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Guidance on Information Requirements and Chemical Safety Assessment

Part D: Framework for exposure assessment

Version 2.0
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Guidance on Information Requirements and Chemical Safety Assessment
Part D: Framework for exposure assessment

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Preface

This document describes the information requirements under the REACH Regulation 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 the REACH Regulation.

The original versions of 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/documents/10162/13559/mb_63_2013_consultation_procedure_for_guidance_revision_2_en.pdf

The guidance documents can be obtained via the website of the European Chemicals Agency at:

http://echa.europa.eu/web/guest/guidance-documents/guidance-on-reach

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 until 1 June 2015

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	Changes	Date
Version 1	First edition	May 2008
Version 1.1	Footnote added	July 2008
Version 1.2	Corrigendum: i. replacing references to DSD/DPD by references to CLP; ii. implementing minor recommendations from nanomaterials from the RIP-oN3 report; iii. Appendix D-3 (Names and descriptions Environmental Release Categories) to align with updated Chapter R12 Version 2); iv. additional minor editorial changes/corrections.	October 2012
Version 2.0	Redraft: Based on the experience with exposure scenario building and chemical safety assessments from the first two registration waves the document was completely re-drafted. This gave also the opportunity to increase consistency and to remove duplications with regard to other Guidance documents on use and exposure, namely R.12, R.13 and R.14 to R.16. This version also integrates relevant sections of Part F of the Guidance on IR &CSA (into section D.6 and Appendix D-1) that has been made obsolete. The document was re-drafted with the aim to produce a concise document explaining the key principles and content elements to be considered when carrying out an exposure assessment under REACH. The updated guidance includes a number of new elements: • Overall, generic workflow on exposure assessment; • Principle added: Addressing the whole life cycle of a substance in the assessment includes a sufficient understanding on the different compositions and forms a substance may have on use, and the related hazard characteristics. Such understanding should also cover transformation products that may occur on use or in the environment; • Principle added: Integrate exposure assessment and risk characterisation per contributing scenario in Chapter 9. Use chapter 10 of the CSR for characterisation of combined risks from different sources; • Principle extended: Make to the extent possible use of information generated by downstream sectors regarding uses and conditions of use relevant for their processes and products (i.e. use maps, SpERCs, SCEDs, SWEDs); • Principle extended: Make use of standardised templates, phrases and exchange-formats when communicating exposure scenario information down the chain. As a consequence the title was changed from “Exposure scenario building” to “Framework for exposure assessment”.	August 2016

Convention for citing the REACH regulation

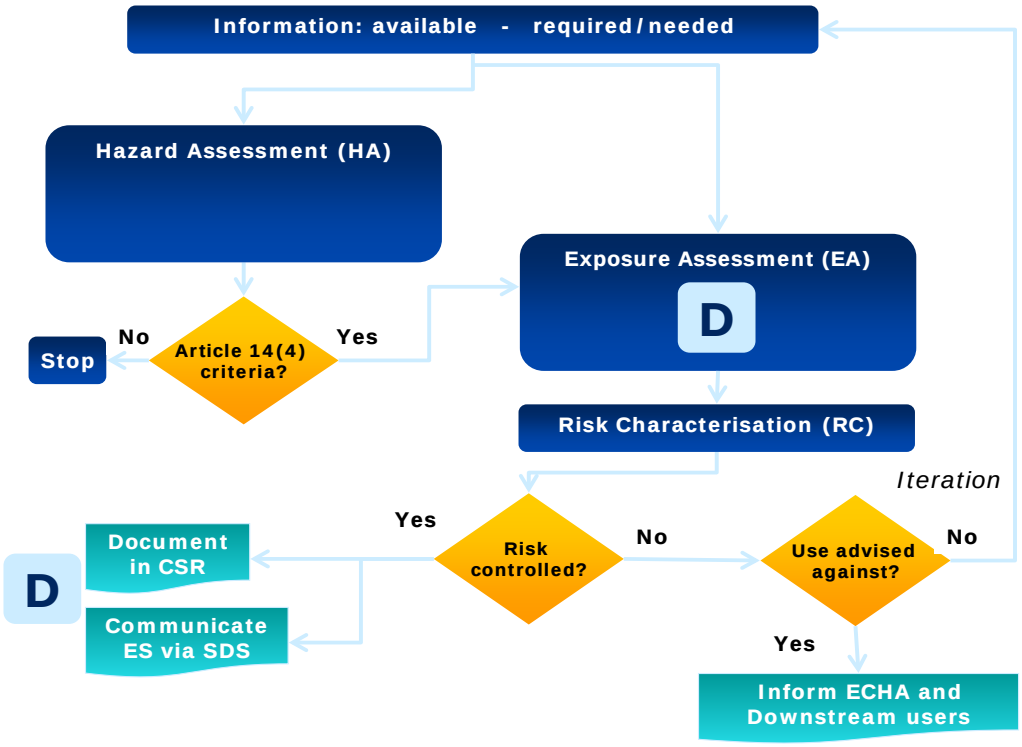
Where the REACH regulation is cited literally, this is indicated by text in italics between quotes.

Table of Terms and Abbreviations

See Chapter R.20

Pathfinder

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



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D.1. INTRODUCTION

D.1.1 Purpose and overview

This guidance sets out the principles for carrying out an exposure assessment to determine the conditions of safe use for all the uses of a substance registered under REACH. It is therefore relevant for those who have the obligation to carry out an exposure assessment for their substances, i.e. mainly registrants.

This guidance covers exposure to environment, workers and consumers. More detailed information on the exposure assessments for these groups is provided in specific guidance documents.

Figure D- 1 outlines the general workflow for exposure assessment. It includes referencing to the corresponding sections in this Guidance document and where available, more specific ECHA Guidance documents.

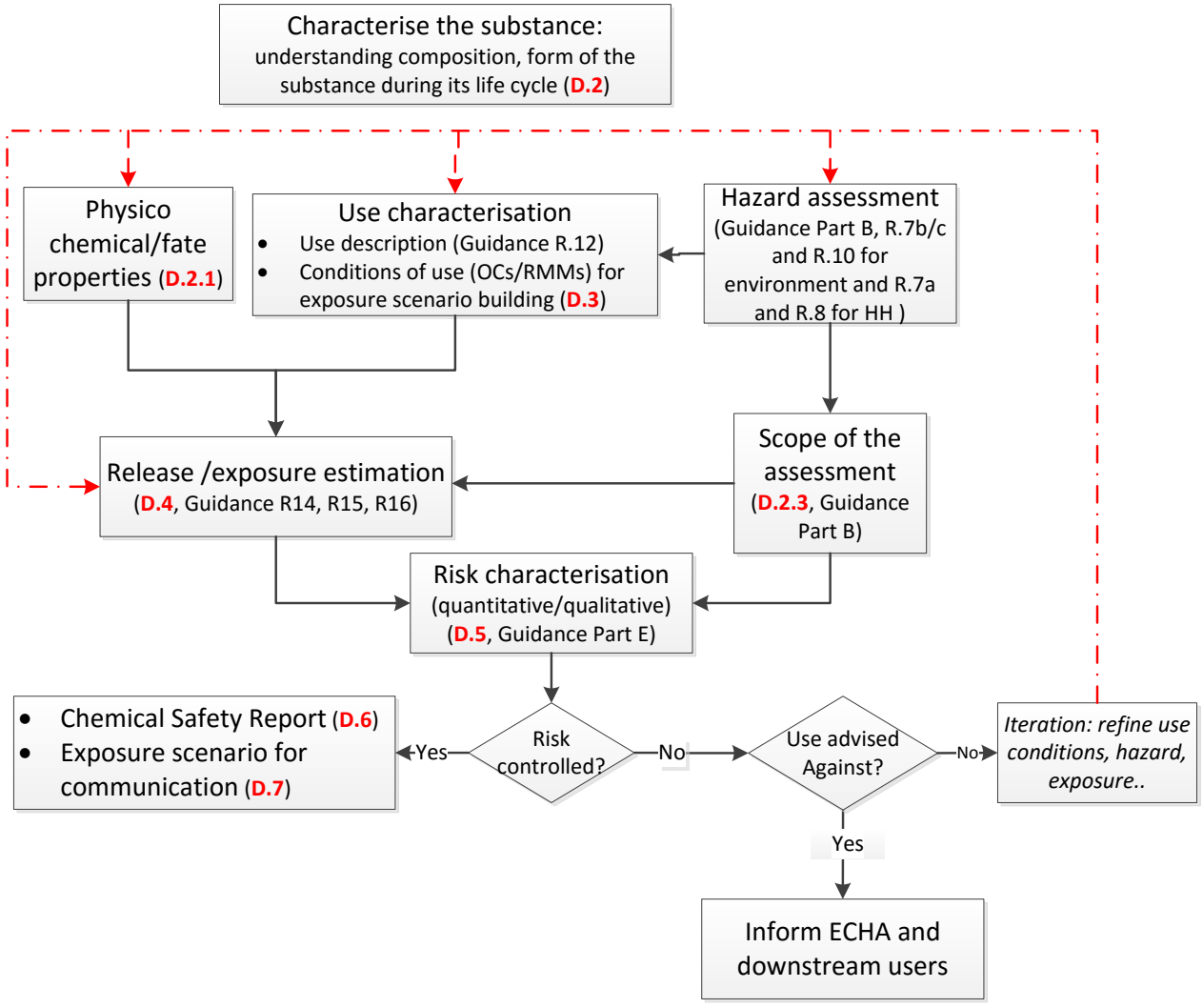

Figure D- 1: General workflow for deriving exposure scenarios

More detailed workflows are contained in *Chapters R.14 to R.16 of the Guidance on IR&CSA* on exposure assessment.

D.1.2 Exposure assessment in REACH

According to Article 14 of the REACH Regulation, registrants of substances are obliged to carry out a safety assessment for their substance if their manufactured or imported amount exceeds 10 tons per year. If the substance fulfils the criteria for any of the hazard classes or categories listed in Article 14(4)[2] or is assessed a PBT/vPvB, the safety assessment must include exposure assessments for all uses of the substance the registrant intends to support, and a corresponding risk characterisation. Article 14 further defines some conditions under which the CSA does not need to be performed.

The CSA starts from understanding the substance properties as well as its uses and conditions of use. The substance properties depend on the compositions, forms and transformation of the substance and the corresponding hazards that may be relevant during its life cycle. Based on this understanding, the scope of the exposure assessment can be determined, i.e. which hazards are to be addressed, for which environmental compartments and which routes of human exposure.

The outcome of the exposure assessment is the generation of Exposure scenarios (ES) for the different uses. ES are sets of information describing the conditions under which the risks associated with the identified use(s) of a substance can be controlled. The conditions of use include:

- operational conditions (OC), for example the duration and frequency of use, the substance amount used, or the process temperature and
- the necessary risk management measures (RMM), e.g. local exhaust ventilation or a certain type of glove, waste water treatment or exhaust gas treatment.

The outcome of the CSA is reported in the Chemical Safety Report (CSR), which is submitted to ECHA as part of the registration dossier.

The exposure assessment aims to describe the conditions of safe use (= control of risk) for each activity contributing to a use. For each of the ***contributing activities*** (CA) a corresponding set of conditions of use is to be determined, which is then called a ***contributing scenario*** (CS).

Contributing scenarios should be defined for humans (workers or consumers) and for the environment. Together they form the exposure scenario corresponding to a use. There are no strict rules on how to best combine the CS for humans and that for the environment into well-defined exposure scenarios. Experience shows however that usually it is best to combine the (multiple) CSs for workers (or consumers) for a use with one environmental CS only. On the other hand, conditions of safe use for the environment may be better represented by splitting the workers (or consumer CSs) into more than one use, or by combining more than one environmental CS into one ES. The following examples may help to define the scope of an exposure scenario in this respect:

- Consumer products being released down the drain after use may all be combined into one exposure scenario, which then includes one CS for the environment and a contributing scenario per type of consumer product.
- Professional uses related to coating operations, paint stripping or sanding largely differ in their conditions depending on whether they are carried out in a controlled

[2] These are:
- 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;
- hazard classes 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;
- hazard class 4.1;
- hazard class 5.1.

indoor environment or at outdoor construction objects like bridges or building facades. It is recommended to define two distinct uses (exposure scenarios) for outdoor and indoor construction works in this case as both environmental and workers conditions differ.

