Inquiry processing

1. Purpose

To describe the assessment of inquiry dossiers submitted to ECHA according to Article 26(1) of the REACH Regulation and the steps taken to ensure that the data sharing among potential and previous registrants can take place. This procedure on inquiry processing also covers the data requests submitted according to Article 12(2) of the REACH Regulation.

2. Scope

This procedure starts when the submission of an inquiry dossier is considered as complete after passing the automated mandatory submission checks conducted by the Dossier Submission & PIC Unit (C1). It ends when a communication with the result of the assessment is sent to the potential registrant via REACH-IT, and when applicable, to any previous (potential) registrants.

3. Description

Inquiry dossiers can be divided in two types:

- Inquiries according to Article 26(1): submitted by potential registrants of non-phase-in substances or by potential registrants of phase-in substances which were not pre-registered by the potential registrant.
- Information requests according to Article 12(2): submitted by registrants which have reached their next tonnage threshold and require additional information.

Potential registrants submit their inquiry dossiers by filling in a IUCLID dossier. Only the inquiry dossiers for which the submission is considered as complete because they have passed the Business Rules check are accepted for the inquiry process and enter the REACH-IT inquiry workflow.

The handling of inquiry dossiers is divided into four stages:

Stage 1 – Screening and allocation of inquiries (see 3.1)

The Inquiry Process Coordinator (PC) screens the dossiers in order to ensure a proper handling of potential Conflict of Interests (CoI). During this screening, the PC also checks if there are inquiries that should be regarded as “re-submissions” (inquiry dossiers for which the system can find previously rejected inquiries for the same substance from the same legal entity). Based on the screening, an inquiry either is allocated to the relevant Scientific Dossier Manager (SDM) (allocation might be done for initiating or verifying the case) or is made available for being claimed by any SDM.

Stage 2 – Assessment of the scientific and technical information regarding the substance identity (see 3.2)

A SDM with Substance Identification (SID) expertise will be responsible for the dossier. The SDM will assess the dossier in order to identify the substance inquired about and to verify its identity. Previous registrants or previous potential registrants of the same substance are also identified at this stage and comparisons are made between the information provided in their submitted dossiers. These comparisons help to establish substance sameness in order to bring all previous potential registrants and potential registrants of the same substance into contact. This will enable the data sharing to take place among potential and previous registrants.

After the assessment and the identification of any potential previous registrants and/or previous potential registrants for the same substance, the SDM either accepts or rejects the inquiry.

The SDM prepares the communication and the relevant annexes for the potential registrant, which are then verified by another SID expert. The results of the assessment and its verification (quality check) are recorded in REACH-IT.

Stage 3 – Processing of data requests (see 3.3)

A SDM with Data Sharing (DS) expertise claims the task on a voluntary basis.

REACH registration dossiers are subject to an automated search process, which produces a table containing the relevant data to be shared. The SDM might correct manually the automated results.

Notification of New Substances (NONS) submitted under Directive 67/548/EEC, which are not available in REACH-IT because they had not been updated, are processed manually by the SDM.

A SDM with DS expertise prepares the communication and the relevant annexes for the potential registrant, which are then verified by another SDM with DS expertise. The results of the assessment and its verification (quality check) are recorded in REACH-IT.

Stage 4 – Communication of the inquiry results (see 3.4)

The assessment of any inquiry dossier will result in the sending via REACH-IT of a communication to the potential registrant with relevant annexes. In case the inquiry is accepted and previous registrants and/or previous potential registrants exist, communication to these relevant parties is also automatically sent out via REACH-IT.

3.1. Stage 1 - Screening and allocation of inquiries (step 1 on the flowchart)

All inquiry dossiers, which have passed the BR checks (PRO-0002), are accepted for processing.

The Inquiry PC screens all the inquiry dossiers received, and checks if there is any potential CoI (WIN-0105). A record is made in ECHA's Document Management System indicating whether a potential CoI was found or not.

The Inquiry PC also checks for each inquiry if it relates to a "re-submission". In such cases, whenever possible, the inquiries are allocated to the same SDM and to the same verifier who dealt with the original case.

Any inquiry dossier that is not allocated to a specific SDM by the PC, is available to be claimed by any SDM.

