

IUCLID 6

Version 7.0.1 - Format changes 2023 release webinar

8th June 2023





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



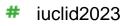
Question and answers session

- Q&A using Slido
- Lasts until 16:00 (EET) on the webinar day
- You can keep your questions anonymous
- We will answer your questions during the day
- All Q&As will be published on the webinar pages after the event

https://echa.europa.eu/-/iuclid-6-2023-format-changes-release

Joining as a participant?







Agenda for today



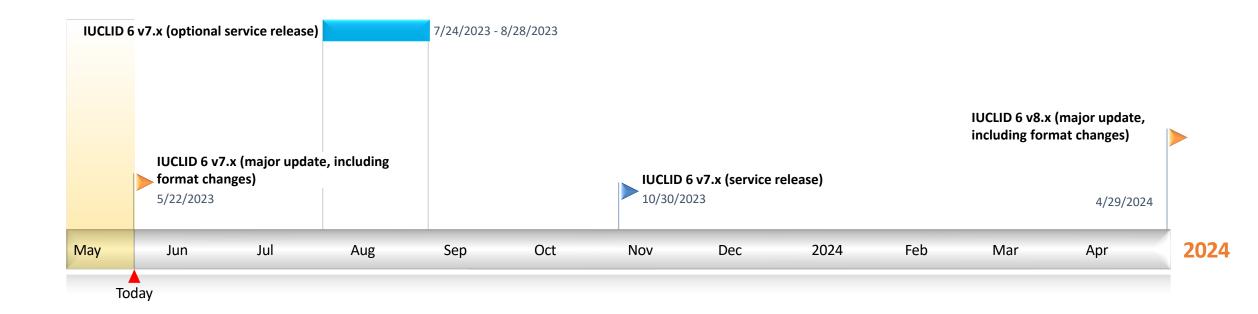
Introducing the IUCLID 2023 format release

IUCLID version 7.0.1





Release plan



Information on planned releases

• Up-to-date information on

https://iuclid6.echa.europa.eu/plannedreleases

• Details are added closer to the releases

- Functionality
 - Transfer of annotations
 - Modification history for dataset extraction
 - Export of dossiers advanced options
 - Report generator improvements
 - Compare datasets
- Data representation
 - Data representation: duplicate information removed
 - When a new Document is created, the default name will reflect the Parent Node's name in the Table of Contents which the User is currently working in
 - Hierarchical picklists can now be displayed for regular picklist datatypes
- Validation rules
 - Validation rules updated for a number of Working Contexts



Release notes

- Details about the releases are maintained in the Release notes* published on the IUCLID website
- Release notes are updated each time a IUCLID release is . shared with (a group of) users

* https://iuclid6.echa.europa.eu/documents/1387205/1809509/IUCLID 6 Release Notes.pdf

IUCLID 6 Release notes - v7.0.1 Page | 1 **TABLE OF CONTENTS** 2 VERSION 7.0.1 (PUBLIC RELEASE 22 MAY 2023)...... 19

1



Overview of main scope items

• Format updates



• New features and improvements





Upgrade and Migration

- Existing IUCLID data are migrated to the new format automatically during the upgrade to the new version (using the IUCLID updater tool)
- Installation types
 - For Desktop versions, a backup is automatically taken during the upgrade
 - ECHA Cloud users have their instances upgraded by default
 - For Server installations, refer to the installation and upgrade manual (make sure backups are taken)

https://iuclid6.echa.europa.eu/documentation



Exchange of data / compatibility

- All IUCLID 6 files can be imported to the latest version of IUCLID
- From the latest IUCLID 6 version (v7) you can export files compatible to the previous major version (v6), if needed (but incompatible data fields will be saved as attachments)





Upgrade recommendations

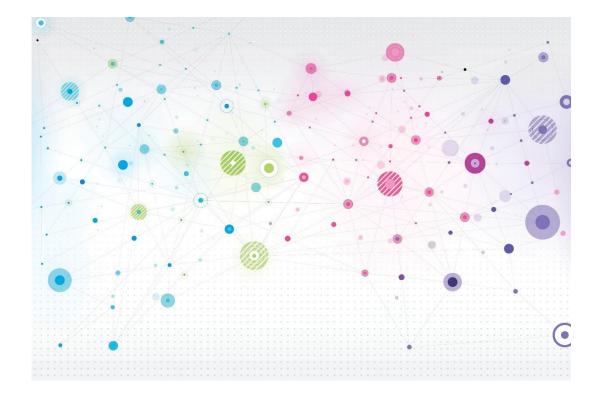
- Upgrade to the latest version as soon as possible
- Follow recommendations from the relevant authorities in terms of data submission
 - Some authorities can accept dossiers in several versions of IUCLID

