IUCLID Feedback

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Overview of IUCLID

- IUCLID is a key software application (database), fit for the regulatory (re-)approval of Pesticides (Regulation 1107/2009) in analogy to other European Regulations as REACh or Biocides for the european market.
- It is an advantage to have in one chemical database (designed for regulatory purposes), chemical data information that can be archived, reused, transformed, and shared between companies, consultants and authorities to fulfil the respective requirements for the inclusion/renewal of active substances and potentially(?) for registration of plant protection products (dossier).
- The adoption of IUCLID to submit dossiers, has required from authorities and industry a huge effort, going beyond the technical/scientific knowledge:
  - Training for all users involved (level: new, intermediate, expert): software
  - Training (dossier creation: relevant cases): technical work
  - Training for confidential data/CBI justifications
  - Training (regulatory process: dossier submission, resubmission, updates, dossier defence, commenting phase, etc.): regulatory work
- Time and cost for dossier preparation has increased significantly.

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Organization of Information in IUCLID

- Table of contents is intuitive for each regulatory purpose
- OHT templates are fits for purpose. New OHT templates should be added or be modified (as example UV spectra).
- Some points are not clearly defined:
  - Level of summary details (study records, overall summary record, flexible records)
  - The use of information in some entities: for example change log.
  - Confidential information datapackage: actual Doc J
  - Task forces and LEO´s
  - Risk assessment
- For some Chapters of the dossier, IUCLID has to be tuned or amended in order to fulfill the current regulation data requirements (with the consequent need to upgrade the software).

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IUCLID dossier writting

- The existing IUCLID manual is focused on filling OHT cells, flexible records. The manual should have examples and screenshots, as the biocides and REACH manual have, and a pathway to explain how the different entities are linked, to be able to generate reports as EU dossier templates (Doc M´s, L, N´s, etc). It should be clarified if the dossier format as stated in SANCO/10181/2013– rev. 6. is mantained or is going to be modified.

- Improvement for some tecnical aspects:
  - Rich text fields better than plain text fields in some cases
  - Data uploader is a must for complex tables, example PEC values, etc. But this approach can be difficult for small/medium companies.
  - Issues when you refer data of studies for active substance/product to be summarized in datasets
  - Table of contents tree: below the literature reference for each study record to add the study report number
  - Is it technically possible to add a submask in IUCLID to show only OHT fields relevant to EU evaluation when you select the specific “working context”? New users have issues to summarize the fields and extent of details at each summary record/overall summary/flexible record.
  - Cloud/server versions sometimes does not fit (delay of implementation/testing vs dossier submission)
  - Although IUCLID is a flexible application software, some information is difficult to be allocated at the database. Therefore, if later this information is required in order to generate automatically a document, the reallocation will be necessary, for example attchments, new points at ToC, etc.

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Reports overview

- Powerful tool
- Is not clear sometimes how the data is extracted to configure the format and the specific document layout, paragraphs, etc. User must have intermediate/expert knowdledge to view the code and understand the logic behind.
- Actual IUCLID reports does not fit one to one to the current EU format dossier documentation. Therefore, it is necessary to clarify the position of MS´s and EFSA on what is required. We understand that the idea is to be able to generate EU dossier format (or to be modified) directly from IUCLID and not to attach at the database documents made by hand and poorly detailed summaries in IUCLID only refering to the specific M document, etc.

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IUCLID Data submission

- Problems during the implementation of IUCLID since March 2021 were solved with the support of EFSA.
- Required to have a more detailed guidance with representative cases/examples for dossier submission/resubmission and specific for task forces dossier submission, or when data for active substance and plant protection product belongs to different companies. Dossier header data
- Issues for resubmission dossiers if the rules for the validation tool change between dossier updates or further requests.
- No possibility to submit dossier if the plattform is under mantainance. Timelines are very tight if any technical issue occurs.
- It is a good improvement that we can view the progress of the data file upload (percentage of completion)
- Expected communication plattform similar to R4Bp3 (Biocides) in development or in the pipeline?

Major and Minor changes to the IUCLID format

- Required to have a roadmap in advance of the implementation of changes related to pesticides registration and how this impact the existing datasets:
  - Technical (new points, new OHT templates, new Business/Quality rules, links, etc)
  - Submission plattform
- The time granted to implement the changes is sometimes not enough, considering the deadlines given for the reply, due to the complexity and/or the season of the year.

Confidentiality issues

- Massive work for industry
- Increase the workload for the electronic dossier writting and finalization/QAU of dossier for submission.
- Guidance with representative cases and screenshots should be issued, to harmonize the process and requirements.
- Verification is promoting bottlenecks.
- Flagging and plain text field is not useful when redacting complex justifications, redundant (study summary, field text record, K file)
- Major issue to define confidential data at the whole dataset, to avoid that for technical issues, the confidential information is released through the filtered dossier to the public.
- Confidential filtering should be tuned and a compromise should be established when we have bordeline cases.

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Conclusions

- IUCLID is a useful database and was designed for regulatory purposes. Experience from REACh and Biocides is available.
- Chemical data can be easily transferred for different regulatory purposes:
  - Move from a diferent regulatory geographical area context (OECD approach)
  - Move between regulations (REACh, BPR and Pesticides)
  - NAS/AIR to dRR´s
- If the electronic datasets contais good quality summaries and information:
  - Traceability (Transparency)
  - Fast admisibility
  - Electronic sharing
  - Archiving
  - Fast dossier documentation (for example reference list, representative batches)
  - Issuing Commenting tables, monography
  - Reuse data (common metabolites, etc.)

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