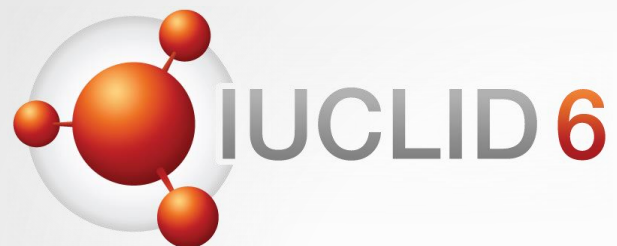
A stylized molecular structure logo consisting of a large central orange sphere with three smaller orange spheres attached to it by thin red lines. The entire structure is set against a white, semi-transparent circular background.

IUCLID 6





IUCLID 6

Version 1.0.0 / 29 April 2016



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



Content

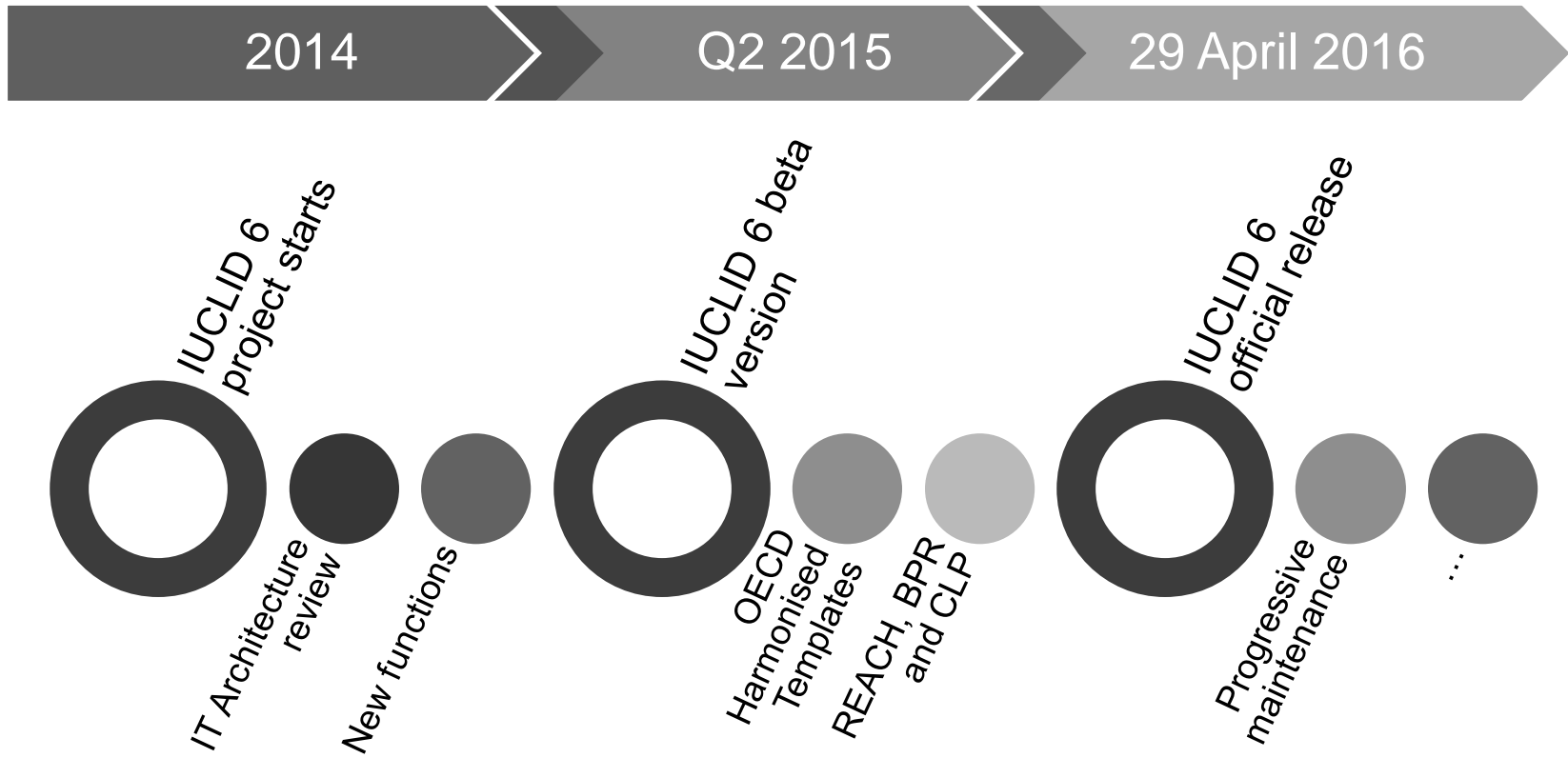
- ◆ IUCLID 6 project
- ◆ IUCLID 6 features
- ◆ IUCLID 6 format changes



