IUCLID Feedback: Industry Perspective

Monika Bross (BASF), Andrew Whyte (ADAMA)

IUCLID PSN meeting – 31 January 2022

Submission Backdrop

IUCLID Software – Release of future versions

- **Release cycles**:
  - 7th of February 2022 - intermediate release
  - 25th of April 2022 - service release
  - June – July 2022 (ECHA Cloud Services) - intermediate release
  - 31st of October 2022 - service release
  - 25th of April 2023 - major release, including format changes
- **Positive:**
  - Significant format changes announced very well in time
    -> change of IUCLID documents (e.g. OHTs) in April 2023
  - Release notes available for the February 2022 release
- **Unclear:** Changes in validation and filtering rules

Our expectation: Early information of changes, comprehensive testing prior to official releases (with stakeholder involvement)

Submission Backdrop

IUCLID Software – Questions on validation and filtering rules

- When are ruleset changes planned? Is this aligned with the release cycles above or separate?
- What are the transition periods for any ruleset changes? E.g. how long are they treated as info/warning only and do not prevent a submission.
- How can planned ruleset changes be tested / evaluated by industry prior to the date when they are made effective?
- How is ECHA / EFSA is planning to deploy changes to the different rules (validation rules, filtering rules) for “local” installations, when they are to be effective outside of the major release cycle? Are these patches or full installations?
- How can a user see for a specific IUCLID installation, what rulesets are applied? (assuming that they are versioned differently from the IUCLID format and the IUCLID software).

Submission Backdrop

IUCLID Software – Questions on validation and filtering rules (cont.)

- Several validation rules can not always sense fully be fulfilled and need significant improvement
  e.G. QLT PPP 027, QLT PPP 009

Our expectation for further development of filtering rules (Doc. J): Set-up of a dedicated subgroup with company experts, MS representatives and EFSA / ECHA

Our expectation for further development of validation rules: Set-up of a dedicated subgroup with company experts, MS representatives and EFSA / ECHA

Our expectation for further development of IUCLID: Validation rules are dynamically displayed on a working context/dataset level upon information input

Submission Backdrop

IUCLID – Admissibility and submission check

- Experience with the new process indicates that there are several checks resulting in delays and additional resource demands at notifiers and the RMS / EMS:
  - At submission: IUCLID validation check
  - Study notification (NoS ID) (EFSA)
  - Actual dossier check for completion (RMS or EMS)
  - Confidentiality / CBI (EFSA except for NAS)
- For many dossiers, the outcome of the checks results in an upload of a revised dossier version causing validation failures in case of version updates. The dossiers seem to continually require updates by the release of new versions.

Our expectation: The process should be driven by the applicable Regulations and not result in delay.

Submission Backdrop

IUCLID Software – Confidentiality checks

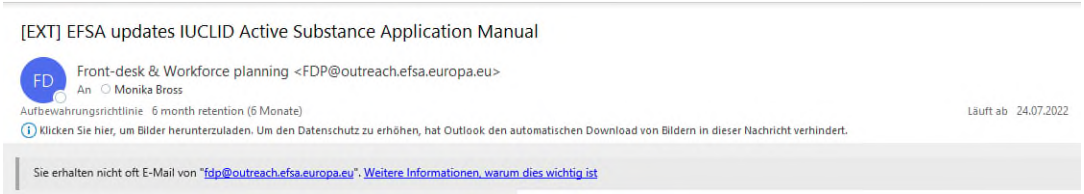
- Unclarity about need of confidentiality claims for data related to GDPR
- Confidentiality Claim setup for attached documents leads to repetitive entries difficult to review -> significant improvements needed
- CLE notes the revised active substance manual and would fully welcome an addendum to the manual fully outlining applicant responsibilities

CLE Proposal: Work either with a central IUCLID document with cross-referencing or use “old” confidentiality claim tables in pdf.

Submission Backdrop

IUCLID Communication and Guidance

- **Positive: Email notification on changes, establishment of a LinkedIn Group**



- **Room for improvement:**
  - Better documentation, especially a good delta documentation that you can hand over to experts and that are mainly domain-centric / entity-centric
  - Delta documentation of format changes to be published well in advance of new release, according with status (etc. planned, agreed, …..)
  - Transition period between publication and put into force
  - Online knowledge base that is searchable (e.g. preferably not as MS Teams chat)

Submission Backdrop

IUCLID Communication and Guidance

- **Room for improvement (continued):**
  - Improved knowledge management - Relevant information not distributed between many sites (Zenodo, EFSA, ECHA, OECD One), rather in one resource
  - Better online FAQ, updated as needed, with info tagged according to the release it applies to
  - Improved organization of backlog or agreed format and functional changes, currently it is hard to search for suggested / planned changes of a specific document or domain, because there is too much free text
  - Instructions for the csv functionality (version 6.6)

Submission Backdrop

IUCLID moving forward – Suggestions for improvements

- IUCLID will require further and significant changes before adding most of its potential value and being fit-for-purpose for crop protection submissions. For making IUCLID work, further changes are essential.
- One important goal would be to improve the user-friendliness for people entering data into IUCLID. E.g. by
  - Electronic transfer of data into IUCLID
  - Improvement of Metapath (part of the MUG)
  - Cross references between different datasets
  - Consistency of drop-down lists
  - Removal of character limitations in rich text fields
  - Removal of limitations in the selection of study types
  - Residue section 6.3 (and others?): Drop down list for selection of GAPs
  - Improvement of the functionality for validation check (substance level) by inclusion of dynamic tools
  - Inclusion of more comprehensive errors messages
  - Display of the study No. (company identifier) in the literature references