

# Settling disputes arising from the failure to reach an agreement on joint submission of data and data-sharing

## 1. Purpose

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

- by potential/existing registrants regarding access to data according to REACH Regulation Articles 27(5) and 30(3) in conjunction with Articles 2, 4 and 5 of the Implementing Regulation on joint submission of data and data-sharing
- by potential/existing registrants regarding access to joint submission according to REACH Regulation Articles 11 and 19 in conjunction with Article 3 of the Implementing Regulation on joint submission of data and data-sharing
- by potential/existing registrants regarding disagreements on who shall perform a test missing within the SIEF according to REACH Regulation Article 30(2)
- 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 the avoidance of unnecessary animal testing, which is an objective laid down in Article 25(1) of REACH and Article 62(1) of BPR
- to ensure compliance with the joint submission obligation (Articles 11 and 19 REACH).

The provisions and mechanisms are in place to ensure that:

- disputes are processed in conformity with the relevant legislative requirements,
- the legislative deadlines are respected and the Agency's internal requirements for processing disputes are met,
- the "One Substance, One Registration" principle (joint submission obligation) under the REACH Regulation is applied, 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 on sharing the data and/or access to the joint submission. The process finishes when the Agency issues a decision or when the Agency closes the claim without a decision due to a withdrawal by the claimant.

## Linkage to ECHA Process System

<b>L1. Activity:</b>	01 Registration, data-sharing and dissemination 16 Biocides
<b>L2. Process:</b>	01.05 Data-sharing 16.11 Disputes
<b>L3. Sub-process:</b>	01.05.01 Disputes 27(6) 01.05.02 Disputes 30(2) 01.05.03 Disputes 30(3)

## 3. Description

### 3.1. General

Dispute claim is submitted by the claimant by filling in a webform available on the Agency's website. 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 joint submission of data and data sharing for non-phase-in and for non-pre-registered substances under REACH – Articles 11, 19 and 27(5) of the REACH Regulation in connection to Articles 2, 3, 4 and 5 of Commission Implementing Regulation on joint submission of data and data-sharing (flowchart in section 4.1; WIN-0038).
- b) Failure to reach an agreement on who shall conduct a new test on a phase-in substance which is not available within the SIEF – Article 30(2) of the REACH Regulation (flowchart in section 4.2).
- c) Failure to reach an agreement on joint submission of data and data sharing for pre-registered substances before the vertebrate animal studies subject to the dispute have been submitted to ECHA– Articles 11, 19 and 30(3) of the REACH Regulation in connection to Articles 2, 3, 4 and 5 of Commission Implementing Regulation on joint submission of data and data-sharing (flowchart in section 4.3; WIN-0041).
- d) Failure to reach an agreement on joint submission of data and sharing of vertebrate animal studies that have been submitted to ECHA for pre-registered substances – Articles 11, 19 and 30(3) of the REACH Regulation in connection to Articles 2, 3, 4 and 5 of Commission Implementing Regulation on joint submission of data and data-sharing (flowchart in section 4.4; WIN-0041)
- e) Failure to reach an agreement on sharing of data on active substance or biocidal product under BPR – Article 63(3) and 95 of the BPR (flowchart in section 4.5; WIN-0211).

In all cases, the settling of disputes consists of three stages:

#### 1. Pre-processing

The Disputes team ensures that all the necessary information is available in order for the claim to be processed.

#### 2. Decision making process

**Settling disputes arising from the failure to reach an agreement on joint submission of data and data-sharing**

The Disputes team assesses the information provided and prepares a proposal, in collaboration with the Legal Advisor, for the final decision to be adopted by ECHA and to be signed by the Executive Director (ED) or its delegate.

### 3. Follow-up (where required)

After the final decision is sent, the Disputes team takes further steps.

The process is carried out within fixed deadlines determined by the REACH Regulation, BPR or by the internal deadlines established in consideration of the Code of good administrative behaviour for the staff of the European Chemicals Agency in their relation with the public starting from the date when the information submitted by the parties is complete.

The Process Owner is responsible for:

- Ensuring that the procedure is followed,
- Proposing corrective actions in the case of deviations (this responsibility can be delegated to sub-process owners)
- 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.

The Process Coordinator is a member of the Disputes team designated by the Process Owner to coordinate the implementation of this procedure. The Process Coordinator is replaced by another member of the Disputes team if there is a case of potential conflict of interest. In case of potential conflict of interest, the Process Owner is replaced by the Activity Owner, the Deputy Executive Director, or the Executive Director or its delegates.

For each claim, a member of the Disputes team is designated by the Process Coordinator to handle it, after a check of potential conflicts of interest by the designated Interest Manager. This member of the Disputes team ensures that the assigned claim is handled correctly and is responsible for organising the necessary documents/notes for the file, for the communications sent to parties, for performing the assessment of the claim and for finalising all the communications to be sent. The member of the Disputes team is also responsible for filing all the documents relating to the claim.

A second member of the Disputes team is a person designated for a specific claim to perform a check on all internal documents, communications and decisions prepared by the first member of the Disputes team.

## **3.2. Detailed description**

### **3.2.1. Failure to reach an agreement on joint submission of data and data sharing for non-phase-in and for non-pre-registered substances under REACH**

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>

#### **3.2.1.1.Pre-processing**

##### Receipt of the webform

The Disputes team checks that all the relevant documentary evidence has been provided.

##### Request for further information

If the webform or the attached documentary evidence provided to the Agency is not complete, the Disputes team requests further information from the claimant.