IUCLID 6 project



IUCLID 6 schedule



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



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:

<http://iuclid6.echa.europa.eu/web/iuclid/documentation>



Modernised interface
New technological platform

New format

Advanced
security

Main tasks

Substance

Mixture / Product

Template

Category

Annotation

Dossier

Tools and administration

User tools

Import

Bulk export

Plug-ins
redeveloped

Plugins

Validation assistant

Report generator

Query tool

Dissemination tool

Fee calculation

Help system

Inventories

Legal entity

Legal entity site

Reference substance

Contacts

Chemical inventories

Literature reference

Test material information

Test material inventory

New help
system

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

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

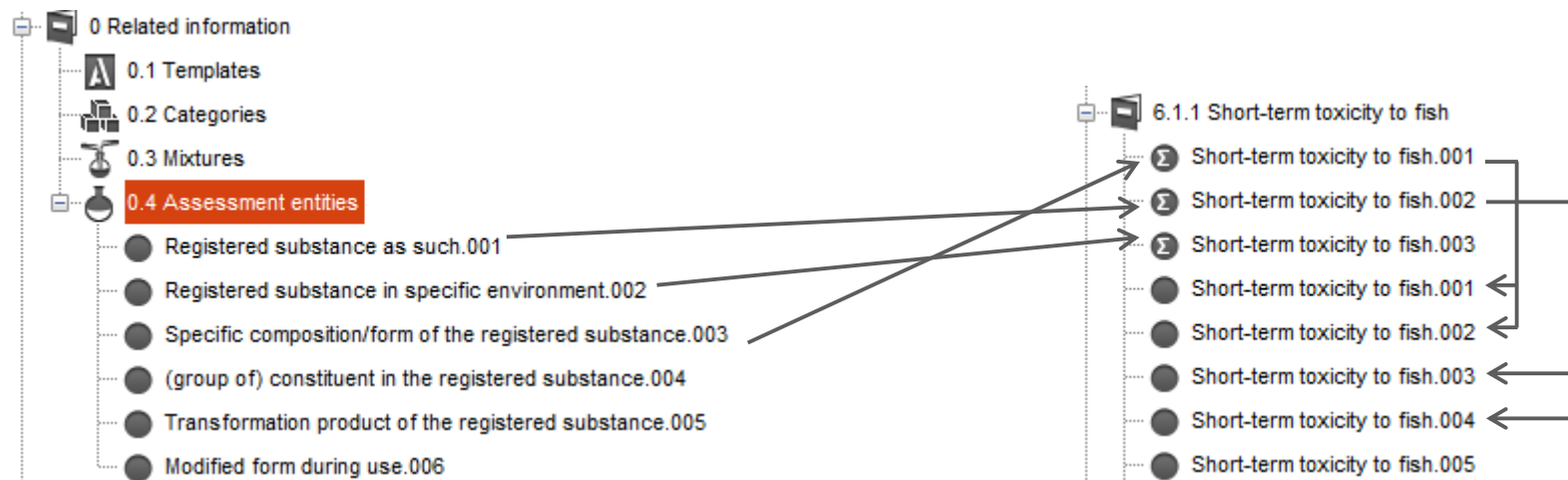
- to group substance property data-sets for the assessment
- to clearly explain the assessment approach and to improve understandability of disseminated information
- opportunities for the assessor to make his case more transparent (non mandatory)

Assessment Entity

- 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:

