





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





# **IUCLID** 6

Version 2.0.0 release

15 November 2017





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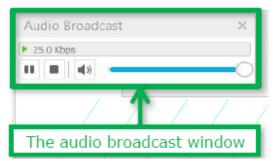




#### Audio troubleshooting

- 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



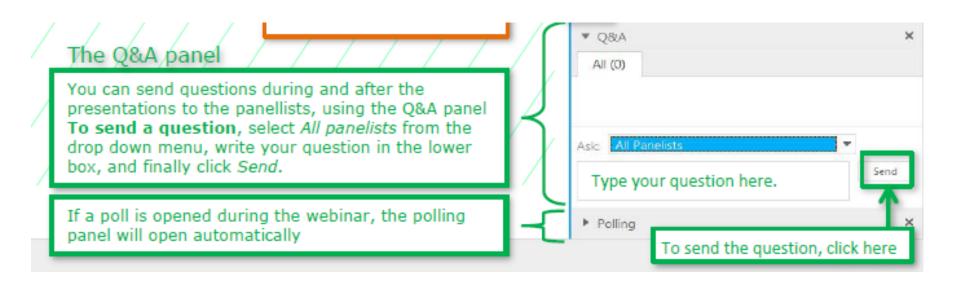






#### The Q&A panel

- You can post your questions during the entire webinar
- Before the Q&A session, 5 minutes will be left to send additional questions





### The Q&A panel

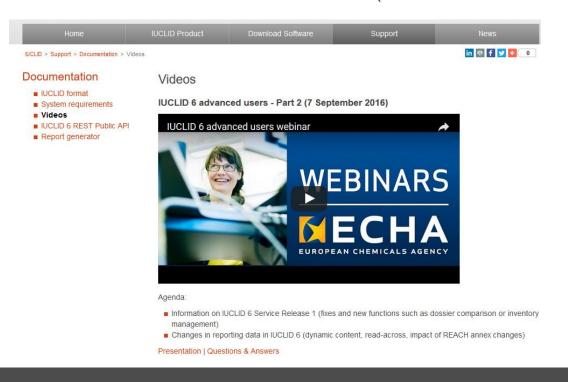
- Questions will be answered privately, i.e. you will not see each others questions and answers
- We will answer the most frequently asked questions at the end of the webinar
- Your questions will be kept anonymous





#### Recordings

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





# **IUCLID** webinar



### Agenda for today

What?	Who?	When?
Welcome and introduction	François Le Goff	12:00 (EEST)
Information on IUCLID 6.2	Mark Roberts	
Compatibility between IUCLID versions Installation and update	François Le Goff	
Fee calculator	Alexis Quintana-Sainz	
Update on ECHA Cloud Services and IUCLID Cloud	Tommy Hägg	
Questions and Answers session	All participants ECHA	Until 13:00

### Information on IUCLID 6.2

#### **IUCLID** news

14/11/2017

#### Update of IUCLID 6 available

A new version of IUCLID has been published on the IUCLID website. It includes improvements, such as updated formats taking into account the latest OECD test guidelines and GHS/CLP requirements.

The updated IUCLID (version 6.2) introduces:

- An update of the IUCLID format to take into account the latest developments of the OECD test guidelines, the support of new online dossiers for REACH purposes and the latest updates of the CLP Regulation and the Globally Harmonised System for Classification and Labelling (GHS).
- A new export option that allows exchange of data with previous versions of IUCLID 6.
- A fee calculator that will inform REACH registrants about their fee before they submit their dossier.

Updating IUCLID to the latest version is not mandatory. Companies can continue preparing their dossiers and notifications with the IUCLID 6 versions published earlier as ECHA's completeness check remains unchanged. However, the update is strongly recommended, for example, to fully benefit from the new features and to have the optimal use of Chesar, ECHA's Chemical Safety Assessment and Reporting tool.

The IUCLID Cloud for SMEs service will be automatically updated to the latest version in the coming days – users do not need to do anything. SMEs and their consultants are encouraged to use the cloud service for ease-of-use and better collaboration for creating the registration dossiers.

A webinar presenting the new version and offering practical advice on how to update is taking place on 15 November from 12:00 to 13:00 Helsinki time. You can register from the link below. ECHA's Helpdesk will assist users with any questions about this update.

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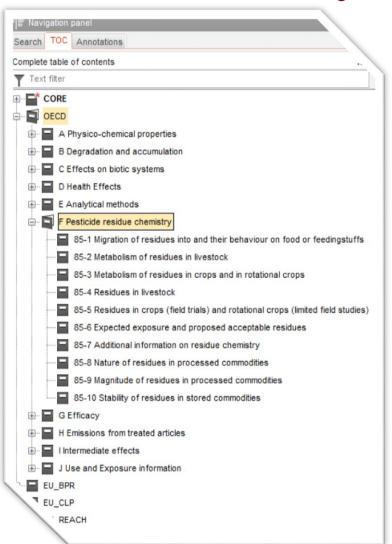




New and updated Pesticides' OECD Harmonised Templates (OHTs)

The OECD have updated their series of **OECD Harmonised Templates** on Pesticide Residue Chemistry to cover the entire set of OECD Test Guidelines.

The new and updated OHTs are included in version 6.2 of IUCLID

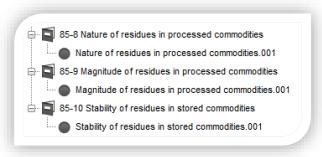




#### New and updated Pesticides' OECD Harmonised Templates

There are **three New** OHTs (document type: endpoint study record):

- Nature of residues in processed commodities
- Magnitude of residues in processed commodities
- Stability of residues in stored commodities



All (7) other Pesticides OHTs have also been updated

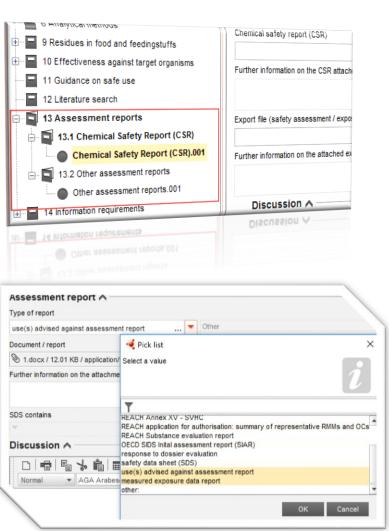
#### Specific update: Metabolism of residues in crops and in rotational crops

- A merger of two previous templates
- Duplicate fields removed
- New endpoint options available to address residues in crops and rotational crops respectively

