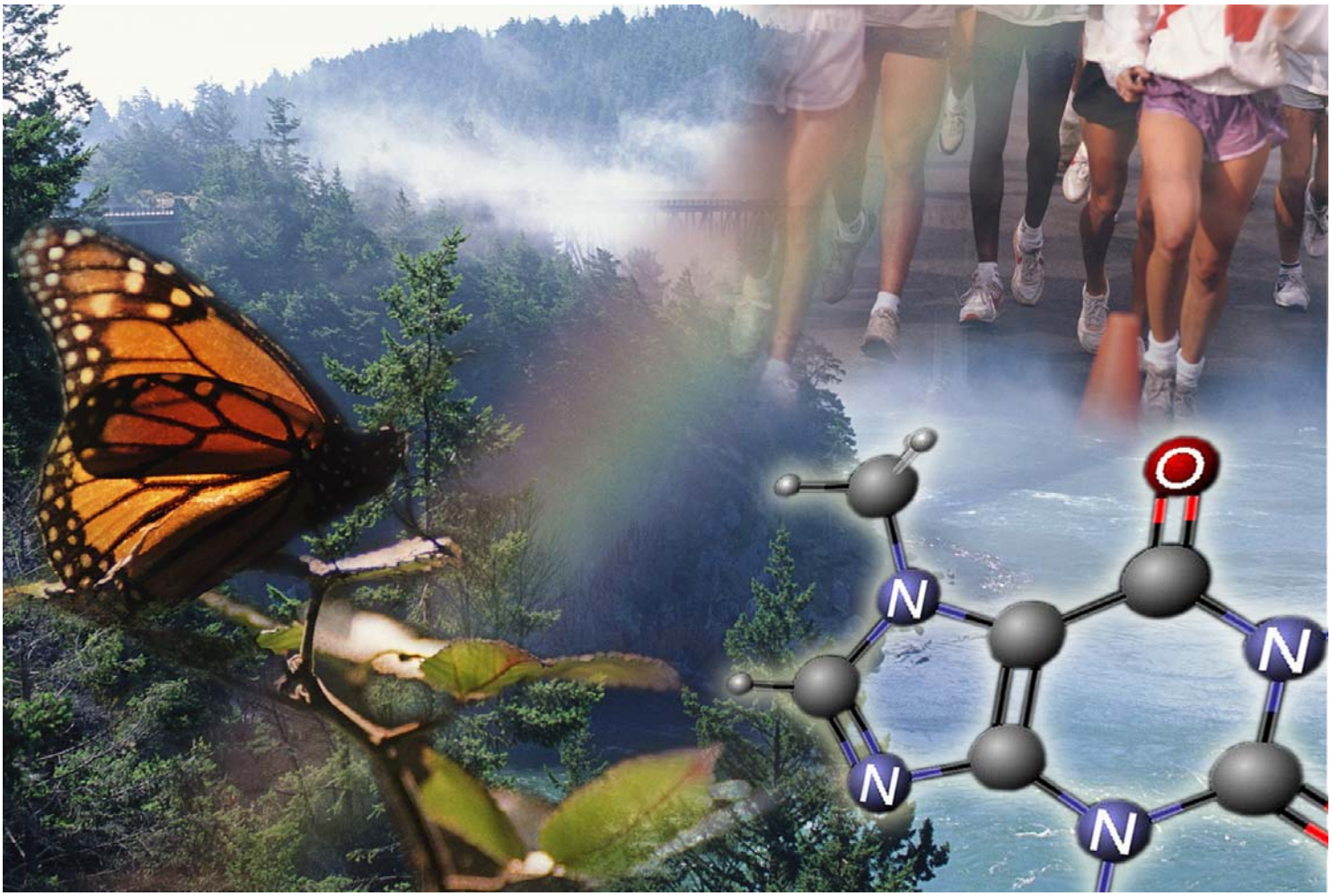
Guidance on information requirements and chemical safety assessment

Part F: Chemical Safety Report



July 2008
(version 2)

LEGAL NOTICE

This document contains guidance on REACH explaining the REACH obligations and how to fulfil them. However, users are reminded that the text of the REACH regulation is the only authentic legal reference and that the information in this document does not constitute legal advice. The European Chemicals Agency does not accept any liability with regard to the contents of this document.

