5th PSN IUCLID sub-group meeting

05 December 2022

FEEDBACK FROM MEMBER STATES

MSs representatives

Trusted science for safe food

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Feedback from [DE]

- Could we establish (more) exchange of first experiences on dossiers submitted using IUCLID, for specific stakeholder groups e.g. risk assessors esp. in PPP area, how/where?
- Was there any wrap up of the hypercare and IUCLID core meeting on closing the IUCLID implementation? If it happened it went by us, then please share material regarding this

Feedback from [DE]

- Proposal: At the last Meeting feedback on report generator (see report generator backlog) was requested. MS gave several suggestions. However, there was no feedback on the state of play of those issues, similar status applies to the general IUCLID backlog.
- At the report generator workshop at ECHA and during the IUCLID OECD Meeting it became known, that the templates are maintained at a GitHub repository.
- ***This highly appreciated.*** As it is possible to provide issues there, it might be a better and more interactive to moderate issues at this location, instead of an Excel-sheet.

- It might help to move towards having GitHub issues to communicate issues with the report generator-templates. This could serve as a test, if it is feasible to move into such a tool for the general IUCLID-Backlog, e.g. to discuss general issues, that are faced with the first experiences on dossier submission.
- Also other people can see, what questions have been asked. This works towards a community driven knowledge base.

Feedback from [DE]

- As follow-up to the 28th PSN-Meeting (October 2021), it was stated

  "DE is invited to share by 31/10 their draft/extract of the EU-RAR template following their work started at MS level to address eventual shortcomings of the current template (e.g. administrative nature / formatting issues etc) for distribution to PSN members and to avoid parallel work.")*

*the templates were provided, but a contact person is required to address certain issues. So far, we haven't heard back (might have been lost in translation :-))

Proposal:

- Since there is >10 a of in-house experience with templates and report-generator is a great tool, we would like to **create IUCLID report generator templates that** gather the information in IUCLID-Dossier(s) and **create a** basically **filled RAR/DAR-Template**

- Advantages
  - Less copy pasting
  - Less work on formatting
  - Increase in preparation of assessment work
- What are we missing?
  - We might be naïve to some issues**
  - What kind of features would you like to see implemented?
- Would you like to join?
  - Then we would actively invite you to the repository, once we start

Feedback from FR

- We would like to have some information regarding the public consultation on MRL dossiers as the results of this consultation need to be integrated in the ER, according to the administrative guidance.
- The public consultation on the dossier is launched for 3 weeks, but for the time being we have no insight on the starting date of this period, so that we cannot anticipate the date when the information will be available.
- Is there a timeframe that EFSA has foreseen to make a dossier available for the public consultation?
- Also can EFSA explain where the results of the consultation will be available and how EMS will be informed on it (we have seen a folder on EFSA DMS, will EMS receive a notification when consultation will be opened / closed?).
- How can EMS anticipate launching of public consultation by EFSA and availability of questions to be answered in the annex?

Feedback from NL

Regarding re-submission of a dossier for m.o. after the first admissibility check we received the following feedback from the applicant:

The **new IUCLID release version (Oct. 2022) is in place**. This is a **different version to the one used for the initial application submitted in June 2022**. The dossier structure (table of contents) for microbial active substances/ plant protection products (data set) has been changed according to the new data requirements for microbials, which would only become mandatory in May 2023 and which would not be applicable for this application.

Therefore, we would like to inform you in advance that -when the updated IUCLID dossier will be done to address the points from the admissibility check, and submitted via the official submission portal-, **it is expected that the IUCLID dossier that Ctgb will receive will differ significantly from the initial version. Initial testing in the ECHA cloud suggests that various data points from several sections will be assigned to new data points or will be moved to other places, e.g. into the new section '11 Previously used documents now obsolete, kept until April 2024'**. As a consequence, **the numbering of data points in the new IUCLID dossier version Oct-22 will not correspond anymore to the relevant legislation or to the numbering used in the SANCO-format Summary Dossier**.

How should the applicant be advised? Is it for the applicant to get access to an old version of IUCLID?

Feedback from NL

Ctgb extracted a validation report from IUCLID and asked the applicant to either resolve the rules or to provide justifications in the VA report in Excel format and add the VA report in Excel format to the IUCLID dossier.

Ctgb received the following response:

I am not able to reproduce the validation report you sent me. We are now using : IUCLID 6 version 6.19.0, build of 17/06/2022 16:08. It would be helpful to know which version CTGB is using, is that something you could share with me?

The versions we get are managed by technidata for us, and I know sometimes a cloud version is updated earlier. Each time updates are made, also the warnings seem to change. For example, I entered the notification ID as [redacted] and did not get a quality warning, and I still do not get one. But now there is a warning in the Excel you sent me that says it should be written as [redacted]. These changes in what is flagged make it very difficult to address everything.

Ctgb is using IUCLID 6 version 6.27.2, build of 04/11/2022 01:46.

According to the applicant the version 6.19.0 is the last stable version they have access to.

How should the applicant be advised?

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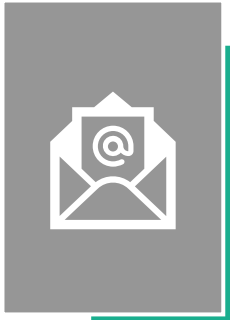

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