Guidance on information requirements and chemical safety assessment

Part B: Hazard Assessment

Draft new chapter B.8
Scope of Exposure Assessment

… 2010

Draft Version 0.1

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. After acceptance by the Member States Competent Authorities the guidance documents had been handed over to ECHA for publication and further maintenance. Any updates of the guidance are drafted by ECHA and are then subject to a consultation procedure, involving stakeholders from Member States, industry and non-governmental organisations. For details of the consultation procedure, please see:
http://echa.europa.eu/doc/FINAL_MB_30_2007_Consultation_procedure_on_guidance.pdf

The 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).

Convention for citing the REACH regulation

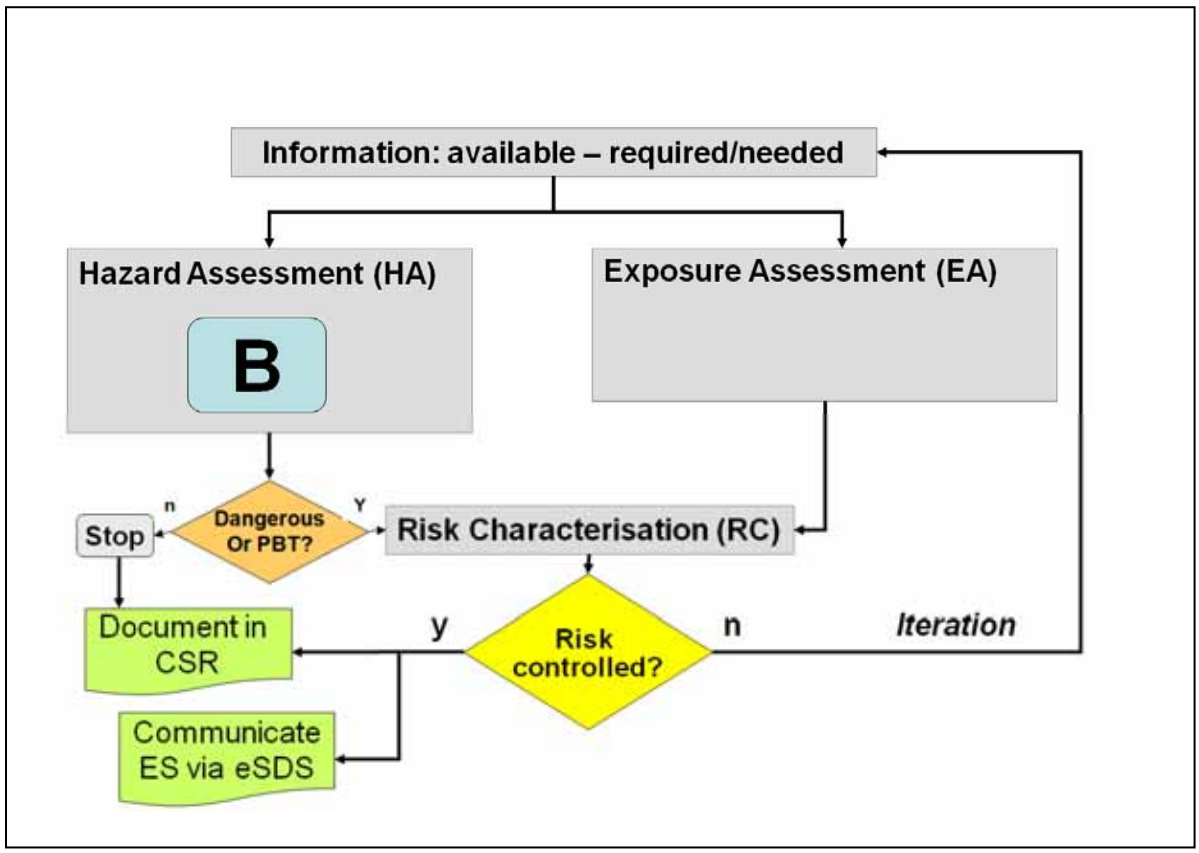
Where the REACH regulation is cited literally, this is indicated by text in italics between quotes.

