PESTICIDE STEERING NETWORK – IUCLID SUBGROUP 8th meeting

29th February 2024

09:30-17-00

Minutes agreed on 20 March 2024

Location: Web conference

Attendees:

- Network Participants:

Country	Organisation
Austria	• 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
Denmark	• DEPA
Estonia	• Agriculture and Food Board
Finland	• Finnish Safety and Chemicals Agency (Tukes)
France	• French Agency for food, environmental and occupational health & safety (ANSES)
Germany	• Federal Office for Consumer Protection and Food Safety (BVL) • BfR
Greece	• Ministry of Rural Development and Food
Hungary	• National Food Chain Safety Office
Ireland	• Pesticide Registration Division, Department of Agriculture, Food & the Marine
Italy	• ASST FBF Sacco - ICPS
Lithuania	• The State Plant service under the Ministry of Agriculture
Malta	• MCCAA • Malta Competition and Consumers Affairs Authority
Monaco	• CTGB
Netherlands	• Ctgb - Board for the Authorisation of Plant Protection Products and Biocides
Norway	• The Norwegian Food Safety Authority
Poland	• Ministry of Agriculture and Rural Development • Merit Mark
Portugal	• Direção-Geral de Alimentação e Veterinária (DGAV)
Slovak Republic	• Central Control and Testing Institute in Agriculture • UKSUP

Slovenia	• The Administration of the Republic of Slovenia for Food Safety, Veterinary Sector and Plant Protection
Spain	• INIA-CSIC
Sweden	• Swedish Chemicals Agency • Swedish Food Agency

- Observers:

Turkey: Ministry of Agriculture and Forest Plant Protection Central Research Institute
Montenegro: Administration for Food Safety, Veterinary and Phytosanitary Affairs
Bosnia and Herzegovina: Food Safety Agency of Bosnia and Herzegovina

- European Commission/Other EU Agencies representatives:

ECHA, European Commission

- Industry Representative:

Belgium: European Crop Care Association (ECCA), International Biocontrol Manufacturers Association (IBMA), Crop Life Europe (CLE)
Germany: GAB Consulting (only for Agenda Item 5)

- EFSA:

PREV: Alessia Scarlato, Lucien Ferreira Da Costa, Giovanni Bernasconi, Angelo Colagiorgi
FDP: Chiara Macchi, Alessandro Delfino, Lucrezia Meriggi, Benedicte Vagenende, Alessandra Giarola
IDATA: Adrian César Razquin, Dayana Buzle, Edoardo Carnesecchi, Tomas Rovesti
LA: Matthias Hasler, Iris de Williencourt, Xhestina Myftaraj
TS: Pierfranco Ferronato

1. Welcome and apologies for absence

The Chair welcomed the participants and new members from Italy and observers from Bosnia and Turkey.

2. Adoption of agenda

The agenda was adopted without changes.

3. Action items from previous meetings

EFSA briefed on the action items 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

- **DK** asked clarifications on the open action point on the "improving search by a substance within a dossier e.g. metabolites".

EFSA clarified that under the OECD Activity #2 on improving the IUCLID User Interface, the option of searching across dossiers is under investigation and has been prioritised.

- **CLE** invited MSs to express interest in organising a workshop on NoS.

4. IUCLID Latest news and & updates

EFSA presented an update on the status of various IUCLID support activities/material (administrative guidance, manuals and Virtual Tour of the MS); provided some recommendations to applicants and MS on dossier creation and processing; described the new "Contributor" role which will be added to the Dossier Header in the IUCLID 6.8 release and provides a new role in a Joint submission to be used e.g. when data are provided by means of a letter of access (i.e. not by an applicant directly); clarified the new Question number creation in OpenEFSA; described a new temporary solution to be used by applicants (and all other actors) in the context of attachments provided for consideration in the assessment report and provided an update on Report Generator activities.

Q&A

- **AT** asked whether the confidentiality request assessment must be carried out by the RMS on a consolidated dossier for a New active substance (NAS) dossier.

EFSA clarified that a second confidentiality decision is needed in case there were requests for additional data and new confidentiality requests. The recommendation is to carry it out at the end of the process.

