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EUROPEAN CHEMICALS AGENCY

GUIDANCE

# Guidance on data sharing

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April 2012

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**Guidance on data sharing**

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# Preface

This guidance document describes the data sharing mechanisms for phase-in and non-phase-in substances under REACH. It is part of a series of guidance documents that are aimed to help all stakeholders with their preparation in fulfilling their obligations under the REACH regulation. These documents cover detailed guidance for a range of essential REACH processes as well as for some specific scientific and/or technical methods that industry or authorities need to make use of under REACH.

The guidance documents were drafted and discussed involving all stakeholders: Member States, industry and non-governmental organisations. The European Chemicals Agency (ECHA) updates these guidance documents following the Consultation procedure on guidance. These guidance documents can be obtained via the website of the European Chemicals Agency (http://echa.europa.eu/web/guest/support/guidance-on-reach-and-clp-implementation). Further guidance documents will be published on this website when they are finalised or updated.

The legal reference for the document is the REACH Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006[1].

1 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.

# DOCUMENT HISTORY

| Version | Comment | Date |
|---|---|---|
| Version 1 | First edition | September 2007 |
| Version 2 | Full revision of the Guidance addressing structure and content. The whole Guidance has been revised by correcting or deleting mistakes and inconsistencies related to the actual implementation of the data sharing processes, and to the roles and duties of the involved actors. The content has been reworked with the aim to restrict the scope to Title III of the REACH Regulation and to add the description of dispute processes. The structure has been reviewed to render the document clearer and more readable. Information already covered by technical manuals or falling under the scope of other guidance documents has been removed and link provided.<br><br>The update includes the following:<br><br>- Revision of section 1, by eliminating and amending out of date information and restructuring the text in order to reflect the Guidance update. The order of the subsections has been modified. Addition of list of key principles for data sharing identified during the first years of the actual implementation of the data sharing processes.<br><br>- Amendment of section 2 on Legal references in order to better cover the data sharing disputes.<br><br>- Creation of 2 main sections (3 and 4) covering respectively data sharing for phase-in substance within SIEFs and data sharing for non-phase-in substances through the inquiry process.<br><br>- Original sections 3, 4 and 5 have been merged in new section 3 in order to cover the full data sharing process for phase-in substances, from pre-registration to SIEF operation. A new sub-section addressing the scenario where new co-registrants need to join an existing joint submission has been added. Out of date information has been deleted. The information about pre-registration has been revised and reduced in order to focus on late pre-registration and actors entitled to late pre-register. Technical information has been removed and replaced by references to existing manuals. Information concerning substance identification and sameness of substance has been reduced and replaced by references to specific guidance. Subsection on the list of pre-registered substances and related actions has been updated. Information on lead registrant has been updated and reduced by giving reference to the Guidance on Registration. A new sub-section with more details on SIEF agreements and possible elements which could be included has been added. | April 2012 |

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| Version 2 | The sub-section covering the right to refer to data and legitimate possession has been updated in order to reflect the latest CARACAL decision and clarify the concepts.<br><br>- A new sub-section covering data sharing disputes according to Article 30(2) and 30(3) and on available legal remedies against ECHA decisions has been created and included in new section 3 on data sharing within SIEFs.<br><br>- Section 4 on Inquiry process has been revised by eliminating out of date information and amending the text according to the current practice. Information to be submitted in the inquiry and possible outcomes of the process have been added. The stepwise workflow has been extended and better described in order to provide comprehensive set of information to those involved in the inquiry process. A new sub-section addressing the scenario where new co-registrants need to join an existing joint submission has been added.<br><br>- New sub-section covering data sharing disputes according to Article 27(5) and available legal remedies against ECHA decisions has been created and included in new section 4 on data sharing for non-phase-in substances.<br><br>- The section on joint submission has been updated to take account of current practice and the information on lead registrant has been merged in section 3. A new sub-section covering post- registration data sharing obligations has been added.<br><br>- The section on Cost Sharing has been revised in order to correct editorial mistakes and clarify the language without any substantial changes. It has been explained that the section covers the sharing of cost related to studies, but other costs related to SIEF activities need to be considered in cost sharing models.<br><br>- The section on Forms of Cooperation has been revised in order to correct editorial mistakes and clarify the language. A new example suggesting an alternative form of cooperation has been added.<br><br>- The section on Competition Law has been revised by replacing the reference to EC Treaty by a reference to the Treaty on the Functioning of the European Union (TFEU).<br><br>- Deletion of Annex 1 and inclusion of updated charts in the relevant sections of the Guidance. | April 2012 |

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| Version 2 | - Deletion of Annex 2 and inclusion of the examples in the relevant sections of the Guidance. Only minor changes and corrections have been made.<br><br>- Deletion of Annex 3 and inclusion of the information relevant for data sharing in the main text. Reference to Guidance for Downstream Users made when relevant.<br><br>- Deletion of Annex 5 and inclusion of cost sharing examples in the relevant section. The examples 9 ("Volume factors") and 10 ("New parties") have been replaced by new examples. Only minor changes and corrections have been made to the other examples.<br><br>- Deletion of Annex 6.<br><br>- Reference to the Data Submission Manuals, REACH-IT Industry User Manuals and Practical Guides published by ECHA. A new annex listing all the documents mentioned in the guidance has been added.<br><br>- Special "NB boxes" have been added throughout the document to draw the reader's attention to important concepts and reminders that particular attention should be paid to.<br><br>- Editorial corrections. | April 2012 |

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# ABBREVIATIONS

| | |
|---|---|
| CAS | Chemical Abstracts Service |
| CBI | Confidential Business Information |
| CMR | Carcinogen, Mutagen and Reprotoxic |
| CSR | Chemical Safety Assessment |
| DNEL | Derived No-Effect level |
| DSD | Dangerous Substance Directive (67/548/EEC and related ATPs) |
| DSM | Data Submission Manual |
| DU | Downstream User |
| ECHA | European Chemicals Agency |
| EINECS | European Inventory of Existing Commercial Chemical Substances |
| ELINCS | European List of Notified Chemical Substances |
| EPA | US Environmental Protection Agency |
| EU | European Union |
| GLP | Good Laboratory Practices |
| HPV | High Production Volume |
| IUCLID | International Uniform Chemical Information Database |
| IUM | REACH-IT Industry User Manual |
| IUPAC | International Union of Pure and Applied Chemistry |
| LE | Legal Entity |
| LR | Lead Registrant |
| MS EA | Member State Enforcement Authority |
| OECD | Organisation for Economic Co-operation and Development |
| OR | Only Representative |
| (Q)SAR | (Quantitative) Structure-Activity Relationship |
| REACH | Registration, Evaluation, Authorisation and restriction of Chemicals |
| RMM | Risk Management Measure |
| RSS | Robust Study Summary |
| SDS | Safety Data Sheet |
| SIEF | Substance Information Exchange Forum |

NB: A comprehensive list of definitions of relevant terms is available consulting the ECHA-Term database on the ECHA website.

# 1. Introduction

## 1.1 OBJECTIVE OF THE GUIDANCE DOCUMENT ON DATA SHARING

The present Guidance Document aims to provide practical guidance on the sharing of data as required under REACH, within the same SIEF and between different SIEFs for phase-in substances and between multiple registrants of the same non-phase-in substances.

Additionally the structure aims to allow the whole set of information related to phase-in substances and to non-phase-in substances to be discussed in separate dedicated sections (respectively sections 3 and 4).

The Guidance contains practical recommendations to help companies meet their data sharing obligations and includes a detailed description of the following processes:

- The late Pre-Registration;
- The formation of SIEF;
- Data Sharing for phase-in substances (within a SIEF) and potential related data sharing disputes;
- Data Sharing for non-phase-in substances and potential related data sharing disputes;
- Mandatory joint submission of data.

Figures and examples are provided in each section in order to support the description and explanation of each specific process.

Specific explanations on Cost sharing mechanisms, on the protection of Confidential Business Information (CBI), on Competition rules, and on forms of cooperation, including consortia are also provided.

## 1.2 OVERVIEW

The REACH Regulation 1907/2006 of 18 December 2006 sets up a system for the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) and establishes the European Chemicals Agency (ECHA).

### 1.2.1 REGISTRATION OBLIGATION

Since 1 June 2008, companies manufacturing chemical substances in the EU or importing them into the EU in quantities of 1 tonne or more per year have been required to register them under REACH. The registration obligation also applies to companies producing or importing articles containing substances present in quantities of 1 tonne or more per year that are intended to be released. Registration requires the submission of relevant and available information on intrinsic properties of substances, as per the requirements set out in the relevant Annexes to REACH. For substances manufactured or imported in quantities of 10 tonnes or more a Chemical Safety Report has also to be submitted.

NB: Specific mechanisms and procedures have been introduced by REACH to enable companies to share existing information before submitting a registration dossier in order to increase the efficiency of the registration system, to reduce costs and to reduce testing on vertebrate animals.

### 1.2.2 PHASE-IN AND NON-PHASE-IN SUBSTANCES

The Regulation sets out different procedures for registration and data sharing of "existing" ("phase-in") substances (as defined in Article 3(20)) and "new" ("non-phase-in") substances.

Phase-in substances are substances which:

- are listed on the European Inventory of Existing Commercial Chemical Substances (EINECS) (Article 3(20)(a)) or

- were manufactured in the EU, or in countries acceding to the EU on 1 January 1995, on 1 May 2004 or on 1 January 2007, but not placed on the market in the 15 years before REACH came into force (i.e. 01 June 2007) (Article 3(20)(b)), or

- were placed on the EU market or in countries acceding to the EU on 1 January 1995, on 1 May 2004 or on 1 January 2007, and were considered polymers but, according to the 7th amendment (92/32/EEC) of the Dangerous Substance Directive (67/548/EEC), are no longer considered polymers. This includes substances that meet the criteria but are not currently on the No Longer Polymers (NLP) list (Article 3(20)(c)).

Non-phase-in substances can be broadly defined as the "new" substances. They include all substances that do not meet the definition of a phase-in substance, as given in Article 3(20) of the Regulation.

For more details on the phase-in or non-phase-in status of a substance, please consult the Guidance on Registration available on the guidance section of the ECHA website at http://www.echa.eu/web/guest/guidance-documents/guidance-mainly-for-industry-use.

### 1.2.3 TRANSITIONAL REGIME FOR REGISTRATION

Phase-in substances that are (late) pre-registered can benefit from extended registration deadlines as per Article 23. Registration is nevertheless required before the end of the (extended) registration deadline (see Figure 2 in section 3.1.2).

Non-phase-in substances that are to be manufactured or imported in quantities of 1 tonne or more per year, cannot benefit from extended registration deadlines and have to be registered by the company before the start of its activities. The same applies to phase-in substances that have not been pre-registered.

### 1.2.4 PRE-REGISTRATION AND LATE PRE-REGISTRATION

According to Article 23, in order to benefit from the extended registration deadlines, each potential registrant of a phase-in substance manufactured or imported in quantities of 1 tonne or more per year is required to "pre-register" the phase-in substance concerned. The period for pre-registration was from 1 June 2008 until 1 December 2008.

NB: Without pre-registration, substances need to be registered before they are manufactured in or imported into the EU or placed on the EU market, and cannot benefit from the extended registration deadlines.

REACH lays down a special provision in order to allow legal entities manufacturing or importing phase-in substances in quantities of 1 tonne or more ***for the first time*** (by that legal entity) after 1 December 2008 to be able to benefit from the extended registration deadlines. These companies may use the option of the "late pre-registration" and submit the pre-registration information to ECHA in accordance with the conditions of Article 28(6) of the REACH Regulation. For more details on the late pre-registration option, please consult section 3.1.

As was the case for pre-registration, late pre-registration is to be made through the REACH-IT system managed by ECHA. For technical details please consult the REACH-IT Industry User Manual (IUM) on "Online Pre-registration", available on the ECHA website at http://www.echa.eu/web/guest/support/dossier-submission-tools/reach-it/pre-registration.

For each pre-registered substance a dedicated pre-SIEF page is created with the aim of bringing pre-registrants together and facilitating the formation of a SIEF. Similarly, late pre-registrants are included in any existing pre-SIEF page. For more details and practical information please consult the REACH-IT IUM on "Pre-SIEF" and the available web page at http://www.echa.eu/web/guest/regulations/reach/substance-registration/substance-information-exchange-fora.

After 1 January 2009, the list of all substances pre-registered by companies before 1 December 2008 was published on ECHA's website, together with the corresponding first envisaged registration deadline for each substance on the list. The list is available on the ECHA website at http://www.echa.eu/web/guest/information-on-chemicals/pre-registered-substances. It also contains names and other identifiers of substances that pre-registrants have indicated as being related substances [2].

### 1.2.5 INQUIRY PRIOR TO REGISTRATION

The duty to inquire applies for non-phase-in substances and phase-in substances that have not been pre-registered by a potential registrant and cannot benefit from the late pre-registration option. The inquiry process requires potential registrants to inquire from ECHA whether a registration has already been submitted for the same substance. This is to ensure that data are shared by the relevant parties, so that the requirement for joint submission of data, according to Articles 11 and 19, may be complied with.

### 1.2.6 SUBSTANCE INFORMATION EXCHANGE FORUM (SIEF)

Article 29 of REACH provides for the formation of a SIEF to share information among manufacturers and importers of the same "phase-in" substance, as well as allowing participation of data holders (e.g. downstream users) and other stakeholders to prevent duplication of testing, especially testing on vertebrate animals.

According to Article 29(2), the aims of the SIEF are:

1- to facilitate data sharing for the purposes of Registration, and

2- to agree on the classification and labelling of the substances concerned;

As a general rule, there will be one SIEF for each phase-in substance.

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2 Related substances are substances which may be used for (Q)SAR, grouping (or category approach) and read-across (REACH regulation, Annex XI; Section 1.3 and 1.5)

In a first step, pre-registrants of substances with the same identifier have to establish whether their substance is the same for the purpose of data sharing and joint submission. This should be done on the basis of the criteria set out in the Guidance for identification and naming of substances under REACH. Once agreement on the sameness of the substance has been reached, the SIEF is formed. For more detailed information, please consult sections 3.1 and 3.2.

Other stakeholders (such as manufacturers and importers of the substance in quantities of less than one tonne, downstream users and Third Parties[3] - hereinafter "data holders") who hold information on the substance appearing on the list, are then able, on a voluntary basis, to:

1. sign into REACH-IT

2. be inserted into the pre-SIEF page

3. inform that they too hold relevant information.

Any registrant of the same substance that has registered his substances before the extended registration deadline is a mandatory member of the SIEF (whether or not he is included on the pre-SIEF page).

Pre-Registrants in a SIEF are free to start organizing themselves as they see fit to carry out their obligations under REACH. They may use different forms of cooperation to do so, including the creation of a "consortium", to fulfil their data sharing obligations and/or to meet other objectives under REACH. Likewise, it is possible that a SIEF consist of more than one consortium and a number of independent parties. For more information on possible forms of cooperation and examples please consult section 8 of this Guidance.

### 1.2.7 JOINT SUBMISSION OF DATA

Potential registrants are required to organise themselves in order to submit jointly information on their substances which are considered to be the same ("one substance = one registration" principle).

As per Articles 11(1) and 19(1), multiple registrants for the same substance, whether phase-in or non-phase-in, must:

1- give their assent to the one registrant who will first submit joint parts of the dossier;

2- submit jointly the information on the intrinsic properties of the substance in their registration dossier as per the requirements set in Article 10.

In addition potential registrants may decide to submit jointly part or the whole Chemical Safety Assessment/ Chemical Safety Report (CSA/CSR)[4] and to agree that the Guidance on safe use may be part of this joint submission.

3 These include companies holding information on classification and labelling which may not be obliged to join a SIEF but may be willing to share such information. For more information, please consult the "Introductory guidance on the CLP Regulation" available at http://www.echa.eu/web/guest/guidance-documents/guidance-on-clp. Furthermore non EU companies are also able to join a SIEF as data holders when they are willing to provide and share relevant information.

4 For more information about the submission of a fully or partially joint CSR, refer to the Data Submission Manual (DSM) on "How to submit a CSR as part of a Joint submission" available on the ECHA web site at http://www.echa.eu/web/guest/joint-submission-lead.

NB: In case where companies decide to opt-out from part(s) of the joint submission in relation to information to be submitted jointly, their dossier will be identified by ECHA for prioritisation for compliance check according to Article 41(5)(a).

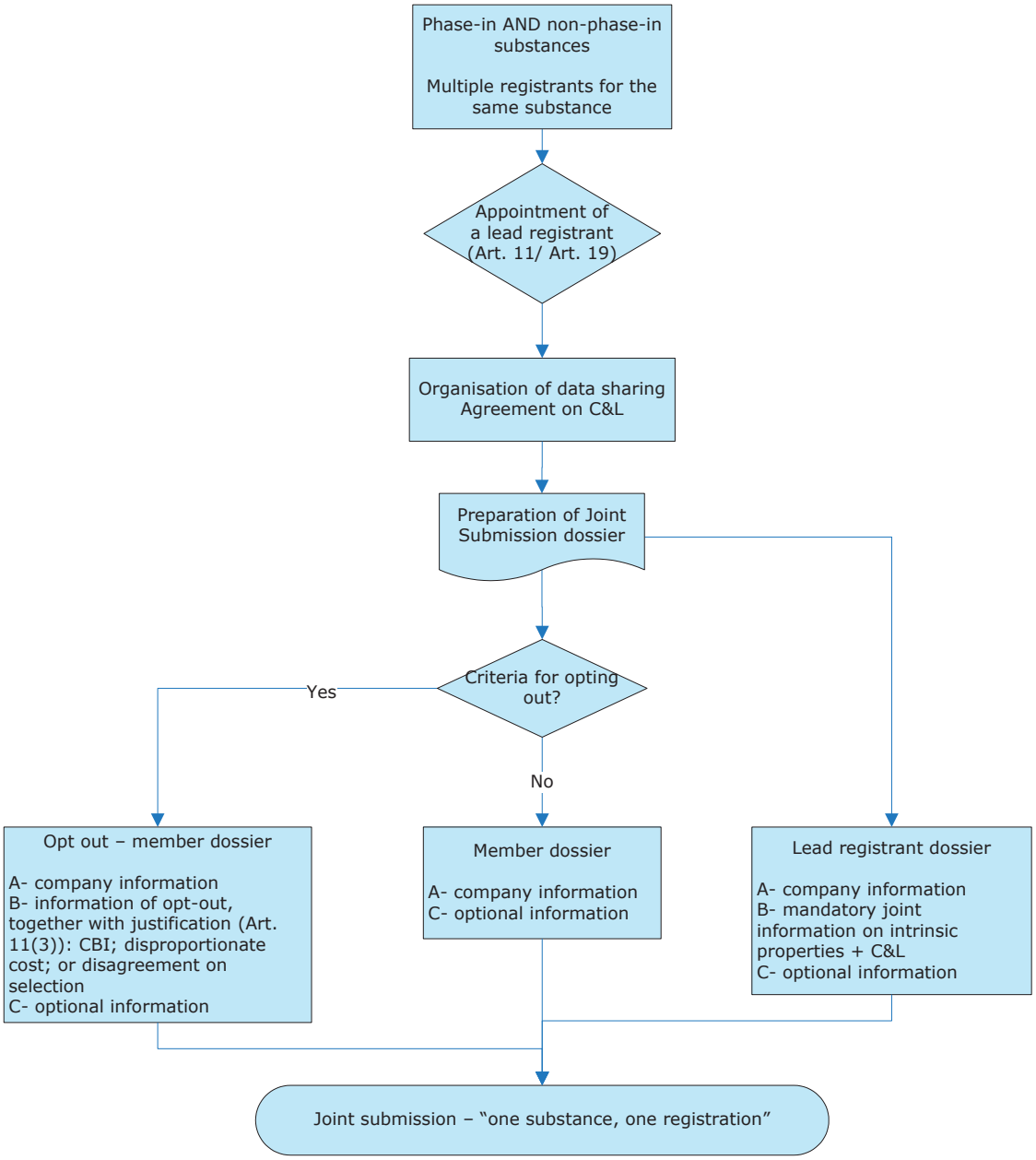



Figure 1: Overview of the process of the joint submission of data

### 1.2.8 DATA SHARING DISPUTES

The REACH Regulation provides for procedures which can be followed in cases where registrants do not reach an agreement on the sharing of information.

Article 27 sets the rules in relation to disagreement on information regarding non phase-in substances and Article 30, sets the rules in relation to disagreement on information regarding phase-in substances.

## 1.3 KEY PRINCIPLES FOR DATA SHARING

- REACH requires registrants and/or potential registrants to make every effort to ensure that the cost of sharing the information required for registration are determined in a fair, transparent and non-discriminatory way. In this respect, Title III of the REACH Regulation lays down specific provisions for phase-in and non phase-in substances.

- The obligation to make every effort applies to any information requested whether it concerns data involving testing on vertebrate or other data not involving testing on vertebrate animals.

- All parties must fulfil their data sharing obligations in a timely manner. Potential registrants are encouraged to allow a reasonable time for the negotiations before the registration and to initiate their efforts early to ensure the sharing of the information even before the actual submission of the joint dossier.

- As data sharing activities take place outside REACH-IT, companies are advised to carefully record any communication with another party, as this may be requested by ECHA in the context of a data sharing dispute claim or by national competent authorities for enforcement purposes.

- In accordance with REACH, ECHA has set up procedures to assist in the resolution of data sharing disputes. Data sharing dispute procedures must be initiated as a last resort, i.e. only after all the possible efforts and arguments have been exhausted and the negotiations have failed.

- A potential registrant initiating a data sharing dispute procedure with ECHA must demonstrate the efforts made by all the parties to reach an agreement and must provide appropriate documentary evidence.

- Pending the processing of a data sharing dispute, ECHA encourages all parties to continue making every effort to reach an agreement.

- The ECHA decision on any dispute will be based on an assessment of the parties' respective efforts to reach an agreement on the sharing of the data and its costs in a fair, transparent and non-discriminatory way. A potential registrant can only expect a favourable decision from ECHA if it is evident from the information made available that he has made every effort to reach an agreement before contacting ECHA.

- Any potential registrant involved in a data sharing dispute must always obtain a decision from ECHA, granting the permission to proceed with registration/ to refer to the requested studies, **before** submitting the registration dossier. Dossiers submitted while a data sharing procedure is still pending will not comply with the data requirements.

- Beside data sharing obligations, the registrants of the same substance, whether phase-in or non-phase-in, shall also fulfil their obligation to submit jointly data in accordance with Article 11 or 19 of the REACH Regulation.

## 1.4 LINKS TO OTHER REACH GUIDANCE DOCUMENTS AND TECHNICAL DOCUMENTS

Potential registrants and data holders are encouraged to take into account other relevant Guidance documents, in particular the Guidance on registration.

Most importantly, potential registrants should consult carefully the Guidance for identification and naming under REACH, for the determination of the identity of their substance.

The Guidance on information requirements and Chemical Safety Assessment will provide details on how to fulfil the information requirements on intrinsic properties of substances, including how to obtain and evaluate available information from sources including publicly available databases (also by read-across and other non-testing methods, *in vitro* test methods and human data) and special factors affecting information requirements and testing strategies. Furthermore, Part F of the latter document provides detailed methodological guidance on how to complete a Chemical Safety Report (CSR).

The duties of downstream users are covered in the Guidance for Downstream Users.

All these ECHA guidance documents are available on the "support" section of the ECHA web site at: http://www.echa.eu/web/guest/support/guidance-on-reach-and-clp-implementation.

NB: Other and more technical documents have been issued to support the potential registrants to fulfil their REACH obligations: Questions & Answers documents (e.g. on inquiry, on data sharing and related disputes, etc.), REACH-IT Industry User Manuals and Data Submission Manuals. All these documents should be read in combination with this Guidance document and are available at http://www.echa.eu/web/guest/support.

## 1.5 LINK TO THE CLP REGULATION AND RELATED GUIDANCE

The CLP Regulation (EC) No 1272/2008 does not contain any provisions on data sharing. Nevertheless, manufacturers, importers and downstream users who are not subject to registration under REACH can contribute as data holders to the SIEF process. This is further explained in the Introductory Guidance on the CLP Regulation available at: http://www.echa.eu/web/guest/regulations/clp/classification.

# 2 Legal framework: relevant legal provisions

## 2.1 DATA SHARING AND AVOIDANCE OF TESTS

The rules on data sharing and avoidance of unnecessary testing are provided in Title III and in Articles 40(3)e and 53 of the REACH Regulation, which should be interpreted in view of Recitals 33, 49, and 54 of the Regulation.

As specified in Article 25(1), the objective of these rules is to avoid vertebrate animal testing, which must only be carried out as the last resort, and to limit the duplication of other tests. As a general rule, the REACH Regulation requires the sharing of information on the basis of a fair compensation. However, according to Article 25(3), after 12 years from the date of the submission of the study summaries and robust study summaries in the framework of a registration, this data may be used, without compensation, only for the purpose of registration by another manufacturer or importer.

Article 25(2) defines the scope of the data sharing obligation by reference to the type of data to be shared. This obligation applies to technical data and information related to the intrinsic properties of substances. However, EU rules on competition law must be respected by the potential registrants. Therefore the article states that information related to the market behaviour of the registrants, in particular as regards production capacities, production or sales volumes, import volumes or market shares, must not be exchanged. This is to prevent concerted practices or the creation of the conditions for abuses of dominant position.

## 2.2 DATA SHARING AND JOINT SUBMISSION

As specified in Recital 33, the "joint submission and the sharing of information on substances should be provided for in order to increase the efficiency of the registration system, to reduce costs and to reduce testing on vertebrate animals".

In order to enable test data to be shared, and thus avoid unnecessary testing and reduce costs, wherever practicable, registrations should be submitted jointly, in accordance with the rules on joint submission (Articles 11 and 19 of the REACH Regulation).

Therefore Article 11 imposes the obligation for potential registrants of the same substance to jointly submit data and lists situations where the opt-out from the joint submission of data is possible if properly justified. Article 19 sets out similar provisions for isolated intermediates.

> NB: The joint submission obligations therefore have an impact on data sharing activities with subsequent registrants, especially in relation to data contained in dossiers already submitted by previous registrants.

## 2.3 INQUIRY, (LATE PRE-)REGISTRATION AND DATA SHARING

Whereas Article 25 provides for the principle of avoiding unnecessary testing, Chapters 2 and 3 of the same title III of REACH introduce specific mechanisms to share information among registrants. These mechanisms are different depending on the status of the substance.

The rules for non-phase-in substances and non-pre-registered phase-in substances are laid down in Title III, Chapter 2 (Articles 26 and 27).

Article 26 regulates the inquiry process as follows:

26(1) – inquiry to ECHA and information to be submitted;

26(2) – communication from ECHA in case of substances which were not previously registered;

26(3) – communication from ECHA of name and contact details of previous registrant(s) and potential registrant(s), and of existing data requirements, in case of substances previously registered less than 12 years earlier;

26(4) – communication from ECHA in case several potential registrants have made an inquiry about the same substance.

Article 27 organises the data sharing process, as follows:

27(1) – potential registrant is to request information from previous registrant(s);

27(2) – obligation to make every effort to reach agreement for both parties;

27(3) – obligation to make every effort to share costs in a fair, transparent and non discriminatory way;

27(4) – communication between previous and potential registrants of information in case of agreement;

27(5) – communication with ECHA in case of failure to reach an agreement;

27(6) – decision of ECHA on whether to give permission to the potential registrant to refer to the information submitted by the previous registrant in his registration dossier;

27(7) – potential appeal against an ECHA decision under Article 27(6);

27(8) – extension by four months of the waiting period, upon request by the previous registrant (Art. 27(4) and 27(6)).

The rules for phase-in substances (as per the definition given in Article 3(20)) are given in Title III, Chapter 3 of REACH.

Article 28 describes the pre-registration of phase-in substances. The relevant provisions are as follows:

28(1) – submission of a pre-registration dossier to ECHA;

28(2) – pre-registration period;

28(3) – no extended registration deadline if no pre-registration;

28(4) - publication of the list of pre-registered substances comprising the names of the substances, including their EINECS and CAS number and other identifiers of substances that pre-registrants have indicated as being related substances, and the first envisaged registration deadline;

28(6) – late pre-registration period for first time manufacturer or importer;

28(7) – submission of information on pre-registered substances by data holders.

Article 29 structures the provisions for the formation (and functioning) of Substance Information Exchange Fora (SIEFs), as follows:

29(1) – participants in the SIEF;

29(2) – aim of each SIEF;

29(3) – overall approach - duties of the participants.

Article 30 structures the provisions on the data sharing process of phase-in substances involving test data and requiring agreement between the SIEF participants as follows:

30(1) – data gap analysis by SIEF participants before testing is carried out – obligation to answer any request within one month;

30(2) – decision of the Agency specifying which member shall perform a test where no agreement is reached between the SIEF participants;

30(3) – data sharing dispute process in case the owner of a vertebrate study refuses to provide proof of the costs of the study or the study itself.

In case the dispute occurs before submission of the registration dossier of the study owner the Agency can decide to prevent a registration being made by the owner of the study and to require the members of the SIEF to repeat the test under specific circumstances if the applicable conditions specified in article 30(3) are satisfied.

In any case, when a data involving testing on vertebrate animals has already been submitted as part of a registration dossier, ECHA will give the party which has made every effort to reach an agreement permission to refer to the information in the registration dossier of the previous registrant(s);

30(4) – procedure related to refusal to share non-vertebrate animal studies;

30(5) – appeal against ECHA's decision under Article 30(2) and (3);

30(6) – penalties by MS EAs.

## 2.4 DATA SHARING AS AN OUTCOME OF DOSSIER EVALUATION DECISIONS

Article 53 sets out the obligation to share data as an outcome of dossier evaluation decisions for registrations. The decision taken by the Agency according to Article 53(1) is very similar to the decision taken by the Agency according to Article 30(2) deciding which parties in a SIEF must perform a test.

53(1) – decision of the Agency designating the party who must perform a test if no agreement is reached between the registrants and/or downstream users;

53(2) – cost sharing in case a registrant/downstream user performs the test;

53(3) – provision of a copy of the full study report by the registrant/downstream user who performed the test;

53(4) – claims for remuneration.

## 2.5 COMPETITION RULES

In addition to compliance with the provisions of the REACH Regulation, potential registrants must ensure that they comply with other applicable rules and regulations. This applies in particular to competition rules, as specified in Recital 48 and in Article 25 (2) of the REACH Regulation which refers to the notion of restriction of certain market behaviours.

Recital 48 specifies that "This Regulation should be without prejudice to the full application of the Community competition rules".

Article 25(2) mentions that "(…) Registrants shall refrain from exchanging information concerning their market behaviour, in particular as regards production capacities, production or sales volumes, import volumes or market shares."

As discussed in section 7 of the present Guidance Document, in the context of REACH and information exchange, the most relevant provision is Article 101 of the Treaty on the Functioning of the European Union (TFEU), which prohibits agreements and practices that restrict competition. For more details, please consult the legal text available on the EUR-Lex web site.

# 3 Data sharing for phase-in substances

## 3.1 LATE PRE-REGISTRATION

After the pre-registration step which ended on 1 December 2008, late pre-registration is the process whereby first time manufacturers and importers of 'phase-in substances', or producers/importers of articles with an intended release have to submit a set of information to ECHA in order to benefit from the extended registration deadlines[5] described in Article 23 of the REACH Regulation. This will apply on the basis of specific conditions laid down in Article 28(7) and only to those who intend to register for tonnage bands where the corresponding extended registration deadline has not yet passed.

This section of the Guidance provides additional information on the late pre-registration process for phase-in substances.

### 3.1.1 FIRST-TIME MANUFACTURERS OR IMPORTERS

A first-time manufacturer or importer is a manufacturer or importer who manufactures or imports a substance into the European market[6] in quantities of 1 tonne or more for the first time after 1 December 2008.

The first-time manufacturer/importer can benefit from the transitional periods (as per Article 28(6)) if he (late) pre-registers (1) at the latest six month after the substance's manufacturing or import exceeds the one-tonne threshold, and (2) at least 12 months before the relevant deadline for registration set out in Article 23 of the REACH Registration.

Therefore first-time manufacturers or importers have to submit their late pre-registration before 1 June 2012 or 1 June 2017, whichever corresponds to their relevant tonnage threshold (respectively 31 May 2013 or 31 May 2018).

NB: Companies manufacturing or importing substances for which the first registration deadline applied (30 November 2010) cannot benefit from the late pre-registration and need to go through an inquiry process before being entitled to manufacture or import in the European market (see chapter 4).

Each legal entity who would be required to register a phase-in substance after 1 June 2008 may late pre-register that substance. These legal entities include:

- first time manufacturers and importers of phase-in substances on their own or in preparations in quantities of 1 tonne or more per year, including intermediates;

- first time producers and importers of articles containing substances intended to be released under normal or reasonably foreseeable conditions of use and present in those articles in quantities of 1 tonne or more per year;

- "Only-representatives" of non-EU manufacturers whose substance(s) is/are for the first time imported in quantities of 1 tonne or more per year.

5 For more information on the definition of the extended registration deadline, please refer to the Q&A on Pre-registration available on the "support" section of the ECHA webpage at: http://www.echa.eu/web/guest/support/faqs.
6 In this context the European market is intended as the European Economic Area, composed by the 27 EU Member States and Norway, Liechtenstein and Iceland.

Only Representatives are legal entities appointed by non-EU manufacturers to fulfil the obligations of importers. Only natural or legal persons: (i) established in the EU and, (ii) having sufficient background in the practical handling of substances and the information related to them, may be appointed as Only Representatives (Article 8). When an OR is appointed for one or more substance(s), he becomes responsible for the volume of this/these substance(s) manufactured by this non-EU manufacturer and imported into the EU. For more details on the Only Representative's roles and duties, please consult the Guidance on registration.

NB: When a phase-in substance is manufactured, imported or used in the production of an article by several EU legal entities belonging to the same company, each legal entity has to late pre-register separately. Manufacturing sites that do not have a separate legal personality are not required to individually late pre-register because the obligation to register needs to be fulfilled by the legal entity they belong to. An Only Representative can represent several non-EU manufacturers of one given substance, but he needs to (pre)register separately for each legal entity he represents.

For more details on the definition of legal entity and on who is responsible for registration please consult the Guidance on registration available in the "support" section of the ECHA website.

*Manufacturers and importers of substances below 1 tonne per year*

Manufacturers and importers of phase-in substances or article producers and importers containing phase-in substances in quantities of less than 1 tonne per year do not need to (late) (pre-)register. However, they may decide to late pre-register based on their intention to manufacture or import the substance in quantities of 1 tonne or more in the future.

NB: Companies that exceed the 1 tonne threshold after 1 December 2008 are still entitled to late pre-register within 6 months of first manufacturing, importing or using the substance in quantities of 1 tonne or more per year and no later than 12 months before the relevant registration deadline. To do so they need to submit the relevant information to ECHA (as set in Articles 23 and 28(6) – see above).

### 3.1.2 IS LATE PRE-REGISTRATION OF PHASE-IN SUBSTANCES OBLIGATORY?

(Late) Pre-registration is only obligatory if companies want to benefit from extended registration deadlines. Phase-in substances can also be registered immediately.

As a general rule, the obligation to register phase-in substances applies from 1 June 2008, unless these substances were pre-registered before the expiry of the pre-registration deadline on 1 December 2008 or late pre-registered before the relevant deadline for late pre-registration as described in section 3.1.1.

All manufacturing, placing on the market and use of such substance between 1 December 2008 and the date of suspension of activities may be subject to penalties according to national law. This also means that the downstream uses of these substances may be at risk.

### 3.1.3 THE BENEFITS OF (LATE) PRE-REGISTRATION

Pre-registration (and hence late pre-registration) allows potential registrants to benefit from extended registration deadlines. More specifically:

1) Depending on the tonnage and on the intrinsic properties of the substance, (late) pre-registration allows manufacturers and importers to continue manufacturing, importing and using phase-in-substances until the extended registration deadlines (as shown in Figure 2).

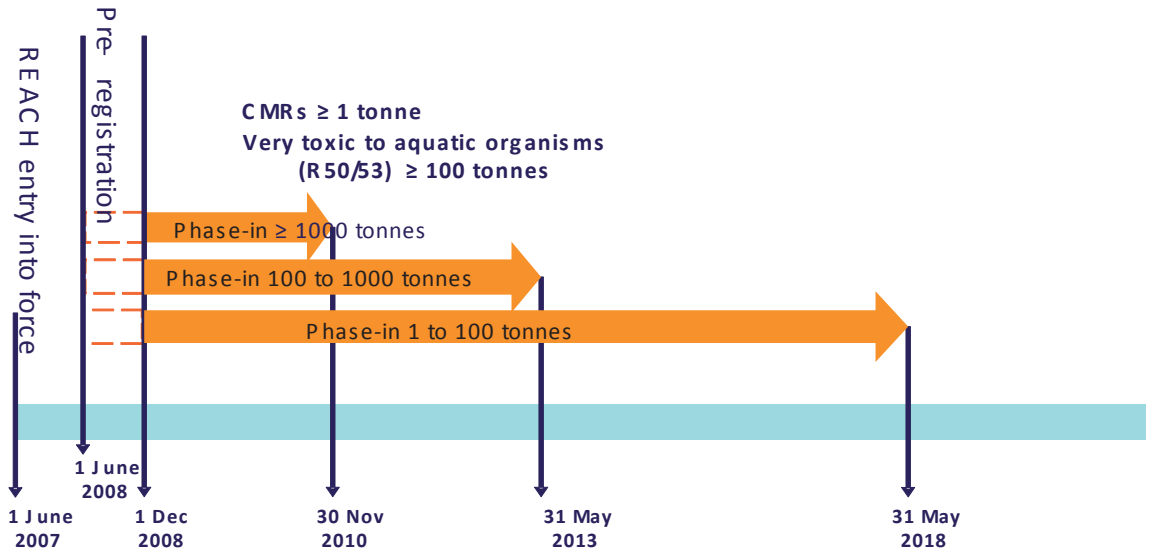



Figure 2: Extended deadlines for registration

After this date, the placing on the market of such substances without registration would be possible only in the case where the manufacturer or importer stopped manufacturing or importing before the registration deadline[7].

2) (Late) pre-registration also gives companies additional time to organise the collection and selection of available data, the sharing of existing data, and the generation of missing information required by the REACH Regulation, as described in this section and in section 6.

In the case where a first time manufacturer or importer cannot late pre-register (between 1 June 2012 and 1 June 2013 and between 1 June 2017 and 1 June 2018) he:

- cannot start the manufacturing/ importing activities involving the substance and has to register before manufacturing or importing;

- has to inquire, and consequently fulfil his data sharing and joint submission obligations (where applicable);

- can only start the manufacturing/ import activities involving the substance a minimum of three weeks after the submission date of the registration dossier, unless he receives an indication to the contrary from ECHA.

7 According to what discussed in CA/99/2010 (rev.3) the registration does not apply to manufacturers or importers that have manufactured or imported pre-registered substances before the registration deadline and ceased such activities and simply act as suppliers of these substances after the registration deadline.

