PESTICIDE STEERING NETWORK – IUCLID SUBGROUP 8th meeting

22nd November 2023
09:30-16:30
Minutes agreed on 12 December 2023

Location: Webconference

Attendees:

- Network Participants:

Country	Name
Austria	Klaus Leder
Belgium	Philippe Castelain Wim Hooghe
Croatia	Dubravka Čelig
Czech Republic	Hana Kubátová-Hiršová Milan Svoboda Martin Beníšek
Denmark	Alf Aagaard
Estonia	Elise Joonas
Finland	Marika Päällysaho
France	Suzanne Pierlot Marie Hermant
Germany	Falko Frenzel Christian Sieke Tobias Opialla Daniela Marutzky Wolfgang Janzen
Greece	Melita Ourania
Hungary	Agnes Stier
Ireland	Sadhbh O'Dwyer
Lithuania	Elena Barzdėnienė
Malta	Nicole Cilia
Netherlands	Hanneke Westland
Poland	Monika Debek Aneta Choderska
Slovak Republic	Marta Galusová
Slovenia	Anja Palman Mehikić Sanja Vranac Polona Slokan
Spain	Jose-Luis Alonso Prados Violeta Carrasco
Sweden	Christoffer Österwall Maria Bighiu

- Observers:(IPA country)
  Zorka PRLJEVIC

- European Commission/Other EU Agencies representatives:
  Valerio Spinosi, François Le Goff, Dorota Burchard-Sosnowska, Leea Kooko

- Industry Represenative:
  Jose Juanes, Adi Cornelese, Marc Teiwes, Agata Jakubowska, Andrew Whyte, Viktoria Eriksson

- EFSA:

  PREV: Alessia Pia Scarlato, Giovanni Bernasconi, Lucien Ferreira, Tomas Rovesti, Angelo Colagiorgi

  IDATA: Adrián César Razquin, Edoardo Carnesecchi, Dayana Buzle

  FDP: Alessandro Delfino, Chiara Macchi, Silvia Mazzega, Lucrezia Meriggi

  LA: Matthias Hasler, Iris De Williencourt, Xhestina Myftaraj

  TS: Pierfranco Ferronato

1. Welcome and apologies for absence

The Chair welcomed the participants.
Apologies were received from Ana Mrnjavčić (Croatian Agency for Agriculture and Food) and Francesca Pace (MCCAA).

2. Adoption of agenda

The agenda was adopted with the following change:

One presentation from Marc Teiwes (CLE) and additional questions received by AT before the meeting were added under Item 14 (AOB).

3. Action items from previous meetings

EFSA briefed on the action items resulting from previous IUCLID PSN sub-group meetings. Actions "completed", "in progress" and "not started" 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. The file is regularly updated after each meeting with new action items.

4. IUCLID Latest news and & updates

EFSA presented latest news and updates on IUCLID submissions.
It was communicated that the updated IUCLID manual on MRL applications and the "mini" manual on Microbial Active Substance Application have been published on Zenodo and that two new trainings are available on the EU Academy platform. It was announced that the administrative guidance will be circulated with Member States by mid-December for commenting and published in spring 2024. It was reminded that virtual tour with MSs is ongoing and will resume in January 2024.
EFSA continued reminding good practices for compiling IUCLID dossiers (naming, CBI flags, no DAR/RAR attached to the dossier). The procedure for addressing new validation errors and to update dossiers in compliance with confidentiality assessment decisions (during post- admissibility phase) were clarified.
On the activities of the filtering rules working party EFSA reminded that Document J is scheduled for removal in April 2025 and a "DAR Volume 4" report will be generated in support of RMS. Updates on filtering rules for Literature Reference Entity and on Analytical methods document scheduled for implementation in April 2024 were presented. EFSA reminded that as of April 2024 the "reduced UNLESS_CONF" approach will be applied to filtering and that the auxiliary rules will be switched off (this implies that any text included in the "Other" or "Remarks" fields in dropdown lists will be published). The new filtering rule for Analytical Methods was also presented. Requirements for different IUCLID installations were clarified.