# UCLID 6

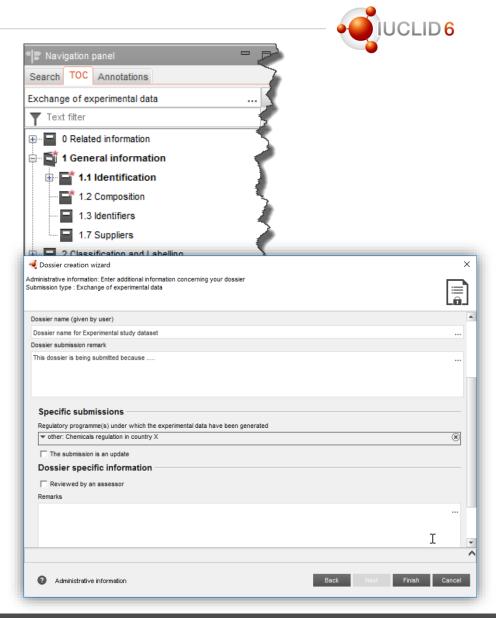
#### CSR and assessment reports

- Section 13 contains assessment reports
- The 'Assessment reports' Section had been increasingly used to cover the specific needs of the Chemical Safety Report – CSR
- All elements for the CSR are now gathered in Section 13.1, including the documentation of Part A which documents a summary and declaration of risk management measures
- Section 13.2 can now be used to store information solely about Other assessment reports, and includes two new report types to select for this purpose:
  - measured exposure data report
  - use(s) advised against assessment report



#### Exchange of experimental data

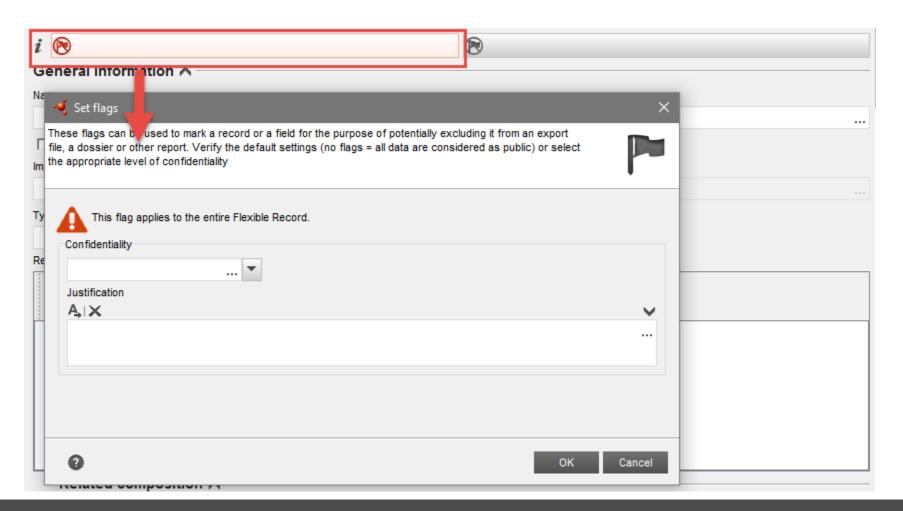
- New submission type already introduced in IUCLID 6 version 1.3.0
- New in version 6.2: this submission type can be used for creating dossiers in order to exchange experimental data outside of a specific regulatory context
- Legal entity automatically included in the dossier header
- We would recommend anyone using this dossier header to include which regulatory programme(s) the data was originally generated for





### Splitting of the IUCLID flags

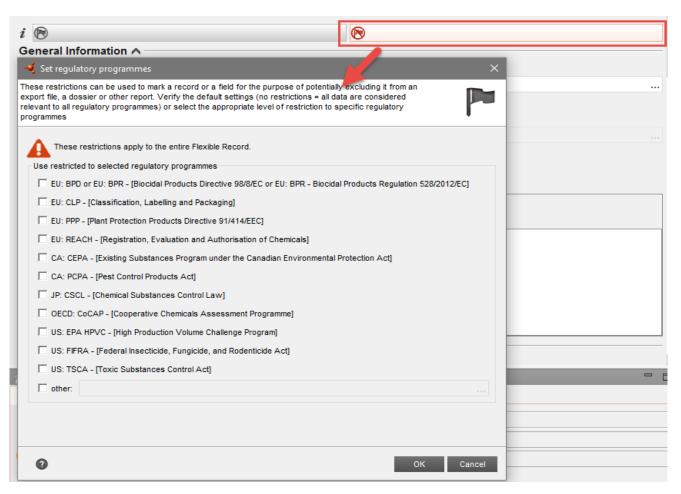
Document-level Confidentiality flag





### Splitting of the IUCLID flags

Regulatory programmes





#### **IUCLID** flags

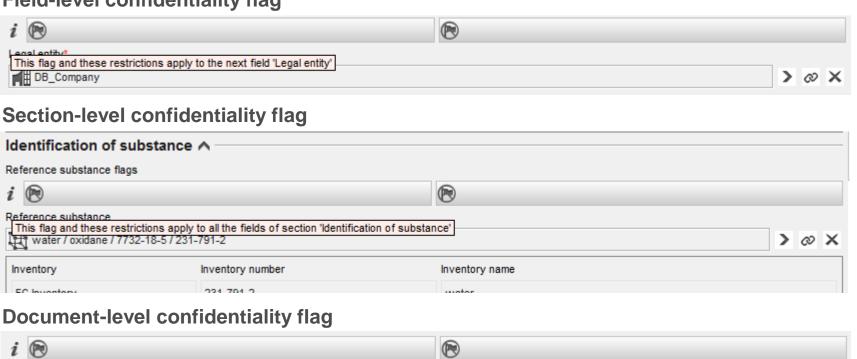
General Information A

Name

This flag and these restrictions apply to the entire Flexible Record.

Each document element (field, section, or even the document itself) is now explicitly linked to a confidentiality claim and a regulatory programme.

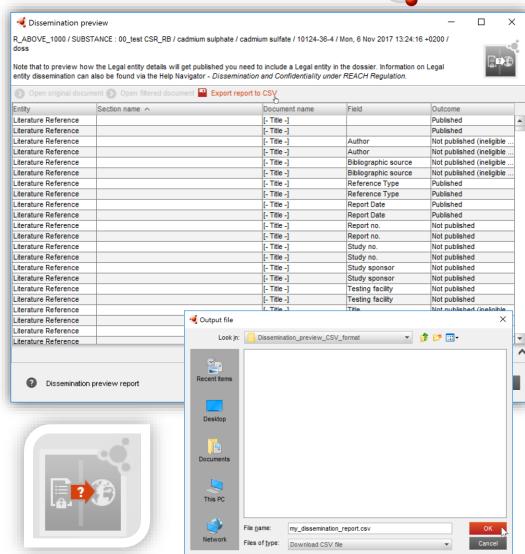
#### Field-level confidentiality flag





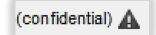
#### Dissemination preview

- Possibility to export and save the dissemination preview report as CSV file
- The report can then be opened in MS Excel
- In MS Excel, the report can then be further filtered and sorted, for example:
  - to only show the information which is published, or certain sections

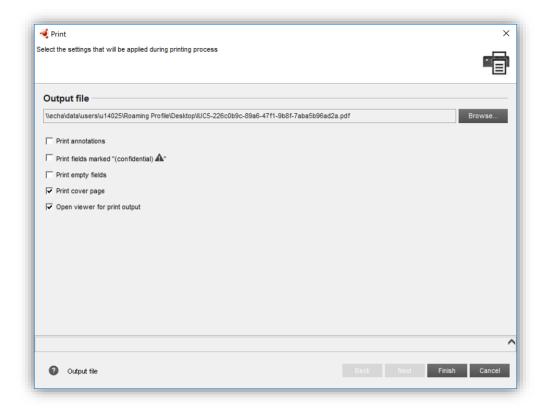




### Print option



- New option added to allow users to decide if they wish to print a record or a dataset for the fields marked confidential in IUCLID
- This option also extends to the printing of entities in IUCLID for example
  - Reference substances
  - Literature references
  - Legal entities







