

# REACH IT tools training

Luxembourg  
9 April 2018

Margot Mägi  
Valérie Lasseigne-Phrakonkham  
Directorate of Registration  
European Chemicals Agency

# Agenda

- Overview of REACH IT tools
- From the dossier submission to registration
- REACH-IT main functionalities
- REACH-IT member online submission wizard
- IUCLID 6
- Completeness check and manual verification
- Exercise 1: creating a member dossier in IUCLID cloud
- Read-across in IUCLID
- Chesar in a nutshell
- Exercise 2: submitting a member dossier to REACH-IT
- ECHA support and guidance. DCG solutions.
- Q&A

## **The aim of the training today is...**

- ... to get a flavour of all the main IT applications relevant for REACH
- ... to be able to choose the right tools for yourself
- ... not to be afraid for the REACH IT tools
- ... to know where to find help
- ... to ask us questions

# IT tools for REACH



## IT tools for REACH

### Data generation tools



CHESAR



QSAR Toolbox

### Data preparation tools



IUCLID 6



ECHA Cloud  
Services



REACH-IT

### Data submission tool



REACH-IT

## What application to choose?



**ECHA Cloud Services**

- SMEs
- Consultants working for SMEs
- Always latest version of IUCLID
- Backups by ECHA



- Member registrants
- Agree with all information submitted by the lead

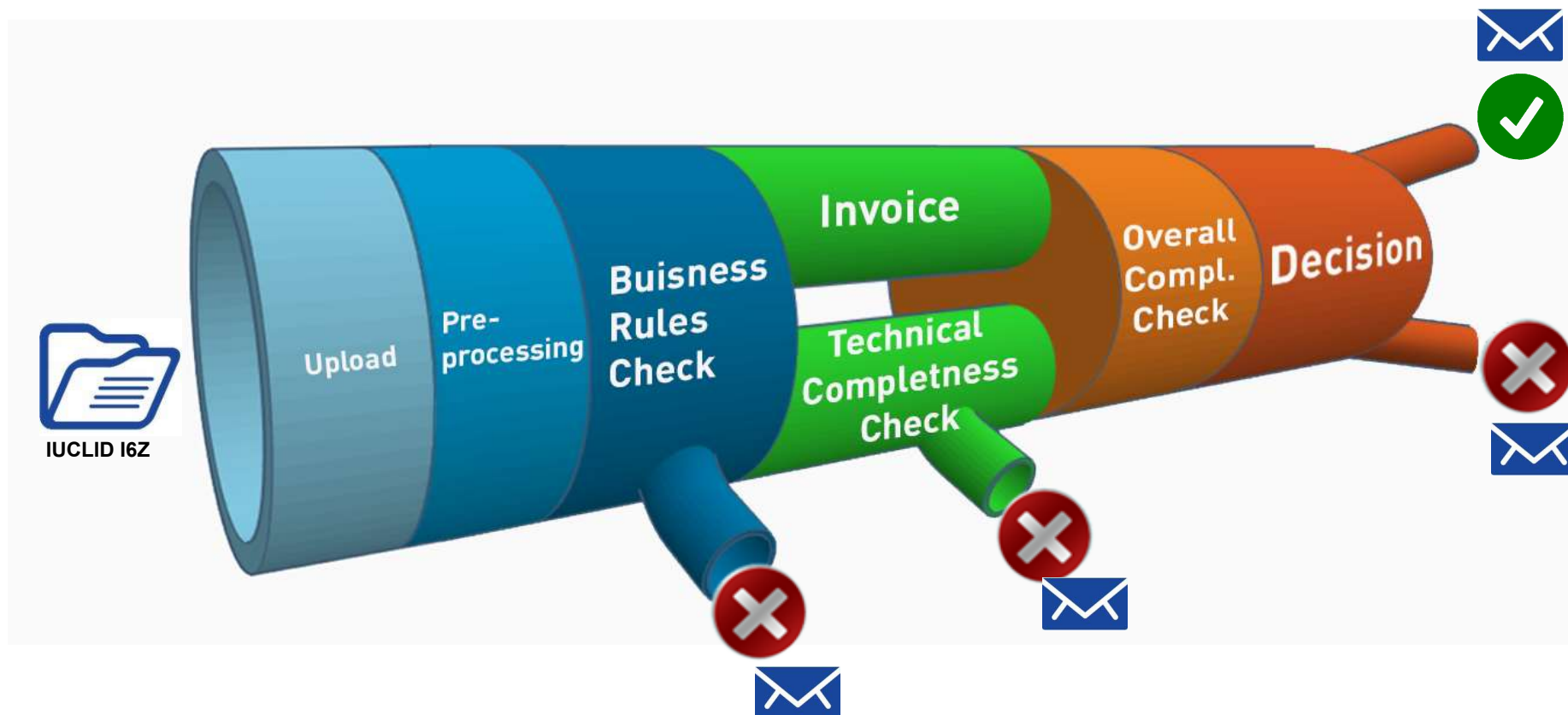


- All others

# **From dossier submission to registration**



## Regulatory processing by the Agency





- Lead submits the registration dossier first
- Members can submit as soon as the lead has passed business rules
- Members are parked until the lead pays and passes TCC
- TCC can take for ECHA up to 3 months after REACH deadline. Outside deadline period it may take up to 21 days
- Registrants with pre-registration and submission by 31 May 2018 can continue their import/production with no interruption
- New registrants on the marked have to submit an Inquiry dossier first and receive a registration number before import/production

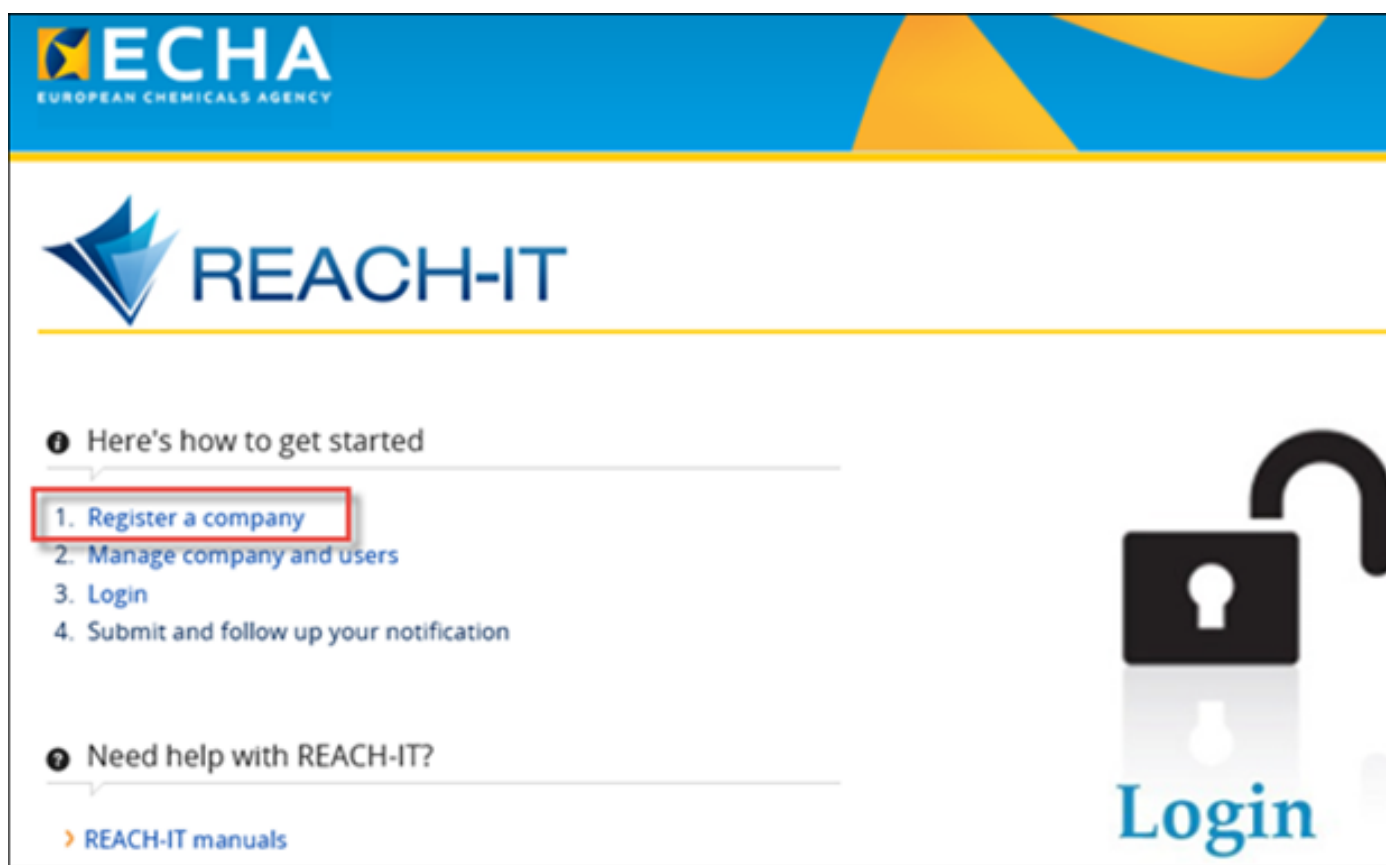


## **Main functionalities**






**Login or create a new company account if you do not have one yet**



The screenshot shows the REACH-IT login page. At the top is the ECHA logo and the text 'EUROPEAN CHEMICALS AGENCY'. Below this is the REACH-IT logo. A section titled 'Here's how to get started' contains a list of steps: 1. Register a company (highlighted with a red box), 2. Manage company and users, 3. Login, and 4. Submit and follow up your notification. Below this list is a section titled 'Need help with REACH-IT?' with a link to 'REACH-IT manuals'. On the right side of the page, there is a large graphic of an open padlock with the word 'Login' written below it.

**ECHA**  
EUROPEAN CHEMICALS AGENCY

 **REACH-IT**

**Here's how to get started**

1. Register a company
2. Manage company and users
3. Login
4. Submit and follow up your notification

**Need help with REACH-IT?**

[REACH-IT manuals](#)

**Login**

## REACH-IT home page

The screenshot shows the REACH-IT home page for a user named Margot Mägi from Training Company. The interface includes a top navigation bar with links for Tasks (1), Substances, Messages, and a Quick search by number field. A left sidebar contains a Menu dropdown. The main content area features a greeting, a news section for REACH-IT SAT-IT-1, and three large circular widgets: 'Submit a dossier' (with a 'View all types' button), 'Tasks (1)' (with a 'View all tasks' button and a breakdown of 1 new task, 1 close to deadline, and 0 passed deadline), and 'Substances (0)' (with a 'View all substances' button and a breakdown of 0 in progress submissions, 0 my favourites, and 0 failed submissions).

REACH-IT Training Company TrainingCompany Tasks (1) Substances Messages Quick search by number

Menu

Hi Margot Mägi Training Company

REACH-IT NEWS

25 Aug 2015 REACH-IT SAT-IT-1 This is the SAT (1) 1 REACH-IT environment.

**Submit a dossier**

Prepare online in REACH-IT Upload a IUCLID dossier Webform applications

View all types

**Tasks (1)**

Close to deadline 1 New 0 Passed deadline

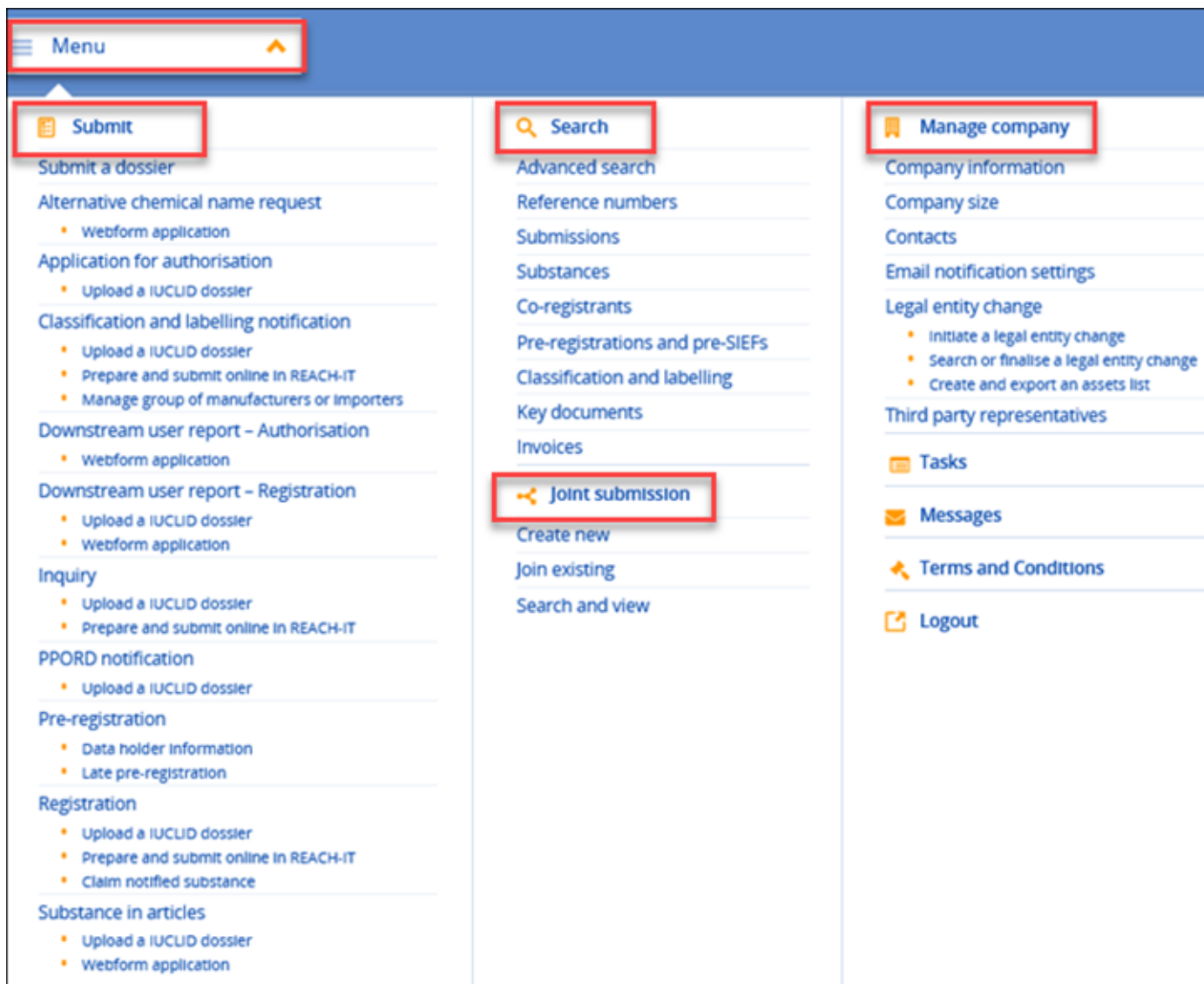
View all tasks

**Substances (0)**

In progress submissions 0 My favourites 0 Failed submissions

View all substances

# Main menu



The screenshot displays the ECHA Main menu interface. A blue header bar at the top contains a 'Menu' button with a hamburger icon and an upward arrow. Below the header, the menu is organized into three columns. The first column, titled 'Submit', lists various submission options such as 'Submit a dossier', 'Alternative chemical name request', 'Application for authorisation', 'Classification and labelling notification', 'Downstream user report – Authorisation', 'Downstream user report – Registration', 'Inquiry', 'PPORD notification', 'Pre-registration', 'Registration', and 'Substance in articles'. The second column, titled 'Search', includes 'Advanced search', 'Reference numbers', 'Submissions', 'Substances', 'Co-registrants', 'Pre-registrations and pre-SIEFs', 'Classification and labelling', 'Key documents', 'Invoices', and a 'Joint submission' section with options for 'Create new', 'Join existing', and 'Search and view'. The third column, titled 'Manage company', contains 'Company information', 'Company size', 'Contacts', 'Email notification settings', 'Legal entity change', 'Third party representatives', 'Tasks', 'Messages', 'Terms and Conditions', and 'Logout'. Red rectangular boxes highlight the 'Menu' button, the 'Submit' section header, the 'Search' section header, and the 'Joint submission' section header.

**Menu**

**Submit**

- Submit a dossier
- Alternative chemical name request
  - Webform application
- Application for authorisation
  - Upload a IUCLID dossier
- Classification and labelling notification
  - Upload a IUCLID dossier
  - Prepare and submit online in REACH-IT
  - Manage group of manufacturers or importers
- Downstream user report – Authorisation
  - Webform application
- Downstream user report – Registration
  - Upload a IUCLID dossier
  - Webform application
- Inquiry
  - Upload a IUCLID dossier
  - Prepare and submit online in REACH-IT
- PPORD notification
  - Upload a IUCLID dossier
- Pre-registration
  - Data holder information
  - Late pre-registration
- Registration
  - Upload a IUCLID dossier
  - Prepare and submit online in REACH-IT
  - Claim notified substance
- Substance in articles
  - Upload a IUCLID dossier
  - Webform application

**Search**

- Advanced search
- Reference numbers
- Submissions
- Substances
- Co-registrants
- Pre-registrations and pre-SIEFs
- Classification and labelling
- Key documents
- Invoices
- Joint submission**
  - Create new
  - Join existing
  - Search and view

**Manage company**

- Company information
- Company size
- Contacts
- Email notification settings
- Legal entity change
  - Initiate a legal entity change
  - Search or finalise a legal entity change
  - Create and export an assets list
- Third party representatives
- Tasks
- Messages
- Terms and Conditions
- Logout

The submission process cannot be saved so ensure you have all the required information before you begin.

**Dossier type: \*** Registration

**Submission type: \***

Select the option which defines the company's ownership structure. The options "Linked company" and "Partner company" can be combined. Please select the different structures that apply. You can find the ECHA website <http://echa.europa.eu/support/small-and-medium-sized-enterprises-smes/how-to-determine-the-company-size-category>. An em...

Topic help

Checklists  
in wizards

Are you ready to submit your dossier? Before continuing, make sure that:

- ✓ You are part of the joint submission, if one exists for your substance.
- ✓ The company size is correct. You can find out how to determine the company size if you are unsure.
- ✓ The VAT number and billing address in REACH-IT are up to date, and optionally you have a purchase order number: they will appear on the invoice.
- ✓ The contact persons for this dossier has been defined, and the contact details are up to date.

certain information from the dossier will be published on the website without further notice. Use the information plugin in IUCLID to ensure that the information will be published.

Continue to upload dossier >

Page help

### Need help?

You have now launched the submission wizard for your selected submission type. The submission wizard will guide you through the steps of the submission process.

In each step of the submission process you will find customised information relevant for your submission type. Remember to refer to the checklist on each wizard step to receive detailed assistance for your submission.

In the *Submission details* step, you will first choose the dossier type applicable to your submission: application for authorisation, classification and labelling notification, downstream user report, inquiry, PPORD notification, registration or substance in articles. If you are submitting a Registration, you will also need to specify the submission type: individual or joint submission. Remember that you will not be able to submit an individual registration if a registration for the same substance already exists. If this is the case, you need to contact your co-registrants and join the joint submission. You may search for your co-registrants and existing joint submissions on the *Advanced search* page in REACH-IT.

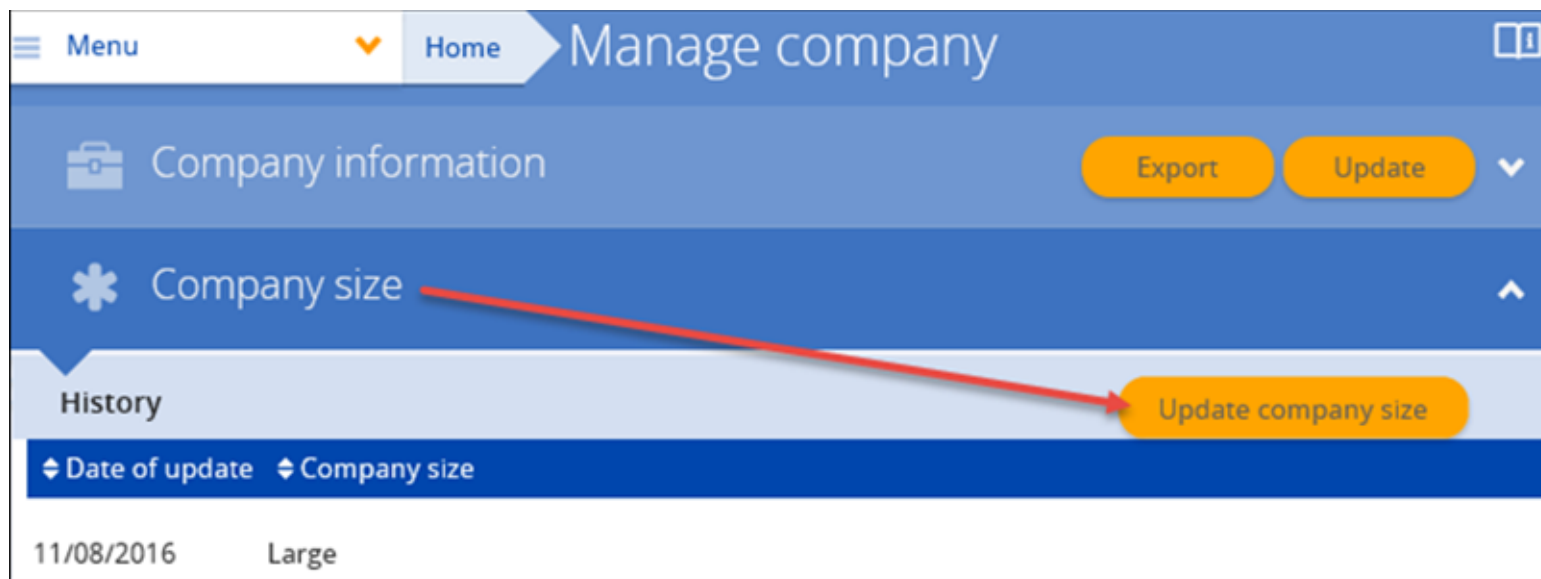
In the *Upload dossier* step, you can upload your IUCLID dossier. If the upload is successful, you will see an overview of your dossier details. You will also see if your IUCLID dossier are already in REACH-IT. If you want to upload a new dossier successfully or you want to update an existing one, you need to click on 'Want to upload a new file?'. More information on how to prepare your dossier can be found on the [IUCLID manuals page](#).

