Guidance on information requirements and chemical safety assessment

Part D: Exposure Scenario Building

October 2012

(version 1.2)

Guidance for the implementation of REACH

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PREFACE

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

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

This document relates to the REACH Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006[1] and its amendments as of 31 August 2011.

1 Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006).

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Convention for citing the REACH regulation

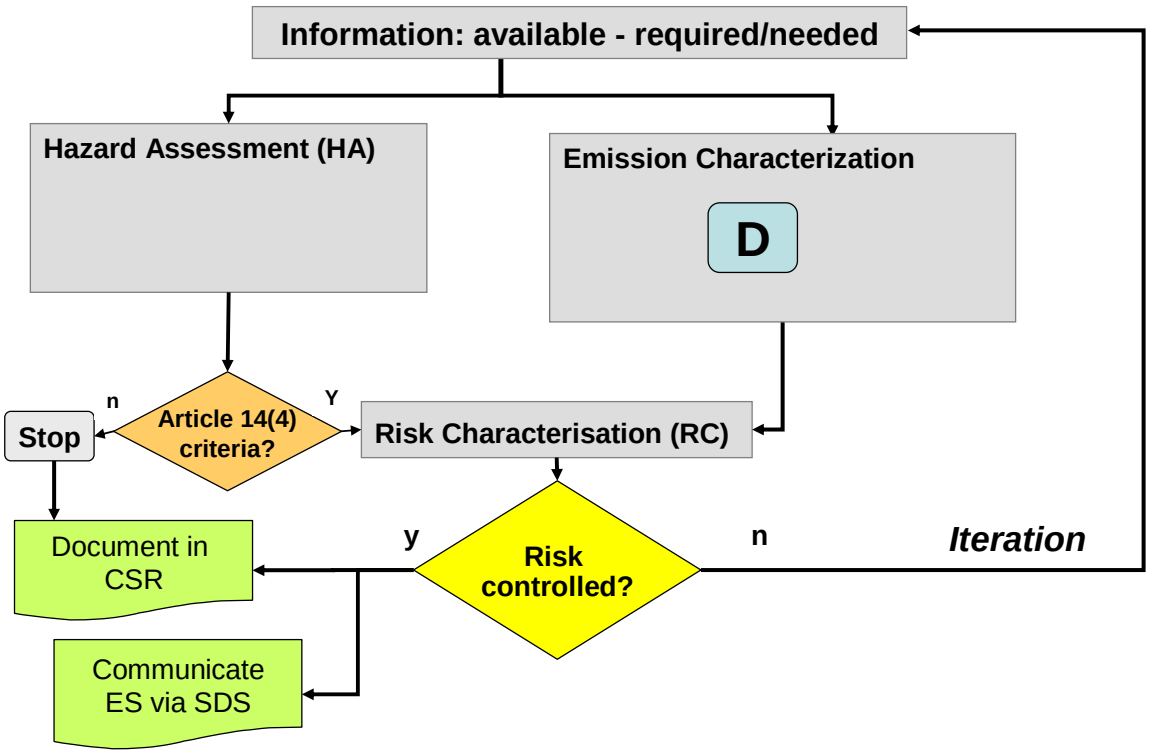
Where the REACH regulation is cited literally, this is indicated by text in italics between quotes.

Table of Terms and Abbreviations

See Chapter R.20

Pathfinder

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



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D.1 INTRODUCTION

D.1.1 Aim of this module

This module explains how to conduct exposure assessment covering the development of exposure scenarios and exposure estimation. The main focus of this module is on how exposure scenarios (ES) can be developed. It also contains an overview on exposure estimation whereas more detailed guidance on exposure estimation can be found in Chapters R.14 to R.18. The exposure scenario guidance regards both the core content of information to be collected as well as the step-wise procedure to build the final exposure scenarios for a substance, as an integrated part of the iterative CSA.

An exposure scenario is a set of information describing the conditions under which the risks associated with the identified use(s) of a substance can be controlled. It includes operational conditions (for examples the duration and frequency of use or the amount used, the process temperature or the pH) and necessary risk management measures (e.g. local exhaust ventilation or a certain type of glove, waste water and gas treatment). 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, and/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.

Chapter D.2 describes the core contents of an exposure scenario under REACH. It presents an overview on the most common determinants of exposure and recommends a standard format for the final exposure scenario. This also includes a list of the most common types of operational conditions (OC) and risk management measures (RMM) to be considered in ES development. Supporting guidance on measures to control risks is contained in Chapter R13.

Chapter D.3 suggests a standard workflow of 14 steps, including the main outputs to be delivered, starting from use identification and ending with the final exposure scenarios for the substance. It also includes guidance on the dialogue processes needed in the supply chain to arrive at useful exposure scenarios in an efficient way.

Chapter D.4 provides guidance on developing the contents of an exposure scenario: Activities in the life cycle (Section D.4.2), description of use and short title of exposure scenario (Section D.4.3), preset initial exposure scenarios (Section D.4.4), conditions of use for controlling risks (Section D.4.5). Details on the use descriptor system can be looked up in Chapter R.12 and details on risk management measures and operational conditions used to control risks are given in Chapter R.13.

Chapter D.5 provides an overview on exposure estimation. This includes guidance on the role of measured data as well as a brief explanation on a number of tools available to estimate exposure. The strength and limitations of these tools in the context of REACH are further discussed in Appendix D-1. Exposure scenario building and the corresponding exposure estimation should be carried out in a tiered manner, starting with available information, including conservative assumptions of exposure levels. The concise TGD focuses on such Tier 1 assessments. If these fail to demonstrate that a substance can be used in a way that risks are controlled more refined assessments may be performed employing more detailed exposure information which can be processed with more refined exposure estimation tools, Also, if the available data allow it is also possible to directly carry out a higher tier assessment, Supporting guidance on the details of exposure estimation is contained in Chapters R.14 to R.18.

Chapter D.6 briefly describes situation where, based on initial exposure assessment, the M/I may conclude that refinement of the hazard assessment is needed, before the final exposure scenario can be derived.

Chapter D.7 briefly explains the risk characterisation since the risk characterisation potentially triggers iterations of the initial exposure scenario. More details on risk characterisation is provided in Part E of the guidance.

Chapter D.8 contains guidance on how to finalise the exposure scenario. This includes how to integrate the operational conditions and risk management measures for the relevant exposure routes and target groups into a consistent final exposure scenario for a specific use or uses.

Finally, Chapter D.9 builds the bridge to the use of exposure scenarios in the context of the CSR and the extended safety data sheet (SDS), and makes reference to Part F and Part G of the guidance.

D.2 CONTENTS OF EXPOSURE SCENARIOS

D.2.1 Aim of section

Chapter 2 describes the core contents of an exposure scenario under REACH. It presents an overview of the most common determinants of exposure and recommends a standard format for the final exposure scenario.

D.2.2 Overview of core information to be taken into account in ES development

The collection of information for the development of ES must ensure that the ES meets its purpose under REACH. The ES is the basis for a quantitative exposure estimation and the communication tool in the supply chain. To provide a sufficient basis for the exposure estimation, it needs to include the main parameters determining the release and exposure (*determinants*). It needs also to meet the requirements of the downstream users (DU) who are the main recipients of the ES via the extended SDS.

For both above mentioned functions, it is essential that the information covered in the ES is presented in a structured and comprehensive way. This means that as soon as the information for the ES has been collected in a more or less narrative form, the information has to be translated into concise and adequate text modules and parameters. It should be noted that while the language used in an ES may differ for these two different purposes the content has to remain the same. In other words, the operational conditions and risk management measures communicated to the downstream users have to be the same which were assumed to be in place when estimating the exposure levels as a part of CSA. This link should be traceable in the CSR. Thus it is necessary to document how the ES have been developed.

The derivation of the so-called “determinants of release and exposure” plays a crucial role when the information gathered is transformed into the ES specific terminology. A number of examples of determinants are given in the following which often play a central role for release and exposure levels:

- Substance characteristics like e.g. volatility, water solubility or degradability are identified in the hazard assessment and form an essential information input for exposure scenario development. For example, substances with a high vapour pressure (or high toxicity) usually require different types of risk management than substances with low vapour pressure (or low toxicity). Reliable information on substance characteristics are also needed to carry out the exposure estimate, once an exposure scenario has been set up.

- Processes and products should be designed and managed in a way that risks are controlled. Those characteristics driving the exposure should be reflected in the exposure scenario. This includes for example the technical type of activity and the level of containment, the duration and frequency of use, the concentration of a substance in a product or the amount of a substance used per time or application. It also includes the risk management measures taken by the manufacturer or downstream user to control risk.

- The surrounding, in which a process takes place impacts on the exposure as well. For example, using a chemical in a small room or emitting waste water to a small river increase the likelihood that effect levels are exceeded and risks are not controlled. The same applies for example to the body weight and inhalation volume of an exposed worker or consumer. Although the process, the product or the room may be the same, a high inhalation volume per

body weight (e.g. children, or hard working adults) leads to a higher dose. Chapter R.8 includes guidance on how to take account of these conditions in DNEL derivation.

Table D.2-1 Examples of determinants of exposure

Determinants of exposure;	Examples (not exhaustive)	Remarks
Substance characteristics		
Molecular properties	Molecular weight Molecular size	Gives an indication of bioavailability
Physico-chemical properties of substance	Vapour pressure Octanol-water partitioning coefficient Water solubility	Exposure determinant at workplace and in the environment
Stability	Biological degradation, hydrolysis, photodegradation, atmospheric degradation (half-life in water, soil, air)	Exposure determinant related to degradation in environmental compartments incl. sewage treatment
Characteristics of processes and products		
Life cycle stage of substance or product to which the ES refers	Manufacture of substance, formulation, final use of chemical products, service life of substances in articles, waste phase	Identify relevant exposures for all target groups, supports selection of suitable broad ES; supports the selection of pre-set process or product categories in tier 1 tools for exposure assessment.
Type of activity or process	For example: synthesizing substances; mixing substances; using substances as process aids; using chemicals by spraying or by dipping or by brushing; using substances in articles e.g. wearing textiles, spending time in house;	
Time pattern of use	Duration of activity/use Frequency of activity/use	Determinant related to pattern of exposure (short term vs. long term) and corresponding choice of PNEC or DNEL
Technical conditions of use	Level of containment of process Temperature, pH, etc.	Determinant related to exposure of humans and environment
Characteristic of chemical product	Weight fraction of substance Fugacity, dustiness, volatility of product	Determinant related to exposure of humans and environment for mixtures or products
Used quantity	Kg [t] per time or activity	Determinant for the exposure potential per time or per activity
Risk Management Measures	Local exhaust ventilation (workplace) Personal Protective Equipment (workplace) On-site waste (water) treatment e.g. oil-water-separation Municipal sewage treatment, waste treatment Package design preventing dermal or inhalation exposure (product safety)	RMMs as integrated element of the technical product or process, or as additive measure; determinant of the extent to which exposure can be mitigated or prevented;
Characteristics of surrounding		
Surrounding absorbing or diluting releases	Room size and ventilation rate; river water flow; capacity of sewage system	Exposure determinant based on the assumption that even distribution of substance takes place
Biological exposure factors	Inhalation volume, body weight	Determinant of the dose to which a human is exposed and corresponding choice of PNEC or DNEL

Some of the determinants listed in Table D.2-1 are usually not iterated by the registrant but are set to realistic (default) values, namely substance characteristics and surrounding characteristics. Other parameters can and have to be determined in the ES during the iterative process by the registrant. REACH distinguishes two types of these changeable determinants to be reflected in the exposure scenario: the operational conditions (OC) and risk management measures (RMM).

- The operational conditions include any action, use of tool or parameter state ***that prevails*** during manufacture or use of a substance (either in a pure state or in a mixture) that as a side effect might have an impact on exposure of humans and / or the environment
- Risk management measures include any action, use of tool, change of parameter state ***that is introduced*** during manufacture or use of a substance (either in a pure state or in a mixture) in order to prevent, control, or reduce exposure of humans and / or the environment

Table D.2-2 presents the standard format of a final exposure scenario[2]. The ES format may serve as a check list during the whole process of ES development and may support manufacturers, importers and downstream users to concentrate on a core set of information. It is recommended to have the ES format (Table D.2-2) available at any time in order to allocate the information gathered to the initial or final ES. M/I and DU however may decide that certain pieces of information in the template are not needed to demonstrate control of risk, or that other determinants are actually relevant drivers of exposure and hence have to be addressed in the ES[3].

[2] Please note that a new Guidance on Exposure Scenario Format was published in 2010. It is however up to the individual registrant to decide whether he switches to the updated format, he continues to use the format published in 2008 (as per the table D.2-2 below), or he uses a completely different format (as long as the content is compliant with the requirements of Annex I). (See the document "Guidance on information requirements and chemical safety assessment - Exposure Scenario Format in Part D : Exposure scenario building ; in Part F : CSR format" http://echa.europa.eu/documents/10162/13632/information_requirements_esformat_en.pdf accessible via: http://echa.europa.eu/web/guest/support/guidance-on-reach-and-clp-implementation and http://echa.europa.eu/web/guest/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment . The above mentioned document replaces the current paragraph and the table D.2-2 below.

[3] Please note that in June 2012 the second version of ECHA's Chemical Safety Assessment and Reporting Tool (Chesar) was released. Chesar generates the exposure scenarios for the CSR in a more simplified format, which can be viewed within Chesar Manual 4, Annex 2) »

http://chesar.echa.europa.eu/documents/2326902/2424433/chesar2_user_manual_part4_en.pdf

Table D.2-2 Standard format of a final exposure scenario for communication

1	Short title of the exposure scenario
2	Processes and activities covered by the exposure scenario
Operational Conditions of Use	
3.	Duration and frequency of use *Specify for workers, consumers, environment (where relevant)*
4.1	Physical form of substance or mixture; surface to volume ratio of articles *Gas, liquid, powder, granules, massive solids;* *Surface area per amount of article containing the substance (if applicable);*
4.2	Concentration of substance in mixture or article
4.3	Amount used per time or activity *Specify for workers, consumers, environment (where relevant)*
5	Other relevant operational conditions of use *For example* • *Temperature, pH, mechanical energy input;* • *capacity of receiving environment (e.g. water flow in sewage/river; room volume x ventilation rate);* • *wear and tear with regard to articles (if applicable); conditions related to service-life-time of articles (if applicable);*
Risk Management Measures	
6.1	Risk management measures related to human health (workers or consumers) *Type and effectiveness of single options or combination of options on exposure to be quantified [options to be phrased as instructive guidance]; specify for oral, inhalation and dermal route;*
6.2	Risk management measures related to the environment *Type and effectiveness of single options or combination of options to be quantified [options to be phrased as instructive guidance]; specify for waste water, waste gas, protection of soil;*
7	Waste management measures At the different life cycle stages of the substances (including mixtures or articles at the end of service life);
Information on estimated exposure and DU guidance	
8	Exposure estimation and reference to its source *Estimation of exposure resulting from the conditions described above (entries 3-7 and the substance properties; make reference to the exposure assessment tool applied; specify for routes of exposure; specify for workers, consumers; environment);*
9	Guidance to DU to evaluate whether he works inside the boundaries set by the ES *Guidance how the DU can evaluate whether he operates within the conditions set in the exposure scenario. This may be based on a set of variables (and a suitable algorithm) which together indicate control of risk, but which have some flexibility in the respective values for each variable. Note: This will mostly be specific conditions for a certain type of product; this section may also include a link to a suitable (e.g. easy-to-use) calculation tool.* *Where relevant: Other methods for DU to check whether he works within the boundaries set by the ES may be included here as well.*

D.2.3 Overview of exposure scenario Development Steps

Exposure scenarios shall be developed for:

i) the manufacturing process; and

ii) for identified uses including own uses by the M/I, and uses further down the chemical supply chain and consumer uses;

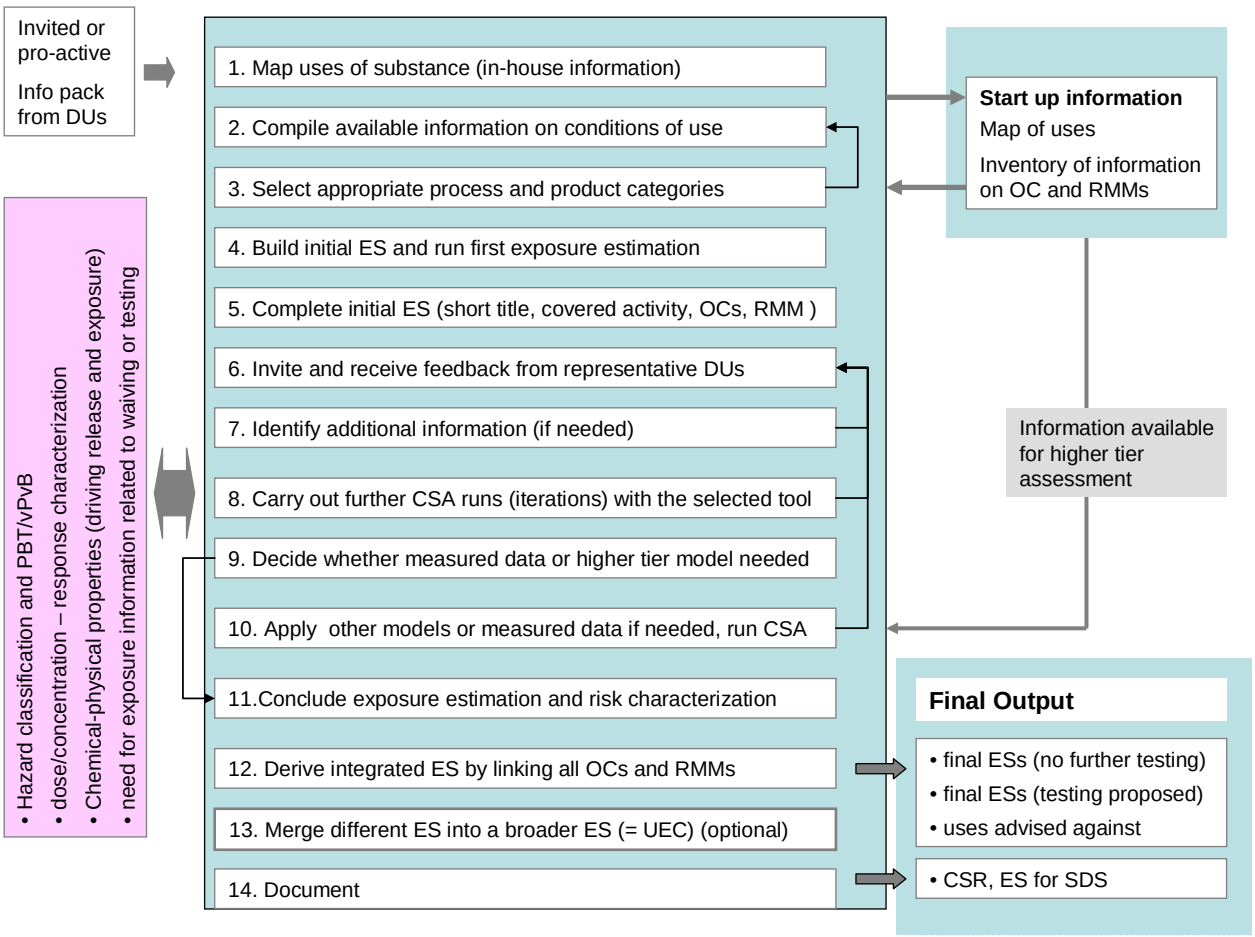
iii) life cycle stages resulting from manufacture and identified uses (article service life and waste life stages).

