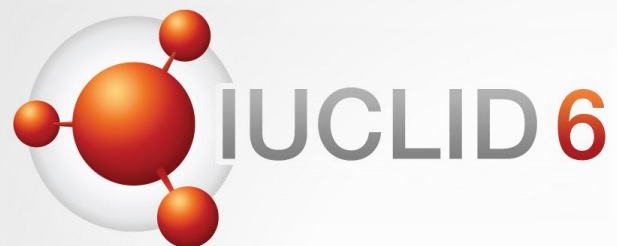


IUCLID 6





IUCLID 6 webinar

Advanced users – part 2

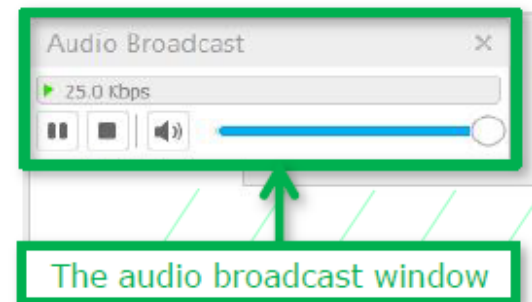
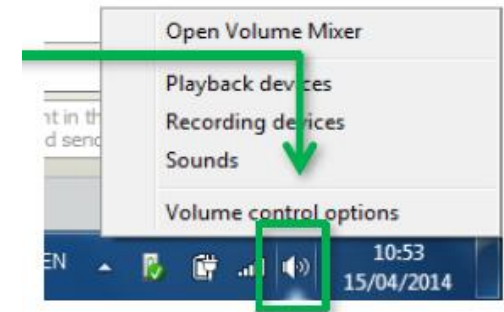


IUCLID 6 is developed by the European
Chemicals Agency in association with the OECD

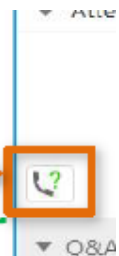


Audio troubleshooting

- If the volume is too low, try to increase the sound volume of your computer.
- If the audio cannot be heard at all, verify that the audio broadcast window shows a green triangle and that the volume slider is not too low.
- If the problem persists, you can use a telephone for receiving audio.
 - Click the button shown above to *Request Audio*
 - Select *Use phone*, enter your phone number
 - Click on the *Call me* button



The *Request audio* button is only needed to connect audio by phone should the audio broadcast not work properly.



Agenda for today

What?	Who?	When?
Welcome and introduction	F. Le Goff	11am (EEST)
Information on the next service release <ul style="list-style-type: none">Fixes for known issuesNew features<ul style="list-style-type: none">Replace during importInventory managementComparison tool	F. Le Goff M. Roberts	11:05
Changes in reporting data in IUCLID 6 <ul style="list-style-type: none">Dynamic content validation of fieldsHow to report read-across informationImpact of REACH annex changes	A. Malkia	11:35
Sending additional questions	All participants	11:55
Questions and Answers session	All participants ECHA	Until 12:15

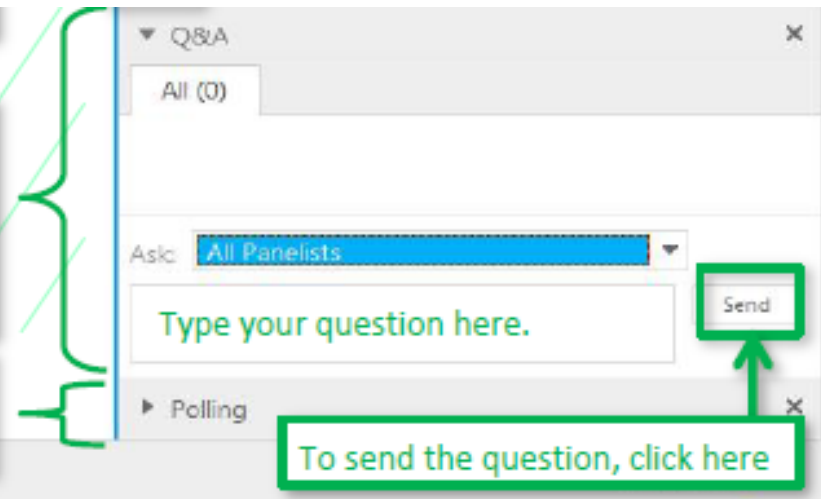
The Q&A panel

- You can post your questions during the entire webinar
- Answers will be given during the webinar and also provided in written form after the event
- Before the Q&A session 5 minutes will be left to send additional questions

The Q&A panel

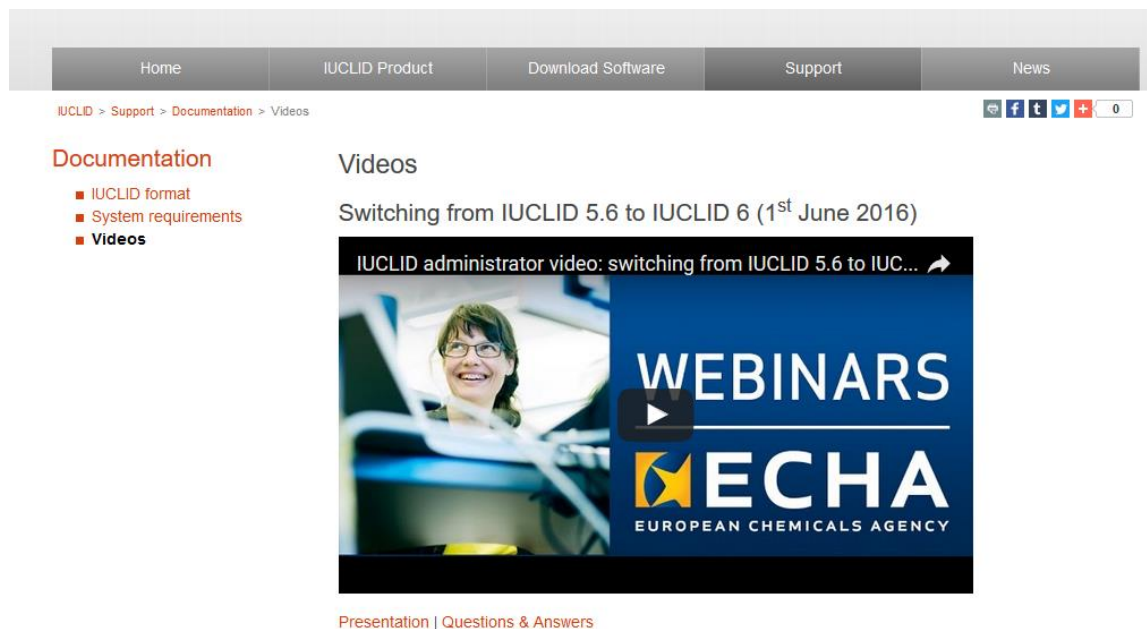
You can send questions during and after the presentations to the panellists, using the Q&A panel
To send a question, select *All panelists* from the drop down menu, write your question in the lower box, and finally click *Send*.

If a poll is opened during the webinar, the polling panel will open automatically



Recordings

- After the meeting, we will publish on the IUCLID 6 website:
 - The recording of the webinar (presentations)
 - Questions and answers (written document)

A screenshot of the IUCLID 6 website's "Videos" page. The page has a navigation bar with "Home", "IUCLID Product", "Download Software", "Support", and "News". Below the navigation bar is a breadcrumb trail: "IUCLID > Support > Documentation > Videos". There are social media icons for Facebook, Twitter, and YouTube, along with a "0" in a box. On the left, under "Documentation", there are links for "IUCLID format", "System requirements", and "Videos". The main content area is titled "Videos" and features a video player with the title "Switching from IUCLID 5.6 to IUCLID 6 (1st June 2016)". The video player shows a woman smiling and a blue banner with the text "WEBINARS" and the ECHA logo (European Chemicals Agency). Below the video player, there are links for "Presentation" and "Questions & Answers".

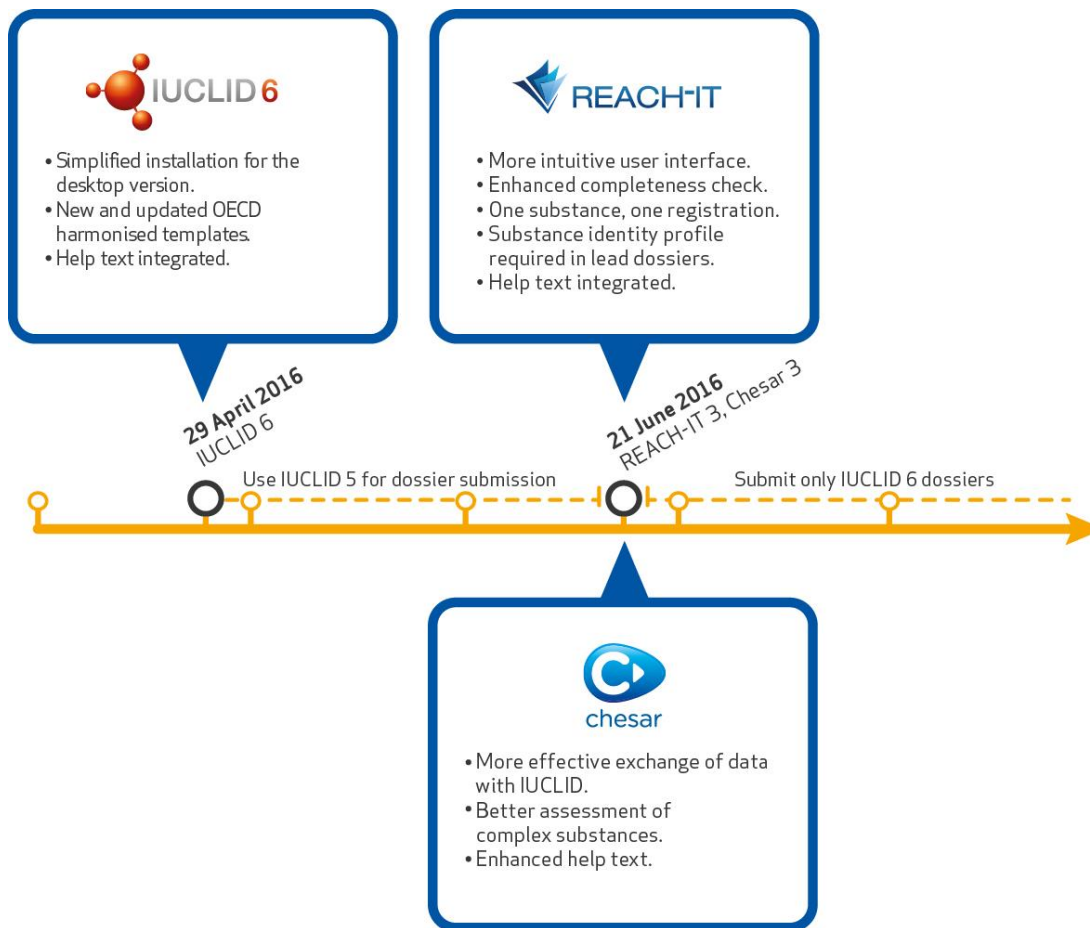
Feedback on IUCLID 6 release
Future updates



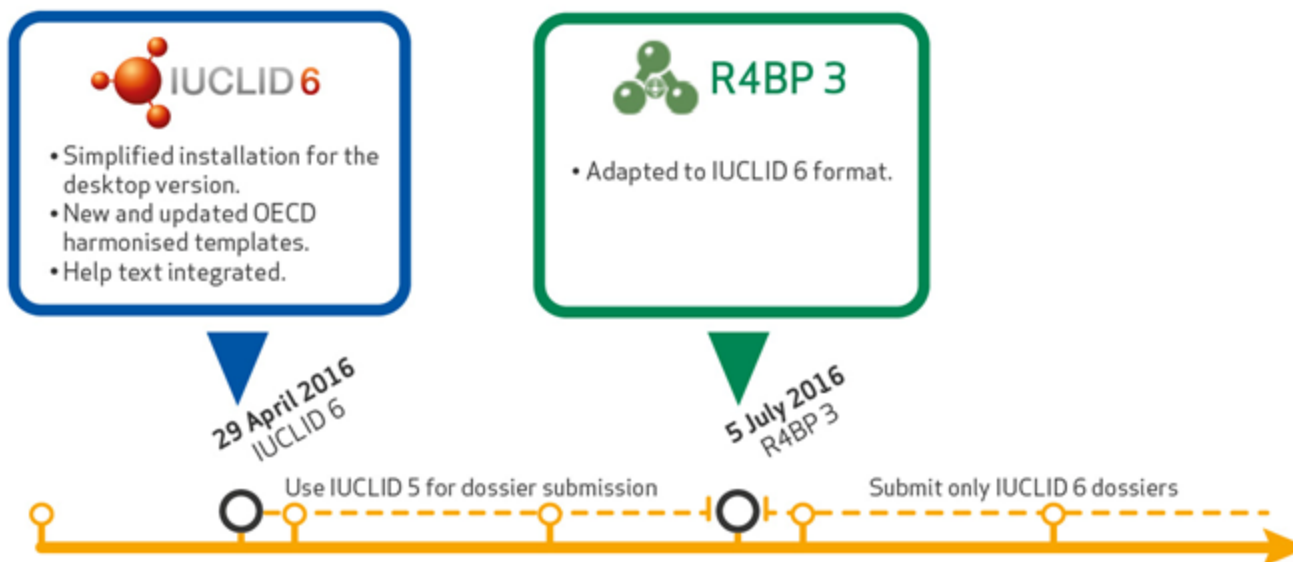
IUCLID 6 and ECHA's submission tools



REACH-IT



R4PB 3



Maintenance release of 21st of June 2016

- Content highlights
 - Bug fixes
 - Improvements to the CSR
 - Final configuration of the Dissemination preview
 - Help system update
 - Communication with Chesar 3
- Release made available with an updater
 - First installation of IUCLID 6: use the installer
 - Want to upgrade your IUCLID 6: use the updater
- Release notes available on the IUCLID 6 website (Download page)

IUCLID > Download Software

Download Software

› [IUCLID 6 installer and updater: which one should I download](#)

› [Desktop version for 32-bit computers](#)

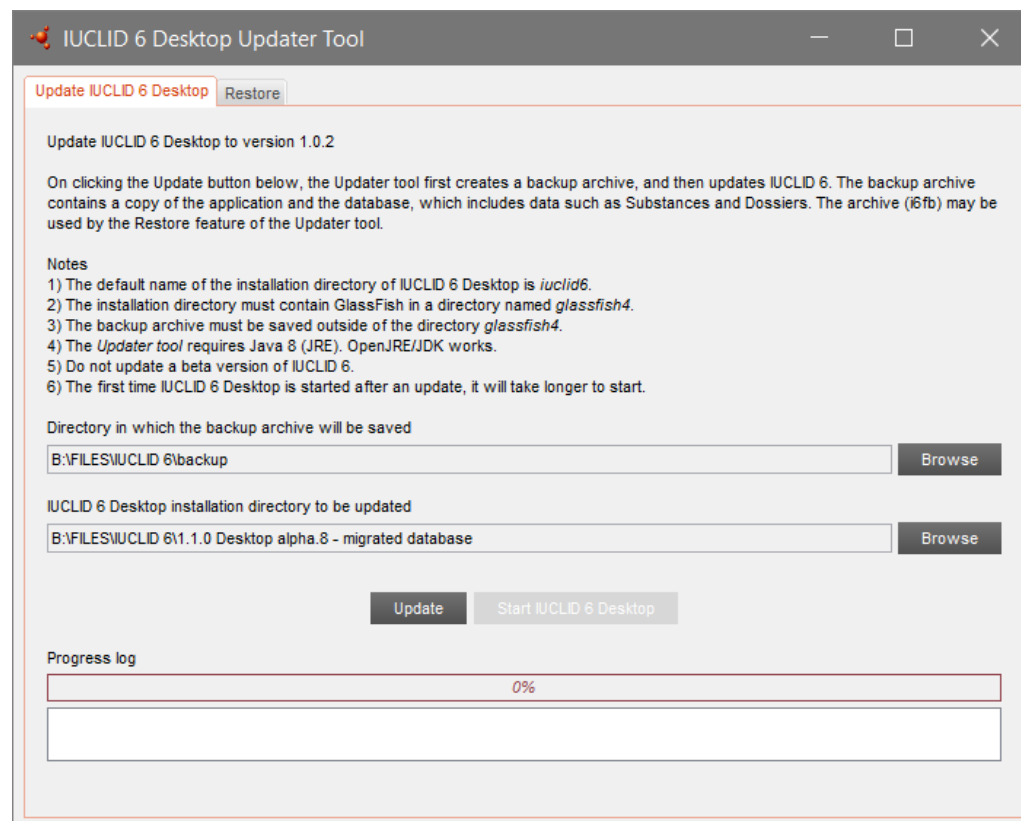
› [Desktop or Server - which is better for me?](#)

In connection with your IUCLID 6 download, you might want to consult the following links:

[Presentation on IUCLID 6](#) | [Release notes](#) | [IUCLID 6 manuals](#) | [FAQ](#)

Updater

- Download the updater to your IUCLID 6 installation folder and run it from there
- A backup is always taken before the update in order to restore the system if needed
- Specify a location for the backup
- Specify the location of your IUCLID 6 installation

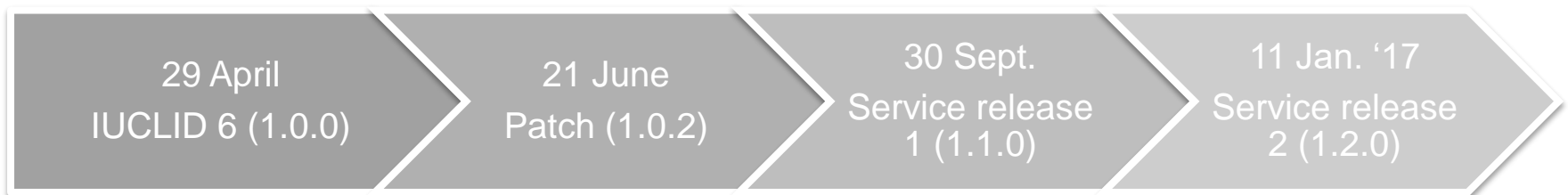


Future updates



Timelines

- Service releases of IUCLID 6 will be made available **twice** a year
- 2016-2107 transition period
 - 30 September 2016
 - 11 January 2017
 - **April 2017**
 - **October 2017** (can contain format update)
- Like in IUCLID 5, backward compatibility ensured



Service release 1 - scope

- Dossier comparison
- Inventory management tool
- Improvements to the User Interface (contrast, font size, Mac / Linux)
- Quality rules for the validation assistant
- Public API (1st version)
- Improvements
 - Clipboard
 - Filtering
 - Aggregation
 - Report generator and CSR
 - Help
 - Manual validation rules
 - Import (replace option)
 - Chesar plug-in (compatible with next Chesar version only)
- Fixes
 - Migration issues
 - Performance issues
 - Search
 - User permissions
 - Undo function
 - Field labels

Bug fixes

Known issues

› Q36. I attempted to export or run the Validation assistant on a IUCLID 6 dataset/dossier, or to create a dossier from a dataset. The operation is unsuccessful and I get an error at the top of the IUCLID window: "An error happened at the server". The error log points to a NullPointerException. What is the problem?