#### Decision on inadmissibility

If after the request for further information, the provided additional information is still incomplete, or is not provided within the set deadline, the recommendation of the Disputes team to the ED will be to decide that the claim is inadmissible.

#### Request for information from the other party

If the claimant has provided all the relevant information and documentary evidence, the Disputes team requests the other party to provide their documentary evidence relating to the arguments and justifications they used, if any, during the negotiations with the claimant, within a set deadline. If the other party fails to submit this information, the Disputes team proceeds and only takes into account the available evidence.

### **3.2.1.2. 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 allows the ED or its delegates to decide whether or not the claimant shall be granted an access to the joint submission and/or a permission to refer to the data already submitted.

### **3.2.1.3. Decision**

The Disputes team prepares one of the following decisions/communications which is reviewed by the Legal Advisor before it is submitted to the ED or its delegate.

#### Decision requesting to continue the negotiations

If it is not demonstrated, by documentary evidence, that the claimant has met their obligation to make every effort to reach an agreement on the terms of access to the joint submission and/or on sharing of the data and its costs, the recommendation of the Disputes team to the ED will be to reject the claim and request the parties to continue the negotiations.

#### Request for proof of payment, reminder and potential decision not granting the claimant access to the joint submission and/or permission to refer to the requested data

If it is demonstrated by documentary evidence that the claimant has met their obligation to make every effort to reach an agreement on terms of access to joint submission and/or on the sharing of the data and its costs, the recommendation of the Disputes team to the ED will be to grant the claimant access to the joint submission and/or permission to refer to the data already submitted by the previous registrant(s). In this case, the Disputes team first communicates the result of the assessment to the parties and requests from the claimant a proof of payment of a share of the costs incurred by the previous registrant. In case this information has been already provided to the Agency, a decision granting access to the joint submission and/or permission to refer will be issued (see below).

If the claimant does not provide the proof of payment within six months from the request, the Disputes team sends a reminder to the claimant indicating that a final 10 working day deadline has been set.

If the Agency does not receive a proof of payment or request for withdrawal of the claim by the final deadline, the recommendation of the Disputes team to the ED will be to decide that

the claimant is not granted the access to the joint submission and/or the permission to refer to the requested data.

#### Decision granting the claimant access to the joint submission and/or permission to refer to the requested data

Upon receipt of the proof of payment, the recommendation of the Disputes team to the ED will be to grant the claimant the access to the joint submission and/or the permission to refer to the requested data.

#### **3.2.1.4. Withdrawal by the claimant**

The claimant can withdraw the claim at any stage before the final decision is issued by the Agency. The claimant needs to inform the Agency of this intention in writing and the Disputes team confirms in writing to the claimant, and if relevant to the other party, that the claim is closed without the final decision.

#### **3.2.2. Failure to reach an agreement in a SIEF**

According to Article 30 of REACH, a SIEF member can inform the Agency regarding disputes resulting from a disagreement on who shall conduct a new test (Article 30(2)) and regarding disputes resulting from a disagreement on the principle and/or the conditions of access to joint submission and of sharing existing vertebrate studies (Article 30(3)).

##### **3.2.2.1. Failure to reach an agreement on who shall conduct a new test on a phase-in substance which is not available within the SIEF**

A claim regarding the dispute is submitted using a webform on the Agency's website, available at: <https://comments.echa.europa.eu/comments/cms/article302.aspx>

##### **3.2.2.1.1 Pre-processing**

###### Receipt of the webform

The Disputes team checks that all the relevant documentary evidence has been provided.

###### Request for further information

If the webform or the attached documentary evidence provided to the Agency is not complete, the Disputes team requests further information from the claimant.

###### Decision on inadmissibility

If after the request for further information, the provided additional information is still incomplete, or is not provided within the set deadline, the recommendation of the Disputes team to the ED will be to decide that the claim is inadmissible.

###### Request for information from other parties (where necessary)

If the claimant has provided all the relevant information and documentary evidence, the Disputes team requests the other parties to provide any documentary evidence relating to the arguments and justifications used during the negotiations, within a set deadline. This step is taken into account only where there are two parties who volunteered and disagreed on who shall perform the test. In the case where there are no volunteers, the step is skipped.

##### **3.2.2.1.2 Decision making process**

Based on the provided information, the Disputes team assesses who shall conduct the test on the basis of objective criteria, including active participation in the preparation of the dossier and the deadline applicable to the respective registration of the SIEF members.

#### **3.2.2.1.3. Decision on who performs the new test**

The Disputes team prepares the decision which is reviewed by the Legal Advisor before it is submitted to the ED, who decides which SIEF participant will conduct the test on behalf of the others.

Those participants that do not carry out the study themselves will have the right to receive the full study report within two weeks following payment to the participant that performed the test.

#### **3.2.2.1.4. Withdrawal by the claimant**

The claimant can withdraw the claim at any stage before the final decision is issued by the Agency. The claimant needs to inform the Agency of this intention in writing and the Disputes team confirms in writing to the claimant, and if relevant to the other parties, that the claim is closed without the final decision.

#### **3.2.2.2. Failure to reach an agreement on joint submission of data and data sharing for pre-registered substances before the vertebrate animal studies subject to the dispute have been submitted to ECHA**

A claim regarding the dispute is submitted using a webform on the Agency's website, available at: <https://comments.echa.europa.eu/comments/cms/article303.aspx>.

