IUCLID 5

Current status and planning

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REACH-IT / IUCLID Stakeholders Day
26 March 2009, Helsinki
Topics Covered

• Brief history

• Some figures

• Products within the IUCLID 5 project
  – Delivered
  – Under Development
  – Planned
International Uniform Chemical Information Database

- 1993: First version of IUCLID for the European Existing Substances Regulation (793/93/EEC)

- 1999: IUCLID becomes the recommended tool for the OECD HPV Programme.

- 2000: IUCLID is the software prescribed in the EU Biocides legislation to notify existing active substances (Art. 4 of 1896/2000/EC)

- IUCLID 4 is installed in about 500 organisations worldwide (chemical industry companies, EU Member State Competent Authorities, OECD Secretariat, US-EPA, Japan METI, third party service providers).
Art. 77.2(e): The Agency [...] shall undertake the following tasks: [...] establishing and maintaining database(s) with information on all registered substances [...] 

Art. 111: The Agency shall specify formats and make them available free of charge, and software packages and make them available on its website for any submissions to the Agency.

... For the purposes of registration, the format of the technical dossier referred to in Article 10(a) shall be IUCLID. The Agency shall coordinate the further development of this format with the Organisation for Economic Cooperation and Development to ensure maximum harmonisation.
Towards IUCLID 5

• 2003: complete overhaul of IUCLID 4 is decided by the Commission to prepare for REACH

• 2005-2007: A&D and development of IUCLID 5

• June 2007: release to the public

• 2004-...: OECD and EC agreed on a standard XML format (OECD Harmonised Templates) to store data

• 93 templates available

RIP 2

OECD Expert Group on Harmonising Templates
What is IUCLID 5 for?

- IUCLID 5 is a substance database
- It must be used for creating REACH registration dossiers
- REACH-IT re-uses parts of the IUCLID 5 database structure
- IUCLID 5 is also used for creating reports for other chemical programs, e.g.:
  - OECD HPVC Program
  - US HPV Challenge Program
  - Japan HPV Challenge Program
  - Swiss new chemicals notification
Stakeholders

Users community

- Commission
- MSCAs
- OECD
- Other countries
- ECHA (IMG)

Industry

- OECD IUCLID Expert Group Panel
- IUCLID Helpdesk
Figures: Jun 2007 – March 2009

- **User Accounts on the IUCLID Download Site:**
  - 25,285 active
  - plus 4,766 not active (never clicked the activation link)
  - Over 13,500 new accounts since 1.6.2008

- **Downloads:**
  - Standalone: 19,981 (of which 15,392 the Windows setup kit)
    - Over 10,000 since 1.6.2008
  - Distributed: 2,811
    - Over 1,400 since 1.6.2008

- **LEOs: 23,371**
  - Over 15,500 since 1.6.2008
  - Germany 3,901
  - United Kingdom 2,498
  - Italy 1,955

- **Service Desk Tickets: 4500**

- **iuclid.echa.europa.eu** or **iuclid.eu**
Number of registered users
IUCLID project after release of IUCLID 5

- IUCLID 4 to IUCLID 5 migration tool (latest version 12/2007)
- IUCLID 5 Pre-registration tool (March 2008)
- Performance testing (2007-2008)
SNIF migration plug-in

- Migrates SNIF files, which have been exported out of the NCD database, to IUCLID 5 files
- Conversion to substance datasets or dossiers
- Available since November 2008
- Over 400 downloads
IUCLID 5.1 (first Service Release)

• Bugs fixed
  – print out from HTML area looses text if "<" is used
  – format mask not respected for single numeric fields without a unit
  – empty cells in table rendered without borders
  – re-import of Dossier, after deletion, not possible due to boiling point decimal place problem
  – dossier creation timestamp disappears when clicking on it
  – etc.

• Windows Vista® certification

• Available since 16/01/2009

• Over 2,300 downloads
  – 1,900 standalone version
  – 400 distributed version
### Query Tool plug-in

**Basic search functionalities**

- There are 40 queries offering the possibility to search for over 200 data fields.

