Pesticides Residues & Plant Health (PLANTS)

3rd Pesticide Steering Network - IUCLID Subgroup Minutes of the meeting

Held on 04 May 2022, TELE-conference

Participants

- **Member States (including EFTA Countries)**

Country	Name
Austria	Klaus LEDER
Belgium	Philippe CASTELAIN
Croatia	Dubravka CELIG
Croatia	Karlo HALTRICH
Croatia	Ana MRNJAVCIC VOJVODA
Czech Republic	Martin BENISEK
Denmark	Alf AAGARD
Estonia	Uku ROONI
Finland	Marika PAALLYSAHO
France	Suzanne PIERLOT
Germany	Daniela MARUTZKY
Germany	Friederike BREUER
Germany	Tobias OPIALLA
Greece	Ourania MELITA
Hungary	Tamas GRIFF
Hungary	Adel JANKA
Italy	Angela SANTILIO
Lithuania	Elena BARZDENIENE
Malta	Nicole CILIA
Netherlands	Hanneke WESTLAND
Poland	Aneta CHODERSKA
Portugal	Anabela BARATA

Portugal	Bento CARVALHO
Portugal	Fernanda PEREIRA
Slovenia	Polona SLOKAN
Spain	Jose Luis ALONSO-PRADOS
Sweden	Christoffer OSTERWALL
Slovakia	Lenka GURSKA KRAJCOVICOVA

- **Stakeholders**

Organization	**Name**
Crop Life Europe	Monika BROSS
Crop Life Europe	Andrew WHYTE
European Crop Care Association	Manuel DUARTE
European Crop Care Association	Hans MATTAAR
International Biocontrol Manufacturers Association	Adi CORNELESE
International Biocontrol Manufacturers Association	Philippe KESSLER

- **European Commission**

Department	**Name**
DG SANTE	Domenico DESERIO
DG SANTE	Valerio SPINOSI

- **European Chemicals Agency**

ECHA	Dorota BURCHARD-SOSNOWSKA
ECHA	Leea KOKKO
ECHA	Francois LE GOFF

- **EFSA**

Unit	**Name**
Plant Health & Pesticides Residues	Giovanni BERNASCONI **(chair)**
Integrated data	Edoardo CARNESECCHI
Integrated data	Adrian CESAR RAZQUIN
Pesticides Peer Review	Angelo COLAGIORGI
Plant Health & Pesticides Residues	Lucien FERREIRA DA COSTA

Plant Health & Pesticides Residues	German GINER
Legal Affairs Services	Simone GABBI
Legal Affairs Services	Delphine GERBAUD
Legal Affairs Services	Matthias HASLER
Front-Desk & Workforce Planning	Alessandro DELFINO
Front-Desk & Workforce Planning	Chiara MACCHI
Risk Assessment Logistic	Laura MARCHESE
Front-Desk & Workforce Planning	Silvia MAZZEGA
Methodology and Scientific Support	Jane RICHARDSON
Integrated data	Tomas ROVESTI
Plant Health & Pesticides Residues	Alessia Pia SCARLATO
Front-Desk & Workforce Planning	Sofiya SHOPOVA
Front-Desk & Workforce Planning	Bénédicte VAGENENDE **(chair)**

1. Welcome -Apologies for absence and Tour de Table

The chair welcomed participants and asked new members to briefly introduce themselves.

2. Adoption of Agenda

The chair informed that presentation foreseen under Item 13 of the afternoon session was cancelled as no updates were available for this topic and informed that Giovanni Bernasconi from EFSA PLANTS Unit would be chair for the afternoon session. Agenda was adopted.

3. Closed action items from previous meetings

EFSA presented the list of action items resulting from previous meetings either already closed or in progress. An excel file listing all action points collected within the IUCLID subgroup has been uploaded under the Teams channel of the subgroup for consultation by members. The file will be regularly updated after each meeting with new action items.