Table of Terms and Abbreviations

See Chapter R.20

Pathfinder

The figure below indicates the location of Chapter B.8 within the Guidance Document



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B.8 SCOPE OF EXPOSURE ASSESSMENT

B.8.1 Background and aim of the chapter

REACH specifies in Annex I that an exposure assessment shall consider all stages of the life-cycle of the substance resulting from the substance's manufacture and the identified uses. It shall cover any exposures that may relate to the **hazards identified** during the hazard assessment that is performed first as part of the chemical safety assessment. In other words, the exposure assessment should address the different "types and nature of adverse effects that an agent has as inherent capacity to cause in an organism, system or (sub) population"[2]. Adverse effect means a "a change in the morphology, physiology, growth, development, reproduction, or life span of an organism, system, or (sub)population that results in an impairment of functional capacity, an impairment of the capacity to compensate for additional stress, or an increase in susceptibility to other influences".[3]

The final aim of exposure assessment is to achieve safe use of the substance. Thus the exposure scenario(s) developed need to ensure "control of risks" resulting from all identified hazards.

Article 14(1) and (4) of REACH requires that an exposure assessment and a subsequent risk characterisation is to be carried out for substances subject to registration, which are manufactured or imported in a quantity equal to or greater than 10 tonnes/year, and meeting the criteria for being classified as dangerous under Directive 67/548/EEC[4] or being assessed to be a PBT/vPvB in accordance with the criteria specified in Annex XIII to REACH. If the substance is to be classified for at least **one** type of physicochemical[5] (= physical), health or environmental hazard, a full exposure assessment according to Annex 1 is required. This exposure assessment shall cover all hazards identified according to section 1 to 4 of this Annex. **Please note:** This guidance is based on the understanding that substances can have hazardous properties that do not result in classification, i.e classifiable hazards are a particular subset of hazards that may be identified and characterised during the hazard assessment.

The current guidance chapter aims to support registrants determining the required scope of the exposure assessment based on the outcome of the hazard assessment. It is based on the principles and guidance already contained in other chapters of the Guidance on Information requirements and Chemicals Safety Assessment (IR/CSA Guidance). This guidance does not cover the scope of exposure assessment for PBT/vPvB substances and for waiving of information requirements according to Annex XI (3).

[2] http://www.who.int/ipcs/publications/methods/harmonization/en/terminol_part-II.pdf - OECD definition of hazard identification.

[3] http://www.inchem.org/documents/harmproj/harmproj/harmproj1.pdf - OECD definition of adverse effects (IPCS RISK ASSESSMENT TERMINOLOGY, 2004):

[4] from 1 December 2010, replaced by the criteria for the hazard classes and/or categories specified in Article 58(1) of Regulation (EC) No 1272/2008). Article 58(1) of Regulation (EC) No 1272/2008 refers to the following hazard classes or categories set out in the relevant parts of its Annex I: hazard classes 2.1 to 2.4, 2.6 and 2.7, 2.8 types A and B, 2.9, 2.10, 2.12, 2.13 categories 1 and 2, 2.14 categories 1 and 2, 2.15 types A to F; 3.1 to 3.6, 3.7 adverse effects on sexual function and fertility or on development, 3.8 effects other than narcotic effects, 3.9 and 3.10; 4.1 and 5.1.

[5] Equal to "physical" under CLP Regulation

B.8.2 General principles

The hazard assessments for **human health** and the **environment** according to Annex I includes three steps:

1. Evaluation of information[6]
   - hazard identification based on all available information and
   - establishment of quantitative dose (concentration) – response (effect) relationship or semi-quantitative or qualitative analysis, where this is not possible
2. Classification and labelling
3. Derivation of PNECs and DNELs

The assessment for **physicochemical hazards** shall cover, as a minimum, potential effects to human health due to explosivity, flammability and oxidising potential. The assessment aims to derive appropriate classification and labelling (see Section 2 in REACH Annex I). However particular considerations should also be given to the dust explosion hazard of powders (Chapter R.9.1.3 of Chapter 9 of the IR/CSA guidance), i.e there may be a potential for dust explosion even though a substance as such is not to be classified for explosivity by friction, mechanical shock or thermal shock.

Companies preparing a registration dossier and carrying out a Chemical Safety Assessment (CSA) will need to decide on i) whether exposure assessment and risk characterisation is needed at all, and if yes, ii) which is the required scope of the exposure assessment. Thus, the result of the hazard assessment may trigger one of the following scenarios:

- The substance does not meet the classification criteria at all, in particular neither for physicochemical, human health or environmental hazards, nor is it assessed as being a PBT/vPvB substance: exposure assessment is not mandatory. Please note: This does not prevent the registrant however from carrying out an exposure assessment and thus exceed the requirements of the regulation. .
- The substance meets the classification criteria for **at least one** physicochemical, toxicological or environmental hazard or is assessed as being PBT or vPvB: exposure assessment should be considered for all standard exposure endpoints (see Table 1).