Legal entity

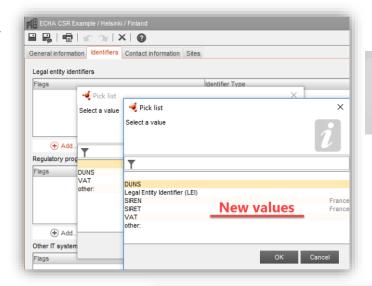
# Additional points of data entry and configuration

### **Legal entity**

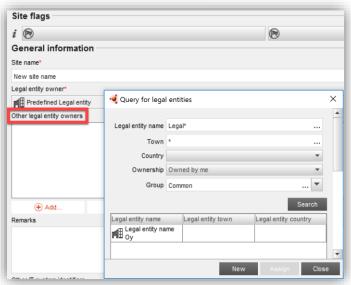
 Legal entity identifiers picklist extended

### Legal entity site

 Add more than one legal entity per legal entity site by selecting 'Add' and searching for existing legal entities, or creating a legal entity









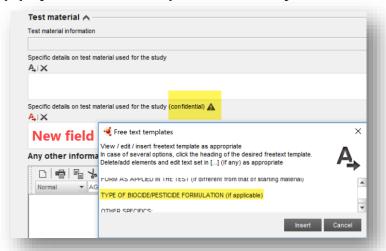
### Additional points of data entry and configuration

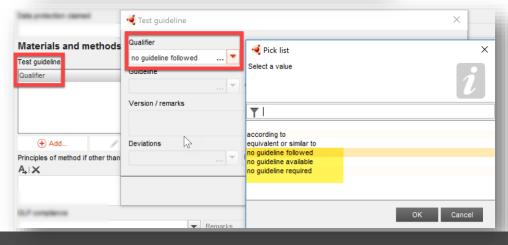
### Materials and Methods (changes apply to all endpoint study records)

 Existing field: Specific details on test material used for the study

**Text template** extended to include: Type of biocide/pesticide formulation (if applicable)

- New field: Specific details on test material used for the study (confidential)
- Extended conditional formatting to cover version / remarks







### Additional points of data entry and configuration

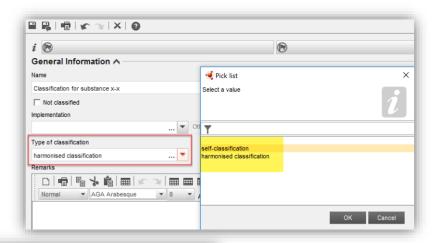
Section 2.1 (GHS)

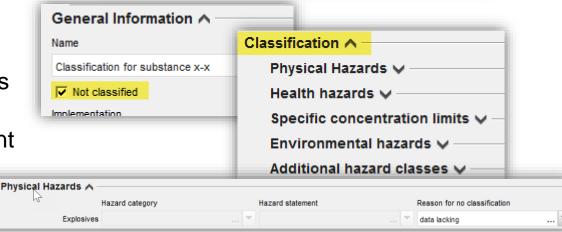
New field: <u>Type of classification</u>

Can now distinguish selfclassification from harmonised classification

New <u>Dynamic content</u>

If the 'Not classified' checkbox is ticked, it will disable all hazard categories and hazard statement picklists under the Classification header





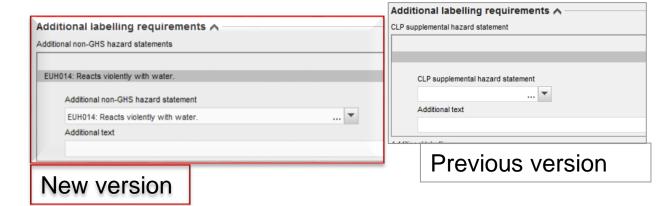


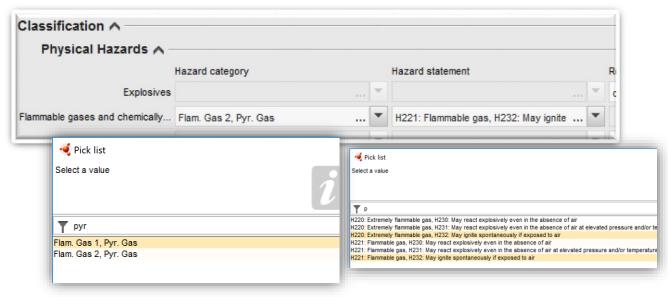
### Additional points of data entry and configuration

Section 2.1 (GHS)

Under additional labelling requirements, non-GHS hazard statements can be entered

The physical hazard 'flammable gases and chemically unstable gases' has extended hazard category and statement picklists







### Additional points of data entry and configuration

#### Other changes to note

New field: Type of water added to the Endpoint summaries of:

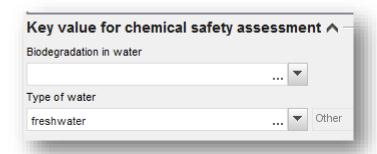
- 5.2.1 (Biodegradation in water: screening tests)
- 5.2.2 (Biodegradation in water sediment simulation tests)

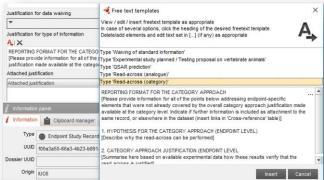
To differentiate between the type of water used in the study; marine, freshwater, or 'other'

In all endpoint study records, the field: <u>Justification for type of information</u> has an extended **Text template** to include '**Readacross (category)**' to provide a summary for the justification of a category approach and to address endpoint-specific elements not covered by the justification made in the overall category approach

The repeatable block for Surface treatment in Composition (1.2) can now be claimed as confidential









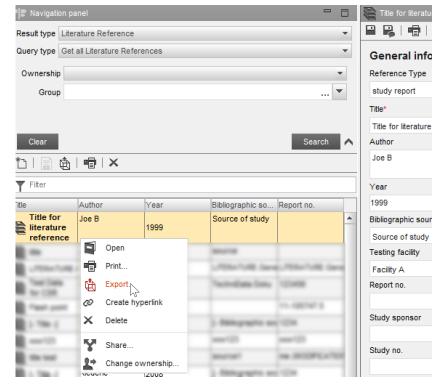
#### Literature references

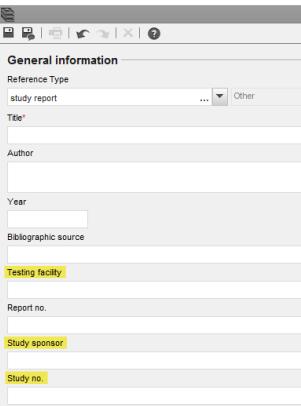


### Label changes:

Testing laboratory → Testing facility Company owner → Study sponsor Company study no. → Study no.