<table>
<thead>
<tr>
<th>Data object</th>
<th>Number of queries</th>
<th>Number of query able fields</th>
</tr>
</thead>
<tbody>
<tr>
<td>Category</td>
<td>3</td>
<td>5</td>
</tr>
<tr>
<td>Dossier</td>
<td>12</td>
<td>84</td>
</tr>
<tr>
<td>Legal Entity</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>Mixture</td>
<td>6</td>
<td>42</td>
</tr>
<tr>
<td>Reference Substance</td>
<td>2</td>
<td>11</td>
</tr>
<tr>
<td>Site</td>
<td>2</td>
<td>4</td>
</tr>
<tr>
<td>Substance</td>
<td>10</td>
<td>68</td>
</tr>
<tr>
<td>Template</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>Unknown</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>40</strong></td>
<td><strong>222</strong></td>
</tr>
</tbody>
</table>

![Diagram](image)
Query Tool plug-in functionalities

• IUCLID 5 Query Tool plug-in
  • provides an extended query possibility offering simple access to a defined set of business-relevant information
    • 91 Endpoint sections
    • 76 Endpoint summary sections
    • 3 Additional Information Sections
    • 170 Sections in total
    • ca. 880 Fields counted in the endpoint sections (configurable part)
    • ca. 820 Fields counted in the endpoint sections (administration part)
    • 91 Query for exiting studies
    • 76 Query for exiting summaries
    • 3 Query for exiting Additional Information Sections

• ca. 1900 Query fields in total
  • Note: Numerical ranges have not been counted as one field and not as 4.

• Tested by Industry and MS CAs representatives in October 2008

• Available since 26/01/2009
• Over 600 downloads
The IUCLID 5 Query Tool uses a Query Indexer, which:

- tracks all changes made to IUCLID 5 data,
- extracts and prepares the data for fast and convenient search operations.

The Query Indexer creates an index table in the IUCLID 5 database.

The Query Executor uses the index table to find IUCLID 5 data that matches the query criteria entered by the user.
Query Tool plug-in
Query executor

- Query has to be defined by “blocks”

- Top-level elements of a query block
  - Substance
  - Mixture
  - Template

- Sub-levels
  - Annotations (will find only annotated documents)
  - Dossier header (will find only dossiers)
  - Sections < 4 (will find substance and mixture documents)
  - Sections ≥ 4 (will find information within endpoint study records and endpoint summaries)
Translations of the User Manual

• What has been translated?
  – A: Introduction
  – B: IUCLID 5 purpose and general structure
  – C: Getting started – sample session for beginners
  – D: IUCLID features and How-to guides

• Workload
  – From the 2,200 pages of IUCLID guidance, 750 have to be translated in EU languages
  – 256 A4 page full of text
  – 55 pictures containing text

• Deliverables
  – IUCLID 5 plug-ins
  – PDF documents

• Available since 04/02/2009
• More than 300 downloads
CSR plug-in

- **Aim of the plug-in**
  - Facilitate the production of Chemical Safety Reports based on an IUCLID 5 dataset or dossier
  - Based on the CSR format published on the ECHA website

- **Status of the project**
  - Prototype tested in ECHA and by Industry representatives
  - After the testing period, bugs have been fixed and new improvements were decided
  - Publication is planned very soon
WEB Services interface

• WEB Services
  – Increase interoperability, and lower the costs of software integration and data-sharing with partners.
    • WS make it possible for computer programs to communicate directly with one another and exchange data regardless of location, operating systems, or languages.
  
  – Allows the integration of IUCLID 5 with external systems like REACH-IT or …

  – New Licence Agreement is required

  – Publication is planned end of Q1, beginning of Q2/2009
Other planned plug-ins

• Bulk export
  – Publication is planned beginning of Q2/2009

• Exchange literature references
  – Publication is planned beginning of Q2/2009

• Technical Completeness Check
  – Publication is planned end of Q2/2009

• Dissemination plug-in
  – Publication is planned for Q3/2009

• Bulk Legal Entity change
  – Analysis phase
• **Service Release 2**
  – bug fixes
  – user-requested enhancements
    • Inquiry dossier template
    • Adaptation of Section 3.5 (Identified uses and Exposure Scenarios) [09/07/2008] User Guide for Reporting Identified Uses in IUCLID 5
    • Enhancement of printing functionality
    • Inquiry dossier creation
    • Etc.

• **Change of data model → release synchronised with REACH-IT release**

• **Publication is planned for Q4/2009**
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Thank you for your attention