ECHA
EUROPEAN CHEMICALS AGENCY

GUIDANCE IN A NUTSHELL

# Data sharing

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

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**European Chemicals Agency**

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

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# 1. Introduction

This Guidance in a Nutshell provides a concise and simple introduction to the data sharing obligations foreseen by Regulation (EC) No 1907/2006 (the REACH Regulation) for registrants of phase-in and non-phase-in substances. 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 Area[1] (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 27 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 relased 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 unneccesary 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 unneccesary 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.

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. 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 it is under industry's responsibility to decide how to best comply with data sharing obligations. ECHA has set up procedures and provides guidance to assist registrants. 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, registrants of the same substance are required to ensure that certain parts of the information required for a registration is submitted jointly. REACH specifies that some of the information has to be submitted together, some has to be submitted individually and some other information can be submitted jointly on a voluntary basis. REACH introduces the concept of the "lead registrant" who is appointed by the registrants of the same substance to submit on their behalf the dossier (the "joint dossier", as explained in chapter 6 of this Guidance in a Nutshell) 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") substances[2] 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 succesfully pre-registered or late pre-registered[3] will benefit 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 preceeding the sharing of data, where ECHA puts them into contact with previous and potential registrants of the same substance. These two scenarios are described respectively in chapters 3 and 4 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:

- the quality of the available data: this should be scientifically established, following internationally recognised guidance (e.g. OECD guidance).

[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 and 1 January 2007) 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] More information on late pre-registration are provided in section 3 of this document but the registrant is advised to consult the Gudiance 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 dedtails.

- 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 addreseed in a framework of fairness, transparency and non-discrimination.

The Guidance on data sharing provides more details, suggestions and examples on possible cost sharing approaches. It provides an example of a "checklist" which intends 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. These should be detailed in a data sharing agreement. Different models and formats are provided by Industry associations and are available on the Internet. Nevertheless (potential) registrants are free to organise themselves as it best suits them and to agree on the most appropriate cost sharing method.

Registrants cannot be forced to pay for studies that they do not need. 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.

Administrative work and communication necessary for the preparation and the submission of the joint submission and the creation of the joint chemical safety assessment may also give rise to costs which, although they are not data sharing costs, should be shared among the joint registrants.

## 2.5 Information sharing and competiton 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 law[4], 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.

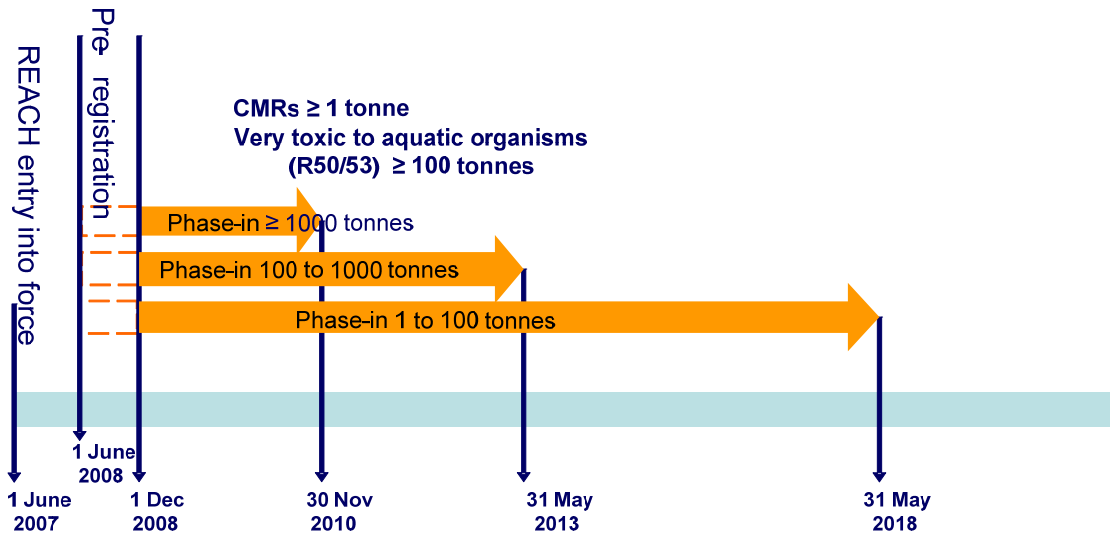
# 3. How does the data sharing process for phase-in substances work?