Some authorities can reject the latest version of

 IUCLID until they have updated their systems to the new version

Export to previous major version

Some authorities can accept only the latest version of IUCLID



Overview of format changes

IUCLID version 7.0.1

- Francois Le Goff
- Dorota Burchard-Sosnowska



Overview of format changes: introduction

IUCLID version 7.0.1

• Francois Le Goff



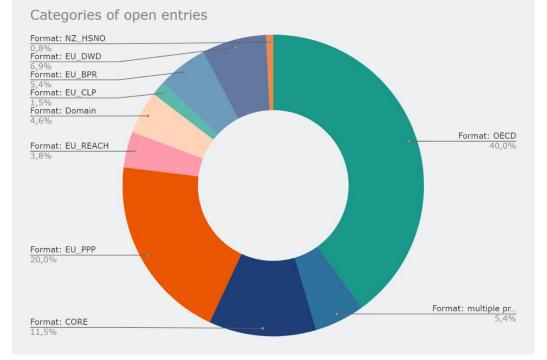


Organisation in Definition providers



Requirements

- IUCLID users, including organisations that have implemented IUCLID, are regularly providing feedback and requirements, this includes changes to the IUCLID format
- These requirements are collected all year long
- For the preparation of the format changes published in May 2023, requirements have been collected, reviewed, prioritised and 130 of them have been translated into change proposals



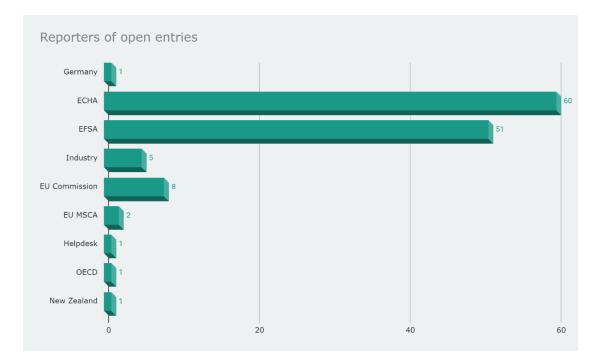
Repartition, by definition providers, of format changes requests for the May 2023 release of IUCLID



Main drivers of the 2023 update

- Apart from the standard maintenance of the format based on IUCLID users feedback, the main drivers for this format updates are:
 - REACH annexes updates
 - EU Drinking Water Directive support
 - EU PPP microorganisms update
 - Improvement of data collection and processes in:
 - ECHA: REACH, BPR, CLP
 - EFSA: PPP
 - Replacement of the SPC XML Editor by IUCLID
- This proposal also takes into account changes approved at the OECD level in 2022



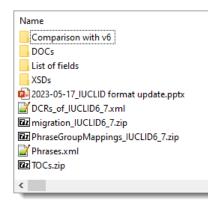


Origin of prioritised requirements



Format documentation package

- All XML Shema Definitions files (.xsd) ۰
- User-readable IUCLID documents representation (.doc)
- List of all IUCLID fields (.xls)
- Comparison file showing the differences compared to the previous version of the format, i.e. v6 compared to v7
- Migration rules implemented in IUCLID
- Dynamic content rules, to describe the conditional display rules linked to specific IUCLID fields in the IUCLID 6 web interface



IUCLID format

From this page you can download information related to the IUCLID 6 format for the major versions of IUCLID 6 that have been published to date. The archives per major version are

- IUCLID 6 v7, published on 19th of May 2023 🗄 (.zip | 31.8 MB) IUCLID 6 v6, published on 17th of October 2021 (.zip | 25.1 MB) - (updated on 16.12.2021)
- IUCLID 6 v5, published on 28th of October 2020
- (.zip | 24.7 MB) IUCLID 6 v4, published on 30th of October 2019 🔥 (.zip | 20.2 MB)
- IUCLID 6 v3, published on 24th of October 2018 🗄 (.zip | 16.1 MB)
- IUCLID 6 v2, published on 15th of November 2017 A (.zip | 15.0 MB)
- IUCLID 6 v1, published on 29th of April 2016

🔥 (.zip | 14.7 MB)

The format is expressed for all IUCLID 6 entities and documents in the general-purpose mark-up language XML, and XML Schema definition files (.xsd). In addition, the format is made available in a more readable version (.doc).

