PESTICIDE RECIDUES UNIT

1st Pesticide Steering Network - IUCLID Subgroup Minutes of the meeting

Held on 1 October 2021, 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	Suzanne PIERLOT
Germany	Marc LOSCHE
Germany	Anne WILKENING
Greece	Ourania MELITA
Hungary	Tamas GRIFF
Ireland	Brendan MURRAY
Italy	Angela SANTILIO
Lithuania	Elena BARZDENIENE
Malta	Nicole CILIA
Netherlands	Hanneke WESTLAND
Norway	Marit EVJEN
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

- **European Commission**

Department	**Name**
DG SANTE	Valerio SPINOSI

- **European Chemicals Agency**

ECHA	Francois LE GOFF

- **EFSA**

Unit	**Name**
Evidence Management	Edoardo CARNESECCHI
Evidence Management	Adrian CESAR RAZQUIN
External Engagement and Communication	Joy DUGGINS
Legal & Assurance services	Simone GABBI
Application Desk	Karine LHEUREUX

Application Desk	Chiara MACCHI
Pesticide Residues	Laura MARCHESE
Evidence Management	Jane RICHARDSON
Pesticide Residues	Alessia Pia SCARLATO
Pesticide Residues	Benedicte VAGENENDE (**chair**)

1. Welcome and Apologise for absence – 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. EFSA's feedback on first IUCLID submissions

EFSA presented PPP submissions received in IUCLID which included: 3 New Active Substance dossiers, 24 Renewal dossiers, and 15 MRL applications. Participants were informed of the most common issues based on the first submissions with the tool and were given examples of temporary workarounds and asked to contact EFSA for any support need. Tips for consultants and third parties were presented, as well as how to deal with large attachments and general pre-submission advice.

Q&A

After the presentation the following points have been discussed:

- CLE asked whether Hypercare will be open until March 2022 and if the Microsoft Teams channel would still be functional. EFSA clarified that Hypercare FMB would be fully operational until March 2022 and the Teams channel would not be closed but that one should move into using the PSN IUCLID sub-group ad hoc channel. EFSA also clarified that, for support on submissions above 1 GB applicants should contact hypercare.iuclid@efsa.europa.eu (until end of March) and for general support on submissions (GPSA or PSA) APDESK.applications@efsa.europa.eu.
- EFSA asked feedback on several items including the proposal of refining access to submission details available in the portal for third parties submitting dossiers on behalf of the applicant. Industry supported this change.
- CLE asked clarifications on conditions to access public IUCLID dossiers. EFSA clarified that the official channel for dissemination of information is the OpenEFSA portal. Credentials are always required in order to access the dossiers via this channel and conditions of use must be accepted before accessing the portal
- Clarifications on the concept of a light dossier were asked by NL. EFSA clarified that the light dossier should be used for re-submissions of renewal or new active substance dossiers. Only in addition to the structured data only new or amended attachments are included in the light dossier submission. Use of the change log in IUCLID is required to indicate studies which are updated or have been previously assessed.
- PT asked if an automatic notification would be received via email. EFSA confirmed that currently an e-mail notification is being sent to the e-mail address provided by the RMS. If MSs are not receiving the notification, advised to check spam or 'focussed' e-mail filters. If no e-mails have been received MSs are invited to inform

EFSA. SANTE added that notification emails are mostly addressed to functional mailboxes of different organizations, hence one should clarify which email is being used as it is important to identify. SANTE encouraged MSs to make use of official tools (IUCLID) for exchange of documents and also reminded applicants to carefully check what is going to be published using the available IUCLID functionalities (dissemination preview and the filtered dossier).

- AT asked that when a notification of a dossier arrives, to be able to see directly the active substance name in email object. The active substance is in the e-mail if the applicant provides – slide about QLP_PPP_021 provides details on how to ensure this is always provided

ACTION POINT: MSs to send an email message to EFSA in case they are not receiving alert email messages (IUCLID.servicemanager@efsa.europa.eu).

