2nd Pesticide Steering Network - IUCLID Subgroup Minutes of the meeting

Held on 31 January 2022, TELE-conference

Participants

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

Country	Name
Austria	Klaus LEDER
Belgium	Philippe CASTELAIN
Czech Republic	Martin BENISEK
Denmark	Alf AAGARD
Estonia	Uku ROONI
Finland	Paivi ARVILOMMI
France	Marie HERMANT
Germany	Daniela MARUTZKY
Germany	Fredrerike BREUER
Germany	Ann Kristin DIEDERICH
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	Bento CARVALHO
Slovenia	Polona SLOKAN
Spain	Jose Luis ALONSO-PRADOS
Sweden	Christoffer OSTERWALL

Slovakia	Marta GALUSOVA
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	Agata JAKUBOWSKA
International Biocontrol Manufacturers Association	Adi CORNELESE

- **European Commission**

Department	**Name**
DG SANTE	Valerio SPINOSI

- **European Chemicals Agency**

ECHA	Francois LE GOFF
ECHA	Gabor ZSOLT

- **EFSA**

Unit	**Name**
Integrated data	Edoardo CARNESECCHI
Integrated data	Adrian CESAR RAZQUIN
Pesticides Peer Review	Angelo COLAGIORGI
Pesticides Residues & Plant Health	Lucien FERREIRA DA COSTA
Legal Affairs Services	Simone GABBI
Legal Affairs Services	Matthias HASLER
Front-Desk & Workforce Planning	Chiara MACCHI
Risk Assessment Logistic	Laura MARCHESE
Front-Desk & Workforce Planning	Silvia MAZZEGA
Methodology and Scientific Support	Jane RICHARDSON
Pesticides Residues & Plant Health	Alessia Pia SCARLATO

Front-Desk & Workforce Planning	Sofiya SHOPOVA
Front-Desk & Workforce Planning	Benedicte VAGENENDE (chair)
Engagement & External Relations	Annelies VERWIMP

1. Welcome -Apologies for absence and Tour de Table

The chair welcomed the participants and each participant briefly introduced him/herself.

2. Adoption of Agenda

The agenda was adopted without changes.

3. IUCLID latest news & updates

EFSA presented the latest news and updates on IUCLID. Participants were reminded of the most recent communication and engagement activities that were set in place for keeping applicants up to date on the upcoming changes to the tool. The main communication channels are the EFSA applicants' toolkit webpage, the LinkedIn group, the Stakeholder newsletter (subscription page here: https://europa.us10.list-manage.com/subscribe?u=e6bc309c39d67dee1eb0bf114&id=7ea646dd1d) and targeted emails (registration on ConnectEFSA: https://connect.efsa.europa.eu/RM/s/). Participants were informed that a revised active substance manual has been published (https://zenodo.org/record/5888226#.Yf0yr9_MJPY) following IUCLID 6.6 version release; other manuals will be published shortly. In the coming months trainings for applicants and for general public on IUCLID will be published. Participants were asked to express the need for additional training on specific topics using the IUCLID PSN Teams channel available for participants. EFSA reminded the attendees once again that there is no need to communicate the submission of a dossier via mail to EFSA. Lastly, two issues were highlighted: 1. unsolicited resubmission of dossiers which causes duplication of work and 2. personal data management, resulting in EFSA not currently publishing dossiers because of the presence of personal data in the attachments of the IUCLID dossier. A better and optimized process is needed and will be discussed further together with SANTE.

Q&A

After the presentation the following points have been discussed:

- MS AT and ES reminded that according to the national provisions, specific documents might be needed from the applicant when submitting a dossier. Applicants are therefore invited to consult the national websites

(AT:https://www.ages.at/en/plant/pflanzenschutzmittel/examination-evaluation-admission-information#c6706

ES:https://www.mapa.gob.es/es/agricultura/temas/sanidad-vegetal/productos-fitosanitarios/registro/menu.asp
https://portalwebpro.inia.es/serviciosyrecursos/ServiciosOficiales/Pages/Productos-

Fitosanitarios.aspx) to check requirements under national provisions before submission of a dossier.

- MS DE asked clarifications on the frequency of spontaneous re-submissions of applications. Based on the experience with IUCLID applications submitted in the last months EFSA reported that re-submissions without specific request from regulatory bodies are common and that applicants are currently being asked to submit proof of request for re-submission by the RMS. This "control" mechanism will cease once the submission portal is upgraded and applicants can re-submit without seeking EFSA's support.