You can now export Literature references

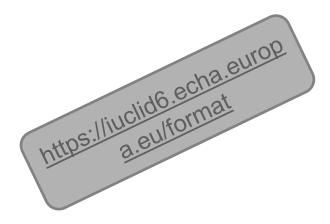






#### Format changes

- The information concerning the IUCLID format is available on the IUCLID website
- Changes introduced in the new IUCLID version are detailed in 'Release Notes'



#### **IUCLID** format

#### Introduction and resources to download

REACH Article 111 ("Formats and software for submission of information to the Agency") states,

"The Agency shall specify formats and make them available free of charge [...] on its website for any submissions to the Agency Member States, manufactures, importers, distributors or downstream users shall use these formats [...] in their submissions to the Agency pursuant to this Regulation. [...] For the purposes of registration, the format of the technical dossier [...] shall be IUCLID. The Agency shall coordinate the further development of this format with the Organisation for Economic Cooperation and Development to ensure maximum harmonisation."

Please note that the IUCLID 6 application follows this format intrinsically and IUCLID 6 users need not worry about Article 111 compliance.

You can download all information related to the IUCLID 6 format for the different main IUCLID 6 versions alread published. The information of the downloadable archives is organised according to the information presented the end of this page.

- IUCLID 6.1 format, published on 29<sup>th</sup> of April 2016
- 📥 (.zip | 14.7 MB)
- IUCLID 6.2 format, published on 15<sup>th</sup> of November 2017 🏥 (.zip | 15.0 MB)

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

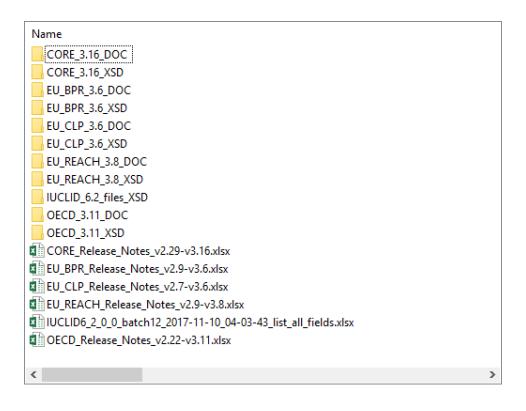
IUCLID 6 is built as a platform and is a modular system. The IUCLID 6 format is separated in different groups ('legislations') depending on its source identified in the table below.

#### IUCLID 6 legislations and file format

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#### Format changes documentation



# Report generator



#### Update to the Chemical Safety Report

Compatible with the latest version of IUCLID v6.2

New Annex III (Mode of action)

Annexes	32
1. Annex: References	33
2. Annex: Information on Test Material	34
3. Annex: Mode of action / Human relevance Framework	35

- New section for Additional toxicological effects (CSR chapters 5.10.1.4 & 5.10.3)
- Use information in CSR chapter 2 is displayed according to the Type of CSR selected in Section 13.1 combined with the Related assessment in the various uses under Section 3.5
  - E.g. If the Type of CSR 'Joint CSR (joint uses)' is selected, then the use information will be printed only if 'use assessed in a joint CSR' or 'use assessed in a joint CSR but not a lead's own use' is then selected in the Related assessment of a use record

Readability improvements (for example, removal of labels when not used, table header

colouring)

#### 1.3. Physicochemical properties

Table 1.1. Physicochemical properties

Property	Description of key information	Value used for CSA / Discussion
Physical state		Value used for CSA: gaseous at 20°C and 101.3 kPa
Vapour pressure		Value used for CSA: 23hPa at 32K

# Report generator



#### Other reports available to run inside IUCLID 6.2

A number of other reports are also available in IUCLID 6.2

You will find these reports under 'Type of report' when you run The Report Generator wizard

Section information

Name given to the Document:

Function and mode of control.001

Bibliographic

Year: 1222

source: source

Section No. 6.1

Author: Author

1. Literature References

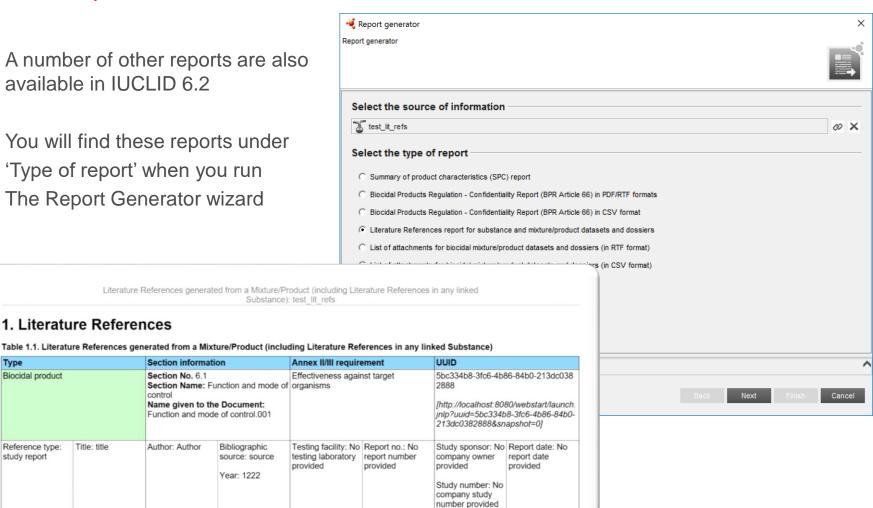
Title: title

Type

Biocidal product

Reference type:

study report



## Report generator



#### Other reports available and compatible with IUCLID 6.2

- Summary of Product Characteristics report (for uploading into SPC Editor)
  - Can be generated from mixture/product datasets/dossiers as an XML
- Literature references report (RTF)
  - Can be generated from both substance and mixture/product datasets/dossiers
- Attachments report for BPR datasets and dossiers (RTF)
  - Can be generated from mixture/product datasets/dossiers
- Attachments report for substances (RTF)
  - Can be generated from substance datasets/dossiers
- BPR Confidentiality report (Article 66), for BPR datasets and dossiers (RTF/PDF/CSV)
  - Can now be generated as a CSV file and opened in Excel

# Compatibility between IUCLID versions



### **IUCLID 6 2.0.0**



#### Note for REACH users

- IUCLID 6 is updated on 15 November. The new version (6.2) brings fixes and improvements.
- Although this update contains improvements, it is not mandatory for the users that need to
  prepare REACH registrations as ECHA IT systems will continue to be fully compatible with the
  version of IUCLID 6 published in April 2016 as well as this new version.
- In order to minimise the impact of this new version, ECHA has managed to provide a new export option that allows to exchange data generated with different versions of IUCLID 6.
- IUCLID users have the liberty to choose the most appropriate time for their IUCLID update (e.g. before or after the deadline) and still be able to submit dossiers to ECHA or exchange data between users, regardless of when they decide to update.
- The changes in this new version of IUCLID have no impact in the completeness check decisions by ECHA.