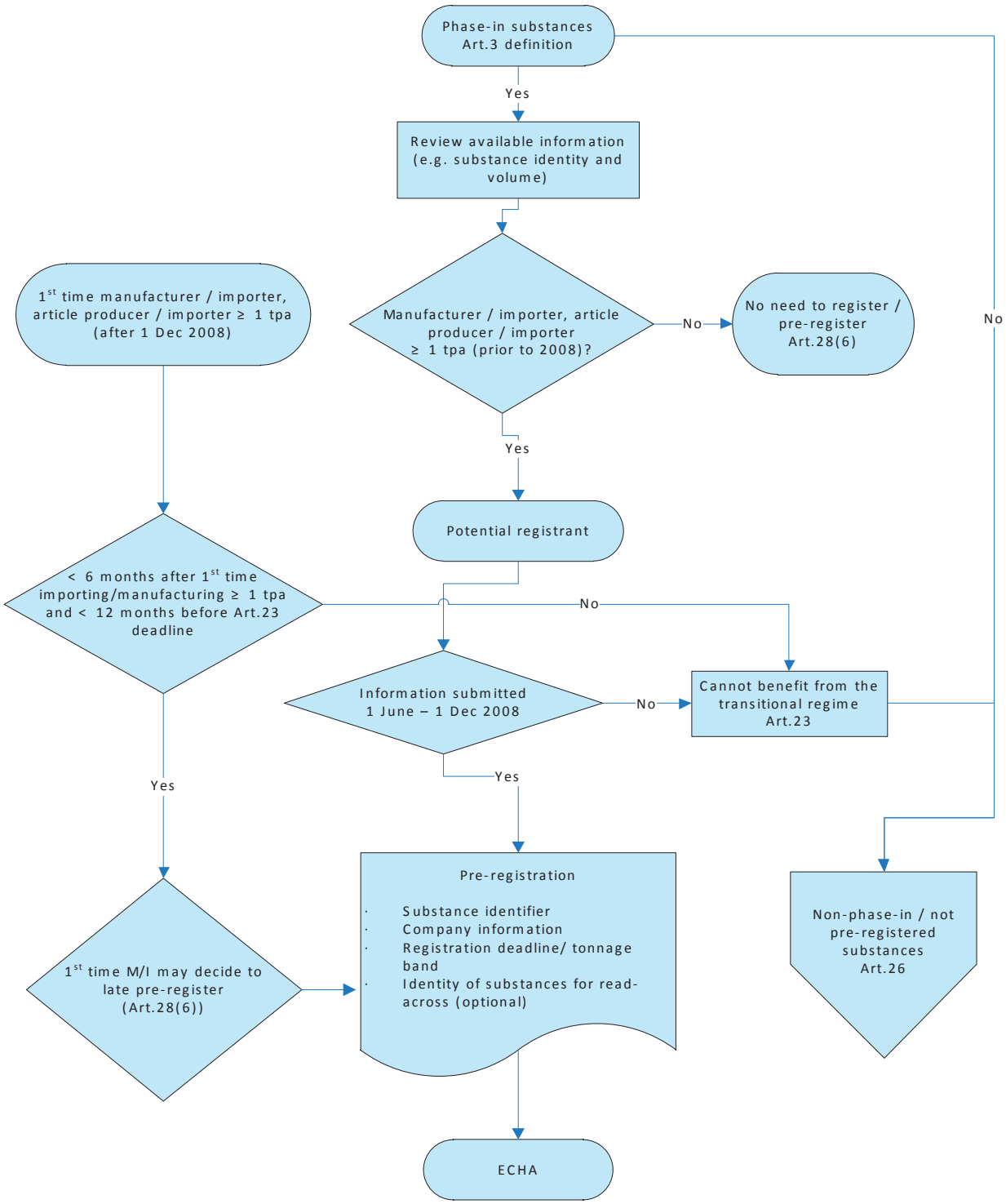



Figure 3: Late pre-registration option for phase-in substances

For more details, please consult Section 4 of this Guidance.

### 3.1.4 IS THERE AN OBLIGATION TO REGISTER PRE-REGISTERED SUBSTANCES?

Pre-registration, including late pre-registration, does not have to be followed by registration, if, for example, the potential registrant decides, before the registration deadline, to cease manufacture or import of the substance, or if the manufactured or imported quantity drops below 1 tonne per year before the registration deadline.

However, the pre-registrant should bear in mind, that all potential registrants have data sharing obligations according to Article 29(3): "*SIEF Participants shall provide other participants with existing studies, react to requests by other participants for information, collectively identify needs for further studies (…) and arrange for such studies to be carried out*". This means that other SIEF members may request information for the purpose of registration and, if pre-registrants are in possession of such information, they will have to share it in accordance with Article 30 of the REACH Regulation[8] .

### 3.1.5 HOW TO LATE PRE-REGISTER A SUBSTANCE?

Pre-registration takes place when the company submits electronically to ECHA the required information on a substance. For more details, please consult the REACH-IT Industry User Manual (IUM) on "Online Pre-registration", available at: http://www.echa.eu/web/guest/support/dossier-submission-tools/reach-it/pre-registration.

NB: Information from pre-registration can be amended/updated at a later date, except for the substance identifiers. For more details, please consult the REACH-IT FAQ on the ECHA website at http://www.echa.eu/web/guest/support/faqs.

One year before the last registration deadline, i.e. on 31 May 2017, the pre-registration tool will be closed completely. Companies that need to register after this date will have to submit an inquiry instead of a (late) pre-registration.

### 3.1.6 ESTABLISHMENT OF IDENTIFIERS FOR PRE-REGISTRATION PURPOSES

Whenever the *same* substance needs to be registered by one or more manufacturer(s) or importer(s), Article 11 (or Article 19 for isolated intermediates) of REACH applies and parts of the data need to be submitted jointly. Importantly, this "One Substance - One Registration principle" applies to both non-phase-in substances and phase-in substances (refer to Figure 1 and see for more information section 6.1).

For phase-in substances this applies to all manufacturers and importers, whether they have pre-registered or have decided to register without pre-registration.

The establishment of whether more than one manufacturer or importer manufactures or imports the *same* substance is a two-step process:

- In a first step, manufacturers and importers need to establish the correct numerical identifiers under which they intend to late pre-register or register the substance.

- In a second step, potential registrants who late pre-registered their substance under the same identifier need to establish whether their substance is the same for the purpose of SIEF formation and joint submission and verify that their substance has not also been (late) pre-registered or registered under other identifiers. This step is concluded by an agreement on the sameness of the substance for all potential registrants and the establishment of a SIEF. For more details, please consult the fact sheet "SIEF Formation and Data sharing" available on the ECHA website at http://www.echa.eu/en/web/guest/reach-2013.

8 A company which pre-registered a phase-in substance can de-activate his role in the pre-SIEF page at any time. However it is important to note that the data sharing obligations still remain. Technical details are provided in the REACH-IT IUM on pre-SIEF available at http://www.echa.eu/web/guest/regulations/reach/substance-registration/substance-information-exchange-fora.

The substance identifiers often correspond to an existing EINECS or CAS entry or similar numerical identifiers but there are also cases where one EINECS entry covers several substances or where several EINECS entries may correspond to one and the same substance for the purposes of REACH. There are also phase-in substances for which no EINECS/CAS entries or numerical identifiers exist (in particular cases related to Art. 3(20) (b) and (c)). This may trigger the splitting or merging of pre-SIEF. When this is the case, it is advisable to inform ECHA.

The information required by REACH for pre-registration purposes does not include information on the composition of the substance. Therefore, the accuracy of identifiers used for pre-registration is critical to facilitate the further steps in data sharing. REACH requires pre-registrants to submit identifiers for the substances (e.g. EINECS number, CAS number).

NB: Since the first step to establish sameness is to pre-register under the correct identifier(s), it is strongly recommended that companies read carefully the Guidance for identification and naming of substances under REACH prior to submitting information in the context of late pre-registration, as it gives guidance on how substance identity can be established based on the composition and/or the chemistry of the substance.

The objective of the Guidance for identification and naming of substances under REACH is to give guidance for manufacturers and importers on identifying and recording the identity of a substance within the context of REACH. The document provides guidance on how to name the substance. It also gives guidance on when substances may be regarded as the same for the purpose of REACH. Identifying equivalent substances is important for data sharing and for the joint submission, in particular in the process of pre-registration and SIEF formation of phase-in substances but also for inquiries relating to non-phase-in substances.

In particular for human toxicity, information must be generated whenever possible by means other than vertebrate animal tests, through the use of alternative methods, for example, information from structurally related substances (grouping or read-across), subject to appropriate scientific justification.

REACH does not give the possibility to register different substances under the same joint submission.

### 3.1.7 ESTABLISH THE FIRST ENVISAGED REGISTRATION DEADLINE AND THE TONNAGE BAND FOR (LATE) PRE-REGISTRATION

The registration requirement is triggered by the volume (yearly tonnage) of the substance manufactured or imported (or present in an article, if applicable). Each potential registrant has to indicate the envisaged registration deadline and tonnage band, while the actual amount of production and/or import will eventually determine the relevant registration deadline and obligations. The volume will also determine the information to be submitted in the registration dossier. The Guidance on registration describes how this is to be calculated for phase-in and non-phase-in substances, on their own, in preparations or in articles.

### 3.1.8 THE LIST OF PRE-REGISTERED SUBSTANCES

Based on the information submitted by potential Registrants, ECHA has published on its website a list of all pre-registered substances.

The list specifies for each substance the name of the substance including its EINECS/EC and CAS number if available and other identifiers, as well as the first envisaged registration deadline. The list as published by ECHA does not show the identity of the potential registrants.

Some substances were pre-registered and did not previously have an EC Number assigned (or for which a pre-registrant did not indicate the existing assigned EC Number). Consequently REACH-IT allocated automatically a numerical identifier, the so-called "list number", to substances for which no previous EC number entry is given by the legal entity submitting the "dossier" in question (be it a pre-registration, inquiry or a registration). The format of the list numbers is similar to that of an EC Number.

For example, 6xx-xxx-x is allocated in case the CAS RN only was provided, and 9xx-xxx-x where no CAS RN or any other numerical identifier (i.e. only substance chemical name) was provided.

These list numbers do not have any legal status and cannot be regarded as valid and legally approved EC numbers. Consequently they are considered only as "technical" identifiers to simplify the processing of dossiers (whether inquiries, registrations or others). Therefore, until the substance identification is done by ECHA, those list numbers are not to be used in documentation other than correspondence between ECHA and the registrant, i.e. not in the extended-SDS. Indeed the vast majority of list numbers have not been checked for correctness, validity or for whether the conventions outlined in the Guidance for identification and naming of substances under REACH have been complied with.

Substances can also be assigned a list number by ECHA's Substance Identification team after an inquiry (the format in this case is 7xx-xxx-x). All other EC numbers (i.e. those published in the OJ) are official and may continue to be used by registrants:

- 2xx-xxx-x EINECS (European Inventory of Existing Commercial chemical Substances)
- 3xx-xxx-x EINECS
- 4xx-xxx-x ELINCS (European List of Notified Chemical Substances)
- 5xx-xxx-x NLP (No-Longer Polymers)

Following the publication of the list, "data holders", as defined in section 3.2.3.2 below, may wish to share the information they have at their disposal. They can do so by joining a pre-SIEF for that substance and indicating to the other pre-Registrants which data are available. For more details, please consult REACH-IT Industry User Manual on "Pre-SIEF", available on the ECHA website at http://www.echa.eu/web/guest/regulations/reach/substance-registration/substance-information-exchange-fora.

NB: Data holders have been requested to submit information on pre-registered substances as early as possible after 1 January 2009. There is no requirement in REACH for a data holder to notify ECHA of their willingness to join a SIEF with a view to sharing data. If data holders wish to share data, it is however highly recommended that they identify themselves as early as possible after the publication of the list of pre-registered substances to facilitate the data sharing process. The earlier data holders indicate their interest, the more likely will it be that the potential registrants will be able to share relevant data from data holders in time before the compilation of the Registration dossier.

Hence for data sharing purposes, data holders can identify themselves and join the SIEF even after a joint submission has been submitted.

REACH-IT offers the possibility to further describe the data that is held by data holders, especially on precisely what form of the substance was tested so that the other SIEF members can better identify the relevance of the study. Whilst giving due consideration to the potential CBI issues this might raise, data holders are encouraged to use this possibility where applicable.

**Request by downstream users of phase-in substances not appearing on the list of (pre-) registered substances**

The publication of the list of pre-registered substances also gives the opportunity for downstream users to ascertain that all substances they need in their own processes are on the list and that at least one legal entity in EU has expressed an intention to register.

NB: Downstream users checking the list of pre-registered substances can never be sure that the substances present on the list of pre-registered substances have been pre-registered by their current supplier or that their supplier will eventually register. Manufacturers and importers are therefore encouraged to communicate to the downstream users as early as possible their intention to register the substance. Likewise, downstream users are encouraged to contact their suppliers as soon as possible in order to find out about their intentions and where necessary look for alternative future sources of supply.

Downstream users are also advised to consult the list of registered substances prior to contacting the ECHA Helpdesk, should their substance(s) be missing from the list. For more details please consult the Guidance for Downstream Users.

## 3.2 FORMATION OF SUBSTANCE INFORMATION EXCHANGE FORUM (SIEF)

REACH provides for the formation of "Substance Information Exchange Forums" (SIEFs) to share data among manufacturers and importers of pre-registered phase-in substances as well as allowing downstream users and other stakeholders (data holders) who have relevant information (and are willing to share it in exchange for fair compensation) to share this information with potential registrants.

This sub-section specifies who the participants in a SIEF are, what their rights and duties are, and how and when a SIEF is formed.

REACH includes provisions related to the appointment of a lead registrant for joint submission purposes (Art. 11(1)). The designation of the lead registrant as well as the SIEF management is under the responsibility of the SIEF participants.

Please be aware that SIEF formation is industry's responsibility.

### 3.2.1 THE PRE-SIEF PAGE AND THE AVAILABLE INFORMATION

When a potential registrant pre-registers a substance corresponding to an EINECS entry (or other identifiers) and is the first one to do so, REACH-IT triggers the creation of a dedicated web-page (pre-SIEF page). At this point in time, this page can only be seen by the potential registrant(s) of that substance or, in case of read across, by the potential registrant(s) of the structurally related substance(s) (with a view to exchanging each other's contact details).

Several pre-SIEFs may operate in parallel, although they are covering the same substance. This might not immediately come to the attention of members of these pre-SIEFs. Therefore, potential registrants are advised to review the entries in the pre-registration list and to assess their relevance to their own activities, as forming a single SIEF can also be done by using the read-across facility provided by REACH-IT. Indeed REACH-IT allows the potential registrant(s) to indicate that read-across is possible between structurally related substances.

They may subsequently come to the conclusion that they have the same substance and merge into one SIEF. Similarly, members of a (pre-)SIEF may also conclude that the substances they are dealing with are not the same (hence they do not correspond systematically to the identifiers of the pre-SIEF). In such a case they may have to split the SIEF to reflect the differentiation of the substances.

The page displays the following information:

- Substance identification
- The corresponding entry in EINECS, i.e. IUPAC name or substance description;
- EINECS and CAS numbers;
- The individual details of the potential registrant(s), i.e.:
  - o Identity and contact details via an .xml file (or those of the Third Party Representative if he elected not to disclose his company name for this substance);
  - o The tonnage band, the status, the role, the preregistration number and the envisaged registration deadline;
  - o Whether he was the first to indicate his willingness to act as a facilitator in the SIEF formation.
- The other substances in relation to which data can be shared (read-across). Hence pre-registrants can see their own pre-SIEF participants but also the participants from the "read-across" pre-SIEFs.

When another legal entity subsequently pre-registers a substance with the same identifier, it is automatically added to the same dedicated web-page. The new potential registrant sees all other potential registrants of the same[9] substance.

For more details, please consult the REACH-IT Industry User Manual on "Pre-SIEF" available on the SIEF section of the ECHA website.

At this stage, it is already possible for potential registrants having pre-registered a substance with the same identifier and appearing on the same web-page to contact each other and start first discussions, e.g. on substance identity and SIEF formation.

For more details, please consult the fact sheet "SIEF Formation and Data sharing" which is available on the ECHA website in the REACH 2013 section and in the SIEF section.

You need to also consider that your SIEF may be already active (for more information please see section 3.3.7).

9 Wherever in this section reference is made to the same substance, this refers to a substance/substances pre- registered with the same identifier. This does not mean that this substance/these substances are necessarily the same for the purpose of SIEF formation and registration.

### 3.2.2 THE SIEF

A SIEF will be formed for each pre-registered substance when the discussion on the sameness confirms that the participants have indeed the same substance and when they agreed on the chemical identifier to be used.

The roles, rights and obligations of the participants in the SIEF differ and are further described in section 3.2.3.

As indicated in its name, a SIEF is a forum to share data and other information on a given substance.

The aims of the SIEF are to:

- Facilitate data sharing for the purposes of registration, thereby avoiding the duplication of studies, and

- Agree on the classification and labelling of the substance concerned where there is a difference in the classification and labelling of the substance between the potential registrants.

Participants in a SIEF are free to organise themselves as they see fit to carry out their duties and obligations under REACH, i.e. to share data, especially those involving vertebrate animal testing. The organisation used for the SIEF co-operation may also be used to jointly submit the relevant information.

The choice of the form of cooperation between SIEF participants is based on the principle of contractual freedom.

NB: Even if the formation of the SIEF takes place at a given point in time, its management is an iterative process with new members joining in a continuous manner. The concept is further clarified in section 5.5.5. For more information, please also consult section 8 of this guidance document.

### 3.2.3 THE SIEF PARTICIPANTS

Several categories of parties are "participants" in SIEFs, as specified in Articles 29 and 30. These are (1) "potential registrants" and (2) "data holders" (including downstream users and Third Parties). Registrants who registered the substance earlier and all parties according to Article 15 are also participants of the SIEF. The obligations of potential registrants and data holders are described below.

#### 3.2.3.1 Potential registrants

Potential registrants are those parties who have (late) pre-registered by submitting Article 28(1) information to ECHA on a given phase-in substance. These include:

- manufacturers and importers of phase-in substances having (late) pre-registered that substance.

- Producers and importers of articles having (late) pre-registered that phase-in substance if intended to be released from articles.

- Only Representatives of non-EU manufacturers having (late) pre-registered that phase-in substance.

*Third Party Representative*

Any manufacturer or importer may appoint a Third Party Representative for certain tasks e.g. data sharing. This is typically the case when a company does not wish to disclose its interest in a particular substance as this may give indications to competitors about production or commercial secrets.

NB: Whenever a manufacturer or importer considers information which may need to be exchanged for data sharing purposes to be sensitive, a Third Party Representative may be nominated at the time of (late)pre-registration. Companies should be aware that contact details indicated at (late)pre-registration stage will be available to all potential registrants of the substance(s) pre-registered under the same identifier (in the given SIEF) as well as to potential registrants of all other substances for which read-across has been indicated unless a Third Party Representative has been appointed.

The identity of a manufacturer or importer who has appointed a Third Party Representative will not be disclosed by ECHA to other manufacturers or importers.

Additionally, a Third Party Representative can represent several legal entities but will appear as a separate SIEF participant for each different legal entity he represents.

The legal entity nominating a Third Party Representative retains the full legal responsibility for complying with its obligations under REACH.

NB: The manufacturer or importer legally remains the pre-registrant or registrant. The "Third Party Representative" must not be confused with the "third party holding information" ("data holders"), nor with an "Only Representative".

#### 3.2.3.2 Data holders

Note that REACH does not provide for data holders to have an active role in deciding on the studies to be included in joint submissions nor on the classification and labelling proposals. Data holders can thus only provide data to active members (potential registrants) of the SIEF and request cost sharing for the data supplied, where relevant.

The contact details of data holders will be made available on the pre-SIEF page of the substance and can be seen by all pre-Registrants. Data holders will not get access themselves to any information displayed on the pre-SIEF pages.

Any person holding information relevant to a phase-in substance and entitled to share it can identify himself and lodge a request to ECHA with a view to being a participant in the SIEF for that substance, to the extent that they will provide the information to other SIEF members that request it. They can do so by submitting to ECHA any or all of the information listed in Article 28(1).

Data holders may include:

- Manufacturers and importers of phase-in substances in quantities of less than 1 tonne per year who have not pre-registered.

- Downstream users who may be in possession of data, and thus have a lot to contribute in the collection of data to be used for registration, possibly in relation to intrinsic properties, but in particular in relation to quantification of exposure and estimation of risks. Hence, downstream users need to be involved as early as possible in the data sharing process. In accordance with the provisions of Article 28(7) of the REACH Regulation, downstream users may submit information on pre-registered substances as well as any other relevant information for those substances, with the intention of becoming a member (data holder) of the corresponding SIEF.

Information from downstream users may help potential registrants to waive certain tests based on lack of exposure (absence of risks for instance, or irrelevance of test type due to no exposure). Indeed, exposure-based waiving is fundamental to reducing the need for animal testing.

NB: Downstream users are advised to establish contact with their suppliers and to obtain information as soon as possible regarding the formation of a corresponding SIEF, rather than wait for potential registrants to contact them. Specifically, when downstream users have valuable data regarding safety, including hazard data, uses, exposure and risks, it is recommended that they communicate as early as possible with their suppliers in order to ensure to best possible use of their data.

- Other third parties holding information on phase-in substances, such as:

  - Trade or industry associations, sector specific groups and consortia already formed.

  - Non Governmental Organisations (NGOs), research laboratories, universities, international or national agencies.

  - Manufacturers of a substance who have no interest in registering a substance under REACH because they do not produce or place it on the market in Europe (e.g. a non-EU manufacturer who does not export into the EU).

When indicating in the REACH-IT system the pre-registered substances on which they hold information, the data holders will have the possibility to indicate other types of information, in particular with regards to safety, such as hazard data and information on uses. They can usefully indicate their intention to share data for read-across where relevant. On the pre-SIEF page (in REACH-IT) the data holder will not see the identities of the pre-SIEF members, but his information (contact details and data available) are visible for the pre-SIEF member(s), who then need to decide whether to contact the data holder.

It must be underlined that REACH does not provide for data holders to have an active role in deciding on the studies to be included in the joint submission and on classification and labelling proposals. Data holders will not be involved in pre-SIEF discussions. They will be considered as members of the relevant SIEF once formed.

Potential registrants may only start investigating data availability once the SIEF is formed and when they have identified data gaps (see section 3.3 below). In any case potential registrants are likely to first review the data they have in their possession before contacting any data holder mainly to fill data gaps. At this stage, they can launch requests for missing data (this is mandatory if the missing data involve vertebrate animal testing). Potential registrants must bear in mind that there may be several SIEFs corresponding to the entry in the list of pre-registered substances. Requests must consequently be sent to all data holders corresponding to the entry in the list of pre-registered substances, and possibly those in another entry if the final SIEF is the result of a merger of several pre-registered substances.

Potential registrants will then assess the relevance of using such data held by data holders taking into account relevance, adequacy and reliability. This will require data holders to communicate information on the identity of the substance used in generating the test data they wish to share. Data holders are therefore also recommended to consult the Guidance on identification and naming of substances under REACH for the data they have available and which they wish to share under REACH.

For more details, please consult http://www.echa.eu/web/guest/information-on-chemicals/pre-registered-substances.

NB: Data holders should be aware of the identity of the substance to which the data they are holding relates in order to allow potential registrants to ascertain the relevance to their substance. They should consult the Guidance for identification and naming of substances under REACH of substance when determining the identity of the tested substance.

### 3.2.4 SIEF FORMATION FACILITATOR

In order to initiate and facilitate discussions after pre-registration and the exchange of the information, one SIEF participant may volunteer to be the "SIEF Formation Facilitator" (SFF). If so, they need to identify themselves via the pre-SIEF page. Ideally, a potential registrant ready to become the lead registrant in the SIEF should act as SFF or candidate lead registrant in the pre-SIEF.

NB: The SIEF Formation Facilitator (SFF) does not have a formal recognition in the REACH Regulation, while the role of the lead registrant is mandatory and specifically foreseen in REACH. Acting as a SFF is voluntary and not legally binding, i.e. the legal entity volunteering is taking the initiative to contact the others within the pre-SIEF. Similarly, the SFF may freely review his position at any moment.

Additionally where the current SFF is not carrying out his function effectively, or is slowing down / blocking the process, SIEF members may ask the SFF to abandon the role and set a deadline for a response. Ultimately SIEF members are free to work without the cooperation of the SFF.

For more detailed information, please consult the REACH-IT Industry User Manual on "Pre-SIEF"available at http://www.echa.eu/web/guest/regulations/reach/substance-registration/substance-information-exchange-fora.

The initial steps for the SIEF Formation Facilitator or designated lead registrant may be any or all of the following:

- Running a survey to identify the potential registrants with clear intention to register (as the pre-SIEF may include companies not willing to take an active role);

- Designation of a lead registrant (unless this has already been done);

- Proposing the form of co-operation between the parties and possible internal rules (see section 8); i.e. whether the co-operation should be limited to the SIEF obligations (data sharing and classification and labelling) or whether it should be extended to cover other objectives;

- Running a survey regarding the availability of study endpoints and who could perform the necessary technical work (either the potential registrants themselves or a contracting Third Party or a combination of both), eg. prepare an inventory of available data within the SIEF;

- Organising the exchange of data, e.g. launch the queries for data within the SIEF;

- Channel the communication with other SIEFs, in case read across applies;

- Ensure a smooth entry of late (pre-)registrants in the SIEF.

ECHA advises all companies to decide what role they wish to take in the SIEF. For more details, please consult the ECHA website and in particular the page "SIEF" available at http://www.echa.eu/web/guest/regulations/reach/substance-registration/substance-information-exchange-fora

You need also to consider that your SIEF may be already active and discussions at SIEF formation stage may have already taken place (see section 3.3.7 for more information).

### 3.2.5 SIEF FORMATION

Article 29 of the REACH Regulation provides that all potential registrants and data holders for the "same" phase-in substance must be participants in a SIEF. The REACH Regulation leaves the responsibility for defining "sameness" to SIEF participants. Similarly the regulation does not foresee any formal step to confirm the formation of the SIEF.

The assessment of the exact nature of an EINECS entry and the different substances it may cover must be carried out by the manufacturers or importers who should be aware of the composition of the substance. It is, therefore, up to them to take the responsibility of defining precisely the substance for which a SIEF will be formed.

In order to reach an agreement on the sameness of a substance, potential registrants must enter into pre-SIEF discussions. As a consequence, a SIEF is formed when the potential registrants of a substance in the pre-registration list agree that they effectively manufacture, intend to manufacture or import a substance that is sufficiently similar to allow a valid joint submission of data.

Due to the fact that data holders are not able to view the details of the potential registrants who have pre-registered under the same identifier, it is the role of the potential registrant(s) to decide whether the available data are relevant to its substance(s) and to communicate further including with data holders, in order to gather the missing data.

NB: ECHA will not participate in discussions between potential registrants to nominate a lead registrant, nor will ECHA confirm or question the creation of a particular SIEF. Potential registrants should work towards forming SIEFs as soon as possible to ensure sufficient time remains to organise the sharing of data and to prepare the registration dossier.

For more details, please consult REACH-IT Industry User Manual on "Pre-SIEF", available on the ECHA web pages at http://www.echa.eu/web/guest/regulations/reach/substance-registration/substance-information-exchange-fora.

Following the sameness review, three situations are possible:

(i) all potential registrants agree that their substances are the same; or

(ii) one or more potential registrants consider that their substance is not the same as substance(s) pre-registered by the other participant(s), in which case the other participant's(s') data may not be relevant to describe their substance's profile. In this case, it is for potential registrants to decide among themselves what SIEF(s) are to be formed to represent each of the substances so identified. In this context, the main criteria for deciding on the sameness of a substance should be those laid down in the "Guidance for identification and naming of substances under REACH" and whether or not data sharing would give a meaningful result that can be used throughout the SIEF. It is important to underline that the formation of several SIEFs is only possible when the substances are indeed different.

(iii) one or more potential registrants consider that their substance is the same as one or several substances pre-registered under (an)other identity code(s) to conclude that these substances are sufficiently similar to allow data sharing within one SIEF.

If SIEF participants disagree on substance identity/sameness and a participant considers that it should be part of a SIEF created by other parties for a given substance, that participant has the possibility to formally request to join the SIEF and request the right to use or refer to the data he is missing to proceed with his Registration. In case this request is refused, the rules of Article 30(3) and (4) apply.

NB: The principle of joint submission applies with regards to registrants of the same substance.
The formation of several SIEFs for the same substance violates data sharing obligations.

You need also to consider that your SIEF may be already active and discussions at SIEF formation stage may have already taken place (see section 3.3.7 for more information).

#### 3.2.5.1 Competition and confidentiality issues

While the exchange of information required for the purpose of checking the similarity of the substances will generally not raise concerns under the EC competition rules, there may be instances where participants should be particularly careful. These are further explained in section 7 of the present Guidance document.

The same exchange of information will generally not reveal confidential business information (CBI) either. Nevertheless companies may want to retain information, particularly when it involves confidential data, such as know-how or sensitive information.

If a satisfactory solution cannot be found, the potential registrant concerned can "opt-out". For more details please consult section 3.3.5 and 6.3 of this Guidance document.

#### 3.2.5.2 Examples of identity issues and related solutions

*A. Substance pre-registered under a wrong EINECS entry*

If the process of verification of substance identity with pre-registrants of the same and/or similar identifiers leads to the conclusion that the substance fits more into the SIEF formed by the pre-registrants of a similar rather than the original identifier, an adjustment is still possible during SIEF formation. It is however not possible to make modifications beyond refinement of substance identity (e.g. joining a SIEF of an unrelated

substance to the one that has been pre-registered). In this case, the potential registrant may eventually register the substance under a different identifier than the one used for the pre-registration. This does not lead to any failure in the registration.

*B. There are several EINECS entries for the same substance*

In case there are several EINECS entries which correspond to one and the same substance for REACH purposes, a similar solution can apply: during the pre-registration period, manufacturers and importers may have decided to submit an additional pre-registration for one of those alternative EINECS entries in order to regroup all participants into one single SIEF.

Earlier pre-registrations can now simply become inactive (although data sharing obligations remain). For more information on inactive status (in the pre-SIEF page), please consult the REACH-IT Industry User Manual on "Pre-SIEF" available on the ECHA web site at http://www.echa.eu/web/guest/regulations/reach/substance-registration/substance-information-exchange-fora. Please contact ECHA if you need support in de-activating a large number of pre-registrations at once.

*C. The EINECS entry for a substance covers several different substances*

If the substance of one potential registrant appears to be sufficiently different to prevent data sharing with some or all other potential registrants of the pre-SIEF, a split of the EINECS entry should be considered. This may occur in the case of very broadly defined EINECS entries. When the exchange of the specifications of their substance leads to the conclusion that their substances are not the same, potential registrants of the original pre-SIEF may decide to split into several SIEFs (see section 3.2.1 above).

*D. Phase-in substances where no EINECS/CAS entries or other numerical identifiers exist (in particular cases related to Art. 3(20) (b) and (c)).*

In these cases, the name of substances as pre-registered should be the starting point in clarifying substance identity and the composition of the SIEF. When, based on the Guidance for identification and naming of substances under REACH, these substances are regarded the same, a SIEF will be formed and data sharing and joint submission obligations apply.

As the submission of the numerical identifiers at pre-registration does not include information on the actual composition of the substance, this could lead in some cases to a situation in which the potential registrants will not be registering the "same" substance (e.g. because the EINECS entry describes several substances).

In assessing the identity of the substances, potential registrants are advised to read the Guidance for identification and naming of substances under REACH carefully.

### 3.2.6 THE LEAD REGISTRANT

Under the REACH Regulation the role of lead registrant is a mandatory role laid down in Article 11(1). The lead registrant is defined as the '*one registrant acting with the agreement of the other assenting registrant(s)*' and it is he who must first submit certain information.

REACH does not specify rules as to how the lead registrant should be selected. The lead registrant must act with the agreement of the other assenting registrants and submit the joint submission dossier, which contains information on the intrinsic properties of the substance. Lead registrants are encouraged to submit their registrations well before the relevant registration deadline.

After agreeing on the substance identity (being similar for all), the potential registrants have to agree on:

- who will be the lead registrant;

- which information will be submitted jointly (in particular whether the CSR or part of it will be submitted jointly).

It means that all the manufacturers, importers and only representatives concerned by a substance (independently from the tonnage band) should participate in the discussion as soon as possible and agree on a lead registrant and the information to submit jointly.

The lead registrant may be one of those registrants who plan to submit their registration dossier by the earliest registration deadline from amongst all the potential registrants.

However, this is not an obligation: the joint registrants have the possibility to appoint any potential registrant as lead registrant, including one from amongst those with a lower tonnage (for instance, because the joint registrants have together pre-registered many other substances and have decided to share the workload of managing the joint submissions). In such a case, the lead registrant would have to submit a dossier (including studies for the higher tonnage) by the first registration deadline that applies to the SIEF members. Although the dossier submitted by the lead registrant with the agreement of the other assenting registrants will have to contain the information required for the highest tonnage of those registrants, the lead registrant will only need to pay the fee corresponding to his own tonnage.

#### 3.2.6.1 How to appoint the lead registrant?

- Scenario 1: If only one potential registrant volunteers to become lead registrant he needs to persuade the other potential registrants to agree to appoint him as lead registrant;

- Scenario 2: If two or more potential registrants volunteer to become lead registrant, they can seek an agreement between themselves as to who will be the lead registrant and request endorsement by all potential registrants. If the volunteers cannot agree, then it is recommended that the other potential registrants appoint the lead registrant.

- Scenario 3: If no potential registrant volunteers to become lead registrant, the lead registrant may be the EU manufacturer or EU importer with the highest interest in registration (e.g. highest tonnage, most data, …). However the lead registrant still needs to be endorsed by all potential registrants.

#### 3.2.6.2 SIEF Agreement

The functioning of the SIEF, to be agreed by all SIEF participants, may be detailed in a SIEF agreement. SIEF participants are free to choose the form and the clauses to be included in such an agreement. The agreement may consist of a combination of SIEF operating rules, participation processes, data and cost sharing mechanisms and other important aspects that the SIEF participants may consider on a case by case basis. Some of the points which may be included in such an agreement are:

1. Mode of selection of the lead registrant;

2. Duration of the lead registrant's role (consideration of what will happen after the last registration deadline);

3. Internal rules of designation/ transfer: the initial lead registrant may transfer the lead registrant role in the joint submission to another registrant, as per the internal rules defined and agreed in the SIEF agreement. The practical steps for assigning the lead registrant's role to another SIEF participant occur in REACH-IT: the lead registrant is only allowed to leave the lead of the joint submission object (in REACH-IT) if he assigns the new lead registrant role to a joint submission member and if, in REACH-IT, the JS member accepts the lead registrant assignment.

In case the lead registrant ceases to manufacture or import the substance, the lead registrant role may need to be transferred to one of the other joint registrants. The existing rules on choosing a new lead registrant apply. If ceasing of manufacture or import of the substance occurs after receipt of a draft decision on evaluation, the lead registrant cannot continue his duties as his registration is no longer valid (see Article 50(3) of the REACH Regulation). A new lead registrant must be selected and the role be transferred to him. In other cases of ceasing of manufacture or import of the substance by the lead registrant (before the receipt of an evaluation decision), the existing lead registrant may continue to carry out his duties, as his registration for the substance is still valid (however the tonnage is set to zero). In such a situation, the transfer of the lead registrant role may be preferable so as to facilitate the communication with the Agency and other members (both current and future) of the joint submission because the lead registrant currently manufactures/imports the substance;

4. Form of cooperation between the parties: details of the participation processes and obligations and liability of the SIEF participants (both lead registrant and members of the joint submission) during the SIEF processes;

5. Form of access to the information (e.g. the letter of access, related conditions, …);

6. Compliance with competition rules and confidentiality obligations for all the parties;

7. Governing laws for the relationship in the SIEF and the mechanisms for disputes resolution;

8. Cost sharing mechanisms (for more information please consult section 5 of the present guidance document);

REACH describes the task of the lead registrant in jointly submitting information. In order to identify the responsibility of each potential registrant in case of conflict, it is recommended that all the potential registrants keep written records of the agreements made in a SIEF (e.g.: who is the lead registrant, who is responsible for communication, representation of data owners,…).

NB: Different types of standards and templates of agreements are already available and used by different industries for data sharing purposes.

Potential registrants may therefore wish to contact industry associations and other sources in order to be provided with examples and support.

### 3.2.7 INTER-SIEF RULES (GROUPING, READ-ACROSS)

Avoiding unnecessary animal testing is a main objective underlying the provisions for data sharing in REACH. One way of achieving this is to use data relating to structurally related substance(s), if it can be scientifically justified. Reading data across different substances should always be carried out using expert judgment. The Guidance on information requirements and Chemical Safety Assessment explains in detail how and when reading across can be made (in particular Chapter R.5). Furthermore the Practical Guide on "how to report read-across and categories", available at http://www.echa.eu/en/web/guest/regulations/reach/evaluation provides useful information on this issue.

It is not mandatory for participants in different SIEFs to share data, even though it is in line with the objective of reduction of animal (particularly vertebrate) testing and registration costs. Therefore every request for access to studies across different SIEFs will have to be negotiated on a case by case basis by the potential registrants wanting to take share access to the studies (please also read sections 3.3.3 for the "collective route" and 3.3.5 for the "individual route" of this guidance may be considered).

Potential registrants are invited to explore all read across potential with a view to avoiding unnecessary testing on vertebrate animals

NB: when using the read-across or category concept in a registration dossier, registrants always need to provide a scientifically relevant justification.

### 3.2.8 WHAT ARE THE OBLIGATIONS OF SIEF PARTICIPANTS?

All SIEF Participants must:

- Agree to the appointment of a lead registrant according to Article 11(1)
- React to requests for information from other participants (within one month according to Article 30(1));
- Provide other participants with existing studies both those on vertebrate animals and others, if requested.
- Request missing data information related to vertebrate animal testing from other SIEF participants; they may also request other non- animal data from other SIEF participants;
- Collectively identify needs for further studies to comply with Registration requirements;
- Make arrangements to perform the identified studies;
- Agree on classification and labelling where there is a difference in the classification and labelling of the substance between potential registrants (see section 3.3.4). However there may be more than one classification and labelling, in a given joint registration dossier (e.g. different impurities).

Data holders must respond to any request from potential registrants if they hold the data relating to this request. Data holders are not entitled to request data.

The enforcement of obligations imposed on SIEF participants laid down in the REACH Regulation will be under the remit of national authorities.

A liability of SIEF participants may also result from the breach of contractual arrangements between the parties.

Data holders, like other SIEF participants, should be mindful of property rights and quality issues when making representations and granting rights to studies available to them.

### 3.2.9 END OF SIEF

According to Article 29, "each SIEF shall be operational until 1 June 2018". This date coincides with the last registration deadline for phase-in substances, meaning that by that date all pre-registrants should have registered their substances, unless they have decided to cease their activities involving that substance or have not exceeded the 1 tonne per annum threshold which triggers registration obligations.

