

# Exposure Scenarios Guidance for DU-mmies



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### Target group:

**This guidance is intended for the downstream users (DU) of chemical substances and all other persons who will have to read Exposure Scenarios (ES) and check whether the latter cover their uses of the substance.**

*This document contains guidance on certain aspects of REACH Regulation with the best aim to provide guidance, explanations and clarifications on the topic of question. Individuals must exercise their independent judgment in determining its appropriateness for a particular purpose. Further information received following the time scale as foreseen by REACH and the guidance policies as described in the REACH implementation programs will be added when it becomes available.*

*The author reserves the right not to be held responsible for the topicality, correctness, completeness or quality of the information provided. Liability claims regarding damage caused by the use of any information provided, including any kind of information that is incomplete or incorrect, will therefore be rejected.*



## 1. INTRODUCTION

The EU REACH Regulation (No 1907/2006) requires the ‘safe use’ of chemicals throughout the supply chain. In order to do so, REACH imposes specific duties and obligations on the various actors of this supply chain, the manufacturers & importers and the downstream users of the substances, also with regard to communication.

For produced and/or imported at or above 10 tons/year and meeting the classification criteria as dangerous, [PBT](#) (Persistent Bioaccumulative Toxic)/ [vPvB](#) (very Persistent, very Bioaccumulative), safe use is described in Exposure Scenarios ([ES](#)).

An [ES](#) refers to the set of conditions, including operational conditions ([OC](#), for example the duration and frequency of use of the amount used, the process temperature or the pH) and risk management measures ([RMM](#), for example local exhaust ventilation or a certain type of glove, waste water and gas treatment), which describe how a substance can be manufactured or used safely during its life-cycle and how the manufacturer/importer of the substance can control (at his site), and/or recommend how Downstream Users ([DU](#)) should control exposure of a substance to humans and the environment. The definition of ES covers a set of requirements, obligations and rights further explained in e.g. the following [ECHA](#) guidance documents: Part D. Exposure Scenario Building and Exposure Scenario Format<sup>1</sup>, Guidance for Downstream Users<sup>2</sup>.

ES are part of the Chemical Safety Assessment/Report ([CSA/CSR](#)) submitted by the Registrant of the substance and attached to the extended Safety Data Sheets ([eSDS](#)) communicated to the Downstream User.

In practice, [ES](#) are to be established by the Registrants of the substance (the manufacturer/importer) and communicated through the supply chain to inform the Downstream Users how to use the substance safely over the life cycle for man and the environment.

Article 37 (5) of REACH states that “Any Downstream User shall identify, apply -and where suitable, recommend- appropriate measures to adequately control risks identified in [...] the safety data sheet(s) (including the ES) supplied to him”.

This obligation for the Downstream User to comply with the ES developed for his specific use (or to develop an ES by himself if his use is not or is not adequately covered) must be fulfilled at the very latest 12 months after the [DU](#) has received the [eSDS](#) with a registration number (1907/2006 (EC), Article 39).

In practice, this means that the Downstream User is responsible for implementing the practical details recommended in the ES. Therefore, they must check the information on Operational

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<sup>1</sup> [http://guidance.echa.europa.eu/docs/guidance\\_document/information\\_requirements\\_part\\_d\\_en.pdf](http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_part_d_en.pdf).

<sup>2</sup> [http://guidance.echa.europa.eu/docs/guidance\\_document/du\\_en.htm?time=1302854696](http://guidance.echa.europa.eu/docs/guidance_document/du_en.htm?time=1302854696).

Conditions (OC) and Risk Management Measures (RMM) given in the ES provided by the Registrant and compare those with the actual [OCs](#) and [RMMs](#) he has in place.

The purpose of this guidance is to explain how to comply with the requirements regarding the ES as set in REACH.

### 1.1 How does the ES for DU-mmies guidance work?

As a Downstream User, you may have received from the registrant of your substance various sets of information:

- The “full” ES (or Generic Exposure Scenario, [GES](#)<sup>3</sup>) as included in the Chemical Safety Report ([CSR](#)) by the registrant,
- The extended SDS ([eSDS](#)), which is the SDS to which the ES are attached,
- The extended SDS with a short version of the ES<sup>4</sup>,
- ...

It is important to understand the key aspects in this information package that will help you to ascertain if your use is covered by the ES, or, in other words, if you are compliant with what is described in the ES.

