ECHA
EUROPEAN CHEMICALS AGENCY

OECD

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

IUCLID 6

Version 3.16 release

29th April 2019

ECHA EUROPEAN CHEMICALS AGENCY

OECD

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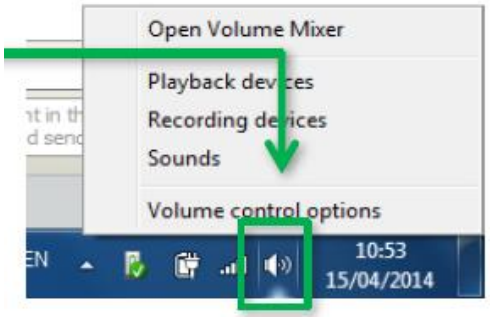
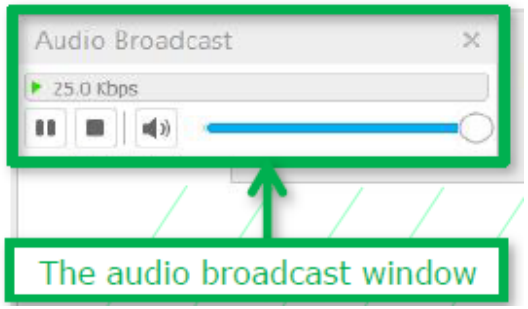
WebEx instructions

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.



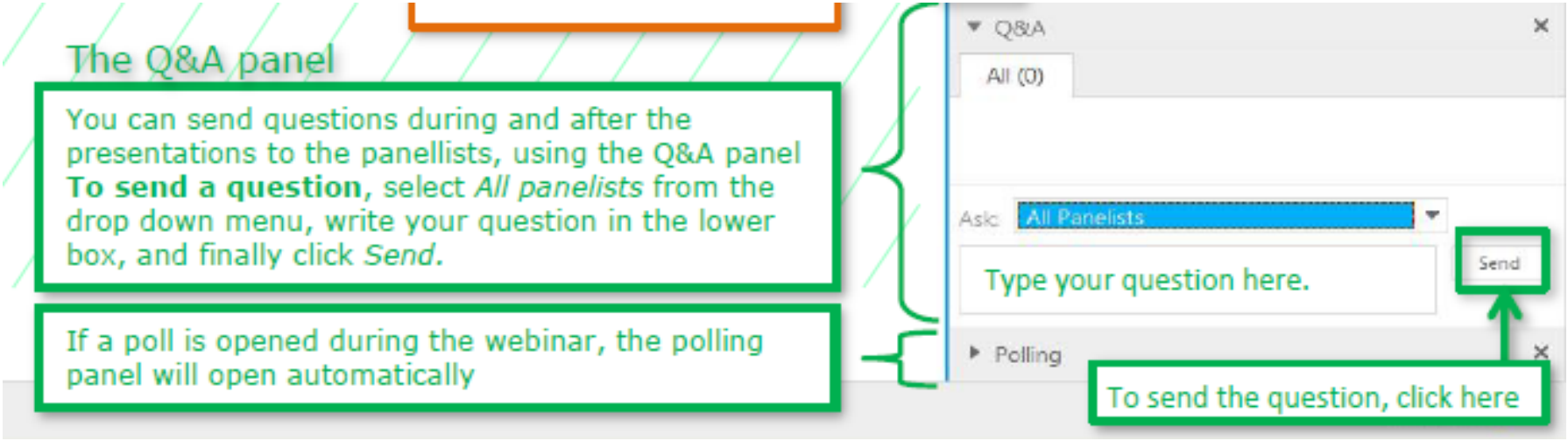
- If the problem persists, you can use a telephone for receiving audio.
  - Click the button shown above to *Request Audio*
  - Select *Use phone*, enter your phone number
  - Click on the *Call me* button

WebEx instructions

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



WebEx instructions

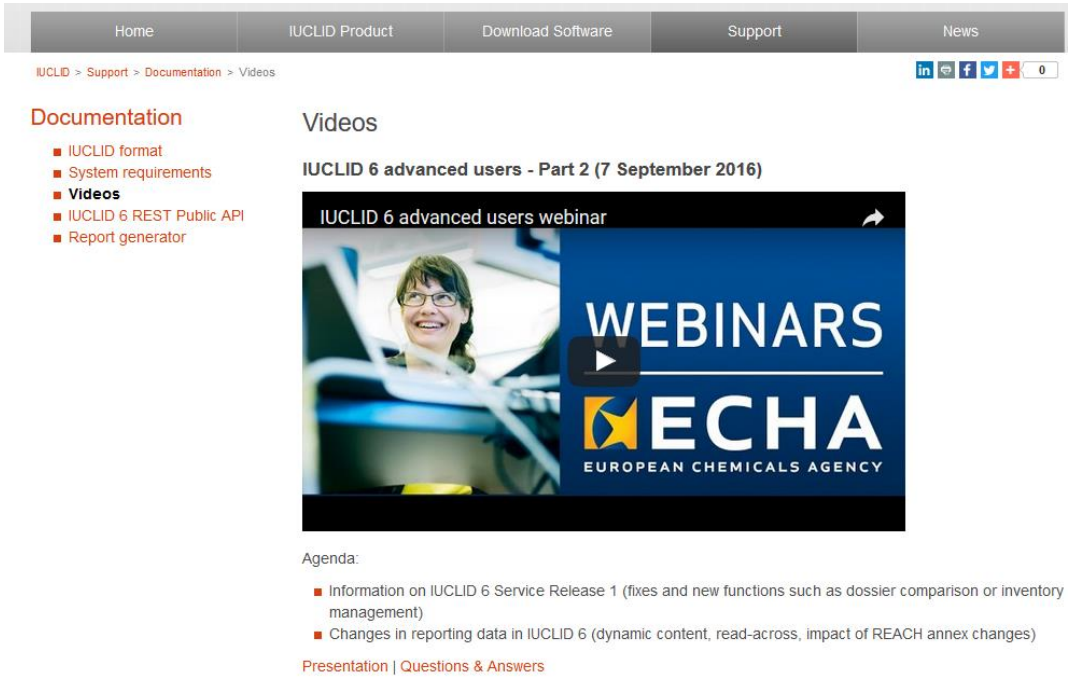
The Q&A panel

- 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

WebEx instructions

Recordings

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

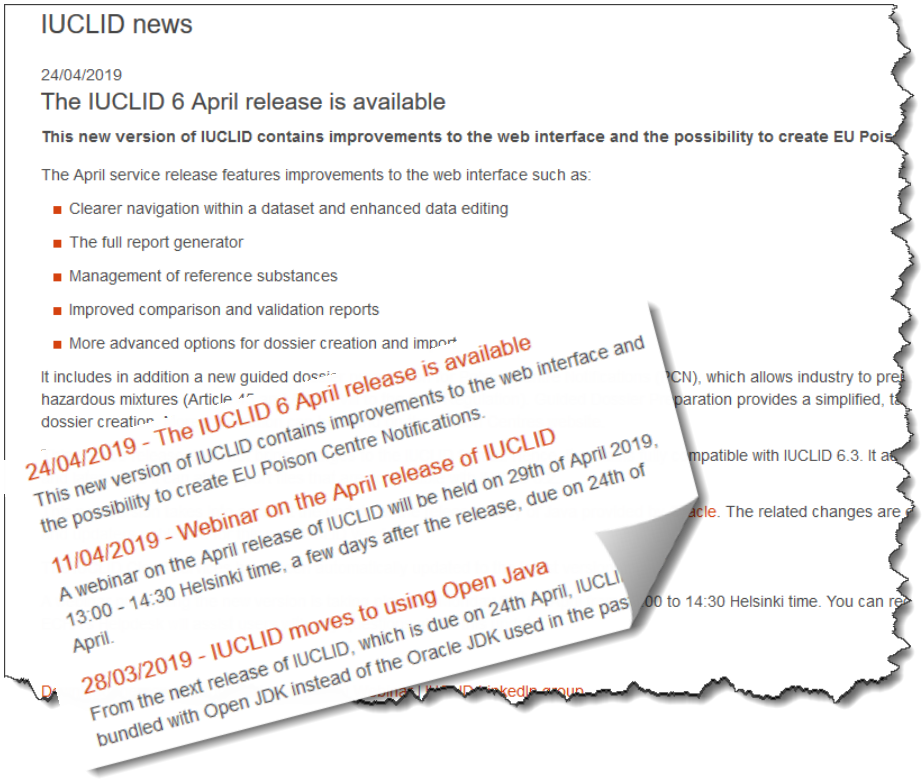


https://iuclid6.echa.europa.eu/videos

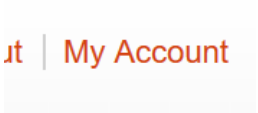
Release of IUCLID 6 (v.3.16)

News alerts

- News alert published on the 28th of March to share some technical information relevant to the release
- Another news alert shared with IUCLID users on the day of the release
- Subscriptions to news alert can be managed from the IUCLID website (My Account | Subscriptions)



https://iuclid6.echa.europa.eu/view-article/-/journal_content/title/the-iuclid-6-april-release-is-available



Subscriptions

☑ iuclid-news-general

☑ iuclid-news-technical

IUCLID webinar

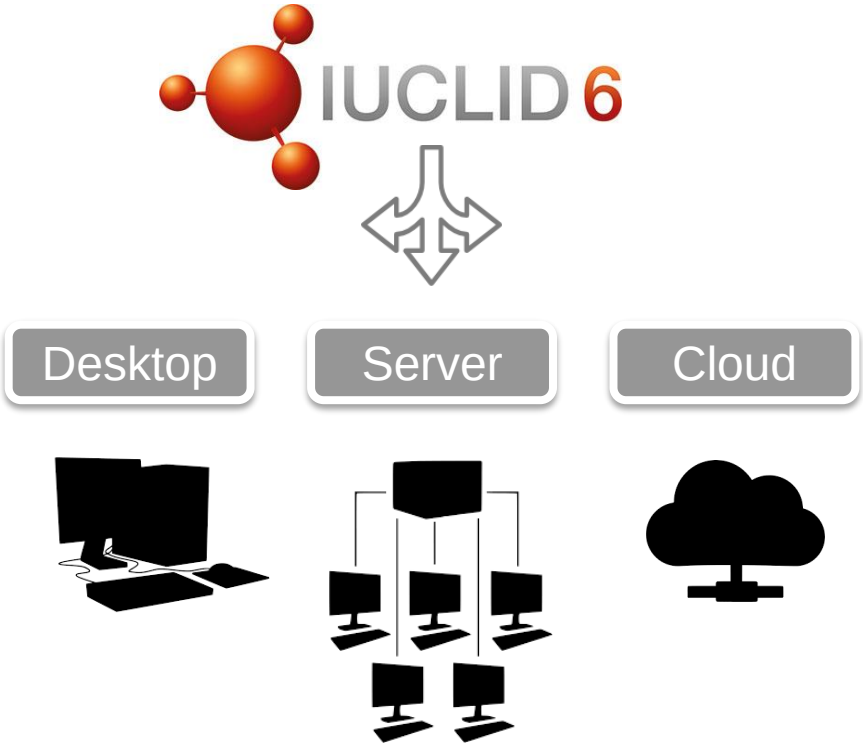
Agenda for today

What?	Who?	When?
Welcome and introduction	François Le Goff	13:00 (EEST)
Scope of the new release	François Le Goff	
Web user interface	Tommy Hägg	
Poison Centre Notifications	Claudia Rimondo	
Questions and Answers session End of webinar	All participants François Le Goff	14:00-14:30

Release of IUCLID 6 (v3.16)

Different distributions of IUCLID

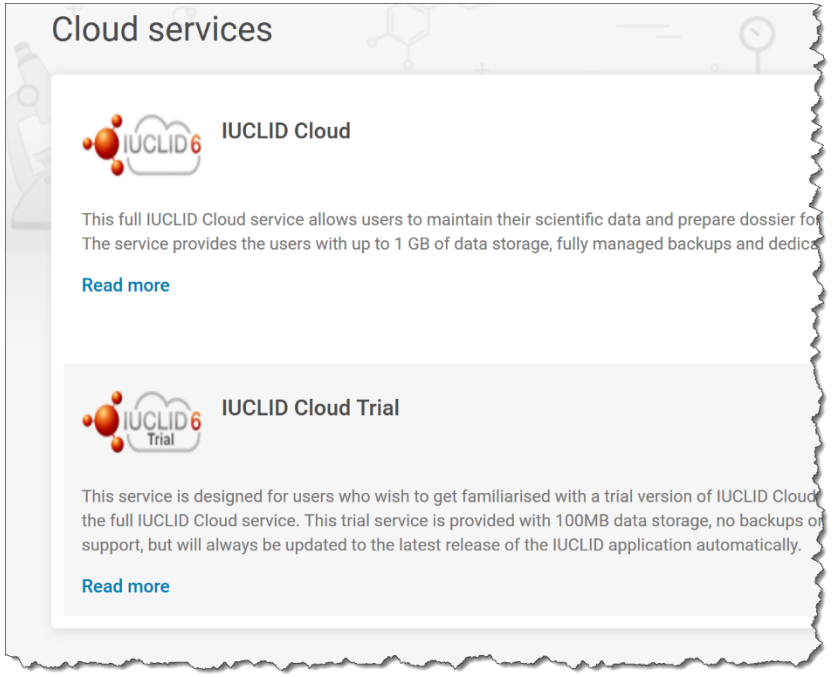
- One IUCLID software, different ways of distributing it
  - Desktop: for single user, on his/her own computer
  - Server: hosted on a server, shared with multiple users
  - Cloud: ECHA Cloud Services, hosted by ECHA, for REACH and CLP users



Release of IUCLID 6 (v3.16)

ECHA Cloud Services

- Cloud instances were updated to the latest IUCLID version on Sunday prior to the release
- The name of the service has changed to IUCLID Cloud as it is not limited anymore to SMEs
- All REACH and CLP users can subscribe
- Updated Terms and Conditions to allow for creation of Poison Centre Notifications



