PESTICIDE STEERING NETWORK – IUCLID SUBGROUP 10th meeting

Minutes of the 10th meeting

11-12 June 2024
14:30-18:00; 09:30-12:30
Minutes agreed on 01 July 2024

Location: EFSA – Parma, Board Room (M10B), Webconference

Attendees:

- Network Participants

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

Slovak Republic	Central Control and Testing Institute in Agriculture
Slovenia	Administration of the Republic of Slovenia for food safety, veterinary sector and plant protection
Spain	Agencia Estatal Consejo Superior de Investigaciones Científicas (CSIC), Centro Nacional Instituto Nacional de Investigación y Tecnología Agraria y Alimentaria (INIA), Ministerio de Ciencia e Innovación
Sweden	Swedish Chemicals Agency, Swedish Food Agency

- **Observers:**
  Turkey: Ministry of Agriculture and Forest Plant Protection Central Research Institute Ankara
  Montenegro: Administration for Food Safety, Veterinary and Phytosanitary Affairs

- **European Commission/Other EU Agencies representatives:**
  European Chemicals Agency (ECHA), European Commission

- **Industry Representative:**
  Belgium: European Crop Care Association (ECCA), International Biocontrol Manufacturers Association (IBMA), Crop Life Europe (CLE)

- **EFSA:**
  PREV: Alessia SCARLATO, Lucien FERREIRA DA COSTA, Angelo COLAGIORGI, Manuela TIRAMANI, Chloe DE LENTDECKER, Mathilde COLAS
  FDP: Chiara MACCHI, Alessandro DELFINO, Bénédicte VAGENENDE, Alessandra GIAROLA, Silvia MAZZEGA, Lucrezia MERIGGI
  IDATA: Adrian CESAR RAZQUIN, Pierlorenzo ROLANDO, Dayana BUZLE, Edoardo CARNESECCHI
  LA: Iris DE WILLIENCOURT, Silvia SCHENONE
  TS: Pierfranco FERRONATO
  PLANTS: Rositsa SERAFIMOVA

1. Welcome and apologies for absence

The Chair welcomed the participants. Apologies were received from Norway.

2. Adoption of agenda

The agenda was adopted without changes.

3. Action items from previous meetings

EFSA briefed on the actions resulting from previous IUCLID PSN sub-group meetings. Actions "completed", "in progress" and "not started" were presented. It was recommended to make use of the backlog files available to collect specific input on Report Generator improvements and Admissibility/Notification of Studies. 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

- No questions were raised.

4. IUCLID latest news and & updates

EFSA gave an update on the latest IUCLID support activities (including the publication of the IUCLID 6.7 test dossiers for all working contexts), provided some recommendations on how to fill in a dossier and reminded applicants and MS of the legal obligation to provide a consolidated dossier for publication at the end of the evaluation process and subsequently at the end of the peer review process if any additional data were requested. EFSA also clarified the situation in relation to the migration of the IUCLID Cloud subscriptions and committed also on behalf of ECHA not to have further delays with future releases. Lastly, an update on Document J dismissal was provided whilst confirming that this is scheduled for April 2025.

Q&A

- **CLE** asked to upload the link to the crosswalks missing on the presentation and asked whether the content of the discussion with Member States during the Vitural tour can be shared with IUCLID sub-group members. **EFSA** replied that the missing link will be added to the presentation before the publication of the presentations. Regarding the Virtual tour, it was explained that the meetings normally follow a standard Agenda focussed on Member States needs and minutes are not prepared. Possibility of sharing highlights from the meetings will be considered by EFSA
- **CLE** commented that they were unable to upgrade their server version of IUCLID after the upgrade to v. 8 because the download website was not available. **ECHA** replied that they experienced an issue with downloads at the beginning of June but that this was then solved.