The scope of exposure assessment is defined according to REACH as 'the assessment shall consider all stages of the life-cycle of the substance resulting from the manufacture and identified uses and shall cover '***any exposures that may relate to the hazards identified in section 1 to 4'*** (cf. section 5.0 of Annex I to REACH). Exposure assessment is not limited only to classifiable[7] hazards or adverse effects observed at doses/concentrations where classification is triggered. Rather it should correspond to all hazards identified in step 1 of the hazard assessment.

Situations where exposure assessment is to be carried out for identified but not classified hazards include, for example, the following cases:

[6] For human health assessment this actually includes two steps – evaluation of non-human information and evaluation of human information.

[7] Types of adverse effects for which classification criteria exist

- No classification criteria are defined for a certain type of hazard (e.g. dust explosion hazard, hazard to the soil and sediment environmental compartments or hazards to air) [8]. Even in the absence of classification criteria, hazards may have been identified (for example by observation of adverse effects in sediment-dwelling or soil-dwelling organisms). Also hazards may be predicted by models (e.g. the equilibrium partitioning method to screen for potential risk in the sediment or soil compartments using the aquatic PNEC).
- Classification criteria are defined (e.g. for aquatic toxicity or long-term toxicity for human health), but based on relevant available information it is concluded that these are not fulfilled and hence the substance is not classified as dangerous [hazardous] for a certain endpoint. Nevertheless there may be adverse effects observed in the eco-toxicity or toxicity studies that need to be considered in the hazard assessment and may lead to the derivation of a DNEL or PNEC.

Based on the identification of hazards, classification and labelling, DN(M)EL and PNEC derivation, the registrant may conclude for which categories of physicochemical hazards, toxicological types of effect and routes of exposure and environmental protection targets exposure assessment according to Annex I is to be performed or can be omitted. In practice, exposure assessment should be considered for all standard exposure endpoints listed in Table 1. However, the registrant may have assessed some types of hazard as not being relevant for the substance, and thus the corresponding exposure endpoints can be omitted[9].

Section 8.3.1 and 8.3.2 provide an overview on the exposure endpoints that may be omitted (due to "*no hazard identified*") for a registered substance, based on the conclusion that:

- classification criteria are not met or
- no adverse effects have been observed at limit dose in the relevant OECD guideline studies on toxicological endpoints or
- aquatic toxicity is unlikely or ,
- no adverse effects have been observed at limit dose in OECD guideline studies on environmental toxicity, taking into account the properties of the substance determining the environmental fate.

If no adverse effects have been observed in a limit test study at highest recommended concentration/dose tested this would normally indicate that no hazard can be identified. Nevertheless the registrant could still derive an *upper limit* DNEL or PNEC with a view to conducting a screening risk assessment.

B.8.3 Standard scope of exposure assessment

Table 1 provides an overview on the scope of an exposure assessment as suggested in the chapters R.8, R.10 and R.16 of the IR/CSA Guidance. Up to 34 exposure endpoints are to be addressed in the a standard exposure assessment. Some of these endpoints may be waived upfront, depending on the outcome of the hazard assessment (see sections 8.3.1 and 8.3.2). Other exposure endpoints may

[8] See Endpoint specific guidance on soil and sediment organisms, plants exposed via air, STP organisms and predators via the food chain as well as assessment of ozone formation, eutrophication and acidification potential and any other relevant environmental hazard (IR/CSR Guidance Chapter R.7)

[9] **Please note**: For a registered substance it is assumed that the information requirements in Annex VI to XI are fulfilled, and that the conclusion on whether a particular classification criterion is met can be made as there is sufficient information available

be sub-differentiated in a higher tier exposure assessment (e.g. sensitive worker or consumer populations).

Table 1: Overview on standard endpoints for the exposure assessment

Hazard assessment section	Target group	Route of exposure or environmental compartment	Type of effect	No of exposure endpoints
Human Health	Worker	Inhalation	acute and long-term,, local and systemic	4
		Dermal and eyes		4
	Consumer	Inhalation	acute and long-term, local and systemic	4
		dermal and eyes		4
		Oral	acute and long-term, systemic	2
	Man via environment	Inhalation	long-term systemic	1
		Oral (food and drinking water)		1
Physicochemical hazards			explosivity	1
			flammability	1
			oxidising potential	1
Environment		water pelagic (freshwater, marine)		2
		water sediments (freshwater, marine)		2
		aquatic food chain (3 levels)		3
		sewage treatment		1
		air[10]		1
		soil (agricultural)		1
		soil food chain		1
Number of standard endpoints for exposure assessment				34

As a result of the comparison of the available hazard information[11] of a given substance with the criteria described in sections 8.3.1 and 8.3.2, it can be decided whether an exposure assessment for a specific target group, type of effect and duration of exposure and a subsequent risk characterisation according to Annex I to REACH is required.

