GUIDANCE

# Factsheet

Guidance on data sharing

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The European Chemicals Agency (ECHA) is issuing a series of Fact Sheets which provide a structured overview of each REACH Guidance Document published by the Agency.

These Fact Sheets are available in the following 22 languages: Bulgarian, Czech, Danish, Dutch, English, Estonian, Finnish, French, German, Greek, Hungarian, Italian, Latvian, Lithuanian, Maltese, Polish, Portuguese, Romanian, Slovakian, Slovenian, Spanish and Swedish.

A Guidance Fact Sheet provides a short summary of the key aspects of the respective REACH Guidance Document including bibliographic information and other references.

If you have questions or comments in relation to this Fact Sheet, please send them by e-mail to: info@echa.europa.eu, quoting the Fact Sheet reference, issue date and language version, given above.

## WHO SHOULD READ THE GUIDANCE ON DATA SHARING?

The Guidance on data sharing has been developed for companies who manufacture chemical substances or import them into the European Community. An updated version of the Guidance on data Sharing was released in April 2012 and this factsheet has been updated to reflect the changes.

Multiple registrants of the same substance are required to share data in the context of a registration under the REACH Regulation.

The guidance is a valuable source of information both for companies inside and outside the European Union, if their products are exported to the EU. Data holders such as downstream users, manufacturers/ importers of substances in quantities below 1 tonne per year, research organisations, laboratories, universities, Non-Governmental Organisations (NGOs), etc, may also find the guidance useful if they possess studies or other relevant technical data on substances and are willing to share them.

## WHAT IS THE GUIDANCE ON DATA SHARING ABOUT?

The Guidance gives practical support to companies to help them fulfil their obligations related to the sharing of data on **both phase-in and non phase-in substances**.

The guidance also explains what ECHA has implemented to facilitate the sharing of data. In addition the guidance illustrates the mechanisms set up to help companies to resolve data sharing disputes in cases where the parties fail to reach an agreement.

The Guidance also covers the following topics:

- Joint submission of data and conditions for opting out;
- Examples of cost sharing mechanisms;
- Forms of cooperation, including consortia;
- EU Competition Law aspects;
- Issues related to Confidential Business Information (CBI).

Data sharing concerns in particular information related to the intrinsic properties of substances. It is obligatory to share studies involving vertebrate animals, as one of the main objectives of REACH is to avoid unnecessary animal testing. For other tests, REACH encourages the sharing of data in order to reduce costs for companies.

The process of data sharing may involve activities that are sensitive with regard to the protection of CBI or compliance with EU competition law. The guidance explains when companies should act carefully in order to avoid the disclosure of CBI or a breach of EU competition law. With regard to the disclosure of CBI, it should be noted that the REACH Regulation provides for the possibility to appoint a Third Party Representative if a company does not want to be visible during certain REACH processes, including discussions on data sharing.

The data sharing obligations are similar for phase-in and non phase-in substances. However different procedures need to be followed in cases where registrants do not reach an agreement on the sharing of information.

## Data sharing for phase-in substances that have been (late) pre-registered

Potential registrants wishing to benefit from the extended registration deadlines for submitting registration dossiers for phase-in substances were required to pre-register these substances. The pre-registration period was from 1 June 2008 to 1 December 2008. First-time manufacturers and importers can still late pre-register (as per Article 28(6) of the REACH Regulation) if they do so within six months of first manufacturing or importing the substance in quantities of 1 tonne or more per year, and no later than 12 months before the relevant deadline for registration.

Companies that pre-registered or late pre-registered the same substance are required to assemble in a Substance Information Exchange Forum (SIEF). A SIEF is not a legal entity or consortium, but rather a forum to share data and other information.

The principal aims of a SIEF are to:

- facilitate data sharing for the purposes of registration;
- agree on the classification and labelling of the substance (where there is a difference in the classification and labelling between the potential registrants).

It is important to note that ECHA will not participate in the discussions within individual SIEFs.

Data holders that possess data on substances may voluntarily join a SIEF and share data. They can notify, based on the list of pre-registered substances, their interest in joining a SIEF as a data holder at any time via REACH-IT (see Chapter 3 of the ECHA Guidance on data sharing).

Each SIEF is to remain operational at least until 1 June 2018. However the SIEF activities may continue after this date.

As a first step, the SIEF participants establish the identity of the substance . The Guidance for identification and naming of substances under REACH gives guidance on how to determine the "sameness" including several examples and should be read carefully.

Within the SIEF, participants must react to requests for information from any other participant and must agree on the sharing of data and costs related to existing studies. Where no relevant study involving tests is available, SIEF participants must agree who is to carry out the tests on behalf of the other participants.

During the negotiations on sharing data and their related costs, disputes may result from a disagreement on who should conduct a new study or on the conditions for sharing existing vertebrate studies. The REACH Regulation provides ECHA with remedies to support the resolution of these disagreements, as explained in section 3.4 of the ECHA Guidance

on data sharing. ECHA may specify which registrant shall perform the test, give permission to refer to the necessary information, to proceed without the information or prevent a registrant from proceeding with registration.