M/I will start his assessment with all available relevant information on the operational conditions and the existing risk management measures in manufacture, identified uses and resulting life cycle stages (initial exposure scenario). Downstream users or their organisation may have already compiled such information in a generic ES format so that M/I can directly proceed with completing the initial ES and estimating exposure for the uses covered. He will then estimate exposure corresponding to the available information. Often in a first iteration, standard tools for exposure estimates that are sufficiently conservative will be applied (Tier 1 assessment).

If measured data on exposure levels are available, reliable, and representative for the operational conditions and risk management measures described in the initial exposure scenario, these data can be used for the exposure estimate. The same applies for cases where there is enough information to use higher tier exposure models for the first estimate.

M/I will collect further details on release and exposure determinants when it is not possible to demonstrate control of risk based on the initial ES unless he decides to refine the hazard data (see Section A.2.6).

The process of developing the ES may vary case by case depending on the available information, but in particular when relatively little information is available upfront, the general process will follow the 14 steps presented in Figure D. 2-1 and further explained in the following text. The standard workflow is based on categorising processes and products in which the substance is used. The choice for specific categories leads to a selection of preset generic exposure scenarios which can be connected to existing tier 1 exposure estimation tools. If M/I has sufficient information available to build exposure scenarios and document the corresponding exposure estimates based on measured data or higher tier models he can shortcut the process. In such situations he can directly go to step 6 (invite DU for feedback) or 10 (run CSA based on measured data or higher tier models), depending on the state of dialogue with the downstream users.



Abbreviations: CSA= Chemicals Safety Report; DU= Downstream User; ES= Exposure Scenario; OC= Operational Conditions; RMM - risk management measures, SDS= Safety Data Sheet; UEC = Use and Exposure Category;

Figure D. 2-1 Steps for ES development related to downstream uses

Please note that the standard workflow (see Section D.3.2) based on pre-set categories and pre-set initial exposure scenarios aims to support consistency and harmonised information structure across the markets. However, M/I may also use the by-pass routes (directly to step 6 or 10 in Figure D. 2-1), in particular when all required information is available from a higher tier assessment. Exposure scenario building can be started without running through the Tier 1 process. However M/I should ensure that the exposure scenario is consistent with the standard format provided in Table D.2-2.

Exposure scenario building related to manufacture and the manufacturer's own use in principle, include the same steps; however in practice the workflow may differ in a number of aspects:

- Step 3-4 may be skipped since M/I may often be able to demonstrate control of risk based on measured data, instead of Tier 1 modelling.
- Step 6-7 may be skipped since there is no need to communicate with DU to increase the knowledge of the registrant.

D.3 OVERALL WORKFLOW AND DIALOGUES

D.3.1 Aim of the section

The aim of this module is to provide an overview on the whole ES building process and the dialogues between M/I and DU needed for that, before going more into technical details. The workflow explains the steps presented in Figure D. 2-1.. For each of the steps, key decisions/conclusions are indicated and the outputs are listed.

D.3.2 Workflow of building exposure scenarios

	Work flow	Output	Proceed to
1	**Map uses of substance**. Analyse the market of the substance based on existing in-house information. Consider how to include identified uses beyond the immediate DU. Assign one to four relevant life cycle stages, as appropriate; apply the standard descriptor system as appropriate; group types of products or customers or relevant process/activities. Use information if pro-actively provided by DUs. Invite DUs to provide information if needed.	• Map of the known DU and consumer-uses in standard terminology of the descriptor system	2
2	**Compile all available information on OCs and RMMs and related release/exposure levels** during the life cycle of the substance; start with existing in-house information. Include information if pro-actively provided by DUs. Invite DUs to provide information if needed.	• Inventory of available information, including measured data	3
3	**Select appropriate** process **or product categories** related to the uses identified. Document the reasons for the choice of category, including relevance of RMMs and OCs. Flag uses, where you are in doubt. First try to use information from step 2 to assign a suitable category. Otherwise, list uses for which no suitable pre-defined product or process category is available. Group uses under the same pre-defined category, where suitable. Define the information needs based on ES standard format and the input tables (initial or for iteration) for the selected tools. Take into account the domain of the tool with regard to the hazard profile and the physical state of the substance to be assessed.	Uses assigned to product and process categories • identification of required data input • identification of entry to Tier 1 exposure estimation tools • uses requiring a higher tier assessment since no suitable category is available	4 9
4	**Build initial exposure scenarios** based on the input data needed for the Tier 1 exposure estimate (see Table D.5-1, Table D.5-3 and Table D.5-4). Check further available information on OCs and RMMs from • DUs and/or their organisations (including intial exposure scenarios) • product or branch specific RMM packages in the RMM library • Literature **Make an initial exposure estimation and initial risk characterisation** by obtaining relevant exposure data for the ES or run a Tier 1 exposure tool; establish the significant[4] routes of exposure and a first estimate on expected exposure levels. Compare any known exposures and/or the predicted exposure	• Initial exposure scenario populated with quantifiable information • First overview on where control of risk is not evident • Assumptions on significant exposure routes • Justification/documentation for not considering certain exposure routes. • Part E, Risk Characterisation	5

[4] The Tier 1 tool may suggest whether one or more routes of exposure are "significant" for a use or not. It is up to M/I to cross-check this suggestion in step 6 and 7 against the information he has collected.

	Work flow	Output	Proceed to
	with the available toxicological knowledge from the hazard assessment in a risk characterisation. It should be justified why certain exposure routes are not addressed.		
5	**Complete initial ES**: Where control of risk can be demonstrated on the basis of initial risk characterisation, complete the initial ES by further describing the corresponding operational conditions and risk management measures. Assign a short title to the initial exposure scenarios. If risks in certain uses are not controlled, further refinement is needed either before going to step 6 or after.	• Initial exposure scenario with RMM advice and description of operational conditions • Uses for which control of risk is unlikely to be demonstrated based on available information	6 7
6	**Invite and receive feedback** from representative customers or DU organisations on whether • relevant uses are (not) covered • RMMs or OCs are appropriate (if not, provide information on existing RMMs and OCs) • the descriptions in the ES are understandable to the addressees	• additional uses • need to revise conditions of use • information on existing conditions of use • rephrase needs • initial ES accepted by DU	7
7	**Identify and use additional information** (if needed), based on feedback:, • progress directly to step 8 or • refine RMM and OC in the initial ES before and/or • refine information on substance properties (e.g. DNEL for a certain route needed)	• refined set of OCs and RMMs • refined set of information on substance properties	8 3-6 Part B: Hazard assessment.
8	**Carry out further CSA runs** (exposure estimates, risk characterisation and uncertainty analysis), and decide on iteration: • further iteration needed • control of risk can be demonstrated • further testing is needed NB: *A decision on whether or not iterations are necessary is needed for all identified uses and all life cycle stages of a substance*	• Input for completing the hazard assessment or leading to testing proposals	9 11 Part E: risk characterisation
9	**Decide whether measured data or a higher tier model is needed,** if the flexibility of the Tier 1 tool is exhausted without demonstration of control of risk. If control of risk can be demonstrated based on tier 1 progress to step 11.	• Conclusions whether control of risk can be demonstrated based on Tier 1 model	11 10
10	**Apply another model or use measured data** to i) refine the exposure scenario and ii) demonstrate control of risk. It may be also an option to not include certain uses in the ES or to describe more specific conditions of use in the ES.	• Conclusions whether control of risk can be demonstrated based on higher tier assessment	11

	Work flow	Output	Proceed to
11	**Conclude the exposure estimation and risk characterisation** (including uncertainty analysis): • RMMs and OCs ensuring control of risk documented in final exposure scenarios • Interim conditions of use recommended to manage the risk, if tests are proposed, and not yet carried out. • Use advised against due to health and environment concerns documented in the CSR • Information on conditions of use needed to finalise the risk characterisation not available from DU or other sources; use therefore not covered in the final ES.	• ES based on all required hazard information • ES but testing proposed • Uses advised against based on health and environment concerns	12 Part E: risk characterisation
12	**Derive the integrated exposure scenario** by linking all OCs and RMMs within the exposure scenario • Document the operational conditions and risk management measures required for human health and environment and the corresponding exposure routes for each (of) the use(s) covered by the ES. • Consider impacts of OC/RMM across exposure routes. Select the OC/RMM leading to control of risk related to all routes of exposure.	Final exposure scenario after internal integration	13
13	**Merge ES if appropriate**: Carry out cross-comparison on the final exposure scenarios and conclude which scenarios to merge based on similarities in risk management and operational conditions.	Final use and exposure categories at different level of integration	14
14	**Document the deliverables** of the exposure assessment • CSR sub-chapter 9 per exposure scenario including: ES description (with necessary explanations) corresponding exposure estimates (with necessary explanations) and risk characterisations. It must be clear from the documentation how the RMM and OC in the final ES are linked to the exposure estimates. • Summary of RMM and OC at the beginning of the CSR • Exposure scenarios in a format that can be annexed to the safety data sheets. If these are different from those in the CSR, ensure consistency with ES in the CSR. • DNELs or PNECs (related to relevant routes of exposure) for incorporation into Section 8 of the SDS • Summaries of RMMs/OCs from all ES for Section 7/8 of the SDS • Uses advised against for sub-section 1.2 of the SDS • Short titles of ES for inclusion in the Annex to the SDS (as required by Annex I of REACH point 5.1.1)	• CSR chapters • Building blocks for the extended SDS	Part F on CSR Part G on extension of the SDS

D.3.3 Organization of Dialogues

A M/I needs to possess sufficient information on the conditions of use downstream to be able to demonstrate control of risk in his CSR. The M/I will need to transmit the relevant information documented in the CSR to the actors further down the supply chain by means of the exposure scenarios annexed to the SDS of that substance. This includes information on appropriate risk management measures and the related operational conditions of use. The information shall cover all subsequent life cycle stages of the substance for which control of risk is documented in the

CSR. This includes life cycle stages beyond downstream use, to the extent that the DU at the bottom of REACH communication chain can contribute to the control of risk with regard to consumer uses, the service life of articles and waste operations.

Since REACH requires the DU to respond to the exposure scenarios they receive, DU will have an interest that the information in the exposure scenario

- covers their uses, and hence the DU do not need to carry out an own CSA
- provides clear and understandable guidance what to do
- suggests measures feasible to be implemented in practice by the addressed downstream user
- includes advice on how to establish whether the DU works within the boundaries of the ES.

There is a common interest between M/I and DU to share information on existing conditions of use and potentially required measures to improve prevention and management of risk. The best way to do this is to organise dialogues before registration.

The workflow in Section D.3.2 includes a number of processes and decisions related to the dialogue between the registrant and actors using the substance downstream. The direct dialogue partners for M/I are his customers. This can be the immediate downstream user directly supplied by the registrant or the distributors, supplying the immediate downstream users in M/I's supply chain. There are at least five types of immediate downstream users that may need to be addressed in the exposure scenarios:

- company using marketed intermediates (outside the conditions set in Article 18) in the chemical industry
- final user of the substance as such or in a mixture in the general manufacturing industry
- formulator or re-packer of an end-use product[5] to be applied by downstream users
- formulator of an end-use mixture to be offered or sold to the general public
- formulator of a mixture sold to further formulators for inclusion into a mixture

In all cases, the dialogue between M/I and his direct customers will need to include information that the direct customer may collect in further dialogues from his customers (and so forth until the endof the REACH communication chain is reached).

It is recommended that M/I makes himself aware of the roles his direct customers play in the supply chain when drafting the initial ES (steps 1-5 in workflow) and when he selects the representative sample of DUs to receive feedback on the initial ES (step 6 workflow).

D.3.3.1 Start with in-house knowledge

The registrant will usually start ES development based on in house knowledge and expertise. Table D.2-2 can be used to compile a number of basic in house questions to be answered for each identified use. For example, do we know:

- how long and how often workers come into contact with the substance?
- whether the substance is applied as a light powder, granule or a liquid?
- which risk management measures (personal protective equipment and other measures) are usually applied by the users?

[5] All uses of the substance/mixture, except those where the mixture is mixed with other substances and/or mixtures to produce a new mixture. End-use here covers use by consumers and professionals (industry and non-industrial conditions)

- whether the substance is finally contained in consumer products, and in which concentration?
- the approximate amount per day that may be used at a local site? Can we make an informed guess on the emission factor from such source?
- the state of the art in waste water treatment applied by the companies using our products?
- the approximate amount per year sold to different downstream user sectors for mixture making?

The internal collection of information will usually include the involvement of HSE (health, safety and environment) experts, product stewards, product managers, marketing departments and customer services:

- Information held by the sales and customers services departments, by product stewards or by product developers. In order to make this information useful under REACH, internal dialogues are needed between these departments and the assessors carrying out the CSA for the substance. This may, for example, include considerations on how to quantify emissions to the environment based on fractions of the substance in certain markets or the size of single customers (local point source).
- Information held by the HSE departments related to hazards and risk management measures applied on site or at working place, including waste water treatment behaviour of the substance and suitable waste management techniques
- Information available from production managers related for example to applicable risk management measures, operational conditions, possibilities to change them and how this may affect waste water or waste gas treatment.
- Frequent responses and questions from customers related to the existing safety data sheets.
- Information received from certain customer groups in preparation for REACH. This may include systematic information on conditions of use (including habits and practice) in the market, as well as available information that characterises the exposure levels typically associated with the conditions of use.

Where more information is needed, selected customers can be asked for further information, in particular with regard to the conditions of use further downstream (including knowledge on measured exposures). M/I should however make himself aware which parts of the market the selected customers represent and whether there are markets, for which access to information through the selected customers is not possible. This will be in particular the case, where a relevant share of the market is supplied through distributors. It is recommended that M/I actively approach the distributors to seek agreement, on how M/I can increase his knowledge on the conditions of use in the distributor's market, without requiring the distributor to disclose confidential business information. The feedback mechanism as outlined in step 6 of the ES building workflow (see Section D.3.2) may be a suitable way of doing this, provided the distributor works as a kind of facilitator. Also, the proposed system for use description and tier 1 exposure assessment will prevent disclosure of confidential business information (CBI) in this process. In some cases, a third party could be appointed to manage CBI.

Whether or not it is useful to work with questionnaires in collecting information depends on the case. Questionnaires sent to customers outside already existing dialogues have to be carefully planned to provide useful information. But it can be quite useful to work with questionnaires in targeted information collection, including situations when M/I needs information on the statistical distribution of certain conditions of use in the market.

M/I or their associations may wish to develop generic ES (GES), i.e. single ES that describes the relevant OC and RMMs for the typical use conditions relevant to operations of a DU sector. GESs

supporting the substance would be oriented towards the areas of application of the substance. The preparation of such GES requires the following:

- a thorough understanding by the M/I of the activities (Uses) through the life cycle of the substance that give rise to exposure/emissions. This requires appropriate communication within the supply chain,
- the evaluation of each of the activities to identify the appropriate RMMs and OCs, in line with the generic workflow as described in Section D.3.2 and the other sections of part D.
- the consolidation of the various RMMs into one composite ES, termed the Generic Exposure Scenario, GES.

For M/Is, developing these GESs are likely to be a resource intensive activity. However, they have the potential advantage of being more understandable to smaller DUs, reducing incidental supply chain dialogue and delivering better consistency in the communication of RMM advice across the substances in the chain. Once a number of GES is developed for certain areas of use, they may form the basis of a GES library which will reduce future efforts as the library is established.

D.3.3.2 Get feedback from customers

Once the initial ESs have been generated based on in-house knowledge, M/I may wish to get feed-back from customers. The customer may be interested to give this feedback and possibly further information as early as possible in order to assist M/I in registering the substance. The downstream users should consider the registration deadlines and provide appropriate information on the conditions of use in due time to enable M/I to take this information into account in exposure scenario building.

Under REACH the downstream user is expected to evaluate whether he operates within the conditions set in the ES[6] communicated to him. In case the DU is a formulator, this refers to i) his own conditions of use (his own formulation processes) and ii) the conditions of use further down the chain (use of substance in mixtures and/or articles).

Thus the feed-back may relate to the following questions: Does the ES provide suitable information to allow the DU to judge whether he works within the conditions of use set by the ES? Do the immediate downstream users see themselves covered and do they find the information provided useful? Do the immediate downstream users see their customers further down the chain covered by the initial ESs received from their suppliers?

When drafting the initial ES and when giving feedback, both M/I and DU should be aware that the DU may see himself confronted with one of the following four situations (see also *Guidance for Downstream Users*, section 5):

1. DU has already implemented/recommended the exposure scenario as phrased by M/I, or he will do so in the future. No particular feed back needed, M/I can proceed.
2. DU applies/recommends measures of similar type as recommended by M/I, and the operational conditions of use are largely the same. He can demonstrate (and document) that the measures are largely as effective as the measures communicated by M/I. =>DU may wish to inform M/I about that fact, however no major follow up needed. Rephrasing of the ES can nevertheless be useful.

[6] For practical reasons, „uses within the ES“[article 37 (4, first para)] and „implementing/recommending as a minimum the conditions described in the suppliers ES' [37, 4 (d)] are assumed to have the same meaning.

3. DU's operational conditions and the effectiveness of RMM are clearly different from what M/I suggests. DU needs to evaluate these differences regarding their significance. The ES may provide a mechanism to carry out such evaluation[7]. The evaluation may also be supported by comparisons to measured exposure data available to the DU. The DU needs to establish whether the differences, when taken together, do not constitute an unacceptable risk. DU needs to establish whether the differences compensate each other to an extent that the resulting exposure is not higher then the exposure communicated to him (using a so-called scaling equation). For example, for systemic effects, exposure time and exposure concentration may balance out each other within certain pre-defined limits. For aquatic toxicity, applied substance amounts and emission factors may outweigh each other (see Appendix G-1 with further examples). => DU and M/I are advised to agree on user friendly tools to carry out such evaluation.
4. DU's practice largely differs from the conditions communicated in the ES and the ES does not provide for a suitable tool to carry out a comparison. However, representative measured data suggest exposure below DNEL or PNEC. In such cases, Article 37 (4d) is not applicable and the DU is obliged to carry out his/her own CSA and send a notification to ECHA. This is because Article 37 (4d) refers to conditions of use and not to predicted or measured exposure levels. => M/I and DU are advised to share information on measured exposure and the corresponding conditions of use before registration. This is to prevent a situation where the single DU would be obliged to carry out DU-CSAs for his raw material, once the registrant submits the extended safety data sheet after registration.