[10] This concerns for example effects on higher plants via the air pathway or impact on the ozone layer.

[11] "Available hazard information" means information available to the registrant when meeting the information requirements laid down in Annex VII to XI and when having carried out step 1 of the hazard assessment. Please note: Already for fulfilling the information requirements considerations on use and exposure may be relevant, e.g. in order to determine the likely/unlikely routes of exposure.

Appendix 1 to 3 of this guidance chapter list the R-phrases and the H-statements corresponding to those criteria which are related to classification and labelling. When an exposure assessment is required (based on Article 14 (4)), the lists can be used to identify those exposure endpoints for which the exposure assessment can be omitted based on classification criteria alone.

B.8.3.1 Toxicological properties

Figure 1 presents in a schematic diagram the decision making process for considering exposure assessment needs for human health related hazards.

For toxicological properties, the decision making process on which exposure assessment needs to be performed for the different populations, routes of exposure, types of effects and duration of exposure is based on the principles already described in Part E (Risk Characterisation) and Chapter R.8 (Dose [Concentration]-Response regarding Human Health) of the IR/CSA Guidance.

For systemic and local effects potentially triggered by **long-term or repeated** exposure it cannot be concluded *a priori* based on classification criteria whether risks are absent or at least controlled. Usually the DN(M)ELs identified in the hazard assessment would have to be compared with exposure estimates based on exposure scenarios to demonstrate control of risks.

However in the following situations part of or all the exposure assessment can be omitted for the purposes of the CSA and the preparation of the CSR.

- **Acute systemic effects (inhalation, dermal and oral route)**

For both workers and consumers particular exposure assessment for short term duration (short term event, peak exposure) and risk characterisation against an acute DNEL will not need to be conducted in the case where an acute toxicity hazard (leading to C&L) has not been identified (see Appendix 1). In line with Chapter R.8 and R.14 of the IR/CSR guidance it is assumed for this case that exposure scenarios ensuring control of risk related to long-term exposure will usually sufficiently limit exposure peaks during short period of time so that risks are also controlled for acute exposure, due to the lower DNEL derived for long-term hazards.