## 3.1 (Late)pre-registration and pre-SIEF

Companies which need to register a phase-in substance can benefit from extended registration deadlines which depend on the tonnage and on the intrinsic properties of the substance[5]. In order to be entitled to do so, companies are required to "pre-register" the phase-in substance concerned. The period for pre-registration was from 1 June to 1 December 2008. Without pre-registration, phase-in substances have to be registered before they are manufactured in or imported into the EU or placed on the EU market in an amount of one tonne(s) or more per year.

Despite the fact that the pre-registration period has ended, manufacturers and importers who manufacture or import a substance into the European market in quantities of 1 tonne or more per year for the first time after 1 December 2008 can still benefit from the transitional period if they fulfil certain conditions. These first time manufaturers and importers are allowed to late pre-register if they do so not more than 6 months after manufacturing or importing exceeds 1 tonne per year and minimum 12 months before the relevant registration deadline.

**Figure 1: Extended registration deadlines for registration of (late)pre-registered phase-in substances**




Besides the benefit of being able to continue manufacturing, importing and using phase-in substances until the relevant registration deadline, (late) pre-registration gives the companies additional time to organise the collection, selection and sharing of available data, and the generation of missing information required by REACH.

[5] For more information on the extended registration deadlines and the conditions under which these may apply, please consult the Gudiance on registration available on the "Support" section of the ECHA web site at echa.europa.eu/guidance-documents/guidance-on-reach.

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.

All potential registrants who have pre-registered or late pre-registered a substance with the same identifiers are automatically listed in the REACH-IT system in the same so 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 decide whether their substance can be regarded as the same[6]. Potential registrants can enter into "pre-SIEF discussions" in order to agree whether they intend to register the same substance.

With the aim to facilitate discussions and the exchange of information following pre-registration, the role of the "SIEF Formation Facilitator" (SFF) was created. Although the role is not formally recognised in the text of the REACH Regulation, one SIEF participant can volunteer to take over the SFF role and take the initiative to contact the other members and conduct discussions.

Following the sameness review, a potential registrant may conclude that his substance is not the same as the substance pre-registered by the other participants. In this case he should actively search for the correct (pre-)SIEF. ECHA provides support in order to facilitate this process and more information can be found by reading the Guidance on data sharing (at echa.europa.eu/guidance-documents/guidance-on-reach) and on the ECHA website in the "SIEF" section (at echa.europa.eu/web/guest/regulations/reach/substance-registration/substance-information-exchange-fora).

## 3.2 SIEF

When companies have agreed that their substance is the same they enter into discussions in the Substance Information Exchange Forum (SIEF) for that substance. REACH foresees that all manufacturers and importers who have pre-registered the same phase-in substance are part of the same SIEF[7]. Other stakeholders, who have relevant information for the same substance (so-called data holders) and are willing to share it, can also be part of the SIEF. There is only one SIEF for each phase-in substance. The main aim of a SIEF is to facilitate the exchange of information between potental 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 particiants, if requested, have to provide other particpants with existing studies both on vertebrate animals and non-vertebrate animals.

[6] The main criteria which should be followed when deciding on the sameness of the substances are those laid down in the Gudiance for identification and naming under REACH which is available in the "Support" section of the ECHA web site at echa.europa.eu/guidance-documents/guidance-on-reach.
[7] More information on the different potential SIEF participants are provided in section 3.2.3 of the Guidance on data sharing.

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 chose 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 chose 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).

ECHA will not participate in SIEF discussions and will 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"[8]. 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 particuar 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 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

[8] More information on who can be data holder and this role within the SIEF is provided in section 3.2 of the Guidance on data sharing.

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. 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 proposals[9].

