ECHA
EUROPEAN CHEMICALS AGENCY

REACH 2018 webinars

Completeness check
Common cases and support

15 March 2018

11.00 – 12.00 Helsinki time

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Common cases

Case 1: I failed technical completeness check for the second time. What are the consequences?

Case 2: My previous submission was a dossier for a Notified New Substance (NONS) with no tonnage band upgrade. Now I will become the lead of a joint submission at the same tonnage band. Can I still rely on the NONS derogation?

Case 3: I am uncertain how my substance is used, where can I find help?

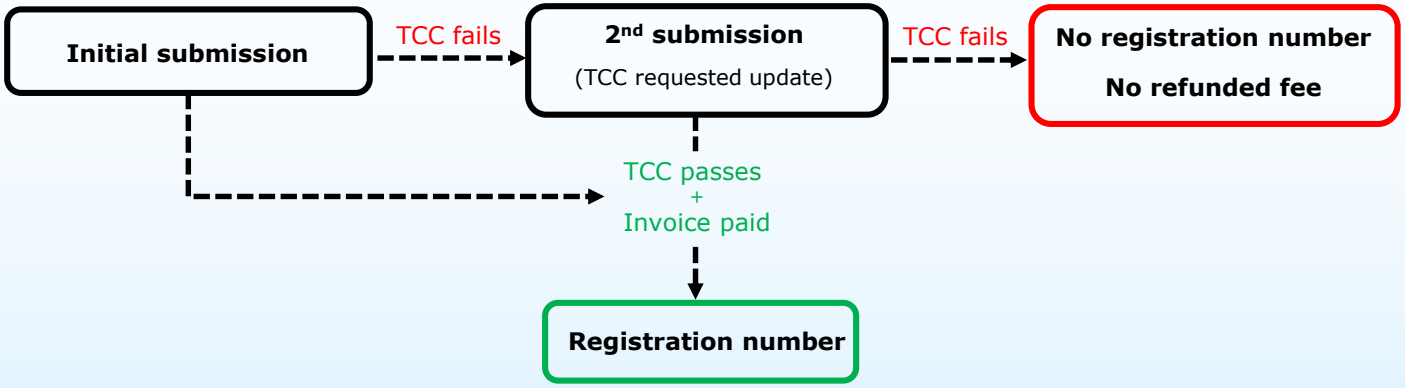
Case 4: My tests were ordered before the end of March, but I have not received the results in time to complete my dossier in time before the deadline. What can I do?

Case 1

I failed technical completeness check for the second time. What are the consequences?

a) Initial submission fails for the second time

- Second failure leads to a rejection of the submission
- No registration number assigned to your substance
- Related fees not refunded
- New submission process can only begin after rejection process has been finalised by us

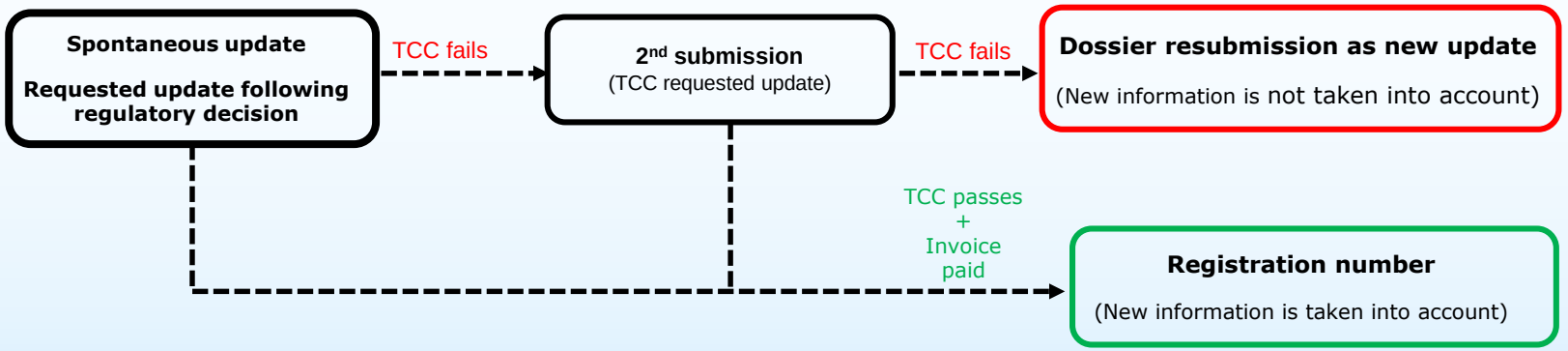


Case 1

I failed technical completeness check for the second time. What are the consequences?

b) Update of existing registration fails for the second time:

- Second failure leads to a rejection of the submission
- New information is not accepted
- You keep your registration number
- New submission process can only begin after the rejection process has been finalised by us



Case 2

My previous submission was a dossier with a NONS with no tonnage band update. Now I will become the lead of a joint submission at the same tonnage band. Can I still rely on the NONS derogation?