Q&A
No questions were raised

4. IUCLID submissions: latest news and updates

EFSA presented the latest news and updates on IUCLID submissions.
Participants were informed that as of 19 April 2022 all requests related to IUCLID (e.g. support with preparation and/or submission of IUCLID dossiers, support on related tools e.g. MetaPath, support to MS during the admissibility check, etc.) must be submitted via the **Ask a question service** (https://connect.efsa.europa.eu/RM/s/new-ask-efsa-request)

and clarified that requestors will be asked to redirect their questions to Ask a question in case old channels are used or personal email addresses are reached.
EFSA informed that as of 26 April all dossiers can be submitted by means of the submission portal and the SFTP scheduling is no longer needed. As regards supporting materials and trainings, participants were informed that the four IUCLID manuals (active substance, MRLs, microbial active substance and basic active substance) have been updated to the IUCLID 6.6 format and no further update has been implemented following the IUCLID April release considering that no format changes were implemented. Next update of the Manuals is planned for April 2023. EFSA also informed that trainings are being prepared ("Most common mistakes in IUCLID submissions and how to solve them" & "IUCLID for the general public") and dates will be advertised soon.
Participants were reminded to regularly consult the Applicants' toolkit page for latest news and updates.
On filtering rules, EFSA reminded that IUCLID filter rules are updated twice a year following the normal IUCLID go-live cycle. Any future major changes will be discussed within the filtering working group of the PSN IUCLID and brought to the PSN IUCLID for approval. Applicants will be informed with advance notice before the changes become applicable so that, if a dossier update is required prior to publication, there is a window of opportunity for doing it.
Based on the latest submissions, EFSA shared most common issues on resubmission of dossiers and problems with personal data left in the IUCLID dossiers or in the attachments. EFSA presented an interim proposal for simplifying identification of personal data in IUCLID dossiers and invited participants to share comments on the proposal.

Q&A

- IBMA asked clarifications on how to manage personal data for published literature in a IUCLID dossier. EFSA clarified that for published literature there is no need to sanitize personal data such as Author's names. In case applicants do not hold copyrights, only citation should be added to the attached sanitized document field.
- Still on published literature, ECCA raised concerns about public consultation phase in case only citations are available for commenting to the public. EFSA clarified that it is not EFSA or MSs responsibility to provide the full study and any request should be addressed to the owner of the study.
- MS BE asked further clarifications on public literature data, raising concerns about the lack of full study for the evaluation phase in case of copyrights issues. EFSA clarified that in such cases, full study report will be available for evaluators as "non sanitized" version and that only "sanitized version" will contain citation.
- CLE confirmed that they will discuss and revert regarding EFSA's proposal on separation between personal data and CBI information and asked updates on next date for publication of validation rules, any consequent update of the IUCLID manuals and updates on next trainings on IUCLID. EFSA replied that new validation rules will be published on Zenodo and that ad hoc message will be added to the applicant's toolkit page. On trainings EFSA confirmed that the first training on the most common mistakes in IUCLID will be delivered in June as previously announced and that the training for general public will be delivered after the summer. In answer to a clarification from CLE, it was indicated the Study specific filtering rules have been amended so that the publication (copyright not owned for reproduction) literature references are filtered in the same way as published literature references.
- MS SE asked clarifications on maximum number of accounts allowed by connect EFSA. EFSA clarified that even if theoretically no limit is set for MSs, maximum number of

licenses has been raised to 9 to keep accounts to a manageable number and to avoid activation of accounts not used on regular basis.
- On communication channels EFSA clarified that FMBs in function will still be maintained for technical exchanges with applicants/MSs, but that all questions related to IUCLID should come via Ask a question service.

ACTION POINTS:

- **EFSA** to update IUCLID manuals with regards to the management of published literature data at next planned release (April 2023)
- **EFSA** to start written consultation on proposal for managing personal data/CBI information on Teams and consider outcome for manuals planned update. Deadline for commenting to be provided in Teams.
- **All participants** to reply to written consultation on proposal of managing personal data/CBI information on Teams.

