# PESTICIDE STEERING NETWORK – IUCLID SUBGROUP
## Minutes of the 7th meeting

19-20 June 2023
14:00-18:00 / 09:00-13:00
Minutes agreed on 07 July 2023

**Location**: Hybrid (M07 EFSA, Parma and online)

**Attendees**:

- Network Participants:

| Country | Name | Surname |
|---|---|---|
| Austria | Klaus | Leder |
| Belgium | Philippe | Castelain |
| Belgium | Wim | Hooghe |
| Croatia | Ana | Mrnjavčić Vojvoda |
| Croatia | Ana | Čale |
| Croatia | Dubravka | Čelig |
| Czech Republic | Martin | Beníšek |
| Czech Republic | Martin | Weiszenstein |
| Czech Republic | Hana | Kubátová-Hiršová |
| Czech Republic | Milan | Svoboda |
| Denmark | Alf | Aagaard |
| Estonia | Elise | Joonas |
| Finland | Marika | Päällysaho-Juujärvi |
| France | Suzanne | Pierlot |
| France | Anne-Sophie | Valton |
| Germany | Daniela | Marutzky |
| Germany | Tobias | Opialla |
| Germany | Falko | Frenzel |
| Greece | Ourania | Melita |
| Hungary | Florian | Sandor |
| Hungary | György | Hegedüs |
| Ireland | Sadhbh | O'Dwyer |
| Lithuania | Elena | Barzdėnienė |
| Malta | Francesca | Pace |
| Malta | Nicole | Cilia |
| Netherlands | Carla | Huizing |
| Netherlands | Cornelia | Blaga |
| Norway | Louise | Arnesen |
| Poland | Aneta | Choderska |
| Poland | Monika | Debek |
| Portugal | Bento | Carvalho |
| Portugal | Julia | Silva |
| Slovak Republic | Marta | Galusova |
| Slovak Republic | Lenka | Gurská Krajčovičová |
| Slovenia | Anja | Palman Mehikić |
| Slovenia | Polona | Slokan |
| Slovenia | Sanja | Vranac |
| Spain | Jose-Luis | Alonso-Prados |

| | | |
|---|---|---|
| Sweden | Anneli | Widenfalk |
| Sweden | Christoffer | Österwall |

- Industry representatives:

| Organization | Name | Surname |
|---|---|---|
| Crop Life Europe | Andrew | Whyte |
| Crop Life Europe | Monika | Bross |
| Crop Life Europe | Marc | Teiwes |
| Crop Life Europe | Viktoria | Eriksson |
| European Crop Care Association | Jose | Juanes |
| International Biocontrol Manufacturers Association | Adi | Cornelese |
| International Biocontrol Manufacturers Association | Agata | Jakubowska |

- European Commission:
  Valerio Spinosi (DG-SANTE)

- Other EU Agencies representatives:
  Francois Le Goff, Mark Roberts and Clara Rueda (ECHA)

- EFSA:
  Plant Health & Pesticides Residues Unit: Giovanni Bernasconi (**chair**), Alessia Pia Scarlato, Lucien Ferreira Da Costa, Luis Carrasco

  Front-Desk & Workforce Planning Unit: Päivi Arvilommi, Alessandro Delfino, Alessandra Giarola, Chiara Macchi, Silvia Mazzega

  Integrated Data Unit: Tomas Rovesti, Adrián César Razquin

  Legal Affairs Services Unit: Matthias Hasler, Federica Bruno, Iris De Williencourt, Simone Gabbi, Silvia Schenone, Xhestina Myftaraj

  Methodology and Scientific Support Unit: Jane Richardson

  Transformation Services Unit: Pierfranco Ferronato

  Environment, Plants & Ecotoxicology Unit: Rositsa Serafimova

**Day 1, 19 June 2023**

## 1. Welcome and apologies for absence

The Chair welcomed the participants.
Apologies were received from Dorota Burchard-Sosnowska (ECHA), Hanneke Westland (Netherlands), Angela Santilio (Italy) and Mathieu Bourget (France).

## 2. Adoption of agenda

The agenda was adopted with the following change:

One presentation from EFSA was added under Item 14 as no presentations were received from Member States.

## 3. Action items from previous meetings

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. The file is regularly updated after each meeting with new action items.

