Guidance on Information Requirements and Chemical Safety Assessment

PATHFINDER

This guidance describes the information requirements under REACH with regard to substance properties, exposure, use and risk management measures, in the context of the chemical safety assessment. It is part of a series of guidance documents that are aim to help all stakeholders with their preparation for fulfilling their obligations under the REACH Regulation.

The Guidance covers:

- the collection of available information regarding the intrinsic properties of substances to be registered
- the assessment of this information against the requirements specified by REACH,
- the identification of data gaps and
- the generation of the additional information required to fill the data gaps.

The Guidance also aims to assist industry in conducting Chemical Safety Assessments and preparing Chemical Safety Reports, when required. A CSR may be required as part of a registration dossier (for non intermediates > 10 t/a), as part of an authorisation application, or as part of downstream user obligations. It also sets out the basic principles for authorities preparing a risk assessment. This may be needed in support of a restriction proposal, of a proposal to include substances into the authorisation regime, or as part of a Substance Evaluation.

The Guidance consists of two major parts: **Concise** guidance (Part A to G) and supporting **reference** guidance (Chapters R.2 to R.20).

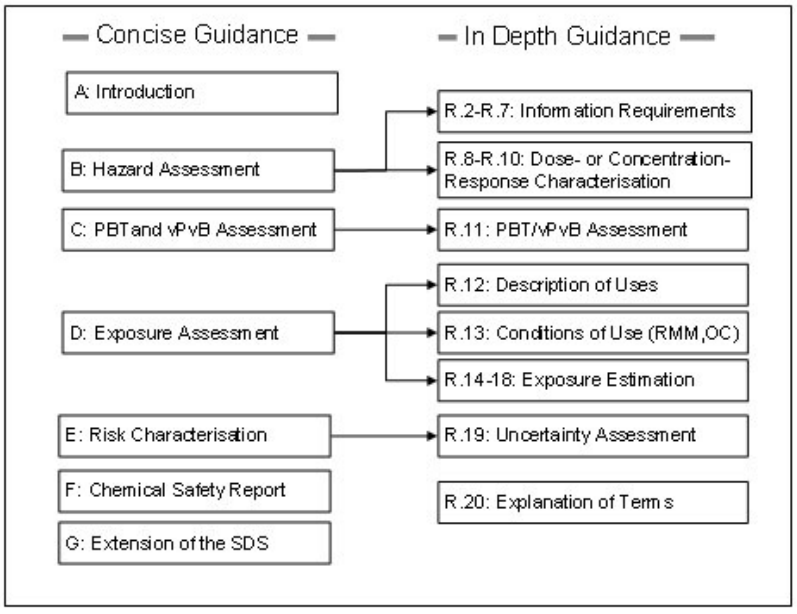

Figure 1: Structure of the Guidance

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**. The links between the concise guidance and the supporting reference guidance are illustrated in Figure 1.

Part A provides an introduction to the guidance for conducting the chemical safety assessment and preparing the chemical safety report for substances manufactured or imported in a quantity of 10 tonnes or more per year (Chapter A.1)[1]. This includes an overview on the intended outcomes and main contents of the chemicals safety assessment (CSA). It also includes the overall approach to making cost-effective decisions during the iterative process of conducting the CSA, and a pathfinder to the different elements of this guidance. Chapter A.2 explains the key facts needed to understand the process of making a chemical safety assessment. The communication and tasks within the supply chain related to the chemical safety assessment are outlined in Chapter A.3. Chapter A.4 describes in more detail, under what conditions an actor may need to carry out a CSA under REACH.

Part B contains concise guidance on hazard assessment. This covers information requirements on intrinsic properties of a substance under REACH, including information gathering, non-testing approaches and the so-called 'integrated testing strategies' for generating the relevant and required information on each endpoint. Part B also provides concise guidance on how to characterise hazards, including where possible derivation of DNELs and PNECs. Each of the sections in Part B corresponds to the more in-depth guidance contained in Chapters R.2 to R.10.
This includes:

- Physico-chemical properties in Section R.7.1
- Determination of *Derived No-Effect-Levels* (DNEL) (or other qualitative or semi-quantitative measures of potency of the substance) in Chapter R.8 and the corresponding chapters of integrated testing strategies for the relevant human health endpoints (Sections R 7.2 to R.7.7 in Chapter 7a). These Sections in Chapter R.7 also include information on how to derive appropriate information for classification and labelling of the substance. However, the guidance on classification and labelling itself is provided elsewhere. See current Annex VI to Directive 67/548 and future *Guidance on Classification, Packaging and Labelling related to the future GHS system* .
- Determination of *Predicted No-effect-Effect levels* (PNEC) in Chapter R.10 and the corresponding chapters of integrated testing strategies for the environment endpoints (Sections R.7.8 to R.7.11 in Chapter R.7b and R.7c).These sections in Chapter R.7 also include information on how to derive appropriate information for classification and labelling of the substance. However, the rules on classification and labelling themselves are provided elsewhere. See current Annex VI to Directive 67/548 and future *Guidance on Classification, Packaging and Labelling* related to the future GHS system. Section 7.13 in Chapter 7c provides guidance related to the particular assessment approaches for hydrocarbons and metals.
- Overall framework for meeting the information requirements on intrinsic properties of substances (Chapter R.2), guidance on collection of available information (Chapter R.3), evaluation of

information (Chapter R.4), guidance on exposure-driven waiving and exposure-triggered testing as well as other adaptations of information requirements (Chapter R.5), in depth guidance on non-testing approaches (Chapter R.6).

Part C contains the concise guidance on how to assess whether or not a substance is persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB). In-depth guidance on the PBT and vPvB assessment, including emission characterisation is covered in Chapter R.11.

Part D details how to develop exposure scenarios and related exposure estimation. This part contains detailed workflows on how to identify uses in the supply chain, how to develop exposure scenarios and finalise them based on the iterations necessary for controlling risks. Chapter D.2 describes the core contents of an exposure scenario under REACH. It presents an overview of the most common determinants of exposure and recommends a standard format for the final exposure scenario. 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. Chapter D.4 provides guidance on developing the contents of an exposure scenario: Activities in the life cycle, description of use and title of exposure scenario, (preset) initial exposure scenarios, conditions of use for controlling risks. Chapter D.5 provides an overview on exposure estimation. This includes guidance on the role of measured data as well as a brief explanation of a number of tools available to estimate exposure. Chapter D.6 briefly describes situation where, based on initial exposure assessment, the M/I 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 characterisation since the risk characterisation potentially triggers iterations of the initial exposure scenario. More details on risk characterisation are 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), and makes reference to Part F and Part G of the guidance.

Part D provides also links to more in-depth guidance on exposure assessment, in particular how to describe uses, how to collect information on operational conditions and risk management measures, and how to carry out exposure estimates. This includes:

- Brief general description of identified uses and how to give exposure scenarios a short title (Chapter R.12)
- Risk management measures and operational conditions for building of exposure scenarios, including guidance on how to determine the effectiveness of risk management measures and how to make use of the risk management library initially set up during the development of the current guidance (Chapter R.13).
- Occupational exposure estimation (Chapter R.14)
- Exposure estimation related to consumers (Chapter R.15)
- Exposure estimation related to the environment (Chapter R.16)
- Chapter R.17 and Chapter R.18 provide guidance on exposure estimates related to life cycle stages subsequent to identified uses (releases from articles and releases from waste life stage).

- Chapter R.20 explains the terms that are essential for the understanding of the Guidance.

Part E contains the guidance on the risk characterisation. In risk characterisation, information on hazard and exposure is combined in the risk characterisation ratio or in qualitative risk characterisation. Both types of information contain uncertainty which needs to be assessed in order to decide on the robustness of the risk estimate. The uncertainty analysis is further detailed in Chapter R.19. Part E also includes guidance on qualitative risk characterisation with regard to non-threshold substances.

Part F details the format and requirements for preparing the chemical safety report, which documents the results of the entire chemical safety assessment. Part F details subsections to the main headings as laid down in section 7 of Annex 1 of REACH and provides guidance on how to present the outcome of the CSA. This includes guidance on how to use the CSR template as published on the ECHAs website.

Part G contains the guidance on preparing the extensions to the safety data sheet (SDS). This contains information on how the exposure scenario information is communicated and implemented within the supply chain. The appendices to Part G include more specific information and/or examples on the tasks of the downstream users potentially to be anticipated by the manufacturer or importer: scaling operations when the DU is evaluating whether he operates within the boundaries of the ES communicated to him; methods applied at formulator's level to process the information received with exposure scenarios from suppliers into useful information for their own customers.