##### **3.2.2.2.1 Pre-processing**

###### Receipt of the webform

The Disputes team checks that all the relevant documentary evidence has been provided.

###### Request for further information

If the web-form or the attached documentary evidence provided to the Agency is not complete, the Disputes team requests further information from the claimant.

###### Decision on inadmissibility

If after the request for further information, the provided additional information is still incomplete, or is not provided within the set deadline, the recommendation of the Disputes team to the ED will be to decide that the claim is inadmissible.

###### Request for information from the other party

If the claimant has provided all the relevant information and documentary evidence, the Disputes team requests the other party to provide their documentary evidence relating to the arguments and justifications they used, if any, during the negotiations with the claimant within a set deadline. If the other party fails to submit this information, the Disputes team proceeds and only takes into account the available evidence.

##### **3.2.2.2.2. 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 allows the ED to decide whether or not

the claimant shall be granted a permission to proceed with the registration without the relevant data. During its assessment, the Disputes team ensures that the data subject to the dispute claim concerns only vertebrate animal studies.

### **3.2.2.2.3. Decision**

The Disputes team prepares one of the following decisions which is reviewed by the Legal Advisor before it is submitted to the ED or its delegate.

#### Decision requesting to continue the negotiations

If it is not demonstrated, by documentary evidence, that the claimant has met their obligation to make every effort to reach an agreement on the sharing of the data and its costs, the recommendation of the Disputes team to the ED will be to reject the claim and request the parties to continue the negotiations.

#### Decision granting to the claimant permission to proceed with registration without fulfilling the relevant information requirement(s)

If it is demonstrated, by documentary evidence, that the claimant has met their obligation to make every effort to reach an agreement on the sharing of the data and its costs, the recommendation of the Disputes team to the ED will be to grant the claimant a permission to proceed with registration without fulfilling the relevant information requirement(s) and, if a joint submission object exists in the ECHA database, to grant an access to the joint submission. Additionally, the Disputes team proposes to the ED to issue a decision prohibiting the other party to proceed with the registration, with regards to the disputed vertebrate animal studies.

### **3.2.2.2.3. Follow-up**

In case the Agency grants to the claimant permission to proceed with registration without fulfilling the relevant information requirement(s), the Disputes team communicates the decision to the enforcement authorities of the Member State, where the other party is established, after the expiry of the three-month appeal period to allow them to take action according to Article 30(6) of the REACH.

If the other party grants the claimant access to the disputed studies within 12 months from the date of the submission of the claimant's registration dossier, the ED issues a decision allowing the other party to proceed with registration.

If the other party does not allow the other registrants to refer to the disputed vertebrate studies, the ED may decide that the missing vertebrate animal studies must be performed by the registrant(s) who did not have access to the available study.

### **3.2.2.3. Failure to reach an agreement on joint submission of data and sharing of vertebrate animal studies that have been submitted to ECHA for pre-registered substances**

A claim regarding the dispute is submitted using a webform on the Agency's website, available at: <https://comments.echa.europa.eu/comments/cms/article303.aspx>

#### **3.2.2.3.1. Pre-processing**

##### Receipt of the webform

The Disputes team checks that all the relevant documentary evidence has been provided.

##### Request for further information

If the web-form or the attached documentary evidence provided to the Agency is not complete, the Disputes team requests further information from the claimant.

#### Decision on inadmissibility

If after the request for further information, the provided additional information is still incomplete, or is not provided within the set deadline, the recommendation of the Disputes team to the ED will be to decide that the claim is inadmissible.

#### Request for information from the other party

If the claimant has provided all the relevant information and documentary evidence, the Disputes team requests the other party to provide their documentary evidence relating to the arguments and justifications they used, if any, during the negotiations with the claimant within a set deadline. If the other party fails to submit this information, the Disputes team proceeds and only takes into account the available evidence.

### **3.2.2.3.2. 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 allows the ED to decide whether or not the claimant shall be granted an access to joint submission and/or a permission to refer to the vertebrate animal data already submitted by the previous registrant(s). During its assessment, the Disputes team identifies whether the information requested (i.e. (robust) study summaries on the substance) has already been submitted to the Agency.

### **3.2.2.3.3. Decision**

The Disputes team prepares one of the following decisions which is reviewed by the Legal Advisor before it is submitted to the ED or its delegate.

#### Decision requesting to continue the negotiations

If it is not demonstrated, by documentary evidence, that the claimant have met their obligation to make every effort to reach an agreement on the terms of access to joint submission and/or on the sharing of the data and its costs, the recommendation of the Disputes team to the ED will be to reject the claim and request the parties to continue the negotiations.

#### Decision granting to the claimant access to the joint submission and/or permission to refer to the requested data

If it is demonstrated, by documentary evidence, that the claimant have met their obligation to make every effort to reach an agreement on the terms of access to joint submission and/or on the sharing of the data and its costs, the recommendation of the Disputes team to the Executive Director will be to grant the claimant access to the joint submission and/or the permission to refer to the vertebrate animal studies already submitted to Agency.

### **3.2.2.3.3 Follow-up**

In case the Agency grants to the claimant an access to the joint submission and/or the permission to refer to the requested data, the Disputes team communicates the decision to the enforcement authorities of the Member State, where the other party is established, after the expiry of the three-month appeal period to allow them to take action according to Article 30(6) of the REACH.