IUCLID 6.3.16 release

Release of IUCLID 6.3

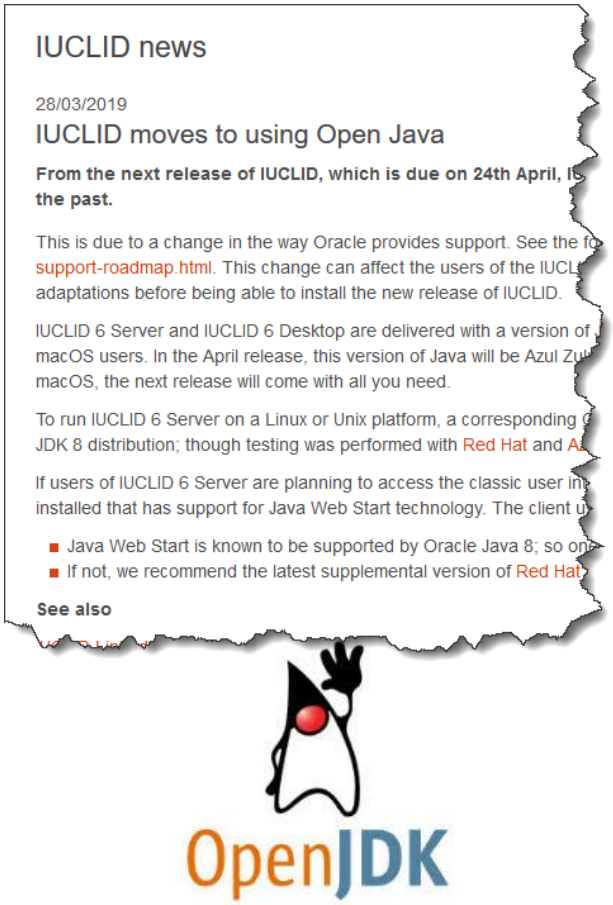
Scope overview

- Web user interface
- Poison Centres Notifications (PCN)
- Other fixes and improvements

IUCLID 6 April release

Fixes and improvements

- Switch to Open JDK 8
  - Oracle is not updating (for free) Java 8 in 2019
  - Java Azul Zulu embedded in the Desktop version
  - For IUCLID Server, different Open JDK distributions can be used (ECHA will use RedHat and Debian)
  - For the IUCLID clients connected to the server
    - RedHat JDK with the IcedTea plug-in is recommended
    - No need for Java when using the web interface



IUCLID 6 April release

Fixes and improvements

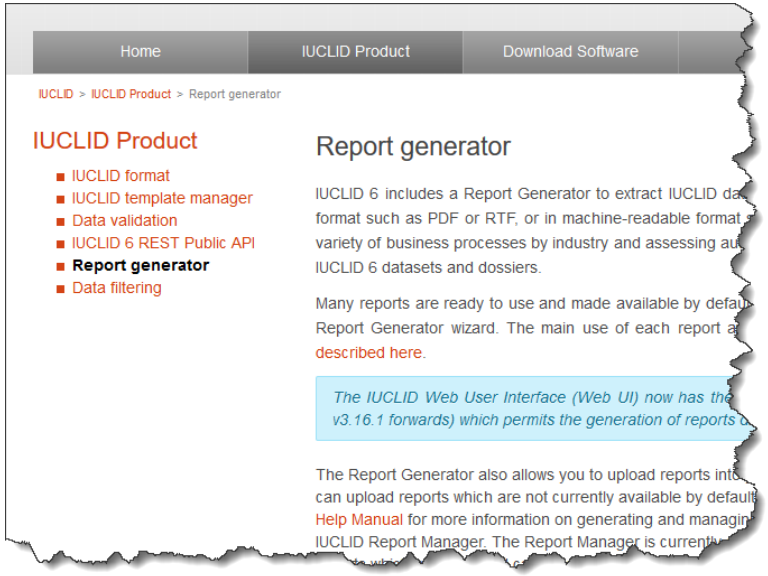
- Summary of Product Characteristics (SPC) under the EU Biocidal Products Regulation can now be imported in IUCLID
  - Mainly to support ECHA and MSCA processes
  - But the feature is available to all users

- Web interface
  - Grouping removed in the list of substances and mixtures: all dossiers and datasets are now listed
  - The Legal entity is displayed in the lists
  - Help updated

IUCLID 6 April release

Fixes and improvements

- New reports available (to be used with the report generator)
  - List of literature references (.csv format)
  - Preview for Poison Centre Notifications (.pdf)
  - Improvements to existing reports
  - All reports are published on the IUCLID website as well (https://iuclid6.echa.europa.eu/reports)



- Validation assistant: improvements and new series of rules for Poison Centre Notifications

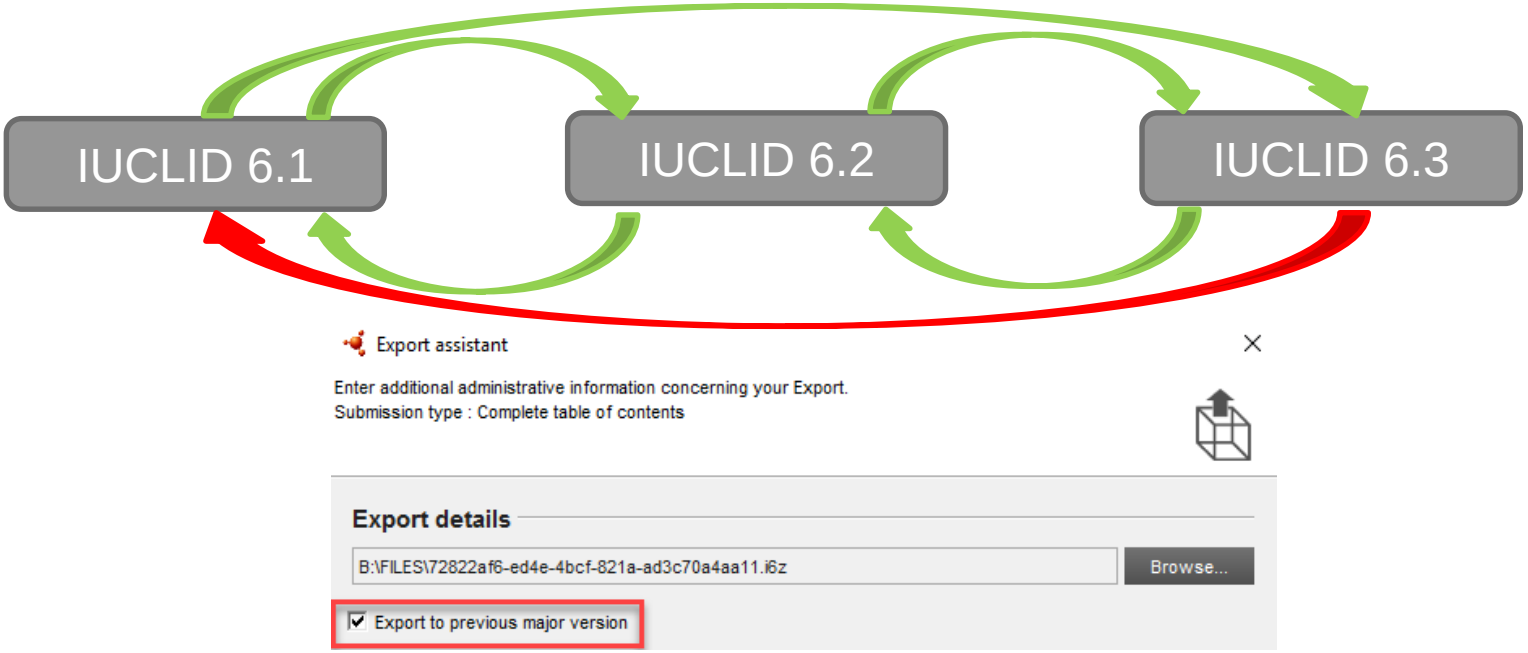
- More information in the release notes:

https://iuclid6.echa.europa.eu/documents/21812392/22308511/IUCLID_6_Release_Notes_3.16.1.pdf

IUCLID 6 April release

Compatibility: no format changes

- **Forward compatibility** provided: all IUCLID 6 files (even IUCLID 5.6) can be imported to the latest version
- **Backward compatibility** offered for the previous major version: export 6.2 files from 6.3
- It is recommended for IUCLID 6.1 users to upgrade to 6.3
- Submission to ECHA can be made with any IUCLID 6 version



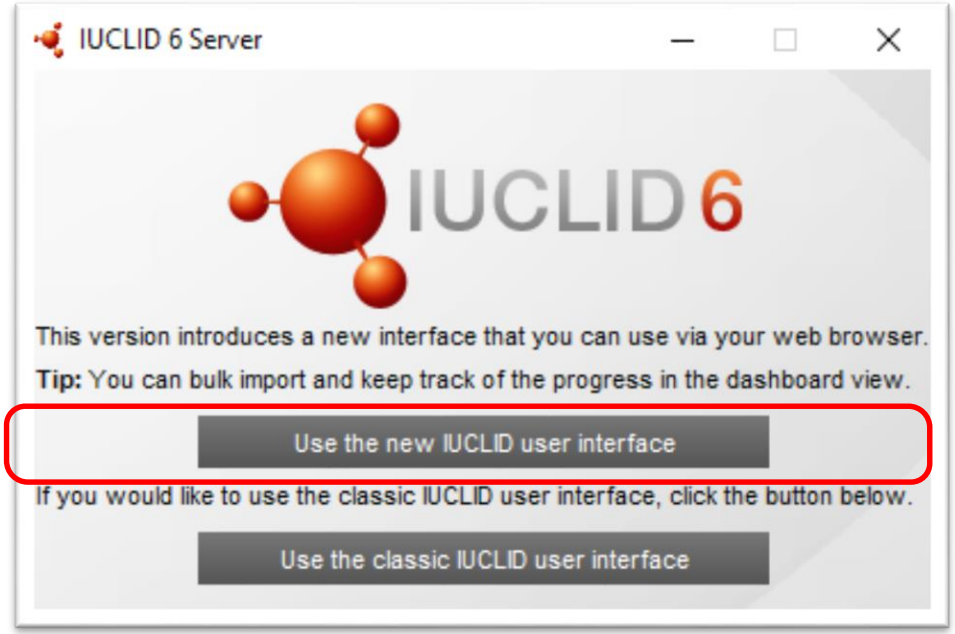
Web user interface

Web user interface

- The new IUCLID web user interface has been available to the IUCLID Cloud users since mid-2017
- Introduced to all IUCLID users since the 6.3 release in October 2018
- In order to successfully complete the switch from the ‘classic’ to the web user interface we need your feedback!
- Please share your comments via the Helpdesk and let us know if you would like to be interviewed.
- We will use your feedback to adjust our plans and align the implementation.

https://echa.europa.eu/contact

IUCLID desktop version: the pre-launch screen



What is the pre-launch screen?

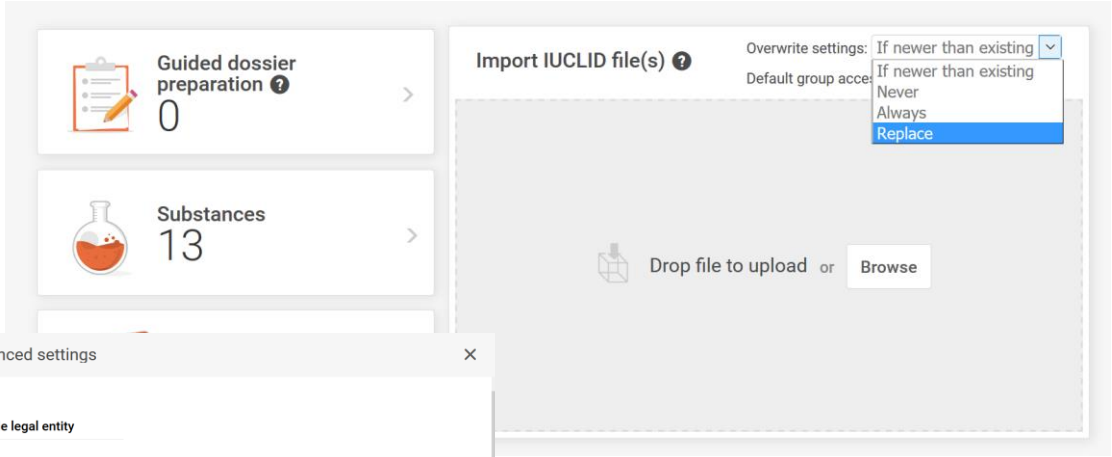
- After installing and launching IUCLID, this screen gives users the opportunity to easily swift between the **classic** and the **web** interface
- The screen shall remain open at all times. If closed, it closes IUCLID.

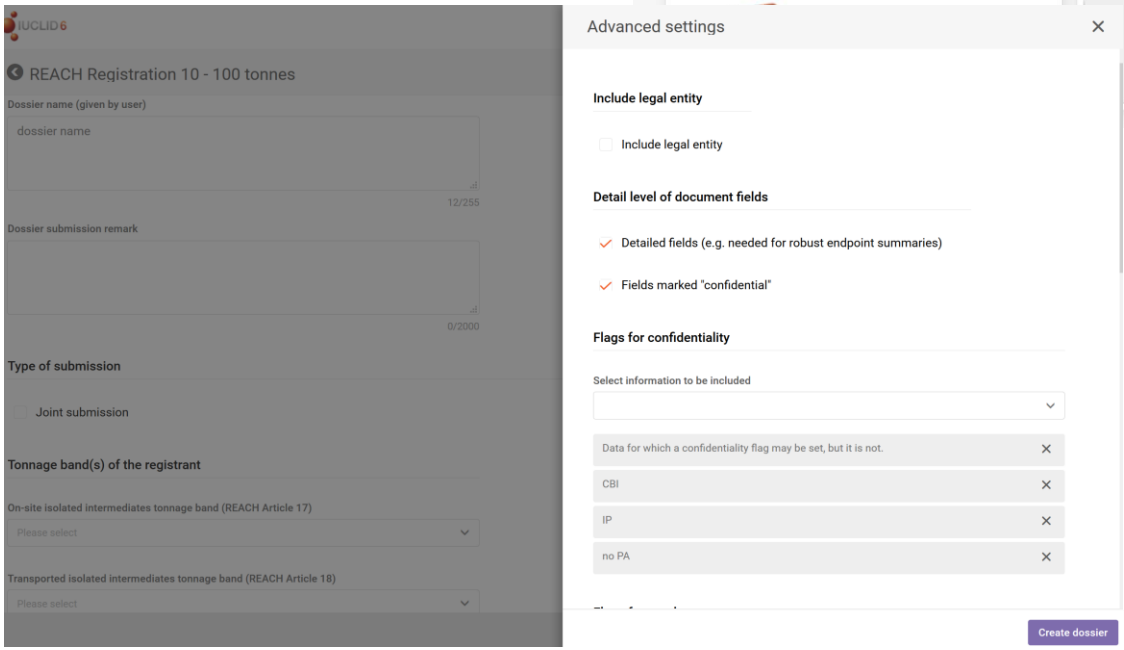
- A new tip is displayed with every launch. Tips give practical advice about features implemented in the IUCLID web interface.