The feedback could for example be facilitated by an interactive website where DUs can make their comments or provide additional information.

D.3.3.3 Agree with DU sector organization on how to make uses known to suppliers

The downstream users of a substance are allowed to make uses known to their suppliers prior to registration and after registration. If DUs provide sufficient information on the conditions of such use one year before the registration deadline (at the latest) they can expect the supplier to i) include the use in his exposure scenarios or ii) to advise against that use based on specified environment or health concerns (see Article 37 (2)(3)).

In order to make such information useful for the suppliers and in particular for the registrants of the substance, it should largely follow the structure of the ES standard template presented in Table D.2-2. In order to keep the information received from the downstream user manageable, M/I may wish to agree with their major customer groups upfront, which information is needed in which form. DU and M/I sector organization may play an important role here to facilitate a structured dialogue towards harmonized approaches.

D.4 DEVELOPING THE CONTENT OF AN EXPOSURE SCENARIO

D.4.1 Aim of the chapter

[7] See section 9 of the ES standard format; a tool (including the supporting information) to help with this evaluation is not necessarily part of the ES but could be also provided at M/I's website or on the website of the corresponding DU sector organisation.

This chapter provides guidance on the contents to be compiled in an exposure scenario. This includes the brief general description of uses, operational conditions of use and risk management measures.

D.4.2 Activities and processes within the life cycle of a substance

Within the CSA, a manufacturer or importer shall assess and document that the risks arising from manufacturing and use of a substance are controlled. According to Annex I (0.3) of REACH, a CSA shall address manufacture and all identified uses of a substance (to the extent that the M/I supports the use or advises against it) and all risks related to consumers, workers and the environment, arising from those uses. It shall consider the use of the substance on its own, in a mixture or in an article as defined by the identified uses. The assessment shall consider all stages of the life-cycle of the substance (Figure D. 4-1) resulting from the identified uses. This includes:

- **Manufacture** of substance in the EU
- **Formulation**: use of substance as such or in mixture for making mixtures (mixing, blending), including filling into containers and re-packaging of substances or mixtures
- **Industrial, professional or consumers[8] uses** of the substance as such or in a mixture in any kind of process, including production of articles:
    - Substance is used as an intermediate and hence consumed in the synthesis of another substance (unless the substance is an onsite or transported intermediate exempted from the CSA requirement on the basis of that it is used under strictly controlled conditions) and/or
    - Substance (as such or in a mixture) is used as processing aid in manufacturing processes, service processes or as a household product. The life cycle ends with reaction on use (e.g. heat stabilizers, reaction promoters, reactive resins), emission to the environment via air and waste water or at waste life stage and/or
    - Substance becomes part of an article (articles service life and the corresponding waste life stage to be considered as additional life cycle stages).
- **Service life** of the substance that has been processed into an article[9], including e.g.
    - substances in plastic, rubber, glass, metal, paper, textile or wood matrix
    - substances in reacted or "dried" mixtures like coatings, adhesives, sealants, putties
    - substances in a metal plating layer
    - substances and mixtures contained in the article matrix, intended to be released (e.g. corrosion inhibitors from packaging, odorants from paper products)
    - mixtures contained within sealed articles (e.g. liquid in a thermometer)
- **Waste life stage:** collecting, treating, disposing off or recycling of the substance contained in waste resulting from the use of the substance as such, in mixtures or articles in any of the life cycle stages before[10].

The volume of substance produced and placed on the market by one manufacturer is distributed into one or more market segments over one or more steps in the supply chain until it reaches its final destination. At each of the life cycle stages exposure to humans or the environment may occur. Consequently a larger or smaller fraction of the substance is lost via emissions and will therefore not enter the next life cycle stage. Figure D. 4-1 visualizes the vertical flow of a substance through the market. In the exposure estimation, the manufacturer must take into account

[8] = use by general public. Consumer uses are not downstream uses in the meaning of REACH.

[9] Using substances in articles is not a downstream use under REACH

[10] Handling or treatment of substances in waste is not a downstream use under REACH.

the sources and different routes on which the substance may lead to exposure of humans and environment. This concerns in particular i) multiple emissions to the regional environment from the different products and market segments to which the manufacturer supplies his product and ii) the various products that may lead to exposure of consumers. A single manufacturer is only obliged to consider multiple exposures for the volume of the substance he is placing on the market. For substances with a widespread or dispersive use, it can be useful on a voluntary basis to consider exposure and emissions for the same substance manufactured or imported by other registrants. Especially, when registrants decide to jointly register such considerations may be crucial as otherwise the risks may be underestimated and lead to action by authorities. Compilation and aggregation of such (possibly CBI sensitive) information can be facilitated by a third party acting on behalf of the SIEF partners.

Between the various life cycle stages, transport, storage and handling may occur. Emissions due to storage, handling, repacking and filling, including local transfer, are assumed to be included within the relevant life cycle stage. Losses during transport are assumed to occur through accidents only. Transport is not considered under REACH.

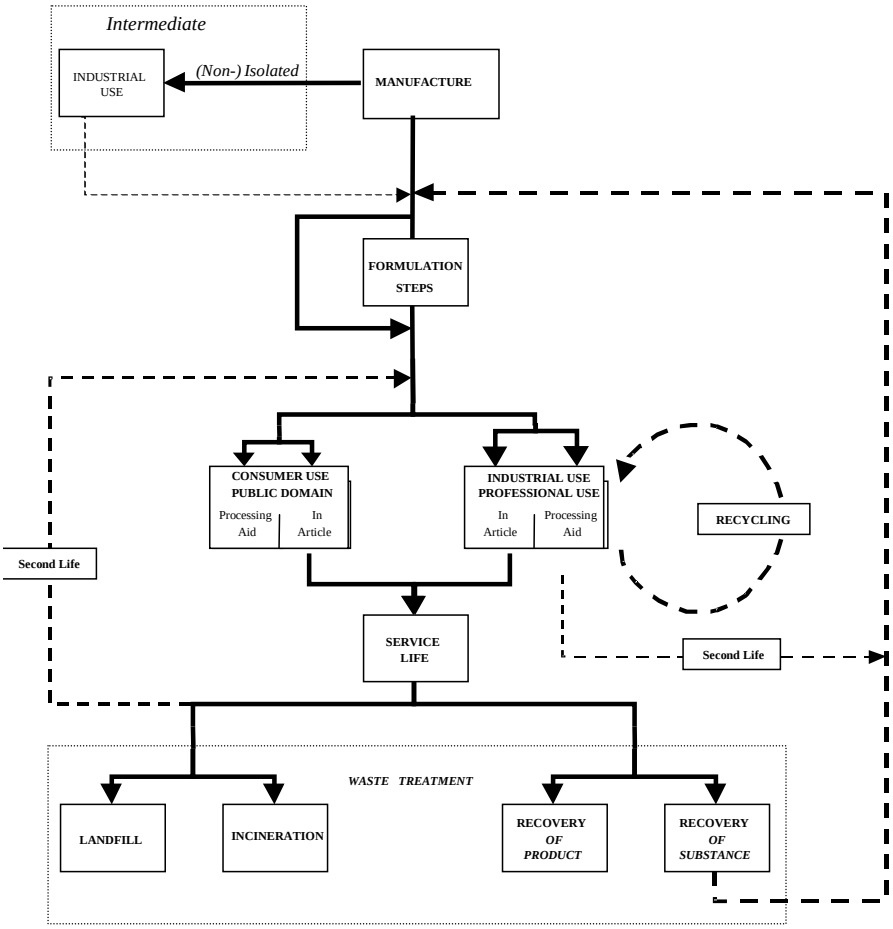


Figure D. 4-1 Life cycle stages of a substance

D.4.3 Brief general description of use and short title of exposure scenarios

D.4.3.1 Functionalities of the descriptor system

Under REACH each manufacturer and importer of substances will have to develop and assess exposure scenarios for his own markets. It would be efficient for him to develop a suite of generic exposure scenarios for the different markets and products, which can be modified case by case if necessary. In doing so, he may be able to link the internal information related to products, markets and customers to exposure and product safety information.

For downstream users it would be efficient to receive standardised exposure scenarios for the relevant applications of the substances in their sector, and not a wide range of different scenarios from different suppliers. In order to support i) the "recycling" of exposure scenario and ii) to facilitate standardisation of exposure scenarios, the following sections outline a system to flag the scope and applicability of an ES in a short title.

Short titles will help the suppliers and customers to structure their communication with each other. Based on the short titles, the DU should be able to quickly establish whether a received exposure scenario *may* cover his uses. It should be also possible for him to describe a use that he wishes to make known to the supplier. The supplier will be interested to receive information on uses in a standardised way from his customers and not in the form of free text letters. Use descriptors can be a useful tool as part of that information package.

The descriptors are designed in a way that they can be used to identify the suitable exposure estimation entry in one of the recommended Tier 1 exposure estimation tool (see Chapter D.5).

Please note: The short title of the exposure scenario is only a label ***and not an ES in itself***. The core content of an exposure scenario are the risk management measures and operational conditions.

The use descriptor system being part of the CSA Guidance is also available in IUCLID 5 to support the description of identified uses in the registration dossier.

D.4.3.2 Definition of the four descriptors

The use description is based on four elements: sector of use (SU), chemical product category (PC)[11], process category (PROC) and article category (AC). This is exemplified in Figure D.4.2

[11] Refers to mixtures and a few types of substances (e.g. intermediates, solvents, …)

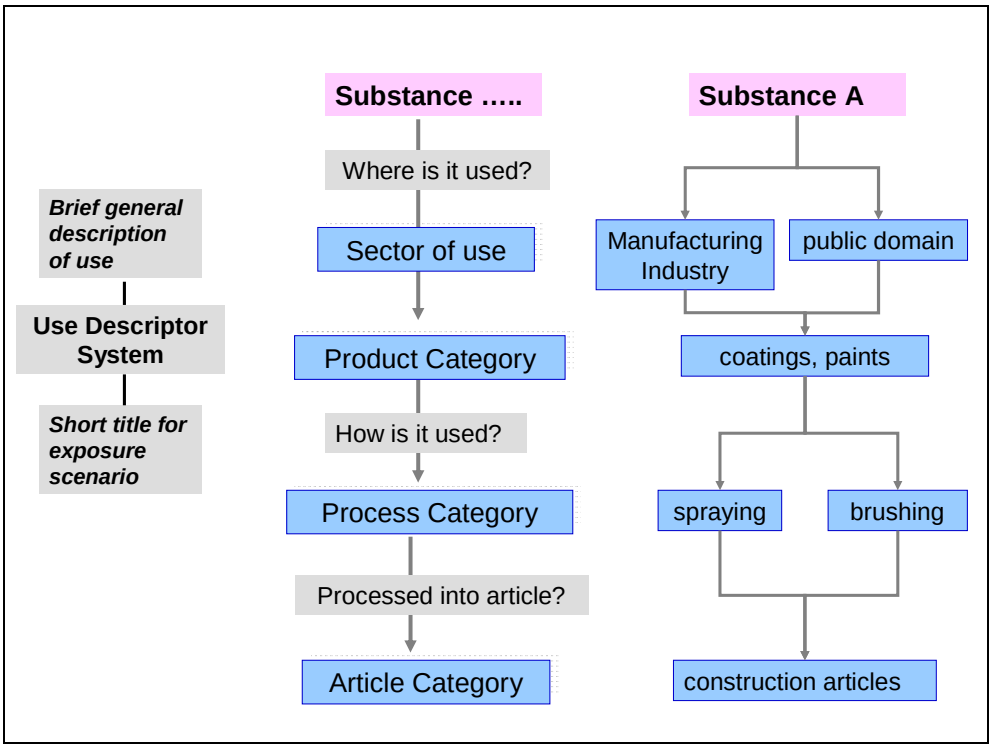


Figure D. 4-2 Descriptor system for short titles and a brief general description of use

Chapter R.12 provides pick-lists for all 4 descriptors and further guidance on how to use the descriptors.

The process categories are derived from the ECETOC *Targeted Risk Assessment* (TRA) related to occupational exposure. They define 19 typical exposure situations at workplace, which can be also linked to default exposure estimates. The descriptor system also includes a number of categories which are not linked to default exposure estimates yet but which may nevertheless be suitable to describe uses.

The product categories are derived from existing use categories of substances as applied in the Technical Guidance Document on Risk Assessment (2004)[12] and in Nordic Product Registers[13], but have been focused on categories of end-use mixtures (industrial, other professional, consumer). The pick-list includes the consumer product categories incorporated into two of the widely used tools related to consumer exposure: ECETOC *Targeted Risk Assessment* (TRA) [14] and ConsExpo[15].

The article categories are built on the categories incorporated into the ECETOC *Targeted Risk Assessment* (TRA) related to consumer exposure.

The *sector of use* categories have been derived from the NACE system but tuned to in a way that they can support communication in the supply chain in a very flexible way.

[12] http://ihcp.jrc.ec.europa.eu/our_activities/health-env/risk_assessment_of_Biocides/doc/tgd

[13] http://195.215.251.229/DotNetNuke/default.aspx (link to the SPIN Database)

[14] http://www.ecetoc.org/tra

[15] http://www.rivm.nl/en/healthanddisease/productsafety/ConsExpo.jsp#tcm:13-42793

Each of the four pick-lists includes a free text field entry to add use description if needed. It is recommended to make as much as possible use of the terminology already defined in existing, internationally harmonized systems (see Guidance Chapter R.12).

D.4.3.3 Flexible use of the four descriptors

Proper description of the identified uses of a substance and meaningful titles of ESs may often need a combination of all four descriptors. But there may be also substances and uses where this is not the case. It is up to the manufacturer or importer to determine the appropriate level of detail and the appropriate level of aggregation to flag the content and scope of an ES. If a title for an exposure scenario cannot be built based on the available entries in the pick-list, it is always possible to add a more suitable description in the free-text field at the end of each list. Iterations may be needed here as well, since the increase in knowledge as a result of the CSA process may lead to modification to the scope of exposure scenarios.

Grouping of uses (at the same or at different life cycle stages) under one ES may be appropriate under the following conditions:

- In general, the same operational conditions and comparable risk management measures apply, and
- the information on the conditions needed to control the risk is relevant to the single recipient/addressee of the ES as annexed to the SDS.

Generalisation of ES for nanomaterials, as with other substances, will always need to be justified. For nanomaterials this would not just be based on substance composition but would also need to take account of other parameters such as particle size distribution. (See appendices on recommendations for nanomaterials to chapters R8, R10 and R14)

NB! Grouping cannot be done on ES titles alone without considering the content of the ES.

Such grouping during the CSA process - or in other words defining use - and exposure categories with different levels of aggregation (relatively narrow to a wide range of uses) - is an important preparatory step for rationalizing the communication of ES down the supply chain. The overall workflow foresees two steps where grouping may play a role: In step 3 when selecting categories to run tier 1 exposure estimates and in step 13 when possibly merging ESs, based on the final risk characterisation. *Use and exposure categories* can only be built based on the results of the CSA (see Section D.3.2, step 13).

D.4.3.4 Example for the brief general description of uses in a CSR

Table D.4-1 illustrates how a “map of uses” based on the standard descriptor system may look after step 1 of the general workflow. The example refers to a solvent with a relatively low hazard profile (classified to have irritant effects to skin and eyes) and a broad market.

Table D.4-1 Overview on uses for a solvent with a broad market[16]

Preparation category		Inter Mediate	Textile dyes	Adhesives Sealants	Auto. Care	Coatings Paint	Building construct.	Ink& Toners	Polishes &Wax	Washing Cleaning	Lubri-cants	Hobby Artist
Process Category for industrial and professional use		PC19	PC 34	PC 1	PC 6	PC 9	PC 10	PC 18	PC 31	PC 35	PC 24	PC 5
PROC 2	Continuous processing operations; occasionally controlled exposure	X	X	X		X		X	X	X		
PROC 5	Mixing/blending in batch process; multi-stage, significant contact	X	X	X		X		X	X	X		
PROC 9	Transfer to small containers (dedicated filling line)	X	X	X	X	X	X	X	X	X	X	
PROC 10	Handling, cleaning of treated surfaces		X		X	X	X	X	X	X		
PROC 13	Immersion operations		X	X	X	X				X		
PROC 11	Air dispersive techniques		X		X	X	X					
PROC 10	Low energy spreading		X		X	X	X	X	X	X		
PROC 15	Laboratory operations	X	X			X		X	X			
Sector of uses for substances such or in preparation												
SU 21/22	End use in public Domain and private households		X	X	X	X	X	X	X	X	X	X
SU 8-10	Chemical manufacture and formulation	X	X	X	X	X	X	X	X	X	X	X
SU 3	General article manufacturing industries		X	X	X	X	X	X	X	X	X	X
SU 16	Semiconductor industry											

[16] Please note that table D.4-1 is not aligned with new version of Chapter R12: Use descriptor system

D.4.4 Pre-set initial exposure scenarios

The use descriptors can help to structure and group the identified uses in a sensible way for exposure scenario building and exposure estimation under REACH. The product and process categories can be used to assign preset assumptions on exposure pathways, typical OCs and RMMs, in order to get the initial exposure assessment started.

The pre-defined exposure scenarios do not always include all relevant determinants that influence exposure for a specific use. In such situation, it must be assessed which impact on the exposure these determinants may have. In some cases, the input of the model can be modified to reflect the impact of additional determinants. For assigning the right categories to a use it can be necessary to first collect more information on the conditions of use (see refinement circle at step 2/3 of the workflow), or to work with the categories of another more suitable Tier 1 tool.

If it is not possible to characterise the use with the available categories and one of the recommended Tier 1 tools in a satisfactory way, the standard workflow stops at this stage and the further development of the ES has to be based on case by case considerations which may include a higher tier assessment. It is for example likely that some hot work operations in the metal industry are not addressed in any of the available Tier 1 tools so far. In such cases, the related sector of industry may initiate development of a tool, or the single registrant will need to carry out a case-specific higher tier assessment, e.g. based on measured data made accessible through his customers.

How to practically run a Tier 1 exposure estimate is briefly explained in Chapter D.5 while detailed information on exposure estimation is given in Chapters R.14 to R.18.

The categories used as entries into the Tier 1 exposure estimation tools refer to the following aspects of the use:

- Category of process or technical activity (worker); see use descriptor *PROC* in Chapter R.12
- Category of chemical product (=type of mixture) or article (consumer); see use descriptor *PC* and *AC* in Chapter R.12

In order to enable environmental exposure estimates for the initial exposure scenarios, *environmental release categories* (ERCs) can be used in step 4 and 5 of the generic workflow as outlined in Section D.3.2 (see Appendix D-3). These reflect the extent of containment and the technical fate of a substance in a process, the production volume of the substances, the number of emission days, the dispersion of emission sources (point sources or diffuse emissions) and the availability of municipal waste water treatment. ERCs have been defined based on a combination of these determinants (see Appendix R.16-1). They include pre-set values for the determinants leading to realistic worst case emission estimates at local or regional scale. Each ERC includes a default release factor which is based on the assumption that no risk management measures are in place (uncontrolled emissions)[17].