- A Notified New Substance (NONS) is a substance that was notified under the previous Directive 67/548/EEC
- NONS substances are considered registered under REACH
- A limited completeness check applies when a NONS registration is updated without any change to the information requirements

Case 2

My previous submission was a dossier with a NONS with no tonnage band update. Now I will become the lead of a joint submission at the same tonnage band. Can I still rely on the NONS derogation?

- When becoming a lead of a joint submission, a full completeness check is applied as the dossier is now the reference point of the joint submission
- NONS derogation is no longer valid
- Submitted dossier needs to pass enhanced completeness check, including manual checks

Case 3

I am uncertain how to describe the uses of my substance. Where can I find help?

- Our guidance on use description explains key elements needed to be reported in IUCLID
- Use maps developed by industry sectors (e.g. detergents, inks, cosmetics) give agreed ways of describing uses for a range of common products
- Use maps library gives an overview of industry sectors who have developed use maps, and a direct access to their use map files
  - Helps you find use descriptions for typical products and associated conditions of use. Realistic basis for your chemical safety assessment
  - Includes use description for workers, consumers and environment exposure assessment

Case 3

I am uncertain on how to describe the uses of my substance. Where can I find help?

Chesar tool supports you in:

- Reporting uses of your substance
- Carrying out your chemical safety assessment
- Generating your chemical safety report and the exposure scenario for communicating conditions for safe use

Case 4

My tests were ordered before the end of March, but I have not received the results in time to complete my dossier in time before the deadline. What can I do?

- This scenario falls under "Directors' Contact Group (DCG)" issue 10.3: Completeness of registration dossiers (Data required in Annexes VII and VIII of REACH not yet available by the registration deadline)
- If your tests were ordered before 31 March 2018, and you have the needed documents to prove so, you are eligible for this scenario
- To continue uninterrupted manufacture or import of your substance, submit your registration by 31 May 2018

Case 4

There are several steps to take before you submit:

1. Contact us and select the option 'regulatory obligation' from the drop down menu
2. Explain your situation and make reference to your specific scenario. In this case the scenario would be: Issue 10.3
3. You will receive an acknowledgment of your request. The email contains more information on the required documentation and a deadline to submit all the paperwork
4. Once you have submitted the documents, we will assess whether your case can be considered as a valid DCG case

