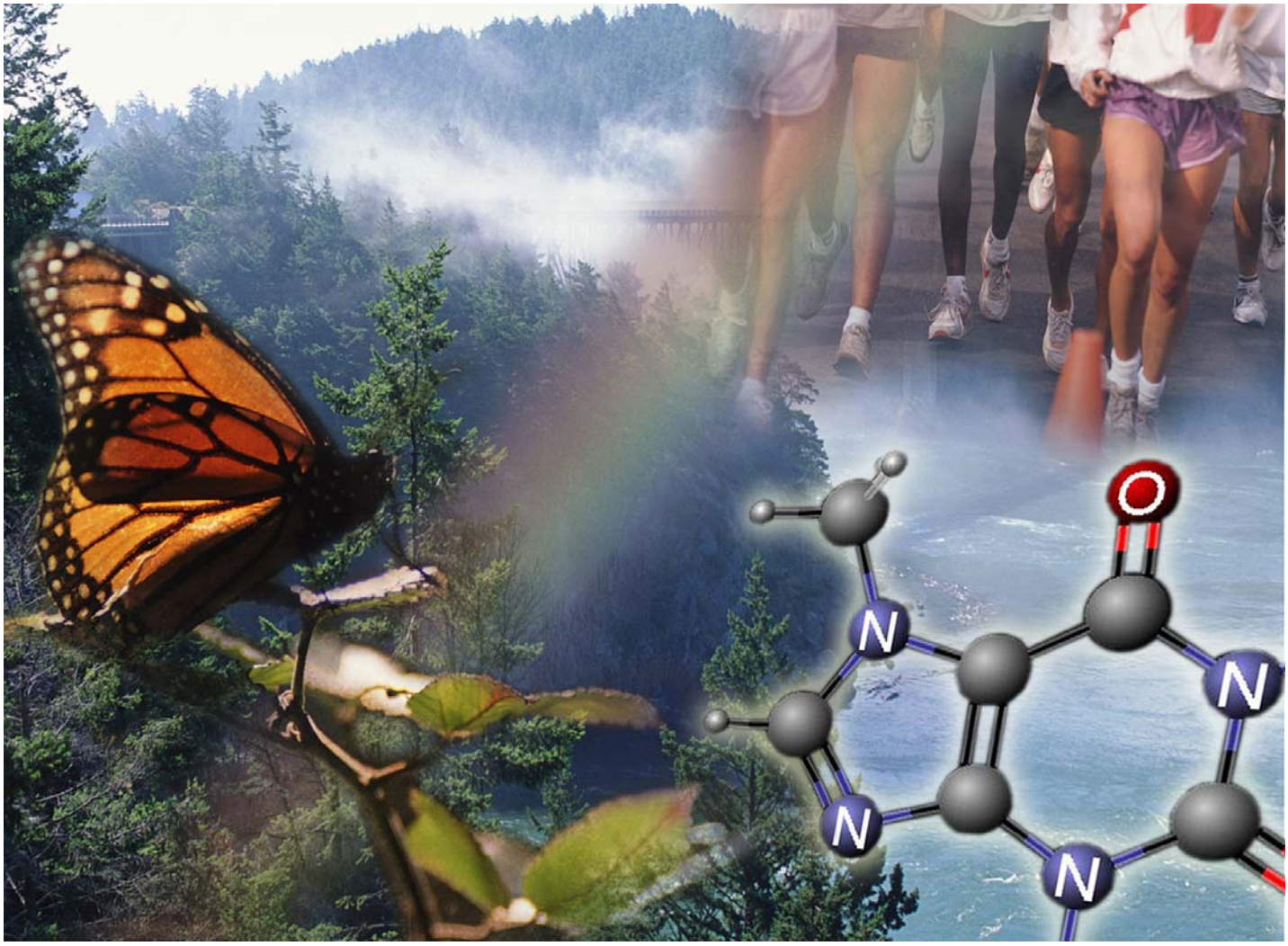
# Guidance on data sharing




## September 2007

Guidance for the implementation of REACH

## LEGAL NOTICE

This document contains guidance on REACH explaining the REACH obligations and how to fulfil them. However, users are reminded that the text of the REACH regulation is the only authentic legal reference and that the information in this document does not constitute legal advice. The European Chemicals Agency does not accept any liability with regard to the contents of this document.

# PREFACE

This guidance document describes 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 for 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 within the REACH Implementation Projects (RIPs) lead by the European Commission services, involving all stakeholders: Member States, industry and non-governmental organisations. These guidance documents can be obtained via the website of the European Chemicals Agency (http://echa.europa.eu/reach_en.asp). 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 Corrigendum to 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 (OJ L 396, 30.12.2006)

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**ABBREVIATIONS**

| | |
|---|---|
| CAS | Chemical Abstracts Service |
| CBI | Confidential Business Information |
| CMR | Carcinogen, Mutagen and Reprotoxic |
| DNEL | Derived No-Effect level |
| DU | Downstream User |
| ECHA | European Chemicals Agency |
| ECJ | European Court of Justice |
| EINECS | European Inventory of Existing Commercial Chemical Substances |
| ELINCS | European List of Notified Chemical Substances |
| EPA | Environmental Protection Agency |
| EU | European Union |
| FELS | Fish Early Life Stage |
| GLP | Good Laboratory Practices |
| HPLC | High Pressure Liquid Chromatography |
| HPV | High Production Volume |
| ICCA | International Council of Chemical Associations |
| IUCLID | International Uniform Chemical Information Database |
| IUBMB | International Union of Biochemistry and Molecular Biology |
| IUPAC | International Union of Pure and Applied Chemistry |
| MERAG | Metal Risk Assessment Guidance |
| OECD | Organisation for Economic Co-operation and Development |
| PBT | Persistent Bioaccumulative Toxic |
| PNEC | Predicted No Effect Concentrations |
| QSAR | Quantitative Structure-Activity Relationship |
| REACH | Registration, Evaluation, Authorisation and restriction of Chemicals |
| RIP | REACH Implementation Project |
| RMM | Risk Management Measure |

| | |
|---|---|
| RSS | Robust Study Summary |
| SARs | Structure Activity Relationships |
| SDS | Safety Data Sheet |
| SEG | Stakeholder Expert Group |
| SIEF | Substance Information Exchange Forum |
| TGD | Technical Guidance Document |
| TRIPs | Trade Related Aspects of Intellectual Property Rights |
| UDS | Unscheduled DNA synthesis |
| UVCB | (substances of) Unknown or Variable composition, Complex reaction products or Biological materials |
| vPvB | Very Persistent and very Bioacccumulative |
| WTO | World Trade Organisation |

# 1 INTRODUCTION

## 1.1 Overview

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

Registration Obligation

After 1 June 2008, companies manufacturing or importing chemical substances in the EU in quantities of 1 tonne or more per year will be required to register them under REACH. Registration 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 a minimum the requirements set out in the relevant Annexes to REACH, and when this is not available, the generation of information, including testing. For substances manufactured or imported in quantities of 10 tonnes or more also a Chemical Safety Report has to be submitted. Specific mechanisms and procedures have been introduced by REACH to enable companies to share existing information before submitting a registration in order to increase the efficiency of the registration system, to reduce costs and to reduce testing on vertebrate animals.

Phase-In and Non Phase-In Substances

The Regulation sets out different procedures for registration and data sharing of “existing” (“phase-in”) substances and “new” (“non-phase-in”) substances. Phase-in substances are substances which are listed on the European Inventory of Existing Commercial Chemical Substances (EINECS), or that have been manufactured in the EU or countries that have acceded to the EU before 2004[2] but not (yet) placed on the EU market, at least once after 1 June 1992, or are so-called "no-longer polymers"[3] (and are commonly referred to as "existing" substances). Non phase-in substances can be broadly defined as the “new” substances. They include all substances that do not meet the definition of phase-in substance as given in the Regulation.

[2] An update to include Romania and Bulgaria is being prepared.

[3] A "No longer polymer" is a substance which was placed on the EU market between 18 September 1981 and 31 October 1993 inclusive, was considered as notified under Article 8 (1) of the 6th amendment of Directive 67/54/EEC (and hence did not have to be notified under that Directive), but which does not meet the REACH definition of a polymer (which is the same as the polymer definition introduced by the 7th amendment of Directive 67/548/EEC).

Transitional Regime for Registration

Phase-in substances that are pre-registered with ECHA will benefit from extended registration deadlines. Registration will nevertheless be required before the end of the (extended) registration deadline, as follows:

| *Substance properties/Yearly Volume* | *Deadline for Registration of Phase-In Substances* |
|---|---|
| CMR[4] ≥ 1 t/y<br>R 50-53[5] ≥ 100 t/y<br>Other substances ≥ 1000 t/y | 30 November 2010 |
| Other substances *≥ 100 t/y* | 31 May 2013 |
| Other substances *≥ 1 t/y* | 31 May 2018 |

Non phase-in substances that are manufactured or imported in quantities of 1 tonne or more per year, will have to be registered by the company before the start of its activities involving these substances. The same applies to phase-in substances that have not been pre-registered.

Pre-Registration

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 substances concerned. The period for pre-registration is from 1 June 2008 until 1 December 2008.

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 will still be able to benefit from the extended registration deadlines if they submit the pre-registration information to ECHA in accordance with the conditions of Article 28(6) of the REACH Regulation.

Pre-registration shall be made through the REACH IT system managed by ECHA.

By 1 January 2009, a list of all pre-registered substances and substances for which the available information is relevant for QSAR, grouping of substances and the read-across approach (identified by their EINECS and CAS and other identity codes) will be published on ECHA's website, together with the first envisaged registration deadline.

Early registration

Companies can opt for immediate registration from 1 June onwards. In order to do so there are two possibilities:

i) a company can decide to pre-register between 1 June 2008 and 1 December 2008 and register at any time before relevant deadlines. In this case, the company does not have to

[4] Classified as carcinogenic, mutagenic or toxic to reproduction, categories 1 and 2, in accordance with Directive 67/548/EEC.

[5] Classified as very toxic to aquatic organisms and may cause long-term adverse effects in the aquatic environment (R50-53) in accordance with Directive 67/548/EEC.

interrupt its activities related to the substance; nevertheless, it needs to make sure that the relevant rules for pre-registered substances, in particular Articles 28 to 30 (see Section 3.1) are respected.

ii) a company can also decide not to pre-register and to file an inquiry instead. In this case, the company must suspend manufacture or import between 1 June 2008 and the time a complete registration dossier has been submitted. In addition, it has to be noted that the three week waiting period after registration must be respected before manufacturing or importing can start again (see Sections 6.4 and 6.5).

In both cases this 'early registrant' will be part of or will have to align its registration dossier with the joint submission. He may also opt-out for some or all information and give a justification according to Article 11(3).

Substance Information Exchange Forum (SIEF)

REACH provides for the formation of a SIEF to share information among Manufacturers and Importers of the same "phase-in" substances, as well as allowing participation of Downstream Users and other stakeholders to prevent duplicate testing, especially testing on vertebrate animals.

As a general rule, there shall be one SIEF for each phase-in substance. In a first step, Pre-Registrants of substances with the same identifiers in the list of pre-registered substances will have to establish whether their substances are indeed the same for the purpose of SIEF formation and registration. This should be done on the basis of the criteria set out in Guidance on substance identification. Once agreement on the sameness of the substance has been found, SIEFs will be formed.

Other stakeholders, such as Manufacturers and Importers of substances in quantities of less than one tonne, Downstream Users and Third Parties who hold information on the substances appearing on the list (hereinafter "Data Holders") will then be able to submit relevant information on a voluntary basis with the view to providing their information for fair recompense in the SIEF for that substance. Registrants of the same substance that have registered their substances before the extended registration deadlines are mandatory members of the SIEF.

The aims of the SIEF are to facilitate data sharing for the purposes of Registration, and agree on the classification and labelling of the substances concerned. In addition, the SIEF may also be a starting point or a suitable platform for participants to organize among themselves the mandatory joint submission of data, as provided for in Article 11 of REACH, including as an option the exchange of the data needed to perform the Chemical Safety Assessment (CSA), drafting the Chemical Safety Report (CSR) and agreeing on guidance on safe use that may be part of this joint submission.

SIEF and Forms of Cooperation / Consortia

Pre-Registrants in a SIEF are free to start organizing themselves as they see fit to carry out their obligations under REACH. They can use different forms of cooperation to do so, including the creation of a "consortium". REACH however does not require SIEF Participants to form a consortium and a consortium can be formed between SIEF Participants (or participants of different SIEFs and other parties) for data sharing purposes and/or to meet other objectives under REACH. Likewise, it is possible that a SIEF consists of more than one consortium and a number of independent parties.

Joint Submission of Data

In addition to required aspects (data sharing and classification and labelling), the SIEF members may also use the contacts they have made with other potential registrants to organize among themselves the mandatory joint submission of data, as provided for in Article 11 and 19 of REACH, including as an option the exchange of the data needed to perform the Chemical Safety Assessment (CSA), drafting the Chemical Safety Report (CSR) and agreeing on guidance on safe use that may be part of this joint submission.

Inquiry prior to registration

For non-phase-in substances, but also for phase-in substances that have not been pre-registered by a potential registrant (including those substances that are intended to be registered before the end of pre-registration), a duty to inquire applies. This inquiry process requires Potential Registrants to inquire from ECHA whether a registration has already been made for the same substance. This is to ensure that data are shared by the relevant parties. In case of the same substance joint submission of data according to Article 11 and 19 applies.

## 1.2 Objectives of the Guidance Document on Data Sharing

The present Guidance Document aims to provide practical guidance on data sharing for Phase-In and Non Phase-In Substances under REACH.

It includes a detailed description of the following processes:

- The Pre-Registration Process;
- The Formation of SIEFs;
- Data Sharing within SIEF;
- Data Sharing for Non Phase-In Substances;
- Joint Submission of Data and Opt Out.

It also contains practical recommendations to help companies meet their obligations and achieve their objectives.

Specific guidance is also provided on:

- Cost sharing mechanisms;
- The protection of Confidential Business Information (CBI);
- Competition Law, and
- Forms of Co-operation, including Consortia.

**Flow Charts** are provided in **Annex 1** to describe each specific process.

**Examples** of the relevant pre-registration and data sharing processes are provided in **Annex 2**.

A **schematic overview** of the above processes for phase-in and non-phase-in substances is provided below:

Chart I
General overview of data sharing process: phase in substances

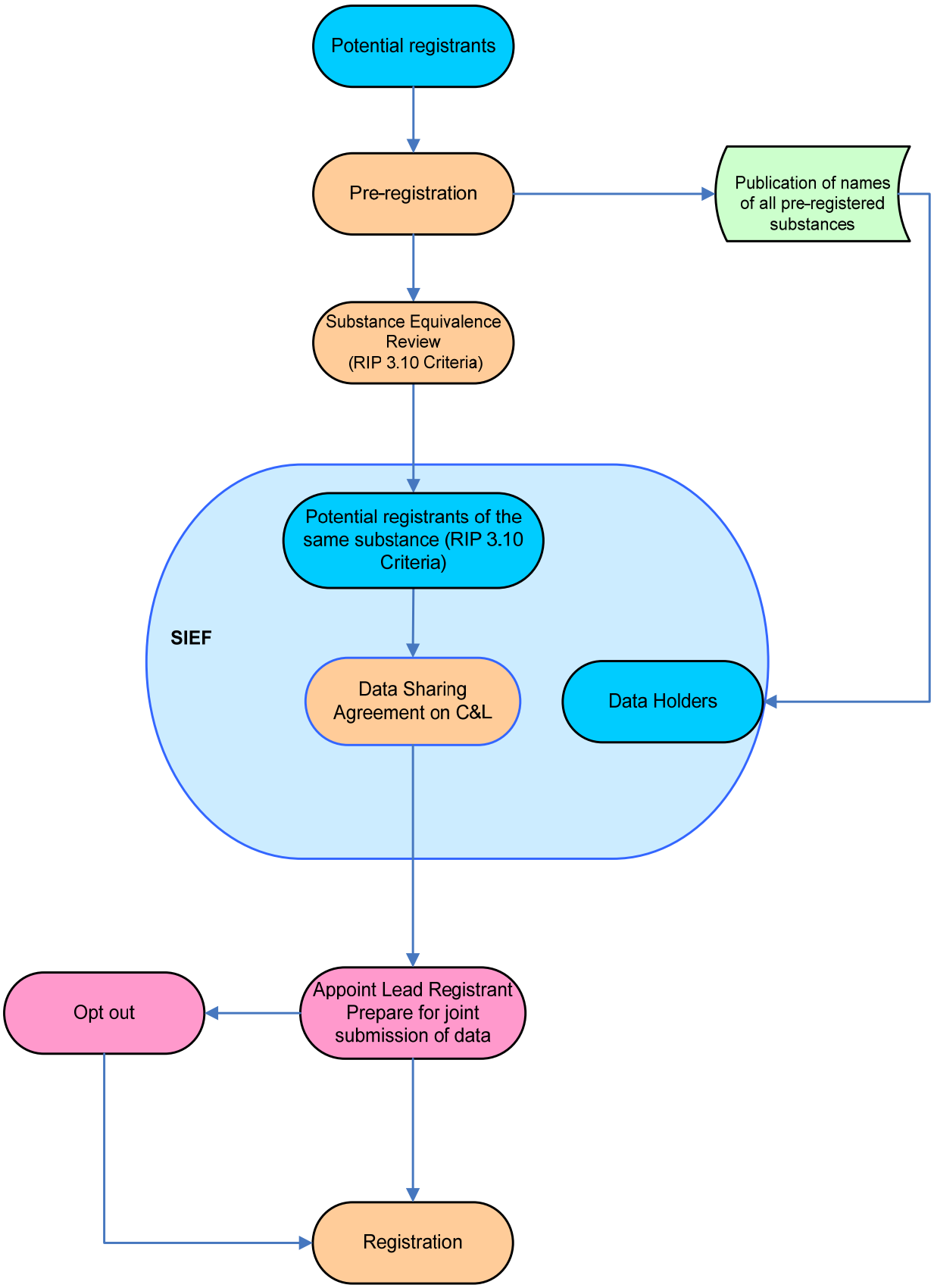
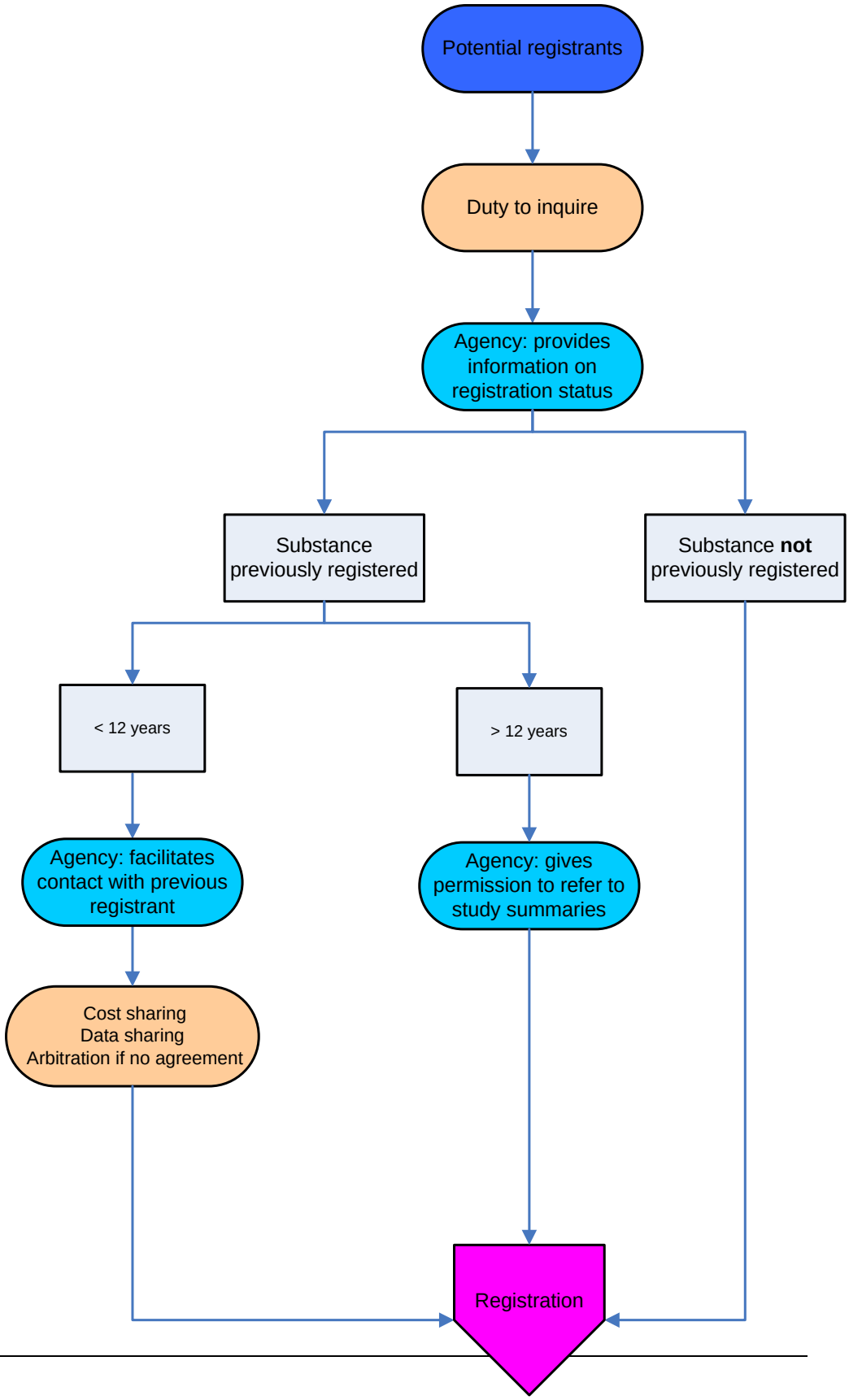


Chart II
General overview of data sharing process: non-phase in substances



## 1.3 Link to the other REACH guidance and processes

This guidance is not intended to be used as stand alone guidance. Potential Registrants and Data Holders are encouraged to take into account other relevant Guidance Documents, in particular the Guidance on registration.

For detailed methodological guidance on how to complete a chemical safety report (CSA), including guidance on how to read across, identify and measure environmental fate and physico-chemical properties, and make human health and environmental assessments, the Guidance on the Chemical Safety Report should be consulted.

Guidance needed for fulfilling 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 is covered in the Guidance on information requirements.

The duties of Downstream Users are covered by Guidance for Downstream Users.

Finally and most importantly, when assessing the identity of the substances, Potential Registrants should consult the Guidance on substance identification carefully.

# 2 LEGAL FRAMEWORK: RELEVANT LEGAL PROVISIONS

## 2.1 Pre-Registration and Data sharing

The rules on data sharing and avoidance of unnecessary testing are provided in Title III of REACH.

As spelled out in Article 25, the objective of these rules is to avoid vertebrate animal testing so that it is carried out as the last resort. As a general rule REACH requires the sharing of information on the basis of a compensation mechanism. However, after 12 years from the date when such studies were submitted, the study summaries and robust study summaries provided in support of a registration dossier shall be freely available for a subsequent registration.