IUCLID 6 April release – Web interface

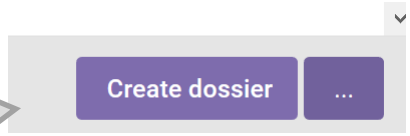
Advanced dossier creation and import settings (without document selection step)

Advanced dossier creation allows a user to include or exclude data based on certain criteria, such as Confidential data





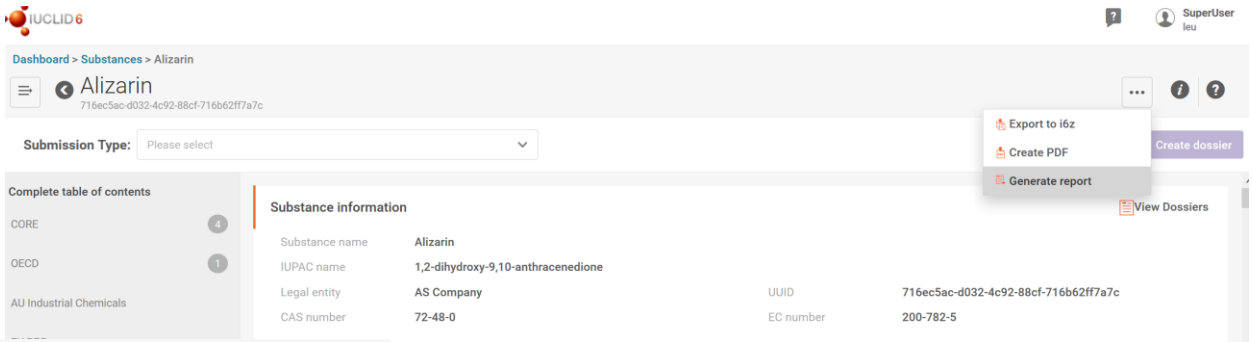
Advanced import settings allows a user to select which IBS Group can access the imported i6z file, and how to deal with existing data

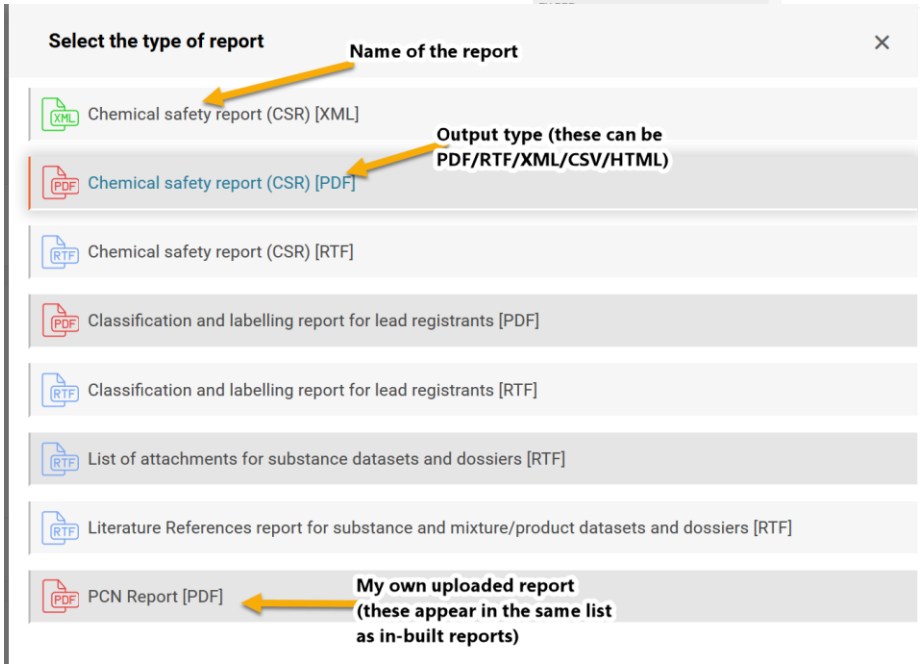


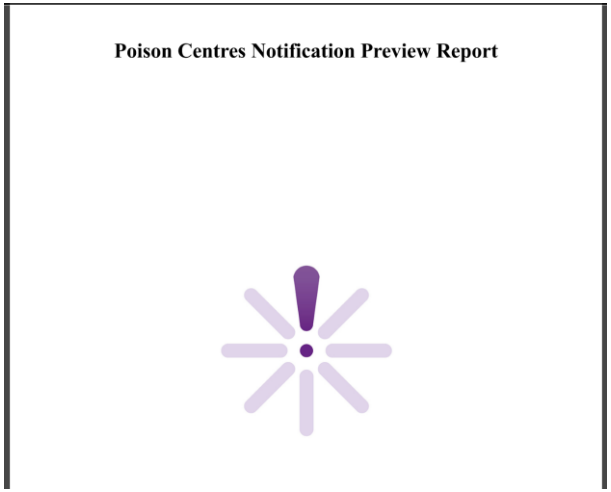
IUCLID 6 April release – Web interface

The report generator

Managing reports (i.e. uploading your own configured reports) can still be done via the classic swing interface



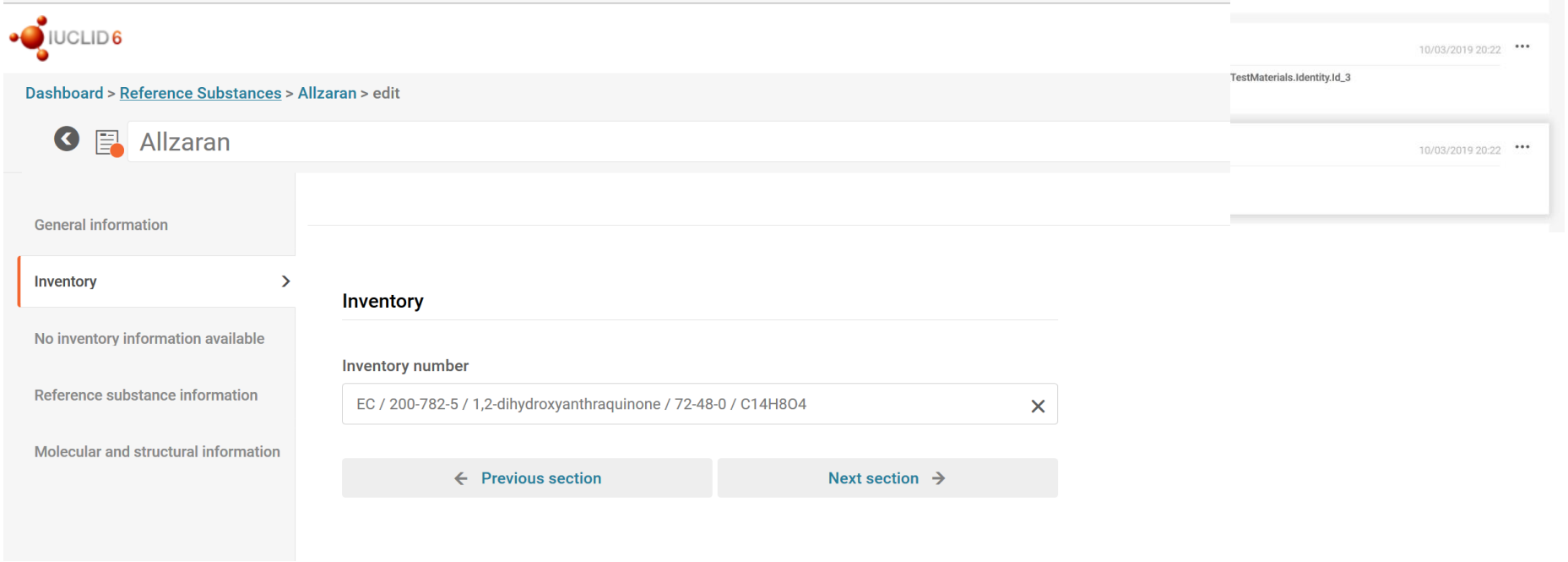




IUCLID 6 April release – Web interface

Reference substance management

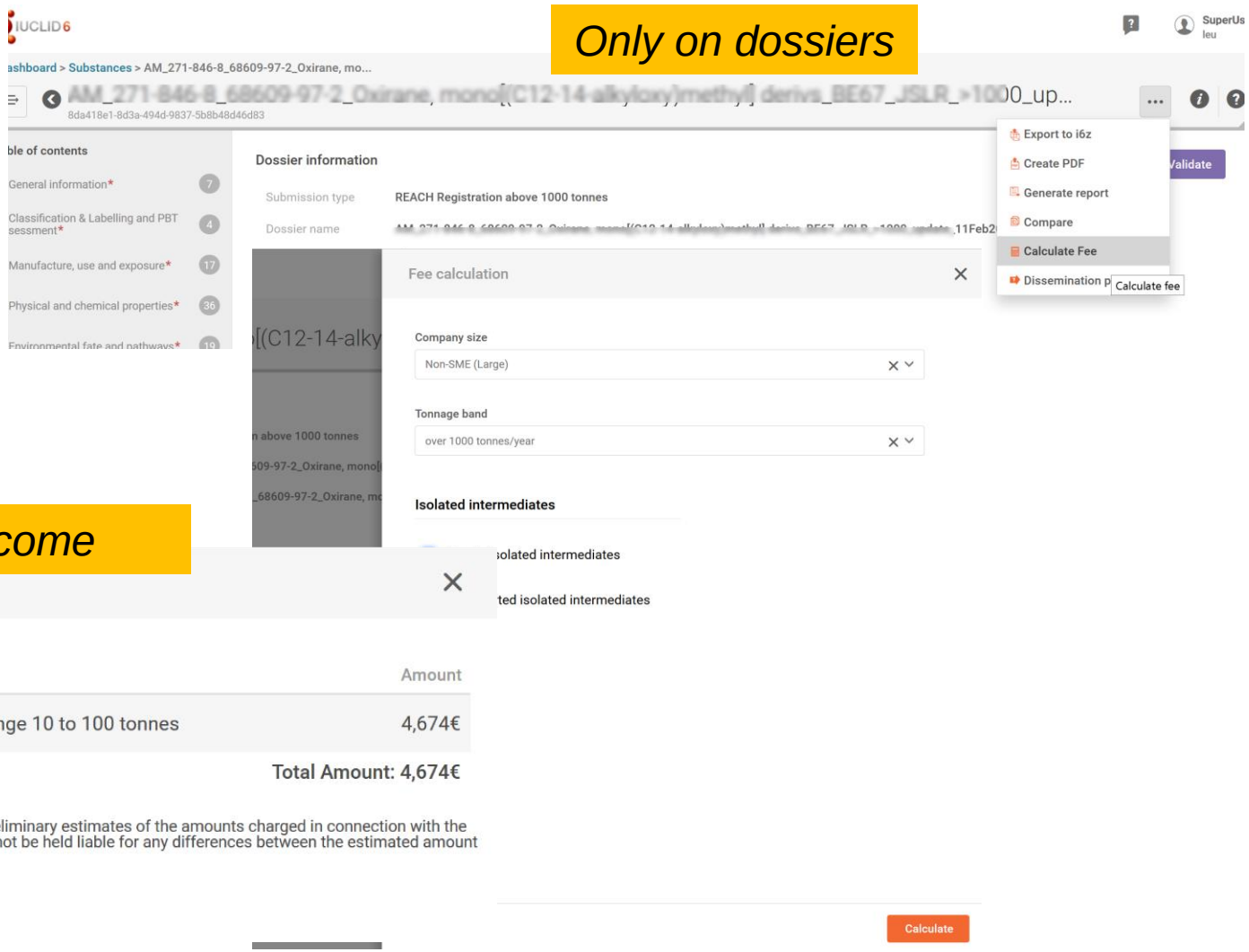
- View reference substance
- Search by CAS/EC/IUPAC identifiers plus R.S name
- Create reference substance
- Edit reference substance



IUCLID 6 April release – Web interface

Fee calculator

Only on dossiers



Outcome

Fee calculation

Fee description	Amount
Fee for registration of substances in the range 10 to 100 tonnes	4,674€

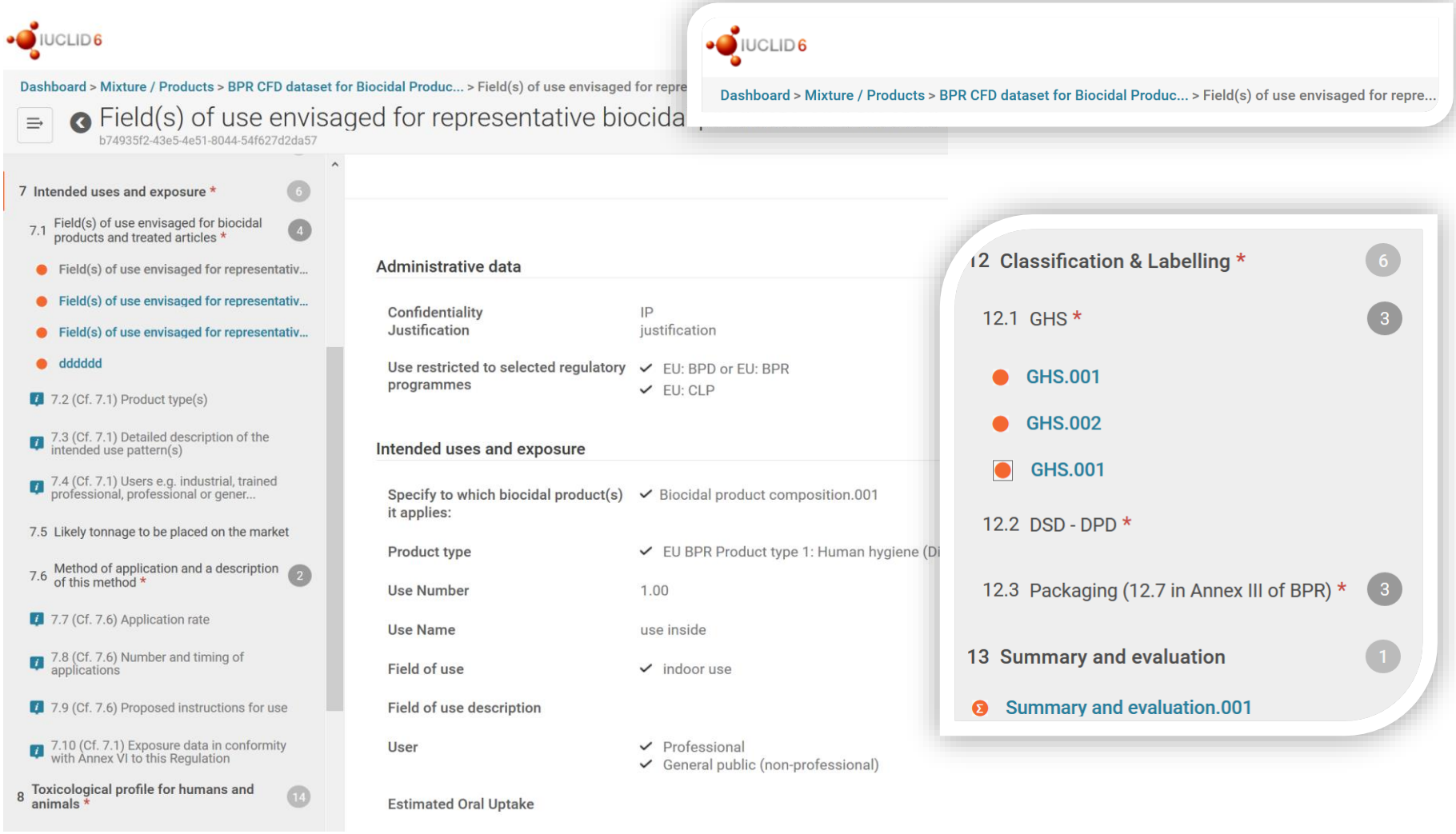
Total Amount: 4,674€

Disclaimer: please note that this tool provides only preliminary estimates of the amounts charged in connection with the submission of information to authorities. ECHA shall not be held liable for any differences between the estimated amount and the amount charged in the actual invoice.

