Guidance on data sharing

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European Chemicals Agency

Mailing address: P.O. Box 400, FI-00121 Helsinki, Finland
Visiting address: Telakkakatu 6, Helsinki, Finland

Preface

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

The guidance documents were drafted and discussed involving all stakeholders: Member States, industry and non-governmental organisations. The European Chemicals Agency (ECHA) updates these guidance documents following the Consultation procedure on guidance (http://echa.europa.eu/documents/10162/13608/mb_63_2013_revision_consultation_procedure_guidance_en.pdf). These guidance documents can be obtained via the website of the European Chemicals Agency (http://echa.europa.eu/guidance-documents/guidance-on-reach). Further guidance documents will be published on this website when they are finalised or updated.

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

[1] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC.

DOCUMENT HISTORY

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

included has been added.

The sub-section covering the right to refer to data and legitimate possession has been updated in order to reflect the latest CARACAL decision and clarify the concepts.

- A new sub-section covering data sharing disputes according to Article 30(2) and 30(3) and on available legal remedies against ECHA decisions has been created and included in new section 3 on data sharing within SIEFs.
- Section 4 on Inquiry process has been revised by eliminating out of date information and amending the text according to the current practice. Information to be submitted in the inquiry and possible outcomes of the process has been added. The stepwise workflow has been extended and better described in order to provide comprehensive set of information to those involved in the inquiry process. A new sub-section addressing the scenario where new co-registrants need to join an existing joint submission has been added.
- New sub-section covering data sharing disputes according to Article 27(5) and available legal remedies against ECHA decisions has been created and included in new section 4 on data sharing for non-phase-in substances.
- The section on joint submission has been updated to take account of current practice and the information on lead registrant has been merged in section 3. A new sub-section covering post- registration data sharing obligations has been added.
- The section on Cost Sharing has been revised in order to correct editorial mistakes and clarify the language without any substantial changes. It has been explained that the section covers the sharing of cost related to studies, but other costs related to SIEF activities need to be considered in cost sharing models.
- The section on Forms of Cooperation has been revised in order to correct editorial mistakes and clarify the language. A new example suggesting an alternative form of cooperation has been added.
- The section on Competition Law has been revised by replacing the reference to EC Treaty by a reference to the Treaty on the Functioning of the European Union (TFEU).
- Deletion of Annex 1 and inclusion of updated charts in the relevant sections of the Guidance.
- Deletion of Annex 2 and inclusion of the examples in the relevant sections of the Guidance. Only minor changes and corrections have been made.
- Deletion of Annex 3 and inclusion of the information relevant for data sharing in the main text. Reference to Guidance for Downstream Users made when relevant.
- Deletion of Annex 5 and inclusion of cost sharing examples in the relevant section. The examples 9

	("Volume factors") and 10 ("New parties") have been replaced by new examples. Only minor changes and corrections have been made to the other examples. - Deletion of Annex 6. - Reference to the Data Submission Manuals, REACH-IT Industry User Manuals and Practical Guides published by ECHA. A new annex listing all the documents mentioned in the guidance has been added. - Special "NB boxes" have been added throughout the document to draw the reader's attention to important concepts and reminders that particular attention should be paid to. - Editorial corrections.	
Version 3.0	Full revision of the Guidance to take into account and implement the provisions laid down in the Commission Implementing Regulation (EU) 2016/9 on joint submission and data sharing. Several key aspects covered in the guidance have been reviewed in order to reflect the new clarifications in the new Regulation (in particular cost sharing mechanisms, Joint submission obligations, cooperation agreements, disputes). Obsolete information has been deleted and latest experience on data and cost sharing implemented. The update includes the following: - Revision of Section 1 by improving the definition of phase- and non-phase-in substances and underlying the data sharing obligations among registrants of both types of substances. Integration of key principles from the Implementing Regulation. Made clear the relevance of data generated under Biocides Product Regulation. - Revision of Section 2 by adding reference to the Implementing Regulation and description of its Articles. - Revision of Section 3 on data sharing rules for phase-in substances by eliminating or amending out of date information and underlying the remaining applicability of the pre-registration. Introduction of the concept of Substance Identity Profile and its importance for SIEF formation. Introduction of key issues to be included in every data sharing agreement according to the Implementing Regulation. Shift of the burden of the data sharing activities from the Lead Registrant to the co-registrants in general. Introduction of need to agree on a cost sharing mechanism which includes a reimbursement mechanism. Clarification about information to be provided to new potential registrant has been added. Sections on data sharing disputes according to Article 30(3) swapped and revised to align with current practices. - Revision of Section 4 on inquiry by eliminating or	November 2016

amending out of date information and further clarifying the applicability of the 12-year rule. Concept of Co-Registrant page added. Concept and importance of SIP added. Clarified that data sharing obligations apply to inquirers and pre-registrants/SIEF members together. Sections on disputes revised to align with current practices.

- Revision of Section 5 on costs sharing by explaining the requirements clarified by the Implementing Regulation (in particular itemisation and distinction between study and administrative costs). Clarification about administrative costs and what could include added. Need to consider possible future costs and variable number of co-registrants stressed. Limited applicability and need to justify risk premium clarified. Clarification about data sharing related to read-across and substance category added. New section on higher tier studies superseding lower tier studies added. Further development of the section on new studies required after registration by diving into 3 subsection to address testing proposals after compliance check, substance evaluation decisions and other dossier updates. Clarified that renegotiations requests should be well grounded. Cost sharing examples reviewed.

- Section 6 on joint submission revised by stressing the OSOR principles and its applicability to both inquirers and SIEF members together. New subsection on intermediates and possibility to submit a separate joint submission added. Concept and relevance of the SIP concept added. Added the option foreseen by the Implementing Regulation to make use of the right to opt-out from the jointly submitted data in case it can ascertain that it does not need to share vertebrate data. Clarified the need for the opting-out registrant to discuss with other co-registrants about the relevance of the information separately submitted. A new subsection about disputes concerning the access to the joint submission has been added.

- Section 7 on competition rules further developed by adding reference to Article 102 TFEU and to the prohibition to abuse dominant positons.

- In section 8 on forms of cooperation it has been further stressed and described the potential high variability of the agreements and forms of cooperation.

- Annex 1 on data exchange form updated.

- Addition of new Annex 3 with examples of cost itemisation.

-Addition of new Annex 4 listing the sections relevant under the Biocides Product Regulation.

- Flowcharts updated to align with current practice and updated text.

- Reference to Industry User Manuals and Data Submission

	Manuals removed; reference to help text embedded in REACH IT and to the "Manuals on preparation of REACH and CLP dossiers" included. - Editorial corrections.	
Version 3.1	Corrigendum to add a missing footnote in figure 1, correct formatting of section 4.1 and correct spelling in section 4.6.	January 2017
Version 4.0	Revision of the Guidance to take into account the end of the phase-in scheme on 31 May 2018. REACH Title III provisions applicable are now Articles 25, 26 and 27. The Implementing Regulation 2019/1692 has confirmed that, from 31 December 2019, Articles 26 and 27 REACH apply to all substances alike. Obsolete information has been deleted, namely references to phase-in substances, pre-registration and SIEFs. The update includes: - The inquiry process under Article 26 REACH and related data sharing obligations before submitting a registration; - Data sharing among existing registrants: as a result of dossier or substance evaluation decisions, or in case of tonnage upgrade; - Data sharing for read-across purposes; - Clarification of other legal obligations. The objective of the Guidance is to provide advice on the sharing of data and cost as required under REACH between multiple registrants of the same substance. It contains practical recommendations to help companies meet their data sharing obligations, explaining the underlying principles and providing examples. As such, the update also removes the sections on dispute proceedings from the Guidance. These proceedings are described in the relevant parts of the ECHA website.	xx 2022

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ABBREVIATIONS

BPR	Biocide Products Regulation
CAS	Chemical Abstracts Service
CBI	Confidential Business Information
CMR	Carcinogen, Mutagen and Reprotoxic
CSR	Chemical Safety Assessment
DNEL	Derived No-Effect level
DSD	Dangerous Substance Directive (67/548/EEC and related ATPs)
DU	Downstream User
ECHA	European Chemicals Agency
EEA	European Economic Area
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of Notified Chemical Substances
EPA	US Environmental Protection Agency
EU	European Union
GLP	Good Laboratory Practices HPV High Production Volume
IUCLID	International Uniform Chemical Information Database
IUPAC	International Union of Pure and Applied Chemistry
LE	Legal Entity
LR	Lead Registrant
NEA	National Enforcement Authority
OECD	Organisation for Economic Co-operation and Development
OR	Only representative
(Q)SAR	(Quantitative) Structure-Activity Relationship
REACH	Regulation on the Registration, Evaluation, Authorisation and Restriction of Chemicals
RMM	Risk Management Measure
RSS	Robust Study Summary
SDS	Safety Data Sheet
SIEF	Substance Information Exchange Forum
SIP	Substance Identity Profile
TFEU	Treaty on the Functioning of the European Union

NB: A comprehensive list of definitions of relevant terms is available consulting the ECHA-Term database on the ECHA website (http://echa-term.echa.europa.eu/.

1. INTRODUCTION

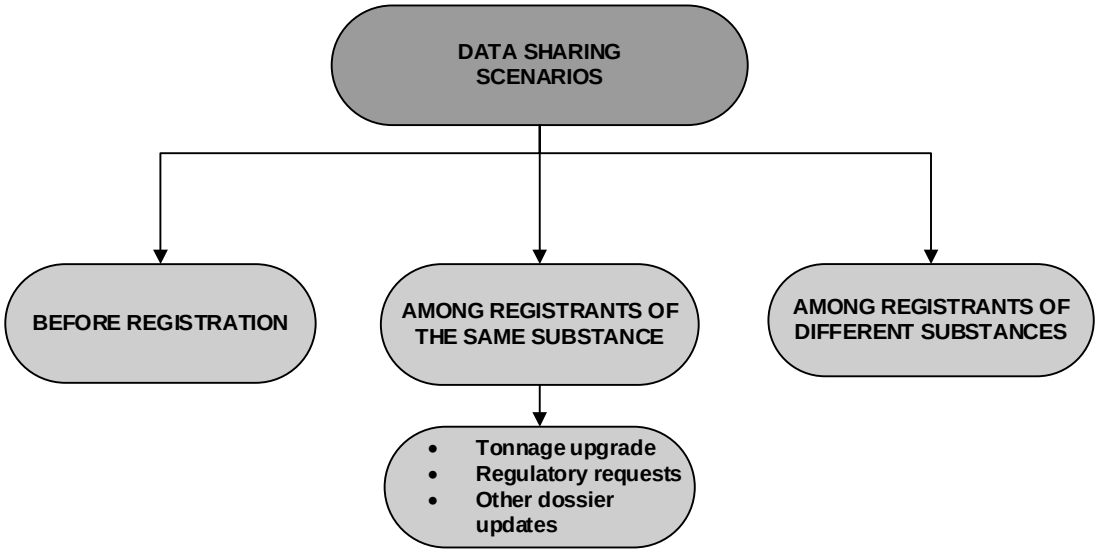
1.1. Objective of the guidance document on data sharing

The present guidance document aims to provide practical guidance on the sharing of data and cost as required under REACH (i.e. costs related to both (i) the data and (ii) the creation and management of the data sharing agreement and the joint submission of information) between multiple registrants of the same substance. Its goal is also to facilitate sharing of data between registrants of structurally similar substances where use of read-across can be applied.

The Guidance contains practical recommendations to help companies meet their data sharing obligations and other instances where data sharing is recommended, and includes a detailed description of the following processes:

- Data sharing before submitting a registration dossier: the inquiry process and the determination of the data needs ;
- Data sharing among existing registrants of the same substance, upon tonnage upgrades, regulatory requests for new studies or other dossier updates;
- Data sharing among registrants of different substances (read-across and category).

Specific explanations on cost sharing mechanisms, on the protection of Confidential Business Information ('CBI'), on competition rules, on copyright and other intellectual property rights relating to the data, and on forms of cooperation, including consortia, are also provided.



1.2. Overview

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

1.2.1. Registration obligation

Since 1 June 2008, companies manufacturing chemical substances in the EU[2] or importing them into the EU in quantities of 1 tonne or more per year have been required to register them under REACH. The registration obligation also applies to companies producing or importing articles containing substances present in quantities of 1 tonne or more per year that are intended to be released from the article. Registration requires the submission of relevant and available information on intrinsic properties of substances, as per the requirements set out in the relevant Annexes to REACH. For substances manufactured or imported in quantities of 10 tonnes or more a Chemical Safety Report has also to be submitted (see section 5.3, *Chemical Safety Report*, of the Guidance on Registration).

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

1.2.2. Phase-in and non-phase in substances

Article 3(20) REACH defines phase-in substances as those meeting at least one of the following criteria:

(a) it is listed in the European Inventory of Existing Commercial Chemical Substances (EINECS);

(b) it was manufactured in the Community at least once between 1993 and 2008, but not placed on the market by the manufacturer or importer, provided the manufacturer or importer has documentary evidence of this;

c) it was placed on the market in the Community by the manufacturer or importer before the entry into force of this Regulation and it was considered as having been notified in accordance with the first indent of Article 8(1) of Directive 67/548/EEC in the version of Article 8(1) resulting from the amendment effected by Directive 79/831/EEC, but it does not meet the definition of a polymer as set out in this Regulation, provided the manufacturer or importer has documentary evidence of this, including proof that the substance was placed on the market by any manufacturer or importer between 18 September 1981 and 31 October 1993 inclusive.

These substances were subject to a transitional regime of ten years, pursuant to Article 23 REACH. Such substances had to be pre-registered by a certain deadline and, on this basis, different deadlines were set for the submission of registration dossiers.

For phase-in substances, the starting point was the pre-registration in accordance with Article 28 REACH. Upon pre-registration, the potential registrant became a participant of the Substance Exchange Information Forum ('SIEF') for that substance according to Article 29(1) REACH. The purpose of the SIEFs was to facilitate the sharing of information on the same phase-in substance among manufacturers, importers, data holders and other stakeholders, in order to prevent the duplication of testing, i.e. studies regarding the properties of the substance, thereby avoiding the duplication of studies and of costs. The companies who had pre-registered a substance were thus members of the SIEF by law.

[2] The term 'EU' used in this document covers the States belonging to the European Economic Area. The EEA is composed of the EU Member States and Iceland, Liechtenstein and Norway.

With regard to data sharing obligations, the phase-in substances followed the regime prescribed by Article 30 REACH when they had been pre-registered. This provision sets the data sharing obligations amongst the SIEF participants, and the corresponding data sharing dispute mechanism.

Manufacturers and importers that had timely pre-registered a phase-in substance benefitted from extended registration deadlines depending on the dangerous properties of the substance and on the quantities of substance manufactured or imported. The last deadline expired on 31 May 2018.

All other substances were considered non-phase in substances and were subject to Articles 26 and 27 REACH.

1.2.3. End of the 'phase-in scheme' and Substance information exchange fora (SIEFs)

Under Article 23 REACH, the last registration deadline for phase-in substances was 31 May 2018. Accordingly, Article 29(3) REACH established that SIEFs would cease to be operational from 1 June 2018.

This date marked the end of the phase-in scheme and, accordingly, Articles 28 to 30 REACH ceased to be applicable to data sharing to any negotiation that would have started after that date. From 1 June 2018, Articles 26 and 27 REACH apply indistinctly to all substances.

This entails, with regard to data sharing, that the provisions of Title III, Chapter 2 REACH, apply to all substances alike. This starts with the duty to inquire prior to registration. Indeed, the inquiry process requires potential registrants to inquire from ECHA whether a registration has already been submitted for the same substance, according to Article 26 REACH. This is to ensure that data are shared by the relevant parties. The inquiry obligation also applies in case of tonnage upgrade, pursuant to Article 12(2) REACH.

These principles are confirmed by Implementing Regulation (EU) 2019/1692 on the application of certain registration and data sharing provisions after the expiry of the final registration deadline for phase-in substances[3] ('Implementing Regulation 2019/1692'). This Implementing Regulation clarified the cut-off date until which the data sharing provisions concerning phase-in substances should either no longer apply or only apply in specific circumstances.

With regard to data sharing obligations, Article 3 of Implementing Regulation 2019/1692 made also clear that after registering a substance, registrants must continue to fulfil their data sharing obligations in a fair, transparent and non-discriminatory way. The efforts and data generated in the framework of a registration will be continuous between the joint submission of the data and after, for instance following substance or dossier evaluation. For that purpose, the same provision states that registrants may use informal communication platforms similar to the ones used during the phase-in scheme, even though the SIEFs are no longer operational.

With regard to the duty to inquire and the sharing of data for substances that used to fall under the phase-in scheme, Article 4 of Implementing Regulation 2019/1692 clarified that Article 30 REACH ceased to be applicable, even exceptionally, after 31

[3] Commission Implementing Regulation (EU) 2019/1692 of 9 October 2019 on the application of certain registration and data sharing provisions of Regulation (EC) No 1907/2006 of the European Parliament and of the Council after the expiry of the final registration deadline for phase-in substances, OJ L 259, 10.10.2019, p. 12–14.

December 2019, and that, after that date, pre-registrations are no longer valid.

1.2.4. Key principles for data sharing

REACH requires existing registrants and/or potential registrants to make every effort to reach an agreement on sharing of data and ensure that the cost of sharing the information required for registration are determined in a fair, transparent and non-discriminatory way. Implementing Regulation (EU) 2016/9 on joint submission and data sharing[4] ('Implementing Regulation 2016/9') established rules to ensure an efficient implementation of the already existing data sharing and joint submission obligations.

The obligation to make every effort applies to any information requested, whether this concerns data involving testing on vertebrate animals, other data not involving testing on vertebrate animals, or conditions of access to joint submission. Article 25 REACH stipulates that animal testing has to be conducted only as a last resort.

Parties are only required to share the cost of information they need to submit. If a party already has data that it considers valid for a certain endpoint, this party should not have to ask access to or pay for the data already submitted. This applies also to the administrative costs.

All parties must fulfil their data sharing obligations in a timely manner. Potential registrants are encouraged to reserve a reasonable time for the data sharing activities before the date by which they need a registration.

As data sharing activities take place outside REACH-IT[5], companies are advised to carefully record any communication with another party, as this may be requested by ECHA in the context of a data sharing claim or by national competent authorities for enforcement purposes.

In accordance with Implementing Regulation 2016/9, co-registrants have to keep detailed documentation of the data costs as well as corresponding administrative costs incurred in relation to data sharing. In the absence of such detailed documentation, parties have to make every effort to collate proof or to make the best approximation of such costs.

Fees and revenues originating from data sharing activities under the REACH Regulation should follow the "not for profit" principle and solely serve to cover budget needs for preparing and maintaining registration dossiers.

1.2.5. Joint submission of data

There are two distinct obligations stemming from the fact that multiple entities are registering the same substance. The first is the obligation to share data. The second is that registrants of the same substance are required to organise themselves in order to submit jointly information on the substance, according to Articles 11(1) and 19(1) REACH. This means that if registrants agree that they manufacture or/and import the same substance, they should submit jointly the information on the properties of the

[4] Commission Regulation (EU) 2016/9 on joint submission and data sharing in accordance with Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), OJ L 3, 6.1.2016, p.41.

[5] REACH-IT is the central IT system that supports Industry, Member State competent authorities and the European Chemicals Agency to securely submit, process and manage data and dossiers. These three parties each have access to specific functions of REACH-IT which they can use to fulfil their requirements under the REACH and CLP regulations. REACH-IT also provides a secure communication channel between these three parties to help them coordinate the processing and evaluation of data and dossiers.

substance, with a lead registrant submitting this data on behalf of the other registrants. Exceptions to this principle are described in Article 11(3) and 19(2) of REACH, and must be justified accordingly. In those cases, registrants can submit separately in their own registration dossier different data than the data submitted by the lead registrant, and they may submit their dossier as an opt-out. However, even in such cases, all registrants of the same substance are still required to be part of the same 'joint submission' in REACH-IT. Being part of the same joint submission in REACH-IT does not mean that registrants shared data on the substance, but only that they consider that they are manufacturing / importing the same substance.

Note that what is called above as being part of the same joint submission is referred to as being 'part of the existing registration for that substance' in Implementing Regulation 2016/9. However, for consistency with the terminology used in REACH-IT and in other ECHA's documents, the word 'joint submission' is used in the present Guidance to reflect this concept of being part of the same registration. This must be distinguished from the actual joint submission of data, or references to the jointly submitted data, which address the situation where a lead registrant submits data on behalf of other assenting registrants, as per Article 11(1) and 19(1) of REACH.

Due to the reduced information requirements, registrants of substances used only as intermediates are for practical reasons technically allowed to form a parallel joint submission for intermediates only. However, registrants are encouraged to form one unique joint submission per substance whenever possible. For more information, please refer to the Guidance on Registration, section 4.3, *Joint submission of data*.

1.3. Legal framework

The present section introduces the currently relevant framework applicable to data sharing. As explained in section 1.2.3, the provisions of of Title II, Chapter 3 (i.e. Articles 28 to 30 of REACH) are no longer applicable.

1.3.1. Data sharing and avoidance of unnecessary tests

The rules on data sharing and avoidance of unnecessary testing are provided in Articles 25, 26, 27, 40(3)(e) and 53 REACH, which should be interpreted in view of Recitals 33, 49 and 50 REACH.

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

Article 25(2) defines the scope of the data sharing obligation by reference to the type of data to be shared. This obligation applies to technical data and information related to the intrinsic properties of substances. However, EU rules on competition law must be respected by the potential registrants (see section 7 of this Guidance document). Therefore parties shall refrain from sharing information related to the market behaviour of the registrants, in particular as regards production capacities, production or sales volumes, import volumes or market shares. This is to prevent concerted practices or the creation of the conditions for abuses of dominant position.

Implementing Regulation 2016/9 was introduced to respond to the need to ensure a full implementation of the data sharing provisions laid down in REACH (see below section 1.3.5).

In addition, Implementing Regulation 2019/1692 was introduced to address the end of the phase-in scheme and to clarify that the data sharing provisions now applicable to all substances are those in Articles 26 and 27 REACH.

1.3.2. Data sharing and joint submission

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

There are two distinct obligations stemming from the fact that different entities are registering the same substance:

a) the sharing of data pursuant to Title III REACH is necessary in order to avoid unnecessary animal testing, and allows for the sharing of costs and their consequent reduction for co-registrants;

b) the joint submission of information, in accordance with Articles 11 and 19 REACH, is essential to guarantee the efficiency of the registration system and the reduction of costs. Please refer to the Guidance on Registration, section 4.3, *Joint submission of data*, for more detailed information.

1.3.3. Inquiry and data sharing

Articles 26 and 27 of REACH introduce specific mechanisms to share information among registrants.

Article 26 regulates the inquiry process as follows:

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

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

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

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

Article 27 organises the data sharing process, as follows:

27(1) – potential registrant requests information from previous registrant(s);

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

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

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

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

27(6) – decision of ECHA on whether to give permission to the potential registrant to

refer to the information submitted by the previous registrant in its registration dossier;

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

27(8) – extension by four months of the waiting period to start manufacture or import of the substance after having submitted a registration, upon request by the previous registrant.

In addition, Article 12(2) REACH establishes that, in case of tonnage band upgrade, the rules in Article 26(3) and (4) apply, adapted as necessary. Due to the reference, in Article 26(3), to Article 27, the data sharing provisions apply too, in addition to those relating to the inquiry.

1.3.4. Data sharing as an outcome of dossier evaluation and substance evaluation decisions

Article 53 sets out the obligation to share data as an outcome of dossier and substance evaluation decisions for registrations, as follows:

53(1) – obligation of the registrants and/or downstream users to make every effort to reach agreement to designate the party who must perform a test; decision of ECHA if no agreement is reached and communicated to the Agency within 90 days;

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

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

53(4) – claims for remuneration.

1.3.5. Effective application of REACH provisions on joint submission of data and data sharing

Implementing Regulation 2016/9 lays down specific duties and obligations for parties to agreements when data sharing is required according to REACH. As expressed in Recitals 2 and 3 of Implementing Regulation 2016/9, it was recognised that good management practices need to be promoted and certain rules established in order for the data sharing system to operate effectively.

In particular, this Implementing Regulation stresses the need to share both administrative costs and costs relating to information requirements in a transparent manner, and only among those registrants for which such costs are relevant. It also clarifies the mandatory elements which should be included in each agreement.

Furthermore Implementing Regulation 2016/9 clarifies the role of ECHA in ensuring the effective implementation of the “one substance, one registration” principle and that all registrants of the same substance are part of the same joint submission[6].

Article 1 of Implementing Regulation sets the subject of the Regulation: laying down duties and obligations for parties required to share information under REACH.

Article 2 sets the rules to ensure transparency in data sharing processes:

- 2(1) – data sharing agreement to be reached and elements it must include;
- 2(2) – possibility for existing agreements to waive the obligations to itemise

[6] As explained above in section 1.2.6, Implementing Regulation 2016/9 uses the concept of the same registration.

and right for new potential registrants to request it;

- 2(3) – obligation to document cost and reimbursement yearly and keep the documentation for a minimum of 12 years.

Article 3 reinforces the "one substance, one registration" principle:

- 3(1) – role of ECHA in ensuring that all registrants of the same substance are part of the same registration;
- 3(2) – role of ECHA in ensuring that subsequent submissions of information by registrants that were allowed by ECHA to refer to already submitted information are also part of the existing joint submission;
- 3(3) – a registrant who is not required to share already submitted tests on vertebrate animals can submit separately part or all the information to be submitted jointly (opt-out); obligation to inform any previous registrant and ECHA in case of separate submission of part or all of the information.

Article 4 sets the rules to ensure fairness and non-discrimination:

- 4(1) - the condition for each registrant to be required to share only costs which are relevant for its own registration applies also to administrative costs;
- 4(2) – applicability of cost-sharing models also to future registrants and need to consider costs resulting from potential substance evaluation decisions; factors to be considered in setting the cost sharing model to be included in the data sharing agreement; clarification that costs resulting from substance sameness establishment should not be subject to cost sharing between previous and potential registrants;
- 4(3) – equal share of the costs is to be paid in case of disagreement on the cost-sharing model;
- 4(4) – reimbursement mechanisms to be envisaged and factors that must be considered;
- 4(5) – potential waiver of the reimbursement mechanism and right for potential registrants to request such mechanism be included in the cost-sharing model;
- 4(6) – data sharing obligations related to substance evaluation decisions for any registrant ceasing its activity;

Article 5 states that in case of data sharing dispute pursuant to the relevant articles of REACH, the compliance of all parties with the provisions of the relevant articles of Implementing Regulation 2016/9 must be taken into account by ECHA.

1.4. Other legal obligations

1.4.1. Competition rules

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

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

Article 25(2) mentions that "*(…) Registrants shall refrain from exchanging information concerning their market behaviour, in particular as regards production capacities,*

production or sales volumes, import volumes or market shares."

As discussed in section 7 of the present Guidance document, in the context of REACH and information exchange, the most relevant provisions are Articles 101 and 102 of the Treaty on the Functioning of the European Union ('TFEU'), which prohibit agreements and practices that restrict competition and forbid undertakings holding a dominant position in a market from abusing that position. For more details, please consult the legal text available on the EUR-Lex web site at http://eur-lex.europa.eu/homepage.html.

