Guidance on information requirements and chemical safety assessment

Part A: Introduction to the Guidance Document

May 2008

LEGAL NOTICE

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

PREFACE

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

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

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

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

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

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A.1 HOW TO WORK WITH THE GUIDANCE DOCUMENT

A.1.1 Aim of this module

The aim of this module is to provide an introduction to the Guidance Document for conducting the chemical safety assessment and preparing the chemical safety report for substances manufactured or imported in a quantity of 10 tonnes or more per year (Chapter A.1)[2]. This includes an overview on the intended outcomes and main contents of the chemicals safety assessment (CSA) as documented in the chemical safety report (CSR). It also includes the overall approach to cost-effective decisions during the iterative process of conducting the CSA, and a pathfinder to the different elements of this guidance.

Chapter A.2 explains the key facts needed for understanding the chemical safety assessment. The communication and tasks within the supply chain related to the chemical safety assessment are outlined in Chapter A.3. Chapter A.4 describes more in detail, in which situation an actor under REACH may need to carry out a CSA.

A.1.2 What is the Chemical Safety Assessment about?

A.1.2.1 Overview of the CSA Process

REACH is based on the principle that industry should manufacture, import or use substances or place them on the market in a way that human health and the environment are not adversely affected. The chemicals safety assessment (CSA) is the instrument to:

- Assess the intrinsic hazards of substances including determining the hazard classification, further characterising hazards, including where possible derivation of no-effect-levels (Derived No-effect-Levels for human health, Predicted No-Effect-Concentrations for environment), and assessing properties relating to persistence, bioaccumulation and toxicity (PBT). This includes generation of new information if needed.

In addition, when the substance is classified as dangerous or assessed to have PBT or vPvB[3] properties:

- Assess the emission/exposure of man and environment resulting from manufacture and uses throughout the life cycle of the substance. This includes the generation of sufficiently detailed information on uses, use conditions and emissions/exposures of the substance.
- Characterise risks following such emission/exposure.
- And ultimately identify and document the conditions of manufacture and use which are needed for controlling the risks to human health and the environment. This includes operational conditions (OC) and risk management measures (RMM). In REACH this set of information is called ***exposure scenario (ES)***.

[2] Guidance on collection and evaluation of information related to use and exposure required according to Annex VI point 6 for substances between 1 and 10 t/y is not covered in this guidance. For information consult the [[Link=Guidance on registration#file=registration_en]].

[3] very persistent, very bioaccumulative

The goal of the assessment is not to establish whether or not there is a risk, but to identify and describe the conditions under which the risks are controlled. Risk are regarded controlled when the estimated exposure levels do not exceed the predicted no effect levels (DNEL or PNEC). For substances for which such no-effect levels cannot be determined, the risk characterisation consists of semi-quantitative or qualitative assessment of the likelihood that adverse effects are avoided. More specifically, for substances fulfilling the PBT and vPvB criteria, the risks can be concluded to be controlled when the emissions and exposures are minimised by the implementation of the ES. In addition, for physico-chemical hazards the likelihood and severity of an event occurring due to these properties has to be negligible. (Section 6 of Annex I). **In the rest of the guidance, these requirements will be referred to as 'control of risks' and 'controlled risks'**.

Control of risk includes operational conditions such as the duration and frequency of use, the amount or concentration of a substance in an activity, or the process temperature. It also includes the necessary risk management measures, such as: e.g. local exhaust ventilation, wearing certain types of gloves, application of general or particular waste water and exhaust gas treatment.

The CSA requirements as laid down in Annex I of REACH provides a high degree of flexibility on how to derive results, depending on the available information on substance properties, the outcome of the hazard assessment, the classification and labelling and the exposure estimation. The manufacturer or importer (M/I) should determine the most effective and efficient way to control risks and to document this.

The CSA is meant to deliver the following outputs:

- Assessment of any hazards the substance may present. This includes i) evaluation and integration of available information ii) the classification and labelling of the substance and a conclusion on whether the substance is regarded as PBT/vPvB, and iii) the derivation of the hazard threshold levels for human health and the environment.
- Where the assessment shows that the substance meets the classification criteria or the PBT or vPvB criteria, it is required to identify the conditions under which the risks arising from manufacture and use(s) of a substance can be controlled; i.e. exposure scenarios (ES).
- The entity carrying out the assessment documents the relevant data, judgements, justifications and conclusions in a chemicals safety report (CSR) for its own records. It however also includes the CSR in the registration dossier (or authorisation application) for the substance to be sent to the Agency

- When ES are developed, the company carrying out the assessment shall implement the conditions of use controlling risks at its own installations. It shall also inform its direct customers and the actors further down the supply on the conditions of use (i.e., the operational conditions and risk management measures) ensuring control of risk. For this purpose the relevant information from the CSR is compiled into one or more exposure scenarios (ES) to be annexed to the extended safety data sheet (eSDS).

Figure A. 1-1 provides an overview on the different elements of the chemicals safety assessment.

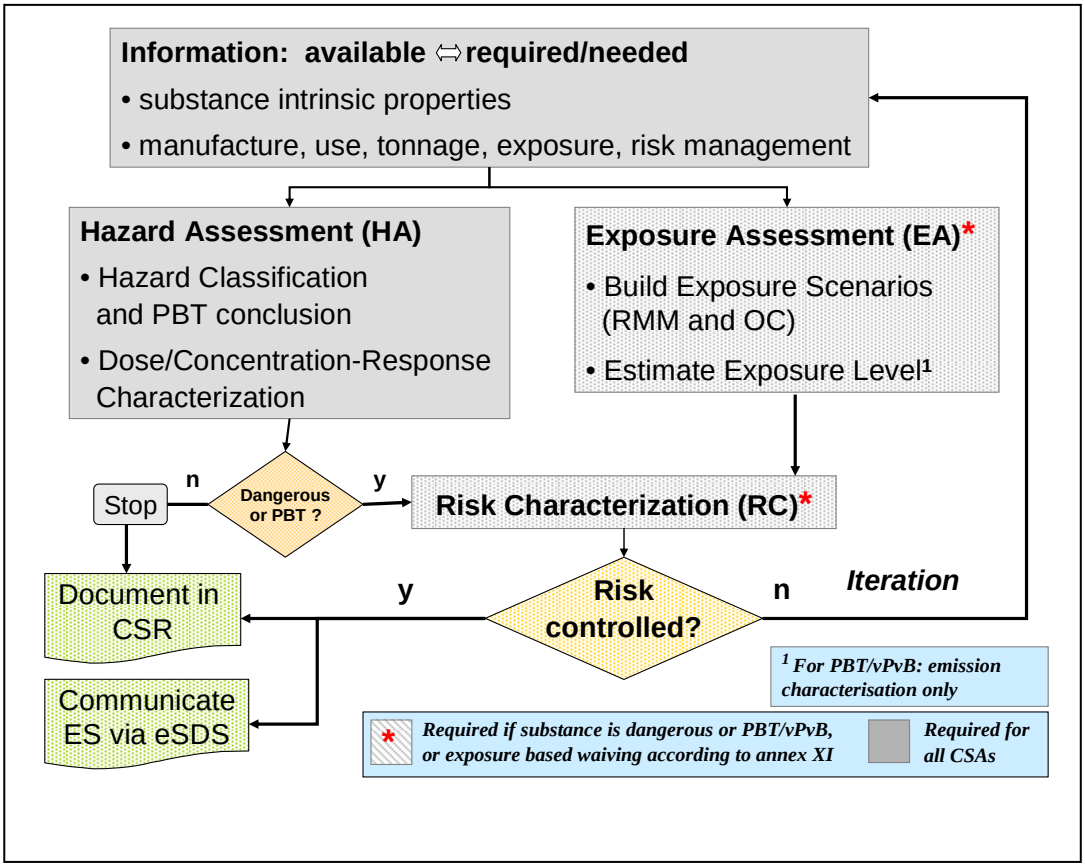


Figure A. 1-1: Overview of the CSA process

A.1.2.2 Compiling and assessing available information

The first step in the CSA process is to compile and evaluate all available relevant information. This includes the intrinsic properties of the substance, manufacture and use, the subsequent life-cycle stages, and the related emissions and exposures.

This compilation will form the foundation for all further CSA activities, e.g. targeting the hazard assessment, and can be a basis for the exposure assessment where required.

The information generation process for intrinsic properties under REACH is based on a 4-step procedure:

- Step 1: Collect **available information** on intrinsic properties on a substance and share this information (to the extent possible) with other companies (Guidance on data sharing).

- Step 2: Compare standard **information requirements on intrinsic properties** as laid down in annex VII to X with the principal options in annex XI to deviate from the standard requirements, and based on this determine the **information need**. Note that this may be an iterative process, taking into account information on manufacture, use and exposure. In some cases, an exposure assessment may be required to justify that certain standard information is not needed (exposure based waiving). Likewise use and exposure information may trigger generation of further information (exposure triggered testing).
- Step 3: Identify information gaps by comparing the **available** information with the information **needed**.
- Step 4: Generate new data and/or propose testing strategy

In this respect, the CSA is not only a method to develop exposure scenarios and to demonstrate control of risk but also to support the evaluation process from available information on substance properties (step 1) to establishing the need to generate new data (step 4).

A.1.2.3 Hazard Assessment

Hazard assessment makes use of the information generated in the 4 steps described above. During hazard assessment it may turn out that further information on the intrinsic properties of the substance is needed (iteration process). The hazard assessment includes the following evaluation tasks:

- carry out the classification of the substance (related to its inherent hazards) based on the rules of Directive 67/548[4].
- further evaluate the physicochemical hazards of the substance.
- evaluate in which environmental compartment the substance will predominantly end up (e.g. depending on degradability and distribution behaviour between air, water, sediments and biota).
- evaluate how mobile the substance is (e.g. volatility, water solubility, dustiness) and, depending on the uses, which routes of exposure, which need to be taken into account.
- derive no-effect levels for human health (DNEL) and the environment (PNEC) from available testing results and other appropriate information on the various endpoints; take into account the foreseeable routes of exposure and populations. When no DNEL can be derived a qualitative or semi-quantitative characterisation of the potency/hazards should be made.
- determine whether the substance should be regarded as a (very) persistent, (very) bioaccumulative and toxic substance. If this is the case, conduct an emission characterisation (including quantification of emissions and identification of likely routes of exposure).

[4] Currently in the EU, dangerous substances and preparations must be classified and labelled according to Directives 67/548/EEC and 1999/45/EC respectively. It should be noted that these Directives will be repealed and replaced with the EU Regulation on classification, labelling and packaging of substances and mixtures, implementing the Globally Harmonised system (GHS) in the EU. Guidance to this Regulation is under development in the REACH implementation project 3.6. ([[Link=Guidance on Classification, Labelling and Packaging#file=ghs_en]])

If the substance is not to be classified dangerous or is not considered to be a PBT/vPvB substance based on all information that is available and all information needed to characterise the intrinsic properties, the CSA can stop here (see Figure A. 1-1). The results are to be documented in chapters 1 to 8 of the CSR.

A.1.2.4 Exposure assessment and risk characterisation

The exposure assessment shall cover any exposure that may relate to hazards identified in the hazard assessment.

If the substance is to be classified dangerous (or PBT or vPvB) for any endpoint, an exposure assessment and risk characterisation has to be carried out (step 5 and 6 according to REACH Annex 1). This comprises an assessment of the expected exposures under the actual or anticipated conditions of use. These exposure levels are used to characterise the risks by comparing them with the outcome of the hazard assessment.

As noted above this description of use conditions controlling the risks is the core part of an e***xposure scenario (ES)*****.** An ES includes operational conditions (OC) and the necessary risk management measures (RMM). If a manufacturer or importer fails to describe relevant and realistic measures that control risks for a substance in a certain use he can not cover this use in his exposure scenario, or he has to explicitly advise against that use in the safety data sheet. Exposure scenario building is likely to include dialogues i) between substance manufacturers and downstream users and ii) from downstream user to downstream users further down the chemical supply chain (see Figure A.3-1 and

Figure A.3-2).

