

# Guidance on information requirements and chemical safety assessment

## Part D: Exposure Scenario Building Draft Update of Exposure Scenario Format



.... 2009  
(version 2.0)

## **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](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](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<sup>1</sup>

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<sup>1</sup> 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**

| <b>Version</b> | <b>Comment</b>   | <b>Date</b> |
|----------------|--|-------------|
| Version 1      | First edition  | May 2008    |
| Version 1.1    | Footnote added   | July 2008   |
| Version 2.0    | <p>Revised Exposure Scenario Format replacing the last paragraph (including Table D.2.2) of section D.2.2. The revision includes:</p> <ul style="list-style-type: none"><li>• Specification of the generic format for four different exposure assessment cases<ul style="list-style-type: none"><li>○ Uses of substance by workers</li><li>○ Uses of substance by consumers</li><li>○ Handling of articles by workers during service life</li><li>○ Handling of articles by consumers during service life</li></ul></li><li>• Inclusion of additional sub-headlines to specify the type of conditions determining the exposure (including strictly controlled conditions).</li><li>• Removing the detailed numbering of the fields. Guidance part F and the CSA Tool will however include structured fields.</li><li>• Additional field in the title section for inclusion of short free-text title in supply chain specific terminology.</li><li>• 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.</li><li>• Additional field in section 3 for inclusion 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).</li><li>• Re-written guidance explaining the formats.</li></ul> | ..... 2009  |

## Revised Standard Formats For Exposure Scenarios<sup>2</sup>

Table D.2.2.1 to D.2.2.4 present four standard formats of a final exposure scenario for inclusion in both, the CSR section 9 (CSR-ES) and the annex to the extended safety data sheet (eSDS-ES).

The formats are not obligatory. Registrant may also choose to present the required information in a different way. M/I and DU may also 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.

The four generic formats cover the following activities with a substance

- format related to workers' use, including conditions controlling workers' exposure and conditions controlling the environment exposure.
- format related to consumer's use, including conditions controlling consumers' exposure and conditions controlling the environment exposure.
- format related to the service life (and subsequent waste life stage) following from downstream uses, including conditions controlling workers' and environment exposure<sup>3</sup>.
- format related to the service life (and subsequent waste life stage) following from downstream uses, including conditions controlling consumers' and environmental exposure<sup>4</sup>.

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 textile finishing chemicals from textiles is largely controlled by the process conditions during finishing and 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.

Each of the formats consists of four sections:

- The title section describes in short terms which uses and activities with a substance are covered by the exposure scenario. This includes free-text elements and the standardised use descriptors as contained in guidance chapter R.12. The registrant can also indicate in the title section which methods have been used for exposure assessment (not applicable for the eSDS-ES).
- Section 2.1 includes all operational conditions and risk management measures having been assessed as determining workers/consumers exposure. 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 for workers are sorted in order of the hierarchy foreseen by the *Chemicals Agent Direc-*

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<sup>2</sup> 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.

<sup>3</sup> It is assumed that the service life of substances being part of dried/cured preparations 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.

<sup>4</sup> It is assumed that the service life of substances being part of dried/cured preparations usually takes place on the surface of an article (coatings), between two articles (adhesives) or inside an article matrix (resins). This include also coatings on elements of buildings.

tive<sup>5</sup>. The measures controlling risks for consumers are predominantly to be addressed under product characteristics (first sub-headline). For the risk management measures information on the required/assumed efficacy are to be reported.

- Section 2.2 includes all operational conditions and risk management measures having been assessed as determining environmental exposure. 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 efficacy are to be reported (if applicable).
- Section 3 (only applicable for the eSDS-ES<sup>6</sup>) can be used to communicate information related to exposure estimation and risk characterisation to the downstream users.
- Section 4 (only applicable for 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) low use quantities (without reducing the emission factor) or by ii) measures reducing the emission factors if high quantities of a substance will be used. In an exposure scenario it may be sufficient to provide one combination of i) use volume and ii) efficacy of emission control measure resulting in a limited release rate. It is 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). Analogue adaptations may be possible among the determinants driving workers exposure.