1.4.2. Confidential business information ('CBI')

REACH requires companies to share information and data in order to avoid duplicate testing. However, some of this information, or data, may be considered by companies to be confidential business information ('CBI') and is thus considered as protected. What is considered as CBI, the specific provisions in REACH, and how to protect such information in different scenarios is discussed in section 8, below.

1.4.3. Copyright

The "legitimate possession" or "permission to refer" required by Article 10 REACH could be considered as derived directly from intellectual property law[7]. Recital 52 REACH establishes that a data owner should be able to claim compensation from registrants who benefit from the data for a period of 12 years, in order to respect its legitimate property rights.

According to copyright law rules, facts and data used to create a study summary are generally not copyright protected. Copyright covers only the form or mode of expression. As such, the study summaries at issue in data sharing negotiations can be subject to copyright protection or other intellectual property rights. See section 9, below.

1.5. Links to other REACH guidance documents and technical documents

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

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

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

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

[7] The Berne Convention for the Protection of Literary and Artistic Works (1886), as last amended in 1979.

All these ECHA guidance documents are available on the “support” section of the ECHA web site at: http://echa.europa.eu/guidance-documents/guidance-on-reach.

NB: Other and more technical documents and supporting tools have been issued to support the potential registrants to fulfil their REACH obligations: Questions & Answers (e.g. on inquiry, on data sharing and related disputes, etc.; available at http://echa.europa.eu/support/qas-support/qas) and Manuals (available at http://echa.europa.eu/manuals). Furthermore, help text is provided within REACH-IT to support the user.

1.6. Link to the CLP Regulation and related guidance

Regulation (EC) No 1272/2008 ('CLP')does not contain any provisions on data sharing. Nevertheless, manufacturers, importers and downstream users who are not subject to registration under REACH but own information on the hazards and the classification of the substance, may voluntarily decide to share data. This is further explained in the *Introductory Guidance on the CLP Regulation* available at: http://echa.europa.eu/web/guest/guidance-documents/guidance-on-clp.

1.7. Link to BPR and related guidance

According to Article 63(1) and (4) of Regulation (EC) No 582/2012 ('the Biocidal Products Regulation'), applicants "*shall make every effort to reach an agreement* [with data owners] *on the results of the tests or studies requested by the prospective applicant*." and "*Compensation for data sharing shall be determined in a fair, transparent and non-discriminatory manner having regard to the guidance established by the Agency*".

Part of this guidance document therefore applies to data sharing under the BPR. Annex 4 provides an overview of relevant sections of this guidance applicable (fully or partially) to BPR purposes. Note that the provisions from Implementing Regulation 2016/9 (explained in section 1.3.5) do not apply for the purposes of the BPR.

A special series of Practical Guides on data sharing specifically under the BPR is also available on the ECHA website at http://echa.europa.eu/practical-guides/bpr-practical-guides.

Data submitted under Directive 98/8/EC (no longer in force) or Regulation 528/2012 concerning the placing of biocidal products on the market may be of interest for potential registrants, even though data owners under the biocides regime do not have the obligation to share their data for the purpose of registration in the current data sharing regime under REACH.[8] See section 2.2.2.2 for further information on data sharing with entities who are not registrants of the same substance.

[8] Such entities were part of the SIEFs during the phase-in scheme, as described in Article 29(1), referring to Article 15 REACH. After the end of the phase-in scheme, the applicable data sharing mechanism is described in Title III, Chapter 2 of REACH (see section 1.2.2 above). The obligation to share data falls on previous and potential registrants only. Data holders in the context of the legislation on the placing on the market of plant protection and biocidal products are now excluded from this obligation, as indicated in Article 16(2) of REACH.

2. DATA SHARING PRINCIPLES

2.1. Actors

The present section details the actors with data sharing obligations, i.e. the potential registrants and previous registrants. The principles presented in this section are also applicable to data sharing between existing registrants, as detailed in section 4.[9] These actors can always designate a representative (e.g. a consultant or a consortium) to hold the negotiations on their behalf. In cases where they do not want to disclose their identity in the negotiations, they can appoint a third party representative as described in section 2.1.3 below.

In addition, there are other entities that may be involved in data sharing discussions, even though they have no obligation to share data. Potential registrants may contact them in order to use the data they own in their registration dossier. However, the data sharing mechanisms set in REACH are not applicable to the sharing of data submitted for different substances (see sections 2.2.2.2 and 2.3 below). These other entities may include:

- Manufacturers and importers of the substance in quantities of less than 1 tonne per year;
- Downstream users of the substance who may be in possession of data;
- Entities having submitted (or owning) data on the substance in the context of the legislation on the placing on the market of plant protection and biocidal products[10];
- Entities owning data on another substance that may be used for the registration of the substance with a read-across adaptation[11];
- Trade or industry associations, sector specific groups and consortia already formed;
- Non-Governmental Organisations (NGOs), research laboratories, universities, international or national agencies;
- Manufacturers of a substance who have no interest in registering a substance under REACH because they do not manufacture or place it on the market in the EU (e.g. a non-EU manufacturer who does not export into the EU).

2.1.1. Potential registrants

Potential registrants are legal entities that intend to register a substance. They include:

- Those who intend to manufacture or import a substance on its own or in mixtures in quantities of 1 tonne or more per year, including intermediates;
- Those who intend to produce or import articles containing a substance 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 ('OR') appointed under Article 8 REACH by a non-EU entity who intends to export to the EU a substance in quantities of 1 tonne or more

[9] Reference to 'potential registrant' should thus be understood in that light.

[10] See footnote 8.

[11] For more details, see section 2.3.

per year, on its own, in mixtures or in articles.

2.1.2. Previous registrants

"Previous registrants" are those who have already submitted a complete registration dossier for the Substance. This also includes registrants who have an inactive registration because they have ceased manufacture pursuant to Article 50(2) REACH.

Previous registrants may or may not be the data owners. Moreover, for the purposes of data sharing, the negotiations may sometimes be conducted with (lead) registrants, consultants, consortia or other representatives/negotiating parties who have rights to the data or to represent the data owners.

2.1.2.1. The lead registrant

Among the previous registrants of a substance, the lead registrant of a joint submission is often the main contact point for the start of the negotiations, since its dossier contains data to fulfil the information requirements.

The role of the lead registrant is specifically foreseen in Article 11(1) REACH for the purposes of complying with the "one substance, one registration" principle by means of joint submission. It is defined as the "*one registrant acting with the agreement of the other assenting registrant(s)*". The lead registrant must first submit certain information on behalf of all the registrants (the "jointly submitted dossier"), before others can submit their member dossiers (that is, the individual information to be submitted by each member of the joint submission).

REACH does not specify rules as to how the lead registrant should be selected. The lead registrant must act with the agreement of the other co-registrants and submit the joint submission dossier (prepared jointly by the co-registrants). All the manufacturers, importers and only representatives concerned by a substance (independently from the tonnage band) should participate in the discussion and agree on a lead registrant and the information to submit jointly.

The lead registrant role does not grant privileges, nor does it entail the obligation to perform all the tasks related to data sharing or the joint submission. For more information, see Guidance on Registration, section 4.3, *Join submission of data*.

2.1.3. Third party representative

Any manufacturer or importer (potential registrants and previous registrants) may appoint a third party representative ('TPR') for certain tasks e.g. data sharing[12]. This is typically the case when a company does not wish to disclose its interest in a particular substance as this may give indications to competitors about production or commercial secrets. Appointment of a TPR is an option to keep the company name confidential during the data sharing and joint submission discussions.

NB: Whenever a manufacturer or importer considers as sensitive information which may need to be exchanged for data sharing purposes to be sensitive, a TPR may be nominated.

[12] Article 4 REACH specifies that a TPR can be appointed "for all proceedings under Article 11, Article 19, Title III and Article 53 involving discussions with other manufacturers, importers, or where relevant downstream users".

The identity of a manufacturer or importer who has appointed a third party representative will be normally not disclosed by ECHA to other manufacturers or importers. However, appointing a TPR should not be confused with the possibility to keep confidential the registrant's name for dissemination purposes (see Article 10(a)(xi) REACH). However, the appointment of a TPR for data sharing and joint submission purposes can be considered as a supporting factor to justify the request for confidential treatment of the registrant's name for dissemination purposes.

When the registrant protects its identity with a TPR when submitting a registration dossier, the name of the TPR will appear to the co-registrants. However, the legal entity appointing the TPR retains the full legal responsibility for complying with its obligations under REACH. In addition, the registration dossier will be submitted by the actual registrant and not by the TPR.

A TPR can represent several legal entities, but will appear in REACH-IT to other registrants as a separate registrant for each different legal entity it represents. The TPR should also not be confused with an OR who is a EU entity acting on behalf of a non-EU manufacturer complying "all other obligations of importers under" REACH.[13]

2.2. Conditions for data sharing

According to Recital 33 REACH, the sharing of information on substances is provided for in order to reduce testing on vertebrate animals, increase the efficiency of the registration system and reduce costs.

This part of the guidance briefly addresses the conditions set out in REACH for the sharing of data between registrants, so as to avoid unnecessary animal testing and the duplication of other tests. The data sharing process before submitting a registration is further developed in section 3 of this Guidance document. For the sharing of data among existing registrants, please refer to section 4 of this Guidance document.

This section focuses on the conditions to be fulfilled for the successful sharing of data in light of the provisions of REACH. It addresses the determination of substance sameness, the data subject to sharing, the agreements and classification and labelling obligations.

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

Exchanging this information will also generally not reveal confidential business information either. Nevertheless companies may want to retain information, particularly when it involves confidential data, such as know-how or sensitive information. If a satisfactory solution cannot be found, the potential registrant concerned can "opt-out". For more details, please consult sections 2.2.3.2, 5.4.2 and 8 of this Guidance document.

[13] Article 8(2) REACH.

2.2.1. Substance sameness

The determination of whether the *same* substance needs to be registered by one or more manufacturer(s) or importer(s) is the trigger for the obligation to share data for the purpose of registration under REACH. The establishment of whether a potential registrant intends to register the *same* substance is a two-step process:

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

In a second step, potential registrants need to establish whether their substance is the same for the purpose of registration and verify that their substance has not already been registered under other identifiers. This step is concluded by an agreement on the sameness of the substance for all potential registrants.

The substance identifiers often correspond to an existing EINECS or CAS entry or similar numerical identifiers. There are also cases where one EINECS entry covers several substances or where several EINECS entries may correspond to the same substance for the purposes of REACH.

The objective of the *Guidance for identification and naming of substances under REACH and CLP* is to give guidance for manufacturers and importers on identifying and recording the identity of a substance within the context of REACH. The document provides guidance on how to name the substance. It also gives guidance on when compositions of substances may be considered to refer to the same substance for the purpose of REACH. Identifying sameness of substances is important for data sharing (as well as, in a second step, for the joint submission: REACH does not give the possibility to register different substances jointly). It is essential to define substance sameness, as it is at the root of most REACH processes.

2.2.2. The data subject to the data sharing obligations

Data sharing must first be reviewed with reference to the information requirements for registration. Essentially, REACH requires manufacturers and importers to collect and, where relevant, generate 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 substances throughout their life cycle. Documenting these obligations requires them to submit a registration dossier to ECHA.

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

- Gathering all existing information (make an inventory);
- Considering information requirements;
- Identifying information gaps considering the information requirements;
- Considering alternative approaches and subsequently, if necessary, generating new information or submitting a testing proposal in line with REACH obligations.

The potential registrants are free to organise these steps as they best see fit. More details on these steps are provided under section 3. As noted above, data sharing obligations apply to the (robust) studies summaries submitted for the same substance, whether it is studies generated on the substance itself or studies generated on another substance, but used by an existing registrant with an adaptation.

However, there is no legal requirement to share data that was only submitted on another substance; yet, in order to fulfil the objective of avoiding unnecessary animal

testing, ECHA encourages sharing data between similar substances (see section 2.3 below).

2.2.2.1. What needs to be shared for registration purposes?

To understand your information requirements, it may be useful to consult the *Guidance on information requirements and chemical safety assessment* available at https://echa.europa.eu/guidance-documents/guidance-on-reach, as well as https://echa.europa.eu/regulations/reach/registration/information-requirements.

You may also consult the practical high-level overview of the REACH requirements for registrants of substances manufactured or imported at tonnages of 1-100 tonnes per year available on the ECHA website at https://www.echa.europa.eu/practical-guides.

Article 10(a) REACH requires each registrant to be "*in* ***legitimate possession*** *of or* ***have permission to refer to*** the full study *report summarised*" in a **study summary** and a (**robust) study summary** which are to be submitted for the purpose of registration.[14]

With regard to the nature of the data, a clear distinction must be made between: (a) the full study report, (b) the (robust) study summary and (c) the results of the study.

a) Normally, when e.g. a toxicological or ecotoxicological study is commissioned, the laboratory in charge will issue a **full study report** and pass it on to the party who commissioned and paid the study. This term is defined in Article 3(27) REACH as "*a complete and comprehensive description of the activity performed to generate the information. This covers the complete scientific paper as published in the literature describing the study performed or the full report prepared by the test house describing the study performed*". Often, the full study report is not published, and in such a case CBI may be claimed; if published, generally, such a publication might be subject to copyright. REACH does not require that this "full study report" be submitted at registration, but rather that the registrant be in legitimate possession or have permission to refer to it. See section 9 of this Guidance document for further details.

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) REACH, e.g.: "*Robust study summary means a detailed summary of the objectives, methods, results and conclusions of a full study report providing sufficient information to make an independent assessment of the study minimising the need to consult the full study report*." (Robust) study summaries are sometimes made publicly available by governments with the consent of the owner of the full study report (e.g., the case of international or national chemical assessment programs such as the EC risk assessment reports, OECD/ICCA HPV program and the US HPV Chemical Challenge Program). (Robust) study summaries will normally be published on ECHA's website, unless a registrant can justify to ECHA why this publication is potentially harmful for the commercial interests of the company or another party. If ECHA accepts the justification, the (robust) study summaries will not be published. See section 8 of this Guidance document for more information.

[14] Article 10(a) REACH in fine states that "*[e]xcept in cases covered under Article 25(3), Article 27(6) or Article 30(3), the registrant shall be in legitimate possession of or have permission to refer to the full study report*".

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

Details on the forms of access to the information and scope of rights granted can be found in section 9.

2.2.2.2. Data sharing with entities who are not registrants of the same substance

As indicated in the introduction to section 2.1, entities who are not registrants of the same substance do not fall under the obligation to share data under REACH.

The negotiations on the sharing of data in this context are subject to contractual freedom. When discussing on the financial compensation for the data, it should be kept in mind that such entities do not bear a share in the registration of the substance. Likewise, they are not required to contribute to any cost linked to the preparation of the dossier or related to the organisation of the data sharing among co-registrants.

In the specific case of sharing of data with registrants of another substance for read-across purposes, see section 2.3.

2.2.3. Data sharing agreements

A data sharing agreement is mandatory according to Implementing Regulation 2016/9. It is within the parties' contractual freedom to agree on the form of their data sharing agreement. However, regardless of the form chosen, the basic principles of fairness, transparency and non-discrimination enshrined in REACH and clarified further in Implementing Regulation 2016/9 apply. In any case, data sharing is not designed to generate profit for the data owner(s), but to share the actual costs incurred. The following mandatory elements, as prescribed in Implementing Regulation 2016/9, must be included:

a) itemisation of the data to be shared and their costs;

b) itemisation and justification of the administrative costs[15];

c) a cost-sharing model, which must include a reimbursement mechanism; any possible future data needs must also be considered to be included in the cost-sharing model.

These elements are explained in detail in the next section (2.2.3.1). Their implementation in practice, as well as the illustration of the principles of transparency, fairness and non-discrimination are detailed in section 5. Several compensation formulas are also described in that section as examples.

The parties must also organise the physical transfer of the data (robust study summaries) among themselves. Because each co-registrant is liable for the information submitted on their behalf by the lead registrant in a joint submission, it is not advisable for the participants to simply receive permission to be part of the joint

[15] More details on the distinction between the different types of costs to be shared are provided in section 5.

submission (i.e. simply receive the technical token to access the joint submission in REACH-IT). Co-registrants should have access to all the information submitted on their behalf in the jointly submitted dossier that they need for their registration and that they have paid for. By paying for a letter of access in order to participate in the joint submission, the co-registrants should have access at least to the endpoint results for which they have paid as well as copy of the robust study summary and study summaries, if available.[16] Having access to this data is important for every registrant to be able to assess the jointly submitted data it is referring to. Details on the forms of access to the information and scope of rights granted can be found in section 9.

A data sharing agreement is also mandatory in case of the sharing of data in the context of an opt-out (see section 2.2.3.2 below).

The data sharing principles are also applicable in case of future registrants requesting to share data. Implementing Regulation 2016/9 entered into force at a stage when many data sharing agreements had already been established and may have been in place for several years. Parties to the agreements have the possibility to unanimously waive the obligation to itemise the cost of the data and establish a reimbursement scheme. Nevertheless, the potential registrant of a substance for which an agreement is already in place shall not be bound by the waiver, if he does not agree. It is up to the parties to address this in the negotiations.

Other contractual arrangements

REACH describes the task of the lead registrant, i.e. to submit the data on behalf of the other registrants. In order to identify the responsibility of each registrant in case of conflict, it is recommended that all the registrants keep written records of the agreements made with regard to the joint submission of data.

The way in which co-registrants cooperate to fulfil their REACH obligations may be further detailed in contractual arrangements. The participants are free to choose the form and the clauses to be included in such an agreement. This agreement is optional (but highly recommended) and may consist of a combination of rules and participation processes, such as:

- Mode of selection of the lead registrant and duration of its role;
- Internal rules of designation/transfer of the lead registrant role, in particular in case the lead registrant ceases manufacture;
- Arrangements in case of legal entity change of a registrant, in particular the lead registrant;
- Forms of cooperation between the parties: details of the participation processes and obligations and liability of the co-registrants;
- Forms of access to the information (e.g. the letter of access, scope of rights granted, right to use for purposes other than registration, right to use data for read-across, other conditions, …);
- Compliance with competition rules and confidentiality obligations for all the parties;
- Mechanisms for resolution of disagreement in relation to the execution of the contract.

The contractual provisions regarding the sharing of data and these further contractual

[16] See section 9.2, 'What is a Letter of Access (LoA)?'.

arrangements may be part of one same agreement. More information on the possible forms of agreement, such as consortia, is provided in section 6.

2.2.3.1. Mandatory elements of the data sharing agreement

The data sharing agreement must be clear and comprehensible to all parties regarding the content of the dossier and the type of access that is received by paying the agreed share of the costs. It must include the following elements. For more details on the practical sharing of costs, see section 5 of this Guidance document.

- **Data itemisation**

The existing registrant must provide information on the specific data to be shared. This information must allow the potential registrant to know the ownership of the data as well as the quality and reliability of the studies. Such information may include the year of the study, whether it is GLP compliant, etc. It must also include a description indicating to which information requirements correspond the data and a justification of how the data to be shared satisfies the information requirement.

[Article 2(1)(a) of Implementing Regulation 2019/6]

- **Cost itemisation**

A cost itemisation lists the costs related to data (endpoint-by-endpoint) and to administrative work. All cost items must be justified. This entails not only the itemisation of the data to be shared, including the cost of each data item, but also the itemisation and justification of related administrative costs. When possible, the latter should be linked to the information requirements. However, this link is not always possible - but in any event, such costs must be itemised and justified accordingly.

Note that the existing registrant cannot request the potential registrant to fulfil preconditions to obtain this cost itemisation. In particular, they cannot request the potential registrant to pay a deposit or pay any fee for that information. In addition, the cost relating to the compilation of information by each registrant for the purposes of establishing substance sameness should not be the subject of cost sharing between previous registrants and potential registrants.

In some cases, having a very detailed cost itemisation may be difficult and not helpful. In such cases, the previous registrant can discuss with the potential registrant whether they would agree not to itemise certain or all elements – potentially for a decrease of the costs.

As noted above, it is not always possible to precisely distinguish data and administrative costs. Nevertheless, all cost items should be itemised and justified so that the potential registrant is able to determine which of them relate to their information requirements.

The new potential registrants have the right to request the itemisation of all relevant costs incurred after the entry into force of Implementing Regulation 2016/9 (26 January 2016) and be provided with proof of previous study costs and best approximation of the itemisation of other previous costs.

[Articles 2(1)(a) and (b) and 4(2) of Implementing Regulation 2019/6]

Data costs

Each individual study has a cost. This cost can consist of the costs for performing a test, the costs for buying access to required studies or the costs of fulfilling the information requirement with a non-testing method. Co-registrants may agree on any cost calculation method they find appropriate. For example, either historical costs or replacement costs can be used. Historical costs are based on actual invoices whereas replacement costs refer to costs for performing the test again. See section 5.3.2 for further details.

Some administrative costs may also be data-specific. For example, costs to conduct a literature search or to develop the reasoning for a data waiver clearly relate to an endpoint and not to the entire dossier.

As the potential registrant only has to pay for data that they actually need, they do not have to pay data-specific administrative costs if they relate to an endpoint which the potential registrant does not need or for which the registrant already has the relevant data.

Administrative costs

Administrative costs are the costs of creating and managing the data sharing agreement between the registrants. This may also cover, where relevant, the cost of creating the IUCLID file for the jointly submitted data.

Some of the administrative costs, however, are not data-specific, but related to general administration of the joint submission. For example, the costs of communicating among co-registrants or managing the access to the joint submission could apply to all members equally.

In any case, the existing registrant must be able to justify the costs and the way they are shared. See Annex III to this Guidance document for examples of data and administrative costs.

- **Cost-sharing method**

The co-registrants must agree on a cost-sharing method they consider appropriate. This method must be fair, transparent and non-discriminatory. In any case, it is important that the method used can be understood by the co-registrants. The cost sharing model shall apply to all registrants of a particular substance, including future registrants.

New potential registrants have the right to request clarifications and justifications for the previously established criteria and have free access to information on cost and data sharing methodologies.

[Article 2(1)(c) and 4(2) of Implementing Regulation 2019/6]

- **Reimbursement scheme**

Each co-registrant's proportion of the costs depends on how many co-registrants share the data. It makes a significant difference if the costs are shared between 2 or 200 co-registrants. As such, each time a new potential registrant shares the data, the overall costs for each co-registrant are reduced.

On the other hand, each time there is an additional registration requirement, the overall costs for each concerned co-registrant may increase. The reimbursement

mechanism must also take account of the possibility for future additional registration requirements for that substance. It is recommended that the reimbursement mechanism agreed between the parties also addresses the conditions applicable in case of voluntary updates.

Having a reimbursement scheme is mandatory and will make sure that the costs are shared in a fair and non-discriminatory manner. When and how frequently the costs are re-calculated needs to be agreed on.

Parties to an agreement already existing when Implementing Regulation 2016/9 entered into force had the possibility to unanimously decide to waive the obligation to itemise the data and/or include the reimbursement mechanism. In such cases, the existing data sharing agreement may not provide for the itemisation of the costs or a reimbursement mechanism. However, the potential registrant is not bound by the decision to waive this obligation unless it provides its signed consent.

[Articles 2(1)(c), 4(4) and (5) of Implementing Regulation 2019/6]

- **Potential further costs**

Registrants must document yearly any further costs incurred in relation to the operation of their data sharing agreement, in particular in view of the reimbursement mechanism mentioned above or in case of spontaneous dossier updates. Such annual documentation must be kept for a minimum of 12 years following the latest submission of a study and shall be accessible within reasonable time and free of charge to both existing and potential registrants.

In particular, the data sharing agreement must include provisions in relation to the sharing of any costs resulting from a potential substance evaluation decision. When a potential registrant wants to register a substance for which a substance evaluation decision was already addressed to existing registrants, the related costs must also be taken into account in the cost sharing model. The data sharing agreement should also contain provisions for any future costs resulting from the generation of additional information requirements, for example as a result of a compliance check decision. Previous registrants cannot force potential registrants to pay upfront for potential costs that they may only incur later.However, the data sharing agreement may provide that, once an evaluation decision has been addressed to several registrants, the costs necessary for the conduct of the study in question may be shared upfront among these registrants to ensure that funds are available to conduct the whole study.

However, the existing registrant must agree with the potential registrants to establish a system that covers these potential future costs. In that agreement, each registrant only needs to pay for what they need to be compliant with REACH.

[Articles 2(3) and 4(2) of Implementing Regulation 2019/6]

2.2.3.2. Data sharing agreements in case of opt-out

Registrants can justify the application of one of the criteria under Article 11(3) REACH which justify the separate submission of certain information. It should be noted that registrants who decide to submit separately some or all the information, may still be required to contribute to a fair share of the costs to access the joint submission (token) and, if relevant and justified, other related administrative costs. For cost allocation and compensation in the context of an opt-out, see section 5.4.2, below.

In addition, registrants who opt-out still have the obligation to share the data submitted in their opt-out dossier upon request by other registrant(s). In this context, they will also have to make every effort to find a fair, transparent and non-

discriminatory agreement to share this data.

2.2.4. Classification and labelling

Registrants are required to provide the classification and labelling of the substance in the registration dossier as described in Annex VI, Section 4 as part of the technical dossier (Article 10(1)(iv)).

The CLP Regulation stipulates that notifiers and registrants shall make every effort to come to an agreed entry to be included in the Classification & Labelling Inventory where notification results in different entries for the same substance. This provision (Article 41 CLP) includes ex-post agreements after notification has already been done. Further details are included in the Manual on "How to prepare a classification and labelling notification", available at: http://echa.europa.eu/manuals.

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

If there are differences in classification and labelling, it should be investigated whether such differences stem from different data information (intrinsic properties) underlying the individual classifications, or from different characteristics of the substances as further explained in the two examples below.

Co-registrants are incentivised to agree with each other on classification and labelling. This does not necessarily mean that the classification and labelling is the same for all manufacturers and importers of the same substance. The same substance may be manufactured through different processes, leading to different impurity profiles, see also section 1.1.7.2 of the *Guidance on the Application of the CLP Criteria* available at: http://echa.europa.eu/web/guest/guidance-documents/guidance-on-clp. The same situation may also occur when different raw materials are used. In these cases, however, data sharing may still be possible, and facilitated in case the lead registrant dossier contains several classifications for the same substance.

Examples:

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

   Discussion: manufacturer B should consider requesting the data from manufacturer A, and both A and B should therefore consider applying the same classification.

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

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

reasonable basis. The respective dossiers will need to specify the various boundary compositions of the substance when these compositions result in different properties. The number of boundary compositions provided in one dossier will depend on the variability of the compositions registered by the different joint submission participants and the fate and hazard profiles of these compositions. Specific data corresponding to each boundary composition must in principle be submitted for the determination of property of that composition. This data may result in the determination of different classification for different boundary compositions.

Does the obligation to share data apply when registrants conclude on a different classification?