The first step in an exposure assessment will often be to describe one or more *initial* exposure scenarios addressing how the substance is currently used throughout the supply chain.

The second step in the exposure assessment is the **exposure estimate** for the different routes of exposure under the conditions of use described in this initial ES. This includes for example the estimation of concentration of the substance in indoor air at workplace or at home, the amount of substance getting into contact with skin when using an article or the concentrations of a substance to be expected in the sediments of a water course. The exposure estimation may be derived from models or from measured data. In both cases, it is key that the predicted exposure corresponds to the operational conditions and risk management measures defined in the (initial) exposure scenario.

The exposure assessment needs to cover manufacture and all identified uses of the substance and to consider all life-cycle stages resulting from the manufacture and identified uses. It needs to cover all relevant human and environmental exposure routes and populations.

For substances for which it is possible to derive no-effect-levels (DNEL or PNEC) the **risk characterisation** has to conclude that the estimated exposure levels do not exceed these no-effect-levels. However, there are also cases where the risk characterisation needs to be based on other approaches:

- For those human health effects and environmental spheres for which it is not possible to determine a DNEL or PNEC, the risk characterisation consists of semi-quantitative or qualitative assessment of the likelihood that adverse effects are avoided.
- For substances fulfilling the PBT and vPvB criteria (see Annex XIII of REACH) the risks can be concluded to be controlled when the emissions and exposures are minimised by the implementation of the ES.
- In addition, the assessment of physico-chemical hazards has to conclude that the likelihood and severity of an event occurring due to these properties is negligible.

In the following parts of the guidance, these requirements will be referred as ‘control of risks’ and ‘controlled risks’.

The CSA can be terminated and documented in the CSR and the relevant ESs can be communicated down the supply chain when

- the CSA demonstrates control of risks for all exposure scenarios
- and when all **information needed** on intrinsic properties has been generated, or relevant testing proposals have been described

Otherwise, further iterations are needed for refining the CSA.

A.1.2.5 Decision making on refining the assessment (Iteration)

Issues related to fulfilling the requirements for intrinsic properties
Manufacturers and importers are obliged to systematically address in their registration dossier the standard information requirements as laid down in Annex VII to XI. This can be done by the results of existing studies, by a testing proposal or by appropriate waiving arguments (see iteration in the information part in Figure A. 1-1).

Issues related to demonstrating control of risks

When the risk characterisation (applicable to dangerous substances) shows that the risks are not controlled there are three principal options to iterate the assessment by including more or other information into his assessment (see iteration in Figure A. 1-1):

- refine the hazard assessment by obtaining more data, which may include the proposal for testing;
- refine the exposure assessment by ensuring that the exposure estimation is realistic and reflects the use conditions defined in the initial ES. Models or monitoring data can be used to this end; or
- refine the conditions of manufacture or use, e.g. by introducing more stringent RMM or changing the OC in the ES.

This iteration continues until control of risks can be demonstrated.

The standard information requirements on inherent properties under REACH are primarily determined by tonnage triggers. Many of the standard requirements may be adapted, omitted (waived), or replaced, or new requirements can be triggered on the basis of hazard, exposure or risk considerations. In addition to that, adaptations of the standard testing regime may also be prompted due to difficulties in testing the substance or availability of alternative information.

Thus the M/I will have to make various decisions which information to use and/or to collect and/or to generate in order to demonstrate control of risk in the most cost-efficient way, including minimisation of vertebrate testing. In balancing which action to refine the assessment is the most cost-effective, the ratio between the cost of the action (testing, modelling, measurement, risk management, changing operational conditions) and the anticipated change in the result of the safety assessment should be considered. The uncertainties related to both the costs and the risk characterisation should be considered. Issues to be taken into account when identifying the most appropriate and cost-efficient approach can include:

- By **conducting additional testing**, eventually more relevant data on the hazards of the substance may become available. This may lead to a lowering of the assessment factors used for derivation of no-effect-levels (DNELs and/or PNECs) and these then become more precise. However, whether or not the additional test data will lead to a higher no-effect-level depends on the toxicity found by conducting additional tests. Thus, the costs of more testing (in terms of animal lives and money) could be weighed against the likelihood that a higher no-effect-level will be achieved.

- If the exposure has been estimated by simple and conservative modelling, the use of a higher tier model may lead to a **more precise estimate of the exposure level.** This may require collection of additional data e.g. on the frequency of use of the substance in a given process. Another option could be to make use of data on measured emission or exposure levels. A refined exposure estimate based on a higher tier model or measured data may result in a lower exposure estimate, thus demonstrating a lower risk. As above, the costs of refining the exposure estimate can be taken into account when deciding on the iteration strategy.

- **Narrowing down the range of uses or introducing additional measures to control the risk** may be an efficient way to reduce emissions and the resulting exposures. Such risk management measures or operational conditions should be proportionate to the risks and feasible in practice, at the registrants own site or by downstream users. Introduction of additional or different RMMs

and/or changing the OCs may be expensive and the impact on the risks should be evaluated carefully before a decision is taken.

When considering the different options to demonstrate fulfilment of standard information requirements and/or control of risk one should distinguish between measures improving understanding about the risks (hazard of a substance and exposure) and those measures actually reducing the risk. Also, manufacturers and importers should consider that investing in increased knowledge on substance properties at M/I level would enable targeted and more cost-efficient risk management measures further downstream. This may help to avoid recommending unrealistically expensive RMM towards the downstream users.

A.1.3 For whom the guidance is needed

For substances manufactured or imported at 10 tonnes per year (t/y) or more, a registrant needs to submit a CSR as part of his registration dossier. General guidance is already given in the Guidance on registration. The current guidance package is meant to outline how to prepare the CSA and document it in the CSR and when needed the safety data sheet (SDS). However, also registrants who are not required to carry out a CSA may benefit from the information provided in Chapters R.2 to R.7.

The guidance is intended also for actors who are required to prepare a CSR under certain circumstances:

- Downstream users (DUs) who need or want to make their own chemical safety assessment / report
- Producers or importers of articles containing substances that are intended to be released from the article, if the substance is not already registered for that use. CSR is required if the substance is present in those articles in volumes above 10 t/y
- Manufactures/importers (M/I) and/or DUs preparing a CSA/CSR as a part of an authorisation application.

This guidance is also intended for use by the European Chemical Agency (ECHA) and EU member state authorities as a reference for their activities relating to the assessment and control of risks under the evaluation, authorisation and restriction procedures. Note that authorities may have different objectives for their assessment activities as compared to individual registrants, e.g. the assessment of cumulative exposure resulting from the overall market volume and pattern of use of a substance.

A.1.4 How to find your way in the Guidance Document

The guidance consists of two major parts: Concise guidance (Parts A – G) and supporting reference guidance (Chapters R.2 to R.19).

Part B contains concise guidance on the hazard assessment. This covers the information requirements on intrinsic properties of a substance under REACH, including information gathering, non-testing approaches and the so-called 'integrated testing strategies' for generating the relevant and required information on each endpoint. Part B also provides concise guidance on how to characterise hazards, including where possible derivation of DNELs and PNECs. Each of the sections in Part B corresponds to the more in-depth guidance contained in Chapters R.2 to R.10. This includes

- DNEL derivation (or other qualitative or semi-quantitative measure of potency of the substance) in Chapter R.8 and the corresponding chapters of integrated testing strategies for the relevant human health endpoints (Sections R 7.2 to R.7.7). These Sections in Chapter R.7 also include information on how to derive appropriate information for classification and labelling of the substance. However, the guidance on classification and labelling itself is provided elsewhere. See current Annex VI to Directive 67/548[5].
- PNEC derivation in Chapter R.10 and the corresponding chapters of integrated testing strategies for the environment endpoints (Sections R.7.8 to R.7.10.).These sections in Chapter R.7 also include information on how to derive appropriate information for classification and labelling of the substance. However, the rules on classification and labelling themselves are provided elsewhere. See current Annex VI to Directive 67/548.[6] Section 7.13 in Chapter 7c includes guidance on the particular assessment approaches to metals and hydrocarbons.
- Information requirements on intrinsic properties (Chapter R.2), guidance on collection of available information (Chapter R.3), evaluation of information (Chapter R.4), guidance on exposure based waiving and exposure triggered testing as well as other adaptations of information requirements (Chapter R.5), in depth guidance on non-testing approaches, in particular QSAR and grouping of substances (Chapter R.6).

Part C contains the concise guidance on how to assess whether or not a substance is a persistent, bioaccumulative and toxic substance (PBT) or very persistent and very bioaccumulative substance (vPvB). In-depth guidance on the PBT and vPvB assessment is covered in Chapter R.11.

[5] It should be noted that this Directives will be repealed and replaced with the EU Regulation on classification, labelling and packaging of substances and mixtures, implementing the Globally Harmonised system (GHS) in the EU. Guidance to this Regulation is under development in the REACH implementation project 3.6. ([[Link=Guidance on Classification, Labelling and Packaging#file=ghs_en]])

[6] see fn above.

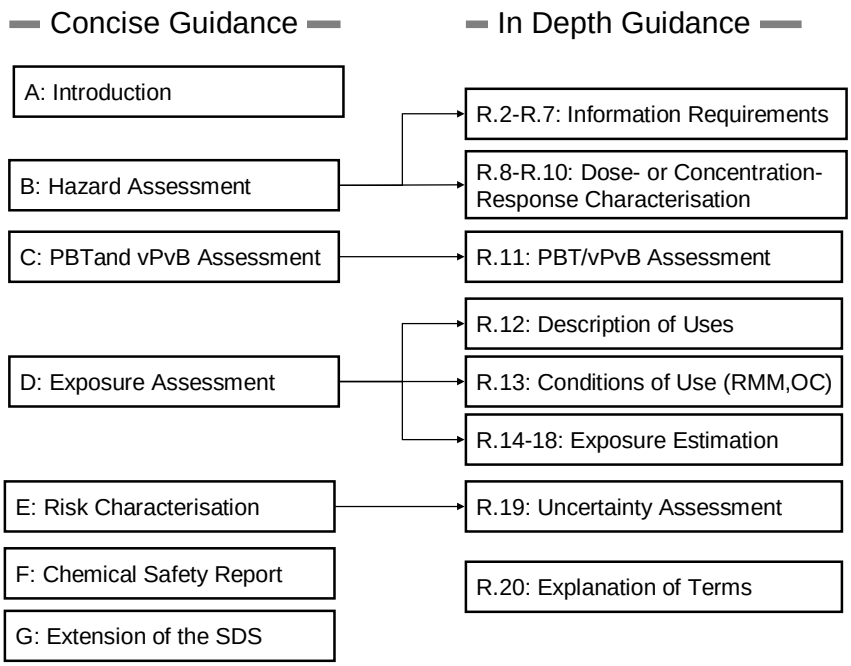


Figure A.1-2: Structure of the guidance document

Part D details how to develop exposure scenarios and related exposure estimation. This part contains detailed workflows on how to identify uses in the supply chain, how to develop exposure scenarios and finalise them based on the iterations necessary for controlling risks. Part D provides links to more in-depth guidance on exposure assessment, in particular how to describe uses, how to collect information on operational conditions and risk management measures, and how to carry out exposure estimates. This includes:

- Brief general description of identified uses and giving exposure scenarios a short title (Chapter R.12)
- Risk management measures and operational conditions for building of exposure scenarios (Chapter R.13).
- Occupational exposure estimation (Chapter R.14)
- Exposure estimation related to consumers (Chapter R.15)
- Exposure estimation related to the environment (Chapter R.16)
- Chapter R.17 and Chapter R.18 provide guidance on exposure estimates related to life cycle stages subsequent to identified uses (releases from articles and releases from waste life stage).

