Guidance on information requirements and chemical safety assessment

Part D: Exposure Scenario Building
Part F: CSR Format

Draft Update of Exposure Scenario Format

DRAFT…. 2010

(version 0.2.), 21.03.10

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

The guidance documents were drafted and discussed within the REACH Implementation Projects (RIPs) led by the European Commission services, involving stakeholders from Member States, industry and non-governmental organisations. After acceptance by the Member States Competent Authorities the guidance documents had been handed over to ECHA for publication and further maintenance. Any updates of the guidance are drafted by ECHA and are then subject to consultation procedure, involving stakeholders from Member States, industry and non-governmental organisations. For details of the consultation procedure, please see
http://echa.europa.eu/doc/FINAL_MB_30_2007_Consultation_procedure_on_guidance.pdf

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]

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).

Document History

Version	Comment	Date
Version 1	First edition	May 2008
Version 1.1	Footnote added	July 2008

Version 2.0	Revised Exposure Scenario Format replacing the last paragraph (including Table D.2.2) of section D.2.2. The revision includes:
	• Specification of the generic format for four different exposure assessment cases
	  o Uses of substance by workers
	  o Uses of substance by consumers
	  o Handling of articles by workers during service life
	  o Handling of articles by consumers during service life
	• Inclusion of additional sub-headlines to specify the type of conditions affecting the exposure (including strictly controlled conditions).
	• Removing the detailed numbering of the fields. Guidance part F and the CSA Tool will however include structured fields.
	• Additional field in the title section for inclusion of short free-text title in supply chain specific terminology.
	• Additional field for the eSDS-ES annex to include additional (use specific) good practice measures which were not addressed in the CSA and which are hence not substance to article 37 (4) obligations.
	• Additional field in section 3 for inclusion of a link to a website from where information on exposure estimates and risk characterisation ratios can be retrieved (instead of direct inclusion in the eSDS-ES).
	• Introduction of the concept of "contributing scenarios" within one exposure scenario
	• Re-written guidance explaining the formats.
		…….. 2010

GUIDANCE FOR IMPLEMENTING THE UPDATES

This update has become necessary in order to support more structured information in the ES as a basis for IT supported generating, storing, processing and communication of exposure scenarios. In particular, there was a need for further development regarding the integration of environmental and human health aspects for one exposure scenario. Emerging good practice in industry on building generic exposure scenarios for workers and the environment has been taken into account. In particu-

lar the work of ECHA and its consultation group for the development of CHESAR delivered some further input.

Compared to the ES format contained in the Guidance published by ECHA in May and July 2008, the suggested content of the ES has not changed. Thus, the updated guidance as such does not require the generation of new contents or the modification of already existing ES contents.
The updated ES allows to document and to process the contents of an ES in a more structured way, and thus enables standardisation and IT support. This would enable a smoother transfer/exchange of information up-and down the supply chain and across industries.
Regarding the three major changes in format compared to the 2008 format the following may be advisable:

- Consumer activities/exposure and worker activities/exposure should be addressed in different exposure scenarios. Thus already existing ES may need to be split.
- The conditions of use during service life should be described in a separate ES, however making a reference to the downstream use leading to the incorporation of the substance into the article. This is to provide more transparency to which life cycle stage and to which actors in the supply an ES refers. Thus already existing ES may need to be split.
- Appropriate connection of the environmental aspects and the human health aspects of an exposure scenario is supported by the newly introduced concept of “contributing scenarios” within one exposure scenario. At the same time this provides the opportunity to cover various uses in a structured way within one ES. The new format may help to check whether the described conditions of use in already existing CSRs can be connected in a transparent and consistent manner to the corresponding exposure estimates and risk characterisation.

It is however up to the single registrant to decide whether he switches to the updated format, whether he continues to use the format published in 2008, or whether he uses a completely different format (as long as the latter one is consistent with Annex I).

Revised Standard Formats For Exposure Scenarios[2]

Table of contents

Table of tables

[2] This text is meant to replace the last paragraph (including Table D.2.2) of section D.2.2 of the Part D of the Guidance on Information Requirements and Chemicals Safety Assessment.

D.2.2.2 **Exposure scenario format**

The exposure scenario *format* is a means to structure the relevant information to be documented in a standardised way. The formats defined in this guidance correspond to the exposure scenario formats in ECHA's tool for Chemical Safety Assessment and Reporting, *Chesar*.

In the exposure scenario, the conditions driving exposure to humans and to the environment are to be consistent. Operational conditions (OC) and risk management measures (RMM) regarding occupational exposure are usually task- or workplace related. Releases to the environment are however mostly assessed at site level or at the level of life cycle stages. Consequently one set of environmental OC and RMM related to a representative site for a use can be connected to several sets of OC/RMM for the different activities of workers carried out at this site. Even if the same activity of workers is carried out under different conditions at this site, these conditions can be still consistent with the conditions related to the environment.

Regarding consumer uses, the same principle is applicable. An exposure scenario for consumer uses would include one set of environmental conditions which may be combined with one or more sets of conditions for human health. This would mean in practice that one exposure scenario may include the use of one or more consumer products.