#### **3.2.2.3.4. Withdrawal by the claimant**

The claimant can withdraw the claim at any stage before the final decision is issued by the Agency. The claimant needs to inform the Agency of this intention in writing and the Disputes team confirms in writing to the claimant, and if relevant to the other party, that the claim is closed without the final decision.

#### **3.2.3. Failure to reach an agreement on sharing data on active substance or biocidal product under BPR**

A claim regarding the dispute is submitted using a webform on the Agency's website, available at: <https://comments.echa.europa.eu/comments/cms/Article633.aspx>

##### **3.2.3.1. Pre-processing**

###### Receipt of the webform

The Disputes team checks that all the relevant documentary evidence has been provided.

###### Request for further information

If the webform or the attached documentary evidence provided to the Agency is not complete, the Disputes team requests further information from the claimant.

###### Decision on inadmissibility

If after the request for further information, the provided additional information is still incomplete, or is not provided within the set deadline, the recommendation of the Disputes team to the ED will be to decide that the claim is inadmissible.

###### Request for information from the other party

The Disputes team requests the other party to provide their documentary evidence relating to the arguments and justifications they used, if any, during the negotiations with the claimant, within a set deadline. If the other party fails to submit this information, the Disputes team proceeds and only takes into account the available evidence.

##### **3.2.3.2. 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 allows the ED to decide whether or not the claimant shall be granted permission to refer to the data they have requested from the other party.

##### **3.2.3.3. Decision**

The Disputes team prepares one of the following decisions/communications which is reviewed by the Legal Advisor before it is submitted to the ED or its delegate.

###### Decision requesting to continue the negotiations

If it is not demonstrated, by documentary evidence, that the claimant has met their obligation to make every effort to reach an agreement on the sharing of the data and its costs, the recommendation of the Disputes team to the ED will be to reject the claim and request the parties to continue their negotiations.

### Request for proof of payment, reminder and potential decision not granting the claimant permission to refer to the requested data

If it is demonstrated by documentary evidence that the claimant has met their obligation to make every effort to reach an agreement on the sharing of the data and its costs, the recommendation of the Disputes team to the ED will be to grant to the claimant a permission to refer to the data they have requested from the other party. In this case, the Disputes team first communicates the result of the assessment to the parties and requests from the claimant a proof of payment of a share of the costs incurred by the other party for generating the data. In case this information has been already provided to the Agency, decision granting the permission to refer will be issued (see below).

If the claimant does not provide the proof of payment within six months from the request, the Disputes team sends a reminder to the claimant indicating that a final 10 working day deadline has been set.

If the Agency does not receive a withdrawal of the claim or the proof of payment by the final deadline, the Disputes team recommendation to the ED will be to decide that the claimant is not granted the permission to refer to the requested data.

### Decision granting to the claimant permission to refer

Upon receipt of the proof of payment, the recommendation of the Disputes team to the ED will be to grant the claimant the permission to refer to the studies subject to the dispute.

### **3.2.3.4. Withdrawal by the claimant**

The claimant can withdraw the claim at any stage before the final decision is issued by the Agency. The claimant needs to inform the Agency of this intention in writing and the Disputes team confirms in writing to the claimant, and if relevant to the other party, that the claim is closed without the final decision.

## **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 final decisions are published on ECHA website. Before publishing ECHA redacts the decision to eliminate the information that is not to be public 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 claims 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 (i.e. close to relevant registration deadlines).

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

All the internal documents and the document to be sent out are prepared by one member of the Disputes team and checked by another member of the Disputes team. The communications to the parties, except the request for proof of payment, are approved by the Process Owner or its delegates. The request of proof of payment and all the decisions are approved by ED or its delegate.

### 3.5. Handling of deviations

All data-sharing disputes where the legal deadline is exceeded (only relevant to Article 27(5) REACH and Article 63(3) BPR) are systematically recorded and handled as deviations.