Chapter R.20 contains a table of those terms that are essential for the understanding of the CSA guidance and which are no defined in the legislation itself.

Part E contains the guidance on the risk characterisation. In the risk characterisation, information on hazard and exposure is combined in the risk characterisation ratio or in qualitative risk characterisation. Both types of information contain uncertainty which needs to be assessed in order to decide on the robustness of the risk estimate. The uncertainty analysis is further detailed in Chapter R.19. Part E contains also guidance on qualitative risk characterisation with regard to non threshold substances.

Part F details the format and requirements for preparing the chemical safety report, which documents the results of the entire chemical safety assessment. Part F details subsections to the main headlines as laid down in section 7 of Annex 1 of REACH and provides guidance on how to present the outcome of the CSA. It also explains how to use the CSR template.

Part G contains the guidance on preparing the extensions to the safety data sheet (SDS). This contains information on how the exposure scenario is communicated and implemented in the supply chain. In an appendix to part G it is exemplified how DUs may scale exposure scenarios according to their conditions of use. Part G also includes an appendix briefly characterising a number of approaches how to process at formulators level the information received with the extended safety data sheets into useful guidance for the users of the preparations.

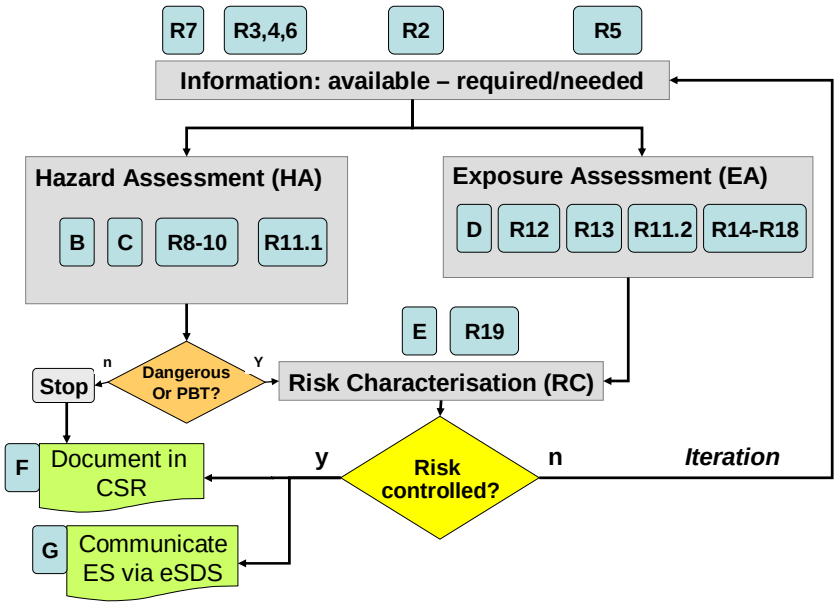


Figure A.1-3: Guidance related to the different elements of the CSA process

A.2 KEY CONCEPTS FOR THE CSA

This section further details the basic elements of the CSA as already briefly introduced in Chapter A.1.

A.2.1 Duty to prepare the CSA

A chemical safety assessment is required when a substance is manufactured or imported at 10 tonnes or more per year. The assessment shall be documented in a CSR to be submitted as part of a registration dossier, in accordance with Articles 10 and 14 of REACH. Annex I of REACH sets out the general provision for assessing the substances and preparing CSRs. One of the primary aims of carrying out a CSA is to define the conditions of use (operational conditions and risk management) under which the risks can be controlled (See Section A.2.5).

The basis for the CSA is the information on the quantity that the individual registrant has manufactured himself or imported and how this amount is used on its own, in preparations or in articles by the registrant, by downstream users and by consumer and to which extent it appears in resulting life cycle stages, including waste. For substances with a widespread or dispersive use, it can be useful on a voluntary basis to consider exposure resulting from emissions of the same substance manufactured or imported by other registrants (i.e., the overall estimated market volume). This may be particularly advisable if the demonstrated margin for the registrants own marketed volume between exposure and derived no effect levels (PNEC or DNEL) is not significant and where a potential risk of the total exposures cannot be ruled out. Such considerations may take place if registrants decide to jointly register their CSA (Article 11(1)).

On a voluntary basis, the participants in the SIEF (Substance Information Exchange Forum, see Guidance on data sharing) could decide (e.g. for reasons of confidentiality) to ask a third party to evaluate their joint volume for risks to human health or environment of substances with a widespread or dispersive use. Respective provisions could prevent community action if risks are expected due to the overall market volume.

A.2.2 Overall CSA process

The CSA normally proceeds in the following sequence (Figure A.2-1):

1. Collection and generation of available and required information on intrinsic properties
2. Human health hazard assessment; including classification and derivation of derived no effect levels (DNELs) (or where that is not possible other indications of the potency of the substance - see Chapter B.7.1 and Chapter R.8).
3. Physicochemical hazard assessment; including classification (see Chapter R.9)
4. Environmental hazard assessment; including classification and derivation of predicted no effect concentrations (PNECs) – see Chapter B.7.2 and Chapter R10.
5. PBT and vPvB assessment (see Part C and Chapter 11)

If, as a result of the hazard assessment, it is found that a substance meets the criteria for classification as dangerous according to the criteria of Directive 67/548/EEC or 1999/45/EC, or is a

PBT or vPvB substance, then exposure assessment and subsequent risk characterisation is required[7]:

6. Exposure assessment (covering development of exposure scenarios and exposure estimation)
7. Risk characterization

CSA iterations might be needed to be able to document that risks are controlled:

8. Potential CSA iterations.

[7] Endpoints constituting a hazard must be included. The Commission states that this does not mean that exposure must be assessed for all endpoints (e.g. exposure assessment may focus on the risk driving endpoints), neither does it mean that exposure should only be assessed for hazards related to the classification or PBT/vPvB properties triggering the exposure assessment in the first place, as the absence of classification for a particular endpoint does not mean that there is no hazard. Finally, it is noted that further details on what exactly a hazard means is a matter of technical assessment. The Commission is working on a proposal for practical implementation of this issue.

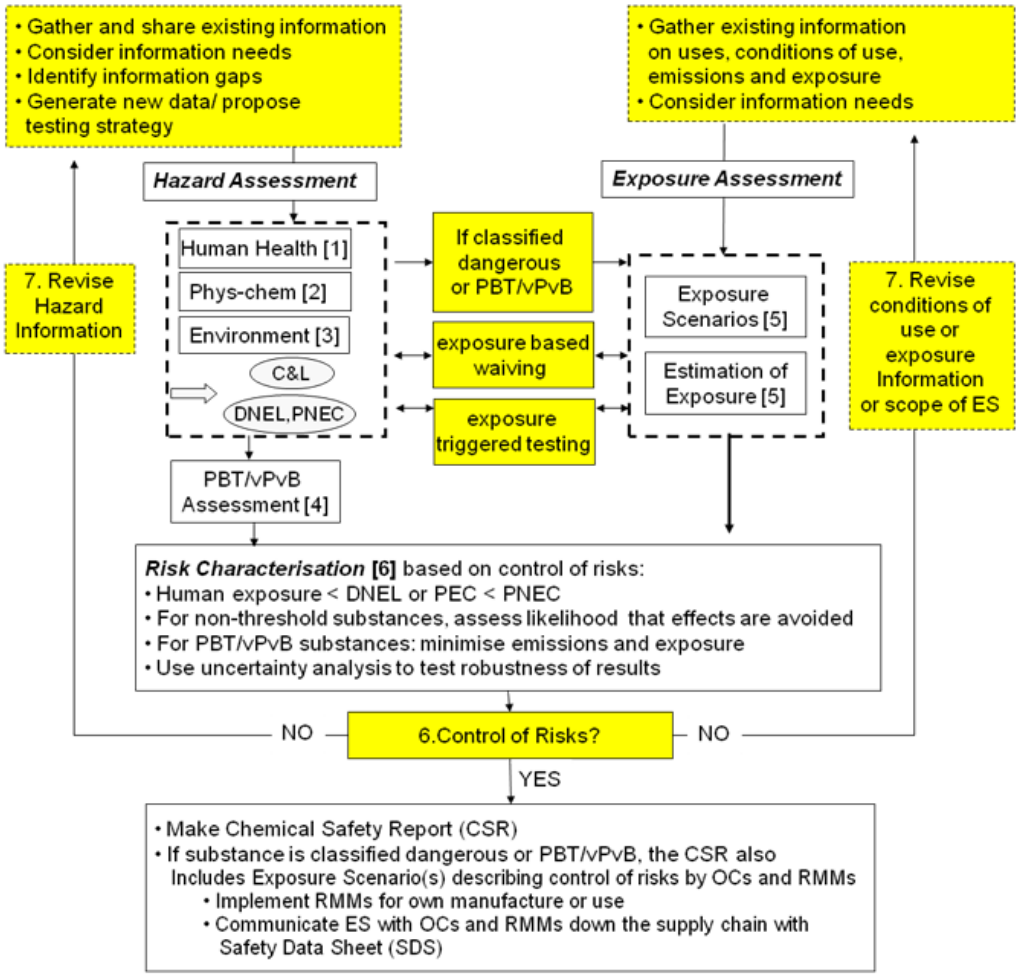


Figure A.2-1: Overview of the steps in the chemical safety assessment.

OC = operational conditions, ES = exposure scenario, RMM = risk management measures DNEL = derived no-effect level, PNEC = predicted no-effect concentrations, PEC = predicted environmental concentrations.

A CSA is flexible, depending on the available information on substance properties, the outcome of the hazard assessment, the classification and labelling and the exposure estimation. The M/I or DU should determine the most effective and efficient way to fulfil the information requirements on intrinsic properties and to control risks, and to document this.

The CSA starts with the collection of all available physicochemical, environmental fate, toxicological and ecotoxicological information that is relevant and available to him regardless of whether information on a given endpoint is required or not at the specific tonnage level. The registrant should also collect information on exposure, use and risk management measures.

This may, for example, include information on manufacture (if within EU), use, handling and disposal of the substance or of articles containing the substance (i.e. covering its whole life cycle), as well as the nature of the exposures, i.e. routes, frequency and duration. Considering the readily available information that is collected, the registrant will be able to determine the initial need to generate further information. Depending on the iterations of the CSA, additional information may need to be collected or generated.

Steps 1-4 of the CSA shall be conducted for all substances manufactured or imported in a quantity of ≥ 10 t/y. The standard information requirements on inherent properties under REACH are primarily determined by tonnage triggers. For those human effects and environmental spheres for which it is not possible to determine a DNEL or a PNEC, the CSA has to assess the likelihood that effects are avoided.

If a substance is assessed to be a PBT or vPvB, all emissions throughout the lifecycle of the substance resulting from manufacture and identified uses need to be characterised and risk management measures and operational conditions should be recommended that minimise emissions and subsequent exposure of humans and the environment.

In REACH Annexes VII to X specific rules are given for adaptation of information requirements, according to which the required standard information requirements for individual endpoints may be modified. The required standard information set may also be adapted according to Annex XI of REACH e.g. in cases where testing is not technically possible, or testing does not appear scientifically necessary, or based on exposure considerations. Based on adequate information on exposure, a decision can be taken whether it is possible to waive tests (exposure based waiving), or if this triggers the need for additional information including exposure based testing.

If, as a result of the hazard assessment and PBT/vPvB assessment it is found that a substance meets the criteria for classification as dangerous (according to Directives 67/548/EEC and 1999/45/EC)[8] or is considered to be a PBT/vPvB, an exposure assessment is required. The exposure assessment consists of the development of exposure scenarios and the related exposure estimation (see Part D). If the substance is not classified as dangerous or is not a PBT/vPvB, an exposure assessment is not needed and the registrant can directly go to documentation of the hazard assessment and PBT/vPvB assessment in the chemical safety report. An exposure assessment may also be required for some types of exposure based waiving even if the substance has not been classified dangerous or PBT/vPvB (See Part B and Chapter R.5).