- **ECCA** commented that consolidating a dossier that was submitted 3 years earlier is an issue due to the format changes, data migration, new VA rules and BRs. **EFSA** reminded that publishing a consolidated version of the dossier is a legal obligation for EFSA, therefore it was recommended to applicants to keep the dossiers up-to-date to the extent possible, even without submitting them.
- **AT** asked whether the final report on the test dossier contract prepared by GAB Consulting GmbH would be published as well as the test dossiers themselves. **AT** also asked whether the RMS should ask the applicant to submit a consolidated dossier after the assessment and whether additional confidentiality requests should also be assessed and if yes, how to do so.
  EFSA replied that all confidentiality requests on all newly submitted data should be assessed and will provide more details after the meeting. On the GAB report, **EFSA** will consider whether to publish it although it was originally decided not to.
- **CLE** commented that for MRL dossiers they have so far provided a dossier update together with the draft evaluation report but never beyond that. **EFSA** reminded that the GAP might change, or new data might be requested even during EFSA's evaluation.
- **CLE** reiterated that consolidating a dossier after several years is a big challenge for applicants, particularly if this has to be done more than once (i.e. at the end of the assessment and after the EFSA output). **EFSA** reiterated the steps of the process and the associated legal obligations. **EFSA** also reminded MS that a number of dossiers submitted in 2021 have not yet been declared admissible and that these dossiers become increasingly challenging to update and process as more time passes.

ACTIONS

- **EFSA** to update presentation with link to the MO crosswalks;
- **EFSA** to consider sharing highlights from Virtual Tour with Member States;
- **EFSA** to consider publishing final report from GAB;
- **EFSA** to clarify in writing the steps associated to confidentiality request assessment regarding additional information and the associated timelines;

5. IUCLID format: planned changes

EFSA presented the planned IUCLID format changes and validation rules in view of IUCLID 2025 release. It is foreseen to create a new document (under the EU_PPP definition provider) to replace the FLEXIBLE_RECORD.AnalyticalInformation (backlog #2230; #2700). EFSA is also considering the revision of the ENDPOINT_STUDY_RECORD.ToxicityToBees (i.e. OHT 50-3) to improve the reporting and structuring of dose-response data according to the *Revised guidance on the risk assessment of plant protection products on bees (Apis mellifera, Bombus spp. and solitary bees)*. The proposal is also to extend the aforementioned changes to OHTs 41 to 54 (backlog #2962). EFSA clarified that an analysis by Germany BfR (under the contract OC/EFSA/SCER/2021/05) on ENDPOINT_STUDY_RECORD.GeneticToxicityVitro (OHT 70) and ENDPOINT_STUDY_RECORD.GeneticToxicityVivo (OHT 71) is ongoing, and results

are expected by September 2024. Regarding the pesticides residues templates, new formats were developed by EFSA and Germany BfR in 2023/2024 namely ENDPOINT_STUDY_RECORD.ResiduesInRotationalCropsNew (OHT 85-5) and ENDPOINT_STUDY_RECORD.MagnitudeResidInProcessedCommNew (OHT 85-9). The changes consist of further harmonisation of picklist with GAP table, MRL classification and FoodEx2 terminology to report processed commodities. The proposed changes are currently being tested and discussed with Germany BfR for implementation in the 2025 IUCLID format release. EFSA also presented a new proposal for improvement of the MRL dossier header. EFSA announced to have completed the analysis of possibilities for data migration from obsolete EU PPP summaries to OECD harmonised summaries and will share it with Industry representatives of the PSN IUCLID shortly.

Regarding validation rules EFSA invited members of the PSN-IUCLID to provide feedback on 1) the new proposed rules for the IUCLID service release of October 2024 and 2) the proposal to switch more quality warnings into business rules by June 28th.

Q&A

- **IBMA** asked clarifications on the proposal to revise OHT 50-3 pointing out that dose-response data might not be needed for microrganisms testing.
  EFSA replied that, if approved by the OECD OHT Expert, changes to OHT 50-3 will be available as such in all working contexts which does not imply a mandatory filling-in of those data (i.e., it depends on the data requirement set by the specific regulation).

