

Data sharing

The document aims to explain in simple terms the main principles and obligations relating to data sharing and joint submission

Version 2.0
February 2017



LEGAL NOTICE

This document aims to assist users in complying with their obligations under the REACH Regulation. However, users are reminded that the text of the REACH Regulation is the only authentic legal reference and that the information in this document does not constitute legal advice. Usage of the information remains under the sole responsibility of the user. The European Chemicals Agency does not accept any liability with regard to the use that may be made of the information contained in this document.

Reference: ECHA-17-G-02-EN
Cat.Number: ED-01-17-055-EN-N
ISBN: 978-92-9495-733-7
DOI: 10.2823/465792
Publ.date: February 2017
Language: EN

The European Chemicals Agency (ECHA) is producing a series of “simplified” versions of the REACH (CLP) guidance documents in order to make the corresponding REACH (CLP) guidance documents published by the Agency more accessible for industry. As short summaries, these documents cannot contain all details included in the full guidance documents. Thus, in case of doubt, it is recommended to consult the full guidance documents for further information.

© European Chemicals Agency, 2017

If you have questions or comments in relation to this document please send them (indicating the document reference, issue date, chapter and/or page of the document which your comment refers to) using the Guidance feedback form. The Guidance feedback form can be accessed via the “Support” section of the ECHA website at: comments.echa.europa.eu/comments/cms/FeedbackGuidance.aspx.

European Chemicals Agency

Mailing address: P.O. Box 400, FI-00121 Helsinki, Finland
Visiting address: Annankatu 18, Helsinki, Finland

Table of Contents

1. INTRODUCTION	4
2. ESSENTIAL TO UNDERSTAND	5
2.1 Obligations on data sharing	5
2.2 Obligation on joint submission	6
2.3 Data sharing for phase-in and non phase-in substances	6
2.4 Cost sharing	6
2.5 Information sharing and competition rules	8
3. HOW DOES THE DATA SHARING PROCESS FOR PHASE-IN SUBSTANCES WORK?	9
3.1 (Late)pre-registration	9
3.2 SIEF	9
3.3 Data sharing activities	10
3.3.1 Sharing data for registration purposes	13
4. HOW DOES THE DATA SHARING PROCESS FOR NON PHASE-IN SUBSTANCES WORK?	14
4.1 The inquiry	14
4.2 Data sharing following the inquiry	16
5. HOW TO PROCEED IN CASE OF DISAGREEMENT?	16
5.1 Disputes within a SIEF	17
5.1.1 Disputes relating to the performance of testing	17
5.1.2 Disputes before the joint submission has been submitted	17
5.1.3 Disputes after the joint submission has been submitted	18
5.2 Disputes following an inquiry	18
5.3 Preventing data sharing disputes	18
6. THE JOINT SUBMISSION	20
6.1 Information which has to be submitted jointly and information which can be submitted jointly on a voluntary basis	20
6.2 Possible separate submission of information	20
6.3 Post-registration obligations	22
6.4 Disputes concerning access to the joint submission	23
7. WHERE TO FIND FURTHER GUIDANCE?	23

1. Introduction

This Guidance in a Nutshell provides a concise and simple introduction to the data-sharing and related obligations for registrants of phase-in and non-phase-in substances foreseen by Regulation (EC) No 1907/2006 (the REACH Regulation) and further clarified by the Implementing Regulation (EU) 2016/09 on joint submission of data and data-sharing (the Implementing Regulation). It describes in brief the main principles of data sharing, the mechanisms which should be followed to comply with the related requirements and illustrates the main aspects that registrants and other parties should be aware of when they are required or are willing to share data. It furthermore introduces the obligation to jointly submit data for registrants of the same substance.

This Guidance in a Nutshell is aimed at managers and decision-makers of companies producing, importing and/or using chemical substances in the European Economic Area¹ (EEA), particularly those belonging to the Small and Medium sized Enterprises (SME) category. Reading this document will allow them to understand the main elements and purposes of the data sharing obligations and to decide whether they need to read the full *Guidance on data-sharing* or not.

Companies located outside of the EEA whose products are exported to the EEA may use this Guidance in a Nutshell to understand the principles of data sharing and the obligations the companies in the EEA, including the Only Representative they may have appointed, have to fulfill.

¹ The European Economic Area is composed of Iceland, Liechtenstein, Norway and the 28 European union Member States.

2. Essential to understand

2.1 Obligations on data sharing

Data sharing is one of the core principles of the REACH Regulation. Since 1 June 2008 companies manufacturing or importing chemical substances in quantities of 1 tonne or more per year or producing or importing articles containing substances in quantities of 1 tonne or more per year and intended to be released have been required to register such substances under REACH. Furthermore for substances manufactured or imported in quantities of 10 tonnes or more per year a Chemical Safety Assessment must also be submitted. Companies which intend to register the same substance are required to share data on this substance and to submit certain information jointly to increase the efficiency of the registration system, reduce costs and avoid unnecessary testing on vertebrate animals. These obligations apply in particular to technical data and information related to the intrinsic properties of substances.

One of the objectives of REACH is to avoid unnecessary testing, especially on vertebrate animals, while ensuring that sufficient information to identify the hazards and the safe use of chemicals is generated and collected. Animal testing should not be duplicated and should be undertaken only as a last resort. Finally, data-sharing and joint submission aim to reduce the overall registration costs and improve the registration system.

Potential registrants have the obligation to request that studies on the same substance involving vertebrate animals are shared, whereas they have the option to request the sharing of data not involving testing on vertebrate animals or of data generated for structurally similar substances. The data sharing mechanisms aim to ensure that sharing of studies which are already available and their related costs is agreed among potential registrants in a fair, transparent and non-discriminatory way. Data owners are to be compensated for an agreed share of the cost incurred, while in some cases existing data can be freely used for registration purposes (data submitted in the framework of a registration more than 12 years before, as mentioned in section 4.2 of this document and in more details in section 4.6 of the *Guidance on data-sharing* available at echa.europa.eu/guidance-documents/guidance-on-reach). When a specific piece of information is missing, (potential) registrants must agree who will undertake the necessary data generation in order for necessary tests to be carried out only once.