- **AT** also asked whether the automated Question creation in OpenEFSA leads to one Question per substance, even in the case of joint submissions and provided an example in which the same dosier had two question numbers.

EFSA replied that the correct approach is one Question number per substance and that there may be cases of duplication if the applicant changed certain identifiers in

their dossier but these are fixed and the duplication is removed as soon as they are identified.

- **DE (BVL)** asked whether the new Contributor role can be used for submitting data on co-formulants too.

It was explained that, in the absence of formal data requirements and guidelines from the Commission on co-formulants, **EFSA** is not in a position to develop a tailored solution for co-formulants at this moment in time. However, the Contributor role can be used for this purpose if needed as it guarantees segregation of the data between the applicant and the formulator(s).

- **DE (BVL)** asked for clarifications on how/when the dossier subject field in a Question would be manually updated in OpenEFSA.

EFSA clarified that between the moment of first submission of an application and its admissibility, the Question would not be amended by EFSA. Upon processing the admissibility of the application, EFSA would also amend the Dossier subject as needed.

- **DE (BVL)** asked where Doc M, etc. should be attached in the dossier (if provided by the applicant as supporting material).

EFSA clarified that they should be uploaded to the « Summary and Evaluation » section.

- **DE (BVL)** asked clarifications on the NoS obligations of the contributor role.

EFSA clarified that if there are new studies commissioned or carried out after 27 March 2021, they will need to be assessed by MSs during the intake phase.

- **CLE** asked which data on co-formulants should be included in IUCLID.

EFSA clarified that the PSN IUCLID is not the appropriate forum for this type of discussion nor is EFSA best placed to reply. Until further guidelines are available, the Contributor role can be used as a temporary solution.

- **CLE** flagged that not all data included in Document M fits into structured data fields, therefore use of rich text fields is currently largely used but not reflected into reports due to technical issues with rich text fields. They also suggested to provide more specific instructions on the use of rich text fields (e.g. which field should be used for reporting info that do not currently have a dedicated IUCLID field).
- **EFSA** took note and clarified that the interim solution proposed is a compromise in view of improving reporting.
- **CLE** welcomed the interim solution for contributing to the assessment report as it will reduce the overall workload. They asked whether this would remove information from the public consultation and does EFSA expect getting fewer comments based on this.

EFSA replied that the information in these documents is not part of the data requirements (so it is not mandatory in a dossier) and summarises information provided in IUCLID. If taken into account by the RMS, it will contribute to the drafting of the DAR/RAR, which will be subject to a public consultation at a later stage. There is therefore no negative impact for the public.

- **CLE** asked whether a consolidated dossier is required at the end of the assessment/peer review even if no additional data requests were made and **EFSA** clarified that this was not the case and that a new dossier is only required if new data were submitted since the previous publication.
- **ECCA** asked whether dossiers for one substance will be merged into a single Question number on OpenEFSA and whether a Contributor must have a Legal Entity in IUCLID.

EFSA replied that dossiers for the same substance will share a question number and that the Contributor must always have a legal entity in order to submit a dossier.

- **DE (BfR)** emphasised that accessibility of attachments provided for consideration in the assessment report (e.g. Document M) should be ensured in published dossiers and that the data model, granularity and the readability/reusability of IUCLID content should overall be improved. This issue arises from a mixture of underlying OHTs and further data points introduced by IUCLID (e.g. annotations). As it is now, data cannot be reused as many free text fields contain data points and even entire free formatted tables. DE also raised concern about the use of Microsoft Teams mentioining that an EFSA reply in relation to concerns they had expressed at the 5th IUCLID meeting is still pending.

Regarding the accessibility/readability of the IUCLID dossier, **EFSA** reminded that ad-hoc training is available for the public in order to facilitate consultations (https://zenodo.org/records/7567722#.ZCw92HZByUk). Concerning transparency considerations linked to the proposed *ad interim* approach, EFSA pointed out that, first, the aim of the public consultation is to collect input on any missing studies not submitted for evaluation, and second, the non publication of attachments provided for consideration in the assessment report (e.g. Document M) will not impact on transparency as the information contained therein is reflected in the corresponding IUCLID records and summaries of the IUCLID dossier and is moreover considered in the preparation of the assessment report which is subject to a requirement of proactive publication in its own right. About the use of Microsoft Teams, EFSA committed to verify if feedback is still outstanding and, if so, to get back to BfR.