Section 3 and 4 of the following ES formats only relate to communication to downstream users (eSES-ES). This information is not part of the exposure scenario to be documented in section 9.1 of the CSR.

The information flagged with (\*) in the presented format is not meant to be communicated in the eSDS-ES but only relates to the CSR-ES. Also the sub-headlines indicating the type of OC/RMM are not necessarily to be displayed in the eSDS-ES however they allow to present the information in a standardised order.

In many assessment cases only part of the information fields will need to be filled. It is advisable not to communicate empty fields or all sub-headlines to the downstream users, but to focus the communication on the practical information/advice contained in the ES.

If the registrants wishes to give additional advice how to practically control/prevent risks but where such measures are not needed for being able to demonstrate control of risk in the CSA a separate information field in the eSDS annex outside the exposure scenario should be used. This is to flag that such measures do not trigger the obligation to carry out a CSA at downstream user level, if the measures are not implemented (measures not being subject to Article 37 (4)).

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<sup>5</sup> 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)

<sup>6</sup> For the CSR, such information is presented in section 9.2 and 10 of the CSR.

Table D.2.2.1 Standard format for exposure scenarios related to uses of substances carried out by workers

| <b>Exposure Scenario Format (1) addressing uses carried out by workers</b>   |  |
|--|--|
| <b>1. Title</b>  |  |
| <b>Free short title</b>  | <i>Short free text (in supply chain specific language) describing the scope of the exposure scenario</i> |
| <b>Systematic title based on use descriptor</b>  | <i>List of identified uses covered in the exposure scenario</i>  |
| <b>Processes, tasks activities covered</b>   | <i>Additional free text specification of the activities or tasks covered (if needed)</i>                 |
| <b>Assessment Method*</b>  | <i>Assessment methods applied to create the final exposure scenario (specify the routes if relevant)</i> |
| <b>2. Operational conditions and risk management measures</b>  |  |
| <i>Brief description of overall operational conditions referring to process categories (PROC) and environmental release categories (ERC)</i>   |  |
| <i>Number of sites using the substance (potentially required to demonstrate strictly controlled conditions of use to justify waiving of information according to Annex XI of REACH)</i>                                    |  |
| <b>2.1 Control of workers exposure</b>   |  |
| <b>Product characteristic</b>  |  |
| <i>Product related conditions, e.g. the concentration of the substance in a preparation, the physical state of that preparation (solid, liquid; if solid: level of dustiness), package design affecting exposure)</i>      |  |
| <b>Amounts used</b>  |  |
| <i>Amounts used at a workplace; note: often this information is not needed for assessment of worker's exposure</i>   |  |
| <b>Frequency and duration of use/exposure</b>  |  |
| <i>Duration (e.g. hours per shift) and frequency (e.g. single events or repeated) of exposure</i>  |  |
| <b>Human factors not influenced by risk management</b>   |  |
| <i>Particular conditions of use e.g. body parts potentially exposed, increased breathing volume in a certain situation of work</i>   |  |
| <b>Other given operational conditions affecting workers exposure</b>   |  |
| <i>Other operational conditions e.g. room volume, whether the work is carried out outdoors/indoors, process conditions related to temperature and pressure</i>   |  |
| <b>Technical conditions and measures at process level (source) to prevent release</b>  |  |
| <i>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)</i>            |  |
| <b>Technical conditions and measures to control dispersion from source towards the worker</b>  |  |
| <i>Engineering controls, e.g. exhaust ventilation, general ventilation; specify efficacy of measure</i>  |  |
| <b>Organisational measures to prevent /limit releases, dispersion and exposure</b>   |  |
| <i>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.</i> |  |
| <b>Conditions and measures related to personal protection, hygiene and health evaluation</b>   |  |
| <i>Personal protection, e.g. wearing of gloves, full body dermal protection, goggles, respirator; specify efficacy of measure</i>  |  |
| <b>2.2 Control of environmental exposure</b>   |  |
| <b>Product characteristics</b>   |  |
| <i>Product related conditions, e.g. the concentration of the substance in a preparation; package design affecting exposure</i>   |  |
| <b>Amounts used</b>  |  |
| <i>Daily and annual amount per site (for point sources); annual amount for wide disperse use</i>   |  |
| <b>Frequency and duration of use</b>   |  |
| <i>Intermittent (&lt; 12 time per year) or continuous use/release</i>  |  |
| <b>Environment factors not influenced by risk management</b>   |  |
| <i>Flow rate of receiving surface water</i>  |  |
| <b>Other given operational conditions affecting environmental exposure</b>   |  |
| <i>Other operational conditions, e.g. indoor or outdoor use of products; process conditions related to temperature and pressure</i>  |  |
| <b>Technical conditions and measures at process level (source) to prevent release</b>  |  |