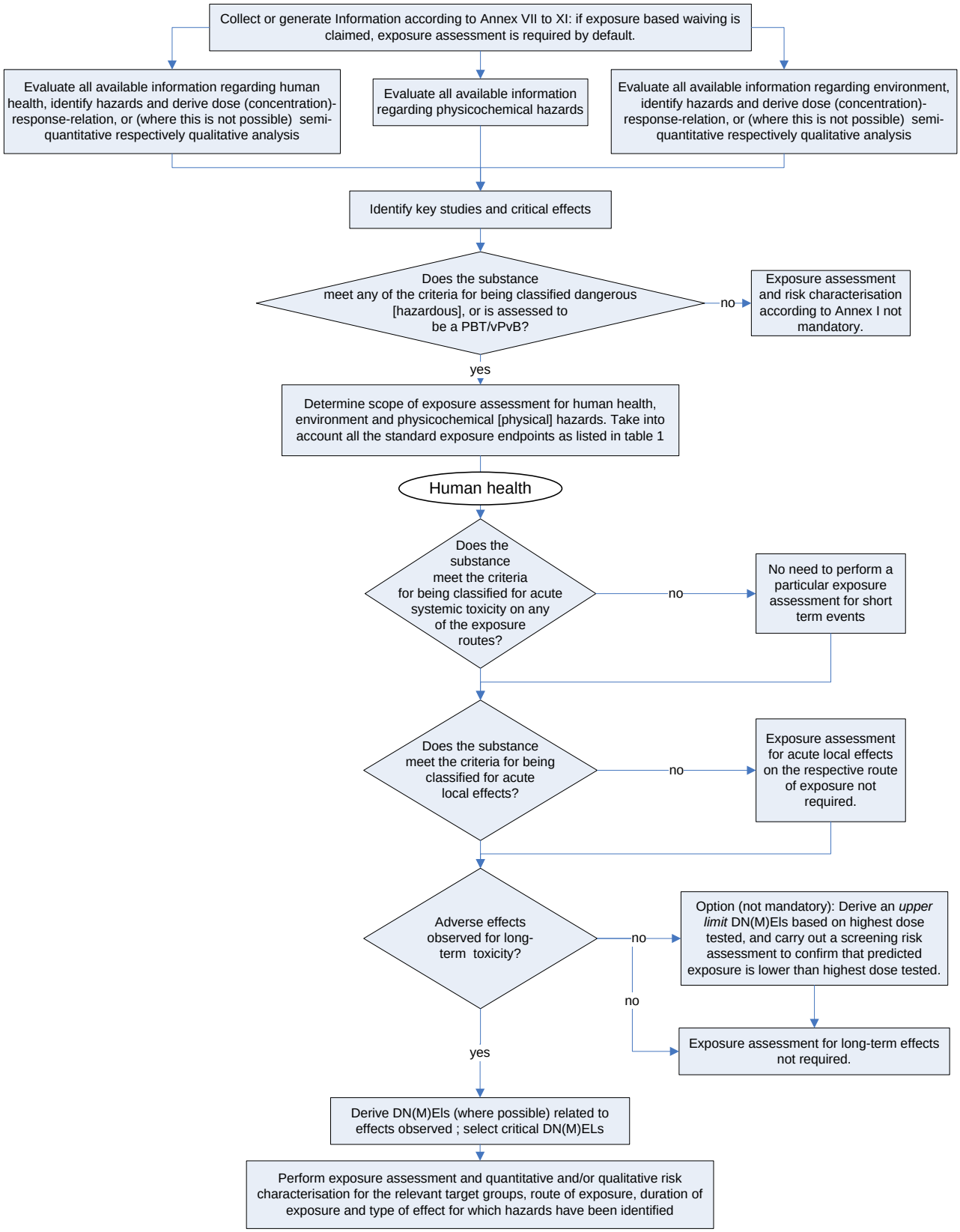
- **Acute local effects (dermal and inhalation route independently)**

For both workers and consumers, an exposure assessment (qualitative and/or quantitative) for acute local effects does not need to be performed for the relevant route if the substance does not meet the classification criteria for irritation, corrosion and sensitization for that route (see Appendix 1).

- **Long-term local and systemic effects (inhalation, dermal and oral route)**

For both workers and consumers no long-term exposure assessment (qualitative and/or quantitative) need to be performed if no adverse effects have been observed for any of the relevant human health endpoints. Also the assessment for exposure of the general population via the environment (food, drinking water and ambient air) can be omitted in this case.

Figure 1: Overview on the decision making process leading to the need to perform an exposure assessment for human health related hazards.



B.8.3.2 Eco-toxicological properties

Figure 2 illustrates the decision making process for considering exposure assessment needs for environmental protection targets

For eco-toxicological properties, the decision making process on which environmental protection targets are to be addressed in the exposure assessment are based on the principles already defined in chapter R.10 and R.16 of the IR/CSA Guidance. For considering the need for an exposure assessment with regard to secondary poisoning, the criteria provided in section B.7.2.7 of the IR/CSA Guidance can be applied. In addition, reference is made to the criteria related to testing of aquatic toxicity and toxicity with regard to micro-organisms in sewage treatment plants, as contained in REACH Annex VII and VIII.

For environmental effects triggered by **long-term** exposure it cannot be concluded *a priori* based on classification criteria whether risks are absent or at least controlled. Usually the PNECs identified in the hazard assessment would have to be compared with exposure estimates based on exposure scenarios to demonstrate control of risks.

However in the following situations, specific or all parts of the exposure assessment and risk characterisation can be omitted for the purposes of the CSA and the preparation of the CSR:

- If the substance has no potential for bioaccumulation or no potential to cause toxic effects if accumulated in the food chain, then the assessment for secondary poisoning is not required. The potential for toxic effects can be established based on classification criteria for repeated dose or reproductive toxicity (see Annex 3); "no potential for bioaccumulation" can be established based on
  - log Kow < 3 (respectively BCF < 100)[12] or [and] ready (rapid[13]) biodegradability
  - log Kow < 3 (respectively BCF < 100) or [and] hydrolysis with half-life < 12 h (see section B.7.2.7 of the IR/CSA Guidance).
- If the substance is assessed as "aquatic toxicity unlikely to occur" (according to column 2 of Annex VII and VIII, section 9.1 of the REACH), then exposure assessment and risk characterisation is not required for aquatic toxicity and toxicity with regard to micro-organisms in sewage treatment plants. Annex VII and VIII make reference to situations where the substance is considered to be highly insoluble or unlikely to cross biological membranes. Such assumptions are to be based on well documented evidence. Please note: Whether or not toxicity is unlikely to occur cannot be concluded from the water solubility of the substance alone. Other available information, such as predicted or observed adverse effects are to be taken into account as well. Thus, there is no fixed solubility cut-off for high insolubility. Please also note that a water solubility < 1 mg/l should not be considered "highly insoluble" but "poorly soluble", triggering long term testing.
- For water soluble substances: If no adverse effects are observed or predicted for aquatic toxicity up to limit dose in OECD guideline studies for all trophic levels, exposure assessment with regard to water (pelagic), sediments and soil may be omitted[14].
- For poorly water soluble substances (i.e. water solubility < 1 mg/l) and other substances expected to largely adsorb to sediments and soil: If no adverse effects are observed or predicted

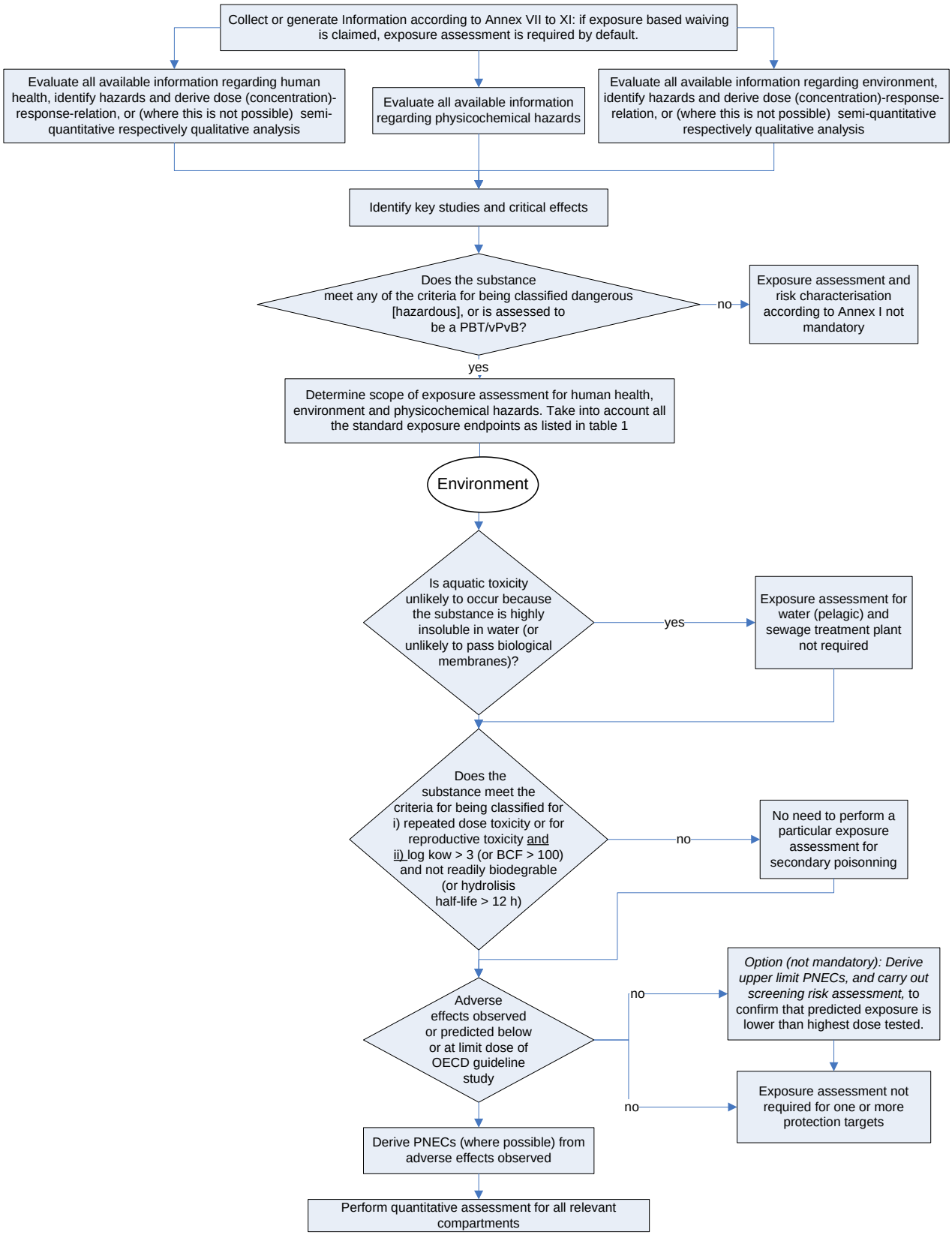
[12] Please note: The log Kow is applicable when it can be assumed that lipid partitioning is the main mode of accumulation. Otherwise only the BCF is applicable