However, the SIEF activities may continue even beyond 1 June 2018, as the efforts and data generated by the SIEF participants in the framework of their registration will be continuous between the submission of the joint registration and after the end of the SIEF, for instance following substance or dossier evaluation. Finally, a subsequent registrant may wish to use the submitted information for registration purposes after 1 June 2018. Registrants are therefore recommended to consider extending their contractual relationship beyond 1 June 2018.

## 3.3 DATA SHARING RULES FOR PHASE-IN SUBSTANCES WITHIN SIEF

Pre-registration entails several obligations for potential registrants. These encompass data and cost sharing, joint submission, update of their information, etc. When they are part of a SIEF, the members and the appointed lead have the responsibility to share information with a view to preparing the joint registration dossier, discussing data quality, need for opt-out etc.

As described in more detail later in this section, potential registrants may decide to follow the "collective" or the "individual" route (opt-out for certain information requirements) to prepare their registration.

### 3.3.1 OVERALL APPROACH TO DATA SHARING

In addition to the obligations of SIEF participants described in section 3.2.8, Article 11 requires that studies and proposals for testing as well as classification and labelling information must be submitted jointly by all registrants of the same substance (According to Article 11, as discussed in sections 3.1.6 and 6.1, the,"one substance, one registration principle,), unless the conditions for opting out apply. This part of the guidance considers both the need to meet the legal obligations under the data sharing process and the process leading to a joint submission. See also section 4 for non-phase-in substances.

Article 30(1) provides that "before testing is carried out", participants in a SIEF inquire whether a relevant study is available within the SIEF. The participants must request the study in case it involves tests on vertebrate animals and may request the study in case of other data. This request for missing information then triggers the obligation for the data owner to provide proof of its cost and further data sharing obligations.

In practice, the potential registrants have the task to organise the data sharing activities: i.e. to use more direct forms of cooperation to gather the required information, to agree on the necessary data package and on the classification and labelling, and to prepare for the joint submission of data.

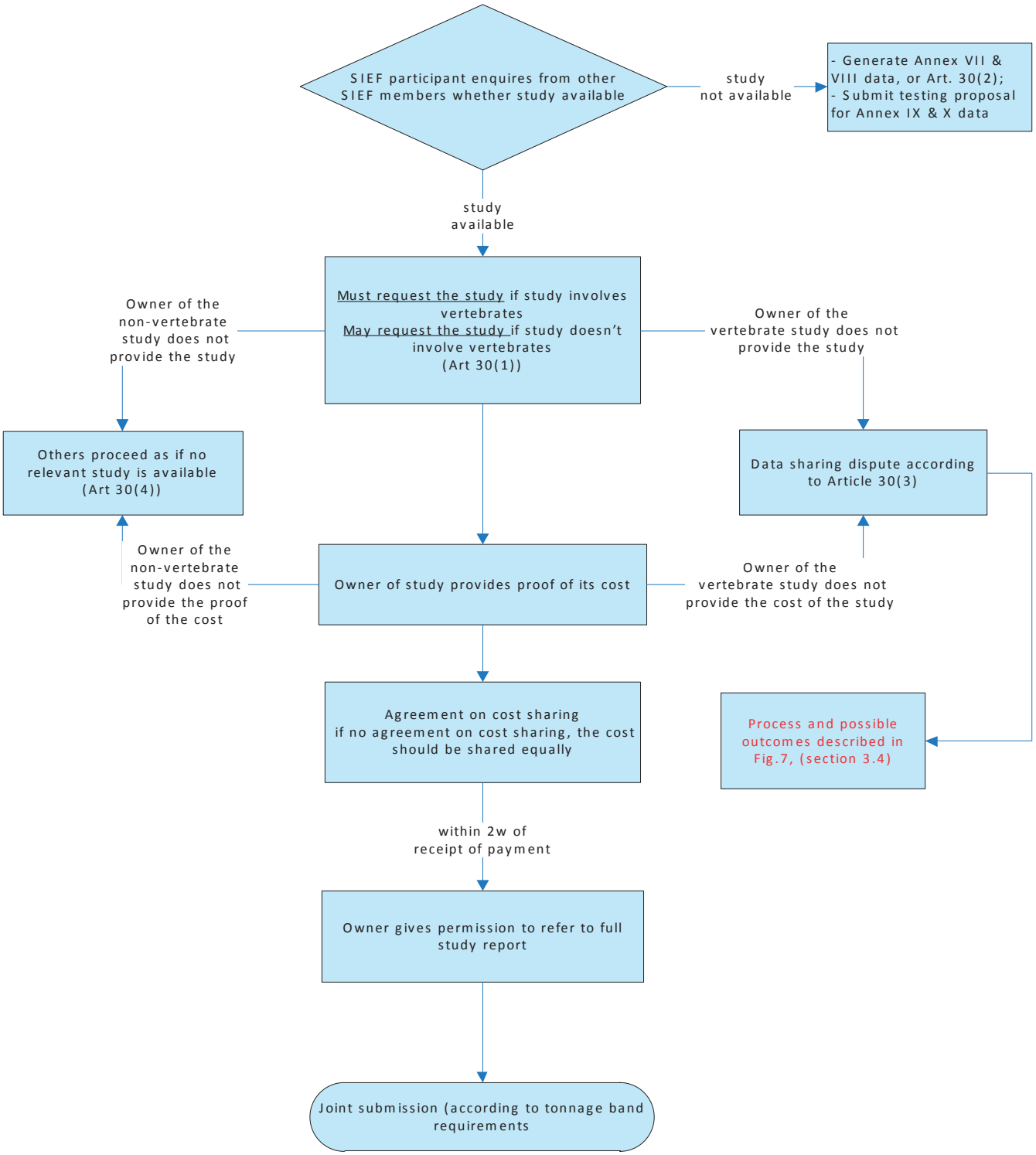



Figure 4: Data sharing principle within the SIEF

These activities can involve a review of all available data (including publicly available data). This review can be delegated to one individual member (or to an external expert), subject to the assent of others. This may allow participants to determine and agree on classification and labelling, selection of studies and testing proposals to be submitted, to agree the content of a possible joint chemical safety report and guidance for safe use, etc. Consequently, it is recommended that SIEF members work together in the identification of existing information (including publicly available data) and data needs, the generation of new information, and the preparation of the joint registration dossier ("collective route"). This option is acknowledged as being very time-consuming, so lead registrant and SIEF participants are free to organise themselves for the benefit of all. However the criteria of fairness, transparency and non discrimination must always prevail in the negotiations.

In case there is a disagreement regarding a specific endpoint, a potential registrant has according to Article 11(3), the possibility to opt out from the joint submission for the particular endpoint. Subsequently the potential registrant does not have to rely upon the full data set prepared and may submit data he already owns or which he considers is more scientifically reliable, relevant and adequate, than the data chosen in the jointly submitted dossier. Opting out does not relieve the potential registrant from his obligation to make available and share data or to be part of the joint submission.

### 3.3.2 FULFIL THE INFORMATION REQUIREMENTS FOR REGISTRATION

Data sharing must first be reviewed with reference to the information requirements for Registration. Essentially, REACH requires manufacturers and importers to collect data on the substances they manufacture or import, to use these data to assess the risks related to these substances and to develop and recommend appropriate risk management measures for using the substance throughout its life cycle. Documenting these obligations requires them to submit a registration dossier to ECHA.

Fulfilling the information requirements for Registration is essentially a four step process, which consists of:

- Gathering existing information
- Considering information requirements
- Identifying information gaps
- Generating new information or submitting a testing proposal in line with REACH obligations

The participants of the SIEF are free to organise these steps as they best see fit.

### 3.3.3 THE COLLECTIVE ROUTE

It is important to stress that REACH gives potential registrants the flexibility to decide how they organise their data sharing and joint submission obligations. This section of the Guidance describes how data sharing can be organised collectively within a SIEF with the view to meet the objectives discussed in section 3.3.1 above, including both the obligations related to data sharing and the preparation for the joint submission of data at Registration.

<u>The following steps are only indicative:</u>

- Step 1 Individual gathering of available information to potential registrants
- Step 2 Agreement on the form of cooperation/cost sharing mechanism

Step 3 Collection and inventory creation of information available to potential registrants

- Step 4 Evaluation of available information within the SIEF
- Step 5 Consideration of information requirements
- Step 6 Identification of data gaps and collection of other available information
- Step 7 Generation of new information/testing proposal
- Step 8 Sharing of the cost of the data
- Step 9 Joint submission of data

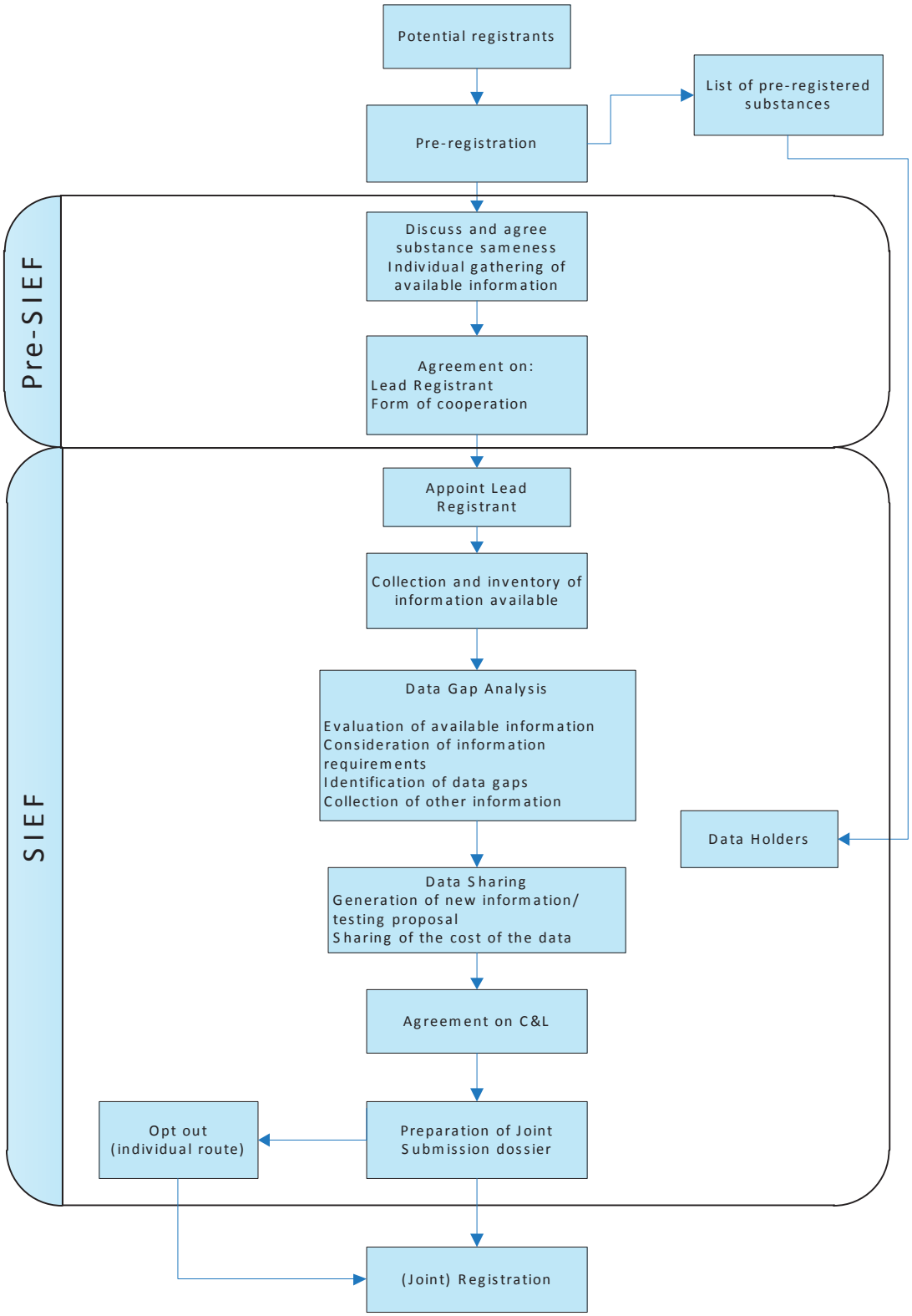



Figure 5: Overview of the data sharing process for phase-in substances; pre-SIEF and SIEF operation

#### 3.3.3.1 Step 1: Individual gathering of available information

Potential registrants should first gather all existing available information on the substance they intend to register. This must include both data available "in-house", as well as that from other sources, such as data in the public domain that can be identified through a literature search.

The search, identification and documentation relating to "in house" information must remain an individual exercise and companies have been encouraged to conduct this data gathering exercise well ahead of the SIEF/data sharing phase, and even before the pre-registration phase as the availability of the data (or lack thereof and therefore the cost of generating the required data) may have been one of the elements which could influence the decision to become a potential registrant for that substance.

NB: Data gathering must be thorough, reliable and well documented, as failure to collate all of the available information on a substance may lead to unnecessary testing with related resource implications.

The information to be gathered by each potential registrant must include all information relevant for purposes of Registration, i.e.:

- Information on the intrinsic properties of the substance (physicochemical properties, mammalian toxicity, environmental toxicity, environmental fate, including chemical and biotic degradation). This information may come from *in vivo* or *in vitro* test results, non-testing data such as QSAR estimates, existing data on human effects, read across from other substances, epidemiological data;
- Information on manufacture and uses: current and foreseen;
- Information on exposure: current and anticipated;
- Information on Risk Management Measures (RMM): already implemented or proposed.

This data gathering exercise is to be done irrespective of the volume. Indeed, if the data requirements at registration depend upon the volume manufactured or imported by each registrant, registrants must register all relevant and available data for a specific endpoint. Nevertheless, they have to share on request data available that correspond to a higher tonnage threshold.

NB: In summary, Step 1 requires each potential registrant to assemble and document all the information on the substance, available in-house (regardless of the envisaged registration tonnage) - including information on the substance's (1) intrinsic properties (irrespective of tonnage), (2) uses, exposure and risk management measures. Potential registrants are encouraged to start gathering all relevant and available information as soon as possible, even before the formation of the SIEF for that substance.

#### 3.3.3.2 Step 2: Agreement on the form of cooperation/cost sharing mechanism

Before potential registrants (and potentially other SIEF Participants) start exchanging information on the data they have available, it is recommended that they first agree on the form of cooperation that best suits them and the main rules applicable to that cooperation, in terms of data and cost sharing.

NB: In summary, Step 2 requires potential registrants (and potentially data holders) to (virtually) meet, discuss and agree on the main elements of the gathering of information, identification of information needs, generation of missing information, and sharing of the costs related to all registration activities.

#### 3.3.3.3 Step 3: Collection and Inventory creation of information available to potential registrants

In step 3, potential registrants should first organize themselves to complete the data collection phase, by collecting all information they have available individually. If literature searches have not been done individually in Step 1, these must be done jointly at this stage in order to gather all available information.

To the extent that available data is not sufficient for registration purposes (Step 6 below), potential registrants must collect data available from (1) data holders, (2) other SIEFs and (3) outside the SIEFs. However, if the potential registrants know in advance, for example from previous contacts, that they do not have a complete data set with their own data, they may decide to contact data holders or other SIEFs early. Information from other SIEFs can be obtained after requesting read–across from another substance.

Collecting data available to potential registrants can be done in the form of a questionnaire structured according to Annexes VI to X of REACH which the lead registrant sends to all potential registrants and that is returned within the requested deadline. This questionnaire may also include a request to communicate the classification and labelling of the substance.

In order to help participants review available data a form is proposed, as an example, in Annex 1.

As the above data is being collected, it should be entered into a common inventory. This would best be in the form of a matrix which compares the data available for each end point (up to the highest tonnage threshold among potential registrants) with the data needs and identifies key elements for each study, including the identity of the data holder.

To the extent that the literature search may require considerable time to be completed, it is recommended that potential registrants continue their work and initiate Steps 4 and possibly 5 below without waiting for Step 3 to be completed.

NB: In summary, Step 3 requires potential registrants to collect and create an inventory of all information on the substance they have available within the SIEF. They may also consider at this stage data available to data holders, in other SIEFs and outside of the SIEFs, in particular in situations where potential registrants know they do not have a full data set for Registration purposes.

#### 3.3.3.4 Step 4: Evaluation of available information within the SIEF

The next step is for potential registrants to evaluate the data available on the substance to be registered. This step may be undertaken by the lead registrant, any other potential registrant, or a representative acting on behalf of all potential registrants.

Essentially, for each endpoint, the following actions must be performed:

- Assess the relevance, reliability, adequacy and fitness for purpose of all gathered data (for more details please consult the Guidance on information requirements for arriving at conclusions on the hazard assessment and for risk characterization).

- Determine the key study for each endpoint: This is the study of greatest relevance taking into account the quality, completeness and representativeness of the study. This is a critical step, as these key studies are generally the basis for the assessment of the substance.

- Determine which information/study (or studies) needs a robust study summary (normally the key study) or a study summary (other studies). A robust study summary should reflect the objectives, methods, results and conclusions of a full study report. The information must be provided in sufficient detail to allow a technically qualified person to make an independent assessment of its reliability and completeness – without having to go back to the full study report (for more details, please consult the Guidance on information requirements).

Depending on the situation, potential registrants may be in possession of only one key study on an endpoint or may have several studies.

(i) If only one valid study is reported on an endpoint:

Potential registrants have to use the information available (robust study summary) for that study so as to conclude on the endpoint (this is later reported in the IUCLID endpoint study summary). If the endpoint study record has been documented sufficiently, potential registrants would only need to use information already summarised in the endpoint study record.

(ii) If more than one valid study is available on an endpoint:

Potential registrants have to use all available information reported in the different endpoint study records in order to conclude on the endpoint. Usually the first information to be used should be the robust study summary of the key study documented in the endpoint study record. The other information should be used only as supporting evidence.

However, there might be cases where there will be more than one key study on a specific endpoint or no key study. In these situations the assessment should be done by using all available information in a weight of evidence approach. In such situations the endpoint study summary should be well documented and all studies discussed to justify the final conclusion.

The same applies when alternative methods (e.g. (Q)SARs, read across, *in-vitro* methods) are used as relevant information for the final assessment and conclusion.

NB: If the lead registrant, any other potential registrant, or a representative acting on behalf of all potential registrants acts, in Step 4, on behalf of all potential registrants, he needs to provide clear justifications for the choice of a given study if requested.

Guidance on how to use alternative methods or a weight of evidence approach, on how to identify and measure environmental fate and physico-chemical properties, and make human health and environmental assessments is available in the Guidance on the Information requirements and Chemical Safety Assessment available at http://www.echa.eu/web/guest/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment.

This approach should be used by the registrant to fill the endpoint study summary with the three following types of information:

- A summary of the data available on a specific endpoint as well as a conclusion regarding the assessment of a specific endpoint for the substance (e.g. reprotoxicity, acute toxicity to fish, biodegradation)

- The classification and labelling of the substance (for human health, environment and physico-chemical properties) as well as a justification for this classification

- PNECs and DNELs values as well as a justification of the reported values.

Technical guidance on how to complete the endpoint study summaries is given in the Guidance on IUCLID. It should be noted that information included in the endpoint study summaries in IUCLID 5 can be automatically extracted to generate the Chemical Safety Report.

NB: In summary, Step 4 requires potential registrants or their lead registrant to evaluate all available data, which includes an evaluation of the quality of the data, the selection of key studies for each endpoint and the drafting of relevant (robust) study summaries.

#### 3.3.3.5 Step 5: Consideration of information requirements

The next step is for potential registrants to identify precisely what are the information requirements for the substance that they intend to register, considering in particular the tonnage band that is relevant to them, the physical parameters of the substance (relevant for technical waiving of tests) and uses/exposure patterns (relevant for exposure based waiving).

NB: Potential registrants are only required to compensate financially for the data required by the REACH Regulation according to their tonnage band.

As described more fully in the Guidance on registration, Article 11 requires registrants to:

- provide all relevant and available physicochemical, toxicological and ecotoxicological information that is available to them, irrespective of tonnage (this includes data from an individual or collective literature search);

- as a minimum, fulfil the standard information requirements as laid down in Column 1 of REACH Annexes VII to X for substances produced or imported in a certain tonnage band, subject to waiving possibilities, as described below.

In all such cases, the registrants should indicate clearly and justify each adaptation in the registration. For each of the REACH Annexes VII to X, Column 2 lists specific criteria (e.g. exposure or hazard characteristics), according to which the standard information requirements for individual endpoints may be adapted (i.e. data waiving).

In addition, registrants may adapt the required standard information set according to the general rules contained in Annex XI of the REACH Regulation which refer to situations where:

- testing does not appear to be scientifically necessary;

- testing is technically not possible;

- testing may be omitted based on exposure scenarios developed in the chemical safety report (CSR).

For phase-in substances, manufactured or imported between 1 and 10 tonnes per year, the full information requirements are only applicable if one or both of the criteria laid down in Annex III are met. In other cases only the physicochemical information requirements in Annex VII need to be fulfilled.

NB: In summary, Step 5 requires potential registrants to identify precisely what their information requirements are, considering in particular the tonnage band relevant to all potential registrants, but also uses/exposure patterns for exposure waiving purposes.

#### 3.3.3.6 Step 6: Identification of data gaps and collection of other available information

At this stage, potential registrants (or any (legal) person preparing the joint dossier) are in a position to compare the information requirements and information gathered and to identify whether there are information gaps and consider how missing information can be generated.

If the potential registrants decided to carry out a collective literature search as mentioned in Step 3 this search will have to be completed before data gaps can be identified leading to the steps described below:

- If the available information is sufficient and the standard information requirements are met, no further gathering of information is necessary. As described in Step 5, even in the absence of data for all the standard information requirements, justification for waiving of the relevant test(s) must be provided in accordance with the criteria under Annex XI.

- In case the available information is considered insufficient, then potential registrants can verify the data available from outside the SIEF, before generating new information or a testing proposal.

First, potential registrants must inquire to the data holders within the SIEF to identify the information/data they have available, either by requesting a relevant study for one (or more) given end-point(s), or by means of a questionnaire linked to Annexes VI to X of REACH, if more data is missing. It is recommended that a short but reasonable delay is given to data holders to communicate on the requested data (e.g. 1-3 months).

If the data gaps still exist, potential registrants can proceed similarly with data holders in other SIEFs (for substances with a potential for (Q)SARs (Quantitative) Structure Activity Relationships) or read-across). It is advisable that data sharing discussions with members of other SIEFs are also managed by the lead registrant on behalf of the SIEF.

- Finally, in some cases, instead of commissioning further testing, the registrant may propose the limitation of exposure through the application of appropriate risk management measures (for more details, please consult the Guidance on information requirements and Chemical Safety Assessment).

Data gaps may be different for each of the relevant tonnage bands. For example, all necessary data may be available for the registration of the substance up to 100 tonnes, but the data is not sufficient for those companies manufacturing or importing the substance above that threshold. In this case, and unless they would have an interest in acquiring additional studies for other or future use, only those companies requiring these studies will need to share the cost of the studies to be generated.

NB: In summary, Step 6 requires potential registrants to identify precisely the data gaps to be filled in. Before animal testing is conducted or a testing proposal is submitted, potential registrants MUST verify whether the missing data is available to data holders within the SIEF. Additionally the potential registrants can verify outside of the SIEF or even with potential data holders not involved in REACH whether this information has already been generated.

#### 3.3.3.7 Step 7: Generation of new information/testing proposal

In case data gaps are identified in Step 1, information on intrinsic properties of substances may be generated by using alternative sources for information other than *in vivo* testing, provided that the conditions set out in Annex XI are met. The registrant may use a variety of methods such as (Q)SARs, *in vitro* tests, weight of evidence approaches, grouping approaches (including read-across).

When an information gap cannot be filled by any of the non-testing methods, the potential registrants have to take action depending on the missing data:

a. in case a study as listed in Annexes VII and VIII (whether or not involving vertebrate animals) is needed for registration, and is not available within the SIEF, a new test will need to be conducted in order to complete the dossier. Consequently the potential registrants must **generate** new information and need to agree on who will conduct the missing study before submitting their joint registration dossier. For more details, please consult the Guidance on Information Requirements and Chemical Safety Assessment available at http://www.echa.eu/web/guest/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment.

b. in case a study as listed in Annexes IX and X (whether or not involving vertebrate animals) is needed for registration, and is not available within the SIEF, the potential registrants must agree on and **prepare a testing proposal** to be submitted as part of the joint registration dossier for ECHA's consideration. Additionally potential registrants have to implement and/or recommend to downstream users interim risk management measures while awaiting the outcome of ECHA's decision (as per Article 40) regarding the testing proposal.

NB: The obligation to prepare a testing proposal also applies when the lead registrant, as a result of the application of the rules in column 2 of the annexes, proposes (higher tier) tests of Annexes IX or X as an alternative to the standard requirements of Annexes VII and VIII.

The procedure to be followed when a relevant study involving tests is not available is described in Article 30(2). Essentially, the potential registrants cannot proceed individually with the generation of missing data and have the obligation to agree on one of them performing the study on behalf of the others. In case no agreement can be found, potential registrants may contact ECHA and request support in identifying the registrant who will perform the missing test. For more details, please consult section 3.4.1.

NB: In summary, when there is no alternative, Step 7 requires potential registrants to either generate new data (when Annexes VII or VIII apply) or to prepare a testing proposal (when Annexes IX and X apply). Testing on vertebrate animals should always be conducted as the last resort.

#### 3.3.3.8 Step 8: Sharing of the cost of the data

Once the potential registrants or their lead registrant have completed the steps above and know the number of potential registrants per tonnage band, they can organise the actual sharing of the available data and communicate the costs involved. This can be done in stages, for example, starting with the available data within the SIEF and then with the newly developed data, or as a single exercise, when all data is available.

However ECHA recommends that the lead registrant, or any person preparing the joint dossier, communicate at regular intervals so as to inform the SIEF participants of the progress of the registration dossier preparation. For more details, please consult the REACH-IT Industry User Manual on "Joint submission" available at http://www.echa.eu/web/guest/joint-submission-lead. Additionally it should be noted that is not in ECHA's remit to assess whether costs are justified. In case of a dispute, ECHA will assess whether the parties involved have made every effort to share the information in a fair, transparent and not discriminatory way. For more details, please consult section 3.4 of this Guidance document.

As described above, it is recommended that potential registrants and data holders agree early on the data sharing conditions.

A few important points must be considered by the parties when doing so:

**What needs to be shared for Registration purposes?**

Article 10(a) requires that the registrant be "in **legitimate possession** of or **have permission to refer to** the full study report summarized in a **study summary** and a **robust study summary** which are to be submitted for the purpose of registration".

Establishing conformity with this provision requires clarifications regarding (1) the nature of the data that is required to be submitted and/or accessible at Registration, and (2) the rights of the registrants to that data.

1. **Nature of the Data**

A clear distinction must be made between: (a) the full study report, (b) the (robust) study summary and (c) the results of the study.

a. Normally, when e.g. a toxicological or ecotoxicological study is commissioned, the laboratory in charge will issue a **full study report** and pass it on to the party who commissioned and paid the study. This term is defined in Article 3(27) as "a complete and comprehensive description of the activity performed to generate the information. This covers the complete scientific paper as published in the literature describing the study performed or the full report prepared by the test house describing the study performed". Often, the full study report is not published, and in such a case CBI may be claimed; if published, generally, such a publication will be subject to copyright. REACH does not require that this "full study report" be submitted at Registration, but rather that the registrant be in legitimate possession or have permission to refer to that full study report.

b. To make the study more easily useable, but yet assessable by a reader, laboratories or other parties prepare **study summaries** or **robust study summaries** of the full study report. These terms are defined in Article 3(28) and 3(29), e.g.: "Robust study summary means a detailed summary of the objectives, methods, results and conclusions of a full study report providing sufficient information to make an independent assessment of the study minimising the need to consult the full study report." (Robust) study summaries are sometimes made publicly available by governments with the consent of the owner of the full study report (e.g. the case of international or national chemical assessment programs such as the EC risk

assessment reports, OECD/ICCA HPV program and the US HPV Chemical Challenge Program). (Robust) Study summaries will normally be published on ECHA's website, unless a registrant can justify to ECHA why this publication is potentially harmful for the commercial interests of the company or another party. If ECHA accepts the justification, the (robust) study summaries will not be published.

c. Extracted from the study report and the study summary is the "**result**" (or conclusion) of the study. The result of certain studies submitted for the purposes of registration will be published on ECHA's website (Article 119(1)(d) and (e)) and cannot be claimed to be confidential. This publicly available information is not sufficient for a third party to submit a registration as any registrant must submit the relevant (robust) study summaries and have permission to refer to the full study report.

2. **Right to the Data (Full Study Report)**

Clear distinction must be made between: (a) ownership of the full study report; (b) legitimate possession of the full study report, (c) right to refer to the full study report and (d) possibly other rights.

a. **Ownership of the full study report** would normally be with the party(ies) who hold all[10] the property rights over the data (data owners). These property rights are borne either automatically (because the owner is the creator of the studies or tests) or through the will of the parties (i.e. contract).

In case the property rights over the data have been licensed by a contract (i.e. assignment of rights, license agreement, letter of access, mandate etc) the person/entity to whom those property attributes have been licensed becomes either full[11] owner of all the property rights over that data (i.e. in case the entire property over the data has been transferred - assignment of rights) or partial owner/user (in case only certain scientific materials have been licensed or only some attributes of the property right have been granted, i.e. a license granted to the lead registrant to use the studies for registration purposes).

b. The notion of **legitimate possession** of the full study report is mentioned in Article 10 of REACH. However, this term is not defined in the Regulation. In case of published information this can be inferred from the legislation applicable to the use of intellectual work, namely copyright law.

The requirement to be in legitimate possession should be read together with REACH Article 30(1) to mean that the registrant is required to hold the right to use the data for the purpose of the registration, although the right to use the data for other purposes could be limited. A possible concrete example would be to have a copy (in electronic or paper form) of the full study report, with the valid right to use the data for registration purposes.

Taking into account that the full study report is primarily an intellectual creation and thus covered by the legislation on intellectual property rights, it would not thus be possible for example to use data stolen from a data owner, or breaching a license agreement.

In addition, intellectual property is a matter of private law, which applies autonomously from the REACH Regulation. Legitimate possession may therefore be questioned under REACH where a breach of intellectual property rights is already established. Such breach can be established exclusively by an authority or court competent in intellectual property.

10 The attributes of the property right are very extensive: e.g. the right to use the data for different purposes (including registration under REACH), re-use the data, translate, exploit, sell, transfer, distribute, reproduce, prepare derivative studies, include the studies/data in other studies etc.

11 When the data owner is acting as a registrant, even though he acquired full ownership over the data, he still might be prevented from using/disposing of the study as he best sees fit. For example, Article 30(1) requires the "owner of the study" to provide proof of cost to the SIEF Participants requesting it.

c. REACH also refers to the **right to refer** to the full study report for the purposes of registration. This concerns the right to refer to a study already submitted for registration by the owner(s) of the full study report or another registrant. Consequently the data owner or the legitimate user of the data can provide a "letter of access" or a license or any other form of agreement to another party (licensee) that is limited to the use of the data for one or more specific purposes, such as for registration under REACH, but without necessarily transferring on to that party a copy of the full study report but only the right to refer to that study;

d. By contrast, a mere copy of the full study report, with no letter of access or right to use the data, is not sufficient for registration purposes, unless the full study report itself is publicly available and not protected under copyright or other relevant intellectual property rights.

NB: Except for specific cases enumerated in Article 10(a) last paragraph, the registrant must be in legitimate possession or have permission (e.g. a letter of access) to refer to a full study report. This also applies to cases where robust study summaries or study summaries can be found on the internet (for example summaries published in the framework of the OECD/ICCA HPV Program).

In addition, regarding electronic information in the "public domain", such information cannot be simply used for the purpose of satisfying the minimum information requirements in a registration. Potential registrants should carefully check to what extent information may be used for free and whether certain uses of those studies infringe copyrights of the owner(s). This also applies to cases where access is given to full study reports by Government agencies (for example through the US Freedom of Information Act or similar legislation[12]) .

The "legitimate possession" or "permission to refer" required by Article 10 of REACH could be considered as derived directly from intellectual property law[13] . According to copyright law rules facts and data themselves which are to be used to create a study summary are generally not copyright protected. Furthermore references and quotation to a work (the full study report in this case) in the study summaries and in the robust study summaries can also be made, provided that mention of the source and the name of the author if it appears in the published full study report shall be made. Copyright covers only the form or mode of expression, but facts and data themselves which are to be used to create a study summary for the purpose of the registration dossier are generally not copyright-protected.

ECHA, on its dissemination website, reminds potential registrants that "pursuant to Article 10 of the REACH Regulation, robust study summaries and study summaries disseminated in [...] portal may only be used for the purpose of satisfying the minimum information requirements in a registration where the potential registrant is in legitimate possession of the full study report or has permission to refer to the full study report." Furthermore "reproduction or further distribution of the information is subject to copyright laws and might require the permission of the owner of that information." Finally the information disclosed is not enough to ensure reliable data which would be of good quality and relevance to fulfil the REACH data requirements.

**How to grant legitimate possession or right to refer to data?**

Legitimate possession or right to refer to a full study report (1) is typically granted by owners of the full study report but (2) is sometimes granted by law or by authorities.

12 This case should not be confused with the access to (robust) study summaries granted by ECHA during the inquiry process, for which the 12-year rule applies. These (robust) study summaries can be freely used for registration purposes. For more information refer to Section 4.6 of this guidance document.
13 The Berne Convention for the Protection of Literary and Artistic Works (1886), as last amended in 1979.

1. Granting legitimate possession or a right to refer to the full study report normally requires an agreement between the parties. When the report is subject to copyright or CBI, granting legitimate possession may take the form of a "license to use" the data, while a right to refer to the data can be granted by a simple "letter of access". While negotiating these agreements, careful attention should also be paid to the rights so granted (right to use for REACH only or also for other purposes), the information provided and possibly the duration of such agreement or access, and associated costs. Furthermore the right to sub-licence may also need to be considered (e.g. the licence is granted to the lead registrant who needs to extend the right to the legitimate SIEF participants).

2. In some cases, the right to use or refer to data is granted by law or regulatory authorities. This is the case pursuant to Article 25 of REACH which provides that "any study or robust study summaries of studies submitted in the framework of a registration at least 12 years previously can be used for the purposes of registration under REACH by any other manufacturer or importer." Hence, according to the "12 year rule" it is possible to refer to any study and robust study summaries without the need to have legitimate possession of them. Additionally Article 10(a) exempts study reports covered under Article 25(3) from the requirement that the registrant shall be in legitimate possession or have permission to refer to them.

This is also the case in specific circumstances under the inquiry procedure (as described in section 4) or when the parties do not agree on data sharing within a SIEF (Article 30(3)). It is however important to note that this specific "12-year rule" relates only to study summaries or robust study summaries submitted in the framework of REACH registration and they may not be freely used for other purposes. This case should not be confused with the access to (robust) study summaries granted by ECHA during the inquiry process, for which the 12-year rule applies. These (robust) study summaries can be freely used for registration purposes. For more information refer to Section 4.6 of this guidance document.

In general, when the studies are publicly available the contained data can be used without the need to contemplate the copyright of the study. However copyright does not allow the potential registrant to copy the text of the study – the fixed expression – into the registration dossier. The data can be used to produce an own study summary. However, the use of published data for the purpose of satisfying the minimum information requirements in a registration purposes still requires legitimate possession or the right to refer to the full study report (i.e. the published study itself on which the study report is based).

In the case of the published full study report, "legitimate possession" or "right to refer to" could in many cases be granted by the purchase of the periodical, albeit not necessarily in all cases. If the status of the published study cannot be deduced from the copyright clause displayed with that study (e.g. the publisher excludes only commercial use), then it is advisable to check with the copyright owner to what extent companies are allowed to use the published studies in their own dossier. If necessary such a right may be obtained through a "Letter of Access" or any other form of agreement ensuring a "license" to use the relevant information for the purpose of registration. Note that the copyright owner might not necessarily be the author of the study, but rather the publisher or the webmaster.

In other words, registrants should try to negotiate with the copyright owner a license that will allow them to refer to the published data.

It is important to note that, wherever joint submission of information in accordance with Article 11 or 19 REACH applies, the check of the conditions of use of the published information must take into account the fact that the information will be used not only by the lead registrant, but also by all the other members of the joint submission for the same substance. If any agreement with the copyright owner or his representative is necessary, it should ensure the legitimate use of the published study for all members of a joint submission.

The extension of the rights over the study can be obtained through a 'letter of access' or any other form of agreement. The agreement needs to ensure that registrants can demonstrate "legitimate possession" of the relevant information for the purposes of the REACH registration.

If the copyright owner refuses to grant a license to potential registrant(s), it should be considered that some parts of the published documents may not be protected by copyright and, therefore, can be included in the registration dossier.

NB: Copyright covers only the form of expression, but not the facts and data included in the work. This type of information can be included in the dossier without the consent of the copyright owner provided that the text from the published study is not copied as such in the study summary. In this case there is no need for prior permission to refer to the data, but references and quotations to the study should be made. Be aware however that the use of published data for the purpose of satisfying the standard information requirement still requires the right to refer to the full study report (i.e. the published study itself on which the study report is based)

The source and the name of the author should be mentioned if they appear in the published article. However, when relying on a copyright exemption, the entire full study report or substantial parts of it cannot be copied as such. In addition, and only very exceptionally, in cases where the arrangement or selection of particular facts may be considered as constituting a completely novel and original expression, these may also be subject to copyright. Furthermore, quotation, also indicating the source and the name of the author, should be used whenever appropriate in accordance with fair practice and to the extent required by the specific purpose of registration, as this should normally also not infringe copyright.

Furthermore, copyright is also subject to certain exceptions which may be applicable. The reproduction right as one of the basic elements of copyright protection, which is relevant in this context, is addressed in Directive 2001/29/EC[14]. The reproduction right is the exclusive right to authorise or prohibit direct or indirect, temporary or permanent reproduction by any means and in any form, in whole or in part for authors, of their works (Article 2(a) of the Directive). There are several exceptions and limitations (Article 5 of the Directive) that could be considered as relevant for the published study material to be used for REACH purposes (e.g. quotation of a work which has already been lawfully made available to the public for purposes such as review (Article 5(3)(d)), use of a work to ensure the proper performance or reporting of administrative proceedings (Article 5(3)(e)). The appreciation of the situation in a particular Member State would thus require checking the actual transposition of the Directive into national law. Apart from national law, national jurisprudence of the particular country would also be relevant to establish the precise context of such an exception.

Therefore, from the EU law perspective alone, no conclusive view can be made as to the possible application of certain exceptions of or limitations to the copyright protection to uses of information for REACH purposes, as it is largely dependent on the applicable national law. The applicable national law is in fact the law where the protection is claimed. It is also important to stress that some aspects of copyright may extend beyond the EU/EEA area (notably when works are published on the internet).

In summary, registrants may be entitled to use the content of a published article in a different form, as long as the appropriate national copyright and/or data protection law(s) have been previously checked and respected. In case of uncertainty, it is recommended to seek legal advice from a national lawyer specialised in the copyright field.