Appendix D-4 and Appendix D-5 connect the process and article categories with the environmental release categories. For example: Each article category is linked to one or more of the ERCs available for articles. Each industrial process category is linked to one or more of the ERCs available for local industrial emission sources.[18]

[17] Please note that the default emission factor reflect process and product techniques as applied in the late 20th century.

[18] Please note that appendices D-4 and D-5 are not aligned with new version of Chapter R12: Use descriptor system

Please note that the default release factors currently used in the ERC approach may need further work in terms of documenting the underlying assumptions. ERCs are meant to be used in situations where the relevant sectors of industry have not yet developed emission estimation modules realistically reflecting the conditions of use in their area. In the long run, more specific sector related environmental release modules may become available that can be used instead of the generic ERCs. Thus ERCs should also be understood as a template and starting point to collect information for ES building rather than only as a tool to estimate exposure for an initial ES. Further guidance see Section D.5.5.1

An example how to use an ERC as a starting point for ES development is illustrated in Appendix D-2

D.4.5 Conditions of use for controlling risk

D.4.5.1 Aim of this section

The determination of appropriate conditions of use to control risks, including evaluation of their effectiveness, is part of the ES generation process. In many cases, current operational conditions and risk management practice may already ensure control of risk, and thus the registrant will only need to demonstrate this in his CSR, and to communicate the appropriate RMM and the related operational conditions in the extended SDS. In other cases, the manufacturer will be unable to demonstrate control of risk based on current practice in the supply chain. In such cases, he needs to i) identify and recommend additional or other risk management measures or ii) identify and recommend changes in the operational conditions of use or iii) advise against certain uses. As an alternative, M/I could invest in refining the exposure estimate or the hazard characterisation in order to lower uncertainty and hence decrease the required level of conservatism in the risk characterisation.

The aim of this section is to provide guidance on

- how to include RMMs in ES building and how to translate RMMs into exposure quantification
- how to express RMMs in a systematic and transparent way and how to use information from the RMM library

D.4.5.2 Operational conditions and risk management

Both, risk management measures and the operational conditions determine exposure. Changes to the operational conditions can do both: contribute to the control of risk (like RMM do), or rather the opposite, create the need for additional RMMs. Consequently, M/I should always consider the risk management measures and the operational conditions in close relation to each other.

In the understanding of the current guidance, both OCs and RMMs address a partially overlapping set of actions, uses of tools, parameter states or specific substance emissions, but differ in ***their intention***: While impact on exposure is only resulting as a side effect from changing the operational conditions, risk management measures are intended to prevent, reduce or limit exposure.

It is important to assess and communicate how the conditions of use (the combination of operational conditions and risk management measures) will impact on exposure in quantitative terms. Thus, the exposure reducing effect needs to be expressed in quantitative terms (to the extent possible) that can be fed into exposure estimation during the CSA. This value can either indicate the absolute effectiveness of a risk management measure, or it can indicate the relative change in the effectives of risk management measures that already exist.

RMMs reducing exposure of one environmental compartment or group of humans may increase exposure of other compartments of groups (e.g. exhaust ventilation at workplace without proper emission control related to the environment). OCs may have different effect on different compartments or groups (e.g. the critical amounts per time or activity related to workplace and environment). Furthermore, reduction of exposures during one life-cycle stage may increase exposure during another life-cycle stage (e.g. disposing of aqueous residues as waste instead of discharge to the sewage system). These interrelations need to be based on common mass balance principles.

D.4.5.3 Types and hierarchy of measures to control risks

REACH requires the exposure assessment and risk characterisation of the single substance in its identified uses. Other factors determining risk at the same time (e.g. other substances, non-chemical factors) will necessarily not be taken into account in a CSA under REACH. Thus, risk management measures identified in a CSA will mostly complement the risk management already required under other legislative frameworks, like under the EU Chemicals Agent Directive (CAD) or the Directive on Integrated Pollution Prevention and Control (IPPC). Information collected and analysed under other frameworks is one source of information to compile risk management measures and operational conditions for exposure scenarios under REACH: e.g. guidance documents worked out by the European Agencies in Bilbao (CAD) and Sevilla (IPPC) or by national authorities (e.g. COSHH Essentials by the UK HSE or TRGs by the German BAuA).

The assessment in a CSA can e.g. lead to the conclusion that the established risk management practices in a certain market or sector of industry are insufficient to control the risk of a particular substance. In such cases, the manufacturer or importer of a substance will suggest additional or other risk management measures. And vice-versa, the downstream user may identify the inappropriateness of risk management measures communicated to him and will communicate up the chain accordingly.

The single substance assessment under REACH may lead also to a set of operational conditions and risk management measures, which are less demanding than the established risk management practices. This should however not lead to the conclusion that the established good practice is over-protective or unnecessary. Since the REACH CSA has mainly a single substance perspective it is not suitable as a method to identify all measures needed to protect human health at the workplace or at home or to protect an ecosystem.

When developing the exposure scenarios for a substance, M/I may need to consider a whole range of measures potentially available to control risks with regard to human health and the environment. As a matter of principle in EU legislation, prevention of risk at the source has priority over end-of the pipe emission abatement, personal protection measures at workplaces or behavioural measures addressed to consumers or workers. In order to define an effective way of controlling the risks and to support the downstream users in complying with these principles of other legislation, M/I should consider the measures to control risks throughout the supply chain in the order of the general hierarchy, e.g.:

- Which uses of a substance should be prevented? Such uses should be explicitly advised against in the safety data sheet or excluded from the scope/domain of an exposure scenario. This type of measure may promote the implementation of the substitution principle as for example established in the EU legislation on health and safety at workplaces.

- How can the exposure potential to a substance in a mixture or in an article be reduced at product level? Such measures may include changes in the physical state of a product (e.g. low dust grades), and/or limiting migration rates for article matrix and/or reducing the concentration of a

substance in a mixture and/or reducing the amount of substance per time or application. Also the design of packaging belongs under this type of measures.

- Can exposure be prevented or reduced through better containment of processes?
- Can exposure be reduced or limited through limiting the time and/or frequency of working with the substance?
- Is it possible to reduce emission through process integrated measures, e.g. minimising losses of dyes, coatings or inks during the application process?
- Is it possible to reduce or control occupational exposure through local exhaust ventilation?
- Is it possible to reduce emission by applying specific or general air emission and water emission abatement techniques?
- What kind of personal protection equipment (PPE) is needed in which situations?

When selecting measures for the exposure scenario, M/I should take into account, whether the measures are realistic and proportionate with a view to the expected level of exposure, the hazard of the substance and the risk management capacity of the downstream users.

D.4.6 M/I's information sources with regard to risk management

Where the substance is used in the chemical industry itself (manufacturing of substances or formulation of mixtures), manufacturers can be assumed to have sufficient in-house information to compile the risk management measures needed to control the risk and to make assumptions of the effectiveness of the measures. M/I directly supplying end-use mixtures or specialised additives for end-use mixtures can also be expected to have significant in-house information on the conditions of use further downstream. Compared to that, M/I selling their substances as such or in a mixture to formulators or distributors may have less information available in-house.

Where life cycle stages or markets further down the supply chain have to be assessed, the manufacturer should make use of available information on the existing risk management practice and the likely risk management effectiveness under the operational conditions for that use. This applies in particular to situations when engineering solutions (e.g. local exhaust ventilation) are required to control risks. Where such information is not readily available M/I will need to carry out investigations in order to complete his safety assessment.

During the ES development the registrant will probably use RMM information of different nature and from different sources, including:

- A first identification and grouping of typical RMMs may be based on in-house information, including the information contained in the existing SDS supplied to the customers (sections 7, 8 and 13 of SDS).
- RMM packages relevant in certain sectors or for certain product groups, worked out by experts[19] and having proven their effectiveness (documentation available). Downstream user organization and institutes or state agencies for occupational safety and hygiene as well as employer's liability insurance associations may be the holder of such information. Often such "packages" are documented as technical guidance provided by authorities, sector organization or workers insurance organizations. A compilation with examples of such packages is accessible through the RMM library (see Section R.13.4).

[19] E.g. relevant information may be available through risk assessment at workplaces under the Chemicals Agent Directive or application and permits under the IPPC Directive.

- EU Documents and *best available techniques* (BAT) containing information on integrated pollution prevention and control measures in various sectors of industry. *OECD Emission Scenario Documents* (see Appendix R.16.2) containing information on determinants of emissions of substances from various products and processes.
- Scientific publications on the effectiveness of particular risk management measures in certain sectors of industry or certain processes.

D.4.6.1 Effectiveness of RMMs

Information on the mitigating effect of risk management measures is needed for assessing the associated exposure reduction. Thus, the effectiveness of a measure needs to be expressed in a way that it can be fed into exposure quantification. Since the effectiveness of RMMs is often not a fixed value but a distribution depending on various factors, assumptions on the effectiveness of measures usually need documentation of evidence. The empirical data may often be present at company level. However, such data is not always publicly accessible in a well documented form. For further consideration see Section R.13.3.

In general, the effectiveness can be expressed in three ways:

- as a factor by which the exposure is likely to decrease if the measure is added to a given situation (e.g. local exhaust ventilation depending on the type of industry where it is applied; on-site treatment of waste water);
- as an exposure level likely to be not exceeded under a defined set of operational conditions and RMM (see control guidance sheets in the COSHH Essentials system or *VSK*s[20] set up based on TRGS in Germany);
- as prevention of exposure based on the technical description of the measure itself (e.g. suitable type of glove, sealed system) (qualitative description of effectiveness).

Section R.13.4.3.6 explains in more detail how RMM effectiveness (or efficiency) is understood in the context of the RMM Library (see Section D.4.6.2). In this library, the effectiveness is defined as:

- ***RMM effectiveness*** is generally defined as the percentage reduction in exposure concentration or emission (release) produced by application of the risk management measure. However sometimes an absolute exposure value may be a more appropriate indicator.
- In practice, the effectiveness of any RMM varies and cannot be adequately described by a single value. The information in the library on RMM efficiency is determined by two descriptors: a "**typical default value**" (an estimate of the 50th percentile) and a "**maximum achievable**" value (best practice).

If M/I assumes a certain effectiveness of a measure, the source of this assumption needs to be documented in the CSR. It's the responsibility of M/I to make sure that the assumption is taken from a reliable source and applies to the conditions of the specified use (e.g. practices and operation of equipment). This may be based on scientific publications or on the default assumptions used in widely accepted exposure estimation tools. In the RMM library, some RMMs are connected with an indication of the effectiveness. The library provides a link to the corresponding source so the M/I can evaluate the reliability of the information. Where M/I can't demonstrate control of risk without additional RMMs and the effectiveness of a technically suitable RMM cannot be derived from reliable literature, M/I is advised to consult customers (who may have data available e.g., from measurements) or to carry out own measurements.

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

Usually the registrant will assume a certain, realistic effectiveness of a measure and communicate this as a requirement to the DU. It will be on the DU to evaluate whether in practice the measure is implemented as recommended by M/I, e.g. a local exhaust ventilation of a certain effectiveness. Otherwise he will communicate back or carry out an own CSA.

M/I may also identify DU processes in which substances with a certain hazard profile should not be used (e.g. respiratory sensitizers in spray applications). Additive RMMs (e.g. LEV) may not be the right strategy in such cases, regardless of any effectiveness seeming achievable. In such cases, M/I may suggest to switch to a closed system or advise against the use completely (100 % effectiveness).

D.4.6.2 The RMM library

In order to facilitate effective and accurate communication in the supply chains across the European market, M/I and DUs are advised to use a standardised system to structure and describe RMMs. A library of RMMs has been developed containing a first structured collection of available RMMs for the different target groups and exposure routes. This includes product related measures, technical measures, informational measures and organizational measures For more details see Section R.13.4.

The RMM library is meant to be a living instrument under REACH to make accessible the risk management advice existing in various sources across Europe. This may relate to sectors, product groups, processes or single horizontal measures like personnel protective equipment (PPE). The library is available on CEFIC's REACH website[21]. The content of the library, including the information on effectiveness of certain risk management measures has not been validated during the development of the current guidance. Thus the RMM library cannot be quoted in the CSR as providing scientific evidence on appropriateness of RMMs related to a certain exposure scenario.

If a sector organization for example has worked out RMM guidance for certain product groups, a link can be stored in the library to make this information accessible to registrants of substances. Also, *control guidance sheets* for certain standard processes, as for example contained in the *COSHH Essentials* by the UK HSE or published as so called *VSKs*[22] by the German authorities can be identified via the library.

Information from the RMM library can help the registrant or the DU to communicate about RMMs or to identify suitable RMMs for certain products, processes or sectors.

The library is also meant as a tool to communicate the core information of a risk management measure in standardised phrases.

Also, the RMM library provides a starting point for reasonable assumptions on the effectiveness of RMM. However, it remains the responsibility of M/I to make the appropriate assumptions related to the impact of the measures proposed and the responsibility of DU to evaluate whether these assumptions are valid in practice. Thus, the library is a source of information and helps to trace the background of proposed assumption of RMM effectiveness but it is not an expert system.

21 http://www.cefic.org/Industry-support/Implementing-reach/Libraries/

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

D.4.6.2.1 Organisation of the library

The risk management library distinguishes 31 types of RMMs and safety instructions.

Table D.4-2 Overview on RMMs and safety instructions in RMM library

Product-Substance Related:		18	Local Exhaust Ventilation - receptor hoods
1	Limiting concentration of hazardous or non-hazardous ingredient	19	Local Exhaust Ventilation – specialised applications
2	Change of physical state (e.g. powder -> pellet)	**General Dilution Ventilation:**	
3	User friendly packaging (reducing handling)	20	Dilution Ventilation
4	Info / Guidance / Manual other than label and Safety Data Sheet	**Organizational:**	
Marketing and use related		21	Management Systems
5	Marketing and Use - General	22	Operating Practice
6	Product safety / advice	23	Competence and training
Process / Control Change:		24	Supervision
7	Process Control / Change	25	Monitoring
8	Automation	26	Health Surveillance
9	Containment of operator	**Good Hygiene Practices & Housekeeping:**	
10	Cleaning of process equipment	27	Good Hygiene Practices & Housekeeping
11	Spill Containment Measures	**Personal Protective Equipment:**	
12	Reduction and cleaning of air emissions	28	Body protection
13	Reduction and cleaning of waste water	29	Hand protection
14	Reduction of waste, disposal of waste	30	Respiratory protection
Ventilation Control:		31	Face / Eye protection
15	Local Exhaust Ventilation - (partial) enclosure		
16	Laminar Flow Booths & Laminar Flow Benches		
17	Local Exhaust Ventilation - captor hoods		

The library includes different entries to find relevant information:

- Individual measures listed under the 31 headlines presented in Table D.4-2.
- Risk management packages searchable by a combination of product category and sector of use
- List of reference documents, sorted according to consumers, workers and environment

D.4.6.2.2 How to work with the library

M/I may consult the library in the following steps of the general workflow (see Section D.3.2)

- When compiling the in-house information on the conditions related to the uses identified during the mapping, M/I may wish to make himself aware on any sector or product specific RMM guidance developed by sector organisations or authorities (step 2 of the general workflow).
- When building the initial exposure scenario, M/I may wish to replace default assumptions on release and exposure with available information on risk management and the related effectiveness (see step 4 in the general workflow).
- When completing the initial exposure scenario (step 5 in the general workflow), M/I may wish to use already standardised phrases to describe RMMs and the related operational conditions of use.
- When incorporating the feedback from DUs into the ES and when carrying out further iterations, M/I may wish to i) express additional RMMs or refined RMMs in standardised phrases and ii) to identify a realistic effectiveness for such measures. In both cases M/I could consult the library (step 8 of the general workflow).

- When deriving the final, integrated ES (step 12/13 of the general workflow in Section D.3.2) M/I should phrase the core content of the risk management measures to be communicated to DUs based on the standard phrases contained in the library.

Section R.13.4 contains more specific guidance on how to work with the RMM library. Further technical advice on how to operate the excel spreadsheet is contained in the library itself.

D.4.6.3 Workflow for selection and iteration risk management measures

The workflow to identify or refine suitable risk management measures is an integral part of the general workflow as outlined in Section D.3.2. The following table specifies the actions with regard to RMMs and related operational conditions. The left hand column makes reference to the general workflow in Section D.3.2)

Table D.4-3 Workflow to select and iterate risk management measures

Ref No	Work flow	Output
2	**Compile in-house info on RMMs and OCs as a starting point**: These should cover i) e.g., the measures imposed by the Directives 98/24/EC and 89/391/EEC on occupational risk management and ii) the measures foreseen in the BREF documents under the Directive 96/61/EC on Integrated pollution prevention and control and iii) consumer related measures. Compile any advice against certain uses, (as currently listed under section 16 of the current SDS) Evaluate whether these RMMs and OCs cover all uses in the life cycle of the substance M/I is aware of. Flag uses where no in-house information on RMMs/OCs exists, or where the existing information is not detailed enough. Consult the RMM library, whether recommended RMM packages exist for particular product types, sectors of use, or technical processes. NB: *M/I directly supplying end-use mixtures can be expected to have significant in-house information, while M/I selling their substances as such or in a mixture to formulators or distributors may have less information available in- house.* Where M/I has made himself aware that in-house information is largely lacking, and also the RMM library does not provide suitable information for a certain use, M/I will decide whether, when and how to start dialogue with representative customers or their associations.	inventory of availability on substance or use specific in-house information on RMM
4	**Quantify RMM effectiveness in initial ES**. Compile the information needed to carry out a Tier 1 exposure estimate, including the information related to RMMs (e.g. limited concentration of substance; limited amount per application, time, or site; limited use/exposure time; waste water treatment; local exhaust ventilation; ….) and run first exposure estimation. *NB : Where measured exposure data are available of a suitable quality and the underlying RMMs/OCs are known, they can often provide more accurate estimates of RMM effectiveness at the local level.*	Values for input parameters to run a tier 1 exposure estimate
5+6	**Detail OCs and RMMs**. If it seems possible to demonstrate control of risk based on information from step 2 or 4, compile an initial exposure scenario based on the quantitative information from previous step. Follow the objectives and hierarchy of measures as described in Section D.4.5.3. Consider who is expected to understand the RMM/OC advice. Consider whether the immediate DU (customer) is expected to a) **forward** the advice to the next levels in the supply chain or b) will **include** the advice into a safety data sheet for a mixture or c) will **apply** the advice for his own	RMMs and OC covering all identified use(s), based on standard phrases.