CLE commented that the proposal for implementing a new Quality rule checking that always an analytical method is cross-referenced in a Study Summary should not be implemented as such because many studies exist with no associated analytical method. **EFSA** replied that there where already similar doubts on the validity of such a general rule within EFSA

ACTIONS

- All **sub-group members** to give feedback on proposal for change of Dossier header by 28 June
- All **sub-group members** to give feedback on the proposed VA rules by 28 June

6. IUCLID report generator

EFSA reported latest improvements on Report generator.

It was announced that the advanced settings option of selecting documents to run reports is now available also from dossiers (IUCLID 8.4.0) and that the functionality of generating DOCX (Word) documents has been improved with latest releases. The latest developed/updated templates (IUCLID6 v8.0.2) are available on Zenodo: https://zenodo.org/records/11281549

Following a request from France to extend report generation from more than one dossier, EFSA informed that plan is to test the existing dossier aggregation process

used by ECHA on a PPP dossier and analyse whether i) reports can be adapted to cover the requirement, and ii) whether the aggregation process needs improvements or not. IUCLID PSN members could be involved for testing/providing feedback.

EFSA also summarised the feedback received from MSs about the use of annotations in the MRL Application report. Based on this feedback, EFSA will amend the display of annotations in the report as requested and liaise with ECHA to correct some identified bugs in the annotation tool. Although requested by some MSs, EFSA does not foresee implementing Instance Based Security (i.e., restricting the permission to annotate dossiers based on the responsible EMS) anytime soon, due to other priorities. However, it was proposed to EMS to annotate the dossiers on voluntary basis and to communicate to EFSA interest in using the tool systematically. Depending on the intended use of this feature, EFSA will discuss with ECHA further improvements that were suggested in the feedback.

In addition, new or improved reports were shown to participants. All members were invited to provide feedback /report issues.

Q&A

- **CLE** asked whether pictures can be included in the generated reports. EFSA clarified that images in IUCLID are already included in the Reports.
- **AT** asked whether the CLH report will be shaped to include already new requirements for ED classification. ECHA replied that mapping is ongoing and possibility for extending format change is being considered.

ACTIONS

- All **sub-group members** to give feedback on the use of annotations by 15 July

7. Ongoing OECD activities

EFSA updated the group on the status of the following OECD activities aimed at improving some of the IUCLID features: Activity 1 (User Interface improvements), Activity 2 (Reporting improvements) and Activity 3 (Using the same dataset for multiple jurisdictions)

Q&A

DE asked clarifications on the use of IUCLID considering the concept of one substance one assessment. **EFSA** confirmed that IUCLID is the key standard for hazard data in the EU and will be the key format of the European Common Data Platform on Chemicals so it will be crucial for the one substance one assessment approach. **ECHA** also added that IUCLID is not the tool for performing risk assessment, it's the repository of structured data to facilitate the risk assessment.

8. Updates on confidentiality

EFSA presented some points of attention for applicants aiming at optimising the confidentiality decision-making process. EFSA highlighted that the Transparency Regulation prescribes the proactive dissemination of scientific data, studies and other information supporting pesticide applications and reminded that confidentiality may be requested as an exception to transparency requirements and awarded only with regard to confidential business information as set out in Article 63(2)(b)-(d) of PPP Regulation and Article 39(2)(a)-(d) of Regulation (EC) No 178/2002 (GFL) (the so-called "closed positive list"). IUCLID Section 1.8 of the substance dataset (Document J and the attached background materials) are no exception in this regard and compliant confidentiality claims must be filed also for this section. Information cannot be claimed confidential in full, but only if and to the extent that the information falls under the closed positive list. In relation to that, EFSA also stressed the importance of submitting justifications compliant with Article 9 and 10 of the EFSA Practical Arrangements concerning Transparency and Confidentiality. Otherwise, the confidentiality requests may be subject to a request for clarification and, in case of an unsatisfactory reply, rejected.

For personal data, EFSA reminded that the General Data Protection Regulation (GDPR) imposes requirements regarding the protection of natural persons in processing personal data. As the initial non-confidential version of the IUCLID dossier must be published by EFSA, as received from the applicant, EFSA reminded that it is the applicant's responsibility to ensure that personal data is protected under GDPR. Failure to do so may constitute a personal data breach leading to the consequences set out in Articles 33 and 34 and Chapter VIII of the GDPR.