Calculate

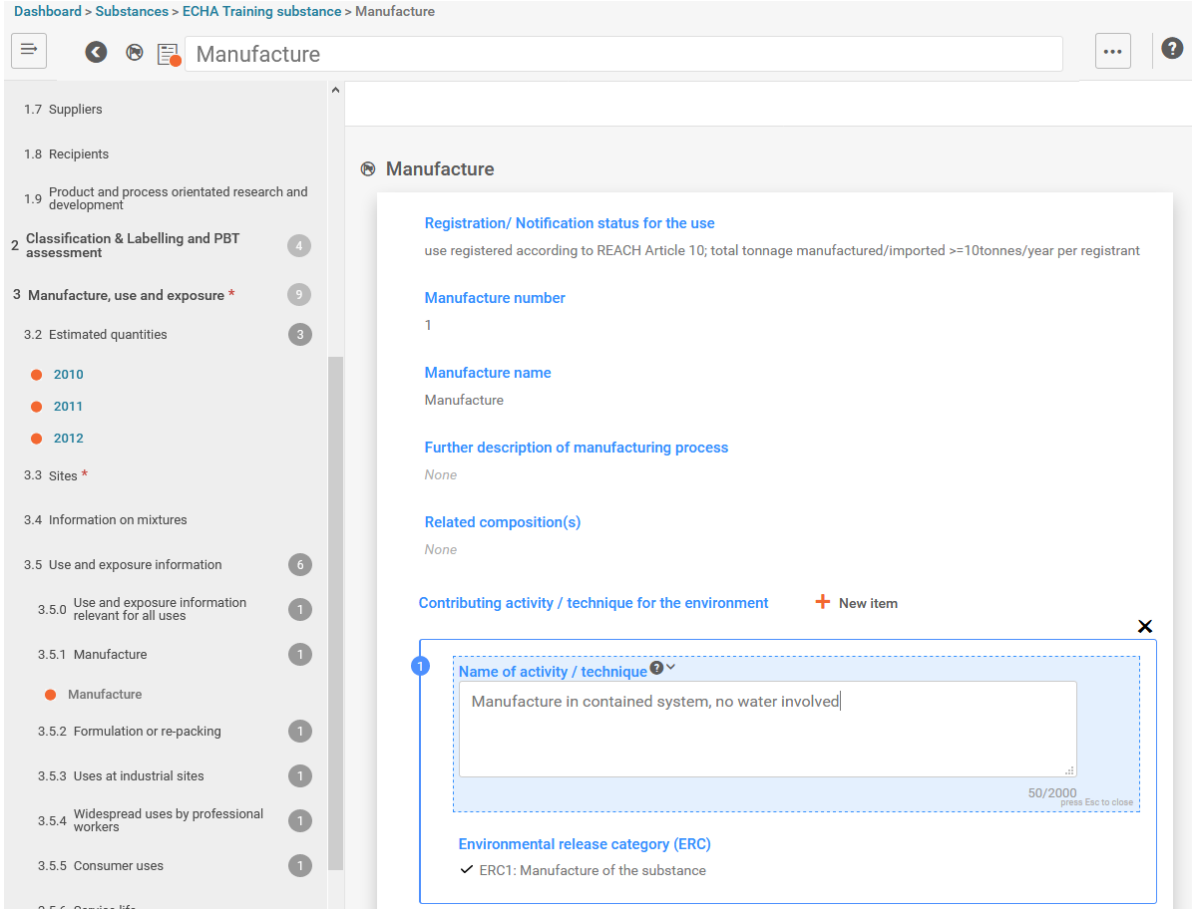
IUCLID 6 April release – Web interface

Improved document navigation (full table of contents when in the document)



IUCLID 6 April release – Web interface

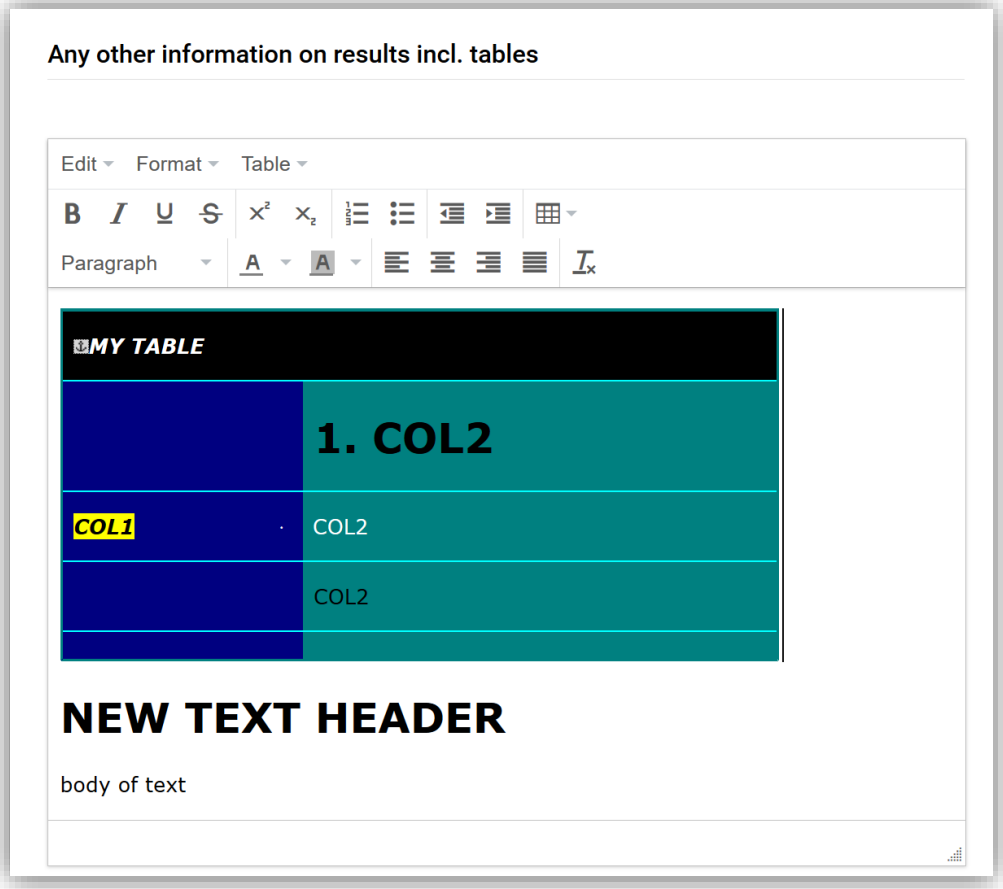
Improved viewing and editing – in-line editing



- No longer a distinction between view and edit mode
- Fields highlight on mouse over and becomes editable on mouse-click
- Remember to save document after editing.
- Improved reading and viewing with colour differentiations, Section groupings and Field highlights

IUCLID 6 April release – Web interface

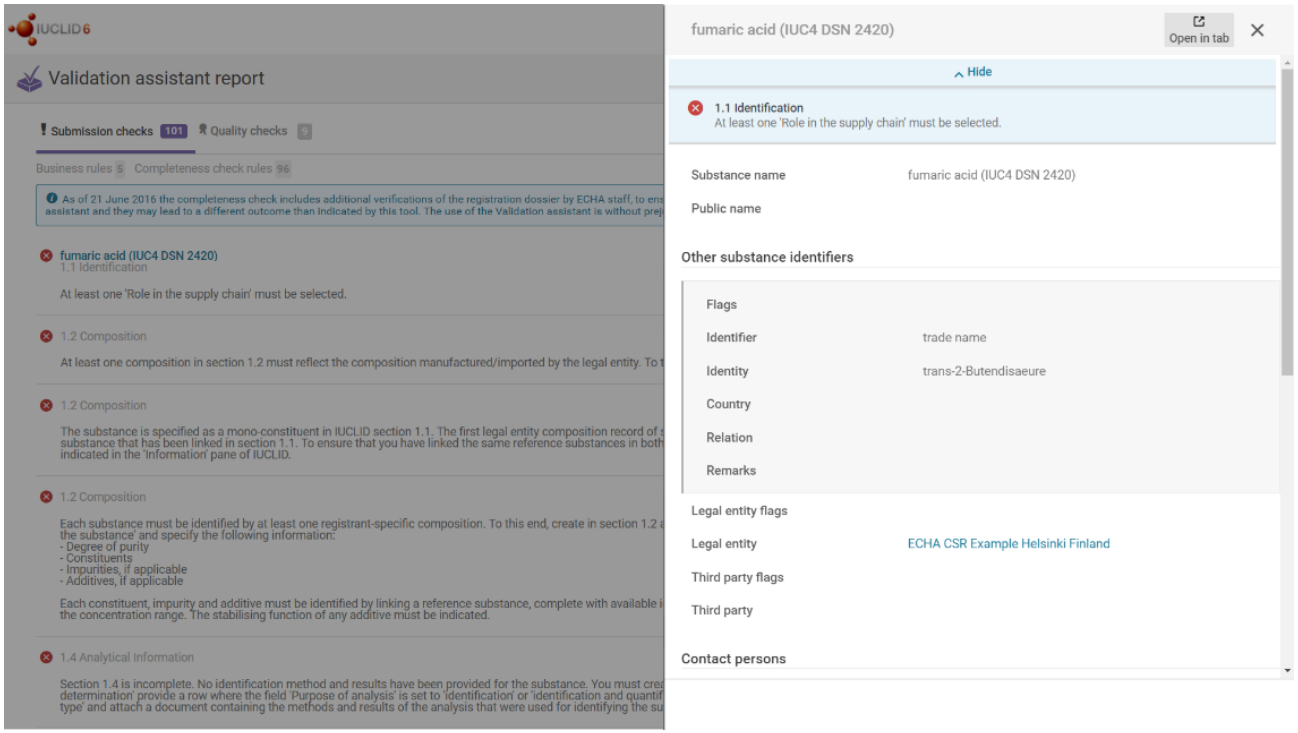
Improved rich-text editor (handles tables and copied content much better)



- New TinyMCE Rich-Text editor
- Handles the copy/pasting of tables much better (keeps the original formatting)
- Easy to use formatting options

IUCLID 6 April release – Web interface

Open validation assistant in sliding Window



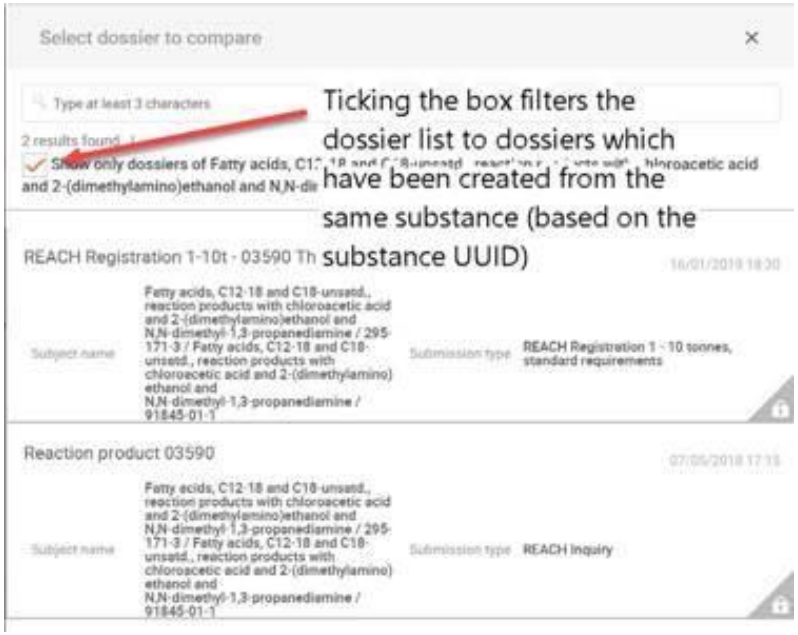
- Aim to simplify the data validation process even further
- Clicking on the link in the validation assistant report opens the referred document in a sliding window
- Click Edit to correct, Save, and Close to return to the VA list

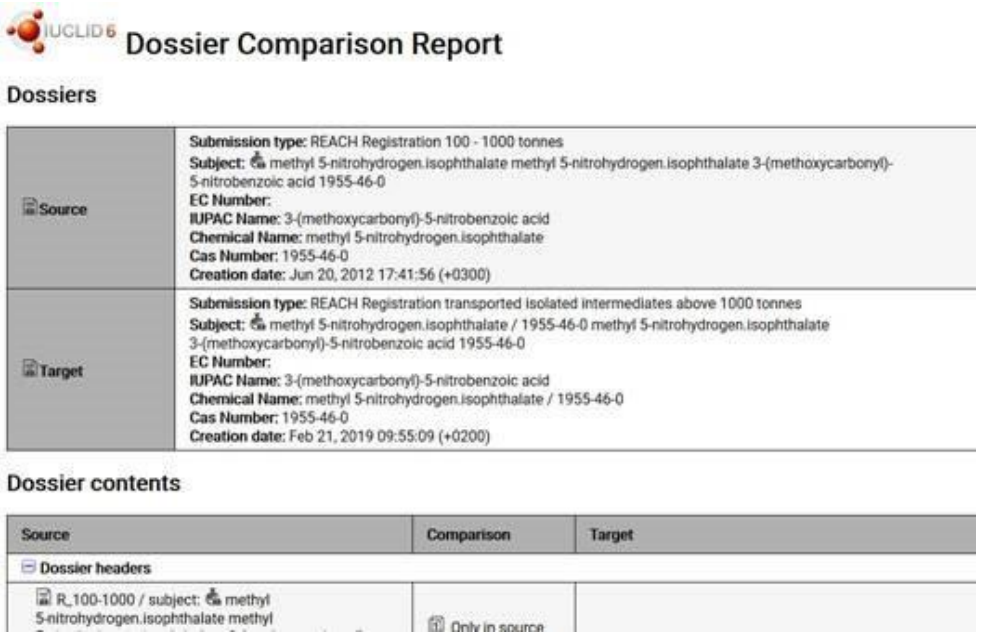
IUCLID 6 April release – Web interface

Improved dossier comparison report

Comparison report compares two dossiers, and checks for what is different or identical between:

- all dossier entities
- All section documents
- All fields which are found to be different





The report has been improved to:

- provide more information on the dossiers compared
- Improve navigation between parts of the report
- Improve information relating to the documents and fields which are different (i.e. field path identifiers)