Q&A

- **FR** suggested further considerations on dossier naming as in cases where dossiers are submitted for the same substance and on the same crops since identification is still difficult.
  EFSA took note for further reflection.
- **CLE** asked whether applicants should wait for RMS/EMS request to address validation warnings or not and sought clarifications on timing to start removing doc J from dossiers under drafting. CLE also asked whether re-evaluation of confidentiality is foreseen after migration. Another question was made on who to contact for re-submitting dossiers after admissibility.
  On validation warnings **EFSA** clarified that it is the RMS/EMS responsibility to check compliance of data requirements checked by the Validation assistant and therefore applicants should wait for RMS/EMS request to update dossiers to address validation warnings. EFSA also reminded MSs of the possibility of pre-admissibility teleconferences with EFSA to discuss about validation errors. On best approach to move towards the removal of document J EFSA took note of the question and will give more precise indications after the meeting. EFSA will also share a mapping file between document J and fields in IUCLID to facile Applicants in this transition.
  On confidentiality assessment EFSA clarified that if confidentiality decision has been already taken when re-distributing data in document J no second evaluation will be done by EFSA.
- **DE (BVL)** asked further clarifications on Document J removal. More specifically on the exact time of the application of the new approach and on how to deal with dossiers under evaluation (will document J be migrated?). DE also asked whether EFSA can advertise this change on the toolkit page to make applicants aware. DE also asked if the change on auxiliary rules will be proactively applied and asked EFSA whether RMS/EMS receive a communication when confidentiality assessment is concluded. EFSA replied that Document J removal is scheduled to be effective as from April 2025 (since most fields are already available for hosting the data now and the last minor changes will be implemented in April 2024) and that the change will be advertised on the EFSA toolkit page. A potential warning displayed in IUCLID is also being considered. On auxiliary rules EFSA clarified that the change will apply only to the remarks field linked to the "other" value of the picklist, not to different "other" fields in IUCLID. In addition, it was explained that EFSA will not re-publish retroactively published dossiers and that change will be applied starting from 2025. On confidentiality EFSA confirmed that RMS/EMS are informed by email and invited DE to flag any exception to this rule.
- **NL** asked whether applicants should address validation errors in the excel table generated by IUCLID (Validation assistant report) and send it back to RMS/EMS as attachment to IUCLID or not. EFSA clarified that Validation assistant report should support RMS/EMS to check completeness of information but also to verify that data are in the correct place in IUCLID. Applicants should therefore update IUCLID dossier addressing the validation errors. Right after the implementation of new validation set of rules, EFSA suggest RMS/EMS to evaluate case by case the impact of each error in order not to block dossiers for long time at the admissibility stage.
- **ECCA** flagged that currently it is not possible to amend confidentiality claims after submission in case of mistakes and that data segregation by different

data owners in the same dossier is difficult. It was also asked to clarify timeframe to address warnings after implementation of new rules for applications under evaluation.
EFSA clarified that if errors in confidentiality are identified dossiers can exceptionally be unpublished to let applicants amend the claims. On validation errors EFSA explained that Applicants will have the opportunity to address warnings and update dossiers by the end of the evaluation process. On data segregation, EFSA took note and will further investigate the issue.

Actions
- EFSA to provide indications on naming of MRL application dossiers
- EFSA to advertise changes related to the decommissioning of Document J on the toolkit page
- EFSA to investigate the impact of Document J removal on cases where data within the dossier are owned by different data owners
- DE to inform EFSA on the exceptions to communication that normally are sent to EMS/RMS on the end of confidentiality assessment

Post meeting note:
Following the discussion at the PSN-IUCLID, EFSA would like to confirm its intention to remove the Document J attachment from IUCLID pesticide dossiers. Existing dossiers will not be affected by the change but newly submitted dossiers will have to include structured data. EFSA will inform stakeholders accordingly and more details will be provided soon.

5. Updates on confidentiality

EFSA informed that an updated "User guide on confidentiality" has been published. The new version integrates information on confidentiality previously available only in the IUCLID Manuals and provides better step-by-step guidance on confidentiality matters. Most important updates have been presented (further refinement of the concept of personal data (PD), specific confidentiality flagging approach for PD, updated CBI/PD justification templates with examples, inclusion of best practices on pesticides confidentiality). The list of pesticides background documents falling within the scope of the EFSA E-submission tool "Portalino" has also been clarified. Procedure for confidentiality processing on the initial DAR/RAR and on the final DAR/RAR/Renewal Conclusion has been presented. Another update of the User Guide on Confidentiality will be published shortly with further clarifications regarding Section C and Section D (insofar as relevant for pesticides background documents) and clarifications on Section A which concerns the general requirements in relation to confidentiality.