The rules for Non-phase-in substances and non-pre-registered substances are laid down in Articles 26 and 27.

Article 26 regulates the inquiry phase as follows:

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

26(2) – communication in case of substances non-previously registered;

26(3) – communication of name and contact details of previous registrant and potential registrant; communication in case of previously registered substance

26(4) – communication in case of several Potential Registrants making an inquiry about the same substance.

Article 27 organizes the data-sharing process, as follows:

Article 27(1) – request of information from previous registrant;

Article 27(2) – obligation to make every effort to reach agreement;

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

Article 27(4) – communication of information in case of agreement;

Article 27(5) –communication to ECHA in case of disagreement;

Article 27(6) – data-and cost sharing rules in case of disagreement.

The rules for Phase-in substances are spelled out in Title III, Chapter 3 of REACH.

The definition of phase-in substance is given in Article 3(20).

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(4) - publication of the list of pre-registered substances and substances for which the available information is relevant for QSAR, grouping of substances and the read-across approach;

28(6) – pre-registration period for first time manufacture or import;

28(7) – submission of information on pre-registered substances by Data Holders.

Articles 29 and 30 organize the formation and functioning of *SIEF*, as follows:

Article 29 – Substance Information Exchange Fora:

29 (1) – participants in the SIEF;

29 (2) – aim of each SIEF;

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

Article 30 – Sharing of data involving tests (requiring agreement on cost-sharing principles):

30 (1) – inquiries by SIEF Participants before testing is carried out;

30 (2) – performance of new studies;

30 (3 to 6) – procedure in case of refusal to share animal and non-animal studies.

Article 11 provides the obligation for Potential Registrants of the same substance to jointly submit data and the list of cases in which opt out from joint submission of data is possible.

Article 19 sets out similar provisions for isolated intermediates.

Article 53 sets out rules for registrants and Downstream Users how to perform a test and share data and costs as a result of a decision taken under the evaluation provisions.

## 2.2 Competition law

In addition to compliance with the provisions of the REACH Regulation, operators shall ensure that they comply with other applicable rules and regulations. This applies in particular to Community competition rules, as specified in recital 48 of the REACH Regulation[6].

As discussed in Chapter 9 of the present Guidance Document, in the context of REACH and information exchange, the most relevant provision is Article 81 of the EC Treaty, which prohibits agreements and practices that restrict competition. The provisions of Article 81 and 82 of he EC Treaty (the latter prohibiting abuses of dominant position) are reproduced in Annex 6 to the present Guidance Document.

[6] Recital 48 specifies that *"This Regulation should be without prejudice to the full application of the Community competition rules"*

# 3 PRE-REGISTRATION

Pre-registration is the process whereby Manufacturers, producers/importers of articles with an intended release and Importers of 'phase-in substances' have to submit a brief set of information to ECHA in order to benefit from the extended registration deadlines.

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

## 3.1 Is pre-registration of phase-in substances obligatory?

No, it is only obligatory if companies want to benefit from extended registration deadlines. Phase-in substances can also be registered immediately.

However, the obligation to register phase-in substances applies from 1 June 2008, unless they are pre-registered within the pre-registration deadlines. In such a case, companies need to follow the procedure of article 26 and inquire prior to registration. As inquiry will only be possible from 1 June 2008, this means that companies registering without pre-registration will need to suspend their activities involving the substance until the inquiry process has been completed and a complete registration dossier has been submitted. This case is described in more detail in Sections 6.4 and 6.5 where such a potential registrant is referred to as the "early registrant".

If a company decides to register between 1 June 2008 and 1 December 2008 without interrupting its activities, it can do so but needs to pre-register before 1 December 2008 and respect the rules of Articles 28 to 30.

## 3.2 What are the benefits of pre-Registration?

Pre-registration allows Potential Registrants to benefit from extended registration deadlines.

More specifically:

1) Pre-registration allows companies to continue manufacturing/ importing/ using Phase-In-substances until:

| *Substance properties/Yearly Volume* | *Deadline for Registration of Phase-In Substances* |
|---|---|
| CMR[7] ≥ 1 t/y<br>R 50-53[8] ≥ 100 t/y<br>Other substances ≥ 1000 t/y | 30 November 2010 |
| Other substances *≥ 100 t/y* | 31 May 2013 |
| Other substances *≥ 1 t/y* | 31 May 2018 |

[7] Classified as carcinogenic, mutagenic or toxic to reproduction, categories 1 and 2, in accordance with Directive 67/548/EEC.

[8] Classified as very toxic to aquatic organisms and may cause long-term adverse effects in the aquatic environment (R50-53) in accordance with Directive 67/548/EEC.

2) Pre-registration also gives companies additional time to organize the collection and selection of available data, the sharing of existing data, and the collective generation of missing information, as described in Chapters 4 and 5 of these Guidelines.

### 3.3 Is there an obligation to register pre-registered substances?

Pre-registration does not have to be followed by registration (e.g. if, before the registration deadline, the potential registrant decides 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). The pre-registrants should bear in mind, however, that other SIEF members may request information required for purposes of registration and, if they are in possession of such information, they will have to supply it.

### 3.4 Who can pre-register?

Each natural and legal person who would be required to register a phase-in substance after 1 June 2008 may pre-register that substance. These persons include:

- Manufacturers and Importers of phase-in substances on their own or in preparations in quantities of 1 tonne or more per year, including intermediates;
- 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 where the substance(s) will be imported in quantities of 1 tonne or more per year.

Non-EU Manufacturers include natural or legal persons who:

- manufacture a substance on its own, in preparations or in articles that is imported into the Community; or
- formulate a preparation that is imported (by an EU Importer) into the Community; or
- produce an article containing substances intended to be released that is imported (by an EU Importer) into the Community.

Non-EU Manufacturers cannot pre-register/register directly the substances that are exported in the EU; either registration is done by Importers or, alternatively, non-EU Manufacturers may be represented by a natural or legal person located in the EU territory, the "Only Representative".

*Only Representatives*

Only Representatives are natural or legal persons 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 Only Representative is appointed, the non-EU manufacturer has the obligation to inform the Importer(s) within the same supply chain (the - direct and indirect - customers of the non-EU Manufacturers) of the appointment. Following such communication the Only Representative takes up the role of the EU Importers, fulfils their registration obligations. He also has to keep available and up-to-date information on quantities imported and customers sold to (including their uses), as well as all information required to meet the obligation to communicate information down the supply chain.

When an Only Representative 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 exported into the EU.

An Only Representative can represent several non-EU manufacturers of a substance.

When an Only Representative is appointed, the Importer(s) will have the status of downstream user and will have to comply with the applicable obligations under REACH. For competition law related aspects please see Chapter 9 of the present Guidance Document.

For guidance on the Only Representative see also the Guidance on registration.

*Legal entity*

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 group, each legal entity has to pre-register separately. The Guidance on registration, provides additional guidance on who is responsible for registration.

**Important:** Pre-registration must be done by each legal entity that is required to register. This means that if a holding company is composed of different legal entities in Europe, each legal entity must pre-register the phase-in substances that they produce or import. Manufacturing sites that do not have legal personality are not required to pre-register because they do not have the obligation to register.

*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 pre-register (as registration is not required). However, they can do so based on their intention to manufacture or import the substance in quantities of 1 tonne or more in the future. It is important to note that companies that exceed the 1 tonne threshold after 1 December 2008 are still entitled to pre-register if they (on their own or via the use of a Third Party Representative) submit the relevant information to ECHA within 6 months from the date where the 1 tonne threshold is first exceeded and provided this is at least one year before the relevant (extended) registration deadline.

### 3.5 Is there a deadline for pre-registration?

Pre-registration information has to be submitted to ECHA between 1 June 2008 and 1 December 2008 (inclusive). There is therefore a single pre-registration period for all phase-in substances for all parties identified in Section 3.3 above. However, in certain cases pre-registration may be submitted later by first time Manufacturers or Importers as described in Section 3.6 below.

### 3.6 First-time Manufacturers or Importers

A first-time Manufacturer or Importer is a Manufacturer or Importer who manufactures or imports a substance in quantities of 1 tonne or more for the first time after 1 December 2008. To benefit from the transitional period as described in Section 3.2, the first-time manufacturer/importer (see Article 28.6) must pre-register (1) at the latest six month after its manufacturing or import exceeds the one-tonne threshold, and (2) at least 12 months before the relevant deadline for registration. First-time Manufacturers or Importers will therefore have to submit their pre-registration before 30 November 2009, 31 May 2012 or 31 May 2017, whichever is relevant in view of their tonnage thresholds. Manufacture or import for the first time means, manufacture or import for the first time from the entry into force of REACH.

### 3.7 What if the deadline for pre-registration is not met?

If a company fails (or does not wish) to pre-register within the applicable deadline (i.e. in most cases 1 December 2008), it will have to suspend its activities involving the substances concerned and register them without delay. In addition it should be remembered that in this case the registrant will also have to inquire at the ECHA if a registration for the substance has been made. All manufacturing, placing on the market and use[9] of such substances between the start of the pre-registration deadline (i.e. in most cases 1 June 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. Activities involving the substances concerned can then only be resumed three weeks after the submission date of the a complete registration dossier.

### 3.8 How to pre-register a substance?

Pre-registration takes place when the company has submitted electronically to ECHA the required information on a substance. This information includes:

- The name(s) of the substance specified in section 2 of Annex VI, i.e.
    - the names in the International Union of Pure and Applied Chemistry (IUPAC) nomenclature or other international chemical name(s);
    - other names (usual name, abbreviation and trade name,)
    - European Inventory of Existing Commercial Chemical Substances (EINECS) number (if available and appropriate);
    - Chemical Abstract Service (CAS) name and CAS number (if available);
    - other identity code (if available);
- The name and address of the pre-registrant and the name of the contact person and, where appropriate, the name and address of a Third Party Representative whom the pre-registrant has selected to represent him for all the proceedings involving discussions with other Manufacturers, Importers and Downstream Users (Article 4);
- The envisaged deadline for registration and tonnage band;

[9] It has to be noted that this does not cover the use of stocks.

- The name(s) of other substance(s) for which the available information is relevant for performing adaptations to the testing requirements, i.e. use of results from (Q)SAR models (Section 1.3 of Annex XI) and read-across approach.[10]

- Optionally, the pre-registrant can indicate whether he is willing to act as "facilitator" in the pre-SIEF discussions – See Sections 3.9 below and 4.5.2.

Pre-registration does not include information on the composition of the substance.

The pre-registration can be done in two ways:

1. by direct encoding of the information on the REACH-IT website (On-line pre-registration)
2. by submission of a 'bulk' pre-registration prepared separately on an specified computer file format required by ECHA and uploaded at the moment of the On-line pre-registration.

A bulk pre-registration allows Pre-Registrants to submit one (or more) file(s) with the pre-registration information for multiple substances. The file has to be in accordance with a certain structure which will be specified and published by ECHA.

REACH-IT will also provide a function to allow parent companies or head offices to submit pre-registration for several legal entities belonging to the same company group ("Super User") provided that all legal entities are informed by the parent company or head office and have access to the information submitted in the pre-registration. Nevertheless, even if this function is used, the pre-registration remains specific for each legal entity.

### 3.9 How to take account of substance identification for pre-registration?

Whenever the *same* substance needs to be registered by more than one manufacturer or importer, Article 11 (or Article 19 for isolated intermediates) of REACH applies and parts of the data need to be submitted jointly. Importantly, this applies both to non phase-in substances as well as phase-in substances. 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 manufacture or import the *same* substance is a two step process:

- In a first step, Manufacturers and Importers need to establish the identity codes under which they pre-register or register the substance. This process is described in this chapter.

- In a second step, Potential Registrants who pre-registered their substance(s) under the same identity code need to establish whether their substances are the same for the purpose of SIEF formation and joint submission and verify whether their substance has not also been pre-registered or registered under other identity codes. This step is concluded by an agreement on the sameness of the substance and the establishment of a SIEF. Guidance on this process can be found in Section 4.5.

10 Additional information on these issues is provided in RIP 3.3

The substance identity often corresponds to an existing EINECS or CAS entry or similar identification code but there are also cases where one EINECS entry covers several substances or where several EINECS entries correspond to one substance. There are also phase-in substances where no EINECS/CAS entries or other identification codes exist (in particular cases related to Art. 3(20) (b) and (c)).

The Guidance on substance identification gives guidance on how substance identity can be established based on the composition and/or the chemistry of the substance. When relevant in dossier and substance evaluation, ECHA will apply the guidance mentioned above to check the identity of a substance and the 'sameness' of several substances.

**Substance identification essentials**

A substance is defined in REACH as “a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition.”

The substance definition in REACH is identical to the definition of a substance that is currently used under the 7th Amendment of the Dangerous Substances Directive (Directive 92/32/EEC amending Directive 67/548/EEC). In both cases, the definition goes beyond a pure chemical compound defined by a single molecule.

The objective of the "Guidance for identification and naming of substances under REACH" (ECHA, June 2007) is to give clear guidance for Manufacturers and Importers on identifying and recording the identity of a substance within the context of REACH. As an important key element of substance identification 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.

The approach to identify a substance depends on the substance type. Substances can be divided into two main groups:

1. “Well defined substances”: Substances with a defined qualitative and quantitative composition that can be sufficiently identified based on the identification parameters of REACH Annex IV section 2. Rules for identification and naming differ for “well defined substances” with one main constituent (in principle >80%) and for substances with more than one main constituent (in principle each constituent >10%): the so-called “mono-constituent” versus “multi-constituent” substances.

2. “UVCB substances”: Substances of Unknown or Variable composition, Complex reaction products or Biological materials. These substances cannot be sufficiently identified based on the composition like it is the case for well-defined substances. For the various substance types under the umbrella of “UVCB”, different identification and naming rules are described in the "Guidance for identification and naming of substances under REACH" (ECHA, June 2007).

bound (e.g. read-across). However, REACH does not give the possibility to register different substances in one (joint) registration.

*Establishment of identifiers for pre-registration*

The information required by REACH at pre-registration does not include information on the composition of the substance. Therefore, the correctness of identifiers used for pre-registration is very important to facilitate the further steps in data sharing. REACH requires Pre-Registrants to submit identifiers for the substances (e.g. EINECS number, CAS number). The alignment of an EINECS number or CAS numbers to a substance has been done according to different working practices during the years. The harmonisation of these practices is reflected in the Guidance on substance identification, which gives guidance on how a substance can be identified.

Because the first step to establish sameness is to pre-register under the correct identity code(s), it is strongly recommended that companies read carefully the Guidance on substance identification prior to submit the pre-registration information.

In order to avoid typing errors and wrong entries, a computer-based pre-registration system has been put in place as part of REACH IT. Upon entering the EINECS (or CAS) number in a pre-registration, the corresponding EINECS entry description will automatically appear in the corresponding field. However, the submission of the identifiers does not include information on the actual composition of the substance. In some cases this could lead to the fact that, although several Potential Registrants have pre-registered the same identifiers (e.g. the same EINECS number), this does not mean that they will be registering the "same" substance (because the EINECS entry describes several substances).

Mono-constituent substances and UVCB substances can be registered using the EINECS number as the proper identifier. In cases of errors in the EINECS entries, sufficient information to proper identify the substance can be given at pre-registration. In some cases the EINECS entries of UVCB substances are defined very broadly. Also in these cases it is recommended to provide additional information (e.g. IUBMB number for enzymes) to improve the process steps following pre-registration (i.e. SIEF formation and Joint submission).

For multi-constituent substances ("reaction mass of A and B") the result of following the approaches as defined in the Guidance on substance identification is the use of more than one EINECS or CAS number to identify one single substance. This will be accepted.

In practice this means that a multi-constituent substance is pre-registered using more than one identifier (usually multiple EINECS numbers) for the different constituents.

**Importantly**, the REACH provisions on data sharing and joint submission of data will apply between those companies pre-registering the "same" phase-in substances. A first step to establish sameness is pre-registration under the correct identity code. It is therefore highly recommended that companies verify the EINECS-entry related to their substance for pre-registration purposes using the Guidance on substance identification.

### 3.10 SIEF Formation Facilitator

In order to initiate and conduct discussions after pre-registration, and facilitate the exchange of the information and data required to form a SIEF and once a SIEF is formed, REACH IT will allow Pre-Registrants to volunteer to be "SIEF Formation Facilitator" by identifying this at pre-registration. Additional guidance on the possible role of the facilitator is provided in Section 4.5.2 below.

### 3.11 How to establish the first envisaged registration deadline and the tonnage band for pre-registration?

Each potential registrant has to indicate during the pre-registration period the envisaged registration deadline and tonnage band, while the actual amount of production and/or import will define in the end the relevant registration deadline and obligations. The envisaged yearly quantity shall be calculated per calendar year. The Guidance on registration describes how this is to be done for phase-in and non phase-in substances, on their own, in preparations or in articles. For phase-in substances that have been imported or manufactured for at least three consecutive years, quantities per year have to be calculated on the basis of the average production or import volumes for the three preceding calendar years (Article 3.30). This rule also applies to phase-in substances intended to be released from articles.

# 4 FORMATION OF SUBSTANCE INFORMATION EXCHANGE FORUM (SIEF)

REACH provides for the formation of a "Substance Information Exchange Forum" (SIEF) to share relevant and available data among all Potential Registrants of the same phase-in substance, as well as allowing Downstream Users and other stakeholders who have, and are willing to share, relevant data to provide/sell their information to potential registrants.

This Section specifies who are the participants in a SIEF, their rights and duties, and how and when a SIEF is formed. It also provides guidance to industry in ascertaining the sameness of the substances pre-registered for purposes of data sharing and the joint submission of data.

## 4.1 What is a SIEF?

REACH provides for the formation of SIEFs to share data among Manufacturers and Importers of pre-registered phase-in substances, phase-in substances registered without pre-registration, holders of information on phase-in substances that are used as plant protection products and biocides as well as allowing Downstream Users and other stakeholders (Data Holders) who have, and are willing to share, relevant information to sell their information to potential registrants.

A SIEF will be formed for each pre-registered substance with the same chemical identity. The participants in the SIEF will essentially be the Potential Registrants and the Data Holders (including early registrants). The roles, rights and obligations of these two groups within the SIEF differ and are further described in Section 4.3.

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 substances concerned where there is a difference in the classification and labelling of the substance between the Potential Registrants.

A SIEF is not a legal entity or a consortium, but a forum to share data and other information on a given substance.

Participants in a SIEF are free to organize themselves as they see fit to carry out their obligations under REACH, i.e. to share data, especially those involving vertebrate animal testing. The organisation structure used for SIEF co-operation may also be used to jointly submit the relevant information. They can use different forms of co-operation to do so as described in Chapter 10 below.

## 4.2 Who are the SIEF Participants?

Several categories of parties will be "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). The obligations of each category of participant are described in Section 4.3 below.

### 4.2.1 "Potential Registrants"

Potential Registrants are those parties who have pre-registered Article 28(1) information to ECHA on a given phase-in substance (see 3.3 and 3.5 above). These include:

- Manufacturers and Importers of phase-in substances having pre-registered that substance.
- Producers and Importers of articles having pre-registered that phase-in substance if intended to be released from articles.
- Only Representatives of non-EU Manufacturers having pre-registered that phase-in substance.

*Third Party Representative*

In respect of the first two categories, any manufacturer or importer may appoint a Third Party Representative for certain tasks relating to data and cost sharing. This is typically the case when a company wishes not to disclose their interest in a particular substance as this may give indications to competitors about production or commercial secrets. Companies should be aware that contact details indicated at pre-registration will be made available to all Potential Registrants of the substance(s) pre-registered under the same identity code as well as to Potential Registrants of all other substances for which read-across possibilities have been indicated. Whenever they consider such information to be sensitive, a Third Party Representative may be used.

The legal entity nominating a Third Party Representative retains the full legal responsibility for complying with his obligations under REACH. In this way the Third Party Representative acts as an “agent” for the manufacturer or importer who remains anonymous vis-à-vis the other stakeholders involved in the SIEF. The identity of a manufacturer or importer who has appointed a Third Party Representative indeed will not be disclosed by ECHA to other Manufacturers or Importers. However that does not make the Third Party Representative the "potential registrant". The manufacturer or importer legally remains the pre-registrant and will be the party that is required to register. The Third Party Representative only has a role in the context of data sharing proceedings. 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 "Third Party Representative" discussed above must not be confused with the "Third Party holding information" as described in Section 4.2.2 below ("Data Holders"), nor with the "Independent Third Party" which may act as a trustee for a consortium or group of companies, as described in other parts of this Guidance Document. “Third Party Representatives” should also not be confused with “Only Representatives” (see Section 3.4).

### 4.2.2 "Data Holders"

Any person holding information/data relevant to a phase-in substance and willing to share it can identify itself and lodge a request to ECHA with a view of being a participant in the SIEF for that substance, to the extent that they will provide information to other SIEF members.

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 of phase-in substances.(Annex 3 provides detailed description of Downstream Users involvement in data sharing under REACH[11])
- 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), 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).

In addition, two categories of Data Holders will automatically be participants in SIEF, as they have already submitted information on phase-in substances either (1) as registrants or (2) in the framework of Community legislation on plant protection products and/or biocidal products:

- Any manufacturer or importer and any producer or importer of an article with intended release under normal or reasonably foreseeable conditions of use who has registered a phase-in substance before 1 June 2018 automatically becomes a data holder. This includes operators that do not pre-register as well as operators that, having pre-registered, decide to register before the relevant deadline of Article 23.
- Any party for which ECHA has information submitted in the framework of the Plant Protection Product Directive (91/414/EC) or the Biocidal Product Directive (98/8/EC) that meet the conditions established in Article 15.

It must be underlined that REACH does not provide for data holder to have an active role in deciding on the studies to be included in the joint submission and on classification and labelling proposals. Data holder can thus only provide data to other active members (potential registrants) of the SIEF and request cost sharing for the data supplied.

### 4.3 What are the obligations of SIEF Participants?

All SIEF Participants shall:

- React to requests for information from other participants;
- Provide other participants with existing studies upon request.

Potential Registrants shall:

- Request missing information from other SIEF participants;

[11] A specific RIP 3.5 addresses Downstream Users under REACH.

- 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 Sections 4.5.1 and 5.4).

Data Holders: Data Holders must respond to any query from Potential Registrants if they hold the data relating to this query. Data Holders, however, are not entitled to request data.

## 4.4 What happens after the Pre-Registration?

The REACH Regulation requires ECHA to publish on its website, by 1 January 2009, a list of pre-registered substances. This publication will have specific effects. It therefore is necessary to distinguish what happens (1) after Pre-registration but before the publication on ECHA's website of the list of pre-registered substances and (2) after that publication.

### 4.4.1 During the pre-registration period (1 June 2008 to 1 December 2008)

When a potential registrant pre-registers a substance corresponding to an entry in EINECS or other identifiers and is the first one to do so, REACH IT triggers the creation of a dedicated web-page. At this point in time, this page can only be seen by the Potential Registrants of that substance and the Potential Registrants of the substance(s) listed in the pre-registration dossier as candidate for the purpose of read across and ECHA.