3.2. Stage 2 - Assessment of the scientific and technical information regarding the substance identity

The SDM assesses the information given in the IUCLID dossier in order to identify the substance and verify its identity. If the identity of the substance is clear and can be verified based on the analytical information given, previous registrants or previous potential registrants of the same substance are identified in ECHA databases (REACH-IT and IUCLID) and listed. Notifiers under Directive 67/548/EEC (NONS) are considered as previous registrants and referred to as such in this procedure.

3.2.1. **Assessment of the dossier** (step 2 on the flowchart)

The information given in the inquiry dossier is assessed based on the information requirements set in Annex VI section 2 of the REACH Regulation, using as needed the interpretation provided in the Guidance for identification and naming of substances under REACH and CLP. To enable the data sharing among potential and previous registrants, the SDM searches in ECHA databases (REACH-IT and IUCLID) if there are other registration or inquiry dossiers for the same substance. Typically, chemical identifiers such as EC/list number, EC/list name, CAS number, CAS name, IUPAC name, structural formula are used as searching criteria.

The information required depends also on the type of the substance being inquired about. The information provided on the identity of the substance needs to be sufficient to enable ECHA to identify previous registrants and previous potential registrants, if existing, so that data sharing can take place. When the provided information is not sufficient and additional information is required in order to identify the substance or to verify its identity, the inquiry is rejected (step 2 on the flowchart).

In case of requests for additional information submitted according to Article 12(2), if the inquiry dossier does not contain the information necessary to identify the substance, the information given in the registration dossier (or in the notification in the case of NONS) is taken into account during the scientific assessment.

During the assessment, the SDM takes into account the information contained in the following public documents:

- Guidance for identification and naming of substances under REACH and CLP
- Question and Answers related to Inquiry at:
    - Question and Answers on inquiry: http://www.echa.europa.eu/qa-display/-/qadisplay/5s1R/view/reach/inquiry

- Question and Answers on Substance Identification: http://www.echa.europa.eu/qa-display/-/qadisplay/5s1R/view/REACH/SubstanceIdentification

- Question and Answers on Data Sharing: http://www.echa.europa.eu/qa-display/-/qadisplay/5s1R/view/reach/data+sharing

- Question and Answers for the registrants of previously notified substances: http://www.echa.europa.eu/qa-display/-/qadisplay/5s1R/view/reach/NONS-Registrants+of+Previously+Notified+Substances

The outcome of the scientific assessment of the substance identity information is a conclusion whether or not the information given in the inquiry dossier is sufficient and consistent in order to identify the substance and verify its identity. Based on the result of the scientific assessment of the substance identity, the inquiry is either:

- **Accepted:** The identity of the substance inquired about is clear, the information given is consistent and the identity of the substance can be verified based on the analytical information given.

- **Rejected:** The identity of the substance inquired about is ambiguous due to missing and/or inconsistent data and/or the identity of the substance cannot be verified based on the analytical information or due to the absence of analytical information.

When the identity of the substance inquired about is clear and the identity can be verified, the SDM accepts the inquiry and confirms the proposed EC/list entry or proposes a new EC/list entry for the substance subject of the inquiry (step 3 on the flowchart).

The SDM also checks if the substance has already been previously inquired about, registered, notified under Biocidal Product Regulation (BPR, Regulation (EU) 528/2012) or under Plant Protection Products Regulation (EC) No 1107/2009. The numerical identifiers, name of the substance and structural formula (if available) are used as search criteria. If several previous registrants and/or previous potential registrants are identified, the information given in the inquiry dossier is compared to the information given in the existing dossiers for the same substance. Based on the information given in the dossiers (identifiers used, composition given and analytical information) it is decided whether the substance can be considered the same.

When an inquiry is rejected, an annex is drafted listing the deficiencies of the dossier that prevent the substance identification (step 4 on the flowchart).

3.2.2. **Preparing the cover letter** (step 5 on the flowchart)

Depending on the result of the assessment, the type of the inquiry and whether or not previous registrants or previous potential registrants exist for the substance, the relevant cover letter is automatically created by REACH-IT.

When an inquiry is accepted, information concerning the EC/List number and EC/List name is included in the cover letter.

When an inquiry is rejected, the cover letter will inform that the identity of the substance subject of the inquiry could not be confirmed. The reasons for rejecting the inquiry and instructions on how to correct the deficiencies present in the submitted dossier are stated in an annex (step 4 on the flowchart) to the cover letter.