› Q37. I migrated a dataset from IUCLID 5 to IUCLID 6. When I tried to copy-paste or type information in a rich text field in the IUCLID 6 dataset, nothing is pasted, or the data is removed from the field when saving. When I print the dataset, the data seems to reappear. What is happening?

› Q38. When I use the print function in IUCLID 6 or when I generate a CSR with the Report generator an error is displayed in the Background Job Console. In the log files the following error is reported: `javax.xml.transform.TransformerException: org.xml.sax.SAXParseException: Premature end of file`

<https://iuclid6.echa.europa.eu/faq>

Service release 1 - scope

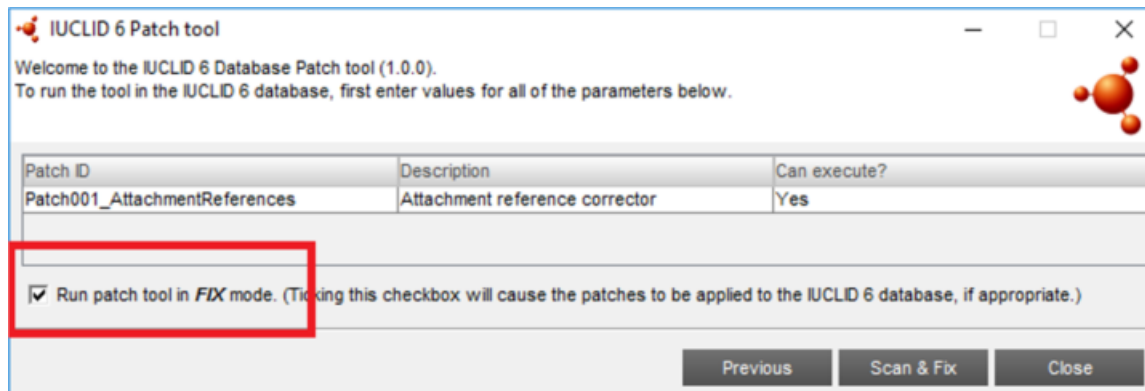
- Dossier comparison
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- Fixes
 - **Migration issues**
 - Performance issues
 - Search
 - User permissions
 - Undo function
 - Field labels

Service Release 1



Database patch tool

- New tool provided to fix issues in the IUCLID 6 database
- Can be run in 'scan' or 'fix' mode
- Backup your database before running the tool
- The tool contains the list of issues for which a fix is provided
- Some fixes will require a connection to a IUCLID 5 database
- If other issues are detected in the future
 - A new version of the tool will be made available
 - The tool will be able to detect the changes previously done



List of fixes

- Corrupted attachments are replaced with a default file
- Biocidal Product Regulation (BPR)
 - Links to the Use information inside the ‘Method of application...’ records: the link to the exact use was missing. This is now added in the field ‘Detailed description of method of application’ (*)
 - Sections 9.2 or 9.1 ‘Further ecotoxicological studies’ are now displayed in BPR dossiers
- Finalisation of the migration of the Test Material in templates inherited by several substances
- Migration of the field ‘Doses / concentrations’ in the documents ‘Developmental toxicity / teratogenicity’ (*)
- Inquiry document: migration errors in the Toxicological information section (*)

() Need connection to the original IUCLID 5 database*

Service release 1 - scope

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 - Undo function
 - Field labels



Chesar users: please, wait for the next update of Chesar 3 before upgrading IUCLID 6

Future updates



Service release 1 - scope

- **Dossier comparison**
- **Inventory management tool**
- Improvements to the User Interface (contrast, font size, Mac / Linux)
- Quality rules for the validation assistant
- Public API (1st version)
- Improvements
 - Clipboard
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 - Report generator and CSR
 - Help
 - Manual validation rules
 - **Import (replace option)**
 - Chesar plug-in (compatible with next Chesar version only)

- Fixes
 - Migration issues
 - Performance issues
 - Search
 - User permissions
 - Undo function
 - Field labels

Future updates



Planned releases

- More information on the planned IUCLID 6 releases can be found on the IUCLID 6 website
- <https://iuclid6.echa.europa.eu/project-iuclid-6#ServiceRelease>

The screenshot shows the IUCLID 6 website interface. At the top left is the IUCLID 6 logo. To the right is a search bar with the text "Search the IUCLID 6 website" and a magnifying glass icon. Below the search bar is a navigation menu with links for "Home", "IUCLID Product", "Download Software", "Support", and "News". In the top right corner, there is a "Sign In" link and a social media sharing bar with icons for email, Facebook, Twitter, LinkedIn, and a share icon, along with a "5" notification badge.

The main content area is titled "IUCLID Product" and contains a sub-section "IUCLID 6 maintenance and service releases". The text below this section states: "After the release of IUCLID 6 to the public, service and maintenance releases are prepared in order to fix reported issues and to provide improvements and new features requested by the users. Under this section the current planning and scope for the future releases are made available for information only and are subject to change (updated on 5 September 2016)."

The planned releases are listed as follows:

- 21st June 2016 (maintenance release)
 - Compatibility with Chesar 3
 - Performance improvements for performance issues detected in dossier creation
- October 2016 (maintenance release)
 - Other user requirements currently not prioritised
 - LDAP connectivity
 - Spell checker
 - Attachments versioning
 - Announcements for IUCLID system administrators
 - Link to email server (e.g. for resetting passwords)

At the bottom of the page, there are logos for ECHA (European Chemicals Agency) and OECD. Text on the right side of the footer states: "IUCLID 6 is developed by the European Chemicals Agency in association with the OECD". A "Legal notice" link is also present in the bottom right corner.

IUCLID 6 Service Release 1

New features highlights

**Replace during import
Inventory Management
Comparison tool**



IUCLID 6 Service Release 1

New features highlights

Replace during import

Inventory Management

Comparison tool





Replace during import

A **True Replace** offering you a complete overwrite of a dataset with the same UUID

Purpose

- The feature allows you to replace an existing dataset (**Template/Substance/Mixture-Product**) with an archived version of that dataset (based on the same UUID) using the Import functionality of IUCLID.

Overview – how it works:

- The replace feature is located inside the Import functionality of IUCLID.
- When you replace an existing dataset with an imported dataset (identified by the same dataset UUID), the existing dataset will then exactly reflect the newly imported dataset, **including its links to other documents and entities.**
- When importing a replacement Template, all Substance and/or Mixture-Product datasets using this Template (as an inherited Template) **will also be updated with the newly imported Template.**

Replace during import



When you replace a dataset, **ALL** documents which are in the existing dataset BUT NOT in the imported dataset, will be deleted.

Note: As a consequence of this, any link in the remaining dataset (after replace during import) which referenced a now deleted document, will be removed. For example, if a Composition record is referenced in section 2.1 (GHS), and the imported dataset deletes this referenced Composition record, the reference in 2.1 (GHS) will also be removed.

Replace during import



How to use the Replace feature



Click on the import icon

Import assistant

Select the files/directories to be imported
Please select the i5z/i6z files to be imported.

Import	Pathname	Filename	Size	Modified
--------	----------	----------	------	----------

+ Add files... X Remove

Content Remarks

The new replace feature is located here

Default action for existing documents (overwrite mode)

Replace Always Never If newer than existing

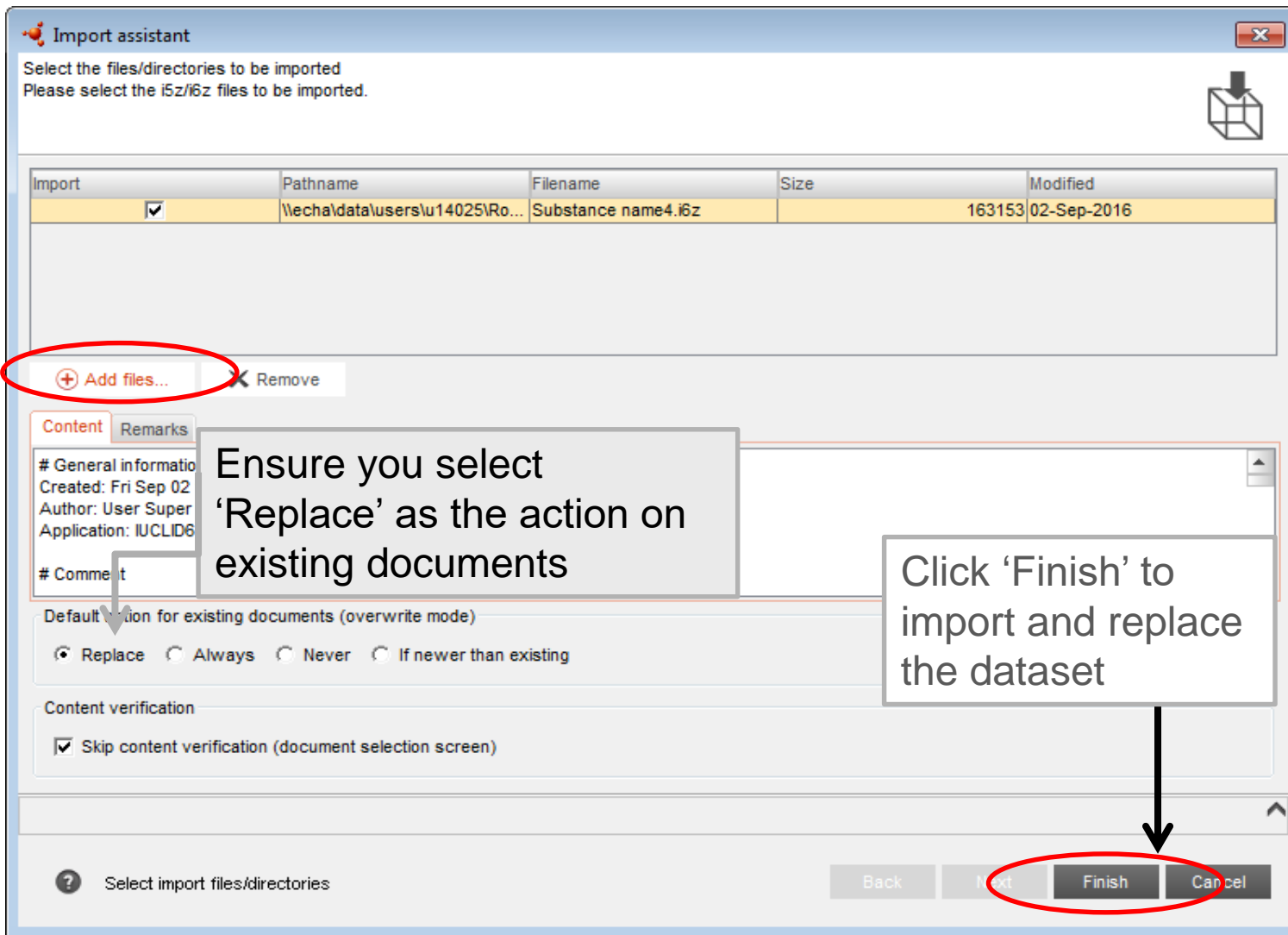
Content verification

Skip content verification (document selection screen)

? Select import files/directories

Back Next Finish Cancel

Replace during import



Import assistant

Select the files/directories to be imported
Please select the i5z/i6z files to be imported.

Import	Pathname	Filename	Size	Modified
<input checked="" type="checkbox"/>	\\echa\data\users\lu14025\Ro...	Substance name4.i6z	163153	02-Sep-2016

Add files... Remove

Content Remarks

General information
Created: Fri Sep 02
Author: User Super
Application: IUCLID6

Comment

Default action for existing documents (overwrite mode)

Replace Always Never If newer than existing

Content verification

Skip content verification (document selection screen)

Back Next **Finish** Cancel

Ensure you select 'Replace' as the action on existing documents

Click 'Finish' to import and replace the dataset

Replace during import



dataset 1 (archived dataset)

Illustrative example

dataset 2 (current dataset)

Replace after import using dataset 1

Navigation panel

Search TOC Annotations

REACH Complete table of contents

Text filter

- 0 Related information
- 1 General information
- 2 Classification & Labelling and PBT assessment
- 3 Manufacture, use and exposure
- 4 Physical and chemical properties
 - 4.1 Appearance / physical state / colour
 - Appearance / physical state / colour.001
 - Appearance / physical state / colour.003
 - 4.2 Melting point / freezing point

Navigation panel

Search TOC Annotations

REACH Complete table of contents

Text filter

- 0 Related information
- 1 General information
- 2 Classification & Labelling and PBT assessment
- 3 Manufacture, use and exposure
- 4 Physical and chemical properties
 - 4.1 Appearance / physical state / colour
 - Appearance / physical state / colour.001
 - Appearance / physical state / colour.001-COPY
 - Appearance / physical state / colour.003
 - 4.2 Melting point / freezing point

Added a new record

Navigation panel

Search TOC Annotations

REACH Complete table of contents

Text filter

- 0 Related information
- 1 General information
- 2 Classification & Labelling and PBT assessment
- 3 Manufacture, use and exposure
- 4 Physical and chemical properties
 - 4.1 Appearance / physical state / colour
 - Appearance / physical state / colour.001
 - Appearance / physical state / colour.003
 - 4.2 Melting point / freezing point

IUCLID 6 Service Release 1

New features highlights

Replace during import

Inventory Management

Comparison tool



Purpose

- To help users better manage their Inventory Entities:
 - Test materials
 - Legal entity
 - Legal Entity site
 - Reference Substance
 - Contact
 - Literature reference

Note: This does not include your ‘Chemical Inventories’

Overview – how it works:

- A user can replace one or more existing entities with a **single inventory entity** of the same type
- When a user replaces an entity, that entity will be replaced in every dataset where it is used: Substance / Mixture-Product / Template / Category (the entities in a dossier are not affected)
 - Note that Contact, Reference Substance and Legal Entity are used in other entities and will **also** be replaced.
- Any entity which is replaced is deleted from the IUCLID database
 - Before using the feature, you can save the contents of your current database using the Backup/Restore tool.