The obligation to share data applies to registrants of the same substance submitting information jointly. Differences in classification and labelling are not a justification for non-sharing of information. Indeed, co-registrants may agree that different classification and labelling may apply to the same substance, for instance if the difference is attributed to a well identified impurity, for which the relevant hazardous properties are known. Consequently, if appropriately justified and demonstrated with transparent documentation, the dossier(s) on a substance can contain more than one classification and labelling.

NB: Co-registrants can also disagree on the classification and labelling of the substance (for reason other than differences in the impurities profile, different interpretation of test results) (pursuant to Article 11(3)(c)). In such a case, REACH allows the member(s) concerned to submit separately part or all the information to be submitted jointly and to submit a separate C&L. However, a registration dossier submitted by a lead registrant on behalf of other registrants can also contain different C&L without the need to opt-out and they are not necessarily an obstacle to data sharing.

It must be noted that different classification and labelling may have an impact on the risk assessment and the possibility of sharing the Chemical Safety Assessment may become questionable.

2.2.5. Conducting data sharing negotiations

When conducting data sharing negotiations, the parties have the obligation to make every effort to reach an agreement on the sharing of data in a fair, transparent and non-discriminatory way. Potential registrants requesting information should specify the exact nature of the information requested from the previous registrant.

Making every effort to reach an agreement requires all parties to find alternative solutions when negotiations are blocked, and to be open and proactive in their communications with the other party. In case a party receives an unsatisfactory reply, which it considers unclear, invalid or incomplete, it is the responsibility of the recipient to challenge that reply, by addressing constructive, clear and precise questions or arguments to the sender. The requests must be justified. Parties are also expected to get acquainted with the principles related to the sharing of data as described in the present Guidance and other ECHA documents.

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

its questions. Please note that Article 27(5) establishes one month as a minimum time-period for discussions on data and cost sharing.

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

Any cost subject to data sharing must be itemised and justified, as noted above in section 2.2.3.1. Any cost sharing mechanism has to be also justified, include a reimbursement mechanism and must not be discriminatory between existing registrants and registrants joining the joint submission at different times. Some examples are provided in section 5 of the present guidance document.

Previous registrants must ensure that (new) potential registrants are only required to share in the costs of information that they are required to submit to satisfy their own registration requirements.[17] This applies also to administrative costs.

If requested, the previous registrant(s) need(s) to provide scientific justifications of the approach followed in the selection of data that is necessary to demonstrate the safe use of the substance.

ECHA provides a dedicated website with practical advice for data sharing negotiations at: http://echa.europa.eu/support/registration/working-together/practical-advice-for-data-sharing-negotiations.

2.3. Data sharing between registrants of different substances (grouping, read-across)

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

Further guidelines are also provided under the Read-across Assessment Framework (RAAF) available at http://echa.europa.eu/support/grouping-of-substances-and-read-across.

As explained above in section 2.2.2, when data on another substance was already used to register a substance, such data will have to be shared if a potential registrant requests so. In other circumstances, data sharing is not mandatory for registrants of different substances. Therefore, the sharing of data in these situations does not fall within mandatory data sharing obligations.

However, it is in line with the objectives of avoiding unnecessary animal (particularly vertebrate) testing (according to Article 25 REACH) and registration costs to do so. Implementing Regulation 2016/9 explicitly encourages the sharing of relevant (animal and non-animal) studies that are conducted on a substance which is structurally similar to the substance being registered, in order to promote the development and use of alternative methods for the assessment of hazards of substances and to minimise

[17] Decision of the Board of Appeal of ECHA of 15 April 2019 in case A-010-2017, *REACH & Colours*, paragraphs 126-151.

animal testing[18].

Every request for access to studies between registrants of different substances will have to be negotiated on a case-by-case basis by the potential registrants wanting to share access to the studies. Potential registrants are invited to explore read across potentials with a view to avoiding unnecessary testing on vertebrate animals.

It is to be noted that the "12-year-rule" (see section 3.1.4.1) applies also for read-across purposes. In other words, (robust) study summaries submitted more than 12 years ago are available for free for the subsequent registrants under REACH, whether it is to register the same substance or another substance (with read-across).

How can a potential registrant contact a registrant from another joint submission in view to sharing data for read-across?

There is no formal procedure to get in contact with the joint submission of another substance for read-across purposes. Potential registrants can look up the details in ECHA's dissemination portal for registered substances, and contact any of the registrants whose name appears, asking for the lead registrant's contact details.

Alternatively, potential registrants can contact ECHA's Helpdesk and request ECHA to share its contact details with the lead registrant of the joint submission of interest. ECHA will then contact the said lead registrant and encourage it to initiate contact.

In addition, potential registrants can also contact the trade organisation coordinating the activities of the manufacturers/importers of the group of substances that they have an interest in. These trade organisations may be in a position to provide information on opportunities for read-across.

[18] See recital 15 of Implementing Regulation 2016/9.

3. DATA SHARING BEFORE SUBMITTING A REGISTRATION DOSSIER

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

Article 26 REACH regulates the process that must be followed by potential registrants before registering and, where relevant, initiating data sharing negotiations: this is called "the inquiry process" and is explained in section 3.1.

Following the inquiry process, potential registrants will be able to identify existing registrants and potential registrants of the same substance. They will then be able to follow the next steps towards registering the substance, depending on whether the substance has already been registered (see section 3.2) or if it has not yet been registered (see section 3.3).

3.1. The inquiry process

3.1.1. The purpose of the inquiry

Articles 26 and 27 REACH regulate the currently applicable process for initiating data sharing negotiations[19]. The inquiry is a mandatory step before the potential registrant is able to proceed with registration. The purpose of the inquiry process is twofold:

1. to determine whether the same substance has previously been registered/inquired about;
2. to facilitate, in view of the sharing of data, contact between the potential registrant and:
    a. the previous registrant(s), if any;
    b. other potential registrants.

In practice, contact is facilitated by ECHA by means of a *Co-Registrants* page, a platform in REACH-IT where the above mentioned parties are listed with their contact details and its current regulatory status (previous registrant, potential registrant).

Is it obligatory to follow the inquiry process?

The inquiry process is a mandatory step prior to registration.[20] This process must also be followed by existing registrants in case of a tonnage band increase where they require additional information to fulfil their registration requirements. This is further described in section 4.1 below.

NB: New studies involving vertebrate animals must not be conducted before the outcome of the inquiry process is known.

An overview of the inquiry process is presented in Figure 1 below.

[19] For information on the history of the data sharing obligations, see sections 1.2.2 and 1.2.3 above.

[20] The inquiry step is mandatory according to the legal text, and can be enforced accordingly by the national enforcement authorities. The inquiry step lessens the risk of negotiating with the wrong previous registrant, or on the wrong substance, which may impact the registration and data sharing obligations.

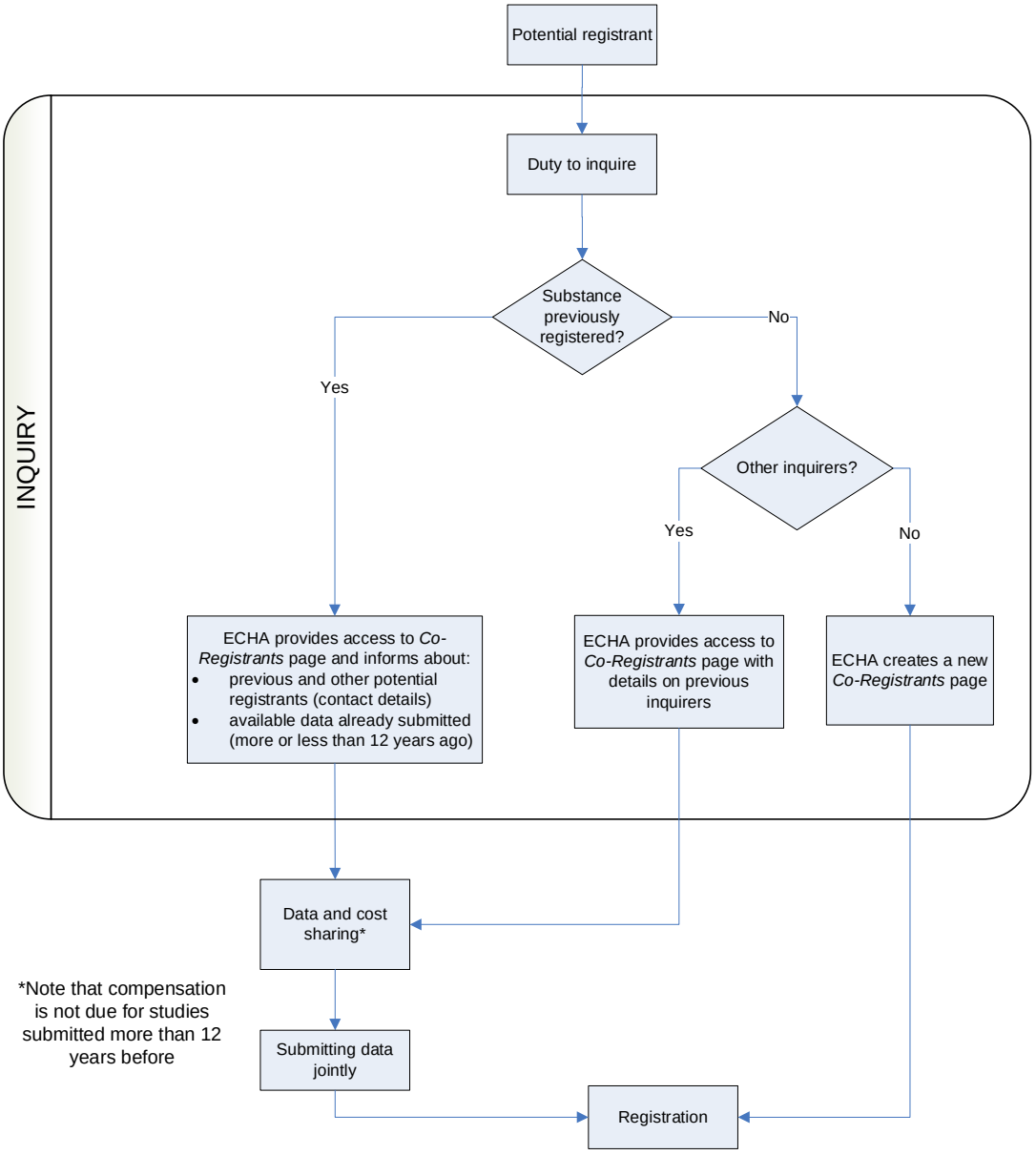


Figure 1: Overview of the inquiry process

3.1.2. Who must inquire?

Any existing legal entity which needs to register a substance must inquire. These legal entities may include:

- Those intending to manufacture or import a substance on its own or in mixtures in quantities of 1 tonne or more per year, including intermediates;
- Those intending to produce or import articles containing a substance 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 appointed under Article 8 REACH by a non-EU entity who intends to export to the EU a substance in quantities of 1 tonne or more per

year.

Non-EU manufacturers cannot themselves inquire about and subsequently register the substances that are exported to the EU. Non-EU manufacturers may decide that either their registration is done by importers or, alternatively, they may be represented by a natural or legal person located in the EU territory, their only representative. An only representative can represent several non-EU manufacturers. In that case, an only representative needs to submit one inquiry per substance per non-EU manufacturer. For more information on the role and duties of the only representative, please consult the *Guidance on Registration*.

3.1.3. Information to be submitted in the inquiry

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

- the identity of the legal entity, as specified in Section 1 of Annex VI to REACH, with the exception of the use sites;
- the identity of the substance, as specified in Section 2 of Annex VI to REACH;
- the information requirements which would require new studies (involving or not involving vertebrate animals to be carried out).

With regard to the substance identity, the information must be sufficient to enable the substance to be identified. This information is identical to that required in the technical dossier for standard registration (section 2 of Annex VI) and is outlined in the *Guidance on identification and naming of substances under REACH and CLP* available at: http://echa.europa.eu/guidance-documents/guidance-on-reach.

For substances used as intermediates, the information to be provided in the inquiry dossier for the identification of the substance has to comply with the same requirements as for non-intermediates.

Providing thorough and accurate information on substance identity is essential to enable ECHA to provide the contact details of existing and potential registrants to the inquirer and so to facilitate all parties in their data sharing obligations.

As for the information requirements for a specific substance, these will depend on the intended tonnage band to be manufactured or imported. The potential registrant needs to identify the list of information requirements for their particular substance in order to facilitate the subsequent data sharing stage. The potential registrant must identify in the inquiry dossier the list of information requirements applying to them.

Practical instructions for the preparation of an inquiry are available in the ECHA manual 'How to prepare an inquiry dossier' accessible at: http://echa.europa.eu/manuals. This document is also available via the help system built into IUCLID.

For more details, please consult the dedicated web page(s)[21] on the ECHA website.

3.1.4. Outcomes of the inquiry process

For most already registered or successfully inquired substances, the processing of the inquiry is done based on the provided numerical identifiers (e.g. EC number). When needed, ECHA further considers the substance identity information in order to determine if the substance has already been registered.

[21] http://echa.europa.eu/regulations/reach/registration/data-sharing/inquiry.

If an inquiry is accepted, the inquirer will receive an inquiry number[22] and ECHA will direct the inquirer to the relevant *Co-Registrants* page in REACH-IT where, if applicable, it can find contact details of the existing registrants and potential registrants of the same substance.

While ECHA directs inquirers to relevant co-registrants, it is still the responsibility of potential registrants and previous registrants to discuss on substance sameness and to decide whether their substances can be registered together. If there is a disagreement, potential registrants can contact ECHA on substance sameness by contacting ECHA's Helpdesk through the webform from ECHA's website.

If ECHA is not able to process the inquiry dossier, due to missing and/or inconsistent substance identity information, the inquirer will receive a communication in REACH-IT describing the necessary changes to submit a successful inquiry dossier.

More details regarding the inquiry process are available in the "Questions and Answers on Inquiry" on the dedicated web page[23] on ECHA web site.

NB: For monitoring the updates in relation to your inquiry, a regular check of incoming messages in REACH-IT is advisable

3.1.4.1. The substance has already been registered

If the substance has already been registered, the potential registrant will find the contact details of the existing registrants and other potential registrants of the same substance on the provided *Co-Registrants page* in REACH-IT.

At the same time, previous registrants and other potential registrants will see the contact details of the inquirer in the *Co-registrants page* under 'Potential registrants'. At that stage, no proactive actions are expected from the previous registrant(s).

In addition, the inquirer will obtain from ECHA information on the available data already submitted, including the contact details of the previous registrant who submitted the data for each specific endpoint. It is the responsibility of the potential registrant to consider which of the information is relevant to fulfil the information requirements in its registration dossier. The potential registrant will also be able to find out whether there is no data for an endpoint (e.g. because no registration was submitted for the higher tonnage band to which the inquirer intends to register).

The situation regarding the compensation of the submitted data differs depending on whether the (robust) study summaries were submitted more than 12 years before or not.

The period of data compensation under REACH is 12 years. This applies to (robust) study summaries submitted in the framework of a registration (in accordance with Article 25(3) REACH) and to data submitted in the framework of a notification made in accordance with Directive 67/548/EEC.[24] In other terms, such (robust) study summaries submitted more than 12 years previously can be used for the purpose of

[22] The registrant should insert its inquiry number in the registration dossier.
[23] http://echa.europa.eu/qa-display/-/qadisplay/5s1R/view/reach/inquiry.
[24] Under the legal framework of Directive 67/548/EEC, data submitted as part of a notification could be used further for the purposes of a subsequent notification after 10 years from the date of submission of the data. Pursuant to Article 25(3) REACH, this period was extended by 2 years to a period of 12 years from the original date of submission to the competent authorities (e.g. data submitted in the framework of a notification on 1 June 2001 continued to be protected under REACH until 1 June 2013).

registration under REACH without compensation. It is to be noted that the "12-year-rule" applies also for read-across purposes. In other words, (robust) study summaries submitted more than 12 years ago are available for the subsequent registrants under REACH, whether it is to register the same substance or another substance (with read-across).

It must be noted that other administrative costs related to the joint submission of these data, e.g. costs related to the preparation and submission of the IUCLID file, may need to be shared.

It is important to distinguish the date of submission from the date of the performance of the study, which pre-dates the submission itself. The 12-year rule applies as of the moment of submission of the particular (robust) study summary, regardless of when it was performed. Additionally, the date of submission of a specific (robust) study summary to ECHA is not necessarily the same as the initial registration date. Indeed the (robust) study summary may have been submitted afterwards (e.g. after a tonnage band increase up to the next level of testing) and hence the 12-year period may not yet have expired. This is illustrated in the table below.

Year of test realisation	Year of (R)SS submission under DSD (67/548/EEC) or REACH	End of compensation period (for REACH purposes)
1985	1985	1997
1985	2000	2012
1985	2010	2022
1985	-	12 years after the (R)SS is submitted for registration purposes

The information provided by ECHA will therefore indicate whether the (robust) study summary has been submitted more than 12 years ago, and therefore whether it is subject or not to compensation.

A given endpoint may be covered by (robust) study summaries submitted both more and less than 12 years previously. Inquiry outcomes can therefore be combined. In that case, some of the (robust) study summaries can be used without compensation, and some is subject to compensation.

NB: It is always the responsibility of the inquirer to assess the quality and relevance of the already submitted data[25] so that, as a registrant, it fulfils its registration obligations. When using (robust) study summaries submitted more than 12 years earlier (e.g. in a NONS notification), it may be that these (robust) study summaries are not of sufficient quality to meet the registration obligations under REACH and the

[25] Data submitted in IUCLID 4 or SNIF format do not contain all the required information and the registrant needs to carefully check and complete the IUCLID file. More details are provided in the Manual on "How to complete a registrations and PPORD dossier" available at: https://echa.europa.eu/manuals.

potential registrant may consider alternatives to ensure completeness and compliance of the registration dossier. Additionally the potential registrant is also advised to ensure with the previous registrant/notifier that the full study report is available.

The next steps to submit a registration dossier in case the substance has already been registered are described in section 3.2 below.

3.1.4.2. The substance has not previously been registered

If the substance has not already been registered, ECHA will either create a new *Co-Registrants* page in REACH-IT if there were no previous potential registrants for the substance, or direct the inquirer to an existing *Co-Registrants* page where the inquirer will find the contact details of other potential registrants.

At the same time, where relevant, other potential registrants will see the contact details of the inquirer in the *Co-registrants page* under. No proactive actions are expected from the other potential registrant(s).

The next steps to submit a registration dossier in case the substance has not been registered yet are described in section 3.3 below.

3.2. Steps to submit a registration dossier when the substance has already been registered

The following sub-sections will describe in a chronological order the possible events in the preparation of a registration dossier by a potential registrant, when the substance has already been registered:

- Gathering of the available information
- Consideration of information requirements
- Establishment of the data needs and identification of data gaps
- Negotiation on data and cost sharing
- Available remedies in case of failure of the negotiations
- (Joint) submission of data
- Possible registration waiting period in accordance with Article 27(8)

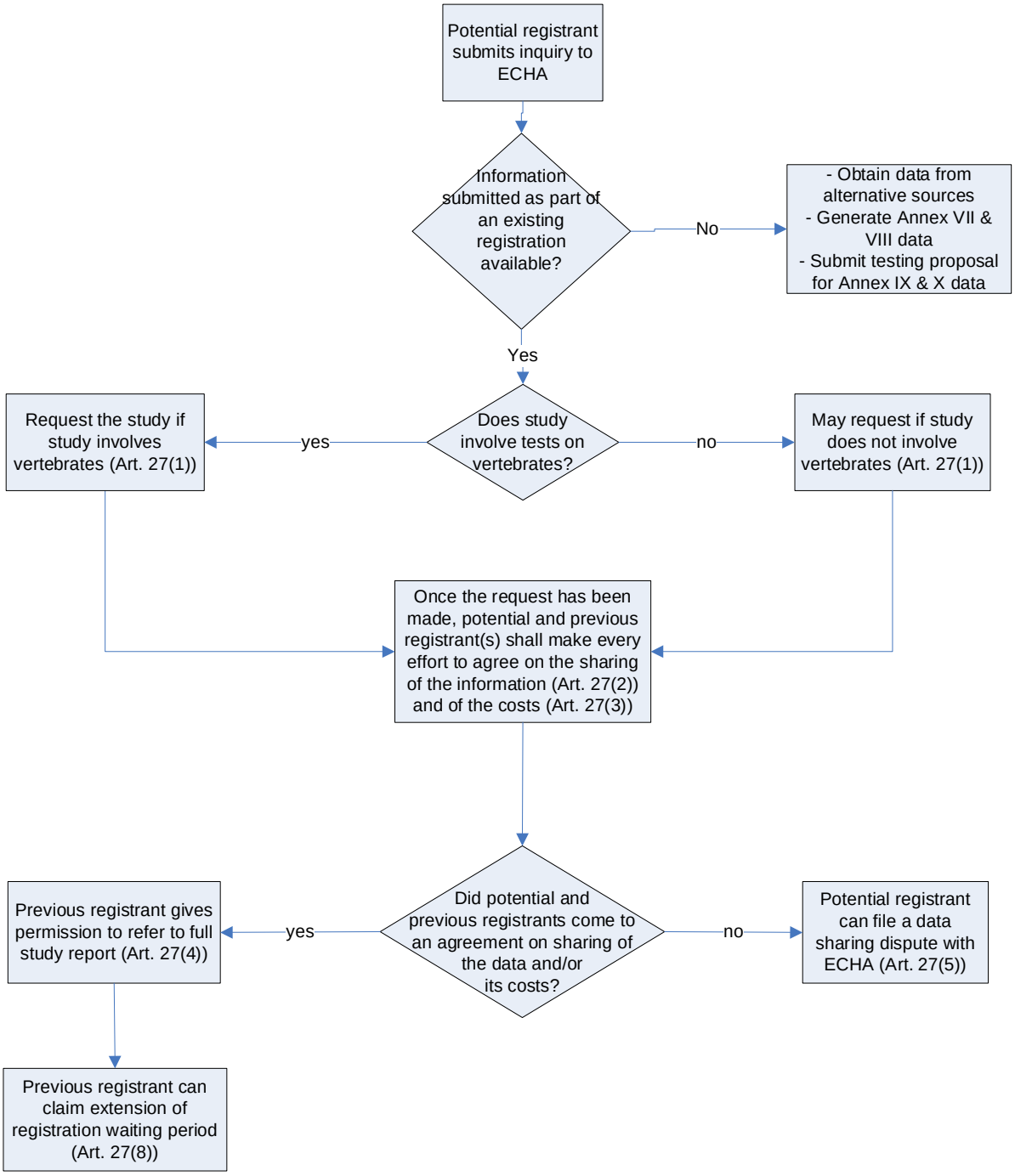


Figure 2: Sharing of data after an inquiry where there is an existing registration

3.2.1. Gathering of the available information

The potential registrant should first gather all existing available information on the

substance they intend to register. Each registrant is individually responsible for making sure that the information it submits in the registration complies with the REACH information requirements relevant to its substance.

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

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

- Information detailing identity of the substance (analytical reports, applicable analytical techniques, standardised methods, etc.);
- 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.

The information to be gathered at this stage should put the potential registrant in a position to also address whether the studies jointly submitted for the substance are also representative for its own composition(s) (see *Guidance for identification and naming of substances under REACH and CLP*).

This data gathering exercise is to be done irrespective of volume. Indeed, even if the standard information requirements depend upon the volume manufactured or imported by each registrant, registrants must also include all relevant and available data for a specific endpoint.[26] All relevant and available information for the registration dossier must include both data available "in-house", as well as from other sources, such as data in the public domain[27] that can be identified through a literature search. The search, identification and documentation relating to "in house" information must remain an individual exercise. In addition, the potential registrant will also have to share, on request, data it intends to submit which corresponds to a higher tonnage threshold.

It should always be considered that, except for the cases enumerated in Article 10(a) last paragraph[28], the registrant must be in legitimate possession or have permission

[26] Article 12(1) REACH and REACH Annex VI, Guidance Note, Step 1.
[27] To be understood as any information published in scientific literature or in electronic format (on internet). Conversely, the term "public domain" in copyright protection suggests that the information is not copyright-protected anymore and may be normally used for free (e.g. the term of the copyright protection has already expired, information in certain open public repositories etc.). However, it is always advisable to enquire on the actual status of the "public domain" and to check respective copyright clauses. Registrants should be cautious in respecting copyright and should not automatically copy published studies, even if the publication itself has been lawfully acquired or accessed, without first having ascertained that the information may be lawfully used for the registration purposes. In case of published studies, it is recommended to check conditions of their use for the registration purposes. See section 9 for further details.
[28] That is (i) if ECHA granted to the potential registrant permission to refer to data and (ii) if the data has been submitted more than 12 years ago and can be used for free for registration purposes.

to refer to the full study report summarised in a (robust) study summary which is to be submitted for the purpose of registration. For more details on the nature of data and right to refer to the data, consult section 9 of this Guidance document.

3.2.2. Consideration of information requirements

The next step is for the potential registrant to identify precisely what the information requirements are for the compositional profile(s) of the substance that it intends to register, considering in particular the tonnage band that is relevant to it, the physical parameters of the substance (relevant for technical waiving of tests) and uses/exposure patterns (relevant for exposure-based waiving).

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

As described in more detail in the *Guidance on Registration*, Article 12 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 a literature search);
- as a minimum, fulfil the standard information requirements as laid down in Column 1 of REACH Annexes VII to X for substances produced or imported in a certain tonnage band, subject to adaptation possibilities, as described below. The simplified list of information requirements is available here: http://echa.europa.eu/regulations/reach/registration/information-requirements.

In case the registrant makes use of a possibility to adapt the information requirement, it should indicate it clearly and justify each adaptation in the registration dossier. Indeed, for each of the REACH Annexes VII to X, Column 2 lists specific criteria (e.g. exposure or hazard characteristics), according to which the standard information requirements for individual endpoints may be adapted or omitted. In addition, registrants may adapt or omit the required standard information set according to the general rules contained in Annex XI of REACH 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)

Note that ECHA also provides a practical high-level overview of the REACH requirements for registrants of substances manufactured or imported at tonnages of 1-100 tonnes per year. This “Practical guide for SME managers and REACH coordinators” is available on the ECHA website at: https://www.echa.europa.eu/practical-guides.

NB: The information requirements have been revised[29] and may change again. If there is no longer a need to provide certain information, the potential registrants do not need to provide or negotiate access for this information (even if the data has already been generated and submitted by the existing registrants) and instead fulfil the new

[29] See for example, skin corrosion/irritation, serious eye damage/eye irritation and acute toxicity.

information requirement via non-animal test methods.

For substances identified in Article 3(20) REACH (eg. EINECS substances), manufactured or imported between 1 and 10 tonnes per year, the full information requirements are only applicable if one or both of the criteria laid down in Annex III of REACH are met[30]. In order to support the registrants, ECHA has generated an inventory of substances for which there is evidence that they would possibly fulfil these criteria (i.e. for those substances submitting only physicochemical information will not be sufficient) and support material outlining an effective step by step procedure for companies to consider REACH Annex III in the context of their registration[31].

When the Annex III criteria are not met, only the physicochemical information requirements in Annex VII need to be fulfilled for phase-in substances below 10 tonnes per year.