For example, Operational Conditions and/or Risk Management Measures in place at the Downstream User’s site may not be completely identical to those specified in the ES coming from the registrant. It may then not be intuitively apparent whether your use of the substance is compliant with the ES.

At this stage, it is crucial to properly understand the content of the ES and the impact of potential differences when checking compliance. ‘Scaling’ makes it possible to demonstrate that a use is covered by an ES, although maybe not all parameters are directly covered by the conditions of use as described in that ES<sup>5</sup>. In the metals sector, some rules and tools have been developed (“scaling tools”) to allow the ‘scaling’ of what is proposed in the ES to some of the downstream users’ conditions when assessing compliance (DU Scaling Tool for environment and [MEASE](#) for occupational exposure). The use of scaling tools ensures that Downstream Users remain within the boundaries of the ES and that human health and environment are sufficiently protected<sup>6</sup>.

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<sup>3</sup> GES are further explained in the glossary. In the metals sector, a GES provides standard OCs and RMMs for a group of sectors and/or workplaces or for common processes, which could be applied at different steps of the lifecycle of the substance (e.g. packaging of powder). GES have also been developed to address the physical form and related intrinsic emission potential of the substance (dust, massive,...).

<sup>4</sup> This shortened version of the ES is currently under development by several consortia to facilitate communication in the supply chain, by increasing consistency across metals and avoiding eSDS from becoming a useless huge number of pages. The objective of this short version of the ES is to avoid repetitions but still contain all relevant information. For more detailed information, reference could be made either to one of the 16 sections of the eSDS or to the full ES available on e.g. the registrant’s website.

<sup>5</sup> ECHA (2008): Guidance for downstream users, [http://guidance.echa.europa.eu/docs/guidance\\_document/du\\_en.htm?time=1302854696](http://guidance.echa.europa.eu/docs/guidance_document/du_en.htm?time=1302854696)

<sup>6</sup> MEASE and the DU Scaling Tool have been developed as Tier 1 assessment tools. Therefore, estimates provided by both tools are intrinsically conservative to ensure a high level of protection of human health and environment

Typically, ES or GES in the metals sector follow the latest format proposed by ECHA<sup>7</sup> as far as possible. It should be noted here that you might well see somewhat ‘deviating formats’; there are two reasons for this: (i) when the development of some ES started very early and formats recommended in earlier versions of the ECHA guidance were used, (ii) some ES were based on existing risk assessment reports, requiring some adaptation of the standard ES format to reflect the specific origin of the data. However, all ES can principally be divided into 4 different sections:

Section 1: Title and Use Descriptors

Section 2: Operational conditions and risk management measures

Section 3: Exposure and risk estimation

Section 4: Guidance to Downstream Users

This Guidance for DU-mmies will take you through the content of an ES, step-by-step, and help you to assess compliance or non-compliance with what has been prescribed by the Registrant.

For each of the sections of the ES, you will get explanations of the meaning and intention of the individual section, and of the implications that specific entries have for the operations conducted at Downstream User level.

Additionally, this guidance provides you with a glossary of terms and list of abbreviations to facilitate understanding of the content of the ES, and makes reference to relevant background documents you may wish to read if you want to go into more detail.

Tips will be given in several sections:



- Metals Tips: Highlighting some metal specificities associated with the specific item discussed or referencing to existing metals tools/guidance



- DU-mmies Tips: To catch your attention



- Short ES-Tips: If the Registrant of your substance has provided you with a shortened ES, some sections of the ES may be missing or presented in a different way



- Scaling tips: These tips highlight the consequences, requirements and limitations for scaling in a specific section. For example, they will stress the binding nature of a specific item in the ES

<sup>7</sup> Exposure scenario format 2010

[http://guidance.echa.europa.eu/docs/guidance\\_document/information\\_requirements\\_ESformat\\_en.pdf?vers=27\\_05\\_10](http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_ESformat_en.pdf?vers=27_05_10)

At the end of most sections, you will be faced with a decisional question aimed at helping you to define compliance. You can either select “YES” or “NO”:

- If you tick “YES”, you simply move on to the next section.
- By ticking “NO” you are indicating that the operations at your site are conducted differently comparing to the ES. DO NOT PANIC, additional guidance is provided for you in this situation!

Finally, as part of the information in the ES is also included in the SDS part of the eSDS, and as the sections shall be consistent, a link to the ‘corresponding’ section in the SDS is provided under several ES sections.

