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Guidance Fact Sheet

INFORMATION REQUIRMENTS AND CHEMICAL SAFETY ASSESSMENT (PART D)

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Guidance on Exposure Scenario Building (Part D)

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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.

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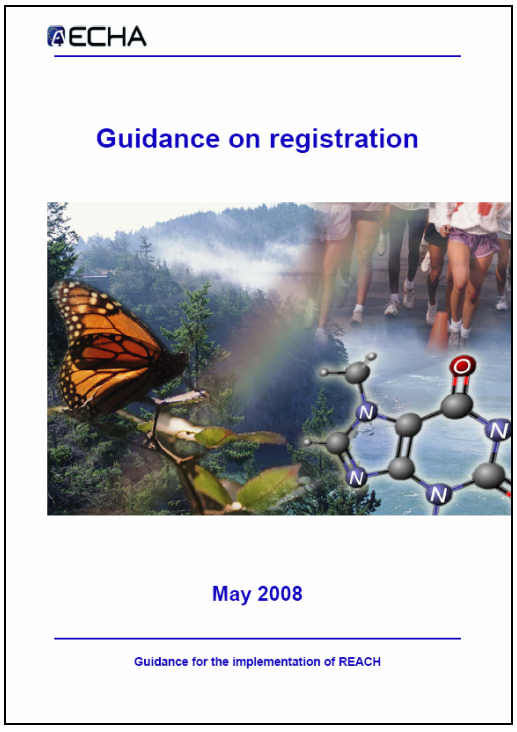

WHO SHOULD READ THIS GUIDANCE DOCUMENT?

If a company manufactures or imports more than 10 tons per year of a substance subject to registration, and the substance is being classified dangerous or being regarded a PBT/vPvB[1] then an **exposure assessment and a risk characterisation** are required This includes building of exposure scenarios for all identified uses, estimating the exposure to be expected and comparing this exposure with the no effect levels determined in the hazard assessment. Based on this the registrant can demonstrate control of risk for all uses and the subsequent life cycle stages of the substance.

The Guidance is also addressed to **downstream users (DUs), producers or importers of articles** and companies applying for **authorisation** who need or want to carry out a chemical safety assessment.

WHAT DOES THE GUIDANCE ADDRESS?

An **exposure scenario** is a set of information describing the conditions under which the risks associated with the identified use(s) of a substance can be controlled. It includes operational conditions (for example the duration and frequency of use or the amount used, the process temperature or the pH) and necessary risk management measures (e.g. local exhaust ventilation or a certain type of glove, waste water and waste gas treatment). In order to cover all uses the registrant will usually need to define a series of exposure scenarios for the different user groups in his market.
Depending on the use, an exposure scenario should describe all relevant factors determining the exposure. The exposure scenarios to be communicated down the supply chain should have a standardised structure:.

- Short title meant to flag the content of the exposure scenario
- Processes and activities covered in the exposure scenario
- Duration and frequency of use (as relevant for workers, consumers and the environment)
- Physical form of the product containning the substance and concentration of the substance
- Amounts used per time and/or activity (as relevant for workers, consumers and the environment)
- Other operational conditions of use
- Risk management measures for uses at industrial sites (workers and environment)
- Risk management measures for uses outside industrial sites (workers and environment)
- Risk management related to uses by consumers (consumer and environment)
- Waste management measures related to the uses covered in the exposure scenario
- Predicted exposure and source of prediction
- Advice to downstream users on how to check whether or not they work within the boundaries defined in the exposure scenario

For each exposure scenario, the Chemical Safety Report (CSR) needs to provide an exposure estimation and a risk characterisation demonstrating that risk are controlled.

Exposure scenario building and the corresponding exposure estimation should be carried out in a tiered manner, starting with available information, including conservative assumptions of exposure levels. The Guidance focuses on such “Tier1” assessments. If these fail to demonstrate control of risk more refined assessments may be performed. This will be employing more detailed exposure information which can be processed with more refined exposure estimation tools.

[1] Persistent, bioaccumulative and toxic substance (PBT); very persistent and very bioaccumulative substance (vPvB)

If a manufacturer or importer is unable to describe relevant and realistic measures that control risks for a substance in a certain use he can not cover this use in his exposure scenario. In consequence the downstream user may need to cease the use or to carry out an own chemical safety assessment. The manufacturer can also explicitly advise against that use in section 16 of the safety data sheet.