- CLE asked for further information regarding the format of the trainings provided. EFSA clarified that the formats will be a series of video tutorials followed by a Q&A. CLE followed with an additional request for clarification on the registration for targeted communications, to which EFSA reminded a maximum of 6 people per company can register with an EFSA account for any pre-application activities via Connect EFSA. Lastly, regarding issues with personal data, CLE asked if EFSA has foreseen changes to amend the Practical Arrangements and the process of moving forward this obstacle. EFSA answered that, for the moment, there is no plan in reviewing the PAs for what concerns this specific topic, however, as the review of the PAs is indeed foreseen, and the issue goes beyond IUCLID dossiers submitted, this is a possibility.

- MS NL asked clarifications on publication of dossiers following re-submissions. EFSA clarified that according to the provisions of the transparency regulation they will publish 1. the dossier as received by the applicants after declaration of admissibility, 2. the new version of the dossier at the end of the confidentiality check (if the case) and 3. the final version of the dossier after evaluation has ended.

- On confidentiality claims and personal data EC added that the topic has been discussed at the last PAFF committee with MSs, reiterating the complexity of the process and that there is no software that can check for confidential information in the pdfs attached. EC followed by stating that, as the current legal requirements (GDPR and GLP) require certain obligations, first responsibility is for the applicant to provide data compliant with both regulations, to which the responsibility of the other actors involved follows.

4. IUCLID filtering and confidentiality

Presentation was given by EFSA on the topic of filtering rules and confidentiality. Proposal for setting four fields in the Substance.Composition document as not published was made by EFSA, as a temporary solution until it will be possible to flag these data correctly. As experience is being built on managing filtering rules, EFSA brought forward some initial points for analysis to check if there might be the need for more sophisticated rules. EFSA proposed a working party on sensitive IUCLID documents to identify and review existing rules for refinement and asked for volunteers to join this working party.

Update was shared on confidentiality features, explaining the revised confidentiality section as present in the new IUCLID active substance manual with examples and going through the justification templates provided. EFSA shared for discussion and endorsement a proposal for decoupling confidentiality request from the personal data request to reduce suboptimal use of the CBI flag and justification box only for personal data resulting in redaction of more information than necessary.

EFSA also presented a proposal for using the remarks field for submission of personal data and asked input to participants on this proposal to be submitted in the IUCLID PSN Teams channel.

Q&A

- CLE welcomes the proposal for a subgroup to review the existing filtering ruleset, highlighting that the CBI flagging in IUCLID is very complicated as is. CLE asked clarification on the next IUCLID October release.

- EFSA welcomed the feedback addressing the points raised regarding the complexity of IUCLID filtering rules to be analysed by the working party.

- EFSA also clarified that the next format release is foreseen by April 2023. Further details on IUCLID version updates are available at: https://iuclid6.echa.europa.eu/it/planned-releases

ACTION POINTS:

PSN members to send input on the proposal for the submission of personal data as remarks on IUCLID PSN Teams channel by 18/02.

EFSA to launch call to create working party on filtering rules.

5. IUCLID features - Validation assistant: Re-use of existing validation assistant rules in the EU PPP context

EFSA presented the existing, updated, and new rules in the IUCLID PPP manuals and documentation. For the April release checks in the other product and other substance datasets will be extended to the administrative information, CBI flag and attachments. EFSA invited participants to provide feedback on the existing rules and to vote for highest priority activities needed.

Q&A

- IBMA expressed concerns about re-utilisation of validation rules already in use under the REACH regulation. EFSA clarified that for m.o. dossiers rules have been already modified in the IUCLID October 2021 release to accommodate specific requirements and invited participants to flag any issue.

- CLE expressed concerns about the consequences of updating submission rules which might cause delays in respecting legal deadlines for submissions. EFSA clarified that Agency IUCLID will be aligned with the industry version of IUCLID (IUCLID 6 version 6.8.0).

ACTION POINT: PSN members to reply to poll on validation assistant rules published on the IUCLID PSN Teams channel.

6. IUCLID features - Report generator: feedback from participants on Literature reference report, new MRL application report, and the new option of document selection

EFSA presented how to access and run the Report Generator and shared updates for upcoming IUCLID 6.8 release going live on 7th of February, going into detail on available reports for PPP for applicants and evaluators. The following 3 main points related to the new release were explained to the participants: MRL application report published in zenodo, list of literature references and the possibility to select documents the report. EFSA opened for discussion the proposal of updating EC guidance documents, to adopt the report generator formats.

