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Guidance Fact Sheet

GUIDANCE ON REGISTRATION

Ref.: ECHA-08-GF-02-EN
Date: 21/07/2008
Language: English

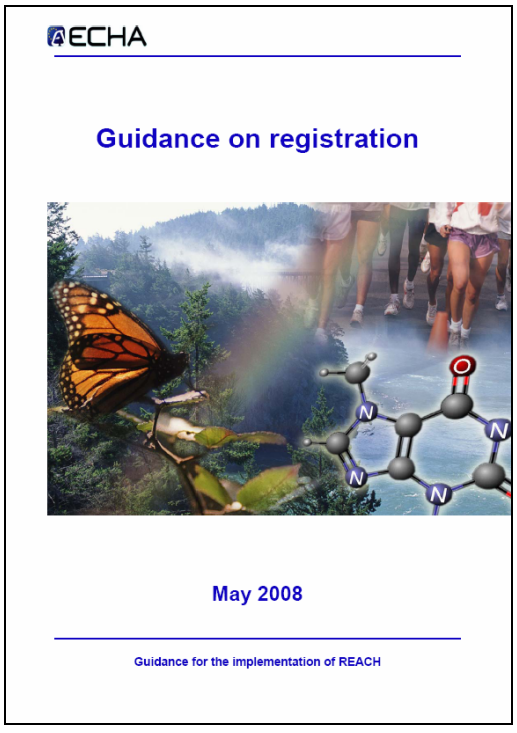
Guidance on registration

The European Chemicals Agency (ECHA) will issue 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:

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, shown above.



WHO SHOULD READ THIS GUIDANCE DOCUMENT?

Under REACH **manufacturers** or **importers** of chemical substances (as such, in preparations or in articles) established in the European Union (EU) have to register their substances under certain conditions. In addition, non-EU manufacturers, non-EU formulators or non- EU producers of articles can appoint **only representatives** who will then have to fulfil the obligations of the importers.

The guidance is therefore mainly addressed to manufacturers, importers and only representatives established within the EU. It may also be a relevant source of information for companies established outside the EU and that export to the EU.

WHAT DOES THE GUIDANCE ADDRESS?

The guidance aims to assist industry in determining which tasks and obligations have to be complied with to fulfil the registration requirements under REACH.

It seeks to clarify whether, when and how registration would be required for a given actor and a given substance. If you have one or more of the following questions you may find the answer in the guidance:

- What are my roles under REACH? Manufacturer, importer, only representative or other?
- What is the role and which are the tasks of an only representative?
- In which form is the substance manufactured or imported: on its own, in preparations or in articles?
- Does the substance fall under the scope of REACH in general or under the scope of registration requirements in particular?
- When to register?
- Is there a need to pre-register, or to inquire whether the substance is already registered?
- What are registrants' obligations regarding sharing data with other companies?
- How to prepare a registration dossier?
- How to fulfill the information requirements laid down in Annex VI to XI of REACH?
- How to report the information in the registration dossier, for example: level of detail needed, how to select a key study, use of IUCLID 5?
- When to update a registration dossier and how to do so?
- What are the tasks of the Agency once the registration dossier is submitted?
- Which information to provide to customers?
- When and how to notify the classification and labelling of a substance to the Agency?

HOW TO READ THIS GUIDANCE?

The guidance has been developed in two parts. The first part of the document is addressed to all potential registrants with and without expert knowledge in the fields of chemicals and chemicals assessment. It explains what the registration requirements are, who is responsible for them and how and when they must be fulfilled. An IT tool, called the Navigator, has been developed to help industry in identifying its obligations under REACH and guide users through the many steps explained in the Guidance on registration.

The second part of the document provides detailed guidance on how to prepare and update a registration dossier. For the technical aspects of preparing a registration dossier links are given to the user manual of IUCLID 5.

Figure 1 in the Registration Guidance provides and overview on the different steps of the registration process, helping to identify the relevant registration obligations and the corresponding guidance.