In the *Additional details* step, you may specify and edit additional information depending on your submission type. If you are submitting an application for...

Turn on all in-page help items

## Determine your company size (1/2)

- If you are an SME, you need to update your company size
- Important because it will determine your fees





## Determine your company size (2/2)

- Go through the checklist to understand the company size definition
- Declare company size and upload documentary evidence



The screenshot shows the 'Declare company size' page on the ECHA website. At the top, there is a navigation bar with 'Menu', 'Home', and 'Declare company size'. Below this, a progress indicator shows three steps: 'Understand the company size definition' (selected), 'Declare company size', and 'Confirmation'. The main heading is 'To determine the company size, you should:'. Below this, there is a list of seven steps, each preceded by a checkmark icon. To the right of the list, there are three informational notes, each preceded by an 'i' icon, and one warning note preceded by a warning triangle icon.

Menu Home Declare company size

Understand the company size definition Declare company size Confirmation

To determine the company size, you should:

- ✓ Consult your accountants, lawyers or tax advisors before declaring the company size
- ✓ Thoroughly familiarize with provisions of the [Commission Recommendation 2003/361/EC](#)
- ✓ Determine if the company is autonomous or if it has relations with other companies (linked or partners)
- ✓ Prepare documents explaining the full ownership structure of the company
- ✓ Have the [documentary evidence](#) at hand for all the companies involved in the ownership structure
- ✓ If you are an only representative, you will need to declare the company size of the non-EU manufacturer, formulator or producer you represent, including relevant information from their linked and partner companies
- ✓ Take the test on [ECHA website](#) to verify your understanding of company size and SME size

**i** The user guide on the SME definition provides you with additional explanations.

**i** If you are unsure about how to assess the company's size correctly, please contact your national helpdesk. If you still have further questions, you may also contact the ECHA helpdesk through the link below.

**i** If you want to change the company size for an already paid invoice, please follow the instructions from the [ECHA website](#).

**!** If ECHA finds that the company size is incorrect; you may have to pay the [administrative charge](#) and also the balance of the correct registration fee(s). Find out what to do if you have incorrectly indicated the SME size category.

## Search and join the JS

- You will see the available joint submissions for the substances you have pre-registered or inquired

The screenshot shows the REACH-IT Advanced search interface. At the top, there's a navigation bar with 'REACH-IT' logo, 'TestCompanyNew', 'TestCompany', 'Tasks (117)', 'Substances', 'Messages (1.0K)', and a 'Quick search by number' link. Below this is a 'Menu' dropdown and a 'Home' button. The main search area is titled 'Advanced search' and features a dropdown menu labeled 'I am looking for:' with 'joint submissions' selected. Below this are two columns of search filters. The left column, labeled 'Locate', includes fields for 'Substance identity (EC, CAS, Name)', 'Joint submission name', and 'Reference number', each with a placeholder 'Please enter a minimum of three characters'. The right column, labeled 'Filters', includes 'Company role' (with a note 'You may select multiple items'), 'Registration type' (with a note 'You may select one item'), 'Show other joint submissions?' (checked), and 'Favorite substances only?' (unchecked). A red arrow points to the 'Show other joint submissions?' checkbox. Below the filters are 'Search' and 'Clear' buttons. The results section shows 'Results 19 results found' and a 'Download results' button. The results are displayed in a table with columns: 'Joint submission name', 'Substance name', 'EC number', 'CAS number', and 'Company role'.

Joint submission name	Substance name	EC number	CAS number	Company role
202-009-7.js	6,6'-di-tert-butyl-2,2'-thiodi-p-cresol	202-009-7	90-66-4	Member
400-080-0	400-080-0	400-080-0		Member

## Search and join the JS: launch the wizard

- You need the JS token provided by the lead

The screenshot shows the REACH-IT Advanced search interface. At the top, there's a navigation bar with 'REACH-IT' logo, user 'TestCompanyNew', and various tool icons. Below this, a search bar shows 'I am looking for: joint submissions'. The results section indicates 'Results 20 results found' and includes a 'Download results' button. A table lists three joint submissions:

Joint submission name	Substance name	EC number	CAS number	Company role
Forminte	formaldehyde	200-001-8	50-00-0	▼
JS dina 4/6/2015	formaldehyde	200-001-8	50-00-0	▼
JS_INT_200-007-0	phenobarbital	200-007-0	50-06-6	▲

Below the table, there are three columns of information:

- Lead registrant:** Delph Baba, Valerie LASSEIGNE-  
PHRAKONKHAM@ext.echa.europa.eu, +358 4 44444444, London, Annankatu 18, 00120 Helsinki, Finland.
- Registration type:** Intermediate
- Supplementary information:** No supplementary information has been provided

At the bottom right, there is an orange button labeled 'Join joint submission', which is circled in green.

## Joint submission page

REACH-IT TestCompanyNew Medium TestCompany Tasks (11/9) Substances Messages (1.0K) Quick search by number

Menu Home Joint submissions JS\_INT\_200-007-0

Overview Submit a IUCLID Dossier Create and submit online Leave joint submission Export assigned EC number

Substance	Joint submission information	Joint submission cover...	Lead registrant contact
<p>Name phenobarbital</p> <p>EC number 200-007-0</p> <p>CAS number 50-06-6</p>	<p>Registration type Intermediate</p> <p>Joint submission name JS_INT_200-007-0</p> <p>Supplementary information -</p>	<p>Tonnage band Transported isolated intermediate 1-1000 tpa</p> <p>Guidance on safe use Not provided by lead</p> <p>Chemical safety report Not provided by lead</p>	<p>Contact details Delph Baba @ Valerie.LASSEIGNE-PHR... +358 4 44444444</p> <p>Publication acceptance Yes</p>

Own dossier Not submitted

Reference number  
N/A  
Company role  
Member

Joint submission contact

Contact details  
Jane Doe  
@ janedoe@chemicals.com  
+358505261007

Edit

Third party representative  
-

Edit

Scope of the joint submission

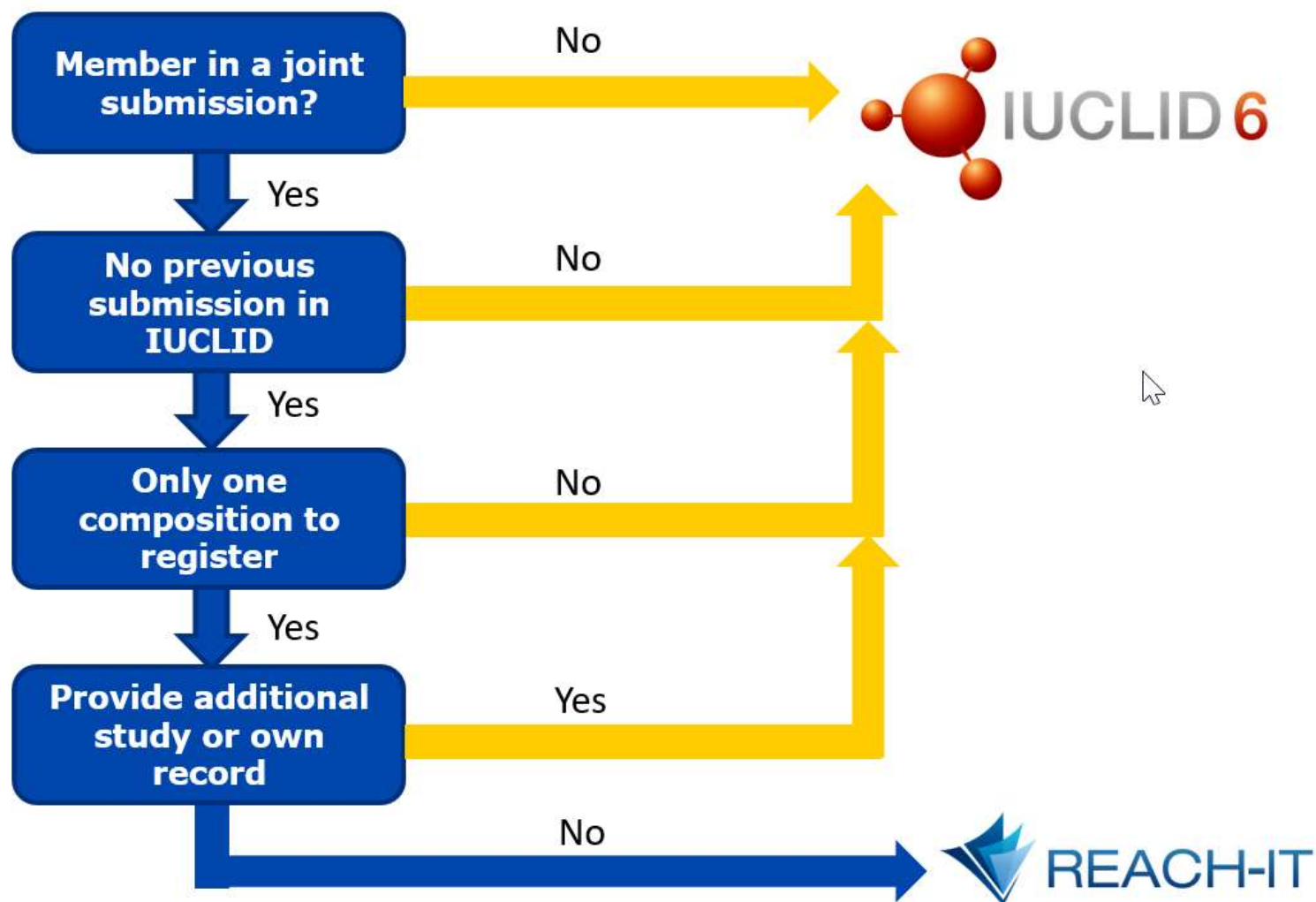
Members of the joint submission Download member details

**Create and submit a member registration  
dossier online in REACH-IT**



## Create and submit a member dossier online

- Simplified way to create a member registration dossier directly in REACH-IT
- Pre-filled information and reduced number of fields
- Step-by-step wizard with online help features
- Mandatory information highlighted
- Automatic saving and possibility to update



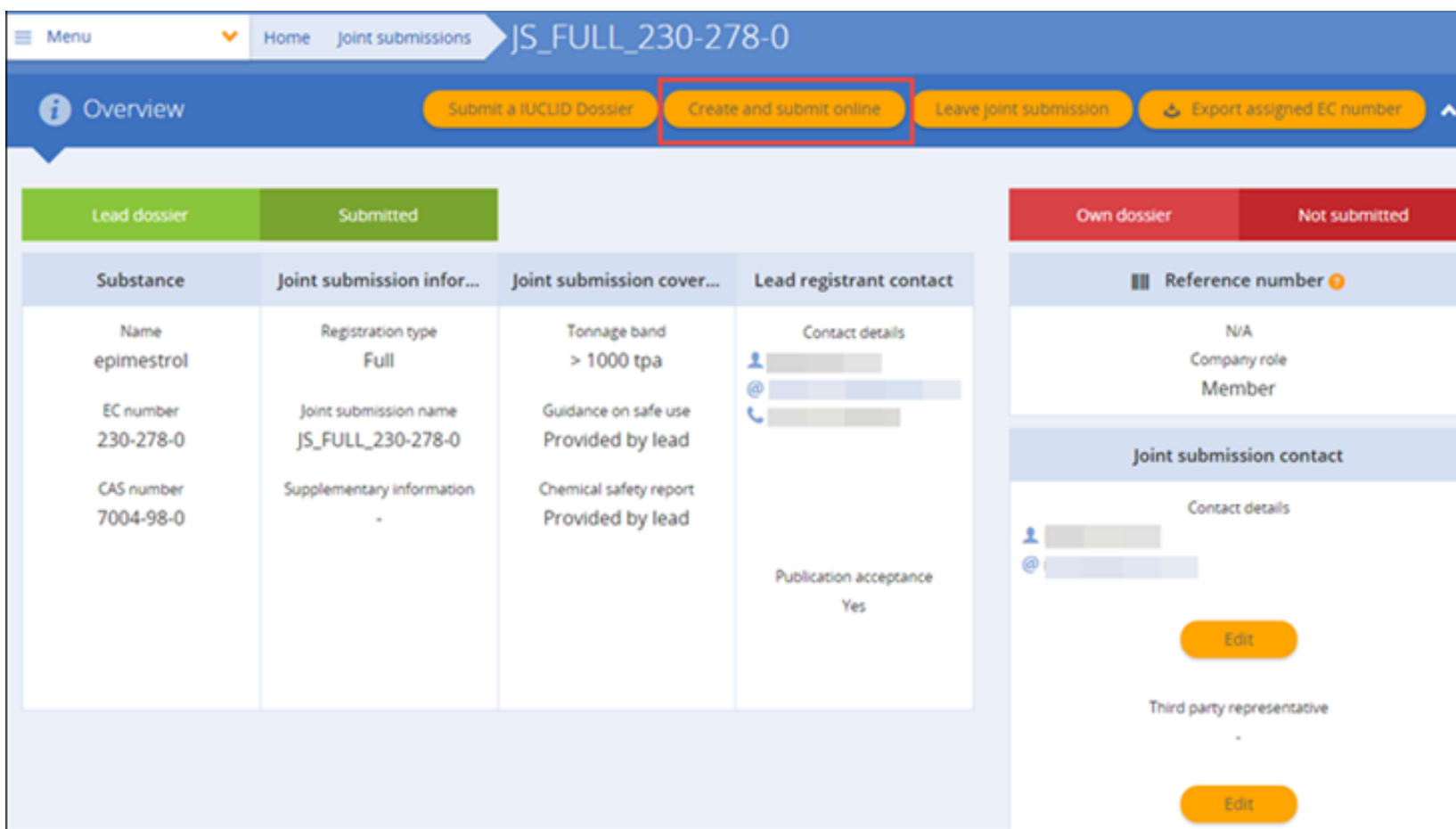
- Same data in IUCLID and in REACH-IT
- Every co-registrant of the joint submission:
  - Substance identity
  - Tonnages of the last 3 years
  - Uses and conditions of use through the life cycle
- Co-registrants 10 tonnes per year or more:
  - Attach chemical safety report, unless agreed with the lead that he will submit on behalf of the members
- Members who need to submit own classification and labelling
- Possibility to indicate confidentiality claims



# How to use the member online wizard



## Start the dossier creation from the joint submission overview in REACH-IT



Menu Home joint submissions JS\_FULL\_230-278-0

Overview Submit a IUCLID Dossier **Create and submit online** Leave joint submission Export assigned EC number

Substance	Joint submission information	Joint submission coverage	Lead registrant contact
Name epimestrol	Registration type Full	Tonnage band > 1000 tpa	Contact details [Redacted]
EC number 230-278-0	Joint submission name JS_FULL_230-278-0	Guidance on safe use Provided by lead	[Redacted]
CAS number 7004-98-0	Supplementary information -	Chemical safety report Provided by lead	Publication acceptance Yes

Own dossier	Not submitted
Reference number N/A	Company role Member
Joint submission contact	
Contact details [Redacted]	
Third party representative -	

## Submit online dossier

### Confirm

You are about to be redirected to the online dossier creation!

An online member registration dossier can only be created if:

- you have not previously submitted for this substance a registration dossier created using IUCLID
- you do not have another member registration dossier for the same substance currently in progress
- your substance is defined by only one composition
- you do not intend to opt-out, i.e. add in your dossier study records or study summaries not provided by the lead
- you do not intend to report more than one C&L that differs from the one provided by the lead
- you are not involved in a data-sharing dispute for this substance
- you do not intend to submit a 1-10 T registration dossier with physicochemical requirements only
- you do not intend to apply for a fee-waiver
- you are not involved in any legal entity change of type merge in REACH-IT

If you do not satisfy any of the above conditions, you cannot prepare your dossier online.  
We advise you to prepare and upload a IUCLID dossier in REACH-IT.

Do you want to continue to the online dossier creation?

Yes, I want to prepare an online dossier

Cancel

## Use the integrated help

The screenshot shows the 'Member joint submission' wizard in REACH-IT. The main header includes the IUCLID logo, the submission title 'Member joint submission for JS\_FULL\_230-278-0', and the chemical name '3-methoxyestra-1(10),2,4-triene-16,17-diol'. A progress bar shows 'Main constituents' as the current step. A green callout bubble points to the 'Change help language' option in the top right corner, which is next to a language dropdown menu set to 'english (en)'. The 'Help' section on the right provides guidance on the wizard's purpose and steps. The main content area contains instructions on defining the substance type and a table for 'Main constituents'.

**Change help language**

Back to REACH-IT

english (en)

**Help**

You have now launched the online dossier creation wizard. The wizard will **guide you through the steps of the member registration dossier creation**. The information entered in each block of the wizard needs to be saved regularly by clicking on the **Save** button. You can quit the wizard at any moment in time and retrieve your draft dossier via the *joint submission overview* in REACH-IT.

Once your dossier has been submitted in REACH-IT, you can follow its submission status using the *submission and substances* pages in REACH-IT. After a reference number has been assigned, the online dossier can be updated from the *joint submission overview* in REACH-IT.

**⚠** You can start the online creation of your member registration dossier at any moment after having joined a joint submission in REACH-IT. Please note that you will only be able to finalise the creation and submit your online dossier after the lead has submitted his own dossier and successfully passed the business rules check.

Are you ready to create an online member registration dossier?