The exposure assessment shall cover manufacture and all identified uses of the substance and the life cycle stages resulting from these identified uses. This includes, where relevant, service-life of articles and the waste life stages of the substance on its own, in preparations or in articles.

The instrument to communicate the practical conditions ensuring control of risks throughout the supply chain is the exposure scenario (see part D). Exposure scenarios are developed in an iterative approach, as part of the exposure assessment.

[8] See previous footnotes related to the future GHS system.

A subsequent step of risk characterisation (part E) is needed to progress from the initial exposure scenario (and the related exposure estimate) to the final exposure scenario (and the related exposure estimate). The final exposure scenario is based on control of risks.

The exposure scenario documents the relevant operational conditions and risk management measures that lead to control of risks for all hazards identified. The relevant information is to be communicated to the downstream users. This is i) to provide practical advice on suitable measures to control risks and ii) to enable the DUs to check whether they in practice comply with the conditions defined in the CSA.

In the risk characterisation (see part E) appropriate no-effect levels for hazards to human health and the environment are compared to the exposure estimates for all relevant combinations of human and environmental exposure estimates, and physico-chemical hazards are evaluated. If no-effect levels can not be established, an assessment of the likelihood that effects are avoided when implementing the exposure scenarios shall be carried out. In addition the risk characterisation needs to consider risks from combined exposure via different routes of exposure or via different sources. If control of risks is not demonstrated, further iterations of the CSA are needed (step 7).

Different options are available to iterate (see also Sections A.2.6 and A.2.7).

- Hazard information can be revised or generated taking the legal obligations on information requirements into account.
- Exposure information can be collected from the supply chain or it can be decided to generate new exposure data on a voluntary basis (e.g., measurements at sites or in the environment) or higher tier models can be applied.
- Or both types of information may be revised.

Once control of risks is demonstrated, the final exposure scenarios including the recommended operational conditions (OCs) and risk management measures (RMMs) for the manufacture and identified uses are to be documented in the CSR (see part F) and communicated to downstream users of the substance in an annex to the SDS (see Part G).

The following sections provide further details on key concepts for the chemical safety assessment.

A.2.3 Hazard Assessment

The chemical safety assessment starts with a hazard assessment. The information collected or generated in the CSA will be used for classification and labelling, PBT/vPvB assessment (see Part C) and for deriving threshold or non-threshold levels for human health and the environment.

In general, information gathering consists of the following steps (REACH Annex VI, Chapter R.2):

- Gather and share existing information;
- Consider information requirements and further information needs (Annexes VI to XI of REACH);
- Identify information gaps;
- Generate new data / propose testing strategy

Different types of information may need to be collected or generated for conducting a CSA. Such information may be obtained from a variety of sources such as in-house data of companies, or by sharing information with other manufacturers and importers of the substance by cooperation in a substance information exchange forum (SIEF) (REACH Article 29).

The hazard assessment shall be conducted based on all available information, and on the basis of the information required in accordance with Annexes VI-XI of REACH (based on tonnage and possible adaptations, see Part B).

Alternative information may be available or generated that can be used instead of in-vivo (animal) test data. Such information includes results of in-vitro tests and information obtained by use of non-testing methods (incl. Quantitative Structure Activity Relationships (QSAR), Structure Activity Relationships (SAR), read-across, categorisation of substances, etc.). Separate guidance is available on integrated test strategies (ITS) in Part B and Chapter R.7.

In some cases, minimal or negligible exposure and risk can be expected for certain populations or environmental compartments. When such low-risk exposure situations exist, waiving of hazard data may be possible. Specific guidance on this issue is available in Chapter R.5. Additional information may be needed as a result of the outcome of the exposure estimation and risk characterisation, so called exposure-triggered testing. If risks to man or the environment are indicated in the CSA, additional data may need to be collected or generated in order to refine the hazard information. At any particular stage, proposals for further testing may be developed so that the necessary information is obtained. Before proposing additional animal testing, use of alternative methods and all other options must be considered.

Dangerous substances and preparations must be classified and labelled according to Directives 67/548/EEC and 1999/45/EC respectively. It should be noted that these Directives will be replaced in the near future with an EU Regulation for Classification, Labelling and Packaging of Substances and Mixtures (CLP) implementing the Globally Harmonized System in the EU.

Human health hazard assessment

Based on the available information, a derived no effect-level (DNEL) has, where possible, to be established. The DNEL is normally expressed as an external exposure level below which an adverse effect on human health is not expected. For derivation of the DNEL the leading health effect for a given exposure pattern (exposure route, population and duration) needs to be selected. The N(L)OAEL (or equivalent dose descriptor) for this health effect needs to be combined with assessment factors for the derivation of the DNEL.

Since DNELs are population, route and frequency dependent, there might be a need for the derivation of more than one DNEL (see Chapter R.8).

For some effects DNELs cannot be derived, either because these are non-threshold effects (e.g. genotoxic carcinogens) or because the available data for some threshold effects do not normally allow setting a DNEL (e.g., sensitizers, corrosive substances or skin/eye irritants). REACH then requires a qualitative assessment. For non-threshold mutagens and non-threshold carcinogens,, an additional (semi)quantitative reference value (DMEL, derived minimal effect level) should be developed, if data allows (See Section B.7.1). The derivation and use of dose-response relationships or other measures of the potency of a substance are discussed in detail in Chapter R.8.

During the hazard assessment, the registrant has the choice to conduct a qualitative or quantitative exposure assessment and risk characterisation, in order to waive specific information requirements (not only for human health). This may require that additional exposure data is gathered at an early stage in the CSA, before it is decided if the substance is finally classified as dangerous or is found to be a PBT or vPvB. This is the trade-off between doing the testing or obtaining better information on exposure to provide a qualitative or quantitative justification for exposure based waiving. Specific guidance on this issue can be found in Chapter R.5.

Human health hazard assessment due to physicochemical properties.

The chemical safety assessment shall also include the human health hazard assessment of physicochemical properties. The potential effects to human health shall be assessed for at least the following physicochemical properties: explosivity, flammability, and oxidizing potential. (see Part B and Chapter R.7 and R.9).

Environmental hazard assessment

Based on the available information, the environmental hazard assessment focuses on hazards for ecosystems in any environmental sphere (water, air, sediment or soil). In addition, hazards for predators in the food chain (secondary poisoning) are considered. Hazards to the microbiological activity of sewage treatment systems are evaluated because proper functioning of sewage treatment plants (STPs) is important for the protection of the aquatic environment. If other hazards are identified such as tainting or ozone depletion/creation potential the hazards should be assessed (see REACH Annex 1 point 0.10)

The PNEC for a specific environmental compartment is regarded as a concentration below which adverse effects on ecosystems will not occur and is derived on the basis of the available information on toxicity to species from relevant environments. The PNEC is derived from toxicity test endpoints (LC50s or NOECs) using appropriate assessment factors (cf. Chapters B.7.2 and R.10).

PBT assessment

The PBT assessment is meant to identify substances that are persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB). These substances are required to undergo further evaluation as the potential for long-term effects, is difficult to predict and the effects such as (bio)accumulation in the environment would be practically difficult to reverse.

For PBT/vPvB substances, all emission sources need to be identified in order to determine effective measures to minimise emissions. Potential PBT or vPvB substances are identified at a screening level and a testing strategy is followed to verify this screening assignment by the inclusion of more data. The PBT assessment is introduced in Part C and further detailed in Chapter R.11.

A.2.4 Concepts related to the development of exposure scenarios

This section details several concepts to facilitate the use of new REACH terms and concepts for the development of exposure scenarios.

A.2.4.1 Identification of uses and description of use conditions

A.2.4.1.1 Identified Use

Under REACH the "use" of a substance *means any processing, formulation, consumption, storage, keeping, treatment, filling into containers, transfer from one container to another, mixing, production of an article or any other utilisation* (REACH article 3(24)). Thus, use has a very broad meaning. However, there are two more specific terms which are key for the registration and the communication in the supply chain:

- *Registrant's own use: means an industrial or professional use by the registrant (REACH article 3(25));*

- *Identified use: means a use of a substance on its own or in a preparation, or a use of a preparation, that is intended by an actor in the supply chain, including his own use, or that is made known to him in writing by an immediate downstream user (REACH article 3(26));*

According to this definition, there are three ways that a use can become an identified use. An actor in the supply chain:

- intends to use (or actually uses) a substance on its own or in a preparation in his own processes or in products manufactured by him or
- places it on market for certain use(s) (directly or via distributors) or
- is informed by one of his immediate downstream users on an existing or intended use.

Making a use known to a supplier does not automatically mean that the supplier has to carry out a CSA for that use and/or that the supplier includes the use into his registration. The supplier may decide:

- That his existing exposure scenarios are already sufficiently covering the newly identified use and supplies the DU with the existing ES. Inclusion of the new use into section 2 of the existing CSR (see Part F) by the M/I can be useful for future registration updates.
- To carry out a CSA and develop a new or modified exposure scenario, covering the newly identified use, and to update the registration file accordingly if the registration has already taken place.
- To not support a use. If this decision is based on a CSA and he is unable to demonstrate control of risks for man or environment using available information this needs documentation and must also include a response to the customer and the Agency in writing. Uses advised against have to be documented under heading 3.7 of the technical dossier and under heading 16 of the SDS.
- To communicate the use further up the supply chain (if the supplier is not the M/I).

A.2.4.1.2 Brief general description of use and short titles of exposure scenarios

Any registrant under REACH is obliged to provide a brief general description of the identified uses in his registration dossier (REACH Annex VI Section 3.5). He furthermore has to update his registration dossier in case of a new identified use or new uses advised against, where the conditions of use are not covered by an ES in the registration. This may imply adaptation of existing ESs or addition of new ESs to the dossier.

When a downstream user makes a use known to a supplier in writing with the aim of making it an identified use, he should at least provide a brief general description of such use to start the dialogue on appropriate conditions of use to control the risks.

If the registrant has to carry out a CSA including development of exposure scenarios, the final exposure scenarios shall be presented under the relevant heading in the CSR, and included into an annex to the safety data sheet. The registrant shall give the exposure scenario an appropriate short title giving a brief general description of the use(s) covered by the ES, consistent with those given in the registration dossier.

It is important to distinguish between the title of an ES and its content:

- Use descriptors / ‘Short Titles’: These briefly describe a use in general terms in the context of i) Annex VI in the registration dossier, ii) use-identification from DU to supplier and iii) in giving an exposure scenario a name. This brief, general description should be based on the use descriptor system as described in Section D.4.3 and Chapter R.12. The short titles will also help

to use the same generic type of exposure scenario for different substances with a similar hazard profile.

- Conditions of use in an ES (not part of the short title): The conditions of use (i.e. the operational conditions and risk management measures) shall be described at a level of detail appropriate: i) to carry out the safety assessment, ii) to ensure control of risks when implemented, and iii) to be communicated in the supply chain in a way that they can be implemented by the (downstream) user.

Consequently the *short titles* are aimed to facilitate communication, transparency, traceability of substances in the market, application of exposure scenarios for various uses and processing in the REACH IT system. Compared to that, the conditions of use in the ES have direct consequences regarding REACH obligations for the actors in the chain.

Also note that there is not necessarily a 'one-to-one' link between ES titles and the conditions of use. There may be several ES for the same 'brief general description of use' as it, for example, may be possible to control the risks from a process by implementation of different risk management measures.

Moreover, different substances may have the same type of use that can be covered by the same ‘brief description of use’, but may require different risk management measures due to different hazardous properties. Likewise, a generic exposure scenario may cover several uses/processes and several brief descriptions of uses may therefore be used to name the same ES. In such a case it can also be considered to have more generic titles for the ES to cover several brief descriptions of identified uses.