- **CLE** commented that a reference list would be useful in the IUCLID public instance so the public can be aware of which studies have/have not been included in a dossier without significant effort. Running standard reports on the public dossiers could also facilitate the process.

EFSA will explore whether it is possible to improve accessibility/user-friendliness of the public instance of the IUCLID dossier taking into consideration concrete suggestions/feedback received.

- **FR** asked which communication had been made concerning the commenting of the updated administrative guidance and a reference to EFSA's email of 8 January was posted in the meeting chat.
- *Post-meeting note: **FR** requested for EFSA to write that the commenting was sent to PSN members and not to the PSN IUCLID subgroup members (who are not always the same) despite the fact that several modifications in the guidance concerned experience gained with IUCLID over time. FR would have preferred the dedicated PSN IUCLID to be consulted. FR also noted that no target consultation was opened in Connect.EFSA for this topic.*

EFSA clarified that, on 8 January 2024 EFSA asked the PSN members for comments on the revision of the Administrative guidance, **before finalisation of the guidance and transmitting for notetaking to the PAFF Committees**. Considering that this document covers procedural aspects as well as aspects related to IUCLID, it was considered appropriate to involve the PSN and ask for a set of consolidated comments per Member State, where comments from peer review and MRL competent authorities were jointly provided. This consultation was run as usual through the PSN channel, as targeted consultations via Connect.EFSA were not yet established in the area of pesticides at the moment in which this consultation was launched. Furthermore, Connect.EFSA is currently used only for targeted consultations that are foreseen by

law. EFSA takes note of FR's comment and may consider the use of Connect.EFSA for future consultations on the update of the administrative guidance.

5. Updates on confidentiality and filtering

EFSA presented some points of attention for Applicants aiming at optimising the confidentiality decision-making process, e.g. in relation to the contact details, the use of automated redaction tools, the format of attachments and the justification. EFSA stressed the importance of complying with Article 9(4)(b) and Article 10 of the EFSA Practical Arrangements concerning Transparency and Confidentiality and recommended the use of the updated CBI justification templates from the User Guide on confidentiality. Moreover, EFSA also raised some points to the attention of Member States aimed at facilitating coordination, notably when requesting a resubmission. It was also recalled that, for NAS/modifications of conditions of approval, the RMS must consult EFSA on the draft confidentiality decision and should communicate the dossier's latest UUID.

On the activities of the filtering rules working party, EFSA presented the upcoming changes linked to the April 2024 release of IUCLID. It was mentioned that the Test Laboratory & Report number will be removed by default for unpublished studies in the Literature Reference Entity, that the 'reduced UNLESS_CONF' approach will be applied and that the auxiliary rules will be switched off in sections "Other" or "Remarks" in association with picklist. The new filtering rule for Analytical Methods was also presented, as well as the change to the filtering rules for Mixture legal entity (from PUBLISHED to UNLESS_CONF). EFSA confirmed that Document J is scheduled for removal in the April 2025 release, and the changes will only apply to new submissions made after April 2025. A "DAR Volume 4" report will be generated in support of RMS and the mapping of Document J elements to the fields in the IUCLID dossier will be made available in the Applicants toolkit by end of March 2024.