Each registrant (manufacturer, importer or only representative) has the obligation to submit his **own dossier** as a member of a joint registration. You are ready to create your online dossier if you have the following at hand:

**Main constituents**

Main constituents
3-methoxyestra-1(10),2,4-triene-16,17-diol EC 230-278-0 CAS 7004-98-0

Substance identification


## First step: Main constituents


**Member joint submission**  
 Member joint submission for JS\_FULL\_230-278-0

Big Company  
 BigCompany BigCompany ( BigCompany )

3-methoxyestra-1(10),2,4-triene-16,17-diol
 EC 230-278-0 CAS 7004-98-0

Main constituents
 Back to REACH-IT

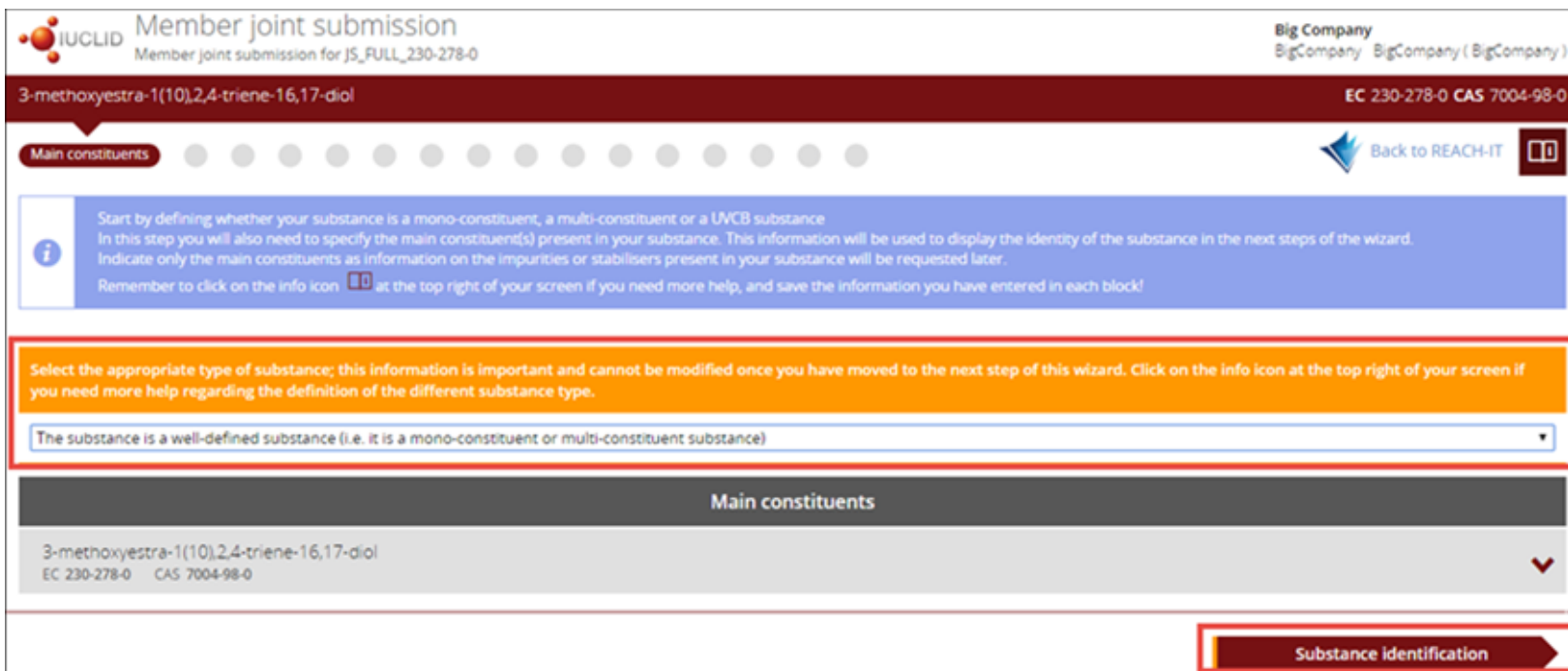
Start by defining whether your substance is a mono-constituent, a multi-constituent or a UVCB substance  
 In this step you will also need to specify the main constituent(s) present in your substance. This information will be used to display the identity of the substance in the next steps of the wizard.  
 Indicate only the main constituents as information on the impurities or stabilisers present in your substance will be requested later.  
 Remember to click on the info icon  at the top right of your screen if you need more help, and save the information you have entered in each block!

Select the appropriate type of substance; this information is important and cannot be modified once you have moved to the next step of this wizard. Click on the info icon at the top right of your screen if you need more help regarding the definition of the different substance type.

Main constituents
3-methoxyestra-1(10),2,4-triene-16,17-diol EC 230-278-0 CAS 7004-98-0

Substance identification

## Move to the next step when required data is filled in



**IUCLID** Member joint submission  
Member joint submission for JS\_FULL\_230-278-0

Big Company  
BigCompany BigCompany ( BigCompany )

3-methoxyestra-1(10),2,4-triene-16,17-diol EC 230-278-0 CAS 7004-98-0

Main constituents

**i** Start by defining whether your substance is a mono-constituent, a multi-constituent or a UVCB substance  
In this step you will also need to specify the main constituent(s) present in your substance. This information will be used to display the identity of the substance in the next steps of the wizard.  
Indicate only the main constituents as information on the impurities or stabilisers present in your substance will be requested later.  
Remember to click on the info icon **i** at the top right of your screen if you need more help, and save the information you have entered in each block!

Select the appropriate type of substance; this information is important and cannot be modified once you have moved to the next step of this wizard. Click on the info icon at the top right of your screen if you need more help regarding the definition of the different substance type.

The substance is a well-defined substance (i.e. it is a mono-constituent or multi-constituent substance)

**Main constituents**

3-methoxyestra-1(10),2,4-triene-16,17-diol EC 230-278-0 CAS 7004-98-0	✓
--	---

**Substance identification**

[echa.europa.eu](http://echa.europa.eu)




## Integrated Business rules and TCC rules

**IUCLiD** Member joint submission  
Member joint submission for JS\_FULL\_230-278-0

















Big Company  
BigCompany BigCompany (BigCompany)

3-methoxyestra-1(10),2,4-triene-16,17-diol EC 230-278-0 CAS 7004-98-0

Trade name and other identifiers

In this step, you can indicate additional identifiers or trade names for your substance. You can also attach analytical information to support the identification and or quantification of your substance. It is also the place to include the descriptions of the methods used to generate this information. You can find more details on how to fill in the information by clicking on the info icon  located at the top right of your screen. Remember to click on the Save button after completing each block!

TCC\_0104\_01 : You must provide analytical information to cover at least one identification, and one quantification approach, as indicated in the 'Purpose of analysis' field.

Trade name and other identifiers	Analytical information												
	<p>TCC_0104_02 : Either the methods and results of analysis must be attached, or if a result was not determined, a justification must be given using the 'Rationale for no results' and 'Justification' fields, clearly stating the reasons for not providing the information.</p> <table border="1"> <tr> <td>Purpose of analysis</td> <td>You may select one item</td> <td> </td> </tr> <tr> <td>Analysis type</td> <td>You may select multiple items</td> <td></td> </tr> <tr> <td>Type of information provided</td> <td>You may select one item </td> <td>Remarks of information provide</td> </tr> <tr> <td>Attached methods/results</td> <td colspan="2"> Upload a document</td> </tr> </table> <p> Show more ...</p> <p>Cancel Save</p>	Purpose of analysis	You may select one item	 	Analysis type	You may select multiple items		Type of information provided	You may select one item 	Remarks of information provide	Attached methods/results	 Upload a document	
Purpose of analysis	You may select one item	 											
Analysis type	You may select multiple items												
Type of information provided	You may select one item 	Remarks of information provide											
Attached methods/results	 Upload a document												

Substance identification

Substance composition




## CSR and Guidance on safe use



**iucld** Member joint submission  
Member joint submission for JS\_FULL\_230-278-0

Big Company  
BigCompany BigCompany ( BigCompany )

3-methoxyestra-1(10),2,4-triene-16,17-diol EC 230-278-0 CAS 7004-98-0

Assessment reports

Use this step to attach supporting documents/reports which justify certain information provided for your substance.  
You can find more details on how to fill in the information by clicking on the info icon  located at the top right of your screen.  
Remember to click on the Save button after completing each block!

Chemical safety report (CSR) or other report	Guidance on safe use
 The CSR was supplied by the lead on behalf of the members	 The Guidance on safe use was supplied by the lead on behalf of the members
Undefined	Undefined

PBT assessment

Undefined

Use information Confidentiality claims

## Confidentiality claims

Member joint submission

Member joint submission for JS\_FULL\_230-278-0

Big Company

BigCompany (BigCompany)

3-methoxyestra-1(10),2,4-triene-16,17-diol

EC 230-278-0 CAS 7004-98-0

Confidentiality claims

Back to REACH-IT

Requests for information not to be disseminated on ECHA website are usually referred to as "confidentiality claims". You can flag certain information as confidential in your dossier as long as you provide a justification.

You can find more details on how to fill in the information by clicking on the info icon located on the top right of your screen. Remember to click on the Save button after completing each block!

Confidentiality claims	
IUPAC name for substance and its main constituents	Not Confidential ✓
Degree of purity and impurities	Not Confidential ✓
Tonnage band	Not Confidential ✓
Registration number	Not Confidential ✓
Legal entity (Owner)	Not Confidential ✓
Role in the supply chain	Not Confidential ✓

Confidentiality claims on assessment reports

Confidentiality claims on trade names

Confidentiality claims on uses

Confidentiality claims on uses advised against

- test

Not Confidential ✓

Assessment reports

Dossier preview

## Review your dossier

**Member joint submission**  
Member joint submission for JS\_FULL\_230-278-0

Big Company  
BigCompany BigCompany (BigCompany)

3-methoxyestra-1(10),2,4-triene-16,17-diol EC 230-278-0 CAS 7004-98-0

[Dossier preview](#)

[Back to REACH-IT](#)

Carefully review the information below before moving to the next step and finalising your dossier/submission.

### Substance identity

3-methoxyestra-1(10),2,4-triene-16,17-diol  
EC 230-278-0 CAS 7004-98-0  
Mono-constituent

### Trade name and other identifiers

### Substance composition

State / form  
Description of the composition  
Degree of purity 90 < C < 99 % (w/w)  
Optical Activity yes  
Remarks

Constituents	Stabilisers
3-methoxyestra-1(10),2,4-triene-16,17-diol EC 230-278-0 CAS 7004-98-0	90 < C < 95 % (w/w)

[Confidentiality claims](#) [Submission to REACH-IT](#)

## Submit in REACH-IT

Menu

Home

Submit a dossier

Submission details

Upload dossier

Additional details  
Big Company

Confirmation

Please review your submission:

Submission details

Dossier type: Registration - Joint Submission

Joint submission name: JS\_FULL\_230-278-0

Company role: Member

Registration type: Full

Online dossier

Substance name: 3-methoxyestra-1(10),2,4-triene-16,17-diol

IUCLID template: REACH Registration member of a joint submission - general case

Dossier UUID: 126efe72-3e79-4731-84bf-14e10a517c03

By confirming this submission, I declare that the information provided is correct, and that the company size and ownership structure have not changed.

Do you agree with this information?

If yes, please confirm your submission

If not, you may edit the information of any step or [Cancel](#) the submission.

i










None of the information will be stored in REACH-IT if you choose to start over or cancel the submission.

## Follow the submission progress

Menu ▼ Home Submission report **CQ785353-21**

**Overview** [Request IUCLID file](#) [Export assigned EC number](#) [Download submission report](#)

**Submission status** **In progress** Submission number: CQ785353-21 Submission date: 10/05/2017 Initial submission

Substance	Dossier type	Contact information	Submission processing steps
Name 4'-fluorobutyrophenone	Registration	Contact details  Soi Le  s@mail.com  +123456789	<div>1  Pre-validation</div> <div>2  Business rules check</div> <div>3  Technical completeness check</div> <div>4  Financial completeness check</div> <div>5  Overall completeness check</div> <div>6  Submission outcome</div>
EC number 209-492-3	Tonnage band 1-10 tpa		
CAS number 582-83-2	On-site isolated intermediate -	Third party representative -	
	Transported isolated intermediate		

## Find your registration decision



The screenshot shows the 'Key documents' section of the ECHA portal. A red box highlights the 'Key documents' header. Below it, a date stamp '10 May 2017' is visible. The main content area displays the following information: 'Final submission result', 'Outcome: Accept', 'Annotation number: SUB-D-2114358912-43-01/F', 'Submission number: CQ785353-21', and 'Legislative status: Final'. A red box on the right highlights a download link for 'REGISTRATI...pdf' with a paperclip icon.



The screenshot shows a PDF document titled '1 (1)' at the top right. It features the ECHA logo and the date '10 May 2017'. The recipient's address is 'Solle1, Annankatu 18, 00100, Helsinki, Finland'. The submission details are: 'Submission date: 10 May 2017', 'Submission number: CQ785353-21', and 'Decision number: SUB-D-2114358912-43-01/F'. The document is titled 'DECISION ON YOUR REGISTRATION' and states: 'Based on Article 20(2) of Regulation (EC) No 1907/2006 ("REACH"), Your registration for [redacted] is complete. This registration entitles you to manufacture/import the substance, or produce or import an article containing it.' It also specifies: 'Your registration covers: • the tonnage band between 1 and 10 tonnes/year'. The registration number is '01-2120259230-66-0000' and the registration date is '10 May 2017'.



## Creating a complete dossier in IUCLID

1

- **Go to IUCLID**
- **Create a substance dataset**
- **Fill-in the information**

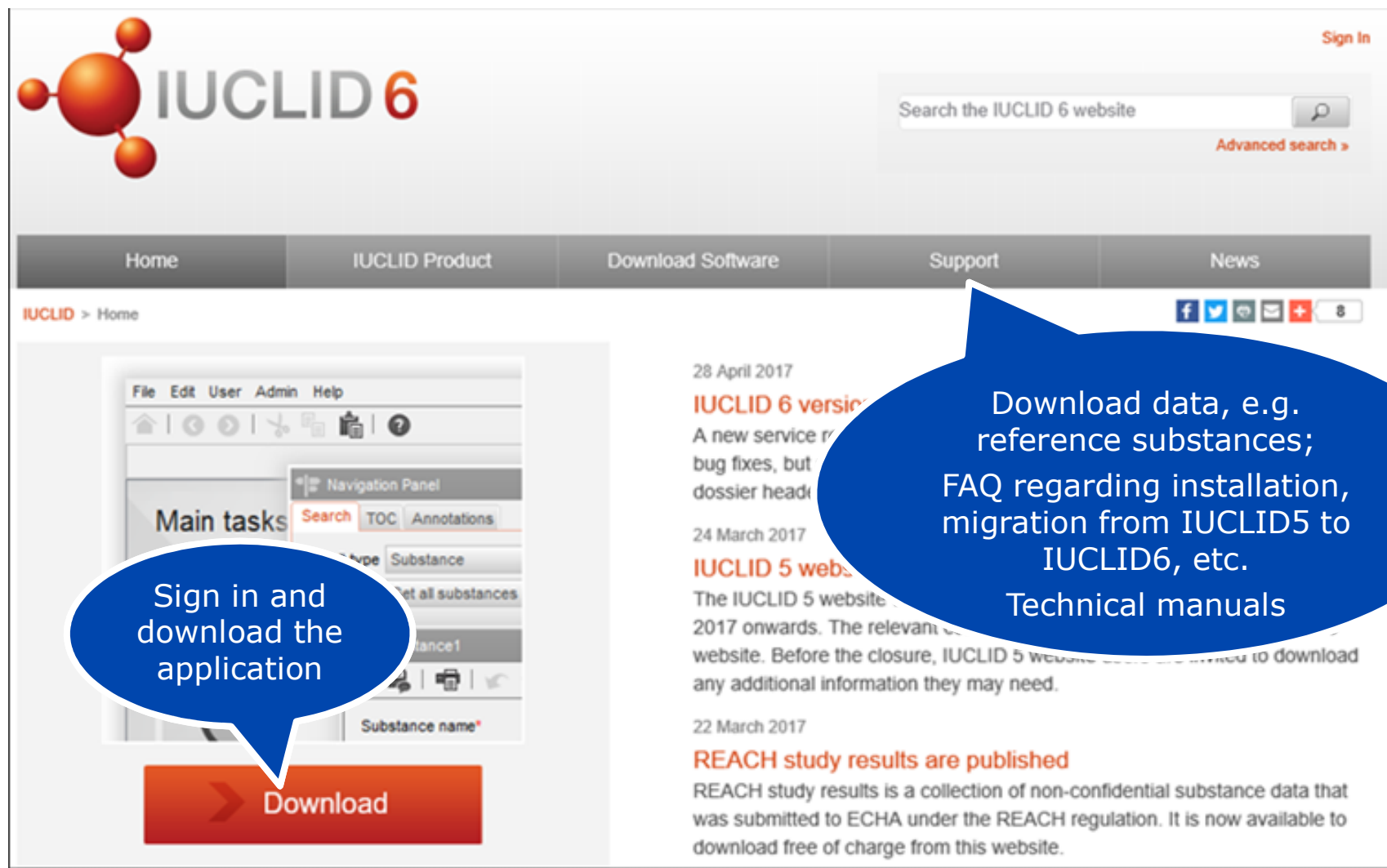
2

- Run the Validation Assistant on the dataset
- Correct the failures

3

- Create the dossier
- Run the Validation Assistant on the dossier
- In case of failures, correct the dataset or re-create the dossier



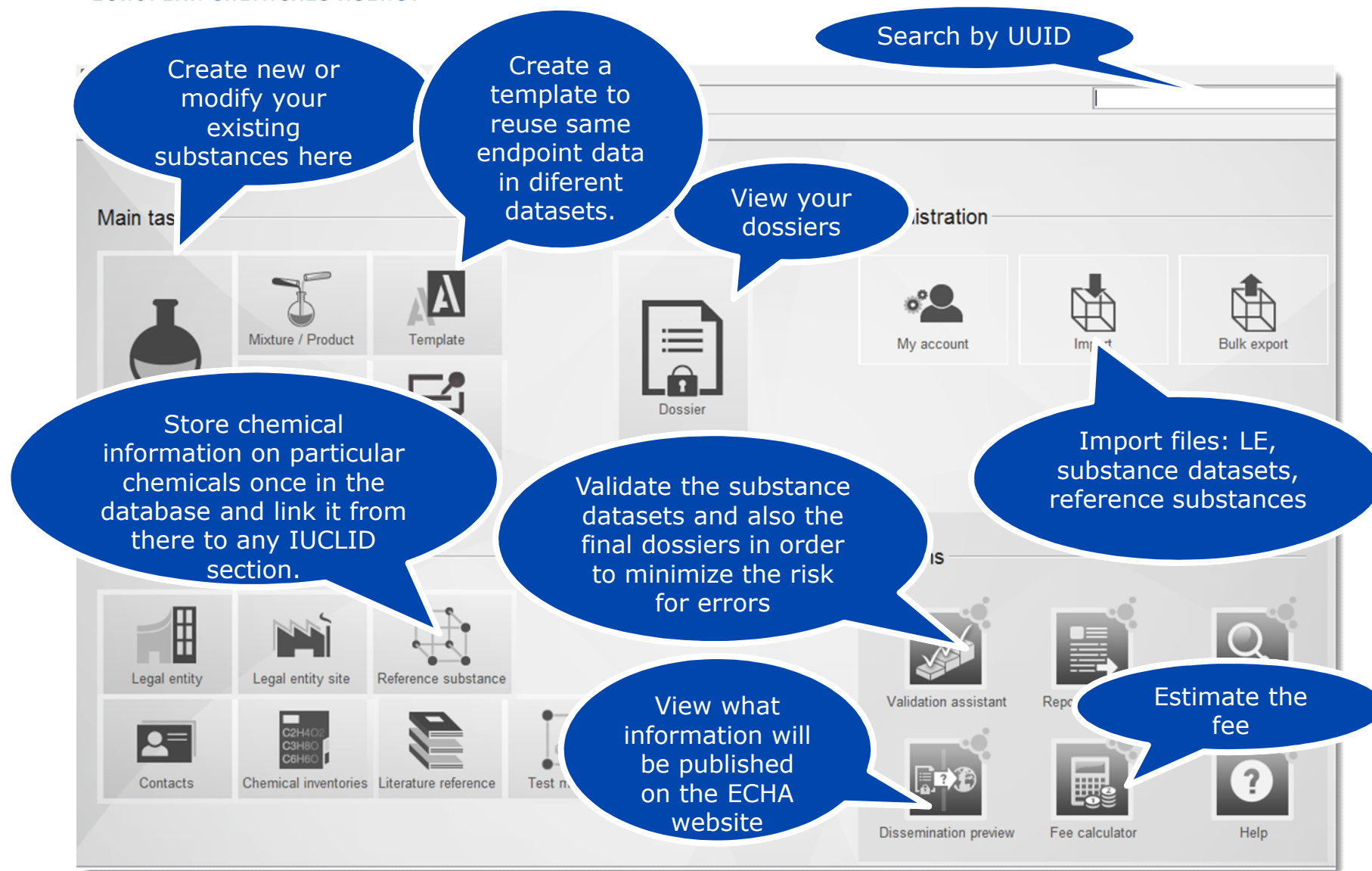


The screenshot shows the IUCLID 6 website. At the top left is the IUCLID 6 logo, which consists of a red molecular structure icon and the text "IUCLID 6". To the right of the logo is a search bar with the placeholder text "Search the IUCLID 6 website" and a magnifying glass icon. Below the search bar is a link for "Advanced search". A navigation menu is located below the search bar, containing links for "Home", "IUCLID Product", "Download Software", "Support", and "News". Below the navigation menu is a social media bar with icons for Facebook, Twitter, LinkedIn, YouTube, and a plus sign for more options. The main content area is divided into two columns. The left column features a preview of the IUCLID 6 application interface, showing a menu with options like "File", "Edit", "User", "Admin", and "Help", and a "Main tasks" section with buttons for "Search", "TOC", and "Annotations". Below the preview is a large red button with a white arrow and the text "Download". A blue callout bubble points to this button with the text "Sign in and download the application". The right column contains a list of news items. The first item is dated "28 April 2017" and is titled "IUCLID 6 version". The second item is dated "24 March 2017" and is titled "IUCLID 5 website". The third item is dated "22 March 2017" and is titled "REACH study results are published". A large blue callout bubble points to the news items with the text "Download data, e.g. reference substances; FAQ regarding installation, migration from IUCLID5 to IUCLID6, etc. Technical manuals".