The page displays the following information:

- The corresponding entry in EINECS, i.e. IUPAC name or substance description;
- EINECS and CAS numbers;
- The individual details of the potential registrant, i.e.
    - Identity and contact details (or those of the Third Party Representative if he elected not to disclose his company name for this substance);
    - The tonnage band for which he is planning to register the substance, and the envisaged registration deadline;
    - Whether he indicated in the pre-registration his willingness to act as a facilitator in the SIEF formation.
- The other substances in relation to which data can be shared (read-across).

When another legal entity subsequently pre-registers a substance with the same identifier, he/she will be automatically granted access to the same dedicated web-page. He/she will be able to see the identity of all Pre-Registrants who have pre-registered the same[12] substance before him/her.

[12] 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 (see Section 4.5).

This subsequent pre-registration will prompt REACH IT to automatically notify by e-mail to all previous Pre-Registrants of the same substance that a modification has occurred in the substance web-page (unless the pre-registrant has turned off the automatic notification function).

If a potential registrant pre-registers a substance for which another legal entity has already submitted a pre-registration, as mentioned above, that potential registrant will be prompted to the corresponding existing page where he will be able to see the identification of all previous Pre-Registrants of the same substance.

If a potential registrant of substance A indicates the possibility to share data with another substance B (read-across), the name of substance B will appear on the substance web-page of substance A and access will automatically be given to all Pre-Registrants of substance A to the substance web-page of substance B by clicking on the substance name. Similarly, the name of substance A will appear on the substance web-page of substance B and Pre-Registrants of substance B will get access to the substance web-page of substance A.

SIEF Participants who do not wish to make their contact details available to other Pre-Registrants should use a Third Party Representative. It is important that Pre-Registrants identify the name of the Third Party Representative when submitting the pre-registration information to ECHA. Otherwise, they will not be able to prevent ECHA from disclosing their details to other Potential Registrants.

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. During pre-registration, companies can also still modify their data by withdrawing pre-registrations and introducing new ones.

### 4.4.2 Publication of the list of pre-registered substances

Based on the information submitted by Pre-Registrants, ECHA will publish on its website, by 1 January 2009, a list of pre-registered substances.

The list published on ECHA's website will specify for each substance the name of the substance including their EINECS and CAS number if available and other identity codes, and the first envisaged registration deadline.

The list will also include the names and other identifiers of related substances, i.e. those for which the available information is believed to be relevant for read across or the use of results from (Q)SARs.

The list as published by ECHA will not show the identity of the Pre-Registrants. This information will only be visible by those who have pre-registered the same substance and those who have pre-registered related substances for read-across.

### 4.4.3 After the publication of the list of pre-registered substances

- **Submission of information on pre-registered substances by "Data Holders"**

Following the publication of the list, "Data Holders", as defined in Section 4.2.2 above, may wish to share with Pre-Registrants the information they have at their disposal on phase-in substances. They can do so by making a submission to ECHA of any or all of the information listed in Article 28.1 of REACH for a given phase-in substance with the purpose of joining a SIEF for that substance. This will be done in a similar way as the pre-registration itself. The practical implementation of this submission of information is currently under discussion.

The contact details of data-holders will be made available on the substance web-page of the concerned substance and can be seen by all Pre-Registrants who have access to the site. Data Holders will not get access themselves to any of the substance web-pages.

**Recommendation: Data Holders should submit information on pre-registered substances as early as possible after 1st January 2009.** There is no requirement/deadline in REACH for a data holder to notify to ECHA their willingness to join a SIEF in view of sharing information. 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 substance to facilitate the data sharing process. The earlier Data Holders indicate their interest, the more likely will the Potential Registrants be able to share relevant data from Data Holders in time before the compilation of the Registration dossier. REACH IT will offer the possibility to further describe the data they hold, especially in terms of the specifications of the tested material, so that the other SIEF members can better figure out 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 will also give the opportunity for Downstream Users to ascertain that all substances they need in their own processes are on the list and there will be no discontinuity in their supply. Should one or several of them be missing in the list, a mechanism is foreseen, through an intervention of ECHA to facilitate contact between Downstream Users and companies who might wish to act as first time Manufacturers or Importers for their substance.

In particular, after the publication of the list, a downstream user of a substance not appearing on the list may notify ECHA of his interest in the substance, his contact details and the details of his current supplier. ECHA will publish on its website the name of the substance. In case a manufacturer or importer contacts ECHA, ECHA can provide contact details of the downstream user to a potential registrant.

This mechanism aims at allowing Downstream User to find another supplier and/or get this other supplier to pre-register under the *late pre-registration* procedure described in Article 28(6).

**Recommendation to Downstream Users:** Downstream Users should be aware of the fact that when substances are present on the list of pre-registered substances this does not give guarantee either that these substances are in effect pre-registered by their current supplier or that their supplier will eventually register the substance. Manufacturers and Importers are encouraged to communicate with the Downstream Users with regard to whether they intend to register the substance. Likewise, Downstream Users are encouraged to contact their

suppliers as soon as possible and well before the end of the pre-registration period (1 December 2008) in order to find out about their intentions and where necessary look for alternative future sources of supply.

**Annex 3** provides detailed guidance on the involvement of Downstream Users in data sharing.

### 4.5 How and when will a SIEF be formed?

Article 29 of the REACH Regulation provides that all Potential Registrants and Data Holders for the "same" phase-in substance shall be participants in a SIEF. However, the REACH Regulation does not define "sameness" and it does not foresee any formal step to confirm the establishment of sameness and the formation of a SIEF.

The assessment of the exact nature of an EINECS entry and the different substances it may cover can only 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, Pre-Registrants must enter into pre-SIEF discussions. As a consequence of this, a SIEF is formed when the Potential Registrants of a substance in the pre-registration list, actually agree that they effectively manufacture, intend to manufacture or import a substance that is sufficiently similar to allow a valid joint submission of data.

Data Holders will not be involved in pre-SIEF discussions. They will be considered as members of a relevant SIEF once it is formed as a consequence of the pre-SIEF discussions between Pre-Registrants of the same identifier (e.g EINECS entry). Since data holders do not know the contact details of the potential registrants who have pre-registered under the same identifier, it is the role of the potential registrants to evaluate for which substance(s) within this identifier the data are relevant and to which SIEF(s) the data holder participates.

ECHA will not participate in the discussions between Potential Registrants and there will be no role of ECHA in confirming or rejecting the creation of a particular SIEF.

However, REACH IT will allow posting information on the creation of SIEFs in two dedicated free fields on the substance web-page. In the first free field, writing rights will only be given to the SIEF Formation Facilitator. In the second free field, all Pre-Registrants of the substance will have writing rights. All messages in these two free fields will be the exclusive responsibility of the authors and ECHA will neither verify nor approve or disapprove their contents.

It is recommended that the SIEF Formation Facilitator uses the first free text field to post messages on the creation of a SIEF and to give contact details and information on further communication tools (e.g. dedicated industry websites). The second free field will allow other Pre-Registrants to give comments (e.g. in case of disagreement with the SIEF Formation Facilitator). Both free fields will allow only a limited number of characters and should therefore only be used for key messages and referring to further contact details and/or communication tools.

**Recommendation**: potential registrants should work towards forming SIEFs as soon as possible to ensure sufficient time remains available to organise data sharing and prepare the

registration dossiers, in particular for high volume substances considering the registration deadline of 30 November 2010.

### 4.5.1 How to determine the sameness of substances?

In assessing the identity of the substances, Potential Registrants are invited to read and use the Guidance on substance identification carefully.

For substances with a well-defined composition (i.e. mono-constituent and multi-constituents substances) the sameness of the naming is in principle sufficient to be able to share data even though certain impurities might lead to a different classification/hazard profile. Only in cases where all data is clearly not suitable for the other substance these substances can be regarded as different (e.g. in case of very different physical properties which have essential impact on the hazard properties, like water solubility).

For UVCB substances also – in general - the name is leading to determine the 'sameness'. If the name is the same, the substance is regarded the same, unless available data shows the contrary.

In most of the cases the substances that have been pre-registered under the same entry in EINECS (either defined by its EINECS or CAS number, or its description of the entry) will be the same substance and, after a quick check by Potential Registrants for gross errors, there will be a general agreement that a joint submission of data is possible and cooperation between Potential Registrants can start immediately.

In certain cases, however, the exact nature of the substance covered by an EINECS entry will have to be scrutinised in order to ascertain whether it can be covered by the same joint submission of data and that the relevant hazard data can be purposefully exchanged. Typically, this may happen in the following situations:

- The description in EINECS given for a substance can be very broad to the extend that the physical-chemical and (eco)toxicological properties of the different substances covered by this one entry are not sufficiently similar to use the same data to describe it. This may particularly be the case for UVCBs.
- Substances for which there is more than one entry in EINECS and that are considered the same based on the Guidance on substance identification.

**Outcome of the sameness analysis**

Following the sameness review, three situations are possible:

(i) all Potential Registrants agree that their substances are the same and that they may proceed with data sharing within a SIEF for that substance; 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)'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) shall 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 on substance

identification 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. The formation of several SIEFs for the same substance violates data sharing obligations.

(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 proceed with data sharing within one SIEF

Once a SIEF is formed data sharing obligations become obligatory within the SIEF. In addition, the principle of joint submission also applies with regard to substances covered by the same SIEF.

**What happens in case of disagreement over substance identity/sameness?**

If parties disagree on substance identity/sameness and a party considers that it should be part of a SIEF created by other parties for a given substance, that party has the possibility to formally request to join the SIEF and request access to the data he is missing to proceed with his Registration. In case access is refused, the rules of Article 30(3) and (4) apply. This means that in the case of vertebrate animal tests, the party requesting the data shall proceed with registration without fulfilling the relevant information requirement, explaining the reason for this in the registration dossier. The Agency will then need to decide whether or not the position taken by the requesting party is justified and SIEF participants are required to share the data and whether or not the further steps described in Article 30(3) apply to this case. Normally, such a decision will also clarify whether data sharing rules for tests not involving vertebrate animal tests pursuant to Article 30(4) apply.

**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, as further explained in Chapter 9 of the present Guidance Document.

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

In such cases, participants could consider several options, including screening the information that is shared, or granting restricted access to selected company staff (preferably with the signature of a confidentiality agreement), or the appointment of an independent Third Party or trustee. These options are further described in Chapter 11 hereto on CBI.

If a satisfactory solution cannot be found, the potential registrant concerned can “opt out” with a view to submitting a separate registration (see Section 8.4 of this Guidance for further details about “opt out”).

**Examples of identity issues and related solutions:**

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

Before 1st December 2008, it is possible to pre-register the substance a second time in the appropriate EINECS entry. The earlier pre-registration can still be withdrawn at this stage or become dormant (i.e. the pre-registrant is not an active participant in the SIEF). After 1st December 2008, refinements in the context of SIEF formation are still possible. If verification of substance identity with pre-registrants of the same and/or similar identity codes leads to the conclusion that the substance fits more into the SIEF formed by the pre-registrants of a similar rather than the original identity code, 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 such a case, any activities involving the substance must be suspended and can only be resumed as soon as a full registration dossier has been submitted. Moreover, the pre-registrant may be subject to penalties according to national law for violating registration obligations, as the substance has not been pre-registered and therefore the registration obligations apply from 1 June 2008.

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

In case there are several EINECS entries for the same substance, a similar solution can apply: during the pre-registration period, manufacturers and importers may decide to submit an additional pre-registration in one of those EINECS entries in order to regroup all participants in one single SIEF. Earlier pre-registrations in the other entries can be withdrawn or simply become dormant.

It should be noted that the fact that there are several pre-SIEFs operating in parallel on the same substance might not come immediately to the attention of participants. Therefore, Potential Registrants are invited to review the possible entries in the pre-registration list and assess the relevance of forming a single SIEF. This can also be done by using the read-across facility provided by REACH IT. This allows the potential registrant to indicate even after the end of the pre-registration period that read-across is possible between two substances. Potential registrants of both substances will then be able to see each other's contact details. They may subsequently come to the conclusion that they have the same substance and merge into one SIEF.

*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, a split of the entry should be considered. This will in general occur in the case of errors in EINECS or very broadly defined EINECS entries. To this end, participants should exchange the specifications of their substance in view of assessing the equivalence and the possibility to submit jointly the hazard data set. Whenever this leads to the conclusion that their substances are not the same, several SIEFs should be formed.

*D. Phase-in substances where no EINECS/CAS entries or other identification codes 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 point of departure to clarify substance identity and the composition of the SIEF. When based on the Guidance on substance identification, these substances are regarded the same, a SIEF will be formed and data sharing and joint submission obligations apply.

### 4.5.2 How can communication within SIEF be facilitated? SIEF Formation Facilitator

Exchange of information within a SIEF will be greatly facilitated if one participant agrees to play the role of a coordinator and initiate the acting together.

REACH includes provisions related to a Lead Registrant for testing and joint submission purposes (see REACH art. 11.1.) and it would be helpful if the "Lead Registrant to be" or another participant would take the initiative already at the SIEF formation stage.

While there are no specific provisions in REACH to that effect, REACH IT will offer the possibility for Potential Registrants when pre-registering to indicate their willingness to act as a "SIEF Formation Facilitator" so as to facilitate the identification of a potential leader.

It is important to specify that:

- Acting as a SIEF Formation Facilitator is voluntary and does not entail any specific obligation. It simply means that the company/companies volunteering are those expected to take the initiative to contact the others within the pre-SIEF;
- Ticking the box in REACH-IT to indicate willingness to act as “SIEF Formation Facilitator” is not legally binding. It means that the “potential SIEF Formation Facilitator” could freely review his position at any moment and decide to not play the role of facilitator.
- The SIEF facilitator does not have a formal recognition in the REACH Regulation, while the role of the Lead Registrant is mandatory and specifically foreseen in the Regulation.

The role of a facilitator should start in the "pre-SIEF" phase, during which Pre-Registrants exchange information to ensure they all belong to the same SIEF. For example, the facilitator can contact all Potential Registrants and organize the exchange of information on the identity of the substance. As a second step, when the SIEF is formed, he can propose means of organizing exchange of substantial information on the substance. Alternatively, the SIEF can already at an early stage agree on a Lead Registrant who might take over the organisation of the information exchange and the preparation of the joint submission. Any other organisation form is equally possible, as REACH does not set any conditions in this respect.

In case the information to be exchanged is considered commercially sensitive by one or more Potential Registrants (e.g. because of an impurity content that can give indication on a production process), the facilitator or designated Lead Registrant can propose a confidentiality agreement or the use of an independent Third Party or trustee who can handle the confidential information on behalf of Potential Registrants.

The next step may be for the facilitator or designated Lead Registrant to make proposals related to any or all of the possible following steps:

- The form of co-operation between the parties and possible internal rules (see Chapter 10);
- Who could perform the necessary technical work (either the Potential Registrants themselves or a contracting Third Party or a combination of both);

- Scope of the co-operation: 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;
- Organization of the exchange of data;
- Designation of a Lead Registrant (unless this has already been done).

The facilitator or designated Lead Registrant may also potentially carry out several other organisational tasks on behalf of the Potential Registrants, such as:

- Channel the communication with other SIEFs, with which read across applies
- Ensure a smooth entry of late registrants in the SIEF
- Launch the queries for data in SIEF
- Prepare an inventory of available data within SIEF

In some cases, the tasks that the facilitator or designated Lead Registrant may propose to undertake will be substantial and it might be appropriate for the parties to consider a financial compensation for the resources spent by the facilitator or designated Lead Registrant, beyond the initial contact and proposal, in particular when the facilitator would provide services that otherwise would have to be compensated.

### 4.5.3 When will Data Holders join the SIEF?

Data Holders can submit information on phase-in substances after the publication of the list of pre-registered substances by ECHA. At that stage, however, the SIEF or SIEFs for the substance, as pre-registered, may not yet be formed.

Data Holders will not be involved in pre-SIEF discussions. They will be considered as members of all SIEFs once formed as a consequence of the pre-SIEF discussions between Pre-Registrants of the same EINECS entry.

Potential Registrants will only start investigating about data availability once the SIEF is finally formed and when they have identified data gaps (See Section 5 below). At that stage, they can launch queries for missing data (this is mandatory if the missing piece of data involves vertebrate animal testing). In doing so, Potential Registrants must bear in mind the fact that there may be several SIEFs corresponding to the entry in the list of pre-registered substances. Queries 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 data held by Data Holders taking into account the identity of the substance covered by the SIEF and the provisions laid down in Section 7.2. This will require Data Holders to communicate information on the identity of the substance. Data Holders are therefore also recommended to review identity information on the basis of the criteria laid down in the Guidance on substance identification for the data they have available and when deciding to contribute for REACH data sharing purposes.

**Recommendation**: Data Holders should be aware of the identity of the substance relating to the data they are holding in order to allow Potential Registrants to ascertain the relevance to

their substance. They should approach the establishment of the identity of the tested substance and the relevance of that in relation to the substances pre-registered in a similar way as the Pre-Registrants (i.e. based on the Guidance on substance identification).

### 4.6 Inter-SIEF rules (grouping, read-across)

The avoidance of unnecessary animal testing is a main concern underlying the provisions of REACH. One way of achieving this is to use data relating to another substance for your own substance, if it can be considered that the substances are similar enough to justify it. Reading data across different substances should always be carried out according to expert judgment. The Guidance on information requirements under REACH explains in detail how and when reading across can be made. Beyond the technical aspects of read across, other issues must be considered.

When pre-registering, a company manufacturing substance A has the possibility to indicate those other substances (e.g. substance B) with which reading across may be considered. ECHA will make this information available to the participants in the SIEF corresponding to the other substance, who will have the possibility to see the identity of the Pre-Registrants of substance A and send queries for data sharing. Similarly, Pre-Registrants of substance A will be able to see the identity of the participants in the SIEF of substance B and send data sharing queries. Indicating read-across is also still possible after the end of pre-registration (e.g. after checking the list of pre-registered substances).

It is worth noting that the fact that substance B is flagged as a potential read cross substance when pre-registering A does not necessarily mean that a pre-registrant of substance B has flagged the same opposite reading across with A. Reading across from A to B will consequently be indicated to the B SIEF, irrespective of the fact that no B participant has flagged this reading across in his own pre-registration.

There is no cascading of reading across, though. In case SIEF A reads across with SIEF B and SIEF B reads across with SIEF C, there is no automatic connection between SIEF A and SIEF C. The validity of reading across is always based on an expert judgment and cascading across several substances cannot be assumed to be valid unless scientifically checked for validity. It is impossible to address all possible cases involving reading across, the validity of which should always be assessed on a case by case basis.

It is not mandatory for participants in different SIEFs to share data, even though it is encouraged by REACH in order to reduce animal testing and curb compliance costs. A direct consequence of this is that the data sharing provisions of REACH do not apply. Every request for access to studies across different SIEFs will have to be negotiated on a case by case basis by the concerned companies. In order to facilitate this negotiation, the options proposed in sections 5.3.3. (for the collective route) and 5.5.4 and 5.5.5 (for the individual route) of this guidance may be considered.

REACH IT is designed to allow the exchange of data requests with other SIEFs and pre-registrants are invited to explore all read across potential.

## 4.7 End of SIEF

According to Article 29, last sentence, "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 threshold which triggers registration.

However, it is important to note that data generated by the SIEF in the framework of registrations may continue to be protected from unauthorized use by other Potential Registrants, beyond 1 June 2018. In addition, there may be a need to generate data after the end of SIEF, for instance in the context of an update.

Registrants may, therefore, consider to extend the forms of cooperation between them beyond 1 June 2018. At least, it is recommended to foresee mechanisms to deal with compensations for studies that may be requested by new registrants after 1 June 2018.

However, the end of SIEF will end the application of the mandatory data sharing provisions within SIEFs described in Chapter 5 below. From that time, the rules for data-sharing for non-phase-in substances will become of general application and will be the framework for data-sharing (see Chapter 6).

## 4.8 Liability related to data sharing

In addition to obligations of SIEF Participants laid down in REACH (as specified in detail in Section 4.3) and sanctions contemplated by the Member States for non compliance with those obligations, national law will govern the liability of SIEF Participants (and other REACH actors).

The liability of SIEF Participants may be engaged, for example, in cases of misrepresentation of the quality of the studies provided to other participants in SIEFs, or that of a Lead Registrant engaged for failure to register a substance in time (unless the failure can be attributed to other SIEF members). These issues are not dealt with by REACH, and can be affected by contractual arrangements between parties, subject to national law.

As a general rule, private parties are free to organise their relationship by contract and to organise their contractual liability, subject to the mandatory provisions of the national law of the Member States that, for example, may rule that some liabilities cannot be contracted out.

Below is a list of issues that the different categories of SIEF should be careful about when sharing information under REACH as they may trigger their liability:

- Potential Registrants are liable towards the authorities for the content of their own registration. But they may also be liable towards other Potential Registrants (within or outside a SIEF) for example for misrepresentations related to the ownership or the quality of studies or information provided[13].

[13] It should be noted that this liability may also exist in relation to Potential Registrants from other SIEF(s) for which the substance has been identified at the pre-registration stage as potentially relevant for read-across or the use of results from (Q)SARS.

- With regards to independent Third Party Representatives and Only Representatives, it is advisable to specify a clear allocation of obligations and responsibilities by contract between the SIEF or non-EU manufacturer and his representative. It should be noted that such contractual arrangements cannot eliminate the responsibility of an Only Representative under REACH and can only affect the relationship between the Only Representative and the non-EU manufacturer.

- Similarly, it seems advisable for companies using independent Third Parties to exchange confidential information to make contractual arrangements between the affected companies and the independent Third Party.

- Lead Registrants will prepare the part of the dossier which will be submitted jointly on behalf and with the agreement of the other registrants. Technically, only the Lead Registrant will submit the joint part of the dossier on the REACH IT system

- Data Holders, as other SIEF Participants, should be mindful of property rights and quality issues when making representations and granting rights on studies available to them.

- Unless a consortium has legal personality, consortium members will generally be jointly liable towards Third Parties. Respective liability of consortium members between themselves can be organised in the Consortium agreement.

# 5 DATA SHARING RULES FOR PHASE-IN SUBSTANCES WITHIN A SIEF

This section of the Guidelines describes and discusses the rules applicable to data sharing for Phase-in substances within a SIEF among Potential Registrants and Data Holders. It also addresses classification and labelling issues within a SIEF.

## 5.1 Overall approach to data sharing

Article 29.3 describes the fundamental rule for the functioning of a SIEF as follows:

> *"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".*

In addition, 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, 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.

Article 30.1 provides that "before testing is carried out", participants in a SIEF inquire whether a relevant study is available within the SIEF. If it is available, the participants shall request that study (in the case of tests on vertebrate animals) and may request it (in the case of information not involving tests on vertebrate animals). 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, however, it may often be more practical to use more direct forms of co-operation to gather required information, to agree on the necessary data package and on classification and labelling, and to prepare for the joint submission of data. This can involve a joint review of all available data (including publicly available data). This more complete exchange may allow participants to determine and agree on classification and labelling, draft study summaries, agree on testing proposals, jointly draft a chemical safety report, agree on 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”).

