ECHA
EUROPEAN CHEMICALS AGENCY

Questions and Answers on Inquiry

2 Q&A on inquiry

LEGAL NOTE
This Questions and Answers document contains information on obligations under the REACH Regulation (hereafter referred to as REACH or the REACH Regulation) explaining how to fulfil them. This Q&A document has been generated by the European Chemicals Agency (ECHA).

However, users are reminded that the text of the REACH Regulation (Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC) is the only authentic legal reference and that the information in this document does not constitute legal advice. The European Chemicals Agency does not accept any liability with regard to the contents of this document.

Questions and Answers on Inquiry

Reference: ECHA-12-QA-06-EN
Publ.date: November 2012
Language: EN

If you have questions or comments in relation to this document please send them (quote the reference and issue date) using the information request form. The information request form can be accessed via the Contact ECHA page at:
http://echa.europa.eu/about/contact_en.asp

European Chemicals Agency

Mailing address: P.O. Box 400, FI-00121 Helsinki, Finland
Visiting address: Annankatu 18, Helsinki, Finland

Table of Contents

1. Submission of an inquiry

1.1 Why does a potential registrant need to make an inquiry?

Any potential registrant of a non phase-in substance or of a phase-in substance, which was not pre-registered, has a duty to inquire from ECHA whether a registration has already been made for the same substance (Article 26 of the REACH Regulation). A registrant, who is about to update their dossier, because they reached the next tonnage threshold, shall also previously submit a request for additional information, in a similar process to the inquiry (Article 12(2) of the REACH Regulation). This legal obligation helps ensure that data are shared by the relevant parties and that animal testing is not unnecessarily repeated.

Studies submitted at least 12 years previously can be used without compensation, for the purposes of registration. They will be attached to ECHA's communication to the potential registrant. Studies submitted less than twelve years previously will be listed in the letter, along with the legal entity that has submitted it. In order to use these studies for registration, the potential registrant will need to find an agreement with the other entity.

Further details on the inquiry procedure can be found on the ECHA website at:
http://www.echa.europa.eu/web/guest/support/dossier-submission-tools/reach-it/inquiry

1.2 I submitted my inquiry dossier to ECHA. What happens next?

Once received by ECHA, your inquiry dossier will go through some mandatory submission checks and will be assessed.

If ECHA is able to process your inquiry dossier, you will receive via REACH-IT a communication which states your inquiry number as well as details of available (robust) study summaries, as appropriate. The internal message you will receive contains a link to the Co-Registrants Page, which will inform you on the contact details (identity, email and address) of the previous and potential registrants (i.e. inquirers that received an inquiry number) of the same substance.

If ECHA is not able to process your inquiry dossier, due to insufficient and/or inconsistent information provided on your substance identification, you will receive via REACH-IT a communication detailing additional information required. Where applicable, you will need to prepare a new inquiry dossier including the information requested in the communication and submit it to ECHA.

1.3 ECHA was not able to process my first inquiry due to missing and insufficient information and requested me to submit a new one. Do I have to state the submission number from my previous inquiry in my re-submission?

There is no requirement to state the previous submission number(s) in your new submission. However we recommend when submitting a new inquiry dossier to state the previous submission number(s) in the dossier header as such information is useful to ECHA and it may facilitate the processing of your inquiry

1.4 How does the Third Party Representative (TPR) function work for inquiry?

As per Article 26(3) and (4) of the REACH Regulation, ECHA has the obligation to communicate information to the inquirer and not to a designated third party representative (TPR).

Therefore, the result of the inquiry process will always be communicated directly to the inquirer. However, as per Article 4 of the REACH Regulation, when informing other existing and potential registrants, ECHA will use the contact details of the TPR instead of those of the potential registrant. Consequently, the TPR contact details are the ones included in the relevant Co-Registrants page.

1.5 My inquiry could not been processed by ECHA due to insufficient/inconsistent information. Is there a deadline for re-submitting an inquiry?

No, there is no deadline for re-submitting an inquiry dossier to ECHA.

1.6 What is the deadline for processing inquiries?

The REACH Regulation does not impose any timeframe on ECHA for processing an inquiry. ECHA responds to inquiries as promptly as possible.