A.2.4.1.3 Descriptors for Uses

The legal text of REACH does not define in which form the brief general description of use has to be given. However, communication in the supply chain and effective implementation of the exposure scenario concept depend on harmonised language across the European market. Consequently, a standardised descriptor system for uses has been developed. The system has been incorporated in the REACH registration software (IUCLID 5) for registration purposes and is foreseen to be the backbone for assigning short titles to ES in the IT support tools under development.

It consists of four descriptors, each one allowing to select the appropriate level of detail to briefly characterise the use:

- Sector of use. This is used to describe in which sector of trade and industry a substance is used on its own or in preparations. This descriptor also covers the use in private households and the public domain.
- Chemical product category. This describes the type of preparation (mixtures) in which the substance is used.
- Process category. This describes the type of technical process categories or operation units in which the substance on its own or in preparations is used. They have an impact on the exposure to be expected and hence on the risk management measures needed.
- Article categories. This describes the type of article into which the substance is incorporated (if relevant).

The use descriptor system is further explained in Section D.4.3 and Chapter R.12.

A.2.4.2 Determinants of release and exposure and exposure assessment

Determinants of release and exposure represent the main information that needs to be collected for making an exposure scenario and for estimating the related exposures. Determinants of exposure can relate to (i) substance characteristics (ii) the operational conditions and risk management measures and (iii) the surroundings where the substance is used or into which the substance is emitted.

In principal, these so-called determinants of exposure may differ from use to use, however based on current experience it is possible to define a set of key determinants of exposure which are relevant in most cases (see list of key information/determinants in Table D.2-1). These include for example the volatility, water solubility and dustiness of the substance, the amounts used, the duration and frequency of use, the amount of energy applied while using the substance, and the different kinds of risk management measures.

Based on the list of key determinants, the registrant can target his information collection

i) to develop one or more initial exposure scenarios and
ii) to carry out first estimate of exposure by use of standard tools (see Part D).

A.2.4.3 Function and content of exposure scenarios

A.2.4.3.1 Function and content of the initial and final ES

The exposure scenario for an identified use (or a group of uses) describes the conditions under which a dangerous substance/PBT/vPvB (or a group of substances) can be used whilst controlling risks.

The ES is an instrument for communicating operational conditions and risk management measures that are suitable to ensure control of risks to the users throughout the supply chain. Different ESs will probably be needed to cover identified uses at different steps in a supply chain. At the same time, the ES describes the key determinants driving the pattern and level of emissions and exposure as a basis for exposure assessment and risk characterisation in the CSA. This includes the suitable measures to control exposure of the environmental compartments (air, water, sediment and soil) and exposure of certain target groups, like consumers and workers.

The ES must cover both:

- the operational conditions of use (exposure determinants such as amount used, application process, duration and frequency of use, conditions of the receiving environment),
- the risk management measures (emission or exposure determinants such as waste water treatment or local exhaust ventilation).

The initial exposure scenario describes the typical conditions of use as existing in the market of a substance, based on readily available standard information. If it can be demonstrated that these conditions of use control the risks, the initial exposure scenario will become the final exposure scenario. The Final ES will be:

- documented as a subchapter in Chapter 9 of the CSR format
- and communicated as an annex to the extended safety data sheets to the users.

If it turns out that control of risks cannot be demonstrated for current practice or based on available information, or that other than the standard determinants play a significant role, iterations of the CSA have to be made (see Section A.3.1 and Part D).

A.2.4.3.2 Use and exposure categories

The level of detail required in describing an exposure scenario will vary substantially from case to case, depending on the use of a substance, its hazardous properties and the amount of information that can be made available to the manufacturer or importer. Exposure scenarios may describe the appropriate risk management measures and operational conditions for several individual processes or uses of a substance. An exposure scenario may thereby cover a large range of processes or uses.

Under REACH such an exposure scenario can be called *use and exposure category* (UEC) (Definition in Article 3) or simply *broad exposure scenario*.

It is important to note that this categorisation-option in the legal text is based on activities with a substance (see use definition Article 3 (24)) or processes. Other criteria to build UEC such as exposure routes, exposure patterns (time) or sectors of use are not mentioned in REACH.

M/I would group those activities/processes under one UEC for which the risk can be controlled by *the same set of operational conditions and risk management measures*. How broad such a category is defined, and whether other categorisation-criteria are applied in addition, is the choice of the registrant. However, the UEC must still correspond to the structure and the content of the exposure assessment in the CSR. The possible broadness may be also limited in that respect that a too broad grouping may negatively impact on the usefulness of the UEC for the downstream user.

The use descriptor system suggested in Section D.4.3 and Chapter R.12 of the Guidance Document is built on categories of processes/activities (descriptor 3) and product categories (descriptor 2 and 4). It can be used to identify pre-populated initial exposure scenarios (including OC and RMM) and to link these with exposure estimation tools. It thus supports exposure related categorisation of processes/activities/products relevant in the market of a substance.

A.2.4.3.3 Generic exposure scenarios

The term *generic* exposure scenario is not defined in REACH. In the context of the current guidance, a generic ES means an exposure scenario covering the typical conditions of use for a certain type of chemical product in the corresponding sectors of industry.

A generic ES (GES) may be defined as a single ES that describes the relevant OC and RMMs for the typical use conditions relevant to operations of a DU sector, in particular SMEs. This means that the GESs supporting the substance are oriented towards the areas of application of the substance. Thus DUs only have to select the GES(s) relevant to the sector for which the GES is intended and for which the use is supported. To account for potentially different substances with differing hazard and physico-chemical characteristics being used for the same application, it is necessary to support each GES with a statement specifying the ‘boundaries of application’. This may provide additional help to DUs on the extent to which the advice can be reliably applied.

A.2.4.4 Exposure Scenarios for substances in preparations

Where a substance is being used in a preparation, an ES might need to be developed for this use of the substance. Depending on the situation, either the M/I or the DU can take the initiative to develop the initial ES that includes the identified use of the substance in a preparation. The risks associated with this use need to be covered in the exposure assessment, as part of the life-cycle of the substance that includes the downstream uses.

The formulators usually have the necessary knowledge on operational conditions and RMMs appropriate for formulating and using the preparation. Initial ESs could therefore also be made by the formulator.

It would facilitate the formulator's task of consolidating ES for single substances into an SDS for the preparation, if the registrants would tune the ES for the individual substances to the needs of the formulators (see Guidance for Downstream Users)[9]

In most cases, a preparation containing classified substances in a concentration greater than the concentration limits in REACH Article 14 will lead to the classification of the whole preparation as dangerous. This corresponds to the current requirements for classification and labelling under the EU Dangerous Preparations Directive (1999/45/EC).

The formulator has to provide appropriate information on safe use to his professional or industrial customers. In some cases, an ES for one of the substances in the preparation may cover the whole preparation. In such case, the relevant exposure scenario can simply be passed on if considered appropriate. In other cases, it could occur that the single exposure scenarios for the different dangerous components in the preparation sold to the customers may lead to conflicting advice related to safe use of the whole preparation. Then, the formulator may need to consolidate the different exposure scenarios into one ES or SDS for the preparation.

REACH does not require that the ESs for the individual substances in a preparation have to be merged when a formulator prepares a SDS. However, any DU shall identify and where suitable recommend appropriate measures to control risks identified in a SDS for the entire preparation. This implies that the different pieces of information are taken into account when developing a SDS for the preparation. The SDS for the preparation should offer consistent advice on operational conditions and risk management measures in the main body of a SDS and in ES(s) annexed to the SDS. The relevant methods can be looked up in the guidance on preparations in the Guidance for Downstream Users, section 14.

If a preparation supplied to the customer is not classified as dangerous but contains a dangerous substance (with ES(s) received by the formulator) in concentration exceeding any of the thresholds laid down in Article 31(3) of REACH, additional communication obligations may exist from the DU to the end-user, for instance communicating specific conditions of use (including use conditions or uses advised against), the identity and the hazard identification of the relevant component(s) of the preparation. However, it may be that it is not always relevant to attach a certain ES to a SDS for a non-dangerous preparation, for instance, if the ES for that substance defines that the substance can be used in the preparation below a defined concentration level without further RMMs or OCs, and the substance is present in the preparation below that concentration.

[9] Further guidance is expected as a result of ongoing work within industry which is going to be discussed at a workshop in May 2008 organised by ECB. Relevant outcomes may be integrated into the current guidance as an appendix to the guidance Part G.

A.2.4.5 Exposure scenarios for substances in articles

According to REACH Article 3(3), an article is an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition. Typical articles are textiles, paper sheets, plastic or glass bottles and tyres.

A substance incorporated into an article becomes part of that, e.g. dye stuffs in textile-articles, pigments in plastic articles or stabilisers in tyres.

The substance then enters into the service-life-stage of the article. A registrant of a dangerous substance has to cover all identified uses and resulting life cycle stages in his CSA/CSR. If the incorporation of the substance into an article is an identified use, he has to include the service-life stage and final waste stage into his CSA/CSR.

If a DU incorporates a dangerous substance (on its own or as part of a preparation) into an article, the SDS received from the supplier may or may not contain an exposure scenario covering the process of incorporating the substance into the article as well as the service life and waste life stage of the article. If his conditions of use are outside an ES received, the DU has the choice of informing his supplier of this use or carry out an own safety assessment for the substance in that use. Note that this type of DU is also an article producer and may have additional article producer obligations (see Section A.4.2).

As will be further explained in Section A.4.2, the article producer will under certain circumstances have to register substances intentionally released from articles and/or notify contained substances of very high concern. These activities may also require conducting a CSA/CSR and possibly preparation of exposure scenarios.

Guidance on how to build exposure scenarios for the service life stage and the waste life stage of articles can be looked up in Part D and R.13.

A.2.5 Identification and documentation of control of risks in the CSR

The iterative CSA process of hazard assessment, exposure assessment and risk characterization ends when the information requirements for intrinsic properties are fulfilled and risks are shown to be controlled for all exposures and all exposure scenarios. If additional testing is required for tests mentioned in Annexes IX or X before control of risks can be demonstrated, this should be identified and a justified request for testing should be submitted to the European Chemicals Agency (ECHA) as part of the registration dossier. While waiting for results of further testing, interim operational conditions and RMMs intending to manage the potential risks that were identified in the CSA need to be put in place and, where relevant, recommended to downstream users and recorded in the exposure scenario.

The final exposure scenarios including the recommended operational conditions (OCs) and risk management measures (RMMs) for the manufacture and identified uses are to be documented in the CSR (see Part F) and communicated to downstream users of the substance annexed to the SDS (see Part G).

A.2.6 Iterations of the CSA

If, based on the initial ES, it cannot be demonstrated in the CSA process that risks are controlled, further work is needed. In an iteration of the CSA, information at any point of the assessment cycle can be re-assessed and refined. The CSA process can be refined in any number of iterations, until

risks are shown to be controlled. Such iterations must be realistic to the extent that the recommended operational conditions (OCs) or RMMs can be implemented in practice.

The following refinement options are available, depending on what the assessor and his company consider being the most efficient strategy. It should be noted that refinement has two meanings.

The first is based on refinement of the information that goes into the CSA, to more accurately reflect the current conditions without actually changing any conditions of use. The second meaning is the actual refinement or improvement of operational conditions and risk management in practice, which is then reflected in the input into the CSA. This may include more stringent as well as less stringent measures to control the risk.

Improving the hazard information - if a limited toxicity data set is available to derive PNECs or DNELs, it is common to use relatively large assessment factors (see Part B) In such cases, collecting additional information may lead to the use of less stringent assessment factors that account for the increased confidence in the data (cf. Chapter B.7 on DNEL and PNEC derivation,). However, the risk characterisation may also point out that certain risks are not controlled and that additional data needs to be collected. This may occur for instance if the CSA points to significant emissions to the soil compartments. In such a case, additional soil toxicity data may need to be collected.

Improving the exposure information – Iterations on exposure data or on assumptions may be necessary by adapting or improving any default input values for which this is considered necessary: refinement of data on substance properties, emission data, exposure assumptions, model definition or complexity (e.g., go to less conservative assumptions), or replace model predictions by measured data.