It is important to underline that while it is under industry's responsibility to decide how to best comply with data sharing obligations, the Implementing Regulation requires that a data-sharing agreement is stipulated between the parties registering the same substance. It prescribes also certain elements which have to be included in each agreement. Nevertheless registrants are free to choose and agree on the form of cooperation and the data sharing approach they consider appropriate.

2.2 Obligation on joint submission

Besides these data sharing obligations (mentioned in chapter 2.1 above), registrants of the same substance are required to be part of the same joint registration. REACH introduces the “one substance, one registration” principle, which is further strengthened by the Implementing Regulation. Certain parts of the information required for a registration have to be submitted jointly in a “joint dossier” (as explained in chapter 6 of this Guidance in a Nutshell). REACH specifies the information which has to be submitted together, but requires that some other information has to be submitted individually and some other can be submitted jointly on a voluntary basis. REACH also introduces the concept of the “lead registrant” who is appointed by the registrants of the same substance to submit on their behalf the joint dossier containing the information which needs to be submitted jointly.

2.3 Data sharing for phase-in and non phase-in substances

The data sharing principles apply to both “existing” (so-called “phase-in”) substances and “new” (so-called “non-phase-in”) substances² and the obligations are the same. However the REACH Regulation sets out different mechanisms in order to bring into contact registrants of phase-in and registrants of non-phase-in substances. Registrants of phase-in substances which have been successfully pre-registered or late pre-registered³ benefit or have benefited from extended registration deadlines while for all the other substances (non-phase-in substances and phase-in substances not (late)pre-registered) registration is required before the 1 tonne threshold is reached. In the first case potential registrants discuss the substance identity and data sharing in a so-called Substance Information Exchange Forum (SIEF). In the second case the potential registrants are required to follow the inquiry process preceding the sharing of data, where ECHA puts them into contact with previous and potential registrants of the same substance (regardless the phase-in or non phase-in status). These two scenarios are described in chapters 3 and 4 respectively of this Guidance in a Nutshell.

2.4 Cost sharing

The generation and collection of data required for registration under REACH imply costs for the registrants. REACH requires that parties sharing data on the same substance must make “every effort to ensure that the costs of sharing the information are determined in a fair, transparent and non-discriminatory way”. Data owners and registrants who need information should enter into discussions in order to agree on the nature of the data they are going to share and on the cost sharing approach. REACH does not require companies to have ownership of the data and studies they need to fulfill the registration requirements. They must have legitimate possession or the right to refer to them from the owner(s) (more details on this are provided in chapter 3.3 of the parent *Guidance on data-sharing* available at echa.europa.eu/guidance-documents/guidance-on-reach).

As suggested in the parent *Guidance on data-sharing*, the above requires parties to discuss and reach an agreement on the following aspects.

² Phase-in substances are substances which are listed in EINECS, or substances that have been manufactured in the EU (including accession countries on 1 May 2004, on 1 January 2007 or on 1 July 2013) but have not been placed on the EU market after 1 June 1992, or so-called “no-longer polymers”. Non phase-in substances are those not meeting any of these three criteria (described in Article 3 (20) of the REACH Regulation).

For more details on the phase-in or non-phase-in status of the substances, please consult the *Guidance on registration* available in the “Support” section of the ECHA website at echa.europa.eu/guidance-documents/guidance-on-reach.

³ Please note that the pre-registration step ended on 1 December 2008. Late-preregistration is still possible for those who intend to register in the lowest tonnage band and only before 1 June 2017. More information on late pre-registration are provided in section 3 of this document but the registrant is advised to consult the *Guidance on registration* and the dedicated section of the ECHA website at www.echa.europa.eu/web/guest/support/dossier-submission-tools/reach-it/pre-registration for more details.

- The quality of the available data: this should be scientifically established, following internationally recognised guidance (e.g. OECD guidance).
- The economic value of the data: studies should be accurately and transparently valued, taking into account their scientific quality as a starting point; several correcting factors may increase or reduce this value and these should be considered on a case by case basis (e.g. deviation from standard protocols may reduce the value of a study for data sharing purposes).
- The approach to define the cost allocation and compensation between parties involved; Potential registrants need to agree on a cost sharing model which is fair, transparent and non-discriminatory.

All these elements are to be addressed in a framework of fairness, transparency and non-discrimination.

With the entry into force of the Implementing Regulation a data-sharing agreement became a mandatory element to be agreed among co-registrants. The Implementing Regulation does not prescribe the form for such an agreement and leaves it up to the contractual freedom of the parties. Nevertheless the following elements must be included:

- a) itemisation of the data to be shared and their costs;
- b) itemisation and justification of the administrative costs;
- c) a cost-sharing model, which must include a reimbursement mechanism and consider possible future costs to be shared.

The *Guidance on data-sharing* provides more details, suggestions and examples on possible cost sharing approaches. It provides examples which are intended to help interested parties to identify the relevant factors to be considered when organising a data quality review and related cost sharing activities. Aspects linked to the management of a SIEF and communication activities are only some of the activities which may trigger costs. Relevant costs to be shared are either related to data or to administrative work. These should all be itemised and detailed in a data-sharing agreement. Annex 3 of the parent Guidance provides a non-exhaustive list of possible cost items to be potentially considered.

Costs may be generated to pay to perform a study, acquire access to data owned by third parties, monitor performance or fulfil an information requirement with alternative methods. All these are examples of costs related to data.

Administrative work and communication necessary for the management of the SIEF, for the preparation and submission of the joint submission and for the creation of the joint chemical safety assessment may also give rise to costs which, although they are not directly linked to information requirements, have to be shared among the joint registrants.

Different models and formats are provided by industry associations and are available on the internet. Nevertheless (potential) registrants are free to organise themselves as best suits them and to agree on the most appropriate cost sharing method.

Costs included in the data-sharing agreement and to be shared need to be proven and justified. In case of difficulties in retrieving such a justification (when, for example, the costs were generated before the entry into force of the Implementing Regulation), it is required that the parties make every effort to collate proof of such past costs.

It is to be noted that the Implementing Regulation entered into force at a stage when many SIEFs and data-sharing agreements had already been established. The parent Guidance

explains the possibility foreseen by the Implementing Regulation to unanimously waive some of the obligations for which an agreement is already in place.

Registrants cannot be forced to pay for studies that they do not need or for administrative costs not related to their information requirements and obligations. They also cannot be forced to pay before they actually need the data. This becomes relevant especially where some registrants of pre-registered phase-in substances submit their registrations later than the other registrants because of their respective tonnage band.