**Sign in and download the application**

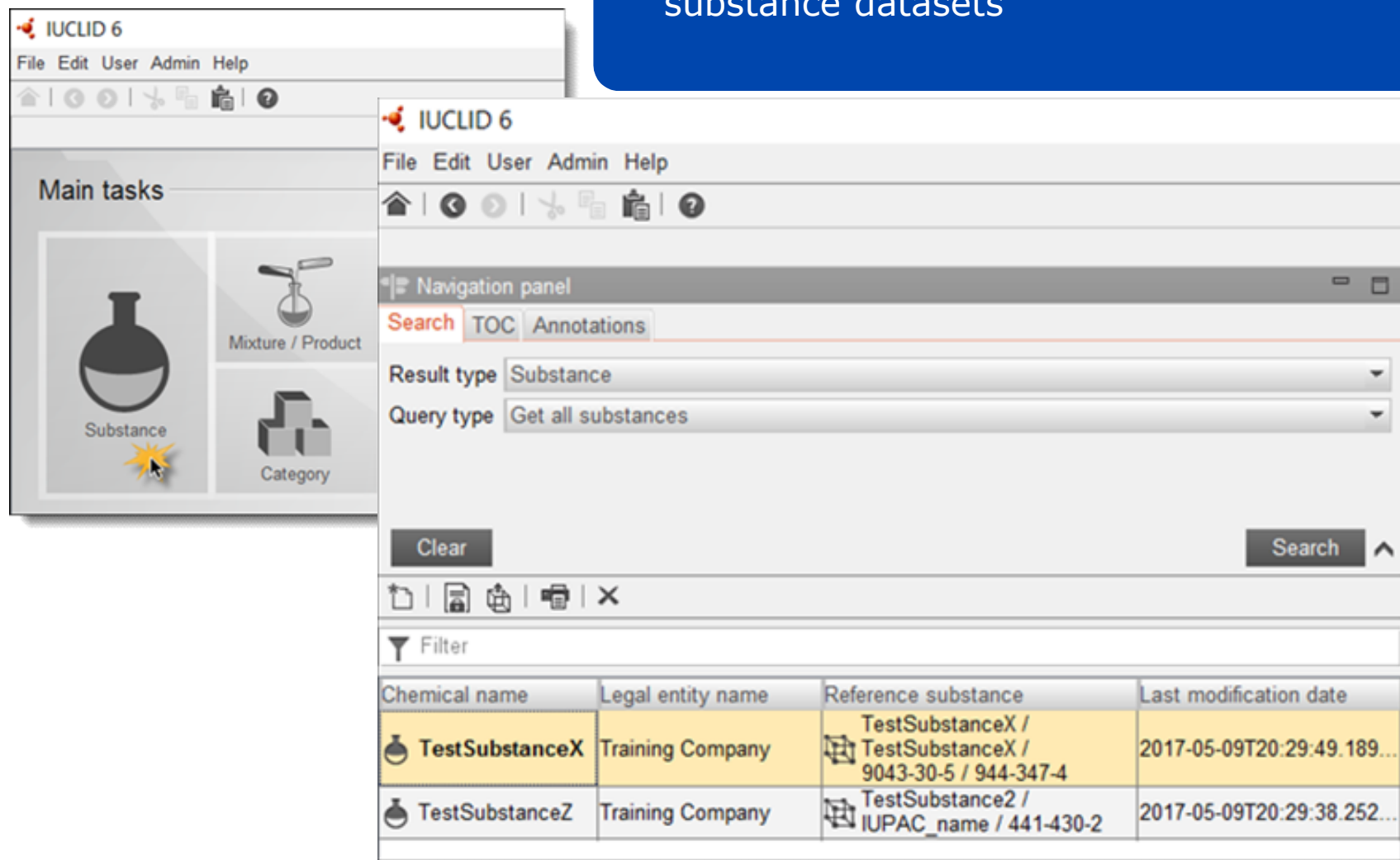
**Download data, e.g. reference substances; FAQ regarding installation, migration from IUCLID5 to IUCLID6, etc. Technical manuals**

## Main functionalities







## Datasets' list

- Find your dataset from the list of all the substance datasets

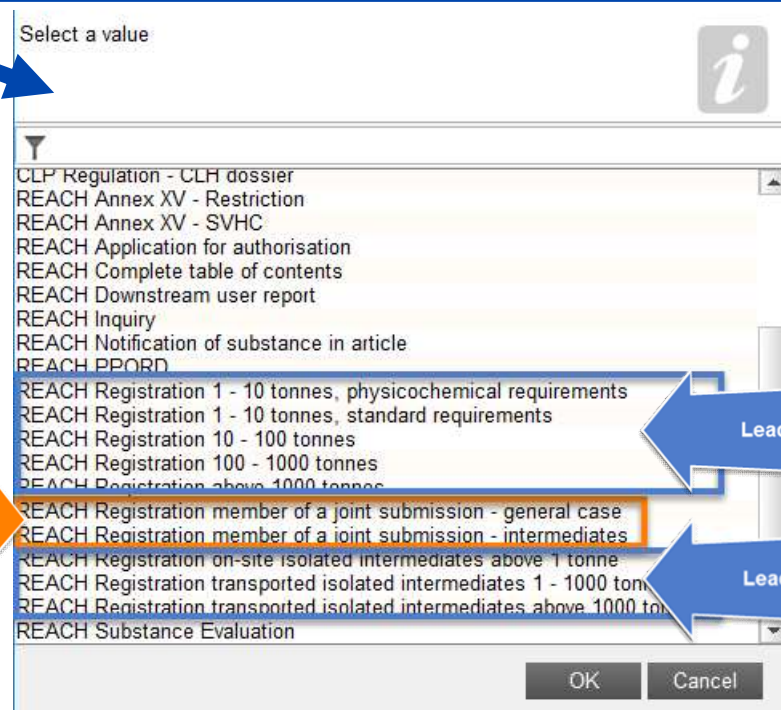
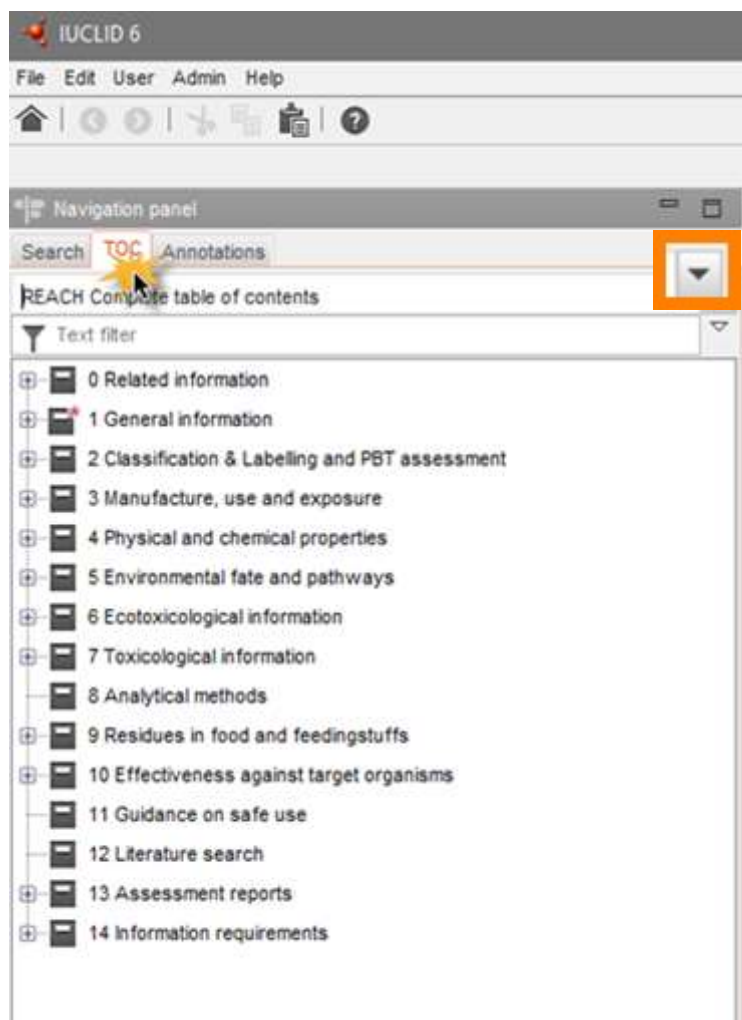


The screenshot displays the IUCLID 6 software interface. On the left, the 'Main tasks' panel shows four icons: 'Substance' (a round-bottom flask), 'Mixture / Product' (a flask with a stirrer), 'Category' (three stacked cubes), and 'Substance' (a starburst icon). The 'Substance' icon is highlighted with a mouse cursor. The main window shows the 'Search' tab selected in the 'Navigation panel'. Below the navigation panel, there are dropdown menus for 'Result type' (set to 'Substance') and 'Query type' (set to 'Get all substances'). A 'Clear' button is on the left and a 'Search' button is on the right. Below these is a 'Filter' input field. At the bottom, a table displays search results with four columns: 'Chemical name', 'Legal entity name', 'Reference substance', and 'Last modification date'.

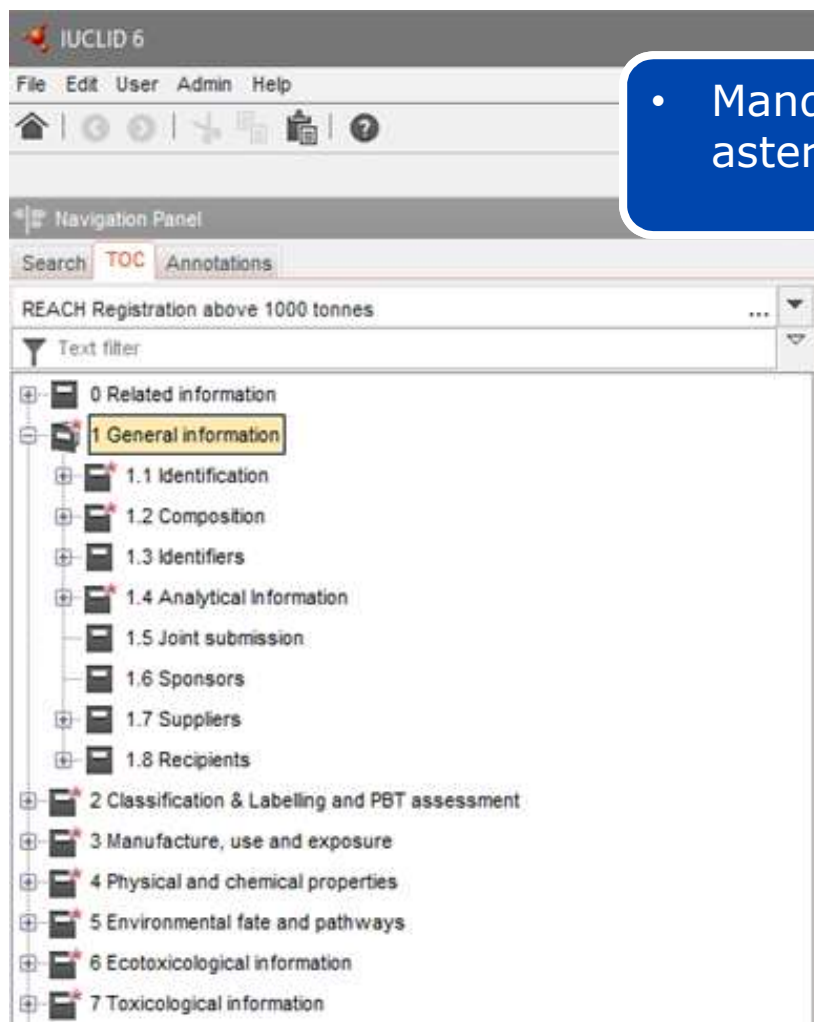
Chemical name	Legal entity name	Reference substance	Last modification date
 <b>TestSubstanceX</b>	Training Company	 TestSubstanceX / 9043-30-5 / 944-347-4	2017-05-09T20:29:49.189...
 <b>TestSubstanceZ</b>	Training Company	 TestSubstance2 / IUPAC_name / 441-430-2	2017-05-09T20:29:38.252...

## Dataset's content

- Click on 'TOC' to display the table of content of the dataset
- By default, the view is 'REACH Complete'
- Select the relevant view from the black arrow



## Section tree



- Mandatory sections are marked with a red asterisk \*



## Data requirements

- Lead data requirements compared to the member data requirements

Navigation panel

Search **TOC** Annotations

REACH Registration 1 - 10 tonnes, standard require ...

Text filter

- 0 Related information
- 1 General information
- 2 Classification & Labelling and PBT assessment
- 3 Manufacture, use and exposure
- 4 Physical and chemical properties
- 5 Environmental fate and pathways
- 6 Ecotoxicological information
- 7 Toxicological information
- 8 Analytical methods
- 11 Guidance on safe use
- 12 Literature search
- 13 Assessment reports
- 14 Information requirements

Search **TOC** Annotations

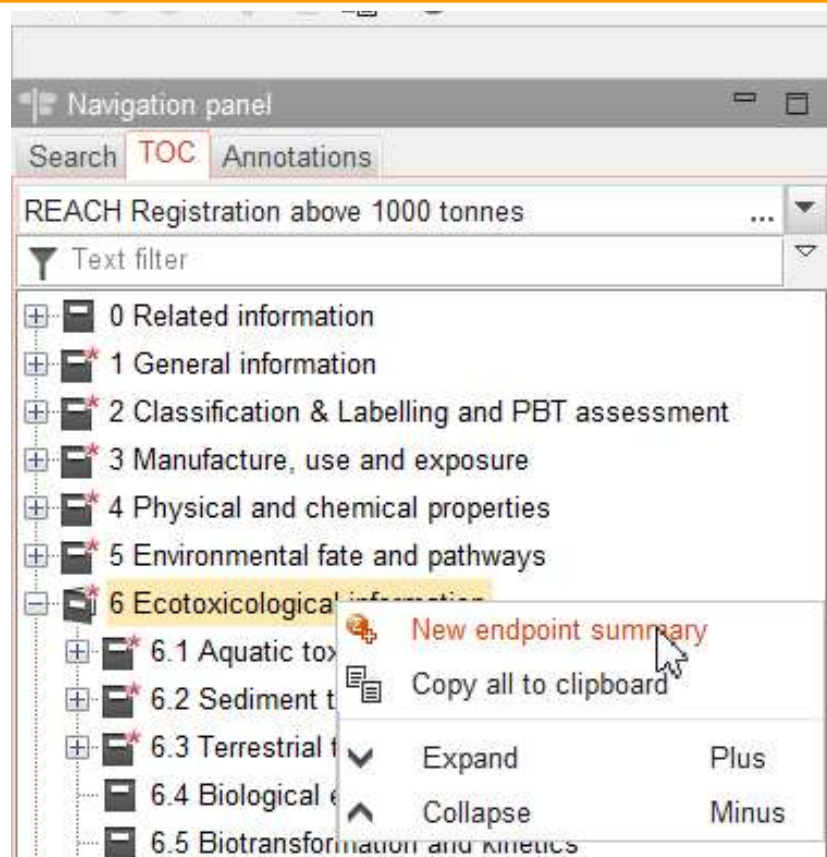
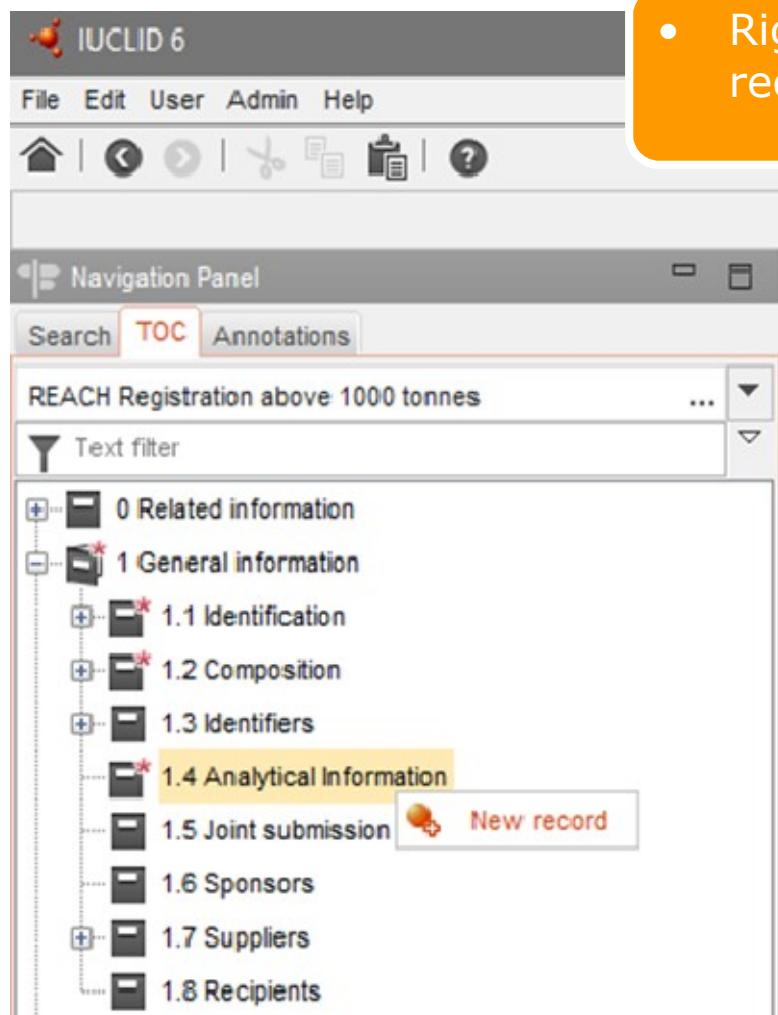
REACH Registration member of a joint submission - ...

Text filter

- 0 Related information
- 1 General information
- 2 Classification & Labelling and PBT assessment
- 3 Manufacture, use and exposure
- 4 Physical and chemical properties
- 5 Environmental fate and pathways
- 6 Ecotoxicological information
- 7 Toxicological information
- 8 Analytical methods
- 11 Guidance on safe use
- 12 Literature search
- 13 Assessment reports
- 14 Information requirements

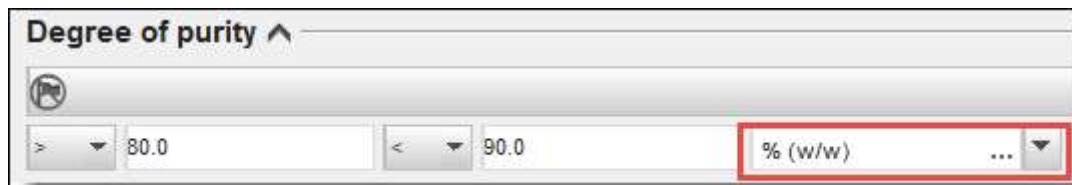
## Filling-in a dataset

- Right-click on a section to create a new record or a new endpoint summary



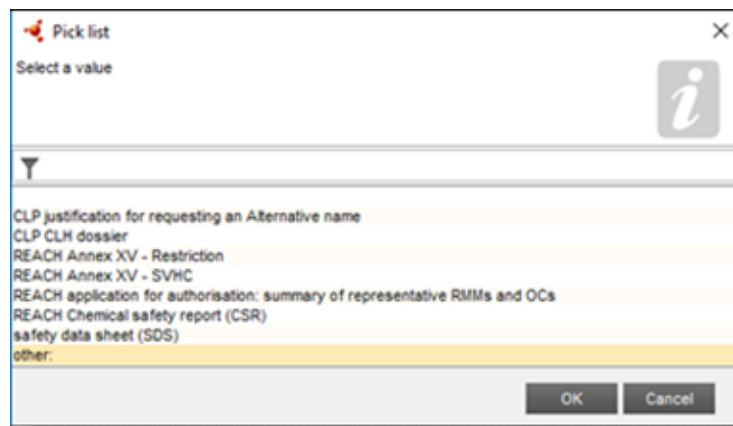
## Tips for filling in a dataset 1/2

- Every value must be followed by a unit



A screenshot of a software interface for 'Degree of purity'. It features two input fields: the first contains '80.0' and the second contains '90.0'. To the right of these fields is a dropdown menu currently showing '% (w/w)'. The entire dropdown area is highlighted with a red rectangular box.

- Every 'other' must be followed by a justification in the designated free text field



A screenshot of a 'Pick list' dialog box. It has a title bar with a red icon and the text 'Pick list'. Below the title bar is a search bar with the placeholder text 'Select a value' and an information icon (i). A list of options is displayed below the search bar, including 'CLP justification for requesting an Alternative name', 'CLP CLH dossier', 'REACH Annex XV - Restriction', 'REACH Annex XV - SVHC', 'REACH application for authorisation: summary of representative RMMs and OCs', 'REACH Chemical safety report (CSR)', 'safety data sheet (SDS)', and 'other:'. The 'other:' option is highlighted in yellow. At the bottom right of the dialog are 'OK' and 'Cancel' buttons.