14 Directive 2001/29/EC of the European Parliament and of the Council of 22 May 2001 on the harmonisation of certain aspects of copyright and related rights in the information society, OJ L 167, 22.6.2001, p. 10.

**Determining ownership: origin of the data**

Data (full study reports) usually belong to (1) companies, (2) industry associations, (3) consortia, or (4) official bodies:

1. Companies: When companies carry out studies themselves or commission them, they then normally have full ownership rights on the studies, including the right to grant access to that data. Within a group of companies, the data may be held by one single legal entity within the group and will not necessarily be disclosed to other companies of the same group without a specific agreement. Indeed only data owners who are part of the same SIEF are bound by the provisions of Article 30. Data owners who are outside the SIEF are not obliged to share data under REACH.

A study can be considered as available within the SIEF if access to the full study report may be obtained by every potential registrant through requesting it from other SIEF participants (either on the basis of an agreement in line with Article 30(1) or through an ECHA decision under Article 30(3)). This presupposes that the study is either directly owned by any of the SIEF participants or in case the study owner is outside the SIEF, a SIEF participant is nonetheless allowed to share the study with other SIEF participants, especially if that study has already been submitted to ECHA.

2. Industry associations: In certain cases, trade associations commission studies and hold data on behalf of their members. The issue here is to determine the owner(s) of the data, i.e. the Association, its members, or the members of a specific "interest group" within the association. This will usually require reviewing the by-laws of the Association and/or documents constituting the interest groups, for example. These documents may also determine the rights of companies that decide to leave the association or the group.

3. Consortia: Companies within a consortium may decide to share existing data or generate new data. Ownership of the data will normally be determined by the rules of the consortium contract or in separate arrangements when the study is shared or commissioned. Normally, the rights to the data are granted to those contributing to the costs of the data. As mentioned above, in some cases, the consortium agreement limits the rights of the consortium members to use the data they share or generate, so that they may not enjoy "ownership" rights to that data.

4. Official bodies: Studies are also generated by government agencies, research institutes, universities or international organizations and are also copyright protected. Ownership normally lies with the government, university or the international organization. Right to refer to the data will have to be requested from the body in question. Importantly, it is not because the study summary or full study report is published by these official bodies that it can be freely used for registration purposes. In some cases it may be copyrighted or belong to another party holding full ownership rights to that study.

**How and when can the data and costs be shared?**

SIEF participants are free to organise their cost sharing.

Several compensation formulae are described in this guidance document as starting points (see section 5). Also, the parties must organise the physical transfer of the data (RSS, or letter of access) among themselves.

When potential registrants include manufacturers and importers of substances in different tonnage bands, different registration deadlines will apply. In such cases, agreement on data and cost sharing between potential registrants may be reached before the first registration deadline. The data sharing compensation must therefore be clearly justified and agreed by all SIEF members so that they are fair, transparent and non discriminatory. Actual payment of the share of the cost is required (at the time of registration, unless otherwise agreed among potential registrants).

NB: In summary, under Step 8, potential registrants organise among themselves the actual exchange of data and compensation thereof, so that each potential registrant is entitled to register on time ahead of his required registration deadline and is/has properly compensated for the data he has/is provided/(with), to have access to the information he needs to complete his registration, potential registrants are only required to pay for studies which they need in accordance with their tonnage bands.

#### 3.3.3.9 Step 9: Joint submission of data

All existing relevant and available information gathered when preparing a joint registration dossier has always to be documented by the lead registrant in the technical dossier. For substances manufactured or imported in quantities of 10 tonnes (or more) per year per registrant he must also document it in the chemical safety report (CSR). At least all the information required under Article 10(a) for the technical dossier and under Article 10(b) for the chemical safety report (CSR) needs to be documented in the specified reporting formats (Annex I of the REACH Regulation).

The lead registrant will also have to request confidential treatment of data (Art 10(a)(xi), if appropriate.

The provisions of Article 10(a) must be complied with by all registrants in a joint submission.

### 3.3.4 CLASSIFICATION AND LABELLING

Agreement on classification and labelling is one of the two objectives of a SIEF. Registrants are required to provide the classification and labelling of the substance in the registration dossier as described in Annex VI, Section 4 as part of the technical dossier (Article 10(1)(iv)).

The CLP Regulation stipulates that notifiers and registrants shall make every effort to come to an agreed entry to be included in the Classification & Labelling Inventory where notification results in different entries for the same substance. This provision (Article 41 of CLP) includes ex-post agreements after notification has already been done, but is not necessarily an agreement prior to notification which is based on discussions (and data sharing) in a SIEF. Further details are included in section 5.3 of Data Submission Manual on "How to Prepare and Submit a Classification and Labelling Notification Using IUCLID", available at http://www.echa.eu/web/guest/support/dossier-submission-tools/reach-it/notification-to-the-cl-inventory.

It is recommended that early in the SIEF process potential registrants exchange information on the classification and labelling that they individually apply. It can be reasonably anticipated that if there is no difference in classification and labelling between participants, this is a good indication that data can be shared.

If there are differences in classification and labelling, SIEF participants can then investigate whether such differences stem from different data information (intrinsic properties) underlying the individual classifications, or from different characteristics of the substances as further explained in the two examples below.

**Examples**

1. Manufacturer A classifies his substance for a given health hazard on the basis of a study which is not available to manufacturer B. Manufacturer B does not classify for the same health hazard due to lack of adequate and reliable data and other information.

Discussion: manufacturer B should request, in accordance with the provisions of Article 30(1), the missing data from manufacturer A and both A and B should therefore consider applying the same classification.

2. Both manufacturers A and B have adequate and reliable studies on a given hazard. The study on the substance from manufacturer A suggests classification. Another study on the substance which is available to manufacturer B suggests no classification. However this is due to the fact that the substances manufactured by manufacturer A and B have a different hazard profile because of differences linked to the production process (e.g. impurities, isomers).

Discussion: the classification differs due to different impurity profiles while both studies are sound. The possibility of sharing data between manufacturers A and B for the respective hazards does not have a reasonable basis.

Prospective registrants of the same SIEF are required to agree with each other on classification and labelling. This does not necessarily mean that the classification and labelling is the same for all manufacturers and importers of the same substance. The same substance may be manufactured through different processes, leading to different impurity profiles, see also section 1.1.7.2 of the Guidance on the Application of the CLP Criteria available at: http://www.echa.eu/web/guest/regulations/clp/classification. The same situation may also occur when different raw materials are used. In these cases, however, data sharing may still be possible.

**Can data be shared when classification and labelling differ?**

The obligation to share data applies to registrants of the same substance that are in the same SIEF. Differences in classification and labelling are not a justification for non-sharing of information. Indeed, the SIEF participants may agree that different classification and labelling may apply to the same substance, for instance if the difference is attributed to a well identified impurity, for which the relevant hazardous properties are known. Consequently and if appropriately justified, the joint registration dossier submitted by the lead registrant can contain more than one classification and labelling.

NB: Members of the SIEF can also disagree with the lead registrant on the classification and labelling of the substance (for reason other than differences in the impurities profile, different interpretation of test results) (pursuant to Article 11(3)(c)). In such a case, REACH allows the SIEF member(s) concerned to opt out from the joint submission and to submit a separate C&L. However a joint registration dossier can also have different C&L without the need to opt-out and they are not necessarily an obstacle to data sharing.

However, it must be noted that different classification and labelling may have an impact on the risk assessment and the possibility of sharing the Chemical Safety Assessment may become questionable. More information and helpful material on C&L and CLP Regulation is available on the ECHA website at http://www.echa.eu/web/guest/regulations.

### 3.3.5 DATA SHARING: INDIVIDUAL ROUTE (OPT-OUT)

Registrants must comply with their REACH obligations by proceeding as per Article 30 of the REACH Regulation (i.e. data sharing). Registrants who opt-out must still participate in the joint submission.

NB: Registrants are allowed to opt-out for certain or all given endpoints but must remain member of the joint submission.

Hence the steps described below only apply for the endpoints for which registrants can justify application of one of the three criteria under Article 11(3).

- Step 1 Individual gathering and inventory of available information
- Step 2 Individual consideration of information requirements
- Step 3 Sharing of available data, if needed
- Step 4 Joint submission of data – Opt Out

Steps 1 to 3 are the same as those described above in the "collective route" except that they will be conducted individually. They are only summarized below.

#### 3.3.5.1 Step 1 - Individual gathering and inventory of available information

Step 1 requires the potential registrant to assemble and document all the information on the substance that he has available in-house on the substance's; (1) intrinsic properties (irrespective of tonnage), (2) uses, exposure and (3) risk management measures, and to perform a literature search.

#### 3.3.5.2 Step 2 - Individual consideration of information requirements

Step 2 requires each potential registrant to identify precisely what are the information requirements for the substance he intends to register, considering in particular the tonnage band that is relevant to him. In considering their information requirements, potential registrants may consider the possible application of data waivers, for instance on the basis of uses/exposure pattern.

#### 3.3.5.3 Step 3 - Sharing of available data

The potential registrant still has data sharing obligations on the studies he owns.

Before the study is made available to the requesting participant(s), an agreement has to be reached on the cost of sharing the requested information according to the following procedure:

- The owner of the study is obliged to provide proof of its cost to the participant(s) requesting it within one month of the request.
- The cost of sharing the information has to be determined in a fair, transparent and non-discriminatory way (see section 5).
- In case no agreement can be reached, the cost will be shared equally.

Following settlement on cost sharing, unless otherwise agreed, the owner must give permission to refer to the full study report within 2 weeks of receipt of payment.

Please refer to section 3.3.3.8 for guidance on the status of data to be shared, including legitimate possession.

#### 3.3.5.4 Step 4 - Joint submission of data

Joint submission of data is described in section 6 below. Being part of joint submission object is compulsory. The "individual route" can be used only in cases where sharing data with data holders takes place or when companies have justified reasons to opt-out from the joint submission of data (for detailed information see section 6.3).

### 3.3.6 DATA SHARING WITH DATA HOLDERS

Data holders should receive a financial compensation for the data they share with potential registrants. As data holders have no obligation to register the substance, they do not have "a share" in the registration of the substance and therefore are not involved in the preparation of the joint registration dossier. Likewise, they are not required to pay any cost linked to the preparation of the dossier or related to the organisation of the data-sharing among SIEF members.

NB: Nevertheless, in order to facilitate the process data holders willing to share relevant information should make themselves known as soon as possible. Once involved in data sharing discussions they should respond in a timely manner to requests for data and well in advance to the registration deadlines.

### 3.3.7 ADDITIONAL REGISTRANT(S) JOINING THE EXISTING (JOINT) SUBMISSION(S)

If a joint registration dossier already exists some of the steps described above may be omitted (e.g. steps 3.3.3.6 and 3.3.3.7). The potential registrant must then contact the existing (lead) registrant(s) and negotiate on the conditions of joining the joint submission dossier that has already been submitted by the lead registrant on behalf of the other assenting registrants. The potential and the previous registrant(s) (or their representative(s)) must make every effort to agree on the sharing of the information and of its costs in a fair, transparent and non-discriminatory manner. However, if the potential registrant does not agree on the choice of information for certain endpoints (e.g. he may have some studies of his own), he may decide to opt-out for these particular endpoints, but still must be part of the joint submission. For more details on the conditions of the opt-out, please consult Chapter 6.3 of this guidance.

## 3.4 DATA SHARING DISPUTES WITHIN A SIEF

Article 30 of the REACH Regulation sets out the rules applicable to data sharing disputes within a SIEF and covers disputes resulting from disagreement on who shall conduct a new test and disputes resulting from disagreement on the principle and/or the conditions of sharing existing vertebrate studies.

Provision on data sharing and data sharing disputes also apply, as an outcome of evaluation processes (Article 53 of REACH) when new studies need to be performed.

### 3.4.1 DATA SHARING DISPUTES ACCORDING TO ARTICLE 30(2)

In case a study (whether or not involving vertebrate animals) is needed for registration (i.e. it is one listed in Annexes VII and VIII) and is not available within the SIEF, a new test will need to be conducted in order to complete the dossier. Consequently, the SIEF members need to agree on who will conduct the missing study. However despite all their efforts, they may still not find an agreement.

In accordance with Article 30(2) of the REACH Regulation where SIEF participants cannot agree, ECHA should specify which registrant shall perform the test.

All participants who require the study must contribute to the costs for the elaboration of the study by a share corresponding to the number of participating potential registrants. Within three weeks of payment, each SIEF participant has the right to receive a copy of the full study report.

Where no agreement on who shall conduct the new test can be reached among SIEF members, one of the potential registrants can inform ECHA by using a web-form available on the ECHA website at: https://comments.echa.europa.eu/comments_cms/article302.aspx, and by providing the information listed below (the template is provided with the web-form):

- The (company) names of the potential registrants that have tried to reach an agreement;
- The (company) names of the potential registrants supporting the claim that a test is needed;
- The (company) names of the potential registrants volunteering to perform the test.

Based on the information provided, ECHA will select the registrant who will perform the study 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 potential registrants.

Once they have performed the study, the registrant must provide the full study report to those potential registrants who require the test and have paid a share corresponding to the number of participating registrants, within 2 weeks of the payment.

NB: This procedure only applies in case of disagreement on who shall perform necessary testing and not in case of disagreement on the need to conduct the given study. Therefore submitting the web-form cannot result in imposing a specific new test on other potential registrants disagreeing on the content of the joint submission dossier. ECHA will not assess the reason for the disagreement or whether the testing is required or justified.

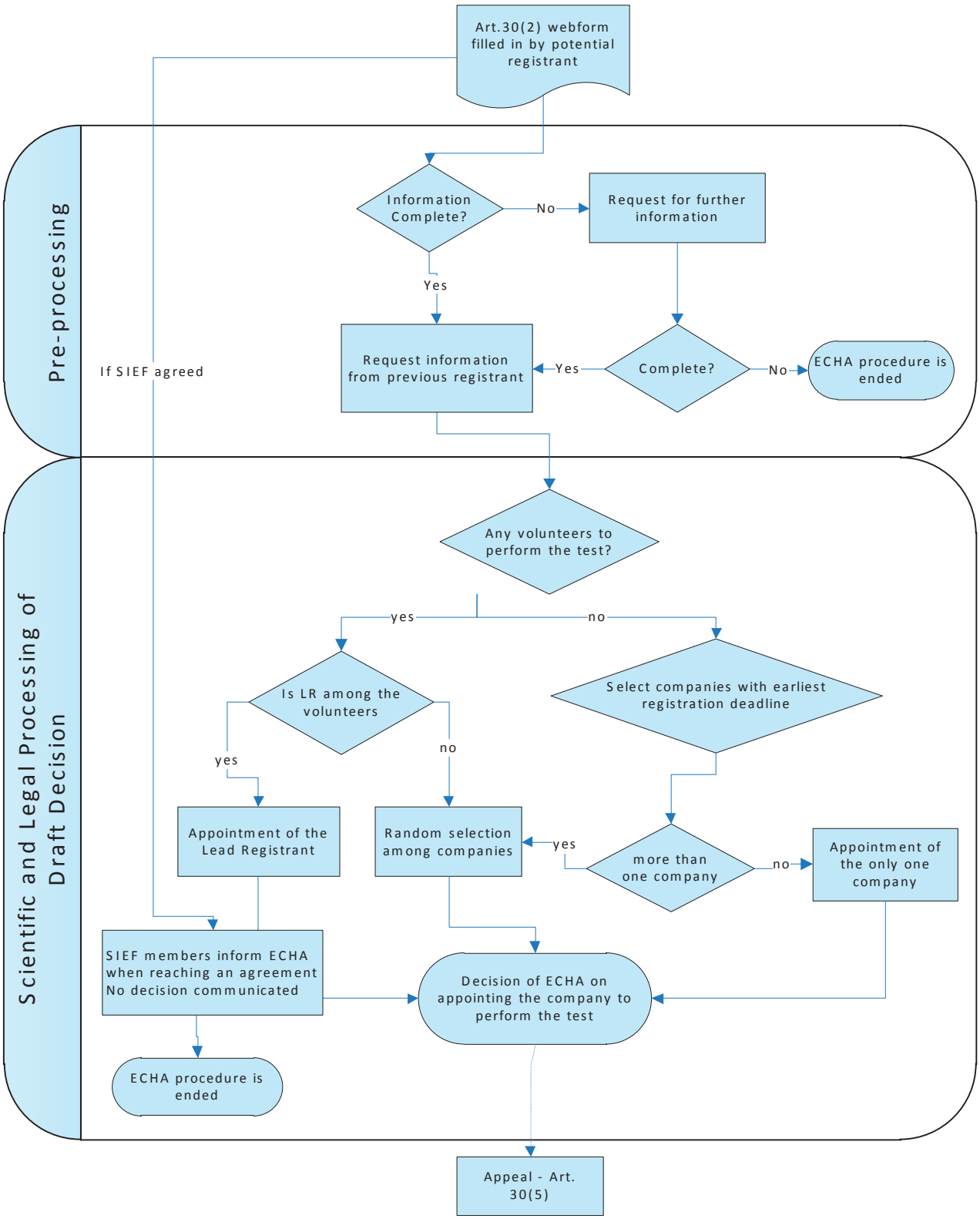



Figure 6: Article 30(2) procedure

Furthermore, ECHA encourages parties to continue to make every effort to reach an agreement on who will perform the study before it designates a SIEF participant. Should an agreement be reached before that decision, the potential registrant who made the claim on the web-form shall inform ECHA as soon as possible.

NB: The potential registrant(s) must obtain a decision from ECHA designating a potential registrant **BEFORE** submitting the registration.

For more details, please consult the 'Questions and Answers on data sharing and related disputes' on the ECHA website at http://www.echa.eu/web/guest/regulations/reach/substance-registration/substance-information-exchange-fora.

### 3.4.2 DATA SHARING DISPUTES ACCORDING TO ARTICLE 30(3)

SIEF participants have an obligation to "*make every effort in reaching an agreement in a fair, transparent and non-discriminatory way*". A SIEF participant making every effort to reach an agreement on the sharing of the data contained in a dossier already submitted can contact ECHA, using a web-form available on the ECHA website, if he considers that another SIEF participant or an existing registrant has not made every effort to share the data. ECHA may decide to give permission to refer to data to parties that have fulfilled their primary obligation to make every effort in reaching an agreement.

#### 3.4.2.1 Data Sharing Disputes according to Article 30(3) before the joint registration has been submitted

In case a SIEF member has requested a vertebrate animal study to be shared as per Article 30(1), during the preparation of the joint registration dossier, and, within one month of receiving the request, the owner of the study refuses to provide the proof of the costs of that study or the study itself, a data sharing dispute according to Article 30(3) may arise. A dispute may also arise on the conditions of the sharing[15].

The potential registrant(s) seeking to inform ECHA about a case related to vertebrate animal data, can contact ECHA using the webform available on the ECHA website at https://comments.echa.europa.eu/comments_cms/article303.aspx.

In principle, the dispute may affect several SIEF participants simultaneously. The SIEF concerned may possibly be represented by one of them, provided that they can all demonstrate that they have made, individually or collectively, every effort to share the requested data.

In practice this procedure only applies to data sharing disputes regarding studies involving vertebrate animals. In case the data sharing dispute also concerns studies not involving vertebrate animals, Article 30(4) requires the potential registrant(s) to proceed with registration as if no relevant study were available in the SIEF. Consequently the potential registrant(s) will have to perform individually such studies, prior to submitting a complete registration dossier.

The potential registrant(s) will have to specify on the web-form the vertebrate animal studies they requested from the data owner. Accordingly, the potential registrant(s) will need to provide ECHA with all the **documentary evidence** demonstrating the efforts that **all parties** have made in order to reach an agreement under fair, transparent and non-discriminatory conditions.

This includes not only the arguments of the requesting potential registrant(s), but also the arguments of the owner of the data. The documentary evidence consists of:

- correspondence requesting the conditions for data sharing;
- correspondence from the owner describing the conditions for the sharing of the data;

15 Further practical information is provided in the Q&A document on "Data sharing and related disputes" available on the ECHA website at: http://www.echa.eu/web/guest/regulations/reach/substance-registration/substance-information-exchange-fora.

- correspondence challenging the conditions imposed by the owner of the data;
- any further justification of, or modification of, the conditions provided by the owner of the data;
- correspondence challenging these justifications that the other participants would consider unfair, non transparent or discriminatory.

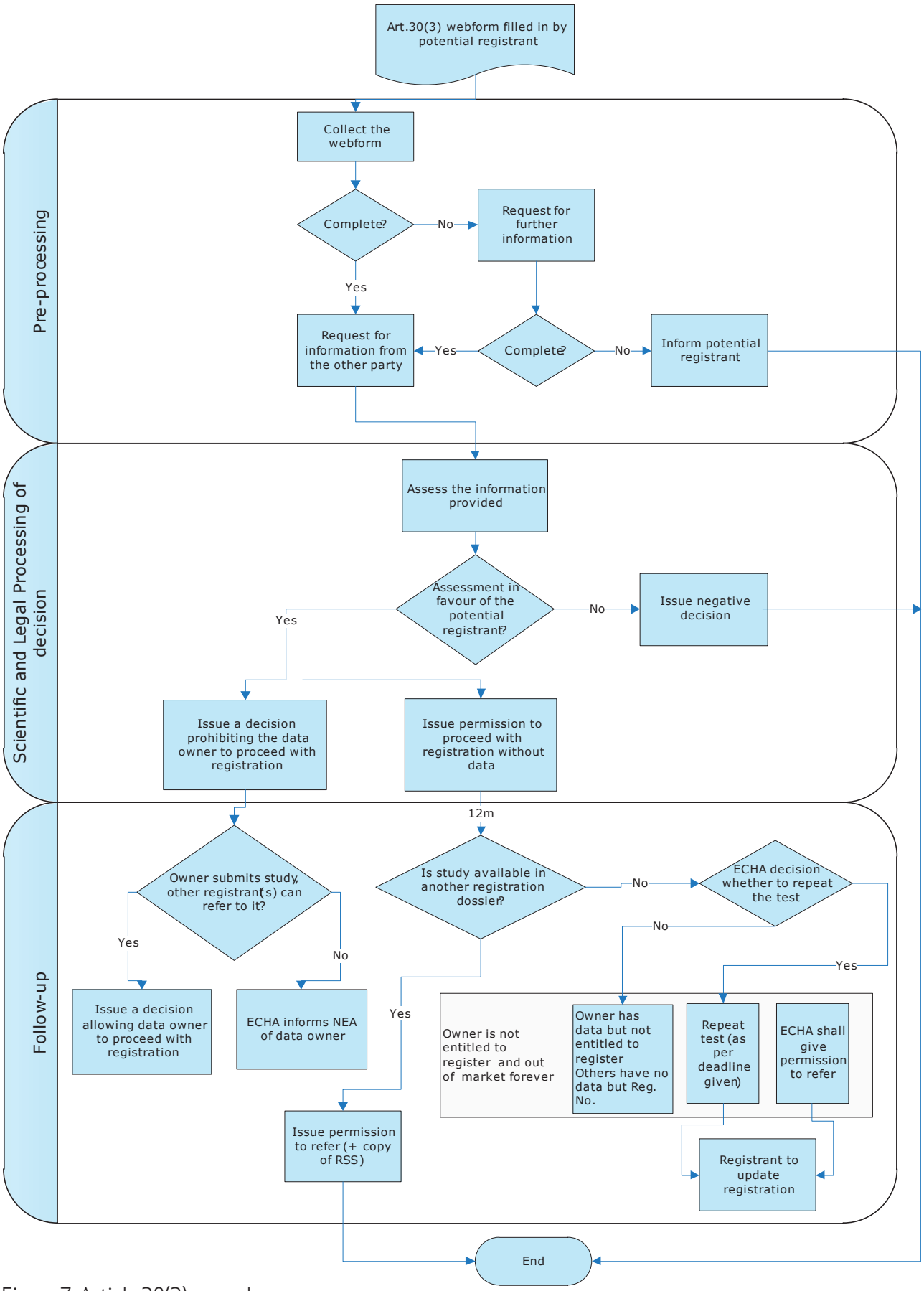



Figure 7: Article 30(3) procedure.

To allow ECHA to make an informed and balanced assessment of the efforts of the SIEF participants requires the potential registrant to provide ECHA with any copies of letters and other documents sent to, or received from, the data owner. ECHA always ensures that such requests are handled in a balanced way, taking into account the interests of both the owner of the data and the other SIEF member(s).

The decision to grant permission to proceed without fulfilling the relevant information requirements will be taken following the receipt of all information. If the data owner does not provide the requested information within the deadline set, ECHA will conduct its assessment and take a decision only on the basis of the available information that was provided by the other potential registrant(s).

Where the data owner has not made every effort to reach an agreement, ECHA will provide the potential registrant(s) with a permission to proceed with registration without fulfilling the relevant information requirement.

Pursuant to Article 30(3) of the REACH Regulation, the owner of the vertebrate animal study will not be able to proceed with his registration until he provides the information to the other SIEF participant(s). As a consequence the defaulting data owner may not be entitled to manufacture or import the substance after the registration deadline applicable to him.

NB: Consequently, for the purposes of registration, the potential registrant(s) must obtain a decision from ECHA granting permission to proceed **BEFORE** submitting the registration without an otherwise required study.

The procedure set out in Article 30(3) of the REACH regulation is only a default mechanism in case of absence of agreement on the sharing of a study involving testing on vertebrate animals. It shall therefore be only initiated as a last resort, after all the possible arguments have been exhausted and the negotiations have eventually failed.

The REACH Regulation provides for ECHA to request a study to be repeated. Even if the registrant(s) are allowed to submit the dossier without the disputed study, the parties shall continue their efforts to reach an agreement on the sharing even after the registration dossier has been submitted.

The appraisal of the facts in the context of a data sharing dispute may result in the determination that the owner of a study has breached their obligation to make every effort to reach an agreement on sharing the study. According to article 30(6) of the REACH Regulation, the owner of a study in breach of this obligation may also be subject to sanctioning to be imposed by the enforcement authorities of the Member State where he is established.

For more details, please consult the document 'Questions and Answers on data sharing and related disputes' available at http://www.echa.eu/web/guest/regulations/reach/substance-registration/substance-information-exchange-fora.

#### 3.4.2.2 Data Sharing Disputes according to Article 30(3) after the joint registration has been submitted

Within the SIEF, a data sharing dispute may arise between existing registrants and subsequent potential registrants. For instance, potential registrants with lower tonnage and therefore later submission deadlines may seek to share the content of a registration already submitted by registrants subject to earlier deadlines. Also, a dispute may arise in the case where the previous registrants (or their representative, in principle the lead registrant) have not replied to several requests for sharing the data in the joint submission, including

by registered mail. A dispute may also arise on the conditions of the sharing, e.g. a case where the previous registrants (or their representative) have only requested the payment of a generic fee for the data contained in the joint registration dossier, without providing detailed information on the costs.

In accordance with the objectives of REACH, the data sharing obligations also apply in the case of studies contained in a registration dossier already submitted. It is the responsibility of all parties (the potential registrant and the previous registrant(s) or their representative) to make every effort to reach an agreement on the sharing of the data and of its costs under fair, transparent and non-discriminatory conditions. Accordingly, Article 30(3) of the REACH Regulation also addresses disputes on the sharing of existing studies involving vertebrate animals contained in a registration that has already been submitted. Such a dispute may relate to more than one individual study involving vertebrate animals and may concern the total set of data contained in the joint submission.

However, in the case of a dispute relating to studies not involving vertebrate animals, Article 30(4) of the REACH Regulation applies requiring the potential registrant(s) to proceed with registration as if no relevant study were available in the SIEF. Consequently the potential registrant(s) will have to perform individually such studies, prior to submitting the registration dossier.

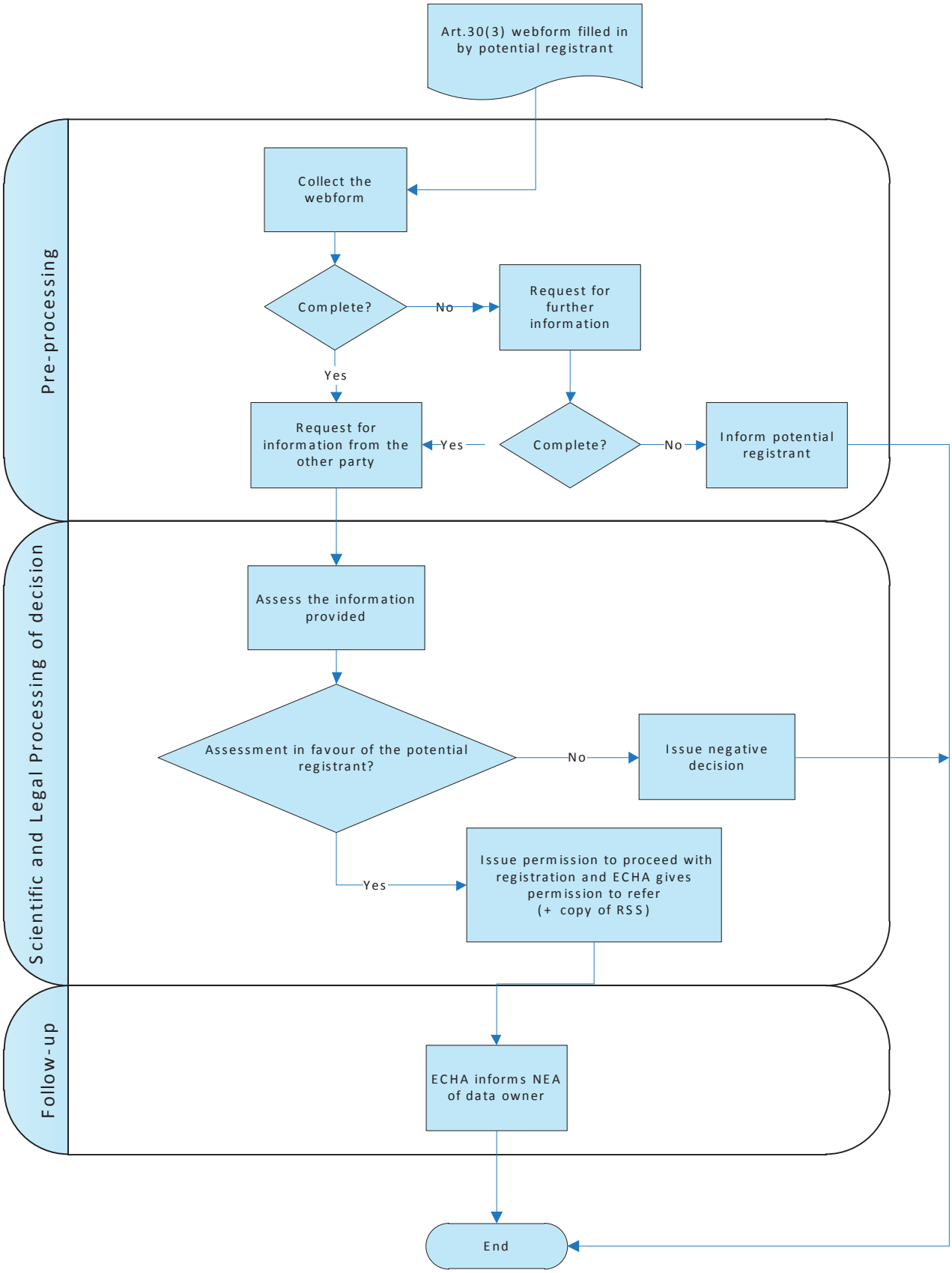



Figure 8: Article 30(3) procedure.

In practice, the potential registrant making every effort to share the data concerning studies involving vertebrate animals contained in the registration (joint submission) dossier can contact ECHA, using a web-form available on the ECHA website at https://comments.echa.europa.eu/comments_cms/article303.aspx.

The potential registrant would have to specify the vertebrate animal studies they had requested from the previous registrant(s) (or their representative).

Additionally, the potential registrant needs to provide ECHA with all the **documentary evidence** demonstrating the efforts that **all parties** have made in order to reach an agreement under fair, transparent and non-discriminatory conditions.

ECHA will take its decision, after assessing whether all parties have met their obligations to make every effort to reach an agreement on the sharing of the data. ECHA will also ensure that such requests are handled in a balanced way, respecting the interests of all parties (the owners of data, the previous registrant(s), the lead registrant and the potential registrant(s)).

If the previous registrant(s) do not provide the requested information within the deadline set, ECHA will conduct its assessment only on the basis of the available information that has been provided by the potential registrant.

This procedure only applies to studies involving vertebrate animals and contained in the registration dossier already submitted. Where the previous registrant(s) (or their representative(s)) have not made every effort to reach an agreement on sharing the costs in a fair, transparent and non-discriminatory way, ECHA will provide the potential registrant with permission to refer to the set of vertebrate animal studies. ECHA will also provide a copy of the relevant (robust) study summaries. The studies concerned are those contained in the joint registration dossier and covered by the negotiations between the potential registrant and the previous registrant(s) (or their representative).

The previous registrant(s) will have a claim on the subsequent registrant(s) for an equal share of the cost, provided that they make the full study report available to the potential registrant(s). The claim will be enforceable in the national courts.

NB: The potential registrant must obtain a decision from ECHA granting the permission to refer to the information **BEFORE** submitting their registration.

The potential registrant will have to indicate in the registration dossier header the reason for not providing the study and to refer to the permission granted by ECHA. Consequently, if the potential registrant is not provided with the information relating to the joint submission (name and security token) by the previous registrant, the potential registrant will not benefit from the reduced fee applicable to a joint submission. Indeed, in the case of an individual submission, Articles 3(3) and 4(3) of the REACH Fee Regulation (EC) No 340/2008 prescribe a specific registration fee. However, if the previous registrants are declared in default of sharing the data already submitted, the potential registrant may have the possibility to claim compensation from the previous registrants before a relevant national court for the extra registration cost incurred.

Other SIEF members involved in disputes in the same SIEF may wish to make a similar claim. They would need to demonstrate that they have individually or collectively made every effort to reach an agreement with the previous registrant(s) (or their representative). Before a claim is made, ECHA recommends that they jointly submit a final notice to the owner of the study to reach an agreement under fair, transparent and non-discriminatory conditions.

The assessment performed by ECHA in the context of a data sharing dispute between a potential registrant and other registrant(s), may result in the determination that the previous registrant(s) have breached their obligation to make every effort to reach an agreement on sharing the data. According to Article 30(6), the parties in breach of this obligation may also be subject to sanctioning imposed by the enforcement authorities of the Member State where they are established. These financial penalties would concern the failure to meet their obligation in relation not only to vertebrate animal studies but also to studies not involving testing on vertebrate animals.

For more details, please consult the 'Questions and Answers on data sharing and related disputes', on the ECHA website.

### 3.4.3 HOW TO CONDUCT NEGOTIATIONS IN ORDER TO PREVENT DATA SHARING DISPUTES

Article 30 imposes on SIEF participants the obligation to make every effort to reach an agreement on the sharing of data in a fair, transparent and non discriminatory way.

In order to prevent disputes on the sharing of information, potential registrants and SIEF participants requesting information should specify the exact nature of the information requested from the data owner.

Making every effort to reach an agreement requires all parties to find alternative solutions when negotiations are blocked and to be open and proactive in their communications with the other party. In case a party receives an unsatisfactory reply, which it considers unclear, invalid or incomplete, it is the responsibility of the recipient to challenge that reply, by addressing constructive, clear and precise questions or arguments to the sender.

Each party must give reasonable time to the other to provide appropriate answers to its questions.

All the arguments must be made between the parties involved. The argumentation challenging the position of each party shall be communicated between those two parties directly and not only with ECHA.

Any cost sharing mechanism has to be justified and must not be discriminatory between registrants joining the joint submission at different times. Some examples are provided in Chapter 5 of the present guidance document.

Previous registrants must ensure that (new) potential registrants are only required to share in the costs of information that they are required to submit to satisfy their own registration requirements.

If existing registrants rely on read-across to develop different dossiers covering several categories of substances, they cannot impose on a subsequent registrant a requirement to purchase data used for the registration of categories of substances that the latter does not manufacture or import, unless they justify the relevance of the data concerned.

If requested, the previous registrant(s) need(s) to provide scientific justifications of the approach followed in the selection of data that is necessary to demonstrate the safe use of the substance, especially if the potential registrants have asked without success to be involved in the selection of that data. In that respect, guidance on the selection of all available and relevant data can be found in the Practical Guide on "How to report data waiving" available on the ECHA website at http://www.echa.eu/documents/10162/17250/pg_report_data_waiving_en.pdf.

Article 30(3) only refers to requests regarding vertebrate animal data. If the potential registrants need to complete their dossier with studies not involving vertebrate animals and have not been successful in reaching an agreement with the data owner (or his representative(s)) on the sharing of this data, Article 30(4) of the REACH Regulation applies. It provides that the potential registrant "*shall proceed with registration as if no relevant study was available in the SIEF*". This requires that, in order to fulfil their registration requirements relating to the registration tonnage band, these studies are performed individually or together with other potential registrants facing similar difficulties.

Nevertheless, Article 30(6) of the REACH Regulation also requires the national competent authorities to penalise the owner of the studies who has refused to provide them.

### 3.4.4 THE AVAILABLE LEGAL REMEDIES AGAINST ECHA DECISIONS

Appeals can be made against certain ECHA decisions, listed in Article 91 of the REACH Regulation, before the Board of Appeal of ECHA.

In accordance with Article 30(5) of the REACH Regulation, the potential registrant or the previous registrants may appeal to the Board of Appeal of ECHA against a decision taken by ECHA under Article 30(3) or 30(2). According to Article 92(2) of the REACH regulation an appeal can also be lodged by a party having a direct and individual concern in the decision. In both cases, the appeal has to be lodged within three months of the notification of the decision to the person concerned or of the day on which the decision became known to the appellant. Additionally an appeal fee must be paid pursuant to Article 10(1) of the Fee Regulation[16] .

## 3.5 DATA SHARING EXAMPLES

### EXAMPLE 1: "Base case"

1. *Parties involved*: Companies A, B, C and D manufacture substance X in the EU, each at above 100 tons per year. Substance X is a mono-constituent substance listed in EINECS. Companies A, B, C and D each pre-registered substance X in July and August 2008. Company B indicated its readiness to serve as a facilitator.

2. Company F (downstream user) then indicated to ECHA that it holds data on substance X.

3. *Pre-SIEF*: Company B calls a meeting of Companies A, B, C and D and proposes to verify whether substance X, as manufactured by each company, is the same under the criteria of the Guidance for identification and naming of substances by exchanging information on substance identification under a proposed confidentiality agreement. All agree.

4. *SIEF Formation*: The equivalence of the four substances X having been confirmed, the SIEF is formed and the four pre-registrants enter into a consortium agreement to agree on the classification and labelling of substance X, share data on the substance, using an expert as "trustee" and to register substance X jointly (but with separate CSR and guidance on safe use). Cost sharing is to be on an equal sharing basis using average replacement costs, as requested from Labs L, M and N.