- In some DU sectors with water based processes (e.g. textile finishing) the size of companies may be very diverse and different application techniques with different release factors may be operated in parallel. On the other hand the contributing activities of the workers may be relatively homogenous. In such cases, it may be sensible to build one exposure scenario only, however with different contributing scenarios for the environment.

It is worth noting that in some cases the same task can be carried out under different conditions e.g. workers handling products with different hazard level needing different levels or risk management. In these cases, it is up to the registrant, or the sector association developing use maps, to decide whether a separate use is created or different contributing activities (CAs) are included in the same use. If separate CAs are created, the CA name should help to understand the difference.

Appendix 12.2. of the R.12 Guidance on use description provides more information on how to split into different uses or contributing activities.

For each contributing scenario, a set of exposure estimates is derived. These are then compared with the predicted/derived no-effect levels from the hazard assessment to calculate the risk characterisation ratios. Where an effect threshold is not available, the risk is characterised in a qualitative manner, which however may still include quantitative information on exposure.

The conditions of safe use as determined in the Chemical Safety Assessment and described in the exposure scenarios for the substance are communicated down the supply chain as part of the safety data sheet.

If the manufacturer or importer of a substance is unable to assess a certain known use and to describe relevant and realistic measures that control the risks, he should not include exposure scenarios for this use in his CSR and the corresponding safety data sheets. He should make his customers aware of this decision in writing. If the registrant however has assessed a use, but finally did not include it based on reasons of protection of human health or the environment, he should explicitly advise against that use in the safety data sheet and in the registration dossier, including the reasons for this decision according to Article 37(3).

Exposure assessment also plays a role for the registrant when determining whether (further) testing of the substance is required for a certain endpoint. Annexes VIII to XI of the REACH Regulation include a number of references to the outcome of the exposure assessment as i) triggering the need for testing or ii) providing an argument for adapting information requirements. These particular outcomes of exposure assessment are not further addressed in this guidance but are covered in *Chapter R.5* of the *Guidance on IR&CSA*.

ECHA together with industry stakeholder organisations and Member States has developed methods and tools to support the exposure assessment itself and the communication of the results to downstream users, the authorities and the general public in a structured, transparent and harmonised way. This work has been done under the CSR/ES Roadmap[3] and discussed in the Expert Network on Exposure Scenarios

[3] http://echa.europa.eu/regulations/reach/registration/information-requirements/chemical-safety-report/csr-es-roadmap

(ENES)[4]. Registrants and downstream sectors are invited to make use of these tools in order to deliver good quality exposure scenarios in an efficient manner.

D.1.3 Joint CSR or individual CSR

The development of ES in the context of a CSA process will largely depend on the approach chosen by registrants. The REACH Regulation (Article 11(1)) foresees the possibilities to submit the CSR individually or jointly. The decision to submit the CSR individually is not an opt-out in the sense of Article 11(3) and therefore does not need a particular justification.

The decision is for every registrant to make, but should be clearly discussed and agreed in the context of the Substance Information Exchange Forum (SIEF). Different considerations may play a role when deciding to develop the CSR together:

- Registrants of the same substance may see advantages in coming to harmonised CSA conclusions and therefore consistent risk management advice to downstream users. In this respect it may play a role whether the substance has the same hazard profile across all registrants;
- Environmental exposure can be assessed on the basis of overall (EU) use tonnages, and thus complementary community risk assessment by authorities may be prevented; the fact that the reported volume is the overall EU tonnage should be flagged by the (single) registrant in the IUCLID registration dossier so that the authorities do not add up volumes from the different dossiers.
- Confidentiality issues may lead to registrants carrying out a separate CSA for some or all uses.

Regardless of the decision, it is important to report in a transparent way in IUCLID which uses are covered by the jointly submitted CSR, and which ones are covered by the individual CSR. In the case of updates related to the joint chemical safety assessment, it is recommended that all member registrants review and update if necessary the use information at the same time as the Lead registrant, in order to ensure consistency with the use coverage reported by the Lead. The update by the members is important as the information published on the ECHA dissemination website reflects the information submitted by all the joint submission participants. Therefore, if the member dossiers still contain outdated information, then this information would also be published on the website, and it would be used for regulatory priority setting e.g. when screening dossiers.

D.1.4 REACH exposure scenarios and other legislation

REACH is not the only legislation in the EU aiming to protect human health and the environment from adverse effects caused by manufacture and use of chemicals. Companies producing or using substances as such, in mixtures or in articles also have risk management and product safety obligations under other legislative frameworks, including but not limited to:

- Health and safety at workplace following the principles as laid down in the EU Chemicals Agent Directive (CAD) and the Carcinogen and Mutagens Directive (CMD);
- Prevention and control of emissions to the environment from industrial sites following the principles laid down in the Industrial Emission Directive (IED) and the Best Available Technique reference documents (BREF);

[4] http://echa.europa.eu/about-us/exchange-network-on-exposure-scenarios

- Control of emissions of volatile organic compounds from certain activities and product (EU VOC Directive and EU Paint Directive);
- Safety related to the use of articles and materials as for example addressed in the EU Construction Products Regulation or the EU Toys Directive;
- Prevention and control of risks related to waste management in general and related to the waste life stage of certain mixtures and articles in particular, e.g. waste solvents, waste oils, cars, electric and electronic devices, batteries, packaging.

In addition, the general liability of site operators and product producers regarding potential adverse impacts of their operations/products on health and the environment also applies to chemicals. Thus, producers of mixtures and articles can use the information generated and communicated under REACH to make themselves aware of risks that may be incorporated into their products.

The particular role of REACH in the interaction with these other pieces of legislation is the generation and communication of **substance specific** information with regard to the hazards intrinsic to the substance, the properties determining the behaviour of the substance and the required conditions to ensure safe use along the supply chain (including waste treatment). Downstream users will know best how their installation or product is designed in order to comply with the different legislations they are subject to. However, the REACH information brings a substance-focussed dimension to safe use of chemicals that complements the site-specific approach (taken under the IED or the CAD and the Carcinogen and Mutagens Directive, CMD).

The REACH CSA for a particular substance may confirm or put into question that the established risk management practices in a certain market, sector of industry or single company are sufficient to control the risk of this substance. In the case where existing RMMs are put into question by the REACH assessment, the manufacturer or importer of a substance will suggest additional or other risk management measures, or he will decide not to support a use (or to advise against it).

Substance specific assessment information can support safety at sites or product safety. Therefore, both registrants and downstream users need to implement mechanisms at company level and at sector level to connect REACH information with the information needs for managing chemicals risks under other legislation. The tools and mechanisms built on the use-map concept form a good basis for this (see section D.3.5).

The following examples illustrate at a high level potential areas of convergence. Compliance with co-existing pieces of legislation may sometimes bring up challenges. There is ongoing work by ECHA[5] and the Commission together with stakeholders to address these challenges.

Example: REACH and the Industrial Emissions Directive (IED)

According to the IED, operators of certain industrial installations are required to operate in accordance with a permit containing conditions set in accordance with the principle and provisions of the IED. These conditions are based on best available techniques (BAT)

[5] http://echa.europa.eu/regulations/reach/downstream-users/other-legislation

http://ec.europa.eu/growth/sectors/chemicals/reach/special-cases/index_en.htm

as described in BAT reference documents (BREF).

The integrated approach is one of the main pillars of the IED. This means that the permits must take into account the whole environmental performance of the plant, covering e.g. emissions to air, water and soil, generation of waste, use of raw materials, energy efficiency, noise, prevention of accidents and restoration of the site upon closure.

When applying for the permit the operator has to provide information on (not an exhaustive list):

- the substances used in or generated by the installation;
- the sources, nature and quantities of emissions from the installation into each medium and their effect on the environment;
- the technology and other techniques for preventing or, if not possible, reducing emissions from the installation.

Substance specific information provided in exposure scenarios will support operators in identifying the most relevant substances (in terms of hazard), their environmental fate and measures to prevent or reduce emissions.

Example: REACH and the Chemical Agents Directive (CAD) and the Carcinogens and Mutagens Directive (CMD)

According to the CAD and CMD, the employer has the duty to identify and assess the risks that hazardous chemicals pose to workers at their specific workplace. This needs to cover all hazardous agents present during a workday, including risks resulting from their combination. If the assessment reveals a risk to the safety and health of workers, the employer has to apply specific protection and prevention measures in accordance with the hierarchy of controls. Employers also have a duty to inform and train their workers.

REACH exposure scenarios describe in generic terms the appropriate conditions for controlling exposure to an individual substance per task or work process (not per workplace!). As an employer under CAD, the downstream user may feed this information into his own workplace risk assessments. At the same time, as an actor under REACH he must document that the existing work practice is in line with the conditions of use described in the suppliers' exposure scenario. If his current practice is not in line with the exposure scenario he has received he must change his practice, or ask his supplier to change the exposure scenario, or inform ECHA about the existence of an own assessment (workplace risk assessment converted into a DU CSR) demonstrating control of risk for the existing practice.

In this way, the verification/adjustment between the registrant's safety assessment and the downstream user's risk assessments for workplaces can be achieved, which may close existing gaps in chemicals safety.

D.2. CHARACTERISE THE SUBSTANCE AND ITS HAZARDS

The Chemical Safety Assessment must cover all the identified uses of the substance and the subsequent life cycle stages (when the substance is incorporated into an article; when the substance becomes a component in waste). The life cycle of a substance ends where it is consumed in the manufacture of another substance, where it is completely destroyed by biological, chemical or thermal processes (in the environment or in waste treatment operations), or where the substance has been recovered from waste to be re-placed on the market as this is considered equivalent to manufacturing a new substance (and therefore registration obligations may apply).

The exposure assessment must take into account the exposure due to transformation and/or degradations products of the original substance that may occur during use or after release into the environment[6].

The purpose of Chemical Safety Assessment under REACH is to assess/demonstrate that the risks arising from a manufactured/imported substance are adequately controlled during manufacture and own use, and that other operators further down the chain can adequately control the risks.

The following sections describe the understanding that a registrant should have on the properties and the life cycle of his substances in order to determine his assessment approach and the corresponding scope of exposure assessment.

D.2.1 Understanding the "chemistry" of the registered substance: compositions, form and transformation products

In a standard safety assessment, the fate and effect properties of a substance are characterised by one set of values carried forward to the exposure assessment. However, there are cases where more than one set of values for the fate and effect properties may be needed. When preparing a registration (and potentially building up the testing strategy) an assessor should therefore consider a number of aspects, based on available information. The starting point for these considerations is a sufficient understanding of the constituents[7], their chemical structure, and their concentration levels. It should also be noted that, for a given substance, the identity and concentration of the constituents may vary from one composition to another. The form in which the substance is available (e.g. morphology, crystalline forms…) may also differ. Such differences in the compositions/forms should be sufficiently known to the assessor. In addition the following considerations have to be made to ensure consistency between the composition/form of the substance placed on the market, the conditions under which the substance will be used and the information to determine the properties of this composition/form.

- Are the compositions/forms of the substance manufactured and placed on the market likely to differ in their exposure behaviour and/or hazard profiles? For example, different compositions (having different hazard profiles) may be marketed for different uses such as industrial uses and consumer uses;

[6] Annex I section 5.2.3. refers to "A characterisation of possible degradation, transformation, or reaction processes…" and section 5.2.4 mentions that "the exposure estimation shall take account of… transformation and/or degradation products…".

[7] The term "constituent" in this guidance includes impurities and additives and applies to mono constituents, multi constituents and UVCBs.