Ref No	Work flow	Output
	processes. Decide on the type of standardised phrases needed to compile the narratives around the quantitative information. M/I will need to make himself aware on the technical language existing in an end-use sector **or** will agree with the immediate DUs of type b) that the appropriate detailing and phrasing of RMM is best done by the immediate DU. Add narrative description on processes, risk management measures and operational conditions as appropriate. Use standardised phrasing from the RMM library or suitable other catalogues (e.g. sector specific) that have been adapted to REACH requirements. Assign a short title. Sent to representative customers for feedback.	
6-9	**Iterate RMMs/OCs.** Depending on feedback from customers, iterate the risk management measures. This may be based on rephrasing, refinement of input parameters by information from representative customers, or by application of RMM/OCs directly accessible through the preferred Tier 1 tool(s). Where this is not possible, use the library to apply additional RMMs that can be transformed into iterations of the Tier 1 tool(s) (see Tables R.13-1 to R.13-3, or go to step 10.	Refined exposure scenario Conclusion whether control of risk can be demonstrated based at Tier 1
10	**Go beyond Tier 1 assessment.** If, based on step 1 to 8, M/I can't demonstrate how risks can be controlled in all identified uses, he can switch to a Tier 2 model or use representative measured exposure data (for further details see Chapters R.14 to R.16).	Refined exposure scenario
12/13	**Integrate the relevant RMMs and OC** within an exposure scenario as appropriate. Consider the interest of the downstream users to receive one set of RMMs/OC leading to integrated risk management at company level.	Final exposure scenarios

D.5 EXPOSURE ESTIMATION

D.5.1 Aim of this section

When an initial exposure scenario has been developed it has to be tested whether the information collected is sufficient to demonstrate that the risks occurring from the manufacture and all identified use(s) are controlled. Often this will be an iterative process, where step-by-step improved exposure estimates are compared to the derived no-effect or minimum effect levels (DNELs, PNECs or DMELs) at each iteration. This can be done by generating exposure estimates for all identified uses described in the exposure scenario.

The process for estimating exposures during the development of exposure scenarios consists of 2 stages: the first step (also termed Tier 1) aims at estimating the 'reasonable worst-case' exposure for the conditions of use described in the initial exposure scenario. Such estimate can be obtained using actual measurements or standard exposure models and where possible, preset conditions of use as defined for certain process or product categories. A subsequent step (sometimes termed Tier 2) may be required if control of risk cannot be demonstrated for the initial exposure scenario in the Tier 1 process. Tier 2 focuses on typical well-defined exposures with appropriate knowledge on the confidence limits involved, based on uncertainty and variability of the relevant parameters.

This section explains how to use available data and estimation models at the Tier 1 level to derive a (semi) quantitative release and exposure estimation for an exposure scenario. Details of the considerations which would apply to Tier 2 evaluations, including exposure estimation methods and algorithms are given in Chapters R.14 to R.18.

D.5.2 Measured exposure data

Ideally, the process for estimating exposure would be based on actual measurements for the use of the substance in each scenario. But this will not always be possible. Therefore, it will often be necessary to either combine actual and modelled estimates of exposure, or to rely solely on modelled estimates. Sometimes it may also be possible to estimate exposure based on measured data for another substance which however possesses similar physico-chemical characteristics or similar properties regarding its environmental fate.

Provided such data are of a suitable quality and are supported with sufficient information that enables them to be seen as being representative of any Exposure Scenario, then such data will reflect the reality of the use rather than any modelled representation. The incorporation of the exposure measurements into the process for exposure scenario development needs to account for a number of considerations (which are described in more detail elsewhere[23]):

- are the data appropriate for the scenario being investigated, i.e. is there sufficient information on RMMs and OCs that were in place when measurements were performed?
- are the data supported by sufficient contextual information such that their relevance to the scenario can be determined?
- have the data been obtained using appropriate sampling and analytical techniques to yield the necessary sensitivity?
- are sufficient data points available to be seen to be representative of the exposure scenario being evaluated?
- have background concentrations been taken into account for particle measurements?

For measured data related to environmental concentrations a number of additional considerations have to be made:

- Have the data been properly assigned to the appropriate spatial scale (local or regional scale) by taking into account sources of exposure and the environmental fate of the substance?
- Have background concentrations been taken into account for naturally occurring substances?

It is also important to recognize that available exposure data have a role not only in the process for developing any exposure scenario, but also in evaluating the effectiveness of the recommended risk management measures (RMMs): The Exposure Scenario describes those RMMs and operational conditions (OCs) sufficient to control workplace exposure to below the DNEL for the substance. Therefore, workplace exposure monitoring constitutes a valuable tool for helping DUs determining the integrity and validity of the exposure control advice received from further up the supply chain. The same applies to measured data on emission of substances to the environment via waste water or waste air and indoor exposure of consumers.

[23] Principles Of Data Quality In Chemical Exposure Assessment, IPCS, 2008

D.5.3 Occupational exposure estimation assessment

In the workplace, exposure to chemicals occurs via three exposure routes: inhalation, dermal contact and oral intake. For the determination of exposure through these routes, one can use either measured data and/or predictive estimation models. Where measured data are available, then these are preferred to exposure estimates derived from models. Furthermore, while measured data might often be available for inhalation exposure, data that characterises dermal or oral exposure is much less frequent. It will therefore be necessary to develop any estimate of exposure for the Scenario based upon combinations of available data (real and modelled estimates). In this respect, all or some of the determinants described in Table D.2-1 could constitute required inputs for the exposure estimation models.

D.5.3.1 Data from measurements

Available workplace exposure data should have a central role in the process for exposure estimation. Extensive guidance has been developed on how exposure monitoring strategies can be developed and implemented to evaluate the effectiveness of recommended risk management advice[24]. Generally, the process for developing any Exposure Scenario would not normally require exposure monitoring to be initiated, but, rather, the process needs to take adequate account of available exposure data from actual, analogous and modelled sources (and see Chapter R.14)

D.5.3.2 Modelling approaches

In principle there is a wide range of exposure estimation models that could be used to estimate exposures for the specific purpose of developing an ES. These models vary in their complexity and purpose. Some models have been developed with a specific intent that are simple-to-use, but inherently conservative, and are therefore best used as initial screening (Tier 1) models i.e. they enable a defined range of ESs and RMMs to be quickly evaluated e.g. the ECETOC TRA, COSHH-BAuA-Tool and Stoffenmanager. Other (often more demanding) models have been developed for other purposes, such as exposures to agrochemicals (e.g. EUROPOEM) or biocidal products (e.g. a range of model approaches in the Technical Notes for Guidance for human exposure to biocides). These models often provide more accurate estimates of true exposures, but because they demand expert knowledge to operate them, are generally only used if a Tier 1 approach indicates a potential for concern. A model approach has also been developed specifically for dermal exposure estimation (RISKOFDERM model).

The focus of this document is on Tier 1 models that have been specifically developed for the occupational exposure estimation. These and some of the other (higher Tier) models are described in more detail in Chapter R.14.

Inhalation

For the inhalation exposure assessment for workers, M/I or DU may consider the ECETOC TRA as the preferred Tier 1 exposure estimation model. As an alternative, one can use the *Easy-to-use Workplace Control Scheme* for hazardous substances (COSHH-BAuA tool). Also the *Stoffenmanager* may be a suitable tool.

[24] Workplace atmospheres – Guidance for the assessment of exposure by inhalation to chemical agents for comparison with limit values and measurement strategy. CEN 689. European Committee for Standardization (CEN), Brussels, 1995.

Dermal

For the dermal exposure assessment for workers, M/I or DU may prefer the ECETOC TRA and RISKOFDERM Dermal model. The RISKOFDERM Dermal Model is considered to be a higher Tier tool and is described in Chapter R.14.

Oral

Oral exposure for workers is generally not assessed as there are currently no methodologies or tools available to do this. It is often assumed that basic personal hygiene mitigates against oral exposure but this is not always the case. Where biological monitoring data are available, all potential exposures, including oral, can be taken into account.

D.5.3.3 ECETOC Targeted Risk Assessment for occupational exposure[25]

M/I may consider the ECETOC TRA model as the preferred tool for estimation of worker exposure by inhalation. For dermal exposure the tool should be used assuming no local exhaust ventilation (LEV), as it has been found that the tool underestimates the dermal exposure when the presence of local exhaust ventilation is assumed. In such case, a check for mass balance of the total exposure (inhalation and dermal) may be useful. The ECETOC TRA model is currently being updated. For further details on how to use the tool and status of the updates see Chapter R.14.

The ECETOC TRA method for estimation of exposure via inhalation and dermal contact is based on the EASE model, which is divided into an inhalation model and a model for potential dermal exposure. The TRA in its current version assumes no personal protection equipment being in place as a risk management measure.

The model for inhalation exposure assumes that the concentration of a substance in the workplace atmosphere can be predicted by analogy with similar situations, in this case, situations where the exposure concentration has been measured. Three types of workplace determinants are used to characterize inhalation exposure:

- the tendency of the substance to become airborne (physical state),
- the way in which the substance is used; an extensive exposure database is used for calibrating the model,
- the means of controlling exposure or of preventing the substance from entering the workroom atmosphere.

The EASE model for dermal exposure, which is used as a basis for the ECETOC TRA model, is much more rudimentary than the inhalation model. It is to a much lesser degree based on measured data, due to the general lack of reliable measured data at the time of the model establishment. The structure for dermal exposure is similar to the inhalation model in that it includes the same three parameters: physical state, pattern of use and pattern of control. The latter two parameters are presented in a simplified form given the lack of reliable data for dermal exposure.

Input data

As input data only a few determinants are needed:

- Duration of activity, use of local exhaust ventilation (yes/no), ECETOC process category[26] (see Appendix R.12-3 and Chapter R.14 for a further description), vapour pressure of substance (if

[25] http://www.ecetoc-tra.org

liquid) or dustiness (if solid). In Table D.5-1 this information is inserted into the ES standard format.

Table D.5-1 Input data needed to run tier 1 exposure estimate related to workers

Information element		TRA	COSHH-BAuA
Substance properties		Vapour pressure	Vapour pressure, boiling point
1	Short title of ES	One/more of 20 pre-set scenarios	*Control guidance sheets* referring to processes and activities
2	Processes and activities		
3	Duration and frequency	Hours per shift	Duration < or > 15 min
4.1	Physical form	Dustiness (for solids)	Dustiness
4.2	Concentration of substance in product	Yes (100 % assumed)	Yes (100 % assumed)
4.3	Amount		Order of magnitude per task [g] [kg] [t]
5	Other relevant conditions		Process temperature
6.1	HH risk management	LEV available? (Suitable RPE available?)[27]	One/more of 3 pre-set control strategies

Output data from the tool (to be used in the CSA):

For inhalation, the estimated exposure is expressed in ppm or mg/m^3, and for dermal contact the estimated exposure is expressed in µg/cm^2. Depending on the contact area, the external, local exposure can be transformed into systemic exposure (100 % uptake to be assumed at Tier 1).

Steps to run the tool.

The current version of the ECETOC TRA tool is available in print (Technical Report No. 93) and on the web (http://www.ecetoc-tra.org).

The process adopted to evaluate risks to human health at the Tier 1 level consists of five steps.

1. Identification of activity/process categories that are relevant for the substance and that represent the intended conditions under which it is manufactured, sold, supplied and used by both workers and consumers. Thus depending on the circumstances of production and use, a substance is likely to be linked to several such scenarios. The relevant scenarios can be picked from a list.

2. Calculation, using suitable models of the predicted exposure for each use (an improved version of the EASE model is used for this).

3. Selection of appropriate 'no effect level' for the hazard category of the substance. For each hazard category, an 'indicative reference value' is defined, separately for inhalation (volatiles and solids) and dermal exposure. The indicative reference value can be an OEL, DNEL etc; this

[26] The term used in the tool is *exposure scenario*. In order to avoid confusion with REACH exposure scenarios, the term process category is used in the guidance.

is indicated as ‘basis of the indicative reference value’.

4. Derivation of the margin of exposure (MoE) by comparison of the result of step (3) with the result of step (2). In the updated version, the term risk characterisation ratio (RCR) will be used.

5. If control of risk cannot be demonstrated, add risk management measures and their impact on the predicted exposure level. In the occupational exposure part of the ECETOC TRA, the user has the possibility to activate the LEV option at the Tier I level. This results in a predetermined exposure reduction depending on the selected use category and the fugacity of the substance. No such options are currently available for personal protection equipment (e.g. mask, gloves) in the ECETOC TRA. However, if the RMM does not interact with the determinants of exposure, it is possible to modify the results of the exposure calculations with the effectiveness of the RMM. *An example: A half-mask may have an effectiveness of 90 % at a certain level of concentration of the substance in air. As the half-mask does not have an impact on the concentration in the air of the room, the calculated exposure concentration can be lowered with 90 %.* The impact of engineering control (e.g. LEV) or containments has to be assessed on a case-by-case basis.

D.5.3.4 Example of a Tier 1 exposure estimate overview table as documented in the CSR

Table D.5-2 presents an example how a Tier 1 exposure prediction for a solvent with a relative low volatility (1.13 hPa) and an occupational exposure limit value of 50 ppm (long-term inhalation) may look like for different conditions of use. Note: The potential registrant has limited the concentration of the solvent to 20 % in the mixture in order to keep the estimated exposure below 50 ppm in open manual applications without local exhaust ventilation.

Table D.5-2 Exposure estimation for workers based on ECETOC TRA (2004)

	Categories of process		Duration of activity	LEV (yes/no)	Max concen-tration in the formulation	Estimated Inhalation Exposure (ppm)	Estimated Dermal Exposure ($mg/cm^2/d$)	Estimated Inhalation Exposure (ppm) Corrected for Max 20 %	Estimated Dermal Exposure ($mg/cm^2/d$) Corrected for Max 20 %
I.1	Industrial	On registrant's manufacturing site: use in closed continuous process with occasional controlled exposures e.g. during maintenance, sampling and equipment break-ins	> 4 hours	Yes	100	0.5	None		
I.2	Industrial	Use in a batch process including chemical reactions and/or the formulation by mixing, blending or calendering of liquid and solid-based products:	> 4 hours	Yes	100	1.8	1		
I.3	Industrial	Dis/charging the substance (or mixtures containing the substance) to/from vessels	> 4 hours	Yes	100	3	0.6		
I.4	Industrial	Filling containers with the substance or its mixtures (including weighing)	> 4 hours	Yes	100	0.6	None		
I.5	Industrial	Use as laboratory agent	> 4 hours	Yes	100	0.1	None		
P.1	Professional*	Spraying of the substance or mixtures containing the substance in industrial applications e.g. coatings	> 4 hours	Yes No	100 (20)	20 **100**	1 1	4 20	0.2 0.2
P.2	Professional	Roller application or brushing of adhesives and other surface coatings	> 4 hours	No	100 (20)	**100**	1	20**	0.2
P.3	Professional	Use for treatment of articles etc (incl. cleaning) by dipping or pouring)	> 4 hours	No	100 (20)	10	1	2	0.2

* The spraying application was assessed both in the absence and presence of LEV

** When using the EASE tool, which provides a more correct assessment of exposure to low volatile substances, the calculated exposure level is 14 ppm: as this is quite similar to the 20 ppm from the ECETOC TRA, this value is carried on in the risk assessment.

D.5.3.5 Easy-to-use workplace control scheme for hazardous substances

This tool, also known as the COSHH-BAuA tool can only be used for inhalation exposure calculations. It can be downloaded from http://www.reach-helpdesk.de/en/Exposure/Exposure.html

This exposure predictive model is based on the assumption that the workplace exposure is determined by two principal factors: the exposure potential of the handled substance and the applied control strategy. While the exposure potential has a positive or enhancing effect on the exposure level, the control strategy has a negative or decreasing effect.

Two general categories determine the exposure potential: those related to inherent physical properties of the material and those related to how the substance is handled, i.e. the conditions of use. For solids, the material's dustiness[28] is the principal property that needs to be considered for the exposure potential. For liquids, 'volatility' is the key determinant and the user needs the boiling point, or the vapour pressure at a stated temperature, and the process temperature. The scale of use (small (g/ml), medium (kg/L) or large (tonnes/m^3) is regarded to be the most important condition to be considered, as it impacts how the material is packaged, transported and used.

The control strategy is defined in considerable detail with a number of factors that aim at exposure reduction. These general control solutions are underpinned by a series of Control Guidance Sheets (CGS) which provide practical examples of each control approach for common industrial unit operations such as weighing and filling.

This tool is to be seen as an approach for filtering out the low-risk workplace situations, and for selecting appropriate control measures. The banding concept is based on the COSHH Essentials approach and is strongly linked to control guidance sheets (see Chapter R.16). The advantage is that it is based on three input parameters only: volatility or dustiness, amount of substance used, and control approach (the duration of exposure is not considered as such, but if the exposure period is < 15 min/day this will affect the exposure level). For further details, see *steps to rune the tool* below.

Input data

As input data a few determinants are needed:

- Information specific for the substance or product in use [volatility (in terms of boiling point or vapour pressure) or dustiness]
- Operational conditions (temperature, amount of substance/product used per task)
- Information on the implemented RMMs (control strategy)
- Information about the exposure period (< 15 min or ≥ 15 min)

Output data from the tool (to be used in the CSA)

The tool predicts a lower and an upper value for the exposure range (in mg/m^3 for solids and ppm for vapours). The upper value of the exposure range should be used for the risk characterisation, i.e. the comparison with the DNEL-value.

Steps to run the tool.

Exposure levels for inhalation using COSHH-BAuA tool are derived in seven steps:

[28] Please note that it is used a subjective assessment of the material's dustiness, not an assessment performed by using the standard EN 15015

1. Determine the emission potential of the substance (the volatility for liquids and the dustiness for solids). The volatility is derived from the boiling point or the vapour pressure taking into account the process temperature. The dustiness reflects the observed particle size of the material (semi-quantitative) and the behaviour of the emitted dust cloud.
2. Select the operational conditions (use band). The use band is defined by the quantity of the substance [small, medium, large] used in the course of the activity.
3. Determine the exposure potential band. The exposure potential is an aggregated determinant combining amount and volatility/dustiness. There are four combined bands which are called *exposure predictor band for* ***solid*** (EPS) or *exposure predictor band* for **liquid** (EPL).
4. Describe the Risk Management Measures (control approach). For controlling substances in the workplace there is a large number of options available. On closer examination these can be grouped into three main categories, based on the degree of containment. These are general ventilation, engineering control, and industrial closed systems.
5. Assess the exposure level by combining the relevant EP band and the relevant control approach (see the corresponding Table R.14-13). If the activity is carried out for less than 15 minutes a day the next lower range can be used. To be conservative, use the upper level for comparison with the DNEL. If the DNEL is not above the upper level of the assessed range, a higher Tier assessment has to follow.
6. Select the suitable control guidance sheet(s) as a basis for the exposure scenario. In step 6, the link to the defined use is made: if the potential exposure level is above the DNEL, select (an) appropriate control guidance sheet(s) for more detailed description(s) of the specific uses. Control guidance sheets are available for all control approaches covering a number of unit operations. They can be downloaded from the internet[29]
7. If control of risk cannot be demonstrated, it is possible to introduce RMMs in the calculations simply by selecting another appropriate control guidance sheet.

D.5.4 Consumer exposure estimation

Consumer exposure estimation will need to consider 3 exposure routes. Each exposure route will need to be calculated separately. An exposure scenario can be derived using a tiered approach to exposure estimation. Initially a 1st tier exposure estimate can be used to derive a “worst case” but not unrealistic approach. Subsequent higher tired estimates can be used to further characterise the exposure.