Q&A

- EC explained that it is planned to align guidance documents and templates with IUCLID in order to allow a better and more efficient use of the system (e.g. using the report generator tool). This is work in progress and will be followed on. EFSA reiterated the importance of not having dealignment between documents on IUCLID and pre-transparency guidance documents on the Commission website.

- IBMA reconfirmed it is of no use to keep old templates in place to avoid double work. EFSA welcomed this feedback and reminded the participants the importance of flagging should they encounter this issue.

- MS AT and DE welcomed EFSA's request for input on the templates and encouraged other participants to share their feedback.

ACTION POINT:

EFSA to discuss and plan transition from existing PPP templates with report generator outputs.

7. IUCLID ToC: latest updates in the Residues section

EFSA presented latest updates in the Residues section, highlighting the importance of using the new formats, sharing lessons learnt and next steps in improving automation in the process.

Q&A

- CLE proposed on working together to create more structured data and less free text data in the fields of IUCLID.

- EFSA informed that in the work programme there is the plan to work on optimising the import function of csv files.

ACTION POINT:

EFSA to follow up with CLE to work jointly on the project for improving the csv import functioning.

8. Microorganism dossier – New ToC mapping

EFSA presented an update on the new Microorganism data requirements and related IUCLID work. In the framework of the European Green Deal and Farm to Fork strategy, the current data requirements on microbial active substances have been revised in order to accommodate the characteristics of the microorganisms in the plant protection products, differentiating them from those of chemical active substances. The new data requirements are to be adopted very soon. Changes in IUCLID updated ToC are to be included in the October release. EFSA advanced call for volunteers across participants to

form a working party with the aim of aligning the table of contents and identifying the need (if any) for new or amended IUCLID documents.

Q&A

- MS DE asked if there is any agreement on how to harmonize deadlines and timelines when new data requirements will entry into force. SANTE confirmed that IT developments should precede implementation of the new requirements (transitional measures will also apply) and that work with EFSA is already ongoing in this direction.

ACTION POINT:

EFSA to launch call to create working party on microorganisms

9. Feedback from Applicants and MSs

EFSA opened and welcomed any feedback from participants.

- First presentation was given by CLE. Positive feedback was given related to early announcements regarding format changes, stating that changes need to be comprehensively tested prior to official release. CLE raised one point on the validation and filtering rules namely, the importance of early warning on the planned changes and on their release. Question followed asking if ECHA and EFSA are planning to release changes to the quality and filtering rules only for the cloud and how this might affect synchronization between industry and what is available in the EFSA instances. As the validation rules need amendment, CLE made proposal to create a dedicated subgroup on the new document J changes, filtering rules together with MSs and experts in this specific field. CLE continued with conveying the need for an additional subgroup on CBI as most dossiers have been withdrawn for GDPR reasons and more clarification on confidentiality issues is needed. CLE claimed that more work needs to be done from EFSA's side on communicating in advance any upcoming guidance documentation. Lastly, need for clarifications and help in understanding error messages was raised.

Q&A

Most points were already addressed by previous presentations. EFSA requested that lack of clarity in error messages (for business rules and validation rules) should be flagged to EFSA including the number/code of the rule concerned.

- Second presentation was given by MS AT describing the pilot project together with BASF applicant of using annotations as a communication mechanism on required updates. The test case covers admissibility and early scientific check and is limited to FATE and toxicology i sections. The results of this activity will be reported back at the next PSN IUCLID subgroup meeting.

10. AOB

11. Date for next meeting

EFSA informed participants that another PSN IUCLID meeting is planned for next April before the planned IUCLID release. A doodle will be sent out soon to collect availability of participants. Following meetings will happen in September and December end of the year, being complaint to the 4 meetings that were initially planned.