1.7 When will I receive the details of other potential and previous registrants?

ECHA can only release contact details of other potential and previous registrants once ECHA has received sufficient information on your substance to identify other potential and previous registrants. The details of other potential and previous registrants will be displayed on the Co-Registrants page related to your substance.

1.8 ECHA has made some comments in my inquiry dossier but has provided us with an inquiry number. Do I have to re-submit our inquiry dossier?

No, you do not need to submit another inquiry dossier for this substance as there is no possibility to update a successful inquiry. However, we recommend that you take into account the comments included in your communication.

These comments are provided to ensure that you understand the scope of your inquiry outcome, and for which you obtained an inquiry number. As a result, you may need to address these comments prior to submitting your registration dossier to later avoid potential issues with substance identity.

1.9 Do I have to specify a production site if I am an importer or an only representative?

Yes, we recommend that you always specify a production site. In the context of an inquiry (Article 26), you should specify in section 3.3 of your IUCLID dataset all production and use sites of the substance.

1.10 I am a potential registrant of an intermediate. Where can I specify this fact in my inquiry dossier?

Inquiry (as per Article 26 of the REACH Regulation), and registration of intermediates (as per Articles 17 and 18 of the REACH Regulation) are considered two distinct processes. For this reason, it is not necessary to specify in your inquiry dossier, the type of registration you plan to submit.

1.11 I am a potential registrant of an intermediate. Do I have to submit spectral data and analytical information as part of my inquiry dossier even though I do not require this information for the registration?

Yes, irrespective of the type of registration, all inquirers have to address the information requirements according to Article 26(1) of the REACH Regulation for an inquiry. As the outcome of the inquiry process may result in the release of contact details of previous registrants and other potential registrant(s) to the new inquirer, it is necessary to be certain that your substances are in fact the same.

This is only possible if the inquirer addresses all the information requirements detailed in Annex VI point 2 of the REACH Regulation – this includes spectral data and analytical information (points 2.3.5, 2.3.6 and 2.3.7 of Annex VI).

1.12 I obtained an inquiry number for my substance, which was assigned a list number and a list name. Where do I get the .i5z file for my substance to be used in my registration dossier?

In the end of the Submission Report related to your inquiry dossier (in REACH-IT) there is a button that will allow you to download the i5z file for your substance data, for the EC/list entry to be used when submitting the registration dossier. First, access the submission report by searching with the relevant submission number. This is the file to use in your registration dossier.

You can find more information in the REACH-IT Industry User Manual Part 11 (section 4.1).

1.13 Where can I find further information that would help me in preparing my inquiry dossier?

When preparing your inquiry dossier, we recommend that you read the following documents:

Guidance for identification and naming of substances under REACH: http://echa.europa.eu/web/guest/guidance-documents/guidance-on-reach

Q&A on substance identification

Data Submission Manual – Part 02 (How to prepare and submit an inquiry dossier)

Data Submission Manual – Part 18 (How to report the substance identity in IUCLID 5 for registration under REACH)

REACH-IT Industry User Manual – Part 11 (Online dossier creation and submission for inquiries)

REACH-IT Industry User Manual – Part 18 – Co-Registrants Page

The four above-mentioned documents are available on the ECHA website at: http://echa.europa.eu/web/guest/support/dossier-submission-tools/reach-it/data-submission-industry-user-manuals

Question and answers on Data sharing and related disputes http://echa.europa.eu/documents/10162/13631/datasharing_q_a_en.pdf. I plan to submit an inquiry dossier in the IUCLID format.

1.14 How can I verify beforehand that my dossier contains enough information to be processed by ECHA?

Before submitting your inquiry dossier, we recommend that you run (i.e. use) the "Technical Completeness Check plug-in" which will identify the fields of your inquiry dossier which deserve particular attention. Indeed the "Technical Completeness Check (TCC) plug-in" assists users in the preparation of an inquiry dossier. You can download this IUCLID plug-in via the IUCLID 5 website (http://iuclid.echa.europa.eu/).

The TCC plug-in supports the preparation of a IUCLID 5 inquiry dossier in two ways:

(i) It performs a check of most of the Business Rules applied to inquiry dossiers in REACH-IT. This enables the user to detect and correct failures already before submitting the inquiry dossier to ECHA.