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| <b>Exposure Scenario Format (1) addressing uses carried out by workers</b>   |
| <i>Process design aiming to prevent releases and hence exposure of the environment; this also includes conditions ensuring rigorous containment; specify effectiveness of containment (e.g. residual losses)</i>   |
| <b>Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil</b>  |
| <i>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 to minimise emissions; specify efficacy of measures;</i><br><i>specify the size of industrial sewage treatment plant (m<sup>3</sup>/d), degradation efficacy and sludge treatment (if applicable);</i>  |
| <b>Organizational measures to prevent/limit release from site</b>  |
| <i>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.</i>   |
| <b>Conditions and measures related to municipal sewage treatment plant</b>   |
| <i>Size of municipal sewage system/treatment plant (m<sup>3</sup>/d); specify degradation efficacy; sludge treatment technique (disposal or recovery); measures to limit air emissions from sewage treatment (if applicable)</i>   |
| <b>Conditions and measures related to external treatment of waste for disposal</b>   |
| <i>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 efficacy of treatment</i>  |
| <b>Conditions and measures related to external recovery of waste</b>   |
| <i>Specify type of suitable recovery operations for waste generated by workers uses, e.g. re-distillation of solvents, refinery process for lubricant waste, recovery of slags, heat recovery outside waste incinerators; specify efficacy of measure;</i>   |
| <b>3. Exposure estimation and reference to its source</b>  |
| <i>Estimation of exposure and risk characterisation ratios (for all route of exposure for workers 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 tool applied;</i>   |
| <i>Alternatively: Include a link to a website from where the information described above can be retrieved.</i>   |
| <b>4. Guidance to DU to evaluate whether he works inside the boundaries set by the ES</b>  |
| <i>Guidance how the DU can evaluate whether he operates within the conditions set in the exposure scenario. This may be based on a set of 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.</i><br><i>Where relevant: Other methods for DU to check whether he works within the boundaries set by the ES may be included here</i> |
| <b>Additional good practice advice beyond the REACH CSA</b>  |
| <b>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</b>  |
| <i>Use specific measures expected to reduce the predicted exposure beyond the level estimated based on the exposure scenario.</i>  |



Table D.2.2.2 Standard format for exposure scenarios related to uses of substances carried out by consumers