IUCLID 6 April release – Web interface

Dissemination preview report improvements

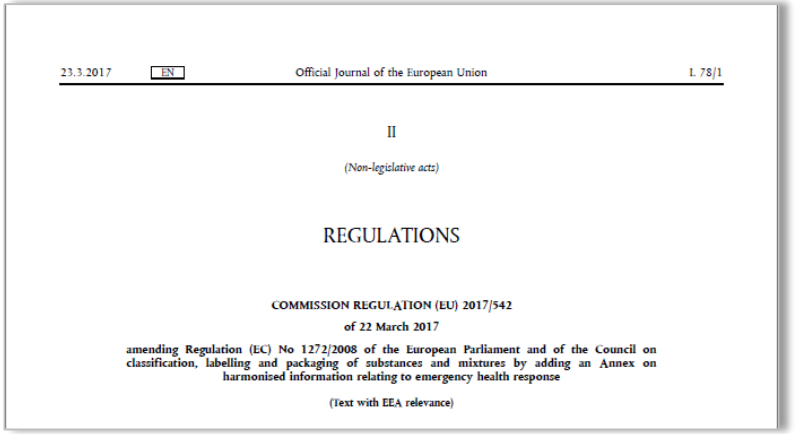
	A	B	C	D	E	F	G	
1	entity	sectionName	documentName	field	outcome	sourceDo	referencedD	path
2	Substance	1.1 Identification	AM_271-846-8_68	Substance / Substance name	Not published	IUC5-9cc3a8f0-d4a9-4ee7-{		SUBSTANCE.ChemicalName
3	Substance	1.1 Identification	AM_271-846-8_68	Substance / Public name	Published	IUC5-9cc3a8f0-d4a9-4ee7-{		SUBSTANCE.PublicName
4	Substance	1.1 Identification	AM_271-846-8_68	Substance / Contact persons / 1	Not published (ineligible for dissemination)	IUC5-9cc3a8f0-d4a9-4ee7-{		SUBSTANCE.ContactPersons[0]
5	Substance	1.1 Identification	AM_271-846-8_68	Substance / Identification of sul	Published	IUC5-9cc3a	IUC5-024c6bca	SUBSTANCE.ReferenceSubstan
6	Substance	1.1 Identification	AM_271-846-8_68	Substance / Type of substance /	Published	IUC5-9cc3a8f0-d4a9-4ee7-{		SUBSTANCE.TypeOfSubstance.(
7	Substance	1.1 Identification	AM_271-846-8_68	Substance / Type of substance /	Published	IUC5-9cc3a8f0-d4a9-4ee7-{		SUBSTANCE.TypeOfSubstance.(
8	Substance	1.1 Identification	AM_271-846-8_68	Substance / Role in the supply c	Not published	IUC5-9cc3a8f0-d4a9-4ee7-{		SUBSTANCE.RoleInSupplyChain
9	Flexible Record	1.2 Composition	Oxirane, mono[(C1	Composition / General Informat	Flagged confidential – Not published	d56b75ac-97b8-3df2-9e5d-		FLEXIBLE_RECORD/SubstanceC
10	Flexible Record	1.2 Composition	Oxirane, mono[(C1	Composition / General Informat	Published	d56b75ac-97b8-3df2-9e5d-		FLEXIBLE_RECORD/SubstanceC
11	Flexible Record	1.2 Composition	Oxirane, mono[(C1	Composition / General Informat	Published	d56b75ac-97b8-3df2-9e5d-		FLEXIBLE_RECORD/SubstanceC
12	Flexible Record	1.2 Composition	Oxirane, mono[(C1	Composition / General Informat	Not published	d56b75ac-97b8-3df2-9e5d-		FLEXIBLE_RECORD/SubstanceC
13	Flexible Record	1.2 Composition	Oxirane, mono[(C1	Composition / Degree of purity	Not published (ineligible for dissemination)	d56b75ac-97b8-3df2-9e5d-		FLEXIBLE_RECORD/SubstanceC
14	Flexible Record	1.2 Composition	Oxirane, mono[(C1	Composition / Constituents / 1	Flagged confidential – Not published	d56b75ac-97b8-3df2-9e5d-		FLEXIBLE_RECORD/SubstanceC
15	Flexible Record	1.2 Composition	Oxirane, mono[(C1	Composition / Constituents / 2	Flagged confidential – Not published	d56b75ac-97b8-3df2-9e5d-		FLEXIBLE_RECORD/SubstanceC
16	Flexible Record	1.2 Composition	Oxirane, mono[(C1	Composition / Constituents / 3	Flagged confidential – Not published	d56b75ac-97b8-3df2-9e5d-		FLEXIBLE_RECORD/SubstanceC
17	Flexible Record	1.2 Composition	Oxirane, mono[(C1	Composition / Constituents / 4	Flagged confidential – Not published	d56b75ac-97b8-3df2-9e5d-		FLEXIBLE_RECORD/SubstanceC

- Ordering of dossier components follows the comparison report hierarchy
- Ordering of section documents based on section numbering (i.e. section 1.1 comes before 1.2)
- Dossier header confidentiality claims are listed at the beginning of the report

Poison Centres Notifications (PCN)

CLP Art. 45 and Annex VIII

- MS' appointed bodies responsible for receiving information to formulate preventative and curative measures in the event of **emergency health response**.
- Information provided by **importers and downstream users** placing mixtures on the market.
- Mixtures **classified as hazardous** (health or physical effects).



23.3.2017 EN Official Journal of the European Union L 78/1

II

(Non-legislative acts)

REGULATIONS

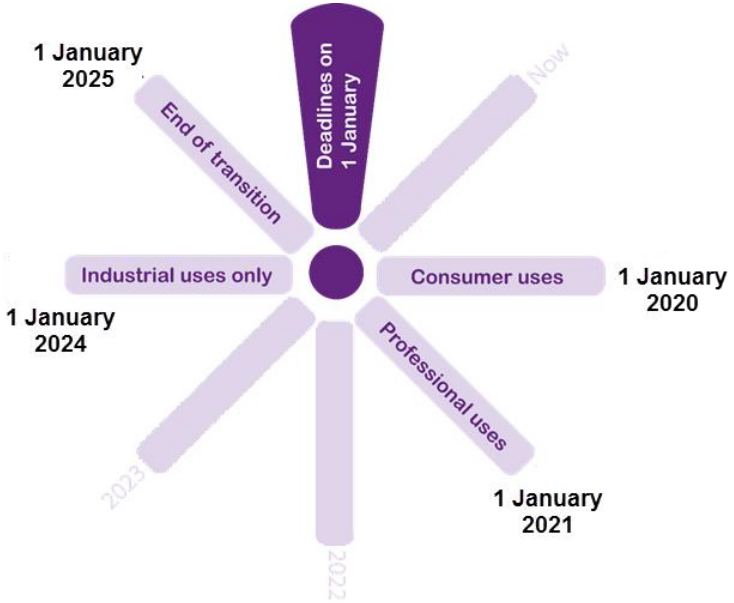
COMMISSION REGULATION (EU) 2017/542

of 22 March 2017

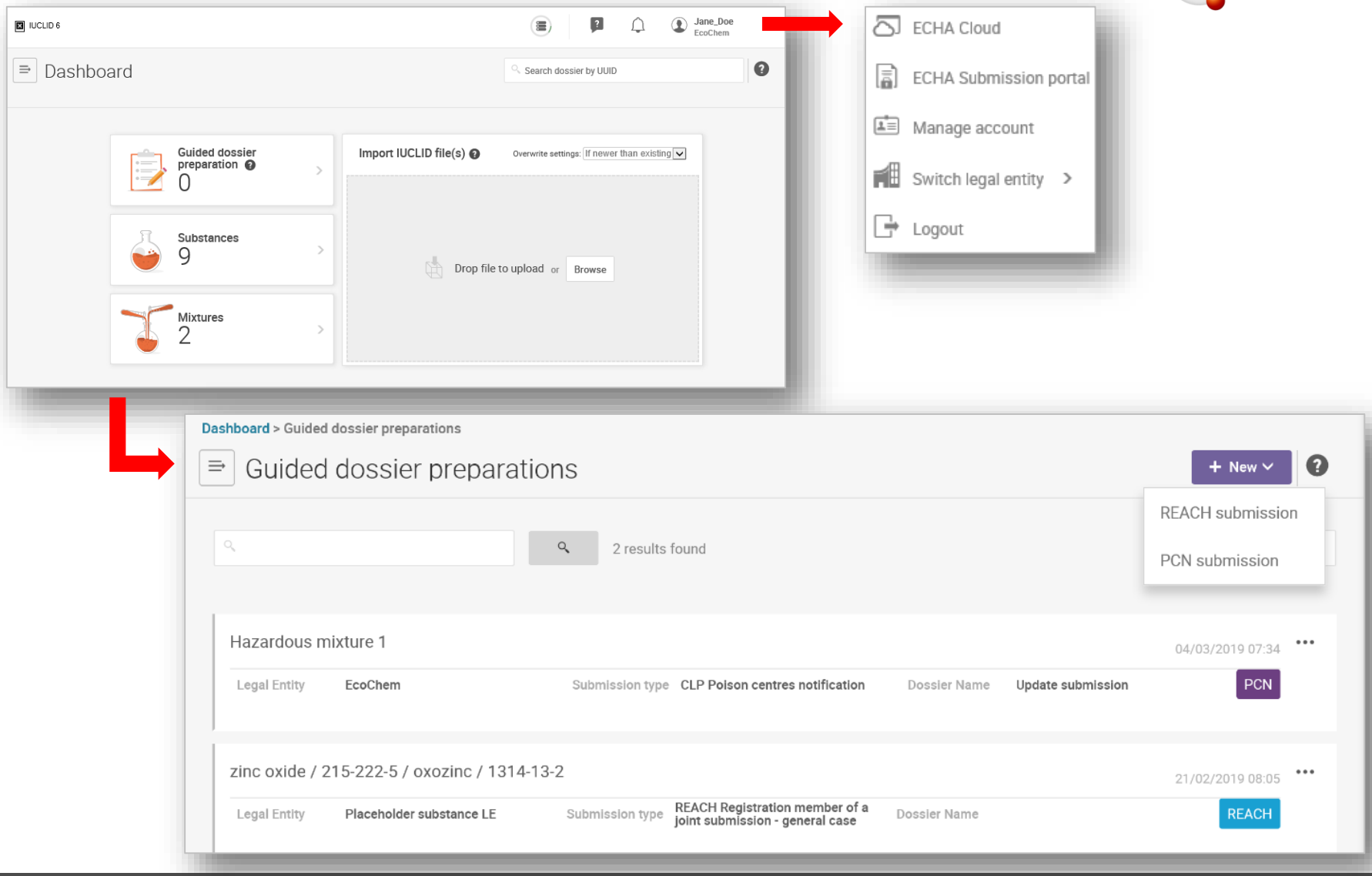
amending Regulation (EC) No 1272/2008 of the European Parliament and of the Council on classification, labelling and packaging of substances and mixtures by adding an Annex on harmonised information relating to emergency health response

(Text with EEA relevance)

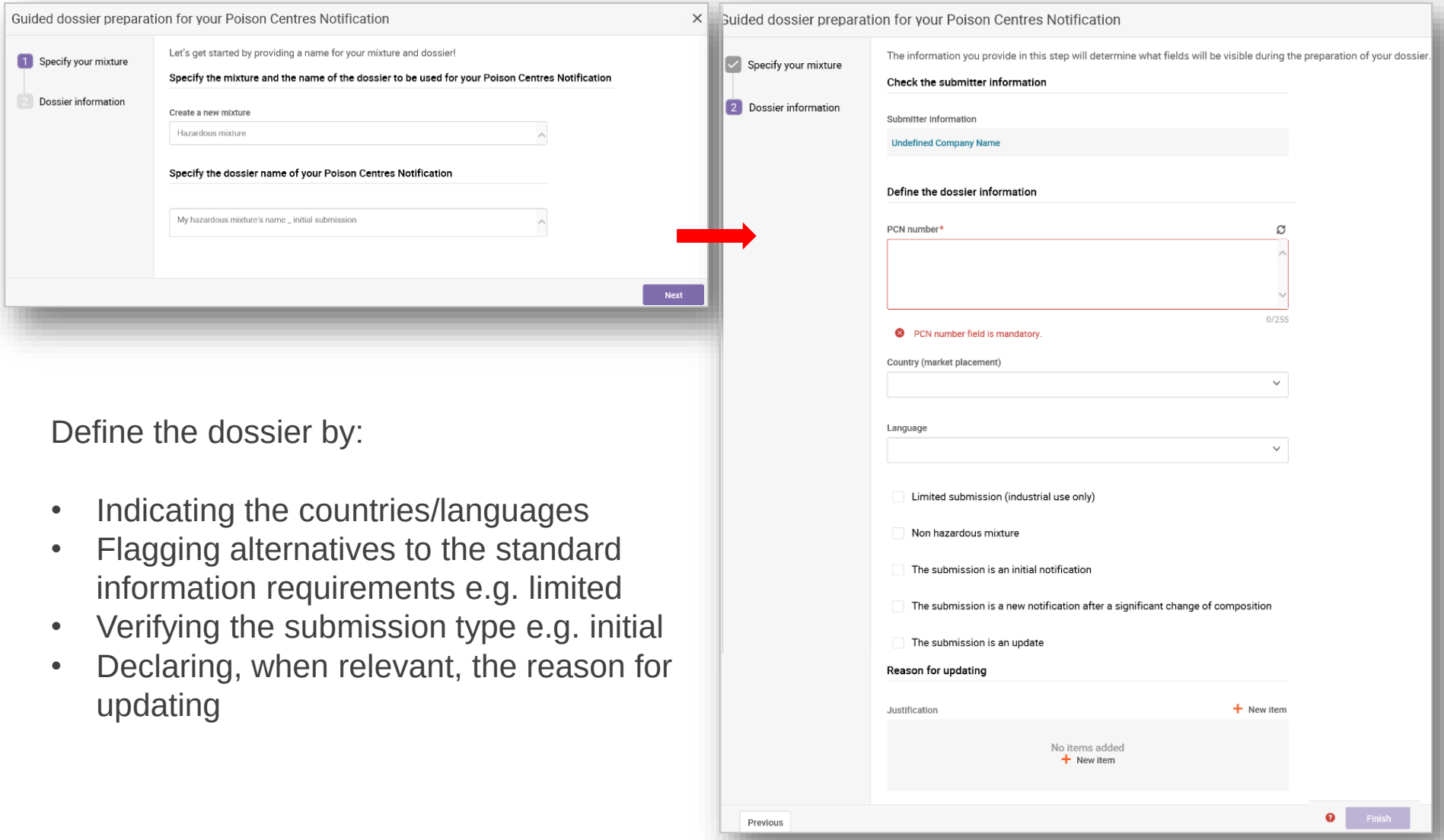
- Annex VIII published in March 2017.
- **Harmonisation** of information:
  - same information requirements in all EU MS
  - preparation of data in a harmonised IUCLID format (.xml)
  - (optional) submission of data possible via central system (ECHA Submission portal)



