Pesticides Residues & Plant Health (PLANTS)

Steering Network - IUCLID Subgroup

Minutes of the 5th meeting

Held on 5 December 2022, TELE-conference

(Agreed on 21 December 2022)

Participants

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

Country	**Name**
Austria	Klaus LEDER
Belgium	Philippe CASTELAIN
Belgium	Wim HOOGHE
Croatia	Ana ČALE
Croatia	Karlo HALTRICH
Czech Republic	Martin BENÍŠEK
Czech Republic	Milan SVOBODA
Czech Republic	Hana KUBÁTOVÁ-HIRSOVÁ
Denmark	Alf AAGAARD
Denmark	Louise LUNDBERG
Finland	Marika PÄÄLLYSAHO
France	Marie HERMANT
France	Suzanne PIERLOT
France	Vincent VAILLANT
France	Gaelle VIAL
Germany	Daniela MARUTZKY
Germany	Falko FRENZEL
Germany	Tobias OPIALLA
Greece	Ourania MELITA
Hungary	Flórián SÁNDOR
Ireland	Sadhbh O'DWYER
Italy	Angela SANTILIO

Lithuania	Elena BARZDENIENE
Malta	Francesca PACE
Netherlands	Cornelia BLAGA
Netherlands	Hanneke WESTLAND
Netherlands	Joanne BORG GALEA
Norway	Louise ARNESEN
Poland	Monika DEBEK
Portugal	Bento CARVALHO
Portugal	Julia SILVA
Slovak Republic	Marta GALUSOVÁ
Slovak Republic	Lenka GURSKÁ KRAJČOVIČOVÁ
Slovenia	Polona SLOKAN
Slovenia	Sanja VRANAC
Slovenia	Anja PALMAN
Spain	Jose Luis ALONSO-PRADOS
Sweden	Christoffer OSTERWALL
Sweden	Anneli WIDENFALK

- **Stakeholders**

Organization	**Name**
Crop Life Europe	Monika BROSS
Crop Life Europe	Andrew WHYTE
Crop Life Europe	Heike WOEHRMANN
Crop Life Europe	Marc TEIWES
European Crop Care Association	Jose Luis JUANES
European Crop Care Association	Hans MATTAAR
European Crop Care Association	Ana PEREIRA
International Biocontrol Manufacturers Association	Adi CORNELESE
International Biocontrol Manufacturers Association	Agata JAKUBOWSKA

- **European Commission**

Department	**Name**
DG SANTE	Valerio SPINOSI

- **European Chemicals Agency**

ECHA	Francois LE GOFF

- **EFSA**

Unit	**Name**
Front-Desk & Workforce Planning	Päivi ARVILOMMI
Front-Desk & Workforce Planning	Alessandro DELFINO
Front-Desk & Workforce Planning	Chiara MACCHI
Front-Desk & Workforce Planning	Patricia ROMEO FERNANDEZ
Front-Desk & Workforce Planning	Bénédicte VAGENENDE
Integrated data	Edoardo CARNESECCHI
Integrated data	Tomas ROVESTI
Legal Affairs Services	Simone GABBI
Legal Affairs Services	Matthias HASLER
Methodology and Scientific Support	Jane RICHARDSON
Pesticides Peer Review	Angelo COLAGIORGI
Pesticides Peer Review	Chloe DE LENTDECKER
Pesticides Peer Review	Isabella DE MAGISTRIS
Pesticides Peer Review	Dimitra KARDASSI
Pesticides Peer Review	Juan Manuel PARRA MORTE
Pesticides Peer Review	Giorgia VIANELLO
Plant Health & Pesticides Residues	Giovanni BERNASCONI **(chair)**
Plant Health & Pesticides Residues	Lucien FERREIRA DA COSTA
Plant Health & Pesticides Residues	Alessia Pia SCARLATO
Plant Health & Pesticides Residues	Emanuela TACCI

1. Welcome -Apologies for absence and Tour de Table

The Chair welcomed the participants.