IUCLID 6 is built as a platform and is a modular system. The IUCLID 6 format is divided up in to different groups ('definition providers') depending on its source identified in the section below. To allow data to be exchanged, it can be exported and imported in the IUCLID i6z format. The following document explains the structure of IUCLID i6z files:

Developers' Guide to the IUCLID i6z Format (.pdf | 1.1 MB) - updated on 19/05/2023

Overview of main changes (harmonised documents)



Proposal from OECD



- This proposal includes changes pushed forward by the OECD Secretariat in 2022 to take into account the evolution of Test Guidelines
 - OHT 41 Short-term toxicity to fish (TG 249)
 - OHT 48-2 Endocrine disrupter testing in aquatic vertebrates in vivo (TG 250)
 - OHT 64 Skin irritation / corrosion (TG 439)
 - OHT 66-1 Skin sensitisation (TG 442C)
 - OHT 66-3 Phototoxicity in vitro (TG 498)
 - OHT 85-5 Residues in crops (field trials) and in rotational crops (limited field studies) (TG 509)
 - OHT 201 Intermediate effects mechanistic information (TG 442C)

WHAT'S NEW

Six revised Templates and three new predefined tables now available online (December 2022)

Six OHTs were revised to cover new/updated OECD Test Guidelines issued in June 2021 (41 and 48-2 from the Effects on Biotic Systems Series; 66-1 and 66-3 from the Health Effects Series; 85-5 from the Pesticide Residue Chemistry Series; 201 from the Intermediate Effects Series). In addition, for OHT 41, three new predefined tables were added to the set of existing ones.

https://www.oecd.org/ehs/templates/

Overview of main changes (harmonised documents)



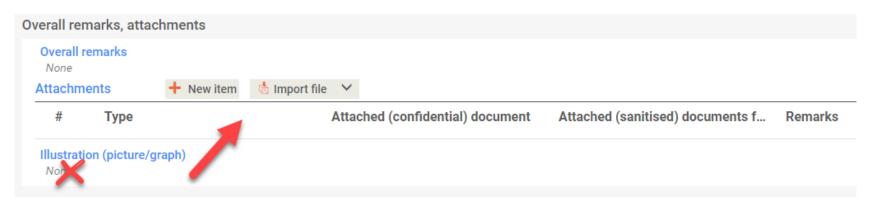
Examples of harmonised documents changes



• 'Study period' field changes from Text to Date: 'start', 'end' + remark

Study period: start date	End date	Remark
03/02/2022 00:00	30/05/2022 00:00	Remark on the study period

• Field 'Illustration' moved to the 'Attachments' fields



Overview of main changes (harmonised documents)



Examples of harmonised documents changes



- REACH annexes revision
 - clarification of the justification for Weight of Evidence

A	dministrative data	1	1	
	Endpoint skin corrosion: in vitro / ex vi	vo		
	Type of information weight of evidence justificati	on/cor	nclusion	

clarification of the dose-setting information

High dose level used yes
Justification for deviation from the high dose level Justification for deviation from the high dose level

A Insert existing templates ✓ Relevance (including coverage) and reliability of each source of information compared with the study normally required for the information requirement Weighing of the sources of information (including overall coverage) to reach an overall conclusion for the information requirer Assessment of the uncertainty in the conclusion compared with the study normally required for the information requirement. 413/32768 Attached justification + New item lmport file ∨ Attached justification Reason / purpose + New item 👘 Import file 🗸 oss-reference Reason / purpose ... Related information Remarks II 1 weight of evidence source Toxicity to reproduction.001 | experimental study None

None

2 weight of evidence source Genetic toxicity in vitro.002

0 ^ 0 ^

on for type of information

- minor changes, for example, new entries in 'Endpoint' or 'Justification for data waiving' picklists

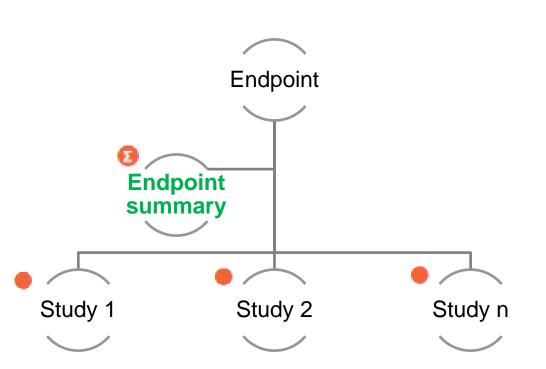
More information about these changes and the impact on REACH registrations: <u>https://echa.europa.eu/-/completeness-check-of-registration-dossiers-what-changes-in-2023-and-how-you-can-prepare</u>

IUCLID format

Harmonisation of endpoint summaries



- The project aimed to fuse any overlapping endpoint summary formats under different definition providers into one single format per endpoint, to be used by all the relevant contexts
 - Harmonisation between legislations
 - Following analysis and discussions with stakeholders, e.g.
 EFSA, NZ EPA, AICIS, ECHA, OECD IUCLID User Group
 Expert Panel, OHT Expert Group
- Besides overlapping formats, review of the remaining endpoint summaries against principles set in the project, for structural consistency
- Include endpoint summaries as OECD Harmonised templates (OHTs) as requested by IUCLID users and stakeholders
- Outcome: 105 endpoint summaries harmonised