Whenever data can be obtained in this way, it is not necessary to follow the formal steps foreseen in Art. 30. The application of these provisions (“individual route”) will mainly apply in cases when a party does not wish to follow the collective route (e.g. in case of disagreement with the other members of the SIEF) or agree to rely on the full data set prepared by one or a group of SIEF members, or where limited data must be shared. The individual route will not release the potential registrant from his obligation to make available and share data.

## 5.2 Four step process to 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.

In order to provide the registration dossier, Manufacturers and Importers are, as a starting point, obliged to collect all available relevant information on the intrinsic properties of a substance regardless of tonnage manufactured or imported. This information has in turn to be compared with the standard information requirements, which largely depends on the quantity of the given substance for each manufacturer or importer. If data gaps are identified, then new testing may have to be conducted or test proposals made.

From the above, fulfilling the information requirements for Registration is essentially a four step process, which consists in:

- Step 1: Gathering existing information
- Step 2: Considering information needs
- Step 3: Identifying information gaps
- Step 4: Generating new information or propose a testing strategy in line with REACH obligations

For most phase-in substances, several companies are producing or importing the same substance and data may be available to some of them as well as with Third Parties. In such cases, the Potential Registrants in a SIEF are bound to share the animal data they have available and to prepare a joint registration dossier. This will affect the way in which they can best organise the four steps described above.

## 5.3 The collective route

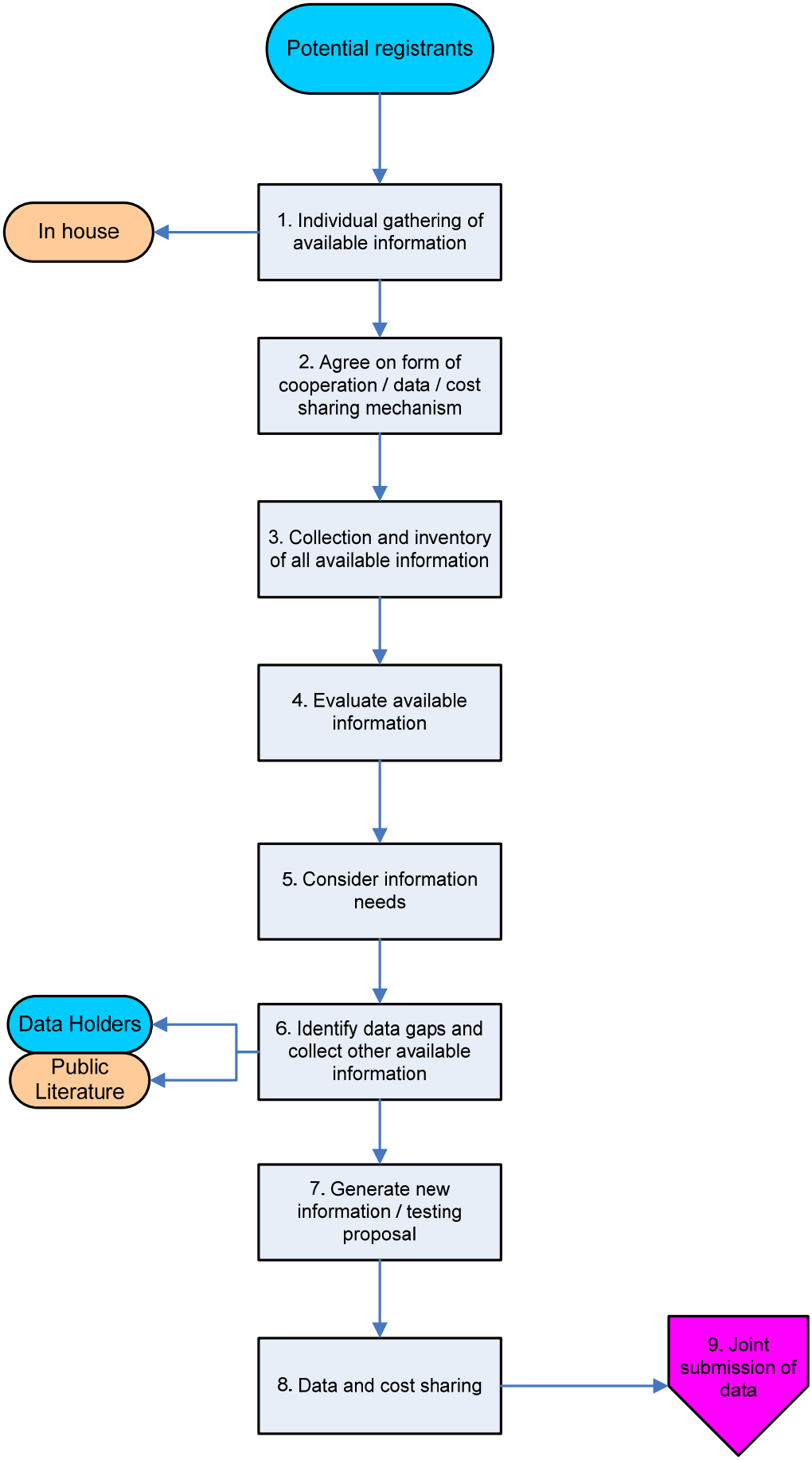
It is important to stress that REACH gives Potential Registrants flexibility to decide how they organise their data sharing and joint submission obligations. This Section of the Guidelines describes how data sharing can be organized collectively within a SIEF with the view to meet the objectives listed in Section 5.1 above, including both the obligations related to data sharing and the preparation for the joint submission of data at Registration.

The following steps are only indicative:

- Step 1 Individual gathering of information available to Potential Registrants
- Step 2 Agreement on the form of cooperation/cost sharing mechanism
- Step 3 Collection and inventory of information available to Potential Registrants
- Step 4 Evaluation of available information
- Step 5 Consideration of information needs

- Step 6  Identification of data gaps and collection of other available information
- Step 7  Generation of new information/testing proposal
- Step 8  Data and cost sharing
- Step 9  Joint submission of data

Chart III
Data sharing process: Collective Route



### 5.3.1 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 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 are 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 be one of the elements they would want to consider before making a decision to become a potential registrant for that substance.

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 should 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, including data they have available that correspond to a higher tonnage threshold. Also, this is needed to avoid duplicate testing by those Potential Registrants that do need the additional data in question and may offer the data owner a source of revenue or a way to mitigate its costs in the data sharing phase.

In order to reduce costs participants may conduct a literature search collectively, i.e. to agree on conducting a single literature search for all SIEF Participants. In such a case they would do the collective literature search as part of step 3.

In summary, Step 1 requires each potential registrant to assemble and document all the information on the substance, that he has 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 - and to conduct a literature search. Potential Registrants are encouraged to start gathering all relevant and

available information as soon as possible, before the formation of the SIEF for that substance and if possible before Pre-registration.

### 5.3.2 Step 2: Agreement on the form of co-operation/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 suit them and the main rules applicable to that cooperation, in terms of data and cost sharing. In this regard, the possible options and recommendations for cost sharing discussed in Section 7 could be discussed and agreed at this stage.

It is important to note that REACH does not prescribe the way in which participants in a SIEF should cooperate, such as by entering into a formal consortium agreement or otherwise. Parties are therefore free to select the form of cooperation that suits them best and allows them to meet their obligations under REACH.

However, pursuing the "collective route" would seem to require agreement between Potential Registrants on the main elements of the gathering of information, identification of information needs, generation of missing information, and cost sharing.

In summary, Step 2 requires Potential Registrants (and potentially Data Holders) to (virtually) meet, discuss and agree on the form of cooperation that best suit them and the main rules applicable to that cooperation, in terms of data and cost sharing.

### 5.3.3 Step 3: Collection and inventory of information available to Potential Registrants

In step 3, Potential Registrants should first organize to complete the data collection phase, by collecting all information they have available individually (including from literature searches). If literature searches have not been done individually in step 1, they 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 (See Step 6 below), it will be necessary for Potential Registrants to collect data available from (1) Data Holders, (2) other SIEFs and (3) outside of 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 rapidly. Information from other SIEF could 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 pursuant to Annexes VI to X of REACH that is being sent to all Potential Registrants by the SIEF Formation Facilitator, the Lead Registrant or otherwise and that is returned to the facilitator, trustee or designated expert. This could 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. A format is proposed in Annex 4.

As the above data is being collected, it should be entered into a common inventory. This would best be 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.

In summary, Step 3 requires Potential Registrants to collect and put together in an inventory all information on the substance they have available between them. As an option, they may also consider at this early 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.

### 5.3.4 Step 4: Evaluation of available information

The next step is for Potential Registrants to evaluate the data available on the substance to be registered.

Essentially, for each endpoint Potential Registrants must:

- Assess the relevance, reliability, adequacy and fitness for purpose of all gathered data (See the Guidance on information requirements for arriving at conclusions on the hazard assessment and for risk characterization. Section 7.2.1 to these Guidelines includes a description of possible means and options for assessing the relevance, reliability and adequacy of data.

- Determine the key study for each endpoint. Normally this is the study of greatest relevance taking into account the quality, completeness and representativeness of the study. In other words they have to determine which study shall be used in the assessment later on, 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 see the Guidance on information requirements).

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

If only one valid study is reported on an endpoint:

Potential Registrants have to use the information available in the robust study summary for that study and to conclude on the endpoint in the endpoint study summary. If the endpoint study record has been documented sufficiently, Potential Registrants would only need to use information already summarized in the endpoint study record.

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.[14]

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. QSARs, read across, *in-vitro* methods) are used as relevant information for the final assessment and conclusion.

Guidance on how to use alternative methods or a weight of evidence approach is available in the Guidance on information requirements and guidance on how to identify and measure environmental fate and physico-chemical properties, and make human health and environmental assessments is available under the Guidance on the Chemical Safety Report. 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 of 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 the justification for this classification
- PNECs and DNELs values as well as the justification of the reported values.

Technical guidance on how to complete the endpoint study summaries is given in Guidance on IUCLID. It should be noted that information included in the endpoint study summaries in IUCLID5 can be automatically extracted to generate the Chemical Safety Report.

In summary, Step 4 requires Potential Registrants to evaluate all available data, which includes an evaluation of the quality of the data, the selection of key studies for each end point and the drafting of relevant (robust) study summaries.

### 5.3.5 Step 5: Consideration of information needs

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).

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);

[14] It may still represent value to the owner. See Section 7.2.1.

- 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.

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)

Additionally, in the case of phase-in substances, manufactured or imported between 1 and 10 tonnes, the full information requirements are only required if one or both of the criteria laid down in Annex III are met. Where the criteria in Annex III are not met only the physicochemical information requirements in Annex VII need to be fulfilled.

In summary, Step 5 requires Potential Registrants to identify precisely what are the information requirements for the substance they intend to register, considering in particular the tonnage band that are relevant to all Potential Registrants, but also uses/exposure patterns for exposure waiving purposes.

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

At this stage, Potential Registrants 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[15].

- If the available information is sufficient and the standard information requirements are met, no further gathering of information is necessary. In case the Potential Registrants consider that the available information is sufficient (even in 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.

[15] If the potential registrants decided to carry out a collective literature search as mentioned in Sections 5.3.1 and 5.3.2 this search will have to be carried out first before data gaps can be identified leading to the steps described below.

- In case the available information is considered insufficient, then Potential Registrants can verify whether data is available outside the SIEF, before generating new information or a testing proposal

  (1) First, Potential Registrants must verify whether Data Holders have the missing data. They can do so by requesting Data Holders within the SIEF to identify the information/data they have available. This may also be done by requesting Data Holders whether they have a relevant study for one or more given end-point, 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 the requested data, e.g. 1-3 months.

  (2) If the data gaps still exist, Potential Registrants can proceed similarly with Data Holders in other SIEFs (for substances with a potential for QSARs or read across).

- Finally, in some cases, instead of commissioning further testing, the registrant may propose the limitation of exposure through the application of risk management measures, e.g. providing closed systems (see the Guidance on information requirements).

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 that case, and unless they would have an interest in acquiring additional studies for other or future use, only these companies requiring these studies will need to share the cost of the studies to be generated.

In summary, Step 6 requires Potential Registrants to identify precisely the data gaps that will need to be filled in before registration dossiers can be filed. Before testing is conducted or a testing proposal made, Potential Registrants MUST verify whether the missing data is not available to Data Holders within the SIEF. They can also request data from Data Holders in other SIEFs.

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

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 ((Quantitative) Structure Activity Relationships), in vitro tests, weight of evidence approaches, grouping approaches (including read-across).

When there is an information gap which cannot be filled by any of the non-testing methods mentioned in step 3, Potential Registrants have to take action depending on the missing test/information:

- when Annexes VII and VIII apply, the registrant has to **generate** new information (see the Guidance on information requirements);

- when Annexes IX and X apply, the registrant has to prepare (following the Guidance on information requirements) a **testing proposal** and submit this as part of the registration dossier to ECHA for its consideration. In this case, registrants have to

implement and/or recommend to Downstream Users interim risk management measures while awaiting the outcome of ECHA's decision regarding the test proposal[16].

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 alone with the generation of missing data. They have the obligation to agree on one of them performing the study on behalf of the others. The agreement has to be reached within a deadline set by ECHA; otherwise the decision will be taken by ECHA itself. All participants who require the study are obliged to 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.

In summary, when there is no other alternative, Step 7 requires Potential Registrants to generate new information (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.

### 5.3.8 Step 8: Sharing of data cost

Once the Potential Registrants have accomplished the steps above, they can organize the actual sharing of the available data and of 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.

It is for the Potential Registrants and Data Holders involved to agree on the terms and conditions of this data and cost sharing and many options exist to structure and organize this. As described in Section 5.3.2 above, it is recommended that Potential Registrants and Data Holders agree on this early in the data sharing process.

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

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

Article 10 (a) last indent requires that the registrant shall 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 in the technical dossier for the purpose of registration".

This 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**

One must distinguish: (a) the full study report, (b) the study summary or robust study summary and (c) the results of the study (as will be published under Art 119.1.d and e)).

[16] It should be noted that the obligation to prepare a testing proposal also applies to situations where the 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.

(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 case CBI may be claimed; if published, generally, such publication will be subject to copyright rights. REACH does not require that this "full study report" be sent to ECHA at Registration, but that the registrant is in legitimate possession or has 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, as follows: "*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.*" "Study summary means a summary of the objectives, methods, results and conclusions of a full study report providing sufficient information to make an assessment of the relevance of the study. (Robust) study summaries are sometimes made publicly available by governments with the consent of the owner of the full study report. This is often the case for studies submitted as part 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. Study summaries and robust study summaries will normally be published on ECHA 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 confidential. Obviously, this information that is publicly available is not enough to submit a registration by a Third Party as any registrant must submit the relevant robust study summaries and study summaries and have permission to refer to the full study report.

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

One must distinguish 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) having commissioned and paid the study. The owner of the full study report generally possesses it legitimately and has the right to use and dispose of it, as it best see fit, including the right to sell it or to grant access to it whether against payment or free of charge. In some situations, however, agreements may exist that restrict the right of the owner(s) to dispose of the study (e.g. restrictions of use in case of a study commissioned by various parties or following a license). Some specific data sharing

rules established by REACH only apply to the "owner" of the study. For example, Article 30.1 requires the "owner of the study" to provide proof of cost to the SIEF Participants requesting it.

(b) REACH refers to **legitimate possession of the full study report** for Registration purposes. This term, however, is not defined. It does not mean ownership, although the owner of the data clearly is also in legitimate possession of that data. In the absence of definition in the legal text, it is for national courts to interpret this term under the control of the European Court of Justice (ECJ). In most legal systems, legitimate possession is defined by the holding of a good and right to use it, although the right to use could also be limited. A possible definition of legitimate possession, would be to have a copy (in electronic or paper form) of the full study report, with the right to use the data[17] for registration purposes. By having the right to use to register, the entity having legitimate possession will not infringe the rights of other parties, such as copyrights[18]. This right to use a study for registration can be granted by the owner(s) of the full study report.

(c) REACH also refers to the **right to refer to the full study report**. This is mainly when the owner of the data provides a "letter of access" to another party that is limited to the use of the data for one or more specific purposes, such as for Registration under REACH (and/or for other regulatory purposes) but without passing on to that party a copy of the full study report.

(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 copyrights or other relevant intellectual property rights.

**Warning**: Please note that except from specific cases enumerated in Art. l0(a) last paragraph, the registrant must be in legitimate possession or have permission (e.g. a letter of access) to refer to the 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, or the US HPV Chemical Challenge Program). In addition, any party downloading studies that are publicly available should carefully check 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).

**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.

[17] See also the OECD Act C(83)96/Final which recommends that a notifier provides certification of the right to use data.

[18] In some legal systems, "possession" for movables means physically holding the thing. This does not appear sufficient for REACH purposes. Possession must be "legitimate", which would exclude for example using stolen data. Further, the protection of the data and reports is primarily an intellectual property right, for which other rules are applicable than for movable goods.

(1) Granting legitimate possession or a right to refer to the full study report normally requires some form of agreement between parties. When the report is subject to copyrights 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 for other purposes), possibly the duration of such agreement or access, and associated costs.

(2) In some cases, the right to use or refer to data is granted by law or regulatory authorities. This is the case of the so-called "12 years rule". Article 25 of REACH 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. Demonstrating "legitimate possession" is not needed for registered data after 12 years, while the right to refer is automatically granted under the "12 years rule". See further Section 6.2. This is also the case in specific circumstances under the "inquiry procedure" (as described in Chapter 6 above) or when the parties do not agree on data sharing within a SIEF (as described in Chapter 5 above). Further, e.g. Article 30.3 states that in certain circumstances, ECHA shall give a permission to refer to data.

**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 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.

(2) Industry associations: In certain cases, trade associations commission studies and hold data on the behalf of their members. The question 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 is 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, 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?**

Several compensation formulae exist for cost sharing, as described in Section 7 to this guidance document. Also, the parties must organize the physical transfer of the data (studies, or letter of access) among each other.

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 will normally be reached before the first registration deadline. However, actual payment of the share of the cost is in principle required at the time of registration, unless otherwise agreed among Potential Registrants.

In summary, under Step 8, Potential Registrants organize among themselves the actual exchange of data and compensation thereof, so that each potential registrant is entitled to register and is/has properly compensated for the data it has/is provided. To have access to the information he needs to complete his registration in exchange for compensation. Potential Registrants are only required to pay for studies they need in accordance with their tonnage bands.

### 5.3.9 Step 9: Joint Submission of Data

All existing relevant and available information gathered when preparing the registration dossier has to be documented by the 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). 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 recommended reporting formats.

In case of a joint submission, the Lead Registrant has to identify himself but also all the other registrants who are part of the joint submission. The same applies to the other registrants who have to identify themselves in their dossier but also the Lead Registrant who submits the dossier on their behalf.

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

For more details on joint submission see Chapter 8.

## 5.4 Classification and labelling

Harmonization of classification and labelling is the second objective of SIEF's. 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)).

Classification is directly dependent on the hazard data of the substance and consequently can only be finally decided once all relevant data have been validated and interpreted by the SIEF Participants.

In accordance with Article 113, all Manufacturers and Importers must notify the ECHA of the classification and labelling of the substances they place on the market as from 1st December 2010, irrespective of when the substance is to be registered for the first time.

It is recommended that early in the process, Potential Registrants exchange information on the classification and labelling that they individually apply to the substance in question, so that the Potential Registrants know whether they all come to the same conclusion or whether there are differences.

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, participants can then investigate if differences in classification and labelling stem from missing information or from different characteristics of the substances as further explained in the two examples below.

**Examples**

**Case 1**: Producer A classifies his substance for a given end point on the basis of a study which is not available to Manufacturer B; Manufacturer B does not classify for the same end point due to lack of data.

**Case 2**: Both Manufacturers A and B have studies on a given end point. The study on the substance from producer A suggests classification. Another study on the substance manufactured by Manufacturer B suggests no classification. The substance manufactured by A may have a different hazard profile because of intrinsic differences linked to the production process (e.g. impurities, isomers).

**Discussion:** In both examples, Manufacturer A classifies and Manufacturer B does not classify. In the first example, Manufacturer B should require in accordance with the provisions of Art 30.1 the missing data to producer A and both A and B should also consider applying the same classification. In example 2, classification does differ and the possibility to share data for some end-points among Manufacturers A and B may be put into question.

Potential 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 produced under different grades, leading to different impurity profiles, which can entail a more stringent classification than the pure substance. The same situation may also occur when different processes or 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 with regard to substances that are in the same SIEF; i.e. it applies with regard to substances that are sufficiently similar. Differences in classification and labelling do not justify that information is not shared.

In particular, there may be instances in which the parties to a SIEF agree that different classification and labelling may apply with regard with the same substance, for instance if the

difference is attributed to a well identified impurity, for which the relevant hazardous properties are known. In addition, members of the SIEF can also disagree as to the classification and labelling of the substance. In this context, REACH allows opting out from the classification and labelling in the context of the joint submission.

Therefore, differences in classification and labelling are not 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 to share the Chemical Safety Assessment may become questionable.

## 5.5 Data Sharing: Individual route

Registrants may also comply with their REACH obligations if they proceed as described in Article 30 of the REACH Regulation. It is important to note that registrants that follow the individual route may still participate in the joint submission if they refer to the studies that are part of the joint submission (following appropriate compensation as required in Article 30 of REACH).

Potential registrants that decide to fulfil their registration obligations under the individual route may follow the following steps:

- Step 1 Individual gathering of available information
- Step 2 Individual consideration of information needs
- Step 3 Identification of individual data gaps
- Step 4 Request for missing data to other SIEF Participants
- Step 5 Sharing of available data, if needed
- Step 6 Generation of new information/testing proposal
- Step 7 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.

Step 4, 5 and 6 are specific steps that follow the procedure described in Articles 30.1, 30.2 30.3 of REACH.

The difficulty with the individual approach is that it does not naturally lead to the joint submission of data (Step 7), a legal requirement unless the companies involved can justify "opt out".

A flow chart describing the data sharing process as described in Articles 30.1, 30.2 30.3 of REACH is provided in Annex 1 to this Guidance Document.

### 5.5.1 Step 1 Individual gathering of available information

Step 1 requires each 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 risk management measures, and to perform a literature search.

### 5.5.2 Step 2 Individual consideration of information needs

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 his information needs, Potential Registrants may consider the possible application of data waivers, for instance on the bases of uses/exposure pattern.

### 5.5.3 Step 3 Identification of individual data gaps

Step 3 requires each potential registrant to compare the information available from Step 1 and the data needs from Step 2 and identify precisely the data gaps that will need to be filled in before registration dossiers can be filed.

### 5.5.4 Step 4 Request for missing data to other SIEF Participants

If the potential registrant lacks data that requires testing for purposes of his registration, he has to communicate with the other SIEF Participants to determine if relevant studies are available.

IMPORTANT: Data sharing is obligatory for studies involving tests on vertebrate animals and voluntary for studies not involving vertebrate animal studies. In other words, the potential registrant is obliged to request studies involving vertebrate animals, while he may request the study if it does not involve vertebrate animals.

Two situations may arise:

- the missing study is available within the SIEF (or in another SIEF based on read-across) (Step 5)
- the missing information is not available within the SIEF (Step 6)

### 5.5.5 Step 5 Sharing of available data

The potential registrant requests the missing studies from the relevant SIEF participant(s).