Improving information on operational conditions - The description of the operational conditions can be refined to get closer to reality, for example duration or frequency of activities can be adapted, (e.g. a default 8 hr/day shift is assumed while in practice it is only 4 hr/day). If further refinement is needed, recommended operational conditions could be tightened or changed.

Improving information on risk management - The initial exposure scenario is based on available information on implemented and recommended RMMs. Therefore, when the residual exposure still suggests the potential for risks, stricter RMMs can lower the exposure. Several options can be explored to improve the information on RMMs. This could be demonstrating and documenting a higher efficiency of the implemented RMMs than the default assumptions. Another option is to add RMMs that were not yet present such as on-site waste water treatment, changing to a closed system or improved recirculation of processing chemicals. In general, safer alternatives or process and technical controls have priority over RMMs based on personal protection equipment.

A.2.7 Iteration strategy

Due to the flexibility of the CSA under REACH, the most efficient strategy to achieve control of risks differs from assessment to assessment. In general, the quickest and possibly most cost-effective approach is to improve the realism of the exposure and risk management assumptions of the assessment. If it can be demonstrated that initial hazard and or exposure information can be replaced by improved and more realistic information, further testing or additional RMMs may not be needed. It may be best to first exhaust the iteration possibilities with the available data or consider collecting additional exposure information or measurements. If enough exposure information is available, more complex exposure models ('higher tier' models) may be employed to get a more precise exposure estimate. Running such models would normally require collection of

additional information related to the use and use conditions of the substance. The trade-off between additional investment in information collection and an improved exposure assessment depends on many factors and varies from case to case. In some cases the safety assessment may lead to the conclusion that certain types of uses can no longer be supported and thus can not be covered by the ES.

Uncertainties are present in all steps of the CSA. Practical guidance has been developed to help the registrant to determine the influence of uncertainties on the risk characterisation at any stage during iterations of the CSA (see Chapter R.19). Uncertainty analysis can be used in the CSA iterations to test the robustness of the risk characterisation, identify the most uncertain inputs to the entire CSA (whether hazard or exposure related) that influence the risk characterisation, and thereby to decide on the most cost-effective way to collect additional information on these elements to improve the CSA and risk management.

A.2.8 Updating the CSA

New information which becomes available after registration may trigger the obligation to update the exposure scenarios, the CSA and the CSR. Then the registration also needs to be updated. Such information is for example:

- A new identified use of the substance promoted by the substance M/I which leads to an update of exposure scenarios.
- A new identified use made known by downstream users in response to the extended safety data sheet and supported by the M/I. This applies if the use cannot be covered by the use conditions in one of the already existing exposure scenarios.
- A new use advised against
- Additional information on the conditions of use for an already identified use, becoming available after the registration that require changing operational conditions or RMMs
- New information on the physicochemical properties or adverse effects of a substance has been identified or results of tests proposed to the ECHA have become available.
- Change in classification.
- If changes of production volume and/or import volume result in a change of tonnage band requiring additional hazard information.
- The exposure scenario or other information needs to be changed due to decisions by the Authorities under REACH procedures (information requested under evaluation(s), granted or refused authorisation or new restrictions, harmonised classification and labelling).

A.2.9 Chemical safety report

The final or updated CSA, including the final exposure scenarios and the associated exposure estimation needs to be documented in the chemical safety report (see Part F) and submitted to the Agency with the technical dossier.

A.2.10 Exposure Scenario annexed to the safety data sheet

The final exposure scenarios can be extracted from the CSR implemented for own uses and converted into the Annex(es) for the extended safety data sheets for downstream uses. Different options exist for the way the ES information is translated to the SDS, as explained in Part G.

One or more different exposure scenario annexes are needed to communicate the information relevant to the respective customers, depending on the diversity of the conditions under which the

substance is used by different downstream user groups. Several identified uses can be addressed in one exposure scenario, if the operational conditions and the risk management measures (leading to comparable levels and patterns of exposure) are the same. Also, the same ES annex may be used for various safety data sheets for different substances, provided it has been demonstrated in the CSRs that control of risks can be ensured. Thus, the exposure scenarios and safety data sheets in the portfolio of the supplier may be combined with each other as appropriate.

A.3 COMMUNICATION IN THE SUPPLY CHAIN

This section will outline the REACH obligations and briefly introduce options in relation to communication within the supply chain(s). As highlighted, early and upfront communication will in many cases significantly facilitate compliance with the requirements. See Part D for further details.

A.3.1 Shared responsibility and communication in the market

Once a substance is classified as dangerous or is found to be a PBT/vPvB, exposure assessment is required to demonstrate control of risks for the entire life cycle of a substance. Exposure assessment may also be required in relation to exposure based waiving (Chapter R.5). This is a shared responsibility for all actors in the supply chain, except those i) transporting chemicals, ii) treating waste for recycling[10] or final disposal and iii) using chemicals in private households.

Companies using substances on their own or in preparations are defined as downstream users under REACH. Consumer use of substances and preparations is not a downstream use, but may be an identified use.

Downstream users incorporating substances into articles are at the same time article producers. Article producers and importers of articles are subject to specific requirements under REACH (see Section A.4.2 and Guidance for articles).

Companies or consumers that are only *supplying* articles (into which substances have been incorporated) are not downstream users according to REACH, but will be referred to as 'article suppliers'. These may also be subject to specific requirements (see Section A.4.3 and Guidance for articles).

A.3.2 Organise dialogues in the supply chain

The identification of uses of a substance is the first step in building exposure scenarios and carrying out a CSA for these scenarios. To carry out the CSA, the manufacturer or importer of a substance needs to possess or to collect sufficient information on how the substance is being used by the various actors in the supply chain. REACH does not require the M/I to collect all the details on uses. However the M/I is obliged to make himself aware of all the conditions which determine exposure, wherever his substance is used throughout his markets. This includes his immediate customers as well as the markets of his customers further down the chain. The level of detail required depends on the hazard profile of the substance, the principal exposure potential connected to the use, and the principal means of risk management the different user groups have at their disposal.

Two mechanisms are foreseen in REACH to increase the knowledge of M/I:

[10] Companies re-introducing recovered substances (on its own or in preparations) as products into the market must however check whether or not they have to register these recovered substances.

Interaction before registration:

The downstream user has the right to make known his use(s), including supporting information on the conditions of use (or information on measured exposure levels) in writing one year before the corresponding registration deadline by the latest (December 1, 2009 for the first registration phase)[11].

Also the manufacturers and importers may start a dialogue with representative customers to get more knowledge on the general or specific conditions of use downstream. There are various ways to start the dialogue. M/I may for example develop initial exposure scenarios based on in-house knowledge, and send these for feedback to selected/all customers before registration. Also visits to selected customer sites may be a useful way to promote the dialogue.

Interaction after registration:

The downstream user can make his use known (including supporting information) for a registered substance at any time after registration. The M/I is obliged to process the received information in order to decide whether i) he can include the use in one of the already existing exposure scenarios or ii) the registration needs to be updated with a new exposure scenario or iii) whether he is unable to support the use based on health and environment concerns.

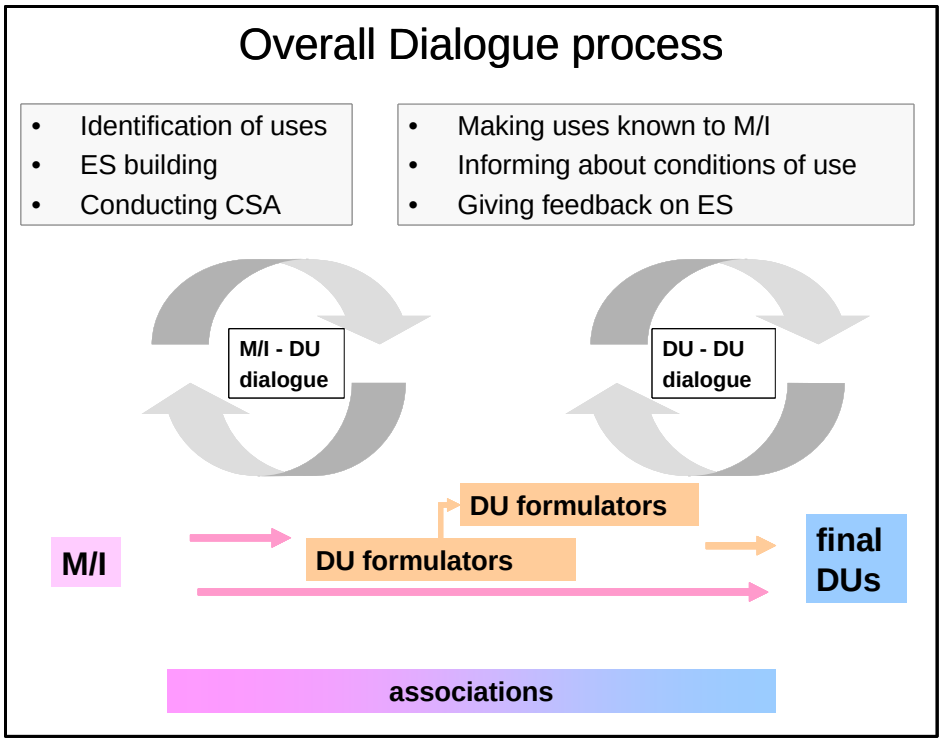


Figure A.3-1: Overview of dialogues in the supply chain.

In order to avoid significant updating of registration dossiers, a high number of downstream user CSAs after registration, and high efforts in communication up and down the chain in single supplier-customer dialogues, coordinated interaction well in time **before** registration should take

[11] Legal reference article 37(2), 37(3)

place. It is therefore recommended that M/I and DU seek co-operation and dialogues through their associations (see overall mechanisms in Figure A.3-1). This may include:

- Reaching agreement on the format and the core content of exposure scenarios among the manufacturers/importers of substances with similar markets
- Reaching agreement among downstream users on the standard conditions of use existing in certain sectors/branches. This may include dialogues between formulators / distributors and the industrial/professional end-users of substances as such or in preparations (see second dialogue circle in Figure A.3-1)
- Reaching agreement between M/Is and DUs on a number of generic exposure scenarios reflecting the conditions of use in a certain market.

Figure A.3-1 illustrates the basic mechanism to increase the knowledge of M/I on the conditions of use in his supply chain (arrows "pumping" information upstream). During its life cycle the substance passes various stages in the supply chain (arrows indicating the substance flow down the chain).

Often M/I does not supply the substance directly to the final downstream users, but various DUs mixing chemicals may sit in between. M/I will receive the information on uses and conditions of use through his immediate customers. In all these activities, the associations at different levels of the supply chain may take an active role in setting up efficient communication systems.

Guidance on how to run the process of exposure scenario building is provided in Part D. This includes a number of suggestions how to organise the dialogues in an efficient way, suitable to manage the registration process under REACH.

A.3.3 Key tasks in the supply chain

Box A-1 provides an overview on the key tasks to be implemented along the supply chain. The key tasks are assigned to the roles defined in REACH. The downstream user role is split into various roles, of which the most important ones are: Formulators (F) of preparations from substances or preparations, and industrial or professional end-users of substances or preparations (E). Industrial end-users of preparations are often at the same time producers of articles. Although consumers are end-users, they are not considered downstream users according to REACH. Some actors may have several roles, e.g. a manufacturer can also be a downstream user, or a formulator can also be an end-user of e.g. a processing aid. For more details on identifying DU roles, see section 2 of the Guidance for Downstream Users.

For each of 14 key tasks identified, Box A-1 gives a reference to the corresponding sections in this guidance, or makes a cross reference to the Guidance for Downstream Users.

The tasks are summarised in

Figure A.3-2.

BOX A-1: KEY TASKS RELATED TO THE CSA, FOR MANUFACTURERS (M), IMPORTERS (I) AND DOWNSTREAM USERS (DUS). DUS CAN BE FORMULATORS (F) OR END USERS.

