10th meeting of the PSN IUCLID sub-group
11-12 June 2024

ON-GOING OECD ACTIVITIES

efsa
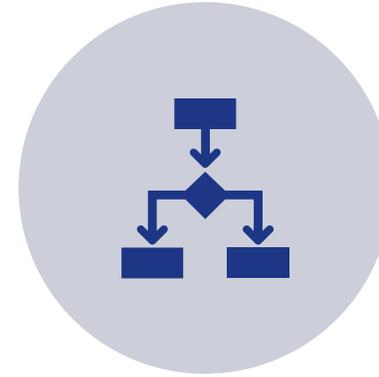EUROPEAN FOOD SAFETY AUTHORITY

STATUS OF EXPERT PANEL PRIORITISED ACTIVITIES

ACTIVITY #1 – USER INTERFACE IMPROVEMENTS

ACTIVITY #2 - REPORTING IMPROVEMENTS

ACTIVITY #3 - USING THE SAME DATASET FOR MULTIPLE RECIPIENTS

ACTIVITY #1 – USER INTERFACE IMPROVEMENTS

ECHA EUROPEAN CHEMICALS AGENCY   OECD Activity 1
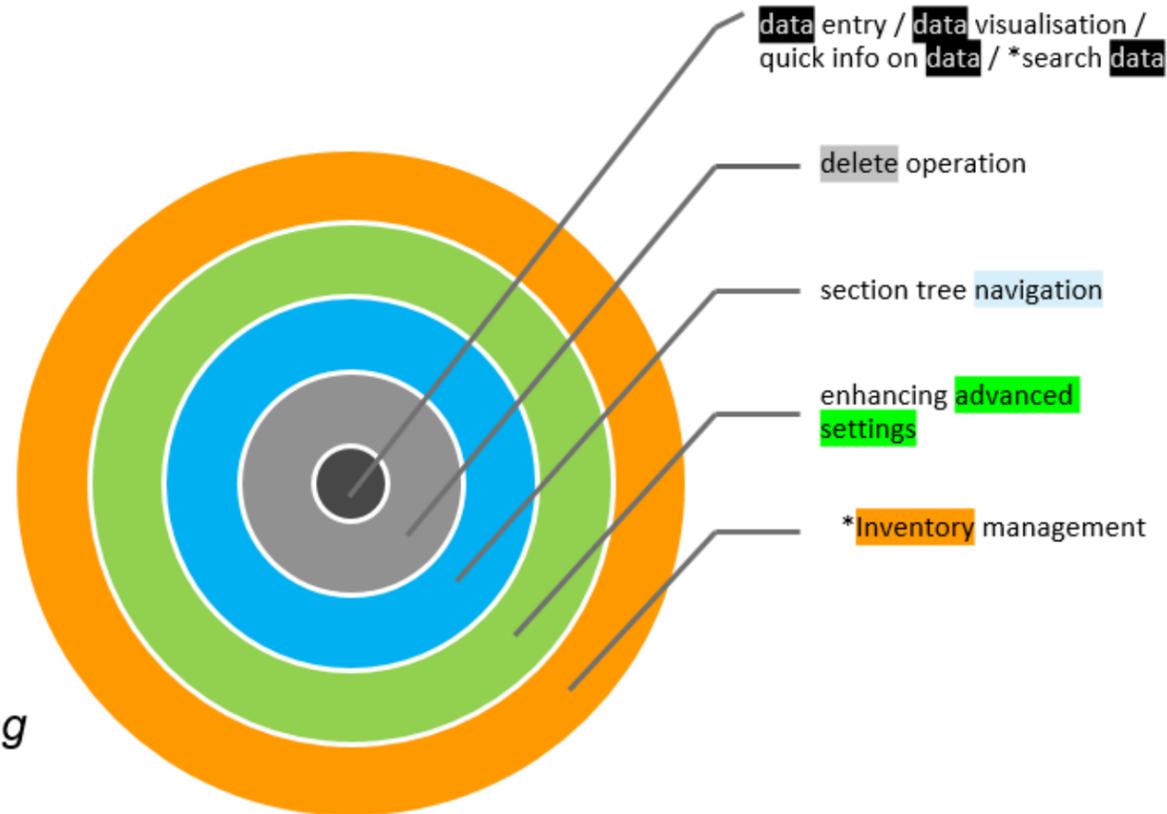
Activity 1 (Overview)