Q&A

- **FR** expressed concerns on potential delays experienced at the stage of dossier resubmission especially for renewal dossiers, would they have to contact EFSA to ensure that the confidentiality assessment has been finalized. **EFSA** confirmed that the call on RMS to coordinate with EFSA before resubmissions aims to ensure a better alignment, especially in the final stages of the confidentiality assessment process. **FR** confirmed that RMS will inform EFSA before asking for a resubmission and hold on the request should that not generate any unreasonable delay.
- **CLE** asked for clarifications on whether to place the data on impurities in a dedicated impurity dataset linked to the mixture dataset or to rely on the new filtering rule linked at the Endpoint Study Record level, currently only implemented for analytical methods, to ensure a correct reporting, especially in the context of Document J dismissal. **EFSA** reminded that as of April 2024 all data on impurities should be included in the dedicated document created for the impurities, including analytical methods. The manuals will be updated, and the Document J mapping will specify where the information would be taken when building the DAR Volume 4 report through the report generator. Clear instructions on how to deal with the removal of Document J will be provided to Applicants and RMS.
- **ECCA** informed that, within the confidentiality draft decision, some issues were encountered with the UUID hyperlinks. **EFSA** explained that UUIDs of literature references were included in confidentiality decision to facilitate identification of literature references concerned by a specific confidentiality request, including by

applicants. **EFSA** further specified that the hyperlinks provided are linked to the dossiers stored in EFSA Agency IUCLID meaning that Applicants do not have access so the literature reference UUIDs are provided to guide applicants.

- **ECCA** asked if co-formulants should still be indicated as a reference entity, and that no mixture should be created to define the composition of a co-formulant. **EFSA** reminded that as a temporary solution the new Contributor role can be used for data on co-formulants as from April 2024.
- **ECCA** asked about the meaning of non-significant impurities. **EFSA** clarified that non significant impurities are the impurities of no concern whose concentration is less than or equal to 1 g/kg.
- **IBMA** asked if a general justification could be provided for the confidentiality claims of studies containing only personal data. **EFSA** reminded that it is still necessary to identify page by page the personal data in the justification and earmark all the personal data in the confidential version of the attachment (and sanitise corresponding information in the non-confidential version) in order to allow EFSA to carry out a proper verification of the applicant's personal data claims.
- **FR, AT, ECCA** and **CLE** volunteered to contribute to testing Document J dismissal. **EFSA** will consider how to involve them in the process later on in the year.

6. IUCLID demo dossiers project summary

EFSA's contractor, GAB Consulting, presented the objectives and implementation of EFSA Tender NP/EFSA/FDP/2022/03. Based on objective 1, IUCLID test dossiers without confidential data were completed and delivered to EFSA for demonstration purposes. It was explained that each part of the IUCLID test dossiers was compiled and issues and areas of improvement were collected. In accordance with objective 2, comments to all available IUCLID manuals and generated reports were provided. Main issues flagged on the manuals were the length of the document and complexity of the presentation of the information. Regarding Reports, all possible templates were tested and bugs and improvements were collected. In addition, comments on general IUCLID improvement were provided. As an example, two critical documents were presented in detail with proposals for enhancement (Biological properties and Analytical methods).

Q&A

- **EFSA** clarified that issues with XML formatting have been solved with the latest IUCLID release. Regarding the equivalence of batches document, it was asked how this could be improved. **GAB** suggested that two options could be followed, namely improving the structure of the flexible record on identity or using the Report Generator to create a table using information reported in the "Test Material" field (provided that clear instructions are given to applicants on how to compile this field).
- **CLE** asked whether the test dossiers are going to be published. **EFSA** replied that this has not been decided yet and will advertise if it is decided to publish on Knowledge junction.
- **CLE** also supported the idea of improving the structure of IUCLID to allow adding the evaluation of the equivalence of batches.

7. Feedback from the M.O. working party

EFSA presented an update on the outcome of the activities of the working party of the IUCLID PSN subgroup on microorganisms. As a main achievement, the mapping of the IUCLID microorganisms Table of Contents fields to the Appendix I of the Explanatory Notes for the implementation of the DRs on MOs and PPP has been presented, including some relevant format changes that will be implemented in IUCLID 6.8 format release. Also, an update was given about the decision of the working party via a dedicated survey to reintroduce a series of IUCLID documents to report short-term toxicity studies in the table of contents of the ecotoxicology section (in both the active substance and the product datasets), previously removed in IUCLID 6.7 release. Finally, the group was informed that the activities of the working party will be put on hold following a closing meeting to take place in the upcoming weeks. The activities will subsequently resume to keep working on the other goals of the working party, i.e. to propose the presentation of information by report generator and to provide recommendation for presentation of information in specific areas (e.g. microbiological consortia).