5. *Data Sharing*: The expert collects all data available among potential registrants, compares it with the data needs at the above 100 tonnage threshold, proposes key studies and identifies data gaps. Consortium members request the expert to conduct a literature search, to request data from Company F and to prepare the necessary robust study summaries and other study summaries. Company F has data on an end point that is missing to the potential registrants and they agree to pay Company F 80% of the costs of that data, each company paying 20%. After the literature search, some data required under Annex IX is still missing and the

16 Commission Reg. (EC) No 340/2008 of 16 April 2008 on the fees and charges payable to the European Chemicals Agency.

potential registrants agree that Company B will conduct the necessary testing (once approved) and will share the study on an equal sharing basis. The potential registrants also agree that Company B will be the "lead registrant".

6. *Joint submission of data*: Company B registers substance X as the lead registrant with a testing proposal for the data missing under Annex IX, on 15 October 2012. Companies A, C and D separately register substance X in November 2012 with a reference to the data submitted and test proposal made on their behalf by Company B.

7. *Registration*: Companies A, B, C and D each receive a registration number.

**EXAMPLE 2: Different tonnage bands**

1. *Parties Involved*: Companies A, B, C and D manufacture and/or import or intend to import substance X in/into the EU. Companies A, B and C manufacture substance X at between 10 and 100 tonnes per year and Company D intends to import substance X into the EU at above 1 tonne in the years to come.

2. *Pre-Registration*: Companies A, B, C and D all pre-registered substance X. Companies A, B and C indicated they will register before 1 June 2013 and Company D before 1 June 2018. Company A indicated its readiness to serve as a facilitator.

3. *Pre-SIEF*: Company A calls a meeting of experts from companies A, B, C and D to receive and review under a confidentiality agreement the information from the other companies necessary to confirm sameness of the substance as produced by each company and classification and labelling information.

4. *SIEF Formation*: The company experts confirm the substances all are the same under the criteria laid down in the Guidance for identification and naming of substances under REACH, but different impurities may justify the differences in classification and labelling. Company A and B propose to enter into a consortium agreement on an equal share basis using replacement costs; company C proposes proportionality according to volume on the basis of historic costs. Company D declares it will not participate in any consortium at this stage. Companies A, B and C decide to appoint a Third Party to act as trustee and to propose a consortium agreement with a "fair" data sharing mechanism; they communicate production volume information to the trustee. They also agree that data collection and review will be made by the three company experts and that Company B will be the lead registrant.

5. *Data Sharing*: The trustee proposes to share costs using a ratio that partly takes into account actual tonnage thresholds (see Annex 1). The experts collect all data available among pre-registrants and compare available data with the data needs at the different tonnage thresholds; they propose key studies and identify data gaps. After the collection exercise and a literature search, the experts conclude that all data required up to 10 tonnes is available but that data is missing in the 10-100 tonnage range. Companies A and B agree to make a test proposal for Company B to conduct testing for the missing data and share the costs on an equal share basis.

6. *Joint submission of data*: Company B registers substance X on 1 May 2013. As the lead registrant, he submits a joint submission on behalf of companies A, C and D. Companies A and C register on 2 May. In 2015, Company D reaches the 1 tonne threshold and would like to register as soon as possible. Company D only needs to submit available data and physico-chemical property information (as its tonnage does not meet Annex III criteria), but still needs to agree with the other parties to be allowed to refer to the lead registrant's submission for that data and classification and labelling. Company D receives the Letter of Access after acceptance of the cost sharing model agreed in the SIEF agreement.

7. *Registration*: Companies A, B, C and D each receives a registration number.

**EXAMPLE 3: Joining an existing joint submission**

1. *Parties involved*: in Company A, a manufacturer of an EINECS-listed substance, has experienced a rapid growth in the yearly volumes manufactured in the period 2008-2011, which brings its three-year average quantities to more than 1 tonne in 2012.

2. *Pre-registration*: Company A pre-registers the substance in June 2012.

3. *Participation in the SIEF*: Company A is granted access to the contact details of Companies B, C and D, which had also submitted a pre-registration for that EC-listed substance. A SIEF has already been formed by Companies B, C and D. Company B has already registered the substance as the lead registrant and has submitted a joint submission on behalf of Companies C & D, while Companies C and D are expected to register in the following months. Based on preliminary contacts and on other information published on ECHA's website, Companies A, B, C and D agreed that the substance is "the same" for data sharing and registration purposes and started cooperating within the SIEF.

4. *Data-sharing*: Company A decides to accept all data already submitted in the framework of the joint submission and joins the existing agreement/ consortium among Companies B, C and D and contributes to the costs in accordance with the data-sharing and cost sharing arrangements in place among Companies B, C and D. Its contribution to the cost is restricted to the information required for the 1 100 tonnage band.

5. *Joint submission of data*: the lead registrant gives the name of the joint submission and a valid token[17] to company A, who joins the joint submission and identifies his contact person. If the joining of company A has an impact on the lead dossier, (e.g. new knowledge on the risk) then the lead registrant needs to update the lead registration dossier to represent the entire joint submission.

6. *Registration*: Company A registers the substance before 31 May 2018 and receives a registration number.

**EXAMPLE 4: Data holder and read across for phase-in substances**

1. *Parties involved*: Companies A and B manufacture phase-in substance X and intend to continue to do so in quantities above 1 tonne per year. Third Party C holds data on a substance Y, for which the conditions for read-across with substance X are met.

2. *Pre-registration and publication of the list*: Companies A and B pre-registered the substance, which was included in the list of pre-registered substances.

3. *Submission of information by data holders*: Third Party C submits information on the substance Y and indicates that the information on this substance is relevant for read-across with substance X. This information and Third Party C's identity is made visible to potential registrants A and B through REACH IT.

4. *SIEF formation*: Companies A and B establish that the substance is the same and that data-sharing is possible for all end-points.

17 For more information and practical details, please refer to REACT-IT Industry User Manual on "Joint Submission" available on the ECHA website at http://www.echa.eu/web/guest/joint-submission-lead.

5. *Data Sharing*: a literature search shows that little data exists and is available on substance X. Companies A and B share the data in their possession and contact data holder C to have access to the information on substance Y to fill the data gaps. This information is also being used by potential registrants in a SIEF for substance Y, for which a share of the cost incurred for its generation has been paid. After having verified that this information can also be used to fill the data gaps for substance X, Companies A and B agree to pay the agreed percentage of the costs incurred for the generation of that data to data holder C.

6. *Joint submission of data*: Company B registers substance X as lead registrant and company A registers later as a member of the joint submission.

7. *Registration*: Companies A and B receive a registration number.

# 4. The "inquiry process": data-sharing rules for non-phase-in substances and phase-in substances not pre-registered

The REACH Regulation provides for separate data sharing provisions for (1) phase-in substances that have been pre-registered (see section 3 of this Guidance) and (2) non-phase-in substances, and/or phase-in substances that have not been pre-registered.

Articles 26 and 27 of REACH regulate the process for initiating the data sharing process related to this second category of substances (section 2.3 of this Guidance).

## 4.1 THE PURPOSE OF THE INQUIRY PROCESS

The purpose of the inquiry process is twofold:

1. to determine whether the same substance has previously been registered/inquired about;

2. to facilitate contact between the previous registrant(s) and the potential registrant(s) and/or other potential registrants, if any. Data sharing is organised between previous registrant(s) and/or potential registrants in order to comply with their joint submission obligation and to submit a joint registration dossier (see Figure 8).

## 4.2 IS IT OBLIGATORY TO FOLLOW THE INQUIRY PROCESS?

Yes. Prior to Registration, a potential registrant of a non-phase-in substance and/or a potential registrant of a phase-in substance who has not pre-registered that substance must inquire with ECHA whether a registration has already been submitted for that substance.

Potential registrants only have to inquire about substances they intend to register. Substances which are no longer manufactured or imported do not have to be inquired about.

NB: New studies involving vertebrate animals should not be conducted before the outcome of the inquiry process is known. There is no deadline to submit an inquiry to ECHA.

NB: The outcome of the inquiry (regarding substance identification and/or data availability) sent by ECHA needs to be reflected in the registration dossier. Additionally ECHA requests the registrant to insert his inquiry number in the registration dossier.

For more details about the inquiry process see Figure 9 below.

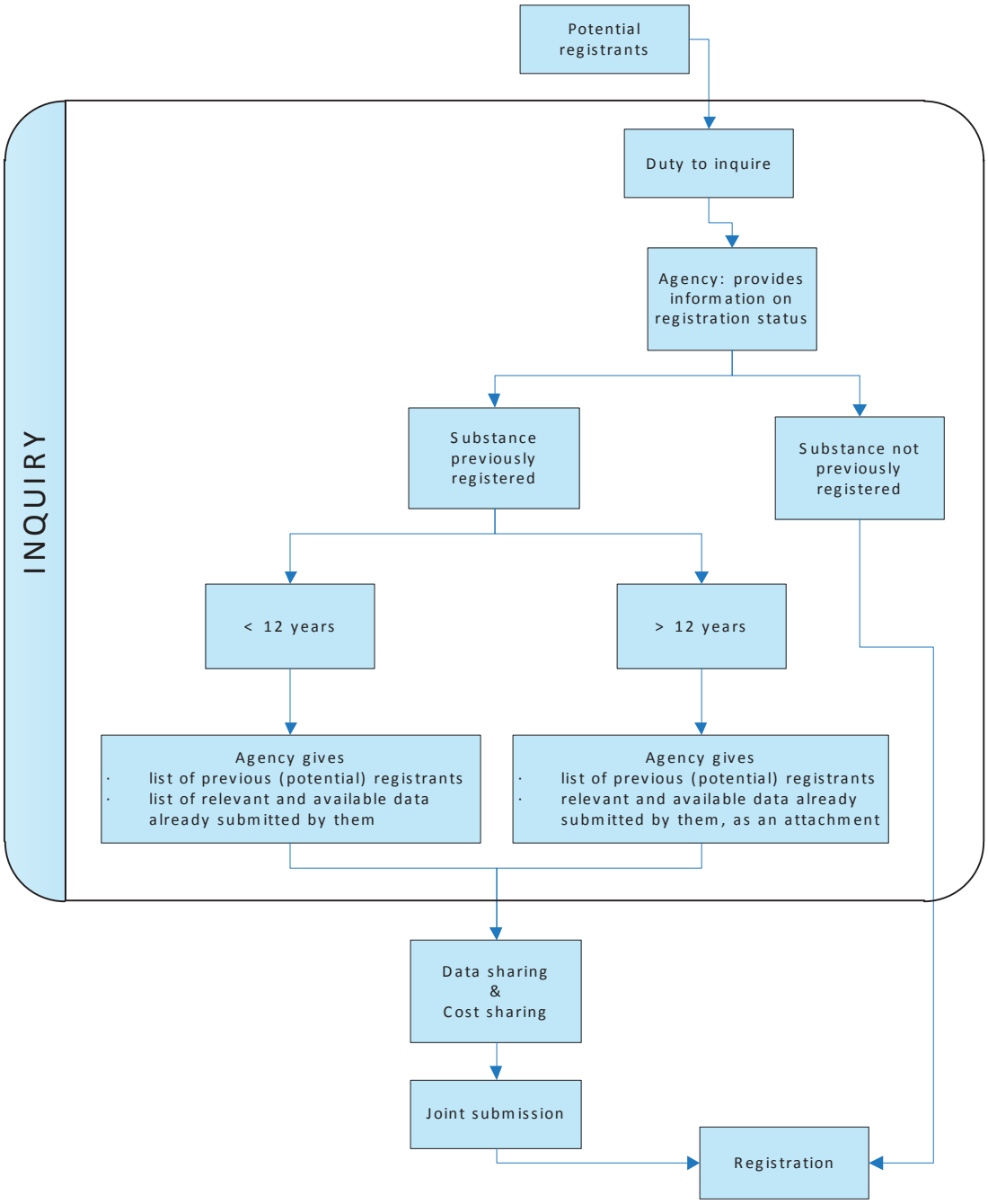



Figure 9: General overview of the inquiry process

## 4.3 WHO MUST INQUIRE?

Any existing legal entity which needs to register a non-phase-in substance or a phase-in substance that was not pre-registered and which has no possibility to late pre-register the substance according to Article 28(6). These legal entities may include:

- manufacturers and importers of non-phase-in substances or phase-in substances that have not been pre-registered on their own or in preparations in quantities of 1 tonne or more per year, including intermediates;

- Producers and importers of articles containing substances (non-phase-in substances or phase-in substances that have not been pre-registered) intended to be released under normal or reasonably foreseeable conditions of use and present in those articles in quantities of 1 tonne or more per year;

- "Only Representatives" of non-EU manufacturers who import substance(s) (non-phase-in substances or phase-in substances that have not been pre-registered) in quantities of 1 tonne or more per year.

For more details on late pre-registration of phase-in substances, please consult section 3.1 of the present guidance and the Guidance on Registration available at http://www.echa.eu/web/guest/guidance-documents/guidance-mainly-for-industry-use.

NB: Non-EU manufacturers cannot inquire about/ register directly the substances that are exported to the EU. Non EU manufacturers may decide that either their registration is done by importers or, alternatively, they may be represented by a natural or legal person located in the EU territory, their "Only Representative".

Similarly, an Only Representative (OR) can represent several non-EU manufacturers of a substance. In that case, an OR needs to submit one inquiry per substance per non-EU manufacturer. For more information on the role and duties of the Only Representative please consult the Guidance on Registration.

## 4.4 SUBSTANCES SUBJECT TO THE INQUIRY PROCESS

According to Article 26 of the REACH Regulation, the inquiry process applies to non-phase-in substances and phase-in substances that were not pre-registered (see section 2.3 of this Guidance document).

Non-phase-in substances are substances that do not meet the definition of phase-in substances as provided in Article 3(20) of the REACH Regulation. They have therefore either not been placed on the market before 1 June 2008 or were listed on ELINCS (and considered as being registered according to Article 24).

Phase-in substances subject to the inquiry process are those that have not been pre-registered by a given legal entity. Potential registrants of these phase-in substances must stop manufacture or import and inquire with ECHA whether a registration has already been submitted for that substance. Subsequently they need to register before resuming manufacture or import.

## 4.5 INFORMATION TO BE SUBMITTED IN THE INQUIRY

As part of their inquiry, the potential registrant must submit the following information (Article 26(1)):

- the identity of the legal entity, as specified in Section 1 of Annex VI to REACH, with the exception of the use sites;

- the identity of the substance, as specified in Section 2 of Annex VI to REACH;

- their information requirements which would require new studies involving or not vertebrate animals to be carried out by him.

For more details, please consult the dedicated web page(s) on the ECHA website.

## 4.6 OUTCOMES OF THE INQUIRY PROCESS

As part of the inquiry process the substance identification, as provided by the inquirer/potential registrant, is verified by ECHA.

If an inquiry is accepted, the inquirer will receive an inquiry number and information on other inquirers (potential registrants) and previous registrants of the same substance as well as details of the requested (robust) study summaries, as appropriate. More details are available in the "Questions and Answers on Inquiry" document and on the dedicated web page on the ECHA web site.

### 4.6.1 THE "12-YEAR RULE"

The period of data compensation under REACH is 12 years. This applies to (robust) study summaries submitted in the framework of a registration (in accordance with Article 25(3)).

Article 24(1) provides that the12-year rule also applies to data submitted in the framework of a notification made in accordance with Directive 67/548/EEC. Article 24(1) provides that a notification in accordance with that Directive is regarded as a registration to which ECHA has assigned a registration number.

Under the legal framework of Directive 67/548/EEC, data submitted as part of a notification could be used further for the purposes of a subsequent notification after 10 years from the date of submission of the data. Pursuant to Article 24(1) of the REACH Regulation, this period was extended by 2 years to a period of 12 years from the original date of submission to the competent authorities (e.g. data submitted in the framework of a notification on 1 June 2001 will continue to be protected under REACH until 1 June 2013).

NB: The date of submission of a specific test result to the competent authority is not necessarily the same as the original notification date. Indeed the test may have been submitted afterwards (e.g. after a tonnage band increase up to the next level of testing) and hence the 12-year period may not yet have expired[18] .

Consequently, according to Article 25(3) (and the criteria described), data which was submitted for the first time in the context of the previous legislation more than 12 years previously, will not be subject to compensation.

The data requested by the inquirer in his inquiry dossier will therefore fall into one of the three categories described in the following sub-sections.

18 Please be aware that data submitted in IUCLID 4 or SNIF format do not contain all the required information and the registrant needs to carefully check and complete the IUCLID 5 file. More details are provided in the Data Submission Manual on "How to Complete a Technical Dossier for Registrations and PPORD Notifications" available at: http://www.echa.eu/reachit/dsm_en.asp.

### 4.6.2 THE SUBSTANCE HAS ALREADY BEEN REGISTERED AND THE RELEVANT INFORMATION HAS BEEN SUBMITTED LESS THAN 12 YEARS EARLIER

ECHA will invite the inquirer to make every effort to reach an agreement for the sharing of the information and provide him without delay with:

- the name(s) and address(es) of the previous registrant(s) and of other inquirers (i.e. potential registrants);
- the list of relevant and available data already submitted by them.

At the same time, ECHA will inform the previous registrant(s)/inquirer(s) (i.e. potential registrants) of the name and address of the inquirer/potential registrant. At that stage, no proactive actions are expected from the previous registrant(s). The inquirer will need to contact them to join the joint submission.

### 4.6.3 THE SUBSTANCE HAS ALREADY BEEN REGISTERED AND THE RELEVANT INFORMATION HAS BEEN SUBMITTED MORE THAN 12 YEARS EARLIER

ECHA will provide the inquirer without delay with:

- the name(s) and address(es) of the previous registrant(s) / inquirers (i.e. potential registrants);
- the relevant and available data already submitted by them.

ECHA will also provide the available information as an annex to the inquiry communication letter. If the inquirer decides to use the information submitted more than 12 years earlier, the data is not subject to any financial compensation to the previous registrant(s).

In parallel ECHA will also inform the previous registrant(s)/inquirer(s) (i.e. potential registrants) of the contact details of the inquirer/potential registrant. At that stage, no proactive actions are expected from the previous registrant(s). The inquirer will need to contact them to join the joint submission.

NB: It is always the responsibility of the inquirer to assess the quality and relevance of the information received by ECHA so that, as a registrant, he fulfils his registration obligations. When using study summaries submitted more than 12 years earlier (e.g. in a NONS notification), it may be that these study summaries are not of sufficient quality to meet the registration obligations under the REACH Regulation and the potential registrant may consider alternatives to ensure compliance of the registration dossier. Additionally the potential registrant is also advised to contact the previous registrant/ notifier to ensure full study summary is available.

A given endpoint may be covered by information submitted both more and less than 12 years previously (indicated in the inquiry communication). It is the responsibility of the potential registrant to consider which information is relevant to fulfil the information requirements in his registration dossier.

### 4.6.4 THE SUBSTANCE HAS NOT PREVIOUSLY BEEN REGISTERED OR IT HAS BEEN REGISTERED BUT THE REQUESTED INFORMATION IS NOT AVAILABLE

ECHA will in any case inform the inquirer without delay whether the name(s) and address(es) of the previous registrant(s)/ other inquirers are available. In parallel, where applicable, ECHA will also inform the previous registrant(s)/ inquirer(s) (i.e. potential registrant(s)) of the name and address of the contact details of the inquirer. At that stage, no proactive actions are expected from the previous registrant(s). The inquirer will need to contact them to join the joint submission.

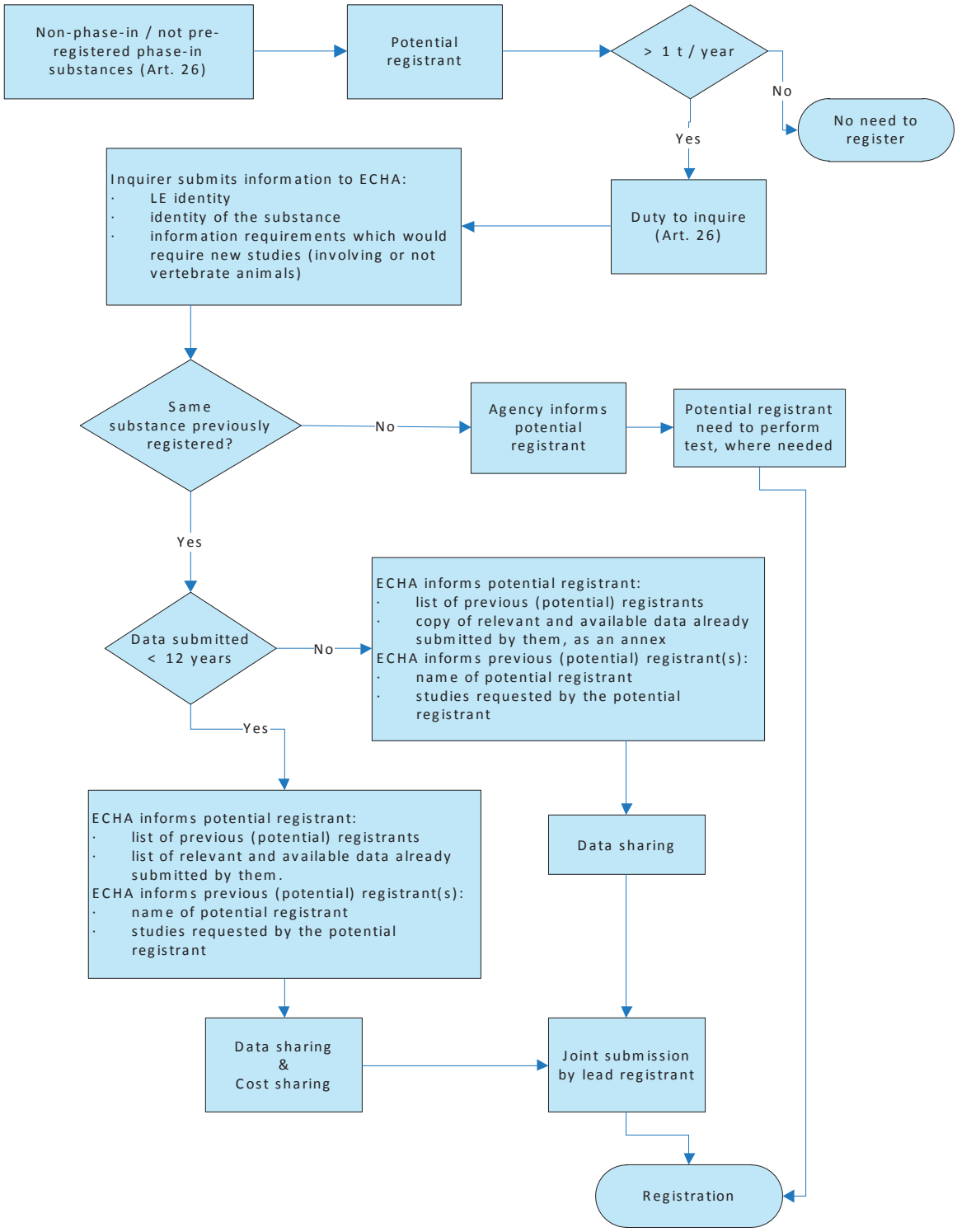



Figure 10: Detailed inquiry process followed by joint submission

## 4.7 DATA SHARING BETWEEN REGISTRANTS FOLLOWING AN INQUIRY

Data sharing is one of the key principles in the REACH Regulation. By sharing information on substances and submitting dossiers jointly, companies increase the efficiency of the registration system, reduce costs and avoid unnecessary testing on vertebrate animals.

Pursuant to Articles 11 or 19, multiple registrants of the same substance have an obligation to submit jointly information on their substance as described in Article 10(a) and (b). For this process, ECHA recommends following similar steps as for phase-in substances. Additionally the potential registrants need to identify, pursuant to Article 11(1), early in the process a lead registrant acting on behalf of the other assenting registrants (who will also create the Joint Submission Object in REACH-IT).

Potential registrants have an obligation to request from previous registrant(s)/ data holder(s)/ data owner(s), studies involving vertebrate animals, whereas they have the option to request the sharing of data not involving testing on vertebrate animals. In any case, if a study is requested, the data owner is obliged to share it, whether or not the study involves testing on vertebrate animals. In case the potential registrant(s) need to carry out tests required to satisfy their registration requirements, they need to make use of all available data (e.g. read across or validated (Q)SAR Models) in order to avoid testing on vertebrate animals.
In order to prepare the joint registration dossier potential registrants may follow the indicative steps described below.

- Step 1 Individual gathering and inventory of available information
- Step 2 Consideration of information requirements
- Step 3 Agreement on the form of cooperation and identification of a lead registrant
- Step 4 Identification of data gaps and collection of other available information
- Step 5 Negotiation on data and cost sharing and possible outcomes
- Step 6 Generation of new information/testing proposal
- Step 7 (Joint) Submission of data

### 4.7.1 STEP 1 - INDIVIDUAL GATHERING AND INVENTORY OF AVAILABLE INFORMATION

Potential registrants should first gather all existing available information on the substance they intend to register. This must include both data available "in-house", as well as from other sources, such as data in the public domain that can be identified through a literature search.

NB: Data gathering must be thorough, reliable and well documented as failure to collate all of the available information on a substance may lead to unnecessary testing with related resource implications.

The information to be gathered by each potential registrant must include all information relevant for the purposes of Registration, i.e.:

- Information on the intrinsic properties of the substance (physicochemical properties, mammalian toxicity, environmental toxicity, environmental fate, including chemical and biotic degradation). This information may come from *in vivo* or *in vitro* test results, non-testing data such as QSAR estimates, existing data on human effects, read-across from other substances, epidemiological data;

- Information on manufacture and uses: current and foreseen;

- Information on exposure: current and anticipated;

- Information on Risk Management Measures (RMM): already implemented or proposed.

This data gathering exercise is to be done irrespective of volume. Indeed, if the data requirements at Registration depend upon the volume manufactured or imported by each registrant, registrants must register all relevant and available data for a specific endpoint. Nevertheless, they have to share on request data they have available that correspond to a higher tonnage threshold.

NB: Step 1 requires each potential registrant to assemble and document all the information that he has available in-house on the substance, including information on the substance's: (1) intrinsic properties (irrespective of tonnage), (2) uses, exposure and risk management measures. It also requires him to perform a literature search.

It should be always considered that, except for the cases enumerated in Article 10(a) last paragraph, the registrant must be in legitimate possession or have permission to refer to the full study report summarised in a (robust) study summary which is to be submitted for the purpose of registration. For more details on the nature of data and right to refer to the data, please consult section 3.3.3.8 of this Guidance document.

### 4.7.2 STEP 2 - CONSIDERATION OF INFORMATION REQUIREMENTS

Step 2 is for potential registrants to identify precisely what the information requirements are for the substance that they intend to register, considering in particular the tonnage band that is relevant to them, the physical parameters of the substance (relevant for technical waiving of tests) and uses/exposure patterns (relevant for exposure-based waiving).

As described in more details in the Guidance on registration, Article 11 requires registrants to:

- provide all relevant and available physicochemical, toxicological and ecotoxicological information that is available to them, irrespective of his own tonnage band (this includes data from an individual or collective literature search);

- at the minimum, fulfil the standard information requirements as laid down in Column 1 of REACH Annexes VII to X for substances produced or imported in a certain tonnage band, subject to waiving possibilities, as described below.

In all such cases, the registrant should indicate clearly and justify each adaptation in the registration dossier. Indeed, for each of the REACH Annexes VII to X, Column 2 lists specific criteria (e.g. exposure or hazard characteristics), according to which the standard information requirements for individual endpoints may be adapted (i.e. modified both specifying possibilities for waiving, or specifying when additional information is needed).

In addition, registrants may adapt the required standard information set according to the general rules contained in Annex XI of the REACH Regulation which refer to situations where:

- testing does not appear scientifically necessary;
- testing is technically not possible;
- testing may be omitted based on exposure scenarios developed in the chemical safety report (CSR)

NB: Step 2 requires each potential registrant to identify precisely what their information requirements are, considering in particular the tonnage band that is relevant to him. In considering his information needs, a potential registrant may consider the possible application of data waivers, for instance on the bases of uses/exposure pattern.

### 4.7.3 STEP 3 - AGREEMENT ON THE FORM OF COOPERATION AND IDENTIFICATION OF A LEAD REGISTRANT

Before potential registrants start exchanging information on the data they have available, it is recommended that they first agree on the form of cooperation that best suits them and the main rules applicable to that cooperation, in terms of data and cost sharing.

Under the REACH Regulation the lead registrant is a mandatory role laid down in Article 11(1), defined as the 'one registrant acting with the agreement of the other assenting registrant(s)' and it is he who will first submit certain information described in Article 10.

REACH does not specify rules as to how the lead registrant should be selected. The lead registrant must act with the agreement of the other assenting registrants and submit the joint submission dossier, which contains information on the intrinsic properties of the substance. Lead registrants are encouraged to submit their registrations first i.e. prior to the members of the joint submission object (JSO).

NB: Step 3 requires potential registrants (and potentially data holders) to (virtually) meet, discuss and agree on the main elements of the gathering of information, identification of information needs, generation of missing information, and sharing of the costs related to all registration activities.

### 4.7.4 STEP 4 - IDENTIFICATION OF DATA GAPS AND COLLECTION OF OTHER AVAILABLE INFORMATION

Step 4 requires the potential registrant(s) to compare the information available from Step 1 and the data needed in the joint registration dossier as identified in Step 2. They will need to identify precisely the data gaps to be filled in before the registration dossiers can be submitted.

NB: The potential registrant(s) must liaise with the data owners to confirm the substance sameness, i.e. whether the existing studies are appropriate for their substance.

### 4.7.5 STEP 5 - NEGOTIATION ON DATA AND COST SHARING, AND POSSIBLE OUTCOMES

Once a request to share studies submitted less than 12 years previously has been made, REACH requires that both the potential and the previous registrant make every effort to:

- ensure an agreement on the sharing of the information requested by the potential registrant;

- ensure that the cost of sharing the information are determined in a fair, transparent and non-discriminatory way (see section 4.9).

As examples sharing of data could be considered as:

- not fair, if the data owner requests 100% of the cost of the study he paid where there are several other registrants and the cost could be shared by all;

- not transparent, if the data owner requests the payment of a generic fee for the data contained in the joint registration dossier, without providing detailed information on the costs of the individual studies.

- discriminatory, if the cost sharing model is applied differently for different potential registrants.

The lead registrant (or their representative) who acts on behalf of all potential registrants needs to provide clear justifications on the choice of studies to be used for each endpoint. Where an agreement is reached (in accordance with Article 27(4)) the previous registrant / data owner will make available to the potential registrant the agreed information. The data owner will also give the potential registrant permission to refer to the full study report.

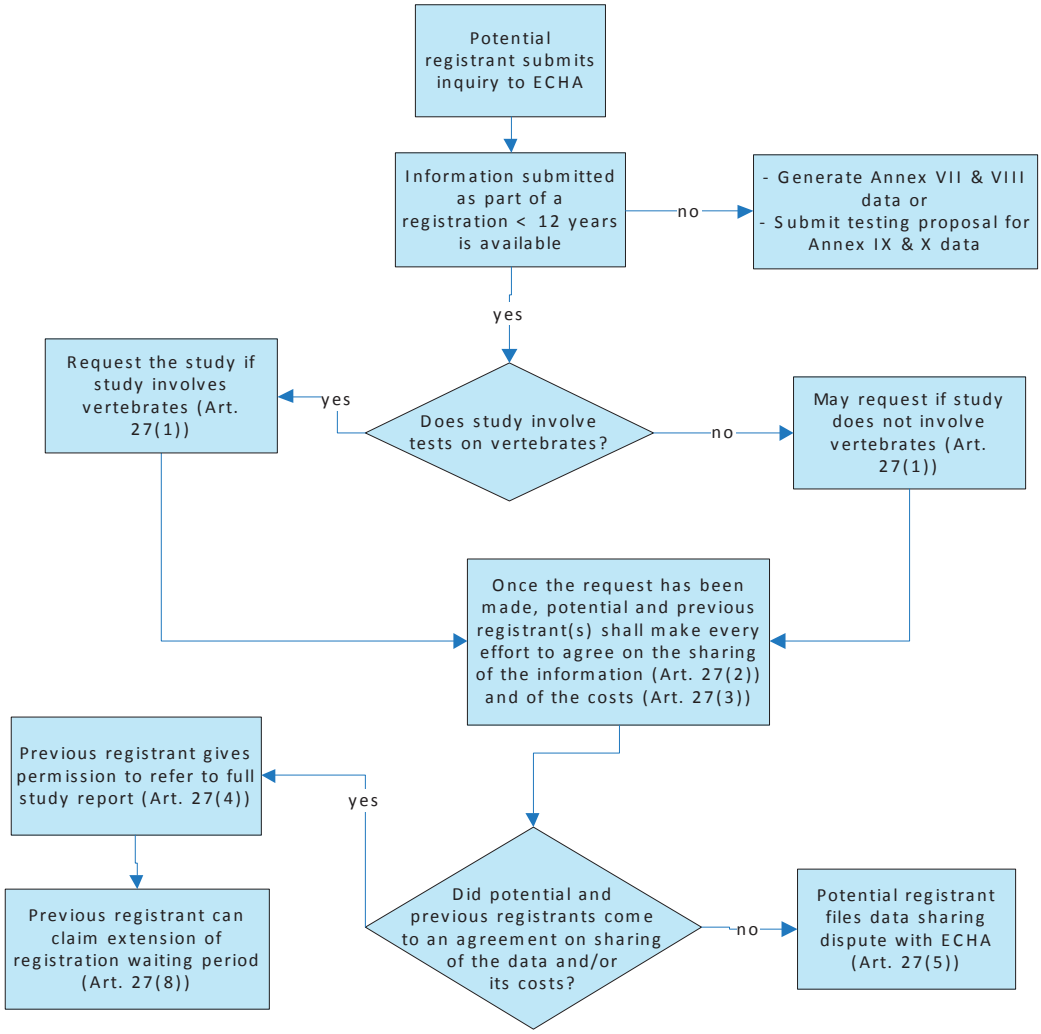



Figure 11: Data sharing for non-phase-in substances and phase-in substances not pre-registered

### 4.7.6 STEP 6 GENERATION OF NEW INFORMATION/TESTING PROPOSAL

In case data gaps are identified in Step 1, information on intrinsic properties of substances may be generated by using alternative sources for information other than *in vivo* testing, providing the conditions set out in Annex XI are met. The registrant(s) may use a variety of methods such as (Q)SARs ((Quantitative) Structure Activity Relationships), *in vitro* tests, weight of evidence approaches, and grouping approaches (including read-across).

When there is an information gap which cannot be filled by any of the non-testing methods, potential registrants have to take action depending on the missing data:

- in case a study as listed in Annexes VII and VIII (whether or not involving vertebrate animals) is needed for registration, and is not available within the SIEF, a new test will need to be conducted in order to complete the dossier. Consequently the potential registrants must **generate** new information and need to agree on who will conduct the missing study before submitting their joint registration dossier. For more details, please consult the Guidance on Information Requirements and Chemical Safety Assessment available at http://www.echa.eu/web/guest/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment;

- in case a study as listed in Annexes IX and X (whether or not involving vertebrate animals) is needed for registration, and is not available within the SIEF, the potential registrants must agree on and **prepare a testing proposal** to be submitted as part of the joint registration dossier for ECHA's consideration. Additionally potential registrants have to implement and/or recommend to downstream users interim risk management measures while awaiting the outcome of ECHA's decision (as per Article 40) regarding the testing proposal.

NB: The obligation to prepare a testing proposal also applies when the lead registrant, as a result of the application of the rules in column 2 of the Annexes, proposes (higher tier) tests of Annexes IX or X as an alternative to the standard requirements of Annexes VII and VIII.

Step 6 requires potential registrants to generate new data (when Annexes VII or VIII apply) or to prepare a testing proposal (when Annexes IX and X apply). Testing on vertebrate animals should always be the last resort.

### 4.7.7 STEP 7 (JOINT) SUBMISSION OF DATA

All existing relevant and available information gathered when preparing the joint registration dossier has to be documented by the lead registrant in both the technical dossier and, for substances manufactured or imported in quantities of 10 tonnes (or more) per year per registrant, in the chemical safety report (CSR).

Once the potential registrants (or their lead registrant) have completed the steps above, they can organise the actual sharing of the available data and communicate the costs involved. This will most probably be done in stages, when a new potential registrant contacts the lead registrant, but also when newly developed data become available.

However ECHA recommends that the lead registrant, or any person preparing the joint dossier, communicate at regular intervals so as to inform the existing/ potential registrants of the progress/ update of the registration dossier. The lead registrant should use the information contained in the ECHA communication sent to them when new inquirer(s) contact ECHA and keep record of all contact details.

As described in Articles 3(3) and 4(3) of the REACH Fee Regulation (EC) No 340/2008, a specific reduced registration fee will be levied by ECHA for the joint submission of the registration dossier.

Potential registrant(s)/inquirer(s) being part of the Joint Submission Object, may still opt-out (as per the criteria of Article 11(3)) for some endpoints where they own data. For more details on the criteria for opting out, please consult section 6.3 of this Guidance document.

### 4.7.8 ADDITIONAL REGISTRANT(S) JOINING AN EXISTING (JOINT) SUBMISSION(S)

If a joint registration dossier already exists some steps may be omitted (e.g. steps 4.7.3, 4.7.4, 4.7.6). The potential registrant must contact the previous (lead) registrant(s) (contained in the inquiry communication letter sent by ECHA) and negotiate on the conditions of joining the joint submission dossier that has already been submitted by the lead registrant on behalf of the other assenting registrants. The potential and the previous registrants (or their representative(s)) must make every effort to agree on the sharing of the information and of its costs in a fair, transparent and non-discriminatory manner. However, if the potential registrant does not agree on the choice of information for certain endpoints (e.g. he may have some studies), he may decide to opt-out for these particular endpoints, but still must be part of the joint submission. For more details on the conditions of the opt-out, please consult Chapter 6.3 of this guidance.

NB: In case inquirers have proceeded and registered individually, they need to update their registration dossier: first they need to identify a lead registrant who will create the Joint Submission Object (JSO), and then agree on the content of the joint submission dossier. Consequently, the existing registrants must update their dossier as part of the joint submission registration (as lead registrant and members).

According to Article 24(2), if a notification under Directive 67/548/EEC exists, the notifier will only need to submit a REACH compliant dossier (according to Articles 10 and 12) if the quantity of the notified substance reaches the next tonnage threshold.

If a SIEF exists for the substance that the inquirer inquired about, the inquirer will be put in contact with the SIEF members, but will not be officially part of the SIEF (which is the result of an "active" pre-registration). However this does not prevent all registrants of the same substance from sharing data and submitting their registration jointly (and all be part of the same JSO).

## 4.8 REGISTRATION WAITING PERIOD IN ACCORDANCE WITH ARTICLE 27(8)

Article 21 provides that "*a registrant may start or continue the manufacture or import of a substance or production or import of an article, if there is no indication to the contrary from the Agency in accordance with Article 20(2) within three weeks after the submission date, without prejudice to Article 27(8)*". In this context manufacturing or importing of a substance can only start after the end of the three weeks period after submitting a registration (except when a longer period has been requested in line with Article 27(8)).

