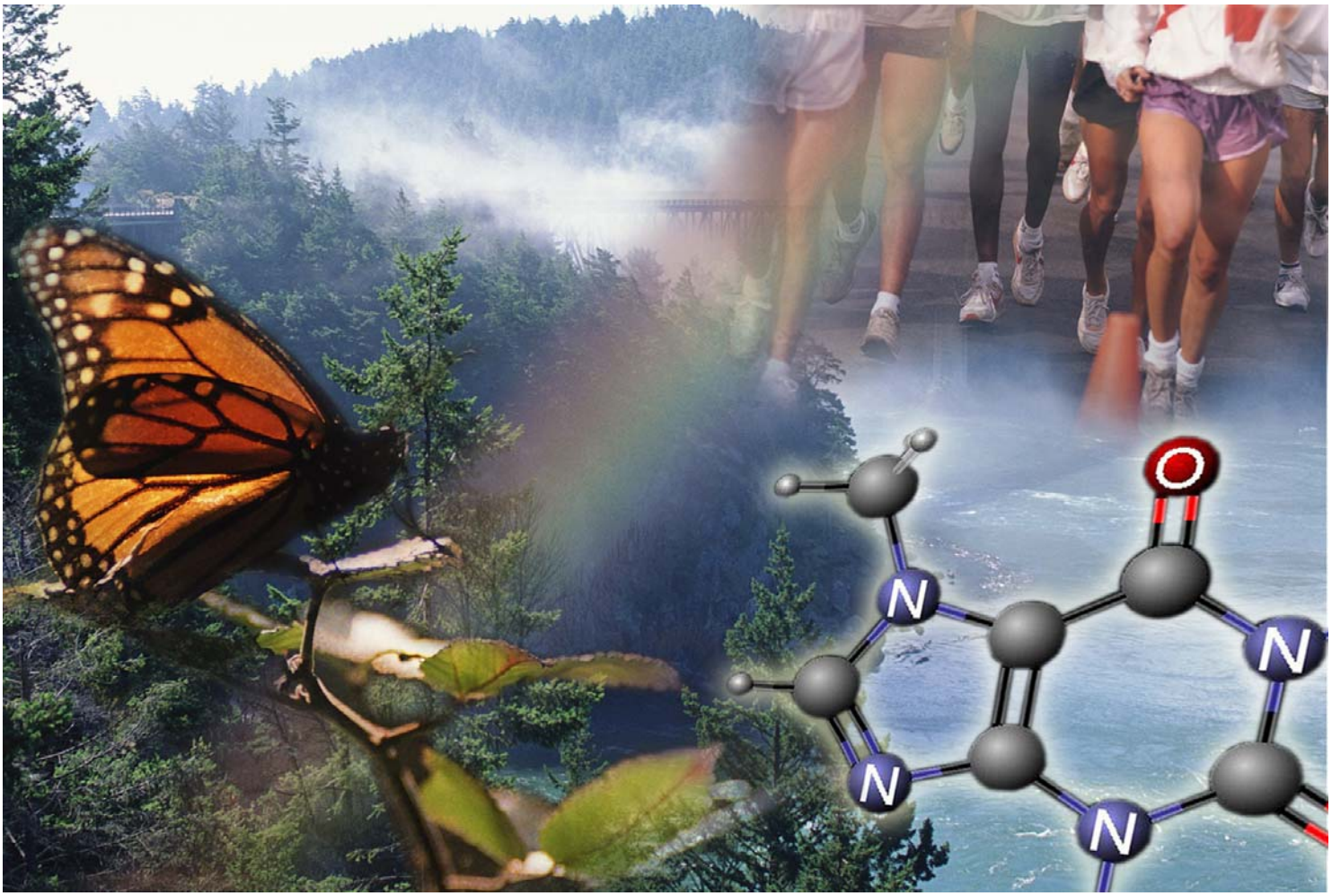
Guidance on information requirements and chemical safety assessment

Part G: Extending the SDS



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Guidance for the implementation of REACH

LEGAL NOTICE

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

PREFACE

This document describes the information requirements under REACH with regard to substance properties, exposure, uses 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/about/reach_en.asp). Further guidance documents will be published on this website when they are finalised or updated.

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

***Please note*: Further guidance on exposure scenarios for preparations may be added as Appendix G-2 at a later stage. Additional note for the REACH competent authorities: The outcomes of the workshop on exposure scenarios for preparations on May 19 and 20, 2008 (organised by the European Chemicals Bureau) will be reported at the REACH CA meeting in June. This will include a proposal for possible further guidance needs.**

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

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Convention for citing the REACH regulation

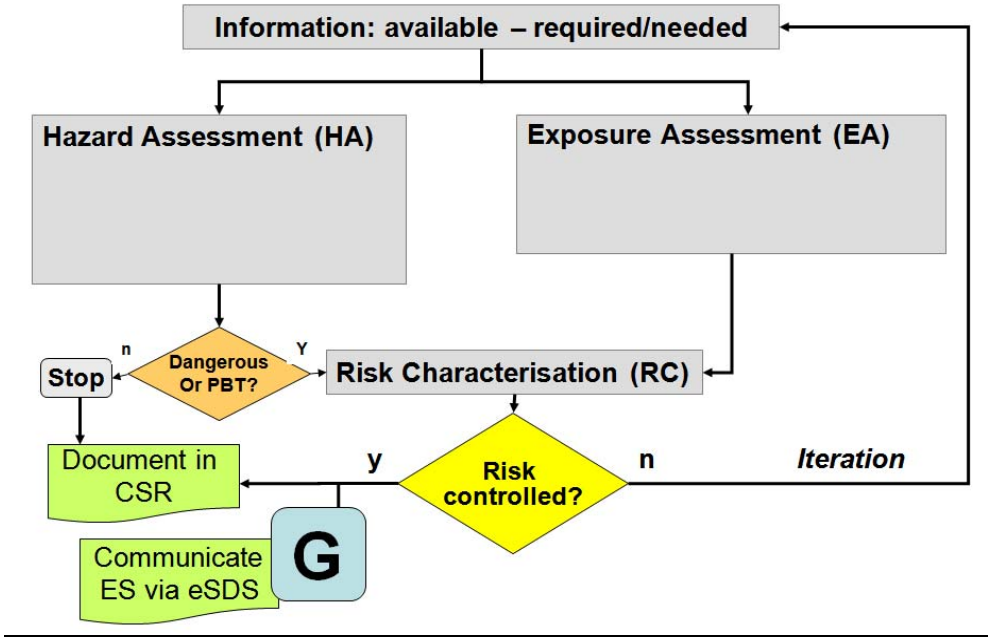
Where the REACH regulation is cited literally, this is indicated by text in italics between quotes.