For substances manufactured or imported in quantities of 10 tonnes (or more) per year per registrant, a chemical safety report (CSR) must be submitted. At least all the information required under Article 10(a) REACH for the technical dossier and under Article 10(b) REACH for the chemical safety report (CSR) needs to be documented in the specified reporting formats (Annex I of REACH).

The information requirements for certain types of intermediates are reduced and there is no requirement to carry out a chemical safety assessment for them. If the substance is an intermediate, the registrant needs to provide any information which is available to it for free. Thus, it does not need to pay a share of the costs of the data. The only exception to that rule concerns the registration of a transported isolated intermediate in quantities of more than 1000 tonnes per year, where requirements of Annex VII apply and thus potential registrants will need to share data and its costs with the existing registrants.

Further information on substances used as intermediates and their possibly reduced information is available in section 2.2.5, *Obligations related to registration of intermediates*, of the Guidance on registration and in the Practical Guide “How to assess whether a substance is used as an intermediate under strictly controlled conditions and how to report the information for the intermediate registration in IUCLID”, available at https://www.echa.europa.eu/documents/10162/23036412/pg16_intermediate_registration_en.pdf.

3.2.3. Establishment of the data needs and identification of the data gaps

Based on the identified information requirements, the potential registrant may verify whether it already has the relevant studies or whether further data are needed. To do so, the potential registrant must also evaluate the data it owns, in particular regarding its relevance, reliability, adequacy and fitness for purpose.

The data owned by a potential registrant that is used in its registration will be subject to the data sharing obligation if co-registrants ask for it, whether it involves testing on

[30] See Article 12(1)(b) REACH and Article 2 of Implementing Regulation 2019/1692. See also Commission Regulation (EU) 2018/1881 of 3 December 2018 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annexes I, III,VI, VII, VIII, IX, X, XI, and XII to address nanoforms of substances, OJ L 308, 4.12.2018, p. 1–20

[31] For more information please visit the Annex III dedicated webpage in the ECHA website at http://echa.europa.eu/support/registration/reduced-information-requirements.

vertebrate animals or not.

If the potential registrant needs further data, it can negotiate access to individual studies or to all the data that were already submitted, as described in section 3.2.4 below.

The following items can also be negotiated and their costs shared among co-registrants (although they are not obliged to share any of these):

- Chemical safety report ('CSR'): For registrations above 10 tonnes a year, registrants need to submit a CSR, which can be the same as the existing registrants' one, or the potential registrant's own. When preparing an own CSR, a potential registrant should not be requested to pay any costs related to the preparation of the existing registrant's CSR.
- Guidance on safe use of the substance: For registrations between 1–10 tonnes a year, as the CSR is not needed, more information in the guidance on safe use section of the registration dossier must be submitted[32].

At this stage, the potential registrant is in a position to compare the information requirements against the information available to it and the information already submitted in the registration for the substance. On this basis, it can identify whether there are information gaps and consider how missing information can be generated.

If the available information is sufficient and the standard information requirements are met, no further gathering of information is necessary. Where relevant, justification for adapting the relevant test(s) must be provided in accordance with the criteria under Annex XI.

In case the available information is considered insufficient, the potential registrant must first verify whether there are other potential registrant(s) identified in the *Co-Registrants* page that may have relevant data. This can be done by requesting a relevant study for one (or more) given end-point(s), or by means of a questionnaire linked to Annexes VI to X of REACH, if more data are missing. It is recommended that a short but reasonable deadline is given to potential registrants to communicate on the requested data (e.g. 1-3 months).

If there are no other potential registrants, or they do not own relevant data, the potential registrant can verify whether entities that are not (potential) registrants of the substance own relevant data, in particular registrants of other substances. See the introduction of section 2.1 for a list of such possible entities and sections 2.2.2.2 and 2.3 on the sharing of data with such entities. It is advisable that, when sharing data in this context, it is ensured that access rights are obtained for any co-registrants who would need this information for their registration purposes.

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

Data gaps may be different for each of the relevant tonnage bands. In principle, there is no need to make data gaps analysis for registrations of intermediates, except for a registration of a transported isolated intermediate in quantities of more than 1000 tonnes per year.

In case a data gaps remains, the steps to take are described below in section 3.4.

[32] See section 6 of Annex VI to REACH.

3.2.4. Negotiation on data and cost sharing

When there is an already existing registration for the substance, the potential registrant who inquired about its substance using the same identifier needs to contact the previous registrant(s), identified on the *Co-Registrants* Page to which access is granted after a successful inquiry.

As a first step, the potential registrant needs to agree with the previous registrant(s) that data already submitted are also relevant for the substance it specifically manufactures or imports. This agreement may result in the adaptation of the boundary composition reported in the jointly submitted dossier. More details are available in the *Guidance for identification and naming of substances under REACH and CLP*.

On this basis, the potential and previous registrant(s) must negotiate on the conditions to share the data that has already been submitted by the lead registrant on behalf of the other assenting registrants.

Potential registrants have an obligation to request from previous registrant(s), studies involving vertebrate animals, whereas they have the option to request the sharing of data not involving testing on vertebrate animals. In any case, if a study is requested, the previous registrant(s) is obliged to share it, whether or not the study involves testing on vertebrate animals.

The potential and the previous registrants (or their representative(s)) must make every effort to

- find an agreement on the sharing of the information requested by the potential registrant;
- ensure that the costs of sharing the information are determined in a fair, transparent and non-discriminatory way.

Some advice on how to conduct successful negotiations can be found under section 2.2.5 above. The mandatory elements to be included in a data sharing agreement can be found in section 2.2.3.1, and practical illustrations of the principle of transparency, fairness and non-discrimination in cost-sharing can be found under section 5.

The previous registrant who negotiates access to the data needs to provide clear justifications on the choice of studies to be used for each endpoint. It is to be stressed that potential registrants should be provided with transparent and clear information on data access options and their costs, as well as the conditions for joining the joint submission. This applies also in case the parties to an existing agreement agreed to waive the obligation to include itemisation and/or a reimbursement mechanism.

Costs that need to be considered in any cost sharing agreement may be of various nature, i.e. related to tests (study costs) and related to administrative work (either related to a particular information requirement or general administrative costs). Companies should be aware of the content of the information when they obtain the right to refer to it, and they should assess the quality and adequacy of the data.

As indicated in section 3.1.4.1 above, if some of the (robust) study summaries were submitted for the first time, in the framework of a REACH registration or of a notification made in accordance with Directive 67/548/EEC, more than 12 years previously, they will not be subject to compensation. Note thatadministrative costs related to the joint submission of information may need to be shared.

Where an agreement is reached (in accordance with Article 27(4) REACH), the previous registrant/data owner will make available to the potential registrant the agreed information. The data owner will also give the potential registrant permission to refer to the full study report.

It must be noted that if the potential registrant does not agree on the choice of information for certain endpoints (e.g. if it already has relevant studies), it may decide to opt-out for these particular endpoints, but it still must be part of the joint submission. For more details, see Guidance on Registration, section 4.3.3, *Conditions for opting out from the jointly submitted data*.

NB: Before sharing data on a substance, the potential registrant has an interest in discussing with the previous registrant(s) to confirm that the substance they each manufacture or import are sufficiently similar for data to be shared, in order to ensure that the existing studies are appropriate for their substance.

3.2.5. (Joint) submission of data

There are two distinct obligations stemming from the fact that two entities are registering the same substance. The first is the obligation to share data. The second is that registrants of the same substance are required to organise themselves in order to submit jointly information on the substance, according to Articles 11(1) and 19(1) REACH. Therefore, if registrants agree that they manufacture or/and import the same substance, they will have to register this substance jointly.

The overall aim of the joint submission obligation is the submission of one registration per substance (ideally also covering the intermediate use of the substance), in respect of the "one substance, one registration" principle. However, exceptions related to the joint submission of certain information explicitly set out in Articles 11(3) and 19(2) REACH may apply. While applying these exceptions, the registrants must remain part of the same joint submission, regardless of whether some or none of the required information is submitted jointly. All information submitted for a given substance, whether jointly or as a separate submission, forms a set of data describing the hazardous properties of and the risks associated with the substance.

Therefore, once the co-registrants have completed the steps above, they can submit their registration dossier, referring to all[33], or some, or none of the jointly submitted data in the lead registrant's dossier. For more details on the criteria for opting out, please consult the Guidance on Registration, section 4.3.3, *Conditions for opting out from the jointly submitted data*.

As described in section 2.2.3 above, contractual freedom applies to the way co-registrants organise themselves regarding the joint submission of data. However, ECHA recommends that the lead registrant communicates at regular intervals with existing/potential registrants, regarding the registration dossier containing the jointly submitted data, in particular in case of update of this data. The co-registrants can find most up-to-date contact details on the *Co-Registrants* Page in REACH-IT.

Due to the specificity of the situation (in terms of reduced information requirements) and for practical reasons, registrants of substances used only as intermediates, are technically allowed to form a parallel joint submission for intermediates only (see section 4.3.3, *Conditions for opting out from the jointly submitted data*, of the Guidance on registration).

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

3.2.6. Registration waiting period in accordance with Article 27(8)

Article 21 REACH 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, the 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) REACH).

In accordance with Article 27(8) REACH, a previous registrant can request to extend the registration waiting period (in accordance with Article 21(1)) by a period of four months for the new registrant. The request can be submitted to ECHA[34], when a previous registrant and a potential registrant have agreed on the sharing of information submitted less than 12 years previously.

The potential registrant will be informed accordingly by ECHA and, upon receipt of confirmation of its successful registration, will have to wait for an extra period of 4 months before being entitled to lawfully manufacture the substance in or import it into the EU market.

ECHA has no discretion with regard to the request of the previous registrant. It is for the potential registrant to consider whether the request of the previous registrant is applicable in the specific circumstances. Consequently, the potential registrant is expected to document its assessment appropriately.

3.3. Steps to submit a registration dossier when the substance has not been registered yet

If the substance has not been registered yet, the potential registrant may follow the indicative steps described in the present section. If there are several potential registrants, they should gather and follow together the same steps, in order to prepare the submission:

- Gathering of the available information
- Evaluation of the information available
- Consideration of information requirements
- Establishment of the data needs and identification of data gaps
- Sharing of the cost of the data
- (Joint) submission of data

3.3.1. Gathering of the available information

The potential registrant should first gather all existing available information on the substance it intends to register. Each registrant is individually responsible for making sure that the information it submits in the registration complies with the REACH

[34] The procedure is described in the Q&A no 426 available on the ECHA website at http://echa.europa.eu/support/qas-support/qas.

information requirements relevant to its substance.

NB: Data gathering must be thorough, reliable and well documented, as failure to collate all of the available information on a substance may lead to unnecessary testing with related resource implications or incompliances with information requirements. If the administrative cost related to this individual data gathering exercise has an impact on the cost of the study, this needs to be documented.

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

- Information detailing identity of the substance (analytical reports, applicable analytical techniques, standardised methods, etc.);
- 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.

The information to be gathered at this stage should also include that on the boundary compositions that it intends to cover with their registration (see section 3.2.1 and detailed in the *Guidance for identification and naming of substances under REACH and CLP*).

This data gathering exercise is to be done irrespective of the volume. Indeed, if the data requirements at registration depend upon the volume manufactured or imported by each registrant, registrants must register all relevant and available data for a specific endpoint.[35] All relevant and available information for the registration dossier must include both data available "in-house", as well as from other sources, such as data in the public domain[36] that can be identified through a literature search. The search, identification and documentation relating to "in house" information must remain an individual exercise. In addition, they also have to share on request data they have submitted that correspond to a higher tonnage threshold.

It should always be considered that, except for the cases enumerated in Article 10(a) last paragraph[37], the registrant must be in legitimate possession or have permission to refer to the full study report summarised in a (robust) study summary which is to be submitted for the purpose of registration. For more details on the nature of data

[35] Article 12(1) REACH and REACH Annex VI, Guidance Note, Step 1.
[36] To be understood as any information published in scientific literature or in electronic format (on internet). Conversely, the term "public domain" in copyright protection suggests that the information is not copyright-protected anymore and may be normally used for free (e.g. the term of the copyright protection has already expired, information in certain open public repositories etc.). However, it is always advisable to enquire on the actual status of the "public domain" and to check respective copyright clauses. Registrants should be cautious in respecting copyright and should not automatically copy published studies, even if the publication itself has been lawfully acquired or accessed, without first having ascertained that the information may be lawfully used for the registration purposes. In case of published studies, it is recommended to check conditions of their use for the registration purposes. See section 9 for further details.
[37] That is (i) if ECHA granted to the potential registrant permission to refer to data and (ii) if the data has been submitted more than 12 years ago and can be used for free for registration purposes.

and right to refer to the data, please consult sections 3.3.5 and 9 of this Guidance document.

If, following the inquiry, the potential registrant was informed that there are other potential registrants, it must contact them to obtain information on the data available to them. Collecting data available to potential registrants can be done in the form of a questionnaire structured according to Annexes VI to X of REACH. This questionnaire may also include a request to communicate the classification and labelling of the substance. In order to help participants review available data a form is proposed, as an example, in Annex 1.

As the above data are being collected, it should be entered into a common inventory. This would best be in the form of a matrix which compares the data available for each end point (up to the highest tonnage threshold among potential registrants) with the data needs (further information on the consideration of data needs can be found below in section 3.3.3), and identifies key elements for each study, including the identity of the data holder and the cost of the study. Where applicable, also administrative costs linked to the study or to a specific information requirement need to be itemised.

3.3.2. Evaluation of the information available

The next step is for the potential registrant to evaluate the data available on the substance to be registered, where relevant together with the other potential registrants. Essentially, for each endpoint, the following actions must be performed:

- Assess the relevance, reliability, adequacy and fitness for purpose of all gathered data (for more details please consult the *Guidance on information requirements and Chemical Safety Assessment* for arriving at conclusions on the hazard assessment and for risk characterization).
- Determine the key study for each endpoint: This is the study of greatest relevance taking into account the quality, completeness and representativeness of the study. This is a critical step, as these key studies are generally the basis for the assessment of the substance.
- Determine which information/study (or studies) needs a robust study summary (normally the key study) or a study summary (other studies). A (robust) study summary should reflect the objectives, methods, results and conclusions of a full study report. The information must be provided in sufficient detail to allow a technically qualified person to make an independent assessment of its reliability and completeness – without having to go back to the full study report (for more details, please consult the *Guidance on Information Requirements and Chemical Safety Assessment*, Chapter R.7).

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

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

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

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

The potential registrant has 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 information.

However, there might be cases where there is no key study but only supporting information of lower quality. In these situations an assessment should be done to see if all available information may justify a weight of evidence approach. In such situations the endpoint study summary, as well as the justification, should be well documented.

The same applies when alternative methods (e.g. (Q)SARs, read across, *in-vitro* methods) are used as relevant information for the final assessment and conclusion. Guidance on how to use alternative methods or a weight of evidence approach, on how to identify and measure environmental fate and physico-chemical properties, and make human health and environmental assessments is available in the *Guidance on the Information requirements and Chemical Safety Assessment*.

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

- A summary of the data available on a specific endpoint as well as a conclusion regarding the assessment of a specific endpoint for the substance (e.g. reprotoxicity, acute toxicity to fish, biodegradation);
- The classification and labelling of the substance (for human health, environment and physico-chemical properties) as well as a justification for this classification;
- PNECs and DNELs values as well as a justification of the reported values.

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

3.3.3. Consideration of information requirements

The next step is for the potential registrant to identify precisely what are the information requirements for the substance that it intends 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).

If, following the inquiry, the potential registrant was informed that there are other potential registrants, it should contact them so all potential registrants can identify their information requirements.

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

As described in more detail in the *Guidance on Registration*, Article 12 REACH 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 a literature search);
- as a minimum, fulfil the standard information requirements as laid down in Column 1 of REACH Annexes VII to X for substances produced or imported in a certain tonnage band, subject to adaptation possibilities, as described below.

The simplified list of information requirements is available here: http://echa.europa.eu/regulations/reach/registration/information-requirements.

In case the registrant makes use of a possibility to adapt the information requirement, it should indicate it clearly and justify each adaptation in the registration dossier. Indeed, for each of the REACH Annexes VII to X, Column 2 lists specific criteria (e.g. exposure or hazard characteristics), according to which the standard information requirements for individual endpoints may be adapted or omitted. In addition, registrants may adapt or omit the required standard information set according to the general rules contained in Annex XI of REACH 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)

Note that ECHA also provides a practical high-level overview of the REACH requirements for registrants of substances manufactured or imported at tonnages of 1-100 tonnes per year. This "Practical guide for SME managers and REACH coordinators" is available on the ECHA website at: https://www.echa.europa.eu/practical-guides.

NB: The information requirements have been revised[38] and may change again. If there is no longer a need to provide certain information, the potential registrants do not need to provide or negotiate access for this information (even if the data has already been generated and submitted by the existing registrants).

For substances identified in Article 3(20) REACH (eg. EINECS substances), manufactured or imported between 1 and 10 tonnes per year, the full information requirements are only applicable if one or both of the criteria laid down in Annex III of REACH are met[39]. In order to support the registrants, ECHA has generated an inventory of substances for which there is evidence that they would possibly fulfil these criteria (i.e. for those substances submitting only physicochemical information will not be sufficient) and support material outlining an effective step by step procedure for companies to consider REACH Annex III in the context of their registration[40].

When the Annex III criteria are not met, only the physicochemical information requirements in Annex VII need to be fulfilled for phase-in substances below 10 tonnes per year.

For substances manufactured or imported in quantities of 10 tonnes (or more) per year per registrant, certain information must also be documented in the chemical safety report (CSR). At least all the information required under Article 10(a) REACH for the technical dossier and under Article 10(b) REACH for the chemical safety report (CSR) needs to be documented in the specified reporting formats (Annex I of the REACH Regulation).

The information requirements for certain types of intermediates manufactured and used under strictly controlled conditions are reduced and there is no requirement to carry out a chemical safety assessment for them. If the substance is an intermediate

[38] See for example, skin corrosion/irritation, serious eye damage/eye irritation and acute toxicity.
[39] See Article 12(1)(b) of REACH and Article 2 of Implementing Regulation 2019/1692.
[40] For more information please visit the Annex III dedicated webpage in the ECHA website at http://echa.europa.eu/support/registration/reduced-information-requirements.

manufactured and used under strictly controlled conditions, the potential registrant needs to provide any information which is available to it for free. Thus, the potential registrant does not need to purchase a letter of access in order to submit more information on the substance than what was already available to it. The only exception to that rule concerns the registration of a transported isolated intermediate in quantities of more than 1000 tonnes per year, where requirements of Annex VII apply and thus potential registrants will need to share data and its costs with the existing registrants.

Further information on substances used as intermediates and their possibly reduced information is available in section 2.2.5, *Obligations related to registration of intermediates*, of the Guidance on registration and in the Practical Guide "How to assess whether a substance is used as an intermediate under strictly controlled conditions and how to report the information for the intermediate registration in IUCLID", available at https://www.echa.europa.eu/documents/10162/23036412/pg16_intermediate_registration_en.pdf.

NB: This step requires the potential registrant to identify precisely what its information requirements are, considering in particular the tonnage band that is relevant to it. In considering its information needs, a potential registrant may consider the possible application of data waivers, for instance on the basis of uses/exposure pattern.

3.3.4. Establishment of the data needs and identification of data gaps

Based on the evaluation of the information available and the identification of its information requirements, the potential registrant (together with the other potential registrants, where relevant) may verify whether it already has the relevant studies or whether further data are needed.

The data owned by a potential registrant that is used in its registration will be subject to the data sharing obligation upon request by a potential registrant, whether it involves testing on vertebrate animals or not.

The following items can also be negotiated (although registrants are not obliged to share any of these):

- Chemical safety report ('CSR'): For registrations above 10 tonnes a year, registrants need to submit a CSR, which can be the same as the existing registrants' one, or the potential registrant's own. When preparing an own CSR, a potential registrant should not be requested to pay any costs related to the preparation of the existing registrant's CSR.
- Guidance on safe use of the substance: For registrations between 1–10 tonnes a year, as the CSR is not needed, more information in the guidance on safe use section of the registration dossier must be submitted [41].

At this stage, the potential registrant is in a position to compare the information requirements and information available to it. On this basis, it can identify whether there are information gaps and consider how missing information can be generated.

If the available information is sufficient and the standard information requirements are met, no further gathering of information is necessary. Where relevant, justification for

[41] See section 6 of Annex VI of REACH.

adapting the relevant test(s) must be provided in accordance with the criteria under Annex XI.

In case the available information is considered insufficient (including the information available to other potential registrants, where relevant), the potential registrant can verify whether entities that are not (potential) registrants of the substance own relevant data, in particular registrants of other substances. See the introduction of section 2.1 for a list of such possible entities and sections 2.2.2.2 and 2.3 on the sharing of data with such entities. It is advisable that, when sharing data in this context, it is ensured that access rights are obtained for any co-registrants who would need this information for their registration purposes.

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

Data gaps may be different for each of the relevant tonnage bands. In principle, there is no need to make data gaps analysis for registrations of intermediates, except for a registration of a transported isolated intermediate in quantities of more than 1000 tonnes per year.

In case a data gap remains, the steps to take are described below in section 3.4.

3.3.5. Sharing of the cost of the data

Once a potential registrant has completed the steps above, and knows whether there are other potential registrants per tonnage band and what the available data are, it can organise the actual sharing of this data.

If there are other potential registrants, they should communicate the costs involved, including any technical and administrative costs. In this case, a data sharing agreement should be drafted, along with any relevant contractual arrangements the co-registrants decide to enter into. Some advice on how to conduct successful negotiations can be found under section 2.2.5 above.

When agreeing on a cost sharing mechanism, co-registrants need to make every effort to reach a fair, transparent and non-discriminatory agreement. Registrants are required to share only costs related to information they need for REACH registration purposes. This applies also to non-study costs. The mandatory elements to be included in a data sharing agreement can be found in section 2.2.3.1, and practical illustrations of the principle of transparency, fairness and non-discrimination in cost-sharing can be found under section 5. Section 6, below, details possible forms of cooperation. The cost sharing methodology should be freely accessible to every co-registrant and to new potential registrants. Additional clarification on the costs should be provided upon request.

If there are no other potential registrants, the potential registrant is still expected to prepare in case of future potential registrants. Therefore, it must make sure to transparently record the relevant cost in case of future data sharing.

3.3.6. (Joint) submission of data

There are two distinct obligations stemming from the fact that two entities are registering the same substance. The first is the obligation to share data. The second is that registrants of the same substance are required to organise themselves in order to submit jointly information on the substance, according to Articles 11(1) and 19(1)

REACH. Therefore, if potential registrants agree that they manufacture or/and import the same substance, they will have to register this substance jointly.

The overall aim of the joint submission obligation is the submission of one registration per substance (ideally also covering the intermediate use of the substance), in respect of the principle "one substance, one registration". However, exceptions related to the joint submission of certain information explicitly set out in Articles 11(3) and 19(2) REACH may apply. While applying these exceptions, the registrants must remain part of the same joint submission, regardless of whether some or none of the required information is submitted jointly. All information submitted for a given substance, whether jointly or as a separate submission, forms a set of data describing the hazardous properties of and the risks associated with the substance.

If there is only one potential registrant, it may either submit an 'individual' dossier or submit a dossier as a lead registrant. In case there are no other potential registrants and the potential registrant has proceeded to register individually, it will need to update its registration dossier when another potential registrant decides to register the same substance. In such case, both parties will first need to identify a lead registrant who will create the joint submission object, and then agree on the content of the joint submission dossier. Subsequently, the existing registrant will have to update its dossier to be part of the joint submission, either as a lead registrant or as member. In any case, it may still opt-out, under the criteria of Articles 11(3) and 19(2) REACH.

When there are several potential registrants, they should designate among themselves a lead registrant acting on behalf of the other assenting registrants (Article 11(1) REACH, the lead registrant will also create the joint submission in REACH-IT). The lead registrant will then, in principle, submit the dossier on behalf of all co-registrants. The other potential registrants can then submit their registration dossier, referring to all[42], or some, or none of the jointly submitted data in the lead registrant's dossier.

For more details on the criteria for opting out, please consult the Guidance on Registration, section 4.3.3, *Conditions for opting out from the jointly submitted data*.

As described in section 2.2.3 above, contractual freedom applies to the way co-registrants organise themselves regarding the joint submission of data. However, ECHA recommends that the lead registrant communicates at regular intervals with existing/potential registrants, regarding the registration dossier containing the jointly submitted data, in particular in case of update of this data. The co-registrants can find most up-to-date contact details on the *Co-Registrants* Page in REACH-IT.

Registrants of substances used only as intermediates are technically allowed to form a parallel joint submission for intermediates only (see section 4.3.3, *Conditions for opting out from the jointly submitted data*, of the Guidance on Registration).

3.4. In case of identified data gaps

In case data gaps are identified, information on intrinsic properties of substances may be generated by using alternative sources for information other than *in vivo* testing, provided that the conditions set out in Annex XI are met. The registrant may use a variety of methods such as (Q)SARs, *in vitro* tests, weight of evidence approaches, grouping approaches (including read-across[43]). The registrants will have to be able to

[42] As described in Articles 3(3) and 4(3) of the REACH Fee Regulation (EC) No 340/2008, a specific reduced registration fee will be levied by ECHA in case of joint submission of the registration dossier.
[43] Further guidelines are also provided under the Read-across Assessment Framework (RAAF) available at http://echa.europa.eu/support/grouping-of-substances-and-read-across

demonstrate to ECHA (via a dedicated form to be filled in IUCLID for each testing proposal involving vertebrate animal testing) that they have considered non-animal testing methods first, as generating actual tests on animals is to be considered as a last resort.

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

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

b. in case a study as listed in Annexes IX and X (whether or not involving vertebrate animals) is needed for registration, and is not available, the potential registrants must first consider all alternative approaches to fulfil the information requirement. Only if an information requirement cannot be fulfilled using non-testing methods, do the registrants need to agree on and **prepare a testing proposal** to be jointly submitted in the lead's registration dossier for ECHA's consideration. Additionally potential registrants have to implement and/or recommend to downstream users interim risk management measures while awaiting the outcome of ECHA's decision (as per Article 40 REACH) regarding the testing proposal. The procedure to be followed is described in Article 40(3)(e) REACH. For more details, please consult section 4.2.1.

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

4. DATA SHARING AMONG EXISTING REGISTRANTS

Data sharing obligations continue to apply after the registration has been submitted. Co-registrants may need to share data and their costs after that point. As such, any cost sharing model needs to take into account the fact that cost sharing and cost allocation are continuous and dynamic processes, not static ones.

It is important to note that the registrants' data sharing obligations do not stop once the registrants' registration dossier has been submitted. Registrants have further duties which may entail the need to share data and to continue to make every effort to reach an agreement.

Moreover, according to Implementing Regulation 2016/9, registrants are obliged to keep documentation related to data and cost sharing for a period of 12 years following the latest submission of the study (see section 3.1.4.1 on the "12-year rule"). This activity may generate also administrative costs, which may need to be considered. Therefore, the registrants may consider the need to extend their contractual relationship.