4. Feedback from Applicants and MSs on first submissions

First presentation was given by MS FR who has been involved in the IUCLID project since the first Technical Group IUCLID meetings. The difficulty of familiarising with the new tool was discussed, late availability of guidance documents and short deadlines given which did not allow RMS to take the lead on GPSA and RPSA. In regard to the admissibility checks, FR gave their thoughts and proposals on improvements related to IUCLID.

Second presentation was given by *CLE* who have also been involved in the IUCLD project since the first Technical Group IUCLID meetings. They welcomed the PSN subgroup initiative to further enhance the IUCLID platform for PPPs. Regarding the IUCLID software and features, such as validation assistant, they informed that this caused significant increase in workload in very short time periods. They communicated that in general, Hypercare programme was welcome and provided a wealth of information for applicants, although some negative aspects were encountered and that they would welcome further subgroups of this PSN forum involving experts from all stakeholders to further refine and develop IUCLID. Unknown/unclear aspects of IUCLID moving forward were also addressed by the presentation given

Q&A

EFSA took note of points raised by FR and CLE and clarified that deadline for admissibility check is a legal requirement. Regarding the time for generating the Notification of Studies Report, EFSA will investigate internally how to make this step quicker.

5. IUCLID features: Validation assistant: current status and discussion on developments

EFSA presented the existing, updated and new rules in the IUCLID PPP manuals and documentation which consisted of data source, data requirements, confidentiality and attachments, multiple products and dossier header.

Q&A

- EFSA invited participants to provide written comments on making QLT_PPP_021 a failure – comments can be provided under the post in teams

  ES asked whether the validation assistant report should be submitted to applicants. EFSA indicated the excel report should be included in the 'Admissibility' e-mail. Mechanisms to capture justifications for rules not resolved will be analysed

ACTION POINT: EFSA will start written consultation on input on validation assistant using the Teams channel of the IUCLID PSN sub-group.

6. IUCLID features: Report generator

EFSA presented how to access and run the Report Generator, going into detail on available reports for PPP for applicants and evaluators. It was highlighted that all data in a IUCLID dataset can be processed and presented in different formats using Report Generator. Next steps will focus on further developments with report generator but input from both RMS and industry is needed to ensure the documents can address the needs of evaluators

Q&A

After the presentation the following questions/comments were received:

- AT commented that people from industry who actually work with IUCLID and use the report generator were not present in the PSN-IUCLID group. EFSA clarified that the reports are publicly available here: https://zenodo.org/record/5495256#.YWRbjtpBxhE . The OECD IUCLID customisation forum support collaboration between developers using IUCLID. Further details available here: https://community.oecd.org/community/iuclidcustomisation/overview
- Point was raised by CLE on the fact that Word format cannot be routinely used for submission as a sanitized version cannot be made in Word format. EFSA clarified that Report Generator offers versions in PDF and RTF. The use of Report Generator on filtered dossiers automatically creates filtered reports
- CLE reported that currently duplication of work is experienced as same information are reported in IUCLID and in other reports and would welcome additional dialogue in order to develop further the report templates currently available. EFSA welcomed the proposal for further discussion on the refinement/development of report templates.

ACTION POINT: EFSA will start written consultation on input on REPORT GENERATOR using the Teams channel of the IUCLID PSN sub-group.

7. Confidentiality rules and filtered dossiers

EFSA presented lessons learnt and next steps in confidentiality which focused on how to verify confidentiality requests, submission of attachments, personal data, identification of the information claimed confidential and submitting a compliant justification. PSN members were asked to screen applications and perform a light check on the presence of key elements in the confidentiality requests and to share their suggestions in improving the confidentiality justification template currently available and provide feedback regarding current filtering and flagging scheme by 19 October 2021.

Q&A

- A comment was made by AT that if the confidentiality check for renewals is the duty of EFSA, admissibility check is the duty of the RMS and if a dossier is admissible but the confidential data is not input correctly, the RMS should go back to the applicant stating that this would mean that RMS should also run a confidentiality check which goes against what was previously presented by EFSA.

  EFSA replied by confirming the confidentiality decision, so whether or not certain information should be blackened or not, is entirely with EFSA. EFSA also clarified that since once the dossier is declared admissible it is published as it stands by EFSA, it is important that MSs take a proactive stance and perform a light check by verifying that personal data are not patently accessible. If this is the case, MSs should ask the applicant to submit confidentiality requests in accordance with the Practical Arrangements. EFSA will follow-up with the communication on this in writing to all MSs.
- Further comment was made that using such a system is imposing the confidentiality check done by the RMSs.