<http://iuclid6.echa.europa.eu/web/iuclid/documentation>

- 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

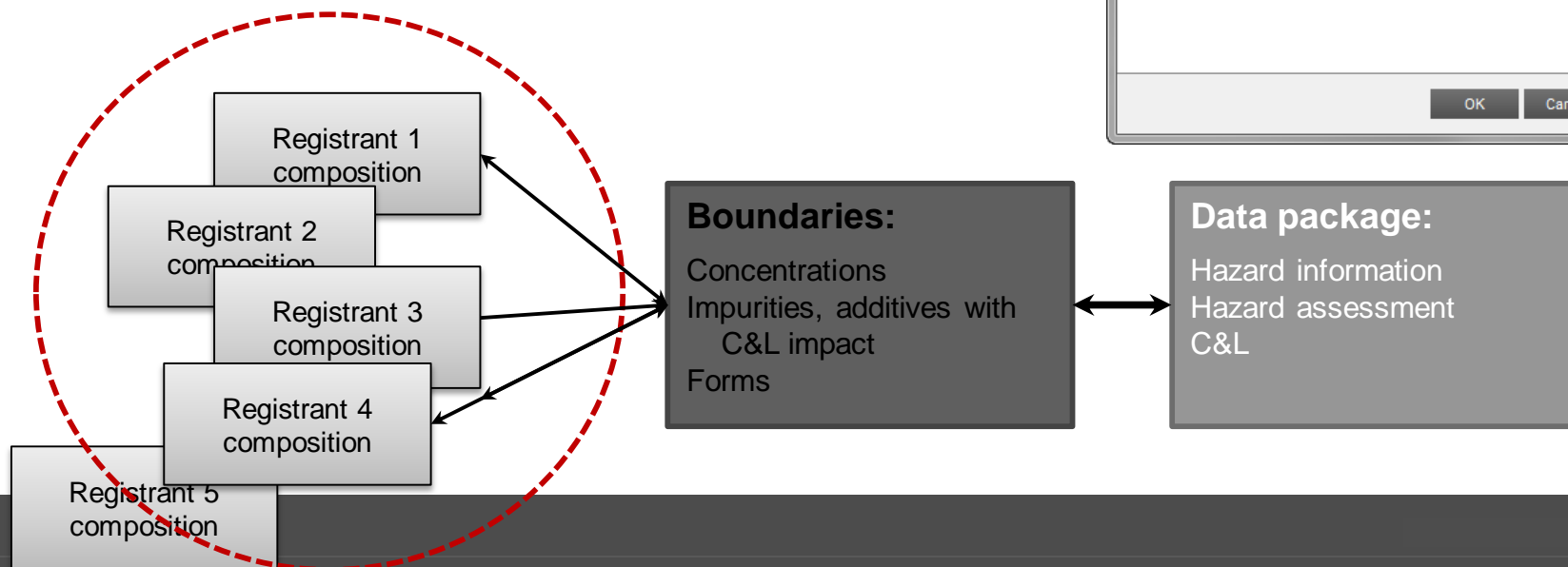
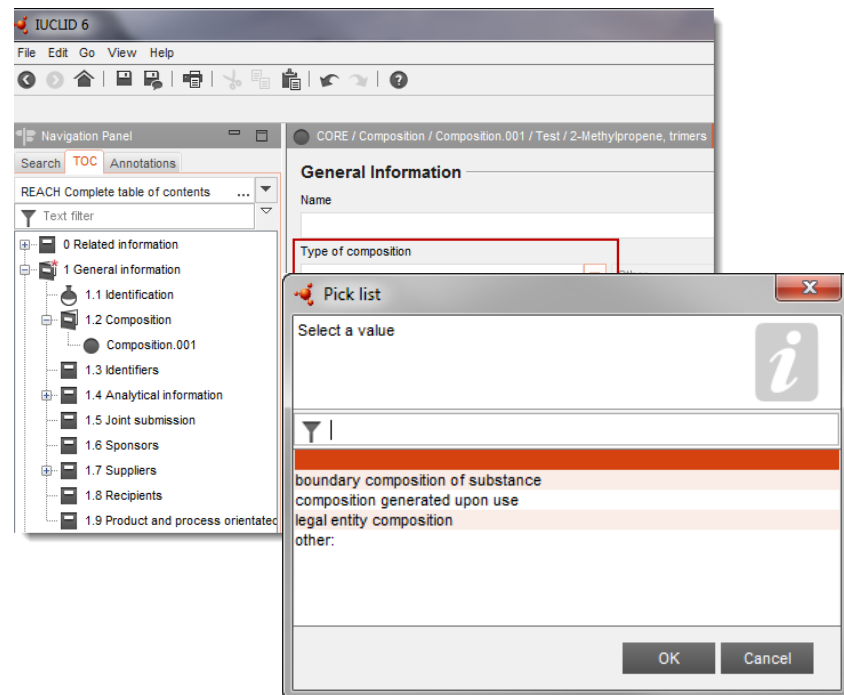
Methods and results of analysis						
Analytical determination						
Purpose of analysis	Analysis type	Type of information ...	Attached methods/r...	Rationale for no res...	Justification	Remarks