**Q&A**

- **CLE** asked clarifications on two action points, namely submission of feedback on Admissibility and NoS check and re-starting of the working party on microorganisms (m.o.).
  **EFSA** explained that a post has been shared on the Teams channel of the Network to collect feedback on Admissibility and NoS check. Regarding the working party on m.o., EFSA confirmed that an email message announcing the reopening of the activities and calling for registrations was sent to members. A file listing the names of the participants is available on the Teams channel of the Network for registering.

## 4. IUCLID Latest news and updates

EFSA presented latest news and updates on IUCLID submissions.
On IUCLID applications, EFSA reminded that it is important to provide adequate and up-to-date contact details within the dossier and to perform sanitization properly, not over-blackening attachments. EFSA also emphasized the importance of filling in the new section of the dossier header which categorizes resubmissions.
On IUCLID support, EFSA informed that the update of the IUCLID Manuals in alignment with latest IUCLID format release is ongoing and that two trainings will soon be available on EU Academy. It was announced that a contract is in place to design demo dossiers and that EFSA is discussing the option of centralizing communication with stakeholders using the Applicants toolkit page.
EFSA flagged the re-starting of the working party on m.o. and advertised the upcoming info-session for Member States on the use of MetaPath.
The use of inherited templates was recommended for managing complex submissions. Their use will be further described in the manuals but applicants should contact EFSA for support if they believe their submission could benefit from this feature. On confidentiality assessment, it was reminded to make consistent claims on identical documents within the same dossier and within joint submissions and to avoid duplication of attachments. The rules for sanitisation of MSS/DER composer files were clarified. EFSA also announced that an update of the EFSA User guide on confidentiality is ongoing.

**Q&A**

- **CLE** highlighted the complexity of managing inherited templates and that having a third party managing the associated submissions would trigger additional costs for the applicants. In addition, CLE flagged that de-merging of datasets of inherited templates is not working properly and asked EFSA/ECHA to investigate. On the decision of EFSA to move towards the option of centralising communication with stakeholders using the Applicants toolkit page, CLE welcomed the initiative and asked to consider adding the RSS feed on the page.
  CLE also highlighted the importance of having updated IUCLID manuals as soon as possible and ideally together with new IUCLID releases and asked EFSA to anticipate the update of the user guide on confidentiality as much as possible.
  On the contract to create demo dossiers, CLE suggested to make sure that all fields are carefully checked by the contractor during the preparation.
  **EFSA** clarified that the use of inherited templates is not mandatory but can be used when other approaches are not working and invited CLE to provide more details on the issue linked to the de-merging of inherited templates. EFSA indicated the importance of removing cross-references before removing inherited templates. Regarding the Manuals, EFSA confirmed that this work was postponed due to the delays with the go-live of the new IUCLID release, but now it is ongoing. EFSA also took note of the suggestion to ensure all fields are checked during the creation of the demo dossiers. Regarding the update of the confidentiality user guide, EFSA confirmed that revision is already ongoing and that the document should be ready by the end of the year.
- **DE** asked to clarify what channels have been used by EFSA to advertise the MetaPath info session and asked for updates on the status of the work on report generator and on the preparation of the demo dossiers.
  **EFSA** clarified that a message on the info session on MetaPath was posted in the EFSA website and promoted via EFSA email distribution lists. Although the registration is publicly available, the live participation is limited to Member States authorities. The recording of the session will be publicly available. EFSA also added that a webinar for Applicants on how to compile the composers has been made available two years ago (https://www.youtube.com/watch?v=x4WwxppTFYg). On the Report generator, EFSA replied that work is ongoing on the List of Endpoints, CLH report, integration with the Annotation tool and on specific reports for the Microorganisms working context. Regarding the demo dossiers, EFSA explained that the contract started in March 2023 and the final deliverables are expected by March 2024.

**ACTIONS**

- **EFSA** to verify whether the Toolkit page can be linked to an RSS feed for informing on page updates.
- **CLE** to share details of the issues encountered with inherited templates.

## 5. IUCLID Validation assistant

EFSA presented an update on the validation assistant rules foreseen for the next release (October 2023). Members were informed that 13 new rules will be implemented, 2 rules will be updated and that 4 quality rules checking the format of the Pre-Application Identifier will be changed into business rules. More information on the Validation Assistant rules can be found in the Rules Master File.