| <b>Appendix 2: Exposure Scenario Format (2) addressing uses carried out by consumers</b>  |  |
|---|--|
| <b>1. Title</b>   |  |
| <b>Free short title</b>   | <i>Short free text (in supply chain specific language) describing the scope of the exposure scenario</i>   |
| <b>Systematic title based on use descriptor</b>   | <i>List of identified uses covered in the exposure scenario</i>  |
| <b>Processes, tasks activities covered</b>  | <i>Additional free text specification of the activities or tasks covered (if needed); if ECETOC TRA is used, here the relevant product subcategories can be flagged.</i> |
| <b>Assessment Method*</b>   | <i>Assessment methods applied to create the final exposure scenario (specify the routes if relevant)</i>   |
| <b>2. Operational conditions and risk management measures</b>   |  |
| <i>Brief description of overall operational conditions referring to preparation categories (PC) and environmental release categories (ERC)</i>  |  |
| <b>2.1 Control of consumers exposure</b>  |  |
| <b>Product characteristic</b>   |  |
| <i>Product related conditions, e.g. the concentration of the substance in a preparation, the physical state of that preparation (solid, liquid; if solid: level of dustiness), package design affecting exposure</i>  |  |
| <b>Amounts used</b>   |  |
| <i>Amounts used per event</i>   |  |
| <b>Frequency and duration of use/exposure</b>   |  |
| <i>Duration of exposure per event and frequency of events</i>   |  |
| <b>Human factors not influenced by risk management</b>  |  |
| <i>Particular conditions of use, e.g. body parts potentially exposed</i>  |  |
| <b>Other given operational conditions affecting consumers exposure</b>  |  |
| <i>Other operational conditions e.g. room volume, air exchange rate</i>   |  |
| <b>Conditions and measures related to information and behavioural advice to consumers</b>   |  |
| <i>Safety advice to be communicated to consumers in order to control exposure, e.g. technical instruction, behavioural advice</i>   |  |
| <b>Conditions and measures related to personal protection and hygiene</b>   |  |
| <i>Usually personal protection measures are not expected for consumer products; however if e.g. gloves are recommended this can be specified here;</i>  |  |
| <b>2.2 Control of environmental exposure</b>  |  |
| <b>Product characteristics</b>  |  |
| <i>Product related conditions, e.g. the concentration of the substance in a preparation; package design affecting exposure</i>  |  |
| <b>Amounts used*</b>  |  |
| <i>Annual amount supplied into the consumer use(s) covered in this exposure scenario</i>  |  |
| <b>Frequency and duration of use</b>  |  |
| <i>Usually continuous use/release to be assumed, unless there are significant seasonal variations.</i>  |  |
| <b>Environment factors not influenced by risk management</b>  |  |
| <i>Flow rate of receiving surface water</i>   |  |
| <b>Other given operational conditions affecting environmental exposure</b>  |  |
| <i>Other operational conditions, e.g. indoor or outdoor use of products</i>   |  |
| <b>Conditions and measures related to municipal sewage treatment plant</b>  |  |
| <i>Size of municipal sewage system/treatment plant (m<sup>3</sup>/d); specify degradation efficacy; sludge treatment technique (disposal or recovery); measures to limit air emissions from sewage treatment (if applicable)</i>  |  |
| <b>Conditions and measures related to external treatment of waste for disposal</b>  |  |
| <i>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</i>                                  |  |
| <b>Conditions and measures related to external recovery of waste</b>  |  |
| <i>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</i>  |  |
| <b>3. Exposure estimation and reference to its source</b>   |  |
| <i>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 tool applied;</i> |  |
| <i>Alternatively: Include a link to a website from where the information described above can be retrieved.</i>  |  |

**Appendix 2: Exposure Scenario Format (2) addressing uses carried out by consumers**

**4. Guidance to DU to evaluate whether he works inside the boundaries set by the ES**

*Guidance how the DU can evaluate whether he operates within the conditions set in the exposure scenario. This may be based on a set of 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 he works within the boundaries set by the ES may be included here*

Table D.2.2.3 Standard format for exposure scenarios related to service life of substances in articles (handling of article by worker)

