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Guidance Fact Sheet

INFORMATION REQUIRMENTS
CHEMICAL SAFETY ASSESSMENT (PART A)

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Information Requirements and Chemical Safety Assessment (Part A)

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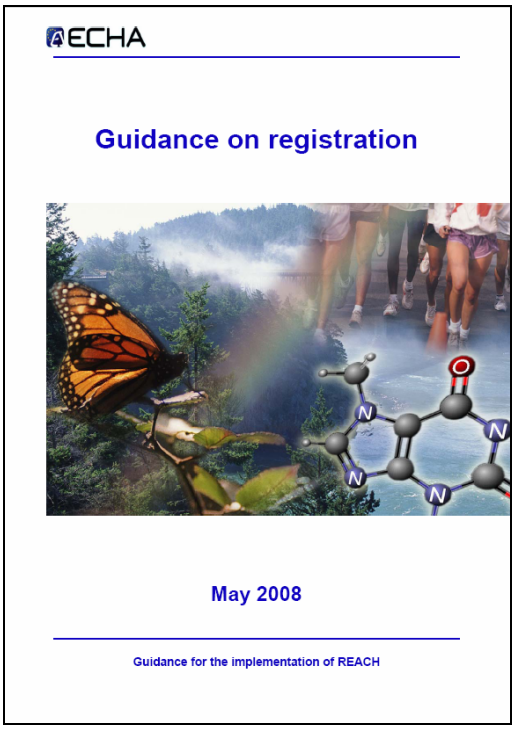
Bulgarian, Czech, Danish, Dutch, English, Estonian, Finnish, French, German, Greek, Hungarian, Italian, Latvian, Lithuanian, Maltese, Polish, Portuguese, Romanian, Slovakian, Slovenian, Spanish and Swedish

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?

Manufacturers or **importers** required to register a substance have to fulfil certain information obligations regarding substance properties, exposure, use and risk management measures. If more than 10 tons per year of such substance is manufactured or imported a chemicals safety assessment is required (except for intermediates under strictly controlled conditions).

The Guidance is also addressed to **downstream users (DUs)** who need or want to make their own chemical safety assessment. This may be relevant in cases where the suppliers' final exposure scenarios do not cover the actual conditions of use of the downstream user.

Producers or importers of articles containing substances that are intended to be released may also need to carry out a Chemical Safety Assessment (CSA). This would be the case if the substance is not already registered for that use, and the substance is present in those articles in total volumes of above 10 t/y

The Guidance is also addressed to companies preparing a CSA/CSR (Chemical Safety Report) as a part of an **authorisation application**.

WHAT DOES THE GUIDANCE ADDRESS?

The requirements related to generation of information for the purpose of registration and the chemicals safety assessment are laid down in a number of annexes to the REACH Regulation:

- Annex VI on the Technical Dossier to be submitted in IUCLID format.
- Annex VII to X on information requirements to characterize the physico chemical, toxicological and ecotoxicological properties of a substance
- Annex III and XI on the rules to adapt or waive standard information requirements depending on the information available, the feasibility and scientific necessity of testing, and the exposure to be expected.
- Annex I on the principles and the general methodology to carry out the chemicals safety assessment, including the format required to document the results in the CSR.

The *Guidance on Information Requirements and Chemicals Safety Assessment* aims to cover all these elements in a package of 28 single documents. It consists of two major parts: Concise guidance (Part A to G) and supporting reference guidance (Chapters R.2 to R.20). The purpose of the **concise guidance** is to support the processes needed to meet the information requirements on intrinsic properties of substances to be registered, and where relevant to carry out a chemicals safety assessment. This includes information collection processes, communication processes and assessment processes. The purpose of the **reference guidance** is to provide in-depth scientific and technical advice.

Part A of the guidance package provides an overview on all the aspects regarding a CSA, the related information requirements and the expected outputs of the CSA process:

- Assessment of any hazards the substance may present. This includes: i) evaluation and integration of available information; ii) the classification and labeling of the substance and a conclusion on whether the substance is regarded as (very) persistent, (very) bioaccumulative and toxic (PBT/vPvB); iii) the derivation of the hazard threshold levels for human health and the environment.
- Where the assessment shows that the substance meets the classification criteria or the PBT or vPvB criteria, it is required to identify the conditions under which the risks arising from

manufacture and use(s) can be controlled. These conditions have to be described in one or more exposure scenarios (ES), depending on the diversity of use conditions. For example: The daily amount of a substance used in an industrial process is to be limited to a certain amount unless additional waste water treatment takes place; or a substance should only be only used in closed industrial processes.

