistent information. In this context, the question was raised on how many confidentiality assessments need to be performed per question number. Furthermore, IBMA pointed out that format changes have led to studies being misplaced or duplicated in sections, causing difficulties for applicants and EFSA.

IBMA concluded by emphasizing the need for a change in the MS attitude towards the IUCLID system, citing the impossibility for applicants to continue with the current "double work". IBMA also stressed the importance of improving the IUCLID system to streamline the evaluation process for microbial active substances.

**Q&A**

EFSA thanked IBMA for the direct and transparent presentation.

- Regarding the difficulties in finding studies, **EFSA** reminded that the IUCLID Manuals include best practices on naming studies that should be followed by the applicant to facilitate the identification of documents whilst avoiding disclosure of personal data. NL also suggested to IBMA to generate the "List of attachments" Report available in IUCLID to facilitate navigation.
- Concerning the practice of Member States to ask the submission of information outside IUCLID, **EC** clarified that it is a legal responsibility of the RMS to prepare the DAR/RAR and it should not be compiled by the Applicant. EC however recognized that the automatic generation of the Reports, especially for micro-organisms applications, is not yet completely fit for purpose and reminded again about the actions ongoing under the management of EFSA in this area.
- On confidentiality, EFSA reminded that there are normally two *different* confidentiality assessments for each IUCLID application dossier: the first confidentiality assessment is performed on the admissible dossier upon declaration of admissibility and the second confidentiality assessment is performed on the final dossier (i.e., the version of the dossier incorporating all additinal data submitted during the risk assessment) upon notification of adoption of EFSA output. As far as the assessment reports are concerned, EFSA reminded that their proactive publication prior to the call for comments on the assessment report is a legal obligation and therefore, if applicants' would like to request certain information to be kept confidential in the assessment report, this would require another confidentiality assessment from EFSA. Upon receipt of the complete assessment report from the RMS, EFSA shares it with the applicant who has two (2) weeks to submit confidentiality requests along with a non-confidential, sanitised version as well as a confidential version thereof via Portalino.
  **Post-meeting note:** with a view to avoiding duplication of efforts, applicants are invited to ONLY claim information confidential in the assessment report that was duly accepted as confidential by EFSA in relation to the associated

application dossier. With reference to the general concerns expressed by IBMA on confidentiality (which may be related to confidentiality requests submitted in the Portalino), in order for EFSA to provide meaningful feedback IBMA is invited to directly contact EFSA clarifying the concrete cases in which the issues mentioned in their presentation arose.

**Actions**

- **IBMA** to contact EFSA and explain the confidentiality issues experienced (to be confirmed whether it concerned submissions in the Portalino)

**CLE**

CLE provided their feedback on the presentation given by EFSA at the 11th PSN-IUCLID meeting concerning IUCLID life-cycle management (namely on format changes and associated migration rules, reuse of the same dataset across different jurisdictions and newly introduced validation rules) and noted that the proposed solutions only mitigate the issue but do not solve it.

CLE also presented their concern regarding Task Force Applications in which not all Task Force members were listed among the applicants in OpenEFSA. They proposed a solution, suggesting the addition of a field for "additional applicants" to name additional legal entities as applicants in case of joint applications.

Additionally, CLE discussed the impact of guidance documents updates and IUCLID, highlighting that OECD Harmonized Templates have a cyclical and structured approach to align with IUCLID format changes. However, they noted that EU guidance documents do not have a similar mechanism, leading to divergence between applicant requirements and the format given for insertion. CLE proposed that guidance document generation and IUCLID structure should work holistically, allowing for the insertion of information fit to applicable guidance documents.

**Q&A**

- On the issues related to life-cycle management of IUCLID dossiers, **EFSA** reiterated that format migration remains a key factor to consider when making decisions about format changes and that alternative solutions can be found if migration represents a limit to a format change. Regarding the issue of reusing the same datasets across jurisdictions, EFSA explained that there are still several constraints imposed by sectorial legislations that should be addressed first before considering a technical solution in IUCLID.
- Additionally, EFSA clarified that adding validation assistant rules retrospectively, in accordance with the data requirements, to dossiers previously submitted should be seen as an added value to ensure that good quality dossiers enter the risk assessment phase.
- **EFSA** took note of the issue of converting quality warnings into business rules, as this could pose challenges during re-submissions given the lengthy evaluation process.
- **ECHA** intervened to reiterate that they are building solutions to face challenges considering past issues regarding the migration following format changes.
- On task forces and publication of applicants on OpenEFSA, **EFSA** clarified that currently the only way of ensuring that an applicant's name is displayed on OpenEFSA os for them to submit a Member dossier within a Joint submission. Such a dossier can essentially be empty (as Member dossiers are not subject to a full validation package) but proves membership to the Task Force. The

suggestion made by CLE is not viable as applicant details are not taken from the dossier header, which often displays the contact details for the third party consultancy which submitted the dossier.