2.5 Information sharing and competition rules

The REACH Regulation requires the sharing of data and exchange of information between companies at different stages of its implementation. In particular the SIEFs are aimed to help the exchange of information on a substance. Significant flows of information between potential registrants may also occur following the inquiry process. Furthermore, data on the substance and its uses may also be exchanged between downstream users and their suppliers in order to facilitate the registration of the substance.

In this context it is important that actors make sure that their exchange of information does not go beyond what is required under REACH. In particular they have to act in a way that is not contrary to EU Competition law⁴, whose objective is to protect competition on the market as a means of enhancing consumer welfare. Companies while complying with REACH must avoid illegal activities (e.g. create cartels) and take precautionary measures whenever they need to exchange sensitive information to prevent infringement of EU Competition law. The *Guidance on data-sharing* provides more information on this issue in its section 7.

⁴ Besides consulting section 7 of the *Guidance on data-sharing*, please refer to the Commission Directorate General Competition's web site ec.europa.eu/competition/index_en.html.

3. How does the data sharing process for phase-in substances work?

3.1 (Late)pre-registration

Companies which need to register a phase-in substance in the lower tonnage band (i.e. 1 to 100 tonnes) and which is not a CMR can still benefit from an extended registration deadline. In order to be entitled to do so, companies are required to “late pre-register” the phase-in substance concerned not more than 6 months after manufacturing or importing exceeds 1 tonne per year and before 1 June 2017⁵. Without (late)pre-registration, phase-in substances have to be registered before they are manufactured in or imported into the EU in an amount of one tonne(s) or more per year.

As was the case for pre-registration, late pre-registration is also not mandatory. Registrants may decide to register a substance prior to commencing manufacture or import in a quantity equal to, or above, 1 tonne per year. Companies should be aware that after 1 June 2008 all manufacturing, placing on the market and use of a substance not registered, pre-registered or late pre-registered is illegal. If this obligation is breached the whole supply chain is at risk.

3.2 SIEF

REACH foresees that all manufacturers and importers who have pre-registered the same phase-in substance are part of the same Substance Information Exchange Forum (SIEF). A SIEF is established when all the companies who have pre-registered or late pre-registered a substance with the same identifiers have entered into discussions and agreed that their substance is actually the same. The REACH IT system has provided a dedicated platform called “pre-SIEF”. This is a concept not foreseen by the REACH Regulation but introduced with the aim to facilitate the discussion between potential registrants and to help them to decide whether their substance can be regarded as the same⁶.

There is only one SIEF for each phase-in substance. The main aim of a SIEF is to facilitate the exchange of information between potential registrants for the purposes of registration and hence avoid unnecessary duplication of studies and agree on the classification and labelling of the substance where there is a difference between that proposed by different registrants.

It may be the case that a manufacturer or importer considers the information to be exchanged for data sharing purposes to be sensitive. He may also not want to disclose his identity to the other registrants. In this case he has the option to appoint a Third Party Representative to carry out data sharing tasks on his behalf.

The members of a SIEF have to react to requests by others for information and work collectively to identify and carry out additional studies in case they are necessary. Potential registrants must request missing data related to vertebrate animal testing from other SIEF participants and may decide to also request other non-vertebrate animal data. This means that SIEF participants, if requested, have to provide other participants with existing studies both on

⁵ Note the period for pre-registration was from 1 June to 1 December 2008. For more information and background information on the extended registration deadlines and the conditions under which these may still apply, please consult the *Guidance on registration* available on the “Support” section of the ECHA web site at echa.europa.eu/guidance-documents/guidance-on-reach.

⁶ The main criteria which should be followed when deciding on the sameness of the substances are those laid down in the *Guidance for identification and naming under REACH and CLP* which is available in the “Support” section of the ECHA web site at echa.europa.eu/guidance-documents/guidance-on-reach.

vertebrate animals and non-vertebrate animals.

As suggested in the *Guidance on data-sharing*, participants in a SIEF should agree on its functioning and may possibly define the details in a SIEF agreement. Companies are free to choose the form and the clauses to be included but the rules, the participation process, the data sharing and cost sharing mechanisms (and other aspects which may be considered on a case by case basis) should be clearly defined. The members of a SIEF are in fact completely free to choose how to organise their cooperation under REACH. The forms of cooperation can vary from a simple structure to more structured and complex organisations (e.g. legally established consortia). Whatever form of cooperation is chosen, companies have the obligation to include in the agreements the elements as requested by the Implementing Regulation (see chapter 2.4 of this Guidance in a Nutshell).

ECHA does not participate in SIEF discussions and does not confirm or disallow the creation of a SIEF or a particular form of cooperation. Nevertheless support and useful information (e.g. examples of cooperation and SIEF management) are provided in the *Guidance on data-sharing* (in particular its section 8) and other documents available on the ECHA website at echa.europa.eu/web/guest/regulations/reach/substance-registration/substance-information-exchange-fora.

REACH gives the possibility to any entity which may not need to register, but holds relevant information on a phase-in substance and is willing to share it, to become a participant in the SIEF for that substance. These entities are identified as “data holders”⁷. On request, they must provide potential registrants (members of the SIEF) with relevant data and request cost sharing for the information supplied. ECHA invites data holders to notify their willingness to join a SIEF to ECHA with a view to share data in order to facilitate the process and help potential registrants to meet their information requirements. Downstream users in particular may have valuable data on safety, including hazards, uses, exposure and risks.

Each SIEF will be operational at least until 1 June 2018, which coincides with the last registration deadline for phase-in substances. However data sharing activities may need to continue after that date following substance or dossier evaluation. Furthermore, new registrants may need to use the already submitted information for registration purposes even after 1 June 2018.

3.3 Data sharing activities

REACH requires manufacturers and importers to collect data on their substance and to use it to prepare the registration dossier and to assess the risks related to this substance and to develop appropriate risk management measures. Whenever necessary data are missing, SIEF participants are required to inquire whether a relevant study is available within the SIEF. This is mandatory for studies involving tests on vertebrate animals and it is possible for other data.

Potential registrants have the task to undertake data sharing activities which can involve the review of all available data, identification of data needs and generation of new information. All these activities will normally require cooperation between parties and companies are free to organise themselves for the benefit of all.