It was highlighted that new rules will focus on strengthening the check of the "Results and discussion" block of the Endpoint Study records. EFSA also clarified that a previous action point raised at the IUCLID PSN meeting of March to consider amending the validation assistant report to include the date/IUCLID version in which the rule was implemented cannot be implemented as IUCLID is used by different organisations under different regulatory purposes and, therefore, ad hoc request cannot be implemented unless agreed by all actors involved.

Members were invited to give live feedback via a SLIDO poll regarding the validation rules. Results of the polls will be considered for developing further the validation assistant.

**Q&A**

- **CLE** asked whether it will be possible to be informed about the availability of new rules in IUCLID Beta for testing.
  EFSA took note.

**ACTIONS**

- **EFSA** to discuss at the working party on m.o. the exact conditions when the MRL flexible summary would be valid for a microrganism working context.
- **EFSA** to inform the PSN members via TEAMS when the first batch of new validation rules for Oct release will be deployed in IUCLID Beta for testing. First batch is expected to be delivered as from 26/06.

## 6. Filtering rules – feedback from the working party

EFSA reported feedback from the working party of the IUCLID PSN on filtering rules. Overview of the composition of the group, main decisions taken and timing for the agreed changes have been shared. It was explained that the working party established filtering rules for all new documents included in the 6.7 release, agreed on a new filtering rule on mixture composition and worked on the establishment of a "Closed list for confidentiality" with the aim to reduce as much as possible the "UNLESS_CONF" documents/fields. A document with the updated filter rule configuration file reducing UNLESS_CONF rules in all dossier types will be circulated for public consultation with an EU survey to collect feedback on the proposal from the working party. Regarding document J, EFSA clarified that aim is ideally to no longer support Doc J from April 2024, this is dependent on the implementation of the required changes for the April release. The proposal to switch off the auxiliary rules on picklists was also explained and will be included in the public consultation. The working party also presented in detail proposals for improving the filtering of the analytical methods template (OHT 87). Members were invited to give live feedback via a SLIDO poll on filtering options for OHT 87. Results of the polls will be considered for developing further rules.

**Q&A**

-**DE** asked EFSA to provide for more details before replying to the question in the SLIDO poll. **EFSA** replied that a new slide explaining the PROs and CONs of both solutions for filtering rules on OHT 87 will be added to the presentation so to share more details and facilitate a decision.

**ACTIONS**
-**EFSA** to share the slides with the PROs & CONs of both solutions for filtering rules on OHT 87.
-**EFSA** to post on Teams the deadline for receiving feedback on the two options by written procedure.
- **All members** to give feedback on option I and II (on OHT 87) presented under point 6 on filtering rules and available in the SLIDO poll.

## 7. EFSA-BfR collaboration

EFSA and BfR gave a presentation on the ongoing collaboration concerning the updates of OHT 85-5, OHT 85-9 and the relevant endpoint summaries. Background and scope of the collaboration were presented. Proposal to update the picklists and the structure of OHT 85-5/9 has been presented. The idea to use FoodEx2 catalogue to define processed items was presented. Organisation of metadata related to other endpoints was also discussed. The proposal to have one OHT for each trial was presented and welcomed to reduce the nested block issue. Members were invited to give live feedback via a SLIDO poll on three questions on the structure on the organisation of data in the IUCLID section on magnitude of residues. Results of the polls will be considered for developing further the IUCLID documents.

**Q&A**

- **EC** asked EFSA and BfR which of the presented options could better fulfil the possibility to feed risk assessment models in the future and asked whether the FoodEx picklist will be discussed at next OECD meeting.
  **EFSA** clarified that data feeding the risk assessment models are rather coming from the endpoint study summaries than from the endpoint study records while the options presented are related to the structure of the endpoint study records (OHTs) to match the possibilities of the "Ruedis" database. As the scope of this collaboration with BfR is also on the ENDPOINT SUMMARIES, the compatibility of these summaries with the RA tools (e.g. PRIMo 4) is also foreseen. On the FoodEX picklists, EFSA also confirmed that this will be discussed at the OECD level.
- **ECCA** flagged that reporting information on the current OHT 85 is extremely time consuming due to the number of CSV files to be uploaded in the nested tables.
  **EFSA** agreed on the simplification of OHT 85 and added there was a new term in the pick list of the cross reference ('method used in study') so that OHT 87 can be cross-referenced from other endpoint studies.

