

Settling disputes arising from the failure to reach an agreement on data sharing

1. Purpose

This procedure document describes the settling of disputes lodged at the Agency:

- by potential or previous registrants regarding access to data according to Article 27(5) of the REACH Regulation in conjunction with Articles 2, 4 and 5 of the Implementing Regulation on joint submission of data and data sharing (EU) 2016/9; and
- by prospective applicants regarding access to data according to Biocidal Product Regulation (BPR) Articles 63(3) and 95.

Effective settling of disputes is pivotal to avoid unnecessary animal testing, which is an objective laid down in Article 25(1) of REACH and Article 62(1) of BPR.

The provisions and mechanisms are in place to ensure that:

- disputes are processed in conformity with the relevant legislative requirements;
- the deadlines are respected and the Agency's internal requirements for processing disputes are met; and
- the responsibilities and decision making are unambiguously defined for all relevant activities.

2. Scope

The process of settling disputes begins when the claimant notifies the Agency through a webform about the failure to reach an agreement. The process finishes when the Agency issues a decision or when the Agency closes the dispute.

3. Description

3.1. General

A dispute claim is submitted by the Claimant by filling in a webform available on the Agency's website regarding its data sharing negotiations with the Other Party. The completed webform is directly received by ECHA's Disputes team.

The following types of disputes are processed:

- a) Failure to reach an agreement on data sharing under REACH – Article 27(5) of the REACH Regulation in connection with Articles 2, 4 and 5 of Implementing Regulation on joint submission of data and data sharing 2016/9 (flowchart in section 4; WIN-0038 "Handling disputes under Article 27 REACH)); and
- b) Failure to reach an agreement on the sharing of data on active substance or biocidal product under BPR – Articles 63(3) and 95 of the BPR (flowchart in section 4; WIN-0211 "Settling data sharing disputes arising from the failure to reach an agreement on sharing data under BPR").

Decision making process

The Disputes team ensures that sufficient information is available in order for the claim to be processed and requests the Other Party to submit evidence of the negotiations at stake.

On this basis, the Disputes team assesses the information received and prepares a decision to be adopted by ECHA and to be signed by the Executive Director (ED) or its delegate within one month (in the case of Article 27(5) REACH) or 60 days (in the case of Article 63 BPR).

This timeline starts counting when ECHA receives the dispute via the webform from the claimant. The timeline is suspended between the day when ECHA asks the Other Party for evidence on the data sharing negotiations, and the day when the Other Party provides this evidence or, if the Other Party does not provide evidence, from the deadline by which it was invited to provide it.

Responsibilities

The Process Owner is responsible for:

- Ensuring that the procedure is followed.
- Proposing corrective actions in the case of deviations.
- Managing and ensuring the check of the conflicts of interest of the Disputes team members (PRO-0067).

In addition, the Process Owner is the controller of personal data under its responsibility, and is responsible as a data controller for the tasks defined in Decision ED/32/2010.

These responsibilities can be sub-delegated.

The Process Coordinator is a member of the Disputes team designated by the Process Owner to coordinate and oversee the correct implementation of this procedure.

Any staff member is replaced, if there is a potential conflict of interest.

Two members of the Disputes team are designated by the Process Coordinator to handle a dispute, after a check of potential conflicts of interest by the Interest Manager. These members of the Disputes team ensure that the assigned claim is handled correctly and organise the necessary documents/notes for the file, communications sent to parties, perform the assessment of the claim and finalise all communications.

3.2. Detailed description

A claim regarding the disputes is submitted using a webform on the Agency's website, available at: https://comments.echa.europa.eu/comments_cms/article275.aspx and https://comments.echa.europa.eu/comments_cms/Article633.aspx.

3.2.1. Pre-processing

Receipt of the webform

The Disputes Team checks that sufficient information to process the claim has been provided.

Request for further information

If essential information for the handling of the dispute is not available, the Disputes team requests further information from the Claimant.

Incomplete information

If after the request for further information, the provided additional information is still incomplete, or is not provided within the set deadline, ECHA closes the dispute.

Request for information from the Other Party

If the Claimant has provided the essential information for ECHA to handle a dispute, the Disputes Team requests the Other Party to provide evidence relating to its negotiations with the Claimant. If the Other Party fails to submit this information within the deadline, the Disputes team only takes into account the evidence provided by the Claimant.

3.2.2. Decision-making process

On the basis of the documentation provided by one or both parties, the Disputes Team assesses the efforts of the parties to reach an agreement in a fair, transparent and non-discriminatory way. The outcome of this assessment forms the basis for the decision whether or not to grant the Claimant a permission to refer.