PREFACE

This document describes the information requirements under REACH with regard to substance properties, exposure, use and risk management measures, and the chemical safety assessment. It is part of a series of guidance documents that are aimed to help all stakeholders with their preparation for fulfilling their obligations under the REACH regulation. These documents cover detailed guidance for a range of essential REACH processes as well as for some specific scientific and/or technical methods that industry or authorities need to make use of under REACH.

The guidance documents were drafted and discussed within the REACH Implementation Projects (RIPs) led by the European Commission services, involving stakeholders from Member States, industry and non-governmental organisations. These guidance documents can be obtained via the website of the European Chemicals Agency (http://echa.europa.eu/reach_en.asp). Further guidance documents will be published on this website when they are finalised or updated.

This document relates to the REACH Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006[1]

1 Corrigendum to Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006); amended by Council Regulation (EC) No 1354/2007 of 15 November 2007 adapting Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) by reason of the accession of Bulgaria and Romania (OJ L 304, 22.11.2007, p. 1).

DOCUMENT HISTORY

Version	Comment	Date
Version 1	First edition	May 2008
Version 2	First revision	July 2008

Convention for citing the REACH regulation

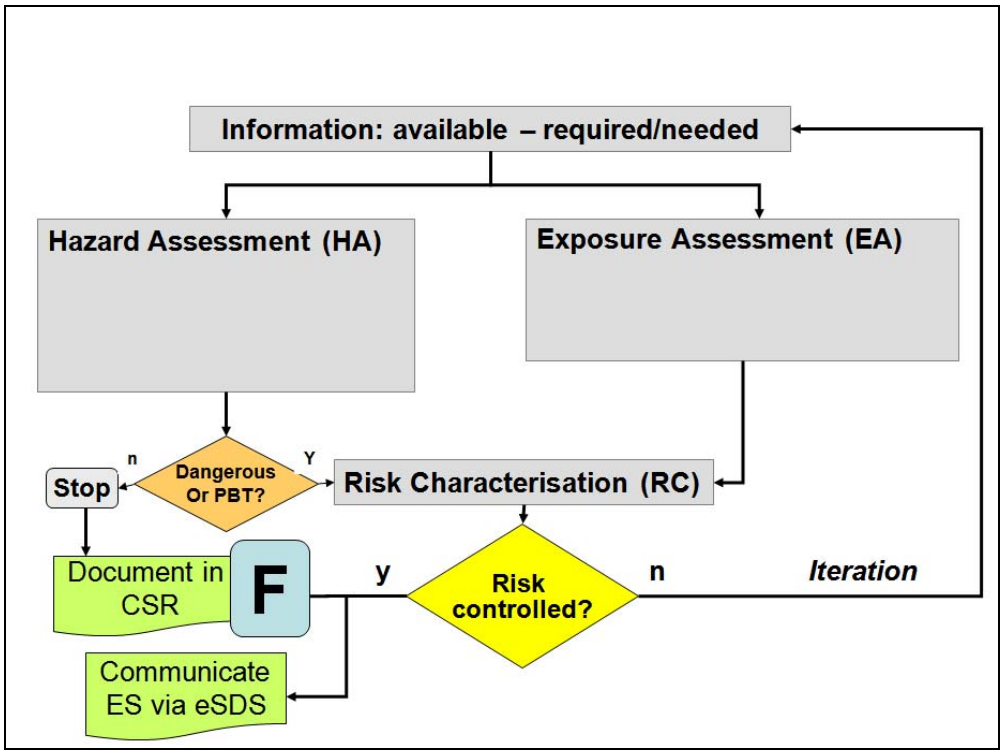
Where the REACH regulation is cited literally, this is indicated by text in italics between quotes.

Table of Terms and Abbreviations

See Chapter R.20

Pathfinder

The figure below indicates the location of part F within the Guidance Document



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F.1 INTRODUCTION

The main goal of the chemical safety report (CSR) is to document the chemical safety assessment (CSA), including its conclusions and results.