Several elements may trigger variations of the model over time and the need to take corrective actions.

One of them is **a variable number of co-registrants**: the number of registrants potentially joining the joint submission is not known in advance. New potential registrants may join an existing joint submission at any time during the "lifetime" of the joint submission, where cost sharing arrangements have already been agreed. For more on the rights of new potential registrants, please refer to section 2.2.3.1.

Any registrant who submitted data separately is subject to the data sharing obligation. Therefore, it might be required to engage in data sharing negotiations with new or existing registrants for the data that it itself submitted.

In addition, **new data may become available** after the data have been jointly submitted, in particular when new registrants bring their own existing information. The existing registrants may agree to include the new information into the jointly submitted dossier to e.g. improve its quality and will thus in principle need to adapt the cost sharing calculation to accommodate this factor. Alternatively, the new registrant may submit an opt-out for the given endpoint, under Articles 11(3) or 19(2) REACH. However, they still need to join the joint submission as a member.

Moreover, there may be **additional registration requirements**: some additional testing and related expenses may be needed which would have an impact on any existing arrangements. The new information might appear as a result of an update of tonnage band of a registrant (section 4.1), of a dossier or substance evaluation (section 4.2) or in any other cases where it is identified that new information must be submitted (section 4.3).

NB: Co-registrants are advised to check carefully the data/cost sharing agreements bearing in mind the elements above (which may trigger variation in the costs) and the iterative nature of the process. The price of the dossier, reflected for example in the Letter of Access, does not reflect only the costs of the total individual studies.

4.1. Data sharing in case of tonnage upgrade

4.1.1. Inquiry step

Existing registrants are also obliged to make an inquiry in case of a tonnage band increase where they require additional information to fulfil their registration requirements. An existing registrant, who registered an intermediate under Article 17(2) or 18(2) REACH, can also submit an inquiry in order to obtain the information necessary to submit its dossier complying with the information requirements of Article 10 REACH.

Pursuant to Article 12(2) REACH, as soon as the quantity of a registered substance reaches the next tonnage threshold, the registrant must immediately inform ECHA of the additional information needed. This step follows the inquiry procedure of Article 26 REACH and it is a necessary formal step for the registrant to start data sharing negotiations with the existing registrant at higher tonnage band. The manufacture or import can continue during the inquiry process and data sharing.

The registrant intending to update tonnage band must identify precisely what are the information requirements for the substance in the relevant tonnage band, the physical parameters of the substance (relevant for technical waiving of tests) and uses/exposure patterns (relevant for exposure based waiving).

Please note that, according to Article 24(2) REACH, a company who submitted a notification (NONS) under Directive 67/548/EEC will need to submit a REACH compliant dossier (according to Articles 10 and 12 REACH) if the quantity of the notified substance reaches the next tonnage threshold.

As outcome of the inquiry, in case relevant data are available, ECHA will provide information on the (robust) study summaries together with the contact details of the previous and potential registrants. It will be indicated whether the data was submitted more than 12 years ago or not and thus whether it is subject to compensation.

On this basis, the inquirer can request from the previous registrants the studies required for the update.

If no data are available, the same principles as described in section 3.4 apply.

4.1.2. Data sharing negotiations

After the inquiry, where applicable, the registrant upgrading its tonnage band must start negotiations on access to the pertinent data on the substance with the relevant registrant(s). The same principles apply as for the sharing of data to submit a registration dossier, see section 3.2.4.

Some advice on how to conduct successful negotiations can be found under section 2.2.5 above. The mandatory elements to be included in a data sharing agreement can be found in section 2.2.3.1, and practical illustrations of the principle of transparency, fairness and non-discrimination in cost-sharing can be found under section 5.

In the case where future data needs have been included in the data sharing agreement, the parties should refer to the agreement. If needed, the parties can refer the issue to the relevant national court.

4.2. Data sharing as a result of a regulatory decision

The evaluation of a registration dossier by ECHA (compliance check or the assessment of a testing proposal) or of a substance by a Member State competent authority may

lead to a request to submit further information, which is not always strictly linked to the information requirements of the individual registrant.

When a regulatory decision requests further information, the registrants concerned by the decision must make every effort to reach an agreement on who will perform the requested test, pursuant to Article 53(1) REACH. ECHA must be informed on who will perform the test within 90 days from the decision. If ECHA is not informed in that period, it will designate one of the registrants to perform the test on behalf of all.

According to Implementing Regulation 2016/9 (Article 4(2)) co-registrants shall consider in their cost-sharing model a mechanism for sharing the costs resulting from a substance evaluation. Pursuant to that Regulation, they are also required to consider the possibility to cover costs of future additional information requirements for that substance other than those resulting from a potential substance evaluation decision (e.g. potential dossier evaluation decision). Such costs shall be justified and indicated separately from other costs in the data sharing agreement. See section 2.2.3.1 above.

Article 53(2) REACH provides that the principle for the sharing of these costs is based on an equal share.

Article 53(3) REACH provides that the registrant who performs the test shall provide each of the other registrants concerned with a copy of the full study report, and it shall have a claim against them accordingly (Article 53(4)).

All the registrants that are addressees of a dossier evaluation decision (testing proposal and compliance check) or substance evaluation decision are therefore bound to submit the study requested in that decision. In principle, the required information must be submitted jointly by the lead registrant so that all the registrants benefit from this submission without further action. However, if a registrant refuses to share the cost of the required study, all the other registrants may decide to submit this study individually (opt out), so that the defaulting registrant would not benefit from a study jointly submitted. In such case, all the registrants having submitted the required study individually would comply with the decision, while the defaulting registrant would not and may therefore be subject to enforcement action.

4.2.1. Dossier evaluation: testing proposals and compliance check

The dossier evaluation decisions pursuant to Article 51 REACH are addressed to all the registrants concerned by the information requirement(s) at issue. New registrants will have to negotiate access to the data used by existing registrants to fulfil the information requirement(s) after a compliance check decision.

In the context of testing proposals applying a read-across approach, registrants may propose a test on the same substance to fulfil the information requirements of different substances. If the read-across approach is justified, ECHA may decide to request a test on the same substance from the registrants of the different substances.

New studies to be generated as a result of an ECHA decision on a testing proposal or the compliance check of the dossier fall under the rules of Article 53 REACH described in introduction of section 4.2.

If the studies requested are already available, have been submitted to ECHA and considered compliant, ECHA would require registrants, as a result of a dossier evaluation decision, to share the said studies pursuant to the data sharing provisions in Title III, in order to avoid the duplication of animal testing.

4.2.2. Substance evaluation

The substance evaluation decisions pursuant to Article 52 REACH are addressed to all registrants concerned. Registrants who ceased manufacture[44] may still be required to share the costs resulting from a substance evaluation decision (Article 50(4) REACH and Article 4(6) of Implementing Regulation 2016/9).

New studies to be generated as a result of an ECHA decision on a substance evaluation fall under the rules of Article 53 REACH described in introduction of section 4.2.

Under Article 4(2) of Implementing Regulation 2016/9, registrants have to agree on a cost sharing mechanism that addresses potential costs following a substance evaluation decision. The proportion of their contribution should be agreed in the data sharing agreement. Registrants may contribute at different levels to the concern identified in the decision on substance evaluation (level of exposure, certain uses, etc). In these cases, the respective contributions can for instance be set in relation to the proportion that each registrant contributes to the concern identified .

When the data sharing agreement is drafted, the exact amount of the actual costs that needs to be shared among the registrants is normally not known. Therefore, parties should agree on a general and abstract cost sharing mechanism or a formula that allows them to deal with the sharing of costs regardless of their amount. This cost-sharing mechanism should in principle apply to any new registrants of the substance.

If there was a past substance evaluation decision on the substance for which a potential registrant was not an addressee, the potential registrant can be requested to share these costs when submitting its new registration dossier, in line with the principles above.

4.3. Data sharing in case of new information/new data gaps

Article 22 REACH establishes a series of obligations to ensure that the information on substances is kept up-to-date, so that chemicals can be used safely.

As a result, registrants must update their registration dossier as soon as new relevant information becomes available.[45] This may have an impact on:

- the classification of the substance;
- the CSR or the safety data sheet, if new knowledge of the risks of the substance to human health and/or the environment becomes available.

These situations may entail the need for further sharing of data. Co-registrants should update their registrations whenever new information becomes available. By following the reports and the recommendations of ECHA, co-registrants can learn what the most common shortcomings are and avoid having the same problems in their own registrations. For example, they should check whether a harmonised classification and labelling has become available for their substance. New information may also come

[44] Pursuant to Article 50(2) and Article 50(3) REACH.

[45] See Commission Implementing Regulation (EU) 2020/1435 of 9 October 2020 on the duties placed on registrants to update their registrations under Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), OJ L 331, 12.10.2020, p. 24–29. For further details, see section 7 of the Guidance on Registration.

from the supply chain or when new members join the joint submission.

In addition, new information may need to be generated following a change in REACH itself (e.g. new requirements).

5. COST SHARING IN PRACTICE

Section 2.2.3.1 above describes the elements that must be included in a data sharing agreement and section 2.2.5 above contains advice to conduct successful negotiations. The present section aims to provide further details on how the sharing of cost can happen in practice.

Section 5.1 contains more practical illustrations of the implementation of the principles of transparency, fairness and non-discrimination.

Further, agreeing on cost sharing requires parties to agree on:

- the reliability, relevance and adequacy of the data (section 5.2, data quality)
- the economic value of the data (section 5.3, data valuation), and
- how the agreed value is shared among parties (section 5.4, cost allocation and compensation)

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

5.1. Illustrations of the principles of transparency, fairness and non-discrimination

Cost sharing aims at sharing the actual expenses and costs related to the registration of a substance under REACH. It is not designed to generate profits for any party.

When agreeing on a cost sharing mechanism, registrants must make every effort to reach a fair, transparent and non-discriminatory agreement. Implementing Regulation 2016/9 facilitates the implementation of these basic principles and clarifies further the REACH provisions on data and cost sharing (as well as the joint submission obligation). The provisions of Implementing Regulation 2016/9 apply both when new registrants join a data sharing agreement that has already been concluded, as well as when co-registrants are setting up a new data sharing agreement.

As examples, sharing of data could be considered as:

- *not fair*, if a previous registrant requests a potential registrant to pay 100% of the costs of a study, while there are several other registrants referring to that study;
- *not transparent*, if the previous registrant requests the payment of a generic fee for the jointly submitted data, without providing detailed information on the costs of the individual studies;
- *discriminatory*, if the cost sharing model is applied differently for comparable potential registrants (e.g. early-birds incentives).

Transparency

Costs which need to be considered in any cost sharing agreement may be of various nature, i.e. related to tests/fulfilling an information requirement (study costs) and related to administrative work (either related to a particular information requirement or general administrative costs).

All costs need to be itemised: information, accessible to all co-registrants, should include a breakdown of each individual cost item. This relates to both study and

administrative costs:

- Costs related to data: any costs required to perform a study, acquire access (co-ownership, possession or right to refer) to data owned by third parties, contract laboratories, monitoring performances or fulfil an information requirement with an alternative method. Such costs need to be clearly related to the respective information requirement (Article 2(1)(a) of Implementing Regulation 2016/9);
- Costs related to administrative work: any cost of managing the data sharing agreement, as well as the joint submission (Article 2(1)(b) of Implementing Regulation 2016/9).

With regard to the administrative costs, it is important for the parties involved to consider all activities that may need to be carried out in the general context of data sharing and cost-sharing/ allocation, as well as the preparation of the joint submission of information for the substance. These activities may include communication activities, the possible use of a trustee, administrative work related to the joint creation of the chemical safety report, etc. Administrative costs should, as much as possible, be itemised on the basis of the data costs. When they are not data specific, and related for example to the general joint submission costs, this must also be clearly justified, and the costs itemised accordingly

NB: Implementing Regulation 2016/9 allows for the obligation to itemise the data to be waived by unanimous consent where the data sharing agreement existed already before the entry into force of that Regulation.

The following is a generic example of what Implementing Regulation 2016/9 requires in terms of itemisation:

Cost item ***(itemisation of all the costs)***	**Tonnage band** ***(tonnage band for which the cost item is relevant)***	**Study cost** ***(if applicable)***	**Administrative costs** ***(related or not to a specific information requirement)***	**Justification** ***(for each cost item)***
Study 1	1-10 t/y	€1000	€70	Justification 1
Study 2	1-10 t/y	€2000	€60	Justification 2
Study 3	1-100 t/y	€3000	€130	Justification 3
Token	n/a	n/a	€150	Justification 4
Communication related to the joint submission of data	1-10 t/y	n/a	€1000	Justification 5
Etc.	…	…	…	…

The cost sharing methodology should be freely accessible to all co-registrants and to new potential registrants. Additional clarification on the costs should be provided upon request.

Registration activities of any nature generating costs need to be documented yearly, must be kept for a minimum of 12 years following the latest submission of a study and must be accessible without delay and free of charge to both existing and potential registrants (Article 2(3) of Implementing Regulation 2016/9). Thus, costs need to be proven and justified. In the absence of such detailed documentation in the context of data sharing agreements concluded before the entry into force of Implementing Regulation 2016/9, it is required that the parties make every effort to collate proof of such past costs, or to make the best approximation of such costs.

The type and details of the itemisation exercise (in particular the level of itemisation) will possibly differ from case to case. They may depend, *inter alia*, on the form of cooperation chosen and its structure (e.g. whether it evolved from an existing form of cooperation or it was set up specifically for REACH purposes) and whether the tasks have been allocated to single substances or group(s) of substances (hence deriving a fully substance-specific cost itemisation could be difficult).

The distinction between study and administrative costs, and the possible relevance of the latter for a specific information requirement, may vary from one joint submission to another. Costs should be transparently recorded and their sources clear to the co-registrants. A non-exhaustive list of possible cost items which could be considered on a case-by-case basis is provided in Annex 3.

The cost-sharing model shall also address possible future costs, namely those following a potential substance evaluation decision, but may also cover other potential future costs resulting from future additional requirements for the registered substance e.g. as a result of a compliance check decision (see Article 4(2) of Implementing Regulation 2016/9 and sections 4.2 and 4.3 of this Guidance). It must be kept in mind that possible further administrative activities triggered by future additional requirements resulting from the evaluation of the dossier also may generate costs.

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

Fairness and non-discrimination

As required under REACH and reaffirmed by Implementing Regulation 2016/9, registrants only need to pay for data they need to fulfil their information requirements. This means that registrants need to share the costs of data that relates to their information requirements, considering the tonnage band they intend to register and type of registration (full or intermediate). This applies to both study and administrative costs.[46]

As with costs related to information requirements, administrative costs shall only be shared where those costs are relevant to the information a registrant is obliged to submit for their registration. Administrative costs that cannot be linked to any specific endpoint should, nevertheless, be shared in a fair way, i.e. proportionally to the information a registrant is required to submit for its registration. As an example, meetings organised to discuss testing proposals relevant for the higher tonnage bands only may have generated costs which should not be borne by registrants in the lower tonnage band or using the substance as an intermediate under Article 17 and 18

[46] Article 27(3) REACH and Article 4(1) of Implementing Regulation 2016/9.

REACH.

Compiling information for the purposes of establishing substance sameness should not be the subject of any cost sharing between previous registrants and potential registrants.[47]

As data submitted for REACH registration purposes are only protected for 12 years after their submission, potential registrants can refer in their registration to data submitted more than 12 years before without having to share the costs associated with those data.

Under specific conditions registrants are allowed to opt-out from certain or all information submitted jointly by the other registrants of the same substance. The opting-out registrant is thus not obliged to share with the other co-registrants the costs of the information from which it opted-out. The opting-out options and related obligations are addressed in detail in the Guidance on Registration, section 4.3.3, *Conditions for opting out from the jointly submitted data*.

The cost calculation model shall include (unless waived by unanimous agreement per Article 4(5) of Implementing Regulation 2016/9) a reimbursement mechanism based on the principle of proportionate redistribution to each participant in the data sharing agreement of their share of the costs where a potential registrant joins that agreement in the future (Articles 2(1)(c) and 4(4) of Implementing Regulation 2016/9). The reimbursement mechanism shall apply equally to existing and future registrants.

It is advisable to agree in advance on the frequency with which costs and possible reimbursements are re-calculated. These will ultimately be a balance between increase in the number of co-registrants and new costs. According to the case possible options could be: annual frequency (keeping in mind that the exercise itself may generate costs), upon expiry of a registration deadline or upon expiry of the 12-year-deadline after submission.

It is important to bear in mind that not all cost factors may be known in detail at the moment the cost calculation model is agreed upon. Therefore, to be able to accommodate such unknown variables, the reimbursement scheme as well as the provisions on future costs might well be limited to a cost calculation mechanism, i.e., a formula as well as deadlines, events or sums triggering their application; it is thus not about agreeing on the distribution of concrete sums upfront before their occurrence.

Joining registrants have the right to request from the existing registrants to revise the cost sharing model and cost allocation, if they have ground to challenge the existing data sharing agreement, i.e. they consider that existing provisions do not comply with the principles of fairness, transparency or non-discrimination. For example, existing registrants may not have taken into consideration aspects relevant for future registrants; what was fair, transparent and non-discriminatory for previous registrants may not necessarily be accurate for new registrants.

Example: Previous registrants agreed on sharing administrative costs equally regardless of tonnage band, while Implementing Regulation 2016/9 requires that administrative costs are shared in relation to information requirements. The potential registrant may challenge this and the previous registrants will need to demonstrate how this model is in line with the principle of fairness. If they cannot justify it, they

[47] Article 4(2) of Implementing Regulation 2016/9.

may need to adapt the cost sharing model.

Additionally, new registrants should not be asked to pay any surcharge or annual increase for not having registered together with the 2010, 2013 or 2018 registrants[48], unless there are legitimate and justifiable reasons for charging additional amounts to later registrants and these have been transparently presented during the data sharing negotiations.

Example: Previous registrants agreed on annual increases[49] of prices for LoA. Potential registrants, who are penalised by it, may challenge this provision[50]. The previous registrants will have to justify such increase. If it cannot be justified in line with the principle of non-discrimination, the previous registrants may need to adapt the cost sharing model.

NB: In case of companies with various affiliates which are separate legal entities, each of them must fulfil its registration obligations separately. Accordingly, each separate legal entity should fulfil its data and cost sharing obligations.

5.2. Data quality

A prerequisite for the valuation of existing studies is to establish their scientific quality. When assessing the reliability, relevance and adequacy of a study, registrants must pay close attention to ensuring that the testing material is properly defined, in particular in case of nanoforms.

5.2.1. Reliability – Relevance – Adequacy

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

- Reliability: relates to the inherent quality of a test report or publication relating to preferably standardized methodology and the way the experimental procedure and results are described to give evidence of the clarity and plausibility of the findings;
- Relevance: is the extent to which data and tests are appropriate for a particular hazard identification or risk characterisation[51];
- Adequacy: defines the usefulness of data for hazard/risk assessment purposes.

When there is more than one study for an endpoint, the greatest weight is normally

[48] See ECHA decision of 12/07/2013 http://echa.europa.eu/documents/10162/21728418/reach_dsd_decision_12-07-2013_en.pdf and Board of Appeal decision of 17/12/2014 (A-017-2013) http://echa.europa.eu/documents/10162/13575/a-017-2013_boa_decision_en.pdf.
[49] Other than inflation (see sections 5.3.2 and 5.3.3).
[50] Decision of the Board of Appeal of ECHA of 17 December 2014 in case A-017-2013, Vanadium, paragraph 46, 56.
[51] In particular, the relevance of the composition of the test material used to generate data in terms of the compositional profile(s) of the substance for which the test data is intended to refer to would need to be considered.

attached to the study that is the most reliable and relevant. This study is generally referred to as the key study. Determining reliability essentially relates to how the study was carried out. Careful consideration must be made of the quality of the study, the method, the reporting of the results, the conclusions drawn and the results themselves in order to be able to generate a (robust) study summary.

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

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

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

5.2.2. Data quality assessment approaches

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

1. The first approach was developed by Klimisch et al. (1997). It uses a scoring system for reliability, particularly for ecotoxicological and health studies. However, it may be extended to physicochemical and environmental fate and pathway studies.
2. The second approach was developed in 1998 as part of the US EPA HPV Challenge Program.
3. Other systems may also be considered, especially if the two approaches seem not be suitable for validation of new techniques of obtaining information.

5.2.2.1. Klimisch scoring system

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

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

2 = reliable with restrictions: "studies or data... (mostly not performed according to GLP), in which the test parameters documented do not totally comply with the specific testing guideline, but are sufficient to accept the data or in which investigations

are described which cannot be subsumed under a testing guideline, but which are nevertheless well documented and scientifically acceptable."

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

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

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

The software-based tool "ToxRTool" (**Tox**icological data **R**eliability Assessment **Tool**), developed within the context of a project funded by the European Centre for the Validation of Alternative Methods (ECVAM), provides comprehensive criteria and guidance for evaluations of the inherent quality of toxicological data, thus making the decision process of assigning reliability categories more transparent and more harmonised. It is applicable to various types of experimental data, endpoints and studies (study reports, peer-reviewed publications) and leads to the assignment to Klimisch categories 1, 2 or 3. More information on the tool is available at https://eurl-ecvam.jrc.ec.europa.eu/about-ecvam/archive-publications/toxrtool.

5.2.2.2. US EPA scoring system

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

Table 1: Data reliability: initial screening criteria by type of information

Data reliability: initial screening criteria by type of information			
Criteria	Required for the following Information Items		
	P/Chem	Env Fate	Ecotox / Human Health

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

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

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

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

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

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

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

Steps to follow

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

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

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

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

5.3. Data valuation

An accurate and transparent valuation of studies is a critical component in the data sharing process. After having assessed the existing studies in terms of their scientific quality (see section above 5.2), a financial value can be determined. Where appropriate, this financial value takes account of correcting factors, which will lead to an increase or reduction of the values assigned.

This section applies mainly to existing studies. It can be assumed that studies generated for REACH purposes as a result of data gap analysis are to be commissioned in a way that the quality of that studies satisfies the requirements of REACH. It can also be assumed that only one study of relevant quality (key study) is generated.

The principles related to data valuation are illustrated in section 5.5 through two examples (see Examples 1 and 2).

5.3.1. What studies should be valued?

From a quality perspective and taking the Klimisch scores as a model, it is recommended that only studies with a reliability rating of 1 or 2, and used on their own, qualify for financial compensation. Study reports with scores 3 and 4 can therefore be deselected from the valuation procedures, as they would not fulfil the REACH legal requirements. Therefore there is little basis for their compensation in comparison with higher quality studies.

However, the information contained in such reports should be considered when the registrants wish to use them as part of a weight of evidence approach (according to Annex XI of REACH, section 1.2). In that case Klimisch 3 reports could satisfy an endpoint as they would be one supporting element of the weight of evidence approach which would rely also on other independent information. Consequently, if the totality of the existing information is sufficient to fulfil the relevant endpoint, these studies could be collectively assessed for valuation purposes in the same manner as in the

case of one single higher-quality study.

5.3.2. Historic versus replacement costs

The owner of a study should provide proof of its cost upon request from the co-registrant(s).

The potential registrant(s) may agree on valuation methods, such as:

- Historical costs: the actual costs to perform the test usually proven with an invoice from the laboratory.
- Replacement costs: estimated costs for performing a study that can be used, for example, when there are no invoices for a study, when a study has been performed in-house or when the scope of an existing study goes beyond the regulatory requirements. In such case, an agreement may be reached on an estimated replacement value. Among others, the following factors may be taken into account in that estimation:
  - The cost of performing the same test;
  - The cost of performing the same type and quality of study;
  - The average of three independent quotations could be used, or a third party could be considered to conduct the assessment of the replacement costs.

  In this respect, the Fleischer list[52] can provide a useful benchmark in the context of data sharing negotiations. It gathers price and capacity information by a survey of twenty-eight independent and corporate laboratories. The survey intended to establish the minimum, average and maximum estimates of costs/prices and the available average and maximum testing capacities.

Implementing Regulation 2016/9 requires an annual documentation of all costs. In the absence of detailed documentation of costs incurred before the entry into force of this obligation, where it is not possible to collate proof of such past costs, the co-registrants shall make every effort to best approximate such costs and may thus agree on alternative valuation methods, such as the replacement cost.

NB: It is the responsibility of the co-registrants to agree on the cost sharing model which is the most appropriate for their specific situation (historical costs, replacement costs or any other). This model must be fair, transparent and non-discriminatory, and comply with the criteria laid out both in REACH and in Implementing Regulation 2016/9.

5.3.3. Correcting factors

Regardless of the valuation methods chosen, parties may want to account for correcting factors that may justify either an increase or a decrease of the value of a study for cost sharing purposes.

The factors that may be taken into account can either increase of decrease the study value.

[52] Manfred Fleischer, 'Testing Costs and Testing Capacity According to the REACH Requirements – Results of a Survey of Independent and Corporate GLP Laboratories in the EU and Switzerland' (2007) 4/3 Journal of Business Chemistry 96–114.

NB: The valuation of costs, including the application of correcting factors, must rely on expenses supported by verifiable documentation or, if such documentation is not available, on expenses that can be appropriately justified. These elements are critical for previous registrants to comply with their obligation of providing "fair, transparent and non-discriminatory" costs. Previous registrants have the obligation to answer any request for clarification on costs which may not be sufficiently transparent to the co-registrants and any potential registrant.

5.3.3.1. Factors increasing the study value

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

- Baseline costs (i.e. expenses for preliminary testing and substance testing according to a standard protocol) may be calculated as an average of the prices charged by two or three agreed testing laboratories according to their price lists. Standard pricing should be assumed and special conditions, such as those granted when commissioning large testing programmes, are not taken into account;
- Development of suitable analytical methods;
- Inflation: when historical costs are used, parties may wish to account for inflation and other relevant elements some of which are not required if replacement costs are used;
- Supplementary analyses (e.g. substance characterisation; stability in test medium; concentration in test medium);
- Alternative analyses: 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[53] 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 and travel expenses related to the performance of this study: in addition to the cost of the experimental work (substance testing and analysis), some administrative expenses related to a particular information requirement have probably occurred (e.g. literature research, processing and professional support by the data owner, travel expenses, archiving of the test substance and raw data, communication with a laboratory). In line with the requirement of an annual documentation of all costs incurred (Article 2(3) of Implementing Regulation 2016/9) these administrative costs need to be justified, i.e., be based on invoices or other objective criteria, e.g. calculation of the costs based on average market price, if available, for the work done in relation to the hours spent for which there is relevant proof. In case this is not possible, these administrative costs may instead be compensated through the application of a duly justified percentage factor. Some examples of variable administrative costs on the basis of the value of the underlying study are provided below (see section

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

5.5). If factual information relating to expenses is available, this may override any other recommendations. In the case of significant deviation, expenses would need to be fully substantiated and documented individually;

- Processing and professional support by the commissioning party (may include study design and /or preparation of test material);
- Preparation of the IUCLID data set and (robust) study summary(ies): the preparation and provision of (robust) study summaries for key studies which may be undertaken by the study owner (or developed by experts commissioned for this task) could be compensated by a percentage of the administrative costs mentioned above. In case of testing for inherent substance properties, the limitation (2) "reliable with restriction" may arise when the study has been conducted at a date prior to the introduction of GLP standards.
- Risk premium: the application of a risk premium is generally not explicitly required but if applied, there must be a justification for it. A potential registrant accessing an existing study has access to a known outcome, while the original decision to conduct a study may have involved a risk for the initiator according to which the project might not have been successful in generating the information desired (with no possibility for reimbursement). Therefore, there may be cases where it may be appropriate to acknowledge this risk for individual studies, especially for recognized problematic substances (for example, UVCBs), or those difficult to test for other reasons. This would mainly be applicable for toxicity or ecotoxicity studies where testing difficulties might reasonably be anticipated. In many other scenarios, there may be no or little justification for the application of this risk premium due to the nature of the testing and/ or the inherent properties of the substance involved. If a risk premium is applied, the requirement for fair and transparent cost sharing requires that both the application as such, as well as the factor applied is justified based on objective criteria. A potential registrant may request such justification in case it is not provided, and may challenge the application and the rate in case of disagreement.
  If studies existed already and were bought by the previous registrants from another data owner, they obviously did not incur any risk about the outcome and therefore no risk premium should be applied. In case of a new study to be generated for which a failure previously occurred, an alternative to the risk premium is to agree on sharing the cost of the actual failure in addition to the share of the re-generated successful study.