⊕ Add... ✎ Edit... ✕ Delete ⬆ Move up ⬇ Move down

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



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

Section 3

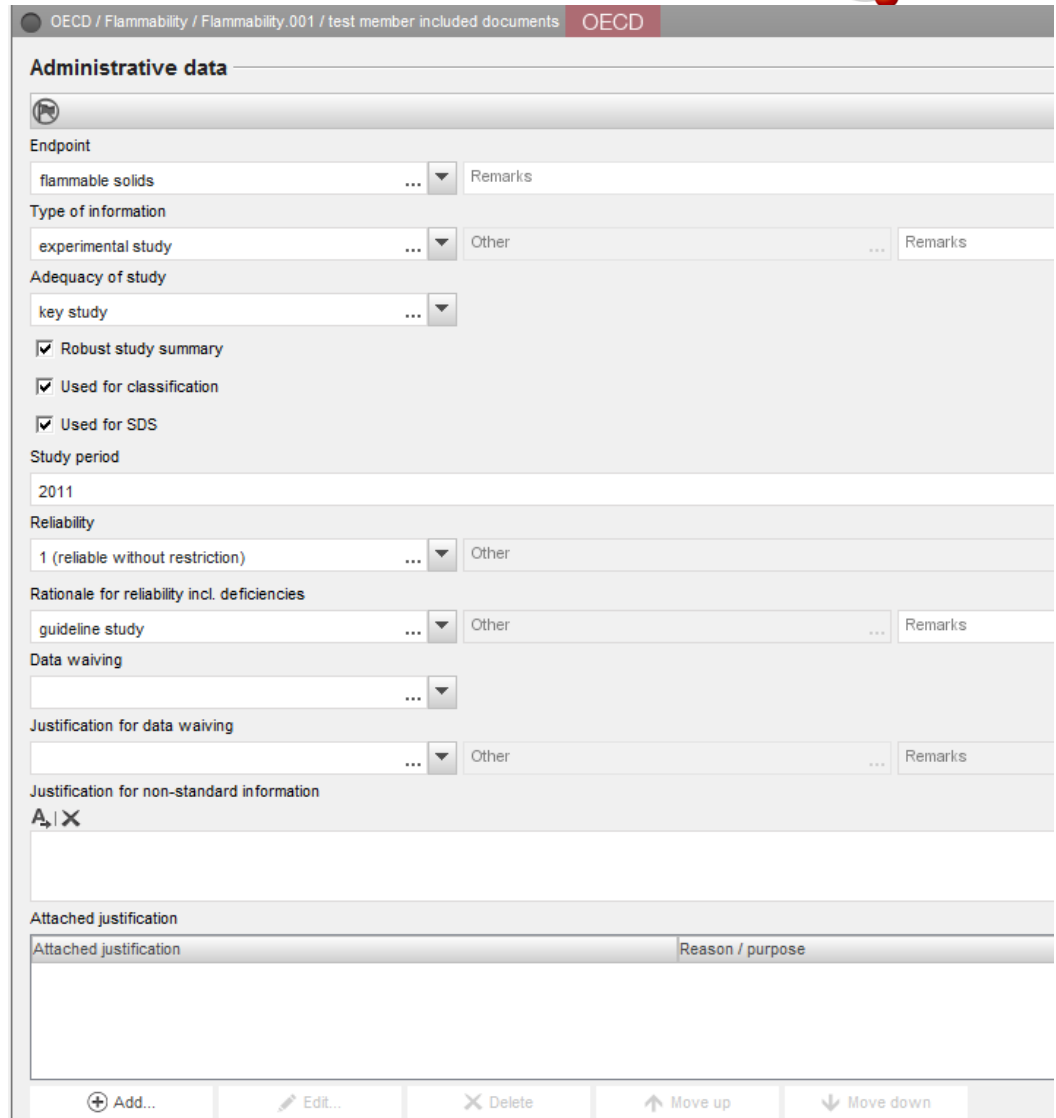
- Section 3.1 removed / migrated
- Section 3.2 minor changes
- Section 3.5 and 3.7: use and exposure information
 - Several records can be created per use, per life cycle stage
 - each use is described through a **name**; the **contributing activities**, which are defined through the CA name and the 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