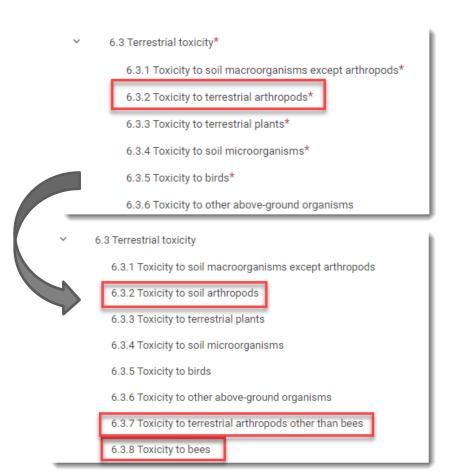


IUCLID format

Toxicity to terrestrial arthropods (OHT 50-2)



- ECHA and EFSA coordinated an inter-agency project on the splitting of the OHT 50-2 'Toxicity to terrestrial arthropods'
 - EFSA, ECHA, NZ EPA, industry members and the OECD Secretariat involved
- The template is now split into three
 - OHT 50-3 Toxicity to bees
 - OHT 50-4 Toxicity to terrestrial arthropods other than bees
 - OHT 50-5 Toxicity to soil arthropods







Example of changes to specific definition providers



New Zealand HSNO: update of Help Texts and Table of Contents



UK REACH: creation of a test extension to explore customisation possibilities (not in production use!)



- EU
 - REACH: changes in 'Opt-out' (justifications) and 'Inquiry' (read-across and update of annexes) documents
 - CLP: update of the EU Product Categorisation System (PCS) and the 'Product information' documents for Poison Centres Notifications
 - SCIP: update of Article categories in the 'Article' document
 - Plant Protection Products: update of existing documents and new documents created to support information requirements for microorganisms
 - EFSA and ECHA: extension of the format to support data dissemination
 - Changes to EU BPR and DWD will be detailed next

More information communicated by the relevant authorities to the relevant user groups

Overview of format changes: focus on EU Biocidal Products Regulation (BPR) and Drinking Water Directive (DWD)

IUCLID version 7.0.1

Dorota Burchard-Sosnowska





Biocides: format changes related to BPR

- 'Biocidal product composition'
 - 'Formulation type' in a product composition only one type allowed for a single product
 - Update of 'Function' picklist (co-formulants)
 - Update of a labels ('Substance generated in situ', 'Product name', 'Trade names of the product')
 - Hide check boxes not relevant for biocides components
- 'Summary of product composition'
 - Update of 'Function' picklist (co-formulants)
 - Add check box 'Substance generated in situ'
 - 'Products Compositions' renamed to 'Related products' (family)
 - Move a check box 'Represents Meta SPC composition' to the top of the document
 - Remove 'Instruction for use' from the label 'Instruction for use and measures to protect humans, animals and the environment' (original label 'Measures to protect humans, animals and the environment' corresponds with a section name in the table of content)



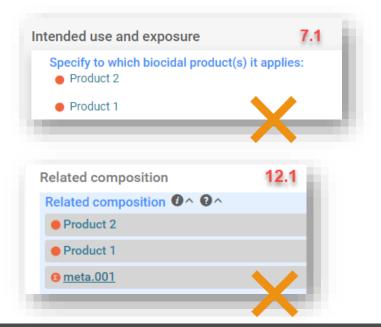
Biocides: format changes related to BPR

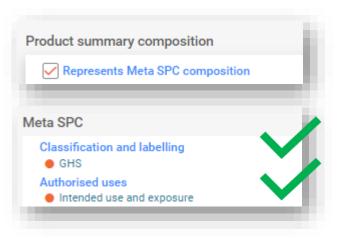
- 'Location of the manufacturing site(s)'
 - Hide field 'Manufacture / own use(s)' in substance and product datasets (relevant to REACH)
 - Hide field 'Specify to which mixture/product(s) it applies:' in substance dataset
- 'Intended uses and exposure'
 - Repeatable data sets created for the exposure data (with a relevant help text and a field 'Remarks')
 - New units 'mg/person/day' and 'mg/animal/day' added to the phrase groups describing estimated uptake
- 'Method of application and a description of this method'
 - New unit 'mg/cm²' (common for repellents) added to the phrase group 'Application rate'
- 'Summary and evaluation'
 - Field 'Other information relevant for the Summary of the biocidal Product Characteristics' removed
- 'Biological properties of the microorganisms': several fields added to classify organisms under assessment

Biocides: format changes related to BPR

Harmonised way of establishing links within a biocidal product family

- links to the composition documents removed from sections 7.1 (Intended use and exposure) and 12.1 (GHS)
- existing links in a 'Product summary composition' to be used









Biocides: transition of the SPC from the SPC Editor to IUCLID

SPC = Summary of the product characteristics

A strategic decision has been taken to further integrate IT tools used for biocides, and replace the SPC Editor by IUCLID