Before the study is made available to the requesting participant, 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 Chapter 7).
- In the case where 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 5.3.8 for guidance on the status of data to be shared, including legitimate possession.

### 5.5.6 Step 6 Generation of new information/testing proposal

The potential registrant cannot proceed alone with the generation of missing data. He is obliged to obtain agreement that one member of the SIEF will perform, or arrange for a Third Party to make the study on behalf of the others. The agreement has to be reached within a deadline set by ECHA; otherwise the decision will be taken by ECHA itself.

In case the participants do not agree otherwise, all participants who require the study are obliged to 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.

### 5.5.7 Step 7 Joint submission of data

Joint submission of data is described in Chapter 8 below. As mentioned above, the difficulty with the "individual route" is that it does not pave the way for the joint submission of data. It is therefore suggested to be used only in cases like sharing data with Data Holders or when companies have justified reasons to opt-out from the joint submission of data.

## 5.6 Data Sharing with Data Holders

Data Holders will receive a financial compensation for the data they share with Potential Registrants, in accordance with the principles set out in the guidance in Section 7. As Data Holders are not expected to register the substance, they do not have stricto sensu “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.

## 5.7 Dispute Resolution in data sharing

The REACH Regulation sets out a specific procedure in case the owner of a study refuses to provide proof of costs of the study or the study itself within a month from the request. The procedure differs for data on vertebrate or non-vertebrate animals.

This process is described in Article 30 (3 to 6) of REACH and schematically in Annex I to the present Guidelines (Chart VI).

### 5.7.1 Data on vertebrate animals

The owner of the study will not be able to proceed with his registration until he provides the requested information and he shall be sanctioned (penalties to be laid down by Member States). In cases where the data holder refuses to provide proof of the cost of the study or the study itself, the potential registrant requesting the information will be able to register without fulfilling the relevant information requirements, which he has to explain in the dossier.

Within 12 months from the submission of the registration dossier, ECHA may, however, decide that the missing test must be carried out by the registrant that did not have access to the available study. In addition, if within this period of 12 months a relevant study has been submitted by another registrant, ECHA shall give him permission to refer to such study (the owner of the second study is entitled to compensation if he makes available the full study report).

### 5.7.2 Data on non-vertebrate animals

The other SIEF Participants must proceed with registration as if no relevant study is available in the SIEF. They will therefore have to carry out the test in order to obtain the information needed to meet the requirements of the registration dossier.

However, the owner of the study who refused to provide proof of cost or the study will be penalized (penalties to be laid down by Member States).

# 6 THE "INQUIRY PROCESS": DATA-SHARING RULES FOR NON-PHASE-IN SUBSTANCES AND REGISTRANTS OF PHASE-IN SUBSTANCES WHO HAVE NOT PRE-REGISTERED

REACH provides for separate data sharing provisions for (1) phase-in substances that have been pre-registered (as described in Chapters 3 to 5 of these Guidelines) and (2) non-phase-in substances, as well as phase-in substances that have not been pre-registered.

The process in place to initiate the data sharing process for this second category of substances is generally referred to as the "inquiry process". It is regulated in Articles 26 and 27 of REACH.

The inquiry process is essentially a three-step process whereby:

- The potential registrant must inquire with ECHA prior to registration if the same substance has already been registered;
- ECHA facilitates contact between the previous registrant(s) and the potential registrant(s) and/or other Potential Registrants, if any;
- Data sharing is organized between previous registrant(s) and/or Potential Registrants including for new tests to be potentially conducted

One of the main differences with the rules for phase-in substances is the early involvement of ECHA and its role in determining substance equivalence before facilitating contacts between registrants.

The inquiry process is described visually in Annex 1 (Chart V).

## 6.1 What substances are subject to the Inquiry Process?

The inquiry process applies to (1) non-phase-in substances and (2) phase-in substances that the manufacturer or the importer (or article producer or importer) does not pre-register.

(1) Non-phase-in substances

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. Phase-in substances are substances which are listed on the European Inventory of Existing Commercial Chemical Substances (EINECS), or that have been manufactured in the EU or countries that have acceded to the EU before 2004[19] but not (yet) placed on the EU market, at least once after 1 June 1992, or are so-called "no-longer polymers"[20] (and are commonly referred to as "existing" substances).

Non-phase in substances are therefore normally new substances, which have not been manufactured, placed on the market or used in the EU before 1 June 2008. However, there

[19] An update to include Romania and Bulgaria is being prepared.

[20] "No longer polymers" are substances which do not meet the definition of a polymer in REACH but were considered as having been notified under Directive 67/548/EEC as they met the polymer definition of the 5th Amendment to that Directive.

may also be cases of substances which have been placed on the market lawfully before that date and do not fulfil the definition of no-longer-polymers but are nevertheless not listed on EINECS. For such cases, it will be important to proceed with registration as soon as possible from 1 June 2008 in order to minimise disruptions of manufacturing, import, placing on the market or use. The European Commission, the Member States and ECHA are committed to searching for practical solutions to such cases. Concerned companies should contact, preferably through their associations, ECHA well in advance of registration (at best before December 2007) to alert on possible problems at registration of these substances. ECHA would then discuss potential solutions with the European Commission and Member States as appropriate.

Non-Phase-In substances also include substances listed on ELINCS that are considered as already registered (Article 24). Whenever ELINCS substances reach a higher tonnage range than the one for which a notification dossier has been submitted, an update is necessary (in this case, the procedure of Art. 12(2) applies).

(2) Phase-in substances

Phase-in substances subject to the inquiry process are those that have not been pre-registered. Potential registrants of such substances must stop manufacture or import of their substance, after 31 May 2008, before making their inquiry.

Potential Registrants of phase-in substances that decide to register without pre-registration under the inquiry process, are mandatory participants of the relevant SIEF once they have registered. They have the obligation to share their data they hold on request. See Section 6.4 below.

## 6.2 Inquiry prior to registration

Prior to Registration, a potential registrant of a non-phase-in substance 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.

With its inquiry, the potential registrant must submit the following information (Article 26.1):

- his identity, as specified in section 1 of Annex VI, with the exception of the use sites;
- the "full" identity of the substance, as specified in section 2 of Annex VI;
- which information requirements would require new studies involving vertebrate animals to be carried out by him; and
- which information requirements would require other studies to be carried out by him.

The inquiring potential registrant will then be confronted with one of the following three situations:

**(1) The substance has already been registered and the relevant information has been submitted less than 12 years earlier**

ECHA will inform the potential registrant without delay of:

- the name(s) and address(es) of the previous registrant(s);

- relevant summaries or robust study summaries already submitted by them.

At the same time, ECHA will inform the previous registrant of the name and address of the potential registrant. The procedure under section 6.3 below will then apply.

**(2) The substance has already been registered and the relevant information has been submitted more than 12 years earlier**

The applicant is not required to request the information from the previous registrants when it is more than 12 years old. If he decides to use the older studies, he is not required to pay any financial compensation to the prior registrants.

As the potential registrant is allowed to register without having access to the full study report (Article 10 (a), last paragraph), the registrant could normally access the results of the studies and the study summaries/robust study summaries. However, in the case of study summaries or robust study summaries for which ECHA has accepted as valid the justification for not publishing them, the registrant should make an express inquiry to ECHA to have access to such studies.

If the same end-point is covered by a newer study, it is the responsibility of the registrant to consider whether the information in the older study is still relevant.

However, the potential registrant has to organise joint submission with the previous registrant.

**(3) Information that the substance has not previously been registered**

The applicant has to carry out all tests required to satisfy his registration requirements, alone or with other possible applicant(s). However, testing on vertebrate animals must be avoided by making use of available data, read across or the results of validated (Q)SAR Models, if this is sufficient for the purpose of registration.

**The "12 Years rule":**

The period of data protection is 12 years. This applies to summaries and robust study summaries submitted in the framework of a registration

In accordance with Article 25.3, the 12 year period starts running from the moment when the information was submitted to the relevant authorities. This means that, when the information has been submitted after the original registration (for instance, following an update), the 12 year period extends beyond 12 years after the registration date.

The 12 year rule is also applicable to data on substances 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 shall be regarded as a registration and that ECHA shall assign a registration number by 1 December 2008.

Under Directive 67/548/EEC, the data protection period is 10 years from submission. As a result of Article 24.1, the data already submitted will benefit from a 2-year extension. However, the original submission date will continue to be the starting date for the application of the 12-year rule. This means that the data submitted in the framework of a notification on 1 June 2001 will continue to be protected under REACH until 2013.

### 6.3 Sharing of existing data between registrants

In cases where information on the substance to be registered has been submitted less than 12 years ago, the following process applies:

**Step 1 – Request for studies**

The potential registrant cannot repeat testing on vertebrate animals and is required to request such information from previous registrant(s). He also has the right (but not the obligation) to request information involving other types of tests.

**Step 2 – Negotiation on data and cost sharing, and possible outcomes**

The potential and the previous registrant shall seek to reach an agreement on data and cost sharing upon receipt by the potential registrant of the contact details of the previous registrant. This can be achieved either by direct agreement or by submission of the matter to an arbitration board whose decision the parties agree to accept.

The costs of sharing the information have to be determined in a fair, transparent and non-discriminatory way (see Chapter 7).

**(1) An agreement is reached**

The previous registrant makes available to the new registrant the agreed information. He also gives the new registrant the permission to refer to the full study report.

**(2) Failure to reach an agreement**

The potential registrant informs ECHA and the previous registrant of the failure to reach an agreement. Within the following month ECHA gives the potential registrant permission to refer to the information he requested.

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 must present his claim before a national court.

The previous registrant may also decide to make the full study available to the potential registrant. In this case, he has a claim for an "equal" share of the cost incurred by him.

The concepts of "share", "proportionate" share or "equal" share of the cost and the cost itself are discussed in Chapter 7 on cost sharing in this guidance.

## 6.4 Relationship of "early registrants" with other potential registrants and SIEFs for Phase-In Substances

Whenever a substance is intended to be manufactured or imported by multiple potential registrants, certain parts of information must be submitted jointly in accordance with the procedure of Article 11. In the case of phase-in substances, this applies to both potential registrants who have and who have not pre-registered their substance. In this context a potential registrant who has not pre-registered his substance, hereafter referred to as an "early registrant", may decide to submit his information before joint submission takes place. In order to meet requirements of Article 26 he shall make an inquiry to the ECHA and he will be informed if the same substance has been already registered or/and if there are other potential registrants.

As, in the case of phase-in substances, the same substance for which a potential registrant has submitted an inquiry can be the subject of pre-registration by other potential registrants, different situations can be identified, as follows:

(1) An inquiry is made before the ECHA is in a possession of contact details of pre-registrants of the same substance. The inquiry process can proceed, leading to registration by the inquiring potential registrant ("early registrant"). If the same substance is then pre-registered and a SIEF is formed, then the early registrant will automatically be a participant in that SIEF (Article 29.1). The early registrant will be a "data holder" in that SIEF with regard to the information he has registered[21]. He will have to update his registration dossier to align it with the joint submission. In particular, he needs to agree with the SIEF whether he or another member of the SIEF will be the lead registrant. Moreover, there needs to be agreement on the information to be submitted jointly. He may also opt-out for some or all information and give a justification according to Article 11(3).

(2) An inquiry is made at a time when a SIEF has been formed or the ECHA is already in a possession of contact details of pre-registrants for the same substance. ECHA informs the inquirer of the contact details of those who have pre-registered with the same substance identifiers (or the contact details of a SIEF formation facilitator if he has already been appointed) to allow data sharing between the inquiring potential registrant and the potential registrants within the SIEF. The inquiring registrant will have to be part of the joint submission with other SIEF members. He may also opt-out for some or all information and give a justification according to Article 11(3).

[21] There is one exception to this principle, and this is when a study available in the SIEF is necessary to complete or update their registration dossier. In this case, early registrants have the right to request that study (and pay accordingly) because they need the information for the purposes of one of the objectives of Article 29.2.

(3) An inquiry is submitted after one or more SIEF Participants have already registered the substance. The inquiry process will follow the normal procedure described in Sections 6.2 and 6.3 above and the registrant(s) in a SIEF will have to share data according to the rules for non-phase-in substances. The new registrant will become a participant to that SIEF once he has registered. In addition, the inquiring registrant will have to be part of the joint submission with SIEF members. He may also opt-out for some or all information and give a justification according to Article 11(3).

## 6.5 Waiting periods for manufacturing and import of substances in case of registrations and updates of registrations

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, it should be noted that 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)). However, in the case of *continuing* the manufacture or import (e.g. after submission of an update of the registration dossier), there is no requirement to interrupt activities during this three weeks period. Please note that, whenever an interruption of activities is necessary to await the end of an inquiry, the three weeks waiting period after registration must be respected before manufacturing or importing can start again.

# 7 COST SHARING

## 7.1 Introduction

As data gathering induces costs, data sharing implies some form of cost sharing. 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.

As described in this Section of the Guidance Document, agreement on cost sharing usually 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 in this Section of the Guidance Document 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 relevant factors when organizing data quality review, data valuations and other cost sharing activities. As described in Section 5 above, in general, it is recommended that an agreement on cost sharing is reached prior to the disclosure of available information by participants.

## 7.2 Data quality

### 7.2.1 Reliability – Relevance – Adequacy

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

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

**Reliability** - evaluating 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** - covering the extent to which data and tests are appropriate for a particular hazard identification or risk characterization; and

**Adequacy** - defining 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. When determining reliability, this 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 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, 1997, 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 crude techniques/procedures which have since become refined; and
- the fact that certain information may have not been recorded (or possibly even measured) for a given endpoint, but that it has since been recognized 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, thus allowing the focus to be on those considered most reliable. Knowledge of how the study has been conducted is essential for all further considerations.

### 7.2.2 Data Validation Approaches

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

(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 other approach was developed in 1998 as part of the US EPA HPV Challenge Program.

Other systems might also be considered.

(1) Under the **first approach, Klimisch et al.** (1997), developed a scoring system which can be used to categorize 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., unphysiologic 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.)."

The use of Klimisch codes provides a useful tool for organizing 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.

**(2) The second approach** developed by the **US EPA** provides more information than the Klimisch system 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 in Table 1 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.

When addressing relevance and adequacy, these aspects will be facilitated by having a clear picture of the reliability of a study. This is because at this stage, one or more key studies per endpoint will have been identified and it will be clear whether full robust study summaries can be prepared which can be used for judging relevance and adequacy.

The use of tools for identifying reliable, relevant and adequate data helps to ensure that high quality data are identified but this does not, however, remove the need for a weight-of-evidence analysis approach during the assessment of data.

Because of the nature of existing data, it is reasonable to expect that there will be some cases in which several studies - some of which may not have passed the initial screen, may be collectively used to address an endpoint, thereby avoiding additional testing.

The pooling of several studies, one or more of which alone may be inadequate to satisfy a specific element is therefore a way that a weight-of-evidence analysis can be applied. For example, if several repeated dose studies are available on a particular chemical 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). Collectively, however, as 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.

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.

Criteria for accepting proposed studies / quality ratings should be agreed in advance. This could recognize a self assessment approach by study owners but in case any problems should

arise, an arbitration mechanism might need to be utilized. This could involve commissioning an expert Third Party to evaluate the initial assessment. If a data supplier does not meet this requirement, then the study may have to be treated as "not assignable" information for the purposes of subsequent valuation and cost sharing (unless proven otherwise).

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 (MERAG Fact Sheet 08, pp 6-12). Other sectorial approaches may also be available.

**Table 1 Initial Screening Criteria for data reliability 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** |

Footnotes to Table 1

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, Salmonella/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.

## 7.3 Study valuation

An accurate and realistic valuation of studies is a critical component in the cost sharing process. Initially, studies should be assessed in terms of their scientific quality and then with this basis established, a financial value can be determined taking account of various mark-up and / or reduction elements, where appropriate. In undertaking a financial assessment, the objective should be to ensure that an adequate and appropriate compensation is made available to the study owner taking full account of the data sharing principles embodied in the REACH legislation.

### 7.3.1 What studies should be valued ?

From a quality perspective and taking Klimisch ratings as a model, only studies with a reliability rating of 1 or 2 should normally qualify for financial compensation. Reports in categories (3) “not reliable" and (4) “not assignable" can therefore effectively be deselected from a valuation procedure whenever higher reliability studies are available. This does not mean that the information contained in such reports should be considered to be of no importance but rather that pragmatically, there is little basis for compensation when they are put into comparison with higher quality studies.

An exception may arise for Klimisch 3 reports if they can satisfy an endpoint via the weight - of - evidence approach described above. In this case, there would be no higher ranking studies available but if the existing information was sufficient to support the endpoint, the studies could be treated for costing purposes in the same manner as that for higher ranking data. Payments in this instance would normally be subject to formal acceptance of the studies and thus avoidance of any repeat testing charges.

### 7.3.2 Historic versus Replacement costs

Article 30.1 requires the owner of a study to provide proof of its cost within one month of a request for that study However, nothing prevents Potential Registrants to agree on other valuation methods, such as the "replacement value", i.e. the price that would be paid today to obtain the same study. Which of those two methods (historic costs or replacement costs) is more appropriate is a matter for discussion within the SIEF.

**(1) Possible correcting factors**

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

Elements which may be included in the valuation process to increase the value of a study are expenses related to the preparation, evaluation and other activities or measures related to the study, including:

(1) Preliminary testing for determining test concentrations;

(2) Substance testing according to the standard protocol;

(3) Development of suitable analytical methods;

(4) Supplementary analyses (e.g. Substance characterization; Stability in test medium; Concentration in test medium)

(5) Administrative and travel expenses;

(6) Processing and professional support by the commissioning party; (may include study design and /or preparation of test material)

(7) Preparation of IUCLID data set and robust study summary.

The valuation should only account for expenses which are supported by verifiable documentation or, if such documentation is not available, expenses that can be justified with sufficient plausibility.

Elements which may be used in the valuation process to decrease the value of a study includes:

(1) the fact that the study is not a GLP study

(2) other possible study deficiencies to determine on a case by case basis.

**(2) Specific Value Elements**

- Expenses for preliminary testing and substance testing according to a standard protocol (baseline costs) may be calculated as an average of the prices charged by two or three agreed testing institutes 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. When testing for inherent substance properties, the limitation (2) "reliable with restriction" arises most commonly from the fact that the study was conducted at a date prior to the introduction of GLP standards.

- 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[22] 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: surcharge to the sum of experimental costs (substance testing and analysis) may be charged for administrative expenses (processing and professional support by the commissioning party, travel expenses, archival of the test substance and raw data). The surcharge should not be fixed but rather should be related to the value of the study concerned. A possible example of variable administrative costs on the basis of the value of the underlying study is used in examples 1 and 2 in Annex 5. If factual information relating to these expenses is available this could, of course, override the use of guideline figures. In the case of significant deviation in excess of the guideline surcharge, however, expenses would need to be fully substantiated and documented individually.

- Robust Study Summary: The 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).

- Risk Premium: The decision to conduct a study involves a risk for the initiator that the project may not be successful in generating the information desired (with no possibility then for any future recompensation). It can be appropriate to acknowledge this in the valuation exercise. This can be particularly true for recognized problematic substances or those difficult to test. When accessing an existing study with a known outcome, there is no exposure to this risk for a new party and accordingly, in certain circumstances, a certainty premium may be assigned to the study. This would only 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 premium due to the nature of the testing and the inherent properties of the substance involved.

- In some cases, additional expenditure may also need to be considered for compensation. This could arise for example where substances have been processed in the ICCA / OECD HPV chemicals programme. There, data normally have already been reviewed and key studies have been selected in a similar way to the identification of a Lead Registrant data package. The value of this activity can be taken into account on the basis of the incurred expenditure, where relevant. This element can encompass all relevant endpoints and is an extra cost on top of the valuation of the studies concerned.

- An illustration of the principles related to study valuation are shown in Examples 1 and 2 in Annex 5.

[22] Provision of analytical procedure or method includes the measures required for testing a method known from the literature for compatibility with the intended use.

## 7.4 Cost allocation and compensation

As mentioned previously, the REACH Regulation requires SIEF Participants and potential and previous registrant(s) in case of non-phase in substances to make every effort to ensure that the costs of sharing information are determined in a ***fair, transparent and non-discriminatory way***. In this section, key factors for consideration in this context together with associated cost sharing mechanisms are reviewed. Cost allocations may be calculated for studies relating to all end points for which information is required according to REACH.

The current value of all study reports should be determined in accordance with the guidelines referenced above. This serves as the measurement base for subsequent cost allocation and compensation. Note that costing activities are not appropriate for reports which are recognized to be in the public domain (see Section 5.3.8 for further guidance on this point).

In the absence of specific rules, Potential Registrants are free to select any cost allocation and compensation mechanism that they perceive to be fair, transparent and non-discriminatory. Possible mechanisms include:

- Sharing data equally, based on the number of parties involved;
- Proportionality, based on production or sales volume or otherwise(please see also Chapters 9 and 11 on competition law respectively CBI);
- Alternative mechanisms using part of the above models in different mode.

The REACH Regulation refers to equal sharing as a default mechanism in some cases and this will be an important element. However, parties are free to agree on any model.

Pursuant to Art. 30(1), registrants are only required to share the costs of information that they are required to submit to satisfy their registration requirement. Therefore, companies cannot be forced to pay for studies that they do not need and they also cannot be forced to pay before they actually need them in their respective tonnage band. However whenever the (potential) registrant requests data earlier, he has to pay on receipt of the data.

### 7.4.1 "Individual route"

In this instance, the study value should be determined using the same principles as described in Section 7.4.2 and then shared by all parties requiring the information for registration purposes. If the data owner is included in this group of Potential Registrants, he would be incorporated into the allocation calculations. If the data supplier has no registration intentions, costs would be distributed only amongst the purchasing parties. If any additions to the number of interested parties occur throughout the lifetime of the SIEF, compensation adjustments would need to be subsequently effected by the study owner(s).

### 7.4.2 "Collective route"

In view of the requirements under REACH for a Lead Registrant consolidated dataset package, this approach is likely to be employed for most data sharing activities.

In this case, solely for the purposes of cost allocation, when addressing a particular end-point, only one study per registrant should normally be proposed (even though all studies may be used for technical support).

Companies participating in the collective route are free to decide on any data compensation mechanism they see fit for purpose. The models explained below have been used in the past and can be considered for apportioning cost between participants; they are however only models. The example provided to illustrate them should be reviewed to fully understand each model. The first set of models (point 1 below) is based on the principle that compensation for a given end point is due by non contributors only for the best study available, i.e. for one study per end point. The second model (point 2 below) deviates from this principle by exempting holders of data which would satisfy their registration requirements from the cost sharing mechanism and the costs are only shared between the holder of the key study and those registrants who do not hold sufficient data.

In this context, it is important to recall that registrants are only required to share the costs of information that they are required to submit to satisfy their registration requirements. Therefore, registrants cannot be obliged to pay a share for more than one study per endpoint, unless additional studies are necessary in order to fulfil the information requirements (e.g. in a weight of evidence approach).