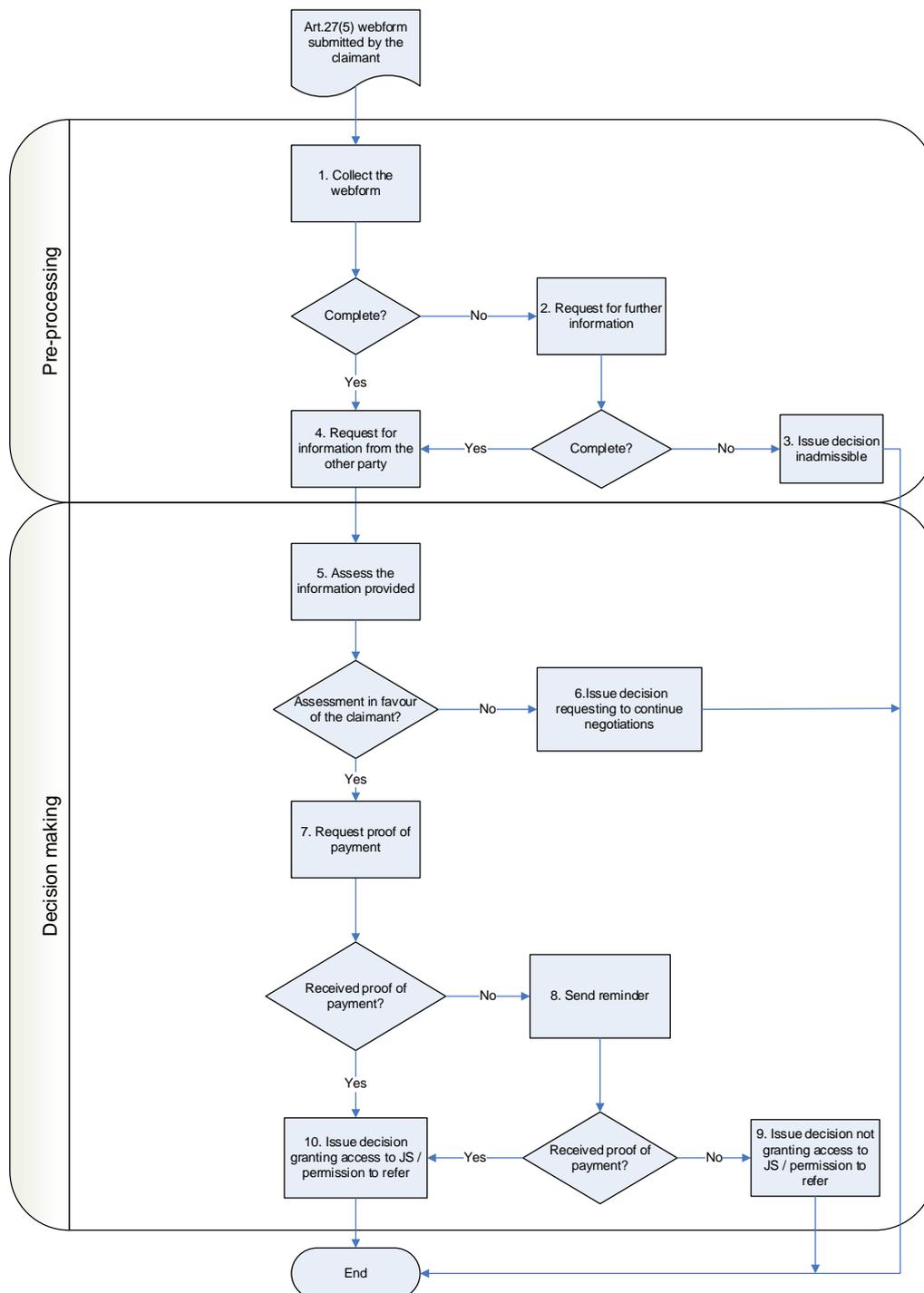
Any deviations from this procedure are documented and appropriate action is taken. If there are significant deviations, the Process Owner and the Process Coordinator are informed immediately in order to define and implement corrective actions.

## 4. Flowcharts

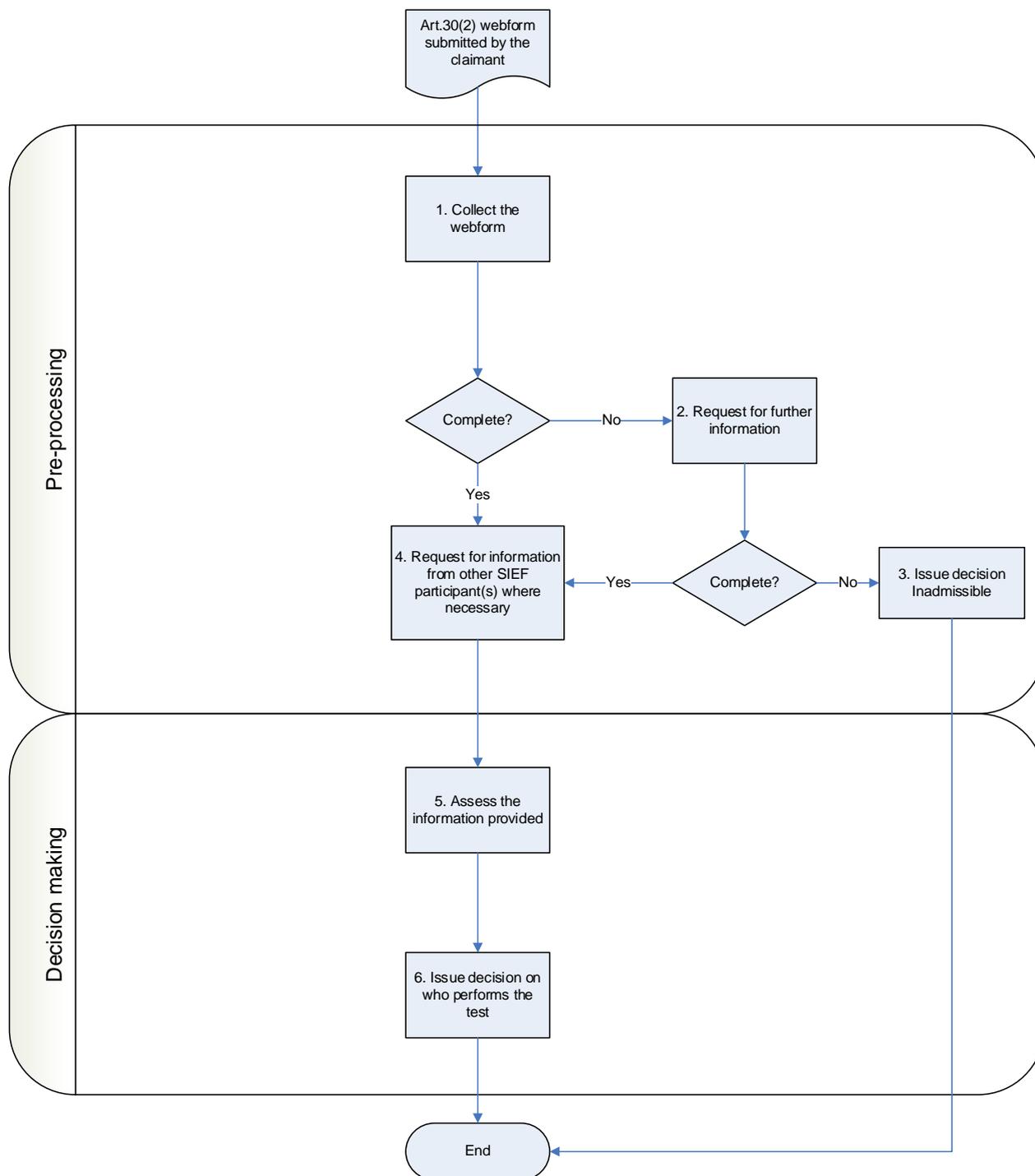
The flowcharts below show the sequence of events and actions taken by the Agency in the processing of data-sharing disputes. Additional information on each of the steps can be found in section 3.2.