The REACH Regulation also sets the rules describing which data[1] must be submitted jointly by a lead registrant acting on behalf of the other registrants of the same substance. In some cases, that must be well justified, a registrant may decide to opt out from the joint registration dossier for some information which otherwise should be submitted jointly. In any case the registrant shall remain a member of the joint submission. The conditions for opting out are further explained in section 6.3 of the ECHA Guidance on data sharing.

### Data sharing for non-phase-in substances and phase-in substances that have not been (late) pre-registered

Data sharing for non-phase-in substances and phase-in substances that have not been (late) pre-registered is initiated after the inquiry process, which provides for the determination of whether the same substance has already been registered and informs the potential and previous registrants of each other's names and addresses. In this way the inquiry process facilitates contact between companies to arrange for the sharing of data and costs.

If the same substance has been registered within the previous 12 years, any new registrant must request from the previous registrant(s) the information involving tests on vertebrate animals, which they require to fulfil their registration obligations. For studies not involving tests on vertebrate animals, but which they require for their registration, they may request the information from the previous registrant(s).

Both the new and the previous registrants have the obligation to make every effort to agree on the conditions of sharing the data and its costs. Any technical data submitted in the framework of a registration more than 12 years previously can be used, without compensation, for the purpose of registration.

During the negotiations on sharing data and their related costs, disputes may result from a disagreement on the conditions for sharing existing studies. The REACH Regulation provides ECHA with remedies to support the resolution of these disagreements, as explained in section 4.9 of the ECHA Guidance on data sharing. ECHA may give permission to the new registrant to refer to the necessary information.

In addition to the data sharing obligations, multiple registrants of the same non-phase-in substance (or non (late) pre-registered phase-in substance), must comply with their joint submission obligations. Therefore they need to identify a lead registrant that will submit the joint registration dossier on their behalf. Also in this case a registrant if well justified may decide to opt-out for certain information which should otherwise be submitted jointly.

## HOW TO READ THIS GUIDANCE DOCUMENT?

The Guidance is structured so that the reader is directed to the chapters that are relevant to him.

- The introductory chapters 1 and 2 contain an overview, including links to other guidance documents, and describe the relevant legal framework.

- Chapter 3 describes the full data sharing process for phase-in substances: (late) pre-registration, SIEF formation, data sharing and the system in place to resolve possible disputes within a SIEF. In particular an explanation is given of who the participants within a SIEF are, distinguishing between potential registants and data holders, describing what the obligations of the participants are and how a SIEF should work. The chapter describes the rules for data sharing within a SIEF, starting with the gathering of available information, up to the submission of data in the technical dossier. A description of how ECHA deals with data

[1] Article 11 of the REACH Regulation specifies the data which should be submitted jointly and those which should be submitted individually by each registrant.

sharing disputes has been added.

- Chapter 4 describes the full data sharing process for non-phase-in substances. In particular the guidance describes the inquiry process (e.g. which substances are subject to this process, what information has to be submitted). The chapter details the rules for data sharing after an inquiry and the mechanisms implemented by ECHA to manage disputes. The Guidance on data Sharing further describes in more detail the obligations of the registrants and the rules for data sharing, starting with the gathering of available information, up to the submission of data in the technical dossier.

- Chapter 5 contains guidance on cost sharing, starting with how to value a study based on two approaches: historic costs versus replacement costs. Subsequently, mechanisms for cost allocation and compensation are described. The guidance contains several examples of models for sharing the costs.

- Chapter 6 contains guidance on joint submission. The conditions and criteria for opt-out are described followed by the consequences and remaining obligations for the potential registrant.

- Chapter 7, 8 and 9 provide guidance on specific topics related to data sharing: EU competition law, forms of cooperation including consortia and CBI.

## KEY ASPECTS

### Sameness of substances

The *sameness of substances* is a key concept with regard to data sharing and joint submission of registration. The criteria to verify whether substances can be regarded as being the same can be checked in Chapter 5 of the ECHA Guidance for identification and naming of substances under REACH and CLP. These criteria should be regarded as a common basis for identifying and naming a substance.

### Joint submission obligation

When a substance is manufactured or imported by more than one company, the companies are required to submit certain information together. This is called the 'joint submission of data' and applies to both phase-in and non-phase-in substances. Registrants are required to jointly submit information on the intrinsic properties of the substance, its classification and labelling and testing proposal(s) (if any). They may, if they agree to do so, also jointly submit the chemical safety report and the guidance on safe use.

Every registrant remains individually obliged to submit a registration dossier for each substance, because, in particular, certain company-specific information has to be provided separately for each registration.

## LINKS TO RELATED MATERIAL

REACH Regulation EC No 1907/2006

REACH Guidance: this section of the ECHA website is a single point of access to general and detailed technical guidance on REACH.

Guidance Fact Sheets and Frequently Asked Questions can be found in the "Support" section of the ECHA website.

## Bibliographic information of the GUIDANCE DOCUMENT

The Guidance on data sharing can be downloaded from the ECHA website (link above).

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