**(1) Data compensation based on study quality-weighted models**

These data compensation mechanisms are illustrated by examples 3, 4 and 5 in Annex 5. These models are based on the principle that compensation for a given end point is due by non contributors only for the best study available

If there is then more than one contributing source, the following guidance may be applied in order to arrive at an appropriate cost allocation. For the purposes of illustration, Klimisch ratings are employed and again, the current value of all relevant reports should be determined first.

**Case (i) : only Klimisch 1 studies available**

By contribution of a category (1) report (“reliable without restrictions”), the share of that contributor is considered as paid for the relevant end point. This applies also for any other parties who contribute reports of equal quality. The cost allocation against this end-point is then borne only by the remaining (non-contributory) parties.

If any 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.

**Case (ii) : Klimisch 1 & 2 studies available**

If reports from both category (1) and (2) (“reliable with restrictions") are available for the same end point, the report with the higher rating will be used as the key study for cost allocation purposes. Contributors supplying a lower rated report contribute according to the difference in value of their study to the key one selected. Other (non-contributory) parties 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 is not in existence and only one or more reports of category (2) are available, the report with the highest assigned value will be selected as the key study for cost allocation. Contributory members will pay by difference (as above) whilst others 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 participants 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 end-points covered.

**(2) Direct data compensation**

This model is illustrated in examples 6 and 7 of Annex 5.

As an alternative to the approach defined above, other more direct cost allocation mechanisms could also be utilized. In all cases, clear rules for the study valuation step need to be firmly established as a prerequisite to applying any distribution mechanism. This could follow the guidance outlined in Section 7.3 or, if there was general agreement / acceptance, a table of nominal costs for all endpoints could be developed by the group.

With study costs established, the following allocation options could be considered:

**Compensation taking several studies into account (Example 6)**

In some cases more then one key study might be needed to cover a certain data requirement. In these cases a mechanism that covers the cost sharing of more then on key study can be envisaged. Under that option, several studies for a given endpoint are used to calculate a total endpoint value. This total value would then be used to define a member contribution. Cost adjustments per participant would be made depending on the value of the studies provided relative to the member contribution required. This route has the benefit of recognizing the full weight of the studies available but in order to avoid the possible situation where the number of existing reports exceeds the number of participants to the sharing process, contributors should normally not be compensated for more than one study per end point. Nevertheless, in that model, non-contributions would compensate more than one study per end point.

**Compensation for key study only (Example 7)**

In this approach, compensation would be based around the key study selected for an endpoint. Other Data Holders for the endpoint would be exempted from the compensation process and only non Data Holders would be expected to provide a financial contribution to the key study holder.

Agreement on key study selection is critical for this mechanism and there could be difficulties to resolve this if a number of comparable studies are available. If necessary, however, more than one key study might be assigned. Example 6 could then be followed in that case.

## 7.5 Further factors

A range of additional factors may also need to be considered when addressing cost sharing issues and these are noted below. In each case, the basic valuation and sharing mechanisms described above may still be applied but with appropriate adjustments then being made at relevant points in the process.

### 7.5.1 Klimisch 3 studies

As mentioned above**,** in certain cases it may be possible that whilst Klimisch (3) studies represent the best information available, by adopting a weight-of-evidence approach this can be sufficient to satisfy the requirements of an endpoint. In this event and assuming that the studies are formally accepted thereby avoiding any repeat testing charges, it would be appropriate to recognize the data in valuation terms in line with the criteria for higher level Klimisch (2) data.

### 7.5.2 Usage Restrictions

Whilst consideration of the costing elements described above should lead to a realistic valuation of a study, this describes its full value assuming there would be no restriction in its use. If usage conditions are to be applied, it becomes appropriate to reflect this limitation in the value figure assigned to the study. Examples of restricted application might include the following situations or a combination of these points:

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.

Beyond the EU countries, some geographic boundaries are placed on areas where the information may be exploited.

In these cases (and perhaps others), deductions in the assigned value of a study for cost sharing purposes should be agreed as a percentage reduction of the original valuation. Allocation of the study value would then follow the normal procedures applicable to any non-reduced study item.

### 7.5.3 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 prevail 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 effect this, in view of the need to have a 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 / usage of bands with relatively narrow volume ranges, allowing to estimate or identify individual volumes (for further details, please see Chapters 9 and 11 of the present Guidance Document).

### 7.5.4 New Studies

If new studies are generated as a consequence of the registration activity (following the necessary approval processes as required), the general principles on cost sharing as explained above for existing studies should be employed for the valuation and assignment of any resultant charges. This would ensure that there is a consistency of approach for all data utilized in the registration process and the format would also be clear then to any party requiring this information at a later stage.

Examples 8 and 9 in Annex 5 give an illustrations of some of the further factor considerations described above.

## 7.6 New Parties

For new parties subsequently joining any existing cost sharing arrangement, the same criteria should be applied in determining the financial contribution to be provided for all end-point data. This would apply also for any situations within existing arrangements where additional registration requirements become necessary due to increases in volume. Following this approach, any credit generated would be allocated to all relevant qualifying parties as appropriate.

Example 10 in Annex 5 gives an illustration of the principles described above.

# 8 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 can, if they agree, also jointly submit the CSR and/or the guidance on safe use.

It is important to note that the "joint submission of data" does not eliminate the obligation for each registrant (manufacturer, importer or Only Representative) to submit as well an individual dossier. For each registration, they 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 where parties decide to submit it jointly also (on voluntary basis) for which they will refer to the joint submission by the Lead Registrant.

It is also important that the provisions of joint submission apply also if registrants decide to register without prior pre-registration and for the non-Phase-In substances (see also chapter 6.4).

The present section will explain the mechanisms of joint submission including the status of Lead Registrant and the opt out conditions described in REACH.

## 8.1 Overview of what shall and what may be jointly submitted for Registration

**Table 2 Summary of data to be submitted jointly and/or separately**

| Joint submission | Separate submission | Joint or separate submission: free decision |
|---|---|---|
| 10(a IV) **Classification and Labelling** of the substance as specified in section 4 of Annex VI | 10 (a I) **Identify of manufacturer or importer of the substance** as specified in section 1 of Annex VI | 10 (a V) Guidance of 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. the relevant sections of this report may included, if the registration considers appropriates, 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) **Info 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 |

### 8.2 Mandatory Joint Submission

The REACH Regulation imposes the joint submission of a part of the Technical Dossier including:

- Classification and labelling of the substance;
- Study Summaries;
- Robust study summaries;
- Proposal of testing;
- 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 a same substance. The joint submission is made on behalf of the other registrants. He has to specify:

- Their names, address, phone number, fax number and e-mail address;
- Parts of the registration which apply to other registrants.

Any other registrant shall identify the Lead Registrant submitting on his behalf specifying:

- His name, address, phone number, fax number, and e-mail address;
- Parts of the registration which are submitted by the Lead Registrant.

If a registrant uses a Third Party Representative in a SIEF, the Lead Registrant will provide ECHA with the coordinates of the Third Party Representative. The registrant represented by

this Third Party Representative has to mention in his own registration dossier the coordinates of his Third Party Representative and of the Lead Registrant acting on his behalf.

## 8.3 Lead Registrant

### 8.3.1 Who is the Lead Registrant?

No rules are developed in REACH Regulation to elect the Lead Registrant. Under the Regulation the Lead Registrant is the one registrant acting with the agreement of the other assenting registrant(s) and who shall submit the "joint dossier".

In case of phase-in substances, the Lead Registrant will be logically one of the Registrants who plan to submit his registration file before the first registration deadline. It means that the "Lead Registrant" will likely be a Manufacturer or Importer registering in the tonnage band of 1000 tonnes or more per year.

However, this is not an obligation: the joint submission registrants have the possibility to appoint a leader with a lower tonnage (for instance, because they together pre-register many other substances and decide to share the workload of managing the joint submissions). In such case the Lead Registrant would have to submit a dossier (i.e. including studies for the higher tonnage) by the first registration deadline that applies to the SIEF members. However, the "Lead Registrant" would still pay the fee corresponding to his own tonnage.

The Potential Registrants have to agree on:

- who will be the Lead Registrant;
- the information to be jointly submitted

Only one Lead Registrant can be appointed per substance (see Chapters 3, 4: one SIEF = one substance = one joint submission = one Lead Registrant) even if several tonnage bands co-exist. This rule applies also to the non-Phase-In substances (see Chapter 6 : one substance = one joint submission = one Lead Registrant).

It means that all the Manufacturers, Importers and Only Representatives concerned by a substance (independently of the tonnage band and of the use of this substance as intermediate) should participate to the discussion as soon as possible and agree on a Lead Registrant and the information to submit jointly.

*How to choose the Lead Registrant?*

- If only one potential registrant volunteers to become Lead Registrant he has to convince the other Potential Registrants to elect him as Lead Registrant.
- If two or more Potential Registrants volunteer to become Lead Registrant, they can seek an agreement between them as to who will be the Lead Registrant and propose it to be supported by all Potential Registrants. If the volunteers cannot agree, then it is recommended that the other Potential Registrants elect the Lead Registrant.
- If no potential registrant volunteers to become Lead Registrant, a mechanism by default is proposed: the Lead Registrant will be the EU Manufacturer or EU Importer with the highest capacity of production or import of the substance.

If an agreement is signed by several registrants, it could include the rules of designation (see Chapter 10 forms of cooperation).

To ensure that the Lead Registrant will fulfil its obligations and to make clear who is acting on behalf of whom, 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 will opt out, etc).

If the Lead Registrant ceases to manufacture or import the substance the previous rules apply to choose a new Lead Registrant.

### 8.3.2 What are the tasks of the Lead Registrant?

The main task of the Lead Registrant is to jointly submit the information described in Section 8.2 above (Mandatory joint submission) as well as, as the case may be, the information described in Section 8.5 below (Voluntary joint submission).

In addition, the Lead Registrant has the following mandatory tasks:

- identify the other registrants in his registration dossier.
- request confidential treatment of data (Art 10(a)(xi), if required

Finally, the Lead Registrant may also act as a contact point for communication within the SIEF and with other SIEFs for “read across” purposes.

The liability of the Lead Registrant is discussed in Section 4.8 above.

## 8.4 Opt-Out

### 8.4.1 What are the opt-out conditions from joint submission?

As explained above, REACH requires the joint submission of studies, testing proposals and classification and labelling information. However, registrants are allowed to opt out from the joint submission under specific conditions (see below). It is important to note that opting out can be partial (*i.e.* for example a registrant may seek to protect confidential business information, or disagree with the Lead Registrant's selection of information, for a particular test, but otherwise use the dossier lodged by the Lead Registrant for all other shared information.)

The right to opt out does not apply to the data sharing obligations, or to opting out of membership of the SIEF. Any exercise of the opt out must be fully justified in each case as prescribed by the REACH text.

### 8.4.2 What are the criteria to opt-out of joint submission?

Paragraph 3 of Article 11 (and repeated in Article 19, which deals with joint submission of data for isolated intermediates) gives three allowed reasons for a registrant to opt out of 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."

Registrants invoking any or all of these conditions are required 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." (Article 11, paragraph 3).

**(1) Disproportionate Costs**

Disproportionate costs might arise when a potential registrant already has a complete set of the necessary test data for his product in his possession, and that joint submission would cause him disproportionate costs. An example could be that the cost sharing formula adopted by a SIEF (or consortium formed by a subgroup within it) is particularly disadvantageous to certain members, who consequently find the cost of tests it is proposed to share have become excessive. The REACH Regulation does not define “disproportionate” costs, registrants relying on this ground to opt out should provide sufficient explanations in their registration dossiers.

**(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 was 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 SIEF The fewer participants in a SIEF, the more likely it is that CBI might be released through indications of sales volumes (for Competition law aspects related to the exchange of volume information, please see Chapter 9 of the present Guidance Document). Although there is no further quantification in the legal text of what constitutes “substantial” detriment, a registrant seeking to use this opt out should at 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.

**(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 product's specific application(s). In such a case he would have to provide a qualitative explanation for why he held this 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 standard, and does not wish to compromise his reputation by being associated with what he sees as inferior material, especially if the authorities later reject it. In such a case there would also be additional administration costs involved with resubmitting a registration dossier with replacement data of higher 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 product 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 his opt out would be grounded in demonstrating the adequacy of the alternative test data he was using, coupled with the disproportionate cost to himself if he otherwise accepted the data proposed by the Lead Registrant.

### 8.4.3 What are the consequences of opting out?

An immediate consequence 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.

In addition, dossiers submitted under the opting out provisions will be prioritised by ECHA in the context of Evaluation (compliance check).

Finally, the registration fees linked to the submission of the registration dossier may be higher in cases where the registrant opts out.

### 8.4.4 What are the remaining obligations of the potential registrant?

In so far as the potential registrant is member of the SIEF, 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 information, 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.

## 8.5 Voluntary Joint Submission

Part of the registration dossier may be submitted jointly or separately on a voluntary basis. This part consists of:

- The Guidance of safe use of the substance
- The 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, see Guidance on the Chemical Safety Report.

Under REACH, 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 detailed guidance on this issue, reference is made to the .

The CSA consists of the following parts:

- Evaluation of the human health and environmental hazards as well as PBT and vPvB assessment;
- Development of exposure scenario(s);
- Refinement of the hazard assessment, if necessary;
- Risk Characterization.

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) and in a horizontal way (between the suppliers carrying out the CSA together, for common uses).

An independent Third Party could be appointed to exchange this information if considered CBI .

**The Guidance on Safe Use of a substance** is a part of the technical dossier (Annex VI section 5) and will correspond to information in the Safety Data Sheet (SDS) for the substance. For detailed methodological guidance on the Guidance of Safe use, reference is made to the Guidance on information requirements.

If a CSR is not required, some confidential data might need to be exchanged to draft the Guidance of Safe Use.

It is important for Industry to consider working together on the CSR and the development of Exposure Scenario via exposure categories. Working together will be cost efficient and important for the coherence and the consistency to perform CSA. However, a separate submission of this part of the Registration dossier may be justified in cases there are CBI

issues and if regular updates of the CSR are contemplated since this could be more complicated to do so via a Lead Registrant that directly by each Registrant.

# 9 INFORMATION SHARING UNDER EC COMPETITION LAW

## 9.1 Introduction

### 9.1.1 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 Community level (hereinafter "EC Competition law"), may apply to REACH and all related activities, including data sharing.

This guidance on EC Competition law is intended to help the REACH actors to assess the compatibility of their activities for sharing data and information in the context of REACH.

Although this guidance focuses on exchange of information, this does not mean that EC Competition law cannot apply to other aspects of REACH related activities.

Data sharing and information exchange may occur at different steps of the REACH procedure (e.g. during pre-Registration, and/or pre-SIEF, and/or SIEF). This guidance is only limited to the most common types of questions related thereto.

Furthermore, this guidance may apply to any form of co-operation that actors may decide to adopt in order to fulfil their obligations under REACH; including consortia (see Chapter 10).

REACH actors should always ensure that their activities comply with EC Competition law irrespective of the form of co-operation they choose.

### 9.1.2 EC Competition law and Article 81 of the EC Treaty in brief

EC 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 practices 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 81 of the EC Treaty).

Any agreement that infringes Article 81 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 81 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 EC Competition law, please refer to the Commission Directorate General Competition's web site: http://ec.europa.eu/comm/competition/index_en.html

## 9.2 Exchange of information under REACH and EC Competition law

The REACH Regulation encourages 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 and in the context of joint registration.

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 EC Competition law, as explained below:

- Firstly, actors must avoid any illegal activity (e.g. creating cartels) when complying with REACH (2.1).
- Secondly, actors should restrict the scope of their activity to what is strictly required by REACH to avoid creating unnecessary risks of infringing EC Competition law (2.2).
- Thirdly, if actors have to exchange information which is sensitive under EC Competition law, then it is advisable that they use precautionary measures to prevent infringement (2.3).

### 9.2.1 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.

**Important:** Any exchange of information under REACH must not be used by actors to organise or cover the operation of a cartel.

### 9.2.2 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 under REACH itself.

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.

Recommendation: Actors should restrict the scope of their exchange of information strictly to what is required for REACH activities.

### 9.2.3 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 EC 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 especially 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.

General guidance is provided below to avoid the risk that the exchange of such volume information, to the extent that it is necessary and opportune under REACH, constitutes an infringement of Article 81.

**(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 such exchanges would not allow parties to align their market behaviour.

| Recommendation: Actors should exchange information only once or on very sporadic basis. |
|---|

(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.

| Recommendation: Actors should refer to their respective tonnage band as defined under REACH and refrain from exchanging individual or more detailed volume figures. |
|---|

**(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 organization, a company, etc. The Trustee will not represent any actor, as he should be independent, and can be hired by the participants to a SIEF, 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 it receives (i.e., disclose it to the participating companies or anyone else) (see also Chapter 6 and Annex 2).

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 shall 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 should 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. It 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.

### 9.3 Recommended tips for REACH actors when working together

| | |
|---|---|
| **Competition compliance** | Ensure that before entering into an exchange of information under REACH you have read and understood the guidance and that you will apply it.<br><br>In case of doubt, or questions, please seek advise (e.g. from 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; dissociate yourself from these and have your position clearly expressed in writing, including in the minutes. |

**Important Note:** Readers of this guidance should not presume that they know all there is to know about EC Competition law just by reading this document.

This guidance is designed to allow REACH actors to make a preliminary assessment of their conduct under EC Competition law.

This Guidance does not intent 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 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.

# 10 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. Indeed, a SIEF in itself has no prescribed legal form. Also, the REACH Regulation does not organize 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.

## 10.1 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 go from loose ways of cooperating (e.g. IT tools to communicate between all SIEF members) to more structured and binding models (e.g. consortia created by means of contracts). Other examples of forms of co-operation may be envisaged for example: one manufacturer provides a full data set to the other manufacturers in a SIEF which are invited to “join” 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.

## 10.2 What is a Consortium?

For the purpose of this guidance document, the term "consortium" will be used to refer to a more organized and formal type of co-operation between parties (implying either a signed agreement or the adoption of operating rules, or reference to an agreed set of general rules).

Importantly, SIEF 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 to a particular SIEF, but can regroup only some of them or participants of more than one SIEF.

## 10.3 How is a Consortium to be created?

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 in view of 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. They will

look for ways to achieve this. 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 co-operation' and signing 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 sectoral association, a consultant, a law firm or any other service provider.

By either signing the consortium agreement, or accepting 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. As a consequence, there is no specific requirement that consortia be organized by way of the creation of a separate legal entity having legal personality under the legislation of a Member State.

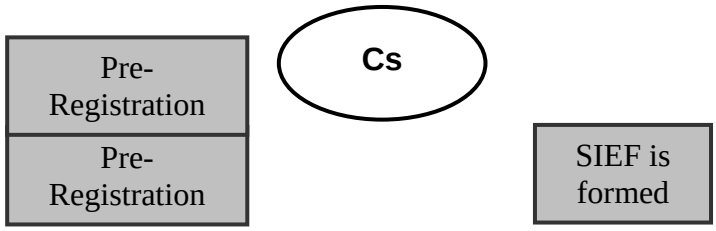
It should be noted that when a consortium is created by a trade association or a law firm it should not be confused with that body, and must be distinctly identified from it.

It may well also be the case that some companies are already organized by having for example either a sectoral group or a consortium preparing the work to be ready for REACH. In this case, they may decide either to continue their co-operation with the same structure, or to create a new parallel structure, or to have any other pattern for co-operating.

In the following examples note that the life of a SIEF may involve one or more pattern of co-operation but these are only to be considered as facilitation. The consortium formation does not bring the SIEF to an end. The SIEF continues to exist through the eleven years specified in the REACH Regulation. Vice versa, a consortium may continue after the SIEF ends.

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 (but to be modified e.g. regarding its composition, if needed). Once they sign the consortium agreement, it is created.




Example 2:

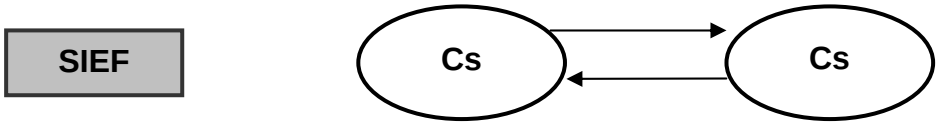
The Companies having pre-registered decide to cooperate for the discussion on the identity check and the sameness of the substance But, not immediately by creating a consortium. They first meet and sign a pre-consortium agreement including appropriate confidentiality clauses. Once the SIEF is created, they decide to create a consortium.


### 10.4 Forms of co-operation in SIEF when using Consortia

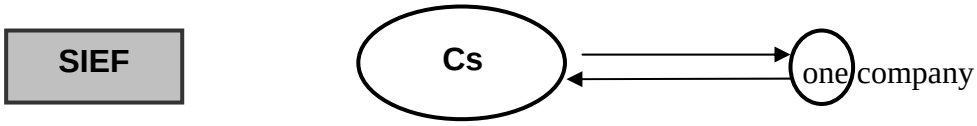
Co-operation by way of consortia to achieve effectiveness of the SIEF, once it is formed may take different forms. You will find a few examples below.

Example 3: Participants in a SIEF decide to form a unique consortium.

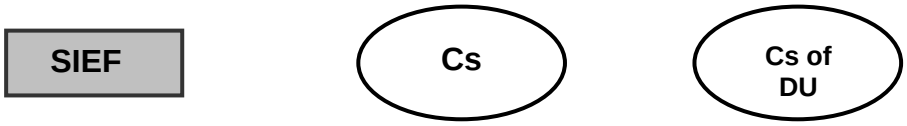
Example 4: Participants in a SIEF may decide to constitute two or more consortia and to organize the co-operation regarding data sharing amongst these consortia (eg if different classification and labelling are foreseen for a substance with the same CAS number). Companies of both consortia are required to cooperate to meet their data sharing and joint registration obligations under REACH.



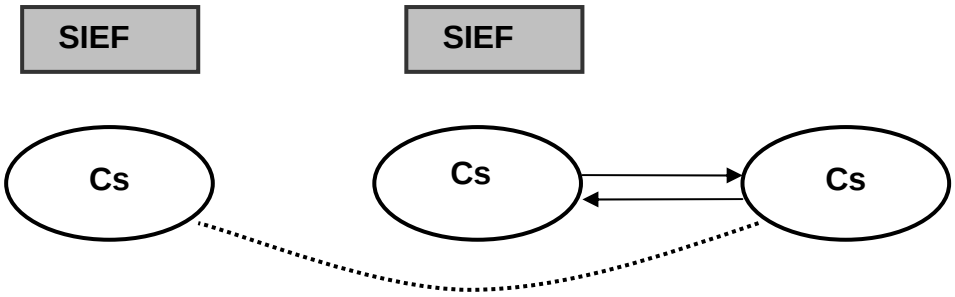

Example 5: A company or a group of companies (participant to a SIEF) decides to stay outside a consortium. In such scenario, the companies that do not belong to the consortia and the companies that belong to the consortia must co-operate regarding data sharing and joint submission (the principles on data sharing within a SIEF described above apply.).