Apologies were received from Brendan Murray (IE), Dorota Burchard-Sosnowska (ECHA), Dubravka Čelig (HR) and Ana Mrnjavcic Vojvoda (HR)

2. Adoption of Agenda

The agenda was adopted without changes.

3. Action items from previous meetings

EFSA briefed on the list of action items resulting from previous IUCLID PSN sub-group meetings. Completed or still open action points 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. EFSA also informed that the Terms of Reference document has been updated to include detailed rules on how to access meetings. The document is available at: https://www.efsa.europa.eu/sites/default/files/2021-08/tems-of-reference-iuclid-psn-subgroup.pdf

4. IUCLID submissions: latest news and updates

Latest news and updates on IUCLID submissions were discussed.
EFSA briefed on the ongoing activities to support applicants and Member States:
- direct support via Ask a Question service;
- collaboration with CTGB to optimise admissibility check;
- round of bilaterals with Member States to discuss most relevant issues and challenges with IUCLID;
- "IUCLID for the general public training" is almost finalised and should be made available in January 2023.

EFSA informed that a revision of the "Administrative guidance for the processing of applications for regulated products" is planned. Stakeholders will be consulted prior to publication planned for Q1 2023.
EFSA also informed that an updated version of the admissibility checklist document is available to the IUCLID PSN members. The admissibility checklist will be included in the updated version of the administrative guidance.
EFSA shared the list of QLT rules that will be converted to BRs as from April 2023 and informed about the new Validation Assistant rules that will be released in April 2023.
EFSA reminded participants what are the cases when an MRL application, which is part of an active substance approval or renewal process, should be submitted separately.

Q&A
-CLE asked for more details on the round of bilateral meetings ongoing with RMSs (what topics were discussed).
EFSA replied that meetings are focused on the analysis of any issues with IUCLID and ECHA cloud services to identify possible solutions. Training needs and ideas for collaboration are also touched.
- CLE asked clarifications on the frequency of the admissibility check for resubmissions and explained the issues related to the repetition of these checks. Pesticide regulations and guidelines are subject of permanent changes and revisions. For keeping the data package actual, industry is running and commissioning studies after submission. As these studies require notification, the NoS ID check results in "new findings". EFSA clarified that the admissibility check should be performed every time a new submission occurs. If a dossier is re-submitted while the EMS/RMSs are still assessing the previous version, they should make use of the 'Compare tool' of IUCLID to see whether there are differences that would have to be re-assessed.
- CLE also asked clarifications on the need for applicants to submit M documents for renewal applications as the administrative guidance reports this is needed only for NAS applications.

EFSA replied that work is ongoing to improve report generator in view of using it for generating documents M (input from MS is much appreciated in this respect) and aim is to achieve this by 2024. The updated administrative guidance will start to reflect changes in this direction.
-ECCA asked clarifications on how EFSA is planning to manage transition from present templates to new templates generated via the Report Generator and whether the updated manuals and administrative guidance will include instructions on the alignment between LE of notifier and LE of submitter as presented by EFSA.
EFSA replied that the plan is to keep improving the Report Generator templates and bring a full set of documents for endorsement to PAFF in 2024.
EFSA confirmed that the IUCLID manual introduction will include instructions on the LE alignment between notifier and submitter.
-FR asked how many accounts are currently permitted for Ask a question service. EFSA replied that up to 9 accounts for each organisation are currently permitted.
- FR and ES flagged that current Report Generator templates are not fully aligned with EU templates and therefore extra work is needed to prepare DARs and RARs.
EFSA reiterated that work on improvements of the Report Generator templates is ongoing also in collaboration with Member States within specific agreements.