5. IUCLID features: Validation assistant - April and October release

EFSA presented the new validation rules released in April with IUCLID version 6.14.4 and those that are planned and will be implemented with the next IUCLID release scheduled for October 2022. As for the April release, the rules implemented are the extension of existing rules to the Metabolites and Other Product datasets.
As for the October release, rules applying to notification of studies identifiers, flexible summaries and a set of rules checking results tables developed under the REACH regulation framework were explained. Participants were invited to comment on the proposed change relating to two existing rules aiming at removing the constraint to check only one literature reference in the Endpoint study records.

Q&A

- IBMA asked clarifications on the relevance of rules developed for chemical active substances for microbial active substances. EFSA clarified that rules will not equally be applied to all working contexts.
- MS DE accepted the proposal of removing the constraint limiting the possibility to attach more than one study to the literature reference document and asked clarifications on cases where a study number is not available. EFSA replied that when a study number is not available a justification should be added in the relevant IUCLID field.
- MS DK asked clarifications on timing of application of new validation rules. EFSA clarified that information will be made available in advance so applicants can be prepared and recommended to run the Validation Assistant according to the latest validation rules before submission and ideally resolve all the warnings rules. If applicants are not able to resolve warnings a justification should be provided in the Validation Assistant Report.
- CLE also welcomed the possibility to attach more than one study to the literature reference document as often large studies must be separated in different pdf.
- MS AT asked clarifications on the type of rules that will be implemented, if they are quality or business rules. EFSA clarified that all new rules released in April are quality rules, not blocking submissions of dossiers. Proposals for changing quality rules to business rules are welcomed. All these proposed changes will be discussed and agreed by the IUCLID PSN before being implemented.

ACTION POINTS:

- **EFSA** to plan written consultation on what quality rules can be changed to business rules. DL for commenting to be provided in Teams.
- **EFSA** to publish the new validation rules in Zenodo and in the Applicants' toolkit and clarifying, on the Applicants' toolkit page, that IUCLID manuals are not updated for validation rules and that a separate document is available.
- **All participants** to reply to written consultation in the Teams channel of the IUCLID PSN on which quality rules can be changed to business rules by provided DL.

6. IUCLID features – April and October release – Update on the submission portal

ECHA presented key IUCLID updates for April 2023 release relevant for PPPs, changes in the cycle of releases and future improvements. This information is also available in the format of a webinar https://echa.europa.eu/-/iuclid-release-webinar

Q&A

- DE asked about the possibility of implementing the search function by study ID. ECHA will investigate whether this is implementable.
- CLE asked clarifications on changing to POSTgreSQL database from Derby database. ECHA clarified that POSTgreSQL could be a better option for storing multiple large dossiers, but this should be discussed with their IT provider or system administrator.

ACTION POINTS:

- **ECHA** to investigate improving search by a substance within a dossier e.g. metabolites (IUCLID backlog item created)

7. IUCLID format: update on harmonisation activities

ECHA presented work on the harmonisation of the endpoint summaries and EFSA presented next improvements in the IUCLID documents giving detailed example of one OHT (50-2).

Q&A

- CLE asked clarifications on the process for implementing harmonisation of summaries and ECHA clarified that before implementation, a consultation phase is foreseen under the OECD governance activities.
- IBMA flagged that additional test guidelines for soil arthropods are available on top of the guidelines considered for the OHT improvement. EFSA and ECHA clarified that all test guidelines will be maintained in the OHTs, while most relevant guidelines (in terms of type of regulatory endpoints, organism and species) were shortlisted for the in-depth analysis of reporting needs in the OHTs.

8. IUCLID format: Microorganisms new data requirements - Update from the working party

EFSA presented the outcome of previous meetings held with members of the working party on microorganisms aimed to revise the working context according to the new data requirements. The timelines of the activities have been shared with the group.