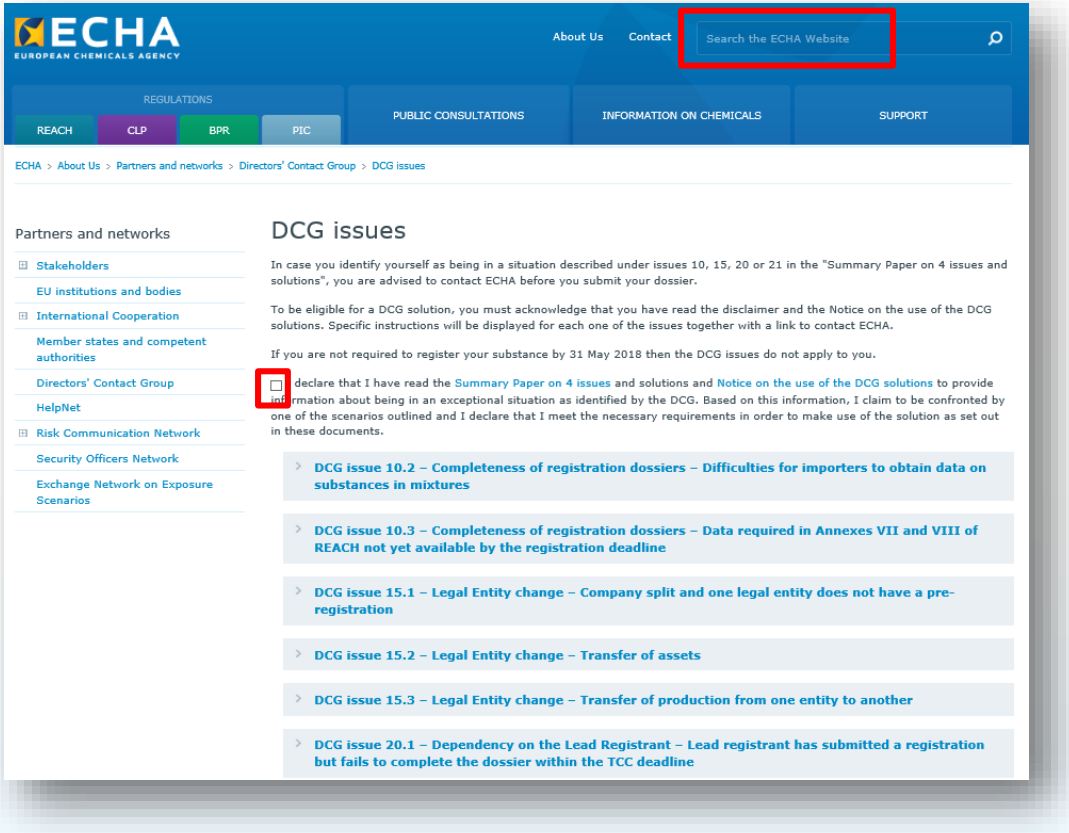
Case 4

- If your DCG case is considered valid, you will receive instructions by email on submitting your registration. This submission will fail the first completeness check and you will get a reasonable deadline to resubmit taking into account the time needed to receive lab results
- Your DCG case will be considered invalid if:
  - Required documents are not provided by the deadline given
  - Some of the documents are missing
  - Documents are not considered valid

In this case, your submission will follow the regular completeness check process and timelines