Q&A
- **CLE and DE (BVL)** asked follow-up questions on Portalino. It was requested to clarify whether Portalino is used only for post transparency applications, whether the tool can be used by MSs (for NAS) and whether it can be employed also for MRL processes.
  EFSA clarified that the tool should be used only by Applicants (data owners) for the submission of confidentiality claims (not by MSs) and that is designated only for post-transparency applications. It was also explained that

it is applicable only to specific MRL processes (Art 12 MRL Review) in the context of a call for data.

- **CLE** asked what the approach on confidentiality is for previously submitted dossiers.
  EFSA is aware that for previously submitted dossiers no detailed guidance was available, but pointed out that Applicants have the opportunity to provide comments onthe draft confidentiality decision after this is issued by EFSA.
- **IBMA** asked how Applicants are made aware that a confidentiality decision was taken by EFSA and what is the contact address to be provided to be informed.
  EFSA replied that applicants are notified by email at the contact detail provided in IUCLID. It was clarified that a generic email address should be inserted in the legal entity field (as published by default), but additional contact details should be included in the "contact details" field.
- **AT** asked whether the DAR/RAR will still be accessible via the DMS and how to manage confidentiality for those cases where new data is added in subsequent updates of the dossier.
  EFSA confirmed that DAR/RAR will still be made available on the DMS and clarified that confidentiality assessment on additional information can still be performed after approval, before publication of the output. For NAS, this step is carried out by the RMS.
- **ECCA** asked clarifications on the confidentiality field of the new IUCLID document "Additional transparency regulation documents".
  EFSA replied that document will be updated and that field will be dismissed as of April 2024. Only information on NoS will be left.

6. IUCLID report generator

EFSA reported latest improvements on Report generator.

It was announced that a new extended functionality allowing to generate report directly from a sub-entity of a parent root entity (e.g. active substance of a composition in a Mixture parent entity) was released with IUCLID 7.0.1 in May 2023.

It was explained that the MRL application Report was improved in collaboration with ANSES and that Annotations have been integrated into the MRL application report to generate a new report to be tested as the new Evaluation report. The MRL evaluation report will work as proof of concept, if successful, proposal will be to convert Documents M to DAR (volume 2).

EFSA flagged the need for testing the new MRL application Report including the annotations and invited Member States to volunteer for testing. It was highlighted that best practices should be established by Member States to annotate dossiers in EFSA Agency as no access rights are implemented.

Update on ongoing development of List of Endpoints report was presented with the aim to share soon a draft version with Member States to seek their feedback.

Status on ECHA's development of CLH report was mentioned. EFSA will contribute to the analysis phase of the report with the view of reusing the code for development of DAR Volume 1 report.

In addition, un update was provided on the status of development of Analytical methods in collaboration with BfR and on the development of Reports for microorganisms which will start once requirements from the working group are finalised.

Q&A

- **DE (BVL)** asked whether tables can be attached to annotations in IUCLID.
  EFSA replied that attachments are allowed to Annotations fields, but further testing would be appreciated
- **DE (BVL and BfR)** supports EFSA's proposal of bringing the new report for discussion at the SCoPAFF.
  EFSA thanked DE for support and clarified that preliminary discussion is needed within the IUCLID PSN before bringing a revised Evaluation Report to SCoPAFF for discussion and approval.

