

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 *Submission and Processing Unit* (Unit A3). 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 substances which have not yet been 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 an IUCLID dossier. Only the inquiry dossiers for which the submission is considered as complete, after passing 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)

For substances where no registrants or potential registrants exist, or those with ambiguous identifiers, the inquiry dossiers are screened and allocated. The screening step is performed to ensure a proper handling of potential Conflict of Interests (CoI) and to check if any inquiry should be regarded as a “re-submission” (inquiry dossiers for which previously rejected inquiries exist for the same substance from the same legal entity). Based on the screening, the inquiry is allocated to the relevant Scientific Dossier Manager (SDM) (allocation is performed to assess the information in the dossier and verify the assessment).

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

An SDM is assigned to the inquiry dossier and assesses the information provided to verify the identity of the inquired substance. Previous (potential) registrants of the same substance are also identified at this stage and the information provided in their dossiers is compared with the information provided in the inquiry dossier, if available. Comparing this data is relevant to ensure that previous (potential) registrants of the same substance are put in contact to facilitate data sharing.

After the assessment of the inquiry dossier and the identification of any 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 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)

REACH registration dossiers are subject to an automated search process, which results in a list with the relevant study summaries' universally unique identifiers (UUIs) to be shared in the co-registrants page of the assigned EC/List number.

The Notifications of New Substances (NONS) submitted under Directive 67/548/EEC, are also subject to an automated search process, which results in a list with the relevant data to be shared in the co-registrants page of the assigned EC/List number. Except for the NONS, that have not been updated under REACH. These are processed manually.

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 results in sending a communication together with the relevant annexes to the potential registrant via REACH-IT. If the inquiry is accepted and previous registrants and/or previous potential registrants exist, the relevant parties will be informed via REACH-IT.

3.1. Stage 1 - Screening and allocation of inquiries

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

All the inquiry dossiers received for substances where no (potential) registrants exist or with ambiguous identifiers (step 1 on the flowchart) are screened for any potential CoI (WIN-0105) and assigned to an SDM (step 2 on the flowchart). A record is made in ECHA's Document Management System indicating whether a potential CoI was found or not.

As part of the screening, the inquiries are also checked to determine if they are regarded as 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 dossier.

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 to verify its substance identity. If the identity of the substance is clear and can be verified based on the analytical information given, previous (potential) registrants of the same substance are searched 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 3 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) for 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 or 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 (potential) registrants, if existing, so that data sharing can take place. When the provided information is ambiguous, additional information is required to verify the substance identity and the inquiry is rejected.

In case of requests for additional information submitted according to Article 12(2), the identifiers assigned are based on the provided numerical identifiers.

During the assessment, the SDM considers 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: <https://echa.europa.eu/support/qas>
 - Question and Answers on Inquiry
 - Question and Answers on Substance Identification
 - Question and Answers on Data Sharing
 - Question and Answers for the NONS-registrants of previously notified substances

The outcome of the scientific assessment of the substance identity information is a conclusion whether the information given in the inquiry dossier is sufficient and consistent to verify its substance identity. Based on the result of the scientific assessment of the substance identity, the inquiry is either:

- **Accepted:** The identity of the inquired substance can be verified based on the information provided.
- **Rejected:** The identity of the inquired substance cannot be confirmed based on the information provided.

When the identity of the inquired substance can be unambiguously 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 4 on the flowchart).

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The SDM also checks if the substance has already been previously inquired about, registered or notified under Biocidal Product Regulation (BPR, Regulation (EU) 528/2012) or 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 (potential) registrants are found, the information provided in the inquiry dossier is compared to the information in the existing dossiers for the same substance. Based on the information provided in the dossiers (identifiers used, composition given and analytical information), it is decided whether the substances 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 5 on the flowchart).

3.2.2. Preparing the cover letter (step 6 on the flowchart)

Depending on the result of the assessment the relevant cover letter is generated in REACH-IT.

- If an inquiry is accepted, the cover letter includes the inquiry number, the EC/List number and EC/List name assigned (step 4 on the flowchart).
- If an inquiry is rejected, the cover letter will inform that the identity of the substance subject of the inquiry could not be confirmed. This letter also includes the contact details of the SDM that assessed the inquiry dossier. 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 5 on the flowchart) to the cover letter.

3.2.3. Quality check of the assessment (step 7 on the flowchart):

The result of the assessment and the communication prepared by the SDM are verified by another expert.

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 includes the correct information (step 4 on the flowchart). For rejected inquiries, the verifier checks that all the reasons for rejecting the inquiry and the instructions to correct the identified deficiencies are clearly explained in the annex provided with the cover letter (step 5 on the flowchart).

If the verifier agrees with the SDM and the inquiry is considered as accepted (from step 8 to 15 on the flowchart), the following outcomes are possible:

- the dossier does not contain data request: the communication is automatically sent out via REACH-IT to the potential registrant. If any previous (potential) registrants exist, they will also be informed of the new potential registrant via REACH-IT.
- the dossier contains data request but there are neither previous registrants nor notifiers under Directive 67/548/EEC: the communication is sent out via REACH-IT to the potential registrant. If any previous (potential) registrants exist, they will also be informed of the new potential registrant via REACH-IT.
- the dossier contains data request and there are data submitted for any of the endpoints requested by the potential registrant, REACH-IT forwards the case to the processing of data requests stage (see section 3.3).

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If 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 (step 16 on the flowchart).

3.3. Stage 3 - Processing of data requests

3.3.1. Assessment of the availability of the requested data (step 12 on the flowchart)

The system automatically retrieves the available information in existing IUCLID dossiers in REACH-IT. For the unclaimed notifications, experts manually check the availability of the data requested in the inquiry dossier.