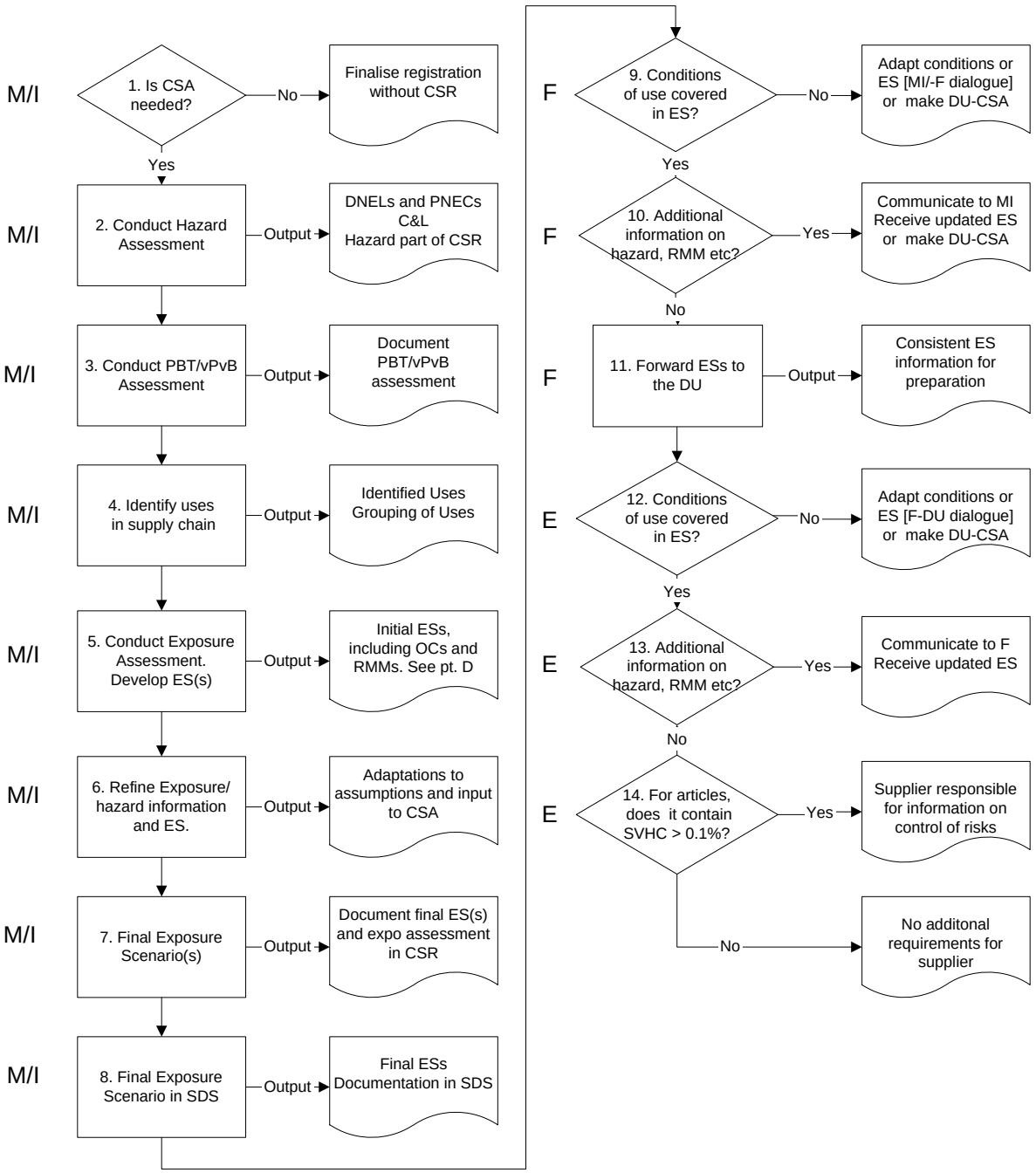
1. M/I: identify if a CSA is needed (substances manufactured or imported on their own or in preparation ≥ 10 t/y or articles produced or imported and containing substances ≥ 10 t/y that are intended to be released). Check the exemptions for this requirement (REACH art. 14).
2. M/I: Conduct hazard assessment: determine the classification and labelling of the substances (if any) and establish the relevant derived no-effect levels (DNELs) and predicted no-effect Levels (PNECs) (see Part B).
3. M/I: Determine if substance is considered to be persistent, bioaccumulative and toxic (PBT) or very persistent and very bioacccumulative (vPvB), and if so, characterise all emissions throughout the lifecycle of the substance that result from manufacture and identified uses (see Part C)
4. M/I: Identification of uses (including those made known by DUs), including as a minimum, a brief general description of identified uses (see Section D.3.3). If the substance does not meet the criteria for classification as dangerous and does not meet the criteria for PBT/vPvB, go to step 7.
5. M/I: For substances classified as dangerous, and/or being PBTs/vPvBs: conduct an exposure assessment and risk characterisation (see Parts D and E). Develop one or more initial exposure scenarios. Describe the conditions of use in the initial ES(s) based on current practice and readily available information (see Part D), with emphasis on
    - Technical description of process and/or activities carried out with the substance
    - Operational conditions of use that are relevant for controlling risks
    - Risk management measures
6. M/I: If risks are not controlled, the hazard and/or exposure assessment has to be refined. The hazard assessment, exposure scenario or the estimation of exposure needs to be iterated until control of risks can be demonstrated (see Part E). This may include
    - modification of risk management measures (RMM) or operational conditions (OC) and/or
    - limiting the uses of a substance covered by the CSA and/or
    - collecting further information on substance properties and refining the hazard assessment
    - refining the estimation of exposure to better reflect the situation where the ES(s) are implemented

    After iteration(s), assess whether risks are controlled (see Part E).
7. M/I: Document the CSA in the chemical safety report (CSR). If an exposure assessment was done, document control of risks based on exposure scenarios and the related exposure estimation (see Part F)
8. M/I: Integration of information relevant for the DU into the extended safety data sheet (see Part G)

9. F: Comparison of the exposure scenario received from supplier with the uses and the actual conditions of use at formulator's level and further downstream; in case the conditions of use are not covered in the exposure scenario, the formulator may take the following action (see Guidance for Downstream Users)
    - adapt his own conditions of use
    - approach the supplier with the aim of identifying his own as well as downstream use and operational conditions and suggest respective modification of the exposure scenario or
    - conduct an own CSA and, where required, report to the Agency or
    - replace the substance by a non dangerous alternative or an alternative with a more suitable ES
10. F: If relevant, communicate to the supplier new information on hazardous properties of the substance not mentioned in the safety data sheet or information that calls into question the appropriateness of risk management measures suggested by the supplier (see Guidance for Downstream Users).
11. F: Forward the exposure scenario information for the different dangerous substances in a preparation to the DU, in an appropriate manner. This is further detailed in Part G and the Guidance for Downstream Users.
12. Professional/industrial end-user of the substance: Comparison of the exposure scenario received from supplier with i) the uses and the actual conditions of use at the level of substance/preparation end-user and ii) the conditions of use in the life cycle stages resulting from the use (service life in articles and waste life stage); in case the conditions of use are not covered in the exposure scenario, the downstream user may take the following action (see Guidance for Downstream Users):
    - adapt his conditions of use and/or the conditions of use in the life cycle stages resulting from his use
    - approach the supplier with the aim of identifying his own use as well as downstream use and operational conditions and suggest respective modification of the ES or
    - conduct an own CSA and, where required, report to the Agency or
    - replace the substance by a non dangerous alternative or an alternative with a more suitable exposure scenario.
13. Professional/industrial end-user of the substance: At any time, communicate to the supplier new information on hazardous properties of the substance that is not mentioned in the safety data sheet or information calling into question the appropriateness of OCs or RMMs suggested by the supplier (see Guidance for Downstream Users).
14. Professional/industrial end-user of the substance and subsequent article suppliers: Industrial end-users are often article producers. These may have notification and registration requirements (see Guidance for articles). Specifically for substances of very high concern on the candidate list, that are contained in articles > 0.1%, they have to supply information to the professional, industrial recipient of the article in order to allow safe use of the article. This obligation pertains to all suppliers in the article supply chain. On request, also supply this information to consumer (see Guidance for articles).

Figure A.3-2: Overview of key tasks to be implemented along the supply chain.

M/I = manufacturer/importer, downstream users are divided in F = formulator and E = end user (professional or industrial) of a substance on its own or in a preparation. Each task delivers an output in the form of information exchange or documentation of the results of the CSA in the ES, the CSR or the SDS



A.4 CSA FOR DIFFERENT ACTORS

A.4.1 CSA for a so-far unsupported use by a DU

Aim

A downstream user may find that the exposure scenarios and the conditions of use contained in it, as received from the upstream supplier, do not cover his actual conditions of use or uses further down the supply chain. The first action a DU can take is to inform this supplier of his use and supporting information to allow his use to become an identified use and the supplier to develop an ES and include it in the SDS. If not, the duty to carry out a CSA for a particular use or for certain conditions of use then shifts from the M/I to a downstream user. This will for instance happens in the following situations:

- A supplier has already advised against a particular use but a downstream user nevertheless wants to apply the substance for such use. The same applies in a situation where a supplier refuses to include a newly identified use from the DU upstream into the SDS, e.g. based on health and environment considerations.
- The downstream user considers the use confidential business information.

In such cases[12] the DU is obliged to take over the responsibility for conducting the CSA for that use (see also Section A.3.2) and, where required, report this to the Agency. More detail on how the DU can check coverage of the ES can be found in the Guidance for Downstream Users.

In those cases, the DU-CSA will need to cover the life-cycle of a substance as its receipt by the downstream user, for his own uses, as well as for identified uses further down the supply chain and resulting life cycle stages, if this is not covered by an ES supplied to him. When a DU decides to prepare his own CSA/CSR, the M/I has no additional obligations to this specific DU, other than communicating the relevant SDSs (on further requirements, see Guidance for Downstream Users).

CSA and CSR

The different steps of a downstream user CSA are detailed in Box A-2. The emphasis of the CSR is on developing exposure scenarios for uses that are not within the boundaries of the ES supplied to the DU by his supplier. The exposure and risk characterisation of the CSA can be refined, if necessary, in order to control risks from the use of the substance.

If additional information on hazard (beyond what the DU has received from his supplier) is needed, the DU should generate or collect this information, if needed supported by a proposal for testing when testing on vertebrates is needed.

It is quite likely that the identified uses a DU wants to assess and notify is related to preparations which possibly contain various classified substances. Developing an ES for preparations is explained in the Guidance for Downstream Users[13]

[12] Unless exempted according to Article 37 (4)

[13] Further guidance is expected as a result of ongoing work within industry which is going to be discussed at a workshop in May 2008 organised by ECB. Relevant outcomes may be integrated into the current guidance as an appendix to the guidance Part G.

Additional duties in the supply chain, in relation to substances in preparations, are listed in steps 9-14 of the general duties of actors in the supply chain (Box A-1).