Actions

- **Member States** to express their interest in testing the new MRL Evaluation Report in IUCLID.
- **EFSA** to launch call for expression of interest

7. IUCLID format: harmonisation and changes

EFSA presented main news of the IUCLID service release that went live on 30 October 2023 and introduced timelines and major changes going live with the next IUCLID format release of next April 2024. It was highlighted that OHTs have been harmonised to allow reporting of (Q)SARanalysis results according to the OECD QSAR Assessment Framework (QAF) and that environmental fate OHTs (OHT 25,27,26 and 29) have been amended to harmonise "results" section. It was flagged that the document "FLEXIBLE_RECORD.MixtureComposition" will report the new list value 'Relevant Impurities' to allow reporting of relevant impurities. EFSA also announced that 2 new documents (FLEXIBLE_SUMMARY.Impurities and FLEXIBLE_SUMMARY.DefinitionResidueBiomonitoring) are under development to report information (dataset) on impurities (relevant, significant, not significant or theoretical) and residue definition for biomonitoring. Regarding Joints submission it was explained that a new role ('Contributor') will be added to the picklist 'Lead Applicant' field that will be replaced by 'Role in the Joint Submission'. Regarding the 'Analytical methods' document it was clarified that comments received during the OECD consultation will be carefully analysed for next round of format changes. EFSA is planning to optimise the Table of Content of the 'Basic Substance'

applications and implement any changes in April 2025 after consultation and agreement with the European Commission. EFSA concluded by summarising all the IUCLID improvement activities ongoing at OECD level.

Q&A

- **CLE** asked clarifications on how to report information about impurities when the new flexible summary on Impurities will be introduced.
  EFSA replied that to avoid technnical issues, the dataset of imputities will be placed at the level of the mixture dataset altough it refers to impurities of the active substance. All data related to impurities e.g. analytical methods etc.., if any, should therefore be reported in the impurity dataset.
- **DE (BfR)**suggested using the Unique Formula Identifier, generated by the Posion Centres Notification, for impurities.

ECCA flagged that during the filtering working party activities the option of reporting impurities at the level of active substance dataset was discussed. **EFSA** clarified that this was discussed with ECHA and that, at the moment, the document will be placed at the level of the mixture dataset although it refers to impurities of the active substance.

8. Any other business

No discussion

9. Feedback from Industry Representatives

CLE gave a presentation on issues with lifecycle management of applications providing practical example and possible solutions.

Q&A

- **EFSA** clarified that the issue of lifecycle management has been brought to the OECD level and is now prioritised under the OECD IUCLID sub-group activity. EFSA also asked to provide more details on the case shown in the presentation to take action on this and reiterated that effort is needed at Member States level to prioritise processing of early submissions. **CLE** replied that more details will be provided and clarified that this example corresponds to one of the early submissions after go live of IUCLID for pesticides.
- **ECHA** clarified that analysis is ongoing on automated migration on PPP teplates. Ad hoc presentation has been provided by ECHA after the meeting and is published together with other meeting material on EFSA's dedicated webpage.
- **ECCA** expressed agreement with issues flagged by CLE on difficult management of different versions during a dossierlife cycle and flagged that migration will affect also generation of documents M and confidentiality. **EFSA** took note.
- **EFSA** added that confidentiality assessment is speeding up and exceptions to standard procedure are also in place (see cases of MRL applications) and encouraged stakeholders to engage dialogue with EFSA.

Post meeting notes:

EFSA and ECHA discussed further on migration options of endpoint summaries. A presentation summarising the proposed approach will be shared together meeting material to let members prepare for commenting.

Actions:

- **CLE** to contact EFSA to provide details on the dossiers shown in the presentation
- **All PSN members** to give feedback on the proposed migration rules as described in the ppt provided by ECHA within 19 January. Details on how to provide feedback will be shared by EFSA in written.

10. Feedback from the M.O. working party

EFSA presented the outcome of the activities of the working party of the IUCLID PSN subgroup on microorganisms. Main achievements (publication of the IUCLID (mini)manual on microbial a.s. applications (*https://doi.org/10.5281/zenodo.10118202*) and the definition of ad hoc list of validation rules for the MO working context), ongoing activities (mapping of IUCLID fields to Appendix I) and activities to be started (optimisation of Report generator, definition of table of contents for ecotox section and recommendation for presentation of information in specific areas (e.g. microbiological consortia)) were presented.

Q&A

- **IBMA** flagged that further efforts are needed as most of the available OHTs are not fit for purpose for microorganisms as they were developed for chemical active substances. **EFSA** replied that is aware of this and that aim of the Working Party on m.o. is exactly to identify need for change and improve documents.

11. Feedback from MSs

MS Germany reported feedback on post-transparency applications.

To improve management of versioning of dossiers in IUCLID it was proposed to include the UUID in the communications to Member States not only at the declaration of admissibility but also after completion of DAR/RAR and after submission of additional information (if any).