- Every justification must be (scientifically) meaningful



## Tips for filling in a dataset 2/2

- Use free text templates as guideline

The screenshot shows a software interface for entering chemical data. On the left, there are several input fields: 'Description of composition', 'Attached description', 'Attached document', and 'Justification for deviations'. The 'Attached description' field is currently selected. A red arrow points from this field to a dialog box titled 'Free text templates'. The dialog box contains instructions on how to use the templates and a list of options. 'Option 2: Composition of a UVCB substance' is highlighted in yellow. Below the options, there is a detailed template for describing the composition of a UVCB substance, including a list of required information points. At the bottom of the dialog box are 'Insert' and 'Cancel' buttons.

**Free text templates**

View / edit / insert freetext template as appropriate  
In case of several options, click the heading of the desired freetext template.  
Delete/add elements and edit text set in [...] (if any) as appropriate

Option 1: Boundary composition of the substance  
**Option 2: Composition of a UVCB substance**

DESCRIBE THE PROCESS BEHIND THE PARTICULAR COMPOSITION OF THE UVCB ...  
SUBSTANCE

- Identity of starting materials/source (and ratio):
- Reaction steps/mechanisms:
- Relevant operating parameters (e.g. temperature and pressure):
- Solvents/reagents used:
- Details on any extraction/isolation steps as appropriate:
- Details on any clean-up/purification steps as appropriate:
- Physical-chemical parameters (e.g. boiling point):

Insert Cancel

## Help needed? Press F1

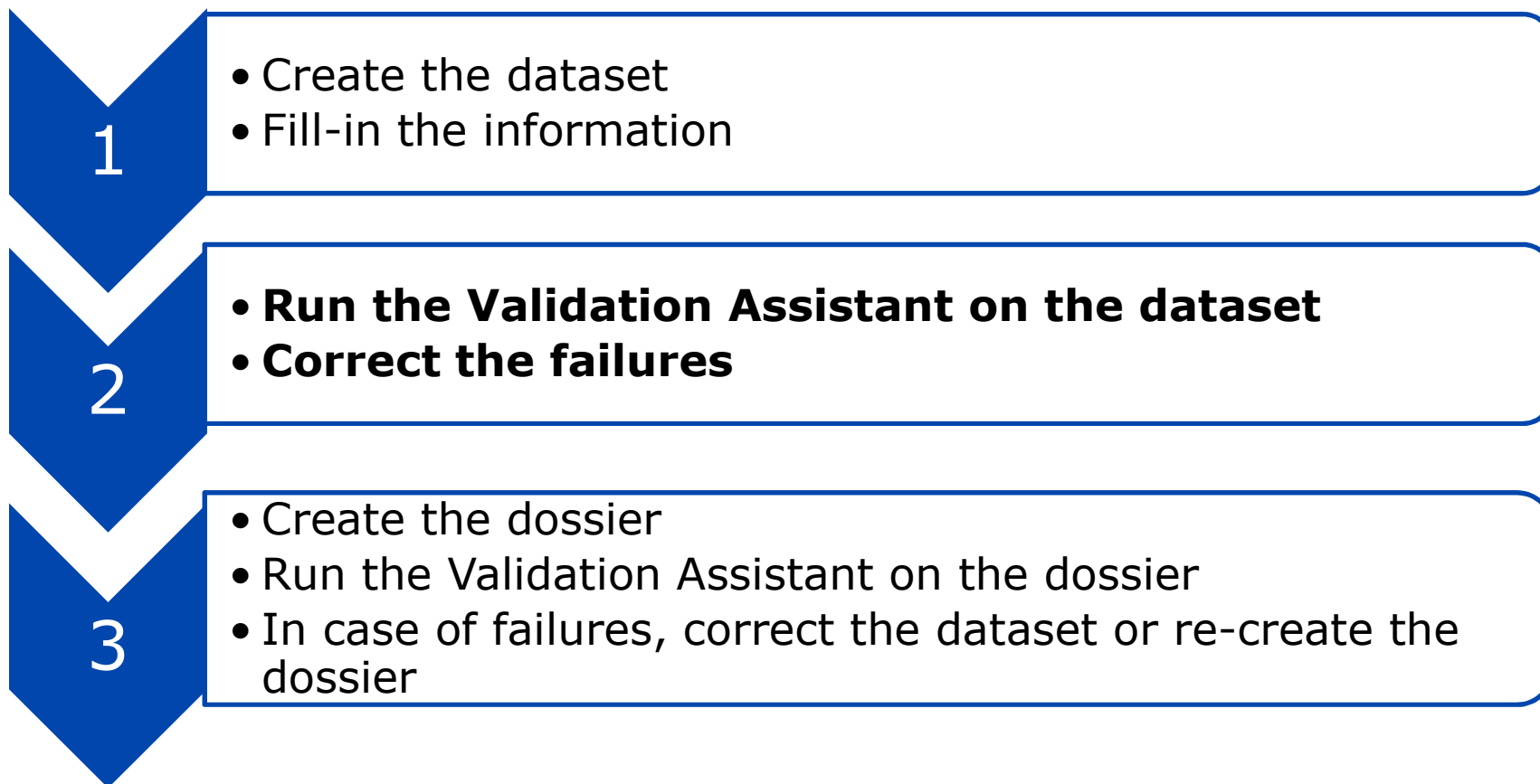
IUCLID contains an embedded Help System. Press F1 to access it. It contains:

- Information on the IUCLID functionalities
- Help text for the IUCLID fields
- Dossier preparation manuals, e.g. how to prepare a registration dossier

# Validation assistant

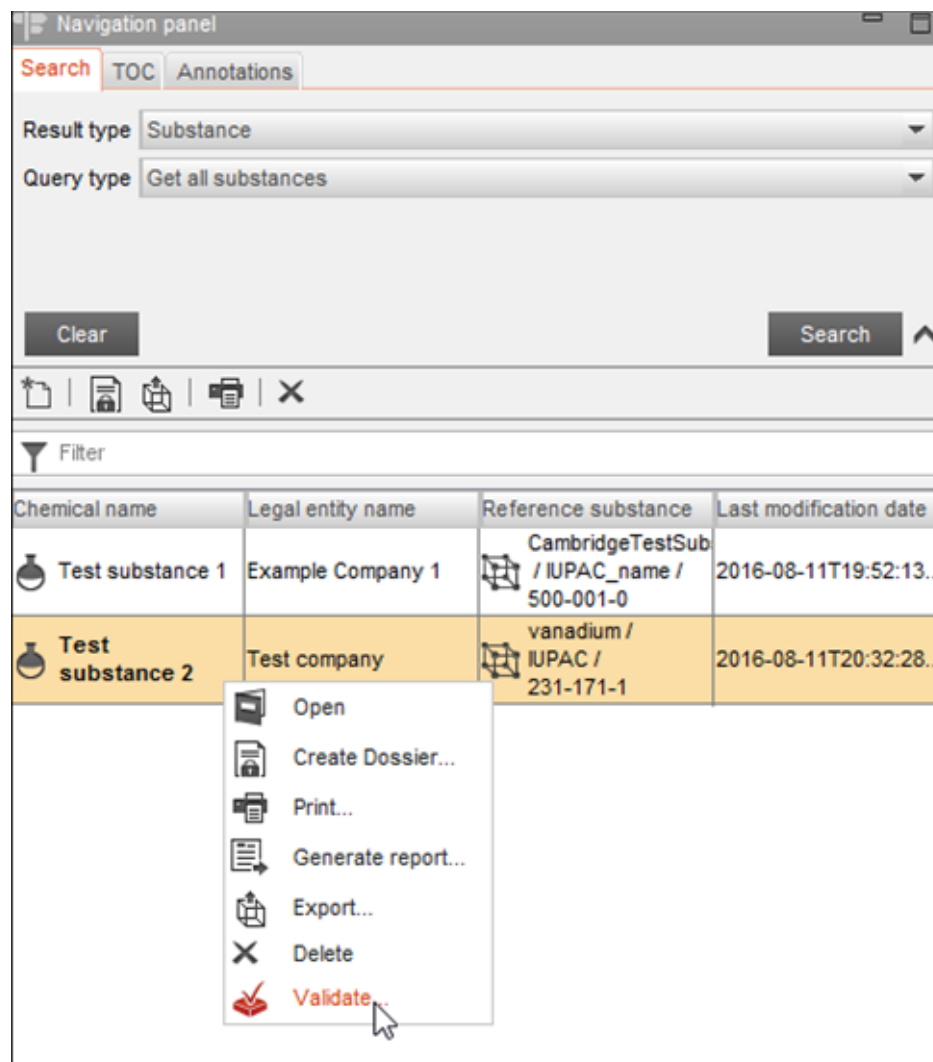


## Creating a complete dossier



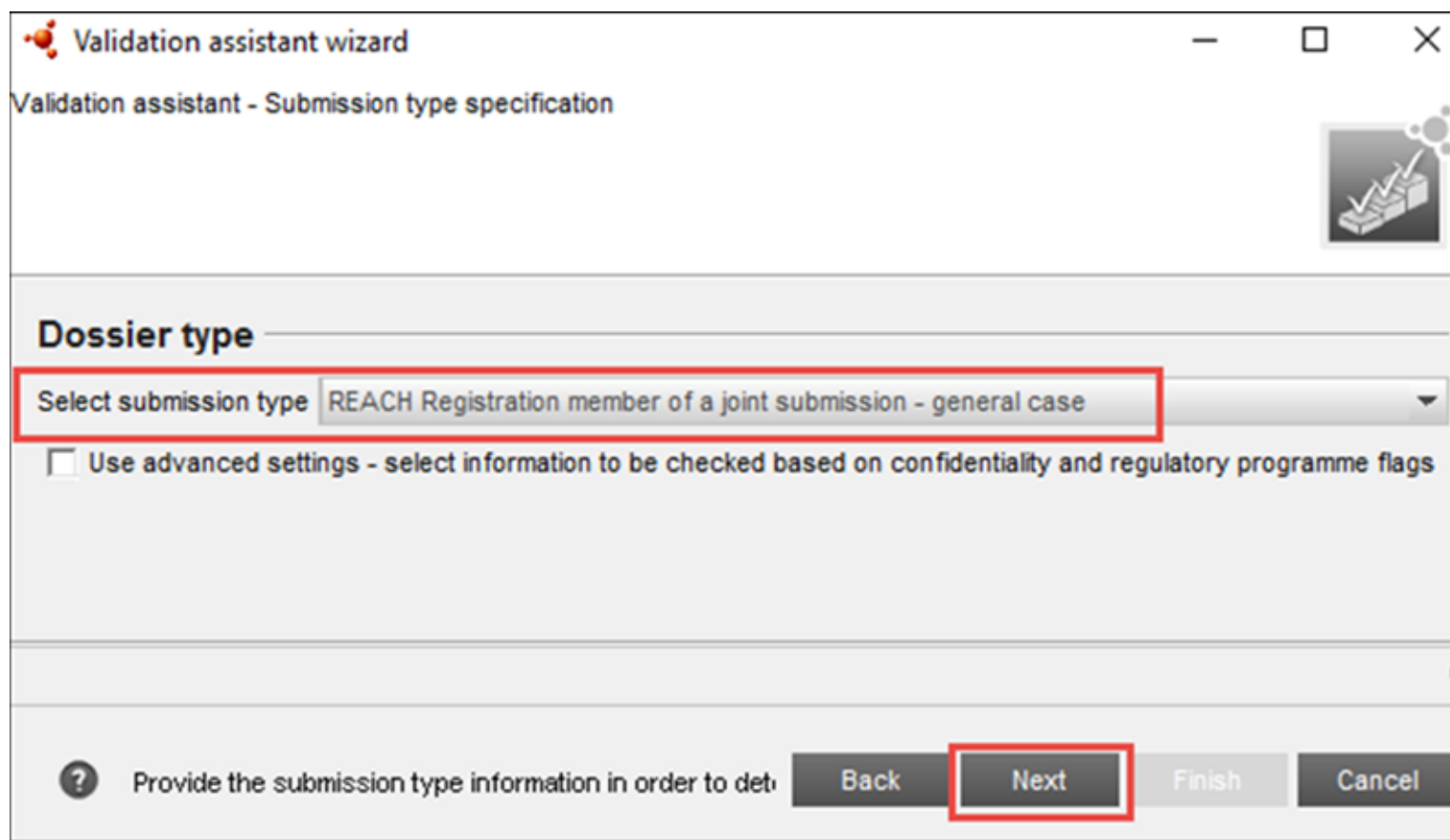
## Validation assistant (1/7)

- Access the substance datasets list
- Right-click on the dataset which you want to check and select 'Validate'



## Validation assistant (2/7)

- Select the submission type



The screenshot shows a window titled "Validation assistant wizard" with the subtitle "Validation assistant - Submission type specification". The window contains a "Dossier type" section with a dropdown menu labeled "Select submission type" showing the selected option "REACH Registration member of a joint submission - general case". Below this is a checkbox labeled "Use advanced settings - select information to be checked based on confidentiality and regulatory programme flags". At the bottom, there is a progress bar and a set of buttons: "Back", "Next", "Finish", and "Cancel". The "Next" button is highlighted with a red box. A red box also highlights the dropdown menu.

Validation assistant wizard

Validation assistant - Submission type specification

**Dossier type**

Select submission type REACH Registration member of a joint submission - general case

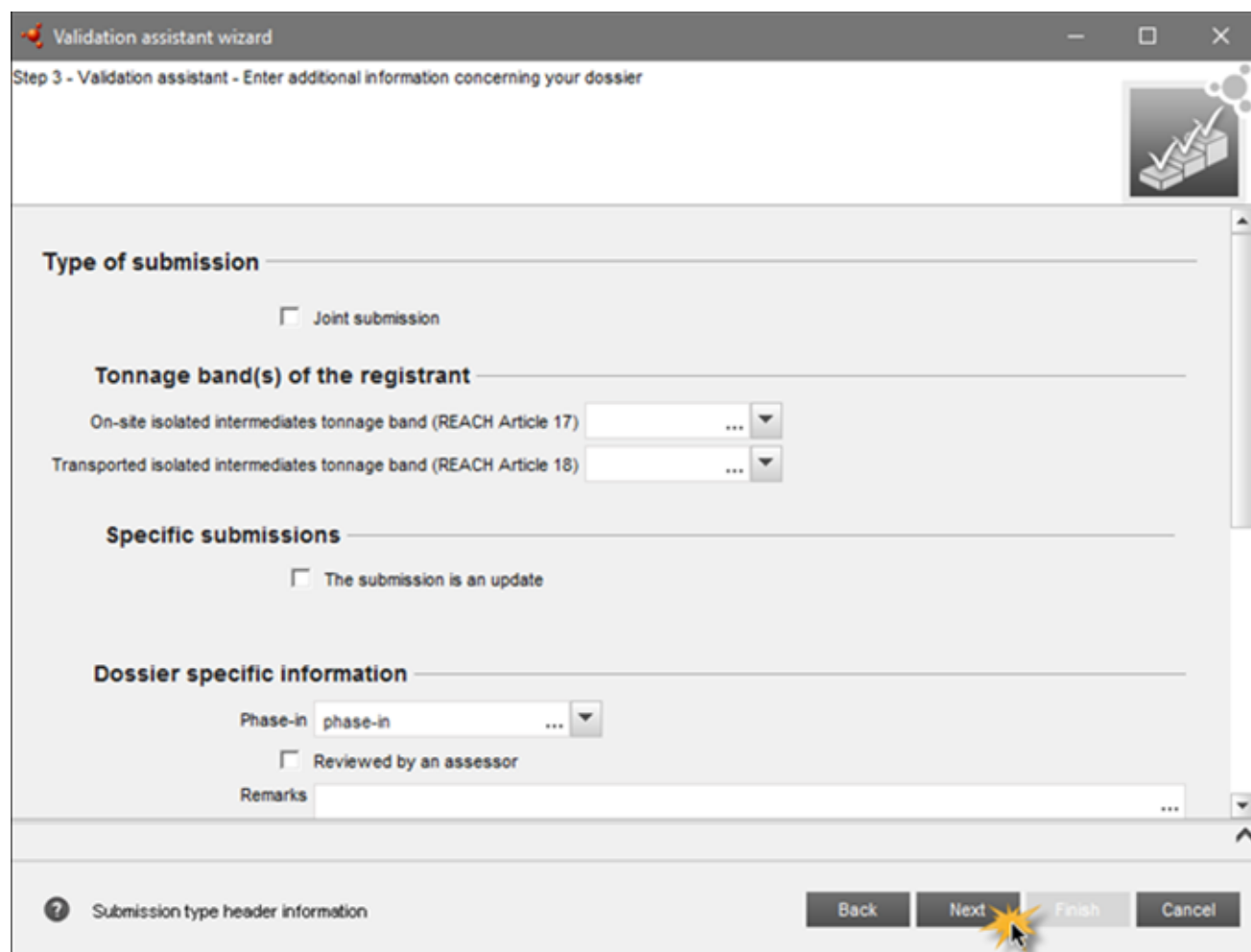
☐ Use advanced settings - select information to be checked based on confidentiality and regulatory programme flags

? Provide the submission type information in order to det

Back Next Finish Cancel

## Validation assistant (3/7)

- Provide the dossier header information to get the correct outcome



The screenshot shows a web-based validation assistant wizard. The title bar reads "Validation assistant wizard". The main heading is "Step 3 - Validation assistant - Enter additional information concerning your dossier". The form is divided into several sections:

- Type of submission**: Includes a checkbox for "Joint submission".
- Tonnage band(s) of the registrant**: Includes two dropdown menus: "On-site isolated intermediates tonnage band (REACH Article 17)" and "Transported isolated intermediates tonnage band (REACH Article 18)".
- Specific submissions**: Includes a checkbox for "The submission is an update".
- Dossier specific information**: Includes a dropdown menu for "Phase-in" (currently set to "phase-in"), a checkbox for "Reviewed by an assessor", and a text area for "Remarks".

At the bottom, there is a progress indicator showing "Submission type header information" as the current step. Navigation buttons include "Back", "Next" (highlighted with a yellow starburst), "Finish", and "Cancel".

## Validation assistant (4/7)

- Correct all the submission checks: both business rules (BR) and technical completeness check rules (TCC)
- Quality checks are recommendations to improve the quality and consistency of your data; not subject to completeness check

**Validation assistant wizard**

Validated entity: TestSubstanceX / TestSubstanceX / TestSubstanceX  
 Time of validation: 2017/05/09 10:57:13  
 Validation scenario: SC01 - Registration, lead >1000, own use 10-100/

**Submission checks (16) !** **Quality checks (2)**

Business rules (2), Completeness check rules (14)

Re-check Open document Open document Copy report Copy selected row(s) Filter: All Rule level: All

Rule	Section number	Section name	Document na...	Message	Rule type	Rule level
BR177	1.2	Composition		Joint submission lead registrants must include at least one composition which describes the collectively agreed boundaries of the registered substance. To this end, indicate in section 1.2 the 'Type of composition' as 'boundary composition of the substance'. Multiple boundary compositions can be provided, if relevant.	Business rule	✖ Failure
TCC_0104_02	1.4	Analytical Information, Analytical determination, (2)	Analytical Information	The 'Analytical information' provided in section 1.4 is incomplete. At least one row must be created in the table 'Analytical determination'. In each row, the following must be provided: - a selection must be made in the 'Purpose of analysis' picklist - at least one selection must be made in the 'Analysis type' picklist - either an attachment must exist in the 'Attached methods/results' field, or a reason for not providing a method/result must be indicated. To this end, make a selection in the field 'Rationale for no results' and insert an explanation in the 'Justification' field, clearly stating the reasons for not providing the information.  Note that the 'Analysis type' field is a multi-select list; if several selections are made, the corresponding results or justifications for all must be provided in the same row. If you select 'other' in any of the	Completeness check	✖ Failure


Validation assistant - Report

Back Next Finish Cancel





## Validation assistant (5/7)





- Location of the failure
- Name of the table
- Number of the row in that table
- Error description

 Validation assistant wizard


Validated entity: TestSubstanceX / TestSubstanceX / TestSubstanceX / 9043-30-5  
 Time of validation: 2017/05/09 20:57:13  
 Validation scenario: SC0144 - Registration, lead >1000, own 10-100/100-1000/>1000, CSR, own GSU

Submission checks (16)  Quality checks (2) 

Business rules (2), Completeness check rules (14)

Re-check  Open document  Open document  Copy report  Copy selected row(s) Filter: All

Rule ^	Section number	Section name	Document na...	Message
TCC_0104_02	1.4	Analytical Information, Analytical determination, (2)	Analytical Information	<p>The 'Analytical information' provided in section 1.4 is incomplete. At least one row must be created in the table 'Analytical determination'. In each row, the following must be provided:</p> <ul style="list-style-type: none"> <li>- a selection must be made in the 'Purpose of analysis' picklist</li> <li>- at least one selection must be made in the 'Analysis type' picklist</li> <li>- either an attachment must exist in the 'Attached methods/results' field, or a reason for not providing a method/result must be indicated. To this end, make a selection in the field 'Rationale for no results' and insert an explanation in the 'Justification' field, clearly stating the reasons for not providing the information.</li> </ul> <p>Note that the 'Analysis type' field is a multi-select list; if several selections are made, the corresponding results or justifications for all must be provided in the same row. If you select 'other:' in any of the picklist fields, the adjacent text field must be filled in.</p>

 Validation assistant - Report Back

## Validation assistant (6/7)

- Refresh the Validation Assistant report after correcting a failure. Click Re-check.