Q&A

- **IBMA** asked clarifications about the decision to reintroduce the documents in the ecotox ToC, acknowledging that additional time was given to the working party members to vote on this topic.

EFSA confirmed that the survey was extended and that additional votes were received. The overall results, taking into account the additional votes, were in favour of the reintroduction of the documents.

- **IBMA** asked EFSA to provide clear instructions on the use of these documents in an updated manual. **EFSA** took note.

8. IUCLID format: harmonisation and changes

EFSA presented the main format changes that will go live with the IUCLID format release in April 2024. EFSA announced that new fields will be introduced in the GAP document to report the concentration of the active substance and 'other active substance' in products applied after dilution with water. EFSA also stressed the importance of using the GAP table template generated via Report Generator to compile the Assessment Report to ensure data in there is consistent with the data submitted in IUCLID. In addition, a few format changes identified by the Working Party on Microorganisms were also presented. Regarding the Validation Assistant (VA) tool, EFSA presented new VA rules which will be available with the new release of IUCLID. Details on VA rules can be found in the following file PPP Validation Assistant Rules_April2024.xlsx. An update was given on a recent activity successfully carried out by ECHA to recover data loss occurred last year with the IUCLID release of May. EFSA also gave an update on the status of the analysis to migrate data from 'obsolete' EU_PPP summaries to the OECD Harmonised Templates and informed the audience that options for migration will be made available for stakeholder consultation.

9. Any other business

No AoB were discussed.

10. Feedback from Industry Representatives

IBMA gave a presentation on issues encountered when reporting information on secondary metabolites in IUCLID dossiers on microbial active substances. In particular, IBMA highlighted that implementing the list of secondary metabolites resulting from stage A of the SANCO guidance document on secondary metabolites (SANCO/2020/12258), i.e. to include the metabolites as substance or reference substance in the dedicated documents (as agreed by the majority of the working party on MOs members), is very time/resources consuming. IBMA asked for MSs support to change the order of the steps in the SANCO/2020/12258 guidance, i.e. to use WGS data earlier in the process in order to exclude the production of secondary metabolites of potential concern, not including these metabolites in the dedicated document in IUCLID.

Q&A:

- **EC** clarified that it is not possible to currently amend the technical aspects of the SANCO guidance on secondary metabolites. In addition, it was clarified that the guidance is not legally binding and that it possible to use WGS data to exclude the production of a metabolite. Nonetheless, there is the need to report this information in the dossier, to allow the evaluators having the complete picture of the assessment done by the applicant on the metabolites.
- **EFSA** clarified that other documents in the dossiers should be used to provide a summary and conclusion of the assessment performed by the applicant on the secondary metabolites.
- **ECCA** suggested that the creation of a database of secondary metabolites to be imported in IUCLID as reference substances can help in filling in the list of secondary metabolites under assessment in the dedicated IUCLID document

11. Non-paper on possible options for obtaining studies submitted in previous dossiers

The European Commission presented the agreed approach for obtaining studies submitted in previous dossiers as reported in the published "non-paper" document https://food.ec.europa.eu/document/download/42baea1e-80b2-4668-84e7-ff752d5c09a5_en?filename=ppp_app-proc_guide_basic_renewal_non-paper.pdf.
Two main options were presented. First option foresees that RMS manages the process directly, while second option is based on the involvement of one consultant. Regarding the timelines, it was clarified that the agreement should be sought ideally before notification of studies allowing sufficient time to reach an agreement with data owners.
It was also highlighted that the admissibility of the renewal application should not be precluded if certain studies cannot be submitted. EC reminded that Member States may also develop or use other possibilities to make studies available - the non-paper can be reviewed and updated in the future.

Q&A:

- **ECCA** asked clarifications on cases for which UK was the original RMS.

EC clarified that no particular issue is foreseen because the newly re-assigned MS will take care of the request.