Using the Inventory Management to replace **Legal Entity 1** and **Legal Entity 2** with **Legal Entity 3**

Legal Entity 1

- Substance
 - Section 1.5
Lead registrant in a joint submission
- Category
- Legal Entity Site

Legal Entity 2

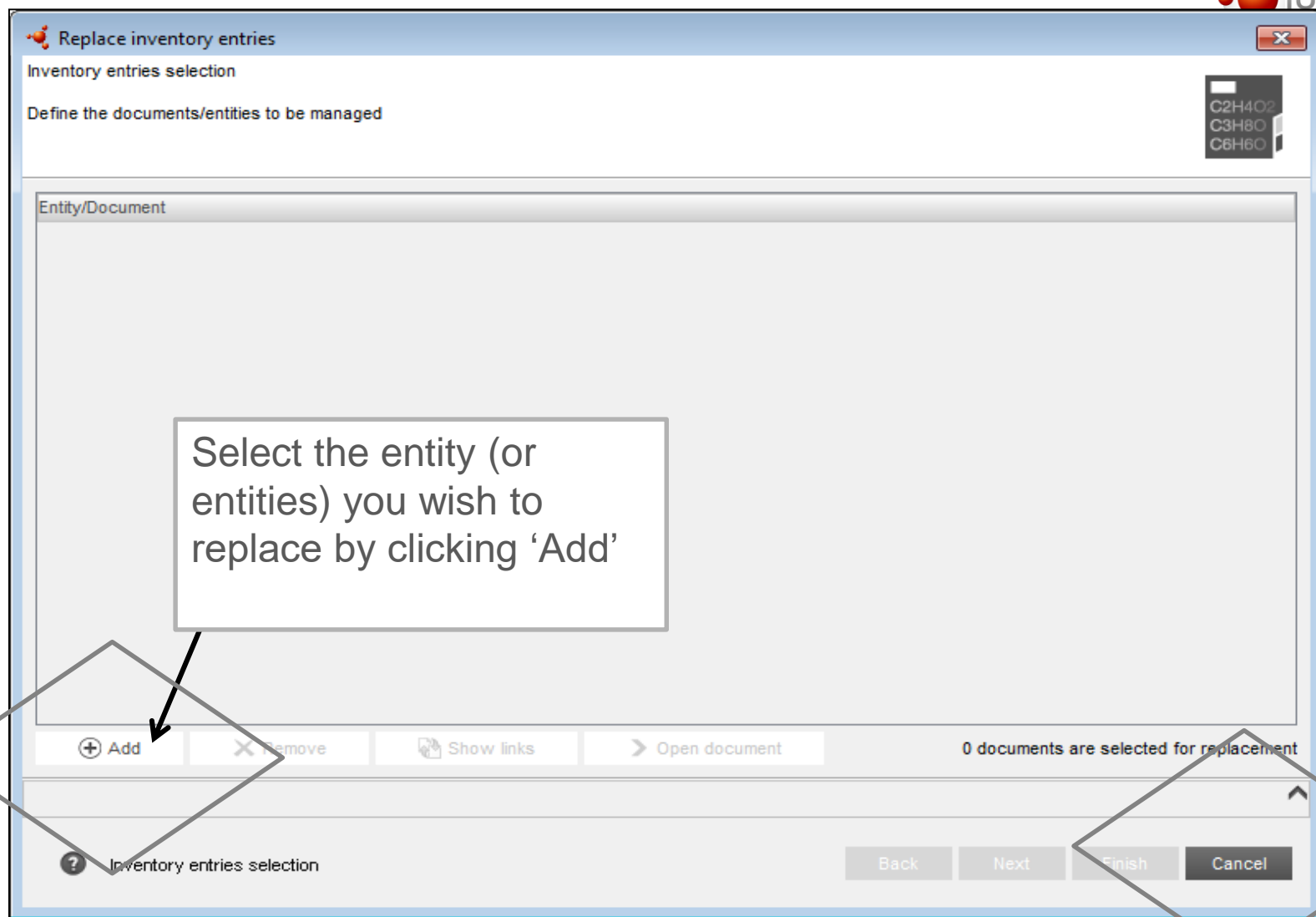
- Substance
 - Section 1.7
 - Section 1.8
- Template
- Mixture-Product
 - Section 1.3

Legal Entity 3

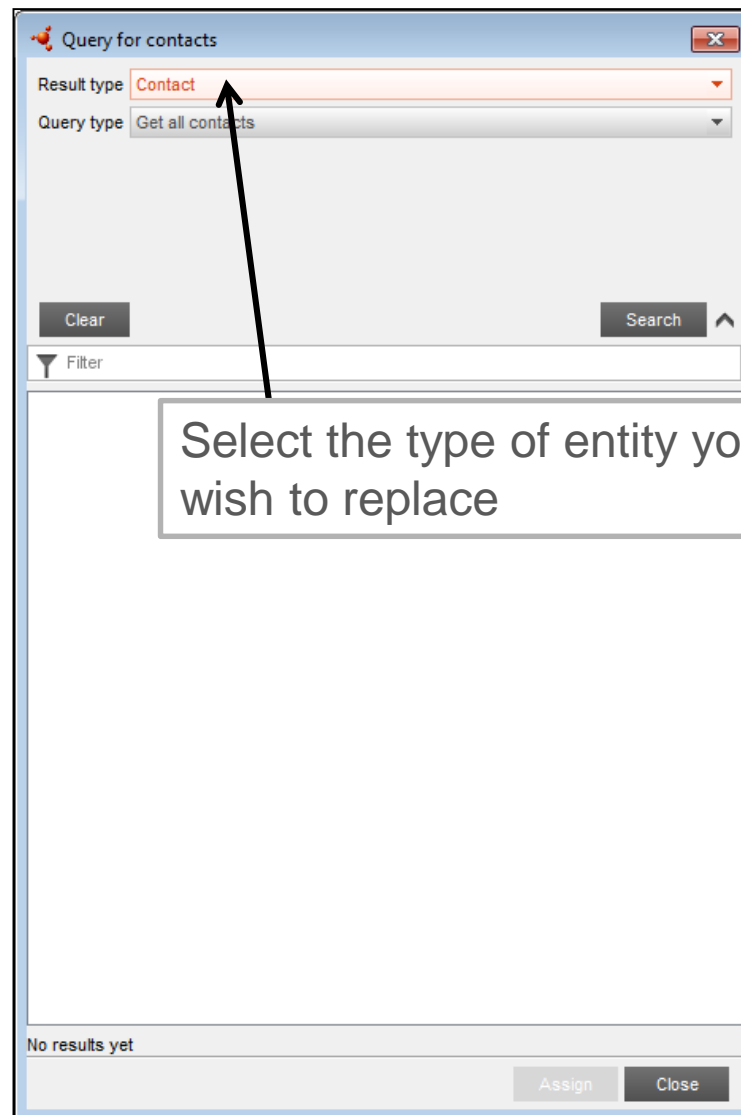
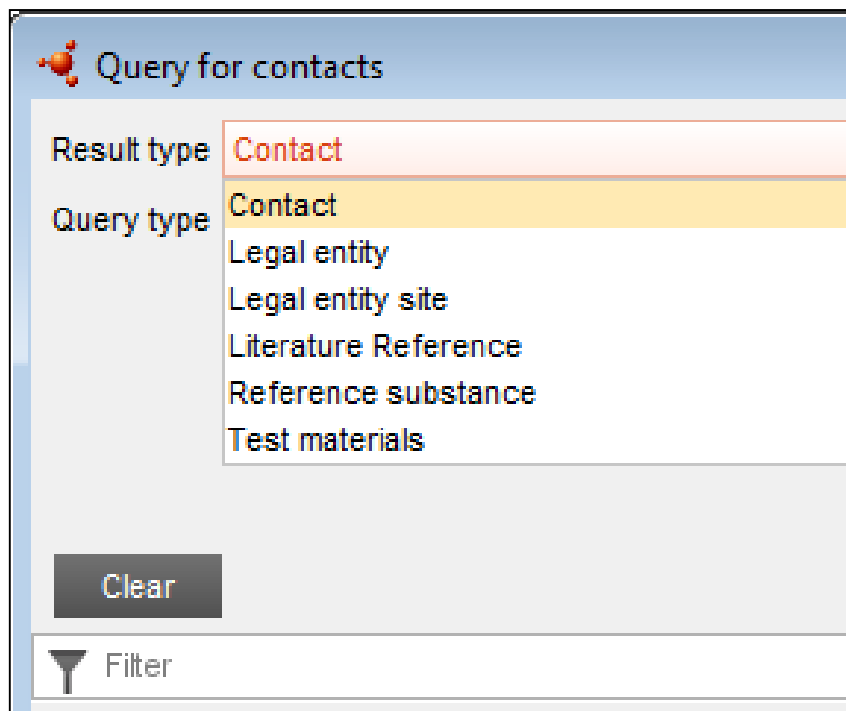
- Substance
 - Section 1.5
 - Section 1.7
 - Section 1.8
- Template
- Mixture-Product
 - Section 1.3
- Category
- Legal Entity Site

- Legal Entity 1 and 2, are also removed from the list of Legal Entities
- When replacing an entity in an Inherited Template, that entity will be replaced in All datasets where that template is used

Inventory Management



Inventory Management



Refine your search using the 'Query Type'

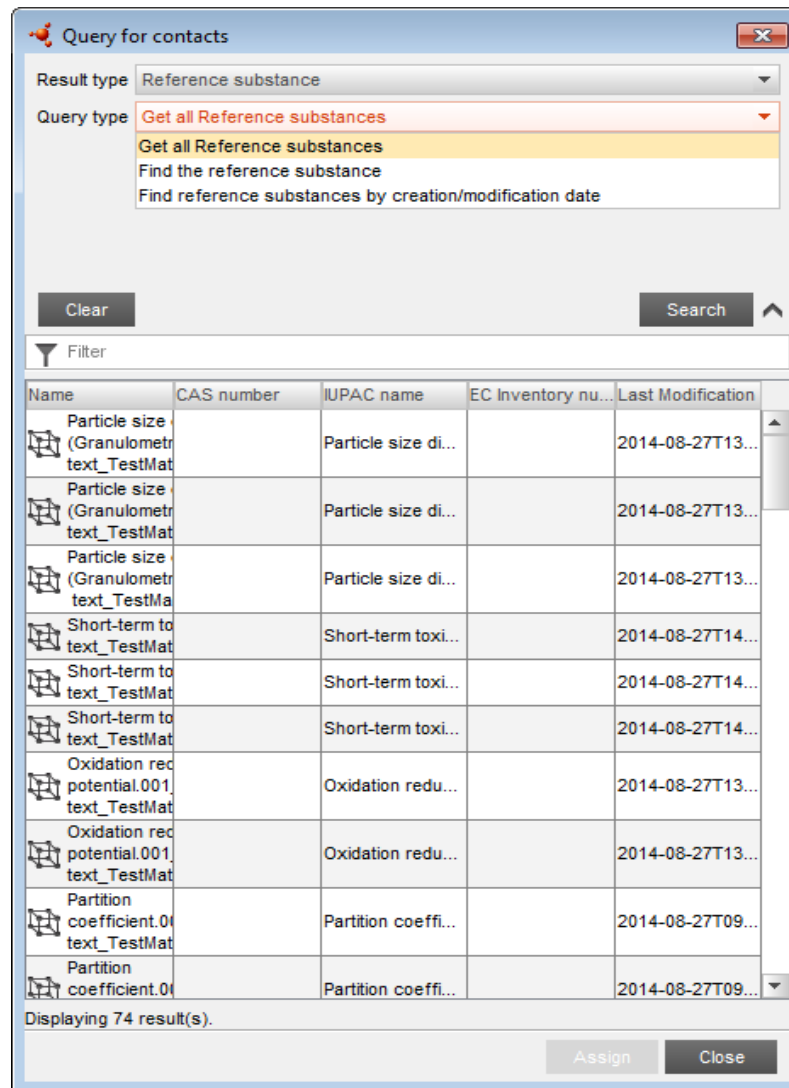
Get all

- Contacts, Legal Entities, Test Materials

Find an entity

- Search using the key information about the entity
- Search through a wildcard asterisk * if not sure as to the whole name

Search by creation/modification date



Query for contacts

Result type: Reference substance

Query type: Get all Reference substances

Clear Search

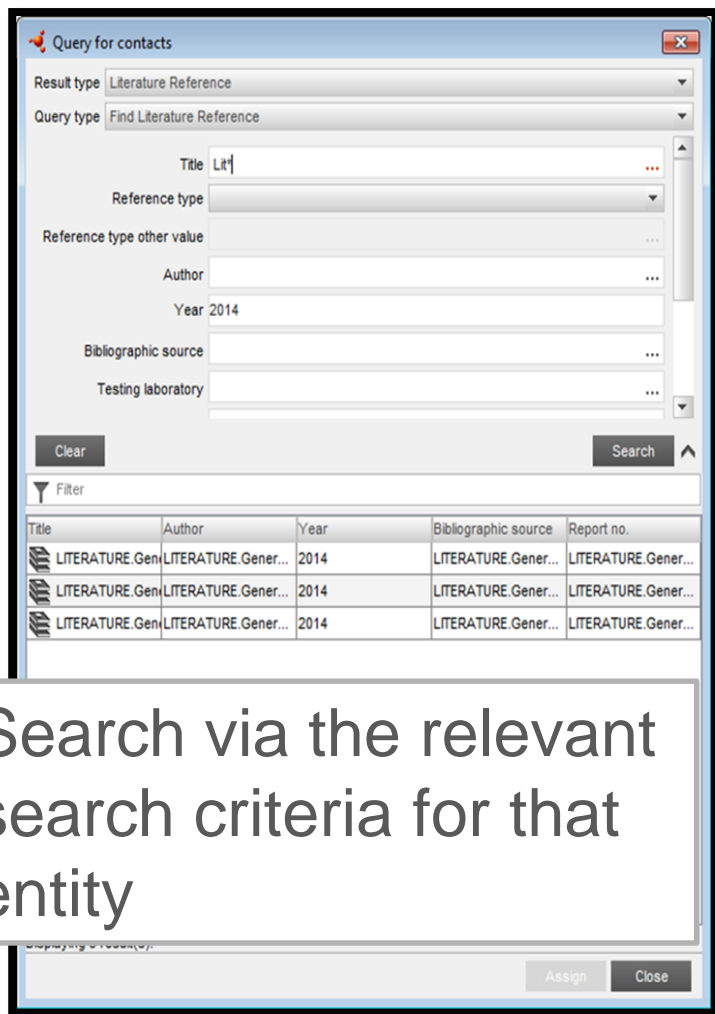
Filter

Name	CAS number	IUPAC name	EC Inventory nu...	Last Modification
Particle size (Granulomet... text_TestMat		Particle size di...		2014-08-27T13...
Particle size (Granulomet... text_TestMat		Particle size di...		2014-08-27T13...
Particle size (Granulomet... text_TestMa		Particle size di...		2014-08-27T13...
Short-term toxi... text_TestMat		Short-term toxi...		2014-08-27T14...
Short-term toxi... text_TestMat		Short-term toxi...		2014-08-27T14...
Short-term toxi... text_TestMat		Short-term toxi...		2014-08-27T14...
Oxidation rec potential.001, text_TestMat		Oxidation redu...		2014-08-27T13...
Oxidation rec potential.001, text_TestMat		Oxidation redu...		2014-08-27T13...
Partition coefficient.01 text_TestMat		Partition coeffi...		2014-08-27T09...
Partition coefficient.01 text_TestMat		Partition coeffi...		2014-08-27T09...

Displaying 74 result(s).

Assign Close

Inventory Management



Query for contacts

Result type: Literature Reference

Query type: Find Literature Reference

Title: Lit

Reference type: [dropdown]

Reference type other value: [dropdown]

Author: [dropdown]

Year: 2014

Bibliographic source: [dropdown]

Testing laboratory: [dropdown]

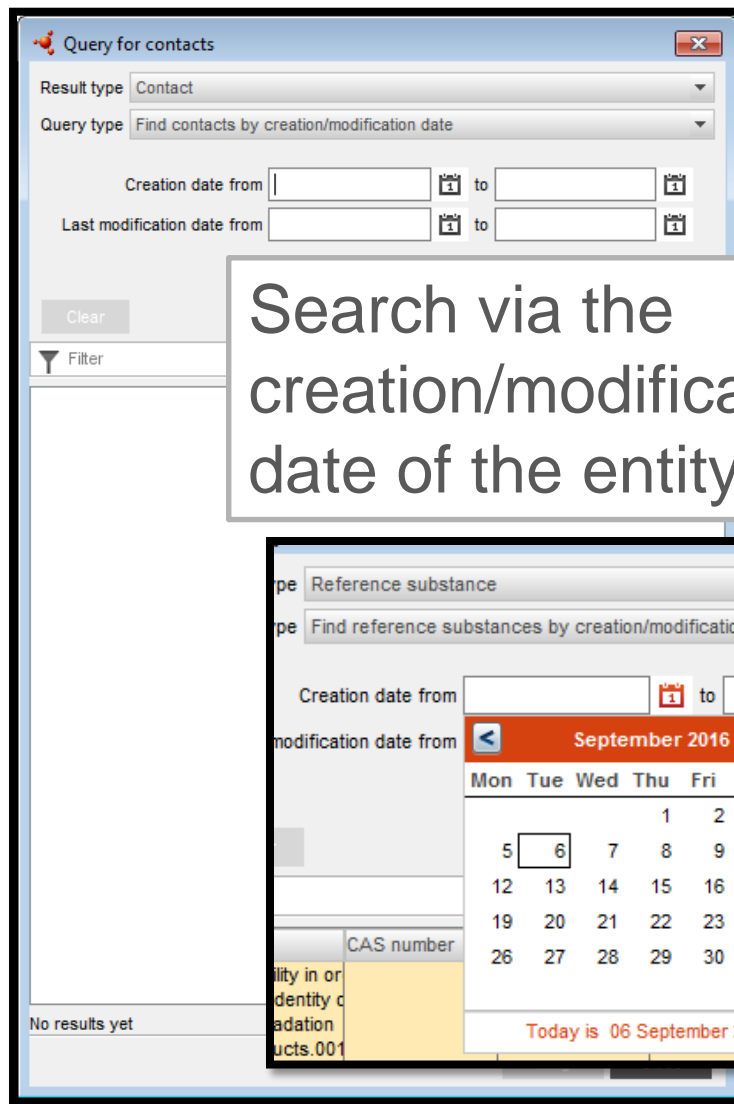
Clear Search

Filter

Title	Author	Year	Bibliographic source	Report no.
LITERATURE.Gen...	LITERATURE.Gen...	2014	LITERATURE.Gen...	LITERATURE.Gen...
LITERATURE.Gen...	LITERATURE.Gen...	2014	LITERATURE.Gen...	LITERATURE.Gen...
LITERATURE.Gen...	LITERATURE.Gen...	2014	LITERATURE.Gen...	LITERATURE.Gen...

