FEEDBACK FROM MEMBER STATES
IUCLID PSN MEETING
29 FEBRUARY 2024

EUROPEAN FOOD SAFETY AUTHORITY

FEEDBACK FROM DE

Admissibility Check: NoS Check

- In recent times, the data extracted by EFSA from the NoS database includes also notified studies without a Pre-Application ID and which are not included in the submitted dossier.
- Challenges dealing with these studies during the admissibility check and beyond. According to the checklist this is not permitted:

  > „A Pre-Application ID must always be notified prior to initiating any pre-submission activity e.g., study notification.“

- The applicants point out that for some studies it is still completely unclear whether and if so in what procedure they will be submitted for the first time in the EU, so the allocation of a dedicated Pre-Application ID is not always possible.
- It is acknowledged that the applicants need to make changes in the NoS DB, to update the information even after the finishing date of a study and to add a study to a different/new Pre-Application ID if needed. At the same time, this possibility might be misused to circumvent a direct assignment of studies to an application process.

FEEDBACK FROM DE

Admissibility Check: NoS Check

- It is difficult for the EMS to decide if a study is relevant or not for an application for studies which are not included in the submitted dossier based only on the title given in the NoS DB. Expert judgement and contact with applicant are needed.
- For many studies, the decision, if a study is relevant for an application or not, can be made by the EMS only if the study is available and after the evaluation of the study. For the admissibility check, the MS can only rely on the information given by the applicant.
- As such, in our opinion, the notified studies without a Pre-Application ID in NoS DB and which are not included in the submitted dossier should also not be included in the data extracted from the NoS DB. Therefore, DE will not assess these studies without the respective Pre-Application ID during the admissibility check, since their relevancy for the application cannot be concluded during the admissibility check.
- In addition, differences between data extracted from NoS DB for different versions of the same dossier has been observed.
- The EMS can be responsible only to check the NoS status as submitted by EFSA for the version declared admissible.
- For changes in the NoS DB after this (e.g. if the applicant removes or adds studies to a pre-application ID), the EMS cannot be held liable.

FEEDBACK FROM DE

Admissibility Check: GAP

- The applicants still struggle with the correct submission of the relevant GAPs.
- According to Article 3(2)(a) of Regulation (EC) No 396/2005, the GAP describes the **intended or registered safe use** of plant protection products, and not the GAP of the residue trials.
- The GAP list needs to include all the crops, for which an MRL is applied for.
- The GAPs should not include the crops from which the residue data is extrapolated, if no MRL is needed for those crops.
- The applicants have difficulty to choose the right crop form the picklist or the right code for groups. Some EPPO codes have other names as the commodities included in Annex I of Regulation (EC) No 396/2005 or the crop lists of the MS. Also some crops have also assigned the corresponding food code of the MRL food classification (code of Annex I), some don’t.
- For some crops, more than one food code is assigned, but only one of the codes is actually applied for.

FEEDBACK FROM DE

Report Generator:

- The documents M and N generated with “Report Generator” still exhibit many problems: information snippets are missing or misplaced; tables are distorted or displayed as plain text; wrong labels; broken layout; cryptic error messages.
- Germany has noticed that not all summarizing documents N (N1-N5) can be generated yet and that the documents M do not cover all the expected content that was contained in documents M submitted by applicants prepared independently from IUCLID. Currently, the content of the documents created through the Report Generator is insufficient and this tool has to be improved. Especially the documents N1 with the overall conclusions and N2 with the endpoints are necessary. In the document M CA Section 3 “Further information“ and the document M CP Section 6 “Efficacy data generated” generated with the Report Generator in IUCLID, chapters should be added according to available templates.
- The quality of the reports is FAR below the current quality of the dossier and the evaluation authorities are not being able to make a final risk assessment based on them. E.g. it is not possible to answer the question "is this substance/product high or low risk in your assessment area" based on the generated reports. The number of required changes is so high, that a point by point list seems not expedient. EFSA should refer to the many documents available from previous procedures.
- Due to the low quality of the generated reports, Germany still relies on documents M and N to be submitted by applicants outside of IUCLID.

FEEDBACK FROM DE

Validation rules so far do not find relatively simple problems in dossiers:

- Wrong OHT used (e.g. an in vivo study is submitted in an in vitro template)
- Screenshots used to fill in tabular data into a free text field
- Proposed solution:

– There should be rules defined in a way that increase the chance to check if the correct OHT was chosen, e.g. working with regular expressions could already help a bit (having less free text fields and more granular data would make this of course easier).

– Screenshots/Images should not be allowed to fill fields of an OHT in IUCLID, except for very special cases (e.g. structural formula, graphs or process/metabolism schemes).