EFSA replied that we have to distinguish between what we define as confidentiality decision making and the admissibility check to be done by MSs. Confidentiality decision is exercise of the discretionary power to decide whether to accept or not accept the confidentiality requests that has be delegated to EFSA for what concerns MRL and renewals of the active substances. In other words, it is the final determination on the applicants' confidentiality request which would then be legally binding and will have to be implemented by the applicant himself in IUCLID. This may result in possibly or not (depending on the content of the confidentiality decision) the disclosure of the information that was initially claimed confidential. Furthermore, due attention should be paid to the fact that for NAS it is for the Member States to take the confidentiality decisions, and therefore MSs have a sheer interest in improving the quality of the applicant's submissions in terms of confidentiality requests.

- CLE asked clarifications about changes on confidentiality rules

  EFSA replied that the gap between when applicant sends the dossier and when EFSA publishes the dossier should be reasonably short so there should not be a too big gap when the new confidentiality rules are set into place. EFSA would also want to be sure that we are sharing confidentiality rules in advance before they go into place so that applicant can see beforehand and comment if necessary.

ACTION POINT: EFSA will start written consultation on input on confidentiality rules using the Teams channel of the IUCLID PSN sub-group.

8. IUCLID 6.6 release main changes to PPP working context

EFSA presented the IUCLID format changes to PPP working context in view of the IUCLID 6.6. release in October 2021. Twenty-three OECD Harmonised Templates (OHTs), 17 PPP documents (ENDPOINT_SUMMARY and FLEXIBLE_RECORD), 3 Domain documents and 2 CORE documents (e.g., FLEXIBLE_SUMMARY, ENDPOINT_STUDY_RECORD) were revised accordingly. Further details on Format changes are available at: Format changes 2021 |OECD. The workplan for 2022 was presented and participants were asked to contribute by entering/commenting on backlog items available at https://docs.google.com/spreadsheets/d/1kFkttA6rXtR2K6LlaauHozq9BSfv6a5EgFDM1GgtmfQ/edit#gid=0 .

Q&A

No questions asked after EFSA presented.

ACTION POINT: EFSA started the written consultation on input on IUCLID improvements using the Teams channel of the IUCLID PSN sub-group.

9. Any other business

9.1 Date for next meeting

EFSA informed participants that another PSN IUCLID meeting would be planned before end of year and a doodle would be sent out to collect availability of participants.

It was mentioned that a specific session of the next meeting should concentrate on the Report Generator, in the meantime EFSA welcomes proposals of topics from members for the next meeting.

10. Open discussion

- MSs mentioned that what they need most and what they still requested from applicants is documents L, M, and D. These are the most important as when they receive documents L and M process them via the Report Generator they notice the documents are different, the same is also true for document D.

  EFSA clarified that applicants need to submit documents M, L and D under the section Summary and Evaluation of IUCLID as specified in the administrative guidance. The recommendation is that they use the available reports in Report Generator and amend them if necessary e.g. to correct a table that doesn't render properly.

- AT asked if all documents that were in the appendence administrative guidance 2019 have been included in IUCLID.

  EFSA replied that L, M and D templates for the report generator tool are already available, but feedback is needed to improve their usability (Consultation will be started in PSN teams). EFSA indicated that since the dossiers are published the information in documents M should be in alignment with that provided in the dossier. Report Generator can help to ensure this.

  ES mentioned that it was important to understand that the Report Generator will help them to have the summaries of the studies, nevertheless, it was highlighted that the report generator should also be able to generate a report comparable to Vol I, being this the most complete and complex document to be created. EFSA asked for examples of the two VOLs in order to compare and then take it from there.

- MSs asked to discuss the use of annotations for the upcoming meeting

  EFSA agreed this would be a topic that could also be discussed in the next Hypercare weekly meeting as an EFSA colleague attended the OECD IUCLID working group where there was a helpful presentation presented by Australia showing how they are using annotation with which they are very active.