- The entity carrying out the CSA needs to document the relevant data, judgements, justifications and conclusions in a chemicals safety report (CSR) for its own records. It also however needs to include the CSR in the registration dossier (or authorisation application) for the substance that is to be sent to the Agency
- When ES are developed, the company carrying out the assessment should implement the conditions of use controlling risks at its own installations. It should also inform its direct customers and the actors further down the supply on the conditions of use (i.e., the operational conditions and risk management measures) ensuring control of risk. For this purpose the relevant information from the CSR is compiled into one or more exposure scenarios (ES) to be annexed to the extended safety data sheet (eSDS).

HOW TO READ THIS GUIDANCE?

Chapter A.1 of Part A of the Guidance provides an introduction to how to conduct the chemical safety assessment and prepare the chemical safety report for substances manufactured or imported in a quantity of 10 tons or more per year. This includes an overview of the intended outcomes and main contents of the chemicals safety assessment (CSA). It also includes the overall approach to cost-effective decisions during the iterative process of conducting the CSA.

Chapter A.1 includes a pathfinder through the 28 single documents of the overall guidance package. The pathfinder is available in 22 languages on ECHA's http://echa.europa.eu/reach_en.html.

Chapter A.2 explains the key elements needed to understand what the chemical safety assessment process is about. This includes:

- an overview on the entire CSA process,
- a brief description of the hazard assessment process,
- describing the conditions of use leading to control of exposure and risk.(exposure scenario building)
- exposure estimation and risk characterization
- iteration of the CSA with i) more detailed information on substance properties (including testing proposals) and/or ii) more detailed information on the conditions of use; and/or iii) narrowing down the range of uses and/or iv) introduction of stricter risk management measures.
- documenting control of risk for all exposure scenarios in the CSR
- placing the exposure scenarios for communication down the supply chain into the annex of the safety sheet

Identifying, implementing and documenting control of risk during the entire life cycle of a substance is a joint exercise within the supply chain. It needs communication down and up the supply chain and definition of tasks depending on the role of companies. This is outlined in Chapter A.3 of the Guidance:

- How to organize dialogue between substance manufactures and down stream users
- What are the different key tasks to be carried out along the supply chain?

Chapter A.4 describes in more detail, in which situations an actor may need to carry out a CSA under REACH.

KEY ASPECTS

Control of risk. The goal of the CSA is to identify and describe the conditions under which the risks are controlled. Risks are regarded as controlled when the estimated exposure levels do not exceed the derived/predicted no effect levels (DNEL or PNEC). For substances for which such no-effect levels for human health and environmental spheres cannot be determined, the risk characterization is based on other methods: Semi-quantitative or qualitative assessment of the likelihood that adverse effects are avoided. More specifically, for substances fulfilling the PBT and vPvB criteria, the risks can be concluded to be controlled when the emissions and exposures are minimized by the implementation of the exposure scenario.

Exposure Scenario: Exposure scenarios are sets of information describing the conditions under which a substance can be used safely (= risks are controlled). An ES includes a short title (to label the content and applicability of the ES), the operational conditions and the risk management measures needed. The **initial** ES describes the conditions of use as known at the beginning of the assessment process. The **final** ES describes the conditions ensuring control of risk as a conclusion of the assessment process.

Information Requirements. The CSA is not only a method to develop exposure scenarios and to demonstrate control of risk but also to support the evaluation process needed to meet the information requirements of Annex VI to X. Every registrant is obliged to collect all available data on substance properties, and additionally information on exposure, use and risk management. Considering all this information together and comparing it with the standard information required in Annex VI to X the registrant should determine the need to generate further information. Based on the results testing proposals can/should be made. a CSA is also required to provide appropriate justification where the registrant wishes to waive standard information based on exposure considerations,.

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.
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 ON THE GUIDANCE DOCUMENT

Guidance Information Requirements and Chemicals Safety Assessment (Part A) 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	1.0
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