Based on these considerations, it is suggested to compose one exposure scenario from different *contributing scenarios*: one contributing scenario related to environment and one or more contributing scenarios related to human exposure. For example:

- An exposure scenario on industrial spray painting may include as contributing scenarios the different tasks and various conditions under which the task is safe to be carried out, e.g.
    - conditions for mixing and filling of equipment (manually)
    - conditions for mixing and filling of equipment (automated)
    - conditions of cleaning the equipment (manually)
    - conditions of cleaning the equipment (automated)
    - manual spraying with local exhaust ventilation (LEV) and no respiratory/skin protection
    - manual spraying without LEV, but respiratory/skin protection applied
    - robot-spraying (closed-automated)
    - conditions during drying of coated article (closed-automated)
    - conditions during drying of coated article (open-ventilated)

- An exposure scenario on indoor consumer uses may include as contributing scenarios different forms of product application, e.g.
    - polishes (e.g. for furniture or shoe maintenance) applied by spraying and wiping
    - polishes (e.g. for furniture or shoe maintenance) applied by pouring and wiping

If the environmental conditions of a use are very different in i) different sectors of end use or ii) different article types, a registrant may need two or more exposure scenarios defined at stage level, driven by the diversity of environmental conditions.

Table D.2.2.1 and Table D.2.2.2 present the exposure formats for the CSR and for the appendix to the extended safety data sheets (eSDS). In the CSR, the exposure scenarios document the conditions of use to which the exposure estimations and risk characterisations relate. The information relevant to downstream users, or a group of downstream users, is transferred from the CSR to the extended

safety data sheet. In addition to the OC and RMM, it is recommended that the eSDS-ES also contains information on exposure levels and assessment methods applied by the registrant. Downstream users may need this information to implement or further communicate the OC/RMM in an appropriate way (see section 2.2.5)

Table D.2.2.1 Exposure scenario format for CSR

9.x.1 Exposure Scenario (1)
Title of exposure scenario
9.x.1.1 Contributing scenario (1) controlling environmental exposure for ...
9.x.1.2 Contributing scenario (2) controlling worker exposure for ...
9.x.1.3 Contributing scenario (3) controlling worker exposure for ...
9.x.1.n Contributing scenario (n) controlling worker exposure for ...

D.2.2.3 **Four standard formats**

Table D.2.2.3 to D.2.2.6 present four standard formats of a final exposure scenario for inclusion into the CSR section 9.x.1 (CSR-ES). These formats include the title section of the ES (short title, activities covered in the ES and corresponding use descriptors) and the section with the operational conditions (OC) and risk management measures (RMM) affecting the exposure. This section is structured with sub-headlines reflecting the different types of OC/RMM that may drive the exposure.

The corresponding section in the CSR for exposure estimation (Section 9.x.2) and the risk characterisation (section 10.x) are not covered here (see Guidance Part F)

Use of these formats is not obligatory. Registrants may also choose to present the required information in a different way. M/I may decide that certain types of information in the format are not needed to demonstrate control of risk in a particular assessment case, or that other types of determinants are actually the relevant drivers of exposure and hence have to be additionally addressed in the ES. Please note however that it is recommended to follow standard format as much as possible, in order to

- facilitate re-use or up-date of assessments already done at the level of the single registrants or within sectors,
- support downstream users in the formulating sectors in processing the received information in an efficient and REACH-conform way,
- facilitate efficient and targeted compliance checks of the registration dossier by authorities.

The four standard formats cover the following activities with a substance:

- Format related to workers uses, including conditions controlling workers' exposure and conditions controlling the environment exposure.

- Format related to consumers uses, including conditions controlling consumers' exposure and conditions controlling the environment exposure. Note: the content of this exposure scenario is to be communicated to the downstream users producing consumer products (mixtures).
- Format related to the service life (and subsequent waste life stage) following from downstream uses, including conditions controlling workers' and environment exposure[3]. Note: the content of this exposure scenario is to be communicated to the downstream users producing articles to be handled by workers.
- Format related to the service life (and subsequent waste life stage) following from downstream uses, including conditions controlling consumers' and environmental exposure. Note: the content of this exposure scenario is to be communicated to the downstream users producing articles to be handled by consumers.

The formats for service life are designed in a way that the title section can be used to keep the link to the preceding downstream use (that actually led to inclusion of the substance into the article matrix). It allows describing the measures potentially needed at level of article production to limit/prevent releases from service life and waste life in articles. For example, releases of finishing chemicals from textiles, is largely controlled by the process conditions during finishing and by the combination of type of fibre and type of finishing chemical. Another example is the combination of polymer type and flame retardant in plastic article production. Depending on the uses of the substance, a registrant may need all four formats to prepare the required exposure scenarios.

D.2.2.4 **Sections of the standard format**

D.2.2.4.1 **Title section**

The title section describes which uses and activities with a substance are covered in the exposure scenario. This includes free-text elements and the standardised use descriptors as presented in guidance chapter R.12. The following information elements can be included in the standard title section:

- Number of the ES
- Title of exposure scenario (free text)
- List of all use descriptors related to the life cycle stage and all the uses under it; includes market sector (by PC) if relevant;
- Name of contributing environmental scenario (1) and corresponding ERC
- List of names of contributing worker/consumer scenarios (2-n) and corresponding PROC or PC/AC
- Further explanations (if needed)
- Title and number of the ES for the downstream use leading to inclusion of the substance into the article (only for ES related to article service life).

[3] It is assumed that the service life of substances being part of dried/cured mixtures usually takes place on the surface of an article (coatings), between two articles (adhesives) or inside an article matrix (resins). This definition also includes coatings applied on the different parts of a building, e.g. the walls, the façade or the window frame.