The *Guidance on data-sharing* illustrates how data sharing can be organised collectively within a SIEF with the view to meet the obligations described above. Chapter 3 of the *Guidance on data-sharing* proposes the following stepwise approach.

1. Each potential registrant should collect and document all available in-house information on

⁷ More information on who can be a data holder and this role within the SIEF is provided in section 3.2 of the *Guidance on data-sharing*.

the substance.

2. Potential registrants should discuss and agree on the main elements of information gathering, identification of data requirements, generation of missing studies and sharing of related costs.

3. The participants in a SIEF should create an inventory of all information available within the SIEF.

4. The data should be evaluated; this step could be undertaken by the lead registrant or by any potential registrant or an appointed third party.

5. Each potential registrant should identify precisely what information he needs, considering in particular the tonnage band.

6. Data gaps should be identified with the view to first verify whether the missing data are available within the SIEF and considering data holders and possibly relevant data outside the SIEF.

7. Missing information should be generated, when possible, by using alternative methods (e.g. (Q)SARs, weight of evidence or grouping approaches). When there is no alternative, potential registrants are required to either generate new studies or, in case Annexes IX and/or X apply, prepare testing proposals⁸.

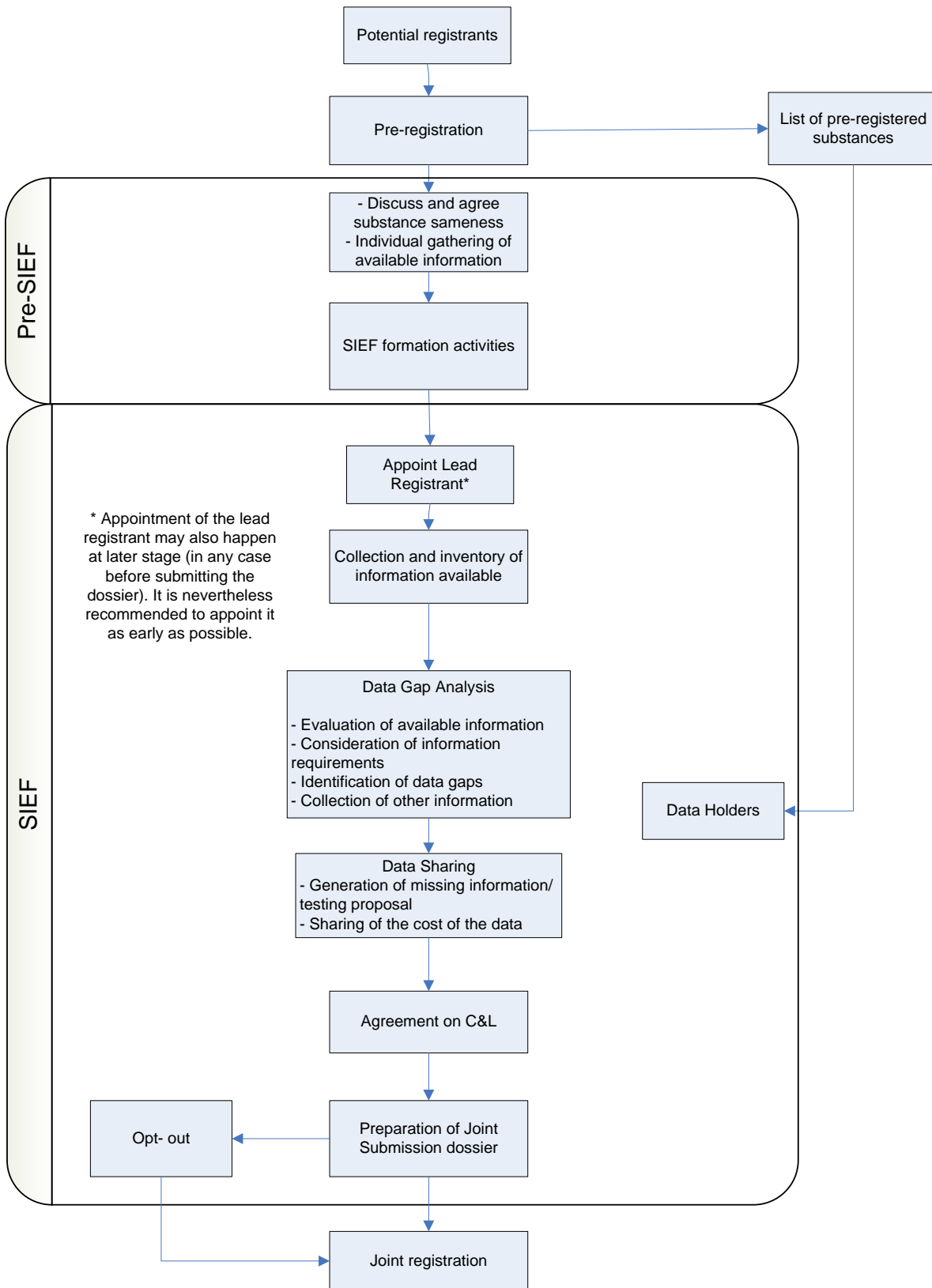
8. The SIEF needs to internally organise the actual exchange of data and fair, transparent and non-discriminatory compensation so that each potential registrant is able to register on time ahead of his registration deadline.

9. Following data sharing, the information that must be submitted jointly is documented in the technical dossier which will then be submitted by a lead registrant chosen by the registrants (see Chapter 6 of this Guidance in a Nutshell for more information on the joint submission obligation).

SIEFs have already been established for most substances that require registration and a joint registration may already exist. Subsequent registrants and existing registrants are also obliged to share the relevant data and their costs. To this end subsequent registrants must contact the existing registrants and negotiate data sharing and the conditions for joining the joint submission. Potential and existing registrants must make every effort to reach an agreement on sharing the information and its costs in a fair, transparent and non-discriminatory way. It should be noted that in this case some of the steps described above may be omitted (e.g. steps 6 and 7).

⁸ In case a study as listed in Annex IX and X is needed for registration and is not available within a SIEF, a testing proposal has to be submitted as part of the joint registration dossier.