Assign Close

Search via the relevant search criteria for that entity



Query for contacts

Result type: Contact

Query type: Find contacts by creation/modification date

Creation date from: [calendar icon] to: [calendar icon]

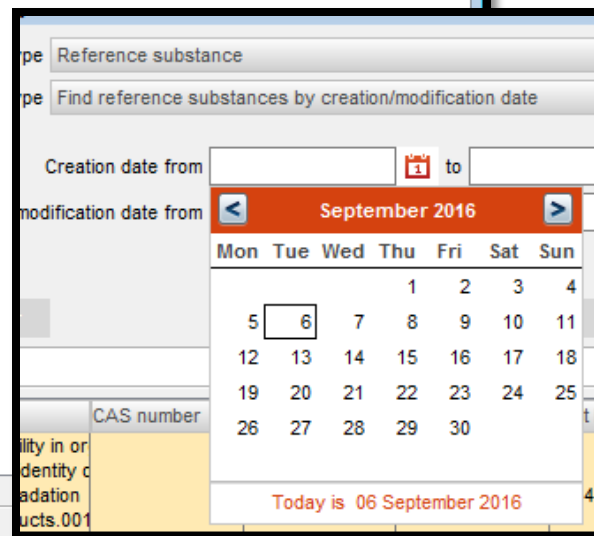
Last modification date from: [calendar icon] to: [calendar icon]

Clear

Filter

No results yet

Search via the creation/modification date of the entity



Creation date from: [calendar icon] to: [calendar icon]

modification date from: [calendar icon]

September 2016

Mon	Tue	Wed	Thu	Fri	Sat	Sun
			1	2	3	4
5	6	7	8	9	10	11
12	13	14	15	16	17	18
19	20	21	22	23	24	25
26	27	28	29	30		

CAS number

Today is 06 September 2016

Inventory Management



Query for contacts

Result type: Legal entity

Query type: Get all legal entities

Clear Search

Filter

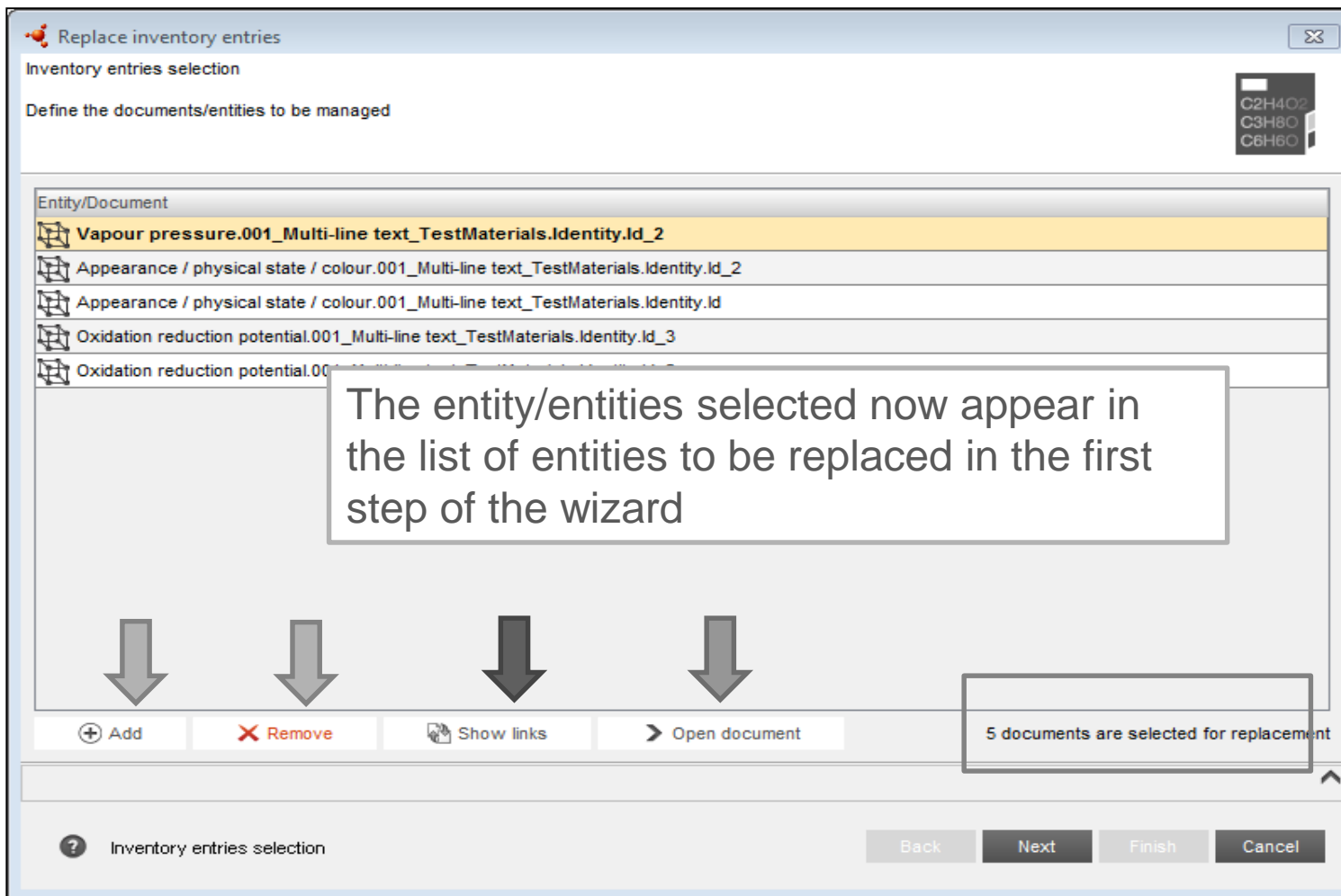
Legal entity name	Legal entity town	Legal entity country	Last modification date
AS Company	Warszawa	Poland	2016-09-02T09:43:4...
Mark r			2016-08-30T08:59:4...
New company	Helsinki	Finland	2016-02-03T16:35:5...
robi LE			2016-03-16T14:41:1...
BP manufacturer	Helsinki	Finland	2013-06-14T10:19:2...

Displaying 5 result(s).

Assign Close

Bulk selection of entities

Inventory Management



Replace inventory entries

Inventory entries selection

Define the documents/entities to be managed

Entity/Document

- Vapour pressure.001_Multi-line text_TestMaterials.Identity.Id_2**
- Appearance / physical state / colour.001_Multi-line text_TestMaterials.Identity.Id_2
- Appearance / physical state / colour.001_Multi-line text_TestMaterials.Identity.Id
- Oxidation reduction potential.001_Multi-line text_TestMaterials.Identity.Id_3
- Oxidation reduction potential.001_Multi-line text_TestMaterials.Identity.Id

The entity/entities selected now appear in the list of entities to be replaced in the first step of the wizard

↓ ↓ ↓ ↓

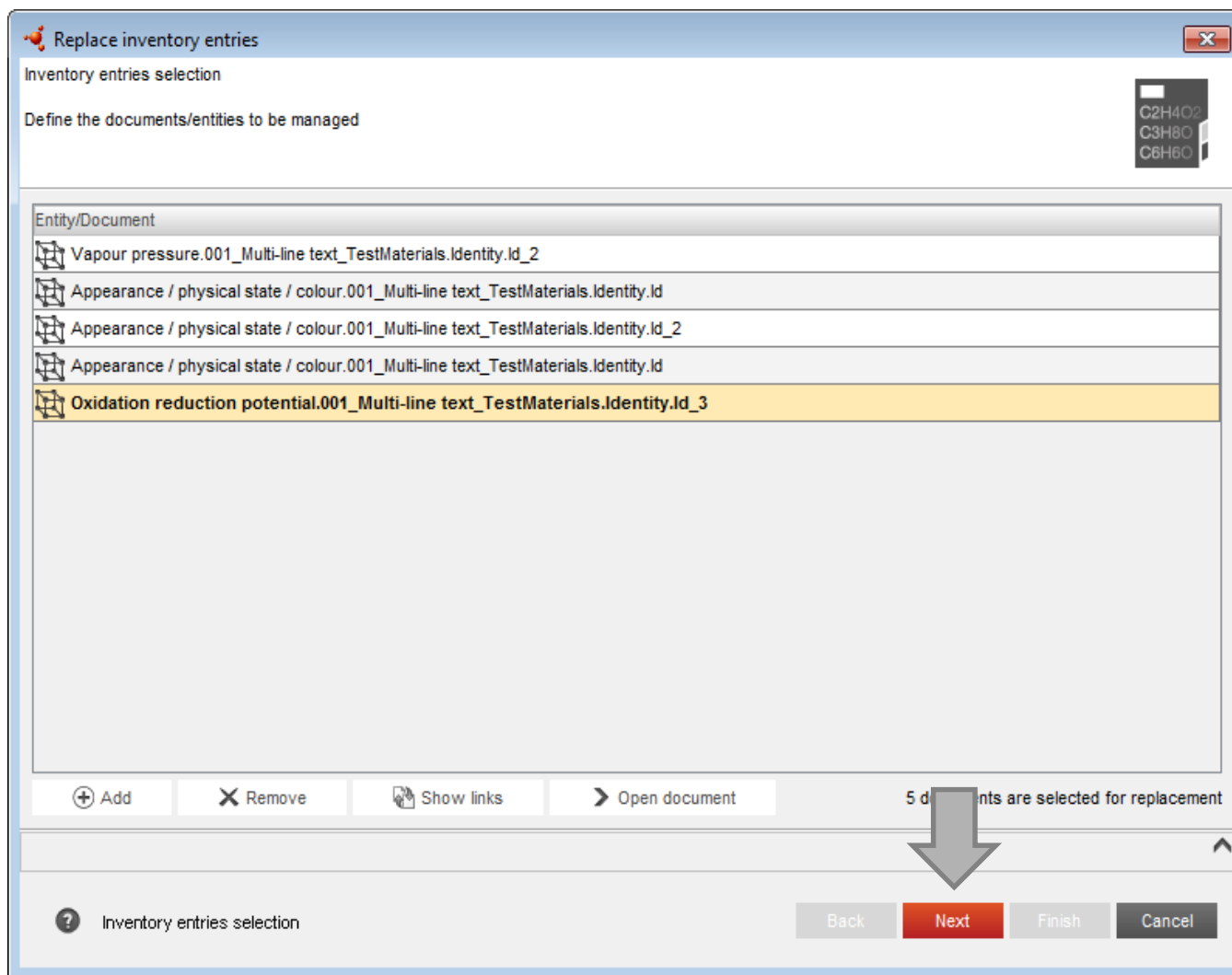
+ Add X Remove Show links > Open document

5 documents are selected for replacement

Inventory entries selection

Back Next Finish Cancel

Inventory Management



Replace inventory entries

Inventory entries selection

Define the documents/entities to be managed

Entity/Document

- Vapour pressure.001_Multi-line text_TestMaterials.Identity.Id_2
- Appearance / physical state / colour.001_Multi-line text_TestMaterials.Identity.Id
- Appearance / physical state / colour.001_Multi-line text_TestMaterials.Identity.Id_2
- Appearance / physical state / colour.001_Multi-line text_TestMaterials.Identity.Id
- Oxidation reduction potential.001_Multi-line text_TestMaterials.Identity.Id_3**

5 documents are selected for replacement

Inventory entries selection

Back **Next** Finish Cancel

Inventory Management



Replace inventory entries

Inventory entries selection

Define the document/entity to replace the selected ones

Select one document to replace the selected ones

Search box with icons: > ∞ X

Select the entity which will replace the previously selected entity/entities

Back Next Finish Cancel

Query for reference substances

Query type: Find the reference substance

Reference: Find the reference substance

Find reference substances by creation/modification date

CAS number (Inventory) ...

Inventory number ...

Inventory name ...

CAS number ...

CAS name ...

IUPAC name ...

Clear Search

Filter

Name	CAS number	IUPAC name	EC inventory nu...	Last Modification
Short-term to text_TestMat		Short-term toxi...		2014-08-27T14...
Short-term to text_TestMat		Short-term toxi...		2014-08-27T14...
				4-08-27T13...
				4-08-27T13...
				4-08-27T09...
Partition coefficient.0 text_TestMat		Partition coeffi...		2014-08-27T09...
Partition coefficient.0 text_TestMat		Partition coeffi...		2014-08-27T09...
Flash point.0				

Displaying 68 result(s).

Assign Close

Use the Query Type to help define a specific entity

Inventory Management



Query for reference substances

Query type: Get all Reference substances

Clear Search

Filter

Name	CAS number	IUPAC name	EC Inventory nu...	Last Modification
Oxidation red potential.001... text_TestMat		Oxidation redu...		2014-08-27T13...
Oxidation red potential.001... text_TestMat		Oxidation redu...		2014-08-27T13...
Short-term toxi... text_TestMat		Short-term toxi...		2014-08-27T14...
Short-term toxi... text_TestMat		Short-term toxi...		2014-08-27T14...
Short-term toxi... text_TestMat		Short-term toxi...		2014-08-27T14...
Partition coefficient.0... text_TestMat		Partition coeffi...		2014-08-27T09...
Partition coefficient.0... text_TestMat		Partition coeffi...		2014-08-27T09...
Partition coefficient.0... text_TestMat		Partition coeffi...		2014-08-27T09...
Flash point.0... text_TestMat		Flash point.001...		2014-08-27T13...
Flash point.0... text_TestMat		Flash point.001...		2014-08-27T13...
Flash point.0... text_TestMat		Flash point.001...		2014-08-27T13...

Displaying 74 result(s).

Assign Close

Assign and move to the Next step

Replace inventory entries

Inventory entries selection

Define the document/entity to replace the selected ones

Select one document to replace the selected ones

Oxidation reduction potential.001_Multi-line text_TestMaterials.Identity.Id_2 / Oxidation reduction potential.001_Multi-line text_TestMaterials.Identity.Id_2

Back Next Finish Cancel






Replace inventory entries

Confirmation of inventory entries replacement



Confirm the documents/entities to be replaced

C2H4O2
C3H8O
C6H6O


Please confirm that the 5 selected entities

Entity/Document
 Appearance / physical state / colour.001_Multi-line text_TestMaterials.Identity.Id
 Oxidation reduction potential.001_Multi-line text_TestMaterials.Identity.Id_3
 Appearance / physical state / colour.001_Multi-line text_TestMaterials.Identity.Id_2
 Vapour pressure.001_Multi-line text_TestMaterials.Identity.Id_2
 Appearance / physical state / colour.001_Multi-line text_TestMaterials.Identity.Id

Entities which will be replaced

 Show links  Open document

will be replaced by the following entry

 Oxidation reduction potential.001_Multi-line text_TestMaterials.Identity.Id_2 / Oxidation reduction potential.001_Multi-line text_TestMaterials.Identity.Id_2

Entity which will be replacing all entities listed above

Once proceeding with this replacement :

- the 5 selected entries will be deleted
- all the references (inside raw datasets) to these 5 entries will

Confirmation of inventory entries replacement

Back Next Finish Cancel

Inventory Management






Replace inventory entries


Confirmation of inventory entries replacement

Confirm the documents/entities to be replaced


C2H4O2
C3H8O
C6H6O

Please confirm that the 5 selected entities

Entity/Document
 Appearance / physical state / colour.001_Multi-line text_TestMaterials.Identity.Id
 Oxidation reduction potential.001_Multi-line text_TestMaterials.Identity.Id_3
 Appearance / physical state / colour.001_Multi-line text_TestMaterials.Identity.Id_2
 Vapour pressure.001_Multi-line text_TestMaterials.Identity.Id_2
 Appearance / physical state / colour.001_Multi-line text_TestMaterials.Identity.Id

 **Show links** > Open document

will be replaced by the following entry

 Oxidation reduction potential.001_Multi-line text_TestMaterials.Identity.Id_2 / Oxidation reduction potential.001_Multi-line text_TestMaterials.Identity.Id_2 >

Once proceeding with this replacement :

- the 5 selected entries will be deleted
- all the references (inside raw datasets) to these 5 entries will be replaced by references to the chosen inventory entry

Back Next **Finish** Cancel

Open the entity itself by clicking on 'Open Document'

Review what the entities are linked to by clicking on 'Show links'