Q&A

- CLE asked clarifications on the timing of application of the changes in the Table of Contents. EFSA clarified that only the ToC will change in October 2022 and a limited number of IUCLID documents will be amended/created in April 2023 and that simple generic documents will used if needed in the interim phase.
- MS AT asked clarifications on transitional period between old and new data requirements applicability. EFSA clarified that submission will be allowed in the original data format and the data will be migrated automatically to the current format when the dossier is transferred to EFSA Agency IUCLID. This is the standard approach when the IUCLID format changes. Most of the IUCLID documents will be re-used and changes are being discussed in the working party on amendments to the biological properties document and documents to record the qualitative assessments.
- MS DE asked clarifications on the parallel availability of different formats. EFSA informed that the original format would still be available in older desktop versions, but in the Agency instance of IUCLID and IUCLID Cloud versions only the latest format would be available as of October 2022.

ACTION POINTS

- **EFSA** to update the applicant's toolkit page with indications on the transitional period between old and new data requirements for microorganism applications. It will be recommended that applicants preparing applications for microorganisms (who often work in the Cloud) should start working on a local instance to finalise their dossier with the old/current format even after the new release scheduled for October 2022.

9. Feedback from Applicants and MSs

EFSA opened and welcomed any feedback from participants.
- A presentation was given by CLE. Positive feedback was given related to early announcements regarding IUCLID releases including format changes, adding some concerns about the number of changes expected on the OHTs and expressing expectation that changes will be announced and tested comprehensively prior to official release. CLE reported that IUCLID data entry today for detailed results is long and complex, and that user-friendliness of the tool should be improved giving specific suggestions for implementation. Specific feedback was given on issues related to the use of MetaPath and complex OHTs. CLE continued with conveying the need for further improvements on the report templates available in IUCLID and further simplification of the management of confidentiality claims. Lastly, need for improvement in the admissibility check phase was raised.

Q&A

ECCA, CLE, MS DE and MS PT asked clarifications on re-submissions of dossiers and errors in validation assistant report. EFSA clarified respective responsibilities of RMS and applicants explaining that applicants are invited to re-run the validation assistant and to resolve or justify any error before re-submission. EFSA also clarified that misalignment between versions of the submission rules has been resolved and currently rules are only updated in EFSA Agency when a new IUCLID release is published on the EFSA website. About admissibility after re-submission, detailed reply was addressed in the risk assessor's

session. On MetaPath EFSA expressed agreement on further improvement of OHTs as data entry will be shifted to IUCLID and clarified that parallel development of MetaPath keeps going for assessment purposes. EFSA added also that further investigation on the reporting of detailed results is still ongoing and will be object of discussion at the Expert Group on the Electronic Exchange of Pesticide Data (EGEEPD) meeting foreseen for 10-11 May.
On confidentiality, EFSA informed that a new guidance is available for applicants (https://www.efsa.europa.eu/sites/default/files/2022-03/user-guide-submission-confidentiality-requests.pdf) and that a webinar will be held after the summer. About simplification of management of CBI/PD EFSA informed that investigation on technical feasibility is currently ongoing internally.
On report generator templates, EFSA welcomed further input from participants to support further improvements and encouraged members to make use of the Report Generator backlog file to flag desired improvements. EFSA also clarified that OECD guidance documents are being followed to create templates, but there are technical limits in IUCLID not allowing 100% overlapping of formats. EFSA also recognised that free text fields are causing formatting issues in the generated reports, but this will be bug fixes were included in the April release and further improvements are planned.

10. AOB

EFSA informed participants that another PSN IUCLID meeting is planned for next September. A doodle will be sent out to collect availability of participants. Following meeting is planned in December, being compliant to the 4 meetings that were initially planned.