Validation assistant wizard

Validated entity: TestSubstanceX / TestSubstanceX / TestSubstanceX / 9043-30-5

10-1000/>1000, CSR, own GSU

**Re-check** | document | Open document | Copy report | Copy selected row(s) | Filter: All | Rule level: All

Rule	Section number	Section name	Document na...	Message	Rule type	Rule level
TCC_0104_02	1.4	Analytical Information, Analytical determination, (2)	Analytical Information	The 'Analytical information' provided in section 1.4 is incomplete. At least one row must be created in the table 'Analytical determination'. In each row, the following must be provided: - a selection must be made from the list of available substances; - at least one selection must be made from the list of available substances; - either an attachment or a reason must be provided for each selection. In this end, make sure that the selection is correct. Insert an explanation for the reasons for not providing the information.  Note that the 'Analysis type' field must be filled in. When several selections are made, the corresponding reasons for all selections must be provided in the same row. When any of the picklist fields, the adjacent text field must be filled in.	Completeness check	

Right-click on a TCC failure to be automatically directed to the error location in IUCLID

Open document | Copy report | Copy selected row(s)

Validation assistant - Report

Back Next Finish Cancel

# Validation assistant (7/7)

The screenshot displays the ECHA Validation Assistant web application. On the left, a 'Navigation panel' shows search filters: 'Result type' set to 'Substance' and 'Query type' set to 'Get all substances'. Below this is a table with 2 results.

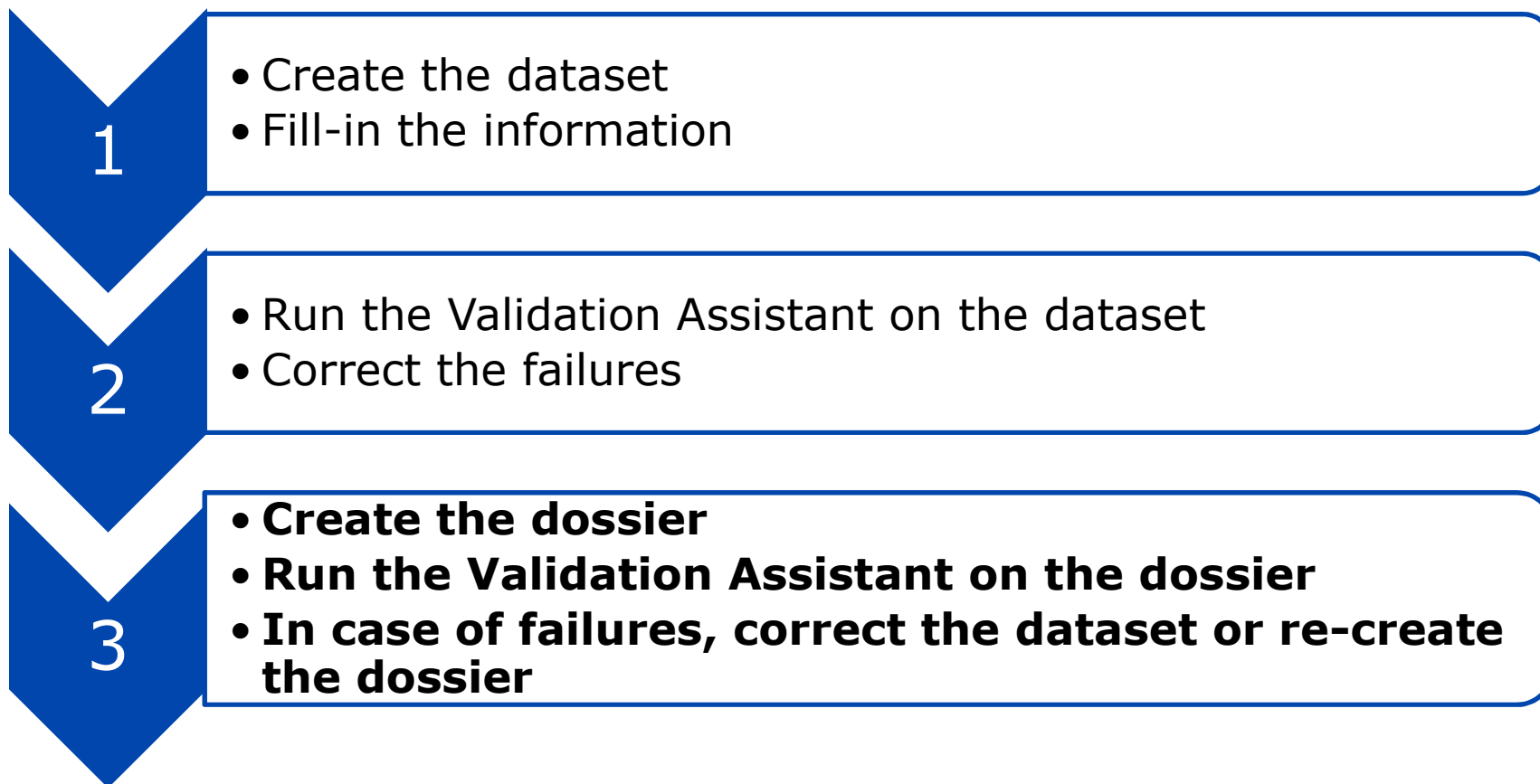
Chemical name	Legal entity	Reference substance	Last modification
TestSubstanceX	Training Company	TestSubstanceX / 9043-30-5 / 944-347-4	2017-05-09T...
TestSubstanceX	Training Company	TestSubstanceX / IUPAC name / 441-430-2	2017-05-09T...

The main area shows the details for 'TestSubstanceX / TestSubstanceX / TestSubstanceX / 9043-30-5'. Fields include 'Substance name' (TestSubstanceX), 'Public name', 'Legal entity flags', 'Legal entity' (Training Company / Helsinki / Finland), 'Third party flags', 'Third party', 'Role in the supply chain', 'Identification of substance', and 'Type of substance'. Below these is an 'Information panel' with 'Type' (Substance), 'UUID' (7be1d159-e702-4585-9e88-7a291cbf9919), and 'Dossier UUID'. A blue callout box with an arrow points to a checkmark icon in the bottom right corner, stating: 'You can (un-)hide the Validation Assistant clicking on this icon'. The bottom right corner also shows a 'SuperUser' profile icon.

# Dossier creation



## Creating a complete dossier



- Select the dataset
- Right-click and create dossier

The screenshot shows the ECHA Dossier creation interface. At the top, there is a 'Navigation panel' with tabs for 'Search', 'TOC', and 'Annotations'. Below these, there are dropdown menus for 'Result type' (set to 'Substance') and 'Query type' (set to 'Get all substances'). A 'Clear' button and a 'Search' button are also present. Below the search area is a toolbar with icons for file operations. A 'Filter' section is visible above a table of substances.

Chemical name	Legal entity name	Reference substance	Last modification date
Test substance 1	Example Company 1	CambridgeTestSub / IUPAC_name / 500-001-0	2016-08-11T19:52:13...
Test substance 2	Test company	vanadium / IUPAC / 231-171-1	2016-08-11T20:32:28...

A context menu is open over the second row of the table, showing the following options:

- Open
- Create Dossier..
- Print...
- Generate report...
- Export...
- Delete
- Validate...

- Select the correct dossier type

The screenshot shows a window titled "Dossier creation wizard" with a close button in the top right corner. The "Substance" tab is selected. Below the tab, the text "Select submission type for a Substance" is displayed. A list of radio button options is shown, with the option "REACH Registration member of a joint submission - general case" selected and highlighted by a red rectangle. Below the list, there is a checkbox labeled "Use advanced settings" which is currently unchecked. At the bottom of the window, there is a status bar with a question mark icon and the text "Select submission type", followed by four buttons: "Back", "Next", "Finish", and "Cancel".

Dossier creation wizard

Substance

Select submission type for a Substance

- ☐ REACH Registration 1 - 10 tonnes, physicochemical requirements
- ☐ REACH Registration 1 - 10 tonnes, standard requirements
- ☐ REACH Registration 10 - 100 tonnes
- ☐ REACH Registration 100 - 1000 tonnes
- ☐ REACH Registration above 1000 tonnes
- ☒ REACH Registration member of a joint submission - general case
- ☐ REACH Registration member of a joint submission - intermediates
- ☐ REACH Registration on-site isolated intermediates above 1 tonne
- ☐ REACH Registration transported isolated intermediates 1 - 1000 tonnes
- ☐ REACH Registration transported isolated intermediates above 1000 tonnes
- ☐ REACH Substance Evaluation

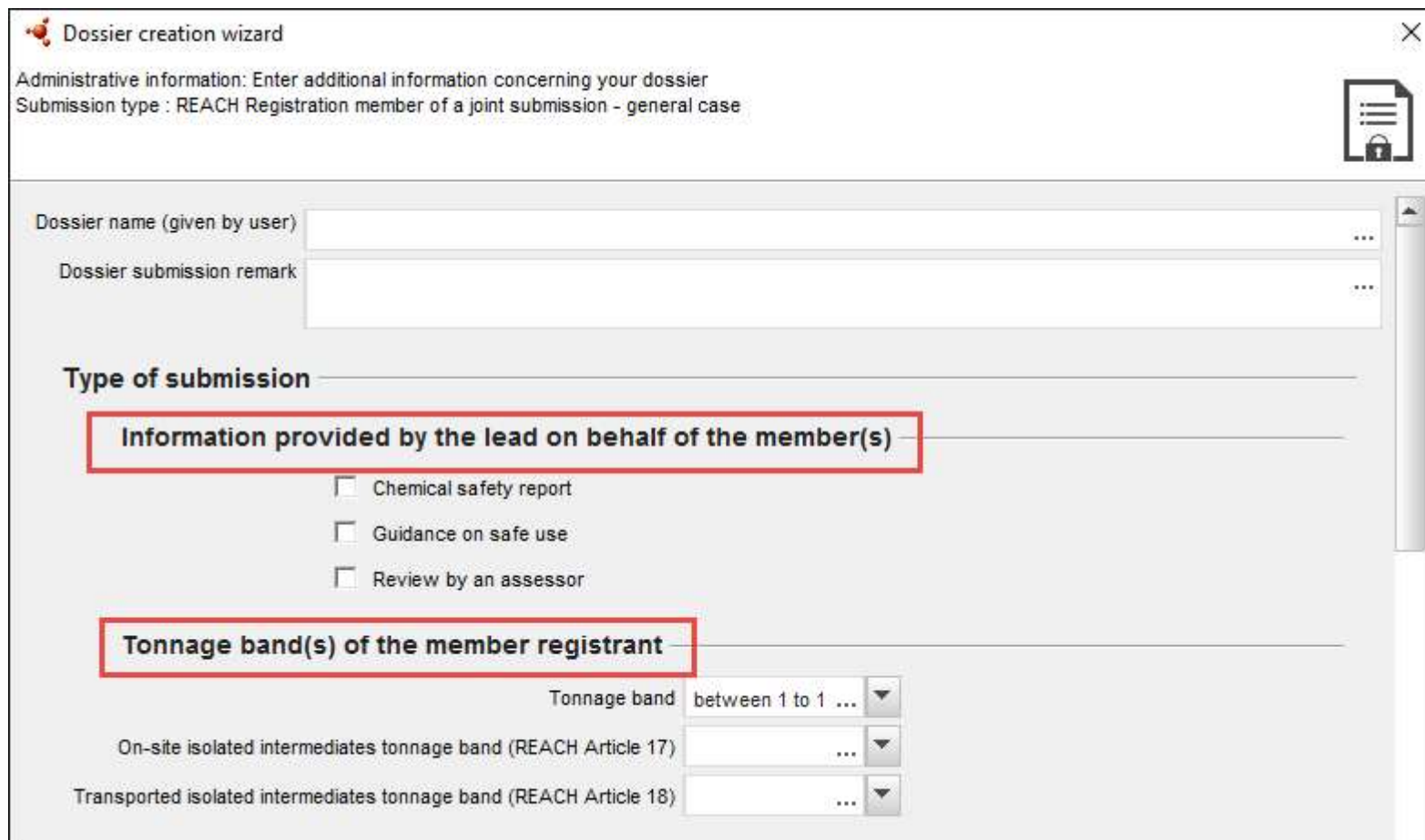
☐ Use advanced settings

? Select submission type

Back Next Finish Cancel

## Dossier creation wizard

- Fill-in the dossier header



The screenshot shows the 'Dossier creation wizard' window. At the top, it says 'Administrative information: Enter additional information concerning your dossier' and 'Submission type : REACH Registration member of a joint submission - general case'. Below this, there are two text input fields: 'Dossier name (given by user)' and 'Dossier submission remark'. The 'Type of submission' section has a dropdown menu with 'Information provided by the lead on behalf of the member(s)' selected. Below this are three checkboxes: 'Chemical safety report', 'Guidance on safe use', and 'Review by an assessor'. The 'Tonnage band(s) of the member registrant' section has a dropdown menu with 'between 1 to 1 ...' selected. Below this are two more dropdown menus: 'On-site isolated intermediates tonnage band (REACH Article 17)' and 'Transported isolated intermediates tonnage band (REACH Article 18)'. The interface is in English and has a clean, professional look.

Dossier creation wizard

Administrative information: Enter additional information concerning your dossier  
Submission type : REACH Registration member of a joint submission - general case

Dossier name (given by user)

Dossier submission remark

Type of submission

☐ Chemical safety report

☐ Guidance on safe use

☐ Review by an assessor

Tonnage band(s) of the member registrant

Tonnage band


On-site isolated intermediates tonnage band (REACH Article 17)


Transported isolated intermediates tonnage band (REACH Article 18)



## Dossier creation wizard

- Fill-in the dossier header for update

 Dossier creation wizard ✕

Administrative information: Enter additional information concerning your dossier  
Submission type : REACH Registration member of a joint submission - general case 

---

**Specific submissions**

☒ The submission is an update

Last submission number AB12345-67 ...

**Reason for updating**

☒ Further to a request/decision from a regulatory body

CCH-C-12345689-01

Number CCH-C-12345689-01 ...

Remarks ...

☒ Spontaneous update

change in classification and labelling

Justification change in classificat ... Other ...

Remarks ...

## Open the dossier

The screenshot displays the IUCLID 6 software interface. At the top, the title bar reads "IUCLID 6" with standard window controls. Below it is a menu bar (File, Edit, User, Admin, Help) and a toolbar. The main workspace is divided into three panels:

- Navigation panel (left):** Shows a tree structure with "R\_JS\_MBER / SUBSTANCE : Test s" and "Test substance 1 / IUPAC\_nam".
- Dossier header (center):** Contains fields for "Dossier submission type" (Name: REACH Registration member of a joint submission - general case; Version: reach 2.0; Dossier name: Test dossier) and "Dossier subject" (Dossier subject: Test substance 1 / IUPAC\_name; Submitting legal entity; Dossier creation date/time).
- Information panel (bottom):** Includes tabs for "Information", "Clipboard manager", "Attachments", "Modification history", and "Annotations". The "Information" tab is active, showing "Type: Dossier", "UUID: 4434153b-6a71-497c-9e6f-e3f669f6a451", and "Dossier UUID: 4434153b-6a71-497c-9e6f-e3f669f6a451".

A red callout box with the text "Copy and paste the dossier UUID here. Press Enter to open the dossier." points to the search bar at the top right, which contains the UUID "4434153b-6a71-497c-9e6f-e3f669f6a451". A dashed arrow points from the "Dossier UUID" field in the information panel to the search bar.

## Validate the final dossier

The screenshot shows the IUCLID 6 software interface. The main window displays the 'Dossier header' and 'Dossier subject' sections. The 'Dossier header' section includes fields for 'Dossier submission type', 'Name', 'Version', 'Dossier name (given by user)', 'Dossier subject', 'Submitting legal entity', 'Dossier creation date/time', and 'Dossier submission remark'. The 'Dossier subject' section includes fields for 'Dossier subject' and 'Submitting legal entity'. A table at the bottom left lists dossiers, with one entry highlighted in yellow. A right-click context menu is open over this entry, showing options like 'Open', 'Print...', 'Generate report...', 'Export...', 'Delete', 'Validate...', and 'Dissemination preview...'. A red callout box points to the 'Validate...' option with the text: 'Right-click on the final dossier and run the validation assistant on it before exporting the dossier.'

Dossier Name	Subject Name	Creation date
R_JS_MBER / SUBSTANCE : Test substance 1 / IUPAC_name / 2016-09-06 / Test dossier	Test substance 1	2016-09-06T10:16:07.956+03:00

Displaying 1 result(s).

## Export the dossier

The screenshot displays the IUCLID 6 software interface. On the left, the 'Navigation panel' shows a search for 'Dossier' with the query type 'Get all dossiers'. Below this, a table lists the search results. A context menu is open over the first result, with the 'Export' option highlighted. A red callout bubble points to the 'Export' option with the text 'Your dossier is ready to be exported.'.

Dossier Name	Subject Name	Creation date
R_JS_MBER / SUBSTANCE : Test substance 1 / IUPAC_name / 2016-09-06 / Test dossier	Test substance 1	2016-09-06T10:16:07.956+03:00

Displaying 1 result(s).

The right-hand side of the interface shows the 'Dossier header' and 'Dossier subject' information. The 'Dossier header' section includes fields for Name, Version, Dossier name (given by user), and Dossier submission type. The 'Dossier subject' section includes fields for Dossier subject, Submitting legal entity, Dossier creation date/time, and Dossier submission remark.

The bottom right corner shows the 'Information panel' with fields for Type, UUID, and Dossier UUID.

# Technical Completeness Check



## Technical Completeness Check (TCC)

- The technical completeness check ensures that all the required elements are in the registration dossier as per Article 20(2) of REACH Regulation
- It is performed on each registration dossier submitted to ECHA – both initial and update submissions
- It consists of automated checks that can be replicated by the Validation Assistant and manual checks performed by ECHA staff

### TCC passes:

- Message from ECHA in REACH-IT
- If the payment (if invoice was issued) is received on time, your submission is complete and a positive decision is sent to you via REACH-IT
  - **Initial submission:** registration number assigned
  - **Update of existing registration:** ECHA will accept the updated information in the database

### Failure of TCC 1<sup>st</sup> time:

- Letter in the REACH-IT task box
- **Both initial submission and update of existing registration:**
  - Only one possibility to submit a complete dossier
  - Deadline specified in the letter



### Failure of TCC 2<sup>nd</sup> time:

- Negative decision in the REACH-IT task box, informing that submission is rejected
- **Initial submission:**
  - Registration number not granted
  - Fee is not refunded (if invoice was issued)
- **Update of existing registration:**
  - The updated information is not accepted into the ECHA database and subsequent processes
  - You keep your registration number

## Manual checks at completeness check

- As of 21 June 2016, the automated completeness check was complemented with additional manual checks by ECHA staff of certain elements of the registration dossier that cannot be checked automatically
- Not displayed by the Validation assistant
- Document with information on manual checks area is published on the ECHA website, under Support -> Manuals:
  - <https://echa.europa.eu/manuals>

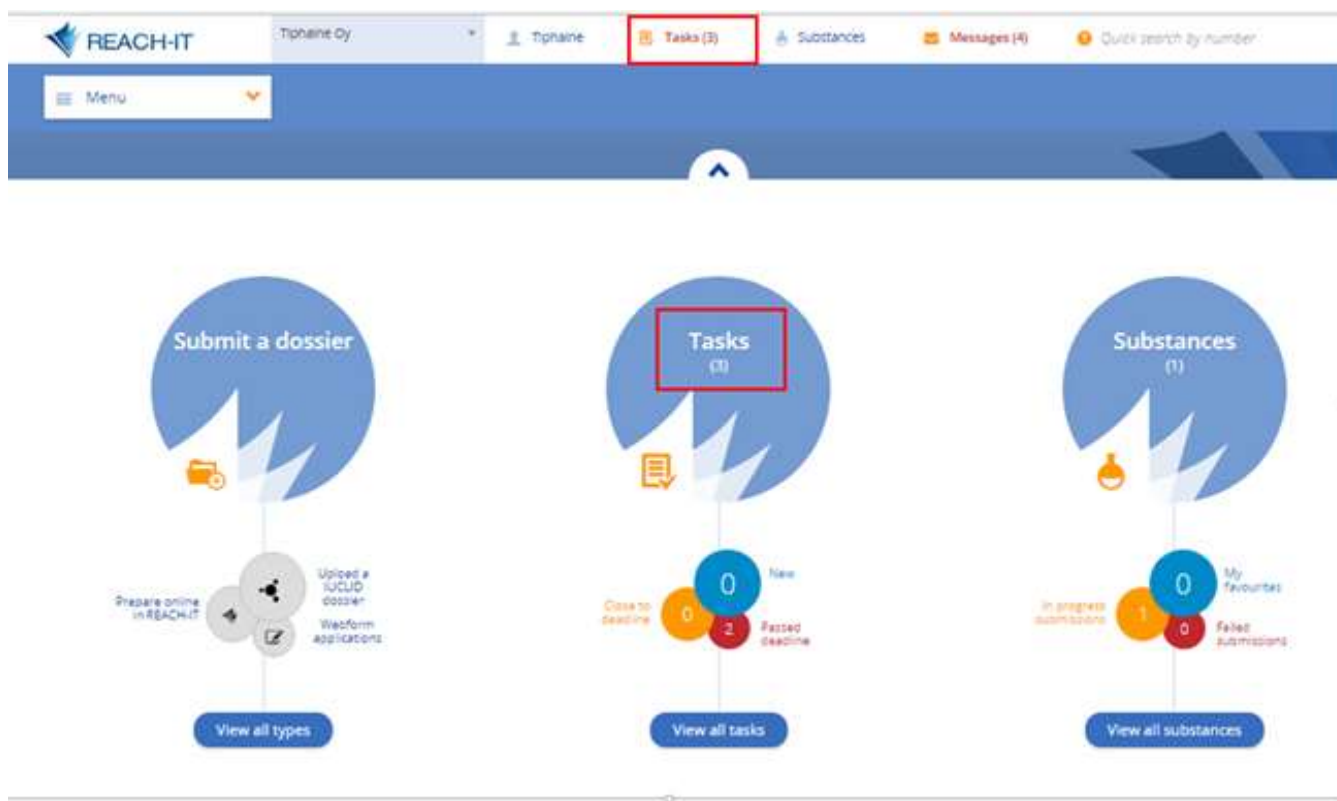
1. **Substance identification** (IUPAC name, composition, manufacturing process description of UVCB substances, analytical information)
2. Justification for **waiving** of standard information requirements (physicochemical, environmental fate and hazard information, toxicological and ecotoxicological information)
3. **Testing proposals** on vertebrate animals (presence of considerations for adaptation possibilities)
4. Justification for waiving of **Chemical safety report**.