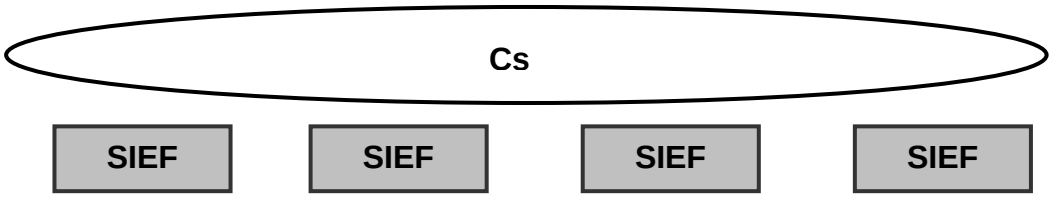

Example 6: Participants in a SIEF (companies, Importers and Data Holders) decide to form a consortium, and Downstream Users decide also to form a consortium to co-operate together, and with the other consortium.




Example 7: Two SIEFs – with three consortia decide to co-operate for specific purposes eg read-across.



Example 8: A major consortium may also be created (eg for a family of substances) for companies to participate in several, but different SIEFs.




### 10.5 Elements of co-operation that may be included in a Consortium

- Conduct or document the identity check;
- Designation in a SIEF of the facilitator or the Lead Registrant (in cases where the consortium groups all SIEF members);
- Organization of the co-operation and thus the consortium;
- Consideration of data (existing data, missing data, new data to be developed);
- Defining data to be shared;
- Facilitating data-sharing and coordination;
- Data valuation, data evaluation (including identification, data access and collection);
- Facilitating 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-SIEFs actions: e.g. joint submission of data, joint registration, and maintaining the life of the consortium even after the joint registration - jointly to follow-up the file until final registration/evaluation, including interacting with ECHA.

It is important to note that when the SIEF has members that are not part of the consortia, the companies of the consortia must cooperate with the companies that are not part of the consortia. The consortia (e.g. through its secretariat) 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.

***C. Duration of the consortium :***

Parties may also decide to have a consortium either just 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 mentioned in the REACH Regulation, for 11 years, or even to keep it afterwards in case they have collectively to answer to some queries for example.

## 10.6 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 owner(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 other cases that 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 which 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 decided and included in the consortium agreement. For example:

- Full members;
- Associate members;
- Observers (either as Third Parties or not)

### 10.7 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 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 co-operation 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 the assistance from a law firm, service provider, sectoral or trade association to manage 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. Organization** | 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<br>Financial year<br>Invoicing and payment<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** | |
| **8. Miscellaneous** | Applicable law<br>Dispute resolution / settlement or choice of jurisdiction<br>Changes to the agreement<br>Dissolution |

# 11 CONFIDENTIAL BUSINESS INFORMATION (CBI)

The REACH Regulation requires companies to share information and data in order to avoid duplicate testing. Some of this information or data may be considered by companies to be confidential business information (CBI) that they consider important to protect. Whether certain information is CBI needs to be determined on a case-by-case basis. CBI issues must not be confused with competition law (see Chapter 9 above) which refers to situations where the sharing of information is likely to lead to distortion of competition.

This Section provides guidance on what companies may do in order to protect their CBI, while complying with their REACH obligations.

## 11.1 What is Confidential Business Information?

CBI is one of the valuable assets of companies, and measures must be taken to protect it.

The REACH Regulation does not define CBI. However, reference is made to information the disclosure of which to the public could be harmful to the concerned party's commercial interests (See Articles 10(a)(xi), 118 and 119) – see Section 11.2 below.

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:

**DEFINITION**: Confidential Business Information

(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.

## 11.2 Are there specific provisions on CBI in REACH?

The REACH Regulation does not contain a specific article or section on the protection of CBI. However, references to the CBI concept are made in several Articles of REACH, which demonstrate that the protection of CBI is a legitimate interest, recognized by REACH, that does 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; 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 that is accepted by ECHA as to why publication of this information is potentially harmful to the commercial interests of himself 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 "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".

### 11.3 Protection of CBI at pre-registration

This section reviews the information that is required to be submitted to ECHA at pre-registration and partially made public by 1 January 2009.

The following data must be submitted at pre-registration:

- The name(s) of the substance specified in section 2 of Annex VI, i.e.

- The name and address of the pre-registrant and the name of the contact person and, where appropriate, the name and address of a Third Party Representative whom the pre-registrant has selected to represent him for all the proceedings involving discussions with other Manufacturers, Importers and Downstream Users;

- The envisaged deadline for registration and tonnage band;

- The name(s) of other substance(s) for which the available information is relevant for performing adaptations to the testing requirements, i.e. use of results from (Q)SAR models (section 1.3 of Annex XI) and read-across approach.

- Optionally, the pre-registrant can indicate whether he is willing to act as "facilitator" in the pre-SIEF discussions

Of that information, by 1 January 2009, ECHA will publish a list of pre-registered substances containing only the substance identifier (EINECS No, CAS No or other identity code) 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 Art 4 of REACH. In that case, it is the identity of the Third Party Representative that shall 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 preserve 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.

**Recommendation**: Potential Registrants wishing to keep their identity secret towards other Potential Registrants should nominate a Third Party Representative at pre-registration.

### 11.4 Protection of CBI during the SIEF Formation

As mentioned in Chapter 4 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 substance identification with the aim to ascertain that one joint registration is possible. 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 willing to protect 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 with using additional personal confidentiality agreements.

(2) In addition to (1), by allowing access to certain documents in a 'reading room' only (copying is not allowed).

(3) In addition to the above, by agreeing to have certain documents reviewed and/or assessed by a Third Party expert (independent consultant), and no-one from the other SIEF Participants will see such documents.

As a minimum, Potential Registrants who intend to protect the CBI character of substance identity information should specify when submitting it 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.

**Recommendation**: It is advisable that potential registrants identify the information they disclose about the properties of their substance that they regard as confidential.

### 11.5 Protection of CBI in the SIEF

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 version 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 sufficiently, a registrant can opt out, and submit its own registration dossier in order to preserve its confidential information. However, the party that opts out is still bound by the data sharing obligations of REACH.

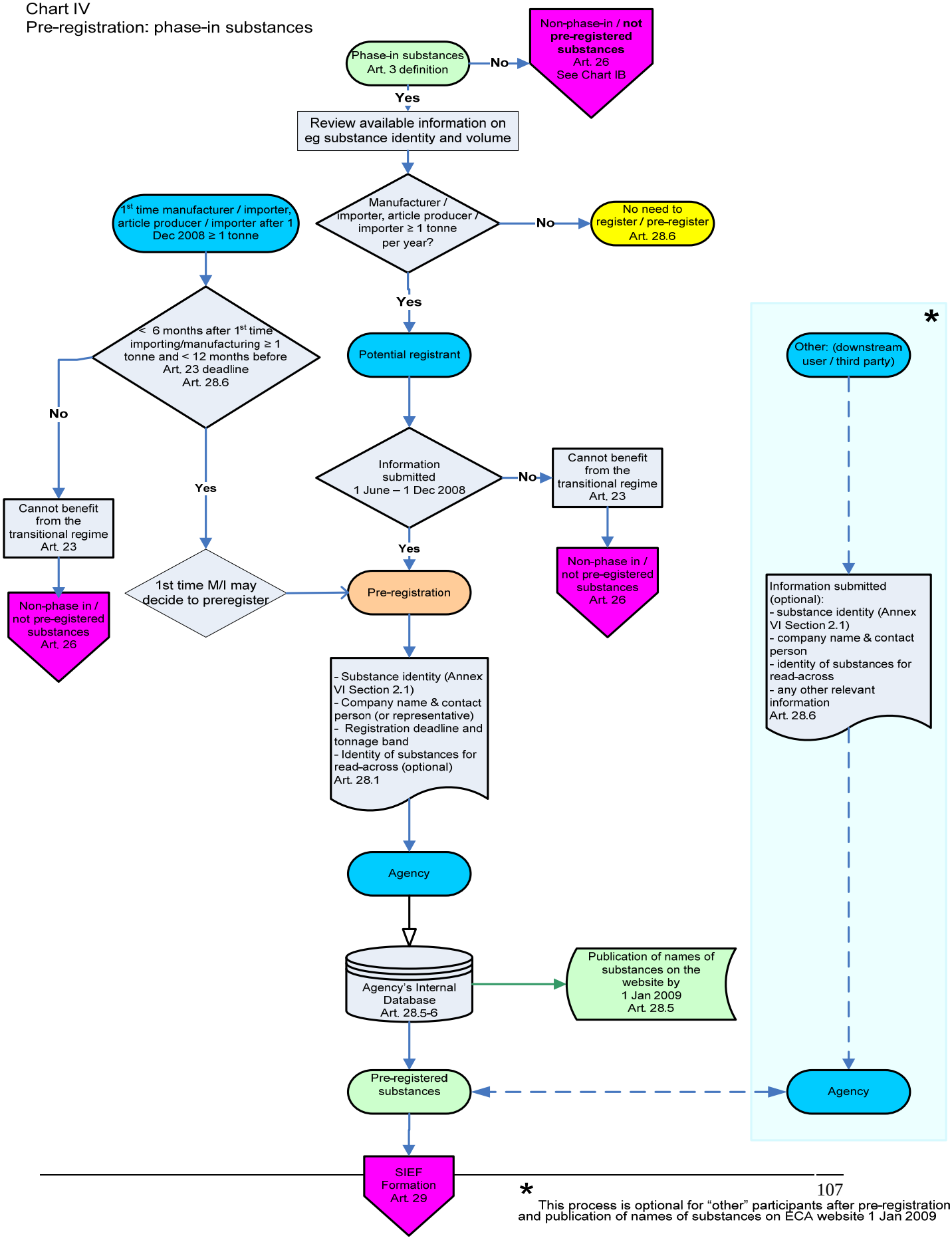
**Recommendation**: To the extend that the information that must be exchanged in the context of registration contains CBI, parties may enter into confidentiality agreements, may prepare non-confidential versions of the documents, or may appoint an independent third party.

### 11.6 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 and for which they request non disclosure on ECHA's website. 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.

# ANNEX 1 PROCESS DESCRIPTION CHARTS

Chart IV
Pre-registration: phase-in substances




* This process is optional for "other" participants after pre-registration and publication of names of substances on ECA website 1 Jan 2009

Chart V
Process Description: non-phase-in and not pre-registered substances (1)

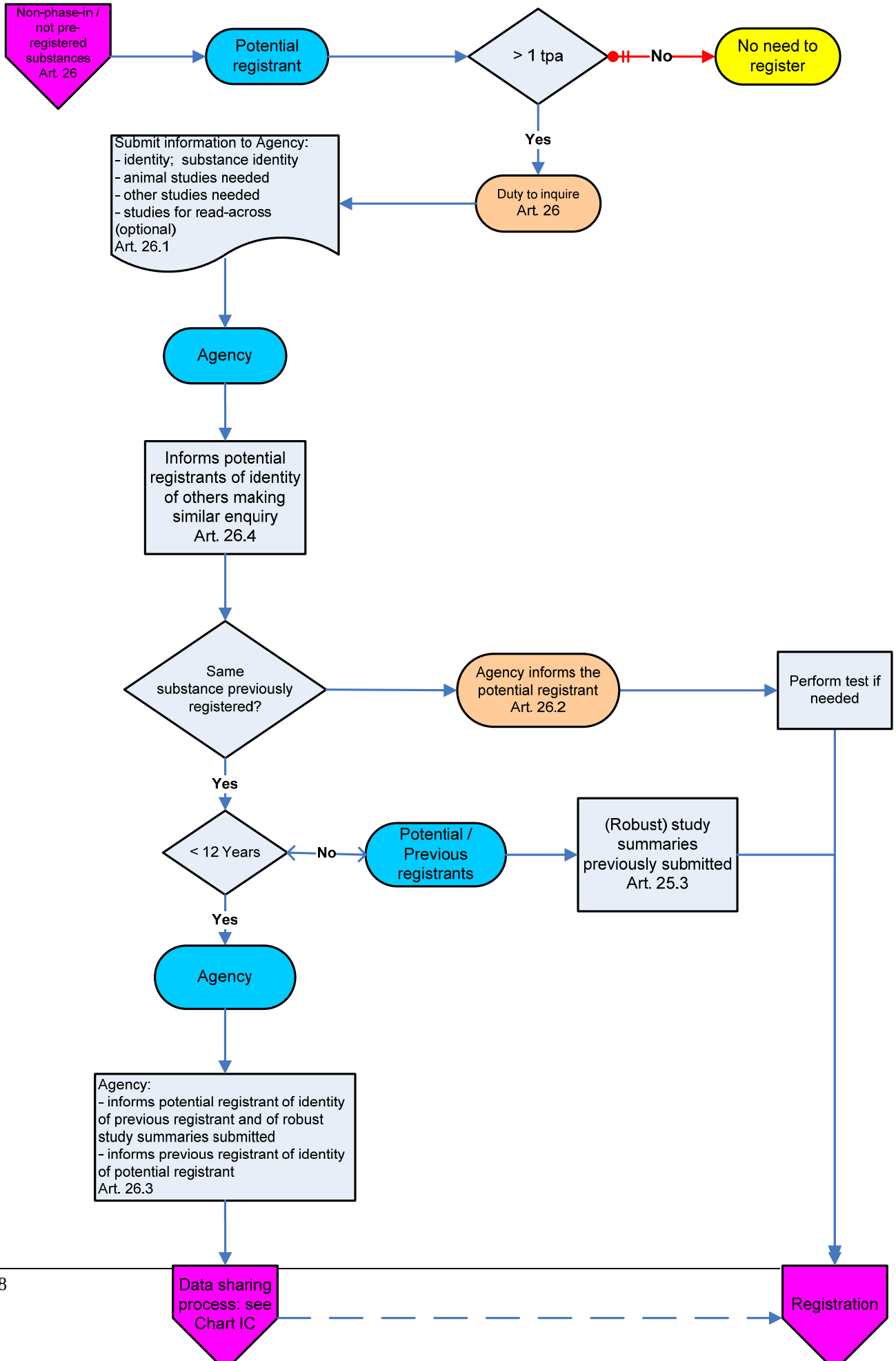


Chart VI
Process Description: non-phase-in and not pre-registered substances (2)

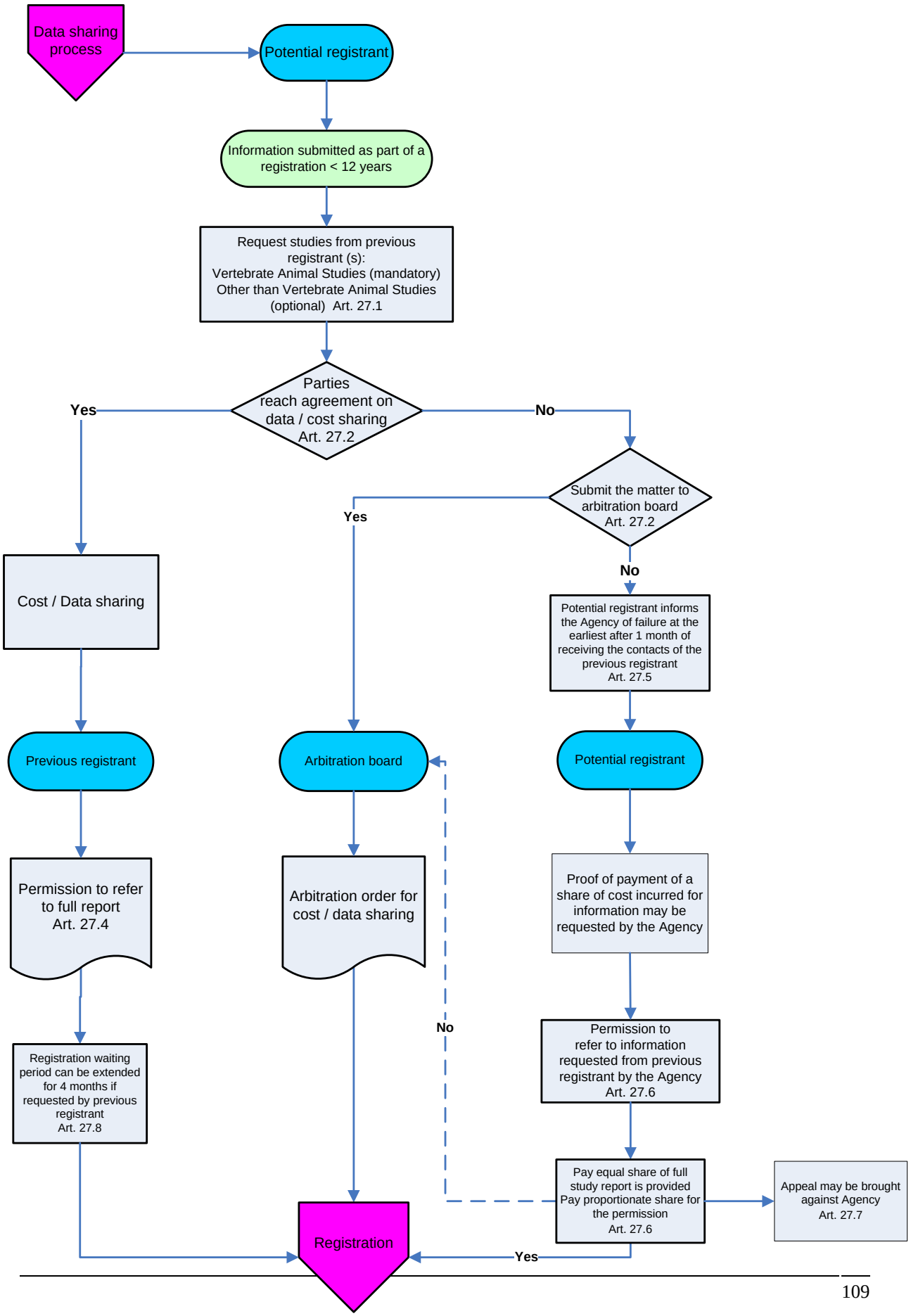


Chart VII
SIEF: sharing of data involving tests

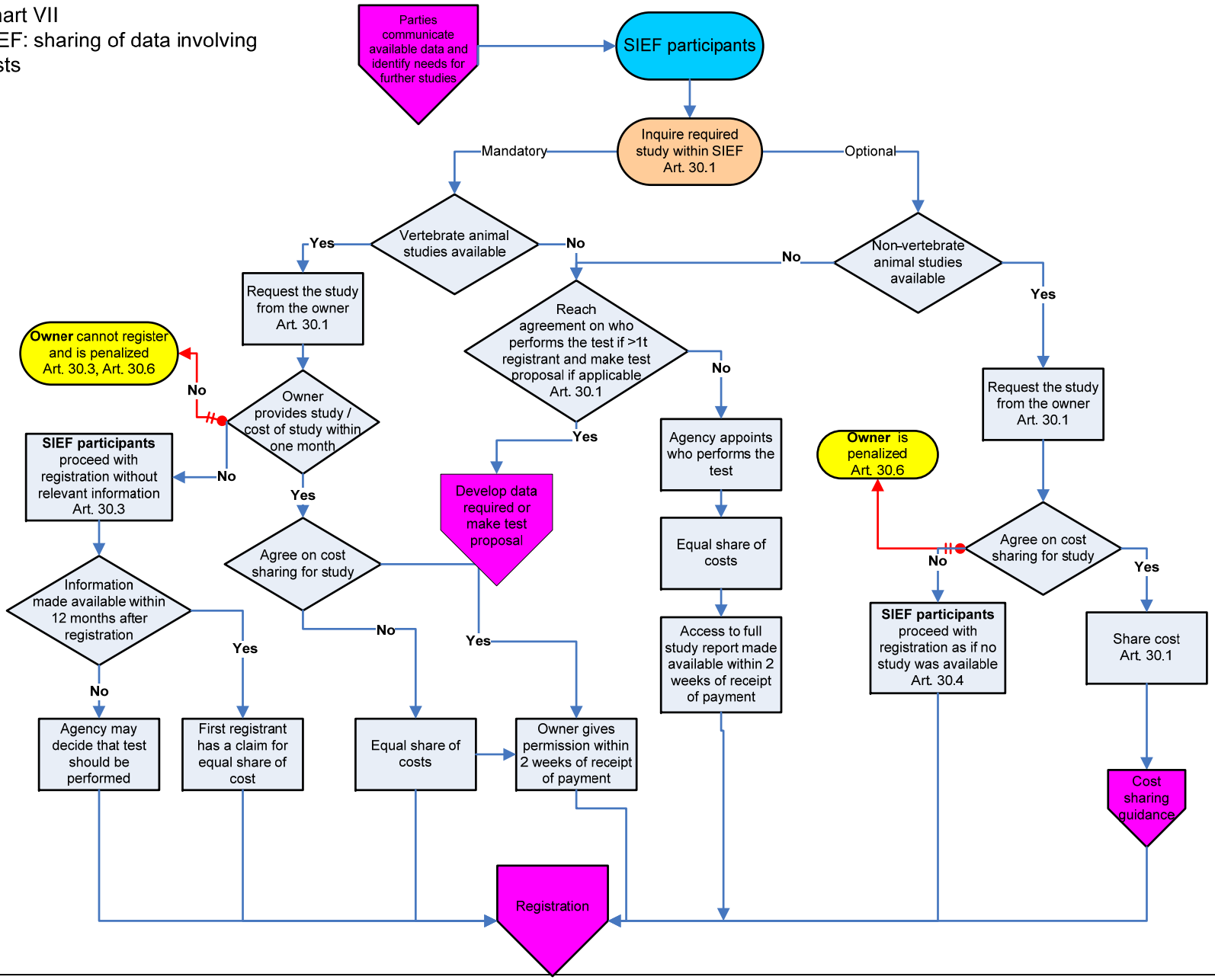
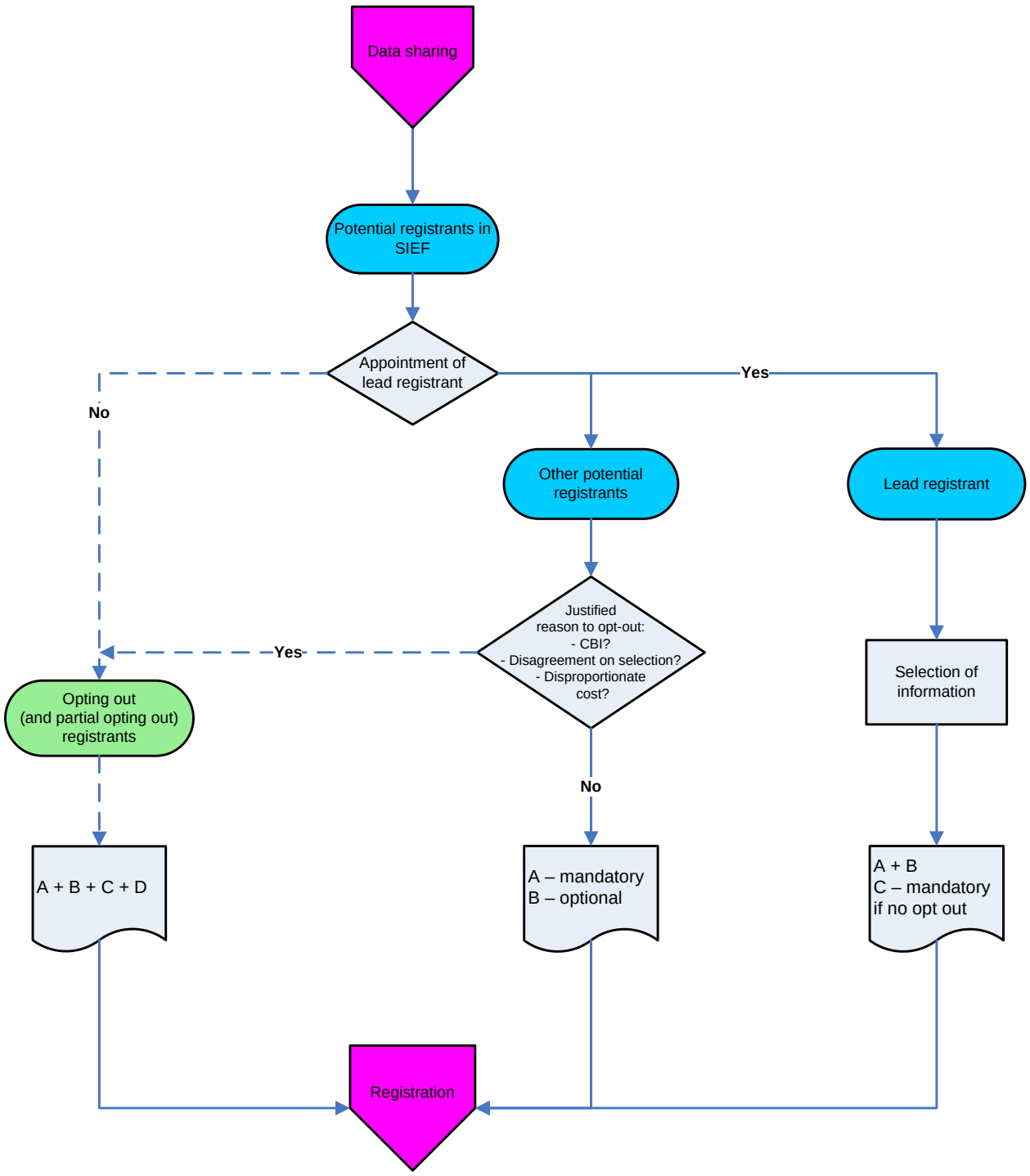


Chart VIII
Joint Submission of Data




**Information to be provided:**

**A** (Art. 11.1):
- identification of importer / manufacturer
- identification of substance
- information on manufacture and use
- exposure information for substances 1-10 tonnes

**B** (Art. 11.1):
- Use of assessor
- Guidance on safe use
- Chemical safety report

**C** (Art. 11.1):
- C&L
- Summaries and robust study summaries of test data
- Proposals for testing strategies

**D** (Art. 11.3):
In case of an **opt-out** (submitting information separately) the data to be submitted includes:
- Disproportionate costs
- Disclosure of commercial sensitive information
- Disagreement with lead registrant on selection of information

## ANNEX 2 PRE-REGISTRATION AND DATA SHARING EXAMPLES

### EXAMPLE 1: "BASE CASE"

1. *Parties involved*: Companies A, B, C and D manufacture substance X in the EU, each above 1000 tons per year. Substance X is a mono-constituent substance listed on EINECS.