Inhalation: In a Tier 1 assessment, it is assumed that all substance is released as a gas, vapour or airborne particulate into a standard room. This may be due to direct release or by evaporation from a liquid or a solid matrix. At subsequent iterations or in higher tier assessments, other parameters are considered such as concentration of substance in the air, the number of rooms, ventilation rate of the room or rooms and the rate at which a substance is released into the room or rooms.

- Dermal, two options:
  - A: The substance is contained in a mixture. This option is e.g., applicable when hands are put into a solution containing the substance under evaluation.
  - B: Substance migrating from an article; applicable for example when residual dyes in clothing are in contact with skin and migrate from the clothing.
- Oral, two options:
  - A: Substance in a product unintentionally swallowed during normal use (Chapter R.15).

[29] The control guidance sheets are identified by a code (e.g. G200). And can be found introducing the code as follows http://www.coshh-essentials.org.uk/assets/live/CODE.pdf. (e.g. http://www.coshh-essentials.org.uk/assets/live/G200.pdf)

- B: Substance migrating from an article; applicable for example when a substance migrates from a pen or textile (Chapter R.17).

To calculate consumer exposure at Tier 1, examples of generic models as provided in Chapters R.15 and R.17. These include EUSES (EC, 2004) ,ConsExpo 4.1 (Delmaar et al., 2005) and GExFRAME.

To simplify the assessment of consumer mixtures or articles, consumer relevant product categories from the use descriptor system (descriptor 3 and 4) can be linked to generic product categories with initial defaults for product composition, applied amount per activity, contact surface area depending on the exposure pathway, and frequency of use. The product categories are based on the consumers section in ECETOC-TRA (ECETOC, 2004) and the categories in the ConsExpo database. The pre-set parameters related to the product categories need to be further detailed in the near future.

The use of higher tier assessments may be needed to further characterise the exposure. This is described in Chapter R.15. Examples of higher tiered models are provided in Appendix R15-3.

Table D.5-3 provides a short overview of the input data needed in the different models.

Table D.5-3 Input data of current Tier 1 tools needed to run tier 1 exposure estimate related to consumers

Information element[30]		ConsExpo	EUSES	TRA
Substance properties				
1	Short title of ES	One or more of 5 pre-set Tier 1 equations, organised by product category and exposure pathway**	One or more of 5 pre-set Tier 1 equations organised by product category and exposure pathway.	One/more of 20 pre-set product categories (mixtures and articles)
2	Processes and activities			
3	Duration and frequency	Hours or uses/day	uses/day	uses/day
4.1	Physical form			
4.2	Concentration of substance in product	Yes	Yes	Yes
4.3	Amount	Per application	Per application	Per application
5	Other relevant operational conditions	Dilution (room size and air exchange) Skin contact area Ingested amount Migration fraction	Dilution (room size and air exchange) Skin contact area Ingested amount Migration fraction	Dilution (room size and air exchange) Skin/mouth contact area Migration fraction
6.2	Consumer risk management	Product integrated measures (via e.g. adapting concentration in product, maximum amount used, migration rates from articles)		

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** ConsExpo contains a database with default values for a large number of consumer product categories. However, these refer to higher tier equations, not to Tier 1.

D.5.4.1 ConsExpo 4.1

The ConsExpo tool can be downloaded for free via www.consexpo.nl.

ConsExpo 4.1 includes a database with default values for a large number of products and uses. When selecting a product, the database provides default scenarios and parameter values for the models. Products with similar exposures are grouped together.

The background of the data used in the ConsExpo database is given in the so-called 'fact sheets' which compile exposure relevant information for a main category of consumer products, such as cosmetics, cleaning products, disinfectants, children's toys and pest control products (also available via www.consexpo.nl). Fact sheets on do-it-yourself products and paint products are in press. The 'General Fact Sheet' (Bremmer et al., 2006) gives general information about the fact sheets, and deals with subjects that are important for several main categories. It gives, for instance, information on anthropometric data and details on housing: such data that are needed in all product fact sheets.

[30] Please note that the data on table D.5-3 have not been updated. as the current version of this document was updated via a corrigendum and therefore does not include substantive changes. However up to date information on these tier 1 tools for consumer's exposure can be found in Chapter 15.

Input data

The input data to the Tier 1 equations are given in Section R.15.4. For a total survey of input data including default values see the reference manual of ConsExpo (Delmaar et al., 2005). A short overview on input data is provided in Table D.5-3 above.

Tier 1 output data from the tool (to be used in the CSA)

The output is the predicted external dose specified for inhalation as mg/m^3, for skin contact as dermal load (mg/cm^2 skin) or external dose in mg/kg bodyweight/day, and for ingestion as external dose in mg/kg bodyweight.

Steps to run the tool

1. Determine the product category based on the standard descriptor system, as input into the Tier 1 calculations.

2. First of all, general data concerning the compound are needed: Amount of product and fraction of substance in the product. The input part "general scenario data" contains pre-sets for body weight, breathing rate of persons and the use frequency. A choice can be made which exposure to assess: inhalation, dermal or oral exposure. Each of the respective sections considers the relevant exposure, and if necessary, uptake.

3. For inhalation exposure, two exposure routes can be modelled at Tier 1: (i) "exposure to vapour" and (ii) "exposure to spray". Exposure to vapour should be modelled by selecting the mode of release to be "instantaneous release" and filling in the other data selected for modelling. The room ventilation rate should be set to "0" (zero) for the first tier assessment. For the exposure to spray situation, a default estimate of 1m^3 should be taken as a room volume to simulate the spray cloud, and additional information is needed at Tier 1 with regard to the propellant versus other constituents in the mixture. Note that this Tier 1 approximation to aerosols (sprays) is a worst-case approximation. Use of appropriate spray models (also included in ConsExpo) is considered a higher-tier approach. For further details, please refer to Chapter R.15.

4. For oral exposure, select between two models:
   1: "oral exposure to product" (similar to oral A), the ingestion model "direct intake".
   2: "Migration from packaging material" (similar to oral B), the "instantaneous release" model.

5. The dermal exposure model is called "Direct dermal contact with product". The two options are distinguished by:
   1: Substance contained in a mixture/medium (dermal A), select the model "instant application",
   2: Substance is migrating from an article (dermal B), select the model "migration".

6. Calculate the exposure values and carry out a risk characterisation at Tier 1 by comparing with the DNEL, DMEL or another appropriate level (see Section B.7.1).

7. In case control of risk cannot be demonstrated, refine the default input parameters in the applied Tier 1 equation, based on more specific information from the ES, from literature or measurements (see Section R.15.3.10) or introduce (additional) product-integrated RMMs. Such product integrated RMM may for example relate to the concentration of a substance in the product.

8. If control of risk is not confirmed by the iteration, a higher-tier assessment may be needed (see Chapter R.14) or it can be concluded that risks are not controlled.

D.5.4.2 EUSES

The EUSES tool can be downloaded for free from http://ihcp.jrc.ec.europa.eu/our_activities/public-health/risk_assessment_of_Biocides/euses.

Input data

The input data to the Tier 1 equations is given in Section R.15.4. A short overview is provided in Table D.5-3 above. For a total survey of input data (including default values) see the EUSES reference manual.

Output data from the tool (to be used in the CSA):

The output is the predicted external dose specified for inhalation as mg/m^3, for skin contact as dermal load (mg/cm^2 skin) or external dose in mg/kg bodyweight/day, and for ingestion as external dose in mg/kg bodyweight.

Steps to run the tool

1. Identify the mixture or article categories in which the substance of interest occurs, based on the standard descriptor system (see chapter R.12).
2. Characterise the pathways of exposure and the exposure determinants, related to the type of use and substance properties. This has to be considered case by case.
3. Check if all needed data have been collected. Check Section R.7.1 for a survey of needed information.
4. Consider how to handle the RMMs in the calculations, see step 4 for ConsExpo.
5. Note that for inhalation of aerosols (sprays) a work-around is needed at Tier 1. For sprays, a default estimate of 1 m^3 should be taken as room volume to simulate the spray cloud. This based on contact time (and inhalation volume in this time) in the immediate spray cloud rather total time of presence in the room during the activity. Alternatively, the higher-tier ConsExpo spray model can be used.
6. Select the EUSES interactive mode, which will guide you through the necessary input specifications. Select “Man exposed via consumer products”. Check if the defaults settings are correct. Specify the physicochemical property data for the substance in question and the relevant determinants for the consumer exposure assessment.
7. Calculate the exposure values and carry out a risk characterisation at Tier 1 by comparing with the DNEL (see Section B.7.1)
8. In case control of risk cannot be demonstrated, refine possibly the default input parameters in the applied release estimation module based on more specific information from the ES, or introduce (additional) product-integrated RMMs.
9. If control of risk is not confirmed by the iteration in step 8, a higher Tier assessment may be needed (see Section R.15.5) or it can be concluded that risks are not controlled.

D.5.5 Environmental exposure assessment

Environmental exposure assessment encompasses all below targets:

- Fresh surface water (including sediment)
- Marine surface water (including sediment)
- Terrestrial ecosystem
- Top predators via the food chain (secondary poisoning)
- Micro-organisms in sewage treatment systems
- Atmosphere – mainly considered for chemical with a potential for ozone depletion, global warming, ozone formation in the troposphere, acidification
- Man indirect, i.e. man exposed via the environment

Both EUSES or the TGD-excel spreadsheet containing the relevant EUSES equations can be used for the exposure calculations for all above targets. They are based on the same algorithms. Invery specific use situations, consider if other models tools are more appropriate to use, e.g.:

- If the substance is used similarly to a pesticide, e.g. as a fertilizer in agriculture, consider to use the tools used in pesticide risk assessment (Section R.16.7.1)
- Offshore chemicals, use CHARM (Section R.16.7.2)

D.5.5.1 Environmental release categories (ERCs) based on EUSES (version 2.0.3)[31]

EUSES has built-in models for conservative release estimation. These are driven by the combination of industry type where the substance is used, the technical function of the substance, the physicochemical properties of the substance and some default assumptions on the dispersion of emission sources. The information can be overwritten with information collected during the CSA process.

However it is not easy to work with the current user-interface as an un-experienced user, in particular where tonnage and use information data is to be specified. The impact of information inputs on the overall results are not always transparent and easy to understand. Also, it is not possible to trace to which extent risk management measures are already assumed in the default emission factors.

In step 4/5 of the generic workflow (see Section D.3.2) M/I may therefore wish to use the newly developed environmental release categories (ERCs) for a Tier 1 assessment under REACH (see Appendix D-3 and Appendix R.16-1). The ERCs are based on the same determinants of exposure as incorporated in EUSES, however with less emphasis on the physicochemical properties of the substance, the industry categories and the substance function in the initial release estimation. The determinants of exposure reflected in the ERC approach are:

- Determinant for the total emission potential: manufactured substance volume per year;
- Determinants for the spatial distribution of emissions: few large users or emission from wide disperse use of the substance; largest single user (leading to a worst case local emission);
- Determinant for distribution of emissions over time (number of emission days);

[31] Please note that this section has not been updated as the current version of this document was updated via a corrigendum and therefore does not include substantive changes. The current available EUSES version at the time of writing of this corrigendum is EUSES 2.1.2

- Determinants for the emission factor via air and waste water;
    - technical fate of substance (consumed in process, incorporated into a product or discharged after use as a processing aid);
    - emission factor driven by process technique; emission factor driven by the use pattern of article;
- Determinant for the dilution at local and regional scale (daily local sewage and river water volume; annual regional river water volume).

In addition to the operational conditions the availability of a municipal sewage treatment plant is reflected in the ERCs.

ERCs have been defined based on a combination of these determinants (see Appendix R.16-1). They include pre-set values for the determinants leading to realistic worst case emission estimates at local or regional scale. Each ERC includes a default release factor which is based on the assumption that no risk management measures are in place[32]. Please note that the default release factors currently used in the ERC approach may need further work for documenting the underlying assumptions that emission factors are conservative and do not take into account emission controls.

- The selection of ERCs needs basic information on the operational conditions of use (see step 2 in the general workflow displayed in Section D.3.2). The following list of questions support the selection of an appropriate ERC to start the exposure scenario development and exposure estimates. It also supports the choices to be made at step 3-5 or the general workflow, when starting ES building from the process and article categories as listed Appendix D-4 and Appendix D-5. Is the substance used in a limited number of industrial sites or has it a broad market with dispersive uses? Based on this information, the assessor can decide whether information on the amount of substance used by a single representative downstream and the conditions of use at that site (RRM and operation conditions) is needed to derive a local exposure estimate.
- What is the technical fate of the substance in that use?
    - In case it is a (non-reactive) processing aid: 100 % losses (before application of RMM) can be expected to waste air, waste water or waste in the initial release estimate.
    - In case the substance is meant to become part of an article matrix: The potential losses can be estimated to be less than 50 % (before application of RMM), but mostly much lower. Overspray in painting operation is here taken as the reasonable worst case for unintended losses of raw materials in a technical process.
    - In case the substance reacts on use, the expected emission to waste water, waste air and waste is likely to be low (< 5 % before application of RMM), except for monomers in thermosets and rubber production.
- Is the substance used indoor (connection to sewage treatment given) or outdoor (no connection to sewage treatment assumed)? This information determines whether the assessor can assume municipal sewage treatment as a risk management measure, which reduces for example the emission of a readily biodegradable (non volatile) substance to ambient water by about 90 %.
- Is the matrix, in which the substance has been included, used under release-promoting conditions, e.g. abrasion of tires and road surfaces or washing of textiles treated with finishing chemicals? If such release-promoting conditions exist, 100 % losses over service life (before

[32] Please note that the default emission factor reflect process and product techniques as applied in the late 20th century.

application of RMM) is assumed as a reasonable worst case. This is based on washing out textile finishing chemical from cloths, or abrasion of brake pads during service life of brake pads in a car,

- Does the processing of the substance takes place in a closed/contained system with corresponding small losses? In this case 5 % losses (before application of RMM) is assumed as a reasonable worst case, taking into account spillages that may occur in transferring substances into machinery or leakage of closed systems in wide disperse use (e.g. motor oils in vehicles)[33].

A pre-selection of potentially relevant ERCs for a use can be directly derived from the descriptor system (see Appendix D-3).

Based on the pre-set releases (before risk management) iterations can be made with regard to the releases from processes and products (before RMM) and the effectiveness of RMMs to be applied (depending on the information collected from downstream users). The emission estimate is fed into the EUSES exposure calculation module. Appendix D-2 provides an illustrative example how to start the development of an exposure scenario from ERC 5 (industrial use of substance resulting in inclusion into a matrix).

The *local concentration* (PEC_{local}) close to a point source emission is calculated as the sum of the concentration from the point source and the background concentration. The *background concentration* or the *regional concentration* ($PEC_{regional}$) is calculated by accounting for all releases over a wider, regional area and by accounting for the distribution and fate of the chemical after the release to the environment. The background concentration is obtained from a so-called **regional distribution calculation** (see Sections R16.5.3.2 and R.16.5.6.8). In obtaining the regional concentration, the M/I has to account for all releases into the environment for his supply chain. However, it can be useful on a voluntary basis to consider exposure resulting from emissions of the same substance manufactured or imported by other registrants (e.g. the overall estimated market volume), see also Section A.2.1. Representative monitoring data may be used for the derivation of the regional and/or local concentrations as well.

Input data

The release estimate (used as an input to exposure modelling based on EUSES) needs the following input information:

- Process or product category of use; total tonnage marketed; tonnage related to considered use (local or wide dispersive) and number of emission days per year; emission fractions to waste water and waste air. Except for the tonnage, the ERCs can be used to retrieve pre-set defaults for the information needed. As already explained, the ERC category can be found from the use descriptors 3 and 4.

Table D.5-4 illustrates where these information will be inserted into the initial exposure scenario.

[33] The assumption of 5 % is possibly not sufficiently conservative and may need refinement.

Table D.5-4 Input data needed to run tier 1 exposure estimation related to environment

Information element		EUSES
Substance properties		Molecular weight, melting point, log P_{ow}, vapour pressure, water solubility, biodegradability
1	Short title of ES	One/more of the pre-set broad environmental release categories (ERCs)
2	Processes and activities	
3	Duration and frequency	Number of emission days per year
4.1	Physical form	
4.2	Concentration of substance in product	
4.3	Amount	Kg/d [t/y] used at a site, in a product group or supplied to the market
5	Other relevant conditions	Emission factors related to processes or products
6.2	Environmental risk management	• Onsite emission abatement, including industrial waste water treatment • Municipal sewage treatment plant (STP)
7	Waste management measures	

In addition the following information on the physicochemical properties and the degradation behaviour of the substance is needed. This is to refine the route specific pre-set emission factors related to the ERCs, or to predict the effectiveness of biological waste water treatment (and to run the exposure modelling in EUSES):

- molecular weight, melting point, octanol-water partition coefficient, vapour pressure, water solubility and biodegradability at aerobic conditions of the substance.

Output data from the tool (to be used in the CSA):

- Local and regional PEC values specified in mg/L (water) or mg/kg (soil and sediment).
- Concentration in food (for the assessment of secondary poisoning) (mg/kg food).
- Regional and local total human doses taken up via the environment of the substance.

Steps to run the tool (EUSES+ERCs)

1. Select the appropriate broad environmental release class for release estimation based on the information available and the identified use as described by the standard descriptor system. See the Section R.16.8.2 for a detailed description of the release categories, and Appendix D-3 to Appendix D-5 for information on linking the use-descriptors to pre-selected ERCs (step 3 in the general workflow).

2. Determine the quantity of the substance which is applied in a process category, product category and/or life cycle stage, and other input parameters for the release estimation module. This may already include modification of pre-sets based on available in-house

information or information received from downstream users (step 4 in the general workflow).

3. Carry out the EUSES-based calculation, using the release rates at local and regional level based on the ERCs and the quantity of the substance in the relevant life cycle steps (see Section R.16.2.1). Calculate the PECs (water, sediment, soil, food) and the regional and local total human doses via the environment and compare with relevant PNECs. If it seems possible to demonstrate control of risk, complete the initial ES and invite DU for feedback (step 4-6 in the general workflow).

4. In case control of risks cannot be demonstrated or the feedback from downstream users requires changes in the OC or RMM, refine the input parameters in the applied release categories, based on more specific information (see steps 7 and 8 in the general workflow). The following possibilities for refinement should be investigated:
   - Get more exact knowledge on the actual number of emission days and fraction of main source by contacting the DU or the branch organisation of the DU.
   - Get more exact knowledge on the actual emission fractions by contact to the DU or the branch organisation of the DU.
   - If the water solubility in the waste water is exceeded in the initial emission estimation, then modify the emission fraction to waste water accordingly.
   - If the substance has a low Henry constant (< 1 $Pa \cdot m^3/mol$), then consider the emission to air as of no importance.
   - Consider the introduction of (additional) RMMs to lower the releases to the environment. When introducing the impact of an RMM, make sure that the RMM was not already included in the applied emission factors. The ERCs for example are defined in away that “uncontrolled” emission is assumed. Quantify the effectiveness of additional RMMs that decrease the overall emitted or released amounts.