Initiating a guided dossier preparation



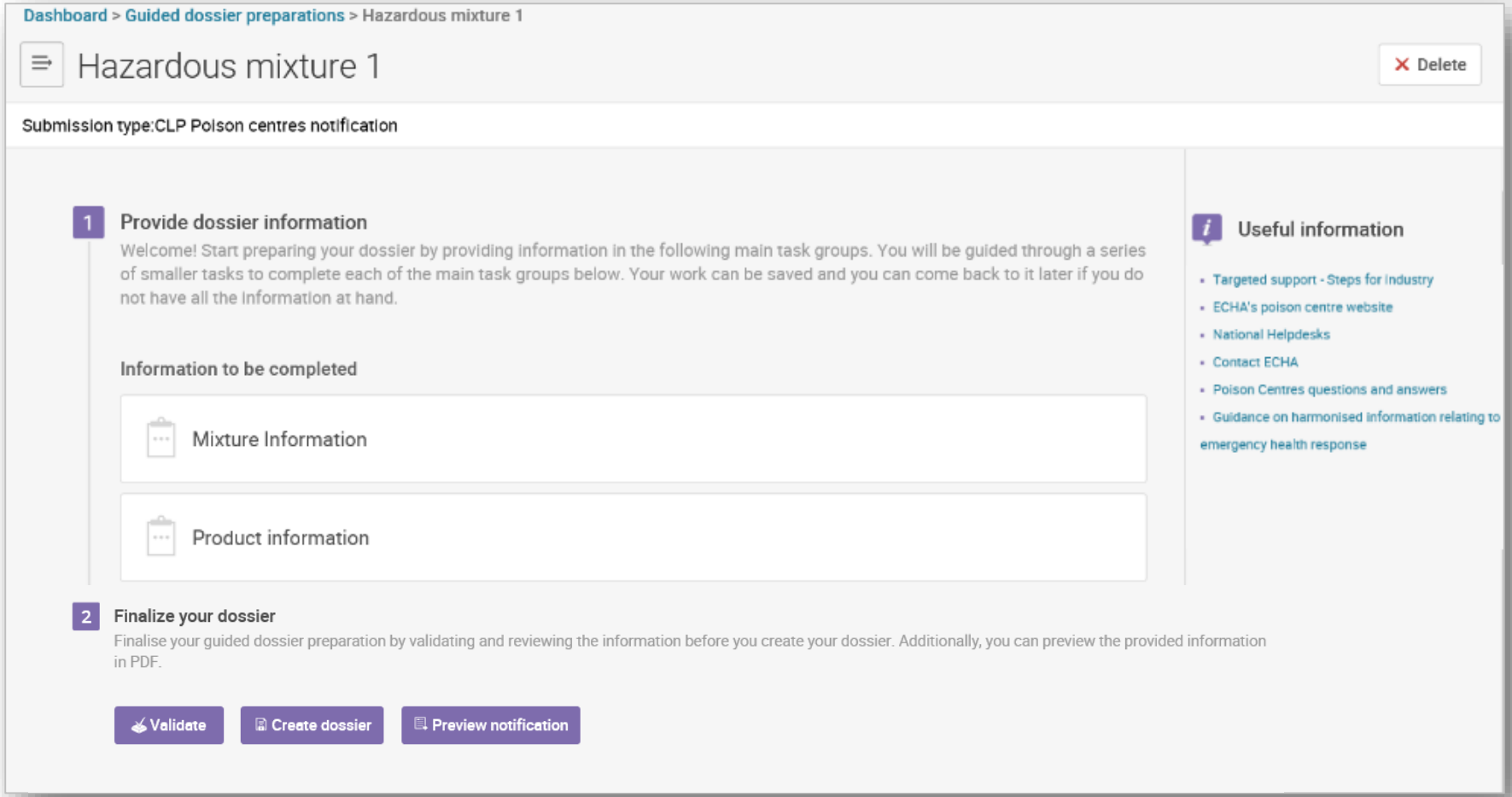
Establishing the dossier context for a new mixture



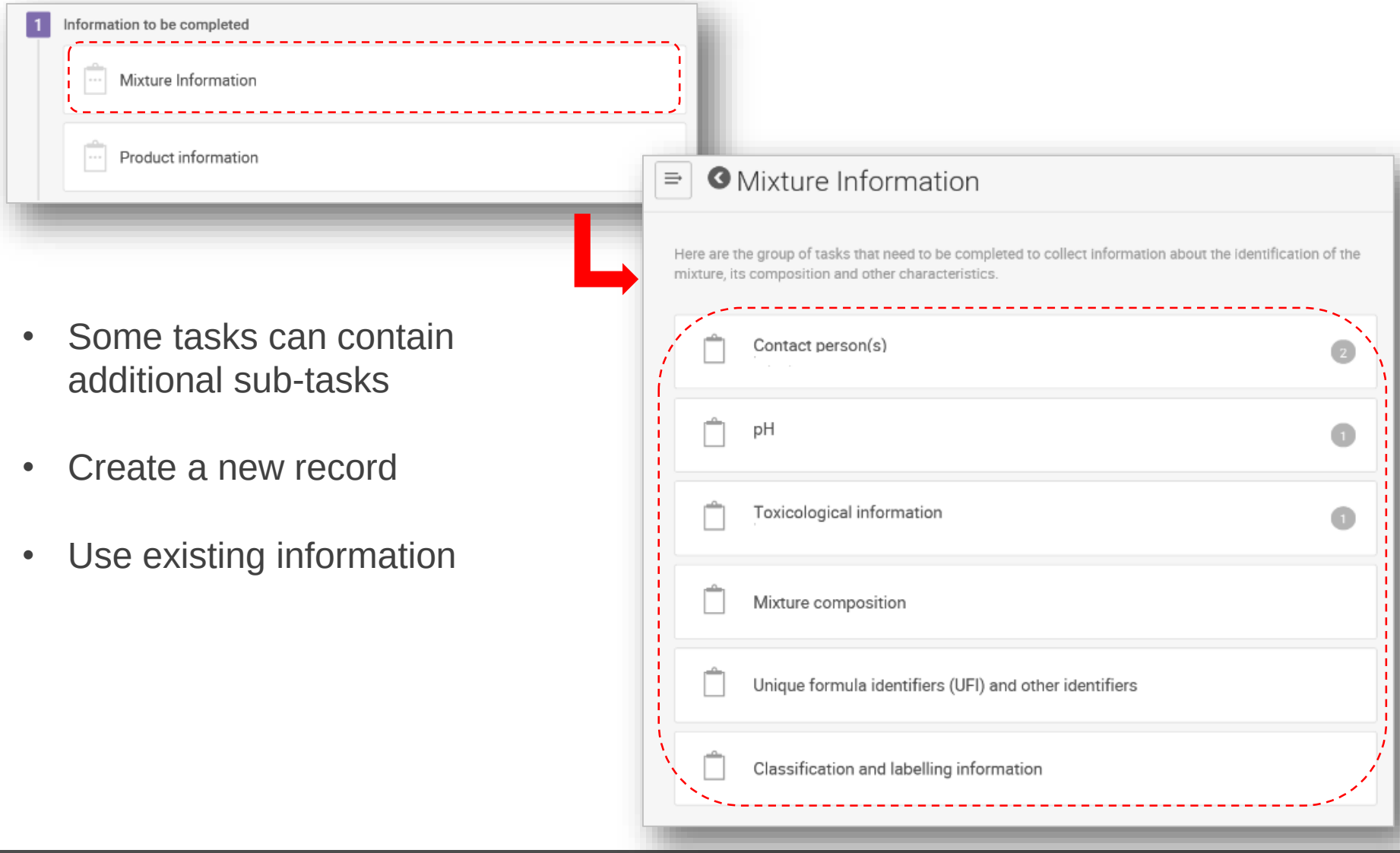
Define the dossier by:

- Indicating the countries/languages
- Flagging alternatives to the standard information requirements e.g. limited
- Verifying the submission type e.g. initial
- Declaring, when relevant, the reason for updating

Guided dossier preparation ‘navigation page’

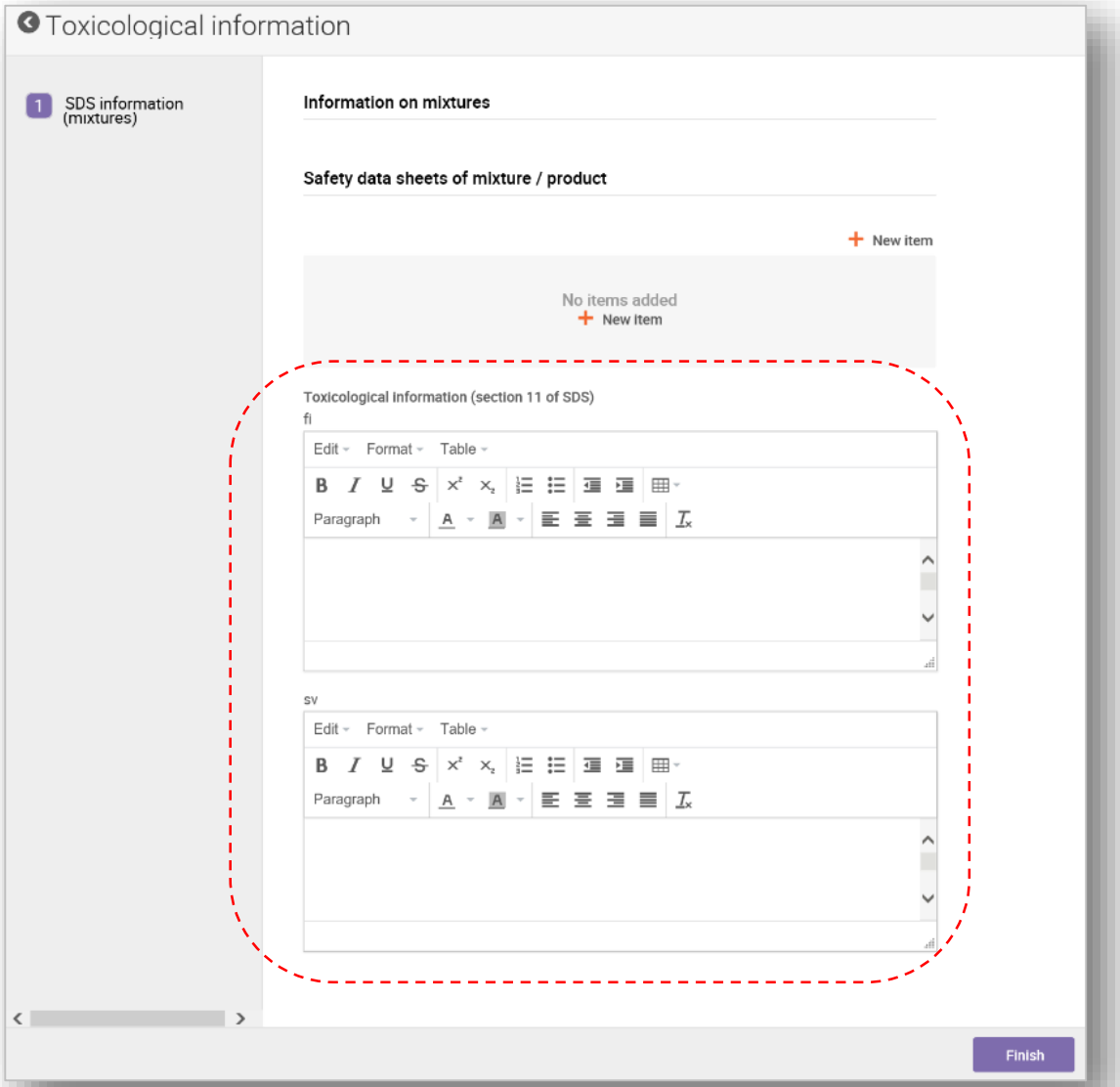


Mixture information task page



- Some tasks can contain additional sub-tasks
- Create a new record
- Use existing information

Multilingual fields



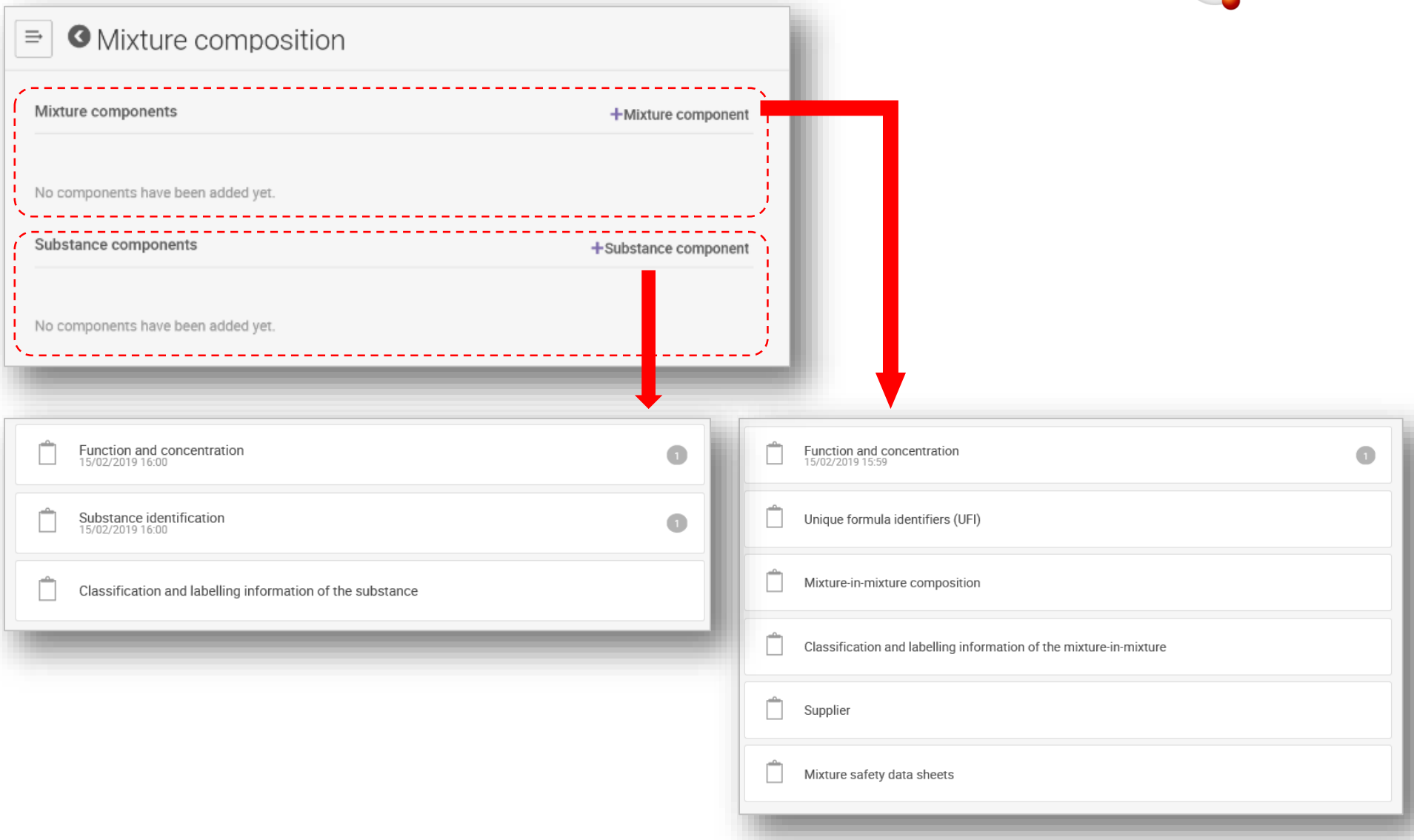
- Toxicological information (mandatory)
- Classification information (where relevant)

