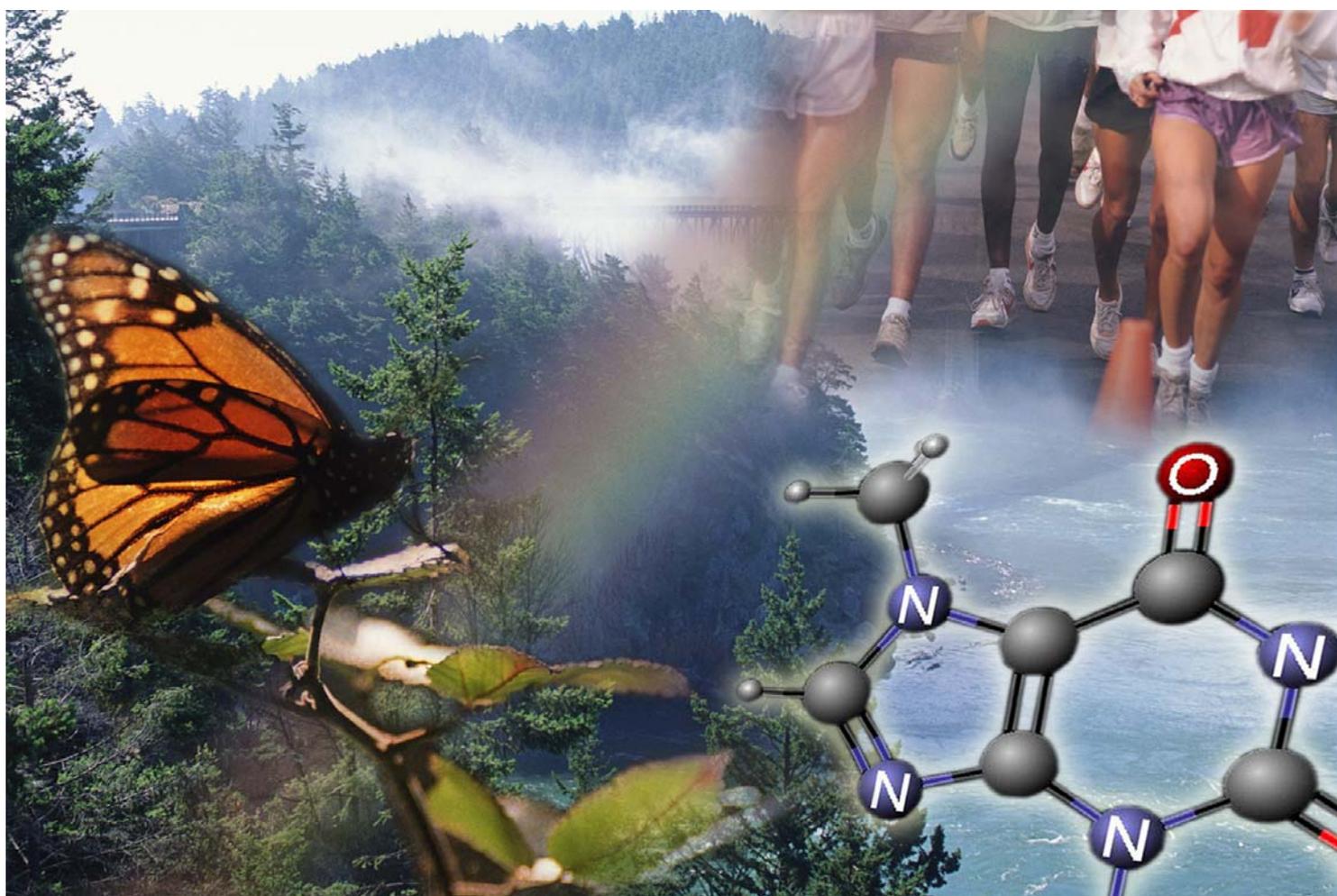


Guidance on information requirements and chemical safety assessment

Chapter R.20: Table of terms and abbreviation



May 2008

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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/about/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 2006¹

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).

TABLE OF TERMS

This table of terms aims to support the understanding related to exposure assessment as part of the CSA process. It is limited to those terms not elsewhere defined or requiring additional explanation, and having been subject to repeated clarification need during the development of this guidance. For further questions on terminology, please also consult the ECHA glossary of terms.

Please note: A corresponding table of terms related to information requirements has not been compiled so far, although a list of terms was part of the draft Chapter R.7c (March version). A disclaimer in section R.7.14 of the draft Chapter R.7c however states: “This collection of definitions was originally written in the development of the technical guidance on information requirements. A number of comments on what was previously termed the glossary have been submitted by various stakeholders. However, they will need to be reviewed by the expert network before any agreed changes in concepts can be introduced and their position clarified in the future document.”