**EFSA** acknowledged the issues with the guidance documents and IUCLID format and will discuss internally to prevent similar occurrences in the future. Regarding the examples provided by CLE, where the IUCLID format does not align with the latest guidance documents, EFSA clarified that the necessary format updates will be discussed internally with relevant experts and prioritised for the next IUCLID major release in 2026 and/or 2027 as deemed relevant.

**Actions**

- **EFSA** to coordinate prioritasion of format changes considering the updates in the relevant EFSA Guidance to ensure alignment between requirements and format

## 10. IUCLID Report generator live demo

EFSA held a live demo on the use of IUCLID report generator starting with an overview of key terminology and explaining the structure and differences between IUCLID datasets and dossiers. A general PPP dossier structure was illustrated, including mixture datasets, active substance dataset, and, where applicable, datasets for metabolites, impurities, and other components.

EFSA demonstrated how to navigate the IUCLID interface and access the report generator. Instructions were given on generating both standard and sub-entity reports, with emphasis on use cases for other representative products.

EFSA then outlined when and why to use the report generator throughout the application lifecycle—by applicant during dossier preparation, at admissibility checks by Member States, and when drafting assessment reports. Three key reports were highlighted for dossiers admissibility purposes and in the assessment report preparation: the GAP table, the List of substances and metabolites, and the Table of analytical methods. Tips were provided for correctly populating fields and using cross-references to ensure complete and consistent outputs.

The session concluded with a recorded demo of the GAP report, showing how RMS and applicants can identify and resolve missing or inconsistent information.

**Q&A**

- **EFSA** reiterated the importance of the GAP table, emphasizing that it is a key trigger for the risk assessment. In this respect, EFSA highlighted the importance of consistent information among the dossier and the Assessment Report on the intended uses reported in the GAP table. Applicants and RMS are strongly encouraged to run the GAP report early in the process to verify information completeness and consistency.

## 11. Updates on confidentiality

EFSA presented the key steps and timelines of the confidentiality assessment that the RMS performs on application dossiers related to the approval of new active

substances (NAS) and the amendment of approval conditions (AMEND), pursuant to Article 7 of Practical Arrangements concerning confidentiality in accordance with Articles 7(3) and 16 of Regulation (EC) No 1107/2009, with a focus on the confidentiality assessment of the valid dossier upon declaration of admissibility.

A reasonable starting point for the RMS to initiate the confidentiality assessment is the publication of the non-confidential version of the admissible dossier by EFSA. Within four calendar weeks from dossier validation, the RMS must consult EFSA on its draft confidentiality decision and EFSA has ten working days to comment.

EFSA recommended that the RMS carry out a diligent assessment, flagging any procedural or technical issues to the applicant *before* sharing the draft confidentiality decision with EFSA. EFSA also highlighted the need for the RMS to assess the confidentiality requests on the related NoS extract, if any.

In order to facilitate EFSA's consultation, RMS should share their draft decision in an editable format, to allow the commenting directly on the draft confidentiality decision. EFSA emphasized that EFSA's role is to provide punctual feedback on substantive issues based on RMS' thorough and precise assessment and indication, in writing, of the outcome for each confidentiality claim.

EFSA also provided guidance on the verification of confidentiality requests and justifications, including the need for the RMS i. to download the "list of confidentiality claims" among the uploaded reports in IUCLID, ii. to check that the attachments which contain confidential information are uploaded in their confidential and non-confidential versions, and that each justification contains a clear identification of the items claimed confidential, the correct legal basis, and a rationale for the award of confidential status.

EFSA also highlighted the importance of putting in writing in the draft decision for *each* confidentiality request the i. reasoning/considerations, ii. conclusions (acceptance/rejection (in full or partial)) and iii. the related consequences (i.e. actions) for Applicants in terms of implementation.

EFSA shared contact information for their Pesticides Confidentiality team and confirmed availability to provide further guidance on specific topics related to confidentiality, including sharing templates for supporting the drafting of confidentiality decisions. Finally, EFSA informed on the upcoming update of the User Guide on confidentiality.