Inventory Management

Replace inventory entries

Replacement report

Report for the inventory entries replacements
Job ID: 6, execution date 02/09/2016 15:07:56

Replaced documents

Entity/Document	Document type	Document UUID
Appearance / physical state / colour.001_Multi-line text_TestMaterials.Identity.Id_2	Reference substance	a85141be-499f-37f2-9ad5-c24c786b0e23
Appearance / physical state / colour.001_Multi-line text_TestMaterials.Identity.Id	Reference substance	fe445b9b-b658-3dd6-b330-a77b7edc710e
Vapour pressure.001_Multi-line text_TestMaterials.Identity.Id_2	Reference substance	26ac2edb-e69a-3802-bad3-d0b940d6cb79
Oxidation reduction potential.001_Multi-line text_TestMaterials.Identity.Id_3	Reference substance	af304eb0118c
Appearance / physical state / colour.001_Multi-line text_TestMaterials.Identity.Id	Reference substance	901402b7bce

Replaced entity/entities

Document that replaced the above list

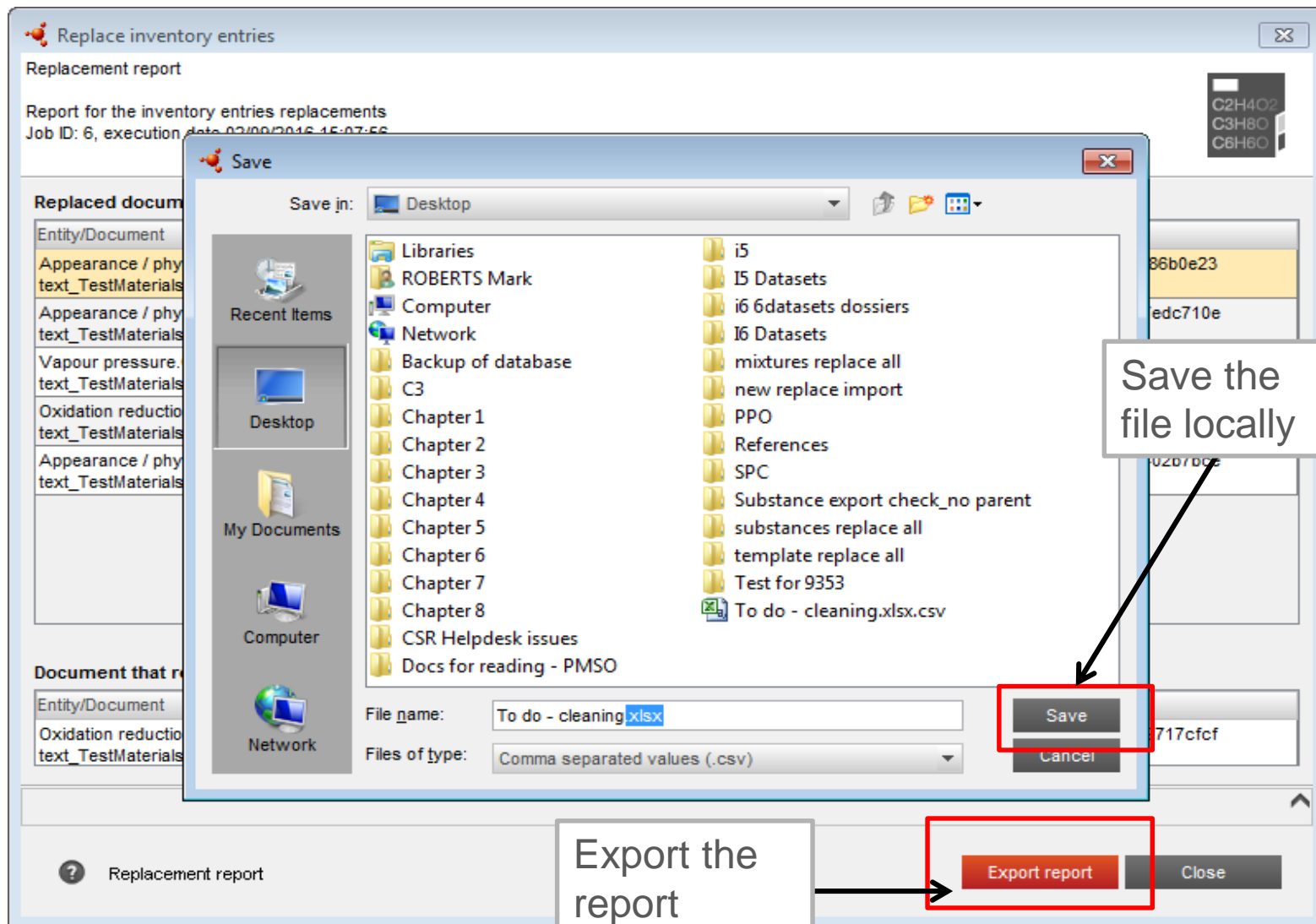
Entity/Document	Document type	Document UUID
Oxidation reduction potential.001_Multi-line text_TestMaterials.Identity.Id_2	Reference substance	1961dd75-0419-316c-9ce2-60a69717cfcf

The entity which has replaced the list above

Replacement report

Export report Close

Inventory Management



The screenshot displays the 'Replace inventory entries' window in IUCLID 6. The window title is 'Replace inventory entries' and it contains a 'Replacement report' section. Below the report, there is a list of 'Replaced documents' with columns for 'Entity/Document' and 'Document that r...'. A 'Save' dialog box is open over the main window, showing the 'Desktop' as the save location. The dialog lists various folders and files, including 'To do - cleaning.xlsx.csv'. The 'Save' button in the dialog is highlighted with a red box. A callout box with the text 'Save the file locally' and an arrow points to this button. At the bottom of the main window, the 'Export report' button is also highlighted with a red box. A callout box with the text 'Export the report' and an arrow points to this button. The 'Close' button is visible next to 'Export report'.

IUCLID 6 Service Release 1

New features highlights

Replace during import
Inventory Management

Comparison tool



Purpose

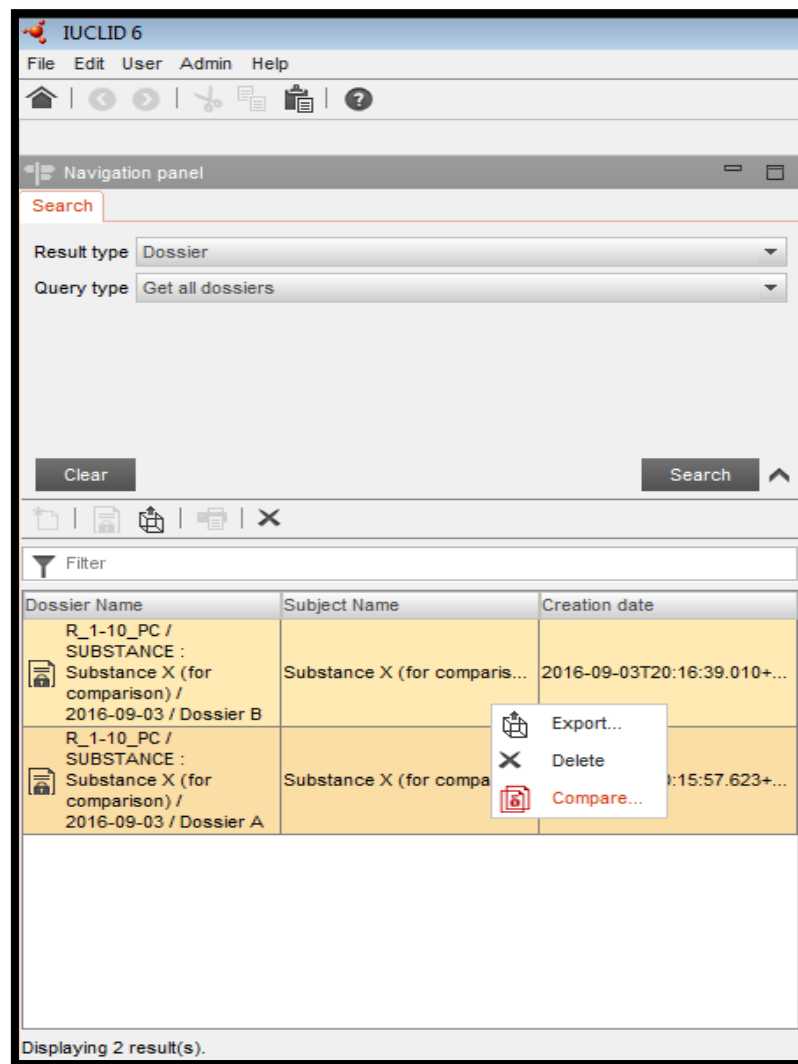
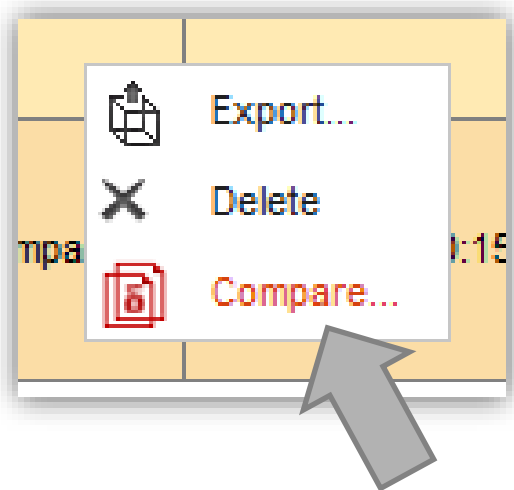
The Comparison tool has been updated and improved in IUCLID 6 to help you:

- To compare whether the same documents exist in two different dossiers, and also
- To compare the **content** of those documents, thereby allowing you to see in much greater detail the similarities and differences between two dossiers

Overview – how it works

- Two dossiers are compared and are considered identical when **ALL** documents within them have the same content of information.
- When the dossiers are found to have same UUIDs but different content, the comparison tool clearly highlights these for you so you can easily identify where the similarities and differences are to be found.

Comparison tool



The screenshot shows the IUCLID 6 application window. At the top is a menu bar with 'File', 'Edit', 'User', 'Admin', and 'Help'. Below it is a navigation panel with a search bar, 'Result type' set to 'Dossier', and 'Query type' set to 'Get all dossiers'. A 'Clear' button and a 'Search' button with an upward arrow are also present. Below the navigation panel is a toolbar with icons for home, save, print, and close. A 'Filter' dropdown is located above a table of search results. The table has three columns: 'Dossier Name', 'Subject Name', and 'Creation date'. Two rows are visible, both containing dossier information for 'Substance X (for comparison)'. A context menu is open over the second row, showing 'Export...', 'Delete', and 'Compare...' options.

Dossier Name	Subject Name	Creation date
R_1-10_PC / SUBSTANCE : Substance X (for comparison) / 2016-09-03 / Dossier B	Substance X (for comparis...	2016-09-03T20:16:39.010+...
R_1-10_PC / SUBSTANCE : Substance X (for comparison) / 2016-09-03 / Dossier A	Substance X (for compa	2016-09-03T15:57.623+...

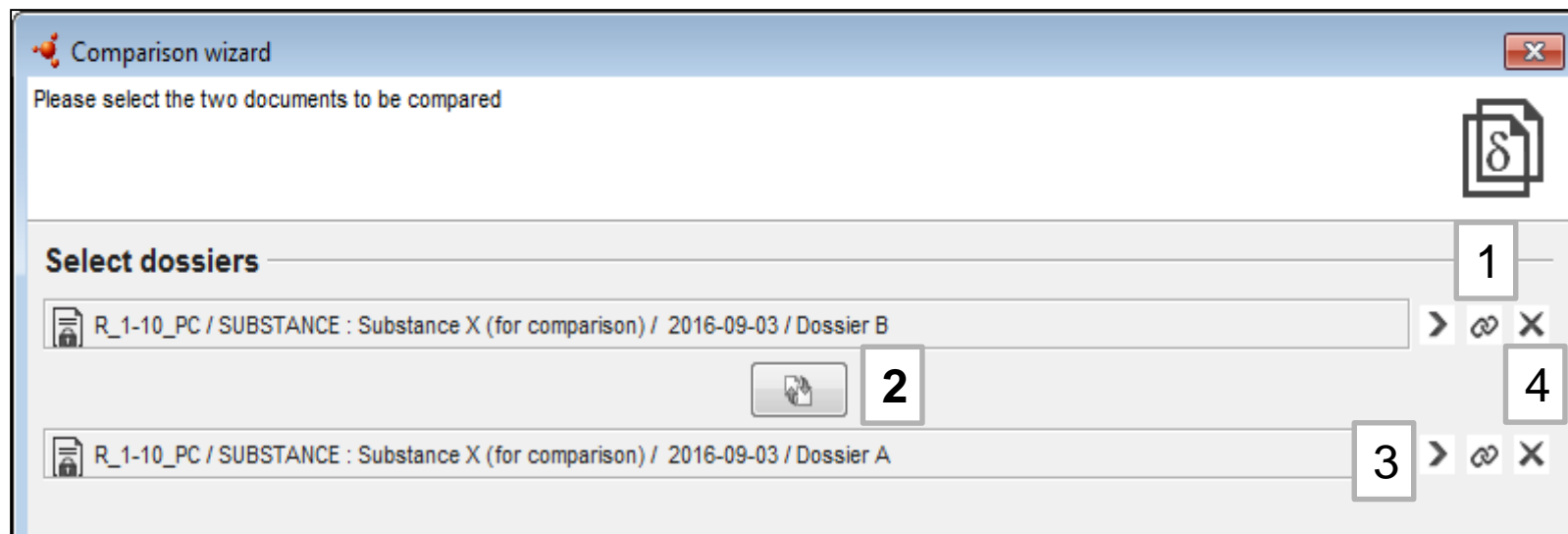
Displaying 2 result(s).

Comparison tool



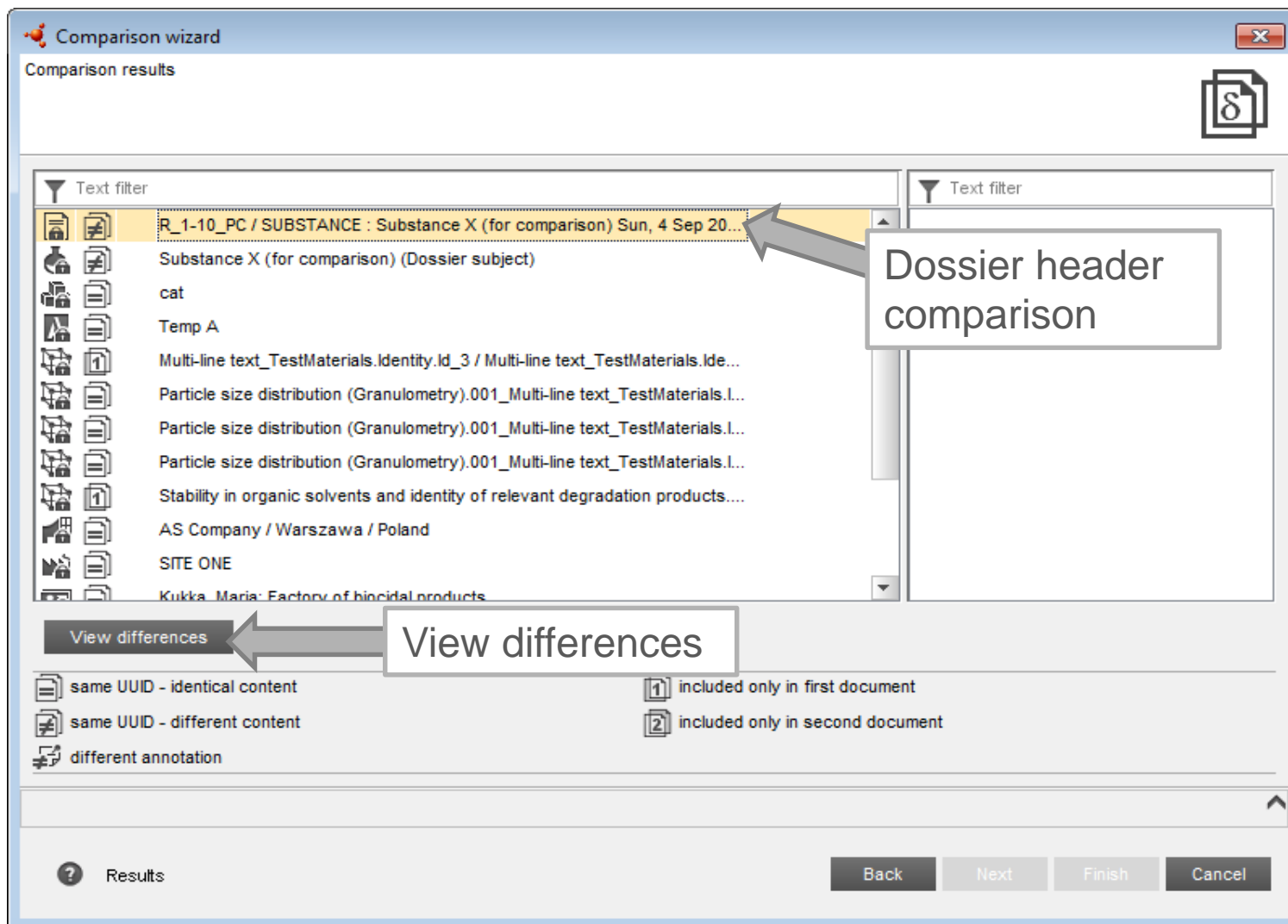
The first step of the Comparison wizard allows you to:

1. Choose a new or different dossier to compare
2. Select which dossier is to be considered as the first/second dossier in the comparison (see the Reference Key in the next wizard step)
3. Display a selected dossier in the data window of IUCLID
4. Remove the currently selected dossier



Comparison tool

Final Comparison step



The screenshot displays the 'Comparison wizard' window with the 'Comparison results' tab selected. The main area shows a list of comparison items, with the top item 'R_1-10_PC / SUBSTANCE : Substance X (for comparison) Sun, 4 Sep 20...' highlighted. A callout box labeled 'Dossier header comparison' points to this item. Below the list, a 'View differences' button is highlighted, with another callout box labeled 'View differences' pointing to it. The bottom section of the window shows a legend for comparison results: 'same UUID - identical content', 'same UUID - different content', and 'different annotation'. To the right of the legend are two icons: a document with '1' (included only in first document) and a document with '2' (included only in second document). At the bottom right, there are buttons for 'Back', 'Next', 'Finish', and 'Cancel'. A 'Results' button with a question mark icon is located at the bottom left.