→ specific effect; specific target organ toxicity – single; specific target organ toxicity – repeated

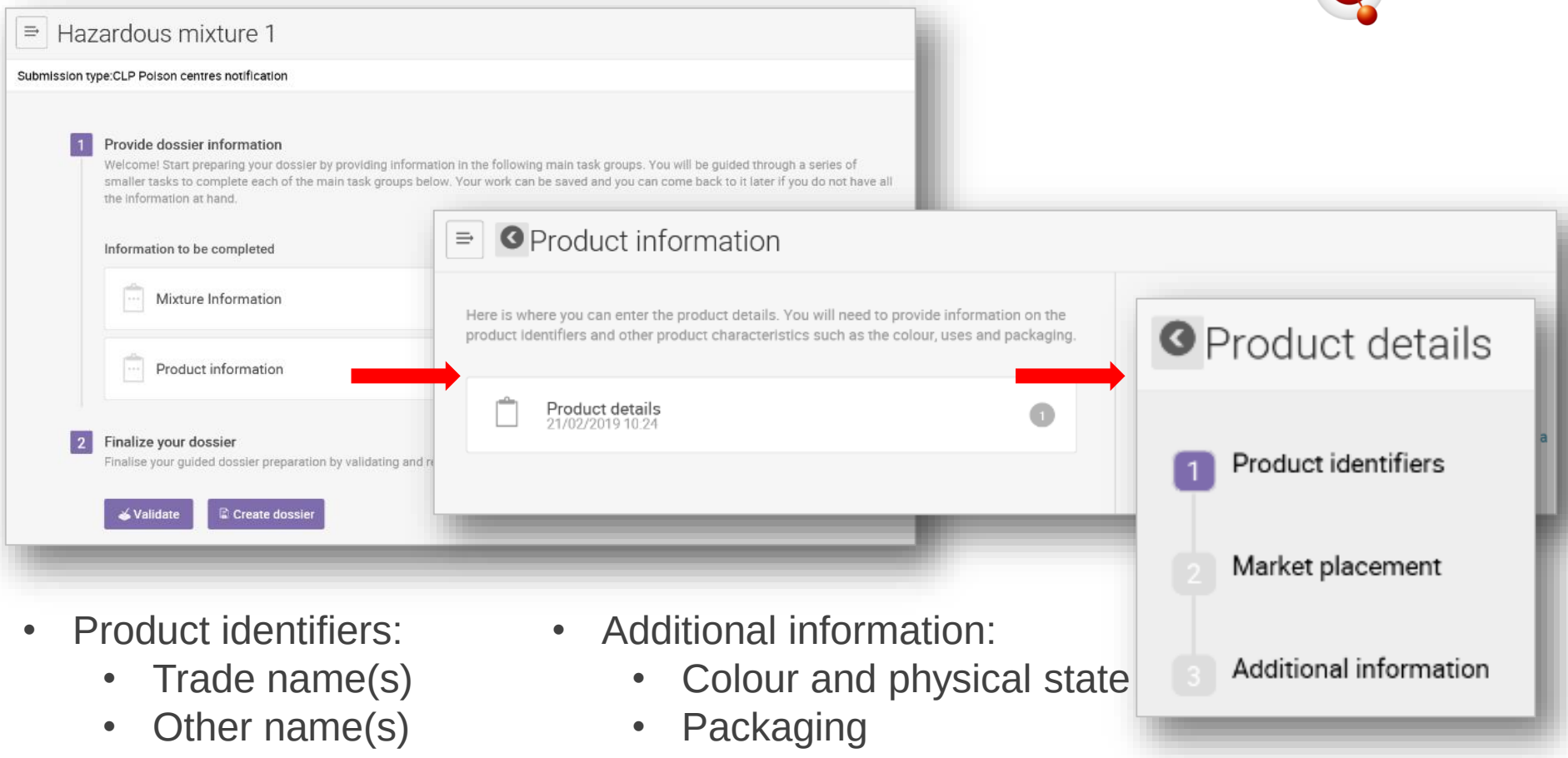
- Labelling information (where relevant)

→ certain Hazard and Precautionary statements

The ‘Mixture composition’ task

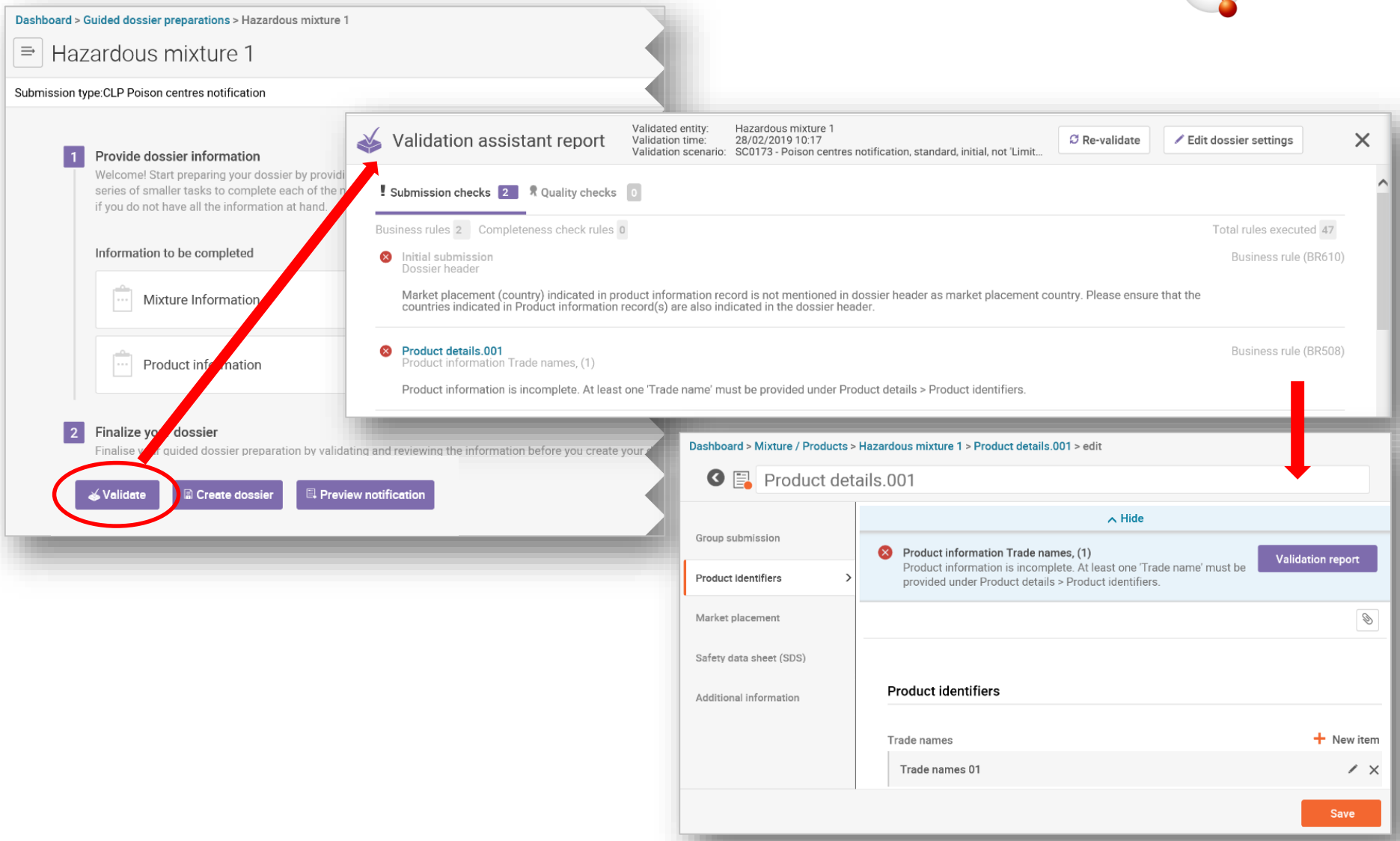


The product information tasks

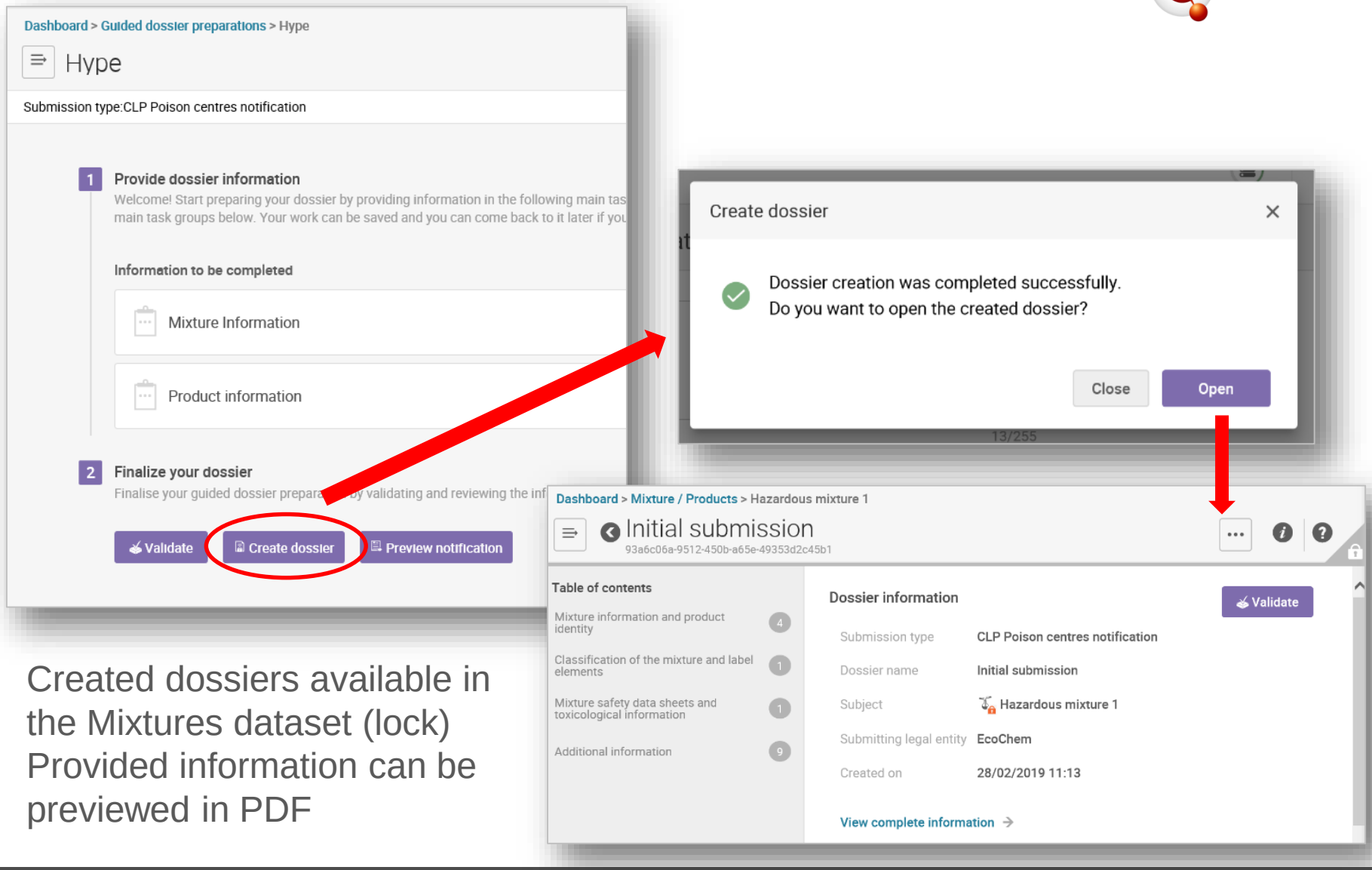


- Product identifiers:
  - Trade name(s)
  - Other name(s)
  - UFI and other identifiers
- Additional information:
  - Colour and physical state
  - Packaging
  - Product use category
- Market placement

Validation assistant and validation report

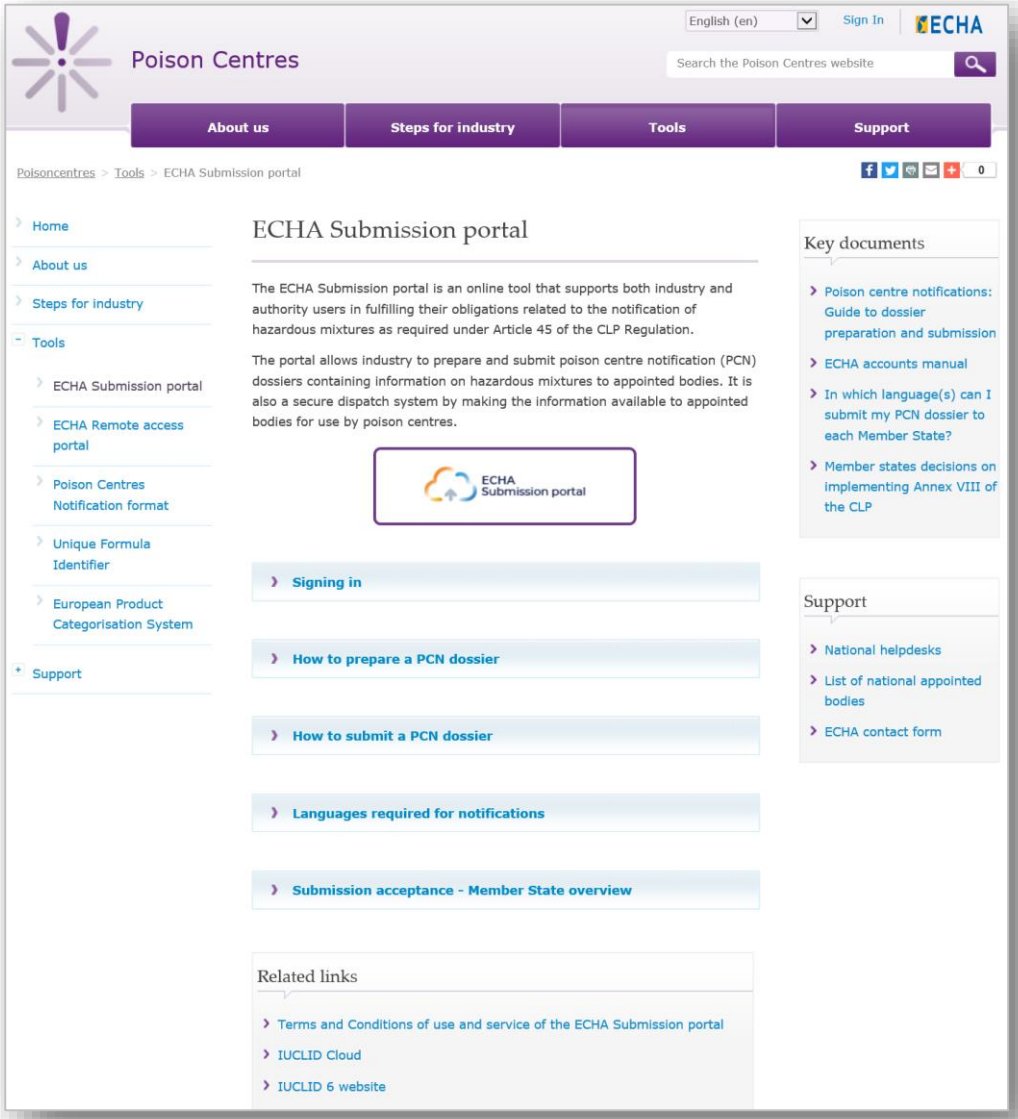


Preview, create and export the dossier



- Created dossiers available in the Mixtures dataset (lock)
- Provided information can be previewed in PDF