Q&A

- **CLE** recognized that the confidentiality decision-making process is becoming a more streamlined process,however, for planning purpose, CLE asked for an indicative timeline of the confidentiality assessment duration per dossier. Specifically, is it still common practice for EFSA to ask the RMS when the RAR is available and then prioritizing based on that. **EFSA** stated that, thanks to the progress made and the continuous efforts deployed to optimize the confidentiality decision-making process, it is now, in principle, in a position to complete the confidentiality decision-making process in a timely manner for all pesticides dossiers recently declared admissible. **CLE** asked if EFSA could confirm that all dossiers deemed admissible are published. CLE noted some of the dossiers that have been considered admissible on OpenEFSA were published, and subsequently removed. **EFSA** responded that, in principle, once considered admissible, initial dossiers are published after a light check on personal data has been performed. An updated non-confidential version of the initial dossier is published upon conclusion of the confidentiality decision-making process if the outcome of the confidentiality assessment so requires.
- **CLE** asked if EFSA is willing to incorporate AI technologies to optimize the assessment process (i.e. sanitisation, text analytics). **EFSA** replied that some pilot tests were undertaken after the entry into force of TR, however they were

unsatisfactory, as the tested tools were not fit for purpose yet. EFSA is closely monitoring market developments, particularly to automate sanitisation.

- **ECCA** reminded that the workload and administrative burden for Applicants have increased dramatically since the TR entered into force. **ECCA** expressed concerns on the IUCLID fields and potential changes of the fields, that may lead to, amongst others, re-sanitising monographies and repeating justifications. **EFSA** took note of ECCA's concerns about the impact of new IUCLID releases on dossier re-submissions. EFSA also reminded that, in relation to confidentiality requests submitted on monographies such as DARs and RARs, the submission of confidentiality requests is eased by the features available in Portalino, that allow applicants to select the compliance statement to Art. 10(b) substantive minimum requirements for CBI from a picklist, without repeating it in writing for each confidentiality request on confidential business information.

9. Feedback from Industry Representatives

IBMA gave a presentation on issues encountered using IUCLID for biopesticides. Need for further adaptation of validation rules and improvement of OHTs to better meet the requirements for biopesticides was flagged. Problems with the migration of dossiers and submission accounts was also highlighted.

Q&A

- **EFSA** thanked IBMA for the contribution and acknowledged that some of the proposals for changes presented by IBMA were already discussed during the meetings of the working party on Microorganisms and a shared decision was taken after discussion with other members of the working party. Regarding migration of summaries, EFSA clarified that the problem reported by IBMA was due to the planned migration of harmonized summaries, which occurred in April 2023.
  Concerning the issue with the migration of IUCLID Cloud subscriptions, EFSA explained that this was an unfortunate and isolated incident and referred to the explanations provided under presentation number 4. **EFSA** also added that re-opening of the WP on microorganisms can be planned to further refine OHTs and proposed to include further explanations in the new manuals regarding the documents for which a waiver is necessary.

CLE gave a presentation on issues encountered with OHTs 85-5, 85-9 and 87, Lifecycle management of applications in IUCLID, pre-application IDs and Public Dissemination, providing practical examples and possible solutions. Availability in assisting with the organisation of a Workshop on notification of studies was also communicated.

Q&A

- **EFSA** thanked CLE for the overview provided on OHTs 85-5, 85-9 and 87 and confirmed that review is already planned for the three OHTs. To facilitate the work on optimization of OHT 85-5, EFSA announced the starting of one ad hoc working party within the IUCLID PSN subgroup. Aim of the working party will

be discussing and consolidating proposals for changes to be shared with OECD during consultation phase.