Table of Terms and Abbreviations

See Chapter R.20

Pathfinder

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



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G.1 AIM OF THIS CHAPTER

The chapter is addressed to manufacturers and importers placing a substance as such or in a preparation on the market. It provides guidance to M/I how to integrate the final exposure scenarios for a substance into Safety Data Sheet to make it an extended SDS. This includes i) general guidance on how the exposure scenarios and the main body of the extended safety data sheet can be combined in a useful way, and ii) specific guidance on the relationship between the Sections 1.2 (identified uses), 7 (handling and storage), 8 (exposure controls) and 13 (disposal considerations) of the SDS and the exposure scenarios in the annex. The chapter does not provide complete guidance on all sections of the eSDS, and it does not cover safety data sheets for substances for which no CSR is required.

G.2 TRANSMISSION OF INFORMATION DOWN THE CHAIN

G.2.1 Life cycle stages to be covered

The registrant transmits the relevant information documented in the CSR to the actors further down the supply chain by means of the extended safety data sheet (eSDS). This includes information on substance properties, appropriate risk management measures and the related operational conditions (OC). This information shall cover all subsequent life cycle stages of the substance for which control of risk is documented in the CSR. Those uses that the registrant did not include in the final exposure scenarios for reasons of health and environmental concerns he should advise against in Section 16 of the eSDS.

The information may include advice that refers to uses and life cycle stages beyond downstream uses under REACH. The addressee of eSDS-information at the bottom of the REACH communication chain is expected to use this advice

- to inform/instruct users of substances or preparations in the general public, even though no safety sheet is required,
- to fulfil his duties related to safety or emission behaviour of articles, as laid down in other legislation (e.g. toys, construction products), and to comply with his duties under Article 33 (if he is an article producer) and
- to fulfil his duties to select appropriate waste disposal routes.

G.2.2 Extended safety data sheet to the immediate downstream user

The ultimate aim is to supply relevant and understandable information to the actors in the supply chain, using the substance as such or in a preparation. The OC and RMM may differ from use to use. Therefore, REACH requires to attach exposure scenarios on individual uses or groups of uses as annexes to the SDS.

While the main body of the SDS contains information relevant to all users of the substance, the information in the ESs is relevant and useful only for certain groups of downstream users.

The immediate DU (the “customer”) next to the registrant (as other DUs as well) has to perform the following actions:

- to check whether the ES fits his own uses, and the uses of his customers as taking place within the boundaries of the ES supplied to him in order
    - to *identify* and *apply* the relevant measures to his own processes
    - to *include* the ES and other information in the eSDS received from the registrant into his own safety data sheet (if he places the substance or preparation on the market), and to *identify* and *recommend* appropriate RMMs to his customers.
- or to carry out an own chemicals safety assessment if the above proves not be the case.

For ***"applying"*** the RMM and OC communicated with the ES, the immediate DU must be able to understand what is communicated to him. Thus the M/I is required to write the ES in a technical language that is understandable to the immediate DU, and contains practically useful information related to his processes.

This includes, for example, mixing processes at formulator's level, processing of a marketed intermediate outside strictly contained conditions in the chemical industry, or the final use of a substance in the general manufacturing industry.

G.2.3 Inclusion of exposure scenarios to SDS for subsequent users

Depending on how diverse the OC and RMM for the substances in the preparation will be further downstream, the i***nclusion*** of the ES can be carried out in different ways. Also, the immediate downstream users for the substance can have very different levels of technical competence to identify, apply and recommend appropriate measures to control risks identified in the safety data sheets supplied to them. Thus, for compiling the eSDS for a substance, the M/I will need to anticipate which role his immediate DUs play in the supply chain. Based on these considerations M/I will present the information in a way that enables the immediate DU to *identify* the measures relevant to be *recommended* to his customers. M/I is expected to phrase the OC and RMMs in a form that they can be *included* and *recommended* in the SDS for a preparation without re-phrasing[2] by his immediate DUs. These DUs may nevertheless decide to add further guidance for their customers in the SDS for the preparation. M/I should be aware of the three principal ways in which the immediate DU may "*include*" the information supplied to him in his communication to actors further down the chain:

- *If the immediate DU is the formulator (or re-packer) of an end-use product[3] for downstream users*: The DU is supposed to extract the relevant information on risk management and OC from the ESs, summarise and include it in Sections 1.2, 7, 8 and 13 of the SDS for the preparation. The SDS for an end-use product (substance or preparation) will often address a well defined group of downstream users, and hence the RMM advice does not need use-specific differentiation. If, however, the same substance/preparation (e.g. a solvent based cleaner) is used under different operational conditions and/or by means of different RMMs, *inclusion* of the received ES may be best done by consolidating the received ES into two or more new exposure scenarios annexed to the SDS for the preparation. This may for example be relevant in situations where a manufacturer or large formulator supplies his products via distributors and re-packers to end-users (industrial or non-industrial).

2 The standard phrases for risk management measures (as contained in the RMM-library) should be therefore constructed in a way that they are understandable for all actors in the supply chain.

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

- *If the immediate DU is the formulator of an end-use preparation to be offered or sold to the general public*: The DU is supposed to extract the relevant information on risk management and OC from the received ESs, summarise and include it in the information for the users (e.g. by means of appropriate use instructions). Such information shall enable the users of the general public to take the necessary measures as regards the protection of human health, safety and the environment.
- *If the immediate DU is a formulator of a preparation sold to further formulators for inclusion into a preparation*: The DU is supposed to extract the relevant information on risk management and OC from the ESs, summarise and include it in Sections 1.2, 7, 8 and 13 of the SDS for the preparation. The SDS for such a preparation still has to contain information relevant for a broader range of downstream users and the corresponding (OC). Differentiation of RMMs and OC related to different user groups may be needed. In such case, *inclusion* may be best done by
    - forwarding the received exposure scenarios to the customer without consolidation (most transparent way of forwarding information) or
    - by consolidating the received ES into several new exposure scenarios annexed to the SDS for the preparation, depending on the technical use of the preparation. For example an additive producer may compile one ES for "additive package used in production of coatings" and one ES for "additive package used in production of polymer compounds".

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 general workflow as outlined in Section D.3.2), and when he selects the representative sample of DUs to receive feedback on the initial ES (step 6 of the general workflow). The title of the final exposure scenario should indicate to which actors in the chain are addressed. Further guidance on formulators how to develop Exposure scenarios for preparations is given in *Guidance for Downstream Users*.

Distributors

Distributors are no downstream users under REACH. Thus, the customer of the distributor is *immediate* downstream user next to M/I. It is recommended that M/I actively approaches the distributors to seek agreement, 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 (CBI). 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 sort of facilitator. In some cases, a third party could be appointed to manage CBI.

G.3 REACH REQUIREMENTS ON EXTENDED SAFETY DATA SHEET

The CSR for a substance includes one or more exposure scenarios as single sub-chapters in chapter 9. Each of these sub-chapters addresses one or more identified, individual uses. For each of these exposure scenarios an exposure estimate and a risk characterisation is required, in order to demonstrate control of risk. The ES in the CSR is meant to document the conditions of use to which the exposure estimate and the risk characterisation refers. Compared to that, the purpose of the ES communicated to the downstream users is to give guidance on how to use the substance in a way that control of risk is ensured. Thus the focus is on guidance which is useful and understandable to the downstream users further down the chain. In order to avoid re-phrasing, the ES chapters in the CSR should contain the RMMs and OCs already in a form that allows direct export into the eSDS system. Nevertheless the CSR chapters can

contain further explanation and justifications which does not need to be communicated to the DUs.