Figure 1: Overview of the data sharing process for phase-in substances



3.3.1 Sharing data for registration purposes

Parties should enter into discussion as early as possible in order to agree on details and conditions on the sharing of data and of related costs. The *Guidance on data-sharing* outlines the main aspects which should be considered and defined while working to reach an agreement on sharing data. The nature of the data to be submitted and/or made accessible for registration should be considered, given that this can be available as full study report, (robust) study summary or study results⁹.

Each registrant is required to be in legitimate possession of, or have the right to refer to, the full study report related to a specific study for the purpose of registration. The *Guidance on data-sharing* explains in more detail these concepts and advises the parties involved to carefully consider them on a case-by-case basis. It is fully under each registrant's responsibility to comply with these rules and to make sure that copyrights are not infringed and data and costs are shared in a fair, transparent and non-discriminatory way. This normally requires an agreement between the parties, even if in some cases the right to refer to certain data can be granted by law. The latter is the case for studies submitted in the framework of a registration at least 12 years previously which can be freely used under REACH for registration purposes (ECHA will facilitate this following an inquiry process as explained in section 4 of this Guidance in a Nutshell and in more detail in the *Guidance on data-sharing*).

⁹ More information on these concepts and their definitions are available in the full *Guidance on data-sharing* (chapter 3.3.3.8) available at echa.europa.eu/guidance-documents/guidance-on-reach and in the ECHA-Term data base available at echa.cdt.europa.eu/SearchByQueryLoad.do;jsessionid=1EABFF357D767E945B028D58AD33CCB3?method=load.

4. How does the data sharing process for non phase-in substances work?

4.1 The inquiry

Inquiry is the process by which potential registrants of non-phase-in substances or phase-in substances which have not been (late)pre-registered must inquire from ECHA whether a registration for the same substance has already been submitted. This is to ensure that data can be shared by the relevant parties (regardless whether they are SIEF participants or inquirers). For these substances an inquiry must always be submitted before proceeding with the registration.

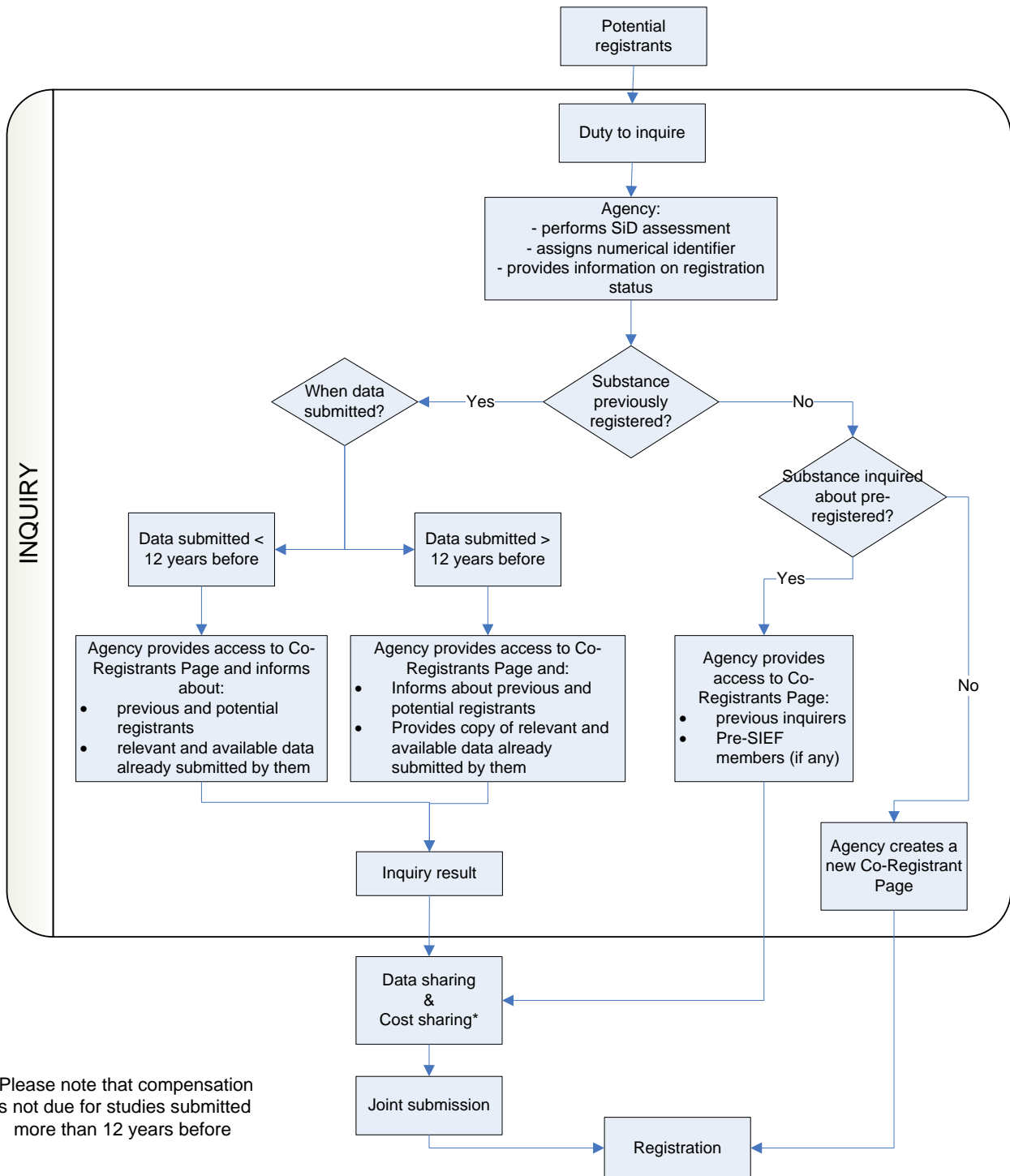
By submitting an inquiry companies have to inform ECHA of their information needs so that the available data can be shared among the registrants of the same substance.

The purpose of the inquiry process is twofold:

- determine whether the same substance has previously been registered or inquired about;
- facilitate the contact between previous registrants and potential registrants.

It is very important when filing an inquiry to provide enough information to allow a precise substance identification. The inquirer is advised to carefully follow the *Guidance on substance identification and naming under REACH and CLP* available at echa.europa.eu/web/guest/guidance-documents/guidance-on-reach.