Settling disputes arising from the failure to reach an agreement on joint submission of data and data-sharing

**4.1. Failure to reach an agreement on joint submission of data and data sharing for non-phase-in and for non-pre-registered substances under REACH**

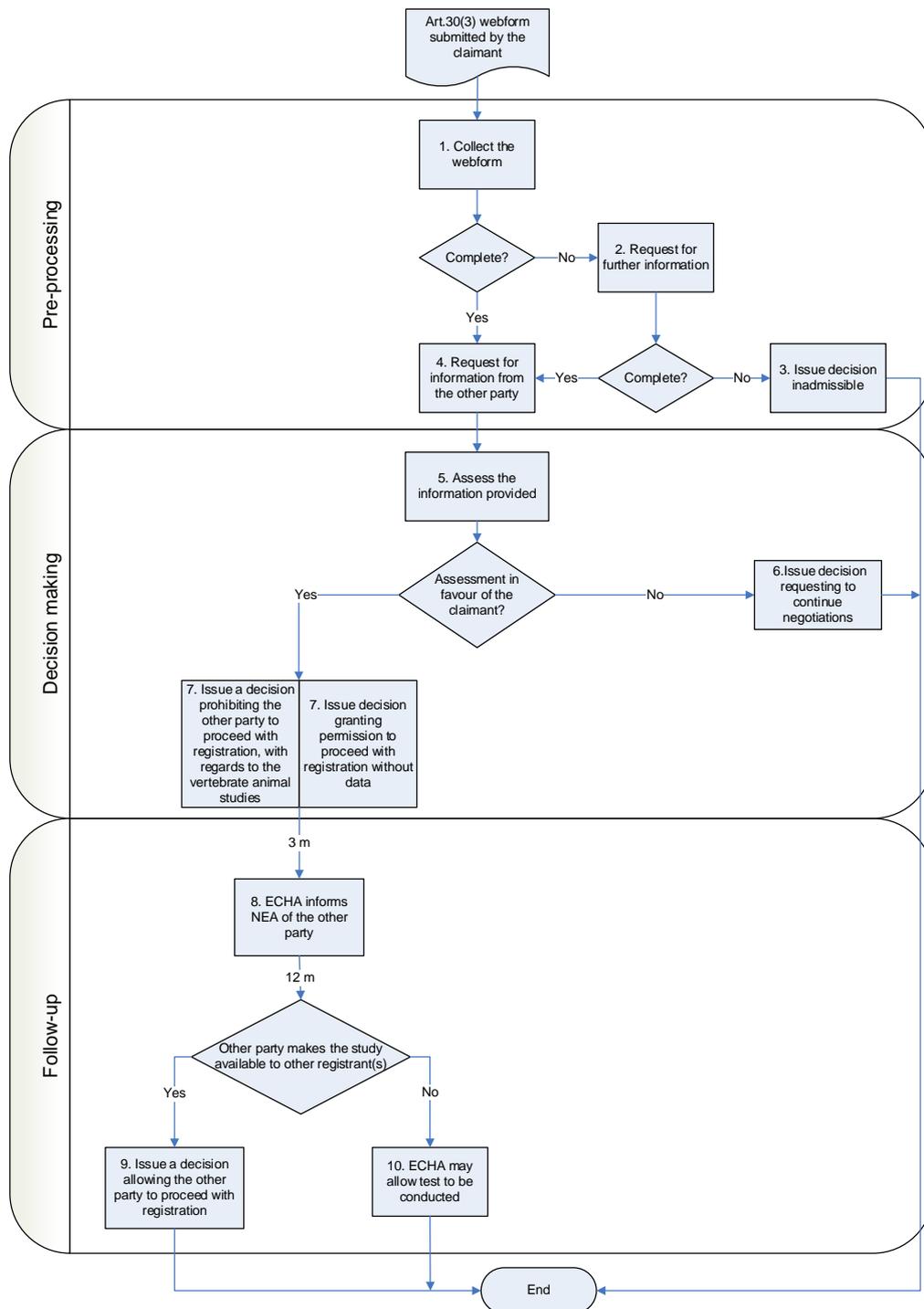


## 4.2. Failure to reach an agreement on who shall conduct a new test which is