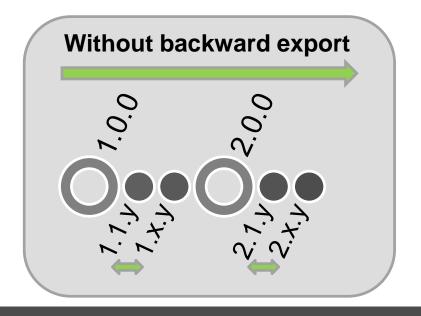
#### Validation assistant

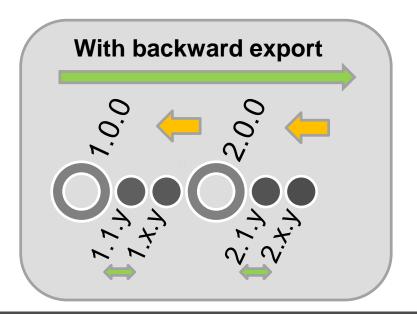
- The Validation Assistant has been updated in order to work in the same way as before, i.e. no impact for REACH users, e.g.
  - Adapted all business rules and completeness check rules that check section 13 to the new IUCLID 6 v.2.0.0 format
- At the same time improvements have been made, for example
  - Implemented new quality rules (QLT) for hazard endpoints (sections 7.3.1, 7.3.2, 7.4.1, 7.6.1, 7.8.1, 7.8.2)
  - Improved completeness check rule TCC\_0102\_20 which checks that UVCB substances contain a composition or a justification for deviations
  - A new validation scenario for the new submission type 'Exchange of experimental data' (outside the REACH or CLP regulatory context)
- Full details are available in the release notes.



#### Extension of the compatibility between IUCLID versions

- Forward migration is still maintained (i.e. the latest version of IUCLID 6 can accept all IUCLID 6, and IUCLID 5.6, files)
- Aim: export of .i6z files from IUCLID 6 v2.0.0 that can be loaded in IUCLID6 v1.x.y
- Backward migration rules have been defined

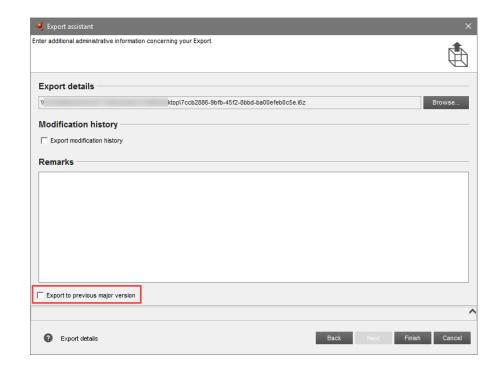






#### Export in the previous version format

- Using the export function, there is an option to export to the previous IUCLID 6 format 'Export to previous major version'
- This option is available for datasets and dossiers
- Also available for bulk export
- You can use this option when you need to exchange information with a user who is still using IUCLID 6 version 1.x





#### What happens when exporting to the previous format?

- Backward migration rules are in place to transfer the information back to its previous location (reverse migration)
- When the backward migration is not possible, for example for new fields or new phrases in picklist, or new documents, the information is migrated to
  - The 'other:' field or a remark field if available (e.g. for picklists)
  - A generic text field (e.g. remarks or summary)
  - An attachment
- The data is kept during backward migration but the structure is lost in some cases
- When migrating back to the latest version of IUCLID 6, the standard migration rules are executed (i.e. the structure lost during the backward export is <u>not</u> recovered)

### Note to Chesar users



#### IUCLID 6.2 and Chesar 3.3

- Chesar 3.2 is compatible with IUCLID 6.1
- Chesar 3.3 is compatible with IUCLID 6.2
- → If you intend to upgrade Chesar to version 3.3 update IUCLID to version 6.2 too
- → If you intend to upgrade to IUCLID 6.2, update Chesar to version 3.3 too



# Installation and update



### Installation



### Desktop

- 1. Download the installer
- Follow the steps of the installer assistant or watch the video tutorial

#### Server

- Download the installation package
- Read the installation instructions

#### **Download Software**

- ) Cloud, Desktop or Server which version of IUCLID is best for me?
- ) IUCLID 6 installer and updater: which one should I download

#### Available downloads

The latest version of IUCLID 6 is 2.0.0, released on Wednesday 15<sup>th</sup> of November 2017.

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

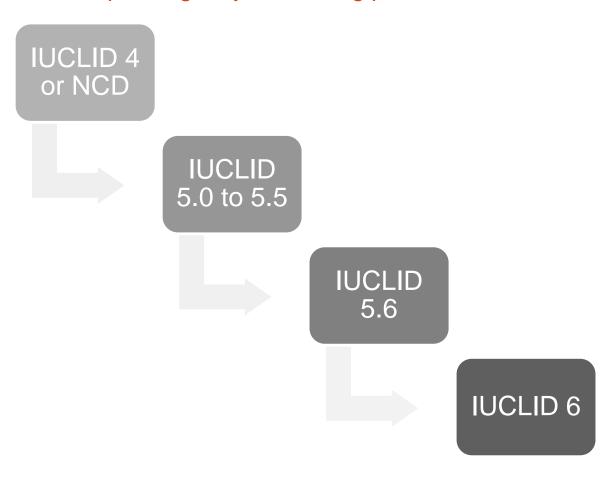
- IUCLID 6 Desktop installer: this download provides all you need to run the IUCLID 6 as a deskton
  - ∰ Windows 64-bit (621 MB) | ∰ Windows 32-bit (642 MB) | ∰ Mac OS X (671 MB)
- IUCLID 6 Server: this download contains all necessary software to run the IUCLID 6 Server version
  using client-server architecture, including its application server.
  - Download (552 MB)
- IUCLID 6 updater: this download provides all you need to update your existing IUCLID 6 application bit computers)
  - Mindows (347 MB) | Mac OS X (347 MB)

#### **Archives**

Looking for older IUCLID versions?



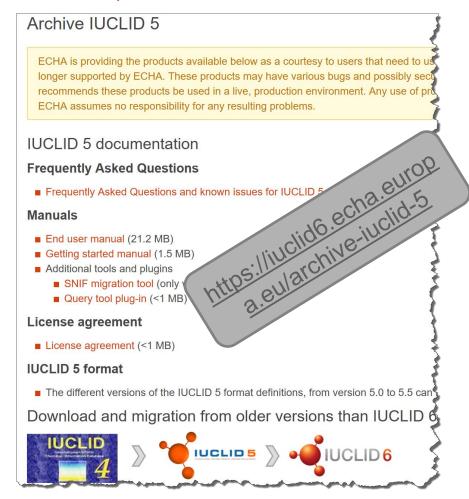
Different processes depending on your starting point