Exposure scenario building should include dialogues i) between substance manufacturers and downstream users and ii) from downstream user to downstream users further down the supply chain. These dialogues should take place well in advance of the first registration deadline in 2010. The goal of such dialogues is

- to get the manufacturers and importers informed about the existing conditions of use in their markets (as far as relevant for exposure)
- to define generic exposure scenarios covering the different categories of products or processes in which the substance is used and
- to find agreement on the way risk management measures and operational conditions should be communicated down the chain.

Such dialogues may take place at the level of sector organisations, or from company to company. Sector organisation may also provide advice to companies how an exposure scenario could look like.

HOW TO READ THIS GUIDANCE?

Chapter D.2 describes the core content of an exposure scenario under REACH. It presents an overview on the most common determinants of exposure and recommends a standard format for the final exposure scenario to be communicated down the supply chain. This also includes a list of the most common types of operational conditions (OC) and risk management measures (RMM) to be considered in ES development.

Chapter D.3 suggests a standard workflow of 14 steps, including the main outputs to be delivered, starting from use identification and ending with the final exposure scenarios for the substance. It also includes guidance on the dialogue processes needed in the supply chain to arrive at useful exposure scenarios in an efficient way.

Chapter D.4 provides guidance on developing the contents of an exposure scenario: Activities in the life cycle (Section D.4.2), description of use and title of exposure scenario (Section D.4.3), preset initial exposure scenarios defined on product categories and process categories (Section D.4.4), conditions of use for controlling risks (Section D.4.5).

Chapter D.5 provides an overview on exposure estimation. This includes guidance on the role of measured data as well as a brief explanation on a number of tools available to estimate exposure related to workers, consumers and the environment. The strength and limitations of these tools in the context of REACH are further discussed in Appendix D-1.

Chapter D.6 briefly describes situations where, based on initial exposure assessment, the manufacturer or importer may conclude that refinement of the hazard assessment is needed, before the final exposure scenario can be derived.

Chapter D.7 briefly explains the risk characterization. The risk characterization potentially triggers iterations of the initial exposure scenario. More details on risk characterisation is provided in Part E of the guidance.

Chapter D.8 contains guidance on how to finalise the exposure scenario. This includes how to integrate the operational conditions and risk management measures for the relevant exposure routes and target groups into a consistent final exposure scenario for a specific use or uses. Finally, Chapter D.9 builds the bridge to the use of exposure scenarios in

the context of the CSR and the extended safety data sheet (eSDS),

KEY ASPECTS

Exposure Assessment: Exposure assessment under REACH consists of exposure building and subsequent exposure estimation. The **exposure scenario** is meant to describe 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.

Exposure estimation: Exposure estimation under REACH is always related to defined exposure scenarios. The estimation can be carried out based on modeling or based on measured data, depending on what is available. Exposure estimation can be carried out in a tiered process starting with conservative assumptions on emissions and exposure (Tier 1 approach supported by IT tools). If the assessor fails to demonstrate control of risk based on these assumptions more details on exposure and a case by case assessment is needed.

Product and process categories: The Guidance includes lists of product and process categories that can be assigned to identified uses of a substance. The categories serve two purposes:

- They allow to link the use pattern of a substance to pre-defined initial exposure scenarios and the related exposure estimates.
- They enable the actors in the market to develop a harmonized way of communication on uses up and down the supply chains. This includes giving exposure scenarios a title.

Operational conditions and risk management measures: Both operational condition and risk management measures differ in their intention: While the impact on exposure is only a side effect from changing the operational conditions, risk management measures are intended to prevent, reduce or limit exposure.

Dual function of the exposure scenario: The exposure scenario(s) are to be documented in the Chemicals Safety Report (CSR) describing the conditions of use the exposure estimation and risk characterization are related to. At the same time, the exposure scenarios should contain practical advice to users on how to use the substance in a safe way. Both functions are equal important and require an appropriate terminology and level of detail.

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.
The Navigator can be found on the REACH Guidance website.

BIBLIOGRAPHIC INFORMATION ON THE GUIDANCE DOCUMENT

Guidance Information Requirements and Chemicals Safety Assessment (Part D) 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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