(ii) It performs a so-called "Substance Identity check", identifying the IUCLID fields of an inquiry dossier that should be filled in or that deserve particular attention.

It is advisable to use the TCC plug-in both while preparing the inquiry substance dataset and on the final dossier before submitting it.

We strongly recommend to address all reported inconsistencies and shortcomings in order to submit an as complete inquiry dossier as possible to ECHA. Please note that the "Substance Identity check" will not assess whether the information submitted is adequate but only if all required filled are complete.

More specific instructions:

Launch the above checks on your substance dataset or dossier by right-clicking the substance/dossier and selecting 'Run TCC'. Additionally, for a substance dataset specify in the next step 'Substance Identity check (for inquiry notification)'. The TCC plug-in will now execute a check of the Business Rules and Substance Identity rules that are applicable to inquiries.

For further information on how to use the TCC plug-in, please refer to the "IUCLID 5 Technical Completeness Check Plug-in User Manual" which is available with the downloaded TCC plug-in.

1.15 Are there new Business Rules in the new automated Inquiry process?

Yes, as Business rules are of significant advantage to the inquiry process. Business rules ensure that no contradicting information is submitted in the inquirer's dossier. After registering a substance, the registrant that needs to update their registration dossier is expected to request only **additional** data to ECHA.

If the inquirer requests data endpoints already contained in their registration dossier, new rules are implemented that will prevent the inquiry dossier from being processed by ECHA and will require action from the inquirer before being able to re-submit their inquiry.

Here is the description of the new Business rules: the registrant has submitted first a standard registration dossier below 1000t (either 1-10t, or 10-100t, or 100-1000t). They submit now in the inquiry dossier a request for data which refers both to information the registrant has, AND to information they do not have.

a. The inquiring Legal entity has already submitted a standard registration dossier for the same substance (based on the same company UUID and the same numerical identifiers)
b. The registration is a full registration

AND

c. The tonnage band is either 1-10t, or 10-100t or 100-1000t

AND

d. The inquiry dossier contains in section 14.1 a request for information:
   i. which the registrant has (based on their tonnage band)
   AND
   ii. which correspond to a tonnage band higher than the one the registrant has.

In the scenario described above, the Business rules will apply and the inquiring company will need to re-submit their inquiry dossier with the corrected request for data.

1.16 Are there situations where my inquiry dossier will be rejected soon after submission?

If you have already registered the substance for which you submit now the inquiry and if your dossier is not the registration of an intermediate or a notification in accordance with Directive 67/548/EEC, no business rules for unnecessary inquiry dossiers will be applied.

However inquiries prior to tonnage band updates are only foreseen for additional information which you may need. Consequently, ECHA will disregard your inquiry insofar as it refers to information requirements, which you have already entered in your full registration dossier.

1.17 What is the confidentiality of the information submitted for an inquiry?

The information submitted for the purposes of inquiry (Article 26(1)) is solely used by ECHA to ascertain whether the same substance has been previously registered or whether there are other inquirers for the same substance. This information will be treated as confidential and will not be published on the dissemination website in accordance with Article 77(2)(e).

In accordance with Article 26(3) and (4), ECHA will provide via the Co-Registrants Page the previous registrants and other potential registrants with your contact details and the list of information requirements you specified in your inquiry. No other substance identification information is disclosed.

1.18 Do I have to wait for the result of my inquiry before submitting my registration?

Yes, you need to wait until you have received a communication from ECHA stating your inquiry number before submitting your registration. Indeed, you may have legal obligations to share data and submit a joint registration. The communication will also contain a link to the Co-registrants page that refers to the substance you have inquired about. On this page you will find the details of previous registrants and potential registrants (if any) which will support you complying with these two obligations.

1.19 I need to update my registration as a result of a tonnage band increase. Do I need to submit an inquiry?

Yes, only if you need additional information to update your registration dossier (i.e. further studies), as a result of an increase of tonnage band, should you submit a request for additional information to ECHA. The process described in Article 12(2) is the same as for inquiry.