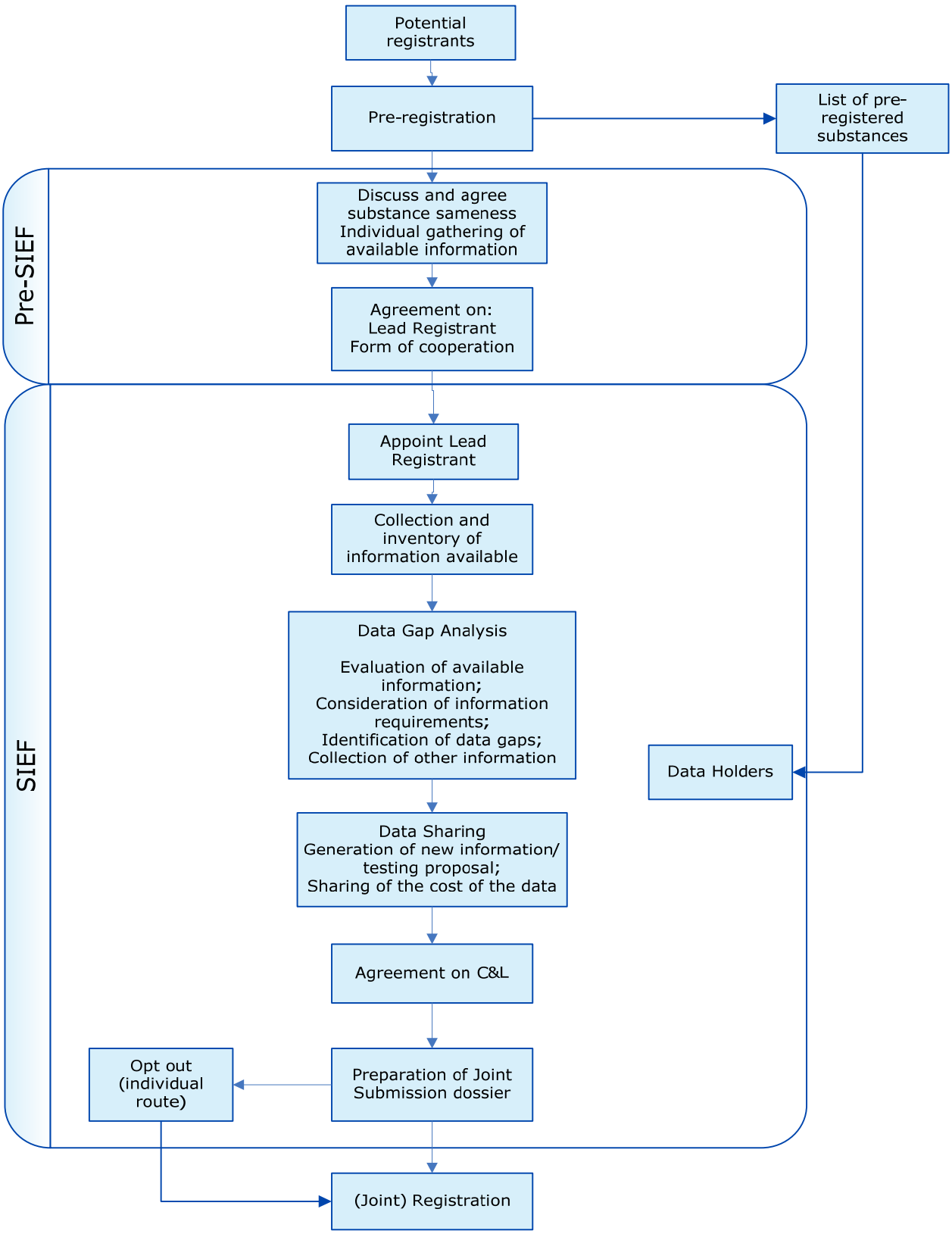
8. The SIEF needs to internally organise the actual exchange of data and fair, transparent and non-discriminatory compensation so that each potential registrant is able to register on time ahead of his registration deadline.

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).

Subsequent registrants and existing registrants are also obliged to share the relevant data and their costs. To this end subsequent registrants will contact one of the existing registrants who must make every effort to reach an agreement on sharing the information. In this case some of the steps described above may be omitted (e.g. steps 6 and 7 above).

[9] 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 2: 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 results[10].

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).

[10] More information on these concepts and their definitions are available in the full Gudance 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. 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.