This guidance is meant to assist the registrant to write a chemical safety report that documents the chemical safety assessment as laid out in Parts A to E of the *Guidance on Information Requirements and Chemicals safety Assessment*. The chemical safety assessment needs to be conducted according to REACH Regulation ((EC) No 1907/2006). The elements to be included in the report are listed in the format provided in Annex I, point 7 of the Regulation.

The 'registration dossier' is the set of information submitted by a registrant for a particular substance to comply with registration requirements. It consists of two main components:

(i) a **technical dossier**, which has to be submitted using IUCLID 5 format

(ii) a **chemical safety report**, which is stand alone document attached in the IUCLID registration dossier.

This guidance briefly describes the content of each section of the Chemical Safety Report.

The CSR should be readily understandable as a stand-alone document. The principles applied, the assumptions made and the conclusions drawn should be transparent. The key data should be easily identifiable without the need to revert to the underlying substance data sets (i.e. the IUCLID substance data set). All relevant information for the chemical safety assessment should be presented.

The CSR is the source from which the information to be communicated further down the supply chain is to be extracted (extended safety data sheet).

A template for the chemical safety report will be available from the ECHA website (http://echa.europa.eu/reach_en.asp)[2]. In appendix 1 to this Guidance you will find the template with specific guidance under each section.

When a CSR is prepared for a category of substances the reporting format will have to be adapted. More guidance on the use of a category approach can be found in R.6.2.

F.2 WRITING THE CHEMICAL SAFETY REPORT

F.2.1 General requirements

The CSR should enable all users to understand the chemical safety assessment and the scientific arguments that support the conclusions of the hazard assessment, and, if the substance meets the criteria for classification as dangerous or is considered to be a PBT/vPVB, exposure assessment and risk characterisation. It is emphasised that key information in the CSR on hazard and exposure must

[2] Select “guidance” on the left panel and then “formats” on the top bar.

be clearly presented and justified, must be traceable to its sources and documented properly with regard to equations, units, references and calculation or IT-tools used.

The CSR should be consistent on the assumptions with regard to hazard, exposure estimation and the recommendations in the exposure scenario. The assumptions on operational conditions and risk management must be traceable in the exposure estimation and consistent with the final exposure scenario in the CSR. This is needed to evaluate whether the exposure scenario, if present, is based on the conclusions of a chemical safety assessment and the recommended risk management measures are valid to ensure control or risks. Therefore, the CSR should clearly present the key studies or information for each section, document the key assumptions and provide an interpretation and conclusion narrative for each section.

Key information that is present elsewhere (e.g. in the technical dossier[3]) should be presented in a brief table format and referenced, rather than repeat the details. A narrative interpretation and conclusion section is usually needed. When there are multiple sources of key data for hazard or exposure, the choice of the key information needs to be justified. This justification can also be reported in the "endpoint summaries" in the IUCLID 5 substance data set and then reported in the CSR.

Annex I of the REACH Regulation includes general provisions for assessing substances and preparing a Chemicals Safety Report (CSR). Section 7 of Annex I includes a format with standard headings that shall be included in the CSR. The CSR needs to contain

i. Conclusions from the CSA. If results were derived by means of quantitative methods, details should be presented to allow an evaluator to reproduce the results. If results were derived by means of a qualitative (weight of evidence) reasoning, this should be reported.

ii. For any endpoint in the hazard or PBT/vPvB sections for which no relevant information is available, the relevant section shall contain the sentence: 'This information is not available'. In addition, a statement could be added if the information is <u>not required</u> for a tonnage band or that the results of the CSA <u>do not indicate</u> that it should be taken into account (e.g., when the CSA does not indicate an exposure-triggered risk to soil organisms as in REACH Annex X-9.4).

iii. For any endpoint in the hazard section a statement that although the hazard information is or could be required, the information can be waived. This needs to be argued and documented in a weight of evidence or quantitative reasoning.

iv. For any endpoint in Annex IX and X or REACH a testing proposal when needed.

v. The reason why information on specific exposure pathways is not reported. This should be clearly stated and argued. The absence of exposure information need to be argued in order to evaluate if exposure based triggers have been correctly considered.

The information of each section of the CSR usually contain both

i. Factual information on hazard or exposure. Where possible, overview information should be presented in a table format, presenting the relevant information and identify the key information or study.

ii. A narrative and an interpretation of results for the chemical safety assessment.