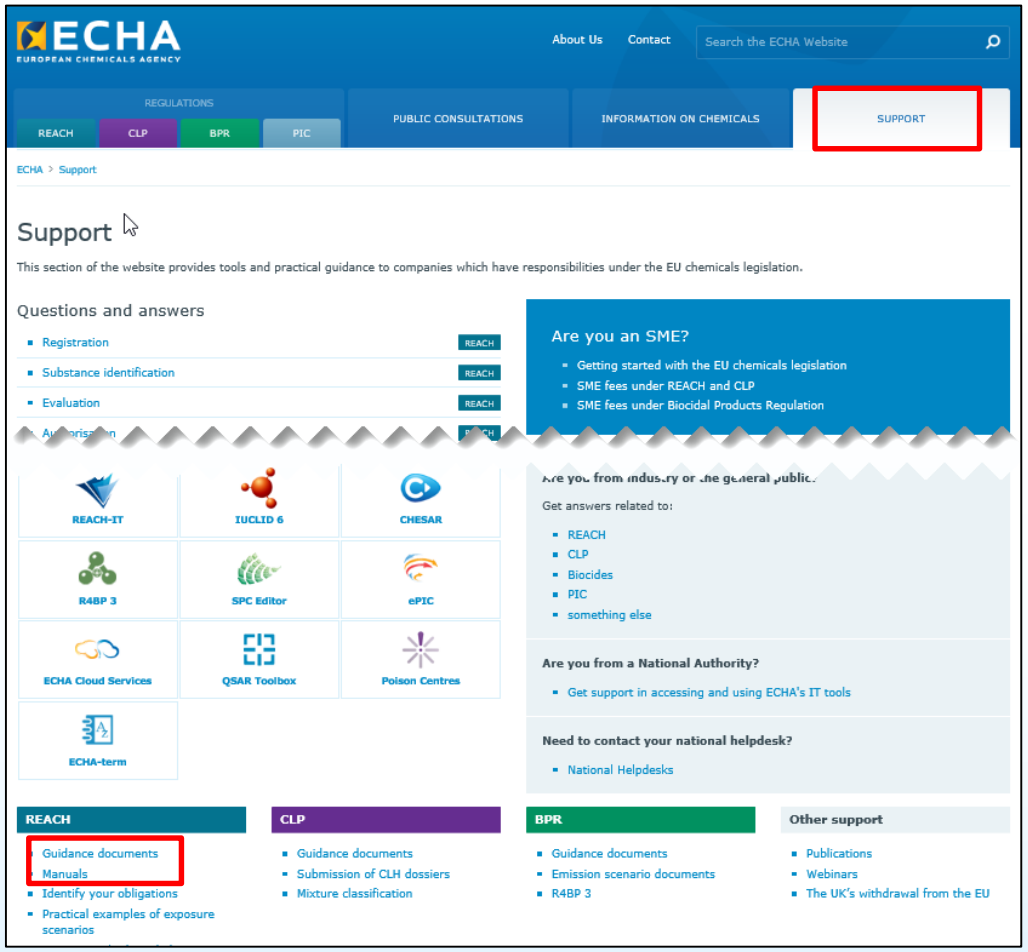
Case 4

DCG requests will be accepted until one week before the registration deadline

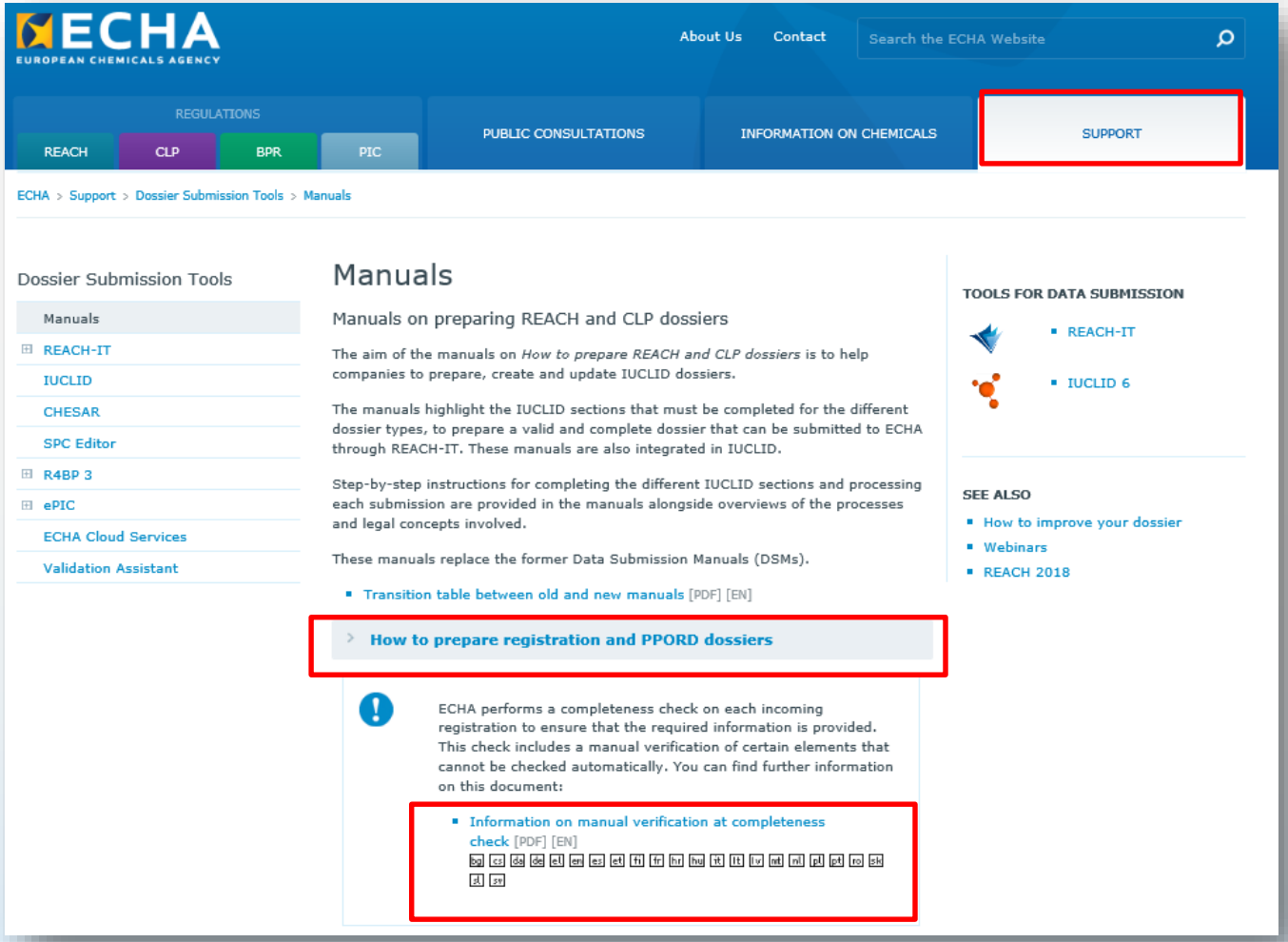