ACTION POINTS:
EFSA to update IUCLID manuals (introduction) with information on legal entity (Notifier Legal entity (LE) vs Submitter/Owner LE)

5. Confidentiality and filtering rules:

Updates from working party on filtering rules
EFSA briefed on the outcome of the meetings of the working party on filtering rules:
- definition of preliminary rules for new/amended documents that will be included in the April 2023 release
- analysis of the "Mixture composition" document and definition of new Validation Assistant (VA) warnings
- confirmation that the mapping of the closed list of items for which a confidentiality request can be made to the list of IUCLID documents containing them is accurate
- ongoing screening of the "UNLESS_CONF" fields in IUCLID that do not contain information from the closed list foreseen by the regulation with the aim of streamlining the Confidentiality Assessment process. Result of this exercise will be shared with IUCLID PSN members when available.

Update on confidentiality assessments
EFSA presented in detail how to manage the submission of claims related to personal data in IUCLID, providing practical examples and informed participants on the timelines to adopt new approach: as of 31 October 2022, applicants can voluntarily submit their dossier in accordance with the new approach to Personal Data (PD).
The new approach to PD will become mandatory as of 01 January 2023.
EFSA will publish an official communication regarding the new approach to PD on relevant EFSA channels, including the EFSA webpage, shortly providing further details and confirming the envisaged date for its entry into application.

Q&A
- CLE asked to clarify responsibility in avoiding publication of personal data.

EFSA clarified that personal data protection in the context of IUCLID is a joint responsibility. However, applicants - as any other actor sharing in responsibility for personal data protection may be held accountable for personal data infringements.
- CLE asked if it has been considered to move the claims for attached studies fully to the Literature References Entity as this could significantly reduce the issue of Unless-Confidential rules in OHTs whilst keeping the option where necessary.
EFSA replied that the Literature Reference entity does not foresee a confidentiality flag and since it is used under other regulatory frameworks, each change should be proposed and discussed at the OECD level. EFSA also asked CLE to bring this point to the Working Party on filter rules for further discussion.
-CLE asked clarifications on long term solutions as the approach shown is transitional. EFSA replied that this would need to be discussed in the Working Party on filter rules and with OECD.

6. IUCLID format: updates from EFSA

EFSA updated on latest changes to the IUCLID format.

EFSA presented core and EU_PPP documents that will be updated with the April 2023 release and briefed participants on the activity of harmonisation of templates. The newly developed Flexible record "Additional Transparency Regulation Information" was introduced. EFSA also presented in detail the migration rules applying after format change.

Q&A
-CLE asked clarifications on whether the list of OHTs changes presented was complete or not. EFSA clarified that the presentation focused only on latest changes, but complete list is available, and link was provided at 4th IUCLID PSN.

- On the new tool for managing confidentiality assessment presented by EFSA at 4th IUCLID PSN meeting CLE asked whether there will be a direct link between the contact detail to be indicated in the new IUCLID document "Additional Transparency Regulation Information" and Salesforce. EFSA clarified that no direct link is set between IUCLID and salesforce but there must be consistency between the contact details provided in IUCLID and Salesforce.
- always on the new tool for confidentiality assessment, CLE asked EFSA to consider giving access to 4 to 5 users (shared between the applicant and third party consultants) and asked whether the new assessment tool has also impact on Portalino.
On the number of accesses, EFSA replied that during testing phase this was already flagged and that the number proposed by CLE will be taken into consideration.
On Portalino, EFSA clarified that Portalino is not related to the Salesforce confidentiality assessment tool.
-ECCA asked clarifications on how the split of the OHT "Toxicity to terrestrial arthropods" will be done.
EFSA replied that the split will be done according to the species and that automatic migration will be possible in this case. In other cases, manual migration will be needed.
EFSA also clarified that when OHTs are deleted, old documents are collected in a section called "obsolete documents" available for copy and paste.
- CLE and PT asked EFSA to consider keeping the obsolete documents for the entire approval life of the substance.