[3] IUCLID 5 substance dataset

F.2.2 Making use of the template in the appendix of the guidance

The CSR template in Appendix F-1 is based on the required standard headings of Annex I of REACH and provides further guidance on how to detail and structure the information under each of these headings. Reference to appropriate sections of the *Guidance on information requirements and chemical safety assessment* is included in each section.

The CSR is meant to document the outcomes of the CSA process according to the *Guidance on Information Requirements and Chemicals Safety Assessment* in a transparent and consistent manner. Thus the template aims to give the relevant information a defined place in the CSR. A standardised sub-structure under the headlines of REACH Annex I as set out in this template is expected to facilitate the further use of the CSR by the registrant (up-to-date documentation of the chemicals safety, source of information for any other REACH processes) and by the authorities, including efficient and transparent dossier evaluation.

Detailing the information in structured field in this template is meant to enable IT support for generating, managing, updating, editing, exporting and importing information in/from/to the CSR and the safety data sheet. As a consequence it is expected that when appropriate IT tools are available they will support the preparation of CSR as presented in this template. A CSA tool, assisting registrant in the elaboration of their exposure scenarios, chemical safety assessment and reporting in their CSR will be developed by ECHA and it is expected to have an initial release in the second half of 2009. In the interim the CSR template is meant to support registrants to structure the content of the CSR. Except for the headlines from Annex 1 section 7, it is however not mandatory to use all or parts of the more detailed sub-structure of the template.

The information fields are to be filled as appropriate, depending on the case. It is up to the registrant to decide and justify

- where information has to be provided in order to fulfil the requirements for hazard and PBT assessment and, where needed, exposure assessment and risk characterisation to demonstrate control of risk,
- and in which data fields no information is needed.

Text should be added when relevant in any section. The documentation should be transparent and cover all assumptions/decision made during the chemical safety assessment in a way that the reader can logically follow how conclusions are reached.

For the hazard part (sections 1 and 2 to 7) subheadings have been added. The general structure for reporting information on each endpoint is the following:

- Overview of study results
- Data waiving, when relevant (including its justification)
- Testing proposal, when relevant (including specifications of the testing proposals and the timetable)
- Discussion (including conclusions on hazard assessment for classification and labelling and chemical safety assessment)

For those sections ECHA is managing a project on identifying the data that could be reported automatically from a IUCLID 5 substance dataset. This project is running in parallel to this one and

integrates IT constraints (mainly on selection and filtering rules for data import from IUCLID 5) as it is planned that a plug-in to IUCLID 5 for that purpose should be made available in autumn 2008.

For exemplification of what will be automatically imported from IUCLID 5, examples have been included.

All the text written in blue and highlighted in grey exemplifies the information that could be extracted automatically from IUCLID 5. The tables will only be displayed if not empty. In the tables the first row describes the content of the information that will be imported from IUCLID 5 using the names of the IUCLID 5 fields. The rules for reporting (in which situation the information will be reported or not depending on the value of the fields) cannot be described in this document. For illustration purposes, an example is sometime provided in a second row.

The subheadings in the exposure scenario part (section 9.x.1 of the CSR format) are consistent with the ES format as contained in Guidance Part D. The corresponding information on the content of each ES (factual information, justification, explanation) can be presented under these headlines. The assessor may choose to use one or more of the tables available in each section to structure the relevant information. These tables largely contain structured data fields for those determinants of exposure that can be addressed by existing tier 1 exposure estimation tools. The tables are designed in a way that they can support the integration of environment and human health aspects at exposure scenario level. Basically the tables suggest to compile i) site related information (covering determinants related to occupational and environmental exposure) and ii) product related information (covering determinants related to occupational or consumer exposure and environmental exposure).

In the exposure estimation part (section 9.x.2 of the CSR format), a series of subheadings and tables defines the information potentially needed to carry out a risk characterization. Information on estimated exposure and measured exposure can be presented side by side. If the exposure scenarios are supported by measured data on exposure, the data presented in section 9.x.2 must correspond to the conditions of use described in section 9.x.1. The same applies to any emission characterization carried out in a section 9.x.2.