ECHA Submission portal



The ECHA Submission portal webpage is available from the ECHA Poison Centre website:

https://poisoncentres.echa.europa.eu/echa-submission-portal

For more information

- Support material to prepare and submit PCN notifications
  - Guide to dossier preparation and submission
  - In which language(s) can I submit my PCN dossier to each Member State?
  - Member states decisions on implementing Annex VIII of the CLP (translated)

  Available at https://poisoncentres.echa.europa.eu/echa-submission-portal

- Regulatory guidance - https://echa.europa.eu/guidance-documents/guidance-on-clp
- PCN Website: https://poisoncentres.echa.europa.eu/
- Contact us: https://echa.europa.eu/contact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Q
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A
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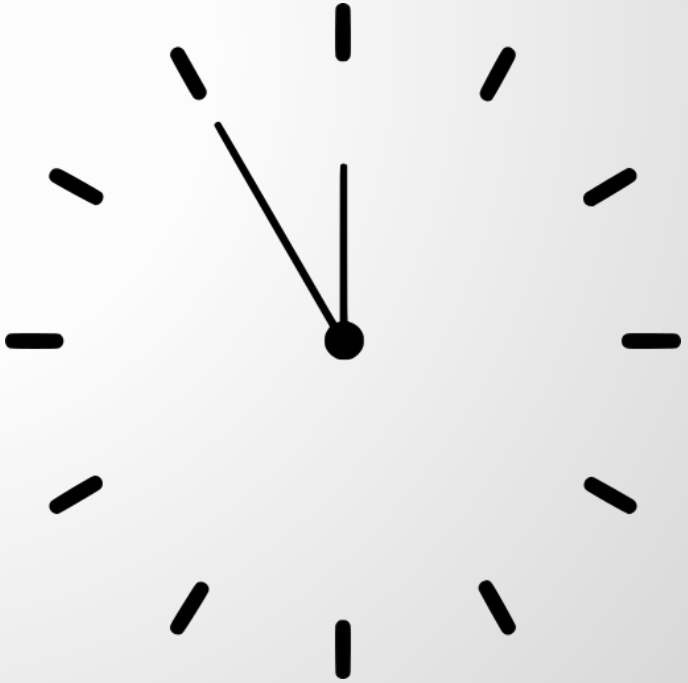
You can continue to send your questions during the next 5 minutes

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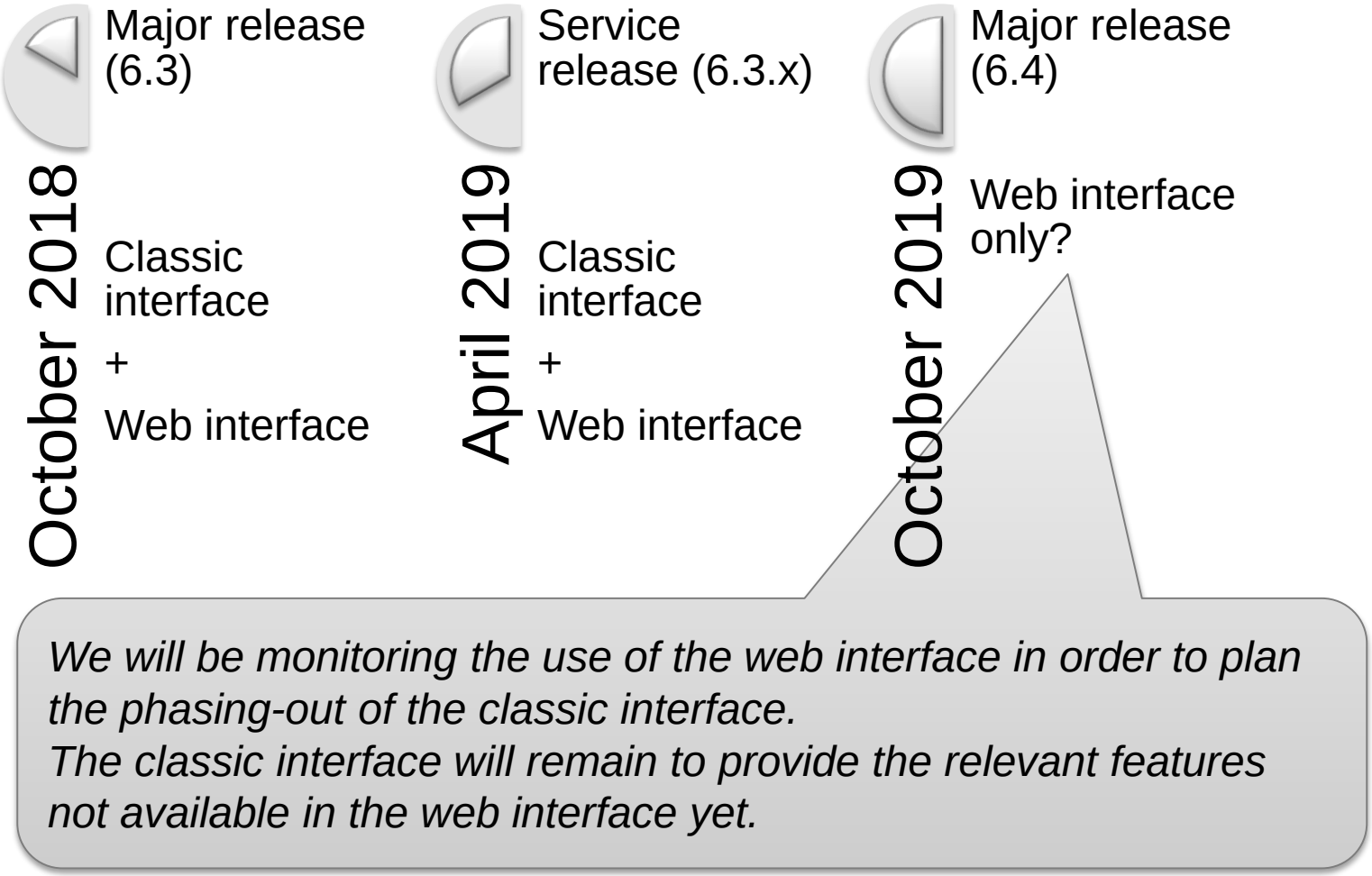
Before ending the webinar

- IUCLID 6.4 – 30th of October 2019
- More information

Transition to the web user interface



IUCLID 6.4 - Web interface

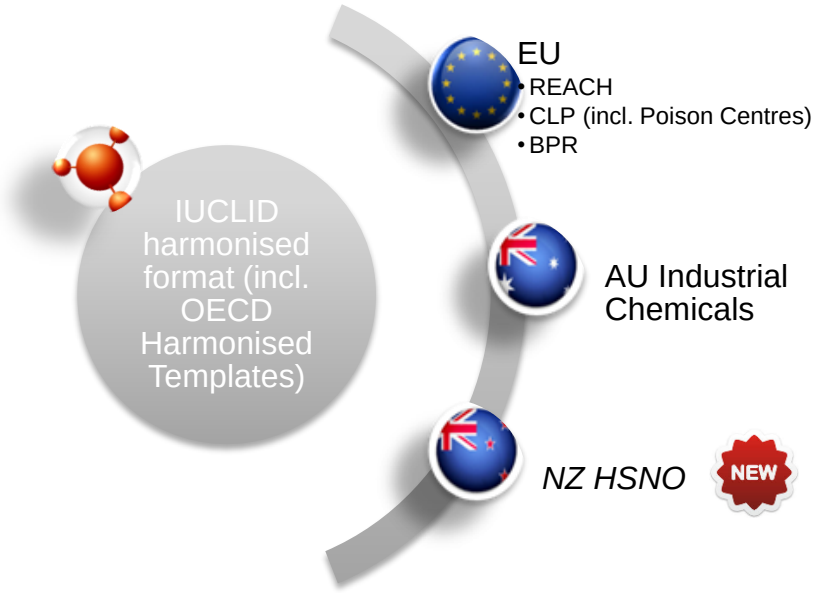
Implementation plan

- Template, categories
- Background jobs
- User profiles
- Remaining entity management (templates, categories, legal entity, sites, contacts, test materials)
- Basic search functionality
- Dynamic content rules
- Document selection in advanced settings
- Bulk operations (bulk copy / print / export)
- Others (lower priority)
  - Inventory manager
  - Advanced report generator
  - Copy as reference
  - DNEL/PNEC calculators
  - Users and roles management

IUCLID 6.4 - format changes

Main reasons for the update of the format

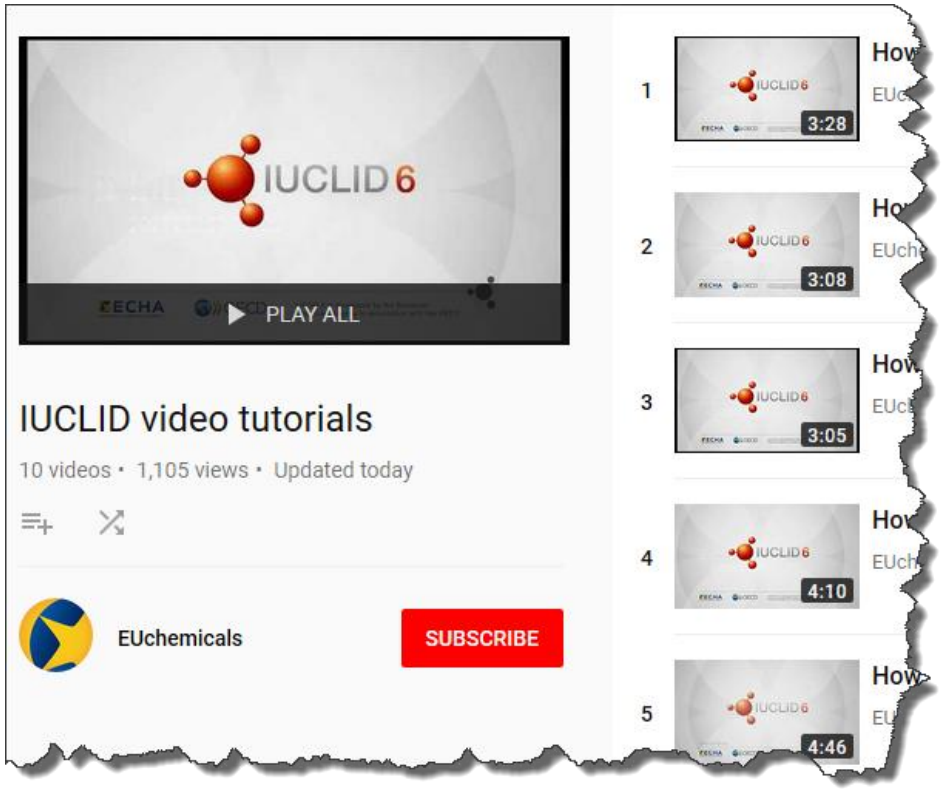
- OECD Harmonised Templates: new templates and updates
- UN GHS (rev. 6&7) and EU CLP (ATP 10-14th)
- Nanomaterials REACH Annex update
- Format changes to support members of the OECD IUCLID User group (Australia, New Zealand)
- 46 different topics in total, addressing requirements from stakeholders



Video tutorials

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

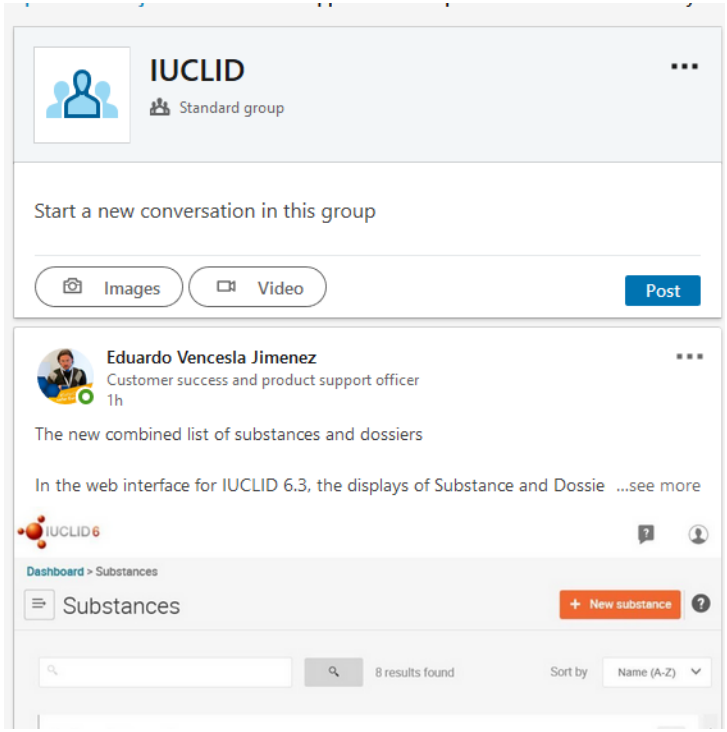
https://www.youtube.com/playlist?list=PLOPGDACSd6qyDkdXwPua1Fjb5bJksY75k



Release of IUCLID 6.3

LinkedIn group

- More information is regularly provided to the members of the IUCLID LinkedIn group
- You can request to join if you have a LinkedIn account



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

Webinar for BPR users

Next webinar

- 15 May 2019 11am EEST

- Web interface for Biocidal Product Regulation users
  - Creating a BPR dossier
  - Report generator
  - Comparison tool

https://echa.europa.eu/-/using-the-iuclid-web-user-interface-for-biocides-submissions

Thank you for your participation

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

ECHA EUROPEAN CHEMICALS AGENCY

OECD

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