- **CLE** highlighted that the same issue was also relevant for other OHTs of the residue section (e.g. OHT 85-4). **EFSA** took note.

**ACTIONS**

- **All participants** to reply to the last question of SLIDO poll presented under point 7 on the collaboration EFSA-BfR.
- **CLE** to propose changes to OHT 85 for further discussion at OECD level. **EFSA** confirmed that 85-5 and 85-9 are in the plan for 2023-2024.
- **EFSA** to bring to OECD level the discussion on FoodEx.

## 8. Any other business

None

**Day 2, 20 June 2023**

## 9. Follow up on the new format release

EFSA presented new features of the latest IUCLID release. The new IUCLID documents to address the change in data requirements were reported.

EFSA flagged that a new section to indicate reason for re-submission is now available in the dossier header document. Issues since the May release were presenteted with releases in which they had been resolved Changes to several OHTs were presented. Other new features such as running of background tasks, the new transfer of annotations and an improved web interface performance were explained. A survey will be shared by ECHA to collect feedback on performance and identify the next improvement areas.

Members were invited to give live feedback via a SLIDO poll on one question on the advanced search function. Results of the polls will be considered for further development.

**Q&A**

- **CLE** informed that they are experiencing issues in uploading big datasets. **ECHA** recommended to check the memory allocation.
- **CLE** also asked whether FooOpenFoodTox will be migrated to IUCLID and will be available to the public. **EFSA** replied that there is a contract ongoing to perform the migration. Once this work is complete it will be published in IUCLID PUBLIC but in a separate section for curate endpoint as opposed to submitted regulatory dossiers.

## 10. Feedback from European Commission

EC gave a presentation on the current state and future possibilities of IUCLID stressing the importance of having structured data to make them re-usable. Potential expansion of the use of IUCLID to other regulatory areas was presented.

**Q&A**

- **FR** flagged that issues encountered post-transparency are not only linked to the use of IUCLID as a new tool but also to the NoS that is causing a lot of delays during the admissibility step because it is time consuming and difficult to be performed.
  **EC** reminded that NoS check is a legal requirement and that EFSA is supporting MSs when needed.
  **EFSA** also added that is supporting the possibility of refining the Practical Arrangements on pre-submission phase and public consultation to review the "study definition" and simplify the NoS procedures. However, EFSA also clarified that the revision of the Practical Arrangement is centralised at the Commission level, and it is therefore up to the Commission to bring this forward.
- **CLE** flagged that, at Industry level, confidentiality and sanitisation are causing a lot of delays and rework of dossiers, with experts now being involved as from the early phases of dossiers creation.
  CLE also explained that NoS check is contributing to the re-work and re-submissions of dossier and proposed to have ad-hoc meeting on NoS with MSs and Industry.
  **EC and EFSA** acknowledged the difficulties and added that the work of the working party on filtering rules will help streamline the confidentiality assessment.
  On NoS, **DE proposed** organising a workshop with all Member States and applicants on Notification of Studies to discuss main issues and points to consider in view of a potential revision of the Practical Arrangements. EFSA is available to participate and support.
- **ECCA** flagged that the use of IUCLID triggered the need of transversal knowledge, and that training is needed, also emphasizing the need for good data/dossiers to be in place for training purposes.
  **EFSA** replied that a contract is in place with a contractor with the aim of creating 14 test dossiers of different types, complexity and size and that this work will support other activities. The contract will be running until March 2024.

**ACTIONS**

- **All members** to provide feedback on issues experienced during admissibility e.g. NoS related procedures etc. Feedback on admissibility.xlsx

- **Industry and Member States** to consider organising workshop on Notification of Studies. EFSA is available to participate and support.

## 11. Feedback from Industry Representatives on IUCLID format (OHT 87)

Industry presented proposals on how to improve the structure of section 4 and OHT 87 to better reflect the current data requirements of Regulation 283/2013 for analytical methods.

**Q&A**

- **EFSA** took note of the suggestions made by Industry and proposed representatives to make a proposal for discussion at OECD level. EFSA also flagged that suitability of the document for microorganisms should be evaluated. Need for a microorganism specific document could be considered by the working party.

- **IBMA** added that re-shape of section 4 could be beneficial also for microorganisms.