The link between i) an exposure scenario for the article service life and ii) the exposure scenario covering the downstream use that leads to the incorporation of the article is needed, to properly address conditions and measures at the level of downstream use that may impact on the releases of the substance from the article. This is further explained in the corresponding Tables D.2.2.5 and D.2.2.6, in the lines marked with (#).

D.2.2.4.2 **Conditions affecting environmental exposure**

Section 9.x.1.1 includes all operational conditions and risk management measures having been assessed by the registrant as affecting environmental exposure. This also includes municipal waste and waste water treatment, although downstream users do not have much influence on how municipal waste (water) operations are conducted. Nevertheless the registrant needs to assess whether the properties of his substance and the exposure profile of the anticipated uses match the expected municipal sewage and waste infrastructure's capability. In order to facilitate structuring of information, a number of default sub-headlines are included in this section indicating the type of operational conditions and risk management measures. The risk management measures controlling risks to the environment are sorted in order of hierarchy, from prevention at source to end-of-the-pipe measures. For the risk management measures, information on the required/assumed effectiveness is to be reported (if applicable and relevant). It may be also needed to describe the technical operational conditions to a level of detail that enables linking to the release estimates in section 9.x.2 of the CSR..

The information in this section of the CSR may be partly or fully transferred to the section 2.1 of an exposure scenario for communication (eSDS-ES).

D.2.2.4.3 **Conditions affecting human health exposure**

The sections 9.x.1.2. to 9.x.1.n include all operational conditions and risk management measures that have been assessed as affecting workers/consumers exposure. These conditions may be included in one or more contributing exposure scenarios. In order to facilitate structuring of information, a number of default sub-headlines are included in this section indicating the type of operational conditions and risk management measures specified. The risk management measures controlling risks for workers are sorted in order of the hierarchy specified in the *Chemicals Agent Directive*[4]. The measures controlling risks to consumers are predominantly to be addressed under product characteristics (first sub-headline), however also other measures might be considered, if deemed appropriate. For the risk management measures information on the required/assumed effectiveness has to be reported (if applicable and relevant)

The information in this section of the CSR may be partly or fully transferred to the section 2.2 of an exposure scenario for communication (eSDS-ES).

D.2.2.5 **Information for the downstream user**

Table D.2.2.2 presents the exposure scenario format for communication to downstream users. The difference to CSR-ES is the addition of section 3 and 4, which are addressed to the downstream user receiving the ES (see Table D.2.2.7). The standard format is structured in a way that information can be easily retrieved (e.g. for IT processing) and analysed (e.g. by a formulator of a mixture). Registrants are therefore advised to make use of the suggested format.

[4] Council Directive 98/24/EC of 7 April 1998 on the protection of the health and safety of workers from the risks related to chemical agents at work (fourteenth individual Directive within the meaning of Article 16(1) of Directive 89/391/EEC)

Section 3 includes information on the exposure estimates and the method of exposure assessment applied by the registrant. Section 4 may contain advice or may make reference to advice on how to compare the conditions described in the ES with the actual conditions at a downstream user's site. Section 3 and 4 of the ES are not meant for inclusion into the CSR

Table D.2.2.2: Exposure scenario format for the extended safety data sheet

1 Exposure Scenario (1)
Title of exposure scenario
2.1 Contributing scenario (1) controlling environmental exposure for ...
2.2 Contributing scenario (2) controlling worker exposure for ...
2.3 Contributing scenario (3) controlling worker exposure for ...
2.n Contributing scenario (n) controlling worker exposure for ...
3. Exposure estimation and reference to its source
Information for contributing scenario (1) Information on contributing scenario (2) Information on contributing scenario (3) Information on contributing scenario (n)
4. Guidance to DU to evaluate whether he works inside the boundaries set by the ES

The information structure of the annex to the extended safety data sheet (eSDS-ES) is the same as for the CSR, however the registrant will need to make the following choices:

- Which information from the CSR-ES to communicate down the supply chain? For some of the sub-headlines there may be no OC or RMM to be communicated, or parts of the information compiled in section 9.1 of the CSR may not be relevant for downstream users.
- How to express the advice to downstream users in standardised phrases?
- Which information from exposure estimation (section 9.x.2 of CSR) and risk characterisation (section 10.x of CSR) to communicate to the downstream user (see table D.2.2.7)?
- Suitable layout of the eSDS-ES, depending on markets, methods of exposure assessment and/or amount of information under the different sub-headlines to be communicated.

D.2.2.5.1 **Information on exposure estimation for the downstream user**

Section 3 of the eSDS-ES should be used to communicate information related to exposure estimation and risk characterisation to the downstream users. Such information can be reported as numerical data (e.g. calculated exposure level and/or risk characterisation ratio), or as a reference (e.g. web-link) to such data. It is recommended that the registrant also includes information which methods and/or tools he has been using for generating the exposure estimates.