Planned Go-Live of the proposed solution is in Q4 2023

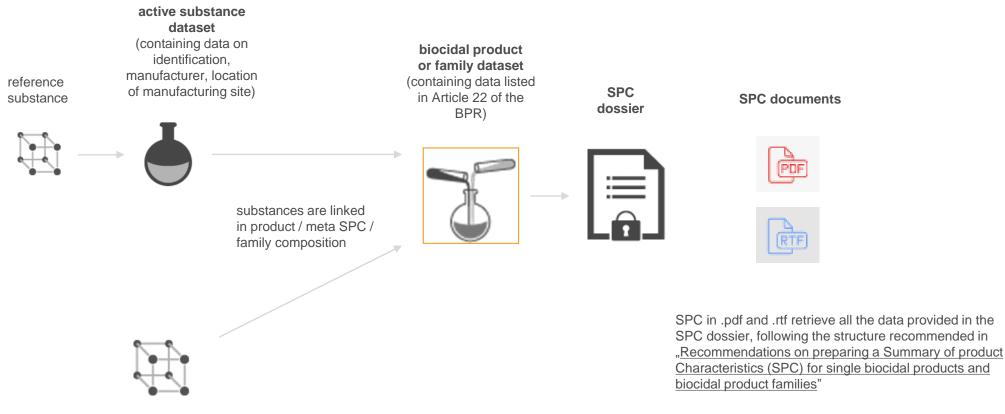
The proposed solution has been tested and commented by key users from Industry, MSCAs and the EU Commission

Features of the SPC Editor have been reflected in IUCLID

Possibility to reuse existing BPR Biocidal product authorisation datasets to create an SPC



Biocides: SPC IUCLID dossier structure



Other substance(s) - reference substance(s) for:

- substance(s) of concern
- substance(s) which are not of concern, but knowledge of which is essential for proper use of biocidal products



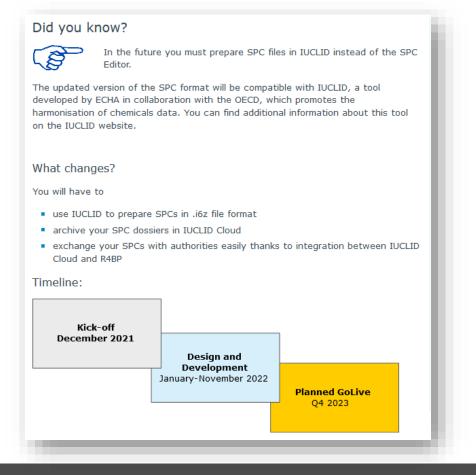
Biocides: format changes related specifically to the SPC

- Update 'Language' phrase group in the SPC dossier header
- Adaptation of phrase groups containing country names to SPC requirements
- New document for 'use-specific directions for use'
- New document for 'other SPC information'



Biocides: More information on the transition of the SPC from the SPC Editor to IUCLID

 More information on transition of SPC to IUCLID can be found on the <u>SPC Editor webpage</u>





Drinking Water Directive in IUCLID: Introduction

- The revised Drinking Water Directive (DWD) aims to protect citizens and the environment from the harmful effects of contaminated drinking water and to improve access to drinking water
- Only substances included in the EU positive list will be allowed to be used in materials in contact with drinking water
- ECHA will establish first EU positive list by January 2025, and will be repsonsible for maintaining it from 2025 onwards
- Applications for addition of new substances, update or removal of existing entries from the UE positive list, will be submitted in IUCLID - the first submissions (notifications) in IUCLID will start in January 2025



DWD Notification of intention

Dossier header

- dossier name
- who is submitting (legal entity)
- material type
- migration level
- Is it a group entry? for organic and cementitious materials
- date of planned application

- Table of contents
 - 1. General information
 - 2. Intended application of the substance





DWD Article 11 application

Dossier header

- dossier name
- who is submitting (legal entity)
- type of application
- notification number
- material type
- migration level
- EUPL name and number for review or removal of a substance...
- Is it a group entry? for organic and cementitious materials
- Is a submission an update?

Table of contents

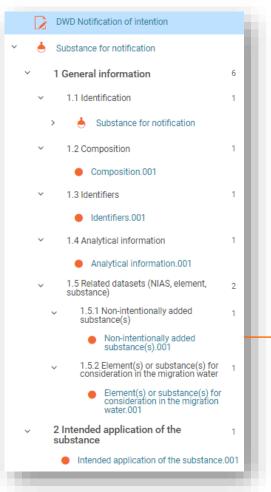


- 1. General information
- 2. Physical and chemical properties
- 3. Intended application of the substance
- 4. Data on migration of the substance, electrochemical tests
- 5. Toxicological data
- 6. Microbiological activity of the substance
- 7. Analytical methods
- 8. Reports

Around 60 harmonised IUCLID documents reused



DWD NIAS, element or substance



If NIAS – non-intentionally added substance - will migrate to the water above some value, it will get a separate dataset and will be assessed as a 'condition of use' of the 'main substance'