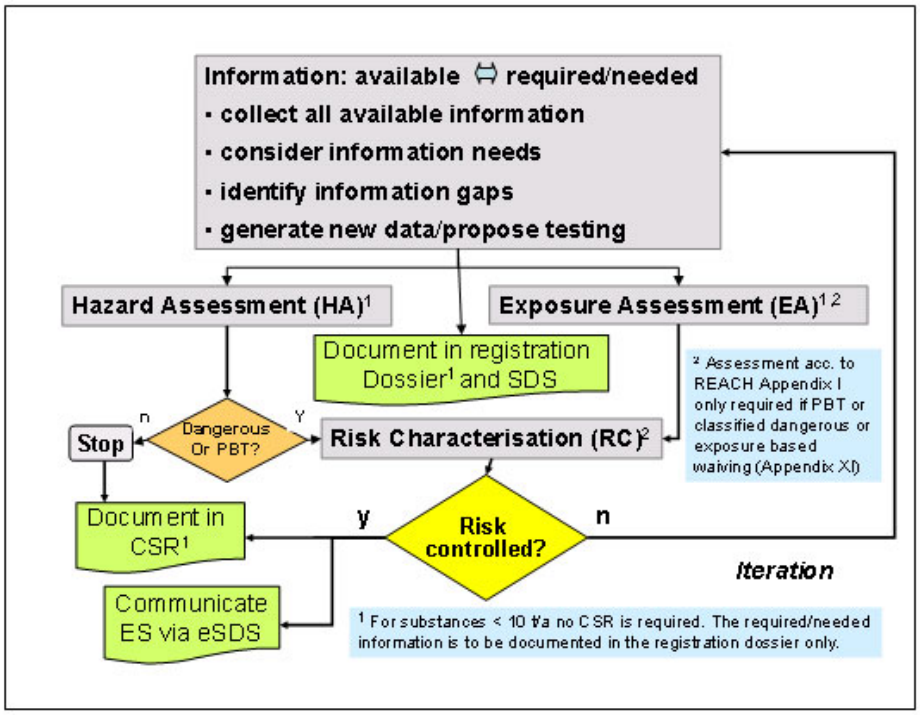

Figure 2: Overall process related to information requirements and chemicals safety assessment under REACH.

Figure 2 above presents an overview of the overall process of collecting and assessing existing information on the intrinsic properties of a substance, including identification of needs to generate new data. It also describes the process of chemical safety assessment additionally required for substances produced/imported in amounts of more than 10t per year.

Figure 3 below illustrates to which steps in the overall process a particular guidance element is related.