D.2.2.5.2 **Advice to downstream users to interpret the boundaries of the exposure scenario**

Section 4 of the eSDS-ES) can be used to communicate particular advice on how to establish whether a downstream user works within the conditions of use set in the exposure scenario. Such advice may be in particular relevant i) when the measures and conditions contributing to control of risk can be combined in various ways within one exposure scenario and ii) these combinations can be described in a linear algorithm. For example, control of risk for surface water can be achieved by i) using small quantities of the substance (without reducing the emission factor) or by ii) measures reducing the emission factors if high quantities of a substance will be used. In the relevant exposure scenario it may be sufficient to provide one combination of i) use volume and ii) effectiveness of emission control measures resulting in a limited release rate. It will then be up to the downstream user to check whether the conditions ensuring control of risk can be also achieved with a combination of other numerical values for volume and emission control (linear scaling)[5]. Analogue adaptations may be possible among the determinants driving workers exposure. For example: The registrant may have carried out an assessment with ECETOC *Targeted Risk Assessment* (TRA) for inhalation, assuming > 4h hour duration of activity and concentration of substance of < 5% in the applied mixture. These conditions are communicated to the downstream user in the exposure scenario. However, the downstream user may consider his company as working still within the boundaries of the exposure scenario if the substance is applied in a concentration up to 100% but only over a time of less then 1 hour (see exposure modifying factors in ECETOC TRA[6]).

Note: For consumer uses, section 4 contains information addressed to the formulator producing the consumer product, not the consumer.

D.2.2.5.3 **Use-specific advice outside the exposure scenario**

If the registrant wishes to give additional advice on how to practically control/prevent risks but these measures are not needed to demonstrate control of risk, as defined by REACH, a separate information field outside the exposure scenario should be used in the CSR and eSDS annex. This is to flag that there is no obligation on the downstream user to carry out a CSA if these measures are not implemented (i.e. the measures are not subject to Article 37 (4)).

D.2.2.6 **Information structure for describing one condition of use**

Each condition of use (OC/RMM) addressed in the ES may be described by a number of information elements. In ECHA's Chemicals Safety Assessment and Reporting Tool Chesar, the following information elements can be reported with regard to one relevant condition of use.

- Name of the condition or measure (e.g. *local exhaust ventilation*)

[5] Please note : Where the downstream user scales down the local amount and/or scales up the dilution factor in the river, in order to compensate for a less effective risk management measures or higher initial release factors, this has an impact on the regional assessment carried out by the registrant. The registrant may need to correct the assumed release factor in order to keep his assessment valid. Thus, a downstream user should communicate back to the supplier/registrant, that he has implemented risk management measures with a lower effectiveness as required in the ES and provide some details on the nature and the effectiveness of these measures

6 http://www.ecetoc.org/index.php?page=tra

- Exposure route and type of effect on which the determinant has an impact in the given case (e.g. *short term and long term inhalation, local and systemic effects*)
- Value[7] of determinant and effectiveness (e.g. “LEV with hood”; effectiveness 95% against situation without LEV)
- Further general explanation on the determinant value (e.g. *95% effectiveness can be achieved with proper installation and regular maintenance by trained personnel*).
- Further explanation for the specific CSR (e.g. *the LEV is used to minimise residual releases from a rigorously contained process, and thus is part of strictly controlled conditions)*

[7] “Value” includes numerical information and non numerical information.

Table D.2.2.3: Standard exposure scenario format for uses of substances by workers

Exposure Scenario Format (1) addressing uses carried out by workers
9.x. Title of Exposure Scenario number x: .....
List of all use descriptors related to the life cycle stage and all the uses under it; include market sector (by PC), if relevant;
Name of contributing environmental scenario (1) and corresponding ERC
List of names of contributing worker scenarios (2-n) and corresponding PROCs
Further explanations (if needed)
9.x.1 Exposure Scenario
9.x.1.1 Contributing scenario (1) controlling environmental exposure for ...
Name of contributing scenario
Further specification
Product characteristics
Product related conditions, e.g. the concentration of the substance in a mixture; viscosity of product; package design affecting exposure
Amounts used
Daily and annual amount per site (for uses in industrial setting) or daily and annual amount for wide disperse uses;
Frequency and duration of use
Intermittent (used < 12 times per year for not more than 24 h) or continuous use/release
Environment factors not influenced by risk management
Flow rate of receiving surface water (m3/d, usually 18,000 m3/d for the standard town by default; please note*: the default flow rate will be rarely changeable for downstream uses.*
Other given operational conditions affecting environmental exposure
Other given operational conditions: e.g. technology or process techniques determining the initial release of substance from process (via air and waste water); dry or water based processes; conditions related to temperature and pressure; indoor or outdoor use of products; work in confined area or open air;
Technical conditions and measures at process level (source) to prevent release
Process design aiming to prevent releases and hence exposure to the environment; this includes in particular conditions ensuring rigorous containment; performance of the containment to be specified (e.g. by quantification of a release factor in section 9.x.2 of the CSR);
Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil
Technical measures, e.g. on-site waste water and waste treatment techniques, scrubbers, filters and other technical measures aiming at reducing releases to air, sewage system, surface water or soil; this includes strictly controlled conditions (procedural and control technology) to minimise emissions; specify effectiveness of measures; *specify the size of industrial sewage treatment plant (m3/d), degradation effectiveness and sludge treatment (if applicable);*
Organizational measures to prevent/limit release from site
Specific organisational measures or measures needed to support the functioning of particular technical measures. Those measures need to be reported in particular for demonstrating strictly controlled conditions.
Conditions and measures related to municipal sewage treatment plant
Size of municipal sewage system/treatment plant (m3/d); specify degradation effectiveness; sludge treatment technique (disposal or recovery); measures to limit air emissions from sewage treatment (if applicable); please note*: the default size of the municipal STP (2000 m^3/d) will be rarely changeable for downstream uses.*
Conditions and measures related to external treatment of waste for disposal
Fraction of used amount transferred to external waste treatment for disposal; type of suitable treatment for waste generated by workers uses, e.g. hazardous waste incineration, chemical-physical treatment for emulsions, chemical oxidation of aqueous waste; specify effectiveness of treatment;
Conditions and measures related to external recovery of waste
Fraction of used amount transferred to external waste treatment for recovery: specify type of suitable recovery operations for waste generated by workers uses, e.g. re-destillation of solvents, refinery process for lubricant waste, recovery of slags, heat recovery outside waste incinerators; specify effectiveness of measure;
9.x.1.2 Contributing scenario (2) controlling worker exposure for ...
Name of contributing scenario 2
Further specification