1.20 How do I submit an inquiry due to tonnage band increase?

For inquiries as a result of a tonnage band increase, ECHA strongly recommends use of the online dossier creation tool as only the registration number for which the tonnage band increase relates to, the tonnage band and the information requirements need to be specified.

For guidance on how to create online an inquiry dossier for a tonnage band increase, please refer to the REACH-IT Industry User Manual – Part 11 (Online dossier creation and submission for inquiries) available at: http://echa.europa.eu/web/guest/support/dossier-submission-tools/reach-it/data-submission-industry-user-manuals

Alternatively, you can submit the inquiry as a IUCLID 5 dossier via REACH-IT. For guidance on how to create an inquiry dossier for a tonnage band increase, please refer to the Data Submission Manual – Part 02 (How to prepare and submit an inquiry dossier) available at: http://echa.europa.eu/web/guest/support/dossier-submission-tools/reach-it/data-submission-industry-user-manuals

The IUCLID inquiry dossier needs to contain as a minimum the following information:

- Section 1.1 of the substance dataset (IUPAC name and EC number)
- Section 1.2 of the substance dataset (full information on the composition of your substance)
- Section 1.3 of the substance dataset (notification or registration number)
- Section 14.1 of the substance dataset (Request for information)

When creating your dossier, please ensure that it is clear that the inquiry relates to an update of a registration by choosing "Type 4: Inquiry for tonnage band increase" as Type of Inquiry in section 14 of your IUCLID substance dataset. Otherwise, your dossier will not be accepted for processing.

Note: If you have notified your substance under Directive 92/32/EEC, and are submitting an inquiry dossier for a tonnage band increase, you must use the same REACH-IT legal entity as the one you have used when claiming the relevant registration number.

2. Request for information

2.1 What happens after we receive an inquiry number and contact details of previous registrant(s) in relation to data sharing?

Following an inquiry the potential registrant will receive a communication from ECHA on whether the substance has previously been registered (or notified under Directive 67/548/EC). In that case, ECHA will provide the potential registrant with a link to the Co-Registrants Page for the related numerical identifier exists and as part of the message.

On the basis of the information described as required in the inquiry, ECHA will also provide the potential registrant with the list of (robust) study summaries already submitted and available.

a) For studies which were submitted at least 12 years previously, ECHA will provide with the inquiry communication in the annotation, a copy of the relevant studies (.pdf format), extracted from its IUCLID database, which can only be used for the purpose of registration by the potential registrant.

b) For studies which were submitted less than 12 years previously, as part of a notification under the previous legislation, or as part of a registration under REACH, ECHA will identify the registrant(s) who have submitted data.

In accordance with Article 27(1) of the REACH Regulation, as a potential registrant,

- you shall, in the case of information involving tests on vertebrate animals, and
- you may in the case of information not involving tests on vertebrate animals,

request the (robust) study summaries required for registration, directly from the previous registrants.

ECHA recommends to contact first, among the previous registrant(s), the lead registrants displayed on the Co-Registrants Page. This communication will enable the potential registrant to request the sharing of existing data from the previous registrant(s), while engaging in negotiations to join/ create the joint registration dossier.

2.2 What does "data available" mean in the attachment I received?

With the release of REACH-IT 2.5, the processing of inquiries at ECHA has been partly automated. The results marked as "data available" in the table listing the availability of information, reflect the endpoints contained within the existing registration dossier(s) which passed the check of completeness on the technical dossier.

2.3 How can I, as a potential registrant, find the lead registrant of the substance they intend to register?

When you open the Co-Registrants Page, and go to the "Registrants" tab, you can view who has already registered your substance. Also in the column "JS role", if it exists, the "lead" registrant will be identified.

2.4 I am having difficulty cooperating with a previous registrant. What can I do?

It is the common responsibility of the potential and the existing registrant(s) to negotiate and agree on the content of the joint registration dossier, submitted by a lead registrant.

In the case of information submitted less than 12 years prior to the inquiry, REACH (as per Article 27(2) and (3)) requires both the potential and previous registrants to make every effort to agree on the sharing of the information and its costs in a fair, transparent and non-discriminatory way.

In case you fail to reach such an agreement you may, as a last resort, contact ECHA in accordance with Article 27(5) of the REACH Regulation. For more details, please consult the "Questions and Answers on data sharing and related disputes" document available at: http://echa.europa.eu/datasharing_en.asp.