3.2.3. Outcome

Decision granting the Claimant a permission to refer to the requested data

ECHA may issue a decision granting the Claimant permission to refer to the studies requested from the Other Party. This decision will be conditional to the submission by the Claimant of a proof of payment to the Other Party of a share of the cost incurred, within two months from the date of the decision. The claimant is not allowed to make use of this permission to refer before (i) having submitted a proof of payment to ECHA within two months of the decision and (ii) having received from ECHA an acknowledgment of receipt of this proof of payment.

If the Claimant has already provided a proof of payment when submitting the claim, ECHA issues a decision granting permission to refer to the relevant studies in the Other Party's registration and the Claimant can make use of this permission to refer to submit its registration dossier.

Receipt or not of a proof of payment within two months

If the Claimant provides a proof of payment within two months, ECHA will acknowledge its receipt and the Claimant can make use of this permission to refer to submit its registration dossier.

If the Claimant does not submit this proof of payment within two months, ECHA will revoke its decision granting permission to refer.

Decision not to grant a permission to refer and closure

If ECHA issues a decision not granting the Claimant permission to refer to the studies requested from the Other Party, the dispute is closed.

Similarly, if the Claimant withdraws the dispute at any point in time, ECHA closes the dispute.

3.3. Record keeping, archiving and publishing

All relevant information related to the settling of disputes is stored and accessed in accordance with the Information Management Policy (POL-0007). The principles for Control of documents and records (PRO-0010) apply. The records are kept in the Agency's filing system and are protected by access rights restrictions. The system administrator grants appropriate access upon approval from the Process Owner.

In addition, the decisions containing an assessment of the parties' efforts are published on ECHA's website. Before publishing ECHA redacts the information that is not to be disclosed in accordance with ATD Regulation.

3.4. Preventive measures

Settling of disputes within the legal deadlines when the workload is high depends on the proper functioning of the procedures set out in this document. Significant variations in the process load are likely to occur, and will depend on the number of disputes submitted by the parties.

Preventive measures are taken and procedures and instructions are in place to prevent undue delays or loss of data, and to react promptly to urgent claims.

The members of the Disputes Team are trained for handling various tasks in order to act as back-up for different roles in order to prevent delays in processing due to unforeseen unavailability of staff.

All internal documents and communications are prepared by one member of the Disputes Team and checked by at least one other member of the Disputes Team. The assessment of efforts and decisions that have legal consequences are authorised by the Process Owner as the delegate of the ED. Other communications to the parties are approved by the Process Owner or its delegates.

3.5. Handling of deviations

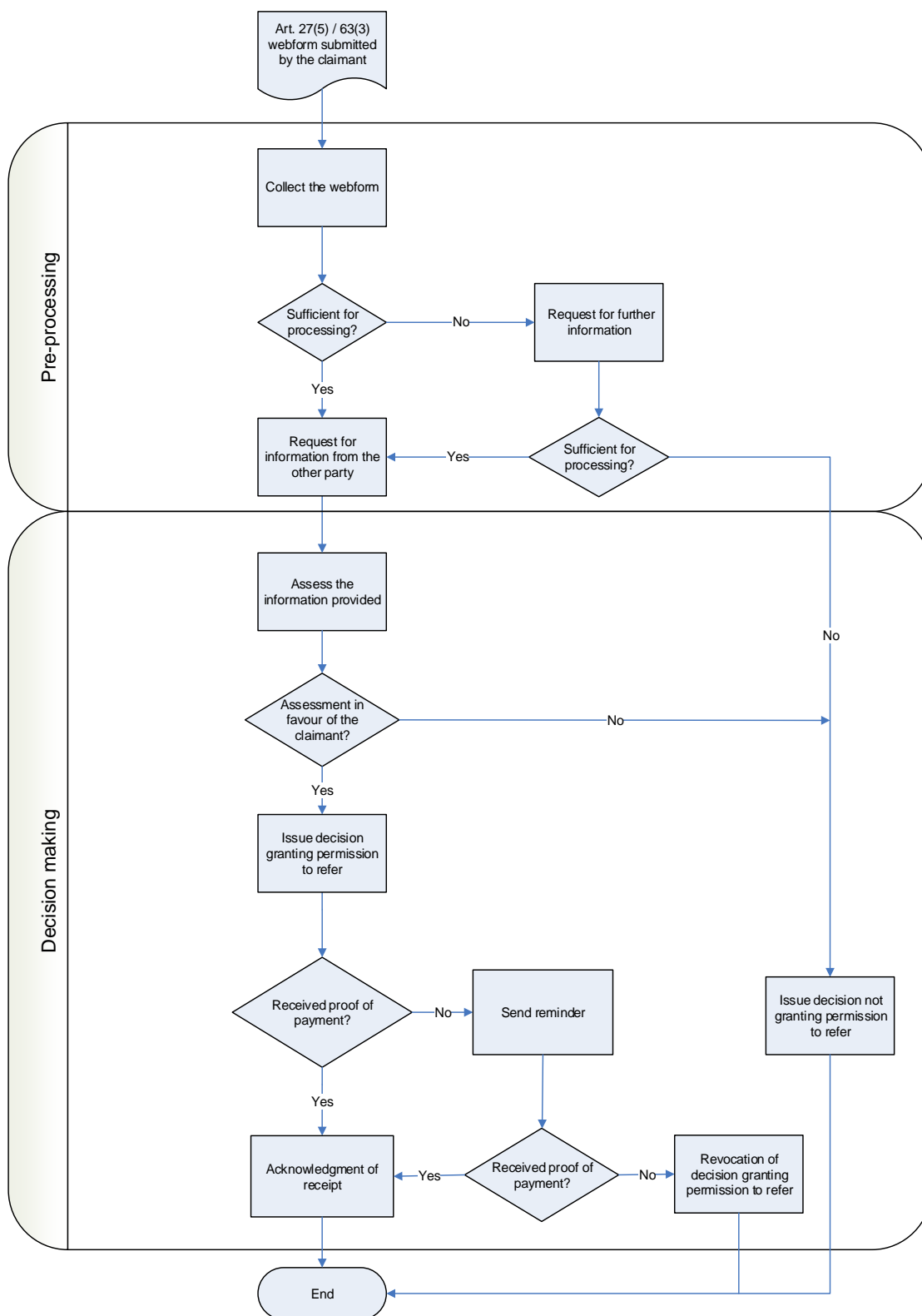
All data sharing disputes where the legal deadline is exceeded are recorded and handled as deviations.