3.2.3. **Quality check of the assessment** (step 6 on the flowchart):

The result of the assessment and the communication prepared by the SDM are verified by another SDM with SID expertise.

The verifier checks that the assessment has been done correctly by following the steps described in sections 3.2.1 and 3.2.2. For accepted inquiries, the verifier checks if the cover letter was correctly created (step 5 on the flowchart). More specifically, depending on whether there are previous registrants, previous potential registrants, notifiers under the Biocidal Product Regulation (BPR, Regulation (EU) 528/2012) or under Plant Protection Products Regulation (EC) No 1107/2009, different paragraphs are included in the letter. In the case of rejected inquiries, the verifier checks that all the reasons for rejecting the inquiry and the instructions on how to correct the identified deficiencies (step 4 on the flowchart) are clearly explained in the relevant annex that is provided with the cover letter.

When the verifier agrees with the SDM and the inquiry is considered as accepted (flowchart: from step 7 onwards) the following outcomes are possible:

- If the dossier does not contain data request: the communication is automatically sent out via REACH-IT to the potential registrant, as well as to any previous registrants and previous potential registrants, if the case may be.

- If the dossier contains data request but there are neither previous registrants nor notifiers under the Biocidal Product Regulation (EU) 528/2012 or under Plant Protection Products Regulation (EC) No 1107/2009: the communication is automatically sent out via REACH-IT to the potential registrant as well as to any previous potential registrants, if the case may be.

- If the dossier contains data request and there are previous registrants or notifiers under the Biocidal Product Regulation (EU) 528/2012 or under Plant Protection Products Regulation (EC) No 1107/2009: REACH-IT forwards the case to a SDM with DS expertise.

When the verifier agrees with the SDM and the inquiry is considered as rejected the communication is automatically sent out via REACH-IT to the potential registrant (from step 7 to step 15).

If the verifier disagrees with the assessment and/or has comments, the case returns to the SDM who performed the initial assessment. The SDM revises the assessment and the corresponding communication. When the reassessment is concluded, the case returns for the verification to the same verifier that was assigned initially to the case. The cycle continues until the verifier agrees with the SDM assessment.

3.3. Stage 3 - Processing of data requests

3.3.1. **Assessment of the availability of the requested data** (step 10 on the flowchart)

The SDM with DS expertise checks if the data requested in the inquiry dossier is available in the existing information ECHA has for the same substance. The system automatically retrieves the available information in existing IUCLID dossiers in REACH-IT. In some specific cases, the results displayed automatically might be amended manually by the SDM. For the claimed NONS that are not available in REACH-IT because they have not yet been updated,

and for the unclaimed notifications, the availability of the data is manually checked by a SDM with DS expertise.

The outcome of the assessment regarding the availability of the requested data is recorded in a table (step 11 on the flowchart) that is sent to the potential registrant as an annex to the communication.

This table is populated according to the following criteria:

Provision of available data submitted at least 12 years previously

Where information has been submitted at least 12 years previously, the (robust) study summary is attached in the table together with the names of the previous registrants corresponding to each endpoint.

Provision of available data submitted less than 12 years previously

If the data has been submitted less than 12 years previously, the name of the legal entity that has submitted the information is indicated in the table.

3.3.2. **Quality check of the provided data** (step 12 on the flowchart)

The result of the assessment regarding the availability of the data requested, the relevant table and the study summaries attachments prepared by the SDM are verified by another SDM with DS expertise (verifier). The verification goes through the same steps as the initial assessment.

When the verifier agrees with the SDM, the inquiry process is concluded and the final communication is sent out via REACH-IT together with all relevant documents.

If the verifier disagrees with the assessment and/or attachments and/or has comments, the case returns to the SDM who performed the initial assessment. The SDM revises the assessment and the corresponding documents. When the reassessment is concluded, the case returns for the verification to the same verifier that was assigned initially to the case. The cycle continues until the verifier agrees with the SDM assessment.