Support

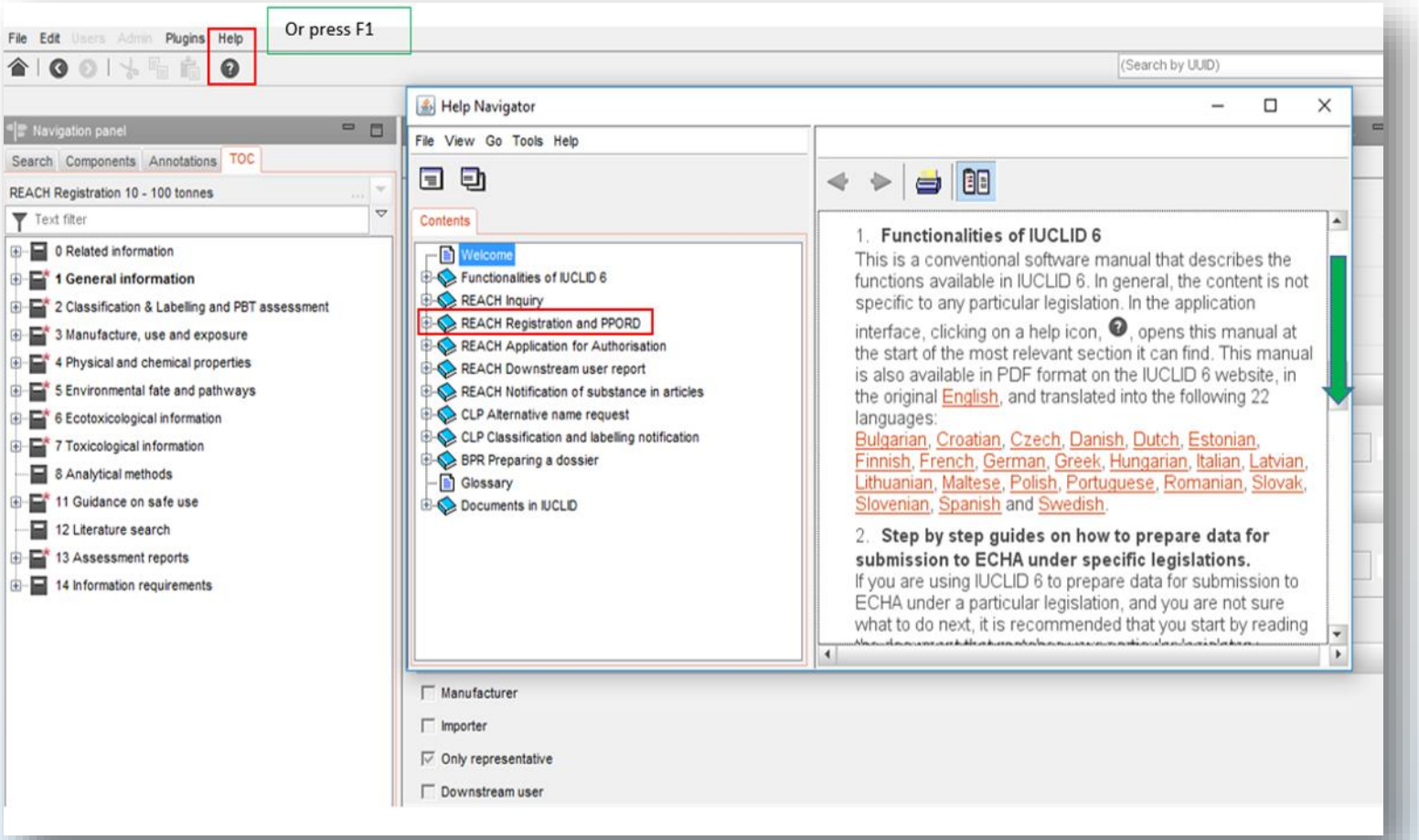
Registration manual



Information on completeness check



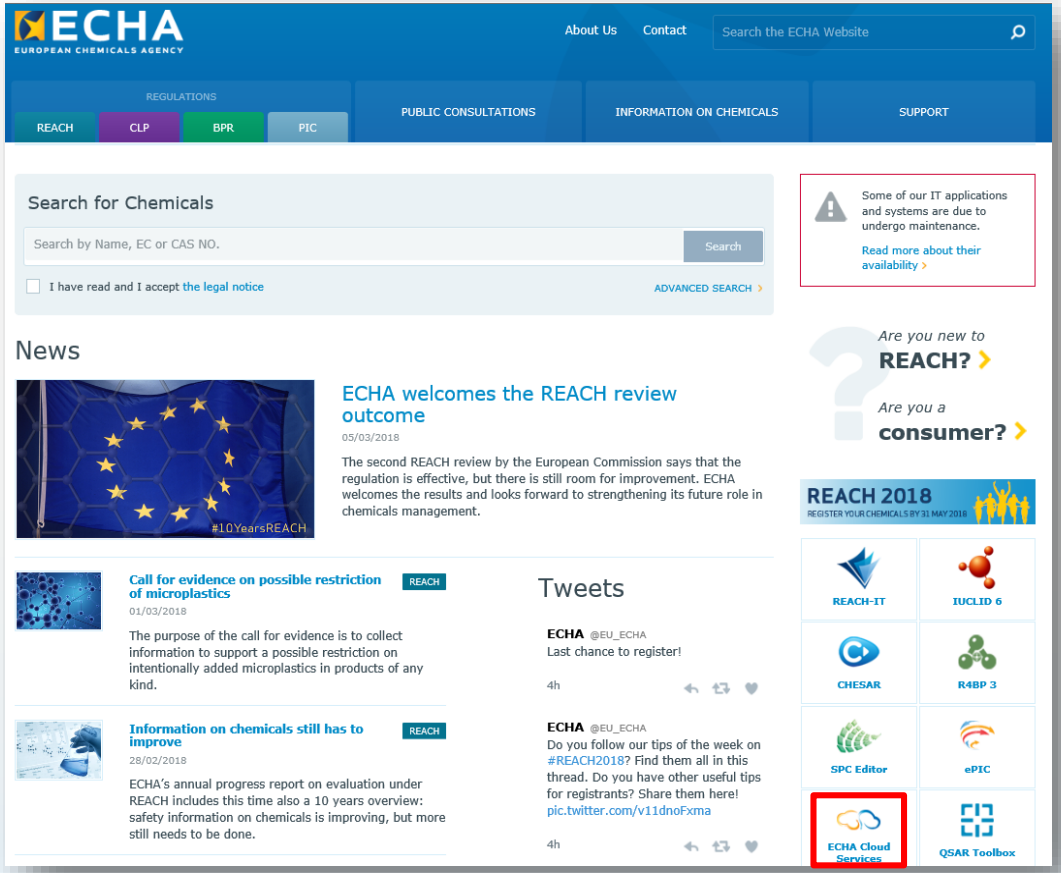