5. Both, the release calculation and the exposure prediction based on EUSES can be further refined by measured data, e.g. waste water concentrations or monitoring data for surface water (higher tier assessment, see step 9 and 10 in the general workflow). However, the assessor should make sure that the CSR includes sufficient documentation that the operational conditions and the RMMs described in the exposure scenario match the conditions under which the measured data were obtained.

Based on the ERCs also the waste life stage can be included into environmental release estimation. The method is explained in Chapter R.18.

D.5.5.2 TGD spreadsheet version

The TGD excel sheet may be an alternative to using EUSES, which was described in the previous section. The tool can only be used for environmental exposure assessment.

The TGD excel sheet, like EUSES, is based on the existing TGD for carrying out risk assessment of existing substances. The determinants of emissions, such as the local amount and the emission factors can be directly inserted into the spreadsheet, giving an immediate result. It has been shown that in some situations the two tools do not give the same results. However the discrepancies have been eliminated now. Nevertheless EUSES should be used as the reference tool, and the results from using the TGD excel sheet should be cross-checked against the results of EUSES.

The TGD spreadsheet uses the same input parameters as EUSES, apart from the fact that release fractions have to be entered manually, and it provides the same output. In a Tier 1 assessment, the TGD Excel sheet should be used together with the emission data obtained from using the ERC.

D.6 REFINING THE HAZARD ASSESSMENT

Based on initial exposure scenario building and the related exposure estimation, M/I may conclude that refinements in the hazard assessment are needed before risk characterisation can be carried out and the final exposure scenario can be derived (see work-flow step 7). This may be related to the following:

- The exposure assessment shows that an exposure route is relevant for which no suitable dose/concentration–response characterisation is available. Action: Generate data and/or derive a DNEL/PNEC or other measures of dose/concentration-response.
- The exposure assessment shows that, based on realistic assumptions, the exposure is too high to demonstrate control of risk with the DNEL or PNEC available. Action: Refine the existing PNEC or DNEL if assessment factors can be decreased based on more in depth assessment, or propose testing.
- The outcome of the exposure assessment demonstrates that exposure is prevented (e.g. by advising against certain uses), or is so low that certain hazard information is not needed. Action: Justify waiving, do not propose additional testing
- The exposure estimate leads to worst case results due to the limited knowledge on the properties driving the environmental fate of a substance. Action: Refine information related to vapour pressure, water solubility, partitioning and degradation behaviour under the conditions relevant for the respective uses.

D.7 RISK CHARACTERISATION

The CSA can be terminated when the risk characterisation shows that risks are controlled for all relevant exposures relating to all exposure scenarios. See Part A and Part E in relation to how control of risk is demonstrated for different types of endpoints, taking into account the uncertainty around the hazard and exposure information. The assessor should convince himself that exposure estimation and the related dose-response information (in particular derived and predicted no-effect levels (DNELs/PNECs) match in terms of time scale (acute or chronic exposure), exposure route, population (worker, consumer) and spatial scale (e.g., homogeneous or near-field exposure; local or regional exposure).

If the risks are not controlled, the registrant can

- Refine the hazard and/or exposure assessment until control of risk can be demonstrated (see Part A on the CSA principles).
- Conclude that some uses may not be safe and thus advised against these.

The reference guidance contains more information on using uncertainty analysis to assist the registrant in interpreting the risk characterisation and refining the iterations in the CSA process (Chapter R.19).

For further guidance on risk characterisation, see Part E of the Guidance Document.

D.8 DERIVE THE FINAL ES

D.8.1 Integration

The final ES is developed from the initial ES and the subsequent exposure estimate and risk characterization. If, based on the initial ES, it cannot be demonstrated in the CSA process that risks are controlled, further work is needed. The CSA process can be refined in a number of iterations. In an iteration of the CSA, information at any point of the assessment cycle can be modified. The final ES documents that under the specified OCs and RMMs, risks are controlled. This may be subject to supervision and enforcement by authorities. The recommendations on conditions of use must be realistic to the extent that the introduction of operational conditions or RMMs that cannot be implemented by a DU should be avoided.

The final ES is valid for the substance and the processes that have been assessed. The ES might also be applicable for other substances with similar properties, if they are used in the same way as described in the final ES; and provided that the substance properties do not change the process conditions or the effectiveness of RMMs significantly.

The ES should integrate occupational, environmental and consumer aspects of handling a substance or mixture at manufacturer or DU level. The following aspects on integrating the different elements of the exposure assessment need to be taken into consideration.

<u>Provide a structured overview in the ES of all OCs and RMMs required for each target group/exposure route for control of risk.</u>

The safety assessment of each target group/exposure route will provide a list of OCs and RMMs needed to ensure control of risk. For example, occupational safety assessment for inhalation could result in OCs/RMMs as maximum temperature, maximum amount, minimum ventilation rate, maximum duration and frequency. At the same time, the environmental safety assessment could lead to a maximum safe amount that can be used per day on the basis of assessed emission rates to water and air, and assuming filtration of waste water prior to discharge to sewage treatment.

<u>Consider if a specified RMM has impact on another safety assessment</u>

In some cases the introduction of an RMM for one target group/exposure route may have impact on another target group/exposure routes. One example is the RMM “ventilation”, which is an RMM for occupational inhalation exposure. The use of the RMM “ventilation” increases the emission rate to air. If this additional emission of substance to air was not considered in the environmental safety assessment, it should be repeated by including the emission to air caused by the introduction of the RMM “ventilation”. Another example is containment of a process. This RMM both decreases the environmental and occupational exposure level. Other examples are: use of gloves (occupational) and filtration (environment) which both increases the emissions to waste. Also, the impact of the handling of the filtration equipment on the occupational exposure should be considered.

<u>Consider mutual dependence of OCs/RMMs</u>

Be aware of the fact that the OCs/RMMs may be mutually dependent and that the impact of their relation on the safety assessments should be assessed. One example is that temperature increases the evaporation, and thus increases both the occupational inhalation and environmental exposure. The result is that the safe amount of product which can be used may be lower (if either occupational

inhalation or environmental exposure determines the safe amount). Therefore, a change of the temperature (e.g. in a process or in the surroundings) may lead to increased exposure, which in some scenarios will need to be controlled by a change of the recommended RMMs.

Derive minimum requirements to common OCs/RMMs

Initial exposure scenario development may lead to a situation that one and the same determinant (e.g. duration of use or amount per action) is given different values for each of the three target groups. This can also be the case for the different routes of exposure. For the final ES, the most conservative OCs/RMMs ensuring control of risk for all target groups/exposure route should be selected. For example, the occupational safety assessment has been confirmed for the following OCs: maximum amount of 100 kg per action (or use), a frequency of 1 action per day, and a maximum duration of 2 hours for each action, whereas the environmental safety assessment resulted in a maximum amount of 50 kg/day. In this case, it could be considered to specify the OCs as: maximum amount of 50 kg per action, a frequency of 1 action per day, and a maximum duration of 4 hours.

Integrate all OCs and RMMs within the ES

After having considered mutual dependence of OCs/RMMs and minimum requirements to common OCs/RMMs, the remaining OCs/RMMs specified in the safety assessments shall be extracted in order to cover all exposure routes and target groups. The information on OCs and RMMs are specified in the ES, preferably by use of standard phrases. The minimum required efficiencies of the RMMs should be specified in the ES.

The final ES should give realistic, non-ambiguous safety advice for manufacture or identified use(s) of a substance, a group of substances or a mixture. It prescribes necessary RMMs for ensuring safe manufacture or use under a given set of operational conditions. For workplace situations the final ES should comply with the objectives and hierarchy of measures imposed by the Chemicals Agent Directive and Directive 89/391/EC.

D.8.2 Advice to DU to check whether he works within the boundaries set by the ES

In order to assist the DU in the evaluation whether he works within the boundaries of the ES, it is recommended that section 9 of the exposure scenario contains references or links to tools or methods that can be used to evaluate the final exposure scenario against the conditions of use at customer level and further down the chain. This may include scaling tools as described in Appendix G-1. The advice should enable the downstream user to document that he works within the boundaries of the ES. This is in particular relevant where M/I has demonstrated control of risk based on a representative calculation example but where the value of some or all of the parameters in this calculation differs from what the DU is really doing. DU may need to demonstrate the equivalence of his OC and RMMs, for example by the following considerations:

- In the TRA model exposure, several factors can compensate each other in their impact on the predicted exposure concentration: time at work place, concentration of substance in mixture, dustiness and availability of local exhaust ventilation. The example in Section D.5.3.4 illustrates how M/I has compensated the absence of LEV in his scenario by limiting the concentration of the substance to 20 %.
- In the EUSES model, the multiplication of local daily amounts, with the emission factor before abatement, the effectiveness of biological waste water treatment and dilution factor in the receiving waters lead to the derivation of the local PEC. Thus each of these factors can compensate changes in the other three, without creating the need to revise the exposure scenario.

In order to better understand the information needs of downstream users, M/I may wish to go to the *Guidance for downstream users*.

D.9 USE OF THE FINAL ES IN THE SUPPLY CHAIN

The final exposure scenario(s) for a substance must be communicated down the supply chain. The format and the phrasing of the exposure scenario should meet three requirements:

- The RMM advice should be practically useful for the recipient of the exposure scenario:
    - The recipient may be a formulating downstream user for whom the ES is a source of three types of information:
        - Practical advice relating to the formulator's own technical activity (mixing substances and/or mixtures).
        - Information relevant to the formulator's choices on product composition and design.
        - Information and advice relevant to the formulator's customers and further downstream users.
    - The recipient may be an end-user for whom the ES is a source of i) practical advice relating to its own technical activity and ii) information relevant with regard to control of risk further down the supply chain (articles and waste).
- The assumptions under which the supplier regards the uses of his customer and the uses further down the chain as safe must be transparent to the downstream user.
- The ES should include brief advice on how the recipient of the ES can check whether the conditions in the ES are met in practice at the user's level.

It is a decision of the M/I how to meet these requirements related to immediate downstream users and downstream users further down the chain. It will largely depend on the condition in his markets and the markets of his customers. In order to allow for flexible communication, it will in most cases be advisable to address the identified uses by a package of individual exposure scenarios referring to certain life cycle steps and/or certain uses (groups of uses). This will also keep the possibility open for the immediate downstream user to simply forward the relevant exposure scenarios to his customers. In particular cases it may also be efficient to integrate all life-cycle stages into one exposure scenario (e.g. in case of short supply chain or very specific uses or limited risk management needs).

APPENDICES

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Appendix D-1: Strength and limitations of the available Tier 1 exposure estimation tools

ECETOC TRA occupational

Strengths

- Clear structure
- A parameter related to process category is used as basis for assessment
- Duration of process/activity is taken into account
- Scenarios (process categories) based on EASE and expert input from industry stakeholders
- The calculated effectiveness of local exhaust ventilation depends on process and is thus not set at a constant value. This is in accordance with observations. However, the tool is currently not able to distinguish between different types and efficiencies of LEVs.

Limitations

- Some process categories appear to overlap; the choice is not always clear
- The number of process categories appears to be insufficient to cover every first Tier assessment
- Processes categories are described in expert language; non experts in the field of worker exposure (assessment) therefore find the tool difficult to use
- Except through differentiation of processes/activities/operation units and in duration of activity, influence of amount of product used on exposure level cannot be taken into account
- Only “local exhaust ventilation” and (indirectly) changes in processes/activities/operation units and duration can be chosen as “risk management measures”
- Web-based version and paper version (ECETOC Technical Report No. 93) do currently not fully agree; the paper tool is at the moment the preferred choice. The foreseen update of the tool will include streamlining in this respect.
- Compared to measured data (RISKOFDERM project) the dermal exposure for situations with local exhaust ventilation is underestimated.
- Please note that at the time of the writing this tool has not been validated for use with nanomaterials (NMs). If the output of the model is used to estimate exposure for NMs, this should preferably be supported by measured data. There should be a clear description in the CSR of the uncertainties associated with the estimated values and the consequences for the risk characterisation.

Compensation for limitations

- Using the most conservative estimate of both process categories if the choice is not clear
- Assume that small amounts are related to short durations of use
- Consistently use the paper version as basis for the estimations (the report can be downloaded from the internet)
- Assume no local exhaust ventilation for dermal exposure estimates (to reach a conservative estimate)

COSHH-BAuA-Tool

Strengths

- Very clear and user friendly structure
- The output has been shown basically sound for a number of ES
- Provides control strategies for a range of common tasks, e.g. mixing, filling, etc.
- Control guidance sheets are available on the Internet

Limitations

- The estimates are generic in nature and therefore uncertain to some extent.
- It is not possible to use the assessed exposure ranges as a basis for further iterations, e.g. considering the duration of exposure (only the influence of short term exposure, i.e. < 15 min/day, is considered)
- Validation of the concept is, as always for exposure estimation models, limited
- Not suited for gases (handled or released)
- Should not be used for tasks where fumes are generated or where dusts are formed through abrasive techniques
- Not suited for CMR substances.
- Please note that at the time of the writing this tool has not been validated for use with nanomaterials (NMs). If the output of the model is used to estimate exposure for NMs, this should preferably be supported by measured data. There should be a clear description in the CSR of the uncertainties associated with the estimated values and the consequences for the risk characterisation.

Compensation for Limitations

As the model estimates are uncertain to some extent, the concept acts on the following conservative assumptions:

- The substance concentration (in products) is assumed to be 100 %.
- The duration of exposure is assumed to be the shift length. If the activity is carried out for less than 15 minutes a day the next lower range of predicted exposure can be assumed and compared with the DNEL.

ConsExpo

Strengths

- Builds on the EU-TGD for *existing and new* substances (2004), which is accepted within the EU
- Contains a database with default values for a range of products and uses (although input data mostly relate to higher tier models, not Tier 1)
- Documentation for default values is available in so called ‘fact sheets’.
- Free of charge.

Limitations

- ConsExpo currently has no explicit facility to work with a diversity of consumer product categories at Tier 1. If default pre-set values for product categories are being developed in near future, a link between these categories or incorporation of these categories in the database of ConsExpo is needed.
- Risk management measures are not mentioned explicitly.
- Please note that at the time of the writing this tool has not been validated for use with nanomaterials (NMs). If the output of the model is used to estimate exposure for NMs, this should preferably be supported by measured data. There should be a clear description in the CSR of the uncertainties associated with the estimated values and the consequences for the risk characterisation.

Compensation for limitations

Product-related RMMs can be accommodated in ConsExpo by changing the input parameters to the Tier 1 equations (see Section D.4.5).

Whenever more detailed information for the product is available (e.g. focussing on specific products instead of product categories), these data should be used instead (The ConsExpo model can be retrieved via www.consexpo.nl, including the associated database and fact sheets).

EUSES Consumer

Strengths

- Builds on the current EU-TGD, which is accepted within the whole EU
- Requires few data
- Free of charge

Limitations

- EUSES currently has no explicit facility to work with consumer product categories subdivided into product categories and article categories. Initial product category settings need to be transferred to the input of EUSES.
- As in any other available consumer exposure tool, risk management measures are not mentioned explicitly.
- Please note that at the time of the writing this tool has not been validated for use with nanomaterials (NMs). If the output of the model is used to estimate exposure for NMs, this should preferably be supported by measured data. There should be a clear description in the CSR of the uncertainties associated with the estimated values and the consequences for the risk characterisation.

Compensation for limitations

- The inclusion of RMM for the consumer can be handled manually in the tools. See step 3 for further guidance.

EUSES/ERCs

Strengths

- Builds on the current EU-TGD, which is accepted within the whole EU
- Requires few data for a first assessment
- Refined data on operational conditions and RMM can be directly inserted into the calculation of emissions at Tier 1 level during the CSA process. The same applies for refined substance characteristics that can be entered into the tool
- Available free of charge from: http://ihcp.jrc.ec.europa.eu/our_activities/health-env/risk_assessment_of_Biocides/euses

Limitations

- For the default emission factors in the current EUSES is it not clear which operational conditions and which risk management measures are assumed to be already in place. Thus iteration may lead for example to a duplication of RMMs already included in the default emission factor.
- The correlations used for the derivation of substance parameters, i.e. mainly partition data, are not valid for inorganic substances and surfactants. Whenever measured partition and degradation data are available, these should be used in the calculations. This is of very high importance for metals, inorganic compounds and surfactants.
- Please note that at the time of the writing this tool has not been validated for use with nanomaterials (NMs). If the output of the model is used to estimate exposure for NMs, this

should preferably be supported by measured data. There should be a clear description in the CSR of the uncertainties associated with the estimated values and the consequences for the risk characterisation.

Compensation for Limitations

- These limitations are the reasons for introducing the ERCs. The ERCs can be loaded in EUSES from input files.
- To introduce the effect of RMMs and changes in the conditions of use, the presets for the ERCs can be replaced with own estimates, information from downstream users or measured data.
- When dealing with metals, inorganic compounds and surfactants, use - if available - measured partition data. For cationic (positively charged) compounds, you may use very high partition coefficients (soil-water, sediment-water, sludge-water). For anionic (negatively charged) compounds you may use very low partition coefficients (soil-water, sediment-water, sludge-water). If no measured partition data are available, you may run a set of simulations: one where you use very high partition coefficients (soil-water, sediment-water, sludge-water) and one with very low partition coefficients. You can then use the results giving the highest predicted risk quotients.

EUSES Spreadsheet

Strengths

- Similar advantages as EUSES for environment and indirect exposure of man.
- For the experienced user having specific release data at his disposal, the emission estimation module in the spread sheet version provides more transparency of the calculations.
- Allows integration in dedicated exposure calculation tools.
- Available free of charge via contact to RIVM (www.rivm.nl) and CEFIC (www.cefic.org).

Limitations

- Not linked to any process or product categories, thus, release data are to be entered manually by user and the effect of RMMs needs to be introduced by reduced emission factors.
- Please note that at the time of the writing this tool has not been validated for use with nanomaterials (NMs). If the output of the model is used to estimate exposure for NMs, this should preferably be supported by measured data. There should be a clear description in the CSR of the uncertainties associated with the estimated values and the consequences for the risk characterisation.

Compensation of Limitations

Spreadsheet software needs to be protected for algorithm stability since it is vulnerable to introducing mistakes. As a default, the sheets in the TGD Excel are write-protected, except the cells for specifying the variable input parameters. Great care should be taken if disabling this write-protection.

Appendix D-2: Example on the use of Environmental Release Categories

The following example aims to illustrate how ERCs can facilitate a Tier 1 release and exposure estimates by M/I. The calculations are based on the pre-sets in the ERC table for emissions to water (see Appendix R.16-1).The pre-sets are extracted from EUSES. The effectiveness of municipal sewage treatment is driven by substance properties (see-look up table based on SIMPLETREAT Model in Appendix R.16-4). The pre-set dilution is either 20.000 m^3 water per day (local source) or $25*10^9$ m^3 per year (diffuse release into the region).