- 10 organisations involved
  - 5 authorities (AICIS, BfR, ECHA, EFSA, NZ EPA)
  - 5 industry (ARCHE Cons., CEFIC, Croplife Europe, Evonik, Eurofins)

- 5 meetings to date (~8hrs meeting time)

- We have now completed the prioritisation of 39 requirements/problem statements

- The top ten requirements/problem statements were initially prioritised

- We expect to have ~2-3 more meetings before the Plenary session (depending on progress)
  - Next meeting 11th June

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ECHA EUROPEAN CHEMICALS AGENCY

OECD Activity 1

Activity 1 (Prioritisation)

- Each organisation got one vote

- 5 Authorities and 5 Industry views reflected

- Broad range of prioritised requirements/problem statements

- Top ten chosen – *next meeting to confirm if anything omitted which should not be*

data entry / data visualisation / quick info on data / *search data

delete operation

section tree navigation

enhancing advanced settings

*Inventory management

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3

ACTIVITY #2 - REPORTING IMPROVEMENTS

ECHA EUROPEAN CHEMICALS AGENCY — OECD Activity 2

Activity 2 (Overview)

- 6 organisations involved
    - 5 authorities (AICIS, BfR, ECHA, EFSA, NZ EPA)
    - 1 industry (Knoell)

- 3 meetings to date (excluding the 2023 Reporting Workshop)

- Expected to have ~1-2 more meeting before the OECD Plenary session
    - To continue info/update on HTML > Docx conversion
    - Update on the transition to HTML based Report templates

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1. Key Areas identified

Data Standardization

Objective
Ensure that data and data formats are harmonised, promoting compatibility with regulatory requirements across diverse chemical legislations/jurisdictions.

Data Validation and Compliance

Objective
Map ideas for data validation tools to ensure the accuracy, consistency and compliance of the data inserted into IUCLID data set.

Language Barrier

Objective
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

2.Data Standardization- Key areas identified

1 Variation in specific field content,

2 Requirements for fields specific to a regulation,

Proposal to focus on endpoint summaries of human toxicology. Copper Oxide data prepared according to various regulatory requirements will be used for this exercise.

Due to the workload of this exercise, the group is considering outsourcing the activity and a draft proposal is being prepared

One Substance One Assessment (OSOA) initiative across EU agencies
Mapping of Data Requirements and Assessment Methodologies Linked to the Regulatory Frameworks and Remits of the Relevant EU Agencies (ECHA, EFSA and EMA) and EC Scientific Committees (SCCS and SCHEER) - Oltmanns - 2023 - EFSA Supporting Publications - Wiley Online Library

Handling of study attachments

👍 Harmonisation needed for easier accessibility across jurisdictions

❗ Attachments: Original, marked, sanitised versions.

👎 Implementation challenges: format changes, migration limitations

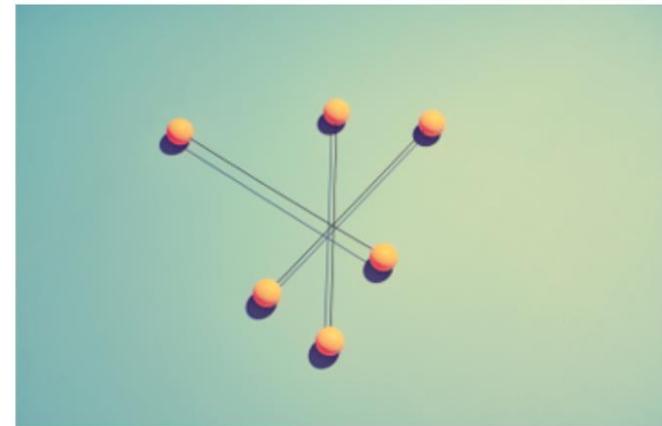*Handling of study attachment moved to Activity 1 dealing with user interface*

3. Data Validation and compliance

1 IUCLID Life Cycle Management – Practical issues and considerations on re-use of IUCLID documents within various PPP submissions were presented to ECHA.

The group concluded that being a PPP specific issue, the work will continue within the domain and the Activity 3 will just be debriefed

2 Harmonisation of Validation rules at OECD

IUCLID Validation Assistant rules for PPP dossiers

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