[13] Term according to CLP

[14] For sediment and soil this is only applicable if the equilibrium partitioning method is applicable (i.e. no specific mode of action, not highly adsorbable, adsorption not driven by factors other than the logKow)

up to limit dose of a relevant OECD guideline study, and taking into account the environmental fate properties of the substance, exposure assessment with regard to water (pelagic) and/or sediment and/or soil may be omitted. For the sake of clarity, it should be emphasised that this exemption from exposure assessment does not apply if the substance meets the criteria for being classified dangerous for labelling with R53 [H414] or is being assessed to be vPvB substance.

Figure 2: Overview on the decision making process leading to the need to perform an exposure assessment for environment related hazards.



APPENDIX 1 Criteria for scoping of exposure assessment for human health

In the hazard assessment, it will be concluded whether any of the following phrases needs to be assigned according to the criteria described in Directive 67/548/EEC[15] and/or in the CLP Regulation. If none of these phrases has to be assigned, no exposure assessment is required for **the inhalation route regarding local acute effects**.

Directive 67/548/EEC	Respiratory Sensitisation Xn R42 May cause sensitization by inhalation Respiratory Irritation Xi R37 irritating to respiratory system
CLP	Respiratory Sensitisation H334 Resp. Sens. 1 May cause allergy or asthma symptoms or breathing difficulties if inhaled Respiratory Irritation H335 STOT SE 3 May cause respiratory irritation

In the hazard assessment, it will be concluded whether any of the following phrases needs to be assigned according to the criteria described in Directive 67/548/EEC and/or in the CLP Regulation: If none of these phrases has to be assigned, no exposure assessment regarding is required for the **dermal route regarding local acute effects.**

Directive 67/548/EEC	**Skin Corrosivity C** R35 Causes severe burns R34 Causes burns **Skin Irritation Xi** R38 Irritating to skin R43 May cause sensitization by skin contact **Eye Irritation (Ocular Lesions) Xi** R36 Irritating to eyes R41 Risk of serious damage to eyes
CLP	**Skin Corrosivity** H314 Skin Corr 1A Causes severe skin burns and eye damage H314 Skin Corr 1B Causes severe skin burns and eye damage **Skin Irritation** H315 Skin Irrit. 2 Causes skin irritation H317 Skin Sens. 1 May cause an allergic skin reaction **Eye Irritation (Ocular Lesions)** H319 Eye Irrit. 2 Causes serious eye irritation H318 Eye Dam. 1 Causes serious eye damage

In the hazard assessment, it will be concluded whether any of the following phrases needs to be assigned according to the criteria described in Directive 67/548/EEC and/or in the CLP Regulation: If

[15] Not applicable anymore for classification of substances from December 1, 2010

none of these phrases has to be assigned, no exposure assessment is required **for acute systemic effects.**

Directive 67/548/EEC	**Very Toxic (T+)** R28: Very toxic if swallowed R27: Very toxic in contact with skin R26: Very toxic by inhalation R39/26 R39/27 R39/28: Dangerous of very serious irreversible effects **Toxic (T):** R25: Toxic if swallowed R24: Toxic in contact with skin R23: Toxic by inhalation R39/23 R39/24 R39/25: Danger of very serious irreversible effects **Harmful (Xn):** R22: Harmful if swallowed R21: Harmful in contact with skin R20: Harmful by inhalation R65: Harmful may cause lung damage if swallowed R68/20 R68/21 R68/22: Possible risk of irreversible effects **Other toxicological properties** R67: Vapours may cause drowsiness and dizziness
CLP	H300 Acute Tox. 2 Fatal if swallowed H310 Acute Tox. 1 Fatal in contact with skin H330 Acute Tox. 2 Fatal if inhaled H370 STOT SE 1 H301 Acute Tox. 3 Toxic if swallowed H311 Acute Tox. 3 Toxic in contact with skin H331 Acute Tox. 3 Toxic if inhaled H370 STOT SE 1 H302 Acute Tox. 4 Harmful if swallowed H312 Acute Tox. 4 Harmful in contact with skin H332 Acute Tox. 4 Harmful if inhaled H304 Asp. Tox. 1 H371 STOT SE 2 (May cause damage to organs (or state all organs affected if known) (state route of exposure if it is conclusively proven that no other routes of exposure cause the hazard) **Other toxicological properties** H336 STOT SE 3 May cause drowsiness or dizziness