STP is the only risk management measure anticipated in the ERC.

Example 1a represents a case for the processing life stage of a substance where control of risk can be demonstrated based on Tier 1 assessment after one iteration. Example 1b represents the same process, however the substance to be registered has a lower PNEC (factor of 50). Onsite risk management is needed to demonstrate control of risk. A second iteration is needed.

The right hand column indicates which information from the ERC pre-set are converted into ES information, and how step by step further information on OCs and RMM are added.

Please note: Using an ERC as a starting point is only sensible if more specific, REACH-fit emission estimation modules have not (yet) been developed by the relevant industrial sectors.

Example 1a: M/I of a textile dye starts to develop the environment part of the ES for the processing life stage. M/Is production volume is 1000 t/a.
Substance properties: Skin Sens 1., H317 (May cause an allergic skin reaction.); Inherently biodegradable; water solubility > 100 g/l; PNEC 500 µg/l

	Action by M/I	Information to section …. of the ES	Resulting exposure estimation
1	Pre-populate the ES with information in-house available	▪ Dipping processes (immersion operations) [PROC13] => section 1 or 2 ▪ Usually industrial setting => section 1 ▪ Usually connected to municipal STP => RMM for section 6 ▪ Concentration in end-use dye stuff 10-50 % => section 4.2	
2	Select an ERC that best reflects the conditions at processing	ERC 5, since substance is intended to become part of the article matrix • Default local amount (1000 t / 20d) = 50 t/d => section 4.3 • Effectiveness of dying process 50 % (50 % losses) => section 5 • Effectiveness of RMM (municipal sewage treatment[34]) 40 % => section 6.2	Default emission to STP (50 %) = 25 t/d Default emission after STP (60 %) = 15 t/d **Local PEC (after dilution 20.000 m^3): 750 mg/l**
3	Carry out iteration based on information available to M/I	▪ Structure of textile finishing sector suggests that usually not more than 150 kg/d of one dye is applied (instead of 50 t/d in the ERC pre-set): => to section 4.3 ▪ M/Is technical guidance to DU suggests a fixation rate of the dye to the relevant types of fibre in an exhaust dye process of 95% in practise (instead of 50 % in the ERC pre-set): => section 5	decrease emission to STP by factor of 3333 (= 7.5 kg/d). **Resulting local PEC: 225 µg/l**
4	Identify critical determinants	The assumption related to 95 % effectiveness is critical for the result. Can be only achieved through dying in exhaust process, not in padding process (effectiveness usually not > 85 %) => section 5 and 9	85 % effectiveness of the dying process would be insufficient to achieve a PEC < 500 µg/l
5	Conclude: control of risk demonstrated for water		

Example 1b: M/I of a textile dye starts to develop the environment part of the ES for the processing life stage. M/Is production volume is 1000 t/a.
Substance properties: Skin Sens 1., H317 (May cause an allergic skin reaction).; inherently biodegradable; water solubility > 100 g/l; PNEC **10 µg/l**

	Action by M/I	Information to section …. of the ES	Resulting exposure estimation
1	Pre-populate the ES with information in-	▪ Dipping processes (immersion operations) [PROC13] => section 1 or 2 ▪ Usually industrial setting => section 1	

[34] SimpleTreat predicts 40 % removal for an inherently biodegradable substance with logP <3.

Example 1b: M/I of a textile dye starts to develop the environment part of the ES for the processing life stage. M/Is production volume is 1000 t/a.
Substance properties: Skin Sens 1., H317 (May cause an allergic skin reaction).; inherently biodegradable; water solubility > 100 g/l; PNEC **10 µg/l**

	Action by M/I	Information to section …. of the ES	Resulting exposure estimation
	house available	▪ Usually connected to municipal STP => section 6 ▪ Concentration in end-use dye stuff 10-50 % => section 4.2	
2	Select an ERC that best reflects the conditions at processing	ERC 5, since substance is intended to become part of the article matrix • Default local amount (1000 t / 20d) = 50 t/d => section 4.3 • Effectiveness of dying process 50 % (50 % losses) => section 5 • Effectiveness of RMM (municipal sewage treatment[1]) 40 % => section 6.2	Default emission to STP (50 %) = 25 t/d => section Default emission after STP (60 %) = 15 t/d **Local PEC (after dilution 20.000 m^3): 750 mg/l**
3	Carry out iteration based on information available to M/I	▪ Structure of textile finishing sector suggests that usually not more than 150 kg/d of one dye is applied (instead of 50 t/d in the ERC pre-set): => to section 4.3 ▪ M/Is technical guidance to DU suggests a fixation rate of the dye to the relevant types of fibre in an exhaust dye process of 95 % in practise (instead of 50 % in the ERC pre-set): => section 5	decrease emission to STP by factor of 3333 (= 7.5 kg/d). **Resulting local PEC: 225 µg/l**
4	Carry out second iteration to add onsite RMMs	▪ Onsite pre-treatment of exhausted bath needed. Suitable methods: Chemical oxidation nano-filtration, flocculation; expected effectiveness 95 %. => section 6.2 ▪ Limit daily amount to 120 kg per site => section4.3	Decrease amount per day by factor 1.25 Increase risk management effectiveness by factor 20 **Resulting local PEC: 9 µg/l**
4	Identify critical determinant	The assumption related to 95 % fixation and 95 % effectiveness of onsite pre-treatment. In addition evidence is needed that that the minimal effectiveness of the STP (50 %) is applicable to the pre-treated waste water.	▪ Regular cross check of effectiveness needed: insert recommendation under section 5 and 9 into the ES.
5	Conclude: control of risk demonstrated for water		

Appendix D-3: Names and descriptions Environmental Release Categories

ERC number	Name	Description
ERC1	Manufacture of substances	Manufacture of organic and inorganic substances in chemical, petrochemical, primary metals and minerals industry including intermediates, monomers using continuous processes or batch processes applying dedicated or multi-purpose equipment, either technically controlled or operated by manual interventions
ERC2	Formulation of preparations*	Mixing and blending of substances into (chemical) preparations in all types of formulating industries, such as paints and do-it-yourself products, pigment paste, fuels, household products (cleaning products), lubricants, etc.
ERC3	Formulation in materials	Mixing or blending of substances which will be physically or chemically bound into or onto a matrix (material) such as plastics additives in master batches or plastic compounds. For instance a plasticizers or stabilizers in PVC master-batches or products, crystal growth regulator in photographic films, etc.
ERC4	Industrial use of processing aids in processes and products, not becoming part of articles	Industrial use of processing aids in continuous processes or batch processes applying dedicated or multi-purpose equipment, either technically controlled or operated by manual interventions. For example, solvents used in chemical reactions or the 'use' of solvents during the application of paints, lubricants in metal working fluids, anti-set off agents in polymer moulding/casting.
ERC5	Industrial use resulting in inclusion into or onto a matrix	Industrial use of substances as such or in preparations (non-processing aids), which will be physically or chemically bound into or onto a matrix (material) such as binding agent in paints and coatings or adhesives, dyes in textile fabrics and leather products, metals in coatings applied through plating and galvanizing processes. The category covers substances in articles with a particular function and also substances remaining in the article after having been used as processing aid in an earlier life cycle stage (e.g. heat stabilisers in plastic processing).
ERC6a	Industrial use resulting in manufacture of another substance (use of intermediates)	Use of intermediates in primarily the chemical industry using continuous processes or batch processes applying dedicated or multi-purpose equipment, either technically controlled or operated by manual interventions, for the synthesis (manufacture) of other substances. For instance the use of chemical building blocks (feedstock) in the synthesis of agrochemicals, pharmaceuticals, monomers, etc.
ERC6b	Industrial use of reactive processing aids	Industrial use of reactive processing aids in continuous processes or batch processes applying dedicated or multi-purpose equipment, either technically controlled or operated by manual interventions. For example the use of bleaching agents in the paper industry.
ERC6c	Industrial use of monomers for manufacture of thermoplastics	Industrial use of monomers in the production of polymers, plastics (thermoplastics), polymerization processes. For example the use of vinyl chloride monomer in the production of PVC.

ERC number	Name	Description
ERC6d	Industrial use of process regulators for polymerisation processes in production of resins, rubbers, polymers	Industrial use of chemicals (cross-linking agents, curing agents) in the production of thermosets and rubbers, polymer processing. For instance the use of styrene in polyester production or vulcanization agents in the production of rubbers.
ERC7	Industrial use of substances in closed systems	Industrial use of substances in closed systems. Use in closed equipment, such as the use of liquids in hydraulic systems, cooling liquids in refrigerators and lubricants in engines and dielectric fluids in electric transformers and oil in heat exchangers. No intended contact between functional fluids and products foreseen, and thus low emissions via waste water and waste air to be expected.
ERC8a	Wide dispersive indoor use of processing aids in open systems	Indoor use of processing aids by the public at large or professional use. Use (usually) results in direct release into the environment/sewage system, for example, detergents in fabric washing, machine wash liquids and lavatory cleaners, automotive and bicycle care products (polishes, lubricants, de-icers), solvents in paints and adhesives or fragrances and aerosol propellants in air fresheners.
ERC8b	Wide dispersive indoor use of reactive substances in open systems	Indoor use of reactive substances by the public at large or professional use. Use (usually) results in direct release into the environment, for example, sodium hypochlorite in lavatory cleaners, bleaching agents in fabric washing products, hydrogen peroxide in dental care products.
ERC8c	Wide dispersive indoor use resulting in inclusion into or onto a matrix	Indoor use of substances (non-processing aids) by the public at large or professional use, which will be physically or chemically bound into or onto a matrix (material) such as binding agent in paints and coatings or adhesives, dyeing of textile fabrics.
ERC8d	Wide dispersive outdoor use of processing aids in open systems	Outdoor use of processing aids by the public at large or professional use. Use (usually) results in direct release into the environment, for example, automotive and bicycle care products (polishes, lubricants, de-icers, detergents), solvents in paints and adhesives.
ERC8e	Wide dispersive outdoor use of reactive substances in open systems	Outdoor use of reactive substances by the public at large or professional use. Use (usually) results in direct release into the environment, for example, the use of sodium hypochlorite or hydrogen peroxide for surface cleaning (building materials)
ERC8f	Wide dispersive outdoor use resulting in inclusion into or onto a matrix	Outdoor use of substances (non-processing aids) by the public at large or professional use, which will be physically or chemically bound into or onto a matrix (material) such as binding agent in paints and coatings or adhesives.
ERC9a	Wide dispersive indoor use of substances in closed systems	Indoor use of substances by the public at large or professional (small scale) use in closed systems. Use in closed equipment, such as the use of cooling liquids in refrigerators, oil-based electric heaters.

ERC number	Name	Description
ERC9b	Wide dispersive outdoor use of substances in closed systems	Outdoor use of substances by the public at large or professional (small scale) use in closed systems. Use in closed equipment, such as the use of hydraulic liquids in automotive suspension, lubricants in motor oil and break fluids in automotive brake systems.
ERC10a	Wide dispersive outdoor use of long-life articles and materials with low release	Low release of substances included into or onto articles and materials during their service life in outdoor use, such as metal, wooden and plastic construction and building materials (gutters, drains, frames, etc.)
ERC10b	Wide dispersive outdoor use of long-life articles and materials with high or intended release (including abrasive processing)	Substances included into or onto articles and materials with high or intended release during their service life from outdoor use. Such as tyres, treated wooden products, treated textile and fabric like sun blinds and parasols and furniture, zinc anodes in commercial shipping and pleasure craft, and brake pads in trucks or cars. This also includes releases from the article matrix as a result of processing by workers. These are processes typically related to PROC 21, 24, 25, for example: Sanding of buildings (bridges, facades) or vehicles (ships).
ERC11a	Wide dispersive indoor use of long-life articles and materials with low release	Low release of substances included into or onto articles and materials during their service life from indoor use. For example, flooring, furniture, toys, construction materials, curtains, footwear, leather products, paper and cardboard products (magazines, books, news paper and packaging paper), electronic equipment (casing).
ERC11b	Wide dispersive indoor use of long-life articles and materials with high or intended release (including abrasive processing)	Substances included into or onto articles and materials with high or intended release during their service life from indoor use. For example: release from fabrics, textiles (clothing, floor rugs) during washing. This also includes releases from the article matrix as a result of processing by workers. These are processes typically related to PROC 21, 24, 25. For example removal of indoor paints.
ERC12a	Industrial processing of articles with abrasive techniques (low release)	Substances included into or onto articles and materials are released (intended or not) from the article matrix as a result of processing by workers. These processes are typically related to PROC 21, 24, 25. Processes where the removal of material is intended, but the expected release remains low, include for example: cutting of textile, cutting, machining or grinding of metal or polymers in engineering industries.
ERC12b	Industrial processing of articles with abrasive techniques (high release)	Substances included into or onto articles and materials are released (intended or not) from/with the article matrix as a result of processing by workers. These processes are typically related to PROC 21, 24, 25. Processes where the removal of material is intended, and high amounts of dust may be expected, includes for example: sanding operations or paint stripping by shot-blasting.
	Other environmental characteristics; please specify	

Appendix D-4: Linking Process Categories to ERCs[35]

	Process categories based on TRA categories for workers[36];	**ERC no**
PROC1	Use in closed process, no likelihood of exposure Industrial ;	1, 6a, 6c
PROC2	Use in closed, continuous process with occasional controlled exposure (e.g. sampling) Industrial;	1, 6a, 6c, 7
PROC3	Use in closed batch process (synthesis or formulation) Industrial;	1, 2, 6a, 6d
PROC4	Use in batch and other process (synthesis) where opportunity for exposure arises Industrial;	1, 6a, 6c, 6d
PROC5	Mixing or blending in batch processes for formulation of mixtures and articles (multistage and/or significant contact) Industrial;	2, 3
PROC6	Calendering operations Industrial;	5
PROC7	Spraying in industrial settings and applications Industrial;	4, 5
PROC8	Transfer of substance or mixture (charging/discharging) from/to vessels/large containers at non dedicated facilities Industrial/professional ;	Covered in the industrial ERC
PROC9	Transfer of substance or mixture into small containers (dedicated filling line, including weighing) Industrial;	Covered in the industrial ERC
PROC10	Roller application or brushing of adhesive and other coating Industrial/professional;	4, 5, 8a, 8c, 8d, 8f
PROC11	Spraying outside industrial settings and/or applications Professional;	8a, 8c, 8d, 8f
PROC12	Use of blow agents in manufacture of foam Industrial;	5
PROC13	Treatment of articles by dipping and pouring Industrial/professional;	4, 5, 6b, 8a, 8b, 8c, 8d, 8f
PROC14	Production of mixtures or articles by tabletting, compression, extrusion, pelettisation Industrial	1,2,3
PROC15	Use a laboratory reagent Professional	8a, 8b

[35] Please note that the tables shown in this appendix have not been updated regarding Chapter R12

[36] additional some operation units that could not be assigned to a TRA category yet

	Process categories based on TRA categories for workers[36];	**ERC no**
PROC16	Using material as fuel sources, limited exposure to unburned product to be expected Industrial/professional	Not applicable
PROC17	Lubrication at high energy conditions and in partly open process Industrial/professional	4, 8d
PROC18	Greasing at high energy conditions Industrial/Professional	4, 8d
PROC19	Hand-mixing with intimate contact and only PPE available. Professional	8a to 8f
PROC Xyz	Other Process or activity	
	Heat and pressure transfer fluids in dispersive use but closed systems	9a, 9b
	Low energy manipulation of substances bound in materials and/or articles	Not yet applicable
	Potentially closed processing operations at elevated temperature	Not yet applicable
	Open processing and transfer operations at elevated temperature	Not yet applicable
	High (mechanical) energy work-up of substances bound in materials and/or articles	Not yet applicable
	Hot work operation	Not yet applicable

Appendix D-5: Linking article categories to ERCs[37]

Appendix D-5: Linking article categories to ERCs		
	Pick-list for article categories [AC]	**ERC No.**
AC02	Passenger cars and motor cycles	10a, 10b
	Other vehicles: Railway, aircraft, vessels, boats, trucks,	10a, 10b
AC03	Machinery and mechanical appliances thereof	10a, 10b, 11a, 11b
AC04	Electrical and electronic products, e.g. computers, office equipment, video and audio recording, communication equipment	11a
	Electrical batteries and accumulators	11a
	Electrical and electronic products: Household appliances (white ware)	11a
AC05	Glass and ceramic products: dinner ware, pots, pans, food storage containers	10a, 11a
AC06	Fabrics, textiles and apparel: bedding and clothing	11b
	Fabrics, textiles and apparel: curtains, upholstery, carpeting/flooring,	11a
AC08	Leather products: apparel and upholstery	11a
AC10	Metal products: cutlery, cooking utensils, pots, pans,	11a
	Metal products: toys	10a, 11a
	Metal products: furniture	10a, 11a
AC11	Paper products: tissue, towels, disposable dinnerware, nappies, feminine hygiene products, adult incontinence products, writing paper	11a, 11b
	Paper products: newspaper, packaging	11a
AC13	Photographic and reprographic articles: cameras, video cameras, =>AC04 possibly more suitable	11a
	Photographic and reprographic articles: films Printed photographs	11a
AC15	Rubber products: tires	10b
	Rubber products: flooring	11a
	Rubber products: footwear	10a, 10b
	Rubber products: toys	11a
	Other general rubber products	
AC17	Wood and wood furniture: flooring	11a, 11b
	Wood and wood furniture: furniture	10a, 11a
	Wood and wood furniture: toys	10a, 11a
C18.1	Constructional articles and building material for indoor use: wall construction, ceramic, metal, plastic and wood construction material, insulating material.	11a
C18.2	Constructional articles and building material for outdoor use: wall construction, road surface, ceramic, metal, plastic and wood material, insulating material.	10a, 10b
C19	Commercial/consumer plastic products like disposable dinner ware, food storage, food packaging, baby bottles	11a

[37] Please note that the tables shown in this appendix have not been updated regarding Chapter R12

Appendix D-5: Linking article categories to ERCs		
	Pick-list for article categories [AC]	**ERC No.**
	Plastic products: Flooring	11a
	Plastic products: Toys	10a, 11a

Appendix: D-5: Linking Article Categories to ERCs		**ERC no**
Scented articles		
AC31	Clothes	11b
AC32	Eraser	11b
AC33	*Entry removed after CA in March 08*	
AC34	Toys	11b
AC35	Paper articles	11b
AC36	CD	11b
AC37	Other scented articles; please specify[38]	
Articles releasing grease and/or corrosion inhibitors		
AC38	Packaging material for metal parts, releasing grease/corrosion inhibitors	11b
AC39	Other articles releasing grease or corrosion inhibitors; please specify[39]	
Other articles with intend release of substances; please specify		
AC40	Other articles with intend release of substances; please specify[40]	

[38] to be specified in free-text field if i) the article is not covered in any of the categories or ii) the registrant wishes to describe the use of the substance manufactured into an article more specific; use the TARIC terminology in such cases.

[39] see previous footnote

[40] see previous footnote