### From IUCLID 4 or NCD (New Chemicals Database)

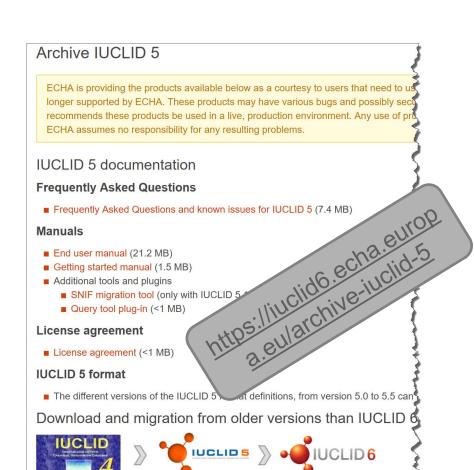
- Download IUCLID 5.1.1 Portable version from the IUCLID 6 website
- Use the Migration tool for SNIF or IUCLID 4 data to convert your files to IUCLID 5 files (.i5z files)
- From there, follow the process
   'Update from IUCLID 5.x'





#### From IUCLID 5.0 to 5.5

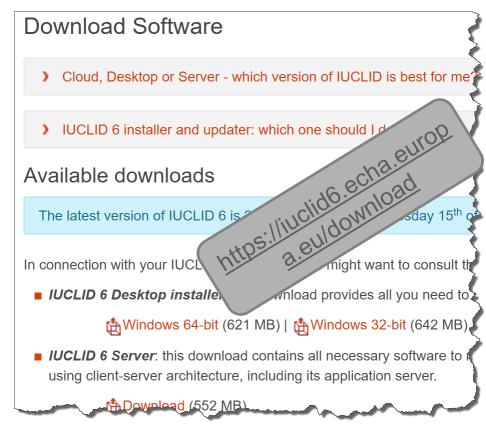
- Export all data from IUCLID 5.x (substances, mixtures, categories, templates, dossiers)
- Download and run the IUCLID 5.6 portable version
- Import all your data to IUCLID 5.6
- From there, follow the process 'Update from IUCLID 5.6'





#### From IUCLID 5.6

- Desktop
  - Use the installer and enter the connection details to your IUCLID 5.6 database
- Server
  - Export all your data from the IUCLID
     5.6 instance (substances, mixtures, categories, templates, dossiers)
  - Import all in a new installation of IUCLID 6 (migration will happen during import)
  - It is recommended to set-up the IUCLID 6 instance beforehand and to create the users as well





### Update from IUCLID 6.x

- Download and run the IUCLID 6 updater
- One upgrader for all Windows & Linux versions
  - Desktop, Win. 32-bit
  - Desktop, Win 64-bit
  - Server
- One upgrader for Mac OS
- It will update any IUCLID 6 installation to the latest version (6.2), migration included

■ *IUCLID 6 updater*: this download provides all you need to upc *bit computers*)

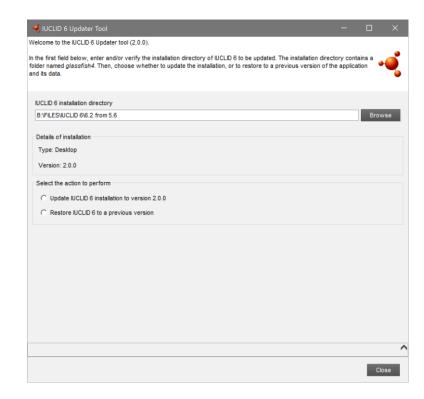
☆Windows (347 MB) | ☆Mac OS X (347 MB)





### **IUCLID** 6 updater

- Select (or verify) your IUCLID 6 installation directory
- You can either
  - Update
  - Restore to a previous version (in case a previous update attempt failed)





### **IUCLID** 6 updater

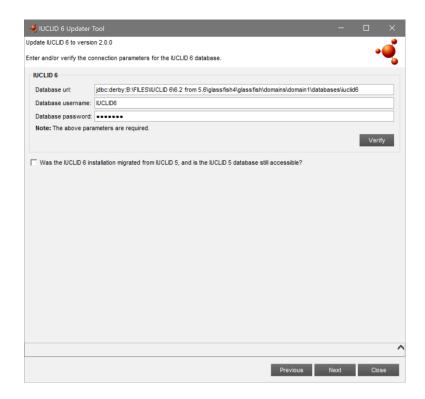
- Select a folder where a backup of your current installation will be saved
- Do not save in your IUCLID 6 installation folder





### **IUCLID** 6 updater

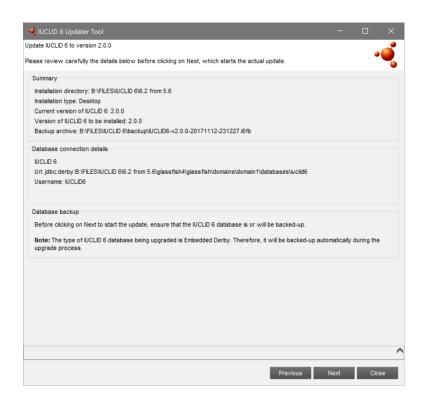
- The connection details for the IUCLID 6 database are detected, please check them
- In case you have your old IUCLID 5
   database, you can enter the connection
   details to launch some database patches
   (optional and not needed if you run the
   patches with a previous IUCLID 6 update)





### **IUCLID** 6 updater

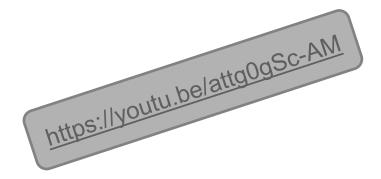
 A summary of the actions that will take place is displayed before launching the update





### IUCLID 6 updater - Video tutorial

- A new video tutorial is available in YouTube to guide the user through the different steps of the updater
- Please have a look!







### Different processes depending on your starting point

IUCLID 4 or NCD

- Download and run 5.1.1 and migrate / export data
- Download and run 5.6 and import data
- Install 6 and import 5.6 data

IUCLID 5.x

- Export 5.x data
- Download and run 5.6, import data and export
- Install 6 and import 5.6 data

IUCLID 5.6

- Desktop: use the IUCLID 6 installer
- Server: install 6 and import 5.6 data

IUCLID 6

• Use the IUCLID 6 updater





- The Fee Calculator allows registrants to estimate the fee to be paid for their REACH dossiers
- The fee calculation is based on the company size, tonnage band and confidentiality claims included in the IUCLID dossier
- Use the calculator before submitting the dossier in REACH-IT and make sure that you:
  - Register in the right tonnage band
  - You haven't claimed unwanted confidentiality claims