Figure 2: General overview of the inquiry process



4.2 Data sharing following the inquiry

Following an inquiry the potential registrant(s) will receive a communication from ECHA on whether the substance has already been registered or notified under the previous Dangerous Substance Directive¹⁰. ECHA will inform the inquirer of the contact details of the existing registrant(s) of the same substance, notifier(s) or other potential registrant(s) (inquirers or pre-registrants), if any, as well as details of the requested data if available. According to REACH, data submitted at least 12 years previously can be freely used for registration purposes by subsequent registrants. If the relevant data have been submitted less than 12 years previously they are subject to compensation; ECHA will provide the inquirer with the details of the data owner inviting the parties to make every effort to reach an agreement for sharing the information.

In parallel ECHA will also inform all the existing registrants and previous inquirers of the contact details of the new inquirer. The latter will need to contact them to join the joint submission (see chapter 6 of this document for more information on the joint submission obligation).

The contacts are facilitated by ECHA by means of the Co-Registrants Page platform in REACH-IT. Here the parties are listed with their contact details and regulatory status (previous or potential registrants).

ECHA suggests organising the data-sharing following a similar stepwise process as for phase-in substances. When there is already an existing registration for the substance, inquirers need to agree with existing registrants that the data already submitted is also relevant for their substance. Once a request to join the joint submission (if exists) and share data submitted less than 12 years previously has been made, both potential and existing registrants have to make an effort to:

- ensure an agreement on the sharing of the necessary information;
- ensure the costs are shared in a fair, transparent and non-discriminatory way.

In case there are no existing registrants and the inquirer has proceeded to register individually, he will need to update his registration dossier when another potential registrant decides to register the same substance. They will need to identify a Lead Registrant and create a Joint Submission dossier.

If a SIEF exists for the same substance, the inquirer will be put in contact with the SIEF members. Even if he will not be part of the SIEF, he is required to share the data and the relevant costs and be part of the joint submission.

5. How to proceed in case of disagreement?

REACH requires registrants and potential registrants to make every effort to ensure that the costs of sharing the information required for registration are determined in a fair, transparent and non-discriminatory way. This obligation applies to any information requested whether it concerns data involving testing on vertebrate animals or other data not involving testing on vertebrate animals. Despite the efforts made, companies may fail to find an agreement on the modality or conditions of data sharing. This could happen when deciding who will be responsible for carrying out a necessary new study or under which conditions to share existing information (e.g. the costs) or to access the joint submission. In accordance with REACH,

¹⁰ Directive 67/548/EC on classification, labelling and packaging of dangerous substances.

ECHA has set up procedures to assist in the resolution of data sharing disputes for both phase-in and non phase-in substances where registrants do not reach an agreement on sharing information as well as disputes regarding the access to the joint submission.

It is important to underline that ECHA will not assess whether the claim (cost or condition under which sharing is proposed) is justified or whether a study is needed or not. ECHA will perform an assessment of whether parties have made every effort to share the information or who shall perform the necessary testing or to agree on the conditions for access to the joint submission (e.g. not to reply to arguments).

The data sharing and joint submission dispute procedures can only be initiated as a last resort, i.e. only after all the possible efforts and arguments have been exhausted and negotiations have failed. Furthermore, ECHA encourages parties to continue to also make every effort to reach an agreement even while the dispute procedure is ongoing and inform ECHA as soon as an acceptable solution is found.

5.1 Disputes within a SIEF

Potential registrants within a SIEF need to enter into discussions and gather and assess all the available data on the same substance. They also need to ensure that the costs of these data are shared in a fair, transparent and non-discriminatory way.

REACH indicates that if a study involving vertebrate animals is required, SIEF members have to ascertain whether it is already available within the SIEF by requesting it within the SIEF. In case of studies not involving vertebrate animals, the member may inquire as to whether it is available within the SIEF or not. In any case, when a request is made, the owner of the study is obliged to make it available to the other registrants, subject to cost sharing.

5.1.1 Disputes relating to the performance of testing

In case a new study (whether or not involving vertebrate animals) is needed for registration and is not available within the SIEF, the members of this SIEF have to agree on who will conduct the study. All participants needing the study are required to participate and share the cost but they may fail to reach an agreement. In this case ECHA will support the companies by deciding who will perform the study on behalf of the others following objective criteria. One potential registrant can inform ECHA and provide all necessary information by using a dedicated web form available on the ECHA web site¹¹. Based on this information and on information received from the other potential registrants, ECHA will select one of the potential registrants who will perform the study and will put it at other members' disposal once they have paid their share of the costs.

5.1.2 Disputes before the joint submission has been submitted

When a study **on vertebrate animals**, which is necessary for the preparation of the joint dossier, is already available within the SIEF a dispute can arise **before the joint registration has been submitted** if, despite all the efforts to reach an agreement, the owner refuses to provide proof of costs incurred for the study(ies). This type of dispute can involve several SIEF participants simultaneously who can be represented by one of them. In this case they should be able to demonstrate that each of them has made every effort to share the requested data. ECHA can help in resolving such disputes if the parties inform the Agency via a dedicated web form. The potential registrants will need to provide ECHA with all the documentary evidence demonstrating the efforts made by all the parties to reach an agreement in order to allow the

¹¹ More information and webforms are available in the dedicated section on “Disputes in practice” of the ECHA website at <https://echa.europa.eu/support/registration/working-together/data-sharing-disputes/data-sharing-disputes-in-practice>.

Agency to make an informed and balanced assessment of such efforts. ECHA can ultimately grant a potential registrant the permission to proceed without fulfilling the relevant information requirements in case he has made every effort to reach an agreement and the data owner has not. In this case the data owner can be barred from proceeding with his own registration.

In case a dispute is lodged with ECHA, if there is no registration submitted yet for the substance, the potential registrant(s) must obtain a decision from the Agency before submitting the registration unless an agreement is reached or he/they has/have obtained the relevant study from another source.

5.1.3 Disputes after the joint submission has been submitted

Within a SIEF, disputes may also arise **after a registration has been submitted** when subsequent registrant(s) need studies involving tests on **vertebrate animals**. If the parties fail to reach an agreement despite all their efforts, ECHA can be approached via a dedicated web form by submitting relevant documentary evidence of the efforts made by all parties. ECHA can decide to grant permission to refer to these studies contained in the already submitted dossier. The decision will be based on a balanced assessment of whether the parties have made every effort to reach an agreement on data sharing in a fair, transparent and non-discriminatory way.