2. *Pre-Registration*: Companies A, B, C and D each pre-register substance X in July and August 2008. Company B indicates its readiness to serve as a facilitator.

3. *Publication*: On 30 December 2008, ECHA publishes the list of pre-registered substances which includes substance X. Company F (Downstream User) then indicates to ECHA that it holds data on substance X.

4. *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, are equivalent under the criteria of the Guidance on substance identification by exchanging information on substance identification under a proposed Confidentiality Agreement. All agree.

5. *SIEF Formation*: The equivalence of the 4 substances X being 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 that substance, using an expert as "trustee" and to register substance X jointly (but with separate CSR and guidance on safe use). Cost sharing shall be on an equal sharing basis using average replacement costs, as requested from Labs L, M and N.

6. *Data Sharing*: The expert collects all data available among Pre-Registrants, compares it with the data needs at the 1000 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 Pre-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 Pre-Registrants agree that Company B will conduct the necessary testing (once approved) and will share the study on an equal sharing basis. Pre-Registrants also agree that Company B shall be the "Lead Registrant".

7. *Joint Submission of Data*: Company B registers substance X as a Lead Registrant with a testing proposal for the data missing under Annex IX on 15 October 2010. Companies A, C and D separately register substance X in November 2010 with a reference to the data submitted and test proposal made on their behalf by Company B.

8. *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 the EU. Companies A and B manufacture substance X above 1.000 tons per year. Company C is a trader who imports substance X between 10 and 100 tons per year and Company D intends to import substance X in the EU above 1 ton in the years to come.

2. *Pre-Registration*: Companies A, B, C and D all pre-register substance X. Companies A and B indicate they will register before 1 June 2010, Company C before 1 June 2013 and Company D before 1 June 2018. Company A indicates its readiness to serve as a facilitator.

3. *Publication*: On 30 December 2008, ECHA publishes the list of pre-registered substances which includes substance X.

4. *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.

5. *SIEF Formation*: The company experts confirm the substances all are the same under the criteria laid down in the Guidance on substance identification, 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 per volume on the basis of historic costs. Company D declares it will not participate to 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 shall be the Lead Registrant.

6. *Data Sharing*: The trustee proposes to share costs using a ratio that partly takes into account actual tonnage thresholds (See Annex 4, page X). 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 1000 tons is available but that data is missing in the 1000+ 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.

7. *Joint Submission of Data*: Company B registers substance X on 1 May 2010 As the Lead Registrant he submits a joint submission on behalf of companies A, C and D. Companies A registers on 2 May. Company C does not see why it shall wait until 2013 and decides to register on 15 May 2010. In 2015, Company D reaches the 1 ton threshold and would like to register as soon as possible. Company D only need to submit available data and physico-chemical property information (as it does not meet Annex III criteria), but still needs to agree with the other parties to refer to the Lead Registrant's submission for that data and classification and labelling. Company D offers a flat fee of 5000 € for receiving the necessary letter of access, which is accepted by the other participants.

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

## EXAMPLE 3: SUBSTANCE IDENTITY ISSUES

Examples on substance identity issues can be found in the Guidance on substance identification.

## EXAMPLE 4: LATE REGISTRANT

1. *Parties involved*: in Company A, a manufacturer of an EINECS-listed substance, has experienced a rapid grow in the yearly volumes manufactured in the period 2007-2010, which brings its three-year average quantities to more than 1 tonne in 2011.

2. *Pre-registration*: Company A pre-registers the substance in June 2011.

3. *Participation in the SIEF* : Company A is granted access to the contact details of Companies B, C and D, which have also submitted a pre-registration for that EINECS-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 agree that the substance is "the same" for data sharing and registration purposes and starts cooperating in the SIEF.

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

5. *Joint submission of data*: Company B submits an update of its registration by adding the name and contact details of company A to the list of other registrants (Companies C and D) on behalf of which the information is submitted as well as the information to which this applies (1-100 tonnage band)

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

## EXAMPLE 5: 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 2009, 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. It has also submitted further information as part of an update in 2000 as a consequence of an increase in production. The information originally submitted is published on ECHA website in the form of summaries/robust study summaries.

2. *Inquiry process - Step 1:* The company 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 indicates to company A the study summaries that may be freely used

by him, i.e. without the need to obtain a permission to refer from company B, as they were notified more than 12 years ago

3. Data sharing: Company A and company B enters into discussion on how to share the "protected" information submitted by company B. After 40 days (following receipt of company B's contact details) of hard negotiations, agreement is still not reached on the sharing of information and on the 41st day, company A informs ECHA and company B of "failure to reach an agreement". ECHA asks company A to give proof that it has paid a share of the costs of the study, after which company A pays ¼ of the costs and ECHA takes a decision giving company A permission to refer to the full study report summarized in the original updated notification report submitted by company B. Company B then decides to make the full study report available to company A and bring the case before the national Court to have its right to an equal share of the costs enforced.

**EXAMPLE 6: 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 during and after the first pre-registration period. 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-register the substance, which is then 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 Pre-Registrants/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.

5. *Data Sharing*: a literature search shows that little data exists and is available on substance X. Companies A and B share their 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 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 be also used to fill the data gap for substance X, Companies A and B accept to pay 40% 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 separately later by making reference to the data submitted by Company A.

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

# ANNEX 3 INVOLVEMENT OF DOWNSTREAM USERS IN DATA SHARING UNDER REACH

The main direct obligations and responsibilities incumbent upon Downstream Users (DU) under REACH are as follows:

- communicate use and safety information up and down the supply chain,
- keep information on uses available, and
- ensure that risks reduction measures are identified (for uses not covered in a safety data sheet or, for non-dangerous substances , other safety information communicated by their suppliers), and implemented (for uses covered in a safety data sheet communicated by their suppliers.

DU do not directly participate in the registration of the substances they use. But they must ensure that these substances are registered by their suppliers for these uses or must develop their own Chemical Safety Reports (CSR) under certain circumstances.

DU may also be in possession of large sets of data, and thus have a lot to contribute in the collection of data to be used for registration, certainly in classification but in particular when it comes to quantification of exposure and estimation of risks.

From the above, DU are a special category of Data Holders (as evidenced in Article 29.1 which talks about "the Potential Registrants, Downstream Users and Third Parties") with the need to involve them as early as possible in the data sharing process.

Registration is the responsibility of Manufacturers/Importers but it can disrupt the supply of substances to DU. It is therefore crucial that DU and suppliers establish good communication and cooperation. This is supported by recital 55 of the Regulation which states that:

> "Manufacturers and Importers of a substance on its own or in a preparation should be encouraged to communicate with DU of the substance with regard to whether they intend to register the substance. Such information should be provided to a DU sufficiently in advance of the relevant deadline if the manufacturer or importer does not intend to register the substance, in order to enable the DU to look for alternative sources of supply."

## 1 Pre-registration

The necessity for DU to be involved in the registration process begins as early as pre-registration. It is only with the publication of the list of pre-registered substances that DU will see if the substances they use have been pre-registered.

For substances that have not been pre-registered, the only recourse DU have is that foreseen in Article 28.5 which gives DU the possibility to contact ECHA and indicate their interest in a missing substance (see 4.4.3.). ECHA will relay this interest, and potentially a manufacturer/importer will respond. The benefit of this mechanism remains limited and does not remove the legal uncertainty because the decision to pre-register and to further register, if taken, lies with the

manufacturer/importer. Article 28.6 allows a DU to become a first time Importer benefiting from the phase-in period corresponding to the respective tonnage band.

For substances that have been pre-registered, DU should also be mindful of the fact that this does not ensure continued supply. Indeed, the fact that a substance has been pre-registered (1) does not guarantee that the substance will remain on the market, since there is no obligation for a manufacturer/importer who has pre-registered a substance to carry on with registration, and (2) does not mean that their own supplier has pre-registered the substance at stake.

It is highly recommended that DUs and SUPPLIERS do establish contact as soon as possible before or during the pre-registration phase in order to ensure that all the phase-in substances they use will be pre-registered by their suppliers. Contact should be maintained throughout the registration process.

## 2 Information to be submitted by DU at pre-registration phase

In accordance with the provisions of Article 28.7, DU 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.

When indicating in the REACH IT system the pre-registered substances on which they hold information, they will also have the possibility to indicate other types of information, in particular with regards to safety, such as hazard data, information on uses. They can usefully indicate their intention to share data for read-across where relevant. Information from DU 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). Exposure-based waiving is fundamental to reduce the need for animal testing.

## 3 Formation of SIEF

The formation of a SIEF will be based primarily on the EINECS or CAS entry under which a substance has been pre-registered. However, “pre-SIEF discussions” will take place between Potential Registrants in order to verify the sameness of the substance they intend to register (see 4.5.4. and the Guidance on substance identification). Data Holders will in principle not be involved in those discussions and they will be considered as members of all SIEFs once formed. Potential Registrants will only start investigating about data availability once the SIEF are formed and when they have identified data gaps.

It is recommended that DU establish contact with their suppliers for given substances and obtain information as soon as possible regarding the formation of a corresponding SIEF, rather than wait for Potential Registrants to contact them.

## 4 SIEF

Whether potential registrant decide to follow the “collective” or “individual” route to prepare their registration (see Sections 5.3 and 5.5), in most cases potential registrants are likely to first review the data they have in their possession before contacting Data Holder, including DU mainly to fill data gaps.

However, DU may have critical data and in some cases it make sense that they participate in SIEF as equal partners with potential registrants..

When DU have a lot of 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.

# ANNEX 4 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 5 COST SHARING EXAMPLES

### EXAMPLE 1: (STUDY VALUATION)

7 Potential Registrants (A, B, C, D, E, F, G) form a SIEF for the same substance, SIEF member A owns a report Klimisch category 1, SIEF member B owns a report Klimisch category 2, SIEF 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 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 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 | € 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 [20] | € 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 |

[20] 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.

## EXAMPLE 2: (STUDY VALUATION)

7 Potential Registrants (A, B, C, D, E, F, G) form a SIEF for the same substance, SIEF member A owns a report (compliant to OECD guideline, SIEF member B owns a report non-compliant to OECD guidelines, SIEF members C,D,E, F and G do not own a relevant study.

The attached example (vapor pressure OECD 104) 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 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 | 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[21] | € 3,000 | | €3,000 | |
| Risk premium (N/A) | 0 | | 0 | |
| Total surcharges | | € 3,000 | | € 3,000 |
| Current report value | | € 14,600 | | € 11,900 |

**EXAMPLE 3: (COST ALLOCATION)**

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):<br><br>24,764 x (173,350 – 147,280) / 173,350 | € 3,724 |
| Financial contribution of other members: 5 x 24,764 | € 123,820 |

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 | € 58,587 |

[21] See footnote 20 above.

| | |
|---|---|
| 127,544 x 147,280 / (173,350 + 147,280) | |

The balance (cost allocation – cost compensation) results in the following:

SIEF member A receives € 68,957

SIEF member B receives € 54,863 (58,587 – 3,724)

SIEF members C, D, E, F, G pay € 24,764 each

**EXAMPLE 4: (COST ALLOCATION)**

Two Klimisch 1 & two Klimisch 2 studies available, one study not assessed in a SIEF consisting of 7 members

Participant A owns a study Klimisch 1, report has been valued € 215,325

Participant B owns a study Klimisch 1, report has been valued € 202,100

Participant C owns a study Klimisch 2, report has been valued € 165,390

Participant D owns a study Klimisch 2, report has been valued € 158,270

Participant E owns a study, which has not been assessed for its quality

Participant F and G do not own a 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><br>(7,134 + 8151 + 30,761 * 3) * 215,325 /<br><br>(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><br>(7,134 + 8151 + 30,761 * 3) * 201,100 /<br><br>(215,325 + 201,100 + 165,390 + 158, 270) | € 29,334 |
| Share for Member C owning Report 3; Klimisch 2<br><br>(7,134 + 8151 + 30,761 * 3) * 165,390 /<br><br>(215,325 + 201,100 + 165,390 + 158, 270) | € 24,006 |
| Share for Member D owning Report 4; Klimisch 2<br><br>(7,134 + 8151 + 30,761 * 3) * 158,270 /<br><br>(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

Participant A receives € 31,254

Participant B receives € 29,334 (Klimisch 1 but not key study / lead value)

Participant C receives € 16,872

Participant D receives € 14,822

Participants E, F and G pay € 30,761 each.

**EXAMPLE 5: (COST ALLOCATION)**

Here we assume SIEF member A owns a Klimisch 2 study, the value of the report has been calculated to be € 158,300.00; SIEF member B owns a Klimisch 2 study, the value of the report has been calculated to be € 145,000.00; SIEF member C owns a Klimisch 2 study, the value of the report has been calculated to be € 144,000.00. The remaining participants of the SIEF, members D-G, don't contribute a 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><br>22,614 x (158,300 - 145,000) / 158,300 | € 1,900 |
| Financial contribution of Member C (Owner of Report 3, Klimisch 2):<br><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><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><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><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

Participant A receives € 33,408

Participant B receives € 28,701 (Klimisch 2 but not key study / lead value)

Participant C receives € 28,347 (Klimisch 2 but not key study / lead value)

Participants D, E, F and G pay € 22,614 each.

**EXAMPLE 6: (COST ALLOCATION - COMPENSATION FOR BEST STUDIES)**

In some cases more then one key study might be needed to cover a certain data requirement. In these cases a mechanism that covers the cost sharing of more then on key study can be envisaged.

Five participants have the following data available for a particular endpoint (with accompanying study valuations as indicated):

Member A : Klimisch 1 study (105 K€) + Klimisch 2 study (80 K€)

Member B : No Data

Member C : Klimisch 1 (95 K€)

Member D : Klimisch 2 (65 K€) + Klimisch 2 (75 K€)

Member E : Klimisch 2 (60 K€)

Study values (using a nominal approach ) are set as Klimisch 1, 100 K€ with Klimisch 2, 70 K€.

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 K€

Participant contribution is then 340 / 5 = 68 K€

In payment / compensation terms;

Member B pays 68 K€

Members A,C, D and E ( all holders of qualifying data ) each receive 17 K€

**For comparison purposes**, treatment of the above 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 K€

In payment / compensation terms;

Member B pays 50 K€ (half of the value of the study)

Member C (holder of the key study) receives 50 K€

**For comparison purposes**, treatment of the above 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 K€ (for each study), giving a total value of 200 K€

In payment / compensation terms;

Member B pays 66.6 K€ (one third of the value of the two studies)

Members A and C (holders of the key studies) each receive 33.3 K€

## 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

SIEF members C, D, E, F and G don't own a study.

SIEF 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%)

SIEF member D declares, he needs to reference the study for global regulatory purposes (includes REACH in the EU) but only requires only a Letter of Access, he will get a reduced allocation by a factor of 30 % (therefore he pays at a rate of 70%)

Other SIEF members will have full usage rights with 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><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><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><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:
SIEF member A receives € 58,246

SIEF member B receives € 45,763 (49,487 – 3,724)

SIEF member C pays € 12,382

SIEF member D pays € 17,335

SIEF members E, F, G pay € 24,764 each

**EXAMPLE 9: (VOLUME FACTORS)**

The following calculation describes a case where there is one study available which is required by four SIEF Participants. We assume in this case the study owner is a Third Party which does not have any obligation to register the substance under REACH. The value of the study has been calculated to be **100,000 €.**

In order to demonstrate the volume impact on the SIEF Participants, two sets of illustrative volume band factors (A & B below) are introduced. Note that other factor ratings could also be selected as agreed by the participants in the process.

| Volume Range | Factor Set A | Factor Set B |
|---|---|---|
| 1 – 10 ktonnes | 1 | 1 |
| 10-100 ktonnes | 5 | 2 |
| > 100 ktonnes | 10 | 3 |

In this example:

SIEF participant A has a volume of 200 ktonnes, SIEF participant B has a volume of 60 ktonnes, SIEF participant C has a volume of 30 ktonnes and participant D has a volume of 8 ktonnes.

Cost allocation analyses using the banding factors above are presented below. For comparative purposes, direct volume allocation and equal share approaches are also included.

Cost allocations for the study (K€) from the four options described above would be as follows;

| Participant | Volume (Ktonnes) | Direct use of Volumes (K€) | Use of Band Factor Set A (K€) (factor 1 or 5 or 10) | Use of Band Factor Set B (K€) (factor 1 or 2 or 3) | Equal shares basis (K€) |
|---|---|---|---|---|---|
| A | 200 | 67 | 47.6 (10) | 37.5 (3) | 25 |
| B | 60 | 20 | 23.8 (5) | 25.0 (2) | 25 |
| C | 30 | 10 | 23.8 (5) | 25.0 (2) | 25 |
| D | 8 | 3 | 4.8 (1) | 12.5 (1) | 25 |
| Totals | 298 (Kt) | 100 K€ | 100 K€ (21 shares) | 100 K€ (8 shares) | 100 K€ |

When considering to base the cost sharing on volumes, please also see section 9 of the present Guidance Document on information exchange under EC Competition law.

**EXAMPLE 10: (NEW PARTIES)**

Cost allocation and compensation

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.

The initial SIEF consisted of 7 members, A – G. A new member H joins the SIEF, SIEF member H does not contribute with a study.

| | |
|---|---|
| Value of key study | € 173,350 |
| Share per member in initial SIEF (173,350 / 7) | € 24,764 |
| Share per member in SIEF after member H joined ( 173,350 / 8) | € 21,669 |
| Additional compensation for each initial SIEF member A – G<br><br>21,669 / 7 | <br><br>€ 3,096 |
| Allocation for new SIEF member H | € 21,669 |

| Participant | Balance 7 SIEF members (Example 3) | Balance 8 SIEF members (Example 11) | Adjusted balance |
|---|---|---|---|
| A | 68,958.14 | 72,053.68 | 3,095.54 |
| B | 54,863.29 | 57,958.82 | 3,095.54 |
| C | -24,764.29 | -21,668.75 | 3,095.54 |
| D | -24,764.29 | -21,668.75 | 3,095.54 |
| E | -24,764.29 | -21,668.75 | 3,095.54 |
| F | -24,764.29 | -21,668.75 | 3,095.54 |
| G | -24,764.29 | -21,668.75 | 3,095.54 |
| H | 0.00 | -21,668.75 | -21,668.75 |

## ANNEX 6 ARTICLE 81 AND 82 OF THE EC TREATY

### *Article 81*

*1. The following shall be prohibited as incompatible with the common market: all agreements between undertakings, decisions by associations of undertakings and concerted practices 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, and in particular those which:*

*(a) directly or indirectly fix purchase or selling prices or any other trading conditions;*

*(b) limit or control production, markets, technical development, or investment;*

*(c) share markets or sources of supply;*

*(d) apply dissimilar conditions to equivalent transactions with other trading parties, thereby placing them at a competitive disadvantage;*

*(e) make the conclusion of contracts subject to acceptance by the other parties of supplementary obligations which, by their nature or according to commercial usage, have no connection with the subject of such contracts*".

*2. Any agreements or decisions prohibited pursuant this Article shall be automatically void.*

*3. The provisions of paragraph 1 may, however, be declared inapplicable in the case of:*

*- any agreement or category of agreements between undertakings;*

*- any decision or category of decisions by associations of undertakings;*

*- any concerted practice or category of concerted practices;*

*which contributes to improving the production or distribution of goods or to promoting technical or economic progress, while allowing consumers a fair share of the resulting benefit, and which do not:*

*(a) impose on the undertakings concerned restrictions which are not indispensable to the attainment of these objectives;*

*(b) afford such undertakings the possibility of eliminating competition in respect of a substantial part of the products in question".*

### *Article 82*

*Any abuse by one of more undertakings of a dominant position within the common market or in a substantial part of it shall be prohibited as incompatible with the common market in so far as it may affect trade between Member States.*

*Such abuse may, in particular, consist in:*

*(a) directly or indirectly imposing unfair purchase or selling prices or other unfair trading conditions;*

*(b) limiting production, markets or technical development to the prejudice of consumers;*

*(c) applying dissimilar conditions to equivalent transactions with other trading parties, thereby placing them at a competitive disadvantage;*

*(d) making the conclusion of contracts subject to acceptance by the other parties of supplementary obligations which, by their nature or according to commercial usage, have no connection with the subject of such contracts.*

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