5.3.3.1. Factors decreasing the study value

Factors decreasing the study value may include:

- Deviations from standard protocol (study is not performed according to the GLP standards);
- Other possible study deficiencies to determine on a case-by-case basis (e.g. for studies prepared in non-REACH context);
- Usage restrictions:
  - Restriction of use for REACH purposes only (as opposed to a study being available for more general exploitation);
  - Geographic restrictions (beyond the EU/EEA Member States) are placed on areas where the information may be exploited;
  - Right to refer to data only and not co-ownership;

- Use as part of category of substances where the study is used only for one substance;

- Test has been made on another substance and used with a read-across adaptation;

- Compensation already received for the performance of the study: only the costs incurred are to be shared and data sharing should not lead to profit-making. Therefore, a registrant who has already received relevant compensation for the performance of the study is in principle expected to take this compensation into account when calculating the final cost that is to be shared with the other registrants;

- Higher tier studies available instead of lower tier studies: in some cases, existing registrants for higher volumes may have applied the rules in column 2 of the REACH Annexes VII-X and proposed higher tier tests of Annexes IX and X to waive the standard requirements of Annexes VII and VIII. This may result in a situation where subsequent lower tonnage band registrants of the same substance would need to refer to the higher tier tests to fulfil their registration requirements. These subsequent registrants, while not obliged to provide higher tier studies due to their lower information requirements, can nevertheless benefit from the higher tier data and thus waive the corresponding lower tier information requirements.

  Where these higher tier studies are shared by the lower tonnage band registrants, the co-registrants could consider agreeing on a cost sharing mechanism that takes into consideration the following two factors: that there is no need for low tonnage band registrants to provide the higher tier studies and that the relevant lower tier studies (which is required for lower tonnage bands) do not exist. As an example, the co-registrants could agree on a replacement cost of such non-existing lower tier study as a fair contribution to the costs of generating the corresponding existing higher tier study. This is in line with the objective of avoiding unnecessary animal testing.

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

NB: Reductions in the assigned value of a study should be agreed as a percentage reduction of the original valuation. Allocation of the study value would then follow the normal procedures (as described above).

5.4. Cost allocation and compensation

Cost allocation should be based on the value of the studies relating to all endpoints for which information is required according to REACH.

NB: Cost allocation activities are not appropriate for data obtained from reports which are no longer subject to compensation for the purposes of registration (see section 3.1.4.1) and the use of which does not lead to any additional expenditure. However, if the use of this data requires scientific justification to be developed (e.g. for read-across justification or for weight of evidence approach justification) or the preparation of (robust) study summaries, the cost of developing the relevant justification or

preparing the (robust) study summary can be subject to cost allocation.

It is the responsibility of the co-registrants of the same substance to select any cost allocation and compensation mechanism (i.e. cost sharing model) so that they are fair, transparent and non-discriminatory and respect the provisions of Implementing Regulation 2016/9 to that effect. Some possible mechanisms may include (list is not exhaustive):

- Sharing data equally, based on the number of parties involved within the same tonnage band (i.e. registrants having the same information requirements); equal sharing of incurred costs could in principle lead parties to agree on co-ownership of data (however, it is still subject to contractual freedom between the parties);
- Sharing data based on the number of parties involved within the same tonnage band, but considering that the ownership lies with only certain registrants; such cost sharing is typical for letter of access (right to refer);
- Sharing data among registrants based on production or sales volume or otherwise (subject to competition rules and CBI, see also sections 7 and 8); such a model may be considered in some cases to be fairer than others, for instance in situations where parties are handling very disparate manufactured or imported volumes;
- Alternative mechanisms using part of the above models in a different way.

Fairness and non-discrimination of cost sharing are to be looked at holistically. There are situations where strict application of sharing the cost according to tonnage band and information requirements might not be the most appropriate option in terms of fairness. For instance, the allocation of study charges could be considered to be imbalanced when considering parties handling very disparate manufactured or imported volumes. This would generally apply for the higher tonnage band (above 1000 tonnes) where registrants may be handling volumes much greater than 1000 t/y and the impact of registration costs on price per kg of substance would be substantially less than for lower tonnages bands.

The use of a volume factor can also be considered for the lower tonnage bands. In this case, a weighing against further tonnage ranges would be assigned thereby effectively increasing the number of shares across which a charge is allocated. For multi-site operators, tonnage may be combined to assign the appropriate banding factor. To implement this, in view of the need to have knowledge of the population of the relevant volume bands, particular care should be taken to recognize any competition or confidentiality concerns which might potentially arise from the application of tonnage bands with relatively narrow volume ranges, allowing to estimate or identify individual volumes. For more details, please consult sections 7 and 8 of the present Guidance Document.

Considerations on the impact of the cost sharing model on the price per kg of substance and considerations on the fairness of a model based on volume factors are presented in Annex B of the report by the European Commission ‘Monitoring the Impacts of REACH on Innovation, Competitiveness and SMEs’. The report is available at: http://ec.europa.eu/growth/sectors/chemicals/reach/studies/index_en.htm

Registrants may rely on a read-across approach to register several substances that are considered as a group, or ‘category’ of substances, due to their structural similarity (see Annex XI to REACH, section 1.5). In such cases, a subsequent registrant may be required to share the costs of data that have been developed for reference substance(s) within that group, or ‘category’, if they are justified and are relevant for

the registration of its own substance. The most common scenario is when data gaps for a certain substance are filled with information obtained from tests on another similar substance.

More complex is where a registration of a group or 'category' of substances covers for example 10 substances and a potential registrant is manufacturing or importing only 1 substance from this group or 'category'. If the potential registrant relies on the read-across approach to fill in data gaps for its substance, i.e. uses tests or studies developed on reference substance(s) within the group, or 'category', the incurred costs of generating that information should be shared with all other registrants of the different substances within the group, or 'category', who also benefit from the same data.

NB: When the owner of the study is at the same time a co-registrant for the substance, it has to include itself into the calculation of the share of the cost to be paid by each co-registrant that needs that study.

5.4.1. Sharing of all the jointly submitted data

Co-registrants are free to decide on any data compensation mechanism they see fit, as long as the agreed mechanism is fair, transparent and non-discriminatory.

Some models which have been used in the past are explained below and can be considered for apportioning costs between participants. However, they are only models. The example(s) provided to illustrate them should be reviewed to fully understand each model.

1. Data compensation based on study-quality weighted models

These data compensation mechanisms are illustrated by examples in section 5.5. These models are based on the principle that compensation by non-contributors for a given endpoint is due only for the best study available (i.e. for one study per end point).

If there is more than one data owner, the following steps may be applied in order to arrive at an appropriate cost allocation. For the purposes of illustration, Klimisch ratings are determined first and employed.

Case (i): only Klimisch 1 studies available

By contributing with a category (1) report ("reliable without restrictions"), the share of the contributor/data owner is considered as paid for the relevant endpoint. This applies also for any other parties who contribute with reports of equal quality. The cost allocation against this endpoint is then borne only by the remaining (non-contributing) potential registrants.

If any reports are jointly owned by a number of potential registrants, each would be considered to have met their obligation for that endpoint from a cost-sharing perspective.

Case (ii): Klimisch 1 & 2 studies available

If reports from both category (1) and (2) ("reliable with restrictions") are available for the same endpoint, the report with the higher rating will be used as the key study for cost allocation purposes. Data owners supplying a lower-rated report are to contribute according to the difference in value of their study from that of the selected key study.

Other (non-contributing) potential registrants support the cost on the basis of the key study value.

If any category (1) reports are jointly owned by a number of contributors, each would be considered to have met its obligation for that endpoint from a cost share perspective. For category (2) study joint owners, contributions would be required as indicated.

Case (iii): only Klimisch 2 studies available

If a report of category (1) standard does not exist and only one (or more) report(s) of category (2) is available, the report with the highest assigned value will be selected as the key study for cost allocation. Contributing potential registrants will pay by difference to the key study costs (as above) while the other potential registrants will support the cost on the basis of the key study value.

Compensation

The total compensation available for allocation, against any endpoint, results from adding together the contributions identified for all potential registrants in line with the guidelines described.

Compensation is then divided among the parties supplying reports in relation to the values of the studies provided against each of the range of endpoints covered.

2. Direct data compensation

As an alternative to the approach defined above, other more direct cost allocation mechanisms can also be used. In all cases, clear rules for the study valuation step need to be firmly established as a prerequisite to applying any distribution mechanism. This model exempts holders of data who would satisfy their registration requirements from the cost sharing mechanism so that the costs are only shared between the holder of the key study and those registrants who do not hold sufficient data. With study costs established, the following allocation options could be considered:

Case (i): Compensation taking several studies into account

In some cases more than one key study may be needed to cover a certain data requirement. Therefore, a mechanism covering the cost sharing of more than one key study can be envisaged, whereby several studies for a given endpoint are used to calculate a total endpoint value. This total value is to be used to define a member contribution. A cost adjustment for each potential registrant is to be made depending on the value of the studies provided relative to the required member contribution.

This route has the benefit of recognizing the full weight of the studies available. However in order to avoid the situation where the number of existing reports exceeds the number of potential registrants in the data sharing process, data owners are normally not compensated for more than one study per endpoint.

NB: in this model, potential registrants that are not contributing would compensate more than one study per endpoint.

Case (ii): Compensation for key study only

Compensation is based around the key study selected for one endpoint. Other data

owners for the endpoint would be exempted from the compensation process and only potential registrants that do not own data are expected to provide a financial contribution to the key study holder.

As agreement on key study selection is critical for this mechanism, there could be difficulties in coming to an agreement if a number of comparable studies are available. However, if necessary, more than one key study may be assigned. Such a choice should however not lead to situation in which a potential registrant not owning data would contribute disproportionately to cost sharing.

5.4.2. Sharing of individual studies in the context of an opt-out

The opt-out mechanism can be used only in cases where companies have justified reasons to opt-out from part or all the jointly submitted data, on the basis of Article 11(3) or 19(2) REACH (for detailed information, see Guidance on Registration, section 4.3.3, *Conditions for opting out from the jointly submitted data*).

When a study is required by a potential registrant who intends to submit it in an opt-out dossier, the principles described in section 2.2 still apply. Every effort has to be made to find an agreement on the cost of sharing the requested study in a fair, transparent and non-discriminatory way (see section 5).

The study's value is determined using the same principles as when all the data is submitted jointly. The cost of the study is shared with all parties requiring it for registration purposes, whether they register by reference to all the jointly submitted data or submit the study in question in an opt-out dossier. Future potential registrants that also require this study (either to register with the jointly submitted data or with an opt-out) will trigger compensation adjustments.

Following agreement on cost sharing, the previous registrant must make the agreed information available to the potential registrant and give permission to refer to the full study report. Please refer to section 9 on the rights to the data.

Even if a potential registrant will not share any of the jointly submitted data (i.e. separate submission of all endpoints), there may still be some administrative costs to be shared with the lead registrant, and agreed on in a fair, transparent and non-discriminatory way. If, despite making every effort, the potential registrant cannot find an agreement with the lead registrant on the access to the joint submission, it can contact ECHA, who will give it a token to access the joint submission.

As required by Implementing Regulation 2016/9 (Article 3(3)), the potential registrant who is not required to share tests on vertebrate animals has to inform any previous registrant (e.g., via e-mail) and ECHA (via the submission of the IUCLID file) about its decision to submit information separately, via an opt-out.

5.5. Cost sharing examples

Examples provided in this section consider and illustrate some of the concepts described above. They aim at providing a more practical explanation but should NOT be considered as the only way to proceed. Registrants may conclude and agree that additional factors should be considered when agreeing on the cost sharing mechanism. Note that all monetary values and magnitude of cost factors are hypothetical and should NOT be considered as an indication of real values. The cost modifying factors included are for illustrative purposes only.

Example 1: study valuation

7 potential registrants (A, B, C, D, E, F, G) intend to register the same substance, company A owns a Klimisch 1 report, company B owns a Klimisch 2 report, companies C, D, E, F and G do not own a relevant study.

The following example does not reflect

- a deduction because of limitation of a study for REACH registration purposes exclusively
- a surcharge for RSS established for a given report.

a) Substance testing

	Report – Klimisch 1	Report – Klimisch 2
Owner	Company A	Company B
Year of testing	2001	1984
Method	OECD Guideline xyz	Similar to OECD Guideline xyz
GLP	Yes	No
Analysis of test substance	Pharmaceutical grade 99.9 %	Unknown, presumably >99%
Stability	Yes	Unknown, presumably yes
Concentration monitoring	Yes	Yes
Comments	Study conducted in accordance with OECD and EC and EPA test guidelines and in accordance with GLP	Several details of test conditions are not given, e.g. sex, age or body weight of the test animals, housing conditions etc. However, the study is acceptable since the general conduct of the study is acceptable, and since a detailed description of the observations is provided in the report.

b) Analyses

	Report – Klimisch 1	Report – Klimisch 2
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

1

2 c) Determination of the current value of the report

Type of expense/surcharge/deduction	Report 1		Report 2	
Preliminary test to determine concentration (range finding)	€ 35,000		€ 35,000	
Test per standard protocol	€ 100,000		€ 100,000	
Without GLP	0		€ -15,000	
Other deficiencies	0		€ -5,000	
Net valuation of substance test data		€ 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
Total experimental costs		€ 148,500		€ 124,800
Administrative costs[54]	€ 10,000		€ 10,000	

[54] The value of € 10 000 (and € 15 000 in example 2) for administrative cost is given here as an example only. Implementing Regulation 2016/9 requires that administrative costs are itemised and related to the actual costs incurred.

Type of expense/surcharge/deduction	Report 1		Report 2	
Risk premium (10 % of experimental costs[55])	€ 14,850		€ 12,480	
Total surcharges		€ 24,850		€ 22,480
Final current report valuation		€ 173,350		€ 147,280

Cost allocation for each company is described in Example 3b (below).

Example 2: Study valuation

7 potential registrants (A, B, C, D, E, F and G) prepare a joint submission for the same substance. Company A owns a report (compliant to OECD guideline), company B owns a report non-compliant to OECD guidelines, companies C, D, E, F and G do not own a relevant study.

The example does not reflect a deduction because of limitation of a study for REACH registration purposes exclusively, nor a surcharge for RSS established for a given report.

a) Substance testing

	Report 1	Report 2
Owner	Company A	Company 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.

[55] See section 5.3.3.

b) Analyses

		Report 1	Report 2
Stability		standard	standard
Concentration monitoring			
	Method	literature	literature
	Development	none	none
	Provision		
	Working days	0	0
	Per diem rate	€ 600	€ 600
	Analysis costs	€ 100 per analysis	€ 100 per analysis
	Number of analyses	0	0

c) Determination of the current value of the report

Type of expense/surcharge/deduction		Report 1		Report 2	
	Preliminary test to determine concentration (range finding)	0		0	
	Test per standard protocol	€ 11,000		€ 11,000	
	Without GLP	0		€ -1,100	
	Other deficiencies	0		€ -1,000	
Net valuation of substance test data			€ 11,000		€ 8,800
	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

Type of expense/surcharge/deduction	Report 1		Report 2	
Net valuation of experimental costs		€ 11,600		€ 8,800
Administrative costs[56]	€ 3,000		€3,000	
Risk premium[57] (N/A)	0		0	
Total surcharges		€ 3,000		€ 3,000
Final current report valuation		€ 14,600		€ 11,800

Example 3a: Study cost allocation – individual studies

Seven potential registrants prepare a joint submission for the same substance. Only one study is available (Klimisch 1, owned by company A) which is identified as the key study. Following the principles illustrated in the previous examples the value has been calculated to be € 210,000.

Value of key study	€ 210,000
Share per company (€ 210,000 / 7)	€ 30,000
Payment by company A (Owner of the report)	€ 0
Payment by other companies: 6 x 30,000	€ 180,000

Cost compensation

Total amount of assigned contributions	€ 180,000
Compensation for company A having the study report € 30,000 x 6	€ 180,000
Compensation for other companies (not having any study)	€ 0

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

Company A receives € 180,000

Companies B, C, D, E, F and G pay € 30,000 each.

In effect, therefore, company A also "contributes" € 30,000 as it supplies a report valued at € 210 000 for a compensation of only € 180,000. The cost sharing can therefore be considered as an example of a fair way of sharing costs.

[56] See footnote 38 above.
[57] See footnote 39.

Example 3b: Study cost allocation – individual studies

Seven potential registrants prepare a join submission for the same substance. Company A owns a Klimisch 1 report (Report 1) and company B owns a Klimish 2 report (Report 2). Report 1 is selected as the only key study. The companies agree that, as described in the guidance, compensation is done for the key study only. The other companies contribute on the basis of this key study only. However, it was also agreed by all seven companies to also include Report 2 in the dossier.

Following the principles illustrated in the previous examples the value of Report 1 has been calculated to be € 210,000 and the value of Report 2 has been calculated to be € 140,000.

Preliminary calculations	
Value of key study	€ 210,000
Share per company (€ 210,000 / 7)	€ 30,000
Payment by company A (owner of Report 1)	€ 0
Payment by company B (owner of Report 2)[58]: 30,000 x (210,000 – 140,000) / 210,000	€ 10,000
Payment by other companies: 5 x 30,000	€ 150,000

The reduction in the amount paid by company B needs to be redistributed equally among all the seven companies as it would be otherwise be borne by company A only.

Adjustments	
Reduction in amount to be paid by company B (€ 30,000 – € 10,000)	€ 20,000
Additional share per company (€ 20,000 / 7)	€ 2,857
Payment by company A (owner of Report 1)	€ 0
Payment (after adjustment) by company B (owner of Report 2): € 10,000 + € 2,857	€ 12,857
Payment (after adjustment) by other companies: € 30,000 + € 2,857	€ 32,857

Cost compensation

Compensation for company A having the key study Report 1 (€ 32,857 x 5 + € 12,857)	€ 177,142
(= € 210 000 - € 30 000 - € 2857)	

[58] Note that the practice (in the example presented) of reducing member B's contribution by a factor corresponding to the fraction of (the difference in values between Report 2 and Report 1) divided by the value of Report 1 is an example of an agreed way to proceed – it is not the only possibility.

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

Company A receives € 177,142

Company B pays € 12,857 to A

Companies C, D, E, F, and G pay € 32,857 to A.

In effect, therefore, company A also "contributes" € 32,858 as it supplies a report valued at € 210 000 for a compensation of € 177,142. The cost sharing can therefore be considered as an example of a fair way of sharing costs.

Example 4: Study cost allocation – individual studies

Seven potential registrants prepare a join submission for the same substance. Two Klimisch 1 & two Klimisch 2 studies are available, as well as one study not assessed.

Company A owns a Klimisch 1 study (Report 1); the report has been valued at € 240,000

Company B owns a Klimisch 1 study (Report 2); the report has been valued at € 200,000

Company C owns a Klimisch 2 study (Report 3); the report has been valued at € 160,000

Company D owns a Klimisch 2 study (Report 4); the report has been valued at € 150,000

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

Companies F and G do not own any relevant study

The companies agree that company A's study is the key study and, as described in the guidance (see 5.4.2 1. Case (i)+(ii) in combination), compensation is done for the key study only. It is agreed that company B should make no financial contribution since it owns a report of equal quality. Therefore, the preliminary calculation below is based on equal contributions from six (rather than seven) companies i.e. including company A, but excluding company B. The other companies contribute on the basis of the key study only. Companies having lower quality data contribute according to the difference in value.

Preliminary calculations	
Value of key study	€ 240,000
Share per company (€ 240,000 / 6)	€ 40,000
Payment by company A (Owner of Report 1; key study)	€ 0
Payment by company B (Owner of Report 2 not being the key study but being rated Klimisch 1):	€ 0
Payment by company C (Owner of Report 3, Klimisch 2 study) 40,000 x (240,000 - 160,000) / 240,000	€ 13,333

Payment by company D (Owner of Report 4, Klimisch 2 study) 40,000 x (240,000 - 150,000) / 240,000	€ 15,000
Payment by company E (Owner of Report 5, but no quality assessment available)	€ 40,000
Payment by company F and G (do not own a Report) 2 x € 40,000	€ 80,000

It is agreed that the reduction in the amount paid by companies C and D needs to be redistributed equally among the six companies (other than B, but including A) as it would be otherwise be borne by company A only.

Adjustments	
Reduction in amount paid by company C (€ 40,000 - € 13,333)	€ 26,667
Reduction in amount paid by company D (€40,000 - € 15,000)	€ 25,000
Additional amount to be shared (€ 26,667 + € 25,000)	€ 51,667
Additional share per company (€ 51,667/ 6)	€ 8,611
Payment by company A (owner of Report 1)	€ 0
Payment by company C (owner of lower value study): € 13,333 + € 8,611	€ 21,944
Payment by company D (owner of lower value study): € 15,000 + € 8,611	€ 23,611
Payment by companies E, F and G: € 40,000 + € 8,611 each	€ 48,611 each

Cost compensation

Compensation for company A owning Report 1; the key study	€ 191,388

Balancing cost allocation and cost compensation leads to the following results

Member A receives € 191,388

Member B pays € 0

Member C pays € 21,944 to A

Member D pays € 23,661 to A

Member E, F and G pay € 48,611 each to A.

In effect, therefore, company A also "contributes" € 48,612 (the same as E, F, G) as it supplies a report valued at € 240 000 for a compensation of € 191,388. The cost sharing can therefore be considered as an example of a fair way of sharing costs.

Example 5: Study cost allocation – Individual studies

Seven potential registrants prepare a join submission for the same substance.

Company A of the joint submission owns a Klimisch 2 study (Report 1), the value of the report has been calculated to be € 158,300.

Company B owns a Klimisch 2 study (Report 2), the value of the report has been calculated to be € 145,000.

Company C owns a Klimisch 2 study (Report 3), the value of the report has been calculated to be € 144,000.

The remaining members D, E, F and G do not own any relevant study.

Company A's study is identified as the key study. However, it was agreed by all seven companies to also include companies B and C's reports in the dossier.

The companies agree that, according to the Guidance's approach, contributing potential registrants will pay an amount calculated by reference to the difference to the key study cost.

Preliminary calculation	
Value of key study	€ 158,300
Share per member (€ 158,300 / 7)	€ 22,614
Payment by company A (Owner of Report 1; Klimisch 2, key study)	€ 0
Payment by company B (Owner of Report 2, Klimisch 2): 22,614 x (158,300 - 145,000) / 158,300	€ 1,900
Payment by company C (Owner of Report 3, Klimisch 2): 22,614 x (158,300 - 144,000) / 158,300	€ 2,043
Payment by companies D, E, F and G (do not own a Report) 4 x € 22,614	€ 90,456

It is agreed that the reduction in the amount paid by companies B and C needs to be redistributed as it would otherwise be borne by company A only. The companies agree that the adjustment to payments should be redistributed equally among all the companies.

Adjustments	
Reduction in amount paid by company B	€ 20,714
Reduction in amount paid by company C	€ 20,571
Additional amount to be shared (€20,714 + € 20,571)	€ 41,285
Additional share per company (€41,285/ 7)	€ 5,897

Payment by company A (owner of Report 1)	€ 0
Payment by company B (owner of lower value study): € 1,900+ € 5,897	€ 7,797
Payment by company C (owner of lower value study): € 2,043 + € 5,897	€ 7,940
Payment by companies D, E, F and G: € 22,614 + € 5,897 each	€ 28,511 each

Cost compensation

Compensation for company A owning Report 1; the key study	**€** 129**,**781

Balancing cost allocation and cost compensation leads to the following results:

Member A receives € 129,781

Member B pays € 7,797 (Klimisch 2 but not key study / lead value)

Member C pays € 7,940 (Klimisch 2 but not key study / lead value)

Member D, E, F and G pay € 28,511 each.

In effect, therefore, company A also "contributes" € 28,519 (nearly the same as D, E, F, and G) as it supplies a report valued at € 158,300 for a compensation of € 129,781. The cost sharing can therefore be considered as an example of a fair way of sharing costs.

Example 6: Cost allocation - compensation for best studies

In some cases more than one key study might be needed to cover a certain data requirement. In these cases a mechanism covering the cost sharing of more than one key study can be envisaged. (See 5.4.2 2 case (i))

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

Company A: Klimisch 1 study (Report 1, cost € 105,000) + Klimisch 2 study (Report 2, cost € 80,000)

Company B: No Data

Company C: Klimisch 1 (Report 3, cost € 95,000)

Company D: Klimisch 2 (Report 4, cost € 65,000) + Klimisch 2 (Report 5, cost € 75,000)

Company E: Klimisch 2 (Report 6, cost € 60,000)

Total number of available studies = 6

The companies decide that Reports 1, 3, 5 and 6 are needed as key studies.

In this case the companies all agree that the selected reports with the same Klimisch scores will be assigned the same nominal value. Study values are therefore set at

€100,000 for Klimisch 1 and € 67, 500 for Klimisch 2.

Using this dataset and the nominal study values described: Total number of studies being used (for calculation purposes) = 4

Total value of these studies = (2 x 100,000) + (2 x 67,500) = € 335,000. Participant contribution is then 335,000 / 5 = € 67,000

In payment /compensation terms: Member B pays € 67,000 (€ 67,000 – € 0)

Members A, C, D and E (all holders of qualifying data) each receive € 16,500 (€ 67,000/4).

Example 7: Valuation with usage restrictions

Seven potential registrants prepare a joint submission for the same substance.

Company A owns report 1 (Klimisch 1) and its value has been calculated to be € 173,350; company B owns report 2 (Klimisch 2) and its value has been calculated to be € 147,280.

Companies C, D, E, F and G don't own a relevant study.

Cost Allocation

Member C will use the study exclusively for REACH and requires only a Letter of Access, it will get a reduced allocation by a factor of 50 % (therefore it pays at a rate of 50%).

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

Other members will have full usage rights to the full study report.