BOX A-2: STEPS TO PREPARE A DOWNSTREAM USER CHEMICAL SAFETY ASSESSMENT (DU-CSA)

1. DU: Consider the need for preparing a DU-CSA (see introduction to section A.3.2).
2. DU: If a DU-CSA is needed, start with identification of uses, including brief general description of identified uses of the substance, starting with the receipt and use of substance by the DU and covering any identified uses further down the supply chain as well as life-cycle stages resulting from own and identified uses, including service life and waste stage (see Part D).
3. DU: Determine if the hazard information in the SDS received is adequate for the identified use(s). Normally, the DNEL/PNEC as supplied can be incorporated in the CSA/CSR. In some cases, additional hazard assessment and DNEL/PNEC calculations may be needed. Further hazard assessment may also be needed for endpoints for which no DNEL can be set (see Part B). If the DU CSA is conducted for a preparation this will entail an integrated advice in the SDS on conditions of use for all classified substances in the preparation (see Part G and Guidance for Downstream Users).
4. DU: Develop initial ES (which may be partly based on the exposure scenario(s) supplied by the M/I), containing a description of conditions of use ensuring control of risk, based on current practice and readily available information (see Part D). This includes
    - technical description of process and/or activities carried out with the substance
    - other operational conditions of use
    - risk management measures

4a. DU: Exposure estimation (quantitative/qualitative) and risk characterisation for each ES (see Chapter D.5 and Part E)

4b. DU: If the risk is not controlled, iteration of the exposure scenario or the assessment needed until control of risks can be demonstrated. This may include

- modification of risk management measures (RMM) or operational conditions and/or
- limiting areas of use of a substance and/or
- collecting further information on substance properties and/or conditions of use
- refining exposure estimation

5. DU: Finalise exposure scenario(s), document them and the risk characterisation in Chapters B.9 and B.10 in the CSR (see Part F)

6. DU: Integration of information relevant for the next DU into the extended safety data sheet (see Part G and Guidance for Downstream Users)

A.4.2 CSA to support registration by a producer or importer of articles

Aim

To support producers and importers of articles[14] in preparing a chemical safety assessment, where required as part of registration of substances in articles.

When is CSA and CSR required

Producers or importers of articles need to register substances in articles, and supply a CSR as part of the registration dossier when all of the following conditions are met:

- The substance is contained in an article, i.e. *an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition* (REACH Article 3(3)).
- The substance is intended to be released during normal and reasonably foreseeable conditions of use
- The total amount of the substance present in the articles is at least 10 t/y per producer or importer. NB: if the substance is present between 1 and 10 t/y per registrant, the substance has to be registered for that use but no CSA/CSR is needed.
- The substance has not been registered for that use (if this would be the case, no registration is required). NB! Potential registrants of substances in articles should in any case consider pre-registration. This is further explained in Guidance for articles.

A registration (and therefore where needed a CSA/CSR) can be requested by the Agency for any substance for which it has grounds to suspect that it is released (including un-intentional releases) and if having grounds to suspect that this release could pose a risk to man or the environment, unless the substance has already been registered for that use. This can apply to substances present in the articles in quantities totalling 1 tonne or more per producer or importer per year.

The guidance on requirements for substances in articles contains more detailed guidance assisting producers/importers of articles in finding out whether or not they have registration requirements under REACH (Guidance for articles)

Scope of the CSA/CSR

The CSA/CSR should focus on exposure to the substance released during service life of the article (see Chapter R.17) (for industrial workers, professional use, consumers and environment) and exposures during the subsequent waste stage (see Chapter R.18). Note that service-life can lead to wide dispersive emissions to the environment including exposure of humans via the environment, depending on substance and matrix properties. The CSR and the ESs contained in it should therefore take account of the potential for exposure by different or multiple pathways, and the emissions from articles during their service-life and waste-stage. The overview of the different steps for a CSA is given in Box A- 3.

[14] NB! As noted in section A.2.8, the producer of an article is considered a downstream user (DU) regarding the process of incorporating a substance (as such or in preparation) into an article. The obligations related to the produced article are different. An article producer will be abbreviated '(P)' of an article, to distinguish this from a manufacturer of a substance (M).

A general framework for exposure assessment of substances in articles can be applied (see Part D und Chapter R.13), independent of whether the assessment is part of the CSA for a substance, or a registration of a substance in an article with intended or un-intended release of a substance.

Other obligations for article producers/importers

Producers/importers (P/I) of articles may have notification and communication requirements related to substances contained in articles, if they are of very high concern (SVHC) and placed on the candidate list for authorisation (Article 7(2)). This is further explained in the Guidance for articles.

Obligations for article suppliers (actors in the article supply chain)

Any supplier of an article may have article supply chain communication requirements related to the content of SVHC. See Guidance for articles for further details.

Finally, it should be noted that substances in articles can be subject to restrictions (see REACH Annex XVII). General and specific duties in the supply chain, in relation to substances in articles, are listed in steps 9-14 of the general duties of actors in the supply chain (Box A- 1).

BOX A-3: STEPS TO PREPARE A CSR FOR SUBSTANCES IN ARTICLES INTENDED TO BE RELEASED. P/I: PRODUCER/IMPORTER.

1. P/I: Consult Guidance for articles to establish possible registration, notification and communication requirements.
2. P/I: If registration is needed, identify if a CSA is needed (Total amount of substance in the articles produced or imported ≥ 10t/y).
3. P/I: Consider pre-registration and how data collection on inherent properties can be established (Guidance on registration)
4. P/I: determine whether or not the substance fulfils the criteria for being classified as dangerous or is a PBT/vPvB (do a hazard assessment and PBT/vPvB assessment) to establish whether exposure scenarios are required (see Parts B and C).
5. P/I: For dangerous/PBT/vPvB substances in articles: Conduct exposure assessment (Part D). It is expected that a set of generic exposure scenarios for article categories can be developed. The initial exposure scenario should contain (see Part D):
    - Description of use and purpose of the article
    - Other operational conditions of use
    - Risk management measures, including packaging or product design
6. P/I: Estimation of release and exposure (quantitative) and risk characterisation (see Chapter R.17 and Part E).
7. P/I: If risk is not controlled, iteration of the exposure scenario or the assessment needed until control of risks can be demonstrated. This may include
    - modification of risk management measures (RMM) or conditions of use and/or
    - limiting areas of use of a substance and/or
    - changing the product design or

- collecting further information on substance properties and/or conditions of use
- refinement of exposure estimates

8. P/I: Final ES, documentation of CSA in the CSR (see Part F)

9. SDS are not required for articles. However, Article 33 communication requirements related to SVHC on the candidate list may apply to all actors in the article supply chain (see Box A-1 and Guidance for articles)

A.4.3 CSA to support the request for authorisation of substances of very high concern

Aim

Some substances are regarded as substances of very high concern (SVHC) due to their hazardous properties, which means they may be subject to authorisation by the Commission. The list of substances subject to authorisation will be contained in Annex XIV of REACH. An application for authorisation needs to be accompanied by a CSR, unless this is already submitted as part of registration of the substance and updated, where necessary.

Category 1 and 2 CMR substances[15] and PBT and vPvB substances are considered SVHC. On a case-by case basis, other substances with scientific evidence of probable serious effects of an equivalent level of concern as the CMR, PBT and vPvB substances, can be identified by authorities and proposed for subsequent prioritisation for and inclusion in Annex XIV (Art. 57). Further information is contained in the Guidance on identification of SVHC and the Guidance on Annex XIV inclusion.

Authorisation of substances is explained in detail in the Guidance on authorisation application. Authorisations can be granted on two bases (Article 60).

a. An authorisation shall be granted if it is demonstrated that the risk to human health or the environment from the use of the substance arising from the intrinsic properties specified in Annex XIV is controlled in accordance with Section 6.4 of Annex I. In this guidance this is referred to as the adequate control route.
b. An authorisation may be granted if it can be demonstrated that the risk to human health or the environment from the use of the substance is outweighed by the socio-economic benefits and if there are no suitable alternative substances or technologies. In this guidance this is referred to as the socio-economic analysis (SEA) route.

It should be noted that authorisation cannot be granted in accordance with "the adequate control route' for PBT/vPvB substances and substances of equivalent concern which have been identified due to PBT/vPvB properties. The adequate control route can neither be applied to CMR (cat 1 and 2) substances or substances of equivalent level of concern for which it is not possible to determine a threshold in accordance with Section 6.4 of Annex I. (Art 60(3)). In these cases, authorisation may only be granted via the so called socio-economic route (see Guidance on authorisation application). Thresholds may be derived for reprotoxic substances and in these cases adequate control could be demonstrated, and the Socio-economic route would not be needed. However, in all cases the CSR needs to be done in accordance with the principles in REACH Annex I.

[15] CMR: Carcinogenic, Mutagenic or Reprotoxic substances.

CSA and CSR

All authorisation applications need to include a CSR or refer to one submitted as a part of a registration dossier. In cases where a CSR is developed or updated for the purposes of an application for authorisation, it only needs to cover the identified uses applied for and can be limited to the risks to human health and/or the environment arising from the intrinsic properties specified in Annex XIV. The hazard assessment part of the applicant's CSR needs to be based on the Annex XV dossier that led the substance to be included in Annex XIV. The remainder of the CSR has to be developed in accordance with Annex I for which the standard guidance on CSA/CSR can be used. Depending on the substance properties this includes a quantitative or a qualitative risk characterisation, in accordance with either Section 6.4 or 6.5 of Annex I and following the general CSA guidance. The steps to develop a CSR to support an authorisation request are detailed in steps 1-7 of Box A- 4.

The CSR for authorisation shall not include risks to human health arising from the use of a substance in a medical device (falling under Directives 90/385/EEC, 93/42/EEC or 98/79/EC). According to Art 62(5)(b) the applicant can provide a justification for not considering risks for man or the environment, based on a permit granted under the IPPC Directive (96/61/EC) or on a prior regulation in the context of the Water Framework Directive (2000/60/EC).

Additional general and specific duties in the supply chain, in relation to authorisation of SVHCs, are listed in steps 9-14 of the general duties of actors in the supply chain (Box A- 1). Further information on the requirements on authorisation application can be found in the Guidance on authorisation application.

BOX A-4: STEPS FOR MAKING A CHEMICAL SAFETY REPORT TO SUPPORT THE APPLICATION FOR AUTHORISATION

1. M/I/DU: Document the SVHC properties of the substance for which an authorisation is applied for (see Part B and Part C). This documentation has to be based on the Annex XV dossier that led the substance to be included on the candidate list and from there to Annex XIV. NB. Hazard information that is given in Annex XIV also defines whether or not the substance is eligible for authorisation applications for the so called 'adequate control' route. It is always possible to apply via the so called SEA route. This information is the basis for the remaining parts of the CSR.
   a. A CSR already exists from a previous registration: If needed, update the CSR with the hazard assessment resulting from the Annex XV dossier and Annex XIV entries. The applicant may decide to cover also other hazardous properties and their risk characterisation to allow comparison to potential alternative substances.
   b. No CSR available: The CSR may be limited to cover risks to human health and/or the environment arising from the intrinsic properties that caused the substance to be included in Annex XIV. The applicant may decide to cover also other hazardous properties and their risk characterisation to allow comparison to potential alternative substances.
2. M/I/DU: Describe the uses for which authorisation is applied for (see Part D)
3. M/I/DU: Develop the initial ES. Description of conditions of use, based on current practice and readily available information (see Part D)

- technical description of process and/or activities carried out with the substance
- other operational conditions of use (OC)
- risk management measures (RMM)

4. M/I/DU: Estimation of emission/exposure (quantitative/qualitative) and risk characterisation (see Parts D and E and PBT assessment)

5. M/I/DU: Iteration of the exposure scenario or the assessment in cases were risks are not controlled

a) If an authorisation is applied for via the 'adequate control' route and if the risks are not controlled, iteration of the exposure scenario or the assessment is needed until adequate control can be demonstrated. This may include:
   - refinement of exposure estimates to better reflect the implemented or recommended conditions of use, e.g. by
     - collecting further information on conditions of use,
     - use of measured data,
     - use of better models, or
   - modification of risk management measures or operational conditions, or
   - narrowing down the areas of use for which authorisation is applied for.

b) If an authorisation is applied for via the SEA route, possibilities to improve control of risks via iteration of the exposure scenario or the assessment need to be considered with a view to ensure minimisation of emissions and exposures as far as possible for SVHC substances, and to ensure that it is likely that adverse effects are avoided. This may include the same actions as listed under step 5.a..

6. M/I/DU: documentation of final exposure scenario(s) and overall CSA in the CSR (see Part F)

7. M/I/DU: Integration of information relevant for the DU into the extended safety data sheet (see Part G).