IUCLID 6 is developed by the European Chemicals Agency in association with the OECD
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IUCLID 6 project
IUCLID 6 schedule

2014
- IUCLID 6 project starts
- IT Architecture review
- New functions

Q2 2015
- IUCLID 6 beta version
- OECD
- Harmonised Templates
- REACH, BPR and CLP

29 April 2016
- IUCLID 6 official release
- Progressive maintenance
IUCLID 6 beta version (June 2015)

Technical upgrade

- New architecture
- New data model
- Renewal of all IT components
- Alignment of the data structure
  - Section 1-3 aligned with the rest of the sections (records can be created)
  - IUCLID document types redefined
    - Flexible records, flexible summaries
    - Fixed records…
  - Data types redefined
  - IUCLID documents ‘harmonised’
    - Use of inherited templates streamlined
- Additional functions (e.g. security, user management)
Scope overview

- IUCLID format update
  - Update of the OECD Harmonised Templates
  - Use and exposure information harmonisation
  - Assessment entity
  - Substance identity
  - Etc.
- Simplification
  - Help system
  - Simplification of user interface and key functions
  - Installation of Desktop version
- IUCLID 6 configuration, development of IUCLID plug-ins
  - Validation Assistant
  - Filtering, Aggregation
  - Report generator
IUCLID 6 features
For an overview of the IUCLID 6 functionalities, please refer to the IUCLID 6 user manual available in IUCLID 6 itself (press F1 in IUCLID 6 or click the Help icon)

The IUCLID 6 manual can also be downloaded from the IUCLID 6 website:

IUCLID 6

- Test material inventory
- New format
- Modernised interface
  - New technological platform
- Annotation inventory
- Advanced security
- Tools and administration
  - User tools
  - Import
  - Bulk export
  - Plugins
    - Validation assistant
    - Report generator
    - Query tool
    - Dissemination tool
    - Fee calculation
    - Help system
- Main tasks
  - Substance
  - Mixture/Product
  - Category
  - Annotation
- Inventories
  - Legal entity
  - Legal entity site
  - Reference substance
  - Contacts
  - Chemical inventories
  - Literature reference
  - Test material information
- Plug-ins redeveloped
- New help system
IUCLID 6 features

Overview of the functions available

- IUCLID entities management (substance, mixture, legal entity...)
- Dossier creation
- Basic search
- Import / export
- Migration of i5z files
- Main engines for:
  - Filtering
  - Printing
  - Validation
- Annotations
- Information panels
- Attachments
- Secured client / server communication
- User management
- Instance-based user permissions
- Help system
- Desktop version installer
- Clipboard manager

Features abandoned

- Light dossiers
- Folders
IUCLID 6 new features

Test Material Inventory

• Test material information centrally managed in an inventory

• Link is made from the Endpoint Study Records
IUCLID 6 supports more transparent data organisation for “complex cases”

If one substance needs multiple datasets 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).
IUCLID 6

Format changes
Format changes

- The updated IUCLID 6 format documentation is available on the IUCLID 6 website:


- Some of the main changes made to the format are introduced in the following slides
Substance identity information

- **Section 1.1 Substance**
  - ‘Other identifiers’ table to capture identifiers used previously, or in other regulatory contexts

- **Section 1.2 Composition**
  - New field to describe the purpose of the composition (e.g. boundary compositions - SIP, LE specific composition)
  - Description for complex substances (UVCB)
  - State / form moved from section 2.1 to section 1.2
  - Nanomaterials parameters

- **Section 1.4 Analytical information**
  - Can be linked to compositions
  - Analytical methods and results of analysis are combined in a table format

![Methods and results of analysis table](attachment:image.png)
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
IUCLID 6 format changes

Section 2.1

• One record per Classification and Labelling information

• Update to GHS version 5 (8th ATP of the CLP Regulation)
  – New hazard category

• Update to GHS version 6, published in 2015
  – New hazard class

• Form of the substance moved to composition
IUCLID 6 format changes

Section 3

- Section 3.1 removed / migrated
- Section 3.2 minor changes
- Section 3.5 and 3.7: use and exposure information
  - Several records can be created per use, per life cycle stage
  - Each use is described through a **name**; the **contributing activities**, which are defined through the CA name and the appropriate descriptors depending on the activity (ERC, PROC, PC, AC); and additional descriptors to provide **market information** (SU, TF...)
  - New fields created, e.g.:
    - Regulatory status for the use (cosmetic, intermediate)
    - EU tonnage
    - Differentiation per use type: art. 10, 17/18, 38
    - Dedicated fields to report use as intermediate and rigorous containment / strict control
  - OECD / REACH information
    - Majority of the use information has been moved to an OECD template
    - Specific REACH fields are kept in a separate document (that links to the OHT)
    - REACH view will be built for filling-in the information but the data will be stored in separate records
IUCLID 6 format changes

Section 3: use and exposure information

• Harmonisation at the OECD level and update of the format to support specific ECHA needs lead to the (technical) split of the format

• As part of the IUCLID simplification, we created a combined view to manage use and exposure information in IUCLID 6 for REACH purposes:
  – Combining OECD and REACH information
  – Combining use and exposure information
  – Customising the entry screens depending on the type of use
    • Article 10, <10 tpa
    • Article 10, >10 tpa
    • Article 17 / 18 (intermediate use): e.g. strictly controlled condition-intermediate use does not need the exposure scenario part
    • Article 38 (DU report)
IUCLID 6 format changes

Sections 4 to 7

- Generic changes to all OECD Harmonised Templates
  - Administrative data (endpoint field to precise the information requirement, data waiving and justification picklists...)

![IUCLID 6 format changes](image)
IUCLID 6 format changes

Sections 4 to 7

- Generic changes to all OECD Harmonised Templates
  - Test material information is now a separate object in IUCLID
IUCLID 6 format changes

Test Material Information – Migration rules (example)

• TMI created as soon as test material information is available in IUCLID 5 (to avoid creation of duplicates, UUID are generated based on data)
  – Identity of test material same as for substance defined in section 1 (if not read-across) {TestMaterials.Indicator}
  – Test material identity and identifiers
• {TestMaterials.Indicator} = Yes: information is retrieved from section 1.1 or 1.2
• EC number, CAS number, EC name and IUPAC names are mapped to existing reference substances or a new one is created
IUCLID 6 format changes

Sections 4 to 7

• New OECD Harmonised Templates
  – #23-2: Self-reactive substances
  – #23-3: Organic peroxide
  – #23-4: Corrosive to metals
  – #23-5: Gases under pressure
  – #48-2: Endocrine disrupter testing in aquatic vertebrates – In vivo
  – #75-3: Endocrine disruptor mammalian screening - In vivo (level 3)
  – #201: Intermediate effects
  – (13 existing nanomaterial templates will be added to the registration dossiers too)

• New REACH records
  – Annex III checklist
  – Downstream user report
IUCLID 6 format changes

Sections 4 to 7

- Update of the endpoint summaries
  - Endpoint summaries are now available for all endpoints
  - Multiple endpoint summaries can be created
  - Link to relevant endpoint study records
Dossier creation

- Opt-out information moved to the dataset

- New picklist element for specifying a tonnage band 1-10 t/y (phys. chem. requirements)

- New spontaneous update reasons
IUCLID 6
Other information
Frequently Asked Questions

- Please also refer to the Frequently Asked Questions page on the IUCLID 6 website:
