

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?

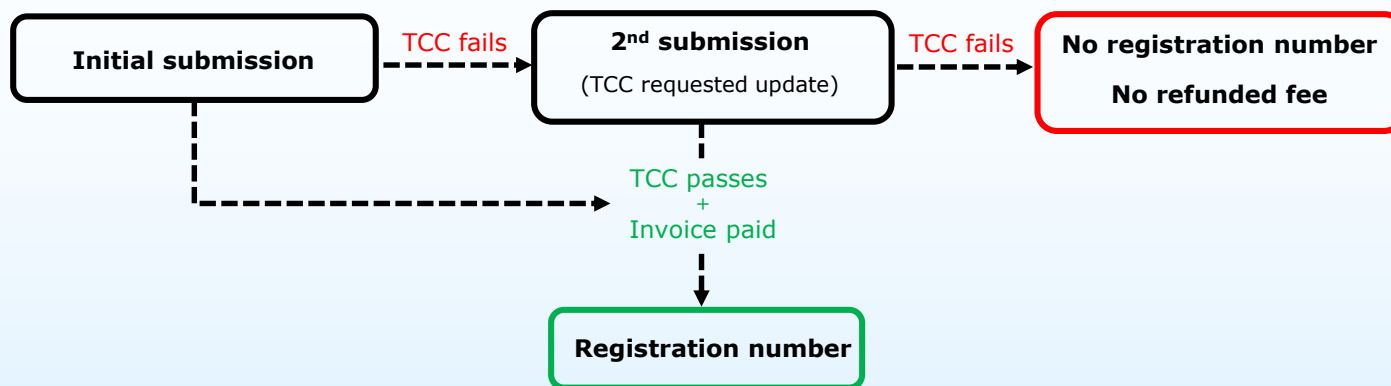


Case 1

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

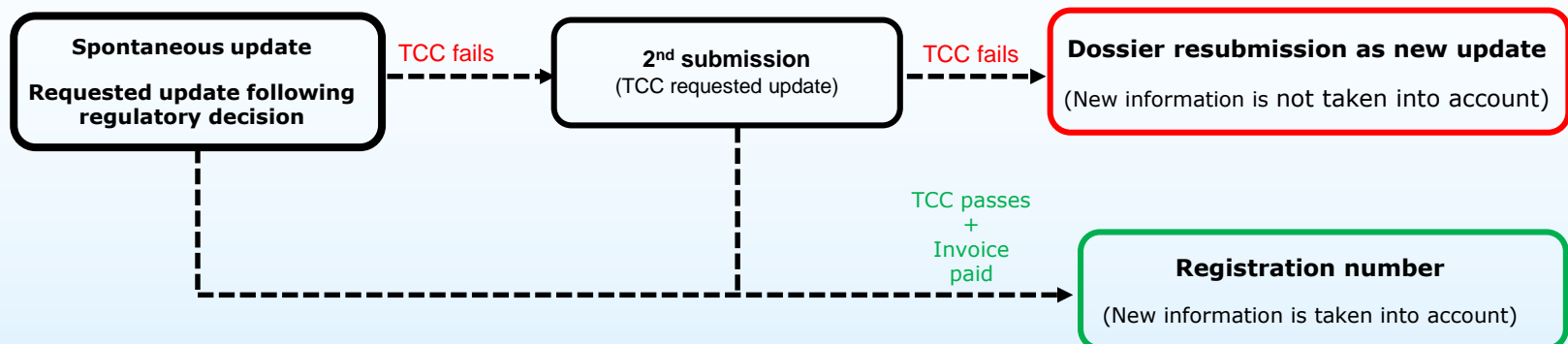


Case 1

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





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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



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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



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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

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REGULATIONS
REACH CLP BPR PIC PUBLIC CONSULTATIONS INFORMATION ON CHEMICALS SUPPORT

ECHA > About Us > Partners and networks > Directors' Contact Group > DCG issues

Partners and networks

- Stakeholders
 - EU institutions and bodies
- International Cooperation
 - Member states and competent authorities
- Directors' Contact Group
 - HelpNet
- Risk Communication Network
 - Security Officers Network
 - Exchange Network on Exposure Scenarios

DCG issues

In case you identify yourself as being in a situation described under issues 10, 15, 20 or 21 in the "Summary Paper on 4 issues and solutions", you are advised to contact ECHA before you submit your dossier.

To be eligible for a DCG solution, you must acknowledge that you have read the disclaimer and the Notice on the use of the DCG solutions. Specific instructions will be displayed for each one of the issues together with a link to contact ECHA.

If you are not required to register your substance by 31 May 2018 then the DCG issues do not apply to you.

declare that I have read the [Summary Paper on 4 issues](#) and solutions and [Notice on the use of the DCG solutions](#) to provide information about being in an exceptional situation as identified by the DCG. Based on this information, I claim to be confronted by one of the scenarios outlined and I declare that I meet the necessary requirements in order to make use of the solution as set out in these documents.

- > **DCG issue 10.2 – Completeness of registration dossiers – Difficulties for importers to obtain data on substances in mixtures**
- > **DCG issue 10.3 – Completeness of registration dossiers – Data required in Annexes VII and VIII of REACH not yet available by the registration deadline**
- > **DCG issue 15.1 – Legal Entity change – Company split and one legal entity does not have a pre-registration**
- > **DCG issue 15.2 – Legal Entity change – Transfer of assets**
- > **DCG issue 15.3 – Legal Entity change – Transfer of production from one entity to another**
- > **DCG issue 20.1 – Dependency on the Lead Registrant – Lead registrant has submitted a registration but fails to complete the dossier within the TCC deadline**

Support





Registration manual

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



Information on completeness check

The screenshot shows the ECHA website interface. At the top, there is a navigation bar with 'About Us' and 'Contact' links, and a search box labeled 'Search the ECHA Website'. Below this is a main menu with categories: REGULATIONS (REACH, CLP, BPR, PIC), PUBLIC CONSULTATIONS, INFORMATION ON CHEMICALS, and SUPPORT (highlighted with a red box). The breadcrumb trail reads: ECHA > Support > Dossier Submission Tools > Manuals.

The 'Manuals' section is titled 'Manuals on preparing REACH and CLP dossiers'. It contains three main paragraphs:

- 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.**

Below these paragraphs, it states: 'These manuals replace the former Data Submission Manuals (DSMs).'

A list of links is provided:

- Transition table between old and new manuals [PDF] [EN]
- How to prepare registration and PPORD dossiers** (highlighted with a red box)

Under the highlighted link, there is a warning icon and text: '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:'

Below this text, another link is highlighted with a red box: 'Information on manual verification at completeness check [PDF] [EN]'. Below this link is a row of small icons representing various document types: PDF, DOC, DOCX, PPT, PPTX, XLS, XLSX, ZIP, RAR, TAR, GZ, PNG, JPG, GIF, SVG, EPS, AI, PSD, INDD, EPUB, MOBI, FB2, EPUB, MOBI, FB2, EPUB, MOBI, FB2.



Registration manual in IUCLID 6

File Edit Users Admin Plugins **Help** Or press F1

Navigation panel

REACH Registration 10 - 100 tonnes


- 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

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



REACH 2018

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About Us Contact Search the ECHA Website

REGULATIONS
REACH CLP BPR PIC PUBLIC CONSULTATIONS INFORMATION ON CHEMICALS SUPPORT

Search for Chemicals

Search by Name, EC or CAS NO. Search

I have read and I accept the legal notice [ADVANCED SEARCH >](#)

News

ECHA welcomes the REACH review outcome
05/03/2018
The second REACH review by the European Commission says that the regulation is effective, but there is still room for improvement. ECHA welcomes the results and looks forward to strengthening its future role in chemicals management.

Call for evidence on possible restriction of microplastics REACH
01/03/2018
The purpose of the call for evidence is to collect information to support a possible restriction on intentionally added microplastics in products of any kind.

Information on chemicals still has to improve REACH
28/02/2018
ECHA's annual progress report on evaluation under REACH includes this time also a 10 years overview: safety information on chemicals is improving, but more still needs to be done.

Tweets

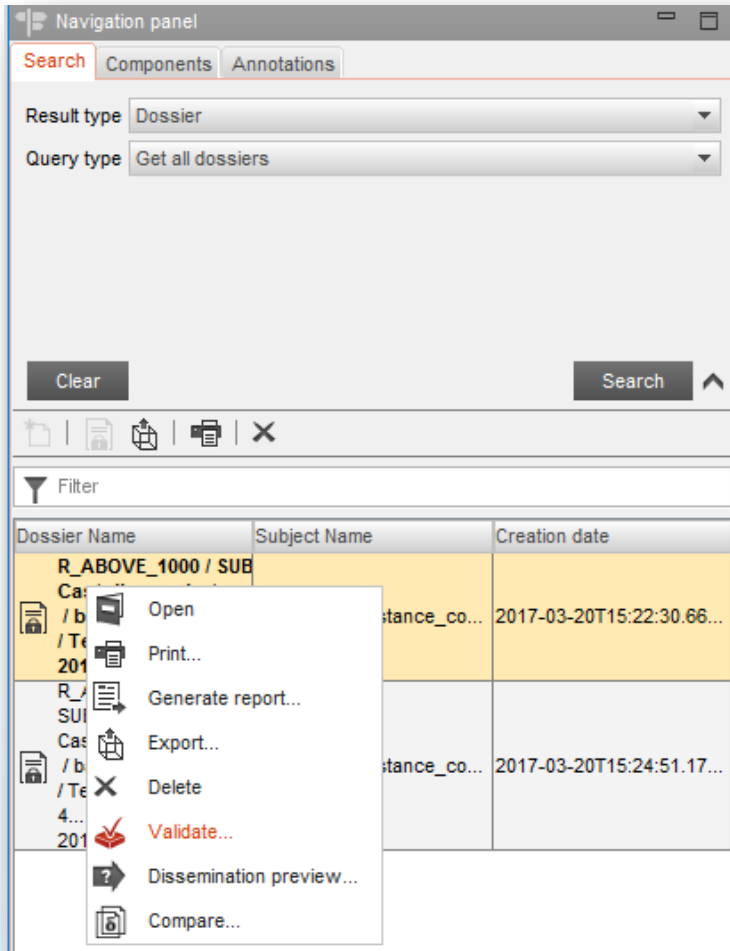
ECHA @EU_ECHA
Last chance to register!
4h

ECHA @EU_ECHA
Do you follow our tips of the week on #REACH2018? Find them all in this thread. Do you have other useful tips for registrants? Share them here!
pic.twitter.com/v11dnoFxm
4h

REACH 2018
REGISTER YOUR CHEMICALS BY 31 MAY 2018

REACH-IT IUCLID 6
CHESAR R4BP 3
SPC Editor ePIC
ECHA Cloud Services QSAR Toolbox

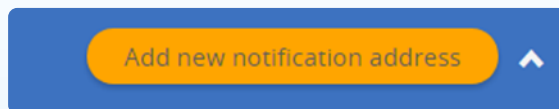
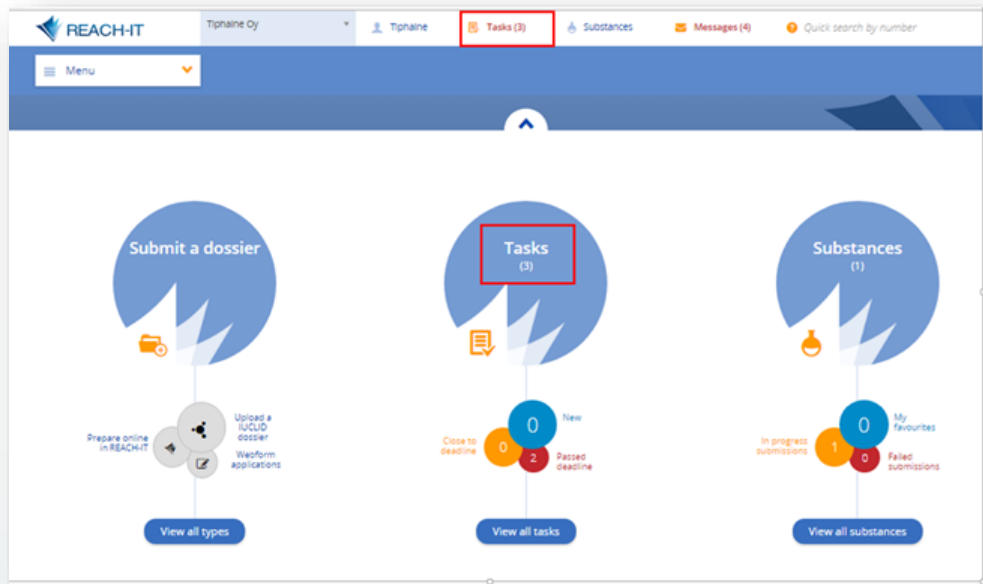
Validation assistant in IUCLID



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

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About Us **Contact** Search the ECHA Website

REGULATIONS

REACH CLP BPR

ECHA > Contact

Contact - REACH

echa.europa.eu/contact

Your request

* Request type
Please select:

* Question
Please describe 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).

Got a question?

Are you from industry or the government?

My question is related to:

- REACH**
- CLP
- Biocides
- PIC
- something else

Are you from a national authority?

- Get support

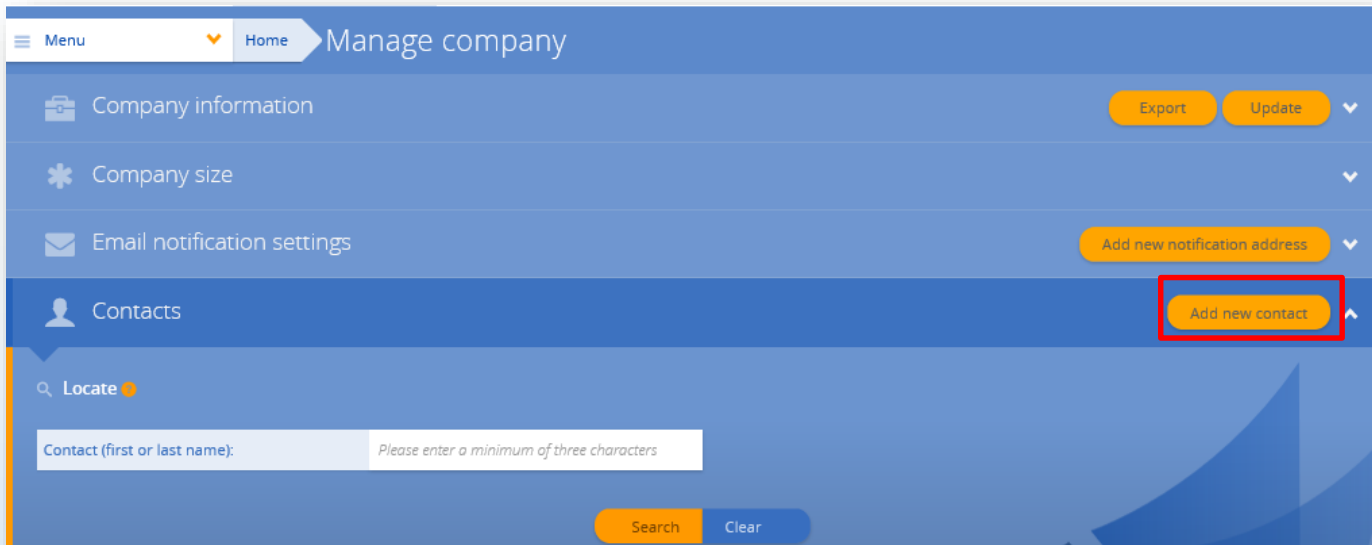
Need to contact your national helpdesk?

- National helpdesks

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



The screenshot shows the 'Manage company' interface in REACH-IT. The top navigation bar includes 'Menu', 'Home', and 'Manage company'. Below this, there are 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. At the bottom, there is a search bar labeled 'Locate' with a search input field containing the placeholder text 'Contact (first or last name):' and a note 'Please enter a minimum of three characters'. The search bar has 'Search' and 'Clear' buttons.

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