IUCLID Feedback: Industry Perspective

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State of Play

- **CropLife Europe welcome the PSN subgroup initiative to further enhance the IUCLID platform for PPPs**
  - Our Member companies against difficult circumstances managed to submit up to now all renewal dossiers via IUCLID before the legal deadlines
  - We would like to thank EFSA and ECHA for the Hypercare programme and their proactive and timely responses to industry issues observed with regards to the submission portal
    - In particular, Members highlighted; *Jane Richardson (EFSA), Chiara Macchi (EFSA), Edoardo Carnesecchi (EFSA), Slav Kissov (ECHA)*
  - Our Member Companies have been significantly involved to date (*IUCLID TG, Hypercare*) in progressing towards a “fit for purpose” IUCLID platform for PPPs and are pleased that this may continue

Submission Backdrop

The IUCLID Software

- Significant workload in very short time period after Entry into Force amidst developing information and via partial testing on a small dataset (*Clodinafop*)
  - Some features such as validation assistant create additional workload to overcome a technical rather than scientific ruleset *e.g.*;
    - QLT_PPP_09: No sanitized version should be required if the key study is a publication itself
    - QLT_PPP_014/18: If a data waiver is provided no additional EP summary should be required
    - QLT_PPP_010: NoS ID entries should not be required for Literature References (*publications, other company data*) which do not fall under the definition of a study according to the PA

Submission Backdrop

The IUCLID Software - *Continued*

- Further improvements of OHTs are required to produce high quality dossiers; automation of data upload/transfer would result in fewer errors compared to manual entry (*e.g. EFate: PEC values*)

- A focus on the continued development of Metapath (*MSS Composer, DER Composer*) is needed and current errors fixed with a high priority. The generation of “valid” files is extremely time consuming. CLE would also appreciate if EFSA could publish the available files on the EFSA webpage and Zenodo in a timely manner

CLE would welcome further subgroups of this PSN forum involving experts from all stakeholders to further refine and develop IUCLID in detail

Submission Backdrop

Hypercare and Guidance

- In general, Hypercare was welcome and provided a wealth of information for applicants;
  - The quality of some of the sessions varied, with short timeframes for both submitting questions and for comprehensive answers of them given
  - Manuals available late and will only be revised *after* the next release. These are mainly in IUCLID table form describing function rather than the type of information EFSA would like to see in the respective fields
  - No "*single source of truth*" for IUCLID questions (*Hypercare chat, presentations, manual*). CLE would appreciate a collated version of issues and resolutions
  - To date no clear guidance on how to produce a good quality dossier, with steps announced after submissions (*NoS search, validation justifications*)

Submission Backdrop

Submission Platform

- Timelines further shortened by use of SFTP platform in many cases
- Patches have been implemented on a user-by-user basis to overcome inherent issues
- Dossiers in general have required updates due to Hypercare information becoming available after submission (*e.g. confidentiality flags, validation rules*)

IUCLID moving forward

- Long term functionality of IUCLID with large datasets is unknown
- Migration to newer versions leads to significant rework of datasets for Dossiers submitted shortly thereafter, without clear overview of changes
- It is still unclear with regards to publication what is made available (*NoS entries*), CLE have significant concerns regarding confidentiality and the risk of unforeseen publication of CBI over time
- Dedicated IUCLID for PPP support may be required long-term, and adequate transition periods established for submissions between versions