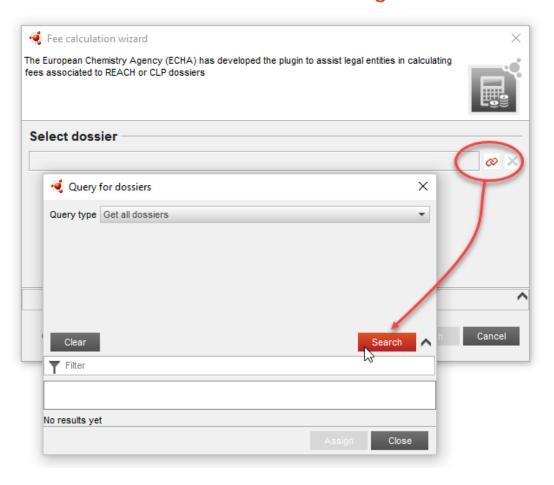


### Launch the Fee calculator from the Plugins menu



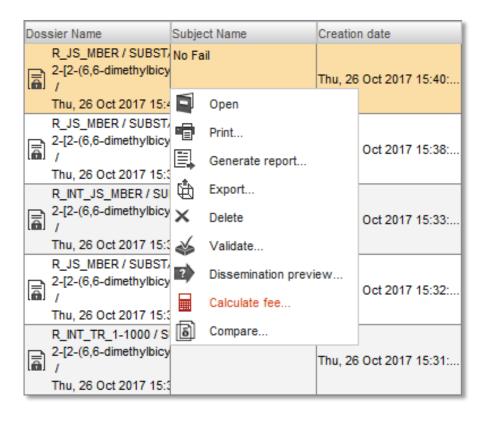


### Launch the Fee calculator from the Plugins menu





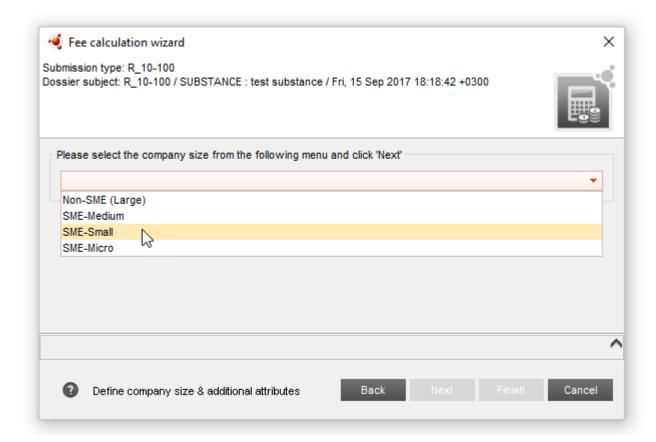
#### Launch the Fee calculator from the Dossier view





### Selecting the company size

- Select the company size as indicated in REACH-IT
- When indicating your company size in REACH-IT make sure that you do it accordance with Commission Recommendation 2003/361/EC





#### Indicators needed for the fee calculation

- Some indicators will appear when there are specific confidentiality claims in the dossier or when the fee waiver has been claimed
- When a confidentiality has been claimed for the IUPAC name and/or the Safety Data Sheet, you will need to indicate whether:
  - the substance is hazardous and if the substance is PBT or vPvB
  - a safety data sheet is required for the substance
- The indicators will appear only if they are relevant for calculating the fee and if the required information is not already included in the dossier
- For calculating the fees of dossiers with tonnage band 1–10 tonnes/year where the fee
  waiver has been claimed, you will need to indicate whether the substance fulfils the
  Annex III criteria

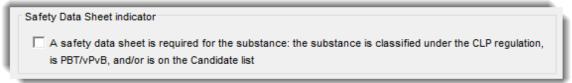


#### Indicators needed for the fee calculation

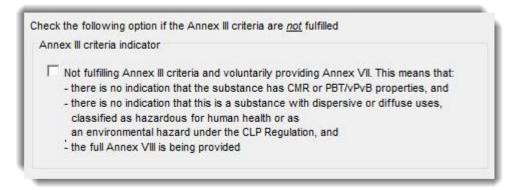
Hazardous substance indicator



Safety Data Sheet indicator



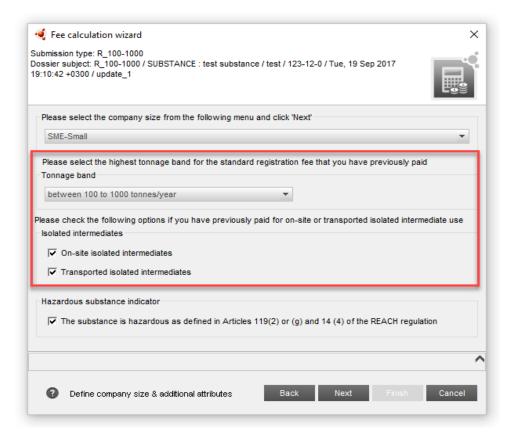
Annex III criteria indicator





#### Calculate the fee of dossier updates

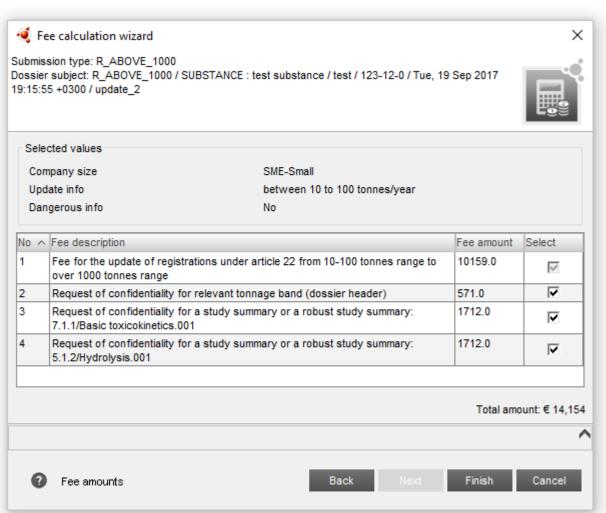
- If the dossier is an update, select the tonnage band of the previous paid submission
- Tick the appropriate box if the on-site or transported intermediate use has been previously paid





#### Result window

- Fees calculated according to the information contained in the dossier and the information you provided in the indicators
- Table with the description and exact amount charged for each fee applied
- Section of the dossier where the confidentiality has been claimed
- At the bottom of the table: total amount of all the fees





#### Remember that...

- The fees calculated by the Fee calculator are only estimates
- The real invoice will be issued by REACH-IT after the submission of the dossier to ECHA



# ECHA Cloud Services and IUCLID Cloud









#### **IUCLID Cloud for SMEs**





- Offers IUCLID to SMEs as a full service where ECHA hosts, maintains, and take care of the back-up of data, in the cloud
- New innovative web user interface that allows easy access to your IUCLID from anywhere at anytime.
- Functionalities tailored for the REACH 2018 deadline
- SME user who would like to move to the Cloud instead of updating their locally installed IUCLID can do so by exporting all their data and import it into the cloud with the bulk import functionality (for data >= IUCLID 5.6)
- Trial service still available for everybody



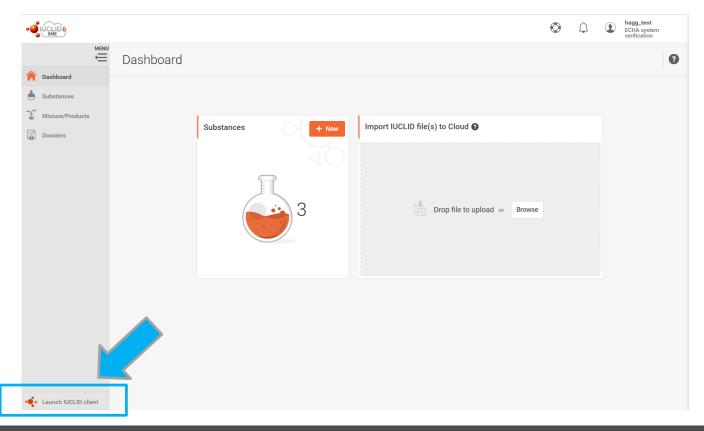
#### **IUCLID 6.2** in the Cloud

- Users of IUCLID Cloud do not have to do any actions. ECHA will take care of the update and migration of your data for you
- IUCLID 6.2 will be introduced to the Cloud on Monday evening 20<sup>th</sup> Nov.
- New subscriptions will be automatically in version 6.2
- Existing subscriptions will be migrated to version 6.2 the following nights with only a couple of minutes of interruption per subscription
  - IUCLID Cloud Trial Migrated by 21<sup>st</sup> Nov. morning
  - IUCLID Cloud for SMEs Migrated by 22<sup>nd</sup> Nov. morning