According to REACH, Annex II, "*the safety data sheet provides a mechanism for transmitting appropriate safety information on classified substances and preparations down the supply chain to the immediate downstream user(s). The information provided in the Safety Data Sheet shall be consistent with the information in the Chemical Safety Report. The relevant exposure scenario(s) shall be placed into an annex of the Safety Data Sheet, to make reference to them under the relevant headings of the Safety Data Sheet easier"*. The safety data sheets shall "*enable users to take the necessary measures relating to protection of human health and safety at the workplace, and protection of the environment*".

The exposure scenarios communicated to the immediate downstream user must contain all information on risk management and operational conditions of use relevant for any actor further down the supply chain. The technical language and the structure in which the information is communicated must be suitable to be understood by these actors.

In Section 8.2 of the eSDS (exposure controls), a summary of the risk management mesasures shall be given across all uses addressed in the exposure scenarios set out in the annex to the SDS. Exposure controls mean in this context, "*the full range of specific risk management measures to be taken during use in order to minimise worker and environmental exposure"*. Also, the relevant exposure thresholds shall be presented under Section 8.1. It is important to ensure that the identified uses under Section 1.2 of the eSDS, the titles of the exposure scenarios in the annex, the operational conditions (e.g. duration and frequency of exposure), the risk management measures and the threshold itself are consistent with each other.

Section 7 of the eSDS shall provide assistance to devise suitable working procedures and organisational measures related to safe handling and storage. This should include advice on general technical measures to prevent exposure of workers and the environment[4].

Section 7.3 refers to products for end-use and can contain references to specific advice existing for control of risk of such products. This section is typically to be completed by companies producing such products. Only in exceptional cases this will be the substance manufacturer himself. Nevertheless quite some guidance exists related to occupational measures specifically addressed to end-products containing substances with specific hazards, e.g. work with products containing isocyanates, epoxides or solvents. If M/I is aware of such guidance, e.g. through information in the risk management library, he should give the corresponding reference under Section 7.3 of the eSDS. The information shall be consistent with the exposure scenario set out in the annex to the safety data sheet.

In summary, there are a number of new elements to be integrated into the existing SDS systems, including:

- The extended safety data sheet under REACH is expected to provide **use related advice** on the operational conditions and the risk management measures suitable to control the risk of a substance.
- In Section 1.2 of the eSDS **all identified uses** relevant to the recipient of the SDS shall be given.

4 Section 7 makes particular reference to article 5 of Directive 98/24 (Chemicals Agent Directive). In article 5 of this Directive the general principles of preventing risks to workers associated with dangerous chemicals agents are laid down.

- The eSDS must include the relevant information to control risk during the **whole life cycle** of the substance. Each M/I is expected to adress all identified uses in his particular supply chain.
- The eSDS is supposed to cover RMMs and operational conditions related to workers, **environment and consumers**. Thus the eSDS is expected to become an important source of information also for environmental managers at production sites and product safety managers.

G.4 GUIDANCE TO CONNECT THE SDS WITH EXPOSURE SCENARIOS

G.4.1 Guidance on how to use section 7 and 8 of the SDS

Annex II of REACH sets requirements how to structure the measures related to occupational and environmental prevention and control of risks in Sections 7 and 8. Table G.1 gives an overview on these provisions.

1 **Table G.1 Information in section 7 ad 8 of the eSDS**

	7.1 Handling	**7.3 Specific uses**	**8.1 Exposure limit values**	**8.2.1 Occupational exposure controls**	**8.2.2 Environmental Exposure controls**
PNECs, DNELs and OELs relevant for the exposure scenarios			**X**		
General occupational RMM and OC, other than personal protective equipment (PPE)	**X**				
Full range of specific occupational RMM and OC				**X**	
Details on equipment if individual measures (PPE) is needed				**X**	
Environmental RMM controlling emission from local exhaust ventilation (LEV), collective ventilation, or collection and disposal of spillage	**X**				
Recommendation related to end-products with specific uses		**X**			
Information on the full range of specific RMM and OC, required to fulfil commitment under community environmental legislation					**X**
Summary of occupational RMM for all identified uses set out in the SDS				**X**	
Summary of environmental RMM for all identified uses set out in the SDS					**X**

In order to implement these requirements in a consistent and user-friendly way, the following rules should be applied:

- Annex II distinguishes between occupational RMMs in Sections 7.1 (general measures aiming to prevent and minimise risks) and 8.2 (complementing, specific measures aiming to limit exposure to levels below the DNEL/PNEC). Certain measures however, e.g. ventilation, is mentioned in both sections.
- Annex II requires to specify measures, how prevention or control of exposure can be achieved. Safety statements like "avoid breathing vapours" or "avoid skin contact" are insufficient to fulfil the requirements.
- The summary on RMMs across all uses covered in the exposure scenario annex shall be placed in Section 8. It is therefore recommended to concentrate the summary of all measures (including those of preventive nature if particularly relevant for a substance or a use) in Section 8.2 of the SDS.
- Section 7.1 of the eSDS should contain general measures to prevent and minimise risks. This includes a whole range of actions, as for example: design and organisation of work systems; suitable equipment and regular maintenance of it; minimisation of duration and extensity of exposure through organisational measures; general ventilation and appropriate hygiene measures[5]. It is recommended not to repeat this type of RMMs in every ES contained in the annex to the SDS, since it is neither substance specific nor are the RMMs particularly geared to an individual use.
- For eSDS related to substances, Section 7.3 of the eSDS is only of limited relevance, since it refers to end-product specific guidance. However if M/I is aware of such guidance related to his substance in end-products (e.g. risk management package related to isocyanate containing products) he can make a reference here.
- In particular concerning directives on occupational health and safety, PPE is the last resort to control risks if the measures related to product design (e.g. low dust grades), process design (e.g. level of containment, closed process, local extraction), workplace (dilution ventilation) or work method (automatisation) are insufficient or not possible. This can for example be the case in maintenance of installation or manual spraying outside industrial settings. Whether PPE is required or not, usually depends on the operational conditions of use which may differ from exposure scenario to exposure scenario. It is therefore recommended to list the type of PPE, and the conditions when to apply it, in each of the single exposure scenarios (if PPE is needed at all under regular operational, cleaning or maintenance conditions).
- If M/I considers it useful to keep further details on PPE in Section 8 of the main body text of the eSDS he should ensure that the i) the <u>details</u> of PPE on the one hand and ii) the <u>summary</u> of use-specific RMMs across all ES on the other hand are kept clearly separate from each other in Section 8.2.1. Two separate headlines are recommended:
    - Summary of risk management measures of substances for which a CSA is required. This summary should be consistent with the summary of RMMs in the CSR.
    - Details on personal protection measures
- Annex II does not specifically mention RMMs and OCs related to consumers, but Section 8 of annex II stipulates that the RMM across all the identified uses shall be summarised in

5 For further detail see part I Chapter 2 of the EU Practical Guidelines related to the Directive 98/24/EC.

section 8 of the SDS. Potential exposure of consumers during the life of the substance resulting from identified downstream uses are to be covered in the CSA for a substance. It is therefore recommended to add an extra section 8.2.3 in the extended safety data sheet to include measures related to consumer uses of the substance (as such or in preparations) and to the service life of the substance in articles. This information is addressed to the downstream users under REACH i) when placing preparations for use in the general public on the market and ii) when processing substances or preparations into articles. It may also facilitate the communication related to substances of very high concern, for which risk management advice beyond downstream uses can be required under Article 7 and Article 33 of REACH.