Link with SDS      Section x<sup>8</sup>: one of the 16 sections of the SDS as defined by Annex II



**Important to stress here is that the overall goal of the Guidance for DU-mmies is to help you to check whether you are covered by the ES received from the Registrant from your substance.**

If, after checking the ES with the aid of this guidance, you conclude that you are not covered although you have done everything to scale the GES according to the guidance, then you need to contact the Registrant who provided you with the eSDS/ES to discuss a way forward.

Please make sure you contact the supplier of the eSDS if you fall under one of these categories listed below:

- if your use is not covered.
- if your operational conditions lead to higher exposure levels than those reported in the ES (e.g. use it more often, larger quantities) and the scaling tools indicate that you are at risk (i.e. the exposure estimate is above the relevant DNEL or PNEC, respectively).
- If you believe that the risk management measures prescribed in the ES are not appropriate.

In Annex I you will find a [‘blank’ template](#) to help you in these contacts with the supplier of the eSDS. The template follows the structure of the ES and enables you to easily comment in the relevant sections where you have questions, comments, or where you fall outside the boundaries of the ES.

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<sup>8</sup> Following the main sections as required by Regulation No. 453/2010.



## 2. DU-mmies Guidance

### Section 1: Title

#### **Free short title:**

#### REASONING:

Based on the free short title, you should be able to initially decide whether the ES you are reading includes your use(s). Please note that the title may cover either:

- a) multiple ES describing different *conditions of use* all relating to the same identified use,

#### **METALS tip**



Under REACH, metal consortia have developed and assessed Generic Exposure Scenarios ([GES](#)) for their members' markets. These can still be slightly modified (and/or made specific) on a case-by-case basis, if necessary.

OR

- b) one ES entailing various identified uses, with similar conditions of use

#### **DU-mmies tip**



The short title of the exposure scenario is only a label *and not an ES in itself*. In cases in which your use does not seem to be covered by the title, please consider the further content of the ES.

#### **Short ES tip**



This section may have been shortened in the short ES. Please check Section 1 of the [SDS](#), as there you will also be able to find the complete overview of ES that the eSDS is covering.

#### **Scaling tip**



Because of their often needed broad applicability domain, in specific cases ES may not explicitly mention individual uses in their short title. As long as a free-short title does not exclude a specific use (for example by mentioning "use in industrial setting", professional uses are excluded), the free short title should not be considered as a limiting parameter for ES scaling.

Link with SDS



Section 1: Identification of the substance/mixture and of the company/undertaking

**DECISION: Do you see your use covered in the short title of the ES?**

**YES**

**NO**

**OK,**  
Please proceed to the next section.

Please first check the other sections of the ES. If you also see that the operational conditions and risk management measures described in the ES in Section 2 are not applicable to your use, please contact the supplier of your ES to

determine whether your conclusion is correct and further refinements can be made.

*BACKGROUND:*

[ECHA R12: "User descriptor system" version 2, March 2010](#)

### **Systemic title based on use descriptor:**

REASONING: In this section you will find a description of the identified use(s) of a substance, using 'descriptors' from the use descriptor system (UDS) as defined in the ECHA guidance R12. The purpose of the [UDS](#) is to facilitate communication in the supply chain. A meaningful description may often need a combination of a maximum of five individual descriptors, namely:

- the sector of use category ([SU](#))
- the chemical product category ([PC](#))
- the process category ([PROC](#))
- the environmental release category ([ERC/SPERC](#)) and
- the article category ([AC](#)).

Please note that some of the use descriptors are important input parameters in specific Tier 1 exposure estimation tools.

#### **METALS tip**



Some metal-specific process categories ([PROC](#)) have been added to the ECHA R12 Use Descriptor System so as to better reflect metals processes and also to allow more accurate metal-specific modelling when using the ECETOC Targeted Risk Assessment tool ([TRA](#)) and MEASE. A detailed guidance on the selection of metal-specific PROCs is provided in the MEASE glossary.

### **How were these descriptors chosen by the supplier of the ES?**

Based on the feedback from consortium members and Downstream Users, an assessment of the relevancy of each of the descriptors was carried out. This assessment also kept the metals GES approach in mind, i.e. grouping uses under one ES if similar Operational Conditions and Risk Management Measures apply. Descriptors were prioritised and sorted for the final list that you will find in this section. Please note that, in cases where numerous [PROCS/ERCs](#) were assigned, only the relevant and worst-case PROC/ERC may have been taken forward for the modelling and the risk characterisation (by this worst case approach all other PROC/ERC are automatically covered). If there were any doubts on the selection of correct PROCs/ERCs, a careful communication process along the supply chain has ensured that only appropriate PROCs/ERCs were included.