Preliminary calculation	
Value of key study	€ 173,350
Share per company (€ 173,350 / 7)	€ 24,764
Payment by company A (Owner of Report 1)	€ 0
Payment by company B (Owner of Report 2 having the lower value): 24,764 x (173,350 – 147,280) / 173,350	€ 3,724
Payment by members E, F and G: 3 x € 24,764 (full share, no reduction)	€ 74,292
Payment by member C, who can use the study (Letter of Access) only for REACH 24,764 * ((100-50)/100)	€ 12,382
Payment by member D, who can use the study for all regulatory purposes, including REACH, but needs only Letter of Access. 24,764 * ((100-30)/100)	€ 17,335

The reduction in the amount paid by companies B, C and D needs to be redistributed among all the companies as it would be otherwise be borne by company A only. It was

agreed by the companies to also take into account the use restriction in the distribution of this amount using the same factors.

Adjustments	
Reduction in amount paid by company B (€ 24,764 - € 3,724)	€ 21,040
Reduction in amount paid by company C (€ 24,764 – € 12,382)	€ 12,382
Reduction in amount paid by company D (€ 24,764 - € 17,335)	€ 7,429
Additional amount to be shared (€ 21,040+ € 12,382 + € 7,429)	€ 40,851
Additional equal share per company to be used as reference (€40,851/ 7)	€ 5,836
Corrected additional payment by company C (50% of € 5836)	€ 2,918
Corrected additional payment by company D (70% of € 5836)	€ 4,085
Additional payment by company B, E, F, G: (€ 40,851 – (€ 2918 + € 4085) /5)	€ 6,770
Final payments	
Final payment by company B: € 3,724+ € 6,770	€ 10,494
Final payment by company C: € 12,382 + € 2,918	€ 15,300
Final payment by company D: € 17,335 + € 4,085	€ 21,420
Payment by companies E, F and G: € 24,764+ € 6,770 each	€ 31,534 each

Cost compensation

Total amount of assigned contributions	€ 141,816

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

Company A receives € 141,816

Company B pays € 10,494

Company C pays € 15,300

Company D pays € 21,420

Companies E, F, G pay € 31,534 each.

In effect, therefore, company A also “contributes” € 31,534 (the same as E, F and G) as it supplies a report valued at € 173,350 for a compensation of € 141,816. The cost sharing can therefore be considered as an example of a fair way of sharing costs.

Example 8: Registration dossier cost allocation - different tonnage bands used as criteria

Fair cost sharing may be organised according to tonnage bands as the REACH information requirements are linked to the tonnage bands and therefore are the main factor affecting cost sharing. The costs of data necessary for a group of registrants falling under a specific tonnage band vary and are usually related to the cost of data, access to which the registrant needs to licence/ acquire for the purpose of submitting its dossier.

Since it is difficult to define a standard proportion between the different tonnages, different approaches may be used.

For substance X, 10 potential registrants have expressed interest in registering the substance. Five of them in the tonnage band of > 1000 t/y, three in the tonnage band of 100-1000 t/y and two in the tonnage band of 1-100 t/y.

The total cost of the data in the dossier is € 1,420,000 and the "administrative costs" (including preparation of the dossier and review by third party) are € 10,000. Total cost is therefore: € 1,430,000.

The lead registrant proposes the following prices for the letter of access (LoA):

Tonnage band	Cost of access to data (€)	Admin costs (€)[59]	Total price LoA (€)
>1000 t/y	250,000	1,300	251,300
100-1000 t/y	50,000	800	50,800
1-100 t/y	10,000	550	10,550

The price structure reflects the fact that the higher tonnage band registration accounts for the higher registration requirements. The amount of the administrative costs to be paid by each registrant varies depending on the tonnage band to which the registrant registers in line with the requirement that a registrant needs to share only the administrative costs that are relevant for its registration requirements (Article 4(1) of Implementing Regulation 2016/9. See section 5.1 for further information).

The total price is then covered: 5 x 251,300 + 3 x 50,800 + 2 x 10,550 = € 1,430,000.

Note that the ratio (weight) how the administrative costs are spread between the different tonnage bands may differ for different substances. It needs to reflect the actual distribution of the administrative costs, and has to be objective and justifiable.

Example 9: Registration dossier cost allocation and balance due to new co-registrants and additional costs (reimbursement mechanism)

Before registration, 100 potential registrants manifested interest in registering the substance. The total estimated price of the dossier including administrative costs is € 1,000,000.

[59] In line with the requirement that a registrant needs to pay only those administrative costs that are relevant for its registration (Article 4(1) of Implementing Regulation), the amount of the administrative costs to be paid by each registrant varies depending on the respective tonnage band.

Following a survey carried out by the lead registrant, 30 legal entities out of the 100 potential registrants have expressed interest in registering in the highest tonnage band.

It has been assumed as a conservative approach that 20 legal entities will actually register within the highest tonnage band (>1000 t/y).

For the cost allocation the agreed approach has been to apply equal sharing per legal entity per tonnage band and to fix[60] a price for lower tonnage bands in case of new potential candidates as follows:

> 1000 t/y: 100% of the Letter of Access (LoA)

100 – 1000 t/y: 50 % of the LoA.

10 – 100 t/y: 20 % of the LoA

< 10 t/y: 5 % of the LoA

The price of the LoA is fixed at € 1,000,000/20 = € 50,000.

By 2010, 20 legal entities registered. The total amount of the fees paid by these co-registrants covers the total cost of the dossier.

After the first registration deadline, e.g. in 2012, 2 new legal entities, which want to register in the highest tonnage band, join the joint submission: they pay € 50 000 each.

Hence 2 X € 50,000 = € 100,000 of income.

The jointly submitted data undergoes compliance check. The outcome leads to a requirement for additional work (delivering of additional data and related assessment work) which is estimated to be € 80 000.

Before the next registration deadline of 2013, 3 new legal entities, which intend to register in the tonnage band 100 – 1000 t/y, join the joint submission, and pay € 25 000 each.

Hence 3 X 25 = € 75,000 income.

According to the originally agreed mechanism, a reimbursement will be made in 2018 after the last registration deadline:

BALANCE

Income 2010	+ € 1,000,000
Income 2012	+ € 100,000
Income 2013	+ € 75,000
Dossier costs	€ -1,000,000
Evaluation costs	€ - 80,000

[60] The percentage/proportion of cost allocated to each tonnage band shall be based on objective criteria. While the price in absolute terms is unpredictable until final registration deadline, the proportion of cost to be borne by each co-registrant before final reimbursement shall be established in a fair, transparent and non-discriminatory way.

Balance	+ € 95,000

It has also been decided to put aside € 10,000 to cover extra additional costs in case of the need to update the dossier after 2018.

Balance	+ € 95,000
Updating costs	- € 10,000
Final balance	+ € 85,000

Number of legal entities above 1000 T tonnage band: 22 Number of legal entities within
100-1000 T tonnage band: 3 Number of reimbursement unit: 22 + 3/2 = 23.5

Value of the reimbursement unit: € 85,000/23.5 = € 3,617

Each legal entity above 1000 T will get back 1 reimbursement-unit: € 3,617

Each legal entity within 100-1000 T will get back 1/2 reimbursement-unit: € 1,808

NB: The frequency of the reimbursements need to be agreed, ranging from e.g. (i) every time a newcomer joins the joint submission to (ii) Q1 of each year. Co-registrants are free to agree on other frequencies which suit best their needs and situation. In any case, the inclusion in the agreement of a reimbursement scheme is mandatory and can be waived only by unanimous agreement of all co-registrants, including future ones.

6. FORMS OF COOPERATION

Potential registrants are free to organise themselves in order to meet their data sharing, classification and labelling and joint submission obligations. After the formal cease of operation of the SIEFs, on 1 June 2018, Implementing Regulation 2019/1692 established that co-registrants are encouraged to use similar informal communication platforms to enable them to meet their continuing registration and data sharing obligations.

6.1. Possible forms of cooperation

There are several possible forms of cooperation that companies can chose to organise their cooperation under REACH. The forms of cooperation can vary from loose ways of cooperating (e.g. IT tools to communicate between all members of a joint submission) to more structured and binding models (e.g. consortia created by means of contracts).

Some industry associations already host dedicated REACH groups, trustees or consortia for groups of substances which could be related or similar. They may be willing to add new substances to the scope of their activities or provide an opportunity for read-across of data. They can be contacted for substance sameness discussions[61].

It is sometimes 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. It is not mandatory to form or be part of a consortium even if in certain cases (some) registrants may agree about the need to form one.

The use of a “consortium agreement” or another formal, written cooperation agreement, are not legally required by REACH. Whatever the form of the cooperation chosen, it is advisable that 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, on the ownership of the studies jointly developed and on the sharing of costs.

Even in cases when a consortium (or any other form of cooperation) is created, it is not mandatory for all existing and potential registrants of the same substance to be part of it. Registrants can decide to fulfil their data sharing obligations without being formally part of any consortium. Registrants have in any case the obligation to reach an agreement to share the necessary data regardless of their participation to a specific form of cooperation.

In some situations a consortium agreement, which may potentially cover one or more substances, or a less formal cooperation agreement could be established between several registrants, actively involved in the preparation of the joint submission. In these cases, new members will enter into specific agreements with the consortium members in order to fulfil their data sharing obligations.

In practice, a potentially wide array of bilateral agreements could be established within the consortium, between different members or with external data holders to grant and clarify ownership, reference and access rights to data. It is recommended that data sharing is centralised. An agreement from the data owner is required. This agreement may be a specific Letter of Access[62] or a licence to use. This agreement is separate

[61] The Contact details of the industry associations that are ECHA's accredited stakeholder organisations are available on ECHA's website. http://echa.europa.eu/about-us/partners-and-networks/stakeholders/echas-accredited-stakeholder-organisations.
[62] See section 9.2, ‘What is a Letter of Access (LoA)?’.

from the data sharing agreement among the co-registrants. It is recommended that such an agreement is valid for all co-registrants including future ones. This would allow co-registrants to use the data without having to individually negotiate access to it.

6.2. What is a consortium?

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

Importantly, a consortium is voluntary and may not necessarily regroup all co-registrants of a substance. REACH actors may decide to create a consortium at any stage of the REACH Process, e.g. either before registration, to ease the process of checking the identity and sameness of a substance with a view to a joint submission of the dossier, or afterwards.

Co-registrants who need to fulfil the obligations of REACH must necessarily co-operate. A co-registrant may propose to the others a means of working together through "formal cooperation" and signing of a consortium agreement, or by adopting common rules. This proposal for a chosen form of co-operation could be made by the co-registrants on their own, or by asking for the services and assistance of a Third Party such as a trade association, a sector association, a consultant, a law firm or any other service provider.

By either signing the consortium agreement, or accepting operating rules by a decision in a meeting, or deciding to refer to a common agreed set of rules (hereinafter only referred to as an "agreement"), participants in the agreement will *de facto* 'create the consortium'. There is no need to have any additional formalities. It should be noted that when a consortium is created by a trade association or a law firm it should not be confused with that body, and must be distinctly differentiated from it.

Some companies may also already be organised by having, for example, either a sector group or a consortium preparing the work to be ready for REACH. In this case, they may decide either to continue their cooperation within the same structure, or to create a new parallel structure, or to have any other pattern for cooperating.

Some consortia created when the SIEFs were operational may continue to exist even after 1 June 2018, since they are distinct from the fora.

6.3. Elements of cooperation that may be included in a consortium's activities

The following elements may be included in the activities of a consortium:

- Conduct and/or document the substance identity check;
- Organisation of co-operation and thus of the consortium;
- Consideration of data (existing data, missing data, new data to be developed);
- Defining of data to be shared;
- Facilitation of data sharing and coordination;
- Data valuation, data evaluation (including identification, data access and collection);
- Facilitation of cross-reading with other substances;

- Organization to preserve the confidentiality of business information and data;
- Cost sharing;
- Data ownership;
- Preparation of letter(s) of access to data for non-consortium participants;
- Liability;
- Classification and labelling;
- Sharing of data after registration, namely when new data requirements arise as a result of a regulatory decision.

6.4. Categories of participants in a consortium

The following categories of participants may be considered to be members of a consortium/cooperation agreement (this list is not exhaustive):

A) Categories strictly deriving from being a co-registrant:

- manufacturer(s);
- importer(s);
- only representative(s);

B) Other categories may be considered, such as:

- downstream user(s), in cases other than those mentioned in (A);
- Third Parties providing services and assistance to a consortium such as trade/industry associations, sectoral associations, service providers, and law firms;
- non-EU manufacturer(s) who are also willing to participate directly, and not only through their EU only representative, although not being entitled to register directly;
- data holder(s) who are willing to share data: for example laboratories, organisations, consultants, trade/ industry associations or downstream user(s) if they have relevant information, for example study data and exposure data.

Different categories of membership with different rights and obligations associated with these categories may be designated and included in the consortium agreement. For example:

- full members;
- associate members;
- observers (either as Third Parties or not).

6.5. 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 Contact details Preamble: including a reference to **REACH** and a **declaration** of intent to **explain** the **overall** purpose of the consortium Scope of **cooperation:** the substances(s) on which the parties will **co-operate.** It may also include the criteria chosen to agree on the identification of the substance(s) Subject of the agreement: list of elements of **cooperation** or tasks on which parties **have** elected to **work** Definitions: **general** reference to the definitions included in **REACH** (Article 3) and additional definitions, if any Duration Identity of an independent third party: if the parties elect to **have** assistance from a law firm, service **provider,** sectorial or **trade** association in managing their consortium
2. Membership	Membership categories: definition, rights and obligations of each category Membership rules: admission, revocation, dismissal of members Change in membership: late entrant / early departure
3. Data sharing	Rules on data sharing and future studies / costs Criteria for valuation of studies / test reports Cost sharing criteria and reimbursement mechanisms Data Ownership Letter of access
4. Organisation	Committees: (membership, attendance, rules of functioning, quorum, voting …) Working language Role of the lead registrants, if any; Role of independent third party, if any
5. Budget and finances	Budget Apportionment – follow-up of registration (additional members to the joint submission) Financial year Invoicing and payment, reimbursement

6. Confidentiality and right of information	Confidentiality clause Who is entitled to access information? Measures in place regarding the exchange of confidential and sensitive information Sanctions in case of breach
7. Liabilities	Before and after the obligations under REACH are fulfilled
8. Miscellaneous	Applicable law Dispute resolution / settlement or choice of jurisdiction Changes to the agreement Dissolution

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7. INFORMATION SHARING UNDER COMPETITION RULES

7.1. Competition law applying to REACH activities

As is expressly stated in REACH, *"this Regulation should be without prejudice to the full application of the Community competition rules."* (Recital 48). Thus, rules of competition law adopted at EU level (hereinafter "Competition rules") may apply to REACH and all related activities, including data sharing.

This section is intended to help the REACH actors to assess the compatibility of their activities for sharing data and information in the context of REACH. Additionally, Competition rules can apply to other aspects of REACH related activities.

Data sharing and information exchange may occur at different steps of the REACH process. This section is only limited to the most common types of questions related thereto. Furthermore, this section may apply to any form of cooperation that actors may decide to adopt in order to fulfil their obligations under REACH (see section 6).

NB: REACH actors should always ensure that their activities comply with Competition rules irrespective of the form of cooperation they choose.

7.2. EU competition law and Articles 101 and 102 TFEU in brief

EU Competition law is not intended to inhibit legitimate activities of companies. Its objective is to protect competition in the market as a means of enhancing consumer welfare. Therefore, agreements between undertakings[63], decisions by associations of undertakings and concerted practice which may affect trade between Member States and which have as their object or effect the prevention, restriction or distortion of competition within the common market are prohibited (Articles 101 TFEU). Similarly, any abuses by one or more undertakings of a dominant position within the internal market is prohibited in so far as it may affect trade between Member States (Article 102 TFEU).

Any agreement that infringes Article 101 is void and unenforceable. In addition, in case of an investigation by the European Commission, the EFTA Surveillance Authority or by a national competition authority, undertakings that have implemented a conduct in breach of Articles 101 or 102 TFEU may face significant fines. Such an investigation may be initiated either by the authority itself, following a complaint by a third party, following a market study or following a leniency application. The most flagrant example of illegal conduct infringing Article 101 TFEU would be the creation of a cartel between competitors (which may involve price-fixing and/or market sharing).

Article 102 TFEU prohibits undertakings holding a dominant position in a market from abusing that position. In the specific context of registration activities under REACH, this provision could cover a variety of conduct and practices that would, for example, allow the lead or any other co-registrants to obtain some kind of unlawful competitive advantage over the other co-registrants/competitors.

For more information on EU competition issues and related FAQs in context of REACH

[63] 'Undertaking' covers any entity engaged in an economic activity, regardless of its legal status and the way in which it is financed.

registration please refer to the Commission Directorate-General for Competition, Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs and Directorate-General Environment document at: http://ec.europa.eu/growth/sectors/chemicals/reach/about/index_en.htm.

7.3. Exchange of information under REACH and EU competition law

REACH requires the sharing of information between companies "*in order to increase the efficiency of the registration system, to reduce costs and to reduce testing on vertebrate animals*" (Recital 33).

REACH provides for significant flows of information between actors, at various stages throughout its implementation process. Examples are:

- during the inquiry, in order to evaluate if a substance has already been registered;
- in the context of information to be shared between downstream users and their suppliers;
- in the context of the sharing of data and the joint submission of registration.

NB: Actors have to make sure that their exchanges do not go beyond what is required under REACH in a manner that would be contrary to EU Competition law, as explained below.

Firstly, actors must avoid any illegal activity (e.g. creating cartels) when complying with REACH. Secondly, actors should restrict the scope of their activity to what is strictly required by REACH to avoid creating unnecessary risks of infringing EU Competition law. Thirdly, if actors have to exchange information which is sensitive under EU Competition law, then it is advisable that they use precautionary measures to prevent infringement. [64]

7.3.1. Avoiding misuse of exchange of information under REACH 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.

[64] For more information on the exchange of information under EU competition law, see Section 2 of the Commission's Guidelines on the applicability of Article 101 of the Treaty on the Functioning of the European Union to horizontal co-operation agreements.

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

7.3.2. The scope of the activities should be limited to what is necessary under REACH

It is important to ensure that the exchange of information under REACH is limited to what is required. Article 25(2) REACH 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 in an unlawful manner.

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

7.3.3. Type of information to be exchanged with caution

Even if most of the information to be exchanged under REACH is unlikely to be problematic under EU Competition law rules (because this information is, to the greatest extent, purely scientific or technical and it may not enable competitors to align their market behaviour), there are instances where actors need to be very careful.

In particular, actors may be induced to exchange information on individual production, import or sales volumes. For example, in the context of a joint CSA/CSR, actors may want to know the aggregate volumes of produced and imported substances by exchanging information on individual volumes, in order to estimate the overall impact on the environment. Actors may also want to share REACH-related costs based on their individual production or sales volumes. In addition, if an only representative, who has to keep certain information like quantities imported up-to-date, represents several non-EU manufacturers of a substance, such manufacturers may be induced to exchange individual volume information between them through their only representative.

Some tips are provided below on how to avoid the risk that the exchange of such volume information, to the extent that it is relevant under REACH, constitutes an infringement of Article 101 TFEU.

7.3.3.1. Reference to tonnage bands rather than individual figures when feasible

REACH mentions that "*Requirements for generation of information on substances should be tiered according to the volumes of manufacture or importation of a substance, because these provide an indication of the potential for exposure of man and the environment to the substance, and should be described in detail*" (Recital 34), thus indicating the use of tonnage bands.

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

7.3.3.2. Use of precautionary measures if individual sensitive information would still need to be exchanged

If under particular circumstances, actors need to either use individual or aggregate figures (for example at the occasion of carrying out of CSA/CSR) or individual figures may be otherwise identifiable, it is recommended to use an independent third party ("Trustee").

Who could be a Trustee? A legal or natural person not directly or indirectly linked to a manufacturer/importer or their representatives. This Trustee may be, for example, a consultant, a law firm, a laboratory, a European/international organisation, etc. The Trustee will not represent any actor, as it should be independent, and can be hired by the members of the joint submission, for example to help for certain activities. It is advisable that the Trustee signs a confidentiality agreement that will ensure that the Trustee undertakes not to misuse sensitive information it receives (i.e. disclose it to the participating companies or anyone else).

The following activities can be facilitated by a Trustee for competition law purposes:

Produce aggregated anonymous figures: When REACH actors need to refer to the aggregate of sensitive individual figures, the Trustee will request the actors to provide their individual input. The input will be collated, checked and aggregated into a composite return that does not give the possibility of deducing individual figures (e.g., by ensuring that there will be a minimum of three real inputs). In addition, no joint discussion must take place between this Trustee and several actors on the anonymous or aggregated figures. Questions should be addressed on an individual basis between each actor and the Trustee, who must 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.

7.4. Excessive pricing

Depending on the circumstances (e.g. high market share, characteristics of the market), co-registrants with a more prominent role (e.g. lead registrant, consortium members) may be considered to be in a dominant position. This is not in itself unlawful, but applying Article 102 TFEU, an undertaking that holds such a position has a special responsibility not to allow its conduct to impair competition in the Internal Market. The concept of abuse is an objective one and there is no need to prove fault or subjective intent on the part of the dominant firm to abuse its position.

A dominant firm charging excessive prices may be considered abusive within the meaning of Article 102 TFEU. These concerns may be relevant in the context of the pricing of LoAs for example. However, the fact that the potential registrants consider the price charged to be high does not demonstrate, in itself, that it is excessive within the meaning of the EU case law on Article 102 TFEU.

7.5. Recommended tips for REACH actors when working together

Competition compliance	Before entering into an **exchange** of information under **REACH** ensure **you have** read and understood this guidance and that **you** will apply it. In case of doubt, or questions, please seek advice (e.g. from a legal advisor).
Record keeping	Prepare agendas and minutes for conference calls or meetings which accurately reflect the matters and discussions held between actors.
Vigilance	Limit your discussion or meeting activities to the circulated agenda. Protest against any inappropriate activity or discussion (whether it occurs during meetings, conference calls, social events, or when working via electronic means – for example using a dedicated intranet). Ask for these to be stopped. Disassociate yourself and have your position clearly expressed in writing, including in the minutes.

NB: This section does not intend to substitute the applicable competition law provisions, as these have been interpreted by the European Courts, and applied by the European Commission and the national competition authorities. This guidance is only designed to allow REACH actors to make a preliminary assessment of their conduct under EU Competition law.

This Guidance is designed in a generic way and thus does not and cannot cover all the different scenarios that may arise from data sharing obligations provided by REACH. In case of uncertainty, ECHA would recommend to seek legal advice from a lawyer specialised in competition law.

7.6. Remedies to report anticompetitive practices

As far as competition enforcement is concerned, national law and EU law operate in parallel. If the practices in question have an effect on intra-EU trade, EU competition rules will be applicable[65]. The European Commission, EFTA Surveillance Authority, National Competition Authorities and national courts are all empowered to apply EU competition rules. The main rules on procedure, including those on case allocation between the Commission and National Competition Authorities, are set out in Council Regulation 1/2003[66].

If, having regard to these procedural rules, it appears that the European Commission is well placed to act, a complaint can be filed. An explanation can be found at the following address: http://ec.europa.eu/competition/contacts/antitrust_mail.html.

It should be noted that, unlike national courts, the European Commission does not have the power to award damages to firms that are victims of a breach of the competition rules.

For more details on the prohibition of anti-competitive behaviour, please consult the relevant webpage of the European Commission - Directorate General Competition, at the following link: http://ec.europa.eu/competition/index_en.html.

[65] For further information, please consult the Commission Guidelines on the effect on trade concept contained in Articles 81 and 82 of the Treaty, OJ C 101 of 27.04.2004.
[66] Council Regulation (EC) 1/2003 of 16 December 2002 on the implementation of the rules on competition laid down in Articles 81 and 82 of the Treaty OJ L 1, 04.01.2003, p.1-25.

8. CONFIDENTIAL BUSINESS INFORMATION (CBI)

REACH requires companies to share information and data in order to avoid duplicate testing. However, some of this information, or data, may be considered by companies to be confidential business information ('CBI') which needs to be "protected". Whether certain information is CBI needs to be determined on a case-by-case basis.

NB: It is important to not confuse CBI issues with competition rules (see section 7 above) which refers to situations where the sharing of information is likely to lead to distortion of competition.

8.1. What is confidential business information?

Confidential business information is one of the valuable assets of companies. Measures may have to be taken to protect this asset.

Many countries have comparable, although slightly different, definitions of CBI. For instance Article 39(2) of the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs), defines CBI as follows:

a. is secret in the sense that it is not, as a body or in the precise configuration and assembly of its components, generally known among or readily accessible to persons within the circles that normally deal with the kind of information in question;

b. has commercial value because it is secret; and

c. has been subject to reasonable steps under the circumstances, by the person lawfully in control of the information, to keep it secret.

8.2. Are there specific provisions on CBI in REACH?

References to the CBI concept are made in several provisions of REACH, which demonstrate that the protection of CBI is a legitimate interest.

Article 118 REACH relates to "Access to Information" held by ECHA. Article 118(1) establishes that Regulation (EC) No 1049/2001[67] shall apply to documents 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 mixture; precise use, function or application of a substance or mixture; precise tonnage of substances and mixtures; links between a manufacturer or importer and downstream user.

Articles 10(a)(xi) and Article 119(2) REACH allow a party submitting certain information to request confidential treatment of that information. The party submitting the information must submit a justification (confidentiality claim) that has to be accepted by ECHA, as to why publication of this information is potentially harmful to their commercial interests or of any other involved party.

Article 11(3)(b) and 19(2)(b) REACH allow registrants to 'opt-out' from the joint submission of data (only for individual endpoints) "if submitting the information jointly would lead to disclosure of information which it considers to be commercially sensitive and is likely to cause him substantial commercial detriment".

[67] Regulation (EC) No 1049/2001 of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents, OJ L 145, 31.5.2001, p. 43–48

8.3. Protection of CBI before the joint submission

As mentioned in sections 2.2.1 and 3 of this Guidance document, before submitting data jointly, potential registrants must ensure that they are producing or importing the same substance in accordance with the criteria set out in the *Guidance on identification and naming of substances in REACH and CLP* with the aim to ascertain that they can submit within the same joint submission. This may in some cases require the exchange of detailed technical information on the composition of the substance, its impurities, and possibly on the manufacturing process. The latter may include the raw materials used, the purification steps etc.

To the extent that this technical information is considered CBI companies may take steps to protect the confidentiality thereof, for instance by:

1. Entering into confidentiality agreements that limit access to documents or other information to specific named persons, or departments, e.g. only the persons working within a regulatory section are allowed to see certain information. This can be strengthened by using additional personal confidentiality agreements.
2. In addition to (1), by allowing access to certain documents in a 'reading room' only (where copying is not allowed).
3. The potential registrant may provide a revised version of the study summary which omits the confidential elements, if possible.
4. If the study cannot be validly used without those elements, the parties may agree to have certain documents reviewed and/or assessed only by a neutral third party expert (independent consultant) or a trustee, who can 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 submission of data.