- Are humans or the environment exposed to a composition that is different to that placed on the market, and where this difference may matter in terms of exposure or hazard profile. This can happen basically because the substance:
    - transforms during or after the use and/or
    - is composed of various constituents, and those constituents significantly differ in their distribution and fate properties (such as vapour pressure, water solubility, adsorption behaviour) leading to a modified exposure of humans or the environment.

Figure D- 2 illustrates the case where a substance is placed on the market in a variety of compositions and forms. When such variants of the substance have different hazard profiles these have to be addressed in the CSA for the substance. This may require multiple assessments on the hazard side and on the exposure side.

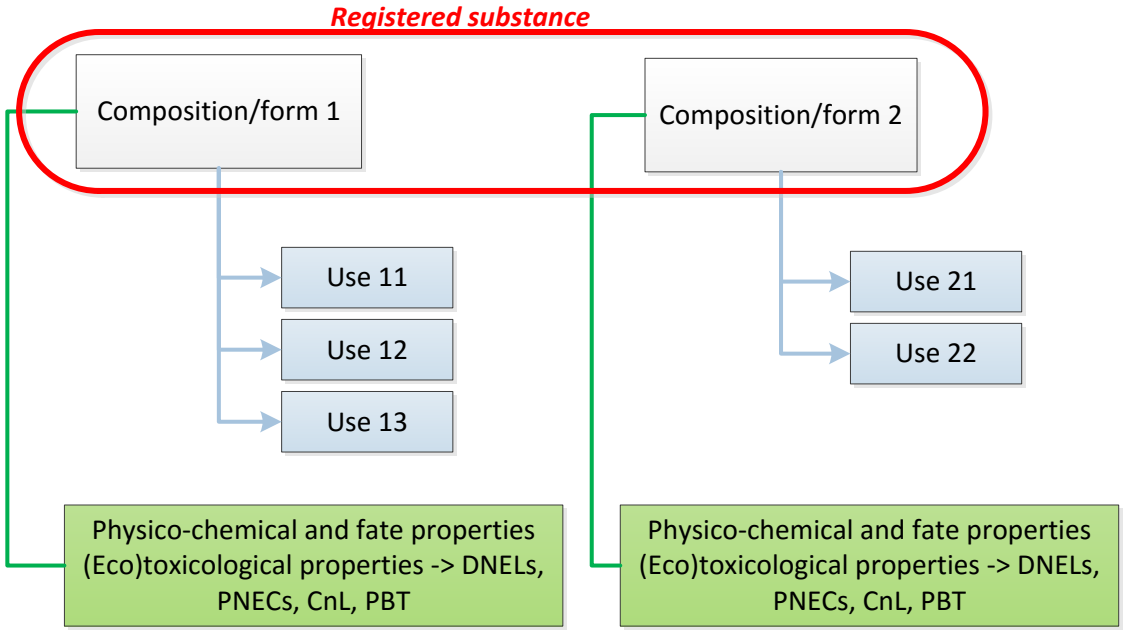

Figure D- 2: Registered substance having different compositions with different hazard profiles, supplied to different uses

Once placed on the market and used, the substance may undergo transformation processes, for example:

- A downstream user changes, on purpose, the form or composition of the substance in order to modify (for technical reasons) its physical or chemical properties and **places the new form/composition on the market**, e.g. grinding bulk material into particulate, purification of the substance;
- The substance is **meant to react** for delivering its technical function (including reaction when incorporated into an article);
- A substance may undergo **unintended transformation**
    - under the conditions of use, e.g. due to energy applied or other substances present in the use process[8];

[8] e.g. chemical reactions like nitrosamine-formation from secondary amines in presence of nitric oxide, peroxide formation in ethers

- subsequent to the use of the substance, in waste (water) treatment or in the environment.

Such transformations on use may lead to exposure to a substance with different intrinsic properties. In particular, new hazard for human health and/or the environment may occur or may disappear, and/or environmental fate properties may change.

To the extent known or foreseeable, such changes in the hazard characteristics of a substance should be taken into account in the registrant's hazard assessment, and in the corresponding scope of the exposure assessment (see section D.2.3). Changes in the hazard characteristics can be considered foreseeable for example, when:

- The specific surface area of a material is significantly increased (i.e. the particle size significantly decreased);
- a substance is meant to be reactive (e.g. bleaching agents, reactive dyes, reactive moisture scavenger, polymerising agents);
- the speciation of a metal changes;
- a substance hydrolyses or biodegrades into smaller chemical structures without being mineralised.

Figure D- 3 illustrates the situation where the composition or form to which humans or the environment are exposed is different from the composition/form as used. Humans and the environment may be exposed to a similar or to different compositions, depending on how the transformation occurs (at which point in time in the process, with which kinetics etc.). Also, if the conditions of use impact on the composition or form to which exposure occurs there may be several compositions/forms (with potentially different fate/hazard profiles), to be taken into account for the assessment of the various uses of the substance. This may be the case for example when the operating temperature leads to evaporation of some constituents but not of others, or when the presence of water determines to which extent a substance hydrolyses before exposure.

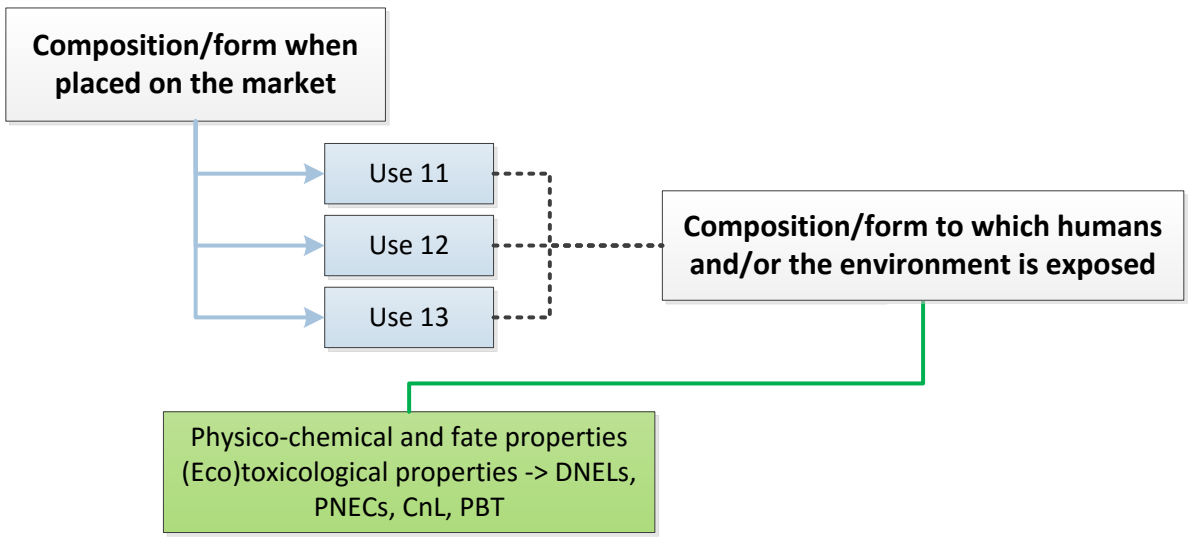

Figure D- 3: The composition(s) to which humans and/or the environment are exposed has a (have) fate/hazard profile(s) different from the composition manufactured/placed on the market.

The considerations above are essential for the clarity and meaningfulness of the registration dossier. Therefore, it is important that they are transparently and clearly

reported in the CSR (see reference to chapter 1 in section D.6.2).

In many cases, the assessor will be able to demonstrate that the properties of the substance can be described by just one set of values to be carried forward to exposure assessment and risk characterisation. In other cases, different sets of properties may be relevant to be assessed as described above.

D.2.2 Defining assessment entities to support transparency

When more than one fate/hazard profile is relevant for a substance, a safety assessor under REACH may be confronted with relatively complex assessment cases, and transparent documentation in the registration dossier may be a challenge. At the same time, authorities will base their decisions, on whether a dossier or substance should be prioritised under any of the REACH processes, on the information in the registration dossier. Absence of information or lack of transparency in general increases the likelihood that further regulatory processes are initiated.

In order to support transparency of assessments, ECHA together with industry stakeholders has developed the so called “assessment entity” approach. It aims to support a transparent organisation of assessment data in IUCLID for substances with a more complex chemistry. The “assessment entity” is a wrapper [container] for a set of substance property data (across endpoints) used for assessment purpose. It enables the assessor to define consistent datasets of properties that are relevant for specific compositions/forms (placed on the market or generated upon use). These datasets are then used to assess the substance over its life cycle, considering its chemical behaviour in the different foreseen uses.

IUCLID6 supports the possibility for the registrant to indicate whether the reported uses are associated with specific compositions/forms. When a new composition or form of the substance is generated during its life cycle (for example a substance is purified, or a bulk form is ground into a nano form), then it is possible to report a “Composition generated upon use” in IUCLID.

Each composition/form can be linked in IUCLID to a classification and PBT assessment record. To report the physico-chemical, fate and hazard properties of the composition/form, assessment entities may need to be defined (for example in case several (groups of) constituents play a role in the assessment or if a substance transforms during the use and both parent and transformation product(s) play a role in the assessment). Those assessment entities can be linked to a composition/form.

When only one composition with a single fate/ hazard profile is relevant for a registered substance then those links are implicit, but as soon as several sets of substance properties are needed, it is essential to make a IUCLID data set transparent and understandable.

When to define assessment entities?

The *assessment entity* concept aims to provide a tool to assist users in documenting complex assessment cases in IUCLID i.e. more than one set of data relevant for the assessment. When the assessment is straightforward, there is no need to apply such a concept.

How does the assessment entity relate to information requirements?

The assessment entity is a support feature and does not impact the REACH information requirements. It may nevertheless help to explain in a transparent way how the information requirements are fulfilled or why a testing proposal has been made.

How does the assessment entity relate to substance sameness?

The assessment entity is a tool for the safety assessment, and has no bearing on the

identity of the registered substance. Even if the assessment of several substances can benefit from the same datasets defined under a commonly used assessment entity, this does not mean that these substances can be registered in the same dossier.

D.2.3 Hazard conclusions determining the scope of assessment

The purpose of the hazard assessment is to identify and characterise the hazards of the substance in terms of classification (category of hazard, extent of hazard) and in terms of PNECs and DNELs/DMELs (where dose-response information exists).

For the hazards identified, the conditions of safe use are to be defined (exposure scenario), exposure estimates are to be derived (corresponding to these conditions), and the resulting risk is to be characterised. Note that if the substance does not meet any of the criteria to be classified hazardous and is not a PBT or vPvB, then exposure assessment is not required and this guidance is not relevant (see also section D.1.2).

Figure D- 4 illustrates in a schematic view how the type of risk characterisation is determined based on the information available for each protection target (for the environment) and route of exposure and type of effect (long/short term, systemic or local effect) for human health. The hazard conclusions are expressed in italic as they can be reported in IUCLID (section 6 and 7 Summary). Not all specific cases are illustrated, and more details are provided in the various chapters of the guidance referred to in the figure[9].

First of all, it needs to be clarified if further testing is required. This depends on the tonnage-driven information requirements (Annex VII to X of REACH) and on the possibilities for their adaptation (column 2 of those annexes and Annex XI).

If specific data are not required (e.g. for low tonnages) then the registrant has to conclude on the hazard on the basis of all available information, either:

- **A hazard is assumed** for the assessment, as hazard cannot be excluded on the basis of the available information. In such a case, the registrant will conclude on some potential level of hazard and carry out a qualitative risk characterisation.
- **No hazard identified** based on all available information.