G.4.2 The exposure scenario and corresponding headlines in the safety data sheet

Table G.2 gives an overview of the relationship between the SDS chapters and the standard entries of the exposure scenario (see Section D.3.2).

Depending on the hazard profile of the substance, the broadness of the market and the structure of the supply chain, there is a variety of options to modify the principal organisation of information in the exposure scenarios and the extended safety data sheets, e.g.

- Section 6 of the exposure scenario could be further differentiated into exposure routes and exposure patterns. It can be also useful to link the risk management advise per route and endpoint directly with the relevant DNEL and exposure prediction. (see Example 3 in Appendix G – 1).
- In a broad ES for a substance with only one or two hazard endpoints of concern, it may be also possible to list the specific RMMs for certain activities in Section 6 of one *composite* exposure scenario.

Table G.2 Content of the ES and the corresponding section in the SDS

Title of section in the exposure scenario (referring to OC and RMM for individual uses or groups of uses	**Include in chapter ….. of SDS or check consistency**
1. Short title of Exposure Scenario	Ensure consistency with 1.2 and eventually 7.3[6]
2. Description of activities/process(es) covered in the Exposure Scenario	No inclusion in main body
3. Operational conditions	
3. 1 Duration and frequency of use for which the ES ensures control of risk;	Ensure consistency with DNEL provided in section 8. Include in 8, where applied to control risk.
4. 1 Physical form of product in which the substance is contained;	Ensure consistency with 9; include in summary in 8.2, where applied to control risk.
4.1a Surface area per amount of article containing the substance (if applicable)	Include in summary in 8.2, where applied to control of risk.
4.2 Concentration of substance in preparation or article;	Ensure consistency with 3; include in summary in 8.2, when applied to control risk.
4.3 Amount used per time or per activity for which the RMMs, in combination with other operational conditions of use ensure control of risk (if applicable)	Include in summary in section 8.2, where applied to control risk.
5. Other operational conditions determining exposure, e.g. temperature, capacity of receiving environment (water flow; room size x ventilation rate), emission or release factors to the relevant compartments, and other	Include in summary in chapter 8.2, where applied to control risk.
6. Risk Management Measures that, in combination with the operational conditions of use, ensure control of risk related to the different target groups	
6.1.1 Occupational measures following the hierarchy of Directive 98/24/EC : type and efficiency of single options or combination of options on exposure to be quantified; options to be phrased as instructive guidance;	Include in summary in section 8.2.1.
6.1.2 Consumer related measures: type and efficiency of single options or combination of options on exposure to be quantified; options to be phrased as instructive guidance;	Include in summary in section 8.2.3
6.2 Environment related measures; type and efficiency of single options or combination of options on exposure to be quantified; options to be phrased as instructive guidance;	Include in summary in section 8.2.2
7. Waste related measures needed to ensure control of risk at the different life cycle stages of the substances (including preparations or articles at the end of service life)	Ensure consistency with 13.
8. Prediction of exposure resulting from the conditions described above (entries 3-6) and the substance properties (to be quantified based on exposure assessment in the CSA); make reference to the exposure assessment tool applied	No inclusion in main body text
9. Guidance to DU to evaluate whether he works inside the boundaries set by the ES	No inclusion in main body text

6 SDS Sections: 1.2 (use of substance); 7 (Handling and storage); 7.3 specific uses); 8 (Exposure controls); 13 (waste related measures)

G.4.3 Standard phrases for risk management measures in the eSDS

The use of standard phrases can simplify the description of risk management measures and operational conditions of use in the exposure scenarios and the main body text of the SDS. To allow for flexibility to cover the majority of different measures and recommendations, a modular system with standard phrases would be appropriate. The phrases could either describe discrete measures in a single, more elaborated phrase and/or address more complex information by combining different short phrases. They should be ideally identical with phrases used in the RMM library to ensure consistency in the terminology and uniqueness of the technical matter described.

The current catalogues of standard phrases, as built into the IT systems for SDS generation at company level, need updating to be made operational under REACH. Most of M/I will need to consider how to further develop their systems regarding the following aspects:

- Most of the standard catalogues do not allow specifying the operational conditions under which risk management measures are to be applied. The same applies to information with regard to the effectiveness of measures.
- Most catalogues do not allow making reference to risk management packages specifically designed to prevent and control risk in using certain product types or carrying out certain tasks at workplace.
- Risk management measures related to the environment are usually limited to spill management and prevention of harm to the sewage treatment micro-organisms. Waste water and waste air treatment techniques are usually not available in the existing catalogues of substance manufacturers.
- Also product related risk management measures as applied by end-product formulators, for example in order to prevent risk at consumer level can usually not be expressed by means of the existing catalogues.

It is recommended that M/I makes himself aware on any progress made in developing a European standard phrase catalogue at association level before starting to update the own system with individual solutions.

RMM phrases suitable to communicate operational conditions and RMMs within REACH, shall be developed for the CSR CSA tool. In addition to standard phrases, also more specific RMM information shall be needed in many cases.

Appendices 1-2 to Part G

Appendix G-1 Methodology on Scaling

Content of Appendix G-1

1.1 Introduction

1.2 Methodologies to be used for scaling

1.3 Step in scaling

1. 4 Examples on scaling for consumer use

1.1 Introduction

Scaling in this context means the use of simple equations in the exposure scenario (ES) by which the downstream user (DU) can demonstrate that he operates within the conditions of the ES provided by the registrant. The aim of this chapter is to guide the registrant on how he can enable the DU to check compliance with the ES if his operational conditions (OCs) or risk management measures (RMMs) differ from those in the ES.

There is very limited experience on the use of scaling for exposure estimations. Therefore, this chapter should be considered as preliminary guidance, and it shall be updated when more practical experience is gained.

Background

The DU is obliged to check compliance with the ES forwarded by the registrant. The information on OCs and RMMs given in the ES should be compared with the actual OCs and RMMs of the DU. In situations, where the OCs/RMMs are not completely identical with the OCs/RMMs specified in the ES, it may still be possible for the DU to ascertain that he is in compliance with the ES. When one or more of the actual OC and RMM differ from those of the ES, it is not immediately apparent whether the use is still in compliance with the ES. For this situation M/I can provide scaling rules as part of the ES to help DUs to check compliance with the ES and to increase the flexibility of ESs for a wider range of downstream users.

