

OECD IUCLID Expert Group

Priotised activities: Activity 3

A Framework for Cross-Jurisdictional
Data Usage

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Priorised Activities

within IUCLID Expert Panel

- i. User interface improvements
- ii. Reporting
- iii. Using the same dataset for multiple recipients
- iv. Data availability / Dissemination
- v. Use of ontologies / extension of the format

Objectives

Activity 3

- Data Standardization: The primary objective in data standardization is to ensure that data and data formats are harmonized, promoting compatibility with regulatory requirements across diverse jurisdictions.
- Data Validation and Compliance: objective is to map ideas for data validation tools to ensure the accuracy, consistency and compliance of the data inserted into IUCLID data set.
- Language Barrier: the objective is to evaluate the current capabilities of language translation within IUCLID and explore ways to enhance automatic translation, facilitating submissions to various regulatory authorities in accordance with national languages.

Data Standardization

Discussion with the expert group

- The need for data distribution in various formats across jurisdictions.
- Challenges in submitting IUCLID data to different recipients with varying catalog requirements.
- The discussion focused on the need for a versatile internal representation of data within IUCLID that covers all regulations but doesn't overwhelm users with unnecessary fields. This allows users to work within the context of their specific tasks whilst preparing a reusable data entry.
- Industry input and concrete examples are crucial for identifying and addressing real-world problems in IUCLID use across diverse regulatory contexts. It was proposed to focus on EP summaries rather than OHTs

Data Validation and Compliance

Discussion with the expert group

- The group highlighted the need for validation rules that can be centrally managed according to OHT and compared according to jurisdictional framework (procedure and country) to promote data reusability across domains (*e.g* REACH, Biocides, PPP, Countries, etc).
- Quality control, especially data consistency over time and IUCLID releases, was recognized as a critical issue. The concept of lifecycle management within IUCLID was proposed to address data stability during long evaluation processes and prevent data loss during migrations.
- In a long-term standardizing data fields and introducing mandatory fields.

Language Barriers

Discussion with the expert group

- Not all jurisdictions use English for submissions.
- Challenges of managing translations and ensuring accuracy.
- The idea of maintaining a central repository in English, with automated translations generated upon request or reporting, was proposed as a feasible solution. The auto-translate would be a basis for a check by applicants since there could be an issue of having legally binding text. This approach would avoid the complexities of managing multiple language versions of the same document.
- Importance of practical solutions and tools for multilingual usage

First achievements

- Data standardisation
 - Proposal for Harmonisation of attaching study reports:
 - All Versions (original, marked, sanitised,...)in 1 Literature reference with appropriate flagging
 - Enhancement of Dossier creation / export to facilitate individual steering
 - In preparation: Overview of different Environmental and Human health endpoint calculation across jurisdictions -> EP summaries?
 - Naming conventions on individual OHTs:
 - No naming conventions should be applied to EPSs by any jurisdiction around the globe
 - Harmonised building of Document n

Thank you