NB: As a minimum, potential registrants who intend to protect the CBI character of substance identity information should specify to the other co-registrants 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.

8.4. Protection of CBI in the joint submission

The scientific studies that companies must share under REACH for the purposes of registration generally do not contain information that can be considered as CBI. However, to the extent that compliance with the data sharing and joint submission provisions involves disclosure of CBI, parties may enter into a confidentiality agreement, may make available non confidential versions of the documents that contain CBI, or may appoint an independent third party to gather the information and prepare the registration dossier.

When this is not deemed sufficient, a registrant can opt-out for some individual endpoints and submit the (robust) study summaries, in its member dossier, so as to preserve its confidential information. However, the party opting out is still part of the joint submission and is still bound by its data sharing obligations under REACH.

In case of opt-out, the justification based on CBI must address the commercial loss which would be sustained if such CBI were disclosed by the joint submission of data. Circumstances will of course vary from case to case, but it would seem necessary in

most cases to demonstrate (1) the route by which confidential information would be disclosed, (2) how it could cause a substantial detriment if it were disclosed (3) that no mechanisms can be used or is accepted by the other party/parties (e.g. use of a trustee) to prevent disclosure.

Examples might include information allowing details of manufacturing methods to be deduced (such as technical characteristics, including impurity levels, of the product used in testing), or marketing plans (test data obviously indicating use for a particular, perhaps novel, application), for example because there are only 2 participants in a joint submission. The fewer participants in the joint submission, the more likely it is that CBI might be released through indications of sales volumes. Although there is no further quantification in the legal text of what constitutes "substantial" detriment, a registrant seeking to use this opt-out criterion should as a minimum provide an estimation of the value of the CBI at stake. This might be done by setting out the total value of business for the product, the proportion potentially affected and the associated gross margin. If a simple calculation of annual loss is not enough to demonstrate "substantial" detriment, a further stage might include an estimate of the forward period over which business might be affected and the consequent calculated net present value of gross margin lost.

8.5. Protection of CBI in the submission of the registration dossier

When submitting a registration dossier to ECHA, the registrants must identify the information they consider confidential, as per Article 119, and for which they request non-disclosure on the ECHA website.

NB: Information which is covered by REACH Article 119(1) cannot be claimed as confidential and any such claims will be disregarded. The information covered by REACH Article 119(1) will always be made publicly available on the ECHA website, in accordance with REACH Article 77(2)(e).

In accordance with Article 10(a)(xi), the request to keep information confidential must be accompanied with a justification as to why the publication of such information could be harmful.

This applies to:

- Information which is covered by REACH Article 119(2);
- Information for which confidentiality was previously granted under Directive 67/548/EEC - for this previous notifiers need to update their dossier indicating which information they wish to keep confidential;
- Any information claimed as confidential which is not covered by REACH Articles 119(1) and (2): in this case the justification may be a short sentence expanding on the confidentiality claim flag type – 'CBI' (confidential business information), 'IP' (intellectual property) or 'No PA' (not publicly available) (e.g. CSR).

To assist registrants a standard justification template has been made available within IUCLID itself. Note also that for confidentiality claims for an IUPAC name (which have not been previously granted under Directive 67/548/EEC) an adequate public name must also be provided.

For technical instructions on how to make a confidentiality request, consult the ECHA

manual, *Dissemination and confidentiality under the REACH Regulation* accessible at: https://echa.europa.eu/manuals.

9. COPYRIGHT AND OTHER INTELLECTUAL PROPERTY RIGHTS OVER DATA

Data sharing in accordance with REACH must also respect intellectual property rights attached to the ownership of the data.

9.1. Determining ownership: origin of the data

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

1. Companies: When companies carry out studies themselves or commission them, they then normally have full ownership rights on the studies, including the right to grant access to that data. Within a group of companies, the data may be held by one single legal entity within the group and will not necessarily be disclosed to other companies of the same group without a specific agreement.
2. Industry associations: In certain cases, trade associations commission studies and hold data on behalf of their members. The issue here is to determine the owner(s) of the data, i.e. the association, its members, or the members of a specific “interest group” within the association. This will usually require reviewing the by-laws of the association and/or documents constituting the interest groups, for example. These documents may also determine the rights of companies that decide to leave the association or the group.
3. Consortia: Companies within a consortium may decide to share existing data or generate new data. Ownership of the data will normally be determined by the rules of the consortium contract or in separate arrangements when the study is shared or commissioned. Normally, the rights to the data are granted to those contributing to the costs of the data. As mentioned above, in some cases, the consortium agreement limits the rights of the consortium members to use the data they share or generate, so that they may not enjoy “ownership” rights to that data.
4. Official bodies: Studies are also generated by government agencies, research institutes, universities or international organizations and are also copyright protected. Ownership normally lies with the government, university or the international organization. Rights 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 the study can be freely used for registration purposes. In some cases the study itself may be copyrighted or belong to another party holding full ownership rights to that study.

9.2. Right to the data

With regard to data sharing for the purposes of REACH registration, a clear distinction must be made between: (a) ownership of the full study report; (b) legitimate possession of the full study report, (c) right to refer to the full study report and (d) possibly other rights.

a) **Ownership of the full study report** would normally be with the party(ies) who hold all[68] the property rights over the data (data owners). These property rights are borne either automatically (because the owner is the creator of the studies or tests) or through the will of the parties (i.e. contract).

In case the property rights over the data have been licensed by a contract (i.e. assignment of rights, license agreement, mandate etc.), the person/entity to whom those property attributes have been licensed becomes either:[69]

- full owner of all the property rights over that data (i.e. in case the entire property rights over the data have been transferred - assignment of rights), or;
- partial owner/user (in case only certain scientific materials have been licensed or only some attributes of the property rights have been granted, i.e. a license granted to the lead registrant to use the studies (only) for registration purposes).

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

The requirement to be in legitimate possession should be read in the REACH context, and understood as meaning that registrants are required to hold the right to use the data for the purposes of the registration, although the right to use the data for other purposes could be limited. A possible concrete example would be to have a copy (in electronic or paper form) of the full study report, with the valid right to use the data for registration purposes.

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

In addition, intellectual property is a matter of private law, which applies autonomously from REACH. Legitimate possession may therefore be questioned under REACH where a breach of intellectual property rights is already established. However, ECHA has no competence to assess claims related to a breach of intellectual property rights. Such a breach can be established exclusively by an authority or court competent in intellectual property.

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

[68] The attributes of the property right are very extensive: e.g. the right to use the data for different purposes (including registration under REACH), re-use the data, translate, exploit, sell, transfer, distribute, reproduce, prepare derivative studies, include the studies/ data in other studies etc.
[69] When the data owner is acting as a registrant, even though it acquired full ownership over the data, it still might be prevented from using/disposing of the study as it best sees fit.

transferring on to that party a copy of the full study report but only the right to refer to that study;

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

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

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

What is a Letter of Access (LoA)?

When a registrant does not own a study report that they require for their registration, they need to agree with its owner on the conditions of using the study report for REACH registration purposes. The owner of the data and the registrant are free to define the rights that will be granted.

If the (robust) study summary of a study has already been submitted to ECHA, a registrant can, for instance, refer to that study in their dossier, provided that they have permission to do so (and a right to refer to the full study report). In that context, the registrant and the data owner must agree on the conditions of the right to refer. The LoA is a term often used to describe the agreement on the sharing of data and granting a right to refer. The intellectual property rights of the data owner must in any case be respected by the potential registrant.

9.2.1. Legitimate possession and right to refer

The “legitimate possession” or “permission to refer” required by Article 10 REACH could be considered as derived directly from intellectual property law[70]. Legitimate possession or right to refer to a full study report is typically granted by owners of the full study report, but may sometimes be granted by law or by authorities. When the report is subject to copyright or CBI, granting legitimate possession may take the form of a **“license to use”** the data, while a right to refer to the data can be granted by a simple **“letter of access”**.

While negotiating an agreement in these terms, careful attention should be paid to the rights granted (right to use for REACH only or also for other purposes), the information provided and possibly the duration of such agreement or access, and associated costs.

[70] The Berne Convention for the Protection of Literary and Artistic Works (1886), as last amended in 1979.

Furthermore, the right to sub-licence may also need to be considered (e.g., the licence is granted to the lead registrant who needs to extend the right to the legitimate co-registrants).

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

Copyright does not allow the potential registrant to copy the text of the study – the fixed expression – into the registration dossier. The data can be used to produce an own study summary. However, the use of published data for the purpose of satisfying the minimum information requirements in a registration still requires legitimate possession or the right to refer to the full study report (i.e. the published study itself on which the study report is based). In other words, registrants should try to negotiate with the copyright owner a license that will allow them to refer to the published data.

It is important to note that, wherever joint submission of information in accordance with Article 11 or 19 REACH applies, the check of the conditions of use of the published information must take into account the fact that the information will be used not only by the lead registrant, but also by all the other members of the joint submission for the same substance. If any agreement with the copyright owner or its representative is necessary, it should ensure the legitimate use of the published study for all members of a joint submission – including potential future members requiring access to the information. The extension of the rights over the study can be obtained through a "letter of access" or any other form of agreement. The agreement needs to ensure that registrants can demonstrate "legitimate possession" of the relevant information for the purposes of the REACH registration.

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

NB: **Copyright** covers only the form of expression but not the facts and data included in the work. Therefore, facts and data can be included in the dossier without the consent of the copyright owner provided that the text of the study is not copied as such into another registration dossier. In other words, a registrant can use the data to produce its own study summary but it has to make appropriate references and quotations to the original study to acknowledge the source of information. In addition, also in cases where a registrant produces the study summary itself, it must have the right to refer to (or be in legitimate possession of) the full study report for its registration.

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

required by the specific purpose of registration, as this should normally also not infringe copyright.

Copyright is also subject to certain exceptions, which may be applicable. The reproduction right as one of the basic elements of copyright protection, which is relevant in this context, is addressed in Directive 2001/29/EC[71]. The reproduction right is the exclusive right to authorise or prohibit direct or indirect, temporary or permanent reproduction by any means and in any form, in whole or in part for authors, of their works (Article 2(a) of the Directive).

There are several exceptions and limitations (Article 5 of the Directive) that could be considered as relevant for the published study material to be used for REACH purposes (e.g. quotation of a work which has already been lawfully made available to the public for purposes such as review (Article 5(3)(d)), use of a work to ensure the proper performance or reporting of administrative proceedings (Article 5(3)(e)). The appreciation of the situation in a particular Member State would thus require checking the actual transposition of the Directive into national law. Apart from national law, national jurisprudence of the particular country would also be relevant to establish the precise context of such an exception.

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

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

NB: ECHA, on its dissemination website, reminds potential registrants that, pursuant to Article 10 REACH, (robust) study summaries and study summaries made publicly available on ECHA's website may only be used for the purpose of registration where the potential registrant is in legitimate possession of the full study report or has permission to refer to the full study report. Furthermore, "reproduction or further distribution of the information is subject to copyright laws and might require the permission of the owner of that information".

The information disseminated on ECHA's website is not enough on its own to fulfil the REACH data requirements since the potential registrant must ensure the relevance, reliability and quality of the data it submits in its registration.

Data submitted more than 12 years before

In some cases, the right to use or refer to data is granted by law or regulatory authorities. This is the case pursuant to Article 25 REACH, which provides that "any study or robust study summaries of studies submitted in the framework of a registration at least 12 years previously can be used for the purposes of registration under REACH by any other manufacturer or importer." Hence, according to the "12-year rule", it is

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

possible to use to any study and robust study summaries, for registration purposes, without the need to have legitimate possession of them.

It is however important to note that this specific “12-year rule” relates only to study summaries or robust study summaries submitted in the framework of REACH registration. These (robust) study summaries can be freely used for registration purposes. They may not be freely used for other purposes.[72]

[72] A full study report is not needed in the cases specified in Article 10(a) REACH. See footnote 14.

ANNEX 1 Example of data exchange form

DATA EXCHANGE FORM

Name of legal entity		
Contact name		
Contact details		
Identity of substance		
Tonnage of dossier		

Test number	**REACH Annex**	**Column 1 Standard requirement** **Information**	**Rating**	**Data availability**				
			Estimated Klimisch rating	Complete study report (my company is owner)	My company has access to complete study report	Reference to data in open literature	Language of the report	Identity of substance for read–across approach
Physicochemical properties – Tonnages 1-10 tpa and 10-100 tpa								
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						

Test number	REACH Annex	Column 1 Standard requirement Information	Rating	Data availability				
7.5.	VII	Vapour pressure						
7.6.	VII	Surface tension						
7.7.	VII	Water solubility						
7.8.	VII	Partition coefficient n-octanol/water						
7.9.	VII	Flash-point						
7.10.	VII	Flammability						
7.11.	VII	Explosive properties						
7.12.	VII	Self-ignition temperature						
7.13.	VII	Oxidizing properties						
7.14.	VII	Granulometry						
7.14. bis	VII	Dustiness						

Mammalian toxicity – Tonnages 1-10 tpa and 10-100 tpa (at 1-10 tpa, consider also the Annex III requirements)								
8.1.	VII	*In vitro* skin irritation or skin corrosion						
8.1.1.	VIII	*In vivo* skin irritation						
8.2.	VII	*In vitro* eye irritation						
8.2.1.	VIII	*In vivo* eye irritation						

8.3.	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 or *in vitro* micronucleus study						
8.4.3.	VIII	*In vitro* gene mutation study in mammalian cells (if negative result in 8.4.1. and 8.4.2.)						
8.4.	VIII	*In vivo* mutagenicity tests (if positive result in any *in vitro* tests)						
8.5.1.	VII	Acute toxicity by oral route						
8.5.2.	VIII	Acute toxicity by inhalation						
8.5.3.	VIII	Acute toxicity by dermal route						
8.6.1.	VIII	Short-term repeated dose toxicity study (28-day) by the most appropriate route of administration						
8.7.1.	VIII	Screening for reproduction/ developmental toxicity						
8.8.1.	VIII	Assessment of toxicokinetic behaviour (based on relevant and available information)						
Ecotoxicity/Environmental fate – Tonnages 1-10 tpa and 10-100 tpa (at 1-10 tpa, consider also the Annex III requirements)								
9.1.1.	VII	Short-term toxicity testing in invertebrates (*Daphnia* preferred)						
9.1.2.	VII	Growth inhibition study in aquatic plants (*algae* preferred)						

9.1.3.	VIII	Short-term toxicity testing on fish						
9.1.4.	VIII	Activated sludge respiration inhibition testing						
9.2.1.1.	VII	Ready biodegradability						
9.2.2.1.	VIII	Hydrolysis as a function of pH and identification of degradation products						
9.3.1.	VIII	Adsorption/desorption screening study						

Physicochemical properties – Tonnages 100-1000 tpa and > 1000 tpa								
7.15.	IX	Stability in organic solvents and identity of relevant degradation products						
7.16.	IX	Dissociation constant						
7.17.	IX	Viscosity						
Mammalian toxicity – Tonnages 100-1000 tpa and > 1000 tpa								
8.6.2.	IX	Sub-chronic toxicity study (90-day) by the most appropriate route of administration						
8.6.3.	X	Long-term repeated toxicity study (≥ 12 months) (exposure/use driven)						
8.6.4	X	Further studies if a particular concern exists						
8.7.2.	IX	Pre-natal developmental toxicity study, first species (rat preferred)						

8.7.2.	X	Pre-natal developmental toxicity study, second species, rabbits (if rat was first species)						
8.7.3.	IX - X	Extended One-Generation Reproductive Toxicity study						
8.7.3.	IX - X	Two-generation reproduction toxicity study (only accepted if was performed before March 2015)						
8.9.	X	Carcinogenicity study (exposure/use driven)						
		Other studies (to be listed below):						
Ecotoxicity/Environmental fate– Tonnages 100-1000 tpa and > 1000 tpa								
9.1.5.	IX	Long-term toxicity testing in invertebrates (*Daphnia* preferred)						
9.1.6.	IX	Long-term toxicity testing in fish (Fish early-life stage (FELS) toxicity test preferred)						
9.2.1.2.	IX	Simulation testing on ultimate degradation in surface water						
9.2.1.3.	IX	Soil simulation testing						
9.2.1.4.	IX	Sediment simulation testing						
9.2.1.	X	Further biotic degradation testing						
9.2.3.	IX	Identification of degradation products						
9.3.2.	IX	Bioaccumulation in aquatic species (preferably fish)						

9.3.3.	IX	Further information on adsorption/ desorption						
9.3.4.	X	Further information on environmental fate and behaviour						
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						
9.4.6.	X	Long-term toxicity testing on plants						
9.5.1	X	Long-term toxicity to sediment organisms						
9.6.1	X	Long-term or reproductive toxicity to birds						
		Other studies (to be listed below):						
Exposure Data								
		Emissions to water						
		Emissions to soil						
		Emissions to air						
		Occupational exposure in manufacture						
		Occupational exposure in use						

		Consumer exposure End of life						

ANNEX 2 List of reference documents mentioned in the guidance

Reference document mentioned in the Guidance	Relevant sections and topic in the *Guidance on data sharing*
Guidance on Registration (http://echa.europa.eu/guidance-documents/guidance-on-reach)	Several topics. Indicated throughout the text.
Manuals on preparation of REACH and CLP dossiers (http://echa.europa.eu/manuals)	Technical details on how to prepare dossiers for different REACH and CLP purposes.
REACH-IT Q&As (http://echa.europa.eu/support/qas-support/qas)	Several topics. Indicated throughout the text.
Practical guides on data sharing under the BPR (http://echa.europa.eu/practical-guides/bpr-practical-guides)	1.7 – Link to BPR and related guidance
Guidance for identification and naming under REACH and CLP (http://echa.europa.eu/guidance-documents/guidance-on-reach)	2.2.1 – Substance sameness 3.2.1 – Gathering of available information 3.3.1 – Gathering of the available information
Guidance on information requirements and Chemical Safety Assessment (http://echa.europa.eu/guidance-documents/guidance-on-reach; https://echa.europa.eu/regulations/reach/registration/information-requirements)	2.2.2.1 – What needs to be shared for registration purposes? 3.2.2 – Consideration of information requirements 3.3.3 – Consideration of information requirements
Practical advice for data sharing negotiations (http://echa.europa.eu/support/registration/working-together/practical-advice-for-data-sharing-negotiations)	2.2.5 – Conducting data sharing negotiations

Reference document mentioned in the Guidance	Relevant sections and topic in the *Guidance on data sharing*
How to prepare an inquiry dossier (http://echa.europa.eu/manuals)	3.1.3 – Information to be submitted in the inquiry
Practical Guide for SME managers and REACH coordinators (https://www.echa.europa.eu/practical-guides)	3.2.2 – Consideration of information requirements 3.3.3 – Consideration of information requirements
Practical Guide "How to assess whether a substance is used as an intermediate under strictly controlled conditions and how to report the information for the intermediate registration in IUCLID" (https://www.echa.europa.eu/documents/10162/23036412/pg16_intermediate_registration_en.pdf)	3.2.2 – Consideration of information requirements 3.3.3 – Consideration of information requirements
Q&As on Data sharing (http://echa.europa.eu/qa-display/-/qadisplay/5s1R/view/REACH/datasharing)	
Dissemination and confidentiality under the REACH Regulation (https://echa.europa.eu/manuals)	8.5 – Protection of CBI in the submission of the registration dossier

ANNEX 3 Cost itemisation

Itemisation of costs to be shared is a requirement according to Implementing Regulation (EU) 2016/9. This is described in section 5 of this guidance.

The following table provides an example of possible cost items to be considered in a data sharing agreement. It is a non-exhaustive list of examples of budget lines used by co-registrants to itemise their data and administrative costs.

Data costs typically refer to costs of fulfilling the information requirements applicable to the registrant. Administrative costs are defined as those costs resulting from the creation and management of the data sharing agreement and the joint submission of information between registrants of the same substance.

Cost item	Cost item type (related to data/studies or related to administrative work)	Notes
Note: Both data cost and administrative cost are to be shared in relation to the information requirement		
Literature search and data gap analysis (data identification, data purchase, data assessment, etc.)	Data	More or less detail can be retrieved on the cost of each information source and review, quality assessment, and other tasks covered by this item.
Data gap filling strategy (data use or reference rights, testing, read-across and grouping justification, testing proposals, waivers, etc.)	Data	More or less detail can be retrieved on the cost of each information source and data gap filling task covered by this item.
Physico-chemical properties and classification	Data	May include tests, expert judgement, etc.
Toxicological assessment and refinement (e.g. additional testing), including human health hazard assessment and	Data	May include testing or alternative to testing, development of grouping and read-across justifications, expert judgement, etc.

Cost item	Cost item type (related to data/studies or related to administrative work)	Notes
Note: Both data cost and administrative cost are to be shared in relation to the information requirement		
classification		
Ecotoxicological hazard assessment and refinement (e.g. additional testing), including environmental hazard and fate assessment and classification	Data	May include testing or alternative to testing, development of grouping and read-across justifications, expert judgement, etc.
Guidance on safe use, safety data sheets, preparation and review and updates of exposure scenarios for communication	Data	May include experts' time, translation costs, supply chain communication software updates, etc. For registrations 1-10 tpa guidance on safe use is more detailed than for registrations >10 tpa
Performance of the chemical safety assessment and preparation of the Chemical Safety Report.	Data	May include literature searches, monitoring work, modelling work, expert judgement, report preparation, etc. Though the Chemical Safety Report can be generated automatically with a plug-in tool, it often requires considerable manual editions by technical experts. For registrations 1-10 tpa a Chemical Safety Report is not required. For registrations >10 tpa the Chemical Safety Report can be prepared jointly or individually.
IUCLID hosting and completion costs	Data / Administration	May include costs to update dossiers to new version of IUCLID (beyond automatic migration). Some IUCLID hosting tools may be itemised as administrative costs, separately from actual IUCLID completion tasks.

Cost item	Cost item type (related to data/studies or related to administrative work)	Notes
Note: Both data cost and administrative cost are to be shared in relation to the information requirement		
Dossier evaluation costs	Data / Administration	May be listed under either data or administrative costs (depending on the case and specific item). These are considered as future costs at the moment of registration – it is important to agree on a mechanism to share future costs resulting from a potential dossier evaluation decision, but it is not in principle necessary to collect funds upfront, given that the exact amount of such costs is not known yet.
Substance evaluation costs	Data / Administration	May be listed under either data or administrative costs (depending on the case and specific item). These are considered as future costs at the moment of registration – it is required to agree on a mechanism to share potential future costs resulting from a substance evaluation decision, but it is not in principle necessary to collect funds upfront, given that the exact amount of such costs is not known yet.
General dossier update and maintenance costs	Data / Administration	May be listed under either study or administrative costs (depending on the case and specific item)
Personnel cost (e.g. administrative staff, secretariat services, etc.)	Data / Administration	Some experts may be involved in the scientific dossier preparation. Their honoraria would in most cases be included in the study costs.
Monitoring of regulation, guidance, etc. & advocacy	Data / Administration	Ad: via (e.g.) membership to sector associations and/or via separate registration for chemicals management policy development tracking tools. Dt: where advocacy is of technical nature (e.g. toxicological or eco-toxicological effects or exposure issues)

Cost item	Cost item type (related to data/studies or related to administrative work)	Notes
Note: Both data cost and administrative cost are to be shared in relation to the information requirement		
Office and logistics (e.g. IT, phone, utilities, printing, archiving, etc.) costs	Administration	Costs need to be related to joint submission activities and cover the substance subject to registration. Other costs (e.g. consortium costs) must be recorded transparently in order to demonstrate that they are related to the substance registration and should not be generic.
Meeting and travel costs for personnel	Data / Administration	Ad: meetings and travel related to management of joint submission. Dt: meetings and travel related to management of the scientific dossier content (e.g. read-across strategy, testing proposals discussions, etc.) should be in relation to information requirements (e.g. meetings related to preparation of CSR are not relevant for 1-10 tpa registrants or meetings for testing proposals are not relevant for 1-100 tpa registrants).
Communication costs (e.g. SIEF communication tools such as IT platform, surveys, website, regular newsletter, etc.)	Administration	Where a common set of tools is used for different joint submissions, this cost item should be re-allocated back per substance.
Legal costs (e.g. drafting of agreements, trustee role, liability insurance, legal advices and opinions, data sharing agreements with data owners, general legal representation in disputes, appeals, court cases, etc.)	Administration / Data	Where a legal support is needed for a specific technical interpretation of a requirement in REACH, this may be itemised as a data/study cost.
Accountancy costs (e.g.	Administration	

Cost item	Cost item type (related to data/studies or related to administrative work)	Notes
Note: Both data cost and administrative cost are to be shared in relation to the information requirement		
accountant, audit, invoices and credit notes financial/bank charges, VAT and other taxes, regular re-calculations of individual costs, etc.)		
Other joint submission set-up costs (e.g. creation of JSO in REACH-IT, token management)	Administration	Those cost are relatively small in comparison to other registration costs Cost of the creation of joint submission object in REACH-IT can be shared equally, as every registrant benefits from it in the same way. Each co-registrant can pay its own cost of obtaining the token to access joint submission.

ANNEX 4 Guidance on data sharing and BPR

Section		Page	Relevance	
1	**Introduction**			
1.2.4	Key principles for data sharing	17	Partially	Also to be applied under the BPR Regulation
1.4	**Other legal obligations**			
1.4.1	Competition rules	22	Yes	
1.4.2	Confidential business information	22	Yes	
1.4.3	Copyright	22	Yes	
2	**Data sharing principles**			Some aspects may be of relevance
2.2.3	Data sharing agreements	30	Partially	
2.2.5	Conducting data sharing negotiations	36	Yes	
3	**Data sharing before submitting a registration**			
3.1	The inquiry process	39	Partially	
3.1.1	The purpose of the inquiry	39	Partially	Purposes and principles are similar; hence, some aspects may be of relevance. Reference is made to the Inquiry page under the BPR Regulation
3.1.2	Who must inquire?	40	Partially	
3.1.4	Outcomes of the inquiry process	41	Partially	
3.2/ 3.3	Steps to submit a registration dossier	44/ 56	Partially	
3.2.2/ 3.3.3	Consideration of information requirements	47/ 59	Partially	
3.2.3/ 3.3.2	Establishment of the data needs and identification of the data gaps/Evaluation of the information available	48/ 58	Partially	
3.2.4/ 3.3.5	Negotiation on data and cost sharing/Sharing of the cost	50/ 62	Yes	
5	**Cost sharing in practice**			

5.1	Illustrations of the principles of transparency, fairness and non-discrimination	69	Partially	
5.2	Data quality	73	Yes	
5.3	Data valuation	77	Yes	
5.4	Cost allocation and compensation	81	Yes	
5.5	Cost sharing examples	85	Yes	
6	**Forms of Cooperation**	101	Partially	Some aspects may be of relevance
7	**Information sharing under Competition rules**	106	Partially	Some aspects may be of relevance
8	**Confidential business Information (CBI)**	112	Partially	Some aspects may be of relevance
9	**Copyright and other intellectual property rights over data**	116	Partially	Some aspects may be of relevance

European Chemicals Agency
P.O. Box 400
FI-00121 Helsinki, Finland
echa.europa.eu