It was not possible during the finalisation of the Guidance to re-activate this network. It is therefore left to future guidance updates to expand chapter R.20 with the relevant key terms essential for the understanding related to information requirements. The list of terms from draft Chapter R.7c (March 08 version) may serve as starting point for this future work.

In the interim the user of the Guidance is advised to use the definitions presented in the single chapters and sections of the Guidance, to refer to the definitions contained in Article 3 of the Regulation, and to consult the [Glossary](#) of the Chemicals Agency.

Term	Definition
Article category	Element of the use descriptor system characterising the type of article in which a substance is contained
Article producer	Reach terminology: Article <i>producer</i> and substance <i>manufacturer</i>
Brief general description of use	Description of identified uses in the registration dossier (see REACH Annex VI, point 3.5)
Broad exposure scenario	Exposure scenarios can cover a wide range of uses. Has the same meaning as a <i>use and exposure category</i> .
Conditions of use	Conditions of use include the operational conditions (OC) and risk management measures (RMM) as described in an exposure scenario

Term	Definition
Control of risks	<p>= risks are controlled.</p> <p>For substances for which it is possible to derive no-effect-levels (DNEL or PNEC) the risk characterisation has to conclude that the estimated exposure levels do not exceed these no-effect-levels. However, there are also cases where the risk characterisation needs to be based on other approaches:</p> <ul style="list-style-type: none"> ▪ For those human health effects and environmental spheres for which it is not possible to determine a DNEL or PNEC, the risk characterisation consists of semi-quantitative or qualitative assessment of the likelihood that adverse effects are avoided. ▪ For substances fulfilling the PBT and vPvB criteria (see Annex XIII of REACH) the risks can be concluded to be controlled when the emissions and exposures are minimised by the implementation of the ES. ▪ In addition, the assessment of physico-chemical hazards has to conclude that the likelihood and severity of an event occurring due to these properties is negligible.
Cumulative = combined exposure	<p>A substance registered by one manufacturer may enter into the environment via different products and processes. In the exposure estimate however the registrant should take into account all routes and pathways. The same applies to consumer exposure to the same substance via different pathways, including indirect exposure via the environment.</p> <p>The registrant is not obliged to take into account the exposure to the same substances from other manufacturers or importers. Nevertheless it can be wise to be aware of the fact that too high cumulative exposure across the substance volumes from different manufacturers may trigger Community action.</p>
Determinants of emissions and/or exposure	<p>Factors determining the exposure and or release when a substance is manufactured or used (including the subsequent life cycle stages: service life and waste disposal). These factors include the characteristics of the substance, the operational conditions and risk management measures.</p>
Downstream use	<p>Use of a substance, either on its own or in a preparation, in the course of his industrial or professional activities. A distributor or a consumer is not a downstream user.</p>
Environmental release categories	<p>A pre-set combination of life cycle stage, distribution of emission sources, fate of substance in the technical process, level of containment, default emission factors (uncontrolled) and presence of waste water treatment, typical for an identified use.</p>

Term	Definition
Exposure assessment	Exposure assessment aims to make a quantitative or qualitative estimate of the dose / concentration of the substance to which humans and the environment are or may be exposed. Exposure assessment under REACH consists of two steps: 1) Development of Exposure Scenarios and 2) Exposure Estimation, which have to be iterated until it can be concluded that the resulting exposure scenarios would ensure adequate control of risks upon implementation.
Exposure scenario	<p>Set of conditions, including operational conditions and risk management measures, that describe how the substance is manufactured or used during its life-cycle and how the manufacturer or importer controls, or recommends downstream users to control, exposures of humans and the environment.</p> <p>The ES in the context of the CSR and in context of the SDS have a different purpose, and thus the content may differ. For example, the ES in the CSR will contain justifications and comments, the ES in the SDS annex will not. However the CSR chapters and their content must be consistent with the content of ES in the SDS.</p>
Exposure estimation	Quantification of exposure related to the operational conditions and risk management measures as described in an exposure scenario. Exposure scenario building and the related exposure estimate together build the exposure assessment.
Final exposure scenario	The final ES is developed from the initial ES, and describes the operational conditions and risk management measures suitable to the control risk in an identified use (or a group of uses) of a dangerous substance.
Generic exposure scenario ²	Exposure scenario(s) for the typical conditions of use(s) of a certain type of substance (e.g. solvents, pigments, resins, detergents) within a certain sector industry (area of use), suitable to control risks for substances with a certain generic hazard profile (e.g. low toxicity , low volatility). Such GES aims to cover the whole life cycle of the type of substance.
Initial exposure scenario	<p>The initial ES describes the current conditions of use based on information readily available to M/I when starting the chemicals safety assessment for the identified use (or groups of uses) for a dangerous substance.</p> <p>The initial ES forms the starting point for the exposure estimate and risk characterisation. An initial ES is a set of assumptions (using the determinants of exposure) on how a process is conducted and which risk management measures are used or should be implemented. The tentative ES may have to be adapted dur-</p>