In accordance with Article 27(8), a previous registrant can request that the registration waiting period (in accordance with Article 21(1)) be extended by a period of four months for the new registrant. The request can be submitted to ECHA, when a previous registrant and a potential registrant have agreed on the sharing of information submitted less than 12 years previously or, following a data sharing dispute, when ECHA grants the potential registrant a permission to refer to the data (see section 4.9 below).

The potential registrant will be informed accordingly by ECHA and, upon receipt of confirmation of his successful registration, will have to wait for an extra period of 4 months before being entitled to lawfully manufacture or import the substance in or into the European market. In case of a tonnage band increase, the manufacturer or importer needs to submit an inquiry and inform ECHA of the additional information he would require to fulfil his registration requirements. However, in this case (i.e. after submission of an update of the registration dossier) the manufacture or import does not need to be suspended.

However, in the case of continuing the manufacture or import (e.g. after submission of an update of the registration dossier), the activities need not be suspended. Whenever an interruption of activities is necessary to await the end of an inquiry, the waiting period after registration must be respected before manufacturing or importing can resume.

ECHA will not assess the validity of the request of the previous registrant and will not check whether data sharing has occurred, and regarding which data, or whether data sharing has been successful. It is therefore the potential registrant's responsibility and liability to assess whether the request of the previous registrant can be considered as valid and applicable. Consequently the potential registrant is expected to document his assessment appropriately.

## 4.9 DATA SHARING DISPUTES AFTER AN INQUIRY

### 4.9.1 DATA SHARING DISPUTE ACCORDING TO ARTICLE 27(5)

Following the inquiry process and after the potential registrant has requested data as per Article 27(1), both the potential and the previous registrants must make every effort to reach an agreement on the sharing of the information and/or the costs (according to Article 27(2) and (3)).

However, where they fail to reach an agreement, according to Article 27(5) the potential registrant can inform ECHA of the failure to reach an agreement with the previous registrant(s) on the sharing of the data or of its costs, at the earliest one month after the original receipt from ECHA of the contact details of the previous registrant(s). The potential registrant shall also notify the previous registrant that they have informed ECHA.

The potential registrant can submit the information on the dispute to ECHA using a webform available on the ECHA website at: https://comments.echa.europa.eu/comments_cms/article275.aspx.

The potential registrant will receive from ECHA the permission to refer to the data, if the previous registrant has not met his obligation to make every effort to share the data and its costs in a fair, transparent and non-discriminatory way, although the potential registrant has made such efforts.

The documentary evidence provided to ECHA needs to include not only the arguments of the requesting potential registrant but also the arguments of the previous registrant. The required documentary evidence consists of:

- correspondence requesting the conditions for data sharing;
- correspondence from the previous registrant describing the conditions for the sharing of the data;
- correspondence challenging the conditions imposed by the previous registrant;
- any further justification of, or modification of, the conditions provided by the previous registrant.

Additionally the documentary evidence needs to demonstrate that:

- the potential registrant has made every effort to share the information and to agree on the sharing of the costs in a fair, transparent and non-discriminatory way;
- the potential registrant has notified the previous registrant(s) that ECHA will be informed of the failure to reach an agreement.

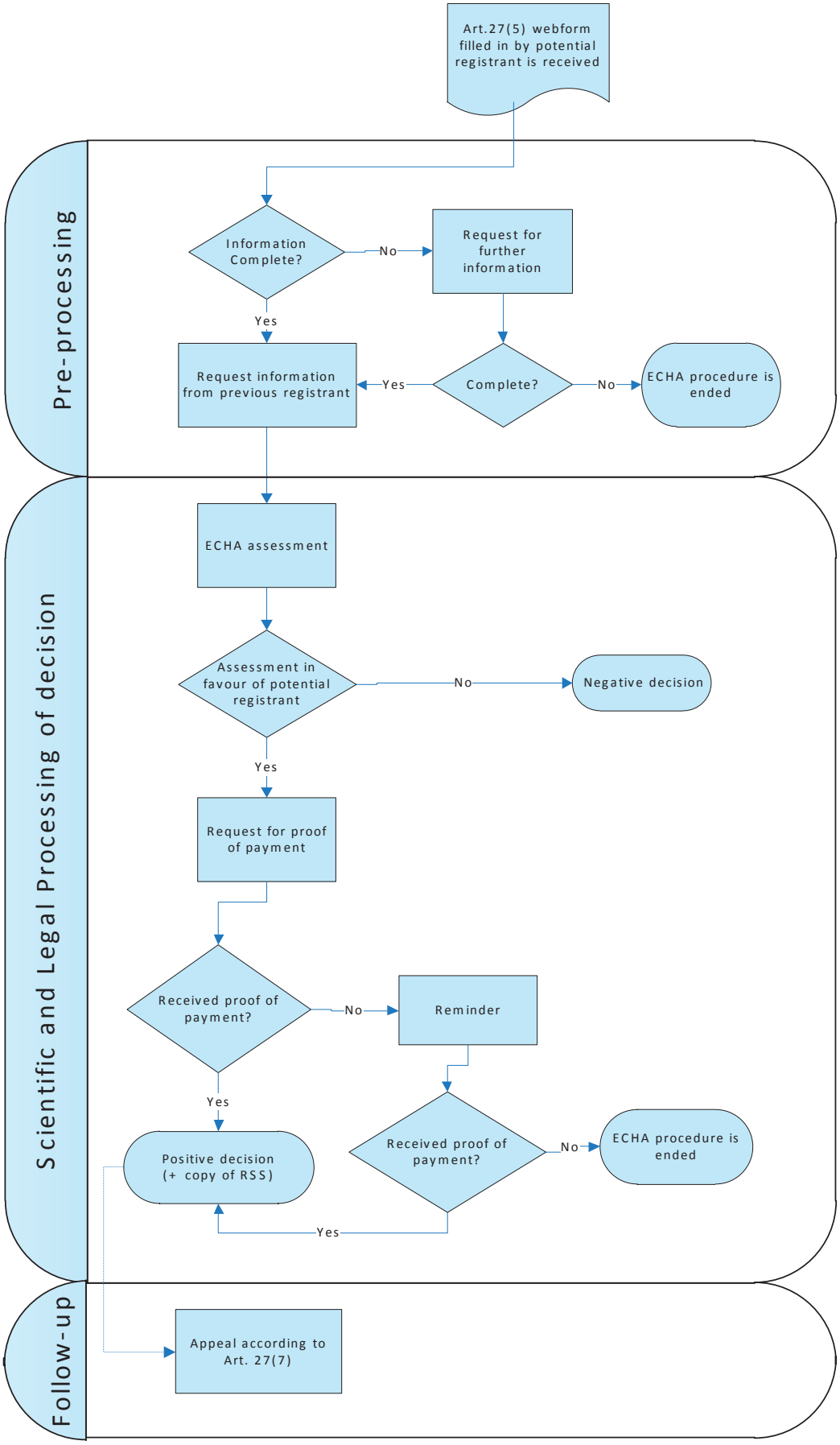



Figure 12: Data sharing dispute according to Article 27(5)

ECHA will always request the previous registrant(s) to provide evidence of the arguments and justifications they used during the negotiations with the potential registrant, if any. ECHA then performs an assessment of whether a party has breached its obligation to make every effort on the basis of the documentation provided by both parties especially in the case of no response to requests for data sharing.

As an outcome of the procedure implemented by ECHA, the potential registrant may receive from ECHA permission to refer to the data, if the previous registrant has not met his obligation to make every effort to share the data and its costs in a fair, transparent and non-discriminatory way, although the potential registrant has made such efforts. Where ECHA grants permission to the potential registrant to refer to the information, it will first ask the potential registrant to provide proof of payment of a share of the costs incurred by the previous registrant for generating the data. The proof of payment may take any appropriate form, including a bank statement or a receipt of a postal order. Upon receipt of this proof of payment, ECHA will provide a copy of the (robust) study summaries on the relevant endpoint(s) and grant the potential registrant a permission to refer to them.

**Compensation claim for data less than 12 years old**

The previous registrant has the right to be compensated for the use of his information by the potential registrant. Specifically, the previous registrant has the right to receive a "proportionate share" of the costs incurred in the development of the studies used by the potential registrant, or an "equal" share if it has made the full study report available to the potential registrant. Although ECHA may ask the potential registrant to provide evidence that he has made a payment to the previous registrant, it is not for ECHA to decide whether such a payment is adequate. In this regard, if the previous registrant considers that the amount paid by the potential registrant is insufficient, he may present his claim before a competent national court or, if so agreed by the parties, use an alternative dispute resolution mechanism.

### 4.9.2 HOW TO CONDUCT NEGOTIATIONS IN ORDER TO PREVENT DATA SHARING DISPUTES?

Article 27 requires both previous and potential registrants to make every effort to reach an agreement on the sharing of data in a fair, transparent and non discriminatory way.

In order to prevent a dispute on the sharing of the information, potential registrants requesting information should specify the exact nature of the information requested from the data owner.

Making every effort to reach an agreement requires all parties to find alternative solutions when negotiations are blocked and to be open and proactive in their communications with the other party. In case a party receives an unsatisfactory reply, which it considers unclear, invalid or incomplete, it is the responsibility of the recipient to challenge that reply, by addressing constructive, clear and precise questions or arguments to the sender.

Each party must give reasonable time to the other for providing appropriate answers to its requests. Previous registrants must ensure that potential registrants are only required to share in the costs of information that they are required to submit to satisfy their registration requirements. If requested, the previous registrant(s) need to provide scientific justifications for the approach followed in the selection of data that is necessary to demonstrate the safe use of the substance, especially if the potential registrants have asked without success to be involved in the selection of that data. In this respect, guidance on the selection of all available and relevant data can be found in the Practical Guide on "How to report data waiving"[19] .

19 In particular, section 2.1.3 «Availability of multiple pieces of information» in Practical Guide available at: http://www.echa.eu/en/web/guest/regulations/reach/evaluation.

All claims must be made between the parties involved. The argumentation challenging the position of each party shall be communicated between those two parties directly and not only with ECHA.

Any cost sharing mechanism has to be justified and must not be discriminatory between registrants joining the submission at the different times.

If existing registrants rely on read-across to develop different dossiers covering several categories of substances, they cannot impose on a subsequent registrant a requirement to purchase data used for the registration of categories of substances that he does not manufacture or import, unless they justify the relevance of the data concerned.

### 4.9.3 AVAILABLE LEGAL REMEDIES AGAINST ECHA DECISIONS

Certain ECHA decisions, listed in Article 91 of the REACH Regulation, can be appealed against before the Board of Appeal of ECHA.

In accordance with Article 27(7) of the REACH Regulation the potential registrant or the previous registrant(s) may lodge an appeal against a decision taken by ECHA, under Article 27(6) to the Board of Appeal of ECHA.

According to Article 92(2) the appeal has to be lodged within three months of the notification of the decision to the person concerned. An appeal can also be lodged by a person having a direct and individual concern in the decision. In that case, the appeal has to be lodged within three months of the day on which the decision became known to the appellant. An appeal fee must be paid pursuant to Article 10(1) of the Fee Regulation[20] .

## 4.10 DATA SHARING EXAMPLE

**Non-phase-in substances/Inquiry process**

1. *Parties involved*: Company A has planned to start manufacturing a non-phase-in substance listed in the ELINCS in 2011, with volumes being expected to exceed 1 tonne during the same calendar year. The same substance was already notified in accordance with Directive 67/548/EEC by Company B in 1995. Company B has also submitted further information as part of an update in 2000 due to an increase in tonnage produced.

2. *Inquiry process - Step 1*: Company A submits an inquiry to ECHA as per Article 26 before carrying out the testing necessary to meet the information requirements and submitting a registration. ECHA informs company A of the names and address of company B, which has now the status of registrant under REACH, and of the relevant study summaries already submitted by him. Company B is also informed of the name and address of company A. At the same time, ECHA provides company A with the study summaries notified more than 12 years previously that may be freely used by him, i.e. without the need to obtain a permission to refer from Company B.

3. Data sharing: Company A and Company B enters into discussion on how to share the "protected" information submitted by Company B. Following receipt of company B's contact details and a month of hard negotiations, agreement is still not reached on the sharing of information and Company A informs ECHA and company B of "failure to reach an agreement". ECHA starts the data sharing dispute procedure and also requests Company B to submit the evidence of the arguments and justifications they used during the negotiations with the Company A. ECHA then performs an assessment of the evidence provided to establish which party has made every effort to reach an agreement on sharing of the data and costs in a fair, transparent and non-discriminatory way.

20 Commission Reg.(EC) No 340/2008 of 16 April 2008 on the fees and charges payable to the European Chemicals Agency.

4. ECHA may decide that Company B has not made all the necessary efforts and grant Company A permission to refer to the (robust) study summary submitted by Company B. ECHA will also request proof of payment of a share of the costs from Company A. In this case, company A will have to decide unilaterally on how much to pay. When ECHA receives the proof of payment it will send the final decision to Company A together with a copy of the (robust) study summaries. Company B can decide to recover their costs and claim proportionate share of the cost incurred by it in a national court, if it considers that the share paid by Company A was not appropriate.

5. ECHA may decide that Company A has not made all the necessary efforts and does not grant Company A the permission to refer to the (robust) study summary submitted by Company B. Both companies will then be requested to continue making every effort in a fair, transparent and non-discriminatory way in order to reach an agreement and to fulfil their data sharing obligations.

# 5 Cost sharing

## 5.1 INTRODUCTION

As required under the REACH Regulation, parties sharing data must make "every effort to ensure that the costs of sharing the information are determined in a fair, transparent and non-discriminatory way" (Article 27(3) and 30(1)). This is particularly important in relation to small and medium sized enterprises.

Therefore agreement on cost sharing requires parties to agree on:

1. the reliability, relevance and adequacy of the data ("Data Quality")

2. the economic value of the data ("Data Valuation"), and

3. how the agreed value is shared among parties ("Cost Allocation and Compensation")

The elements discussed below are neither intended to be prescriptive nor mandatory. They should serve rather primarily as a checklist in order to ensure that all interested parties identify the relevant factors when organising a data quality review and related cost sharing activities.

NB: It is recommended that a data sharing agreement is reached prior to the disclosure of the available information by members of the joint submission.

In this section the aspects related to cost sharing of studies are illustrated. Additionally, it is important for the parties involved to consider all activities that may need to be carried out in the general context of data sharing and cost sharing/ allocation.

Aspects linked to the management of the SIEF, or of the preparation of the joint registration dossier (for non-phase-in substances), including verification of substance sameness, communication activities, the possible use of a trustee, the joint creation of the chemical safety report and possible further activities triggered by evaluation also create costs. All these costs may need to be shared among (potential) registrants in a similar way as those strictly related to study endpoints. The parties may need to ensure that all costs in the agreements between the parties involved are to be taken into account.

## 5.2 DATA QUALITY

### 5.2.1 RELIABILITY – RELEVANCE – ADEQUACY

A prerequisite for the valuation of existing studies is to establish their scientific quality.

In line with the OECD guidance, the process of determining the quality of existing data should take into consideration three aspects, namely adequacy, reliability and relevance of the available information, to describe a given study. These terms were defined by Klimisch *et al.* (1997):

- Reliability: relates to the inherent quality of a test report or publication relating to preferably standardized methodology and the way the experimental procedure and results are described to give evidence of the clarity and plausibility of the findings;

- Relevance: is the extent to which data and tests are appropriate for a particular hazard identification or risk characterisation;

- Adequacy: defines the usefulness of data for hazard/risk assessment purposes.

When there is more than one study for an endpoint, the greatest weight is normally attached to the study that is the most reliable and relevant. This study is generally referred to as the key study. Determining reliability essentially relates to how the study was carried out. Careful consideration must be made of the quality of the study, the method, the reporting of the results, the conclusions drawn and the results themselves in order to be able to generate a robust study summary.

There are several reasons why existing study data may be of variable quality. Klimisch et al, have suggested the following:

- the use of different test guidelines (compared with today's standards);
- the inability to characterize the test substance properly (in terms of purity, physical characteristics, etc.);
- the use of techniques/procedures which have since been refined; and
- certain information may have not been recorded (or possibly even measured) for a given endpoint, but have since been recognised as being important.

At least a minimal amount of information on the reliability of a given study needs to be known before proceeding to determine its relevance and adequacy for assessment purposes and before proceeding to develop a robust study summary. The reliability of data is therefore a key initial consideration which is needed to filter out unreliable studies, and to focus on those considered most reliable. Knowledge of how the study has been conducted is essential for all further considerations.

### 5.2.2 DATA VALIDATION APPROACHES

Two approaches have been proposed by OECD to assist the initial data quality screening of study reports to set aside unreliable study data. Both are compatible and when considering data quality may be used either alone or in combination.

1. The first approach was developed by Klimisch *et al.* (1997). It uses a scoring system for reliability, particularly for ecotoxicological and health studies. However it may be extended to physicochemical and environmental fate and pathway studies.

2. The second approach was developed in 1998 as part of the US EPA HPV Challenge Program.

Other systems may also be considered.

#### 5.2.2.1 Klimisch scoring system

Under this approach, Klimisch et al. (1997) developed a scoring system which can be used to categorise the reliability of a study as follows:

1 = reliable without restrictions: "studies or data... generated according to generally valid and/or internationally accepted testing guidelines (preferably performed according to GLP) or in which the test parameters documented are based on a specific (national) testing guideline or in which all parameters described are closely related/comparable to a guideline method."

2 = reliable with restrictions: "studies or data... (mostly not performed according to GLP), in which the test parameters documented do not totally comply with the specific testing guideline, but are sufficient to accept the data or in which investigations are described which cannot be subsumed under a testing guideline, but which are nevertheless well documented and scientifically acceptable."

3 = not reliable: "studies or data... in which there were interferences between the measuring system and the test substance or in which organisms/test systems were used which are not relevant in relation to the exposure (e.g., non physiological pathways of application) or which were carried out or generated according to a method which is not acceptable, the documentation of which is not sufficient for assessment and which is not convincing for an expert judgment."

4 = not assignable: "studies or data... which do not give sufficient experimental details and which are only listed in short abstracts or secondary literature (books, reviews, etc.)."

NB: The use of Klimisch scores provides a useful tool for organising the studies for further review. Studies which failed to meet essential criteria for reliability would normally be initially set aside if higher quality information is available. However these studies may still be used, as collective information, which is referred to as the "weight of evidence approach" (see below).

#### 5.2.2.2 US EPA scoring system

The approach provided by US EPA provides additional information by describing the key reliability criteria for each group of data elements (see Table 1 below). These criteria address the overall scientific integrity and validity of the information in a study, i.e. reliability. This approach is consistent with the Klimisch approach as any study which does not meet the criteria would also not be assignable under the Klimisch system. Such studies may, however, be considered later as supplementary information to the overall assessment of a particular endpoint particularly if there is no single key study.

TABLE 1: DATA RELIABILITY: INITIAL SCREENING CRITERIA BY TYPE OF INFORMATION

| Criteria | Required for the following Information Items | | |
|---|---|---|---|
| | P/Chem | Env Fate | Ecotox / Health |
| Test Substance Identification (Adequate description of test substance, including chemical purity and identification/quantification of impurities to the extent available) | X | X | X |
| Temperature | X[1] | X | X |
| Full Reference/Citation | X | X | X |
| Controls[2] | | X | X |
| Statistics With some exceptions (e.g. the Salmonella/Ames assays) | | | X |
| Species, strain, number, gender, age of organism | | | X |
| Dose/conc. Levels | | X | X |
| Route/type of exposure[3] | | | X |
| Duration of exposure | | X | X |

1 For vapour pressure, octanol/water partition coefficient and water solubility values.

2 All studies must have negative controls and some studies (e.g. biodegradation, Ames assay) must also have positive controls. If a vehicle is used in the administration of the test agent, vehicle controls should be established and reported. Exceptions may be allowed for acute mammalian toxicity studies.

*3 The route/type of exposure (e.g., oral inhalation, etc for mammalian studies) or test system (static, flow through, etc for ecotoxicity) must be reported.*

Addressing relevance and adequacy will be facilitated by having a clear picture of the reliability of a study. Indeed, one or more key studies may have been identified per endpoint, so it needs to be decided whether full robust study summaries can be prepared to allow judgement on relevance and adequacy.

NB: The use of steps to identify reliable, relevant and adequate data helps to ensure that high quality data are identified and also that other studies will be used as a weight of evidence approach: case where several studies, one or more of which alone may be inadequate to satisfy a specific endpoint, may be used collectively to address one endpoint, thereby avoiding additional (animal) testing.

For example, if several repeated dose studies are available on a particular substance it may be that none would be acceptable by itself due to some protocol deficiency (i.e., low number of test animals/dose group, only one dose group in addition to control group, change in dose amount or frequency during the course of the study, etc). However, collectively if the different studies show effects in the same target organ at approximately the same dose and time, this could be judged to satisfy the repeated dose toxicity data element required.

*Steps to follow*

All reports for consideration should ideally be documented as IUCLID 5 datasets with a Robust Study Summary (if available). If the IUCLID 5 file needs to be generated, however, this may be deferred until study selection(s) for a given endpoint has been made. Generally, robust study summaries would be prepared only for the highest quality or "key" studies in a data evaluation exercise.

It is recommended to agree in advance on the criteria for accepting proposed studies / quality ratings. The steps may for example be:

- a self-assessment by data owners
- a review among the members of the joint submission
- in case of problems, an arbitration mechanism might need to be used. This could involve commissioning an expert Third Party to evaluate the initial assessment.

As mentioned earlier, there may additionally be other ways of evaluating the reliability of existing data, which have been developed to address the specific characteristics of substances that might not be (sufficiently) covered by the generic approaches described above. As an example, for metals, metal compounds and minerals, the MERAG (Metals Risk Assessment Guidance) project proposes criteria to be considered when scrutinising ecotoxicity data for hazard classification. Other approaches may also be available.

## 5.3 STUDY VALUATION

An accurate and transparent valuation of studies is a critical component in the data sharing process. As a starting point, studies should be assessed in terms of their scientific quality. In a second step, a financial value can then be determined taking account of correcting factors, which will lead to an increase or reduction of the values assigned, where appropriate.

### 5.3.1 WHAT STUDIES SHOULD BE VALUED?

From a quality perspective and taking Klimisch scores as a model, it is recommended that only studies with a reliability rating of 1 or 2 qualify for financial compensation. Study reports with scores 3 and 4, and those for which higher reliability studies are available, can therefore be deselected from the valuation procedures. The information contained in such reports should be considered as weight of evidence. There is little basis for their compensation in comparison with higher quality studies.

An exception may arise when Klimisch 3 reports can satisfy an endpoint via the weight of evidence approach and there are no higher ranking studies available. If the existing information is sufficient to support the relevant endpoint, these studies could be treated, collectively, for valuation purposes in the same manner as in the case of higher quality data. Consequently payments would be subject to formal acceptance of the studies.

### 5.3.2 HISTORIC VERSUS REPLACEMENT COSTS

Articles 27(5) and 30(1) require the owner of a study to provide proof of its cost within one month of the request for that study.

Nothing prevents the potential registrant(s) from agreeing on valuation methods, such as the "replacement value", i.e. the price that would be paid today to obtain the same study.

NB: It is the responsibility of the members of the joint submission to agree on the cost model which is the most appropriate (historic costs, replacement costs or any other). This model must be fair, transparent and non-discriminatory.

#### 5.3.2.1 Correcting factors

In case of both models based on historic or replacement costs, parties may want to account for correcting factors that may justify either an increase or a decrease of the value of a study for cost sharing purposes. When historic costs are used, parties may wish to account for inflation and other relevant elements which are not required if replacement costs are used.

Factors increasing the study value may include expenses related to the sample preparation, test evaluation and other activities/ measures such as:

- preliminary analyses for determining test concentrations;
- substance testing according to the standard protocol;
- development of suitable analytical methods;
- supplementary analyses (e.g. substance characterisation; stability in test medium; concentration in test medium);
- administrative and travel expenses;
- processing and professional support by the commissioning party; (may include study design and /or preparation of test material)
- preparation of the IUCLID data set and robust study summary(ies).

Factors decreasing the study value may include:

- deviations from standard protocol (study is not performed according to the GLP standards);
- other possible study deficiencies to determine on a case-by-case basis;
- restriction of use for REACH purposes only;
- use as part of category of substances where the study is used only for one substance;
- use in case of read across, where the substance is not the tested substance.

#### 5.3.2.2 Specific Value Elements

The following elements may need to be taken into account on a case by case basis:

- Baseline costs (i.e. expenses for preliminary testing and substance testing according to a standard protocol) may be calculated as an average of the prices charged by two or three agreed testing laboratories according to their price lists. Standard pricing should be assumed and special conditions, such as those granted when commissioning large testing programmes, are not taken into account.

- If no market prices are available for the calculation of expenses for substance analysis, the following information from the party supplying the report is required for each analytical procedure: (i) a brief description of the methodology, including the limit of detection; (ii) estimated costs for the development or provision[21] of the method; (iii) costs per analysis; (iv) number of analyses performed. In some cases, the development and provision costs may not be cited separately but could be included in the charges made for each analysis.

- Administrative Expenses: in addition to the cost of the experimental work (substance testing and analysis), some administrative expenses have probably occurred (processing and professional support by the data owner, travel expenses, archiving of the test substance and raw data). This surcharge cannot be fixed but may rather be related to the value of the study. Some examples of variable administrative costs on the basis of the value of the underlying study are provided below (see section 5.6). If factual information relating to expenses is available, this may override any other recommendations. In the case of significant deviation, expenses would need to be fully substantiated and documented individually.

NB: The valuation costs must rely on expenses supported by verifiable documentation or, if such documentation is not available, on expenses that can be appropriately justified. These elements are critical for data owners to comply with their legal obligation of providing "fair, transparent and non-discriminatory" costs.

- Robust Study Summary: the preparation and provision of robust study summaries for key studies which may be contributed by the study owner (or developed by experts commissioned for this task) could be compensated by a percentage of the administrative costs mentioned above (ICCA HPV experience supports a maximum value of up to 30% of the administrative costs). In case of testing for inherent substance properties, the limitation (2) "reliable with restriction" may arise when the study has been conducted at a date prior to the introduction of GLP standards.

- Risk Premium: The decision to conduct a study involves a risk for the initiator according to which the project may not be successful in generating the information desired (with no possibility for reimbursement). It may be appropriate to acknowledge this risk, especially for recognized problematic substances or those difficult to test. Indeed a potential registrant accessing an existing study has access to a known outcome so the risk no longer exists. This would mainly be applicable for toxicity or ecotoxicity studies where testing difficulties might reasonably be anticipated. In many other scenarios, there may be little justification for the application of this risk premium due to the nature of the testing and/ or the inherent properties of the substance involved.

- International reviews: the intrinsic properties of substances which have been part of international programs (e.g. ICCA/OECD HPV chemicals programme), have already been reviewed. Therefore, the key studies have already been selected in a similar way. This activity may be taken into account, where relevant, by encompassing all relevant endpoints and adding an extra premium.

NB: For all these specific value elements, the lead registrant(s), the existing registrants, or their representatives, or the parties preparing the dossier, have the obligation to answer any request for clarification on costs which may not be sufficiently transparent to the member(s) of the joint submission.

The principles related to study valuation are illustrated in section 5.6 through two examples (see Examples 1 and 2).

21 Provision of analytical procedure or method includes the measures required for testing a method known from the literature for compatibility with the intended use.

## 5.4 COST ALLOCATION AND COMPENSATION

The REACH Regulation requires all parties to make every effort to ensure that the costs of sharing information are determined in a "fair, transparent and non-discriminatory way". The cost allocations may be calculated for studies relating to all endpoints for which information is required according to REACH. The current value of all study reports serves as the basis for subsequent costs allocation and compensation.

NB: Cost allocation activities are not appropriate for data obtained from reports which are recognised to be in the public domain (see section 3.3.3.8 for further guidance on this point) and the use of which does not lead to any additional expenditure.

It is the responsibility of the potential registrants of the same substance to select any cost allocation and compensation mechanisms (i.e. cost sharing model) so that they are fair, transparent and non-discriminatory. Some possible mechanisms may include (list is not exhaustive):

- Sharing data equally, based on the number of parties involved within the same tonnage band (ie. registrants having the same information requirements);

- Sharing data among registrants having the same information requirements within the same tonnage band based on production or sales volume or otherwise (subject to competition rules and CBI, see also sections 7 and 9);

- Alternative mechanisms using part of the above models in a different way.

Additionally, Article 30(1) of the REACH Regulation refers to equal sharing as a default mechanism in case no agreement can be reached.

NB: Registrants are only required to share the costs of information that they are required to submit to satisfy their registration requirement. Therefore, registrants cannot be forced to pay for studies that they do not need (i.e. one study per endpoint), unless additional studies are necessary in order to fulfil the information requirements (e.g. in a weight of evidence approach). Also companies cannot be forced to pay for studies before they actually need them for their registration in their respective tonnage band.

However whenever a (potential) registrant requests data earlier, he has to pay on receipt of the data.

### 5.4.1 "INDIVIDUAL ROUTE"

A study's value is to be determined using the same principles as described above. The study is then shared with all parties requiring the information for registration purposes. If the data owner is part of the group of potential registrants, the costs of the data are to be incorporated into the allocation calculations. If the data owner has no registration intentions (i.e. he is a data holder), costs are to be distributed only amongst the potential registrants. If any additional interested parties arise throughout the lifetime of the joint submission, compensation adjustments are to be subsequently effected by the data owner(s).

### 5.4.2 "COLLECTIVE ROUTE"

NB: Solely for the purposes of cost allocation, when addressing a particular endpoint, only one study per endpoint is normally to be proposed (even though all studies may be used for technical support).

Potential registrants who are compelled to submit jointly the data set to characterise the intrinsic properties of their substance are free to decide on any data compensation mechanism they see fit for purpose.

Some models which have been used in the past are explained below and can be considered for apportioning costs between participants. However they are only models. The example(s) provided to illustrate them should be reviewed to fully understand each model.

**1. Data compensation based on study-quality weighted models**

These data compensation mechanisms are illustrated by examples in section 5.6. These models are based on the principle that compensation by non contributors for a given endpoint is due only for the best study available (i.e. for one study per end point).
If there is more than one data owner, the following steps may be applied in order to arrive at an appropriate cost allocation. For the purposes of illustration, Klimisch ratings are determined first and employed.

**Case (i): only Klimisch 1 studies available**

By contributing with a category (1) report ("reliable without restrictions"), the share of the contributor/data owner is considered as paid for the relevant endpoint. This applies also for any other parties who contribute with reports of equal quality. The cost allocation against this endpoint is then borne only by the remaining (non-contributing) potential registrants.

If any reports are jointly owned by a number of potential registrants, each would be considered to have met their obligation for that endpoint from a cost-sharing perspective.

**Case (ii): Klimisch 1 & 2 studies available**

If reports from both category (1) and (2) ("reliable with restrictions") are available for the same endpoint, the report with the higher rating will be used as the key study for cost allocation purposes. Data owners supplying a lower-rated report are to contribute according to the difference in value of their study from that of the selected key study. Other (non-contributing) potential registrants support the cost on the basis of the key study value.

If any category (1) reports are jointly owned by a number of contributors, each would be considered to have met his obligation for that endpoint from a cost share perspective. For category (2) study joint owners, contributions would be required as indicated.

**Case (iii): Only Klimisch 2 studies available**

If a report of category (1) standard does not exist and only one (or more) report(s) of category (2) is available, the report with the highest assigned value will be selected as the key study for cost allocation. Contributing potential registrants will pay by difference to the key study costs (as above) while the other potential registrants will support the cost on the basis of the key study value.

**Compensation**

The total compensation available for allocation, against any endpoint, results from adding together the contributions identified for all potential registrants in line with the guidelines described.

Compensation is then divided among the parties supplying reports in relation to the values of the studies provided against each of the range of endpoints covered.

**2. Direct data compensation**

As an alternative to the approach defined above, other more direct cost allocation mechanisms can also be used. In all cases, clear rules for the study valuation step need to be firmly established as a prerequisite to applying any distribution mechanism. This model exempts holders of data who would satisfy their registration requirements from the cost sharing mechanism so that the costs are only shared between the holder of the key study and those registrants who do not hold sufficient data. With study costs established, the following allocation options could be considered:

**Case (i): Compensation taking several studies into account**

In some cases more than one key study may be needed to cover a certain data requirement. Therefore a mechanism covering the cost sharing of more than one key study can be envisaged, whereby several studies for a given endpoint are used to calculate a total endpoint value. This total value is to be used to define a member contribution. A cost adjustment for each potential registrant is to be made depending on the value of the studies provided relative to the required member contribution.

This route has the benefit of recognizing the full weight of the studies available. However in order to avoid the situation where the number of existing reports exceeds the number of potential registrants in the data sharing process, data owners are normally not compensated for more than one study per endpoint.

NB: in this model, potential registrants that are not contributing would compensate more than one study per endpoint.

**Case (ii): Compensation for key study only**

Compensation is based around the key study selected for one endpoint. Other data owners for the endpoint would be exempted from the compensation process and only potential registrants that do not own data are expected to provide a financial contribution to the key study holder.

As agreement on key study selection is critical for this mechanism, there could be difficulties in coming to an agreement if a number of comparable studies are available. However, if necessary, more than one key study may be assigned.

## 5.5 FURTHER FACTORS INFLUENCING COST SHARING

A range of additional factors may also be considered when addressing cost sharing among potential registrants. In each case, the basic valuation and data/ cost sharing mechanisms described above still apply with the appropriate adjustments being made.

### 5.5.1 KLIMISCH 3 STUDIES

As mentioned in section 5.3 (Study evaluation), in cases where Klimisch 3 studies represent the best information available, potential registrants may adopt a "weight-of-evidence" approach which can be sufficient to satisfy a given endpoint's requirements.

NB: Assuming that the combination of studies is formally accepted (in order to avoid repeating unnecessary animal testing), it is recommended to consider, in valuation terms, the data in line with the criteria for higher level Klimisch 2 data.

### 5.5.2 USAGE RESTRICTIONS

In addition to the costing elements considerations, usage conditions are to be applied. It is appropriate to take into account any limitation to usage conditions in the financial value assigned to a given study. Some examples of restricted application might include the following situations (or a combination thereof):

- Usage is limited to REACH purposes only (as opposed to a study being available for more general exploitation).
- The full study report is not being made available but rather a Letter of Access giving authority to refer to the work is proposed.
- One substance's data set is needed and not the full category's.
- Beyond the EU countries, some geographic boundaries are placed on areas where the information may be exploited.

NB: Reductions in the assigned value of a study should be agreed as a percentage reduction of the original valuation. Allocation of the study value would then follow the normal procedures (as described above).

### 5.5.3 VOLUME FACTORS

The allocation of study charges could be considered to be imbalanced when considering parties handling very disparate manufactured or imported volumes. This would generally apply for the higher tonnage band (above 1000 tonnes) but the use of a volume factor can also be considered for the lower tonnage bands. In this case, a weighting against further tonnage ranges would be assigned thereby effectively increasing the number of shares across which a charge is allocated. For multi-site operators, tonnage may be combined to assign the appropriate banding factor. To implement this, in view of the need to have knowledge of the population of the relevant volume bands, particular care should be taken to recognize any competition or confidentiality concerns which might potentially arise from the application of tonnage bands with relatively narrow volume ranges, allowing to estimate or identify individual volumes. For more details, please consult sections 7 and 9 of the present Guidance Document.

### 5.5.4 NEW STUDIES

If new studies are generated as a consequence of the registration activity (as per the REACH requirements), the general principles on cost sharing as explained above for existing studies should be employed for the valuation and assignment of any resulting costs. This ensures a consistency in the approach taken for all data used in the registration of a given substance.

### 5.5.5 COST SHARING AS A "NON-STATIC" PROCESS

Additionally any cost sharing model may need to take into account the fact that cost sharing and cost allocation are continuous and dynamic processes. Indeed several elements may trigger variations of the model over time and the need to take corrective actions:

- A variable number of co-registrants: the number of registrants potentially joining the joint submission is not known in advance. New potential registrants may join an existing joint submission at any time during the "lifetime" of the joint submission, where cost sharing arrangements have already been agreed. They will need to agree to criteria which have been considered in the cost sharing model/ agreement regarding their financial contribution.

- The need for additional registration requirements: some additional testing and related expenses may be needed which would have an impact on any existing arrangements. This could be the case, for example, as an outcome of a tonnage band increase/ update or as the result of a decision from ECHA on a testing proposal or compliance check. Hence cost sharing models may take this approach into consideration, so that any costs generated would be shared among all relevant (potential) registrants as appropriate.

NB: co-registrants are advised to check carefully the data/ cost sharing agreements bearing in mind the elements above (which may trigger variation in the costs) and the iterative nature of the process.
The price of the dossier, reflected for example in the Letter of Access, does not reflect only the costs of the total individual studies.

## 5.6 COST SHARING EXAMPLES

Examples provided in this section are reflecting various concepts described above. They aim at providing a more practical explanation but should NOT be used as the only way to proceed.

**EXAMPLE 1: Study Valuation**

7 potential registrants (A, B, C, D, E, F, G) form a SIEF for the same substance, Member A owns a Klimisch 1 report, Member B owns a Klimisch 2 report, Members C, D, E, F and G do not own a relevant study.

The attached example does not reflect

- a deduction because of limitation of a study for REACH registration purposes exclusively

- a surcharge for RSS established for a given report.

a. Substance testing

| | Report – Klimisch 1 | Report – Klimisch 2 |
|---|---|---|
| Owner | Member A | Member B |
| Year of testing | 2001 | 1984 |
| Method | OECD Guideline xyz | Similar to OECD Guideline xyz |
| GLP | Yes | No |
| Analysis of test substance | Pharmaceutical grade 99.9 % | Unknown, presumably >99% |
| Stability | Yes | Unknown, presumably yes |
| Concentration monitoring | Yes | Yes |
| Comments | Study conducted in accordance with OECD and EC and EPA test guidelines and in accordance with GLP | Several details of test conditions are not given, e.g. sex, age or body weight of the test animals, housing conditions etc. However, the study is acceptable since the general conduct of the study is acceptable, and since a detailed description of the observations is provided in the report. |

b. Analyses

| | | | |
|---|---|---|---|
| Test substance | | standard | standard |
| Stability | | standard | standard |
| Concentration monitoring | | | |
| | Method | Literature | Literature |
| | Development | None | None |
| | Provision | | |
| | Working days | 10 | 8 |
| | Per diem rate | € 600 | € 600 |
| | Analysis costs | € 100 per analysis | € 100 per analysis |
| | Number of analyses | 60 | 50 |

c. Determination of the current value of the report

| Type of expense/surcharge/deduction | | Report 1 | | Report 2 | |
|---|---|---|---|---|---|
| | Preliminary test to determine concentration (range finding) | € 35,000 | | € 35,000 | |
| | Test per standard protocol | € 100,000 | | € 100,000 | |
| | Without GLP | 0 | | € -15,000 | |
| | Other deficiencies | 0 | | € -5,000 | |
| Costs of substance testing | | | € 135,000 | | € 115,000 |
| | Development of analytical procedure/ method | 0 | | 0 | |
| | Provision of analytical procedure/method (10 or 8 working days at € 600) | € 6,000 | | € 4,800 | |
| | Analysis of test substance | € 1,000 | | 0 | |
| | Stability | € 500 | | 0 | |
| | Concentration monitoring (60 or 50 analyses at € 100) | € 6,000 | | € 5,000 | |
| Analysis costs | | | € 13,500 | | € 9,800 |
| Experimental costs | | | € 148,500 | | € 124,800 |
| | Administrative costs[22] | € 10,000 | | € 10,000 | |
| | Risk premium (10 % of experimental costs) | € 14,850 | | € 12,480 | |
| Total surcharges | | | € 24,850 | | € 22,480 |
| Current report value | | | € 173,350 | | € 147,280 |

Cost allocation for each member is described in Example 3 (below).