3.4. Stage 4 - Communication of the inquiry results

3.4.1. **Communication of the results to the potential registrant** (steps 13, 14 and 15 on the flowchart)

The final communications are prepared as follows:

Accepted inquiries:

- A REACH-IT message is sent to the potential registrant. The message contains:
    - a link to the Co-Registrant page in REACH-IT where all the contact details of potential and previous registrants for the same substance subject of the inquiry are displayed.
    - a link to the communication. The communication includes a cover letter with the relevant numerical identifiers (Inquiry number, EC/list number and EC/list name), an annex with the available data that was requested (if relevant), an annex with information regarding previous notifiers under the Biocidal Product Regulation (EU) 528/2012 or under Plant Protection Products Regulation (EC) No 1107/2009 (if relevant).

Rejected inquiries:

- A REACH-IT message is sent to the potential registrant. The message contains:
    - a link to the communication. The communication includes a cover letter and an annex where the reasons for rejection and instructions on how to correct the deficiencies are stated.

3.4.2. Communication of the results to previous registrants and previous potential registrants for accepted inquiries (steps 13 and 14 on the flowchart)

The communication regarding the result of the inquiry assessment is sent to the relevant parties as follows:

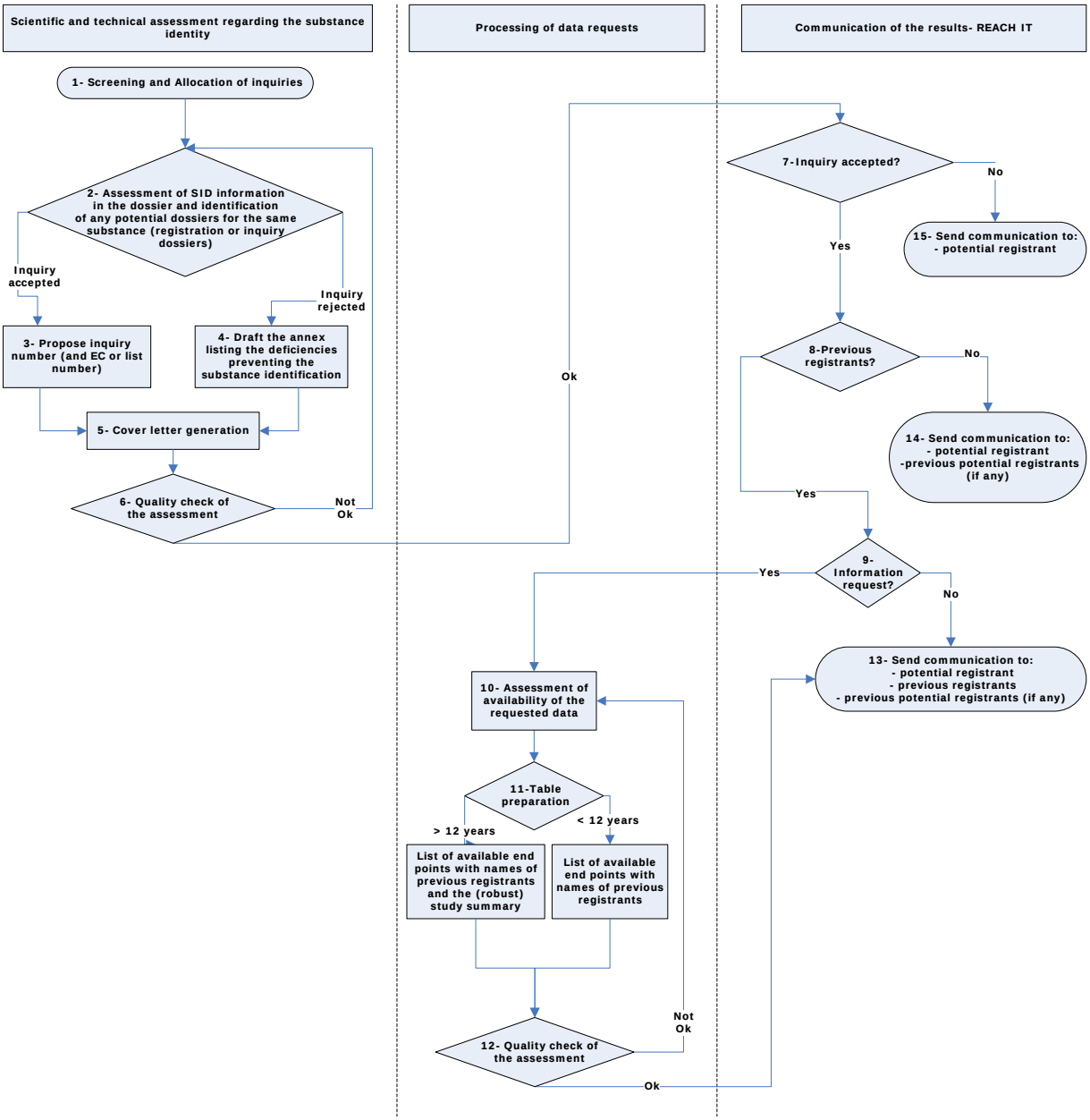
Previous registrants

- Registrants under REACH who have a REACH-IT account: A communication is sent out automatically via REACH-IT containing a link to the Co-Registrants page.
- Previous notifiers that have not claimed their registration: A communication is sent out via registered mail.
- Notifiers under Biocidal Product Regulation (EU) 528/2012 or under Plant Protection Products Regulation (EC) No 1107/2009: A communication is sent out via registered mail.

Previous potential registrants

- Potential Registrants: A communication is sent out automatically via REACH-IT containing a link to the Co-Registrants page.

4. Flowchart


Scientific and technical assessment regarding the substance identity
Processing of data requests
Communication of the results- REACH IT
1- Screening and Allocation of inquiries
2- Assessment of SID information in the dossier and identification of any potential dossiers for the same substance (registration or inquiry dossiers)
Inquiry accepted
Inquiry rejected
3- Propose inquiry number (and EC or list number)
4- Draft the annex listing the deficiencies preventing the substance identification
5- Cover letter generation
6- Quality check of the assessment
Not Ok
Ok
7-Inquiry accepted?
No
15- Send communication to: - potential registrant