|  |   |
|--|---|
| <b>Appendix 3: Exposure Scenario Format (3) addressing service life resulting from downstream use (article handled by worker)</b>  |   |
| <b>1. Title</b>  |   |
| <b>Free short title</b>  | Short free text (in supply chain specific language) describing the scope of the exposure scenario   |
| <b>Systematic title based on use descriptor for article service life</b>   | List descriptors for service life covered in the exposure scenario  |
| <b>Systematic title based on use descriptor for downstream use leading to inclusion in article</b>   | Description of the preceding downstream use; make reference to the relevant exposure scenario if the downstream user needs to take measures to limit/reduce exposure from subsequent life cycle stages. |
| <b>Processes, tasks activities covered</b>   | Additional free text specification of the activities or tasks covered (if needed);  |
| <b>Assessment Method*</b>  | Assessment methods applied to create the final exposure scenario (specify the routes if relevant)   |
| <b>2. Operational conditions and risk management measures</b>  |   |
| Brief description of overall operational conditions referring to article categories (AC), process category (PROC) and environmental release categories (ERC)   |   |
| <b>2.1 Control of consumers exposure</b>   |   |
| <b>Product (article) characteristic</b>  |   |
| 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.     |   |
| <b>Amounts (contained in articles) present at workplace</b>  |   |
| Amounts used at a workplace; note: often this information is not needed for assessment of worker's exposure  |   |
| <b>Frequency and duration of use/exposure</b>  |   |
| Duration (e.g. hours per shift) and frequency (e.g. single events or repeated) of exposure   |   |
| <b>Human factors not influenced by risk management</b>   |   |
| Particular conditions e.g. body parts potentially exposed, increased breathing volume in a certain situation of work   |   |
| <b>Other given operational conditions affecting workers exposure</b>   |   |
| 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) conditions    |   |
| <b>Conditions and measures at level of article production to prevent release during service life</b>   |   |
| Measures taken by down stream users (processing the substance into the article), for example: sufficient storage time of articles before delivery to avoid exposure during transportation  |   |
| <b>Technical conditions and measures to prevent release (at source) from processing of articles</b>  |   |
| 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)                               |   |
| <b>Technical conditions and measures to control dispersion from source towards the worker</b>  |   |
| Engineering controls, e.g. exhaust ventilation, general ventilation; specify efficacy of measure   |   |
| <b>Organisational measures to prevent /limit releases, dispersion and exposure</b>   |   |
| 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.                    |   |
| <b>Conditions and measures related to personal protection, hygiene and health evaluation</b>   |   |
| Personal protection, e.g. wearing of gloves, full body dermal protection, goggles, respirator; specify efficacy of measure   |   |
| <b>2.2 Control of environmental exposure</b>   |   |
| <b>Product (article) characteristic</b>  |   |
| 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; |   |
| <b>Amounts used</b>  |   |
| Annual of substance per year processed into the article;   |   |
| <b>Frequency and duration of use/exposure from service life</b>  |   |

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| <b>Appendix 3: Exposure Scenario Format (3) addressing service life resulting from downstream use (article handled by worker)</b>  |
| <i>365 days per year continuously, unless particular conditions suggest otherwise</i>  |
| <b>Environment factors not influenced by risk management</b>   |
| <i>Flow rate of receiving surface water</i>  |
| <b>Other given operational conditions affecting environmental exposure</b>   |
| <i>Other operational conditions, e.g. indoor or outdoor use of products, abrasive conditions of use or weathering;</i>   |
| <b>Conditions and measures at level of article production process to prevent release during service life</b>   |
| <i>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</i> |
| <b>Conditions and measures related to municipal sewage treatment plant</b>   |
| <i>Size of municipal sewage system/treatment plant (m3/d); specify degradation efficacy; sludge treatment technique (disposal or recovery); measures to limit air emissions from sewage treatment (if applicable)</i>  |
| <b>Conditions and measures related to disposal of articles at end of service life</b>  |
| <i>Type of suitable treatment for waste generated by consumer uses, e.g. municipal waste incineration, specify efficacy of treatment;</i>  |
| <b>Conditions and measures related to recovery of articles at the end of service life</b>  |
| <i>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</i>                           |
| <b>3. Exposure estimation and reference to its source</b>  |
| <i>Estimation of exposure and risk characterisation ratios (for all route of exposure for workers 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 tool applied;</i>   |
| <i>Alternatively: Include a link to a website from where the information described above can be retrieved.</i>   |
| <b>4. Guidance to DU to evaluate whether he works inside the boundaries set by the ES</b>  |
| <i>Guidance how the DU can evaluate whether he operates within the conditions set in the exposure scenario. This may be based on a set of 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.</i>   |
| <i>Where relevant: Other methods for DU to check whether he works within the boundaries set by the ES may be included here</i>   |