Scaling is an element within a flexible and broad exposure scenario. The DUs can be within the exposure scenario, but the exact boundaries of the exposure scenario are not described by fixed values for each parameter. The exposure scenario can be described flexibly with a variety of combinations of OCs and RMMs. If the calculated exposure levels are based on the recommended OCs and RMMs or even stricter, the DU does not have to do any scaling. However, because the parameters do not all work in the same direction, there can be situations where scaling is needed based on the change of OCs/RMMs. The DU can then combine OCs and RMMs differently than proposed by the registrant within the flexibility of the ES to reach the same conclusion on control of risks. Thus scaling does not develop new exposure scenarios with the same equations, but calculates whether the situation of the DU is within the broad exposure scenario described by the registrant.

Steps

For each relevant exposure route, the registrant needs to

1. Determine a set of OCs and RMMs (key determinants of exposure) for which control of risk for the exposure route can be demonstrated. This is the set of OCs and RMMs to be communicated in the ES.
2. Communicate the risk characterisation Ratio (RCR_{ES}) in the ES (use Section 9 of the ES). See chapter E for the calculation of RCR_{ES}.
3. For each of the relevant key determinants, which are likely to vary in the actual use situations

   - assure that the determinants are not mutually dependent
   - describe (by an algorithm or by a reference to publicly available tool) how each determinant that will be varied influences the RCR_{ES}.

     Example (for the environment): the exposure concentration and thus the RCR in the environment is proportional to the actual amount used (M_{Actual}). Thus the algorithm for scaling is: $RCR_{Actual} = RCR_{ES} \cdot M_{Actual} / M_{ES}$, where RCR_{Actual} is the calculated RCR for the actual situation.

   - determine the range for the determinant to which the above algorithm is valid and within which it is reasonable to let the determinant vary.

     Example: the registrant has calculated the consumer exposure concentration for inhalation assuming that all substance applied (M_{ES}) evaporates immediately and distributes completely within the room with a volume V_{ES}, i.e. the exposure concentration for inhalation is calculated as: $C = M_{ES} / V_{ES}$. Thus, the RCR for inhalation exposure is inversely proportional to the room volume as long as complete, homogenous mixing within the room can be assumed. The algorithm for scaling is: $RCR_{Actual} = RCR_{ES} * V_{ES} / V_{Actual} \cdot M_{Actual} / M_{ES}$. The assumption of reasonably complete and homogenous mixing only holds for certain exposure situations and room volumes below a certain size, for example 50 m^3.

   - if the same determinant is relevant for other exposure routes, a range, which holds for all exposure routes should be specified.
   - validate and document in the CSR that the proposed scaling mechanism is valid.

4. Communicate the algorithm and the determinant ranges (in Section 9 of the ES)

1.2 Methodologies to be used for scaling

1.2.1 Linearity

A simple method to calculate whether one condition, i.e. a key determinant of exposure, compensates another can be performed in cases where the relation between the respective determinants of exposure and the resulting levels of exposure is linear. Then, the factor describing the difference between actual conditions and those specified in the ES can be derived and compared with the compensating factors for other determinants. This concept of linear scaling assumes that there are linear relations between the determinants and the exposure level and

thus the RCR. When the linear scaling applies, the DU can check compliance by multiplying or dividing with the ratios between the actual value of an OC and the prescribed value of the OC in the ES.

The basic assumption of linear relations between an exposure determinant and the exposure level cannot be used for qualitative OC, e.g. the physical state of a preparation (liquid, solid or gas). Also, if the relevant parameters are interrelated, e.g. area covered and amount used (relevant for example in surface coating, linear calculation cannot be used. An example of parameters that can be assumed to be independent in a limited range is duration and amount.

Linear relations between the determinants and the exposure level are often valid only for small changes of the variable. Applying the rule over a larger range of the variables requires that the assumption of linearity is indeed valid. So, when using the linear scaling for the ES, the ranges for the determinants, in which the assumption of linearity between the determinant and the exposure level still holds, have to be specified in the ES.

Examples, where the assumption of linearity only holds in a limited range, are:

- Amount used. Linearity between environmental releases to waste water and amount used only holds as long as the water solubility is not exceeded.
- The temperature has a non-linear impact on vapour pressure, which is a key determinant for inhalation exposure.
- The pH can have an impact on the release factor to waste water e.g. from an electrolytic treatment, but the impact is not linear.

In conclusion, it may be considered to apply the linear scaling to increase flexibility, but it should be clear when doing so, that linear or other relationships between variables can be justified and that a sufficient margin of exposure is considered in practice. When applying the rule over a larger change in values for the variables, it is essential to know that the linearity is indeed applicable. This requires that the particular use of linear scaling is well documented in the Chemical Safety Report and is based on accepted algorithms for exposure assessment (e.g., coming from the same equations that constitute the Tier 1 tools). Furthermore, it requires that the linear scaling is well-described in the ES, as well as the relevant boundaries that apply.

If the OCs and/or RMMs differ qualitatively from the conditions described in the ES, an iteration of factors that could compensate each other is not possible.

1.2.2 Non-linearity

In cases, where a simple linear relationship between determinant and exposure level cannot be used, the registrant may prepare a tool enabling the DU to check his own use. Such a tool can have the form of an algorithm, simple look-up tables, an excel sheet, a database, or a web-based tool. It can also be the exposure tool, which the registrant used for exposure calculations, e.g. ECETOC TRA and EUSES. In this case, the registrant needs to inform in the ES, which input parameters have been or can be used for the calculations.

An example of a web-based tool is the tool prepared for the German Textile finishing industry[7]. The tool enables the formulator to check whether - based on his knowledge about the

7 Manual for the screening tool supporting environmental exposure assessment under REACH for substances used in textile finishing developed for the German Umweltbundesamt as part of the R&D project Nr. 202 67 433. Version: 11.11.2005. http://www.reach-info.de/expoanalyse.htm

processes in which his products are used - the Exposure Scenario indicated by the substance manufacturer is appropriate to ensure control of risk or if it needs modification. The textile finisher may use this tool to check whether he works within the conditions of use for control of risk as prescribed by his supplier, or whether he has to modify certain parameters in the exposure estimate to demonstrate control of risks (more realistic exposure estimates).

1.3 Step in scaling

1.3.1 Step 1: Determine a set of OCs and RMMs

The result of this step is a set of OCs and RMMs which are essential for the ES sections 4-7. (See further information in Part D of CSR Guidance).

1.3.2 Step 2: Communicate the risk characterisation ratio (RCR)

The derivation of the RCRs is described in Part E of CSR Guidance. The RCRs should be communicated in the ES if it is assumed that the DU shall carry out scaling calculations himself. The RCRs could be included in Section 9 of the ES.