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)

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...)



OECD / Flammability / Flammability.001 / test member included documents OECD

Administrative data

Endpoint
flammable solids ... Remarks

Type of information
experimental study ... Other ... Remarks

Adequacy of study
key study ...

Robust study summary
 Used for classification
 Used for SDS

Study period
2011

Reliability
1 (reliable without restriction) ... Other

Rationale for reliability incl. deficiencies
guideline study ... Other ... Remarks

Data waiving
...

Justification for data waiving
... Other ... Remarks

Justification for non-standard information
A₂ | X

Attached justification

Attached justification	Reason / purpose

+ Add... Edit... X Delete ↑ Move up ↓ Move down

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

Test material

Test material information

Hydrocortisone

Specific details on test material used for t
A₂ | X

Composition

Type	Link to a substance identity record	Concentration	Remarks
Constituent	hydrocortisone 21-acetate / 200-004-4	ca. 85.0 - % (w/w)	

+ Add... Edit... Delete Move up Move down Go to link target

Composition / purity: other information

analytical grade	Other	Remarks
------------------	-------	---------

Other characteristics

Test material form

liquid	Other	Remarks
--------	-------	---------

Details on test material
A₂ | X

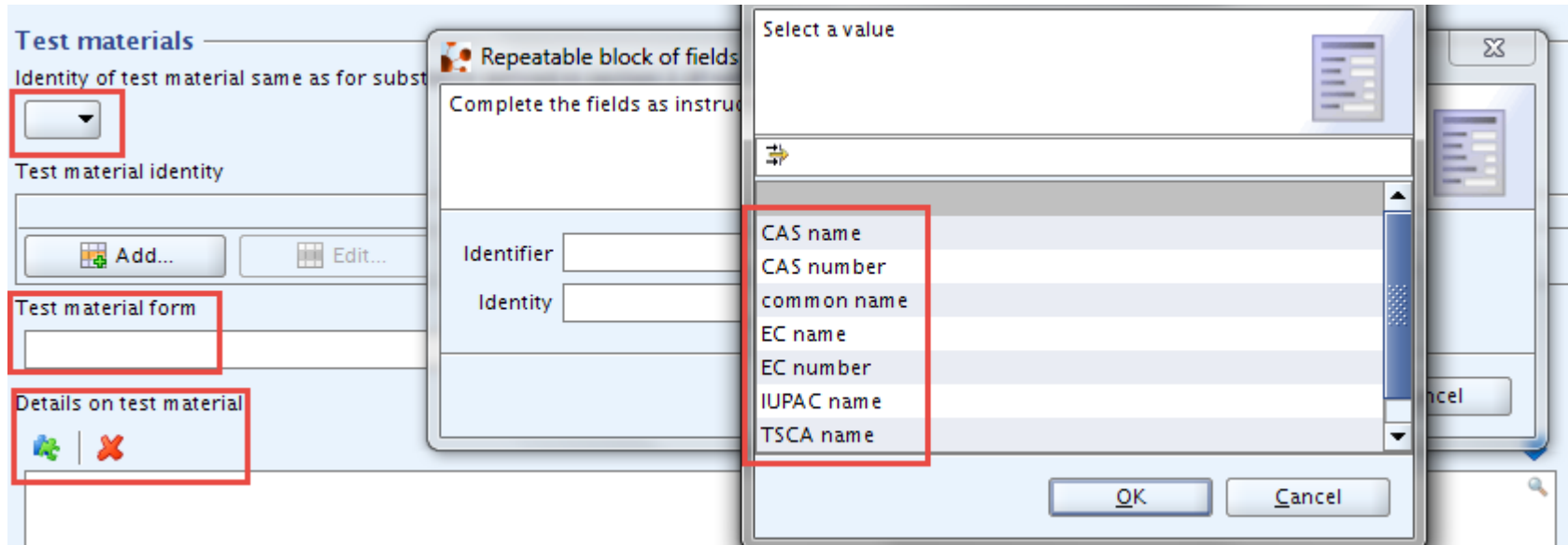
- State of aggregation: ...
- Particle size distribution: ...
- Mass median aerodynamic diameter (MMAD): ...