not available within the SIEF

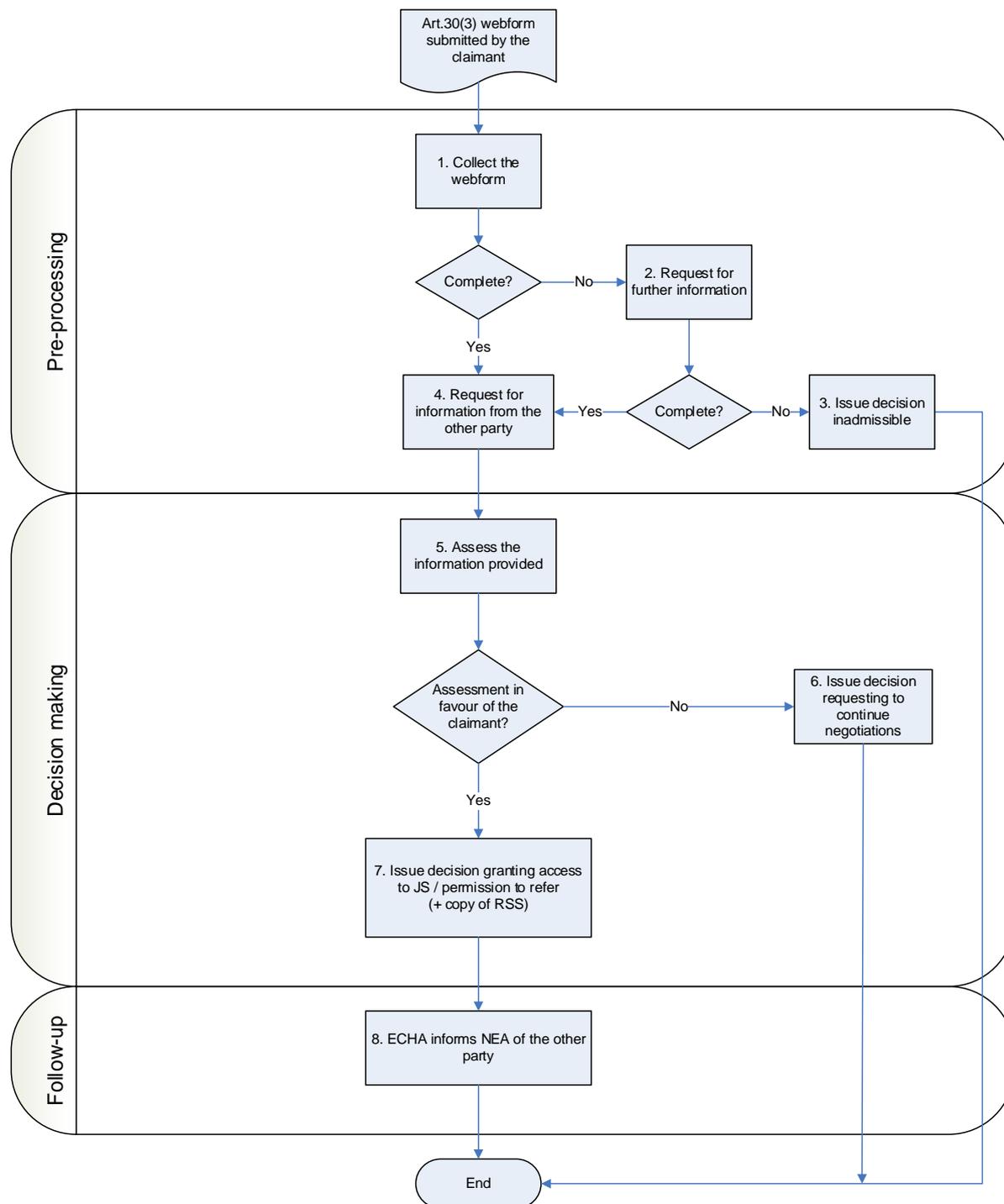


Settling disputes arising from the failure to reach an agreement on joint submission of data and data-sharing

### 4.3. Failure to reach an agreement on joint submission of data and data sharing for pre-registered substances before the vertebrate animal studies subject to the dispute have been submitted to ECHA