² Draft initial definition; refinement needed, depending on how solvent industry and other CEFIC sectors groups further develop the concept.

Term	Definition
	ing the iterative Chemical Safety Assessment until it is shown that risks are controlled. The resulting ESs shall be implemented for own manufacture/use and/or communicated to Downstream Users (DU) as annex to the Safety Data Sheet.
Identified use	<p>Use means: any processing, formulation, consumption, storage, keeping, treatment, filling into containers, transfer from one container to another, mixing, production of an article or any other utilisation;</p> <p>Identified use: means a use of a substance on its own or in a preparation, or a use of a preparation, that is intended by an actor in the supply chain, including his own use, or that is made known to him in writing by an immediate downstream user;</p> <p>Note: Using articles (including the substances contained) or treatment of waste (including the substances contained) is not a <i>use</i> in the meaning of REACH. These life cycle stages result from a downstream use (e.g. processing substances into an article) or a consumer use of substances or preparations.</p>
Operational conditions	Operational conditions include e.g. physical appearance of preparation, duration and frequency of use/exposure, amount of substance, room size and ventilation rate. More general: The operational conditions include any action, use of tool or parameter state <i>that prevails</i> during manufacture or use of a substance (either in a pure state or in a preparation) that as a side effect might have an impact on exposure of humans and/ or the environment.
Risk management measures	<p>Measures that control the emission of a substance and/or exposure to it, thereby controlling the risks to human health or the environment.</p> <p>Risk management measures include e.g. containment of process, local exhaust ventilation, gloves, waste water treatment, exhaust air filters. More general: risk management measures include any action, use of tool, change of parameter state <i>that is introduced</i> during manufacture or use of a substance (either in a pure state or in a preparation) in order to prevent, control, or reduce exposure of humans and / or the environment.</p>
Use outside the conditions described in an exposure scenario	If a downstream user cannot demonstrate that he works within the conditions described in the exposure scenario communicated to him he has the duty to i) carry out an own CSA and/or ii) to inform his supplier that the ES needs to be adapted or an ES that covers the conditions needs to be added to the eSDS.
Preparation/product category	Element of the use descriptor system characterizing the type of chemical product in which the substance is (finally) used. Includes also intermediates and single substances marketed as chemical product. Under the GHS system preparations will be called mixtures.

Term	Definition
Process category	Element of the use descriptor system describing the type of technical processes applied during manufacturing and use (PROCs). In other categorisation systems for occupational conditions, the term <i>operation unit</i> (OU) is used.
Sectors of use	Element of the use descriptor system describing the sector of economy (industry, professional service, private) a substance is used in, as such or in a preparation.
Short title of exposure scenario	<p>Describes the uses and/or subsequent life cycle stages of a dangerous substance addressed in an exposure scenario. The short title of the ES should be consistent with the brief general description of use (see Annex I, point 5.1.1). The building blocks for the short title can be obtained from the use descriptor system (UDS).</p> <p>Note: The short title of an exposure scenario is only meant to label the content of the ES (operational conditions and risk management measures) but is not the exposure itself.</p>
Substitution	Replacement of a substance, or physical appearance of a preparation or a technique with an alternative (less hazardous or lower exposure potential). The registrant of a substance under REACH will usually not recommend the substitution of that substance as a risk management measure. However he can advise against a certain use of the substance or limit the uses covered in his exposure scenario. In this way he may initiate substitution further down the supply chain.
Use and exposure categories	Means an exposure scenario covering a wide range of processes or uses, where the processes or uses are communicated, as a minimum, in terms of the brief general description of use. See REACH Article 3 (38)
Use descriptor system (UDS)	<p>Set of 4 descriptors which can be used i) to briefly describe identified uses in a brief general way and ii) to build the short title of an exposure scenario. The four descriptors are:</p> <ul style="list-style-type: none"> • Sectors of use (SU) • Preparation/product Category (PC) • Process category (PROC) • Article category (AC)