Risk assessor's sessions

11. Admissibility check – Feedback from EFSA

EFSA presented the latest best practices in admissibility check of dossiers, presenting a new draft admissibility checklist document developed ad hoc for Members States. The new admissibility checklist includes a detailed check for all phases of the admissibility check: 1) completeness check, 2) NoS check and 3) light check on confidential/personal data. EFSA invited Member States to check this document available on the Teams channel of the subgroup and submit input for improvement. On completeness check, EFSA reiterated the message to make use of the validation assistant report and shared most common validation rule failures encountered in pesticides dossiers and how to resolve them. About NoS, EFSA clarified steps and shared most common issues. On light check on confidential/personal data, EFSA clarified that this is not an evaluation of confidentiality claims, but only a light check on the presence of unsanitised personal and/or confidential data preventing the publication of dossiers. EFSA gave a live demo to show how to perform the light check and which IUCLID sections and documents EFSA would recommend the MSs to check during the light check on confidential/personal data.

Q&A

Several MSs asked clarifications on the location and information contained in the IUCLID dossier Header. EFSA provided clarifications on this regard.

ACTION POINTS

- **MSs** to review and comment available admissibility checklist adding comments directly in the draft document available on Teams.

12. Admissibility check – Feedback from MSs

- First presentation was from MS FR on most critical points related to IUCLID submissions, namely Notification of Studies, validation assistant report and Report generator templates. On NoS, FR expressed concerns on the difference between the NoS studies list extracted by EFSA and the list of studies extracted by IUCLID and added that annex point reference would be needed in the List of references extracted by IUCLID. On the validation assistant report, FR reported that file is not user friendly as it might have long list of errors and asked EFSA advise on the management of such file.
On report generator templates FR asked to improve current format in order to replicate obsolete templates used pre transparency.
- Second presentation was given by DE. Key points raised were the user friendliness of IUCLID interface (e.g., difficult visualisation when nested repeatable blocks are presented) and interest in having the option of searching within IUCLID by active substance.

Q&A

Most of the points raised by MSs were addressed in previous presentations by EFSA.
- On validation assistant report, EFSA encourages RMS to identify rules which could be converted to Business rules. EFSA is preparing video tutorial to show how to solve the most common validation errors.
- MS PT asked clarifications on best practice for naming endpoint study records and file names. EFSA replied that author names should not be reported in the file name as this would imply disclosure of personal data. More details on naming best practice are given in the IUCLID manuals.
- MS FR asked clarifications on actions needed from RMSs in case non-compliance on personal data is discovered in the IUCLID dossier. EFSA replied that RMS should go back to the applicant and ask for re-submission of the dossier.
-MS ES asked how to deal with Documents M containing personal data. EFSA advised to run the report generator from the filtered dossier to generate a sanitised version.

ACTION POINTS:

- **EFSA** to update IUCLID manuals by including instructions for data on notification of studies (e.g., use of the "share with" function in Connect EFSA). Prior to IUCLID manuals update, new supporting materials will be made available on Zenodo and on the Applicants' Toolkit page.
- **EFSA** to consider adding IUCLID section numbers to NoS report Template generated by IUCLID.
- **EFSA** to record and make available video tutorials on Light check on confidential/personal data (including how to check for blackening) and on Validation assistant report.
- **MSs** to provide for more details on the amendments to the Report Generator available Template using the Report generator backlog available on Teams at the following

link:
https://efsa815.sharepoint.com/:x:/r/sites/PSNIUCLIDsubgroup/Shared%20Documents/02_IUCLID%20PSN%20All%20participants/Resources/Report_generator_backlog.xlsx?d=wd1d0a5edc2ac48dfaae4efc352d18d5c&csf=1&web=1&e=mUpTIL

13. Updates from annotation test case

No presentation was given as no updates were available on this point.

14. Update on data integration activities

EFSA gave a presentation on latest updates on data integration activities introducing activities ongoing for IUCLID integration with OpenFood Tox database, MetaPath software package (including MSS/DER composers), EFSA Genotoxicity database, EFSA Read-across project, EFSA AI4NAMs project, EFSA NAMs projects and EFSA Multi-OMICS project. Further updates were given on IUCLID tools, namely the IUCLID Uploader (KNIME based tool) and the IUCLID Data Extractor

Q&A

No questions were raised.