Guidance on information requirements and chemical safety assessment

Chapter R.20: Table of terms and abbreviations

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Guidance for the implementation of REACH

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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/web/guest/support/guidance-on-reach-and-clp-implementation). 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] and its amendments as of 31 August 2011.

1 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).

DOCUMENT HISTORY

Version 1	First edition	May 2008
Version 1.1.	Corrigendum: (i) replacing references to DSD/DPD by references to CLP (ii) alignment with updated Chapter R12 Version 2 (iii) Additions of terms to the Abbreviations list (iv) further minor editorial changes/corrections	November 2012
Version 1.2	Corrigendum: (i) Correction text corresponding to the abbreviation PNEC (ii) Deletion of the term eSDS (and replacement of its occurrence within this document with “extended SDS”) (iii) Addition of a footnote with an alternative meaning for the abbreviation OR (only representative). Please note that no other revision to add new terms to the list has been made. (iv) Other minor typographical corrections.	September 2013

TABLE OF TERMS[2]

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 *producer* and substance *manufacturer*
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 *use and exposure category*.
Chemical product category (PC)	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.
Conditions of use	Conditions of use include the operational conditions (OC) and risk management measures (RMM) as described in an exposure

[2] The present corrigendum only addresses alignment with the CLP Regulation and other corrections. Thus, the table has not been updated to cover additional issues such as information requirements.

Term	Definition
	scenario
Control of risks	= risks are controlled. 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: ▪ 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	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. The registrant is not obliged to take into account the exposure to the same substances from other manufacturers or importers. Nevertheless in 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.
Determinants of emissions and/or exposure	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.
Downstream use	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.
Environmental release categories (ERC)	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.

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	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. 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.
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[3]	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	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 substance. 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-

[3] 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	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; Identified use: means a use of a substance on its own or in a mixture, 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; Note: Using articles (including the substances contained) or treatment of waste (including the substances contained) is not a *use* 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.
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 ***that prevails*** 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	Measures that control the emission of a substance and/or exposure to it, thereby controlling the risks to human health or the environment. 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 ***that is introduced*** 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.
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 extended SDS.
Process category	Element of the use descriptor system describing the type of

Term	Definition
	technical processes applied during manufacturing and use (PROCs). In other categorisation systems for occupational conditions, the term *operation unit* (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 mixture.
Short title of exposure scenario	Describes the uses and/or subsequent life cycle stages of a 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). 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.
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)	Set of 5 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: • Sectors of use (SU) • Chemical product category (PC) • Process category (PROC) • Article category (AC) • Environmental release category (ERC)

B. Abbreviations

Note - this listing has been updated by adding general abbreviations appearing in the guidance on information requirements and chemical safety assessment.

ABS	**Absorption**
AC	**Article category**
ADME	**Absorption, distribution, metabolism, and excretion**
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 Agents Directive**
CBI	**Confidential business information**
CEN	**Comité Européen de Normalisation (European Committee for Standardization)**
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**
DPD	**Directive 1999/45/EC (Dangerous Preparations Directive, DPD).**
DSC	**Differential Scanning Calorimetry**
DSD	**Directive 67/548/EEC (Dangerous Substances Directive, DSD)**
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 in-creased 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**
EUSES	**European System for the Evaluation of Substances**
EWL	**European waste list**
GDMF	**General decision making framework**
GHS	**Globally Harmonised System of Classification and Labelling of Chemicals**[4]

[4] Globally Harmonised System of Classification and Labelling of Chemicals (GHS), Second revised edition, United Nations New York and Geneva, 2007

GLP	**Good Laboratory Practice**
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**
ISO	**International Standards Organisation**
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**
MMAD	**Mass median aerodynamic diameter**
MoA	**Mode of action**
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[5]	**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**
QSPR	**Quantitative structure–property relationships**
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**
RSS	**Robust study summaries**
SDS	**Safety data sheet**
SME	**Small and medium enterprise**
SI	**The International System of Units**
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**

[5] Please note that in other contexts OR is an abbreviation for "Only representative"

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**
TG	**Test Guideline**
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**
UN	**United Nations**
UN-MTC	**The UN Manual of Tests and Criteria contains criteria, test methods and procedures to be used for classification of dangerous goods according to the provisions of Parts 2 and 3 of the United Nations Recommendations on the Transport of Dangerous Goods, Model Regulations, as well as of chemicals presenting physical hazards according to the Globally Harmonized System of Classification and Labelling of Chemicals (GHS). More information and the latest revision are available at: http://www.unece.org/trans/danger/publi/manual/manual_e.html.**
UN RTDG	**UN Recommendations on the Transport of Dangerous Goods - Model Regulations. It is regularly updated and amended every two years. More information and the latest revision are available at: http://www.unece.org/trans/danger/publi/unrec/rev13/13nature_e.html**
WoE	***weight of evidence***
UVCB	**Substances of unknown or variable composition, complex reaction products or biological materials as defined in the Guidance on substance identification**
vPvB	**very persistent and very bioaccumulative**
wRV	**Worker respiratory volume**