If the data are required based on Annex VII to X, the registrant may still not generate those data either because:

- **Testing is technically not feasible (Annex XI.2).** In such a case hazard cannot be excluded and a qualitative risk characterisation is expected.
- **No emission/exposure is expected to occur (Annex XI.3)[10]**. The exposure assessment should demonstrate that the expected exposure is negligible, and thus the absence of a hazard characterisation can be justified (qualitative risk characterisation). The quantification of residual (very low) exposure may support such assessment.
- The endpoint-specific hazard information can also be waived as a hazard can be excluded based on available information (e.g. Annex VII column 2 waiver for aquatic toxicity for substances which are highly insoluble in water or substances

[9] Those guidance documents can be found at: http://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment

[10] Note that when the registrant decides not to generate data because no emission/exposure is expected (and this is to be justified by the exposure scenario) this applies to all protection targets for the environment or routes/types of effect for human health, when relevant.

unlikely to cross biological membranes). In such a case, the registrant will conclude **no hazard identified** based on available information.

More guidance can be found in *Part B* of the *Guidance on IR&CSA* (sections B1 to B6). Guidance on the testing strategies can be found in Chapter R.7a/b/c.

If data is available, the next step is to assess whether a **hazard is identified**. Hazards are identified according to Sections 1 to 4 of Annex I of REACH. Such identified hazards are of three types:

- hazards for which there are classification criteria and there is information to establish that the substance meets the criteria and is therefore classified;
- hazards for which there are classification criteria, but the severity of the effects seen in the test is lower than the criteria for classification and so the substance is not classified. The registrant should consider whether adverse effects have been observed in studies conducted at the highest practicable and biologically-relevant concentration on toxicological endpoint[11] or environmental toxicity[12]. If the study was not conducted according to the standard EU or OECD guideline and adverse effects are seen (particularly where the dose levels at which effects are seen are only slightly greater than the limit dose in an OECD guideline for that endpoint), the registrant should either provide justification for disregarding the effects (e.g. because they are not biologically relevant), or carry out an exposure assessment as for any other identified hazard.
- hazards for which currently no classification criteria exist, but there is information to show that the substance has such hazardous properties.

If no adverse effects have been observed in studies at the highest recommended concentrations/doses tested, this would normally indicate that **no hazard has been identified** for the protection target or route/type of effect and therefore no DNEL or PNEC can be derived[13]. In such cases, no exposure assessment is required for the protection target or route/type of effect. More guidance can be found in Chapter B.8.4. of *Part B of the Guidance on IR&CSA*).

When effects are observed, it may be possible or not to derive a threshold for no effect (**PNEC/DNEL**) or for minimal effect (**DMEL**). In case a PNEC or DNEL can be derived a quantitative risk characterisation is to be carried out (see section D.5.1), if a DMEL can be derived then a semi-quantitative risk characterisation[14] is to be carried out, and if no threshold can be set, a qualitative risk characterisation is to be carried out (see section D.5.2).

[11] e.g. according to OECD and EU Guidelines such as 1000 mg/kg/d in OECD Guideline as a limit test for 90-day oral toxicity study

[12] e.g. according to OECD and EU Guidelines such as 100 mg/l in OECD guideline as a limit test for acute aquatic toxicity, taking into account the properties of the substance determining the environmental fate

[13] **Please note**: Not always applicable to environmental hazards from substances with low water solubility. Please also note that severe (eco)toxicological effects (e.g. mortality) observed only slightly above the limit dose would still require an exposure assessment.

[14] According to Annex I, a qualitative assessment of the likelihood that effects are avoided shall be carried out, when it is not possible to establish a quantitative dose-response relationship. Section 3.4.1 of Part E of the *Guidance on IR&CSA* explains that DMELs are a semi-quantitative method for this. If exposure is below the DMEL, the risk is regarded controlled to a level of low concern (see *Guidance on IR&CSA* section 3.3.3). Such risk characterisation will include a reference to the conditions of use applied to minimise exposure.

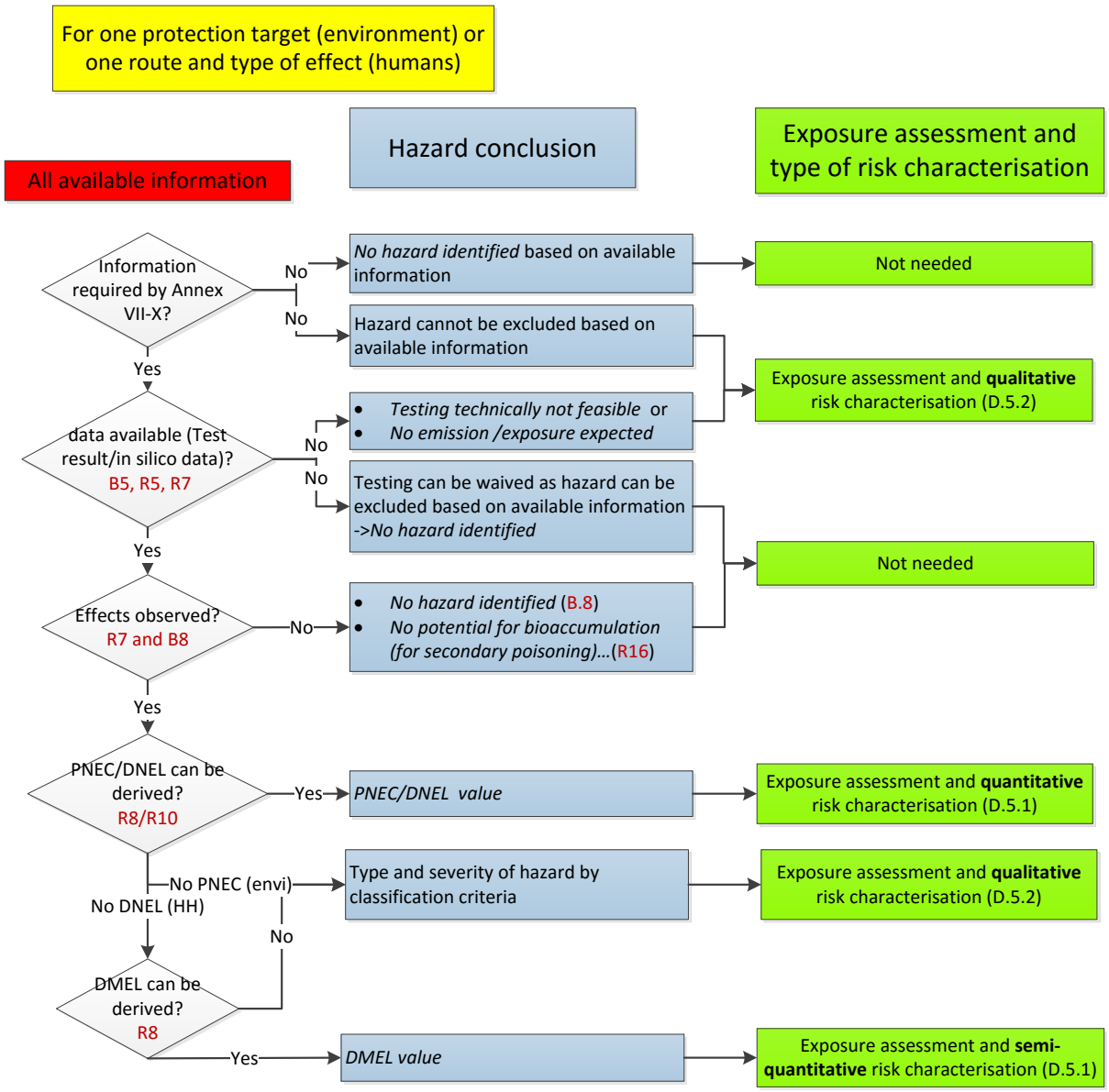

Figure D- 4: Identification of the scope of the assessment and type of risk characterisation for one protection target of the environment or one route of exposure and type of effect for human health

The outcome of the exposure assessment is the generation of Exposure Scenarios (ES). This section describes the core contents of an ES under REACH, i.e. the conditions for safe use. It presents an overview of the most common conditions of use (or exposure determinants).

D.3. CONDITIONS OF USE AND ES BUILDING

D.3.1 Principles and workflow for ES development

Based on the REACH text and the experience gained through the registration process, registrants are advised to follow a number of guiding principles when generating

exposure scenarios:

- An exposure scenario is expected to cover both exposure controls to humans and to the environment with one consistent set of conditions;
- Exposure scenarios should not cover more than one life cycle stage[15] to ensure transparency. Uses of articles into which the substance has been incorporated (referred to as service life further on) are to be addressed in their own exposure scenarios;
- The use and its contributing activities addressed in an ES (its contributing scenarios) should clearly and consistently be identified via intuitive names or titles;
- The conditions of use described in an ES should be practically relevant and concretely verifiable by the actor in the supply chain receiving the ES and carrying out the use;
- ES building should start from the existing conditions of use typically present in a market/sector where the use takes place. The conditions of use described in an exposure scenario should correspond to what can be realistically expected under good [compliant] practice with regard to:
    - health, safety and environment management at company level;
    - inherent product safety for chemical products and articles.
- The different conditions of use relevant in an exposure scenario should be grouped in line with the hierarchy of controls as set out in EU occupational and environmental legislation:
    - inherent product safety (e.g. low dust grades, low concentration, limit amount per application);
    - technical and organisational measures to prevent release/exposure (including efficient application techniques and containment);
    - personal protective equipment and behavioural advice.

Registrants may also identify uses or types of processes in which substances with a certain hazard profile should not be used (e.g. respiratory sensitizers in spray applications). Additional risk management measures (RMMs) (e.g. local exhaust ventilation (LEV)) may not be the right strategy in such cases, regardless of any effectiveness seeming achievable. In such cases, registrants may suggest to switch to a closed system or advise against the use completely.

D.3.2 Overview on conditions of use

The starting point for the exposure assessment is the knowledge or the assumptions on the existing conditions of use. It can be assumed, that the existing risk management reflects what the users of the substance have known so far about the hazards of the substance.

For **activities by workers**, the following determinants (beyond the substance properties, see section D.4.1[16]) play a key role for the exposure levels to be expected:

- Percentage of substance in the mixture/article: The concentration of the substance in a mixture determines the expected exposure level. For local effects on skin and eyes it can be assumed that no effects will occur (and hence the use

[15] More information on Life cycle stages is provided in *Chapter R.12* of the *Guidance on IR&CSA* on use description.

[16] For human exposure, the vapour pressure plays a key role with regard to potential for inhalation exposure.

is safe), if the percentage of the substance in the mixture is below the concentration limit for classification. Also for the inhalation route, the concentration impacts on the exposure to be expected, however also other factors like the vapour pressure (at process temperature) of the substance play a role when assessing substances in liquid form. For substances incorporated into an article matrix various factors may impact on the migration or diffusion behaviour of the substance, and depending on this the concentration may determine the exposure to a smaller or larger extent;

- Physical form of the product: dusty products are less easy to contain than more massive solids or liquids, and thus may lead to higher exposure;
- Duration of activity/exposure: For workers, usually a daily exposure duration of 8h is assumed, and the average concentration over this period of time is estimated. Certain activities may take place repeatedly over a shift but with a total duration of less than 8 hours (e.g. sampling or transferring substances). The average exposure concentration over the shift may be adapted (lowered) accordingly. If a substance meets the classification criteria for acute toxicity, a particular assessment regarding task/ events with short duration but high exposure is required;
- Nature of the activity: an activity can be carried out at higher temperature or where mechanical energy is applied (e.g. machining of surfaces, metal cutting, spraying). These types of activities generally lead to a higher exposure potential;
- Design of the technical process: the technical process can be designed and operated under closed conditions so that the releases to the working environment are negligible;
- Where a process is not fully closed technical measures (risk management measures) can be set to reduce exposure such as physical barriers and ventilation conditions;
- Personal protective equipment: where technical measures are not feasible, personal respiratory protection, dermal and/or eye protection may be advised for risk management purpose.

Note that the management system put in place will impact highly on the effectiveness of the various measures described above to reduce exposure (see section D.3.3).