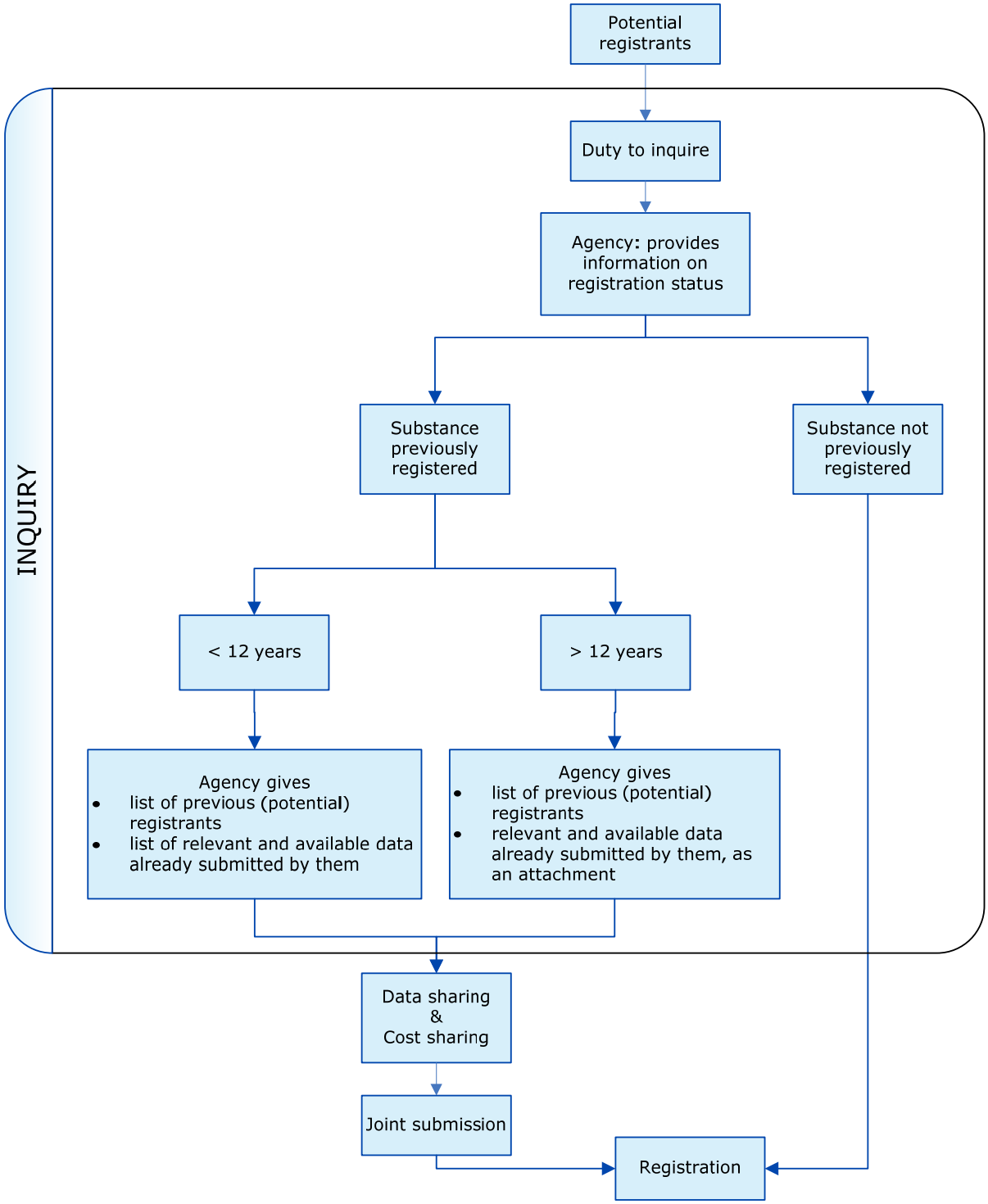
The purpose of the inquiry process is twofold:

- 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 available at echa.europa.eu/web/guest/guidance-documents/guidance-on-reach.

**Figure 3: 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 Directive[11]. ECHA will inform the inquirer of the contact details of the existing registrant(s), notifier(s) or other potential registrant(s), 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.

Once they have shared the available data needed for the registration and the related costs, the potential registrants must agree on a lead registrant who will submit the joint dossier containing the information on the intrinsic properties of the substance (see chapter 6 of this document for more information on the joint submission obligation).

ECHA suggests organising the data sharing following a similar stepwise process as for phase-in substances.

# 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). In accordance with REACH, 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.

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 (e.g. not to reply to arguments).

The data sharing 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 encourges 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

[11] Directive 67/548/EC on classification, labelling and packaging of dangerous substances.

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 site[12]. 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 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.

### 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 vetebrate 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.

In case a dispute is lodged with ECHA, 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.

[12] More information and webforms are available in the dedicated section on "Data sharing" of the ECHA website at echa.europa.eu/web/guest/regulations/reach/substance-registration/data-sharing.

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

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.