DE flagged inconsistencies between information reported in the NoS database and IUCLID dossiers and reported difficulties in in dealing with these differences during admissibility. Regarding justifications for noncompliance with NoS it was asked if evidence is needed that a study it was commissioned before applicability of NoS obligations.

On Doc J removal DE asked whether the document will be removed automatically from dossiers or Applicants will have to remove document, update dossier and re submit.

DE asked clarifications on which attachments are mandatory in the attachments section of the MRL manual introduction chapter.

DE also flagged that after implementation of transparency Regulation, efforts to prepare and update an MRL dossier has increased disproportionally especially when applications concern minor crops.

On management of dossier versioning EFSA replied that clear instructions have been introduced in the last version of the IUCLID Manuals on how to use the remarks field of the dossier header to add information on dossier versioning. Nevertheless, EFSA added that will further reflect on the option of inclusion of UUID in communications with RMS/EMS.

On NoS, EFSA clarified that it is applicant's responsibility to maintain NoS database updated. Regarding justification for non-submission of NoS, it was explained that no evidence is needed when a study is not falling under the requirements for NoS obligations. MSs can seek clarifications with applicants in case of doubts. It was also clarified that applicants have access only to studies submitted by them in the NoS database.

On Document J, replies were provided during Q&A after presentation number 4.

On the MRL manuals, EFSA took note of amending introduction chapter to better clarify when a document is mandatory or not.

On the increased efforts to prepare MRL applications especially for minor crops EFSA flagged that IUCLID is live since a relatively short period of time and that training material and Manuals have been released to support applicants in preparation. EFSA took note of the need for special indications or ad-hoc training for minor crops dossiers and invited DE to the virtual tour to further discuss any post-transparency issue.

Actions:

- **EFSA** to further reflect on the option of inclusion of UUID in communications with RMS/EMS
- **EFSA** to amend introduction chapter of the MRL application manual to better clarify when a document is mandatory or not
- **EFSA** to consider ad hoc training for applications for minor crops

12. IUCLID format: re-use of data

EFSA presented available tools for data reusing (namely Report generator, Data Extractor (DE) and Text Analytics (TA)) providing examples and instructions for using tools.

It was clarified that, DE and TA are not yet supported/implemented in EFSA Agency IUCLID (secure instance) and that are currently being tested internally at EFSA.

DE and TA can be downloaded from ECHA-IUCLID website as industry account and run on a local instance.

EFSA concluded announcing that a survey on the re-use of data will soon be launched for Member State Competent Authorities.

Q&A

- **CLE** asked what dataset in IUCLID Beta is used by EFSA and what can be used by Members to test DE and TA. It was also asked to clarify possible reasons for failing of engine with OCR documents. On OCR EFSA clarified that minimum threshold for resolution is 300 dpi.
  EFSA replied that filtered (non-confidential) dossiers are being used for testing TA and DE. As of 2024 test dossiers will also be available in Beta. Larger dossiers will be delivered next year to test performance with ECHA.
- **AT** flagged that MSs would appreciate having TA and DE in Agency instance to test and give feedback.
  EFSA replied that discussion in ongoing with ECHA on extending the use of the tools also to Agency instance.

Actions:

- **EFSA** to launch the survey on the re-use of data.

13. Any Other Business

- **CLE** gave a presentationon the prioritised activities of the OECD IUCLID Expert Group, under the OECD Activity 3 'Using the same dataset for multiple recipients'
- Questions received by **AT** before the meeting were discussed. AT asked clarifications on the requirements to publish the updated dossier at the end of the evaluation, after a confidentiality decision is taken. EFSA confirmed that there is a legal requirement in the General Food Law requiring pulication of the dossier. For NAS the requirement to publish the updated dossier is also set out in Article 10 of Regulation No (EC) 1107/2009 and for renewals in Article 16 of Regulation No (EC) 1107/2009.
  AT also asked about the dismissal of the Application form for MRL Application as certain information regarding for example the intention to apply for inclusion in Annex IV cannot be indicated in the NAS dossier header. EFSA replied that this aspect will be further investigated.

Actions:

- **EFSA** to reflect on how to improve dossier header considering MRL application form dismissal.