B. Abbreviations

Note - this listing will be update in the final version

ABS	Absorption
AC	Article category
AF	Assessment factor
AS	Allometric scaling
AUC	Area under the curve; area under the blood/plasma concentration curve vs. time curve, representing the total amount of substance reaching the blood/plasma
BCF	Bio concentration factor
BMD	Benchmark dose; The BMD concept involves fitting a mathematical model to dose-response data. The BMD is defined as the dose causing a predetermined change in response.
BMD10	The benchmark-dose associated with a 10% response (for tumours upon lifetime exposure after correction for spontaneous incidence, for other effects in a specified study)
BMDL10	The lower 95% confidence interval of a benchmark-dose representing a 10% response (e.g., tumour response upon lifetime exposure), i.e. the lower 95% confidence interval of a BMD10
BMF	Bio magnification factor
BREF	Best available technique reference document
BSAF	Biological soil accumulation factor
Bw	Body weight
CAD	Chemical Agent Directive
CBI	Confidential business information
CGS	Control guidance sheets
Cmax	Peak plasma concentration
CNS	Central nervous system
CSA	Chemical safety assessment
CSR	Chemical safety report

DMEL	Derived minimum effect level
DNEL	Derived no effect level
DU	Downstream user
DU-CSA	Downstream user chemical safety assessment
DU-TGD	Downstream user technical guidance document
EASE	Estimation and assessment of substance exposure
ECHA	European Chemicals Agency
ED10	Effective dose 10 %; a dose representing an increased incidence of 10 % due to a specific exposure (e.g., to a chemical).
EFSA	European Food Safety Authority
ELR	Excess lifetime risk; additional lifetime risk over the background normal risk (or incidence of disease)
EINECS	European Inventory of Existing Commercial Chemical Substances
EPIWIN	Estimation Program Interface for Windows
EPL	Exposure predictor band liquid
EPS	Exposure predictor band solid
ERC	Environmental release class
ES	Exposure scenario
ESD	Emission scenario document
eSDS	extended safety data sheet
EUSES	European System for the Evaluation of Substances
EWL	European waste list
GDMF	General decision making framework
HBMD10	Human BMD10
HEvE	Human exposure via environment
HH	Human health
HSE	Health safety environment
HT25	Human T25
HtLF	High to low dose risk extrapolation factor
IC	Industry category

IPPC	Integrated pollution prevention and control
ITS	Integrated testing strategy
LC50	Median lethal concentration. The concentration causing 50 % lethality
LCS	Life cycle stage
LD50	Median lethal dose. The dose causing 50 % lethality
LED10	Lowest confidence limit of the ED10
LEV	Local exhaust ventilation
LMS	Linear multistage model
LOQ	Limit of quantitation
M/I	Manufacturer / importer
MoE	Margin of exposure
MTD	Maximum tolerated dose
NACE	Nomenclature générale des activités économiques dans les Communautés Européennes
NAEC	No adverse effect concentration
NAEL	No adverse effect level
NOAEL	No observed adverse effect level
NOEL	No observed effect level
OC	Operational condition
OR	Odds ratio; the ratio of the odds of an event occurring in one group to the odds of it occurring in another group
ORL	Lowest confidence limit of the OR
OU	Operational unit
PBPK	Physiologically-based pharmacokinetic modelling
PC	Chemical product category
PBT	Persistent, bioaccumulative, toxic
PEC	Predicted environmental concentration
PNEC	Predicted no effect concentration
PPE	Personal protection equipment
PROC	Process category

(Q)SAR	Qualitative structure activity relationship, mathematical method to predict e.g. biological activity based on chemical structure
RMM	Risk management measure
RC	Risk characterization
RCR	Risk characterization ratio
RR	Relative risk
RRL	Lower bound exposure value associated with the RR-value of 1.1
SDS	Safety data sheet
SME	Small and medium enterprise
SIEF	Substance information exchange forum
SMR	Standardised mortality ratio
SMRL	Lower bound exposure value associated with the SMR-value of 1.1
sRV	Standard respiratory volume
STP	Sewage treatment plant
SU	Sectors of use
SVHC	Substances of very high concern
T25	The chronic dose rate that will give 25% of the animals' tumours at a specific tissue site after correction for spontaneous incidence, within the standard life time of that species
TARIC	Tarif intégré des Communautés Européennes
TTC	Threshold of toxicological concern
TWA	Time-weighted average exposure
UC	Use category
UCN	Use code Nordic
UDS	Use descriptor system
UEC	Use and exposure categories
UVCB	Substances of unknown or variable composition, complex reaction products or biological materials as defined in the <u>Guidance on substance identification</u>
wRV	Worker respiratory volume