2.5 Can I begin vertebrate testing when I indicated some information requirements and before I receive the result of my inquiry?

No, you cannot. You need to wait until you have received the communication from ECHA, which states your inquiry number together with the list of the requested (robust) study summaries that are available to ECHA.

REACH states that new testing of a substance involving vertebrate animals can only be carried out as a last resort. For chemicals manufactured or imported in a quantity of 100 tonnes or more, no testing shall be conducted for the information specified in Annexes IX and X of the REACH Regulation. Instead, a testing proposal must be submitted in the registration dossier. The Agency shall then evaluate whether the testing proposal is adequate before such a test is performed.

2.6 I, as a previous registrant, have received a message from ECHA in my REACH-IT message box informing me about a new potential registrant for a substance I registered. What to do next?

As the subject of the message indicates, this communication is for your information only (as per Article 26(3)), so you do not need to take any action.

However in case you submitted information less than 12 years prior to the inquiry, and if a potential registrant requests that information from you, REACH requires that you respond in order to enter into negotiation to reach an agreement on the sharing of this information and their associated costs (as per Article 27(2), (3) and (4)).

3. Co-Registrants Page and obligations

3.1 How can I contact the other registrants of my substance to share data?

To support potential and existing registrants to better fulfil their REACH obligations, namely data sharing and joint submission, ECHA has implemented a new functionality in REACH-IT – the Co-Registrants Page.

The page will enable users to access the contact details of existing registrants in real time and directly within REACH-IT. It will also display the endpoints' data requested as part of an inquiry or a request for further information about that particular substance (in a form of a downloadable .pdf document). This aims at facilitating the data sharing discussions between (potential) registrants. The role of the registrants within the joint submission will also be visible for all, so the lead can be easily identified and directly contacted for the purpose of data sharing.

3.2 What information can I access on the Co-Registrants Page?

The Co-Registrants Page provides real-time information, which is variable according to the status of the (potential) registrants:

- Potential registrants, during the 12 months after successfully submitting their inquiry, can see all registrants. However only the leads are marked.
- Potential registrants, beyond the 12 months of their successful submission and if they have not registered, can only see new potential registrant(s) or registrant(s) that have inquired. They can no longer see the existing registrants that did not inquire.
- Registrants can see the roles of all co-registrants, i.e. whether they are lead or member and can see the potential registrants.

3.3 Is only the lead registrant shown to the potential registrant accessing the Co-Registrants Page?

After the release of REACH-IT 2.5, the potential registrant is given access to the same information they have always had. They can see the previous registrant(s) and potential registrant(s). In addition, the lead registrant of the joint submission will be clearly identified. This is to help the potential registrant(s) to identify the appropriate previous registrant to contact in order to join the joint submission.

3.4 Where can I find the up-to-date information on other (potential) registrants of my substance?

Once ECHA has confirmed the identity of the substance inquired about, the new page within REACH-IT is created and provides direct access to the identity and contact details of the other potential and previous registrants of the substance defined by the same numerical identifier. This is a major improvement in comparison to the previous procedure where ECHA sent the contact details in a paper format, reflecting the status at the time of sending.

3.5 How do I know which joint submission I can join?

Multiple registrants of the same substance share two main obligations under the REACH regulation: data sharing and joint submission obligations. Now, registrants can identify who else has registered their substance and therefore shares common obligations under REACH. It is the common responsibility of all (potential) registrants, you included, to form only one joint submission. ECHA strongly recommends that all registrants use this new page as a tool to ensure compliance with these obligations.

For example, no role is displayed next to a registrant that has submitted a registration dossier outside of an existing joint submission. They are required to contact the lead registrant, as they share the same responsibility as the other multiple registrants of the same substance to make every effort and to ensure that they are part of the same joint registration dossier.

3.6 How do I share data on my substance with others?

ECHA provides full transparency to registrants of the same substance that used the same numerical identifier in their dossiers. The REACH-IT Co-Registrants Page displays the endpoints' data requested as part of an inquiry or of a request for additional information. This aims at facilitating the data sharing discussions between existing (and requesters of additional information) and potential registrants.

