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Guidance Fact Sheet

DATA SHARING

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Guidance on data sharing

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 documents will be available in the following 22 languages:

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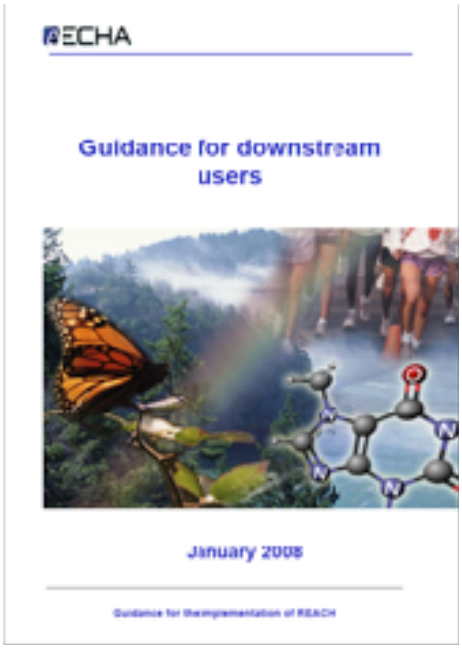

A Guidance Fact Sheet provides a short summary of the key aspects of the respective REACH Guidance Document including bibliographic information and other references.

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 THIS GUIDANCE DOCUMENT?

The Guidance on data sharing has been developed for companies who manufacture in, or import chemical substances into the European Community and are obliged to share data in the context of a registration under the REACH Regulation.

Downstream users or other stakeholders, such as research organisations, laboratories, universities and NGOs, may also find the guidance useful if they possess studies or other relevant technical data on substances and are willing to share it. Moreover, the Guidance is a valuable source of information for companies outside the European Union whose products are exported to the EU.

WHAT DOES THE GUIDANCE ADDRESS?

The Guidance gives practical support on fulfilling the obligations related to data sharing and explains the system put in place by REACH to make this data sharing possible. It also provides information on:

- EC Competition Law aspects
- Forms of cooperation, including consortia
- Confidential Business Information
- Joint submission of data and opt-out
- Examples on cost sharing mechanisms

Data sharing concerns technical data and in particular information related to the intrinsic properties of substances. It is obligatory for tests on vertebrate animals, as the avoidance of unnecessary animal testing is a main concern of REACH. For other tests, REACH encourages the sharing of data in order to reduce costs for companies and duplication of testing.

The process of data sharing may involve activities that are sensitive with regard to the protection of Confidential Business Information (CBI) or the compliance with EC competition rules. The Guidance explains when companies should act carefully in order to avoid the disclosure of CBI or a breach of EC competition rules.

With regard to the disclosure of CBI, it should be noted that the REACH Regulation provides for the possibility to appoint an Third Party Representative if a company does not want to be visible during certain REACH processes, including discussions on data sharing.

The data sharing process is different for phase-in and non phase-in substances[1]. Special rules apply for studies involving tests on vertebrate animals.

Data sharing for Phase-in substances

Registrants wishing to benefit from extended deadlines for submitting registration dossiers are required to pre-register. Pre-registration leads to the formation of a Substance Information Exchange Forum (SIEF) for each substance[1]. Manufacturers and importers of substances in quantities below the threshold of 1 tonne per year and other stakeholders, who legitimately possess data on substances, may voluntarily join a SIEF and share data as data holders. The interest to join a SIEF as a data holder can be notified via REACH-IT once the list of pre-registered substances has been published (see Guidance on Data Sharing Chapter 4 and Annex III).

It is important to note that a SIEF is not a legal entity or consortium, but a forum to share data and other information. Each SIEF remains operational until 1 June 2018. ECHA will not participate in the discussions within individual SIEFs.