1.3.3 Step 3: Assess determinants and formulate scaling algorithms

For each of the relevant exposure routes and target groups for the considered use, the following elements are needed:

1. Consider if the use of scaling is relevant. If for example, the derived RCR is well below 1 and is not expected to be close to 1 for any reasonable values of OC/RMM, there is no reason for scaling. In this case, the ES could be described with a broader (more conservative) set of OCs and RMMs that ensure control of risks.
2. List all determinants specified in the ES for the considered exposure route and target group. On a Tier 1 level, the following determinants would typically be used for scaling:
    - Workers: exposure duration, concentration/amount per activity, RMM effectiveness
    - Consumer: concentration/amount, room volume, duration
    - Environment: amount, release fractions/RMM effectiveness[8], dilution factor
3. List the OCs and RMMs, which are likely to be different in the actual use situations.
4. Check that only mutually independent determinants OCs and RMMs are used for scaling purposes. The assumption of mutually independency often only holds in a limited range, e.g. in the consumer exposure via inhalation the concentration in the air may be expressed as a function of amount used, room volume and ventilation rate[9]. If the ven-

[8] What is important in the environmental exposure assessment are the overall release fractions. These may be composed of two factors: one factor accounting for the release fraction if no abatement is introduced (f_1) and one factor accounting for the efficiency of an abatement (f_2). The overall release factor would then read $f_1*(1-f_2)$ or if f_2 is expressed as a percentage: $f_1*(100-f_2)$.

[9] Please notice that room volume should only be used for consumer exposure estimation and not for worker exposure situations. In normal workplace situations, both in process industry and manual work, the highest concentration of air impurity and the highest exposure is at the place of emission, and the concentration decreases quite rapidly with the distance from the source. As workers very often work close to the emission source, their exposure is much higher than the average in the room.

tilation rate is expressed as hr^{-1}, then it is actually a function of the air exchange rate (m^3/hr) and room volume. Therefore, in this case the determinants to use for scaling are either both air exchange rate (m^3/hr) and room volume or only ventilation rate expressed as hr^{-1}.

5. Start the scaling with the methodology used for exposure assessment for the target group and exposure route. This can be an available Tier 1 tool, an algorithm, or actual measured data. The DU can use for scaling a Tier 1 tool if it is publicly available and is reliable also for non-expert users. In this case, the registrant should use the ES to communicate the input parameters that are needed for the calculations.

   Linear scaling can be used, if the tool or the algorithm expresses linearity between the relevant OCs/RMMs and the derived exposure level. Otherwise, either consider applying non-linear scaling or check in which range of the OC/RMM, the assumption of linearity between derived exposure level and used OC/RMM still holds.

6. If measured data are used, then consider which OCs/RMM have an impact on the exposure level and are likely to vary (see the bullet point list above) and how the impact of the OC/RMM should be quantified. Take for example basis in how the exposure tools quantify the impact of OCs/RMMs on the predicted exposure level (see Chapters R.14 (occupational), R.15 (consumer), R.16 (environment) for more information on the exposure assessment).

7. Find the range in which the OC/RMM can vary. These ranges are determined by the possibility to demonstrate control of risk, that the OCs/RMMs used for scaling are independent of each others, and that the basic assumptions for the derivation of exposure level still hold. In the process of finding and selecting the range include uncertainty analysis of the conclusions (see Chapter R.19 for details on how to make uncertainty analysis).

8. If the same determinant is relevant for other exposure routes, ensure that you are specifying a range, which holds for all exposure routes.

9. Validate and document in the CSR that the proposed scaling mechanism is valid, i.e. control of risks is demonstrated.

1.3.4 Step 4: Communicate the algorithm and the determinants in the ES

The algorithm and the determinant ranges for which the scaling can be used should be communicated in Section 9 of the ES. Further, instructions on how to use the scaling tools and the ranges for the determinants should be clearly communicated.

1. 4 Examples on scaling for consumer use

For illustration, some basic examples on the use of scaling are given in this section. Chapter 5 in *Guidance for Downstream Users* gives DUs guidance how to check compliance check with the exposure scenario.

1 **Example 1** Scaling related to consumer exposure via inhalation

A manufacturer produces a substance, which is mainly used in a surface coating for consumer use. This substance is produced in a tonnage of 1500 t/y and is assessed to be hazardous. Thus, a CSA and an ES for the use situation have to be prepared.

For the consumer exposure via inhalation, the manufacturer takes the following starting points for the determinants:

- Surface area to be covered by the resin is 10 m^2 ($A_{room,ES}$)
- The consumed amount of resin is 0.1 kg/m^2 (m_{ES})
- The amount used is proportional to the surface area: $M_{ES} = A_{room,ES} \cdot m_{ES} = 1$ kg
- The room volume ($V_{room,ES}$) is 50 m^3
- Ventilation rate in the room 0.5 hr^{-1} ($q_{room,ES}$)
- The working temperature is 20°C ($t_{room,ES}$)
- The concentration in the product is assumed to be 100% (C_{ES})
- Exposure duration: 1 hr ($t_{ES,exposure}$)

The manufacturer has evaluated that under these use conditions, homogeneous mixing within the room can be assumed, and that the exposure level for inhalation can be calculated using the following methodology:

Tool applied: ConsExpo 4.1 - Inhalation – Exposure to vapour – model of release: instantaneous release

Determinants used in the calculations: Exposure duration: 1 hr, amount used 5 kg, concentration in product 100%, room volume 100 m^3, ventilation rate: 0.5 hr^{-1}.

The equation which is used in ConsExpo is:

$$C_{air} = \frac{M_{ES} \cdot C_{ES}}{V_{ES}} \times e^{-q_{room,ES} \cdot t_{ES,exposure}} = \frac{A_{ES} \cdot m_{ES} \cdot C_{ES}}{V_{ES}} \times e^{-q_{room,ES} \cdot t_{ES,exposure}}$$

The registrant calculates an RCR_{ES} for inhalation for the above use situation, as 0.8, i.e. below 1[10], and concludes that the use is safe.

The registrant carries out the steps below in order to enable the DU to perform scaling. The numbering below refers to the steps given in section 0.

1) The registrant knows that the OCs in other similar uses of the product may vary, and concludes that he should provide information in the ES enabling the DU to scale the information of OCs/RMMs included in the ES.

2) He prepares the list of relevant OCs/RMMs (see above).

[10] It should be mentioned that 0.8 is rather close to 1, and this would require an uncertainty analysis, This is however beyond the scope of this chapter. Please see Chapter R.19 for more details on this issue.

3) The OCs which he considers likely to vary are: m_{ES}, A_{ES}, C_{ES}, V_{ES} and $q_{room,ES}$.