Exposure Scenario Format (1) addressing uses carried out by workers
Product characteristic
Product related conditions, e.g. the concentration of the substance in a mixture, the physical state of that mixture (solid, liquid; if solid: level of dustiness), package design affecting exposure)
Amounts used
Amounts used at a workplace (per task or per shift); note: sometimes this information is not needed for assessment of worker's exposure
Frequency and duration of use/exposure
Duration per task/activity (e.g. hours per shift) and frequency (e.g. single events or repeated) of exposure
Human factors not influenced by risk management
Particular conditions of use, e.g. body parts potentially exposed as a result of the nature of the activity
Other given operational conditions affecting workers exposure
Other given operational conditions: e.g. technology or process techniques determining the initial release of substance from process into workers environment; room volume, whether the work is carried out outdoors/indoors, process conditions related to temperature and pressure.
Technical conditions and measures at process level (source) to prevent release
Process design aiming to prevent releases and hence exposure of workers; this in particular includes conditions ensuring rigorous containment; performance of containment to be specified (e.g. by quantification of residual losses or exposure)
Technical conditions and measures to control dispersion from source towards the worker
Engineering controls, e.g. exhaust ventilation, general ventilation; specify effectiveness of measure
Organisational measures to prevent /limit releases, dispersion and exposure
Specific organisational measures or measures needed to support the functioning of particular technical measures (e.g. training and supervision). Those measures need to be reported in particular for demonstrating strictly controlled conditions (to justify exposure based waiving).
Conditions and measures related to personal protection, hygiene and health evaluation
Personal protection, e.g. wearing of gloves, face protection, full body dermal protection, goggles, respirator; specify effectiveness of measure; specify the suitable material for the PPE (where relevant) and advise how long the protective equipment can be used before replacement (if relevant)
9.x.1.3 Contributing scenario (3) controlling worker exposure for ...
Name of contributing scenario 3
Further specification
Product characteristic
Amounts used
Frequency and duration of use/exposure
Human factors not influenced by risk management
Other given operational conditions affecting workers exposure
Technical conditions and measures at process level (source) to prevent release
Technical conditions and measures to control dispersion from source towards the worker
Organisational measures to prevent /limit releases, dispersion and exposure
Conditions and measures related to personal protection, hygiene and health evaluation
9.x.1.n Contributing scenario (n) controlling worker exposure for ...

Exposure Scenario Format (1) addressing uses carried out by workers

Name of contributing scenario (n).

Additional good practice advice beyond the REACH CSA

Note: The measures reported in this section have not been taken into account in the exposure estimates related to the exposure scenario above. They are not subject to obligation laid down in Article 37 (4) of REACH, Thus, the downstream user is not obliged to i) carry out an own CSA and ii) to notify the use to the Agency, if he does not implement these measures.

Use specific measures expected to reduce the predicted exposure beyond the level estimated based on the exposure scenario.

Table D.2.2.4 Standard exposure scenario format for uses by consumers

Exposure Scenario Format (2) addressing uses carried out by consumers
9.x. Title of Exposure Scenario number x: .....
List of all use descriptors related to the life cycle stage and all the uses under it; include market sector (by PC), if relevant;
Name of contributing environmental scenario (1) and corresponding ERC
List of names of contributing consumer scenarios (2-n) and corresponding PC and sub-product- categories, as applicable
Further explanations (if needed)
9.x.1 Exposure Scenario
9.x.1.1 Contributing scenario (1) controlling environmental exposure for ...
Name of contributing scenario
Further specification
Product characteristics
Product related conditions, e.g. the concentration of the substance in a mixture; package design affecting exposure
Amounts used
Annual amount supplied into the consumer use(s) covered in this exposure scenario
Frequency and duration of use
Usually continuous use/release (365 days) to be assumed, unless there are significant seasonal variations.
Environment factors not influenced by risk management
Flow rate of receiving surface water (m3/d) (usually 18,000 m3/d by default for the standard town); **please note***: the default flow rate will be rarely changeable for downstream uses;*
Other given operational conditions affecting environmental exposure
Other operational conditions, e.g. indoor or outdoor use of products
Conditions and measures related to municipal sewage treatment plant
Size of municipal sewage system/treatment plant (m3/d) (usually 2000 m3/d by default for the standard town); specify degradation effectiveness; sludge treatment technique (disposal or recovery); measures to limit air emissions from sewage treatment (if applicable;) **please note***: the default size of the municipal STP will be rarely changeable for downstream uses.*
Conditions and measures related to external treatment of waste for disposal
Fraction of used amount transferred to external waste treatment for disposal: type of suitable treatment for waste generated by consumer uses, e.g. municipal waste incineration, hazardous waste incineration: specify efficacy of treatment; provide corresponding instructions regarding separation of waste to be communicated to consumers;
Conditions and measures related to external recovery of waste
Fraction of used amount transferred to external waste treatment for recovery: Specify type of suitable recovery operations for waste generated by consumer uses, e.g. refinery process for lubricant waste; specify efficacy of measure; provide corresponding instructions regarding separation of waste to be communicated to consumers
9.x.1.2 Contributing scenario (2) controlling consumer exposure for ...
Name of contributing scenario 2
Further specification
Product characteristic
Product related conditions, e.g. the concentration of the substance in a mixture, the physical state of that mixture (solid, liquid; if solid: level of dustiness), package design affecting exposure;
Amounts used
Amounts used per event
Frequency and duration of use/exposure
Duration of exposure per event and frequency of events; please note: Tier 1 exposure assessment usually refers to external event exposure, without taking into account the duration and frequency of the event (see Guidance Chapter R.15);
Human factors not influenced by risk management
Particular conditions of use, e.g. body parts potentially exposed; population potentially exposed (adults, children)
Other given operational conditions affecting consumers exposure
Other operational conditions e.g. room volume, air exchange rate, outdoor or indoor use
Conditions and measures related to information and behavioural advice to consumers
Safety advice to be communicated to consumers in order to control exposure, e.g. technical instruction, behavioural advice
Conditions and measures related to personal protection and hygiene
Usually personal protection measures are not expected for consumer products; however if e.g. gloves are recommend this can be