- **AT** asked how can the potential applicant know that the original applicant is no longer supporting the renewal. **EC** replied that the new applicant should anyways

contact the previous data owner to undertsnad they are also supporting to launch negotiation. EC will monitor if there is need to set something different and invited AT to raise any point at PAFF or bilaterally with Sante.

- **CLE** highlighted that for small Companies and in case of a large data package 30 days may not be sufficient to reach an agreement. **EC** noted this points and replied that the non paper is not legally binding, it gives guidance and that flexibility is foreseen for non-standard cases.
- **DE (BfR)** asked clarifications on cases for which ownership of studies changed from first approval. **EC** confirmed such cases may happen and normally Applicants should have this information. For cases where this information is not known, a collective affort shall be made to find solution if such issue is experienced. BfR pointed out that an in-house database for all studies ever under BfR usage exists, as BfR works under the paradigm of One Substance One assessment since >10 years.

12. Feedback from MSs

Presentations were given by **FR**, **DK** and **DE**.

FR reported feedback on Report generator. General issues and specific problems with the phys-chem and analytical methods section of the generated reports were highlighted together with proposals for improvement.

Q&A

- **CLE** confirmed they also experienced loss of information in the generated reports in few cases. On Analytical methods CLE highlighted that, as the OHT format changed recently, older dossiers appear empty and this impacts the quality of the generated reports outside of applicants control. It was also flagged that the labelling of the IUCLID fields is sometimes confusing (e.g. "key value for Chemical safety assessment") and this prevents compilation from experts.

EFSA took note of the issue with loss of information. Regarding dossier compilation, it was reminded that MSs should take the opportunity to ask Applicants to amend dossiers during the Admissibility check phase. It was also flagged that some reports (including future reports such as the List of Endpoints) can help both applicants and MSs to check if key information is provided in the right place in IUCLID. On aggregated reporting EFSA confirmed that this is not possible at the moment, but this will be further explored with ECHA.

- **ECCA** asked to clarify when EFSA plans to make available templates for Report Generator to avoid double work by applicants. Indicative timelines were provided under presentation nr 4.

DK reported that filling in of information such as details from QSAR analysis is often missing and that it is not easy to find information provided upon presentation of a letter of access.

Q&A

- **EFSA** replied that both issues were addressed by presentations 11 and 13.

DE (BfR and BVL) reported issues with Notification of Studies, GAP document and Report Generator. On validation rules it was flagged that stricter rules are needed to improve quality of dossiers submitted by Applicants. DE also asked clarifications on

how to report information on co-formulants. Feedback on the survey on re-use of data and annotations were also presented.

Q&A

- On NoS, **EFSA** replied that, in accordance with the Practical Arrangements, the pre-application ID is a mandatory field, however, this cannot be made mandatory in Salesforce/Connect EFSA for two reasons: first, laboratories who can notify studies do not have access to the PA-ID created by the applicant, secondly, it may happen that a study is planned even if it is not initially clear the scope for which it will be used, so it is not possible to assign a pre-application ID. EFSA clarified that linking is important and if not present, applicants should be asked to correct it. It was also reminded that once linked, the pre-application ID cannot be removed. Regarding the proposal from **DE (BVL)** to not assess a study not linked to a PA-ID if the study is not included in the submitted dossier as the information included in the NoS database is insufficient to take a decision about the relevance of the study, **EFSA** acknowledged this point, but limiting would not be useful for NoS check and would not be in line with what is done for non-pesticides areas. EFSA also agreed that RMSs are responsible until what is declared upon admissibility. MSs were reminded to check the available document developed for NoS to refine the wording if needed.
- On the issues encountered with the GAP document, it was confirmed that such issues have been experienced also at EFSA level when assessing MRL applications. It was acknowledged the fact that EPPO codes (used for crops) and MRL codes (used for commodities) are not easy to match, and this can be confusing for applicants. It is noted that BfR already provided a mapping between EPPO codes and MRL codes to EFSA, however this mapping is not yet sufficient to implement validation rules. EFSA therefore proposed to progress with the creation of a flat mapping between the EPPO codes and MRL codes, with further collaboration with BfR. This way also more sophisticated validation rules could be directly implemented in IUCLID.
- Regarding Validation rules, **EFSA** reminded there are already validation rules checking that the correct endpoint is picked and aim is to progressively convert warnings into blocking business rules. Nevertheless, DE's proposal to develop more rules to avoid that Applicants fill in the wrong field/document was noted for further consideration.
- On co-formulants, **EFSA** reminded that currently there are no data requirements and EFSA is still waiting for guidance from EC, therefore no tailored solution is available under the current circumstances. Nevertheless, there are 2 technical solutions in place to allow submitting data whilst ensuring confidentiality between the applicant and the supplier of the co-formulant, namely inherited templates and the upcoming Contributor role.
- Regarding Text Analytics, **EFSA** replied that further details are provided under Agenda point 13.
- On the use of Annotations, it was clarified that the ongoing pilot phase (limited to MRL dossiers) aims to improve the template allowing MSs to speed up the evaluation process via automated generation of the final report.