**Q&A**

**DE** commented on the usefulness of the instructions for RMS on the assessment of the NoS extract and asked if there was such guidance document for the confidentiality assessment on dossiers. **EFSA** replied that the updated User Guide on confidentiality will soon be published, containing additional guidance for Applicants and RMS. In addition, **EFSA** noted that it will consider producing further guidance for use by RMS in the confidentiality assessment.

**DE** asked which information of the IUCLID dossier is to be included in the non-confidential (sanitized) version of the assessment report to be published prior to the call for comments. **EFSA** indicated that this depends on the outcome of the assessment of the confidentiality requests on the assessment report submitted by the applicant. Upon receipt of the complete initial assessment report from the RMS, EFSA shares the initial assessment report with the applicant who has two weeks to

submit confidentiality requests along with a non-confidential, sanitised version as well as a confidential version thereof via Portalino. EFSA carries out the confidentiality assessment of the assessment reports.

**AT** proposed to use a share-point only for MS for communication between MSs while discussing dossiers.

**Actions**

- **EFSA** to consider producing further guidance for use by RMS in the confidentiality assessment.

## 12. Feedback from MSs

**AT**

The Austrian Agency for Health and Food Safety presented its experiences with the MRL report generated by IUCLID, highlighting the overall impression, important considerations, and areas for improvement. The MRL report is considered well-structured and clear, with a good separation between applicants' and EMS' assessment. However, some minor issues were identified, such as font size inconsistencies, non-functional hyperlinks, and poor-quality figures.

The comparison between the old evaluation report and the new MRL report showed that both reports follow a similar chapter structure, with consistent core findings regarding active substance residues. The new MRL report has a more structured format, with distinct boxes for the EMS and clear instructions for commenting on waivers or proposed MRLs. However, the report may lack fluency in some areas, and tables in grey boxes may appear cramped.

Proposals for improvement included the automatic generation of an additional annex for public consultation, the insertion of the GAP table and submission date in the report, and the embedding of Excel AT intends to continue using the MRL report for upcoming MRL applications and will report any problems and improvement proposals to further enhance the tool.

Overall, the MRL report generated by IUCLID is considered a useful tool, making the work of preparing the ER easier, but some aspects require further improvement.

**Q&A**

**EFSA** thanked AT for sharing their experience with the report generator and confirmed that for EFSA it was possible to perform the evaluation on this new ER format. The assessment is concluded and the ER can be consulted on Open EFSA as supporting document to the published EFSA Opinion (https://open.efsa.europa.eu/questions/EFSA-Q-2024-00270?search=Modification+of+the+existing+maximum+residue+level+for+acetamiprid+in+honey ). All MSs were invited again to test the report and give feedback.

**EFSA** also clarified that the version of the MRL report to be used is the one currently available in the list of "Uploaded IUCLID reports", but following the next IUCLID release, it will be available in the list of "Default" reports with the name "MRL Report".

**DE (BfR)** asked clarifications on the type of application used for testing. AT replied that it was a rather simple MRL Art 10 application on one commodity only. DE (BfR) also asked which version of the dossier was used to generate the report and AT replied that it was the version submitted by the applicant.

**Actions**

- **EFSA** to consider proposals for improvement of the MRL Report as presented by AT

**DE**

**BVL** presented their feedback on the IUCLID system, highlighting one relevant issue that needs to be addressed. They noted that, when generating the List of references with the report generator, the column 'Vert. study Y or N' remains empty throughout the document, and that there is neither a designated picklist under 'Test animals' for 'Vert. Study - Y/N' nor an automatic assignment upon picklist in the field of 'Species', 'Strain', etc.

BVL asked how the RMS should address this issue during the Admissibility Check and what the anticipated approach by EFSA would be in this regard.

**Q&A**

- **EFSA** thanked BVL for their feedback and replied that they are aware of this issue. Currently this field can only be manually filled in by RMS in the generated report. However, this should not have any impact on the decision making process regarding admissibility. It was reiterated that EFSA will discuss possible solutions and inform IUCLID PSN members of the outcome of the analysis accordingly.

In the discussion at meeting end EFSA emphasized that SANTE always welcomes uses of IUCLID as it was intended. DE replied that IUCLID was not intended for dossiers with more studies than a typical REACH dossier (ca. 10 studies), while biocides and PPP dossiers usually have 100 or 500 studies.

## 13. Any other business

No any other business were discussed. EFSA anticipated that next IUCLID PSN meeting will be held online in June 2025. A poll will be circulated to identify best date for the meeting.