Registration manual in IUCLID 6



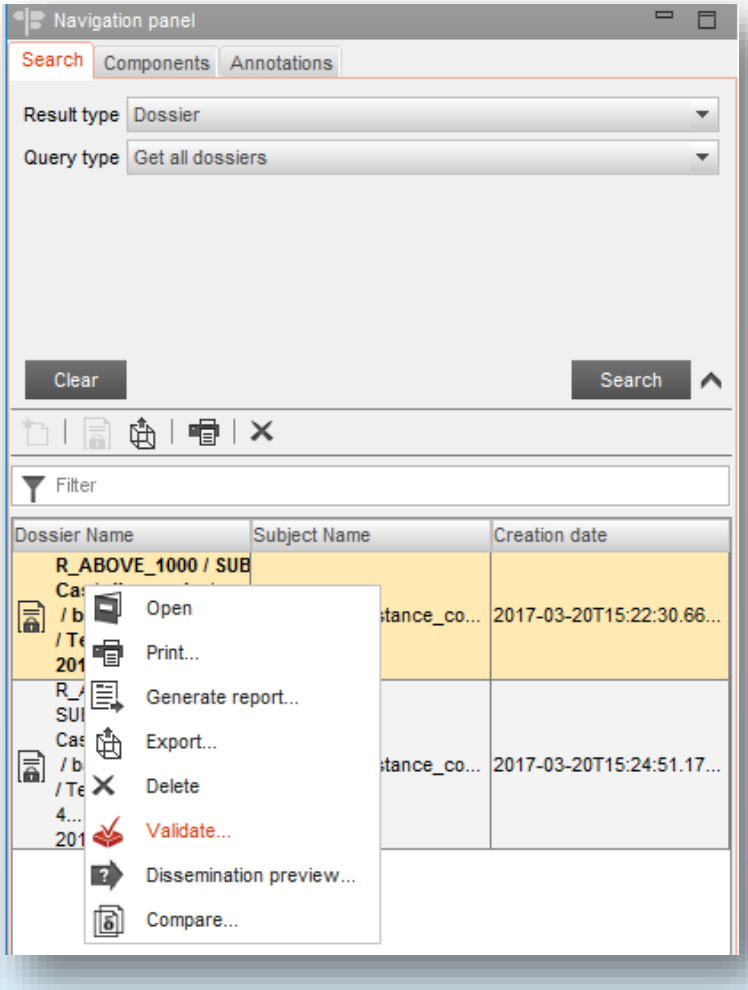
IUCLID

[IUCLID webinars]

IUCLID Cloud
with guided support



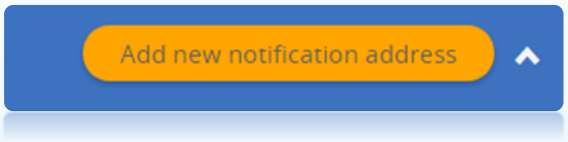
Validation assistant in IUCLID



Run the Validation assistant on your substance dataset and on your dossier before and after creating your dossier