Yes
8-Previous registrants?
No
14- Send communication to: - potential registrant -previous potential registrants (if any)
Yes
9- Information request?
Yes
No
13- Send communication to: - potential registrant - previous registrants - previous potential registrants (if any)
10- Assessment of availability of the requested data
11-Table preparation
> 12 years
< 12 years
List of available end points with names of previous registrants and the (robust) study summary
List of available end points with names of previous registrants
12- Quality check of the assessment
Not Ok
Ok

5. Definitions

Term or abbreviation	Definition
Business Rules	The business rules are automatic checks done in REACH-IT to establish that the submitted dossiers meet a set of minimum requirements. They will ensure that the dossiers can be handled properly and that the required regulatory processes can be successfully carried out.
CoI	Conflict of Interest
DS	Data Sharing
IUCLID	International Uniform Chemical Information Database Software application used to capture and store, submit, and exchange data on chemical substances.
NONS	Substances that have been notified under Directive 67/548/EEC
PC	Process Coordinator
Previous registrants	Covers previous registrants under REACH and NONS.
REACH-IT	Online platform to submit and process dossiers under the REACH and CLP regulations. It also allows ECHA and the Member States authorities to review the dossiers.
SID	Substance Identification
SDM	Scientific Dossier Manager with SID or DS expertise

6. Records

Record name	Security level	Comments
Communication to potential registrant-accepted inquiries	Internal	
Communication to potential registrant-rejected inquiries	Internal	
Communication to other relevant parties	Internal	

7. References

Associated document code	Document name
Regulation (EC) No 1907/2006	REACH Regulation
Regulation (EU) 528/2012	Biocidal Product Regulation
Regulation (EC) No 1107/2009	Plant Protection Products Regulation
Directive 67/548/EEC	Directive on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances.
ECHA-11-G-10.2-EN	Guidance for identification and naming of substances under REACH and CLP
	Guidance on Data Sharing
	Question and Answers on Substance Identification: http://www.echa.europa.eu/qa-display/-/qadisplay/5s1R/view/REACH/SubstanceIdentification
	Question and Answers on inquiry: http://www.echa.europa.eu/qa-display/-/qadisplay/5s1R/view/reach/inquiry
	Question and Answers on Data Sharing: http://www.echa.europa.eu/qa-display/-/qadisplay/5s1R/view/reach/data+sharing
	Question and Answers for the registrants of previously notified substances: http://www.echa.europa.eu/qa-display/-/qadisplay/5s1R/view/reach/NONS-Registrants+of+Previously+Notified+Substances

8. Annexes

N/A