- On lifecycle management issues, **EFSA** explained that discussion is ongoing with ECHA to address short term mitigation measures. For longer term solution, further discussion is needed.
- Regarding pre-application IDs, **EFSA** reminded that the use of pre-appl ID is not mandatory in ConnectEFSA in order to leave flexibility for laboratories and applicants who might not know yet for which application they are notifying a study. EFSA invited CLE to raise these issues at the level of the User IT tool group. CLE commented that the issues described by MS and CLE are not caused by the IT tool (connect.EFSA), but the correlation with the Transparency Regulation and IUCLID submissions. For more generic concerns on NoS and on the provisions of the Transparency Regulation, EFSA invited CLE to share this feedback with EC. On the comment that it is difficult to comment on IUCLID dossiers, **EFSA** communicated that 16 comments have been received on pesticides dossiers out of 34 comments received in total on post tranparency public dossiers from all food areas under the remit of EFSA. EFSA informed that the public instance of IUCLID will be dismissed in 2025 so no changes to the current website are foreseen at present. In parallel, to improve the effectiveness of public consultations, EFSA is developing a communication toolkit for public consultations which will be ready by the end of the year.

ACTIONS

- **EFSA** to include instructions on how to compile the new harmonised summaries in ecotox area in the IUCLID manual for microbial active substances.

10. Latest news from European Commission

The European Commission (EC) gave a presentation on the latest developments on regulatory obligations for co-formulants, safeners and synergists and discussion on the use of IUCLID for such substances.

Q&A

- **CLE** asked clarifications on how the requirements for the inclusion in the database of co-formulants will be complementary with the REACH obligations for single substances.
  EC replied that the building of a data-base will not change the requirements in place. It was also reminded that the use of data provided under the framework of the Poison Center in the CLP Regulation, is not permitted for other regulatory purposes and further discussion is needed on this specific topic.
- **ECCA** asked whether the evaluation of co-formulants will be done at European level following same requirements of renewal applications. **EC** clarified that evaluation of co-formulants will be different.
- **AT** asked clarifications about the co-formulants database and in particular if EFSA will host this database. **EC** replied that actors have been identified, but

the details of the implementation are not decided yet and reminded that aim is to develop a common platform to facilitate assessment of co-formulants by MSs.
- **DK** raised concerns on the complexity of process and flagged that guidelines are needed.
  EC invited all MSs to join the disussion clarifying that a workflow will be shared for commenting at the SCOPAFF. It was also added that timelines for application of new guidance will be clarified by the SCOPAFF.

11. Feedback from Member States

Presentations were given by FR and DE.

FR asked clarifications about definition of studies subject to NoS obligations and raised questions on how to update the ISO name of a substance under evaluation.

Q&A

- **EFSA** clarified that the "Question and answers on EFSA Practical arrangements" was updated in 2023 to clarify what studies are covered by the NoS obligations and invited MSs to consult the document for further details. It was also reminded that MSs are responsible to check whether Applicants have respected NoS obligations. EFSA added that constant dialogue is kept with EC to improve process.
- **EFSA** also invited MSs to share issues on NoS by means of practical examples here. Based on the feedback provided EFSA will decide whether an info session for MSs can be organised.
- On the ISO name **EFSA** reminded that this was addressed under presentation number 4 "IUCLID latest news and updates".

DE presented request for clarifications on the study start date and the study end date to be included in the IUCLID dossiers with practical examples.

Q&A

- **EFSA** confirmed that the experimental starting date is the date relevant for NoS obligations. Only in case this is not clear other dates can be considered. It was reminded the importance of notification by the applicants.
- Regarding the practical examples provided by **DE**, **EFSA** clarified that for those studies, notification was not needed as commissioned before 27 March 2021 and therefore not falling under NoS obligations.
- Regarding the study completion date, **EFSA** explained that it's not relevant for NoS obligations, however, it is the applicant responsibility to keep the NoS database updated.
- **AT** asked whether efficacy studies shall be notified for NAS as not part of the application. **EFSA** clarified that efficacy trials are subject to the notification obligations in the EU and recommended to comply with the obligations as their submissions may be necessary in other regulatory contexts under the EFSA's remit.

ACTIONS

- Based on the feedback that MS will provide on NoS, **EFSA** to decide whether to reply in writing or to organise an info session with MSs.

12. Any Other Business

No AoB were discussed. Next meeting is planned for November 2024.