Exposure Scenario Format (2) addressing uses carried out by consumers
specified here; specify the suitable material for the PPE (where relevant,) and advise how long the protective equipment can be used before replacement (if relevant)

9.x.1.3 Contributing scenario (3) controlling consumer exposure for ...
Name of contributing scenario
Further specification
Product characteristic
Amounts used
Frequency and duration of use/exposure
Human factors not influenced by risk management
Other given operational conditions affecting consumers exposure
Conditions and measures related to information and behavioural advice to consumers
Conditions and measures related to personal protection and hygiene

9.x.1.n Contributing scenario (n) controlling consumer exposure for ...

Name of contributing scenario

Further specification

Additional good practice advice beyond the REACH CSA
Note: The measures reported in this section have not been taken into account in the exposure estimates related to the exposure scenario above. They are not subject to obligation laid down in Article 37 (4) of REACH, Thus, the downstream user is not obliged to i) carry out an own CSA and ii) to notify the use to the Agency, if he does not implement these measures.

Table D.2.2.5 Standard exposure scenario format for service life of substances in articles (handling by worker)

Exposure Scenario Format (3) addressing service life resulting from downstream use (article handled by worker)
9.x. Title of Exposure Scenario number x: .....
List of all use descriptors related to the life cycle stage and all the uses under it; include market sector (by PC), if relevant:
Name of contributing environmental scenario (1) and corresponding ERC
List of names of contributing worker scenarios (2-n) and corresponding PROC
Further explanations (if needed)
Title and number of the ES for the downstream use leading to inclusion of the substance into the article (#)
9.x.1 Exposure Scenario
9.x.1.1 Contributing scenario (1) controlling environmental exposure for ...
Name of contributing scenario
Further specification
Product (article) characteristic
Product related conditions, e.g. the concentration of the substance in the article; volume-to-surface-relationship of the article; fraction of substance amount available for exposure with regard to releases to air, water and soil;
Amounts used
Annual amount for wide disperse processing of the article; daily and annual amount (contained in that article) per site (for point sources);
Frequency and duration of use/exposure from service life
Intermittent (< 12 time per year) or continuous use/release
Environment factors not influenced by risk management
Flow rate of receiving surface water (m3/d) (usually 18,000 m3/d by default for the standard town); **please note***: the default flow rate will be rarely changeable for downstream uses;*
Other given operational conditions affecting environmental exposure
Other given operational conditions: e.g. technology or process techniques determining the initial release of substance from process (via air and waste water); dry or water based processes; abrasive conditions of use; conditions related to temperature and pressure; indoor or outdoor use of products; work in confined area or open air; Other operational conditions, e.g. indoor or outdoor use of products,
Conditions and measures at level of article production process to prevent release during service life (#)
Measures taken by down stream users (processing the substance into the article), for example: article design supporting easy manual or mechanical deconstruction at the end of service life. or no-release during service life;
Technical conditions and measures at process level (source) to prevent release
Process design aiming to prevent releases and hence exposure to the environment; this also includes conditions ensuring rigorous containment; specify performance of containment (e.g. by quantification of a release factor in section 9.x.2 of the CSR);
Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil
Technical measures, e.g. on-site waste water and waste treatment techniques, scrubbers, filters and other technical measures aiming at reducing releases to air, sewage system, surface water or soil; this includes strictly controlled conditions (procedural or control technology) to minimise emissions; specify effectiveness of measures; *specify the size of industrial sewage treatment plant (m3/d), degradation efficacy and sludge treatment (if applicable);*
Organizational measures to prevent/limit release from site
Specific organisational measures or measures needed to support the functioning of particular technical measures. Those measures need to be reported in particular for demonstrating strictly controlled conditions.
Conditions and measures related to municipal sewage treatment plant
Size of municipal sewage system/treatment plant (m3/d) (usually 2000 m3/d by default for the standard town); specify degradation efficacy; sludge treatment technique (disposal or recovery); measures to limit air emissions from sewage treatment (if applicable)); **please note***: the default size of the municipal STP will be rarely changeable for downstream uses.*
Conditions and measures related to disposal of articles at end of service life
Fraction of used amount transferred to external waste treatment for disposal: Type of suitable treatment for waste generated by workers (processing waste or end-of-service-life articles), e.g. municipal waste incineration, specify efficacy of treatment;