# Summary



- Be clear and transparent
- When providing a justification, always summarise the main points of the justification in the expected field, and if needed refer to a section/field where more details are given – note that reference alone is not enough
- Use the correct field to provide the information
- In case your submission has failed TCC, refer to the letter and read through the failure message in Annex 1 carefully
- To avoid introducing new completeness check failures it is not advisable to update any other parts of the dossier than those listed in Annex 1
- Annex 2 of the communication letter provides technical advice on how to update your dossier

- In case of technical completeness check failure, you will receive a new Task in REACH-IT



- Assign a relevant contact person in REACH-IT
- Make sure
  - Contact is responsible for the submission
  - Person can be contacted via phone/email
  - Your contact details up to date

The screenshot shows the 'Manage company' interface in REACH-IT. The top navigation bar includes 'Menu', 'Home', and 'Manage company'. The main content area has several sections: 'Company information' with 'Export' and 'Update' buttons; 'Company size'; 'Email notification settings' with an 'Add new notification address' button; and 'Contacts' with an 'Add new contact' button highlighted by a red rectangle. Below these sections is a search bar labeled 'Locate' with a placeholder text 'Contact (first or last name):' and a note 'Please enter a minimum of three characters'. At the bottom are 'Search' and 'Clear' buttons.

- We may contact you by phone
  - Remind you the technical completeness check deadline is approaching
  - Assist you with complex failures
- Summary email always sent after the call

We are here to help you.



- Webinar on the completeness check process
  - [Completeness check - preparing a registration dossier that can be successfully submitted](#)  
April 2017
  - [REACH 2018 webinar: Completeness check - preparing a dossier and the most common failures](#)  
March 2018
  - [REACH 2018 questions and answers - everything you want to know about registering successfully](#)  
19 April 2018, 11:00-12:30 EET (Helsinki time)

**IUCLID Cloud**



## IUCLID Cloud (1/2)

- A new platform for delivery of Business Information systems in ECHA
- The first service focuses on IUCLID



IUCLID Cloud Trial



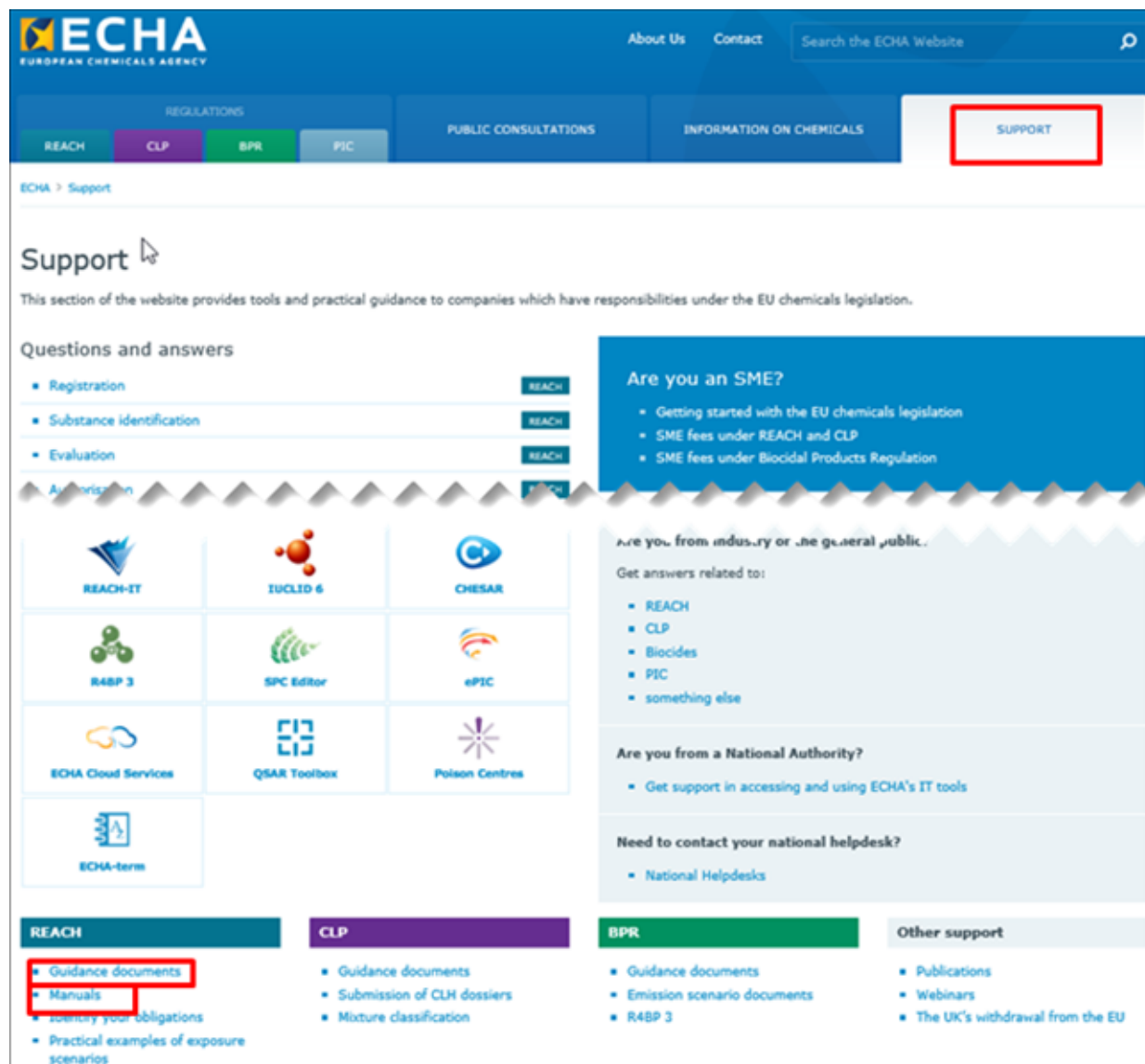
IUCLID Cloud for SMEs

## IUCLID Cloud (2/2)

- Aimed for SME users to prepare registration dossiers under REACH for 2018 deadline
- Work fully on a web browser without installing anything locally
- Automated backup and data recovery in case of data loss
- Immediate subscription activation
- Up to 1 GB of secure data storage
- Target 24/7 availability except for pre-defined maintenance periods occurring outside the working hours
- Controlled service updates with every new release
- Facilitate working anywhere (easier remote access) and delegation to consultants
- IUCLID Helpdesk support during office hours
- Integrated help and support for dossier preparation

# Support and guidance





**ECHA**  
EUROPEAN CHEMICALS AGENCY

About Us Contact Search the ECHA Website

REGULATIONS  
REACH CLP BPR PIC PUBLIC CONSULTATIONS INFORMATION ON CHEMICALS **SUPPORT**

ECHA > Support

## Support

This section of the website provides tools and practical guidance to companies which have responsibilities under the EU chemicals legislation.

### Questions and answers

- Registration **REACH**
- Substance identification **REACH**
- Evaluation **REACH**
- Authorisation **REACH**

### Are you an SME?

- Getting started with the EU chemicals legislation
- SME fees under REACH and CLP
- SME fees under Biocidal Products Regulation

### Are you from industry or the general public?

Get answers related to:

- REACH
- CLP
- Biocides
- PIC
- something else

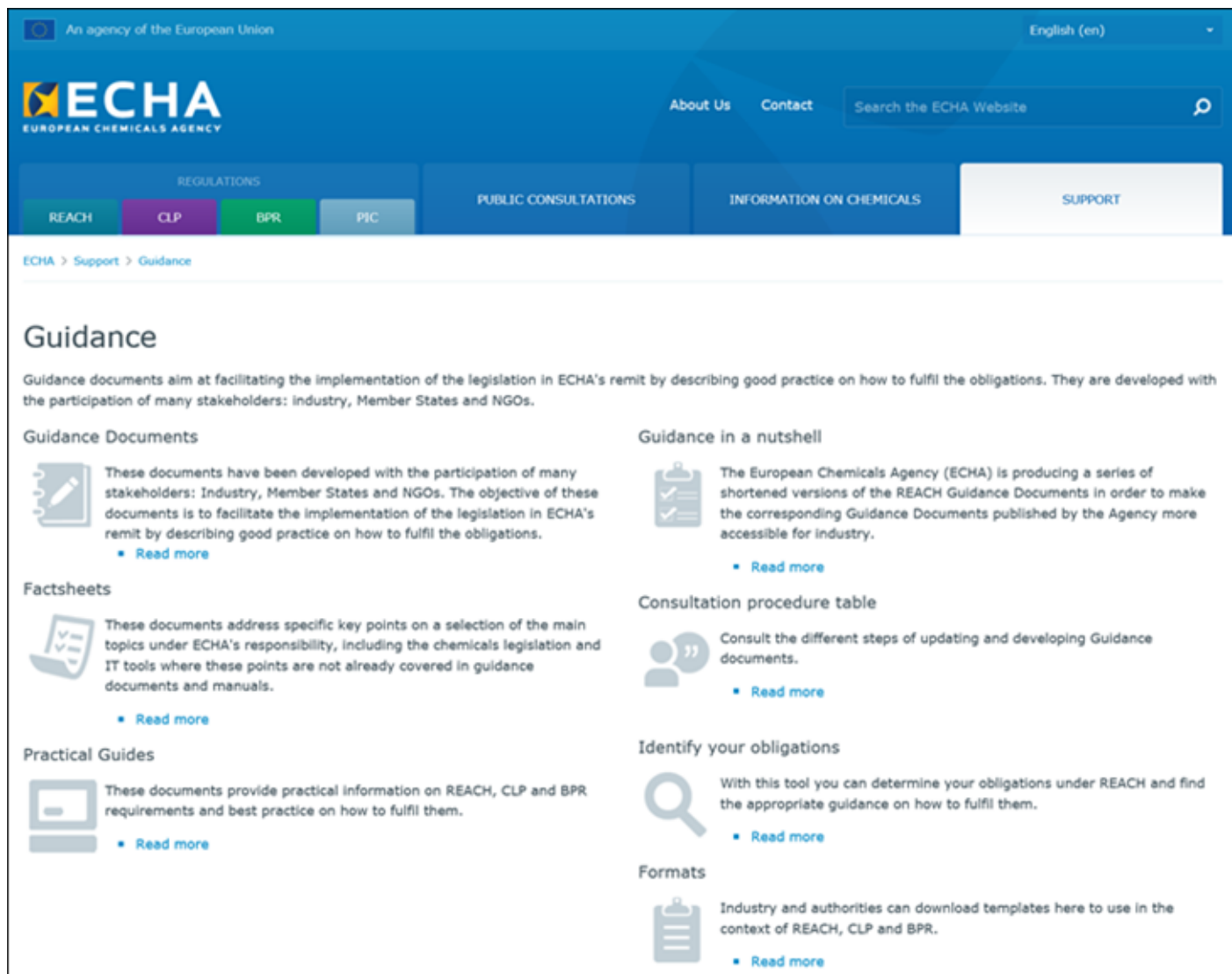
### Are you from a National Authority?

- Get support in accessing and using ECHA's IT tools

### Need to contact your national helpdesk?

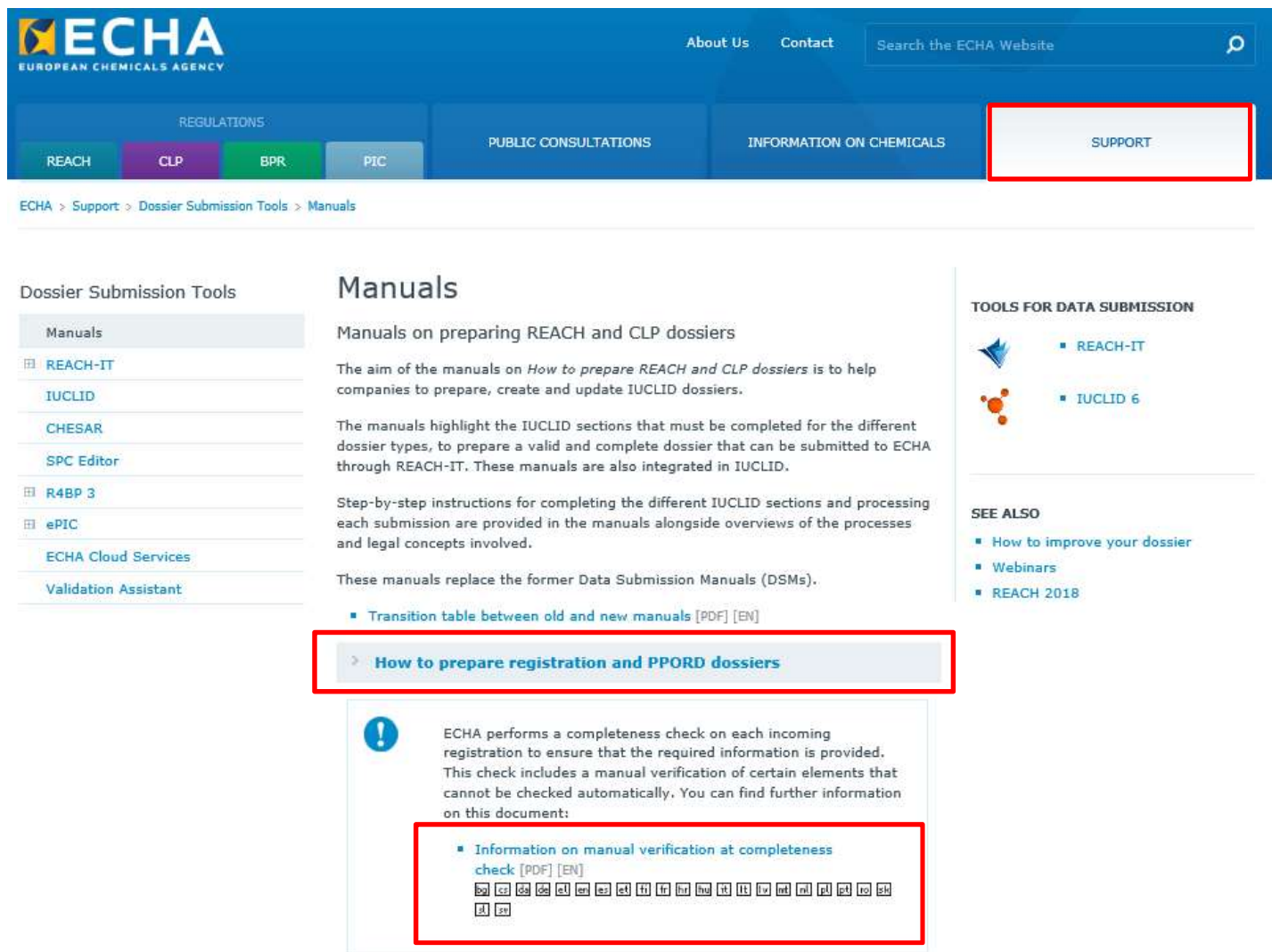
- National Helpdesks

REACH	CLP	BPR	Other support
<ul style="list-style-type: none"> <li>Guidance documents</li> <li>Manuals</li> <li>Verify your obligations</li> <li>Practical examples of exposure scenarios</li> </ul>	<ul style="list-style-type: none"> <li>Guidance documents</li> <li>Submission of CLH dossiers</li> <li>Mixture classification</li> </ul>	<ul style="list-style-type: none"> <li>Guidance documents</li> <li>Emission scenario documents</li> <li>R4BP 3</li> </ul>	<ul style="list-style-type: none"> <li>Publications</li> <li>Webinars</li> <li>The UK's withdrawal from the EU</li> </ul>



The screenshot shows the ECHA website's 'Guidance' page. The header includes the ECHA logo, navigation links for 'About Us' and 'Contact', a search bar, and a language selector set to 'English (en)'. A secondary navigation bar contains categories: 'REGULATIONS' (with sub-links for REACH, CLP, BPR, and PIC), 'PUBLIC CONSULTATIONS', 'INFORMATION ON CHEMICALS', and 'SUPPORT'. The main content area is titled 'Guidance' and includes a brief description of guidance documents. Below this, there are eight sections arranged in two columns, each with an icon, a description, and a 'Read more' link:

- Guidance Documents**: These documents have been developed with the participation of many stakeholders: Industry, Member States and NGOs. The objective of these documents is to facilitate the implementation of the legislation in ECHA's remit by describing good practice on how to fulfil the obligations. [Read more](#)
- Guidance in a nutshell**: The European Chemicals Agency (ECHA) is producing a series of shortened versions of the REACH Guidance Documents in order to make the corresponding Guidance Documents published by the Agency more accessible for industry. [Read more](#)
- Factsheets**: These documents address specific key points on a selection of the main topics under ECHA's responsibility, including the chemicals legislation and IT tools where these points are not already covered in guidance documents and manuals. [Read more](#)
- Consultation procedure table**: Consult the different steps of updating and developing Guidance documents. [Read more](#)
- Practical Guides**: These documents provide practical information on REACH, CLP and BPR requirements and best practice on how to fulfil them. [Read more](#)
- Identify your obligations**: With this tool you can determine your obligations under REACH and find the appropriate guidance on how to fulfil them. [Read more](#)
- Formats**: Industry and authorities can download templates here to use in the context of REACH, CLP and BPR. [Read more](#)



**ECHA**  
EUROPEAN CHEMICALS AGENCY

About Us Contact Search the ECHA Website

REGULATIONS: REACH CLP BPR PIC PUBLIC CONSULTATIONS INFORMATION ON CHEMICALS **SUPPORT**

ECHA > Support > Dossier Submission Tools > Manuals

**Dossier Submission Tools**

- Manuals
- REACH-IT
- IUCLID
- CHESAR
- SPC Editor
- R4BP 3
- ePIC
- ECHA Cloud Services
- Validation Assistant

## Manuals

### Manuals on preparing REACH and CLP dossiers

The aim of the manuals on *How to prepare REACH and CLP dossiers* is to help companies to prepare, create and update IUCLID dossiers.

The manuals highlight the IUCLID sections that must be completed for the different dossier types, to prepare a valid and complete dossier that can be submitted to ECHA through REACH-IT. These manuals are also integrated in IUCLID.

Step-by-step instructions for completing the different IUCLID sections and processing each submission are provided in the manuals alongside overviews of the processes and legal concepts involved.

These manuals replace the former Data Submission Manuals (DSMs).

- Transition table between old and new manuals [PDF] [EN]
- > How to prepare registration and PPORD dossiers**

**!** ECHA performs a completeness check on each incoming registration to ensure that the required information is provided. This check includes a manual verification of certain elements that cannot be checked automatically. You can find further information on this document:

- Information on manual verification at completeness check [PDF] [EN]**

bg cz da de el en es et fi fr hr hu it lt lv ml nl pl pt ro sk sl sv



The screenshot displays the IUCLID 6 software interface. At the top, the menu bar includes File, Edit, Users, Admin, Plugins, and Help. The Help menu is highlighted with a red box, and a green box above it says "Or press F1". Below the menu bar, the main window shows a "Navigation panel" on the left with a "Text filter" and a list of sections. The "Help Navigator" window is open on the right, showing a "Contents" list with "REACH Registration and PPORD" highlighted by a red box. The main content area of the Help Navigator displays the text for "1. Functionalities of IUCLID 6".