Deviations from this procedure are documented and appropriate action is taken. The Process Owner and the Process Coordinator are informed to define and implement corrective actions.

4. Flowchart

The flowchart below shows the sequence of events and actions taken by the Agency in the processing of data sharing disputes. Additional information on each of the steps can be found in section 3.2.

Settling disputes arising from the failure to reach an agreement on data sharing



5. Definitions

Term or abbreviation	Definition
Agency / ECHA	European Chemicals Agency
BPR	Biocidal Products Regulation
Claim	Information from the Claimant to the Agency (through a webform) about the failure to reach an agreement (with supporting documentary evidence)
Claimant	Party submitting the dispute claim
Communication	Information sent to and received by the parties during the process of handling the request/dispute
Decision	Legal act which is binding on the person or entity to which it is addressed. It is subject to appeal according to Articles 27(7) REACH and 63(5) BPR
ED	Executive Director
MB	Management Board of ECHA
Other party	Party negotiating with the claimant on terms of access to joint submission / data sharing
Potential registrant	Legal entity willing to register a substance and that has inquired according to Article 26(1)
Previous registrant	Legal entity that has already submitted a registration dossier for a substance under the REACH Regulation including also for notifications regarded as registrations according to Article 24
Prospective applicant	Legal entity intending to perform tests or studies for BPR purposes
WIN	Work instruction

6. Records

Record name	Security level	Comments
Conflict of interest check	Restricted	
Web-form and documents attached to the web-form	Restricted	

Record name	Security level	Comments
Communications between ECHA, the Claimant and the Other Party	Restricted	
ECHA decisions (including annexes) sent to the Claimant and the Other Party	Restricted	

7. References

Associated document code	Document name
(EC) No 1907/2006	REACH Regulation
(EU) No 528/2012	Biocidal Products Regulation (BPR)
(EU) 2016/9	Commission Implementing Regulation on joint submission of data and data sharing
(EU) 2019/1692	Commission Implementing Regulation on the application of certain registration and data-sharing provisions of REACH after the expiry of the final registration deadline for phase-in substances
(EC) No 1049/2001	Regulation regarding public access to European Parliament, Council and Commission documents (ATD Regulation)
ECHA-16-G-12.1-EN	Guidance on Data sharing
ECHA-15-B-04-EN	Practical Guide on Biocidal Products Regulation: Special Series on Data Sharing – Data Sharing
(EU) 2018/1725	Regulation on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data
ED/32/2010	Tasks, duties and powers of the Data Protection Officer and the Data Controllers
MB/11/2008	Code of good administrative behaviour for the staff of the European Chemicals Agency in their relation with the public

8. Annexes

N/A