Exposure Scenario Format (3) addressing service life resulting from downstream use (article handled by worker)
Conditions and measures related to recovery of articles at the end of service life
Fraction of used amount transferred to external waste treatment for recovery: Specify type of collection system and suitable recovery operation for waste generated by workers, e.g. recycling schemes for substances in batteries, vehicles, , electronic articles, paper article, metal articles; specify efficacy of measure, including re-collection rate; provide corresponding instructions regarding separation of waste to be communicated to workers;
9.x.1.2 Contributing scenario (2) controlling worker exposure for ...
Name of contributing scenario 2
Further specification
Product (article) characteristic
Product related conditions, e.g. the concentration of the substance in the article; volume-to-surface-relationship of the article; fraction of substance amount available for exposure with regard to inhalation and skin contact; nature of the matrix (e.g. metal or plastic); thickness of coating;
Amounts (contained in articles) present at workplace
Amounts used at a workplace (per task or shift); note: sometimes this information is not needed for assessment of worker's exposure.
Frequency and duration of use/exposure
Duration per task/activity (e.g. hours per shift) and frequency (e.g. single events or repeated) of exposure
Human factors not influenced by risk management
Particular conditions e.g. body parts potentially exposed as the result of the nature of the activity
Other given operational conditions affecting workers exposure
Other operational conditions e.g. room volume, whether the work is carried out outdoors/indoors, process conditions related to temperature (processing of article under elevated temperature) or abrasive (dust forming) techniques
Conditions and measures at level of article production to prevent release during service life (#)
Measures taken by down stream users (processing the substance into the article). The temperature, duration and the technology of the operation/treatment (melting, curing, radiation, encapsulation, etc …) are key factors driving the potential emissions during handling and storage of articles. Also, sufficient storage time of articles before delivery may be needed to avoid exposure during transportation.
Technical conditions and measures to prevent release (at source) from processing of articles
Process design aiming to prevent releases and hence exposure of workers; this also includes conditions ensuring rigorous containment; specify efficacy of containment (e.g. residual losses or exposure);
Technical conditions and measures to control dispersion from source towards the worker
Engineering controls, e.g. exhaust ventilation, general ventilation; specify efficacy of measure;
Organisational measures to prevent /limit releases, dispersion and exposure
Specific organisational measures or measures needed to support the functioning of particular technical measures (e.g. training and supervision). Those measures need to be reported in particular for demonstrating strictly controlled conditions (to justify exposure based waiving);
Conditions and measures related to personal protection, hygiene and health evaluation
Personal protection, ,e.g. wearing of gloves, face protection, full body dermal protection, goggles, respirator; specify efficacy of measure; specify the suitable material for the PPE (where relevant) and advise how long the protective equipment can be used before replacement (if relevant)
9.x.1.3 Contributing scenario (3) controlling worker exposure for ...
Name of contributing scenario 2
Further specification
Product (article) characteristic
Amounts (contained in articles) present at workplace
Frequency and duration of use/exposure
Human factors not influenced by risk management
Other given operational conditions affecting workers exposure

Exposure Scenario Format (3) addressing service life resulting from downstream use (article handled by worker)
Conditions and measures at level of article production to prevent release during service life (#)

Technical conditions and measures to prevent release (at source) from processing of articles

Technical conditions and measures to control dispersion from source towards the worker

Organisational measures to prevent /limit releases, dispersion and exposure

Conditions and measures related to personal protection, hygiene and health evaluation

9.x.1.n Contributing scenario (n) controlling worker exposure for ...

Name of contributing scenario

Further specification

Additional good practice advice beyond the REACH CSA
Note: The measures reported in this section have not been taken into account in the exposure estimates related to the exposure scenario above. They are not subject to obligation laid down in Article 37 (4) of REACH, Thus, the downstream user is not obliged to i) carry out an own CSA and ii) to notify the use to the Agency, if he does not implement these measures.

Table D.2.2.6 Standard exposure scenario format for the service life of substances in articles (handled by consumers)