It is important to underline that in case a dispute concerns existing studies not involving vertebrate animals and a solution cannot be found, the registrants can proceed as if no such studies were available and cannot avail of ECHA's settlement mechanism for data sharing disputes.

All potential and existing registrants are encouraged to continue negotiating the sharing of data and costs after the submission of a dispute claim. If they find an agreement, they should inform ECHA thereof. ECHA assessment will only be performed on the basis of the information provided at the time of the submission of the compliant.

5.2 Disputes following an inquiry

Following an inquiry and after a potential registrant has requested data which are subject to compensation (i.e. submitted by another registrant less than 12 years earlier) both the potential registrant and the data owner must make every effort to reach an agreement on the sharing of data and related costs. In case of a failure to reach an agreement despite all the efforts made by both parties the potential registrant can inform ECHA via a dedicated webform and by submitting all relevant documentation of the efforts.

ECHA will assess whether the previous registrant and the potential registrant have met their obligations to make every effort to share the data in a fair, transparent and non-discriminatory way. If ECHA establishes that he has made every effort to reach an agreement, whereas the existing registrant has not, the potential registrant may receive permission from ECHA to refer to the data, on the condition that he provides proof of payment of a share of costs.

5.3 Preventing data sharing disputes

REACH clearly states that registrants and potential registrants have the obligation to make every effort to reach an agreement on the sharing of data and costs. This applies to both phase-in and non phase-in substances.

The dispute resolution processes described above should only be initiated as a very last resort. All parties are encouraged to prevent such disputes through cooperation and an open and proactive communication. Companies should act in a timely manner, be clear and allow

reasonable time to act to the other parties. Making every effort requires everyone involved to find alternative solutions when necessary and suggest approaches which are justified and not discriminatory. In particular previous registrants must ensure that potential registrants are required to share only the costs of information that they are required to submit for their registration requirements. This applies also to administrative costs.

All the costs subject to data-sharing must be itemised and justified. Any cost sharing mechanism should have also to be justified and include a reimbursement mechanism.

This will normally result in a more efficient registration process, where financial and time costs are reduced and the quality of the resulting dossier increases.

A dedicated web page on the ECHA website provides practical advices for companies who are undergoing data-sharing negotiations¹².

Companies involved in data sharing disputes should bear in mind that parties in breach of the obligation to make every effort to reach an agreement on sharing data may be subject to sanctioning by the enforcement authorities of the Member State where they are established.

¹² <https://echa.europa.eu/support/registration/working-together/practical-advice-for-data-sharing-negotiations>.

6. The joint submission

Each potential registrant is individually obliged to submit a registration for each substance for which he is responsible. In cases where the same substance is manufactured or imported by more than one company, the registrants are required to register this substance jointly. They are required to submit certain information together in a so-called joint submission which will be submitted by the designated lead registrant. The lead registrant will act with the agreement of the other assenting registrants. There must be only one joint submission for each substance ("one substance=one registration" principle).

Nonetheless information on the identity of the registrant, on the identity of the substance, on the manufacture and use and, in some cases exposure information, will need to be submitted individually by each registrant. This company-specific information can only be submitted after the lead registrant has made the joint submission.

The requirement to make a joint submission applies to both phase-in and non-phase-in substances and regardless of whether the substance has been pre-registered by all, some or none of the registrants. Also an early registrant, who was originally the only registrant of the substance and therefore submitted an individual registration, must be part of the joint submission once there are several registrants of the same substance.

The joint submission obligation is essential in order to increase the efficiency of the registration process to reduce the costs for registrants and to avoid unnecessary animal testing.

6.1 Information which has to be submitted jointly and information which can be submitted jointly on a voluntary basis

Registrants are required to jointly submit information on the intrinsic properties of the substance (studies and testing proposals, if any) and on its classification and labelling. This information is submitted by the lead registrant on behalf of the other registrants. From a practical point of view it is important to underline that the joint dossier needs to be submitted by the lead registrant before the other registrants submit the individual parts of the registration dossier.

The registrants can decide to also jointly submit as part of the lead dossier the guidance on safe use of the substance, which needs to be consistent with the information provided in the safety data sheet (where this is required), and the Chemical Safety Report (CSR). The CSR documents the Chemical Safety Assessment performed where one is required. In particular it is important for registrants to consider working together for the development of the risk assessment and the exposure scenarios which are important elements of the CSR. This should help the process to be more cost efficient and to ensure consistency in performing the Chemical Safety Assessment.

6.2 Possible separate submission of information

Although the REACH Regulation requires the joint submission of certain data, under specific conditions registrants may have a justification for submitting separately part of or all this common information (opt-out). REACH provides for three situations where an opt-out may be justified.