Use the latest version of IUCLID

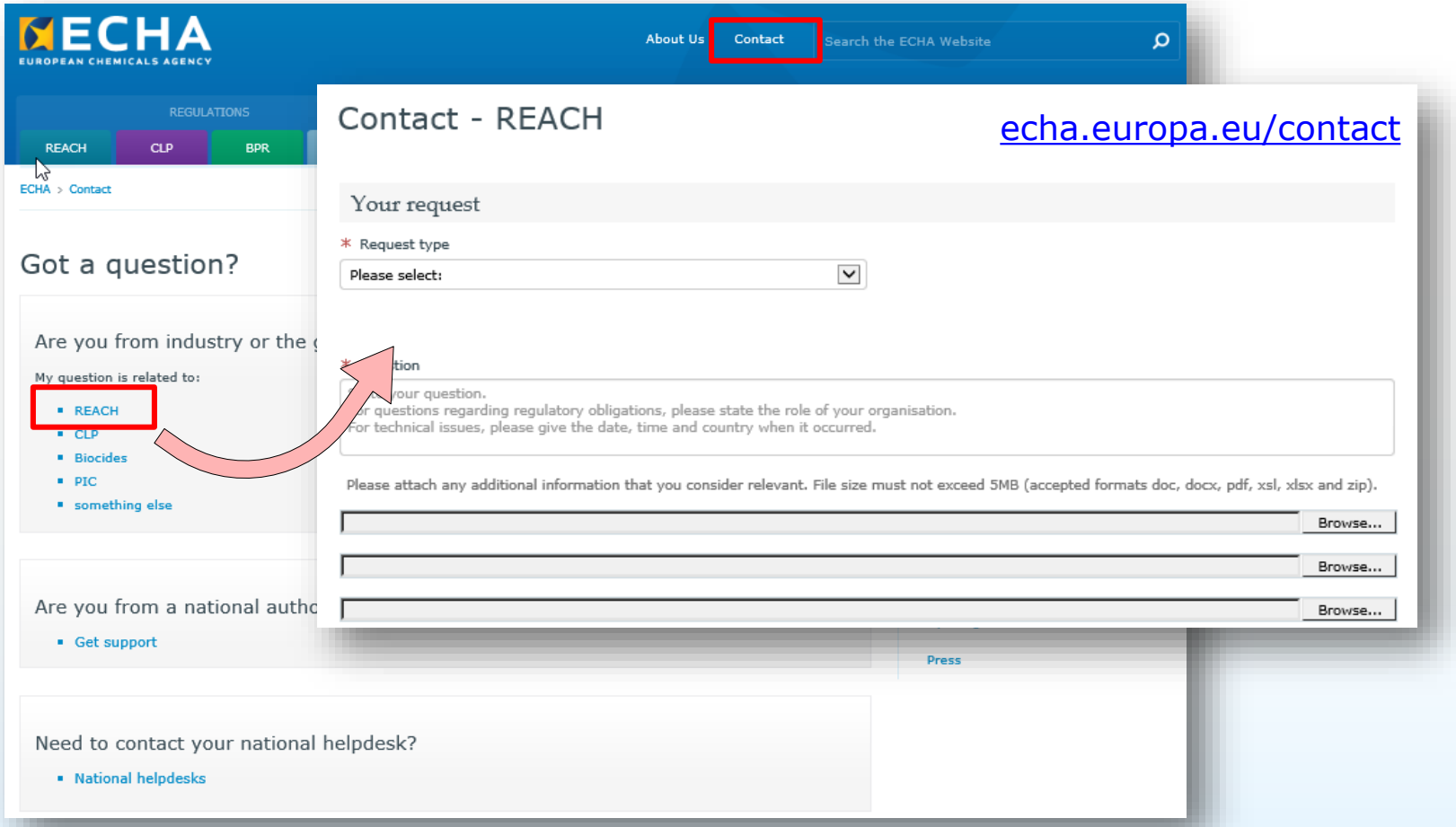
Tasks in REACH-IT



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

Assign a relevant email address under email notification settings

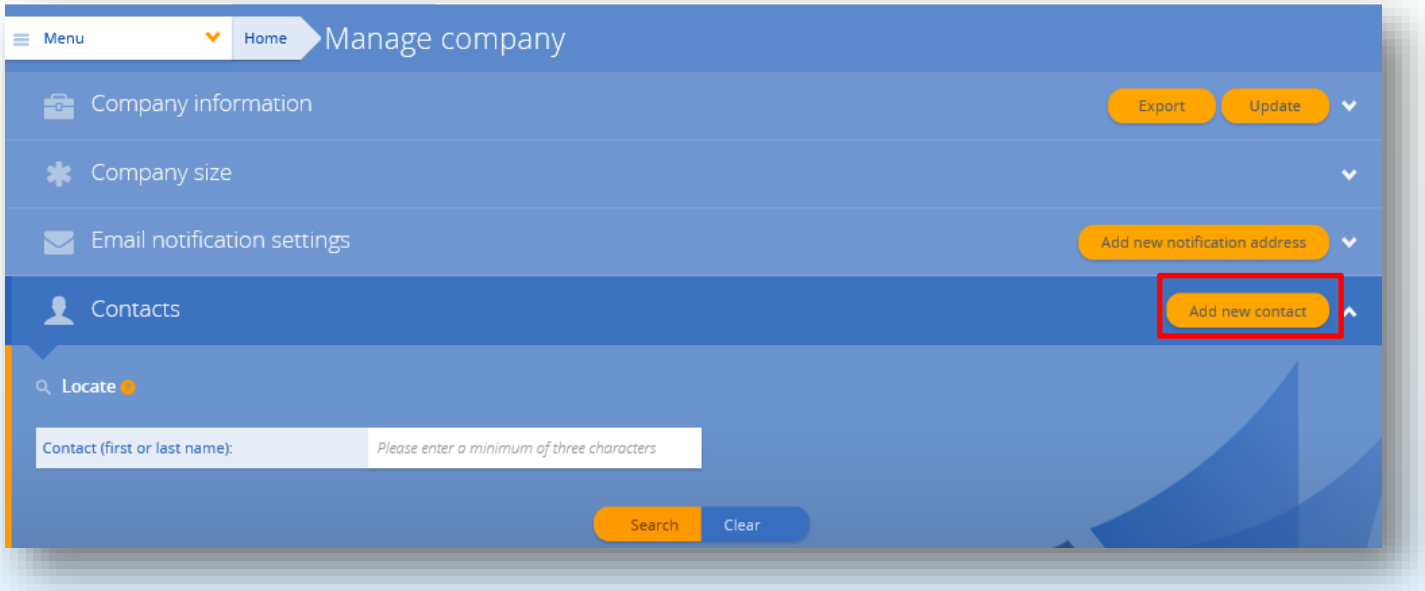
Contact form



Additional support

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



Additional support

- 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

Available support: summary

- Registration manual
- Document on manual verification
- Validation assistant
- Technical completeness check letter
- Contact form
- Additional support