Comparison tool

View Differences results table

Detailed comparison differences

Selected document > R_1-10_PC / SUBSTANCE : Substance X (for comparison) Sun, 4 Sep 2016 20:52:48 +0300 / Dossier J

Filter

show all show only different show only identical

Field	Value in 1st Document		
DOSSIER.R_1-10_PC	Dossier J	<input checked="" type="checkbox"/>	Dossier R
● DOSSIER.R_1-10_PC	Dossier J	<input checked="" type="checkbox"/>	Dossier R
SubmissionType		<input type="checkbox"/>	
● JointSubmission	false	<input type="checkbox"/>	false
InformationProvidedByLead		<input type="checkbox"/>	
● ChemicalSafetyReport	false	<input type="checkbox"/>	false
● GuidanceOnSafetyReport	false	<input type="checkbox"/>	false
● ReviewedByAssessor	false	<input type="checkbox"/>	false
TonnageBandsOfRegistrant		<input type="checkbox"/>	
● TonnageBand		<input type="checkbox"/>	
● OnSitelisolated		<input type="checkbox"/>	
● Transportedisolated		<input type="checkbox"/>	
SpecificSubmissions		<input type="checkbox"/>	
● SubmissionIsAnUpdate	false	<input type="checkbox"/>	false
● LastSubmissionType		<input type="checkbox"/>	
ReasonForUpdating		<input type="checkbox"/>	
● RequestDecisionRegulatoryBody	false	<input type="checkbox"/>	false
● SpontaneousUpdate	false	<input type="checkbox"/>	false
DossierSpecificInformation		<input type="checkbox"/>	
● PhaseIn	phase-in	<input type="checkbox"/>	phase-in

Filter

show all show only different show only identical

Comparison tool



Comparison wizard
Comparison results

Text filter

- R_1-10_PC / SUBSTANCE : Substance X (for comp...
- Substance X (for comparison) (Dossier subject)**
- cat
- Temp A
- Template R
- Multi-line text_TestMaterials.Identity.Id_3 / Multi-line t...
- Particle size distribution (Granulometry).001_Multi-lin...
- Particle size distribution (Granulometry).001_Multi-lin...
- Particle size distribution (Granulometry).001_Multi-lin...
- Stability in organic solvents and identity of relevant ...
- AS Company / Warszawa / Poland
- Mark r
- SITE ONE
- Erkens, Kyle; Organisation a
- Kukka, Maria; Factory of biocidal products
- Particle size distribution (Granulometry).001_Multi-lin...
- ANNO 1
- ANNO 1 (FOR COMP
- Annotation1

Text filter

- REACH Registration 1 - 10 tonnes, physicochemical requirements
 - 0 Related information
 - 0.1 Templates
 - Temp A
 - Template R
 - 0.4 Assessment entities
 - Assessment entities
 - CORE / Registered substance as such / Registered substance as such.001 / Substance X (for comparison)
 - 1 General information
 - 1.1 Identification
 - Identification
 - Substance X (for comparison)**
 - 1.2 Composition
 - CORE / Composition / Composition.001 / Substance X (for comparison)
 - CORE / Composition / CM CMC CMC CM 1 / Temp A
 - 1.5 Joint submission
 - CORE / Joint submission / Joint submission.001 / Substance X (for comparison)
 - 2 Classification & Labelling and PBT assessment
 - 2.1 GHS
 - CORE / GHS / GHS.001 / Substance X (for comparison)
 - CORE / GHS / GHS.001 / Substance X (for comparison)
 - 2.2 DSD - DPD
 - CORE / DSD - DPD / DSD - DPD.001 / Substance X (for comparison)
 - 3 Manufacture, use and exposure

View differences

Legend:
same UUID - identical content
same UUID - different content
different annotation
included only in first document
included only in second document

Results

Back Next Finish Cancel

Comparison tool

Detailed comparison differences

Selected document > CORE / GHS / GHS.001 / Substance B

Filter

show all show only different show only identical

Field	Value in 1st Document	Compare state	Value in 2nd Document
Classes			
Statements			
Labelling			
SignalWord			
HazardPictogramBlock			
HazardPictogram			
HazardPictogram[1]			
Code	GHS02: flame		
HazardStatementsBlock			
HazardStatements			
HazardStatements[1]			
HazardStatement	H200: Unstable explosives.		
AdditionalText	additional text field		
PrecautionaryStatementsBlock			
PrecautionaryStatements			
PrecautionaryStatements[1]			
PrecautionaryStatement	P210: Keep away from heat, hot s...		
AdditionalText			
LabelingRequirementsBlock			
LabelingRequirements			
LabelingRequirements[1]			
SupplHazardStatement	EUH006: Explosive with or without...		
AdditionalText			
AdditionalLabelling			

Hazard pictogram code is only in dossier 1

Precautionary statement is in both dossiers but has different content

Changes in data reporting in IUCLID 6

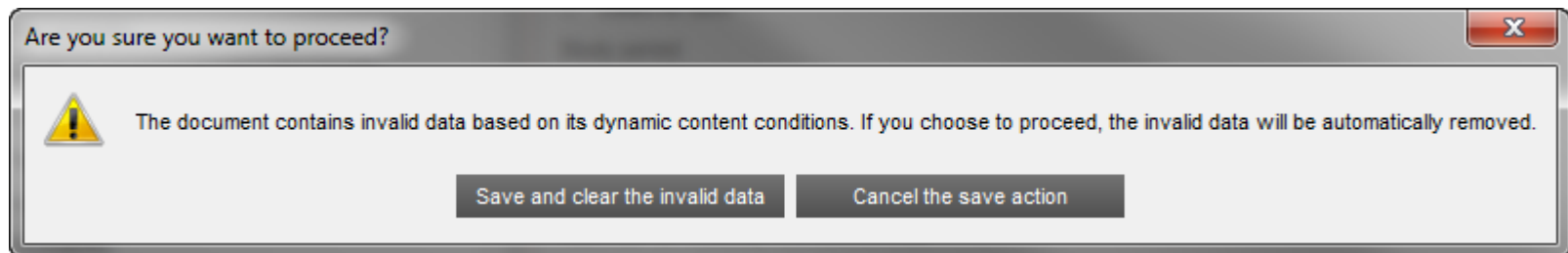


Content

- Dynamic content validation
 - Section 2.1 – GHS
 - Administrative data in endpoint study records
 - Section 3.5.X – Use and exposure information
- Reporting of read-across information in IUCLID 6
- Amendment of REACH Annexes regarding skin and eye irritation, skin sensitisation

Dynamic content validation (1)

- **What?**
 - When the user makes selections in a field that is subject to dynamic content validation, this causes the incompatible fields to become inactive
- **Why?**
 - To support the user in not entering conflicting information in the application.
- **How?**
 - When the user makes selections in a field that is subject to dynamic content validation, the incompatible fields become inactive
 - If the document was migrated from IUCLID 5 and already contains incompatible information, the conflicting content is shown highlighted in orange. If the user tries to save the document, an information message is displayed. The conflicting information must be corrected before saving is allowed.



Dynamic content validation (2)

- **Where?**
- Section 2.1 – GHS:
 - The field ‘Reason for no classification’ is inactive if any of the fields ‘Hazard category’ and ‘Hazard statement’ are filled in, and vice versa.
 - Already in IUCLID 5

Health hazards

	Hazard category	Hazard statement	Reason for no classification
Acute toxicity - oral	<input type="text"/>	<input type="text"/>	data lacking
Acute toxicity - dermal	<input type="text"/>	<input type="text"/>	data lacking
Acute toxicity - inhalation	<input type="text"/>	<input type="text"/>	data lacking
Skin corrosion/irritation	<input type="text"/>	<input type="text"/>	data lacking
Serious eye damage/ eye irritation	Eye Irrit. 2	H320: Causes eye i	

IUCLID 5

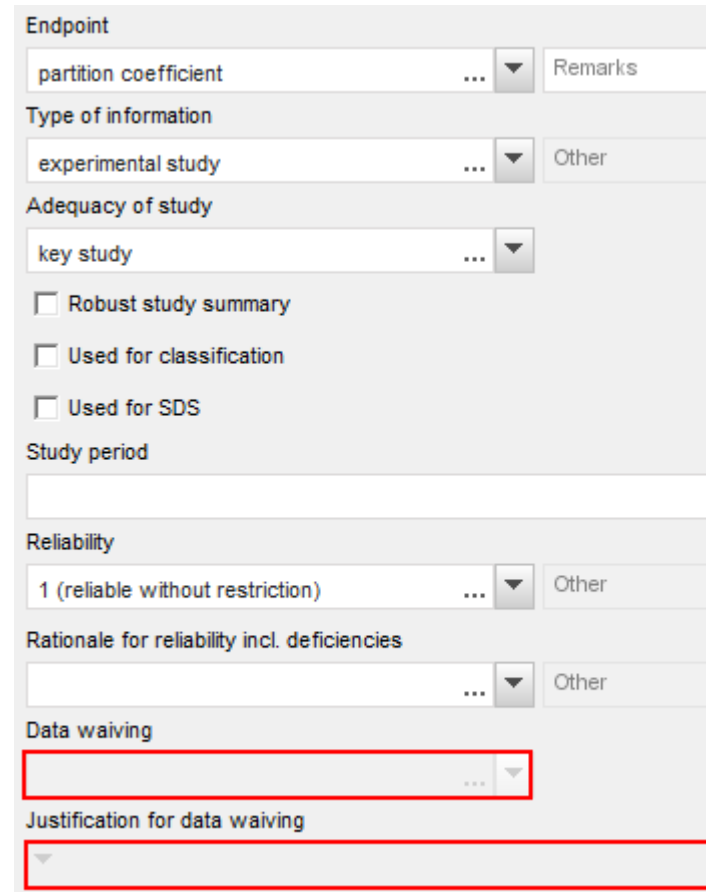
Health hazards ^

	Hazard category	Hazard statement	Reason for no classification
Acute toxicity - oral	data lacking ...
Acute toxicity - dermal	data lacking ...
Acute toxicity - inhalation	data lacking ...
Skin corrosion / irritation	data lacking ...
Serious eye damage / eye irrit...	Eye Irrit. 2	H320: Causes eye irrita...	...

IUCLID 6

Dynamic content validation (3)

- **Where?**
- Endpoint study record – Administrative data:
 - When a new endpoint study record is created, and is indicated as a study, the fields that are relevant for reporting a data waiving are not available, and vice versa



Endpoint

partition coefficient ... Remarks

Type of information

experimental study ... Other

Adequacy of study

key study ...

Robust study summary

Used for classification

Used for SDS

Study period

Reliability

1 (reliable without restriction) ... Other

Rationale for reliability incl. deficiencies

... Other

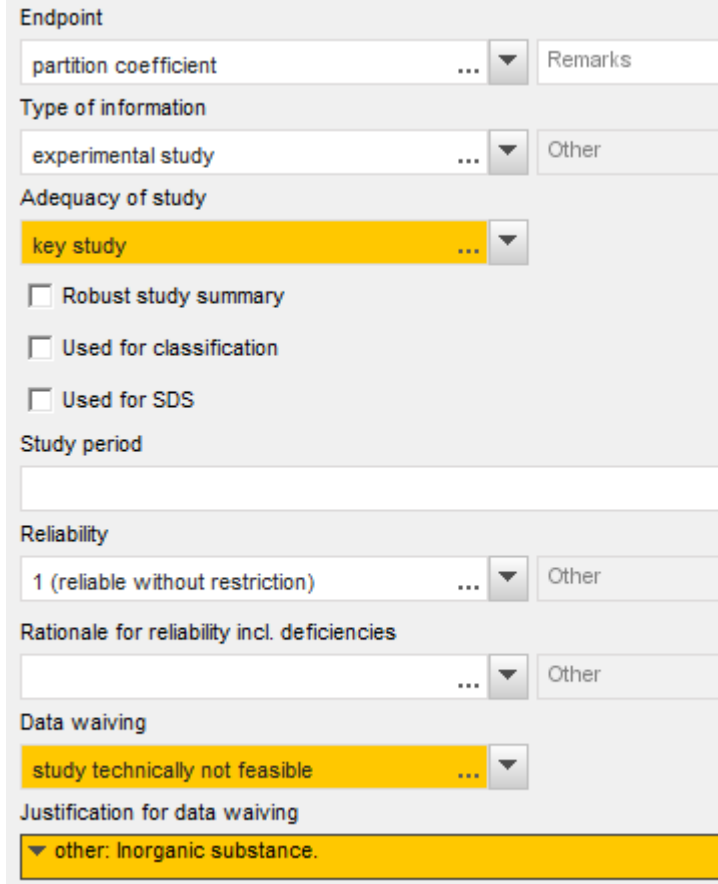
Data waiving

Justification for data waiving

IUCLID 6: Section 4.7, new endpoint study record

Dynamic content validation (4)

- **Where?**
- Endpoint study record – Administrative data:
 - When an endpoint study record has been migrated from IUCLID 5 and contains conflicting information in fields with dynamic content validation, the fields that contain inconsistent information are highlighted in orange.
 - The conflicting information needs to be amended before saving of new information is possible in this document.

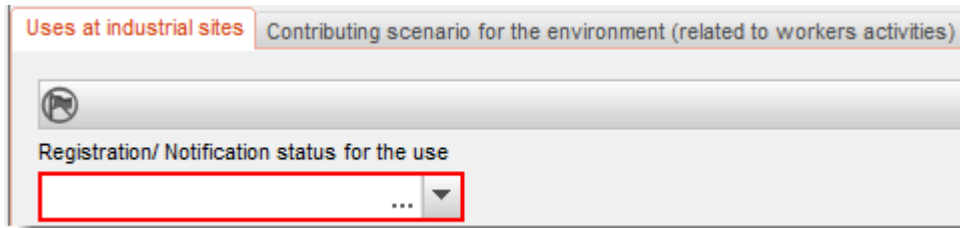


Endpoint	partition coefficient	...	Remarks
Type of information	experimental study	...	Other
Adequacy of study	key study	...	
	<input type="checkbox"/>	Robust study summary	
	<input type="checkbox"/>	Used for classification	
	<input type="checkbox"/>	Used for SDS	
Study period			
Reliability	1 (reliable without restriction)	...	Other
Rationale for reliability incl. deficiencies		...	Other
Data waiving	study technically not feasible	...	
Justification for data waiving	other: Inorganic substance.		

IUCLID 6: Section 4.7, migrated endpoint study record

Dynamic content validation (5)

- **Where?**
- Section 3.5.X – Use and exposure information:
 - The field ‘Registration/notification status for the use’ conditions the availability of the fields in each use record.