APPENDIX 2 Criteria for scoping of exposure assessment for physicochemical hazards

In the hazard assessment, it will have been concluded whether any of the following phrases needs to be assigned according to the criteria described in Directive 67/548/EEC[16] and in the CLP Regulation). If none of these phrases has to be assigned, exposure assessment regarding physicochemical hazards can be limited to dust explosion hazard of powders, if relevant.

Directive 67/548/EEC	E;R2 Risk of explosion by shock, friction, fire or other sources of ignition E;R3 Extreme risk of explosion by shock, friction, fire or other source of ignition O; R7 May cause fire O; R8 Contact with combustible material may cause fire O; R9 Explosive when mixed with combustible material F+; R12 Extremely flammable F; R11 Highly flammable F; R15 Contact with water liberates extremely flammable gas F; R17 Spontaneously flammable in air R10 Flammable
CLP Regulation	H242 Org. Perox. CD Heating may cause a fire H242 Org. Perox. EF Heating may cause a fire Gas: H270 Ox. Gas 1: May cause or intensify fire; oxidiser Liquid: H271 Ox. Liq 1 May cause fire or explosion; strong oxidiser Solid: H271 Ox. Sol 1 May cause fire or explosion; strong oxidiser H272: May intensify fire; oxidiser Gas: H220 Flam. Gas 1: extremely flammable gas Gas: H221 Flam. Gas 2: flammable gas Aerosol: H222 Category 1: extremely flammable aerosol Aerosol:H223 category 2: flammable aerosol Liquid: H224 Flam. Liq. 1 H242 Self-react. CD: Heating may cause a fire H242 Self-react. EF: Heating may cause a fire None Self-react. G Liquid: H224 Flam. Liq. 1, if initial boiling point <35ºC Liquid: H225 Flam. Liq. 2, if initial boiling point >35ºC Solid: H228: Flammable solid Solid: H250, Pyr. Liq. 1: Catches fire spontaneously if exposed to air Liquid: H250, Pyr. Sol. 1: Catches fire spontaneously if exposed to air Liquid: H224 Flam. Liq. 1, if flashpoint<23ºC and initial boiling point <35ºC Liquid: H225 Flam. Liq. 2, if flashpoint<23ºC and initial boiling point >35ºC Liquid: H226 Flam. Liq. 3, if flashpoint>23ºC H200: unstable explosive H201: explosive; mass explosion hazard H202: explosive; severe projection hazard H203: explosive; fire, blast or projection hazard H204: Fire or projection hazard H205: may mass explode in fire

[16] Not applicable anymore for classification of substances from December 1, 2010

	H280: contains gas under pressure; may explode if heated
	H281: contains refrigerated gas; may cause cryogenic burns or injury H240: heating may cause an explosion H241: Heating may cause a fire or explosion H251: Self-heating; may catch fire H252: Self-heating in large quantities; may catch fire H260: In contact with water releases flammable gases which may ignite spontaneously H261: In contact with water releases flammable gases H290: May be corrosive to metals

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2

APPENDIX 3 Criteria for scoping of exposure assessment for environment

In the hazard assessment it will be concluded whether any of the following phrases needs to be assigned according to the criteria described in Directive 67/548/EEC[17] and in the CLP Regulation. If none of the phrases for human health has to be assigned, no exposure assessment regarding secondary poisoning is required.

Directive 67/548/EEC	R48 Danger to serious damage to health by prolonged exposure R60 May impair fertility (cat 1 and 2) R61 May cause harm to unborn child (cat 1 and 2) R62 Possible risk of impaired fertility R63 Possible risk of harm to unborn child R64 Effects during lactation
CLP Regulation	H373: Causes damage to organs through prolonged or repeated exposure (cat 2) H372: Causes damage to organs through prolonged or repeated exposure (cat 1) H360: May damage fertility or the unborn child (cat 1A or 1B) H361: Suspected of damaging fertility or the unborn child (cat 2) H362: May cause harm to breast-fed child

[17] Not applicable anymore for classification of substances from December 1, 2010