4) He knows that the room volume and the ventilation rate may be interdependent. Thus, he introduces the air exchange rate ($Q_{exchange,ES,}$ m^3/hr) in the equation instead:

$$C_{air} = \frac{A_{ES} \cdot m_{ES} \cdot C_{ES}}{V_{ES}} \times e^{-\frac{Q_{exchange,ES} \cdot t_{ES,exposure}}{V_{ES}}}$$

$Q_{exchange,ES} = 50\ m^3 \cdot 0.5\ hr^{-1} = 25\ m^3/hr$

5) All OCs are linear with respect to exposure level, except the room volume and the air exchange rate, so he proposes the following equation for scaling:

$$RCR_{Actual} = RCR_{ES} \cdot \frac{A_{Actual}}{A_{ES}} \cdot \frac{m_{Actual}}{m_{ES}} \cdot \frac{C_{Actual}}{C_{ES}} \cdot \frac{V_{ES}}{V_{Actual}} \times e^{-\frac{(Q_{exchange,ES} - Q_{exchange,Actual} \cdot \frac{V_{ES}}{V_{Actual}}) \cdot t_{ES,exposure}}{V_{ES}}}$$

6) The concentration in the product (C_{Actual}) should be between 0 and 100%.

Basically, the room volume should not be above a certain size, as the assumption of complete mixing does not apply above a certain size. He suggests in the ES that room volume should not exceed 200 m^3 (please notice that this value is only used as an example).

In order to ensure complete mixing, the air exchange rate ($Q_{exchange,Actual}$) should not exceed 2000 m^3/hr (please notice that this value is only used as an example).

2

3 **Example 2** Scaling used in consumer exposure via inhalation

Continued from Example 1 in Section 1.4 of Appendix G-1.

A formulator actually formulates the resin and has received the ES for the substance from the manufacturer. He needs to check if the use of the substance in the resin is in compliance with the received ES, even thought his OCs/RMMs are not completely identical to the OCs/RMMs specified in the received ES.

From section 4-7 in the ES, he retrieves the information:

$A_{room,ES}$:10 m^2

m_{ES}: 0.1 kg/m^2

$V_{room,ES}$: 50 m^3

$Q_{exchange,ES}$ = 25 m^3/hr

C_{ES} = 1.0

Furthermore, he uses the scaling information specified in the ES (from section 9):

RCR_{ES}: 0.8

Algorithm for scaling:

$$RCR_{Actual} = RCR_{ES} \cdot \frac{A_{Actual}}{A_{ES}} \cdot \frac{m_{Actual}}{m_{ES}} \cdot \frac{C_{Actual}}{C_{ES}} \cdot \frac{V_{ES}}{V_{Actual}} \times e^{-\frac{(Q_{exchange,ES} - Q_{exchange,Actual} \cdot \frac{V_{ES}}{V_{Actual}}) \cdot t_{ES,exposure}}{V_{ES}}}$$

The actual OCs/RMMs for the are:

$A_{room,Actual}$:40 m^2 (maximum area considered)

m_{Actual}: 0.05 kg/m^2

$V_{room,Actual}$: 50 m^3

$Q_{exchange,Actual}$ = 200 m^3/hr

C_{Actual} = 20%

He then perform the below calculations, and conclude that the use of the substance in the resin is safe.

Parameter	**Actual**	**ES**	**Safety Ratio**	**Comment**
A(m^2)	40	10	A_{Actual} / A_{ES} = 40 / 10 = **4**	
m(kg/m2)	0.2	0.1	m_{Actual} / m_{ES} = 0.05 / 0.1 = **0.5**	
C (%)	10	10	C_{Actual} / C_{ES} = 0.2 / 1 = **0.2**	In the standard evaluation the pure substance (100%) is evaluated. The specific product contains 20 % of the risk-determining substance.

$Q_{Exchane}$ (m^3/h)	50	25	$e^{-\frac{(Q_{exchange,ES} - Q_{exchange,Actual} \cdot \frac{V_{ES}}{V_{Actual}}) \cdot t_{ES,exposure}}{V_{ES}}} = e^{-\frac{(25 - 50 \cdot \frac{50}{50}) \cdot 1}{50}} = 0.6$		
V_{Room}(m^3)	50	50			
V_{Room}(m^3)	100	100	V_{ES} /V_{Actual} = 50 /50 = **1**		
RCR	RCR_{Actual}	0.8	RCR_{Actual}=RCR_{ES}·0.8·4·0.5· 0.2·0.6·1=0.2	The calculated actual overall RCRActual is below 1. Hence, the specific conditions of use are considered safe. The margin between 0.2 and 1 is relatively small but considered large enough to also ascertain control of risks.	

Example 3 Scaling related to environmental exposure

A manufacturer produces a substance, which is mainly used in a textile finishing industry. This substance is produced in a tonnage of 5,000 tonnes per year and is assessed to be hazardous. Thus, a CSA and an ES for the use situation have to be prepared.

For the environmental exposure (here only waste water), the manufacturer takes the following starting points for the determinants:

- The quantity of product, in which the substance of concern is processed or used per year and site 1000 kg/day (M_{ES})
- The concentration or fraction of the substance in the product 0.1 (C_{ES})
- The emission factor: the fraction of the substance emitted from the process or use to wastewater (before abatement): 0.3 (f_{water})
- Efficiency of an abatement or control technology that reduces the emission to air, surface water or land: 0.95 ($f_{abatement}$)
- The removal of the substance in the STP 0.95 (F_{STP})
- The duration of emission 200 days/year (e.g. working days per year) ($T_{emission}$)
- Water treated in the sewage treatment plant 2,000 m^3/day (CAPACITY)
- Dilution factor in the receiving water body 10 (DILUTION)

The manufacturer has evaluated that under these use conditions that the exposure concentration in surface water can be predicted using the following equation:

$$PEC_{local} = PEC_{regional} + \frac{\frac{M_{ES} \cdot C_{ES} \cdot f_{water} \cdot (1 - f_{abatement})}{T_{emission}} \cdot (1 - F_{STP})}{CAPACITY \cdot DILUTION}$$

$$PEC_{local} \cong \frac{\frac{M_{ES} \cdot C_{ES} \cdot f_{water} \cdot (1 - f_{abatement})}{T_{emission}} \cdot (1 - F_{STP})}{CAPACITY \cdot DILUTION} \; (as\ PEC_{regional} \cong 0)$$

The registrant calculates an RCR_{ES} for surface water for the use situation at 0.2, i.e. below 1, and concludes that the use is safe.

The registrant carries out the below steps in order to enable the DU to perform scaling. The numbering below refers to the steps given in section 1.3.3 in Appendix G – 1.

1) The registrant knows that the OCs in other similar uses of the product may vary, and concludes that he should provide information in the ES enabling the DU to scale the information of OCs/RMMs included in the ES.

2) He prepares the list of relevant determinants (see above)

3) The determinants which he considers likely to vary are: M_{ES}, C_{ES}, f_{water}, $f_{abatement}$, $T_{emission}$

4) None of the determinants are considered interdependent

5) All determinants are linear with respect to exposure level, so he proposes the following equation for scaling:

$$RCR_{Actual} = RCR_{ES} \cdot \frac{M_{Actual}}{M_{ES}} \cdot \frac{C_{Actual}}{C_{ES}} \cdot \frac{f_{water,Actual}}{f_{water,ES}} \cdot \frac{(1 - f_{abatement,Actual})}{(1 - f_{abatement,ES})} \cdot \frac{T_{emission,ES}}{T_{Emission,Actual}}$$

6) The concentration in the product (C_{Actual}) should be between 0 and 100%.