For **activities by consumers**, the following determinants (beyond the substance properties) play a key role in the predicted exposure levels:

- Percentage of substance in the mixture/article (for further details see section on workers exposure above);
- Physical form of the product: For the inherent safety of consumer products the physical form of solids (e.g. tablets rather than powder) and liquids (higher viscosity of liquids to avoid splashes) plays a key role;
- Packaging: For the inherent safety of consumer products the size and design of packaging plays a key role;
- Amount per use event and specific use conditions recommended;
- Frequency of use: Like for workers, the default assumption is that the substance is used on a daily basis, and thus long-term (chronic) exposure is assessed. If evidence is available that exposure (from any use) takes place only on a few days per year (infrequent use), the assessment may be adapted accordingly; in accordance to chapter R 15 (Consumer Exposure Estimation) this adaptation should be made by comparing the exposure estimate per event to a suitable

short-term DNEL, rather than averaging out the exposure in time;

- Duration of exposure: Usually a product-specific duration of the exposure per use-event is determined. If multiple events take place over a day, the duration is to be summed-up. If the exposure duration over the day is significantly shorter than 24 hours, the assessment may be adjusted accordingly (e.g. by lowering the estimated inhalation exposure concentration), depending on the toxicological profile of the substance. If a substance meets the classification criteria for acute toxicity, a particular assessment regarding short events with high exposure is required.

For the release to the **environment**, the following determinants (beyond the substance properties, see section D.4.1) play a key role on amounts released:

- Amounts used at a site, or amounts placed on the market for widespread use by consumers and professional workers;
- Design of the technical process preventing to greater or lesser extent release from the source: this includes for example efficient application of substances to article surfaces (spraying, spreading, immersion, plating) including management of rinsing water;
- Application of risk management measures to lower the releases to the environment: this includes for example onsite waste water treatment or treatment of exhaust air.

The assessor will identify for each of the relevant determinants a value[17] leading to safe use. In practice, various combinations of such values may lead to the same level on control, e.g. low concentration in product used over a longer time, or higher concentration in product used over a shorter time. The assessor should include the most typical combination of determinants/values into the exposure scenario and the downstream user needs then to verify that his actual conditions of use led to a similar level of protection.

The conditions of use are grouped under different headings in the ES according to their type e.g. technical measures, personal protective equipment, etc. Appendix D-1 provides an overview of the different groups which are used as headers in the Exposure Scenario both in the CSR and the ES for communication.

D.3.3 Effectiveness of risk management measures at sites

When the presence of risk management measures is a pre-requisite for safe use, the registrant needs to make assumptions on the effectiveness of the measures he describes in the exposure scenarios. These assumptions need to be made explicit in the CSR and need to be translated into information that can be verified by the downstream user receiving the exposure scenarios.

The effectiveness of a measure needs to be expressed in such a way that:

- it can be fed into exposure quantification (based on modelling) as a factor by which the exposure or release is likely to decrease if a **technical measure** is added to a given situation; e.g. local exhaust ventilation; on-site treatment of waste water before it is released[18];

[17] Note: The “value” can be a number with a unit (concentration, exposure time in hours, amount in tonnes) or a risk management measure with a certain percent effectiveness of removal or reduction.

[18] Note: Effectiveness can usually be provided for technical measures limiting release to air or water, and for technical measures limiting exposure via inhalation and dermal route.

- it can be fed into exposure quantification (based on measurements or modelling) as a factor by which the exposure is likely to decrease when **personal protective equipment** is applied;
- it can support the understanding of the conditions of use where the risk management is integrated into the process design/operation (e.g. closed systems), in this case, a comparison between a process without RMM and a process with RMM would be meaningless. In such cases the quantification of the resulting (residual) exposure or release itself indicates the overall effectiveness of exposure controls.

The assumed effectiveness of the RMM described in a contributing scenario should correspond to what can realistically be expected when the equipment is installed, operated and maintained in an appropriate manner. The specific elements in the companies' health, safety and environmental (HSE) management systems that ensure this should be part of the exposure scenario. The effectiveness of RMM in small sites and mobile services should be assumed to be generally lower than the effectiveness at industrial sites with advanced HSE systems.

In the ES for communication the RMM need to be described in such a way that downstream users can check whether they work in conformity with the risk management effectiveness assumed in the registrant's assessment. Therefore, explanations on how a certain level of effectiveness can be achieved for a given (set of) measure(s) is to be provided as part of the ES communicated downstream.

If a M/I assumes a certain effectiveness of a measure, the source of this assumption needs to be documented in the CSR. It is the responsibility of the M/I to make sure that the assumption is taken from a reliable source and applies to the conditions in the specified use. This includes considerations on whether the conditions of use correspond to good practices in a sector in terms of equipment design, its operation and its maintenance. The assumption may make reference to scientific publications or to the defaults used in widely accepted exposure estimation tools.

D.3.4 Collecting information on the condition of use

When carrying out a CSA, the collection of typical conditions of use may be difficult. The principal option for sourcing information on the conditions of use to be assumed for the CSA are the following:

- Information agreed at sector level is made available by industry sector associations as use maps (see next section);
- In house market knowledge, e.g. from the sales department, technical services to customers or product development. This source of information will in particular play a role for speciality chemicals and/or companies with a large customer base. Single customers may also approach registrants with information on their uses and a request to cover their conditions of use in corresponding exposure scenarios.
- Published documents meant to describe technical processes and/or work processes from the perspective of environmental release or human exposure such as:
    - Emission Scenario Documents (ESDs)[19]: documents developed under the OECD describing the sources, production processes, pathways and use patterns. ESDs aim to quantify the releases of a chemical into water, air, soil and/or solid waste;

[19] http://www.oecd.org/chemicalsafety/risk-assessment/introductiontoemissionscenariodocuments.htm/

- Best Available Techniques (BAT) reference documents (BREFs) developed in the context of the Industrial Emissions Directive (IED, 2010/75/EU). They include techniques and processes used in a specific sector, as well as current emission and consumption levels[20];
- Control sheets including basic advice on exposure controls to hazardous substances in the workplace. It takes the form of straightforward advice in 'factsheets' called 'control guidance sheets' which are sometimes specific to a certain industry sector e.g. Control of Substances Hazardous to Health (COSHH)[21] sheets developed by the UK HSE authority or the so called *VSKs*[22] *developed* by the German authorities.

- Study results and other open literature: these may include for example surveys about habits and practices of consumers or studies about effectiveness of certain type of risk management measures under different sectors/conditions.

D.3.5 Sector use maps including conditions of use

REACH includes the concept that downstream users of chemicals have the right to communicate their uses up the supply chain so that they can be covered in the registration dossier of the manufacturer/importer. However, if this communication takes place between individual companies, there is a risk that the process becomes highly inefficient and ineffective.

The concept of use maps was therefore agreed by industry prior to the REACH 2010 registration deadline as the recommended mechanism to give their input to the first wave of registration dossiers. Use maps are structured descriptions of uses and conditions of use agreed at sector level that registrants can use as input to their registrations.

As mentioned, use maps include the description of use and its contributing activities as well as the references to the corresponding inputs to the exposure assessment of workers, environment or consumers. In the case of sectors with Generic Exposure Scenarios (GESs) available, those may be used for developing use maps. The exposure assessment inputs are also developed according to agreed concepts and structures as Specific Workers Exposure Description (SWED), Specific Environmental Release Categories (SPERCs) and Specific Consumer Exposure Determinants (SCEDs). More details on these are available in the corresponding ECHA guidance documents on workers, consumers and Environment exposure assessments.[23]

The use maps concept brings benefits to all parties:

- Registrants can benefit from relevant information on the uses of substances, and their conditions of use, provided by downstream users. Such information is structured in a way that can be used to prepare their registrations and processed into the exposure assessment tools;
- Registrants ensure that their assessments cover the relevant uses for each sector to which their substances are supplied;
- The quality of the information in the CSA/CSRs improves as it is based on realistic

[20] http://eippcb.jrc.ec.europa.eu/reference/

[21] http://www.hse.gov.uk/coshh/

[22] Verfahrens- und stoffspezifische Kriterien (**VSK**) für die Gefährdungsbeurteilung (TRGS 420)

[23] *See Chapters R.14, R.15 and R.16 of the IR &CSA Guidance* available at: http://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment

uses and conditions of use provided by downstream users therefore authorities can base their decisions on actual information;

- Downstream users receive consistent and harmonised information from different registrants as they are all based on the same input information. As the content of the information to be included in the exposure scenario communicated in the supply chain with the safety data sheet is agreed by downstream users at sector level, the ES are expected to improve and become more meaningful to their recipient.

Use maps are best developed by formulating sectors in cooperation with end-user sectors, which are supplied by registrants. They can address the uses of the substances in subsequent life cycle stages where usually mixtures are used. Use maps therefore reflect conditions of use of mixtures and registrants need to select the pieces of information that are relevant to the particular substance subject to registration. For example, some substances that are part of a mixture may not enter the article service life cycle stage (solvent in a paint) while others in the same mixture will (pigments in the paint).

The CSR/ES Roadmap includes the activity of developing use maps under its scope. This has mainly led to an agreed template for use maps and for the different exposure assessment inputs. The templates are available in the CSR/ES Roadmap website[24]. Information on where to find available use maps by downstream user sectors will be included in the CSR/ES Roadmap pages.

D.3.6 Risk management libraries

In order to facilitate effective and accurate communication in the supply chains across the European market, manufacturers, importers and downstream users are advised to use a standardised system to structure and describe RMMs. At the start of the REACH system, Cefic had set up a library of RMMs, containing a first structured collection of available RMMs for the different target groups and exposure routes (see Appendix D-2). This includes product related measures, technical measures, informational measures and organisational measures. The library includes links to various sources of information. Corresponding to that ECHA had published the Guidance Chapter R.13, providing an initial concept on how to define risk management in the context of a REACH exposure assessment.

The “RMM library” concept was meant to make the risk management advice existing in various sources across Europe accessible. This may relate to sectors, product groups, processes or single horizontal measures like personal protective equipment (PPE). If a sector organisation has for example worked out RMM guidance for certain product/process types this information can be made accessible to registrants of substances used in this sector via a library.

Information from RMM libraries could help the registrants (and DU) to make reasonable assumptions on the effectiveness of RMM. They could also help to define standardised phrases to communicate the core information of a risk management measure.

At the time of publication of this Guidance, neither the Cefic library nor Chapter R.13 of ECHA’s *Guidance on IR&CSA* have been further developed since they were published in 2008. Certain RMM information is also available in:

- Guidance on exposure assessment (*Chapters R.14, R.15 and R.16 of the Guidance on IR&CSA*)

[24] The templates are not available at the time of publication of this Guidance.

- Use maps including SpERCs, SCEDs, SWEDs (see section D.3.5.)
- EScom phrase library (see section D.7.2.2)

D.4. EXPOSURE ESTIMATION

Release and exposure estimation under REACH aim to quantify the expected exposure when the conditions of use as described in the exposure scenario are implemented. Such quantification enables concluding on whether the risks can be adequately controlled. For each contributing scenario, a corresponding exposure data set (for the various environmental compartments or various routes of exposure to humans) is to be derived.

D.4.1 Modelled and measured exposure estimates

Exposure estimates can be derived from modelled predictions or measured data sets. However, measured data that are robust and representative of the situation/use scenario/conditions under consideration are not always available. In addition, the registrant's knowledge on the specific conditions of use downstream is limited; therefore, it is a widely used practice to derive modelled exposure estimates using a few generic standard exposure determinants (= conditions of use), as listed in section D.3.2. The conditions together with the distribution and fate properties of a substance determine the exposure to a substance. Table D- 1 gives an overview on the substance properties that are usually needed as a minimum to run a first Tier exposure assessment.