Risk assessor's sessions

12. Admissibility check – Best practice

EFSA presented the latest experience gathered on admissibility and lessons learned with aim of starting a discussion in support of the MSs workload. Explanation followed of the three process steps of admissibility check performed by the regulatory bodies: completeness check, verification of the NoS information and alignment check for checking presence of key elements of the confidentiality request which are submitted within the IUCLID pesticide application. EFSA reminded MSs that application manuals were recently updated, where the regulatory bodies can find two tables listing where to attach documents in which section of IUCLID for mixture and active substances datasets. EFSA explained that dossiers are to be published as soon as the admissibility is declared by regulatory bodies to be complaint with the Transparency Regulation, but that this practice is currently suspended due to the amount of personal data encountered in the dossiers. EFSA showed examples of issues with sanitization of personal data in the received applications, reminding participants of the importance in sharing the responsibility. EFSA also clarified that a "light check" on personal data can be as simple as opening a couple of sanitised study reports and checking whether they contain personal data as the sanitisation is often performed in a harmonised way within a dossier. EFSA opened the floor for further discussion and feedback from MSs, also inviting participants to share if a checklist is being used by them for the pesticide submissions, asking if there might be willingness to work on one together to streamline the processes across the MSs.

13. Admissibility check – Feedback from MSs

- MS DE shared issue with using a checklist following the ToC on how to prepare dossiers and now following a crosswalk to follow a new ToC. Questions on sanitisation of personal data and resubmissions followed. EFSA reminded participants that applicants should justify the resubmission of the dossier in the remarks field in the dossier header and that this might help MSs in identifying the last submitted application.

- MS AT raised the proposal, for the resubmission issue, on the possibility of moving obsolete versions of a dossier to an archive. MS ES also raised complaints about checklists not adapted to IUCLID new requirements, and that sanitisation of personal data results in an increased work capacity problem, stating it is first responsibility of the applicant to protect personal data. EFSA shared the view of applicants being the data owners to be the first responsible for protecting personal data.

- MS PT made proposal to go back to the applicant before the final admissibility check to get authorisation to archive the previous versions that were not admissible. EFSA takes this point for noted and consideration.

- MS GR expressed interest in developing a new checklist for admissibility check by RMS. Regarding the checklist, MS GR uses the contents of the dossier according to relevant Regulation EC 1107/2009 (article 8) or Regulation EU 1720/2020 (article 6), the procedure for the NoS check and the validation assistant report. Regarding the versions of the dossier, MS GR pointed out that there is a choice in ECHA platform to view versions of the dossier and that there is a message in the screen coming out when you do not see the last version of the dossier. So, if this is not clear maybe another way to flag the last version of the dossier may be developed.

- MS NL shared the exchange, from the legal perspective, with national legal advisors that it is on the RMS and not on the applicant to perform the double check on the personal data. NL currently uses a checklist on NoS document that can be shared.

- EFSA welcomes further input from MSs from discussions at national level with legal advisors on this topic.

- EFSA took note to investigate whether it would be appropriate to remove and archive submitted dossiers which have not been requested by a regulatory body.

ACTION POINTS:

EFSA to share standard text with MSs for raising awareness to applicants regarding the redaction of personal data in the new version of the dossier to be submitted before admissibility check.

EFSA to develop further the NL NoS checklist to be circulated and discussed with MSs.

NL to share the NoS checklist with EFSA. MSs to share any available checklist with other participants.

14. Test case/working party on the use of annotation: Curated endpoint proposal

ECHA presented a proposal to extend the IUCLID annotation feature. This would give the evaluators the possibility to record an alternate assessment of the information contained in a dossier in the annotation layer of IUCLID. This could be the switch of a CBI flag or recording the selection of an alternative critical endpoint. The dossier of the applicant remains unchanged. EFSA opened the floor to discussions to gather the evaluators' point of view and feedback, asking participants if they would consider this as a valid use case to facilitate their work.

Q&A

- MS AT, in response to the use case, highlighted the need to migrate annotations to the latest version of the dossier.

- MS ES asked for clarifications on the obligation for the RMS and evaluators to use the annotation tool when evaluating the dossier. ECHA clarified that there is no obligation to use annotation and that the dossier itself is not changed. The annotation reflects the stores the assessment of evaluators. This is a mechanism to increase transparency and supports automation of dossier processing and assessment report generation.

- MS BE confirmed ES's concerns, stating that the annotation tool is useful but should not be the main tool for the drafting of the assessment report. MS BE clarified that during the drafting of the D(R)AR, supplemental information may be inserted on top of what can be found in the summary dossier, such as information in the open scientific literature, expanded tables, further scientific discussion, and that an annotation tool is not necessarily the best tool to achieve this.

- EFSA reminded participants that the annotation is indeed not mandatory but a tool to facilitate MSs work.

ACTION POINT:

ECHA to further elaborate on the use of annotations for pesticides dossiers.