As SIEF participants, companies shall react to requests for information from

[1] Phase-in substances are substances which are listed in EINECS, or substances that have been manufactured in the EU (including accession countries on 1 January 2007) but have not been placed on the EU market after 1 June 1992, or so-called "no-longer polymers". Phase-in substances are those not meeting any of these three criteria.

other participants and provide them with existing studies in exchange for cost sharing. SIEF participants that intent to register have additional duties such as requesting missing information or making arrangements to carry out necessary studies. As a rule, the REACH Regulation requires that data must be submitted jointly by all registrants of the same substance. In well justified cases a registrant may opt-out from this joint submission. The conditions for opting out are defined in Article 11(3) and Article 19(2) of the REACH Regulation and further explained in section 8.4 of the Guidance on data sharing.

Of particular importance with respect to SIEF formation is the agreement on the "sameness of a substance". Guidance is given on how to determine the "sameness" including several examples. The closely linked Guidance for identification and naming of substances under REACH should also be read carefully.

Data sharing for non phase-in substances and phase-in substances that have not been pre-registered

Data sharing for non phase-in substances and phase-in substances that have not been pre-registered is initiated by an inquiry process with ECHA in order to find out whether the same substance has already been registered.

If the same substance has been registered within the previous 12 years, ECHA will facilitate contact between companies to arrange for the sharing of data and costs. With regard to studies involving tests on vertebrates, any new registrant shall request from the previous registrant the necessary information. For other studies he may optionally do so. If no agreement can be reached, ECHA will give permission to the new registrant to refer to the necessary information. The original registrant has then a right to be compensated by the later registrant(s).

Any technical data submitted in the framework of a registration made 12 years or more previously can be used freely for the purpose of registration.

HOW TO READ THIS GUIDANCE?

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 the link to other guidance, and describe the relevant legal framework.

- Chapter 3 describes the pre-registration process.

- Chapter 4 describes SIEF formation: e.g. who are the participants in a SIEF distinguishing between potential Registrants and data holders, what are the obligations of the participants and how will a SIEF be formed.

- Chapter 5 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 distinction is made between the collective route and individual route.

- Chapter 6 describes the inquiry process: e.g. what substances are subject to this process, what information has to be submitted. This chapter also contains guidance on the relationship between the so-called "early registrant"[2] with other potential registrants within a SIEF.

- Chapter 7 contains guidance on cost sharing starting with how to valuate a study based on two approaches: historic costs versus replacement costs. Subsequently, mechanisms for cost allocation and compensation are described for the individual and collective route.

[2] A potential registrant who has not pre-registered his substance, hereafter referred to as an "early registrant", may decide to submit his information before joint submission takes place.

- Chapter 8 contains guidance on joint submission. The section on opt-out from a joint submission is especially relevant for data sharing. The conditions and criteria for opt-out are described followed by the consequences and remaining obligations for the potential registrant.

- Chapter 9, 10 and 11 provide guidance on specific topics related to data sharing: EC Competition Law, forms of cooperation including consortia and Confidential Business Information.

The Guidance contains several Annexes including, among others, process description charts; on involvement of downstream users in data sharing and on cost sharing examples.

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 check whether or not substances can be regarded the same can be looked up in Chapter 5 of the *Guidance on substance identification*. These criteria should be regarded as a common base for identifying and naming a substance, and thus finding a potential co-registrant and/or data sharing partner of this particular substance.

Joint submission obligation

In cases where 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. Registrants are required to jointly submit information on the hazardous properties of the substance and its classification and labelling and a testing proposal(s) (if any). They may, if they agree, also jointly submit the chemical safety report and guidance on safe use.

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

SIEF

"SIEF" stands for Substance Information Exchange Forum. A SIEF is a forum, formed after the pre-registration phase, to share data on a given phase-in substance.

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 of interpretation between the potential registrants.

LINKS TO RELATED MATERIAL

REACH Regulation EC No 1907/2006
REACH Guidance this 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 REACH section of the ECHA website.

BIBLIOGRAPHIC INFORMATION OF THE GUIDANCE DOCUMENT

Guidance on data sharing can be downloaded from the ECHA website. The document is currently available only in English. The 21 additional EU language versions are expected to be published in autumn 2008.

Version	1
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