**EXAMPLE 2: Study Valuation**

7 potential registrants (A, B, C, D, E, F, G) prepare a joint submission for the same substance, Member A owns a report (compliant to OECD guideline), Member B owns a report non-compliant to OECD guidelines, Members C, D, E, F and G do not own a relevant study.

The example (vapour pressure OECD 104) does not reflect a deduction because of limitation of a study for REACH registration purposes exclusively, nor a surcharge for RSS established for a given report.

22 The value of € 10 000 for administrative cost in this example (and € 15 000 in example 2) was derived using a model that establishes administrative costs as a percentage of the experimental cost. The higher the experimental cost, the lower the percentage.

a. Substance testing

| | Report 1 | Report 2 |
|---|---|---|
| Owner | Member A | Member B |
| Year of testing | 2001 | 1984 |
| Method | OECD Guideline xyz | similar to OECD Guideline xyz |
| GLP | yes | no |
| Analysis of test substance | pharmaceutical grade 99.9 % | unknown, presumably >99% |
| Stability | yes | unknown, reliably yes |
| Concentration monitoring | yes | yes |
| Comments | Study conducted in accordance with OECD test guidelines and in accordance with GLP | Some details of test conditions are not given. However, the study is acceptable since the general conduct of the study is acceptable, and since a detailed description of the observations is provided in the report. |

b. Analyses

| | | | |
|---|---|---|---|
| Test substance | | standard | standard |
| Stability | | standard | standard |
| Concentration monitoring | | | |
| | Method | literature | literature |
| | Development | none | none |
| | Provision | | |
| | Working days | 0 | 0 |
| | Per diem rate | € 600 | € 600 |
| | Analysis costs | € 100 per analysis | € 100 per analysis |
| | Number of analyses | 0 | 0 |

c. Determination of the current value of the report

| Type of expense/surcharge/deduction | | Report 1 | | Report 2 | |
|---|---|---|---|---|---|
| | Preliminary test to determine concentration (range finding) | 0 | | 0 | |
| | Test per standard protocol | € 11,000 | | € 11,000 | |
| | Without GLP | 0 | | € -1,100 | |
| | Other deficiencies | 0 | | € -1,000 | |
| Costs of substance testing | | | € 11,000 | | € 8,900 |
| | Development of analytical procedure/ method | 0 | | 0 | |
| | Provision of analytical procedure/method (0 working days at € 600) | 0 | | 0 | |
| | Analysis of test substance | € 500 | | 0 | |
| | Stability | € 100 | | 0 | |
| | Concentration monitoring (0 analyses at € 100) | 0 | | 0 | |
| Analysis costs | | | € 600 | | 0 |
| Experimental costs | | | € 11,600 | | € 8,900 |
| | Administrative costs[23] | € 3,000 | | €3,000 | |
| | Risk premium (N/A) | 0<br>44,550 | | 0 | |
| Total surcharges | | | € 3,000 | | € 3,000 |
| Current report value | | | € 14,600 | | € 11,900 |

**EXAMPLE 3: Study cost allocation – individual studies**

As shown in Example 1, the value of report 1 (Klimisch 1) has been calculated to be € 173,350; the value of report 2 (Klimisch 2) has been calculated to be € 147,280.

| | |
|---|---|
| Value of key study | € 173,350 |
| Share per member (€ 173,350 / 7) | € 24,764 |
| Financial contribution of Member A (Owner of Report 1) | € 0 |
| Financial contribution of Member B (Owner of Report 2 having the lower value): 24,764 x (173,350 – 147,280) / 173,350 | € 3,724 |
| Financial contribution of other members: 5 x 24,764 | € 123,820 |

23 See footnote 22 above.

Cost compensation

| | |
|---|---|
| Total amount of assigned contributions (123,820 + 3,724) | € 127,544 |
| Share for Member A having the higher value Report 1<br>127,544 x 173,350 / (173,350 + 147,280) | € 68,957 |
| Share of Member B having the lower value Report 2<br>127,544 x 147,280 / (173,350 + 147,280) | € 58,587 |

The balance (cost allocation – cost compensation) results in the following:

Member A receives € 68,957

Member B receives € 54,863 (58,587 – 3,724)

Members C, D, E, F, G pay € 24,764 each

**EXAMPLE 4: Study cost allocation – Individual studies**

Two Klimisch 1 & two Klimisch 2 studies available, one study not assessed in a joint submission consisting of 7 members

Member A owns a Klimisch 1 study; report has been valued € 215,325

Member B owns a Klimisch 1 study; report has been valued € 202,100

Member C owns a Klimisch 2 study; report has been valued € 165,390

Member D owns a Klimisch 2 study; report has been valued € 158,270

Member E owns a study, which has not been assessed for its quality

Member F and G do not own any study

| | |
|---|---|
| Value of key study | € 215,325 |
| Share per member (€ 215,325 / 7) | € 30,761 |
| Financial contribution of Member A (Owner of Report 1; key study) | € 0 |
| Financial contribution of Member B (Owner of Report 2 not being the key study but being rated Klimisch 1): | € 0 |
| Financial contribution of Member C (Owner of Report 3, Klimisch 2 study)<br>30,761 x (215,325 - 165,390) / 215,325 | € 7,134 |
| Financial contribution of Member D (Owner of Report 4, Klimisch 2 study)<br>30,761 x (215,325 - 158,270) / 215,325 | € 8,151 |
| Financial contribution of Member E (Owner of Report 5, but no quality assessment available) | € 30,761 |
| Financial contribution of Member F and G (do not own a Report) 2 x € 30,761 | € 61,522 |
| Total financial contributions | € 107,566 |

Cost compensation

| | |
|---|---|
| Share for Member A owning Report 1; the key study<br>(7,134 + 8151 + 30,761 * 3) * 215,325 / (215,325 + 201,100 + 165,390 + 158, 270) | € 31,254 |
| Share for Member B owning Report 2; Klimisch 1 but not the key study<br>(7,134 + 8151 + 30,761 * 3) * 201,100 / (215,325 + 201,100 + 165,390 + 158, 270) | € 29,334 |
| Share for Member C owning Report 3; Klimisch 2<br>(7,134 + 8151 + 30,761 * 3) * 165,390 / (215,325 + 201,100 + 165,390 + 158, 270) | € 24,006 |
| Share for Member D owning Report 4; Klimisch 2<br>(7,134 + 8151 + 30,761 * 3) * 158,270 / (215,325 + 201,100 + 165,390 + 158, 270) | € 22,279 |
| Total compensations | € 107,566 |

Balancing cost allocation and cost compensation leads to the following results

Member A receives € 31,254

Member B receives € 29,334 (Klimisch 1 but not key study / lead value)

Member C receives € 16,872

Member D receives € 14,822

Member E, F and G pay € 30,761 each

**EXAMPLE 5: Study cost allocation – Individual studies**

Here member A of the joint submission owns a Klimisch 2 study, the value of the report has been calculated to be € 158,300.00.

Member B owns a Klimisch 2 study, the value of the report has been calculated to be € 145,000.00.

Member C owns a Klimisch 2 study, the value of the report has been calculated to be € 144,000.00.

The remaining members D to G do not contribute with any study.

| | |
|---|---|
| Value of key study | € 158,300 |
| Share per member (€ 158,300 / 7) | € 22,614 |
| Financial contribution of Member A (Owner of Report 1; Klimisch 2, key study) | € 0 |
| Financial contribution of Member B (Owner of Report 2, Klimisch 2):<br>22,614 x (158,300 - 145,000) / 158,300 € 1,900 | € 1,900 |
| Financial contribution of Member C (Owner of Report 3, Klimisch 2):<br>22,614 x (158,300 - 144,000) / 158,300 | € 2,043 |
| Financial contribution of Member D, E, F and G (do not own a Report) 4 x € 22,614 | € 90,456 |
| Total financial contributions | € 94,400 |

Cost compensation

| | |
|---|---|
| Share for Member A owning Report 1; the key study<br>(1,900 + 2,043 + 22,614 * 4) * 158,300 / (158,300 + 145,000 + 144,000) | € 33,408 |
| Share for Member B owning Report 2<br>(1,900 + 2,043 + 22,614 * 4) * 145,000 / (158,300 + 145,000 + 144,000) | € 30,601 |
| Share for Member C owning Report 3<br>(1,900 + 2,043 + 22,614 * 4) * 144,000 / (158,300 + 145,000 + 144,000) | € 30,390 |
| Total compensations | € 94,400 |

Balancing cost allocation and cost compensation leads to the following results:

Member A receives € 33,408

Member B receives € 28,701 (Klimisch 2 but not key study / lead value)

Member C receives € 28,347 (Klimisch 2 but not key study / lead value)

Member D, E, F and G pay € 22,614 each.

**EXAMPLE 6: Cost allocation - compensation for best studies**

In some cases more than one key study might be needed to cover a certain data requirement. In these cases a mechanism covering the cost sharing of more than one key study can be envisaged.

Five members have the following data available for a particular endpoint (with accompanying study valuations as indicated):

Member A: Klimisch 1 study (€ 105,000) + Klimisch 2 study (€ 80,000)

Member B: No Data

Member C: Klimisch 1 (€ 95,000)

Member D: Klimisch 2 (€ 65,000) + Klimisch 2 (€ 75,000)

Member E: Klimisch 2 (€ 60,000)

Study values (using a nominal approach) are set as Klimisch 1, €100,000 with Klimisch 2, € 70,000.

Total number of available studies = 6

Using this dataset and the nominal study values described:

Total number of studies (for calculation purposes) = 4

Total value of these studies = (2 x 100) + (2 x 70) = € 340,000

Participant contribution is then 340 / 5 = € 68,000

In payment / compensation terms:

Member B pays € 68,000

Members A, C, D and E (all holders of qualifying data) each receive € 17,000

**For comparison purposes**, treatment of the same example utilising the earlier allocation mechanism would yield the following balance:

Member A receives € 11,283

Member B pays € 21,000

Member C receives € 10,208

Member D receives € 2,059

Member E pays € 2,552

**EXAMPLE 7: Cost allocation - compensation for key study only**

Using again the dataset and nominal study values described in Example 6 but now with the key study assigned as that held by participant C:

Members A, D and E are exempted from the compensation process

Key Study value is € 100,000

In payment / compensation terms

Member B pays € 50,000 (half of the value of the study)

Member C (holder of the key study) receives € 50,000

**For comparison purposes**, treatment of the same example utilising the earlier allocation mechanism would yield the following balance:

Member A receives € 9,403

Member B pays € 19,000

Member C receives € 8,507

Member D receives € 2,716

Member E pays € 1,627

If, however, **both of the Klimisch 1 studies** were accepted as key studies:

Members D and E are exempted from the compensation process.

Key Study value is € 100,000 (for each study), giving a total value of € 200,000

In payment / compensation terms;

Member B pays € 66,600 (one third of the value of the two studies)

Members A and C (holders of the key studies) each receive € 33.300

**EXAMPLE 8: Valuation with usage restrictions**

As shown in examples 1 and 3, the value of report 1 (Klimisch 1) has been calculated to be € 173,350; the value of report 2 (Klimisch 2) has been calculated to be € 147,280.

**Cost Allocation**

Members C, D, E, F and G don't own a study.

Member C will use the study exclusively for REACH and requires only a Letter of Access, he will get a reduced allocation by a factor of 50 % (therefore he pays at a rate of 50%)

Member D needs to reference the study for global regulatory purposes (including REACH in the EU) but only requires a Letter of Access, he will get a reduced allocation by a factor of 30% (therefore he pays at a rate of 70%)

Other members will have full usage rights to the full study report

| | |
|---|---|
| Value of key study | € 173,350 |
| Share per member (€ 173,350 / 7) | € 24,764 |
| Financial contribution of Member A (Owner of Report 1) | € 0 |
| Financial contribution of Member B (Owner of Report 2 having the lower value):<br>24,764 x (173,350 – 147,280) / 173,350 € | € 3,724 |
| Financial contribution of members E, F and G: 3 x 24,764 | € 74,292 |
| Financial contribution of member C, who can use the study (Letter of Access) only for REACH<br>24,764 * ((100-50)/100) | € 12,382 |
| Financial contribution of member D, who can use the study for all regulatory purposes, including REACH, but needs only Letter of Access.<br>24,764 * ((100-30)/100) | € 17,335 |
| Total financial contribution | € 107,733 |

Cost compensation

| | |
|---|---|
| Total amount of assigned contributions (123,820 + 3,724) | € 107,733 |
| Share for Member A having the higher value Report 1<br>107,733 x 173,350 / (173,350 + 147,280) | € 58,246 |
| Share of Member B having the lower value Report 2<br>107,733 x 147,280 / (173,350 + 147,280) | € 49,487 |

The balance (cost allocation – cost compensation) results in the following:

Member A receives € 58,246

Member B receives € 45,763 (49,487 – 3,724)

Member C pays € 12,382

Member D pays € 17,335

Members E, F, G pay € 24,764 each

**EXAMPLE 9: Registration dossier cost allocation - different tonnage bands used as criteria**

Fair cost sharing may be organised according to tonnage bands as the REACH information requirements are linked to the tonnage bands and therefore are the main factor affecting cost sharing. The costs of data necessary for a group of registrants falling under a specific tonnage band vary and are usually related to the cost of data, access to which the registrant needs to licence/ acquire for the purpose of submitting his dossier.

Since it is difficult to define a standard proportion between the different tonnages, different approaches may be used.

In the SIEF for substance X, 10 members have expressed interest in registering the substance. Five of them in the tonnage band of > 1000 t/y, 3 in the tonnage band of 100-1000 t/y and 2 in the tonnage band of 1-100 t/y.

The total cost of the data in the dossier is € 1 420 000 and the "administrative costs" (including SIEF management, preparation of the dossier and review by third party) are € 10 000. Total cost is therefore: € 1 430 000.

The lead registrant proposes the following prices for the letter of access (LoA):

| Tonnage band | Cost of access to data (€) | Admin costs (€) | Total price LoA (€) |
|---|---|---|---|
| >1000 t/y | 250K | 1K | 251K |
| 100-1000 t/y | 50K | 1K | 51K |
| 1-100 t/y / Intermediate under SCC | 10K | 1K | 11K |

The price structure reflects the fact that the higher tonnage band registration accounts for the higher registration requirements. The administrative costs are shared equally (10K / 10) as this is something all the members have benefitted from (e.g. SIEF organisation, preparation of CSR, etc.).

The total price is then covered: 5x251K + 3x51K+2x11K = € 1 430 000.

**EXAMPLE 10: Registration dossier cost allocation and balance due to new co-registrants and additional costs**

The SIEF has a large number of members (e.g. 100 members). The total estimated price of the dossier including administrative costs is € 1 000 000.

Following a survey carried out by the lead registrant, 30 legal entities out of the 1000 pre-registrants have expressed interest in registering in the highest tonnage band.

It has been assumed as a conservative approach that 20 legal entities will actually register within the highest tonnage band (>1000 t/y).

For the cost allocation the adopted approach has been to apply equal sharing per legal entity per tonnage band. It has also been agreed to fix a price for lower tonnage bands in case of new potential candidates as follows:

| | |
|---|---|
| > 1000 t/y: | 100% of the Letter of Access (LoA) |
| 100 – 1000 t/y: | 50 % of the LoA. |
| 10 – 100 t/y: | 20 % of the LoA |
| < 10 t/y: | 5 % of the LoA |

The price of the LoA is fixed at € 1 000 000/20 = € 50 000.

By 2010, 20 legal entities registered. The total amount of the fees paid by these co-registrants covers the total cost of the dossier.

After the first registration deadline, e.g. in 2012, 2 new legal entities, which want to register in the highest tonnage band, join the joint submission: they pay € 50 000 each.

Hence 2 X € 50 000 = € 100 000 of income.

In parallel to SIEF activities, the JS dossier undergoes compliance check. The outcome leads to a requirement for additional work (delivering of additional data and related assessment work) which is estimated to be € 80 000 for the SIEF.

Before the next registration deadline of 2013, 3 new legal entities, which intend to register in the tonnage band 100 – 1000 t/y, join the joint submission, and pay € 25 000 each.

Hence 3 X 25 = € 75 000 income.

According to the originally agreed mechanism, a reimbursement will be made in 2018 after the last registration deadline:

BALANCE

| | |
|---|---|
| Income 2010 | + € 1000 000 |
| Income 2012 | + € 100 000 |
| Income 2013 | + € 75 000 |
| Dossier costs | - € 1000 000 |
| Evaluation costs | - € 80 000 |
| Balance | + € 95 000 |

It has also been decided to put aside € 10 000 to cover extra additional costs in case of the need to update the dossier after 2018.

| | |
|---|---|
| Balance | + € 95 000 |
| Updating costs | - € 10 000 |
| Final balance | + € 85 000 |

Number of legal entities above 1000 T tonnage band: 22

Number of legal entities within 100-1000 T tonnage band: 3

Number of reimbursement unit: 22 + 3/2 = 23,5

Value of the reimbursement unit: € 85 000/23,5 = € 3617

Each legal entity above 1000 T will get back 1 reimbursement-unit: € 3617

Each legal entity within 100-1000 T will get back 1/2 reimbursement-unit: € 1808

NB: the frequency of the reimbursements need to be agreed, ranging from e.g. (i) every time a new comer joins the joint submission, to (ii) Q1 of each year, to (iii) after 1 June 2018.

# 6 Registration: joint submission

REACH registrants are required to jointly submit information on the hazardous properties of the substance (studies and proposals for testing) and its classification and labelling, and may, if they agree to do so, also jointly submit the CSR and/or the guidance on safe use.

NB: the "joint submission of data" does not relieve each registrant (manufacturer, importer or Only Representative) from the obligation to also submit their own individual dossier.

For each joint registration, the members of the joint submission will have to provide individually the information required under Article 10 of REACH, with the exception of (1) the studies and proposals for testing, (2) classification and labelling information, and (3) CSR and/or the guidance on safe use in cases where parties decide to also submit these jointly (on a voluntary basis) for which they will refer to the joint submission by the lead registrant.

NB: The provisions of joint submission apply both to registrants who decide to register without prior pre-registration and to registrants of non-phase-in substances. In particular any early registrants who registered a substance before the joint submission process took place, are required to make every effort to join it.

The present section will explain the mechanisms of joint submission and the opt-out criteria described in REACH. For details on the status and role of the lead registrant, please consult section 3.2.6 of this Guidance document.

## 6.1 MANDATORY JOINT SUBMISSION

The REACH Regulation imposes a requirement for the joint submission of a part of the Technical Dossier including:

- Classification and labelling of the substance;
- Study Summaries;
- Robust study summaries;
- Testing proposal;
- Indication of whether the relevant information has been reviewed by an assessor (on a voluntary basis)

The joint submission will be made by a lead registrant elected by the other potential registrants of the same substance. The registration dossier including the joint information is submitted by the lead registrant on behalf of the other registrants using REACH-IT. The submission of the lead registrant dossier is to be made before the members submit their registrations. Each other potential registrant participating in the SIEF/ joint submission subsequently submits his dossier as a member of the joint submission. If a registrant uses a Third Party Representative he must mention in his own registration dossier the contact details of his Third Party Representative.

NB: If registrants have submitted their dossier outside of the joint submission, they must join the existing joint registration dossier, as otherwise they are not in compliance with their joint submission obligation as per Article 11.

For more detailed technical information, please consult the REACH-IT Industry User Manual (IUM) on "Joint submission" and Data Submission Manual (DSM) on "How to pass Business Rules verification" available at http://www.echa.eu/web/guest/support/dossier-submission-tools/reach-it/data-submission-industry-user-manuals.

## 6.2 OVERVIEW OF THE PART OF THE TECHNICAL DOSSIER THAT MAY BE JOINTLY SUBMITTED FOR REGISTRATION

TABLE 2: SUMMARY OF DATA TO BE SUBMITTED JOINTLY AND/OR SEPARATELY

| Joint submission = Lead dossier (information specific to the substance) | Separate submission = Member dossier (information specific to the LE registering) | Joint or separate submission: decision left to the members of the joint submission |
|---|---|---|
| 10(a)(iv) **Classification and Labelling** of the substance as specified in section 4 of Annex VI<br><br>May be different among members | 10(a)(i) **Identity of manufacturer or importer of the substance** as specified in section 1 of Annex VI | 10(a)(v) Guidance on safe use of the substance as specified in section 5 of Annex VI |
| 10(a)(vi) **Study summaries** of the information derived from the application of Annexes VII to XI | 10(a)(ii) **Identity of substance** as specified in section 2 of Annex VI | 10(b) **Chemical Safety Report** when required under Article 14, in the format specified in Annex I.<br><br>The relevant sections of this report may include, if the registrant considers appropriate, the relevant use and exposure categories |
| 10(a)(vii) **Robust study summaries** of the information derived from the application of Annexes VII to XI, if required under Annex I | 10(a)(iii) **Information on the manufacture and use(s) of the substance** as specified in section 3 of Annex VI; this information shall represent all the registrant's identified use(s). This information may include, if the registrant deems appropriate, the relevant use and exposure categories | |
| 10(a)(ix) **Proposals for testing** where listed in Annexes IX and X | 10 (a)(x) **for substances in quantities of 1 to 10 tonnes, exposure information** as specified in section 6 of Annex VI | |
| Optional: 10(a)(viii) Indication as to which of the information submitted under Article 10(a), (iv), (vi), (vii) has been **reviewed by an assessor** chosen by the manufacturer or importer and having appropriate experience | Optional: 10 (a)(viii) Indication as to which of the information submitted under Article 10(a)(iii) has been **reviewed by an assessor** chosen by the manufacturer or importer and having appropriate experience | Optional: 10 (a)(viii) Indication as to which of the information submitted under Article 10(b) has been **reviewed by an assessor** chosen by the manufacturer or importer and having appropriate experience |

Role and tasks of the lead registrant are addressed in section 3, where the data sharing process for phase-in substance within a SIEF is described.

## 6.3 OPT-OUT FROM CERTAIN INFORMATION ELEMENTS OF THE JOINT SUBMISSION

The overall aim of the joint submission obligation is the submission of one registration per substance (independently of its use). However, exceptions explicitly set out in Article 11(3) of the REACH Regulation may apply.

### 6.3.1 OPT-OUT CONDITIONS FROM JOINT SUBMISSION

As explained in Articles 11(1) and 19(1), REACH requires the joint submission of studies, testing proposals and classification and labelling information. However under specific conditions, registrants may have a justification for opting out from submitting jointly certain information in the joint registration dossier. For example a registrant may seek to protect confidential business information in the specific study, or disagree with the selection of information selected by the lead registrant to be submitted jointly, for a particular test.

NB: Opting out can be only partial. Any information submitted separately by a registrant, in his member dossier, on the basis of Article 11(3), must be fully justified in each case as prescribed by Article 11(3). Even in this case, the registrant still bears the obligation resulting from the joint submission (within or outside the SIEF) and to share data which may be requested from him. Additionally the registrant opting-out will use the joint registration dossier, submitted by the lead registrant for all other shared information.

### 6.3.2 CRITERIA TO JUSTIFY OPT-OUT OF JOINT SUBMISSION

Paragraph 3 of Article 11 (and similarly Article 19, which deals with joint submission of data for isolated intermediates) provides for three situations justifying a registrant to opt-out of the joint submission:

1. it would be disproportionately costly for him to submit this information jointly; or

2. submitting the information jointly would lead to disclosure of information which he considers to be commercially sensitive and is likely to cause him substantial commercial detriment; or

3. he disagrees with the lead registrant on the selection of this information.

However, registrants, willing to submit some information separately ie. invoking any or all of these conditions, are required to:

- Belong to the joint submission;

- Submit their own information to cover the given data requirement;

- Submit a clear and reasoned explanation as to why the costs would be disproportionate, why disclosure of information was likely to lead to substantial commercial detriment or the nature of the disagreement, as the case may be (Article 11, paragraph 3).

#### 6.3.2.1 Disproportionate Costs

Disproportionate costs may arise when a potential registrant already has in his possession a set of the test data for the substance. Therefore the joint submission would cause him disproportionate costs. An example could be that the cost sharing formula adopted by a SIEF is particularly disadvantageous to certain members, so that the cost of tests to share has become excessive. Costs may also be considered disproportionate (i.e.

excessively high) also in the case when the number of potential registrants sharing it is low. This is not considered to be a valid reason, as in fact, and regardless of the cost sharing formula adopted, the study itself may be very expensive. The REACH Regulation does not define "disproportionate" costs, registrants relying on this ground to opt-out should provide sufficient explanations in their registration dossiers.

#### 6.3.2.2 Protection of confidential Business Information (CBI)

The protection of CBI is addressed in the second opt-out criterion. The case must be based on the commercial loss which would be sustained if such CBI were disclosed by joint registration. Circumstances will of course vary from case to case, but it would seem necessary in most cases to demonstrate (1) the route by which confidential information would be disclosed, (2) how it could cause a substantial detriment if it were disclosed (3) that no mechanisms can be used or is accepted by the other party/parties (e.g. use of a trustee) to prevent disclosure.

Examples might include information allowing details of manufacturing methods to be deduced (such as technical characteristics, including impurity levels, of the product used in testing), or marketing plans (test data obviously indicating use for a particular, perhaps novel, application), for example because there are only 2 participants in a joint submission The fewer participants the joint submission, the more likely it is that CBI might be released through indications of sales volumes. Although there is no further quantification in the legal text of what constitutes "substantial" detriment, a registrant seeking to use this opt-out criterion should as a minimum provide an estimation of the value of the CBI at stake. This might be done by setting out the total value of business for the product, the proportion potentially affected and the associated gross margin. If a simple calculation of annual loss is not enough to demonstrate "substantial" detriment, a further stage might include an estimate of the forward period over which business might be affected and the consequent calculated net present value of gross margin lost.

#### 6.3.2.3 Disagreement with the lead registrant on the selection of information

Disagreements over choice of information are likely to fall into one of the following categories.

(i) A registrant may consider the nominated test data is not appropriate to his substance's specific application(s). In such a case he would have to provide a qualitative explanation for his view. This may be the case for example due to differences in the physical form in which the product was supplied, the processes in which it was used, the exposure risks for downstream users, the likelihood of dispersion during use, the probable final disposal routes, and any other relevant arguments.

(ii) A registrant may believe the data proposed for the joint registration is of an unsatisfactory quality standard. The registrant's view may also be influenced by his ownership or otherwise of relevant data and/or the different purposes for which his substance is used.

(iii) In the opposite case to (ii), a registrant might consider the data proposed for use in the joint registration to be of an unnecessarily high standard (and therefore excessively costly), at least for his applications. Justification of this opt-out would be grounded in demonstrating the adequacy of the alternative test data he was using, coupled with the disproportionate cost to him if he otherwise accepted the data proposed by the lead registrant.

(iv) Similarly a registrant may disagree with the number of studies submitted for the same data endpoint, especially in the absence of appropriate scientific justification or if these studies are redundant to fulfil the endpoint.

Registrants invoking any or all of these conditions are required, pursuant to Article 11(3), to "submit, along with the dossier, an explanation as to why the costs would be disproportionate, why disclosure of information was likely to lead to substantial commercial detriment or the nature of the disagreement, as the case may be".

### 6.3.3 CONSEQUENCES OF OPTING OUT

An immediate consequence of opting out will be the further administrative work incurred in justifying the opt-out, and, depending on the reasons cited, the possibility of further correspondence with ECHA. On the other hand, disproportionate costs may be avoided, and confidential business information protected.

However, in case of an opt-out, the registrant will not benefit from the reduced registration fees linked to the submission of the joint registration.

In addition, dossiers submitted under the opting out provisions will be prioritised by ECHA in the context of Dossier Evaluation (compliance check).

### 6.3.4 REMAINING DATA SHARING OBLIGATIONS

The potential registrant is still a member of the joint submission and needs to confirm his membership of the joint submission. He is still required to respond to requests for the sharing of test data in his possession.

In cases where the potential registrant considers that sharing a particular study would lead to disclosure of CBI, he may provide a revised version of the study summary that omits the confidential elements To the extent that the study cannot be validly used without the confidential elements, it might be necessary to employ a neutral third party (independent consultant), to evaluate the study and provide an assessment as to the appropriateness of the confidentiality claims as well as to the utility of the use of the study in the context of the joint registration.

## 6.4 INFORMATION IN THE REGISTRATION DOSSIER PROVIDED JOINTLY ON A VOLUNTARY BASIS

The part of the registration dossier that may be submitted jointly or separately on a voluntary basis consists of:

- The Chemical Safety Report (CSR)
- The Guidance on safe use of the substance

### 6.4.1 CHEMICAL SAFETY REPORT (CSR)

A **Chemical Safety Assessment** (CSA) must be performed and a **Chemical Safety Report** (CSR) must be completed for all substances subject to registration when the registrant manufactures or imports such substances in quantities of 10 tonnes or more per year. The CSR will document that risks are adequately controlled through the whole life-cycle of a substance. For detailed methodological guidance on the various steps, please consult the Guidance on Information Requirement and Chemical Safety Assessment available at: http://www.echa.eu/web/guest/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment.

Also, the duty of carrying out a CSA for a particular use or for certain conditions of use may shift from the manufacturer or importer to a downstream user in particular situations. For details please consult the Guidance on Downstream Users.

The CSA consists of the following parts[24]:

- Human health, physicochemical and environmental hazards assessment, as well as PBT and vPvB assessment;

- Exposure assessment and development of exposure scenario(s), if required;

- Risk Characterization, if required;

Some confidential data such as the uses, or processes used may have to be exchanged in order to carry out this CSA. This information could be exchanged in a vertical way (between suppliers and downstream users) or in a horizontal way (between the manufacturers/importers carrying out the CSA together, for common uses).

An independent Third Party could be appointed to exchange this information if the information is considered to be CBI.

### 6.4.2 GUIDANCE ON SAFE USE OF A SUBSTANCE

As required in Annex VI, Section 5, the technical dossier to be submitted for registration purposes should include the **Guidance on Safe Use of a substance**. This Guidance on the Safe Use needs to be consistent with the information provided in the extended Safety Data Sheet (SDS) for the substance, where such a Safety data Sheet is required according to Article 31. For more details, please consult the Guidance on Chemical Safety Assessment and information requirements and the Data Submission manual on "How to complete a technical dossier for registration and PPORD notification".

NB: If a CSR is not required, some confidential data might need to be exchanged to draft the Guidance on Safe Use.

It is important for industry to consider working together on the CSR and the development of exposure scenarios via exposure categories. Working together will be cost efficient and important for coherence and consistency in performing the CSA. However, separate submission of the CSR and associated exposure scenarios may be justified where there are CBI issues and where regular updates of the CSR are foreseen, since these issues are best handled by individual registrants rather than via a lead registrant.

## 6.5 POST REGISTRATION DATA SHARING OBLIGATIONS

It is important to note that the registrants' data sharing obligations do not stop once the joint registration dossier has been submitted. Registrants have further duties which may entail the need to share data and to continue to make every effort to reach an agreement.

Hence the data sharing process continues beyond the joint submission of data.

- It is also acknowledged that new registrants may always join the SIEF/ existing registrants at a later stage, e.g. ahead of the 2013 registration deadline (for phase-in substances), or when they arrive on the EU market and manufacture/ import a "new" substance (for which they inquired). Hence the main responsibility will be on the lead registrant (and on the "new comer") to communicate clearly. The potential registrant will have to negotiate and agree to the SIEF and data sharing agreements, which are the pre-requisite to enter a group of existing registrants.

24 Requirements concerning CSR are laid down in Article 14 of REACH Regulation.

- The lead registrant may pro-actively invite the individual registrant(s) to join the joint submission and propose to accept the SIEF agreement, so that they fulfil their joint submission and data sharing obligations. Similarly, early registrants are to be proactive in joining the joint submission.

- New registrants may also bring their own existing information, where the joint registration dossier has already been submitted. They consequently may refer to Article 11(3) and opt-out for the given endpoint. However they still need to join the joint submission as a member.

- As per the obligations under Article 22, the registrants (mainly the lead registrant) will have to update the joint registration dossier as soon as new information becomes available.

This may require preliminary data sharing and may have an impact on

  - the C&L of the substance;

  - the CSR or the Safety Data Sheets if new knowledge of the risks of the substance to human health and/or the environment become available;

  - additionally it may trigger the need to perform a new test (testing proposal).

The new information might appear as a result of dossier and substance evaluation, of changes specific to the registrant such as a new identified use, update of tonnage band or change in the regulation itself (new requirement).

- The evaluation of the registration dossier by ECHA (compliance check or the assessment of a testing proposal) or of the substance by a Member State competent authority may trigger new requirements which would need to be addressed within the SIEF (for phase-in substances) or among registrants of a non-phase-in substance, and would lead to a request to submit further information. As a result agreement on generating and/ sharing data and costs will be needed and will lead to an update of the joint submission. Hence data sharing does not only apply to "existing" studies but also to studies which will be needed for ensuring that the registration is and remains compliant with REACH.

- Finally, even beyond 1 June 2018, data generated by the SIEF in the framework of registrations may continue to be protected from unauthorized use by other potential registrants. In addition, there may be a need to generate data after the end of the SIEF, for instance following substance or dossier evaluation. Furthermore, a subsequent registrant may wish to use the submitted information for registration purposes after 1 June 2018.

# 7 Information sharing under competition rules

## 7.1 DOES COMPETITION LAW APPLY TO REACH ACTIVITIES?

Yes, as it is expressly stated in the REACH Regulation "*this Regulation should be without prejudice to the full application of the Community competition rules*." (Recital 48). Therefore, rules of competition law adopted at EU level (hereinafter "Competition rules"), may apply to REACH and all related activities, including data sharing.

This section on the Competition rules is intended to help the REACH actors to assess the compatibility of their activities for sharing data and information in the context of REACH.

Additionally, Competition rules can apply to other aspects of REACH related activities.

Data sharing and information exchange may occur at different steps of the REACH process. This section is only limited to the most common types of questions related thereto. Furthermore, this section may apply to any form of cooperation that actors may decide to adopt in order to fulfil their obligations under REACH (see section 8).

NB: REACH actors should always ensure that their activities comply with Competition rules irrespective of the form of cooperation they choose.

## 7.2 EU COMPETITION LAW AND ARTICLE 101 OF THE TREATY ON THE FUNCTIONING OF THE EUROPEAN UNION (TFEU) IN BRIEF

EU Competition law is not intended to inhibit legitimate activities of companies. Its objective is to protect competition in the market as a means of enhancing consumer welfare. Therefore, agreements between companies or decisions by associations or concerted practice which may affect trade between Member States and which have as their object or effect the prevention, restriction or distortion of competition within the common market are prohibited (Article 101 TFEU).

Any agreement that infringes Article 101 is void and unenforceable. In addition, in case of an investigation by the European Commission or by a national competition authority, companies that have implemented a conduct in breach of Article 101 may face significant fines. Such investigation may be initiated either by the authority itself; following a complaint by a third party; or following a leniency application to the competent competition authority of a party to the unlawful agreement that would like to cease its unlawful activity.

For more information on EU Competition law, please refer to the Commission Directorate General Competition's web site at: http://ec.europa.eu/comm/competition/index_en.html

## 7.3 EXCHANGE OF INFORMATION UNDER REACH AND EU COMPETITION LAW

The REACH Regulation requires the sharing of information between companies "*in order to increase the efficiency of the registration system, to reduce costs and to reduce testing on vertebrate animals*" (Recital 33); it also mentions that SIEFs are aimed to "*help exchange of information on the substances that have been registered*" (Recital 54).

REACH provides for significant flows of information between actors, at various stages throughout its implementation process. Examples are:

- for phase-in substances in the pre-registration and the pre-SIEF stage;
- within SIEF (including for classification and labelling);
- during the inquiry for non-phase-in and phase-in substances, which have not been pre-registered, in order to evaluate if a substance has already been registered;
- in the context of information to be shared between downstream users and their suppliers;
- in the context of joint registration.

NB: Actors have to make sure that their exchanges do not go beyond what is required under REACH in a manner that would be contrary to EU Competition law, as explained below.

- Firstly, actors must avoid any illegal activity (e.g. creating cartels) when complying with REACH.
- Secondly, actors should restrict the scope of their activity to what is strictly required by REACH to avoid creating unnecessary risks of infringing EU Competition law.
- Thirdly, if actors have to exchange information which is sensitive under EU Competition law, then it is advisable that they use precautionary measures to prevent infringement.

### 7.3.1 AVOIDING MISUSE OF REACH EXCHANGE OF INFORMATION TO CONDUCT CARTELS

A cartel is an illegal practice (whether or not reflected in a formal or informal agreement) between competitors who collaborate to fix prices or restrict supply or their production capacities or divide up markets or consumers and that shield the member of the cartel from competition.

Examples of activities to be avoided between competitors:

- Fixing the prices of products or conditions of sale;
- Limiting production, fixing production quotas or limiting the supply of products to the markets;
- Dividing up the market or sources of supply, either geographically or by class of customers;
- Limiting or controlling investments or technical developments.

NB: Any exchange of information under REACH must not be used by actors to organise or cover the operation of a cartel.

### 7.3.2 THE SCOPE OF THE ACTIVITIES SHOULD BE LIMITED TO WHAT IS NECESSARY UNDER REACH

It is important to ensure that the exchange of information under REACH is limited to what is required. Article 25.2 of the REACH Regulation gives examples of information which must not be exchanged: "*Registrants shall refrain from exchanging information concerning their market behaviour, in particular as regards production capacities, production or sales volumes, import volumes or market share*."

Examples of non-public information which must not be exchanged under REACH:

- Individual company prices, price changes, terms of sales, industry pricing policies, price levels, price differentials, price marks-ups, discounts, allowances, credit terms etc;
- Costs of production or distribution etc;
- Individual company figures on sources of supply costs, production, inventories, sales etc;
- Information as to future plans of individual companies concerning technology, investments, design, production, distribution or marketing of particular products including proposed territories or customers;
- Matters relating to individual suppliers or customers, particularly in respect of any action that might have the effect of excluding them from the market.

Actors should also refrain from exchanging technical information if this exchange is not necessary under REACH and especially if this exchange of information may provide competitors with the ability to identify individual company information and to align their market behaviour.

NB: Actors should restrict the scope of their exchange of information strictly to what is required for REACH activities.

### 7.3.3 TYPE OF INFORMATION TO BE EXCHANGED WITH CAUTION

Even if most of the information to be exchanged under REACH is unlikely to be problematic under EU Competition law rules (because this information is to the greatest extent purely scientific or technical and it may not enable competitors to align their market behaviour) there are instances where actors need to be very careful.