File Edit Users Admin Plugins **Help** Or press F1 (Search by UUID)

Navigation panel

Search Components Annotations **TOC**

REACH Registration 10 - 100 tonnes

Text filter

- 0 Related information
- 1 General information**
- 2 Classification & Labelling and PBT assessment
- 3 Manufacture, use and exposure
- 4 Physical and chemical properties
- 5 Environmental fate and pathways
- 6 Ecotoxicological information
- 7 Toxicological information
- 8 Analytical methods
- 11 Guidance on safe use
- 12 Literature search
- 13 Assessment reports
- 14 Information requirements


Help Navigator

File View Go Tools Help

Contents

- Welcome
- Functionalities of IUCLID 6
- REACH Inquiry
- REACH Registration and PPORD**
- REACH Application for Authorisation
- REACH Downstream user report
- REACH Notification of substance in articles
- CLP Alternative name request
- CLP Classification and labelling notification
- BPR Preparing a dossier
- Glossary
- Documents in IUCLID

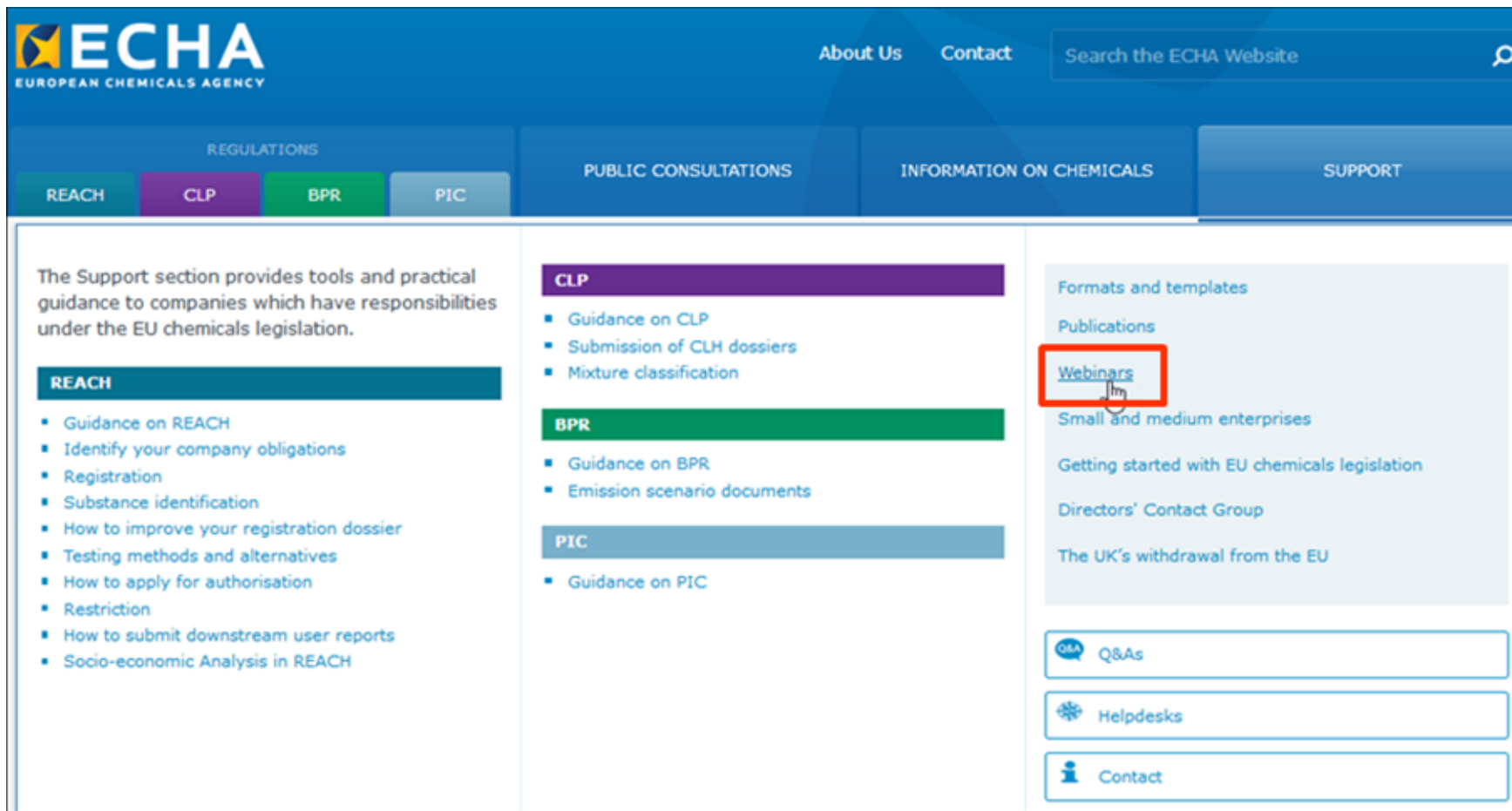
1. **Functionalities of IUCLID 6**

This is a conventional software manual that describes the functions available in IUCLID 6. In general, the content is not specific to any particular legislation. In the application interface, clicking on a help icon, , opens this manual at the start of the most relevant section it can find. This manual is also available in PDF format on the IUCLID 6 website, in the original [English](#), and translated into the following 22 languages: [Bulgarian](#), [Croatian](#), [Czech](#), [Danish](#), [Dutch](#), [Estonian](#), [Finnish](#), [French](#), [German](#), [Greek](#), [Hungarian](#), [Italian](#), [Latvian](#), [Lithuanian](#), [Maltese](#), [Polish](#), [Portuguese](#), [Romanian](#), [Slovak](#), [Slovenian](#), [Spanish](#) and [Swedish](#).

2. **Step by step guides on how to prepare data for submission to ECHA under specific legislations.**

If you are using IUCLID 6 to prepare data for submission to ECHA under a particular legislation, and you are not sure what to do next, it is recommended that you start by reading

☐ Manufacturer  
☐ Importer  
☒ Only representative  
☐ Downstream user



The screenshot displays the ECHA website interface. At the top, the ECHA logo and name are on the left, and navigation links for 'About Us' and 'Contact' are on the right, along with a search bar labeled 'Search the ECHA Website'. Below this is a main navigation bar with categories: 'REGULATIONS' (containing 'REACH', 'CLP', 'BPR', and 'PIC'), 'PUBLIC CONSULTATIONS', 'INFORMATION ON CHEMICALS', and 'SUPPORT'. The 'SUPPORT' section is expanded, showing a list of resources: 'The Support section provides tools and practical guidance to companies which have responsibilities under the EU chemicals legislation.', 'REACH' (with a list of 8 items), 'CLP' (with 3 items), 'BPR' (with 2 items), and 'PIC' (with 1 item). On the right side of the 'SUPPORT' section, there is a list of additional resources: 'Formats and templates', 'Publications', 'Webinars' (highlighted with a red box and a mouse cursor), 'Small and medium enterprises', 'Getting started with EU chemicals legislation', 'Directors' Contact Group', and 'The UK's withdrawal from the EU'. At the bottom right, there are three boxes for 'Q&As', 'Helpdesks', and 'Contact'.

**ECHA**  
EUROPEAN CHEMICALS AGENCY

About Us Contact Search the ECHA Website

REGULATIONS  
REACH CLP BPR PIC

PUBLIC CONSULTATIONS INFORMATION ON CHEMICALS SUPPORT

The Support section provides tools and practical guidance to companies which have responsibilities under the EU chemicals legislation.

**REACH**

- Guidance on REACH
- Identify your company obligations
- Registration
- Substance identification
- How to improve your registration dossier
- Testing methods and alternatives
- How to apply for authorisation
- Restriction
- How to submit downstream user reports
- Socio-economic Analysis in REACH

**CLP**

- Guidance on CLP
- Submission of CLH dossiers
- Mixture classification

**BPR**

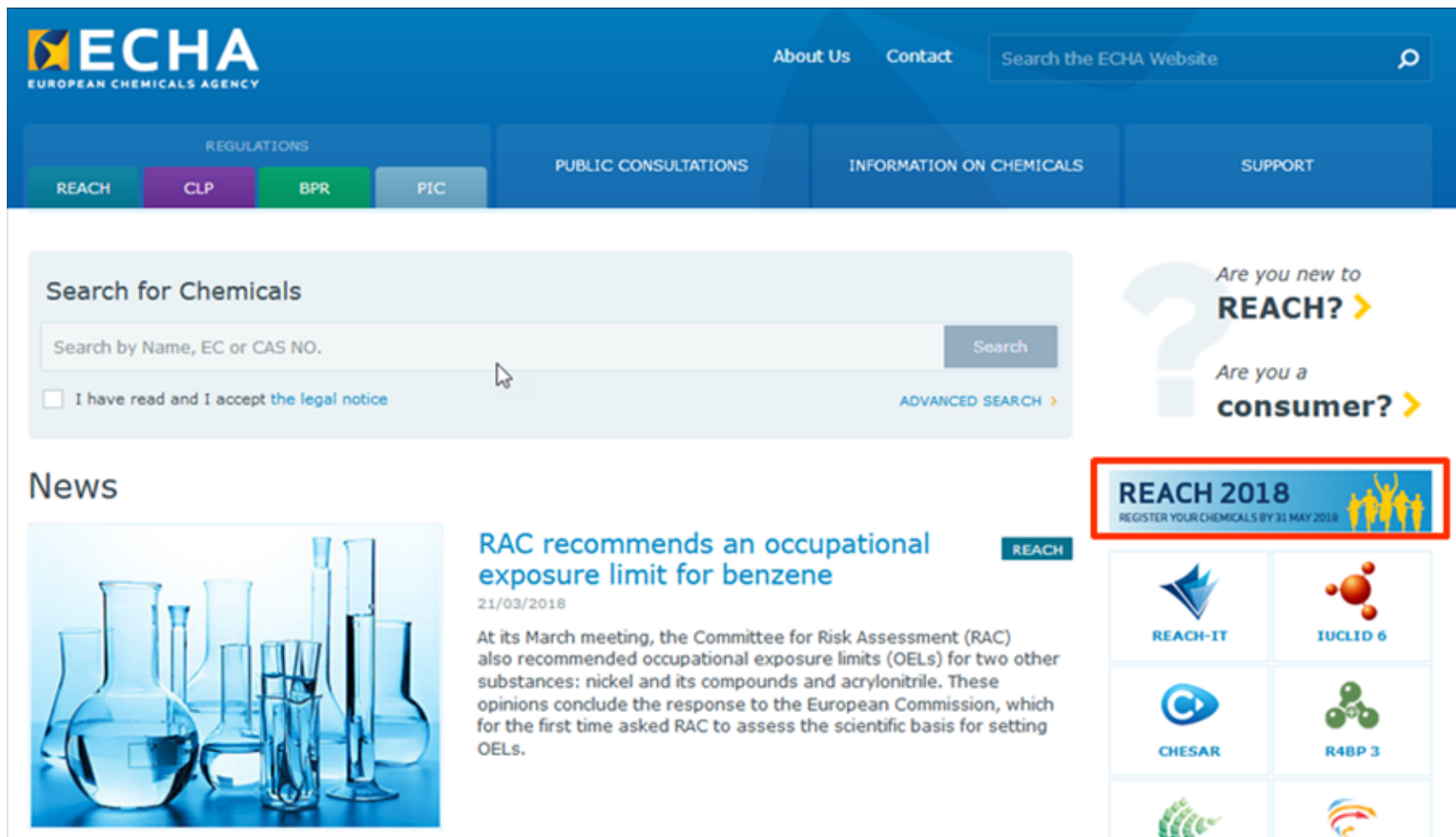
- Guidance on BPR
- Emission scenario documents

**PIC**

- Guidance on PIC

Formats and templates  
Publications  
**Webinars**  
Small and medium enterprises  
Getting started with EU chemicals legislation  
Directors' Contact Group  
The UK's withdrawal from the EU

Q&As  
Helpdesks  
Contact



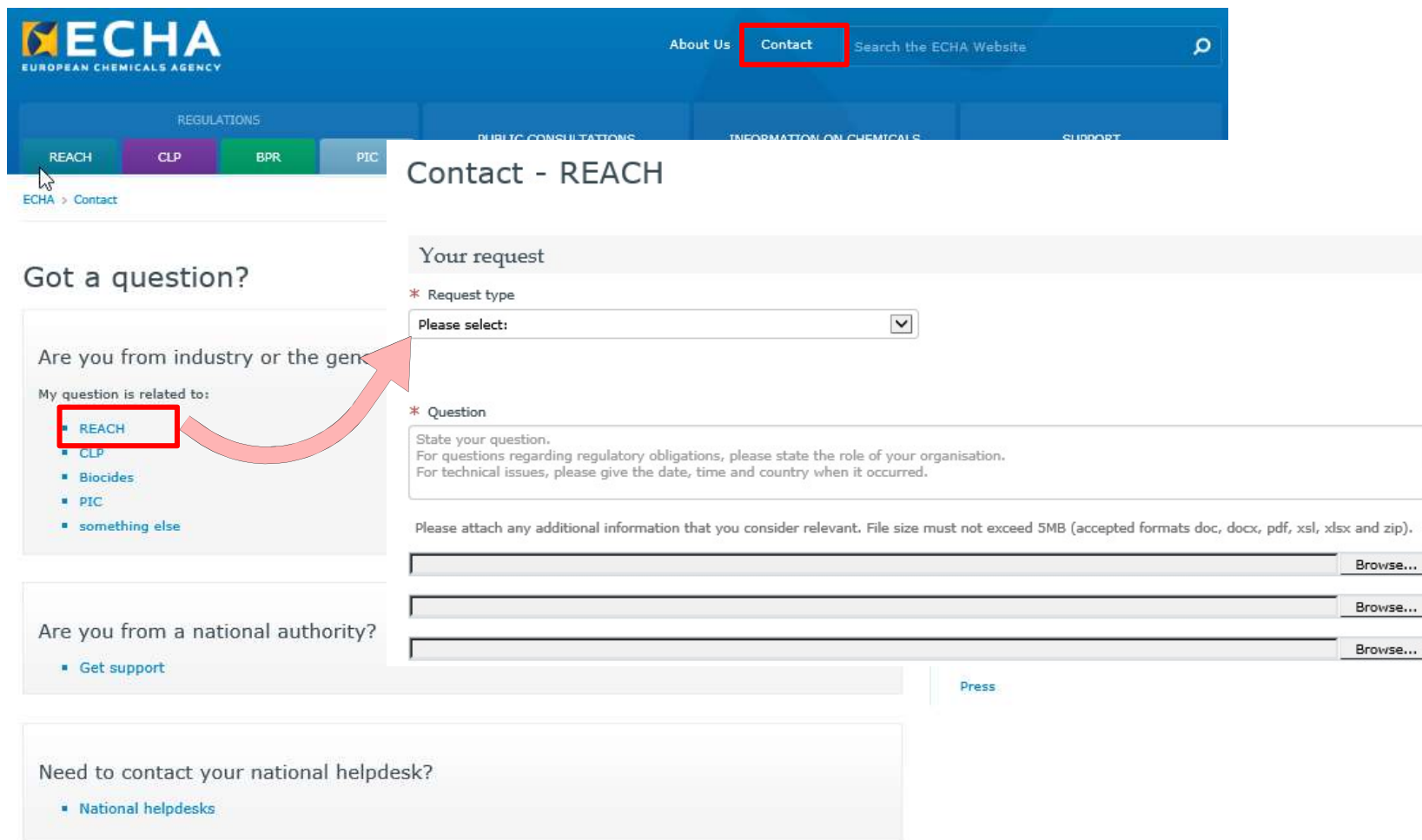
The screenshot shows the ECHA website interface. At the top, the ECHA logo and navigation links (About Us, Contact) are visible. A search bar is present with the text "Search the ECHA Website". Below this, a menu bar highlights "REGULATIONS" with sub-links for REACH, CLP, BPR, and PIC. Other menu items include "PUBLIC CONSULTATIONS", "INFORMATION ON CHEMICALS", and "SUPPORT".

The main content area features a "Search for Chemicals" section with a search bar (placeholder: "Search by Name, EC or CAS NO."), a "Search" button, and a checkbox for "I have read and I accept the legal notice". An "ADVANCED SEARCH" link is also available.

To the right of the search section, there are two promotional links: "Are you new to REACH?" and "Are you a consumer?".

The "News" section on the left displays a headline: "RAC recommends an occupational exposure limit for benzene" dated 21/03/2018. The accompanying text states: "At its March meeting, the Committee for Risk Assessment (RAC) also recommended occupational exposure limits (OELs) for two other substances: nickel and its compounds and acrylonitrile. These opinions conclude the response to the European Commission, which for the first time asked RAC to assess the scientific basis for setting OELs."

On the right side, a red-bordered box highlights the "REACH 2018" banner, which includes the text "REGISTER YOUR CHEMICALS BY 31 MAY 2018". Below this banner is a grid of logos for various initiatives: REACH-IT, IUCLID 6, CHESAR, and R4BP 3, along with other smaller logos.



**ECHA**  
EUROPEAN CHEMICALS AGENCY

About Us **Contact** Search the ECHA Website

REGULATIONS: REACH, CLP, BPR, PIC

PUBLIC CONSULTATIONS

INFORMATION ON CHEMICALS

SUPPORT

ECHA > Contact

## Contact - REACH

Got a question?

Are you from industry or the general public?

My question is related to:

- REACH
- CLP
- Biocides
- PIC
- something else

Are you from a national authority?

- Get support

Need to contact your national helpdesk?

- National helpdesks

**Your request**

\* Request type

Please select:

\* Question

State your question.  
For questions regarding regulatory obligations, please state the role of your organisation.  
For technical issues, please give the date, time and country when it occurred.

Please attach any additional information that you consider relevant. File size must not exceed 5MB (accepted formats doc, docx, pdf, xls,xlsx and zip).

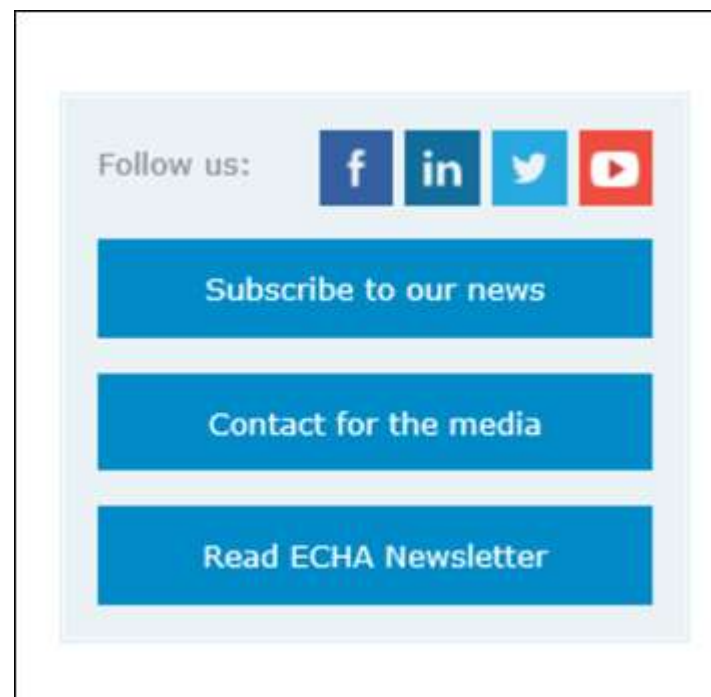
Browse...

Browse...

Browse...

Press

- [Subscribe](#) to our news: Tip of the week
- Follow us on Social media
  - [Facebook](#)
  - [LinkedIn REACH 2018](#)
  - [Linkedin](#)
  - [Twitter](#)
  - [YouTube](#)



- ECHA website <https://echa.europa.eu>
- Guidance document <https://echa.europa.eu/support/guidance>
- Registration manual <https://echa.europa.eu/manuals>
- Document on manual verification <https://echa.europa.eu/manuals>
- Webinars <https://echa.europa.eu/support/training-material/webinars>
- REACH 2018 web page <https://echa.europa.eu/reach-2018>
- Contact form <https://echa.europa.eu/contact>
- Follow us on social media: [Facebook](#), [LinkedIn REACH 2018](#), [LinkedIn](#), [Twitter](#), [YouTube](#)

# Thank you!

Subscribe to our news at  
[echa.europa.eu/subscribe](https://echa.europa.eu/subscribe)

Follow us on Twitter  
[@EU\\_ECHA](https://twitter.com/EU_ECHA)

Follow us on Facebook  
[Facebook.com/EUECHA](https://Facebook.com/EUECHA)