IUCLID6 & REACH-IT: key changes

Information session on updated registration process

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Drivers for changes

• Changes in requirements
• Feedback received
  • Interactions with the Industry IT WG (Cefic, Concawe, Eurometaux)
  • SME visits by ECHA staff and SME workshops
  • Helpdesk
• Technological upgrades

Drivers mentioned earlier today:
• Quality observations on dossiers
• Challenges of the SIEFs (for SME’s)
• Needs for enhanced dissemination
• User requirements collected, proposals presented, reviewed and approved at different levels:
  • EU Industry IUCLID User Group
  • EU MSCA IUCLID User Group
  • OECD Harmonised Templates and OECD IUCLID User Groups
New technology:
- General need to bring the technology up to date
- More possibilities for ‘internationalisation’, i.e. use/acceptance of IUCLID files for other programmes
- Better security model, e.g. support business unit model
- Better support for features like reporting
IUCLID simplification

- Desktop version installation improved
- IUCLID dossier creation online with REACH-IT
- Help system reviewed and Dossier Submission Manuals included
Substance identification profile (SIP)

- Specified in the composition section (1.2) in IUCLID
- The collectively agreed boundaries of the substance in scope of a registration/notification/application
- The ‘glue’ between registrant-specific compositions and the jointly provided hazard data, C&L

Boundaries:
- Concentrations
- Impurities, additives with C&L impact
- Forms

Data package:
- Hazard information
- Hazard assessment
- C&L
IUCLID 6 supports more transparent data organisation for “complex cases”

If one substance needs multiple data-sets for the assessment:

- (group of) constituents behaving differently from each other
- substance transforming during use or in the environment
- different compositions (or forms) with different hazard-profile

“Assessment entity” in IUCLID 6 enables

- to group substance property data-sets for the assessment
- to clearly explain the assessment approach and to improve understandability of disseminated information
- opportunities for the assessor to make his case more transparent (non mandatory)
The Assessment Entity concept is introduced in IUCLID 6 to describe the assessment approach more transparently when needed.

Assessment Entities are defined under section 0.4.

They can be linked to relevant data (via endpoint summaries).
Use and exposure

Structures for use and exposure information:

• support priority setting by the authorities for further regulatory actions:
  • identify among the (potentially) hazardous substances those which have
    • wide dispersive uses
    • uses within the scope of substance evaluation, CLH, authorisation, restriction
  • rank them for further regulatory action based on use specific tonnage information

• provide non mandatory fields supporting registrants in demonstrating low concern, for example:
  • Main tonnage used in contained system with strict control
REACH-IT 2016 and beyond...

• Set the foundation for being an innovative submission tool for REACH & CLP data

• Review of the usability of REACH-IT
  • September 2014 – December 2014: SME workshops
  • Workshops with Industry User Group

• Feedback
  • Workflow (e.g. submit a dossier) and navigation through the system not intuitive
  • Synchronisation between IUCLID and REACH-IT is problematic
  • Status of registration difficult to find/understand
  • Difficult to find co-registrants, joint submissions and the lead
Help embedded in the system
Moving towards a substance centric view
Expected benefits to REACH-IT users

• Improved learnability and memorability in order to reduce cognitive effort
• More intuitive UI preventing users from getting lost in the application
• Improved access and visibility of decisions and communications
• Central management of contact persons and TPRs
• Simplified user management (one user can manage many companies)
• Help texts integrated into the application
Enhancement SIEF experience

• Easier access to information about (potential) co-registrants and existing Joint submissions
• Clearer overview of the Joint submission information
Working with co-registrants

• Improved search for Joint submission:
  • Results clearly indicate the Substance identity, Lead Registrant contact details and type of Joint submission

• Enhanced Lead Registrant nomination scheme
  • Ensure accurate information on the candidate Lead Registrant

• Link between Co-Registrant page and Pre-SIEF:
  • From the Co-Registrant page will be possible to access the pre-SIEF page (but not from Pre-SIEF to CoRP) to get in contact with other potential registrants

• Introduction of the boundary composition ("SIP") in the submission process

• Strengthen the OSOR principle (see: presentation earlier today)
Overview of Joint submission

• Easier, clearer and more comprehensive overview of the Joint submission page:
  • Content of the Joint submission (Substance, registration type, scope, coverage)
  • Easy access to the Lead Registrant up-to-date contact details
  • Clear summary of the own information submitted
  • Ongoing discussion on increasing transparency between all members
### JS 1047 Reproduce

#### Lead Dossier:
- **Substance**: [204-480-4] subathizone
- **EC**: 242-161-1
- **CAS**: 18283-82-4
- **JS Scope**: Scope description goes here
- **Dossier Type**: Registration
- **Tonnage Band**: 1 < 10 t/y
- **Transported Isolated Intermediate**: > 1000 t/y
- **Max. Transported Isolated Intermediate**: > 1000 t/y
- **Guidance on Safe Use**: Yes
- **Chemical Safety Report**: Yes

#### Submitted
- **Name of the Joint Submission**

#### Own Dossier:
- **Reference ID**: 09-2114083626-42-0000
- **Contact Details**:
  - Mr. John Mathews
  - Phone: +303253654

#### Scopes
- **JS Scope 1**
- **JS Scope 2**

#### Constituents
- Hydrogen: 10.30 %
  - EC: 215.605.7
  - CAS: 1333.74.0
- Lithium: 50%

#### Additives
- Hydrogen: 10-30 %
  - EC: 215.605.7
  - CAS: 1333.74.0
- Lithium: 50%

#### Impurities
- Hydrogen: 10-30 %
  - EC: 215.605.7
  - CAS: 1333.74.0
- Lithium: 50%
Expected release dates

• Request from industry for fixed dates release in support of planning;
  • Tentative dates – confirmation by end of the year:
    • IUCLID 6: last week of April 2016
    • REACH-IT 3: last week of May 2016

• Further discussions ongoing with industry representatives (IT WG) to precise the planning and to develop support material

• Get prepared and plan ahead!
Thank you!

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