3.7 What happens if I am one of two companies that submit an inquiry, but no other company has registered the specific substance so far? Will I see the other potential registrant on the Co-Registrants Page?

Yes, you will see each other under the "Potential registrants" tab and the list under the "Registrants" tab will be left empty. Even if you are the only potential registrant, you will be able to access and search the Co-Registrants Page: you will only see yourselves listed under the "Potential registrants" tab.

Similarly, if there is only one registrant, the registrant will be able to access and search and will only see themselves as registrants.

3.8 What happens if a company submits an inquiry for a phase-in substance that has not yet been registered?

There is no link between the pre-SIEF and Co-Registrant pages. However, ECHA always suggests that before submitting the registration dossier, the potential registrant checks the list of pre-registered substances and the list of substances for which a lead registrant has been nominated, which is an indication of a SIEF in activity since the lead registrant has been nominated.

3.9 Why do the contact details of a company that notified a substance under the previous legislation (Directive 67/548/EEC) and did not claim their notification, not show?

The contact details of the companies, which did not claim a registration number for a substance notified under the previous legislation, are not available in REACH-IT and can therefore not be displayed. When it comes to informing the companies, which did not claim a registration number for their notification, ECHA continues to send registered communication to those companies to inform them that there is a new inquiry for a substance they have notified.

With the new Co-Registrants Page, there is only a slight change to the current practice: only the name and country of the notifier is displayed.

3.10 When I, as a registrant/potential registrant, have nominated Third Party Representative (TPR), which contact details are displayed (mine or those of my TPR)?

There is no change from the current practice: only the contact details of the Third Party Representative (TPR) nominated in the inquiry or registration dossier are displayed on the Co-Registrants Page.

Note: A TPR can only be assigned to a notification, which has been claimed. It is not possible to assign a TPR without claiming the registration number for a notified substance.

3.11 In some cases, I have more than one Third Party Representative (TPR). Is the TPR used within the Co-Registrants Page specific to the company or to the inquiry/ registration dossier?

If the same Third Party Representative (TPR) has been nominated as a TPR in several inquiry or registration dossiers, the same contact details (of the TPR) are displayed multiple times.

Note: the same applies for several non-EU manufacturers: the only representative (OR) will be listed as many times as they have submitted an inquiry/ registration for a specific substance.

3.12 Can companies appoint a Third Party Representative after having registered?

Yes, you as a registrant can appoint or change your Third Party Representative by updating your registration dossier.

3.13 How can I see the "history" of my inquiry (e.g. original, re-submitted, etc)?

Only the successful inquiries (with an inquiry number) are visible in REACH-IT. You, as a potential registrant, will see in your own view only the inquiry number regarding your last successful inquiry. If you have requested in your inquiry all data you need in order to register your substance, you would not need to submit a new inquiry and therefore there should not be any "history".

As a registrant, you will see in your own view as well your last successful inquiry, which either refers to the initial inquiry or to one submitted in order to get additional information in view of updating your registration dossier.

3.14 What does ECHA mean by "dynamic" page?

At first, the potential registrant that received their inquiry number is listed under the "Potential registrants" tab. Their information requirements (section 14.1 of the inquiry dossier) are displayed in the table as a link (to a .pdf document). It reflects the content of what the potential registrant requested in their inquiry.

Once the potential registrant registers the substance, they will no longer be listed as potential registrant, but as a registrant. Their data request is no longer shown (as it is assumed that they have included the information they requested in their registration dossier).

Where the registrant reaches the next tonnage band, they need to inform ECHA (section 14.1 of the inquiry dossier) of their request for additional data (Article 12(2)). The information requested is displayed on the Co-Registrants Page ("Registrants" tab) as a link to a .pdf document.

However, as soon as the registrant updates their registration after the inquiry, their data request is no longer shown as it is assumed that they have received the data to update their registration dossier.

Note: The reference date refers to the date the inquiry was accepted (inquiry number assigned and message sent to parties informing them of the inquiry).

EUROPEAN CHEMICALS AGENCY
ANNANKATU 18, P.O. BOX 400,
FI-00121 HELSINKI, FINLAND
ECHA.EUROPA.EU