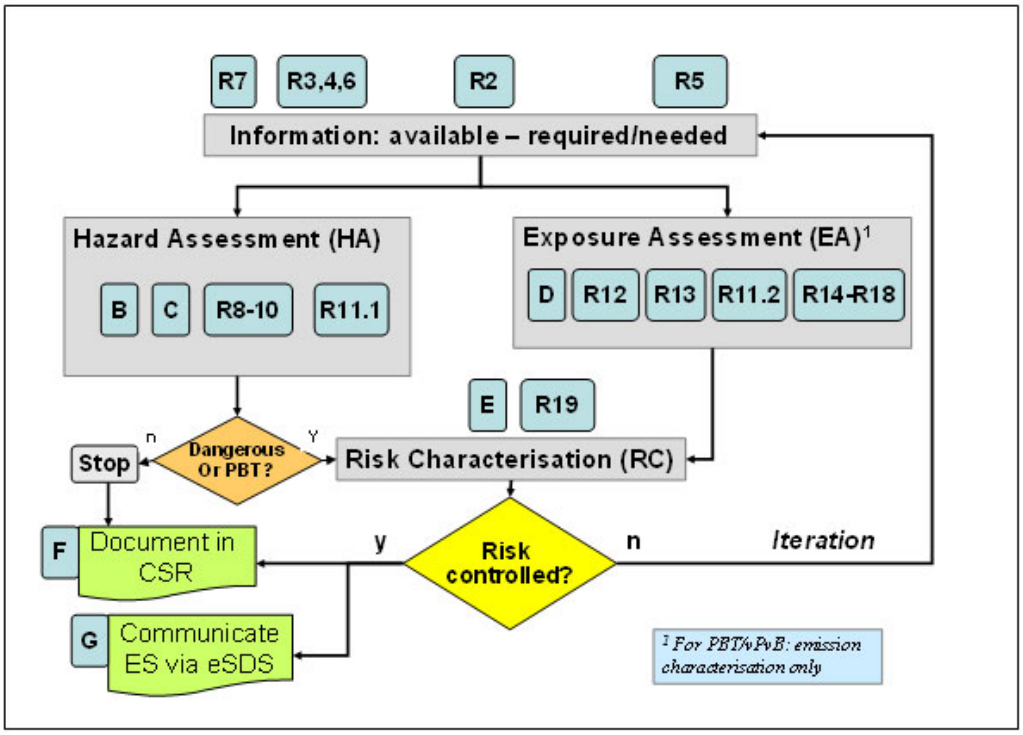

Figure 3: Relationship between the process steps and the guidance elements

Structure of the Guidance on Information Requirements and Chemical Safety Assessment

Part A - Introduction to the Guidance Document

[download PDF version - PART A] [download ZIP version - PART A]

Part B - Hazard Assessment

[download PDF version - PART B] [download ZIP version - PART B]

Part C - PBT Assessment

[download PDF version - PART C] [download ZIP version - PART C]

Part D - Exposure Scenario Building

[download PDF version - PART D] [download ZIP version - PART D]

Part E - Risk Characterisation

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Part F - Chemicals Safety Report

[download PDF version - PART F] [download ZIP version - PART

F]
(Finalised 30/07/08)
[download PDF version - Appendix PART F] [download ZIP version - Appendix PART F]

Part G - Extension of SDS
[download PDF version - PART G] [download ZIP version - PART G]

Information requirements
[download PDF version - Chapter R.2] [download ZIP version - Chapter R.2]

Information gathering
[download PDF version - Chapter R.3] [download ZIP version - Chapter R.3]

Evaluation of available information
[download PDF version - Chapter R.4] [download ZIP version - Chapter R.4]

Adaptation of Information requirements
[download PDF version - Chapter R.5] [download ZIP version - Chapter R.5]

QSARs and grouping of chemicals
[download PDF version - Chapter R.6] [download ZIP version - Chapter R.6]

Endpoint specific guidance
[download PDF version - Chapter R.7a] [download ZIP version - Chapter R.7a]
[download PDF version - Chapter R.7b] [download ZIP version - Chapter R.7b]
[download PDF version - Chapter R.7c] [download ZIP version - Chapter R.7c]
[download PDF version - Appendix R.7.13-2] [download ZIP version - Appendix R.7.13-2]

Characterisation of dose [concentration] - response for human health
[download PDF version - Chapter R.8] [download ZIP version - Chapter R.8]

Physico-chemical hazards
[download PDF version - Chapter R.9] [download ZIP version - Chapter R.9]

Characterisation of dose [concentration] - response for environment
[download PDF version - Chapter R.10] [download ZIP version - Chapter R.10]

PBT Assessment
[download PDF version - Chapter R.11] [download ZIP version - Chapter R.11]

Use descriptor system
[download PDF version - Chapter R.12] [download ZIP version - Chapter R.12]

Risk management measures and operational conditions
[download PDF version - Chapter R.13] [download ZIP version - Chapter R.13]

Occupational exposure estimation
[download PDF version - Chapter R.14] [download ZIP version - Chapter R.14]

Consumer exposure estimation
[download PDF version - Chapter R.15] [download ZIP version - Chapter R.15]

Environmental exposure estimation
[download PDF version - Chapter R.16] [download ZIP version - Chapter R.16]

Estimation of exposure from articles
[download PDF version - Chapter R.17] [download ZIP version - Chapter R.17]

Estimation of exposure from waste life
[download PDF version - Chapter R.18] [download ZIP version - Chapter R.18]
(Finalised 30/07/08)

Uncertainty analysis
[download PDF version - Chapter R.19] [download ZIP version - Chapter R.19]

Table of terms
[download PDF version - Chapter R.20] [download ZIP version - Chapter R.20]

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1. Guidance on collection and evaluation of information related to use and exposure required according to Annex VI point 6 for substances between 1 and 10 t/y is not covered in this guidance. For information consult the Guidance on Registration.