ACTION POINTS:
EFSA to consider extending the maximum number of users to access the new tool for managing confidentiality requests (4-5 accounts per dossier is considered an appropriate number)

7. Feedback from sub-group members

EFSA opened and welcomed feedback from participants. CLE gave a presentation on issues experienced with dossier preparation and gave feedback on the latest IUCLID release. It was highlighted that improvements are needed on functionality and robustness of the tool, on migration and lifecycle management of applications when shifting from old to newer version.

Q&A
EFSA thanked members for active participation to discussion and
- on technical instability of IUCLID, replied that ECHA has already been contacted by two companies and has already solved some of the problems. A patch to fix the known issues will be provided to any companies if they contact ECHA help desk
- on migration concerns, EFSA explained how migration will be managed, reiterating the message addressed by the presentation on format updates (Agenda point 6). As indicated under Agenda point 6, CLE considers it as essential that dossiers are kept as submitted during the entire approval period of an active substance.
- CLE asked EFSA to develop a prioritisation list for migration tool considering that testing time is very close to new release.
- IBMA flagged that when using IUCLID cloud, an error message "Usage threshold is reached" appears when size is exceeded and removing datasets does not help, the error message remains. ECHA clarified that today is only a warning message and does not concern IUCLID dossiers.

ACTION POINTS:
EFSA to consider longer period for storing obsolete migrated documents after ToC changes. ECHA and EFSA to consider whether one year can be granted.

8. Any Other Business – Date for next meeting
No AoB were discussed. EFSA will communicate dates for next meeting soon.

End of General session

Risk assessor's sessions

9. Feedback from EFSA

EFSA presented the planned update of the administrative guidance, clarified how to solve most common issues with accessing the IUCLID agency and reported details on Bilateral meetings with Member States.

Q&A
-FR asked EFSA to consider highlighting the changes in the administrative guidance so to streamline the commenting phase.
EFSA replied that new sections will be highlighted in track changes for better identification.
-SE and NL asked whether there is already a list of RMSs that will be invited to bilaterals and showed interest in participating.
EFSA clarified that meetings are planned with 10 RMSs for the time being and that priority was given to MSs having already post transparency applications in the pipeline for evaluation. MSs interested in participating can proactively contact EFSA at FDP FMB (FDP@efsa.europa.eu) to show interest.

ACTION POINTS:
-**EFSA** to highlight in track changes the modifications on the administrative guidance to optimise the commenting phase
-**MSs** to contact proactively FDP in case in case of interest in participating soon to the round of bilaterals with EFSA (FDP@efsa.europa.eu)

10. Updates on confidentiality

EFSA reminded Member States that, according to PAs concerning confidentiality in accordance with Article 7(3) and 16 of Regulation (EC) No 107/2009, RMSs are required to consult EFSA on draft confidentiality decision on NAS dossier by contacting EFSA at confidentialityrequestassessment@efsa.europa.eu, so to ensure consistency on confidentiality decisions. This is particularly important for NAS & MRL linked applications since the risk assessment for NAS and related MRL dossiers are closely interlinked (e.g., publication consultation for NAS and related MRL are launched simultaneously and there is one common EFSA output).

Q&A
- AT asked whether there is a list of mandatory documents to be prepared before consultation with EFSA.
EFSA clarified that formally MSs should consult the Authority on the draft decision on confidentiality assessment. EFSA has 10 days to comment and MSs 4 weeks to implement the decision and notify relevant stakeholders. EFSA also clarified that if MSs have questions on the applicability of PA, EFSA should be consulted.
- ES asked whether EFSA can draft a template for consultation on confidentiality assessment and provide it to MSs via the IUCLID PSN channel. EFSA agreed on the proposal.