Exposure Scenario Format (4) addressing service life resulting from downstream use (article handled by consumer)
9.x. Title of Exposure Scenario number x: .....
List of all use descriptors related to the life cycle stage and all the uses under it; include market sector (by PC), if relevant;
Name of contributing environmental scenario (1) and corresponding ERC
List of names of contributing consumer scenarios (2-n) and corresponding AC
Further explanations (if needed)
Title and number of the ES for the downstream use leading to inclusion of the substance into the article (#)
9.x.1 Exposure Scenario
9.x.1.1 Contributing scenario (1) controlling environmental exposure for ...
Name of contributing scenario
Further specification
Product (article) characteristic
Product related conditions, e.g. the concentration of the substance in the article; volume-to-surface-relationship of the article; fraction of substance amount available for exposure with regard to releases to air, water and soil; duration of service life;
Amounts used
Annual of substance per year processed into the article;
Frequency and duration of use/exposure from service life
365 days per year continuously, unless particular conditions suggest otherwise(e.g. seasonal use)
Environment factors not influenced by risk management
Flow rate of receiving surface water (m3/d) (usually 18,000 m3/d for the standard town by default); please note*: the default flow rate will be rarely changeable for downstream uses;*
Other given operational conditions affecting environmental exposure
Other operational conditions, e.g. indoor or outdoor use of products, abrasive conditions of use or weathering;
Conditions and measures at level of article production process to prevent release during service life (#)
Measures taken by down stream users (processing the substance into the article: The temperature, duration and the technology of the operation/treatment (melting, curing, radiation, encapsulation, etc …) are key factors driving the potential of emission during handling and storage of article. Other examples: i) dyeing program and compatibility of fibre and dye in textile finishing; ii) compatibility of flame retardant and polymer type; iii) pre-wash of textiles to remove substances from finishing iv)sufficient storage time before delivery in order reduce residual releases of components not sufficiently fixed in the article matrix;
Conditions and measures related to municipal sewage treatment plant
Size of municipal sewage system/treatment plant (m3/d) (usually 2,000 m/d by default for the standard town); specify degradation efficacy; sludge treatment technique (disposal or recovery); measures to limit air emissions from sewage treatment (if applicable); please note*: the default size of the municipal STP will be rarely changeable for downstream uses;*
Conditions and measures related to disposal of articles at end of service life
Fraction of used amount transferred to waste treatment for disposal: Type of suitable treatment for waste (processing waste or end-of-service-life articles) generated by consumers , e.g. municipal waste incineration, specify efficacy of treatment;
Conditions and measures related to recovery of articles at the end of service life
Fraction of used amount transferred to waste treatment for recovery: Specify type of collection system and suitable recovery operation for waste generated by consumer uses, e.g. recycling schemes for substances in batteries, vehicles, household appliances, electronic articles, paper article, metal articles; specify efficacy of measure, including re-collection rate; provide corresponding instructions regarding separation of waste to be communicated to consumers
9.x.1.2 Contributing scenario (2) controlling consumer exposure for ...
Name of contributing scenario 2
Further specification
Product (article) characteristic
Product related conditions, e.g. the concentration of the substance in the article; volume-to-surface-relationship of the article; ; nature of the matrix (e.g. metal or plastic); thickness of coating; fraction of substance amount available for exposure with regard

Exposure Scenario Format (4) addressing service life resulting from downstream use (article handled by consumer)
to inhalation, skin contact and sucking;
Amounts used
Amount of substance (contained in the article) per event;
Frequency and duration of use/exposure from service life
Duration of e.g. inhalation of releases from indoor construction products; frequency and duration of e.g. skin contact to textiles or furniture; please note: Tier 1 exposure assessment usually refers to event exposure, frequency and duration of exposure are not taken into account (see Guidance Chapter R.15);
Human factors not influenced by risk management
Particular conditions of use, e.g. body parts potentially exposed, population potentially exposed (adults, children);
Other given operational conditions affecting consumers exposure from article service life
Other operational conditions e.g. room volume, air exchange rate, outdoor or indoor activity
Conditions and measures at level of article production to prevent release during service life(#)
The process- temperature, duration and the technology of the operation/treatment (melting, curing, radiation, encapsulation, etc) are key factors in evaluating the potential of emission during handling and storage. Measures taken by down stream users (processing the substance into the article), for example: i) dyeing program and compatibility of fibre and dye in textile finishing; ii) compatibility of flame retardant and polymer type; iii) pre-wash of textiles to remove substances from finishing; iv) sufficient storage time before delivery in order reduce residual releases of components not sufficiently fixed in the article matrix during first use.
Conditions and measures related to information and behavioural advice to consumers
Usually not applicable related to articles
Conditions and measures related to personal protective equipment and hygiene
Usually not applicable related to articles

9.x.1.3 Contributing scenario (3) controlling consumer exposure for ...
Name of contributing scenario 3
Further specification
Product (article) characteristic
Amounts used
Frequency and duration of use/exposure from service life
Human factors not influenced by risk management
Other given operational conditions affecting consumers exposure from article service life
Conditions and measures at level of article production to prevent release during service life (#)

Conditions and measures related to information and behavioural advice to consumers

Conditions and measures related to personal protective equipment and hygiene

9.x.1.n Contributing scenario (n) controlling consumer exposure for ...

Name of contributing scenario n

Further specification

Additional good practice advice beyond the REACH CSA
Note: The measures reported in this section have not been taken into account in the exposure estimates related to the exposure scenario above. They are not subject to obligation laid down in Article 37 (4) of REACH, Thus, the downstream user is not obliged to i) carry out an own CSA and ii) to notify the use to the Agency, if he does not implement these measures.

Table D.2.2.7: Section 3 and 4 of the exposure scenario for communication (eSDS-ES)

3. Exposure estimation and reference to its source
Estimation of exposure and risk characterisation ratios (for all route of exposure for consumer and all compartment for the environment) resulting from the conditions described above (entries 2.1 and 2.2) and the substance properties; make reference to the exposure assessment method applied (specify for the routes if relevant); Alternatively*: Include a link to a website from where the information described above can be retrieved.*
4. Guidance to DU to evaluate whether he works inside the boundaries set by the ES
Guidance how the DUs can evaluate whether they operate within the conditions set in the exposure scenario. This may be based on a set of determinants (and a suitable algorithm) which together ensure control of risk, but which have some flexibility in the respective values for each determinant. This section may also include a link to a suitable calculation tool. *Where relevant: Other methods for DU to check whether they work within the boundaries set by the ES may be included here*