0	Type reaction product	
	Link to NIAS dataset hon-intentionally added substance	
	Remarks A short description how the substance became a NIAS / why the substance is considered as a	

Table of contents

- 1. General information
- 2. Physical and chemical properties
- 3. Data on migration of the substance
- 4. Toxicological data
- 5. Analytical methods
- 6. Reports





New documents specific for the DWD format

- Data on migration of the substance *endpoint study record*
- Electrochemical test (passivation) endpoint study record
- Intended application of the substance *flexible record*
 - relevant to DWD Notification of intention
 - relevant to DWD Article 11 application
- Microbiological activity of the substance *flexible record*
- Related datasets flexible record
 - Non-intentionally added substance(s)
 - Element(s) or substance(s) for consideration in the migration water
- Reports: placeholder for reports *flexible record*



IUCLID format changes 2023 webinar

DWD IUCLID format: plan for upcoming months

- The IUCLID format will continue to be worked on in 2023 based on:
 - requirements and feedback from experts
 - development of the legal framework for the DWD applications
- ECHA calls for volunteers to join the Drinking Water Directive IT tools user group which will focus on testing and providing feedback to ECHA – if you are interested, please contact ECHA by e-mail at <u>ECHA_DWD@echa.europa.eu</u>

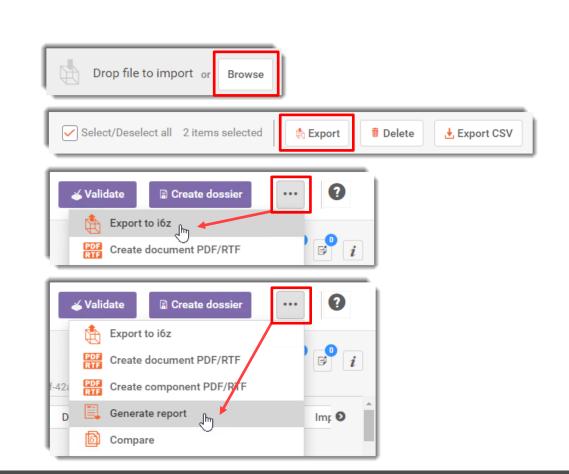
Demonstration of new functionalities

- Robin Allen
- Mark Roberts



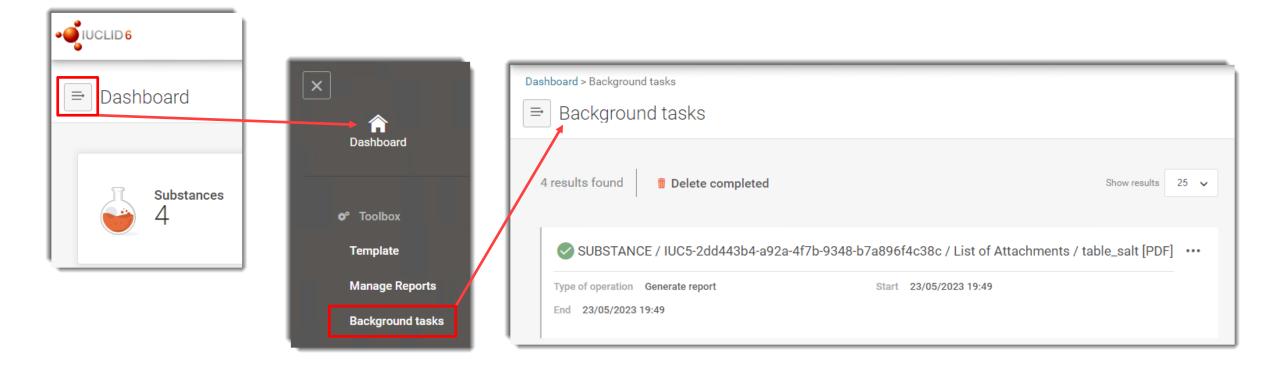
Introduction to background tasks

- Interface added for the management of background tasks of type:
 - Import
 - Export / Export to i6z
 - Generate report
- User benefits:
 - A clear view of what is running in the background.
 - Access to the results of the task whenever it is convenient for the users.
 - Ability to log out of IUCLID 6 Server without affecting the tasks.



Accessing background tasks

• To view the list page, go to the dashboard, and then open the main menu, where there is an item for background tasks.



IUCLID new functionalities 2023 webinar

Background task list page

- There are 4 conditions in which a background job can exist:
- 1. Running -
- 2. Completed successfully
- 3. Cancelled by the user
- 4. Stopped due to error
- Tasks are ordered by start time, most recent first.
- Delete completed applies to all tasks that are no longer running. Deleting a task removes its record from the list, but related data in IUCLID are not deleted.