In particular, actors may be induced to exchange information on individual production, import or sales volumes. For example, in the context of a joint CSA/CSR actors may want to know the aggregate volumes of produced and imported substances by exchanging information on individual volumes, in order to estimate the overall impact on the environment. Actors may also want to share REACH-related costs based on their individual production or sales volumes. In addition, if an Only Representative, who has to keep certain information like quantities imported up-to-date, represents several non-EU manufacturers of a substance, such manufacturers may be induced to exchange individual volume information between them through their Only Representative.

Some tips are provided below on how to avoid the risk that the exchange of such volume information, to the extent that it is relevant under REACH, constitutes an infringement of Article 101 TFEU.

#### 7.3.3.1 Reduce frequency of exchange

Exchanges of individual volume information between actors taking place only once or sporadically (e.g. once every several years) are unlikely to give rise to competition law concerns to the extent that such exchanges would not allow parties to align their market behaviour.

NB: Actors should exchange information only once or on a very sporadic basis.

#### 7.3.3.2 Reference to bands rather than individual figures when feasible

The REACH Regulation mentions that "*Requirements for generation of information on substances should be tiered according to the volumes of manufacture or importation of a substance, because these provide an indication of the potential for exposure of man and the environment to the substance, and should be described in detail*" (Recital 34), thus indicating the use of tonnage bands.

NB: Actors should refer to their respective tonnage band as defined under REACH and refrain from exchanging individual or more detailed volume figures.

#### 7.3.3.3 Use of precautionary measures if individual sensitive information would still need to be exchanged

If under particular circumstances, actors need to either use individual figures or aggregate figures (for example at the occasion of carrying out of CSA/CSR) or individual figures may be otherwise identifiable it is recommended to use an independent third party ("Trustee").

Who could be a Trustee? A legal or natural person not directly or indirectly linked to a manufacturer/importer or their representatives. This Trustee may be for example a consultant, a law firm, a laboratory, a European/international organisation, etc. The Trustee will not represent any actor, as he should be independent, and can be hired by the members of the joint submission, for example to help for certain activities. It is advisable that the Trustee signs a confidentiality agreement that will ensure that the Trustee undertakes not to misuse sensitive information he receives (i.e. disclose it to the participating companies or anyone else).

The following activities can be facilitated by a Trustee for competition law purposes:

- Produce aggregated anonymous figures: When REACH actors need to refer to the aggregate of sensitive individual figures, the Trustee will request the actors to provide their individual input. The input will be collated, checked and aggregated into a composite return that does not give the possibility of deducing individual figures (e.g., by ensuring that there will be a minimum of three real inputs). In addition, no joint discussion must take place between this Trustee and several actors on the anonymous or aggregated figures. Questions should be addressed on an individual basis between each actor and the Trustee, who shall not reveal any other data during such discussion.

- Calculation of cost allocation based on individual figures for cost sharing: Where actors decide that all or part of their cost sharing should be based on their individual figures (e.g. sales or production volumes) or where individual figures may be identifiable, the Trustee will request from each actor to provide the relevant confidential individual information. He will then send to each actor an invoice corresponding to their particular amount. Only the receiving company would see their particular share of the total amount to be paid.

- Companies need to send sensitive individual information to the authorities, without circulating it to the other actors: The Trustee would produce a non confidential version of the same document for the actors or the public that shall not contain sensitive information.

## 7.4 RECOMMENDED TIPS FOR REACH ACTORS WHEN WORKING TOGETHER

| | |
|---|---|
| Competition compliance | Before entering into an exchange of information under REACH ensure you have read and understood this guidance and that you will apply it.<br><br>In case of doubt, or questions, please seek advice (e.g. from a legal advisor). |
| Record keeping | Prepare agendas and minutes for conference calls or meetings which accurately reflect the matters and discussions held between actors. |
| Vigilance | Limit your discussion or meeting activities to the circulated agenda.<br><br>Protest against any inappropriate activity or discussion (whether it occurs during meetings, conference calls, social events, or when working via electronic means – for example using a dedicated intranet). Ask for these to be stopped. Disassociate yourself and have your position clearly expressed in writing, including in the minutes. |

NB: This section does not intend to substitute the applicable competition law provisions, as these have been interpreted by the European Courts, and applied by the European Commission and the national competition authorities. This guidance is only designed to allow REACH actors to make a preliminary assessment of their conduct under EU Competition law.

This Guidance is designed in a generic way and thus does not and cannot cover all the different scenarios that may arise from data-sharing obligations provided by REACH. In case of uncertainty, ECHA would recommend to seek legal advice from a lawyer specialised in competition law.

For more details on the prohibition of antitrust behaviours, please consult the relevant webpage of the European Commission - Directorate General Competition, on the following link: http://ec.europa.eu/competition/antitrust/overview_en.html

# 8 Forms of cooperation

As described above, potential registrants are free to organise themselves in order to meet (1) their SIEF objectives (data sharing and classification and labelling) and (2) the joint submission of data (both for phase-in and non-phase-in substances) as they see fit. Indeed, a SIEF in itself has no prescribed legal form. Also, the REACH Regulation does not define the way participants to a SIEF must cooperate to meet their obligations, nor does it regulate possible forms of co-operation between them for SIEF or other purposes.

It is often presented that "consortium" must be formed (or consortium agreements signed) to organise data sharing and the joint submission of data. This is not the case.

## 8.1 POSSIBLE FORMS OF COOPERATION

There are several possible forms of cooperation that companies can chose to organise their cooperation under REACH. The forms of cooperation can vary from loose ways of cooperating (e.g. IT tools to communicate between all members of a joint submission) to more structured and binding models (e.g. consortia created by means of contracts). Other examples of forms of cooperation may be envisaged - for example: one manufacturer provides a full data set to the other manufacturers in a SIEF who are invited to share this data set via a simple letter of access.

Neither the use of a full "consortium agreement" nor the use of another formal, written agreement is legally required by REACH. However, it is advisable that, whatever the form of the cooperation chosen, the parties agree in writing (this can be by means of a contract but also even by email) on the main rules of data sharing and at least on the ownership of the studies jointly developed, and the sharing of costs.

## 8.2 WHAT IS A CONSORTIUM?

For the purpose of this document, the term "consortium" will be used to refer to a more organised and formal type of cooperation between parties, implying either a signed agreement or the adoption of operating rules, or reference to an agreed set of general rules.

Importantly, SIEFs and consortia are two different concepts and must be clearly differentiated. A SIEF regroups all pre-registrants of the same substance (and other data holders where relevant) and participation to a SIEF is mandatory for SIEF participants under REACH. However, a consortium is voluntary and may not necessarily regroup all participants of a particular SIEF, but can regroup only some of them or participants of more than one SIEF.

REACH actors may decide to create a consortium at any stage of the REACH Process, e.g. before pre-registration, to ease the process of checking the identity and sameness of a substance with a view to the formation of a SIEF, and afterwards.

When a SIEF has been formed, participants in that SIEF who need to fulfil the obligations of the REACH Regulation would necessarily have to co-operate to reach this aim. The facilitator, or any other participant in a SIEF and its related virtual forum, may propose to the others a means of working together through "formal cooperation" and signing of a consortium agreement, or by adopting common rules. This proposal and chosen form of co-operation could be made by the SIEF Participants on their own, or by asking for the services and assistance of a Third Party such as a trade association, a sector association, a consultant, a law firm or any other service provider.

By either signing the consortium agreement, or accepting SIEF operating rules by a decision in a meeting, or deciding to refer to a common agreed set of rules (hereinafter only referred to as an "agreement"), participants in the agreement will de facto 'create the consortium'. There is no need to have any additional formalities. It should be noted that when a consortium is created by a trade association or a law firm it should not be confused with that body, and must be distinctly identified from it.

Some companies may also already be organised by having for example either a sector group or a consortium preparing the work to be ready for REACH. In this case, they may decide either to continue their cooperation within the same structure, or to create a new parallel structure, or to have any other pattern for cooperating.

NB: The life of a SIEF may involve one or more pattern(s) of co-operation but these are only to be considered as facilitation. Consortium formation does not bring the SIEF to an end. The SIEF continues to exist through the eleven years specified in the REACH Regulation. Also, a consortium may continue after the SIEF ends.

## 8.3 EXAMPLES OF COOPERATION

Co-operation by way of consortia to achieve effectiveness of the SIEF, once it is formed, may take different forms.

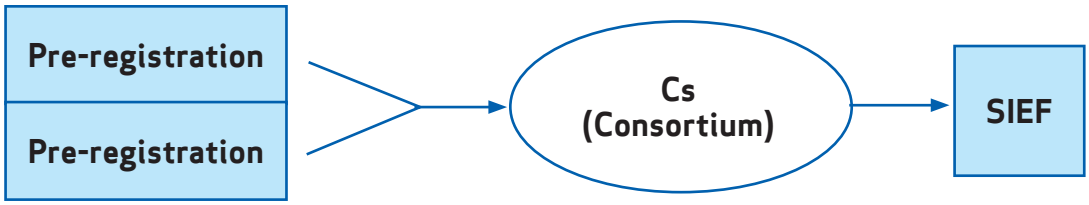
A few examples are given below:

Example 0:

SIEF functions with no consortium: after agreement on the substance identification, the lead registrant and main data owners organise themselves without creating a consortium.

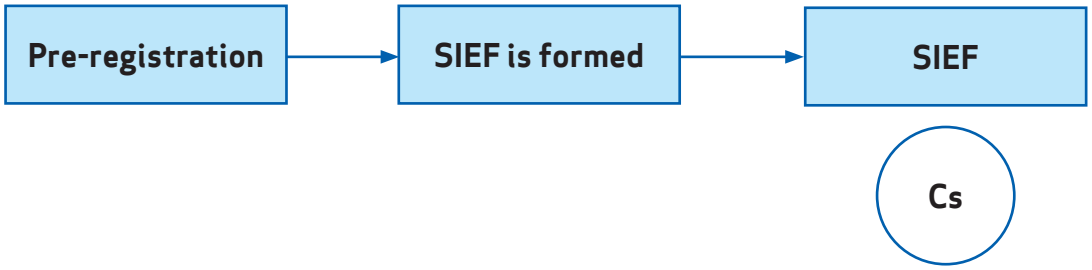
Example 1:

Companies having pre-registered decide to co-operate by way of a consortium for the discussion on the identity check and the sameness of the substance. Once the SIEF is formed they may decide to pursue their activity with the same consortium (which may need to be modified if needed, e.g. regarding its composition). Once they sign the consortium agreement, the consortium is created.



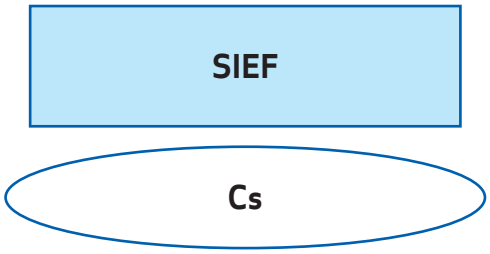
Example 2:

The Companies having pre-registered decide to cooperate for the discussion on the identity check and the sameness of the substance but not by immediately creating a consortium. They first meet and sign a pre-consortium agreement including appropriate confidentiality clauses. Once the SIEF is created, they decide to create a consortium.



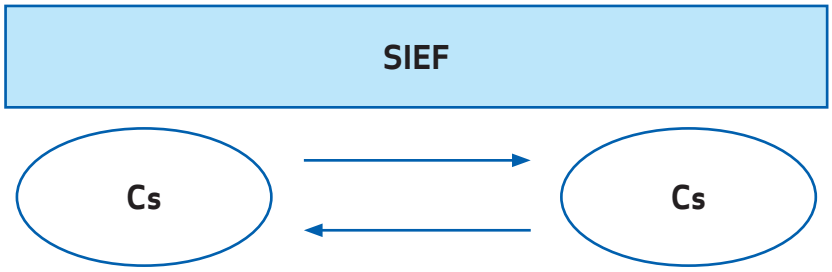

Example 3:

Participants in a SIEF decide to form a unique consortium.



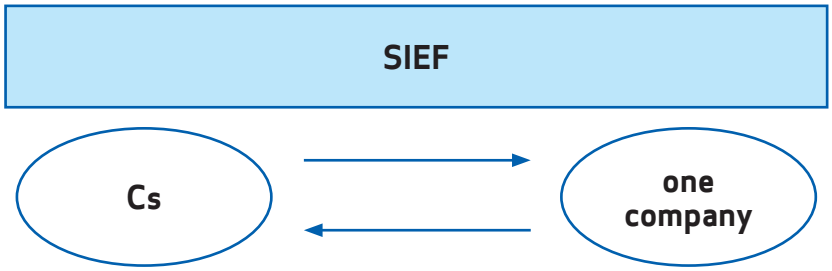

Example 4:

Participants in a SIEF may decide to constitute two or more consortia and to organise the cooperation regarding data sharing amongst these consortia (e.g. if different classification and labelling are foreseen for a substance with the same numerical identifier). Companies of both consortia are required to cooperate to meet their data sharing and joint registration obligations under REACH.



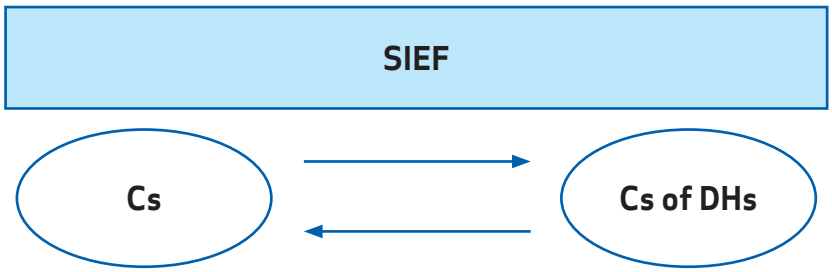
Example 5:

A company or a group of companies (participants in a SIEF) decide(s) to stay outside a consortium. In such a scenario, the companies that do not belong to the consortia and the companies that do belong to the consortia must cooperate regarding data sharing and joint submission (the principles of data sharing within a SIEF described above apply).



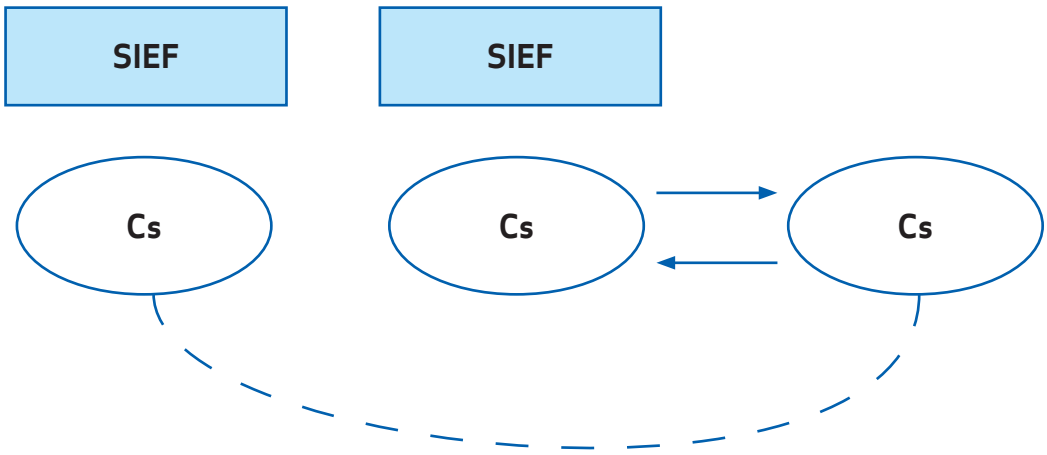

Example 6:

Manufacturers and importers who are members of a SIEF decide to form a consortium. Data holders (DH) also decide to form a consortium to co-operate between themselves and with the consortium.



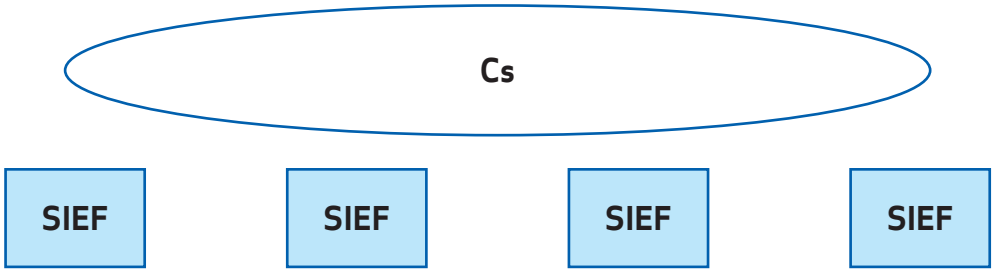

Example 7:

Two SIEFs – with three consortia decide to co-operate for specific purposes e.g. read-across.



Example 8:

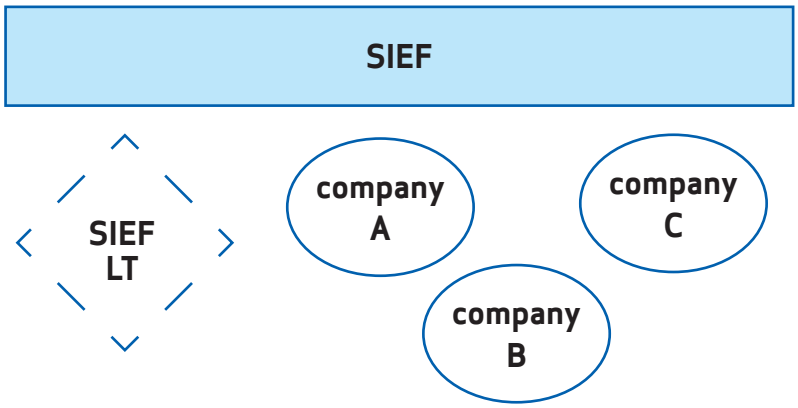
A major consortium may also be created (e.g. for a family of substances) for companies to participate in several, but different SIEFs.




Example 9:

The participants in a SIEF may decide to operate different strategies other than creating consortia. Following the pre-registration and the identification of the SIEF members and their level of involvement, a few participants have volunteered to work together with the lead registrant on the preparation of the dossier on behalf of the SIEF. The SIEF is informed and agrees to grant them permission to take decisions and to assign resources. They commit to monitor and report on progress and deliverables in regard to the preparation and the submission of the registration dossier. They will also handle general SIEF management issues. These companies form what can be called a "SIEF Leadership Team" (SIEF LT) without any formal consortium agreement. The limited number of members of this leadership team (e.g. 4-5) makes this choice more efficient than the creation of a consortium.

Basic contractual arrangements between the members of the SIEF Leadership Team are still recommended via a simplified contract.




## 8.4 ELEMENTS OF CO-OPERATION THAT MAY BE INCLUDED IN A CONSORTIUM'S ACTIVITIES

- Conduct or document the substance identity check;
- Designation in a SIEF of the facilitator or the lead registrant (in cases where the consortium groups all SIEF members);
- Organisation of co-operation and thus of the consortium;

- Consideration of data (existing data, missing data, new data to be developed);
- Defining of data to be shared;
- Facilitation of data-sharing and coordination;
- Data valuation, data evaluation (including identification, data access and collection);
- Facilitation of cross-reading between SIEFs;
- Organization to preserve the confidentiality of business information and data;
- Cost sharing;
- Data ownership;
- Preparation of letter of access to data for non-consortium participants;
- Liability;
- Classification and labelling.
- post-data sharing: joint submission of data, joint registration, and maintaining the life of the SIEF/joint submission/consortium even after the joint registration - jointly to follow-up the file until final registration/ evaluation, including interacting with ECHA.

NB: When a SIEF has members that are not part of the consortia, the companies of the consortia must cooperate, in a fair, transparent and non-discriminatory way, with the companies that are not part of the consortia. The consortia (e.g. through their secretariats) may facilitate this task but it is ultimately the responsibility of all the SIEF members to ensure that the data sharing and joint submission obligations are complied with.

Parties may also decide to have a consortium only to achieve together either some activities before the SIEFs, or the two aims of the SIEF or to maintain it for the full duration of the SIEF as specified in the REACH Regulation, i.e. for 11 years, or even to maintain the consortium beyond this period in case, for example, they need to collectively respond to some queries on their substances.

## 8.5 CATEGORIES OF PARTICIPANTS IN A CONSORTIUM

As mentioned above, there is also no need for the membership of a consortium for SIEF purposes to coincide exactly with the participants in a SIEF. The following categories of participants may be considered to be members of a consortium/co-operation agreement (this list is not exhaustive):

(A) Categories strictly deriving from a SIEF:

- Manufacturer(s);
- Importer(s);

- Only Representative(s);

- Data holder(s) who are willing to share data: for example laboratories, organisations, consultants, trade/industry associations or downstream user(s) if they have relevant information, for example study data and exposure data.

(B) Other categories may be considered, such as:

- Downstream user(s), in cases other than those mentioned in (A);

- Third Parties providing services and assistance to a consortium such as trade/industry associations, sectoral associations, service providers, and law firms;

- Non-EU manufacturer(s) who are also willing to participate directly, and not only through their EU Only Representative, although not being entitled to register directly;

- Potential manufacturers and importers who according to Article 28(6) are considered under the REACH Regulation as potential registrants.

Different categories of membership with different rights and obligations associated with these categories may be designated and included in the consortium agreement. For example:

- Full members;

- Associate members;

- Observers (either as Third Parties or not).

## 8.6 TYPICAL CLAUSES THAT MAY BE INCLUDED IN A CONSORTIUM AGREEMENT

The following list of clauses is to be considered as a non-exhaustive checklist:

| | |
|---|---|
| **1. General Information** | Identity of each party<br>Contact details<br>Preamble: including a reference to the REACH Regulation and a declaration of intent to explain the overall purpose of the consortium<br>Scope of cooperation: the substances(s) on which the parties will co-operate. It may also include the criteria chosen to agree on the identification of the substance(s)<br>Subject of the agreement: list of elements of cooperation or tasks on which parties have elected to work<br>Definitions: general reference to the definitions included in the REACH Regulation (Article 3) and additional definitions, if any<br>Duration<br>Identity of a independent third party: if the parties elect to have assistance from a law firm, service provider, sectorial or trade association in managing their consortium |
| **2. Membership** | Membership categories: definition, rights and obligations of each category<br>Membership rules: admission, revocation, dismissal of members<br>Change in membership: late entrant / early departure |
| **3. Data sharing** | Rules on data sharing<br>Criteria for valuation of studies/tests reports<br>Cost sharing criteria<br>Data Ownership<br>Letter of access |
| **4. Organisation** | Committees: (membership, attendance, rules of functioning, quorum, voting …)<br>Working language<br>Role of the facilitator, if any<br>Role of the lead registrants, if any<br>Role of third independent party, if any |
| **5. Budget and finances** | Budget<br>Apportionment – follow-up of registration (additional members to the joint submission)<br>Financial year<br>Invoicing and payment, reimbursement<br>Taxes and other costs |
| **6. Confidentiality and right of information** | Confidentiality clause<br>Who is entitled to access information?<br>Measures in place regarding the exchange of confidential and sensitive information<br>Sanctions in case of breach |
| **7. Liabilities** | Before and after the obligations under REACH are fulfilled |
| **8. Miscellaneous** | Applicable law<br>Dispute resolution / settlement or choice of jurisdiction<br>Changes to the agreement<br>Dissolution |

NB: All the above applies to potential registrants of both phase-in (SIEF members) and of non-phase-in substances/ phase-in which were not pre-registered.

# 9 Confidential business information (CBI)

The REACH Regulation requires companies to share information and data in order to avoid duplicate testing. However some of this information, or data, may be considered by companies to be confidential business information (CBI) and needs to be "protected". Whether certain information is CBI needs to be determined on a case-by-case basis by ECHA.

NB: It is important to not confuse CBI issues with competition rules (see section 7 above) which refers to situations where the sharing of information is likely to lead to distortion of competition.

## 9.1 WHAT IS CONFIDENTIAL BUSINESS INFORMATION?

Confidential business information (CBI) is one of the valuable assets of companies. Measures may have to be taken to protect this asset.

Many countries have comparable, although slightly different definitions of CBI. For instance Article 39(2) of the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs), defines CBI as follows:

a. is secret in the sense that it is not, as a body or in the precise configuration and assembly of its components, generally known among or readily accessible to persons within the circles that normally deal with the kind of information in question;

b. has commercial value because it is secret; and

c. has been subject to reasonable steps under the circumstances, by the person lawfully in control of the information, to keep it secret.

## 9.2 ARE THERE SPECIFIC PROVISIONS ON CBI IN REACH?

References to the CBI concept are made in several Articles of REACH, which demonstrate that the protection of CBI is a legitimate interest that may require some protection.

Article 118 relates to "Access to Information" held by ECHA. Article 118(2) specifically refers to information the disclosure of which "shall normally be deemed to undermine the protection of the commercial interests of the concerned persons". This includes details of the full composition of a preparation (mixture); precise use, function or application of a substance or preparation; precise tonnage of substances and preparations; links between a manufacturer or importer and downstream user.

Article 10(a)(xi) and Article 119(2) allow a party submitting certain information to request confidential treatment of that information. The party submitting the information must submit a justification (confidentiality claim) that has to be accepted by ECHA, as to why publication of this information is potentially harmful to their commercial interests or of any other involved party.
Article 11(3)(b) and 19(2)(b) allow registrants to 'opt-out' from the joint submission of data (only for individual endpoints) "if submitting the information jointly would lead to disclosure of information which he considers to be commercially sensitive and is likely to cause him substantial commercial detriment".

## 9.3 PROTECTION OF CBI AT LATE PRE-REGISTRATION

The information required to be submitted to ECHA at (late) pre-registration has been partially made public since 1 January 2009.

Indeed ECHA published a list of substances pre-registered containing only the substance identifier (EINECS numbers, CAS number or other numerical identifiers) and the first envisaged registration deadline. This publication raises, therefore, no issues of confidentiality.

In case a potential registrant does not want to be visible to other potential registrants, he has the option to appoint a Third Party Representative, according to Article 4 of the REACH Regulation. In that case, it is the identity of the Third Party Representative that will be visible to other potential registrants. Data holders may also appoint a third party to represent them in their dealings with the SIEF if they want to maintain their identity confidential.

Companies with a number of subsidiaries in the EU may name one of their companies as Third Party Representative. This will preclude information on which substance is produced by which subsidiary becoming known to other potential registrants.

NB: Potential registrants wishing to keep their identity secret towards other potential registrants should nominate a Third Party Representative at pre-registration.

## 9.4 PROTECTION OF CBI DURING SIEF FORMATION

As mentioned in section 3 of this Guidance document, before a SIEF is formed, potential registrants must ensure that they are producing or importing the same substance in accordance with the criteria set out in the Guidance on identification and naming of substances in REACH with the aim to ascertain that they can submit one joint registration dossier. This may in some cases require the exchange of detailed technical information on the composition of the substance, its impurities, and possibly on the manufacturing process. The latter may include the raw materials used, the purification steps etc.

To the extent that this technical information is considered CBI companies may take steps to protect the confidentiality thereof, for instance by :

1. Entering into confidentiality agreements that limit access to documents or other information to specific named persons, or departments, e.g. only the persons working within a regulatory section are allowed to see certain information. This can be strengthened by using additional personal confidentiality agreements.

2. In addition to (1), by allowing access to certain documents in a 'reading room' only (where copying is not allowed).

3. In addition to the above, by agreeing to have certain documents reviewed and/or assessed only by a Third Party expert (independent consultant).

NB: As a minimum, potential registrants who intend to protect the CBI character of substance identity information should specify to the other SIEF members that this information is indeed CBI and, therefore, that it is communicated and can be used only for purposes of the verification of substance identity under REACH.

## 9.5 PROTECTION OF CBI IN THE SIEF/JOINT SUBMISSION

The scientific studies that companies must share under REACH for the purposes of registration generally do not contain information that can be considered as CBI. However, to the extent that compliance with the data sharing and joint submission provisions involves disclosure of CBI, parties may enter into a confidentiality agreement, may make available non confidential versions of the documents that contain CBI, or may appoint an independent third party to gather the information and prepare the registration dossier.

When this is not deemed sufficient, a registrant can opt-out for some individual endpoints and submit the robust study summaries, in his member dossier, so as to preserve his confidential information. However, the party opting out is still part of the joint submission and is still bound by his data sharing obligations under REACH.

## 9.6 PROTECTION OF CBI IN THE SUBMISSION OF THE REGISTRATION DOSSIER

When submitting a registration dossier to ECHA, the registrants must identify the information they consider confidential, as per Article 119, and for which they request non disclosure on the ECHA website.

NB: Information which is covered by REACH Article 119(1) cannot be claimed as confidential and any such claims will be disregarded. The information covered by REACH Article 119(1) will always be made publicly available on the ECHA website, in accordance with REACH Article 77(2)(e).

In accordance with Article 10(a)(xi), the request to keep information confidential must be accompanied with a justification as to why the publication of such information could be harmful.

This applies to:

- Information which is covered by REACH Article 119(2);

- Information for which confidentiality was previously granted under Directive 67/548/EEC- for this previous notifiers need to update their dossier indicating which information they wish to keep confidential;

- Any information claimed as confidential which is not covered by REACH Articles 119(1) and (2): in this case the justification may be a short sentence expanding on the confidentiality claim flag type – 'CBI', 'IP' or 'No PA' (e.g. CSR).

For more details, please consult the Data Submission Manual on "Confidentiality Claims" available at http://www.echa.eu/web/guest/support/dossier-submission-tools/reach-it/data-submission-industry-user-manuals. To assist registrants a standard justification template has been made available at the same location. Note also that for confidentiality claims for an IUPAC name (which have not been previously granted under Directive 67/548/EEC) an adequate public name must also be provided, as described in the Data Submission Manual on "How to derive a Public Name for a substance for use under the REACH Regulation", available at the same location.

# ANNEX 1 Data exchange form

| DATA EXCHANGE FORM | | |
|---|---|---|
| Name of legal entity | | |
| Contact name | | |
| Contact details | | |
| Identity of substance | | |

| Test number | Annex (REACH) | Information requirement | Rating | Data availability | | | | |
|---|---|---|---|---|---|---|---|---|
| | | | Estimated Klimisch rating | Complete study report owned by my company | My company has access to complete study report | Reference to data in open literature | Language of the report | Identity of substance for read across |
| *Phys.-chem.* | | | | | | | | |
| 7.1 | VII | State of the substance at 20° C and 101,3 kPa | | | | | | |
| 7.2 | VII | Melting/freezing point | | | | | | |
| 7.3 | VII | Boiling point | | | | | | |
| 7.4 | VII | Relative density | | | | | | |
| 7.5 | VII | Vapour pressure | | | | | | |
| 7.6 | VII | Surface tension | | | | | | |
| 7.7 | VII | Boiling point | | | | | | |
| 7.8 | VII | Partition coefficient n-octanol/water, flask shake method | | | | | | |
| 7.9 | VII | Flash-point | | | | | | |
| 7.10 | VII | Flammability, liquids | | | | | | |
| 7.11 | VII | Explosive properties | | | | | | |
| 7.12 | VII | Auto-ignition temperature for liquids and gases | | | | | | |
| 7.13 | VII | Oxidizing properties | | | | | | |
| 7.14 | VII | Granulometry (particle size distribution) | | | | | | |
| 7.15 | IX | Stability in organic solvents and identity of relevant degradation products | | | | | | |
| 7.16 | IX | Dissociation constant | | | | | | |
| 7.17 | IX | Viscosity | | | | | | |

| *Mammalian tox.* | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 8.1. | VII | skin irritation (indicate if in vitro) | | | | | | |
| 8.2. | VII | eye irritation (indicate if in vitro) | | | | | | |
| 8.3.1 | VII | Skin sensitisation | | | | | | |
| 8.4.1. | VII | In vitro gene mutation study in bacteria | | | | | | |
| 8.4.2. | VIII | In vitro cytogenicity study in mammalian cells | | | | | | |
| 8.4.3. | VIII | In vitro gene mutation study in mammalian cells | | | | | | |
| 8.4.4. | VIII | Other in vivo mutagenicity test: micronucleus test (OECD 474) or UDS assay (OECD 486) | | | | | | |
| 8.5.1. | VII | Acute toxicity, oral route (OECD 420, 423 or 425) | | | | | | |
| 8.5.2. | VIII | Acute toxicity, inhalation | | | | | | |
| 8.5.3. | VIII | Acute toxicity, dermal route | | | | | | |
| 8.6.1.a/b/c | VIII | Short-term repeated dose toxicity study in rats (28 days), oral/dermal/ inhalation | | | | | | |
| 8.6.2.a/b/c | IX | Sub-chronic toxicity study (90-day) in rats, oral/dermal/inhalation | | | | | | |
| 8.6.3. | X | Chronic toxicity (12 months or longer), rats (Exposure/use driven) | | | | | | |
| 8.7.1.a | VIII | Screening for reproduction/developmental toxicity, rats | | | | | | |
| 8.7.2.a | IX | Developmental toxicity study, rats, | | | | | | |
| 8.7.2.b | IX | Developmental toxicity study, rabbits, | | | | | | |
| 8.7.3/4.a | IX - X | One-generation reproduction toxicity study (enhanced) | | | | | | |
| 8.7.3/4.b | IX - X | Two-generation reproduction toxicity study | | | | | | |
| 8.8.1. | VIII | Assessment of toxicokinetic behaviour (based on required studies) | | | | | | |
| 8.9. | X | Carcinogenicity study/combined chronic toxicity, rats (Exposure/use driven) | | | | | | |
| | | Other studies (to be listed below): | | | | | | |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| *Ecotox. /env. fate* | | | | | | | | |
| 9.1.1. | VII | Short-term toxicity testing on Daphnia | | | | | | |
| 9.1.2. | VII | Growth inhibition study on algae | | | | | | |
| 9.1.3. | VIII | Short-term toxicity testing on fish | | | | | | |
| 9.1.4. | VIII | Activated sludge respiration inhibition testing | | | | | | |
| 9.1.5. | IX | Long-term toxicity testing on Daphnia, 21-days | | | | | | |
| 9.1.6.1 | IX | Fish early-life stage (FELS) toxicity test | | | | | | |
| 9.1.6.2 (or) | IX | Fish short-term toxicity test on embryo and sac-fry stages | | | | | | |
| 9.1.6.3 (or) | IX | Fish, juvenile growth test | | | | | | |
| 9.2.1.1.a | VII | Ready biodegradability - Modified Sturm test | | | | | | |
| 9.2.1.1.b | VII | Ready biodegradability - Closed bottle test | | | | | | |
| 9.2.1.2. | IX | Simulation testing on ultimate degradation in surface water | | | | | | |
| 9.2.1.3. | IX | Soil simulation testing (for substances adsorbing to soil): | | | | | | |
| 9.2.1.4. | IX | Sediment simulation testing (for substances adsorbing to sediment) | | | | | | |
| 9.2.1.5. | | Confirmatory testing on biodegradation rates (aerobic and/or anaerobic) | | | | | | |
| 9.2.2.1. | VIII | Hydrolysis as a function of pH and identification of degradation products | | | | | | |
| 9.2.3. | IX | Identification of degradation products | | | | | | |
| 9.3.1. | VIII | Adsorption/desorption screening study (HPLC method) | | | | | | |
| 9.3.2. | IX | Bioconcentration in (one) aquatic species, preferably fish | | | | | | |
| 9.3.3. | IX | Further studies on adsorption/desorption | | | | | | |
| 9.3.4. | X | Further environmental fate and behaviour studies | | | | | | |
| 9.4.1. | IX | Short-term toxicity to invertebrates | | | | | | |
| 9.4.2. | IX | Effects on soil micro-organisms | | | | | | |
| 9.4.3. | IX | Short-term toxicity to plants | | | | | | |
| 9.4.4. | X | Long-term toxicity testing on invertebrates | | | | | | |
| 9.4.5. | | Long-term toxicity testing on soil invertebrates other than earthworms | | | | | | |
| 9.4.6. | X | Long-term toxicity testing on higher plants | | | | | | |
| 9.5. | X | Long-term toxicity to sediment organisms | | | | | | |
| 9.6. | X | Long-term or reproductive toxicity to birds | | | | | | |
| | | Other studies (to be listed below): | | | | | | |

| *Exposure Data* | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | emissions to water | | | | | | |
| | | emissions to land | | | | | | |
| | | emissions to air | | | | | | |
| | | occupational exposure in manufacture | | | | | | |
| | | occupational exposure in use | | | | | | |
| | | consumer exposure | | | | | | |
| | | end of life | | | | | | |

# ANNEX 2 List of reference documents mentioned in the guidance

| Reference document mentioned in the Guidance | Relevant sections and topic in the Guidance on data sharing |
|---|---|
| Guidance on Registration | 1.1.2 - Definition of phase-in and non phase-in status<br>3.1.1 – Duties and role of OR and definition of legal entity<br>3.1.3 - Details on who is responsible for registration<br>3.1.7 – Calculation of tonnage band<br>3.3.3.5 – Consideration of information requirements for phase-in substances<br>4.3 – Information on legal entities who could inquiry<br>4.7.2 - Consideration of information requirements for non-phase-in substances |
| IUM on Online pre-registration | 1.1.4, 3.1.5 - Technical details on how to (late)pre-register |
| IUM on Pre-SIEF | 1.1.4, 3.1.4, 3.1.8, 3.2.4, 3.2.5 - Pre-SIEF operation, pre-SIEF page and SIEF formation |
| DSM on How to submit a CSR as part of a joint submission | 1.2.7 – Information to be jointly submitted voluntarily or mandatorily. |
| REACH-IT FAQs | 3.1.5 - Manage information submitted for pre-registration |
| Fact sheet SIEF Formation and Data sharing | 3.1.6 - Establishment of a SIEF<br>3.2.1 - Pre-SIEF page and available information |
| Practical Guide on how to report read-across and categories | 3.2.7 – Use data on structurally related substances to fulfil data gaps |
| Guidance on IR/CSA | 3.3.3.4 – Evaluation of information for registration and chemical safety assessment purposes<br>3.3.3.7, 4.7.6 – Generation of new information on phase-in and non phase-in substances<br>6.4 – Information on CSR which may be jointly or individually submitted |
| IUM on Joint submission | 3.3.3.8 – Preparation of joint submission and sharing of costs |
| DSM on How to prepare and submit a Classification and Labelling Notification using IUCLID | 3.3.4 – Classification and Labelling and joint submission |
| Guidance on the Application of the CLP criteria | 3.3.4 - Classification and Labelling and joint submission |
| Q&As on Data sharing and related disputes | 3.4.2 – Data sharing disputes |
| Practical Guide on How to report data waiving | 3.3.3, 4.9.2 – Selection of available and relevant data and cost sharing discussion |
| Q&As on inquiry | 4.6 – Outcomes of an inquiry |
| DSM on How to complete a Technical Dossier for Registration and PPORD Notifications | 4.6.1 – Migration from IUCLUD 4 and SNIFF to IUCLID 5 for registration purposes. |
| IUM on How to pass Business Rules | 6.1 – Submission of joint dossier |
| DSM on Confidentiality clams | 9.6 – Protection of CBI |

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