Table D- 1: Substance physico chemical/fate properties needed for Tier 1 exposure estimation

Substance properties	Needed for example for
Physical state of the substance at 20C	ECETOC TRA workers[25]
Molecular weight	EUSES (environment), ECETOC TRA workers and ECETOC TRA consumers
Vapour pressure	EUSES (environment), ECETOC TRA workers and ECETOC TRA consumers
Water solubility	EUSES (environment)
Melting point	EUSES (environment)
Kow or Koc or Kps	EUSES (environment)
Biodegradation	EUSES (environment)

Occupational exposure estimates usually refer to categories of activities carried out by workers (PROCs). Consumer exposure estimates usually refer to categories of products

[25] The physical state of the substance is needed in the TRA workers to define whether the exposure is driven by the vapour pressure or the dustiness of the product used, or whether the assessment is outside the applicability domain of the tool (e.g. the TRA does not predict exposure for solids in liquid mixture)

for which habits and practices of consumers can be described. Environmental release estimates usually refer to a life cycle stage and the technical fate of the substance after use (substance reacting during the use, processing aid being ultimately released to waste or the environment, or substance remaining in the matrix of an article).

Where it is not possible to demonstrate control of risk on the basis of a lower tier exposure estimation tool, higher Tier modelling (e.g. Stoffenmanager, Riskofderm, ART or specific models in ConsExpo)[26] or sets of measured data (existing data or data specifically generated for CSA under REACH) are required. This may also be necessary when considering the uncertainties associated with the assessment (See section D.5.4). Typical situations where more in-depth release/exposure estimation may be required include for example:

- The assessment cases fall outside of tier 1 models' applicability domain (e.g. solids in liquids for the ECETOC TRA).
- Low volatile substances (non-dusty) with low DNEL in uses where no particular energy (mechanical or thermal) is applied, and therefore no aerosol/fume/dust formation is expected. Reason: tier 1 models may tend to overestimate for such cases the exposure to the vapour phase;
- Substances reacting on end-use, where the exposure to the parent substance is limited due to the reaction rate and hence a rapidly decreasing concentration of the parent over time. Reason: tier 1 models usually do not generate concentration curves over time and thus the initial concentration of the substance in the product determines the exposure estimate which may lead to an overestimation of the exposure of the parent substance during use;
- Non-threshold substances with serious effects (PBT/vPvB, CMR, respiratory sensitizers), where special conditions of use (beyond standard exposure determinants) may be needed to minimise/prevent release and exposure.

REACH requires that existing adequately measured, representative exposure data are taken into account in the exposure assessment, either on their own or in combination with modelled exposure estimates. When measured data sets are used, there should be sufficient contextual information available to derive exposure scenarios (describing the conditions of use leading to exposure measured including any controls that are in operation).

D.4.2 Special case: Exposure estimate for own site

When assessing uses taking place at his own site or at the sites of well-known customers, the registrant usually has access to more site-specific information. He may for example be able to make use of monitoring data related to workers exposure or releases to the environment.

For workers, exposure is usually monitored in order to check the single worker exposure during a workday. Depending on the organisation of the work and assignment of tasks those measured exposure levels may correspond to several tasks by a single worker and not exposure due to a single task. This needs to be transparently explained in the assessment, including a full description of the tasks being carried out during measurements.

[26] See guidance *Chapter R.14* of the *Guidance on IR&SA*, providing an overview on the applicability domain, the inputs and the outputs of the different modelling tools.

D.5. RISK CHARACTERISATION

In the risk characterisation, the registrant demonstrates that the conditions of use described in the exposure scenarios control or prevent release/exposure to an extent that adverse effects could not occur. Where control of risk cannot be demonstrated, the registrant can iterate his assessment by:

- deriving more realistic exposure estimates (e.g. using higher Tier modelling or by generating measured exposure data) or
- refining the hazard assessment (e.g. by generating new data using more appropriate study types and hence lower the required assessment factors) or
- suggesting more stringent operational conditions or risk management measures;
- limiting the supported uses.

Based on the refined assessment, the registrant may then be able to derive final exposure scenarios for which control of risk can be demonstrated.

D.5.1 Quantitative risk characterisation

When a no-effect-level (PNECs, DNELs) can be derived, the risk can be characterised by comparing the expected exposure to the no-effect-level and calculating the risk characterisation ratio (RCR). For many substances, DNELs for long-term systemic effects are available, providing an exposure level to which a person can be exposed 8h per days (worker) or 24h per day (consumer) over a lifetime without adverse systemic effects being expected to occur. Where exposure is limited to shorter duration and/or lower frequency then the assessment may be adapted.

For acutely toxic substances, acute DNELs should be derived for comparison with short periods of high exposure that may occur during the use. Also, where local effects play a role, a DNEL from a corresponding study may be available.

D.5.2 Qualitative and semi-quantitative risk characterisation

For a number of endpoints it is not (always) possible to derive a no-effect-level. However the classification of the substance indicates a certain type and severity of hazard and can be used to determine the appropriate risk management strategy (see also *Part E* of the *Guidance on IR&CSA* Table E.3-1). The qualitative risk characterisation is expected to provide the argumentation that the conditions of use described in the exposure scenario are suitable to control the risks related to the identified hazards. Such arguments may include release/exposure estimates.

For some substances without a no-effect-threshold (in particular carcinogens), a minimal-effect-level (DMEL) may be derived (see *Chapter R.8* of the *Guidanceon IR&CSA*). The DMEL quantifies the likelihood of the adverse effect occurring in a population depending on the exposure level. Then a semi quantitative risk characterisation can be performed. It consists of i) a qualitative argumentation that the conditions of use described in the exposure scenarios are suitable to minimise/prevent exposure and ii) a comparison of predicted exposure against the DMEL.

For substances to be treated as PBT/vPvB based on the outcome of the PBT assessment, emissions to the environment need to be minimised. The risk characterisation should provide the arguments that the conditions of use described in the exposure scenarios (e.g. a closed system) and the releases quantified in the emission estimate represent the best available technique (including non-technical means) to avoid releases. Such arguments should include an explanation of why it is not possible to further reduce the releases as quantified in the release estimate.

D.5.3 Combined risks

Combined exposure to multiple chemicals is out of scope of the Chemical Safety Assessment under REACH. Under REACH the term “combined” relates to exposure from one substance via multiple routes or from multiple sources. Risks from combined exposure are to be considered in various cases described below

By default, the risk characterisation ratios for **systemic health effects** should be summed up across the routes of exposure within a contributing scenario (dermal and inhalation routes for workers plus the oral route for consumers, inhalation and dermal for man via the environment) to generate a total systemic risk characterisation ratio. This RCR must be below 1 for demonstrating safe use.

Exposure from various tasks of a worker is usually not aggregated in REACH registration assessments, as this is typically dependent on site related work organisation. Such combined exposure may be addressed for an own site, but it is difficult to anticipate it across various downstream user sites. Thus, for a generic exposure assessment the most suitable starting point would be the assumption that the task is carried out for 8 hours, and therefore the assessment would be independent of the work organisation of the downstream user. However, a registrant may nevertheless choose to base the occupational exposure scenarios on a duration of less than 8 hours, either because i) the task in practice is short by nature (e.g. based on information from sector use maps) or ii) limiting the duration is a measure to control the risk. The latter may mean that workers should not be further exposed to the substance during the remainder of the shift to guarantee safe use. Under OHS legislation, an employer must assess the risk over the entire shift. The registrant may want to include a corresponding alert in the exposure scenario for communication (see section D.7.)

Analogous considerations apply to **consumer exposure** when the substance is contained in various consumer products potentially used during the same period of time. In addition the exposure from different sources may play a role when a registrant considers basing his assessment for a certain use on the assumption i) that the exposure time during a day is only short (one or few hours) and/or ii) that the substance is only used for a few times per year. If such assumptions are made for a use, the registrant should confirm that there is no evidence of significant additional exposure to the same substance from other uses/products.

Assessment of risks from combined exposure resulting from different sources will usually require measured data sets or more sophisticated (probabilistic) modelling approaches (based on detailed input data sets on distribution of use patterns among consumers). Please note: A simple and robust (Tier 1 type) methodology to assess "co-use/exposure" patterns among consumers is not yet readily available (for references to ongoing work please see the draft updated draft of *Chapter R.15* of the *Guidance on IR&CSA* available at: (http://echa.europa.eu/support/guidance/consultation-procedure/ongoing-reach)

Regarding the **environment**, the **combined release from all uses** and all release routes are by default taken into account at regional level in the EUSES assessments. In addition, for widespread uses, a local assessment must be carried out summing all releases to the waste water system (typically a municipal biological treatment plant).

D.5.4 Uncertainty considerations

In order to support the interpretation of the risk characterisation the registrant should include a reflection on the uncertainties around his assessment, and how they are dealt

with. This may include uncertainties around i) the composition of the substance and its variability (mainly relevant for UVCBs), ii) the properties of the substance (including its hazard), iii) the use pattern of a substance and the conditions of use and iv) the related exposure estimates. The required level of detail for such reflection depends on the case.

The following list provides some typical examples of where a registrant may reflect on the uncertainties in his assessment:

- A registrant may want to indicate where conservative default assumptions (for example in Tier 1 exposure estimation) have significantly impacted on the risk characterisation ratio;
- Where input parameters are highly variable (e.g. composition of a UVCB) a registrant may want to demonstrate that his assumptions on the composition reflects the "worst case" in terms of risk characterisation;
- When the substance fate properties are dependent on the receiving environment (salinity, hardness, pH), there may be the need to check that the risk characterisation ratios remain below 1 for various types of environment. If the RCR is <<1, such calculations may however not be needed;
- Where exposure estimation tools/methods have been used at the boundaries of their applicability domain or reliability in predicting exposure, the registrant may provide arguments as to why he still believes his risk characterisation to be valid. This applies for example for substances with properties where standard exposure models (low water solubility, high adsorption...) do not well support exposure estimation;
- The use of exposure modelling tools requires the assessor to express the given types and conditions of use in form of tool input parameters (i.e. entering a value or selecting among available options). It is well known that these "translations" depend on judgements/interpretation of the single user and may show quite some variability across the users. The registrant may include reflections on the way such inter-user variability of results has been minimised in his assessment e.g. experienced assessors, assessment done as outcome of a group's work, sensitivity analysis etc.;
- When using higher Tier models to predict exposure, more input parameters are needed, which are partly being estimated. Such estimation may involve uncertainties that should be reflected in the assessment.

D.6. BUILDING THE CHEMICAL SAFETY REPORT

D.6.1 General considerations

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 the IUCLID format

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

Note: Registrants are able to report an extract of the information on exposure assessment in the IUCLID format. Chesar[27] supports the extraction of such information into IUCLID. This information in IUCLID may support authorities' processes for example

[27] Chesar is the Chemical Safety Assessment and Reporting tool developed by the European Chemicals Agency to support registrant preparing their CSR and their ES for communication. More information can be found at: http://chesar.echa.europa.eu.

in avoiding the selection of substances when the release and exposure potential from the uses is low.

The main goal of the chemical safety report (CSR) is to document the chemical safety assessment (CSA), including its conclusions and results in a transparent and consistent manner. The CSR is also the source from which the information to be communicated further down the supply chain is to be extracted (extended safety data sheet).

The CSR should enable the reader to understand the chemical safety assessment and the scientific arguments that support the conclusions of the hazard assessment, and, if the substance fulfils the criteria for any of the hazard classes or categories listed in Article 14(4) or is assessed to be a PBT/vPVB, exposure assessment and risk characterisation. It is emphasised that key information in the CSR on hazard and exposure must 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 assumptions on operational conditions and risk management must be traceable in the exposure estimation and consistent with the final exposure scenario in the CSR.

Key information that is present elsewhere (e.g. in the technical dossier[28]) should be presented in a brief table format and referenced, rather than repeating 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.

Annex I of the REACH Regulation includes general provisions for assessing substances and preparing Chemical Safety Reports (CSRs). Section 7 of Annex I includes a format with standard headings that shall be included in the CSR.