### 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

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

Table D.2.2.4 Standard format for exposure scenarios related to service life of substances in articles (handled by consumers)

| <b>Appendix 4: Exposure Scenario Format (4) addressing service life resulting from downstream use (article handled by consumer)</b>   |  |
|---|--|
| <b>1. Title</b>   |  |
| <b>Free short title</b>   | <i>Short free text (in supply chain specific language) describing the scope of the exposure scenario</i>   |
| <b>Systematic title based on use descriptor for article service life</b>  | <i>List descriptors for service life covered in the exposure scenario</i>  |
| <b>Systematic title based on use descriptor for downstream use leading to inclusion in article</b>  | <i>Description of the preceding downstream use; make reference to the relevant exposure scenario if the downstream user needs to take measures to limit/reduce exposure from subsequent life cycle stages.</i> |
| <b>Processes, tasks activities covered</b>  | <i>Additional free text specification of the activities or tasks covered (if needed); if ECETOC TRA is used, here the relevant product subcategories can be flagged.</i>                                       |
| <b>Assessment Method*</b>   | <i>Assessment methods applied to create the final exposure scenario (specify the routes if relevant)</i>   |
| <b>2. Operational conditions and risk management measures</b>   |  |
| <i>Brief description of overall operational conditions referring to article categories (AC) and environmental release categories (ERC)</i>  |  |
| <b>2.1 Control of consumers exposure</b>  |  |
| <b>Product (article) characteristic</b>   |  |
| <i>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, skin contact and sucking;</i>  |  |
| <b>Amounts used</b>   |  |
| <i>Amount of substance contained in the article;</i>  |  |
| <b>Frequency and duration of use/exposure from service life</b>   |  |
| <i>Duration of e.g. inhalation of releases from indoor construction products; frequency and duration of e.g. skin contact to textiles or furniture;</i>   |  |
| <b>Human factors not influenced by risk management</b>  |  |
| <i>Particular conditions of use, e.g. body parts potentially exposed, children potentially exposed</i>  |  |
| <b>Other given operational conditions affecting consumers exposure from article service life</b>  |  |
| <i>Other operational conditions e.g. room volume, air exchange rate</i>   |  |
| <b>Conditions and measures at level of article production to prevent release during service life</b>  |  |
| <i>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</i> |  |
| <b>Conditions and measures related to information and behavioural advice to consumers</b>   |  |
| <i>Usually not applicable related to articles</i>   |  |
| <b>Conditions and measures related to personal protective equipment and hygiene</b>   |  |
| <i>Usually not applicable related to articles</i>   |  |
| <b>2.2 Control of environmental exposure</b>  |  |
| <b>Product (article) characteristic</b>   |  |
| <i>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;</i>   |  |
| <b>Amounts used</b>   |  |
| <i>Annual of substance per year processed into the article;</i>   |  |
| <b>Frequency and duration of use/exposure from service life</b>   |  |
| <i>365 days per year continuously, unless particular conditions suggest otherwise</i>   |  |
| <b>Environment factors not influenced by risk management</b>  |  |
| <i>Flow rate of receiving surface water</i>   |  |
| <b>Other given operational conditions affecting environmental exposure</b>  |  |

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| <b>Appendix 4: Exposure Scenario Format (4) addressing service life resulting from downstream use (article handled by consumer)</b>  |
| <i>Other operational conditions, e.g. indoor or outdoor use of products, abrasive conditions of use or weathering;</i>   |
| <b>Conditions and measures at level of article production process to prevent release during service life</b>   |
| <i>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</i>  |
| <b>Conditions and measures related to municipal sewage treatment plant</b>   |
| <i>Size of municipal sewage system/treatment plant (m3/d); specify degradation efficacy; sludge treatment technique (disposal or recovery); measures to limit air emissions from sewage treatment (if applicable)</i>  |
| <b>Conditions and measures related to disposal of articles at end of service life</b>  |
| <i>Type of suitable treatment for waste generated by consumer uses, e.g. municipal waste incineration, specify efficacy of treatment;</i>  |
| <b>Conditions and measures related to recovery of articles at the end of service life</b>  |
| <i>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</i>   |
| <b>3. Exposure estimation and reference to its source</b>  |
| <i>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 tool applied;</i>  |
| <i>Alternatively: Include a link to a website from where the information described above can be retrieved.</i>   |
| <b>4. Guidance to DU to evaluate whether he works inside the boundaries set by the ES</b>  |
| <i>Guidance how the DU can evaluate whether he operates within the conditions set in the exposure scenario. This may be based on a set of 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.<br/>Where relevant: Other methods for DU to check whether he works within the boundaries set by the ES may be included here</i> |