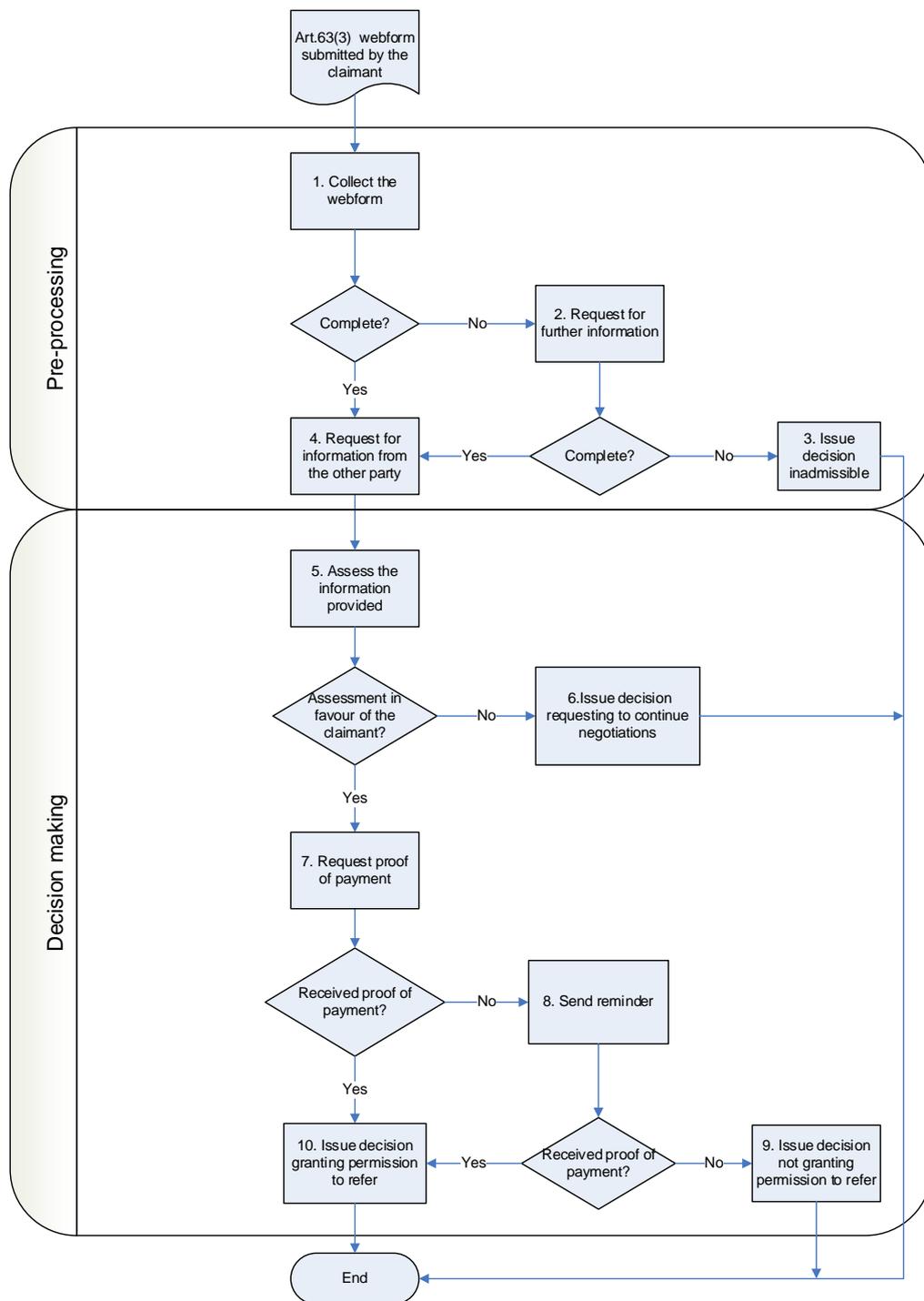


#### 4.4. Failure to reach an agreement on joint submission of data and sharing of vertebrate animal studies that have been submitted to ECHA for pre-registered substances



Settling disputes arising from the failure to reach an agreement on joint submission of data and data-sharing

**4.5. Failure to reach an agreement on sharing data on active substance or biocidal product under BPR**



## 5. Definitions

Term or abbreviation	Definition
Agency	European Chemicals Agency (ECHA)
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) and 30(5) of REACH and to Article 63(5) of BPR
ED	Executive Director
Full study report	Complete and comprehensive description of the activity performed to generate the information (Article 3(27))
JS	Joint submission
MB	Management Board of ECHA
Non-phase-in substance	Substances that do not meet the definition of phase-in substance as given in Article 3(20) of the REACH Regulation
Other party	Party negotiating on terms of access to joint submission / data sharing with the claimant
Phase-in substance	Substance fulfilling at least one of the criteria of the Article 3(20) (a-c)
Potential registrant	Legal entity willing to register a substance and that has inquired according to Article 26(1) or that has pre-registered according to Article 28(1) under REACH
Previous registrant	Legal entity that has already submitted a registration dossier for a substance under the REACH Regulation including also for substances considered to be registered according to Articles 15 and 24
Prospective applicant	Legal entity intending to perform tests or studies for BPR purposes

Settling disputes arising from the failure to reach an agreement on joint submission of data and data-sharing

Term or abbreviation	Definition
Substance Information Exchange Forum (SIEF)	Forum facilitating, for the purposes of registration and classification, the exchange of information between potential registrants of the same substance (Article 29)

## 6. Records

Record name	Security level	Comments
Conflict of interest check	Restricted	
Web-form and documents attached to the web-form	Restricted	
Communications between ECHA, the claimant and the other party	Restricted	
Assessment of the documentation	Restricted	
Assessment report	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
(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
(EC) No 45/2001	Regulation on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data

**Settling disputes arising from the failure to reach an agreement on joint submission of data and data-sharing**

Associated document code	Document name
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
-	(REACH) Questions and answers on data sharing and related disputes <a href="http://echa.europa.eu/qa-display/-/qadisplay/5s1R/view/REACH/datasharing">http://echa.europa.eu/qa-display/-/qadisplay/5s1R/view/REACH/datasharing</a>
	(BPR) Questions and answers on data sharing under BPR <a href="http://echa.europa.eu/qa-display/-/qadisplay/5s1R/view/biocidalproductsregulation/datasharing">http://echa.europa.eu/qa-display/-/qadisplay/5s1R/view/biocidalproductsregulation/datasharing</a>

IQMS document code	Document name
PRO-0010	Control of documents and records
POL-0007	Information Management Policy
PRO-0067	Prevention and Management of potential conflicts of interest
WIN-0038	Settling disputes arising from the failure to reach an agreement on joint submission of data and data sharing for non-phase-in and for non-pre-registered substances under REACH
WIN-0041	Settling disputes arising from the failure to reach an agreement on joint submission of data and data sharing for pre-registered substances
WIN-0211	Settling data sharing disputes arising from the failure to reach an agreement on sharing data under BPR

## 8. Annexes

N/A