The CSR is developed and submitted in the context of the registration dossier, and therefore is subject to the same update considerations. It must be updated when there is new knowledge on the uses or the risks of the substance to human health and/or the environment which leads to changes in the safety data sheet or the chemical safety report. Situations that may trigger the update of the CSR include:

- New use(s) reported or identified for the substance e.g. new market development, or as a result of supply chain communication, new use map available etc.
- Refinement of the existing assessment e.g. more precise information on conditions of use or tonnage per use available.
- Result of a test conducted following the processing of a test proposal
- New registrant(s) join the joint submission and bring(s) new information or new uses or new composition/classification for the substance.

When the CSR has been developed and submitted jointly, it is recommended that the update is discussed and agreed in the context of the joint registration. The Lead Registrant takes care of the updates and the other registrants are informed when the changes have been submitted via an updated registration dossier.

D.6.2 Structure of Chemical safety report

A CSR consists of two parts: A and B with different sections. The paragraphs below briefly describe the content of each section of a Chemical Safety Report.

[28] IUCLID substance dataset

Part A includes:

- Summary of risk management measures: Risk Management measures (RMM) are part of the Exposure scenarios included in section 9 of the CSR. In order to avoid duplication of information, it is recommended to simply refer to the RMM in the ES detailed later on. If a jointly developed CSR has been submitted by the lead registrant, reference to the ES in the joint CSR for all the uses relevant to the single registrant are to be made. Indeed it is important to note that not all registrants supply to all uses in the CSR. Transparency on the uses covered by each registrant is key. In case there are uses (specific to certain registrants) which have been assessed in an own (separate) CSR, the reference is made to section 9 of the own CSR.
- Declaration that risk management measures are implemented: this declaration refers to the RMMs related to the registrants' manufacturing and own use(s). This declaration is specific to each registrant and is submitted separately by each registrant.
- Declaration that risk management measures are communicated: this declaration is also specific to each registrant and his market(s). Consistency with the uses addressed in each registrant's extended SDS is also important.

Part B of the CSR is meant to report the assessment and follows a 10 sections structure.

Sections 1 to 8 of the CSR can be automatically generated by a plug in to IUCLID[29] (report generator) which has been developed to extract the data from a IUCLID substance dataset and report them automatically into a CSR template.

Section 1 is to report the identity of the substance and its physico chemical properties. The identity of the substance the CSR refers to is to be made transparent. Beyond identifiers, information on the type of substance and its (one or more) composition(s) is to be provided. In case several compositions with different hazard profiles are to be covered by the CSR this needs to be clearly explained. Assessment entities may be defined to transparently link information on the composition, the hazard (including classification and PBT assessment), the uses and their exposure assessment and risk characterisation (see section D.2.2).

Section 2 is to report the manufacture and uses of the substance along the life cycle. *Chapter R.12* of the *Guidance* on *IR&CSA* on use description[30] provides explanation on how to describe uses. This includes names for the use and its contributing activities, explanation about the use, standardised use descriptors, any relevant regulatory status and tonnage per use. The tonnage per use is an important information as i) it supports the environmental assessment and ii) it allows authorities to set priorities for further regulatory action taking into account exposure information. Indeed low volumes of wide dispersive uses will lead to lower priority. It should be noted that various types of "tonnage per use" may be used by registrants (for example all EU tonnage or own tonnage) and that transparency is key. More details are provided in *Chapter R.16* of the *Guidance* on *IR&CSA.*

When an exposure assessment is required, all the manufacture and uses should have a related assessment (including exposure scenarios, contributing scenarios, exposure estimates and risk characterisation) in section 9 and 10 of the CSR. Clear links between the use description and the assessment are essential to make the report understandable.

[29] http://iuclid.eu/index.php?fuseaction=home.documentation&type=public#usermanual

[30] http://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment

Uses advised against are also to be reported in section 2.

Section 3 is to report the classification and labelling of the substance (there may be several classifications in case several compositions have different hazard profiles). Explanations on how the classifications have been derived from information reported in section 4 to 7 are to be provided.

Section 4 is to report environmental fate properties, **Section 5** human health hazard assessment, **Section 6** hazards related to physico chemical properties and **Section 7** environmental hazard assessment. For all those sections the general structure proposed 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 the identification of key results for the assessment.

The conclusions on hazard assessment such as derivation of DNELs and PNECs or any other qualitative hazard conclusion should also be included.

Section 8 is to report the PBT and vPvB assessment. This covers the assessment of the PBT or vPvB properties and an emission characterisation in case the substance is identified as being (or handled as if it was) PBT or vPvB (according to the criteria in Annex XIII of REACH). The PBT properties are, as classification and labelling, identified on the basis of the studies reported in section 4 and 7 of the CSR.

Section 9 and 10 are to report the exposure assessment and risk characterisation[31]. Although some information on exposure can be reported in IUCLID this is not exhaustive and therefore section 9 and 10 cannot be generated from IUCLID. They have to be generated from other tools or manually. Chesar can export to IUCLID information on use and exposure and the report generator can generate a full CSR (including section 1 to 10) by merging section 1 to 8 generated from data reported in IUCLID and section 9 and 10 generated from data reported in Chesar.

When exposure assessment is required, the key elements of the assessment approach should be explained upfront is section 9.0 in order to guide the reader of the report. Those explanations may address the following for each target group (environment, human via environment, workers, consumers):

- An overview on the scope of exposure assessment drawn on the basis of the hazard conclusions reported in section 5 and 7 and/or other considerations such as assessed amount for human via the environment.
- Approach to the assessment such as :
    - methods which have been used for exposure estimation and, when needed, why they are adequate
    - whether some generic considerations (relevant for all or most uses) have been used for risk characterisation such as using a concentration limit as a

[31] Please note: For the sake of better readability, the structure recommended slightly deviates from the structure in section 7 of Annex 1 of REACH. The difference is that exposure estimates and risk characterisation are suggested to be reported in section 9 per exposure scenario and not in section 10. On combined exposure and risks across uses may be reported in section 10.

cut off to consider that dermal local effects are controlled

- Specific considerations relevant for all (or most of the) exposure scenarios, such as:
    - Measures driven by physico chemical hazards,
    - Requirements for the personal protective equipment (e.g. glove types) when needed in the contributing scenarios.

For each manufacture and use, an exposure scenario is then to be described containing:

- A title section, corresponding to the use description
- For each contributing activity, a corresponding contributing scenario describing the conditions of safe use. Those conditions are to be reported in a clear and understandable way. A heading structure has been developed in order to group the type of conditions and measure and is presented in Appendix D-1.
- For each contributing scenario (qualitative or quantitative) risk characterisation is to be reported for each relevant compartment of the environment or route and type of effect for human health. Note that risk characterisation for combined routes are also to be reported within each contributing scenario. Exposure estimates are usually needed to perform the risk characterisation. They need to be consistent with the conditions described within the contributing scenario. Considerations on uncertainties may also be provided (see section D.5.4)

More details on how to carry out the assessment is provided in *Chapters R.14, R.15* and *R.16* of the *Guidance on IR&CSA*.

Combined risks across contributing scenarios or across uses (see section D.5.3) are to be reported in **section 10** of the CSR.

Some support and illustration is provided in http://echa.europa.eu/support/practical-examples-of-chemical-safety-reports and http://echa.europa.eu/web/guest/support/guidance-on-reach-and-clp-implementation/formats

D.7. EXPOSURE SCENARIO FOR COMMUNICATION

The exposure scenario for communication, annexed to the safety data sheet (extended SDS), describes the conditions of safe use as determined in the CSA. The conditions described need to ensure safe use from the human health and the environment perspective. The addressees of the exposure scenarios for communication are mainly the health, safety and environment managers in companies, the plant managers and/or the product safety managers.

When generating exposure scenarios for communication, registrants are advised to consider the following points:

- A separate exposure scenario should be built for each identified use, for example, uses belonging to different life cycle stages should be covered by different scenarios
- Not all the exposure scenarios in the CSR may be relevant to be communicated e.g. it may not be appropriate to communicate the exposure scenario for the manufacturing activities of the registrant down the supply chain.
- Harmonisation should be sought both in terms of the structure of the ES and its content. Exposure scenarios for substances enter complex supply chains, so having harmonisation of content and formats among registrants of the same substance is key. The extended safety data sheets are also the main vehicle used to convey the classification agreed among registrants during the SIEF process. Different classifications (due to, for example, a difference in the composition), or differences in hazard because of changes in form, may lead to deviations in recommended conditions of use among suppliers of the same substance.
- Harmonised formats across sectors manufacturing substances in general facilitate the consolidation work that needs to be done to generate safe use information for the mixtures based on substances' Exposure Scenarios. With regards to the structure, the harmonised template published by ECHA[32] is recommended. The use of IT generated harmonised structures can also facilitate the communication of exposure scenarios.
- For some substances that are broadly used, the extended safety data sheet can become quite voluminous. Inserting a table of contents at the beginning of the annex with the exposure scenarios is recommended in order to provide the recipient with an overview that can help him to identify the exposure scenario(s) that are relevant to his use(s). Building such a table of contents with the *structured short titles*[33] is recommended.
- There are pieces of information in the CSR that do not need to be included in the ES for communication. For example, it is not necessary to convey conditions which do not constrain the use of the substance (e.g. duration of the task up to 8 hours per day) or cannot be controlled by the single DUs (amount of substance in a widespread use). However, such conditions are expected in the CSR as they provide transparency on the CSA to authorities.
- Where exposure modifiers based on duration of task have been used in the assessment, the ES for communication should indicate to which extent time is a risk-controlling factor (e.g. by communicating the risk characterisation ratios in

[32] http://echa.europa.eu/support/guidance-on-reach-and-clp-implementation/formats

[33] http://www.cefic.org/Documents/IndustrySupport/REACH-Implementation/Guidance-and-Tools/StructuredShortTitles04112014.pdf

section 3 of the exposure scenario). The recipient may need this information to understand the impacts of task based time limits on the work organisation at his site. It may for example mean that workers after having carried out one task should not be exposed at all to the substance during the remainder of the shift to guarantee safe use.

- The information on safe use from the Exposure scenarios for substances is also meant to be communicated further down the supply chain when the substance has been incorporated into a mixture. Depending on the recipient of the mixture (formulator of mixtures in mixtures, or end-user of the mixture), the formulator has different options to convey the safety information received via the ES of the substances:
    - Attach the exposure scenario of the single substances to the safety data sheet of the mixture. This option applies when registrants place their substance on the market in the form of a mixture, or when formulators supply a mixture to another formulator.
    - Consolidate the ES information for the single substances into one piece of safe use information for the mixture (when the mixture is supplied to end-users). Such a piece of information can be i) included in the main body of the safety data sheet or ii) attached to the safety data sheet. Regardless of the option, the conditions of use resulting from a CSA carried out further up the supply chain need to be highlighted in a clear manner, so that the recipients of the mixture know that the obligations in Article 37 (4) of REACH[34] apply to them.

When carrying their CSA, registrants should already anticipate the communication of the exposure scenarios down the supply chain, i.e. assume the conditions of use as relevant for the use of mixtures by end-users. Such information can be retrieved from use-maps of formulating sectors or from single key customers.

The following sections D.7.1 and D.7.2. provide some more details to facilitate the communication of exposure scenarios in the supply chain. Chesar follows the principles described below when generating the ES for communication.

D.7.1 Selection of information relevant for communication

D.7.1.1 Information relevant for downstream users

The CSR is a source of information for authorities and for the registering company itself. It may contain explanations and justifications that are not relevant for the DU to understand which conditions of use the registrant considers ensuring safe use. The registrants should limit the information communicated with the exposure scenario to information that has a practical relevance for the downstream users:

- Clear definition of the uses and activities covered in the exposure scenario
- Operational conditions assumed in the assessment and the resulting risk management measures required/recommended to ensure safe use including:
    - Conditions with regard to activities of the recipient of the ES himself
    - Conditions with regard to the design and foreseen use of the recipient's products (mixtures and articles) containing the registered substance further

[34] See ECHA Guidance for Downstream users for more information (http://echa.europa.eu/guidance-documents/guidance-on-reach)

down the supply chain

- Conditions with specific needs regarding waste treatment (recovery, disposal)

- Any information that supports the DU in understanding and comparing his own conditions of use with those in the exposure scenario.