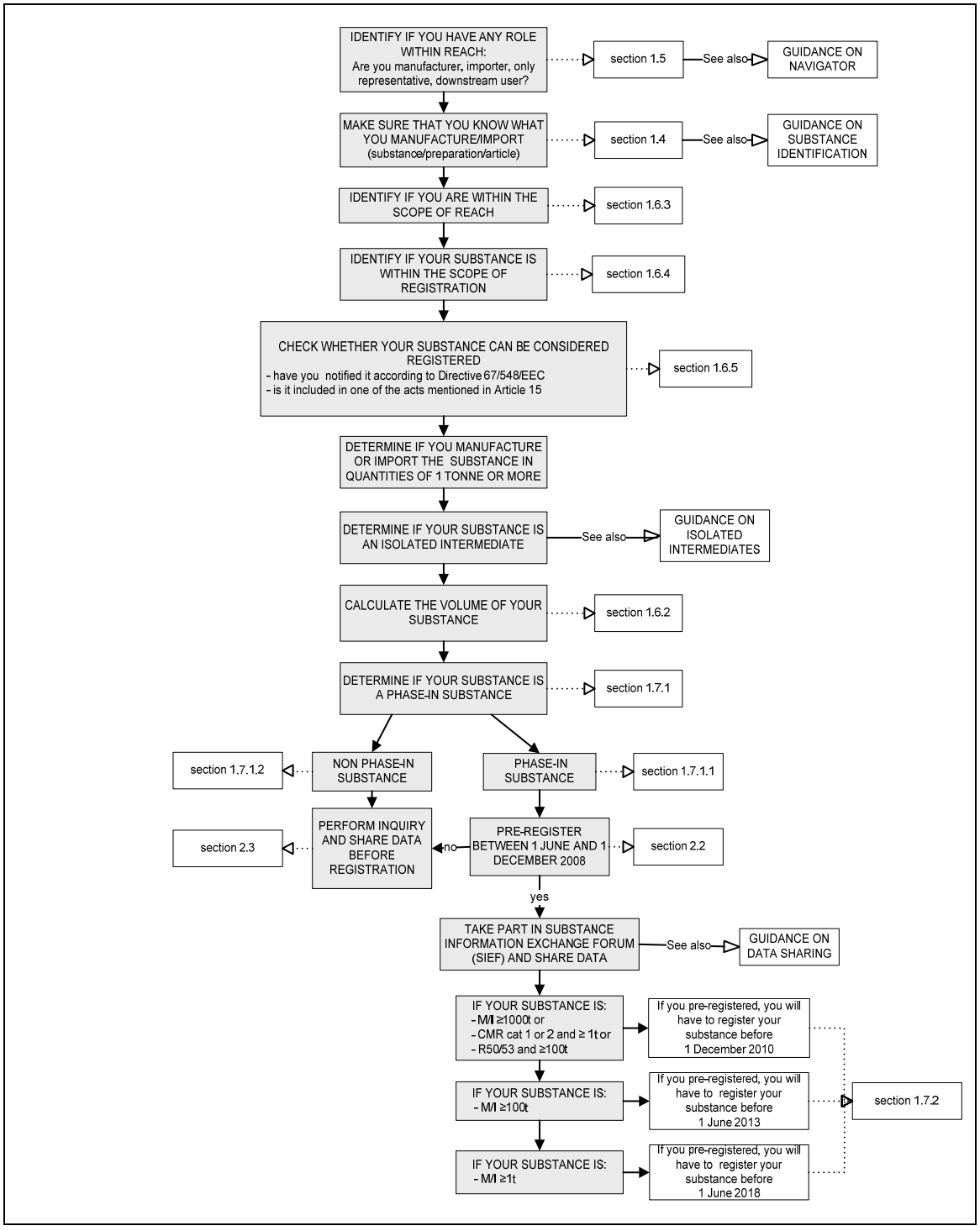


Figure 1 Steps within the registration process and link to the structure of the guidance on registration

KEY ASPECTS

Scope of REACH registration. Certain substances are exempted from REACH either completely or from certain titles (e.g. registration). This can for example be the case for substances covered by other legislation, or for substances for which sufficient information is known so that they are considered to cause minimal risk because of their intrinsic properties. Various additional exemptions are mentioned in Article 2 of the REACH Regulationl. The substance identity, its status under other legislation and its uses are critical in determining whether the substance falls under the scope of REACH registration.

Phase-in process. A special transitional regime exists for substances which were already being manufactured or placed on the market before the entry into force of the REACH Regulation on 1st June 2007 and which were not notified as "new substances" according to Directive 67/548/EEC. For these substances, manufacture and import can continue and the registration can be submitted within extended deadlines. Such substances are called "phase-in substances". To benefit from the transitional regime a future registrant must pre-register his substances between the 1st June 2008 and the 1st December 2008.

Substance regarded as being registered. Active substances regarding their use in plant protection or biocidal products, as well as substances already notified under Directive 67/548/EEC are considered as registered under REACH.

Identification of roles. An individual legal entity may have multiple roles depending on its activities, even for the same substance, e.g manufacturer and/or importer and/or downstream user). It is very important that companies correctly identify their role or roles in the supply chain for each substance they handle. This will be a decisive factor in determining the registration obligations. The "role under REACH" also depends on whether the legal entity is situated within the EU, within the European Free Trade Agreement (EFTA) or within the European Economic Area (EEA). The applicable definitions of "manufacturer", "importer" and "downstream user" are given in Article 3 of the REACH Regulation under point 9,11 and 13 respectively.

Registration dossier. The 'registration dossier' for a substance is the set of information submitted electronically (in IUCLID 5 format) by a registrant to the European Chemicals Agency. It consists of two main components:
(i) **a technical dossier**, always required for all substances subject to the registration obligations,
(ii) **a chemical safety report**, required if the registrant manufactures or imports a substance in quantities of 10 tonnes or more per year. Substances present in low concentrations in preparations (see Article 14(2)), and intermediates under strictly controlled conditions do not need a chemicals safety report.

LINKS TO RELATED MATERIAL

REACH Regulation EC No 1907/2006
REACH Guidance website is a single point of access to general and detailed technical guidance on REACH.
REACH Guidance Fact Sheets can be found in the publications section of the ECHA website.
The Navigator can be found on the REACH Guidance website.

BIBLIOGRAPHIC INFORMATION FOR THE GUIDANCE DOCUMENT

Guidance on registration can be downloaded from the ECHA website. The document is currently available in English. The 21 additional EU language versions are expected to be published in early 2009.

Version	2.2
Pages	124
Date	July 2008
ISBN	not yet available
DOT	not yet available