ACTION POINTS:
-**EFSA** to provide MSs with a template to report the draft decision on confidentiality assessment
-**MSs** to consult EFSA on confidentiality decisions for NAS applications at confidentialityrequestassessment@efsa.europa.eu

11. Feedback from Member States

EFSA welcomed feedback from MSs.
-DK reported technical issues with IUCLID, asked for improvements with format of the report generator and asked advice on how to deal with NoS justifications for studies notified but not submitted because still ongoing at the moment of the submission.
-DE asked where to find conclusive documents of the Hypercare programme and on Report generator asked whether EFSA can consider using an issue management system as common place in software development instead of other means. GitHub is already in use for report-generator templates. It was also requested to receive feedback on the issues raised in the report generator backlog last April. DE also volunteered to collaborate with EFSA on improvements of the Report Generator. DE voiced data protection concerns regarding the use of communication tools such as teams.
-FR flagged that more details on the timelines for public consultation would be needed as currently, it is difficult for them to anticipate the starting of the public consultation and plan their follow up work accordingly.
-NL highlighted issues with microorganism dossier re-submission after a new IUCLID release and with validation assistant report.

CTGB and ANSES shared updates on the ongoing collaborations with EFSA on admissibility check and report generator templates.

Q&A
On technical issues with IUCLID, EFSA clarified that most of the issues are being already solved.
On Hypercare programme, EFSA informed that presentations and meeting minutes of the CORE meetings are available at the following webpage for consultation: https://www.efsa.europa.eu/en/events/advanced-search?f%5B1%5D=event_participant%3A151&sort=computed_sort_date&order=desc
On the use of Teams, it was agreed that this topic would be followed up in writing.
On report generator, EFSA replied that work is ongoing, but MSs are invited to submit their suggestions via the report generator backlog, the IUCLID PSN and the IUCLID customisation forum. Git hub is very technical and could be hard to be used by less experienced users. EFSA also informed that a new template is available ("List of studies report") developed in co-operation with ECHA and other stakeholders during a reporting workshop upon request from DE. The report can be downloaded from IUCLID website (https://iuclid6.echa.europa.eu/it/cross-regulatory-reports) and will be available in IUCLID releases from January 2023 forwards.
EFSA welcomed DE interest in collaborating with the setting of DAR/RAR templates.
On the issues with notification of studies, EFSA replied that when new studies are notified but not submitted in the application, a justification shall be provided by the applicant on the reason why the study has not been submitted. RMSs should evaluate the justification and decide on the admissibility of the dossier, on case-by-case basis.
On public consultation, EFSA acknowledged that delays in confidentiality assessment are having an impact on the starting date for public consultations and agreed to better communicate timelines in this regard.
On resubmissions of microorganism's dossiers, EFSA clarified that the new ToC is available with a couple of new documents. From April 2023, 6 new documents will be available and

recommended to use the new version as no data is lost. EFSA also recommended to liaise bilaterally for this kind of problems.
On the new validation assistant rules that are triggered in dossiers submitted before the release and that are in the process of admissibility check, EFSA recommended RMS/EMS to extract the validation assistant report in excel file format and send it to the applicants for providing justifications for not resolving the rules.

ACTION POINTS:
-**EFSA** to reflect on how to best communicate timelines for public consultation

-**EFSA** to contact DE to start collaboration on report generator
-**EFSA** to clarify in writing the process and responsibilities of study notification for PPP dossiers.

12. Feedback from European Commission

European commission gave a presentation on general challenges with post transparency dossiers (delays in the admissibility check, building up knowledge of the IT system and keeping up with upgrades) and highlighted issues with completeness and quality of basic substances applications received.
EC recommended to refine rules/checks (quality/business) to avoid delays in the admissibility checks, better coordination between NoS information, checks and re-submission, early checks on confidential/personal data requests to avoid delays in the admissibility check and publication of the content of the dossiers, collaboration between users and EFSA to refine report templates and then use them.

13. Open discussion

No additional points were discussed

Closure of the meeting
EFSA informed that next meetings of 2023 will be communicated.

Post meeting note:

EFSA would like to inform that, contrary to what was announced during 4th IUCLID PSN meeting, the go live of the new IT system to manage confidentiality assessment foreseen for January 2023 has been postponed. EFSA is currently working to solve the problems to ensure better customer experience and will communicate a new go-live date when this will be agreed.