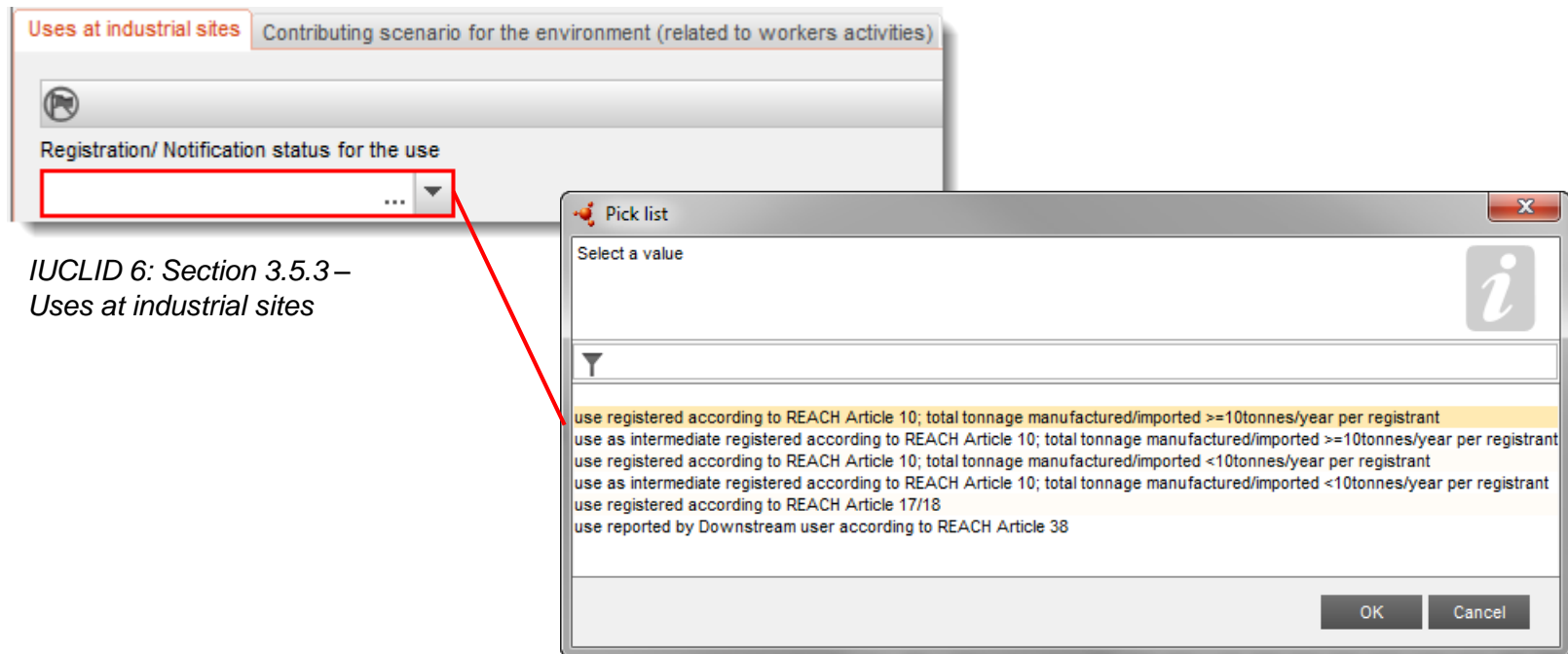


The screenshot shows a software interface with two tabs at the top: 'Uses at industrial sites' (selected) and 'Contributing scenario for the environment (related to workers activities)'. Below the tabs is a grey header bar with a flag icon on the left. Underneath, the text 'Registration/ Notification status for the use' is displayed above a white input field with a red border. To the right of the input field is a small dropdown arrow icon.

*IUCLID 6: Section 3.5.3–
Uses at industrial sites*

Dynamic content validation (6)

- **Where?**
- Section 3.5.X – Use and exposure information:
 - The field ‘Registration/notification status for the use’ conditions the availability of the fields in each use record.

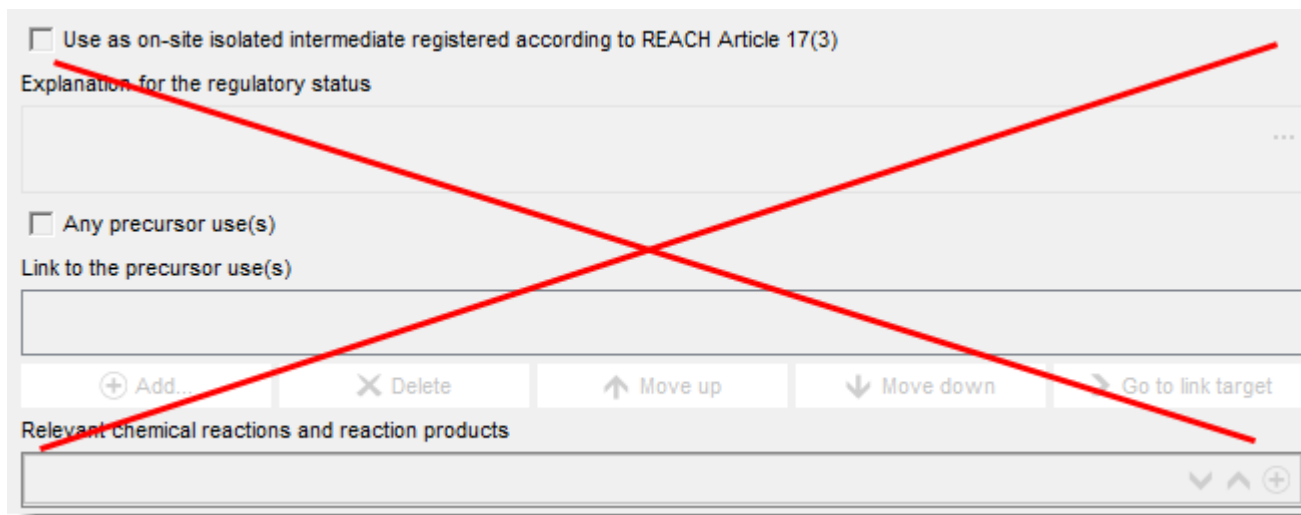


The screenshot shows the 'Uses at industrial sites' section in IUCLID 6. The 'Contributing scenario for the environment (related to workers activities)' is selected. The 'Registration/ Notification status for the use' field is highlighted with a red box. A red arrow points from this field to a 'Pick list' dialog box. The dialog box contains a list of use conditions, with the first option highlighted: 'use registered according to REACH Article 10; total tonnage manufactured/imported >=10tonnes/year per registrant'. Other options include 'use as intermediate registered according to REACH Article 10; total tonnage manufactured/imported >=10tonnes/year per registrant', 'use registered according to REACH Article 10; total tonnage manufactured/imported <10tonnes/year per registrant', 'use as intermediate registered according to REACH Article 10; total tonnage manufactured/imported <10tonnes/year per registrant', 'use registered according to REACH Article 17/18', and 'use reported by Downstream user according to REACH Article 38'. The dialog box has 'OK' and 'Cancel' buttons at the bottom.

*IUCLID 6: Section 3.5.3 –
Uses at industrial sites*

Dynamic content validation (7)

- **Where?**
- Section 3.5.3 – Uses at industrial sites:
 - **use registered according to REACH Article 10; total tonnage manufactured/imported ≥ 10 tonnes/year per registrant.**
 - Fields for reporting information on intermediates are inactive



Use as on-site isolated intermediate registered according to REACH Article 17(3)

Explanation for the regulatory status

Any precursor use(s)

Link to the precursor use(s)

+ Add... X Delete ↑ Move up ↓ Move down → Go to link target

Relevant chemical reactions and reaction products

IUCLID 6: Section 3.5.3 – Uses at industrial sites

Dynamic content validation (8)

- **Where?**
- Section 3.5.3 – Uses at industrial sites:
 - **use registered according to REACH Article 17/18.**
 - Tabs for reporting contributing scenarios for workers and the environment are inactive
 - Fields for reporting information on intermediates are active



The screenshot shows the IUCLID 6 interface for 'Uses at industrial sites'. The 'Uses at industrial sites' tab is active, and the 'Contributing scenario for the environment (related to workers activities)' tab is highlighted with a red border. Below the tabs, there is a section for 'Registration/ Notification status for the use' with a dropdown menu set to 'according to REACH Article 17/18 ...'.

IUCLID 6: Section 3.5.3 – Uses at industrial sites

Reporting of read-across information (1)

- **Background:**
 - In IUCLID 5, read-across information was reported differently, depending on whether a grouping/category approach, or analogue approach was used.
 - Read-across is one of the main areas where the quality of the provided information has been a concern.
 - Decision to streamline the reporting approach to support clarity of information.
- **IUCLID 6:**
 - Read-across is always reported as a source-target structure.
 - Important change: endpoint-specific read-across justification must be provided in the target record.

Reporting of read-across information (2)

1. Category approach:

- Source information, i.e. the experimental data from the group of substances, is provided in the category member substance datasets.
- Target information, i.e. the outcome of the read-across, is provided as an endpoint study record in the substance dataset of the registered substance, with the 'Type of information' set to "read-across based on grouping of substances (category approach)".
- Similar to IUCLID 5 approach, but limited target record information to be provided compared to a normal endpoint study record; only fields that reflect the read-across exercise are to be filled in; not fields related to experimental setup (available in source data).

Reporting of read-across information (3)

2. Analogue / supporting substance approach:

- Source and target information to be provided in the substance dataset of the registered substance in separate records.
- Source data are reported as a normal experimental study record, filled in according to the instructions for a robust study summary. The test material information identifies the substance on which the test was done.
- Target data are reported as a separate endpoint study record with ‘Type of information’ field set to “read-across from supporting substance (structural analogue or surrogate)”.
- The information to be provided is limited in comparison to a normal endpoint study record; only fields that reflect the read-across exercise are to be filled in; not fields related to experimental setup (available in source record).

Reporting of read-across information (4)

2. Analogue / supporting substance approach:

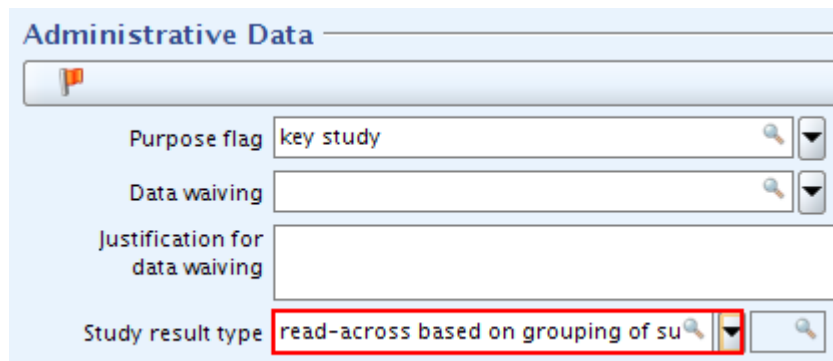
	Endpoint study record	Source record	Target record
i	Administrative data	X	X
	Endpoint	X	X
	Type of information	X	X
	Adequacy of study	X	X
	Robust study summary		
	Used for classification	X	X
	Used for SDS		
	Study period	X	
	Reliability	X	
	Rationale for reliability incl. deficiencies	X	
	Data waiving		
	Justification for data waiving		
	Justification for type of information		X
	Attached justification		X
	Cross-reference		X
ii	Data source	X	
iii	Materials and methods	X	
iv	Test materials	X	X
v	Result and discussion	X	X
vi	Overall remarks, attachments	X	X
vii	Applicant's summary and conclusion	X	X

X = relevant chapters/fields; X = subject to completeness check

Reporting of read-across information (5)

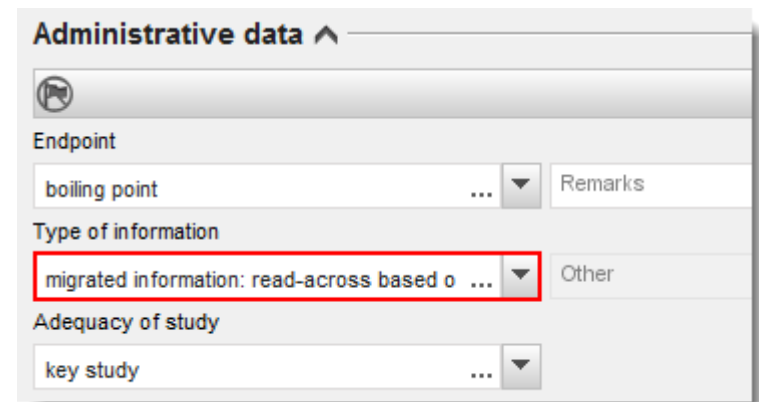
Migration from IUCLID 5 to IUCLID 6:

- Migration from IUCLID 5 was done adding the tag “migrated information” to the ‘Type of information’ field, and such records are checked at completeness check as normal experimental study records (one complete record required).
- Strongly recommended, for the benefit of clarity and data quality, to move to the new approach whenever possible.



The screenshot shows the 'Administrative Data' form in IUCLID 5. It includes fields for 'Purpose flag' (set to 'key study'), 'Data waiving', 'Justification for data waiving', and 'Study result type'. The 'Study result type' field is highlighted with a red box and contains the text 'read-across based on grouping of su'.

IUCLID 5: read-across record



The screenshot shows the 'Administrative data' form in IUCLID 6. It includes fields for 'Endpoint' (set to 'boiling point'), 'Type of information' (set to 'migrated information: read-across based o'), 'Adequacy of study' (set to 'key study'), and a 'Remarks' field. The 'Type of information' field is highlighted with a red box.

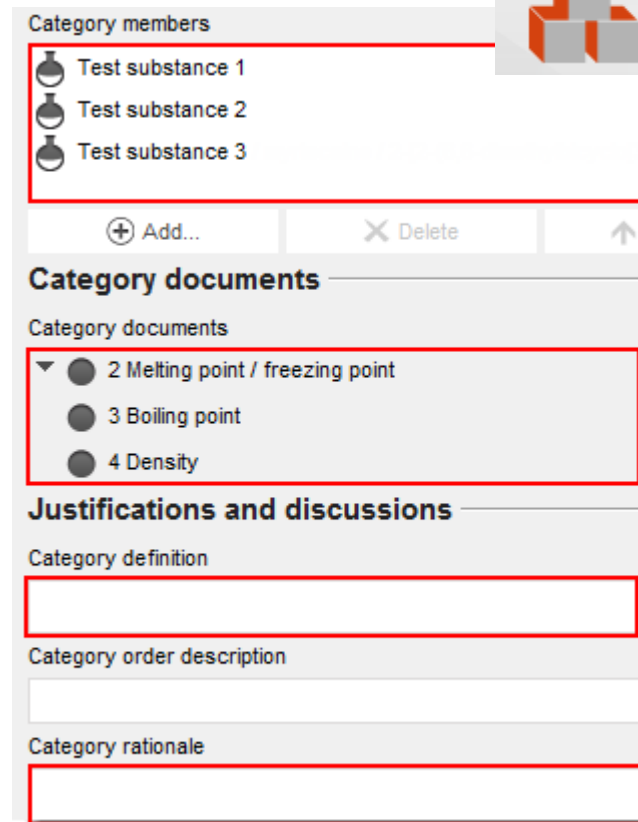
IUCLID 6: migrated read-across record

Reporting of read-across information (6)

Migrated data – checklist for category approach:

- Category object exists, and contains the full documentation of the category definition and rationale behind the grouping.
- Category member datasets contain the source data used in the read-across.
- As in IUCLID 5.

Source data: category and its members



The screenshot displays the IUCLID 6 interface for managing a category. It is divided into several sections:

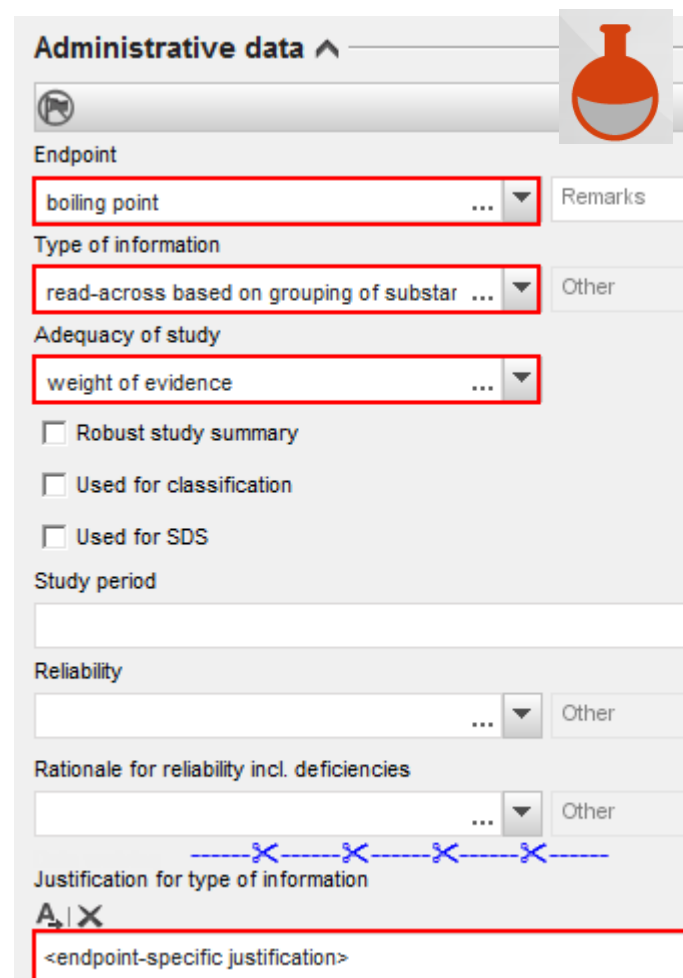
- Category members:** A list containing three entries: "Test substance 1", "Test substance 2", and "Test substance 3", each with a flask icon. Below the list are buttons for "Add...", "Delete", and an upward arrow.
- Category documents:** A section with a dropdown arrow and three entries: "2 Melting point / freezing point", "3 Boiling point", and "4 Density", each with a circular icon.
- Justifications and discussions:** A section containing three text input fields:
 - Category definition:** An empty text box.
 - Category order description:** An empty text box.
 - Category rationale:** An empty text box.