)ash	aboard > Background tasks	
⇒	Background tasks	
7	results found Delete completed Show results	25 🗸
_	O 0a19db84-845a-4401-a620-03c384fc1d6b_IUC6.4_DISSv4.3.0_substance_dataset.i6z	
	Type of operation Import Start 23/05/2023 20:22 End	
+	364351a8-bfe8-473a-b00c-0c14e5946e5b_ECB5-8ef70421-5418-4845-9c68- 65222a2d8f95_0.i6z	
	Type of operation Import Start 23/05/2023 20:22 End 23/05/2023 20:22 23/05/2023 20:22 23/05/2023 20:22	
	S7d97423-579b-411f-b116-177a96930bb4_IUC6.4_DISSv4.3.0_substance_dataset.i6z	
	Type of operation Import Start 23/05/2023 20:19 End 23/05/2023 20:21 23/05/2023 20:21 23/05/2023 20:21	
	🗴 2f472c80-0995-44a8-bf7f-dc57040c3739_nacl_doss_4_anns_v1_corrupt_header_i6z 🛿 Error	
	Type of operation Import Start 23/05/2023 20:18 End 23/05/2023 20:18 23/05/2023 20:18 23/05/2023 20:18	



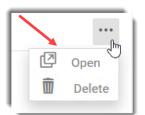
Background task three-dot menus



• A task that is running can be cancelled. All actions associated with it are undone, as though the process had not been started.



• A completed task for *Generate report* or *Export* allows the report or the exported data to be downloaded at any time after completion.



A completed task for *Import* allows the imported entity to be opened in the data window. *Import* of multiple i6z files at once in a zip file creates a background task per i6z file.



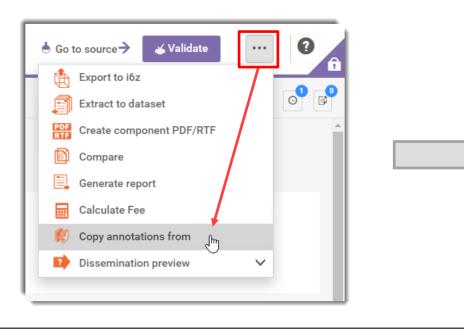
Cancelled and erroneous tasks have only the option to be deleted.

Copy annotations from

- Copy annotations from is used to copy annotations between dossiers. It works for dossiers whose subjects are either *substances* or *mixture/products*. It is aimed mainly at the evaluation process carried out by a competent authority, but other uses are possible.
- Factors to consider:
 - 1. Works only for *dossiers*, not *raw datasets*;
 - 2. The *annotation* must have been attached to the *dossier* after dossier creation, not to the dossier subject when it was a *raw dataset*;
 - 3. The two *dossiers* must have the same subject, judged by UUID;
 - 4. The *annotation* must not be attached to a dossier header;
 - 5. Copying can be done from newer to older, and older to newer dossiers.

Accessing Copy annotations from

- Copy annotations from is accessed from the three-dot icon at the top of the data window whilst viewing a dossier.
- The feature provides a list of only dossiers that have the same subject as the selected dossier. Select the dossier from which annotations will be copied.



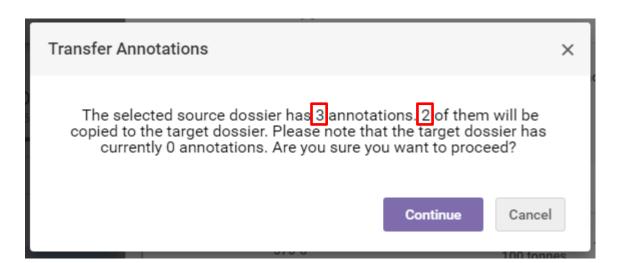
	to copy annota	Q	2 items found		
				S	ort by Newest first
Test Annotati	ons copying do	ssier v2 added r		s 23/	05/2023 23:39 🛽
Subject name	Iron oxide / 215- 570-8	Submission type	REACH Registration 10 - 100 tonnes	Dossier UUID	8f178845-b4f8- 48db-a7ae- 6da9d2ed5295
Test Annotations copying dossier v1				23/	05/2023 23:34 [2
	Iron oxide / 215-		REACH Registration 10 -	Dossier UUID	4f1955ce-224c- 4399-849d-



IUCLID new functionalities 2023 webinar

Predicted effect of Copy annotations from

- On selecting a dossier from which to copy annotations, a window pops up that states the number of annotations that will be copied if you click on *Continue*.
- Annotations that were attached to the dossier subject before dossier creation are not counted.
- Annotations in a dossier header are counted, but not copied.
- In the example to the right, there are 3 annotations attached to the source dossier, but only two will be copied because one is in the dossier header.



Helpdesk tips and conclusions

Sevarine Sosingot





1. Use the correct contact forms

- Utilizing the correct contact forms helps us provide faster replies and better service.
- When you use the correct contact form, we receive important metadata that helps us to understand your request better. (for example IUCLID version, database type, request type etc)
- It also ensures that your ticket is routed to the correct queue, so that it can be handled by the appropriate team.