The outcome of the assessment regarding the availability of the requested data is listed under the 'Studies' section on the Co-Registrants page in REACH-IT, or is sent to the potential registrant as an annex to the communication.

The 'Studies' section on the Co-Registrants page in REACH-IT 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 universally unique identifier (UUID) of a (robust) study summary is listed under 'Studies', subsection 'Studies submitted at least 12 years ago', together with the names and contact details 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 and contact details of the legal entity that has submitted the information is indicated under 'Studies', subsection 'Studies submitted less than 12 years ago' on the Co-Registrants page.

3.3.2. Quality check of the provided data (step 13 on the flowchart)

A second expert verifies the availability of (robust) study summaries from dossiers submitted at least 12 years previously.

When the verifier agrees with the initiator, the inquiry process is concluded, and the final communication is sent out via REACH-IT together with all the relevant documents. The previous (potential) registrants will also be informed of the new potential registrant via REACH-IT.

3.4. Stage 4 - Communication of the inquiry results

3.4.1. Communication of the results (steps 14, 15 and 16 on the flowchart)

The results are communicated to the potential registrant as follows:

Accepted inquiries:

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

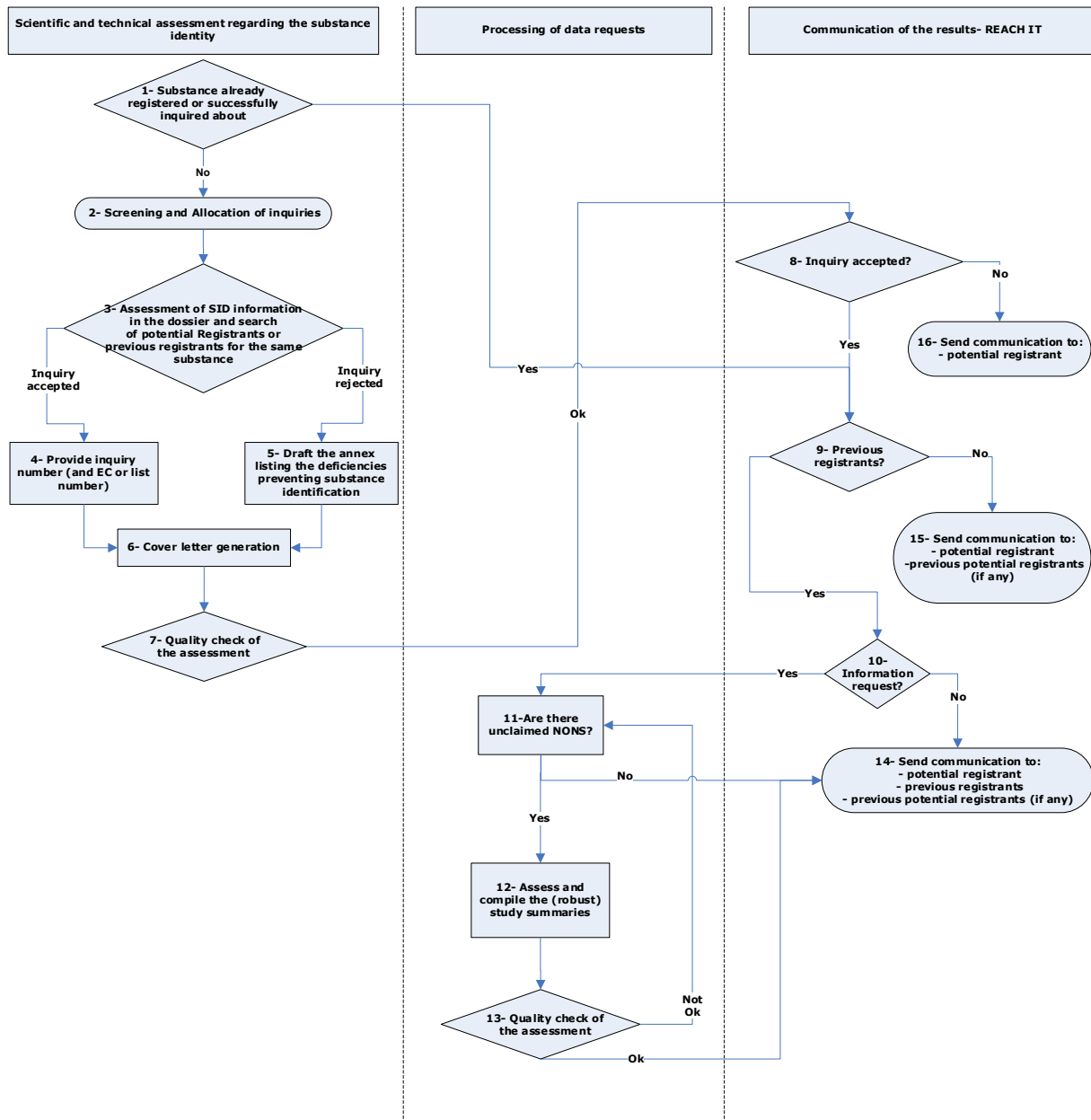
If there are previous (potential) registrants, they are automatically informed about the existence of the new potential registrant via REACH-IT with a link to the Co-Registrants page.

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 with the reasons for rejection and instructions on how to correct the deficiencies.

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4. Flowchart



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5. Definitions

Term or abbreviation	Definition
Business Rules (BR)	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
Previous (potential) registrants	Covers previous potential registrants and 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.
SDM	Scientific Dossier Manager

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	

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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
	https://www.echa.europa.eu/web/guest/support/qas-support/browse Question and Answers on Substance Identification Question and Answers on Inquiry Question and Answers on Data Sharing Question and Answers for the NONS-registrants of previously notified substances

8. Annexes

N/A