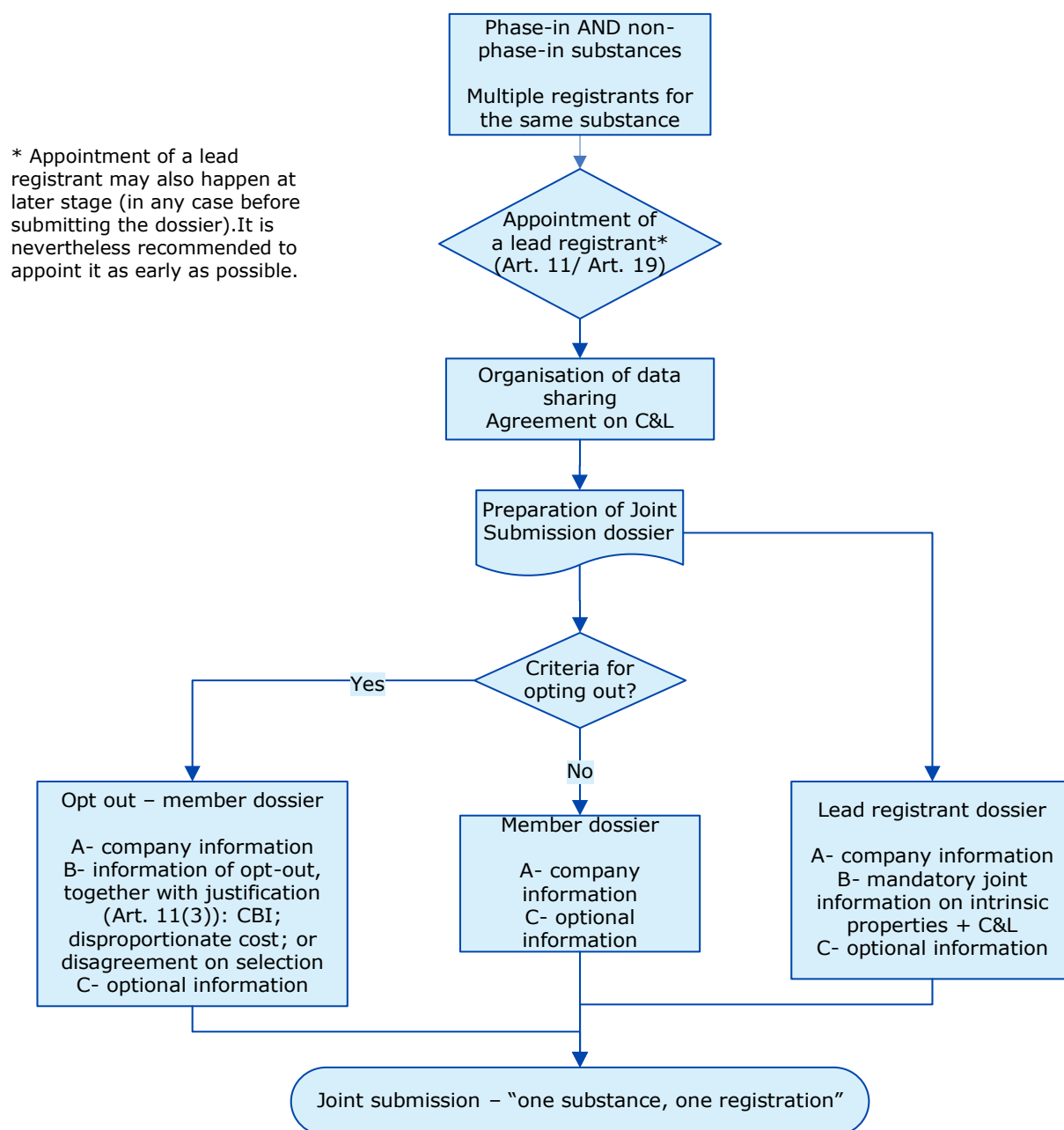
- a) It would be disproportionately costly for the registrant to submit this information jointly. This may be the case when e.g. the registrant has already in his possession a set of data for the substance or the cost sharing formula adopted by the SIEF is particularly

disadvantageous.

- b) Submitting certain information jointly would lead to the disclosure of information he considers commercially sensitive and this would cause commercial loss. This can be the case when, e.g. sharing of such information may lead to the disclosure of manufacturing methods or marketing plans.
- c) He disagrees with the lead registrant on the selection of certain information for reasons which can be based on relevance or quality of such data.

The separate submission of information can be related to specific endpoints of the joint submission and a justification must be given for each endpoint submitted separately. A potential registrant may also decide to submit separately all the information which must be submitted jointly. In any case the registrant still has to be part of the joint submission and retains certain obligations resulting from the joint submission (e.g. sharing of administrative costs) and to share data which may be requested from him. In case of an opt-out the registrant will not benefit from the reduced registration fees granted to the members of the joint submission and in addition its dossier will be prioritised by ECHA in the context of the dossier evaluation (compliance check).

Figure 4: Overview of the process of the joint submission of data



6.3 Post-registration obligations

It is important to note that registrants' data-sharing obligations do not stop once the joint registration dossier is submitted. The data-sharing process continues beyond the data of submission as new registrants may join at any time and the dossier may need to be updated as new information becomes available. In particular the evaluation processes (evaluation of the dossier or of the substance) may trigger new requirements which would need to be addressed among relevant co-registrants and may generate costs to be shared.

6.4 Disputes concerning access to the joint submission

All co-registrants are obliged to make every effort to reach an agreement on the joint submission. This applies also in case a potential registrant has decided to submit separately part of all the information. In case of failure to agree on the conditions of the joint submission, the potential registrants may lodge a dispute claim to ECHA requesting to be granted the access to the joint submission.

7. Where to find further guidance?

This Guidance in a Nutshell should provide you with a summary and short explanation of the data-sharing principles and related obligations under Title III of the REACH Regulation. However it is recommended to consider whether you need to consult the *Guidance on data-sharing* in case you may need to meet data sharing requirements. This is available at <https://echa.europa.eu/guidance-documents/guidance-on-reach>.

The *Guidance on data-sharing* provides more detailed examples and explanations of the concepts and procedures introduced by the present document. Additional insight may also be gained by consulting in particular the following documents and web pages:

- *Guidance on registration* (in particular section 2.3 on the status of the substance, section 3.3 on joint submission and section 4.2 on pre-registration) at <https://echa.europa.eu/guidance-documents/guidance-on-reach>.
- ECHA web page on data sharing (providing subsections dedicated to specific topic and other useful support material) at <https://echa.europa.eu/regulations/reach/registration/data-sharing>.
- ECHA web page on joint submission (providing more information on the joint submission process and obligations) at <https://echa.europa.eu/regulations/reach/registration/data-sharing/joint-submission-of-data>.
- ECHA web page on working together with co-registrants at <https://echa.europa.eu/support/registration/working-together>. Specific subsection provides more information and advice on:
 - o Practical advice for new SIEFs (<https://echa.europa.eu/support/registration/working-together/practical-advice-for-new-siefs>);
 - o Joining an existing registration: practical advice for data-sharing negotiations (<https://echa.europa.eu/support/registration/working-together/practical-advice-for-data-sharing-negotiations>);
 - o Data-sharing disputes in practice (where the links to the forms to initiate a dispute are provided) (<https://echa.europa.eu/support/registration/working-together/data-sharing-disputes/data-sharing-disputes-in-practice>).
- ECHA REACH 2018 web page (<https://echa.europa.eu/reach-2018>) which contains key information to support the preparation for the 2018 registration deadline.

EUROPEAN CHEMICALS AGENCY
ANNANKATU 18, P.O. BOX 400,
FI-00121 HELSINKI, FINLAND
ECHA.EUROPA.EU