– It needs to be discussed, in what places images are really required. For the three given examples good examples for textual representation exist (InChI/SMILES/IUPAC-Name; Data and R-Code; Mermaid source code) which would allow better versioning and data reuse.

– Have more granular data format to allow proper information processing

FEEDBACK FROM DE

Composition of co-formulants:

- The composition of co-formulants is usually not available for applicants due to confidentiality reasons but has to be considered for the assessment of the formulation.
- In the past, manufacturers of co-formulants provided this information directly to the RMS or within zonal applications to the zRMS.
- As EFSA asks meanwhile for the evaluation of co-formulants used in representative formulations, the question arose how this information, not only confidential for the public but also for the applicant, will/can be included in IUCLID and made available to the MS. This information most of the time cannot become part of the applicants dossier. Will there be a special dossier/dossiers? How will this process be organised?

FEEDBACK FROM DE

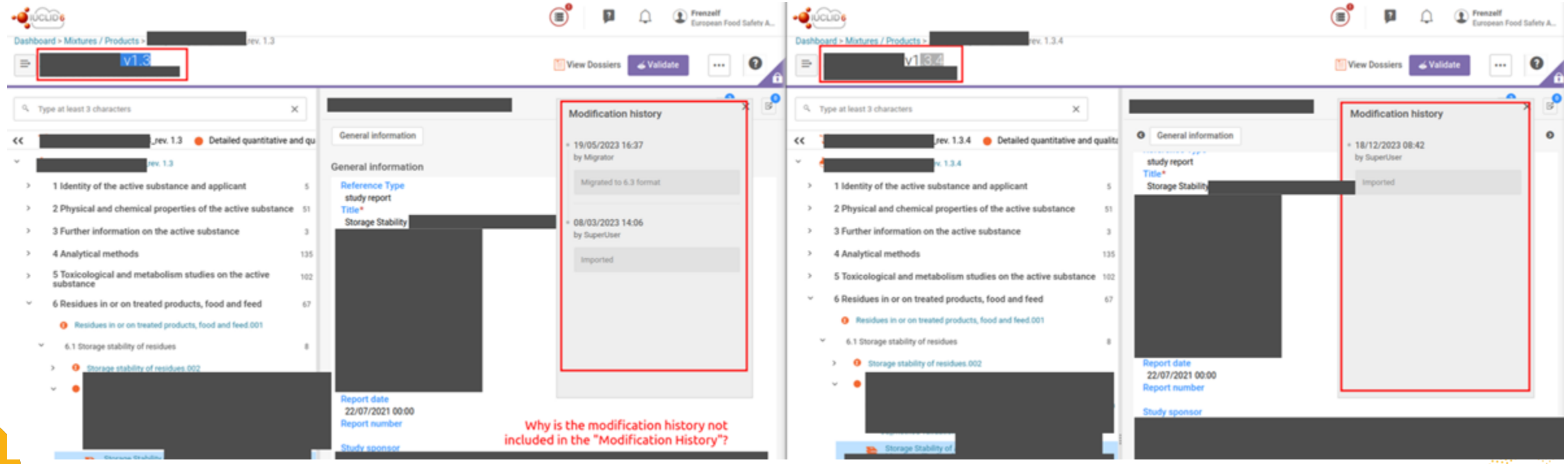
Tools for data re-use and search:

- Technical possibilities of tools for data reusing (Data Extractor and Text Analytics) are inadequate documented on the ECHA-IUCLID website. What is the current project status? Is it planned to add these tools in EFSA Agency IUCLID for IUCLID Central Submission System?
- To evaluate business values of these tools it is necessary to get an appropriate overview of the functionalities, e.g. through presentations, comprehensive documentation and access to trial instances of the tools -> what are EFSA's plans regarding this?

FEEDBACK FROM DE

Modification History

Why is the modification history not included in the Modification *history*?



FEEDBACK FROM DE

Evaluation in IUCLID-Dossiers with the help of **annotations**:

- Using annotations in IUCLID PPP Assessment Framework is currently not fit for purpose. The intention is understood by DE but current implementation –as seen in biocides– does not enhance the assessment workflow. Annotations in IUCLID do not support substitution rules or grants annotation modification rights to user groups or user subgroups. At the moment anyone with rights for annotations can change annotations. Especially since all users work as “EFSA-Members”.
- Prior discussing the release or testing of annotations in PPP, one should define the envisaged usage in assessment procedures according to workflow steps. The capabilities of the current implementation need to be checked carefully accordingly. Those steps are crucial for proper feature implementation in order to avoid risking a system collapse. As EFSA proposed usage, EFSA should propose a detailed workflow, so MSCAs can comment if this can be implemented or what legal requirements have to be accommodated.
- DE had asked for but didn’t receive the required information during testing. Before more time is spent or requested on this, the envisaged processes have to be defined (as suggested in the written feedback submitted).

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