Technical support



I need support with:



2. Provide detailed information in your request

- Describe the steps you were performing before encountering the issue. The more specific you can be, the better. This will help us recreate the problem and identify the root cause.
- If applicable, provide screenshots of the steps you took. Visual aids can greatly assist us in diagnosing and resolving the issue promptly.
- Include screenshots of any error messages or warnings you encountered. This information will allow us to investigate the issue accurately and provide you with the most appropriate solution.
- Provide us with all the relevant log files. These files often contain valuable information about the underlying issue, assisting us in troubleshooting more efficiently.



3. Review the support page on our website

- Approximately 70% of the questions we receive already have answers in our Manuals and Frequently Asked Questions (FAQ) section.
- Review carefully the user manuals and documentation provided on our website: <u>https://iuclid6.echa.europa.eu/support.</u> They provide valuable information and instructions on Installing, updating and using the IUCLID 6 software effectively.
- Reviewing documentation before submitting a support request will save you time and help you find the answers you need more quickly.



- The new release is available in our website at <u>https://iuclid6.echa.europa.eu/</u>
- It includes format changes (your data will be migrated during the upgrade procedure), new features and improvements
 - Check the release notes for further details

Question and answers session

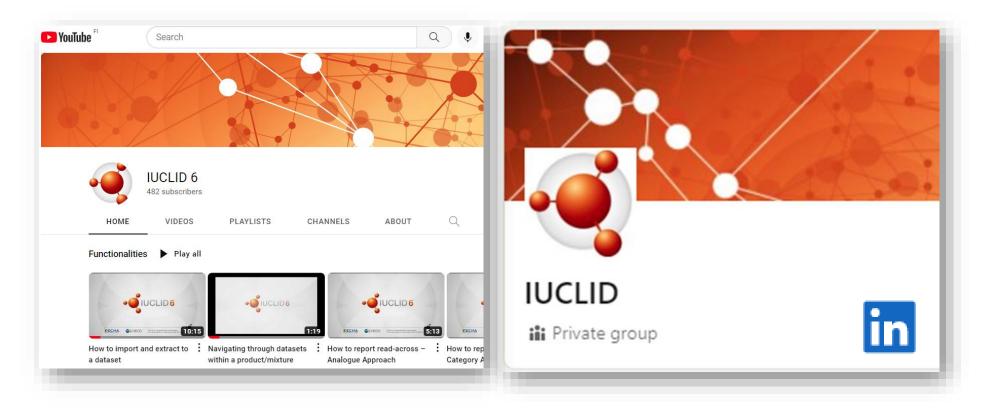
- Q&A using Slido open until 16:00 (EET)
- You can keep your questions anonymous
- All Q&As will be published on the webinar pages in the upcoming days at <u>https://echa.europa.eu/webinars</u>





IUCLID in social media

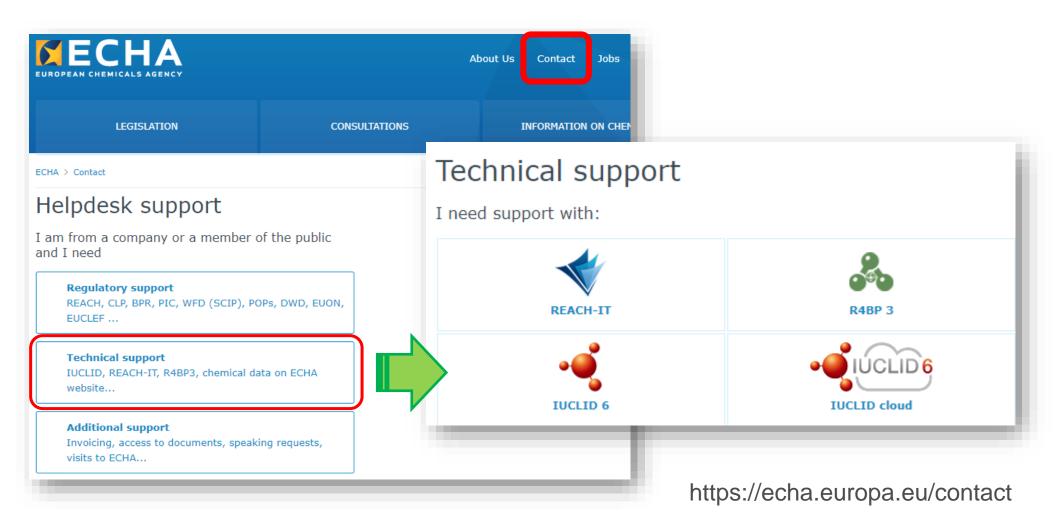




IUCLID YouTube channel with video tutorials

IUCLID LinkedIn group with latest news about the tool







Thank you for your participation