The testing phase is not a commitment to implement the use of annotations. Based on the outcome of this exercise further discussion will take place at next IUCLID PSN meeting and a shared decision will be taken.
In addition, no workflow is established yet, because the use of this tool is new.

- On issues with Modification history not appearing, **ECHA** clarified that the full modification history can be included when creating/exporting a dossier, but this is an

option to be chosen by the applicant. The minimum that is always included is the last modification date/time.

- **DE (BfR)** flagged that IUCLID PSN Terms of Reference still refer to IUCLID as MVP. **EFSA** took note and asked DE to make comment via National FP to proceed with amendment.

ACTIONS

- **EFSA** to further explore with ECHA the generation of aggregated reports
- **EFSA** to investigate if changing labelling of key values fields for PPP working context is possible, otherwise further explain in the Manual.
- **DE (BfR**) to include specifications for refinement of validation rules regarding *in vitro*/*in vivo* studies on the file available for IUCLID PSN members: "Validation Rules_backlog.xlsx"

13. IUCLID Format: results from the IUCLID date re-use survey

EFSA presented the results of the survey on IUCLID data reuse for risk assessors, which was launched on 19th December 2023 to gather feedback from Member States and EFSA staff on their use cases and needs. The survey was primarily aimed at identifying areas to focus on and at addressing any potential requests for improvements. The results of the survey show that all the listed IUCLID tools (i.e., Data Extractor, Data Uploader, Text Analytics and Report Generator) have been used by at least one participant. Overall, the majority of participants would appreciate EFSA to further improve the aforementioned tools to facilitate the risk assessment of pesticide data in IUCLID. Extensive feedback and requests for improvements were provided for Report Generator. All suggestions will be addressed and prioritised as needed. The majority of participants would be willing to collaborate with EFSA to improve IUCLID tools, with a focus on Report Generator and Data Extractor. Those participants which are in favour of collaborating with EFSA will be contacted soon. The complete list of feedback and comments received was made available in Annex I, which can be found attached at the end of the presentation.

Q&A

- **DE (BfR)** asked as to why it was initially requested to have a consolidated answer per Member State, when the results were presented in a way that suggested answers from individual people. It would help in the future to either collect data in a format that is suitable to create consolidated answers or to have individual answers, and aggregate those when a consolidated view is required E.g. calculating an average of weightings is easily possible. The wording on the slides was: "Which of the following roles best describes you? National government official/EFSA's contractor/European institution employee/official" This does not reflect submission in an aggregated way per Member State as originally requested.

EFSA replied that the results were presented in an aggregated way. The survey was conducted at MSCA level rather than at organisation level in order to have alignment and a clear vision within the MSCA on what is needed in terms of tools to support the risk assessment in the near future and to prioritise further development at EFSA level.

- *Post meeting note **DE**: different authorities within one Member State can have very different requirements, e.g. BVL coordinates assessments while BfR (and others) conduct assessments. BVL has a dossier centric view while BfR assesses substance centred (under the paradigm of one substance one assessment).*

14. Any Other Business

No AoB were discussed. Next meeting will be held on 11-12 June 2024