- **ECCA** flagged that new format of OHT 87 requires more time to fill in all new tables especially for cases when information is needed for more than one analyte.

- **DE** clarified that in the context of the collaboration with EFSA, also revision of OTH 87 is under the radar with the aim of improving the report generator and expressed interest to contribute to the proposal to OECD.

**ACTIONS**

- **CLE and DE** to prepare amendments to OHT 87 which can be included in the annual OECD consultation prior to inclusion in the 2024 format release

## 12. Submission portal

ECHA gave a presentation on the current and future features of the ECHA submission portal flagging that goal is to develop one industry portal simple and centralised, by 2026 (tentative). Participants were reminded that a webinar with further details is available on the ECHA website. https://echa.europa.eu/it/-/the-future-of-echa-s-submission-systems

**Q&A**

- **EFSA** asked whether the new portal will impact ECHA accounts and whether it will reduce submission times.
  **ECHA** replied that the development is still in an early phase to address these questions, but took note of them.

## 13. EFSA-Anses collaboration

ANSES presented the status of the collaboration with EFSA on improvement of the report generator and annotation tool.

Phases of the project and details on the testing of the annotation tool were shared. ANSES clarified that aim is to develop a new template for generating the Evaluation Report in IUCLID with the report generator.

**Q&A**

- **DE** asked whether the template is available on github.
  **EFSA** clarified that no template is available yet as currently the collaboration is at the stage of agreeing on data requirements. A standalone report on annotations is available though.
- **ECCA** suggested the use of annotations to communicate with applicants and flagged that edit rights and access are not limited currently, but limitations would be needed.
  **EFSA** clarified that the annotation tool is not intended to be used for communication with applicants. The pilot project by ANSES will serve as basis to test whether it is efficient to use this tool to generate the evaluation report automatically. EFSA also reminded that IUCLID is not a workflow tool, but it is used only as a repository of information. Communications with applicants should be tracked with official letters.
- **AT** flagged the importance of limiting the modification of annotations to ensure transparency and reminded that similar work should be considered for the DAR.
  **EFSA** replied that analysis is being done on an MRL application. For AIR-NAS there is already a structured process for commenting and that we could follow same level of transparency, but this is out of scope of the collaboration with ANSES.

## 14. Feedback from MSs

No presentations were submitted by Member States.
EFSA used this slot to give a presentation on the post- admissibility phase.
EFSA presented main post-admissibility steps and reminded that confidentiality assessment is a responsibility of the RMS for new active substance dossiers and mandatory consultation of EFSA applies to each and every RMS confidentiality assessment for NAS dossiers to ensure consistency between EFSA's & RMS' confidentiality assessments on identical or similar items included in pesticide dossiers.

**Q&A**

- **DK** asked clarifications on the timing for performing confidentiality assessment.
  **EFSA** clarified that the assessment should be done as soon as possible after the declaration of admissibility and reminded MSs to consult EFSA on the decision made.

## 15. Other feedback from Industry representatives

CLE gave a presentation on the life-cycle management of dossiers and datasets flagging issues on the maintenance of multiple datasets for cases where several regulatory processes are ongoing in parallel on the same substance (e.g. parallel renewal and MRL application).

CLE also flagged issues with migration.

**Q&A**

- **ECHA** clarified that IUCLID principle is to re-use same data set and adapt it according to the specific working context. It was acknowledged that this is working for other regulatory frameworks (such as REACH) but it is not fully optimised for PPP yet. ECHA also reassured that no information is lost during migration and that migration is important to ensure information is available for everyone in the same structure. EFSA and ECHA acknowledged the difficulties and reminded that work is ongoing.

**ACTIONS**

- **CLE and EFSA** to use the OCED Expert Group Multiple jurisdictions activity to analyse improvements to dossier lifecycle management.

## 16. Any Other Business

- **NL** flagged issues in reporting literature data for biopesticides.
- EFSA replied that this point should be discussed at the working party on microorganisms re-staring soon. There is already a short presentation available ReportingLiterature.pptx

**ACTIONS**

**EFSA** to address point raised by CTGB at the MO working party

Date for next meeting: Chair informed that one more meeting will be organised virtually in October 2023. One open session will be organised unless Member States will flag the need of discussing specific point in closed sessions.

## Closure of the meeting