### Exporting in the previous version of IUCLID from the Cloud

• The functionality to export has not yet been introduced to the browser interface. In order to export in the previous format users need to launch the Client and export it as explained earlier

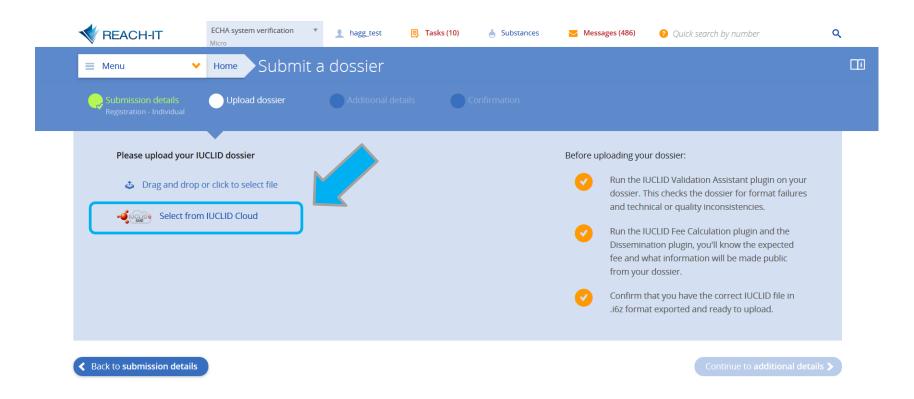






### Integration with REACH-IT

 Users of the IUCLID Cloud for SMEs can now directly submit Cloud created dossiers in REACH-IT without exporting and importing them

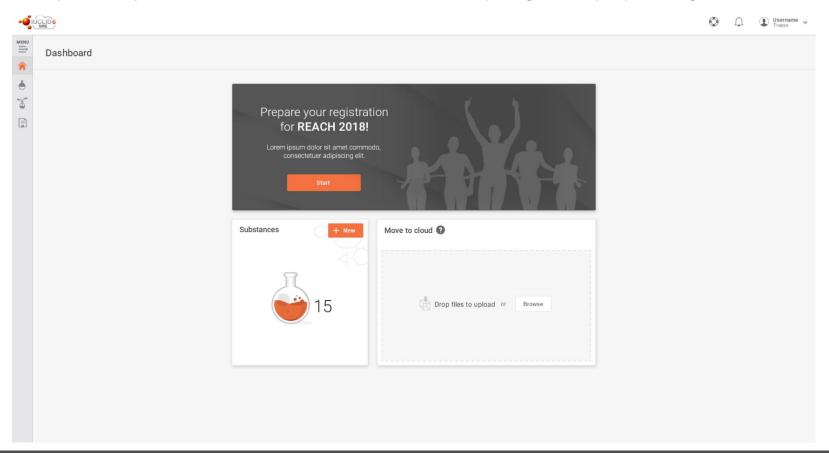


# IUCLID Cloud – Coming feature



### Support for creating REACH 2018 dossiers

Early January a new feature will be introduced to help beginners prepare registration dossiers

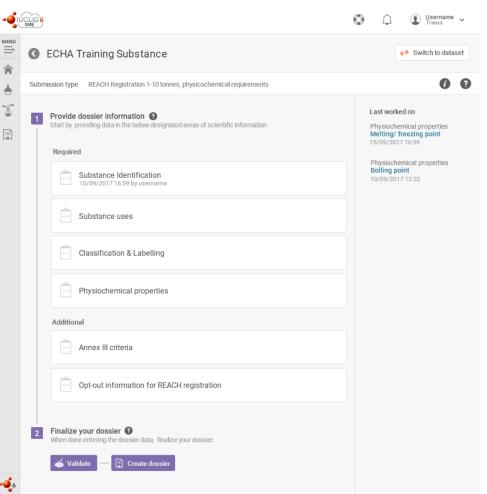


# IUCLID Cloud - Coming feature



### Support for creating REACH 2018 dossiers

 The dossier creation is divided up into smaller tasks that are accompanied with help

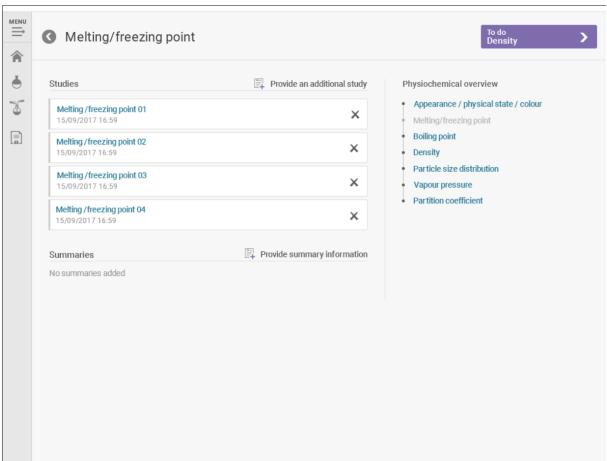


# IUCLID Cloud - Coming feature



### Support for creating REACH 2018 dossiers

 The dossier creation is divided up into smaller tasks that are accompanied with help



# You can continue to send your questions during the next 5 minutes









# More information



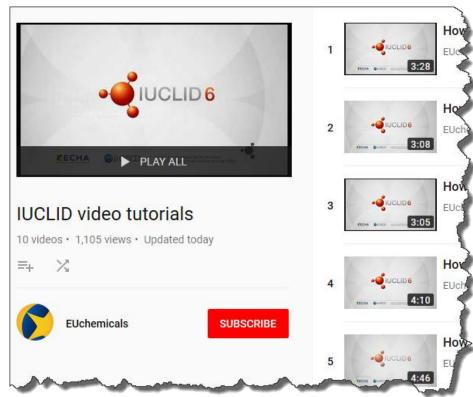
# **IUCLID 6**



#### Video tutorials

- Please check our video tutorials on the YouTube playlist
  - Install IUCLID 6
  - Update IUCLID 6
  - Run the Validation Assistant
  - IUCLID Cloud videos
  - **–** ...





# **IUCLID 6**



#### News and next events

LinkedIn group

#### https://www.linkedin.com/groups/12043483

- Platform to exchange, discuss and provide feedback on the use of IUCLID and on future evolutions of the product
- Join now to be involved in the development of our database





# Thank you for your participation

echa.eu iuclid6.echa.europa.eu oecd.org/ehs/templates





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