Confidential details on test material
A₂ | X

- Analytical purity: ...
- Impurities (identity and concentrations): ...
- Composition of test material, percentage of components: ...

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



Sections 4 to 7

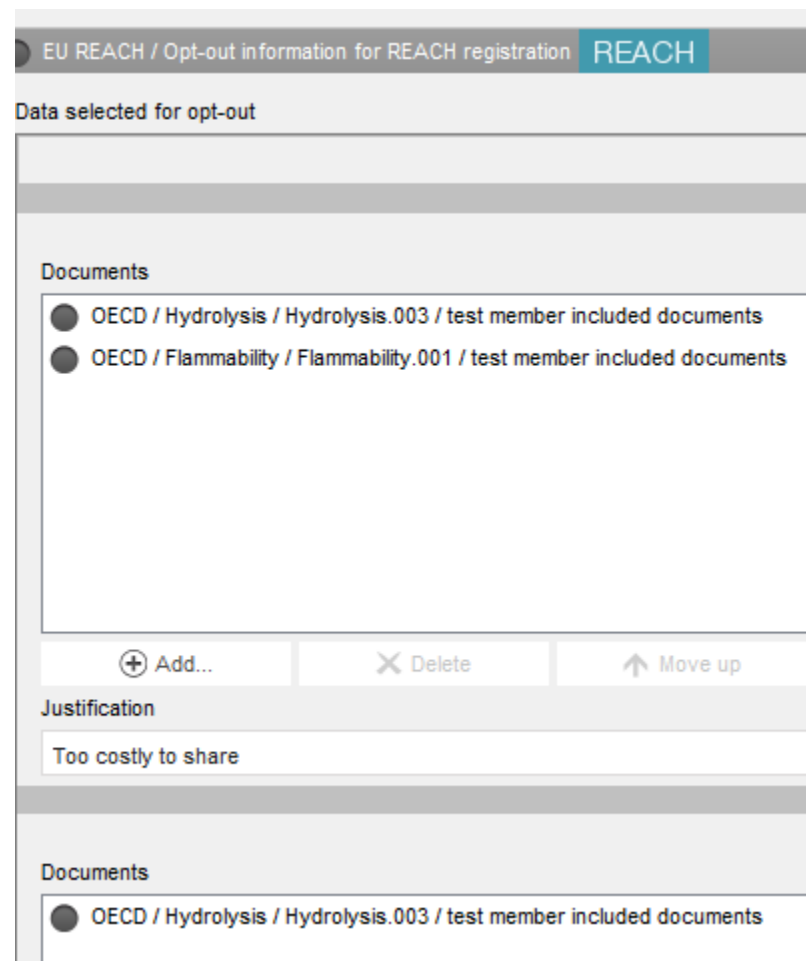
- New OECD Harmonised Templates
 - #23-2: Self-reactive substances
 - #23-3: Organic peroxide
 - #23-4: Corrosive to metals
 - #23-5: Gases under pressure
 - #48-2: Endocrine disrupter testing in aquatic vertebrates – In vivo
 - #75-3: Endocrine disruptor mammalian screening - In vivo (level 3)
 - #201: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

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



EU REACH / Opt-out information for REACH registration **REACH**

Data selected for opt-out

Documents

- OECD / Hydrolysis / Hydrolysis.003 / test member included documents
- OECD / Flammability / Flammability.001 / test member included documents

+ Add... X Delete ↑ Move up

Justification

Too costly to share

Documents

- OECD / Hydrolysis / Hydrolysis.003 / test member included documents

IUCLID 6

Other information



Frequently Asked Questions



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

<http://iuclid6.echa.europa.eu/web/iuclid/faq>



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