The ES for communication should be neither excessively descriptive nor too general or vague. When sector-specific use maps from downstream user organisations are available the level of information from such use maps is meant to strike the right balance. When products are used in very specific situations, a higher level of detail may be expected.

Conditions that are additional good practice advice for the downstream user (i.e. those that have not been used in the assessment and therefore are not required to reach the reported risk characterisation) can be included in the ES for communication e.g. 'ensure procedures and training for emergency decontamination and disposal are in place'; however, they should be clearly differentiated, under a corresponding header 'Additional good practice advice' with 'Obligations according to Article 37(4) of REACH do not apply', to flag their non-mandatory nature.

Finally, consistency needs to be ensured between the different parts of the exposure scenario as well as with the information provided in the main body of the safety data sheets, mainly section 8 on Exposure controls/Personal protection where RMMs are also reported.

D.7.1.2 Information where the hazard changes during use

The provision of extended safety data sheets can also be applied to the following cases:

- **substances where changes of form or composition during downstream uses lead to hazardous properties.** According to Article 5(1) of the CLP Regulation, the classification shall relate to the forms or physical states in which the substance is placed on the market and in which it can reasonably be expected to be used. This does not explicitly include hazards due to reaction products, but registrants are advised to apply analogue principles. The registrant should communicate down the supply chain i) to which extent uses where transformations with potential hazard changes take place, are covered in his CSA, ii) which risk management measures are potentially needed and iii) which uses he does not support. DU obligations under Article 37 of the REACH Regulation (including data generation obligations) will apply accordingly when such information is communicated.

- **substances where form changes or reaction during use lead to disappearance of hazardous properties.** In such cases, there is no need to communicate exposure scenarios for the uses of the non-hazardous form or reaction product(s) of the substance.

Note: When the substance placed on the market does not fulfil the criteria to be classified "hazardous" but hazards can be expected to appear during use, the communication foreseen under Article 32 of the REACH Regulation would apply (i.e. duty to communicate information down the supply chain when a safety data sheet is not required). The established SDS format would be the most suitable to inform about these hazards and the related risk management measures. Where a registrant informs about such hazards, but does not support the use, or where the DU is aware of the changes during use, but chooses not to inform the supplier, a DU CSR may be appropriate.

D.7.2 Means of communication

ECHA, together with stakeholders, have worked under the CSR/ES Roadmap[35] to develop a number of products that can support companies to generate or communicate exposure scenarios of substances in the supply chain. Additional support is also available for formulators or end-users that handle exposure scenarios information. Implementing the solutions below is also of help to the actors further down in the supply chain as the information reaches them in a more structured and harmonised way.

D.7.2.1 Exposure scenario format

The REACH Regulation does not define a specific format for the ES for communication; however, experience has shown that all parties can benefit from working with a harmonised structure. An ES for communication typically consists of four sections:

1. Title
2. Conditions of use affecting exposure
3. Exposure estimation and reference to its source[36]
4. Guidance for Downstream Users on how to evaluate whether he works inside the boundaries set by the ES (conformity check[37])

ECHA has published some annotated templates to explain the recommended format following these four sections. The annotated templates show downstream users what they can expect to see in an exposure scenario for a substance. They may also be useful for registrants to understand how to structure the ES for communication. The templates describe the type of information that is included in each section. Different templates have been developed for different life cycle stages; Appendix D-1 gives an overview of the headers expected in the ES which are also relevant for the ES for communication.

In addition, practical examples of ES for communication have been published[38]. These examples are based on the previously published illustrative example of a CSR in order to show how the information in the CSR can be extracted and conveyed through the ES for communication.

The templates and examples are available at

http://echa.europa.eu/support/guidance-on-reach-and-clp-implementation/formats

D.7.2.2 ESCom phrases

An important part of the harmonisation efforts is for companies to use the same wording for the content of the exposure scenarios. Exposure scenarios are part of the Safety Data Sheets and therefore they have to be translated into the language(s) of the recipient's country. Having agreed wordings also facilitates translations.

The ESCom project[39] has developed a catalogue of standard phrases for exposure scenarios, which is available to be used by all interested parties. The phrases are made

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[35] http://echa.europa.eu/regulations/reach/registration/information-requirements/chemical-safety-report/csr-es-roadmap

[36] Note that section 3 may not always be relevant for communication

[37] Such guidance may for example describe how scaling can be applied for the specific ES, or how a DU can practically demonstrate that the target effectiveness of a risk management measure is achieved.

[38] http://echa.europa.eu/support/practical-examples-of-exposure-scenarios

[39] http://www.cefic.org/Industry-support/Implementing-reach/escom/

available with some additional information that defines for which sections this phrase is relevant, or who is the originator of the phrase. The catalogue of standard phrases is continuously improved to include additional phrases or refine existing ones, it is therefore regularly updated.

D.7.2.3 ESCom XML exchange format

Exposure scenarios are usually exchanged in the supply chain in a document format. Processing the information from the exposure scenarios can be time consuming, as it often has to be imported into company IT systems first. In order to facilitate this inclusion of the information in company systems, the ESCom project has also developed an XML format to convey the exposure scenario information electronically in addition to the normal document format. Providers of IT systems are encouraged to implement this XML format in their systems to be able to generate and receive ES in this way in order to avoid manual typing of the information into various systems.

D.7.2.4 Structured short title

The first section of the recommended structure of the ES is the ES title. This section includes information on the activities that are covered by the ES, and it is a crucial piece of information for DU when they are deciding which is the ES that covers their use(s).

The structured short title is a combination of descriptors that, put together, give a first indication to the recipient of whether the ES is relevant for his use(s). It consists of the life cycle stage, the information on the markets or sectors in which the use takes place, and may include additional information which should also be based on standard phrases.

The structured short title is not the Exposure scenario name, which should reflect the scope of the ES using as much as possible standard phrases too.

Chapter R.12 of the *Guidance on IR&CSA* on use description provides more information on the difference between ES titles and structured short titles.

APPENDIX D-1 : STRUCTURE FOR CONDITIONS OF USE WITHIN EXPOSURE SCENARIOS

The following tables list headers for structuring the reporting of conditions of use within contributing scenarios (both for the CSR and for the ES for communication). Explanation is provided with regard to the type of conditions of use which may be reported under the one or the other header.

D.7.3 Uses by workers

D.7.3.1 Contributing scenarios for workers

Header	Information typically included in this section
Product (article) characteristics	Physical form of the product [gas/liquid/solid] and level of dustiness (for solid products); concentration of substance in product; package design affecting exposure;
Amount used (or contained in articles), frequency and duration of use/exposure	Duration per task/activity during a shift; frequency of exposure (e.g. single event or repeated);
Technical and organisational conditions and measures	Process design determining the exposure (e.g. closed systems, containment); remote operation of process; ventilation conditions; barriers preventing dermal contact; specific organisational measures (e.g. regular maintenance, instructions, training, supervision) to support the functioning of the technical measures;
Conditions and measures related to personal protection, hygiene and health evaluation	Personal protective equipment (PPE): respiratory protection (including type and effectiveness), dermal protective clothes and gloves (including suitable material); face and eye protection; biomonitoring data and health surveillance program where relevant for a specific substance;
Other conditions affecting workers exposure	Place of use (indoor/outdoor); room volume; operating temperature and pressure conditions;
Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply	Good practice advice beyond the obligatory measures that were the basis for the CSA (not mandatory for the downstream user to implement).

D.7.3.2 Contributing scenario for the environment

Header	Information typically included in this section
Product (article) characteristics	Concentration of substance in product; viscosity of liquid product; package design (or transport equipment) affecting release;
Amount used, frequency and duration of use (or from service life)	Amount per industrial site [tonnes per day and year]; frequency of release from industrial site (e.g. if infrequent release only)
Technical and organisational conditions and measures	Process design determining the initial release (e.g. closed systems, containment; specific rinsing techniques or closed loop processing aids); techniques for onsite pre-treatment of waste water and treatment of exhaust air; specific organisational measures supporting the functioning of particular technical measures; onsite-collection of waste; onsite treatment of waste;
Conditions and measures related to Biological Sewage Treatment Plant	Type of plant (standard municipal or site specific industrial with specific effectiveness); size of treatment plant (default 2000 m3/d but can be adapted for specific industrial sites);sludge treatment technique;
Conditions and measures related to external treatment of waste (including article waste)	Suitable treatment techniques for waste disposal (e.g. hazardous waste incinerations, chemical-physical treatment of emulsions or surface treatment baths, chemical oxidation of aqueous waste); suitable techniques for recovery of waste (e.g. re-distillation of solvents, refinery process for lubricant waste)
Other conditions affecting environmental exposure	Flow rate of receiving surface water (default 18000 m3/d but can be adapted for industrial site); place of use (indoor/outdoor);
Additional good practice advice. Obligations according to Article 37(4) of REACH do not apply	Good practice advice beyond the obligatory measures that were the basis for the CSA (not mandatory for the downstream user to implement).

D.7.4 Uses by consumers

D.7.4.1 Contributing scenarios for consumers

Header	Information typically included in this section
Product (article) characteristics	Concentration of substance in product; physical form of the product [gas/liquid/solid], level of dustiness (for solid products), spray, viscosity for liquid products; package design affecting exposure;
Amount used (or contained in articles), frequency and duration of use/exposure	amount of product used per event; duration of exposure event; frequency of use;.
Information and behavioural advice for consumers	Safety advice to be conveyed to consumers (e.g. instructions for use). *It should be noted that personal protective measures are usually not expected for consumer uses.*
Other conditions affecting consumers exposure	Type of room (size and ventilation), place of use (indoor/outdoor)

D.7.4.2 Contributing scenario for the environment

Header	Information typically included in this section
Product (article) characteristics	Concentration of substance in product; product or package design affecting release;
Amount used, frequency and duration of use (or from service life)	*Normally no information is communicated under this section*
Conditions and measures related to external treatment of waste (including article waste)	Advice to be conveyed to consumers on the appropriate route of disposal/recovery (e.g. separate collection as household chemical, battery collection)
Other conditions affecting environmental exposure	Place of use (indoor/outdoor)

APPENDIX D-2- OVERVIEW ON CEFIC'S RMM LIBRARY[40]

Table D- 2: Overview on RMMs and safety instructions in Cefic's RMM library

Product-Substance Related:	
1	Limiting concentration of hazardous or non-hazardous ingredient
2	Change of physical state (e.g. powder -> pellet)
3	User friendly packaging (reducing handling)
4	Info / Guidance / Manual other than label and Safety Data Sheet
Marketing and use related	
5	Marketing and Use – General
6	Product safety / advice
Process / Control Change:	
7	Process Control / Change
8	Automation
9	Containment of operator
10	Cleaning of process equipment
11	Spill Containment Measures
12	Reduction and cleaning of air emissions
13	Reduction and cleaning of waste water
14	Reduction of waste, disposal of waste

Ventilation Control:	
15	Local Exhaust Ventilation - (partial) enclosure
16	Laminar Flow Booths & Laminar Flow Benches
17	Local Exhaust Ventilation - captor hoods
18	Local Exhaust Ventilation - receptor hoods
19	Local Exhaust Ventilation – specialised applications
General Dilution Ventilation:	
20	Dilution Ventilation
Organizational:	
21	Management Systems
22	Operating Practice
23	Competence and training
24	Supervision
25	Monitoring
26	Health Surveillance
Good Hygiene Practices & Housekeeping:	
27	Good Hygiene Practices & Housekeeping
Personal Protective Equipment:	
28	Body protection
29	Hand protection
30	Respiratory protection
31	Face / Eye protection

[40] The Cefic RMM Library is undergoing an update which was not concluded at the time of publication of this Guidance. Please verify current status on the Cefic website.

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