# 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 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 opt-out

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

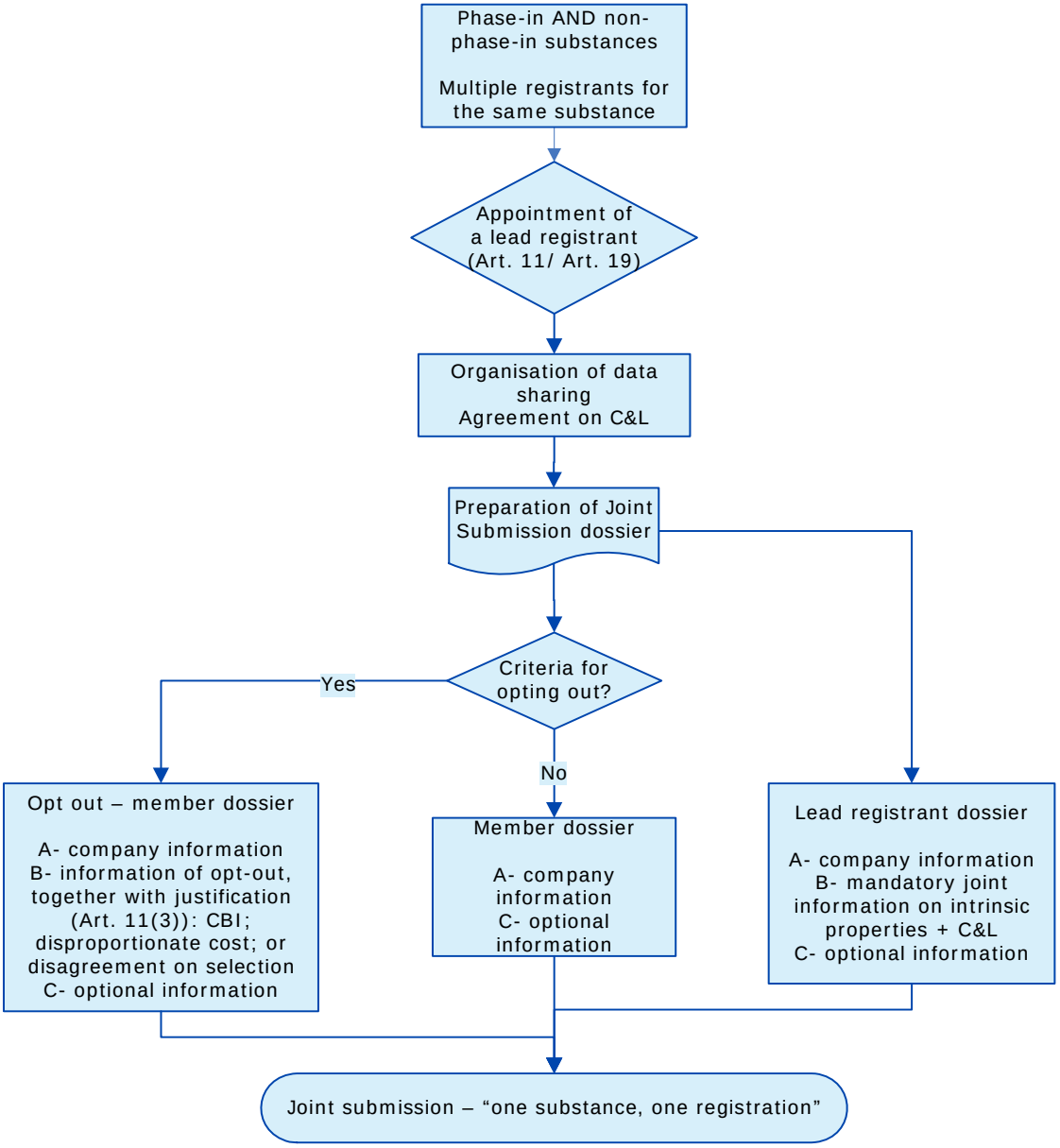
a) It would be disproportionately costly for the registrant to submit this information jointly. This may be the case when e.g. the registrant has already in his possession a set of data for the substance or the cost sharing formula adopted by the SIEF is particularly disadvantageous.

b) Submitting certain information jointly would lead to the disclosure of information he considers commercially sentitive and this would cause commercial loss. This can be the case when, e.g. sharing of such information may lead to the disclosure of manufaturing 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.

In any case opting out can only be related to specific endpoints of the joint submission and a justification must be given for each endpoint submitted separately. The registrant still has to be part of the joint submission and retains data sharing obligations. 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**



# 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 echa.europa.eu/web/guest/regulations/reach/substance-registration/data-sharing.

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 echa.europa.eu/web/guest/regulations/reach/substance-registration/data-sharing.

- ECHA web page on SIEF (in particular the link to "Q&As on data sharing and related disputes" and other useful manuals is provided) at echa.europa.eu/regulations/reach/substance-registration/substance-information-exchange-fora;jsessionid=6A3A572FB58C1B9E1DFAC58BA7D50BD4.live2.

- ECHA web page on data sharing (where the links to the forms to initiate a disputes are provided) at echa.europa.eu/web/guest/regulations/reach/substance-registration/data-sharing.

- ECHA REACH 2013 web service (available at echa.europa.eu/web/guest/reach-2013) which contains key information to support the preparation for the 2013 registration deadline.

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