The $f_{water,Actual}$ and $f_{abatement,Actual}$ would be between 0 and 1.

The $T_{Emission,\ Actual}$ should be between 1 and 365 days.

Example 4 Scaling used on environmental exposure

Continued from Example 3 in Section 1.4 of Appendix G-1.

A textile manufacturer actually applies the substance and has received the ES for the substance. He needs to check if he is in compliance with the received ES, even thought his OCs/RMMs are not completely identical to the OCs/RMMs specified in the received ES.

From section 4-7 in the received ES, he retrieves the information:

M_{ES}: 1000 kg/day

C_{ES}: 0.1

$f_{water,ES}$: 0.3

$f_{abatement,ES}$: 0.95

$T_{emission,ES}$: 200 days/year

Furthermore, he uses the scaling information specified in the ES:

RCR_{ES}: 0.3

Algorithm for scaling:

$$RCR_{Actual} = RCR_{ES} \cdot \frac{M_{Actual}}{M_{ES}} \cdot \frac{C_{Actual}}{C_{ES}} \cdot \frac{f_{water,Actual}}{f_{water,ES}} \cdot \frac{(1 - f_{abatement,Actual})}{(1 - f_{abatement,ES})} \cdot \frac{T_{emission,ES}}{T_{Emission,Actual}}$$

The actual OCs/RMMs for his use are:

M_{Actual}: 750 kg/day

C_{Actual}: 0.1

$f_{water,Actual}$: 0.35

$f_{abatement,Actual}$: 0.98

$T_{emission,Actual}$: 150 days/year

He then performs the calculations shown below, and concludes that his use is safe.

Parameter	Actual	ES	Safety Ratio	Comment
M(kg)	750	10000	M_{Actual} / M_{ES} = 750 / 1000 = **0.75**	
C (-)	0.1	0.1	C_{Actual} / C_{ES} = 0.1 /0.1 **= 1**	In the standard evaluation the pure substance (100%) is evaluated. The specific product contains 20 % of the risk-determining substance.
f_{water}(-)	0.35	0.3	$f_{water,Actual}/f_{water,ES}$ = 0.35/0.3=1.16	

$f_{abatement}$ (-)	0.98	0.95	$\frac{(1-f_{abatement,Actual})}{(1-f_{abatement,ES})}=\frac{1-0.98}{1-0.95}=0.4$	
$T_{Emis-sion}$(days/year)	150	200	$T_{Emission,ES}/T_{Emission,Actual}$=200/150=1.33	
RCR	RCR_{Actual}	0.3	$RCR_{Ac-tual}=RCR_{ES}\cdot 0.3\cdot 0.75\cdot 1\cdot 1.16\cdot 0.4\cdot 1.33=0.14$	The calculated actual overall RCR_{Actual} is below 1. Hence, the specific conditions of use are considered safe.

Appendix G-2 Examples and guidance related to exposure scenarios for preparations[11]

Chapter 14 "Information on preparations to be delivered by formulators" of the guidance for Downstream Users contains, between others, guidance on how to prepare Exposure Scenarios for preparations. Also Chapter 7 "Making a downstream user chemical safety assessment" of that guidance is relevant in relation to assessment of preparations.

These chapters give guidance in relation to assessment and development of exposure scenarios for preparations, including special preparations – such as alloys. Whenever substances in (special) preparations have limited availability for exposure, this should be taken care of on a case-by-case basis based on scientific arguments to be presented the CSR of M/I or the DU.

Section 14.3 of the *Guidance for Downstream Users* outlines a workflow at formulators level on processing the information received with exposure scenarios and safety data sheets from his suppliers into useful risk management guidance for his customers. In future, a formulator may wish to also apply alternative or complementary approaches compared to what is suggested in the current guidance. In the following, the guidance-approach and two alternative/complementary approaches are briefly described[12]. All three approaches are going to be further investigated and tested by industry, and based on this additional guidance may be developed.

Downstream User Guidance as is it stands

Systematically compile all relevant information on the preparation's ingredients into a spreadsheet (see DU Guidance Figure 14-2 and Table 24). Based on this, select the appropriate set of OC and RMM that would lead to control of risk for the whole preparation under the conditions it is likely to be used. In this process, remove duplicates and inconsistencies related to the set of risk management measures and operational conditions. Respect the hierarchy of risk management measures as laid down in the Chemicals Agent Directive (CAD) and the Directive on Integrated Pollution Prevention and Control (IPPC). Take into account additivity of hazards from different substances if the hazards relates to the same endpoint.

Approach based on the rules of the Dangerous Preparation Directive (DPD)

Compile concentration and hazard classification of the single substances. Apply the calculation rules of the DPD to identify the lead substance(s) driving the classification of the whole preparation. Select the RMM/OC of these substances and assume that they would cover all dangerous components in the preparations exceeding the cut-off concentration as laid down in article 14(2) and article 31(3). Check whether dangerous substances exceeding these concentrations in the preparation but not leading to classification of the preparation may nevertheless present a risk further down the chain. If this is the case, the formulator may need forwarding additional risk management advice received from suppliers. The formulator may also take into account i) risk management measures with regard to hazards for non classifiable end-points and ii) good practise measures not necessarily specifically addressing the risk of a particular substance in the preparation.

[11] Updated based on the outcomes of the Workshop on *Exposure Scenarios for preparations and Generic Exposure Scenarios*, organised by the European Chemicals Bureau (ECB) in cooperation with the European Chemicals Agency (ECHA) and ECETOC, held in Varese, Italy on May 19 and 20, 2008.

12 It is assumed that the formulator has already evaluated that the use conditions of his products are covered by the ES received for the different components (see DU Guidance Section 14.3, note j)

The formulator may come to the conclusion that the classification rules of the DPD do not sufficiently address the relative risk related to the single components of a preparation. In such cases additional considerations may be needed with regard to the availability of single components for exposure.
Please note: Based on the classification rules of the DPD alone, risk management and operational conditions controlling the emission to the environment for all substances contained in a preparation cannot sufficiently be identified.

The critical component(s) approach (CCA):

Compared to the DPD approach, the hazard of the component is expressed through the relevant DNEL/PNEC, and the availability for exposure is not only expressed as concentration of the substance in the preparation only, but also as the relative potential to be available for actual exposure. This may include availability related to volatility of the substance, migration behavior in a matrix or comparable factors.

Compile the concentration of the substance in the preparation, the relevant DNELs/PNECs and the availability factor of the single substances in the preparation, and compare the resulting risk indices. Select the RMM/OC of the substances with the highest relative risk per route of exposure and per endpoint and assume this would cover all components in the preparation.

Please note: Further guidance on development of exposure scenarios for (special) preparations may be added to the downstream user guidance and/or to this appendix in the future. Any results from exemplification and testing the approaches by trade and industry groups may be taken into account in such update.