Reporting of read-across information (7)

Migrated data – checklist for category approach:

- In the target endpoint study record of the registered substance dataset:
 - Set the ‘Type of information’ to “read-across based on grouping of substances (category approach)”
 - Set the ‘Adequacy of study’ to the appropriate value depending on how you use the read-across to fulfil the information requirement (typically “key study” or “weight-of-evidence”)
 - Leave empty the fields that relate to the experimental setup and the validity of the source information (provided in source data)
 - Add the endpoint-specific justification in the field ‘Justification for type of information’.

Target data: read-across record in substance dataset of registered substance



Administrative data ^

Endpoint
boiling point ...

Type of information
read-across based on grouping of substar ...

Adequacy of study
weight of evidence ...

Robust study summary
 Used for classification
 Used for SDS

Study period
[Empty field]

Reliability
[Empty field] ... Other

Rationale for reliability incl. deficiencies
[Empty field] ... Other

Justification for type of information
[Empty field]

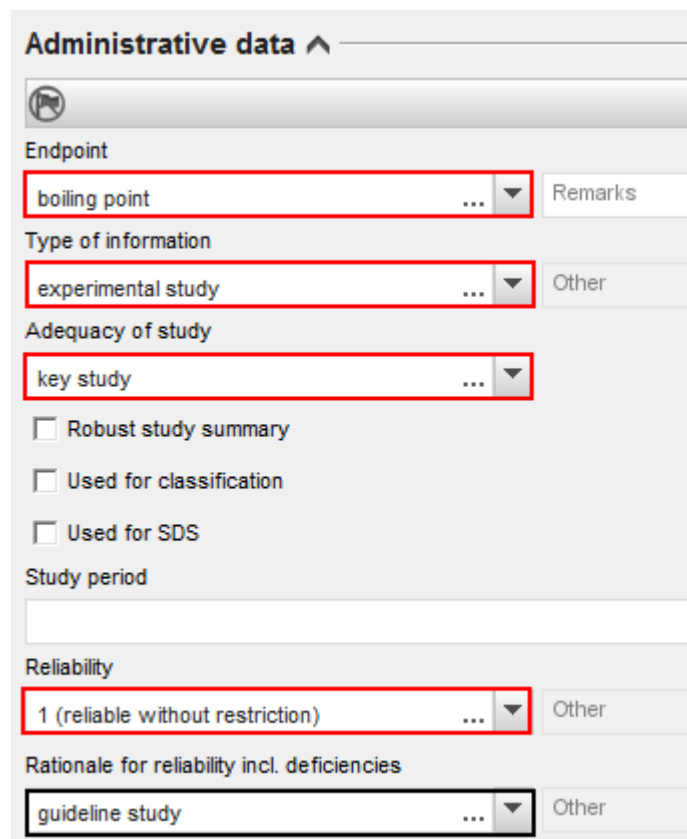
<endpoint-specific justification>

Reporting of read-across information (8)

Migrated data – checklist for analogue approach:

- Split the read-across information into source and target data.
- The source record
 - Set the ‘Type of information’ to “experimental study”
 - Set the ‘Adequacy of study’ to “key study”
 - Fill in the source record as a normal experimental study record; should reflect a standalone study summary on the source material.
 - Ensure that all the information provided reflects the source data.

Source data: experimental study



Administrative data ^

Endpoint
boiling point ...

Type of information
experimental study ...

Adequacy of study
key study ...

Robust study summary
 Used for classification
 Used for SDS

Study period

Reliability
1 (reliable without restriction) ...

Rationale for reliability incl. deficiencies
guideline study ...

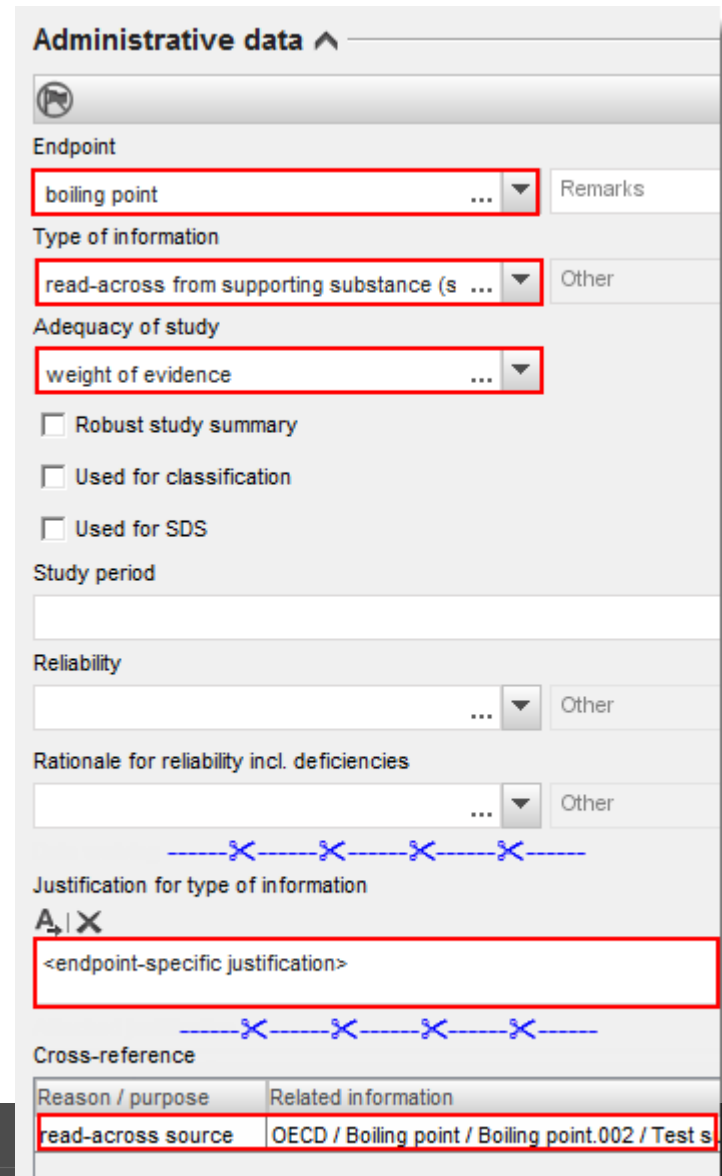
Reporting of read-across information (9a)

Migrated data – checklist for analogue approach:

– The target record

- Set the 'Type of information' to "read-across from supporting substance (structural analogue or surrogate)"
- Set the 'Adequacy of study' to the appropriate value depending on how you use the read-across to fulfil the information requirement (typically "key study" or "weight-of-evidence")
- Leave empty the fields that relate to the reliability of the source information (provided in source data)
- Add the endpoint-specific justification in the field 'Justification for type of information'.
- Under 'Cross-reference', link to the endpoint study record which contains the source data.

Target data: read-across record



Administrative data ^

Endpoint
boiling point ... Remarks

Type of information
read-across from supporting substance (s ... Other

Adequacy of study
weight of evidence ...

Robust study summary
 Used for classification
 Used for SDS

Study period

Reliability
... Other

Rationale for reliability incl. deficiencies
... Other

Justification for type of information
A | X
<endpoint-specific justification>

Cross-reference

Reason / purpose	Related information
read-across source	OECD / Boiling point / Boiling point.002 / Test s

Data reporting in IUCLID 6



Target data: read-across record

Reporting of read-across information (9b)

Checklist for analogue approach:

- The target record
 - Leave empty the fields that relate to the experimental setup of the source study (provided in source data)
 - Identify the read-across target material in the field 'Test material information'
 - Fill in the result for the read-across target material
 - Under 'Applicant's summary and conclusion', indicate (if applicable) how estimated effects relate to C&L criteria for target substance, and how results impact distribution of target material.
 - Briefly summarise read-across approach and applicability of results in the Executive summary (optional).

The screenshot shows a data entry form for a read-across record. The form is divided into several sections:

- Data source** (dropdown menu)
- Materials and methods** (expandable section)
 - Test guideline**: A table with columns 'Qualifier' and 'Guideline'.
 - Principles of method if other than guideline**: A text field with a search icon and a close icon.
 - GLP compliance**: A dropdown menu and a 'Remarks' field.
 - Other quality assurance**: A dropdown menu and an 'Other' field.
 - Type of method**: A dropdown menu and an 'Other' field.
- Test material** (expandable section)
 - Test material information**: A text field containing 'testene', which is highlighted with a red box.
- Results and discussion** (expandable section)
 - Boiling point**: A table with columns 'Key result', 'Boiling pt.', and 'Atm. press.'. The row containing a checked box, '100.0 °C', and '1.0 atm' is highlighted with a red box.
- Overall remarks, attachments** (dropdown menu)
- Applicant's summary and conclusion** (dropdown menu)

Reporting of read-across information (10)

Analogue approach, source and target records are not identical:

	Chapter/ / field	Source record	Target record
i	Administrative data		
	Endpoint	same	same
	Type of information	experimental study	read-across...
	Adequacy of study	key study	key study or weight of evidence (if used to fulfil information requirement)
	Reliability	X	
	Rationale for reliability incl. deficiencies	X	
	Justification for type of information		endpoint-specific justification for read-across
	Attached justification		X
	Cross-reference		link to source record
	ii	Data source	X
iii	Materials and methods	X	
iv	Test materials	tested material	read-across target material (main constituent of registered substance, component of more complex substance, etc.)
			Result for target material, including any corrections for MW etc.
v	Result and discussion	experimental result	
vii	Applicant's summary and conclusion	GHS criteria and implications for distribution of substance for source material. Executive summary of experimental study.	GHS criteria and implications for distribution of substance for target material. Executive summary of read-across approach.

Amendment to REACH Annexes VII and VIII (1)

- **What?**

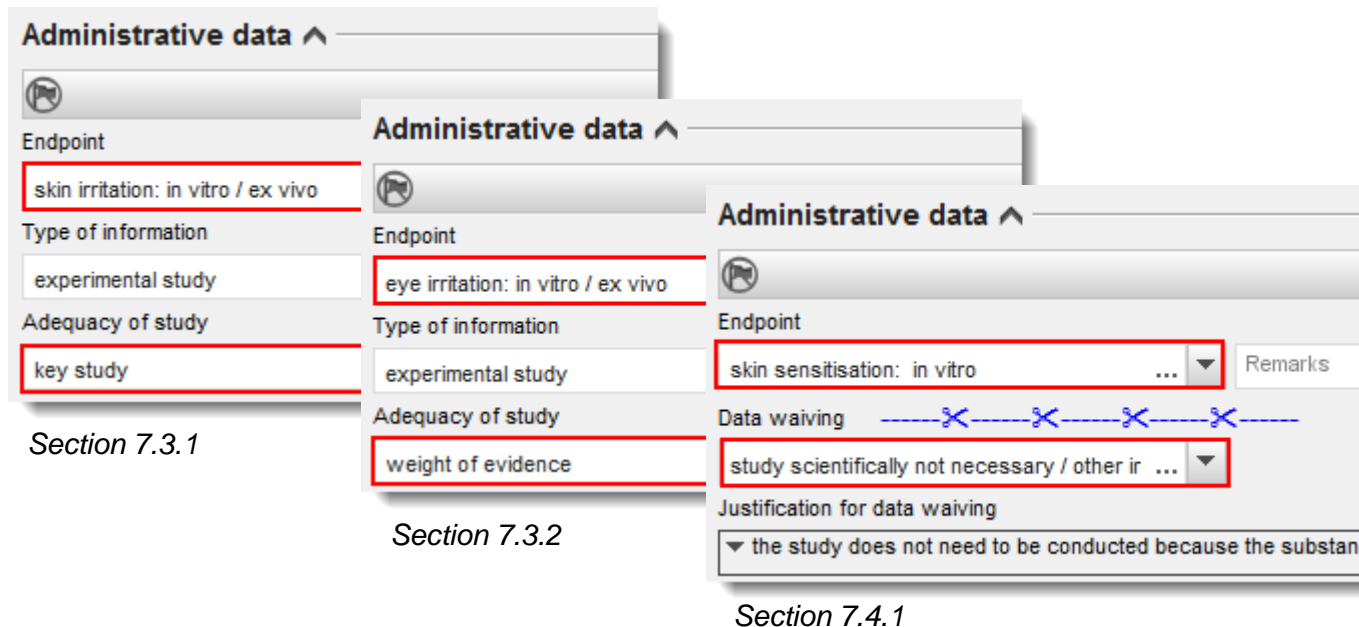
- Information requirements on skin corrosion/irritation and serious eye damage/eye irritation amended; entered into effect on **June 21, 2016**.
- Amendment makes the *in vitro* studies the standard information requirement at Annexes VII and VIII; *in vivo* studies to be considered only if *in vitro* studies are not applicable, or results are not adequate for classification and risk assessment.
- Amendment to the skin sensitisation requirement has been approved; prepared for publication in the Official Journal of the EU in the **coming month**.
- Amendment makes *in vitro* or *in chemico* studies the standard information requirement at Annex VII; *in vivo* studies to be considered only if *in vitro/in chemico test methods* are not applicable, or results are not adequate for classification and risk assessment. In such cases, the murine local lymph node assay (LLNA) to be used.

https://echa.europa.eu/view-article/-/journal_content/title/reach-annexes-amended-registrants-to-use-alternative-test-methods
<http://eur-lex.europa.eu/eli/reg/2016/863/oj>
<http://ec.europa.eu/transparency/regcomitology/index.cfm?do=search.documentdetail&XMmA1sY1+dPFA15wY23QjBDn7Qd++m5oh9aiDXqCyio=>

Amendment to REACH Annexes VII and VIII (2)

- **Consequence for reporting in IUCLID?**

- To be complete, registration dossiers with Annex VII requirements and above, must contain at least one endpoint study record addressing the *in vitro* (*in chemico*) requirement;
- Endpoint study record must be key study, weight of evidence, or data waiving.



The image displays three overlapping screenshots of the IUCLID 6 administrative data form, illustrating different reporting options for endpoint studies. Each screenshot shows a different selection in the 'Endpoint', 'Type of information', and 'Adequacy of study' fields, with red boxes highlighting these selections.

- Section 7.3.1:** Endpoint: skin irritation: in vitro / ex vivo; Type of information: experimental study; Adequacy of study: key study.
- Section 7.3.2:** Endpoint: eye irritation: in vitro / ex vivo; Type of information: experimental study; Adequacy of study: weight of evidence.
- Section 7.4.1:** Endpoint: skin sensitisation: in vitro; Data waiving: study scientifically not necessary / other ir ...; Justification for data waiving: the study does not need to be conducted because the substance...

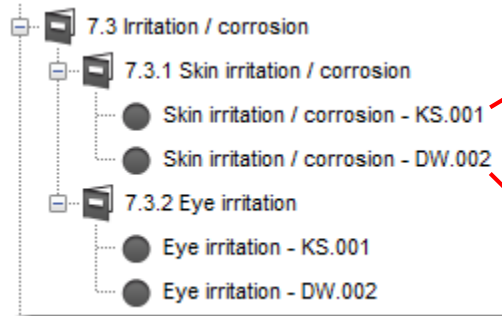
Amendment to REACH Annexes VII and VIII (3)

- **Consequence for reporting in IUCLID?**

- **If an *in vivo* study exists** that was carried out or initiated before the Annex amendment took effect, this should be reported as an endpoint study record with the appropriate ‘Adequacy of study’, and the ‘Endpoint’ selection “... in vivo”.
- **In addition**, you must include another endpoint study record in the same section, with the ‘Endpoint’ selection “... in vitro”, indicate it as a Data waiving with rationale “study scientifically not necessary / other information available”, and the following ‘Justification for data waiving’ picklist selection:
 - an in vitro skin irritation study does not need to be conducted because adequate data from an in vivo skin irritation study are available (section 7.3.1)
 - an in vitro eye irritation study does not need to be conducted because adequate data from an in vivo eye irritation study are available (section 7.3.2)
 - other: + free text: “an in vitro or in chemico skin sensitisation study does not need to be conducted because adequate data from an in vivo skin sensitisation study are available” (section 7.4.1)

Amendment to REACH Annexes VII and VIII (4)

- **Consequence for reporting in IUCLID?**
 - Example: section 7.3.1, information from existing *in vivo* study available



Administrative data ^

Endpoint
skin irritation: in vivo ... Remarks

Type of information
experimental study ... Other

Adequacy of study
key study ...

Administrative data ^

Endpoint
skin irritation: in vitro / ex vivo ... Remarks

Data waiving ----- ✂ ----- ✂ ----- ✂ ----- ✂ -----

study scientifically not necessary / other infor ...

Justification for data waiving
▼ an in vitro skin irritation study does not need to be conducted because adequate data from an in vivo skin irritation study are available - [study scientifically not necessary / other information available]

! Add a link in the 'Cross reference' table of DW record to the KS record, to show where the *in vivo* information is provided.

Questions and answers

Please send your questions for the next 5 minutes, using the Q&A panel



Questions and answers





More information

echa.eu

iuclid.eu

iuclid6.echa.europa.eu

oecd.org/ehs/templates





Thank you for your participation



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