With regard to the [SU](#), please note that, so as to facilitate the reading of the ES and avoid confusion, some of the registrants did not list all the SUs and [NACE](#) codes they received from their DU in the ES. They proceeded more "generically", proposing key descriptors corresponding to the main user groups (industrial, consumer, professional, SU3, SU21 and SU22) in line with the updated R12 guidance on the UDS (March 2010). Where necessary, these key descriptors were completed by supplementary descriptors corresponding to sectors of end-use (SU0-SU24).

**Scaling tip**



It should be noted that the assignment of use descriptors to uses is intrinsically a matter of interpretation. For example, PROCs may be assigned from the viewpoint of a process flow (i.e. by assigning PROCs 1 to 4), by looking at the activities actually conducted (e.g. grinding could result in PROC21 or PROC24) or by focusing on other parameters such as the scale of operation (PROC7 vs. PROC11 for *industrial* or *professional* spraying, respectively). As a consequence, the ES should be carefully checked in order to ascertain whether or not “missing” use descriptors are intrinsically covered by other use descriptors. If after such double-checking, specific processes remain uncovered by the ES, the associated use has to be considered as not being covered.

**DECISION: Do you think that the use you are checking is properly described by the user descriptors?**

**YES**

**NO**

OK,  
please proceed to the next section.

Please check the ECHA Guidance R12 to examine which additional descriptors are missing. Communicate to your supplier the missing use descriptors (using Annex 1 for example). Also check the section on processes, tasks and activities covered. If after this, a specific activity remains uncovered, please refer to the section below.

*BACKGROUND:*

[ECHA R12: “User descriptor system” version 2, March 2010](#)

**Processes, tasks and/or activities covered**

REASONING: The [PROC](#) can be cited here, followed by its meaning in the UDS: e.g. PROC 1: used in closed process.

The processes, tasks and activities covered by the (G)ES are reported here, usually in the form of a short text or list. This text or list will pinpoint the tasks/activities where exposure to the substance of relevance in this ES is to be assessed. Please check whether you have activities that are not listed that could generate higher or different exposures.

**DU-mmies tip**



If small deviations of the ES are needed to reflect the OCs and RMMs at your site, you should document your assessment of and compliance with the ES.

For the description of workers' activities, PROCs may have been used, with some explanations for the substance of relevance in the ES: e.g. PROC 26: packaging of metal X powder.

**Short ES tip**



This section may have been deleted in the short version of the ES. You can find it back in the full ES or in the CSR.

You may encounter here the term: "[contributing exposure scenario](#)". Please consult the explanation provided in the glossary.

**Scaling tip**

The same as mentioned above for the use descriptors applies here. Please see above for further information.



**DECISION: Do you think all your activities/tasks/processes related to the substance of interest entailing exposure are covered in this exposure scenario?**

**YES**

**NO**

**OK,**  
please proceed to the next section.

Please map the complete production process. Note down the processes, tasks or activities where exposure to the relevant substance could not be excluded and cross check with the list provided in the ES. Once you have identified which processes/tasks are missing, fill them in logical order and [communicate to your supplier](#).

**BACKGROUND:**

[ECHA R12: "User descriptor system" version 2, March 2010](#) , [ECHA Part D4 "exposure scenario format" May 2010](#).

**Assessment Method:**

**REASONING:** The methodology that has been used for assessing exposure is mentioned here - for example, use of measured data, or use of Tier 1 or higher tier exposure estimation tools. Overall, this section informs you about how the exposure levels were derived and which tools have been used.

Since these tools and methods are often described in more detail in sections of the Chemical Safety Report (CSR; Chapter 9) and/or in appendices to which you as a DU may not have full access, the standard exposure assessment methods are briefly summarised here below:

Modelled data for occupational inhalation and dermal exposure can be obtained from various modelling tools (e.g. MEASE, ECETOC TRA). In addition to monitoring data of inhalation and dermal exposure, biomonitoring data could be used. Biomonitoring data (e.g. measurement of the substance or applicable bio-marker in blood or urine) integrate all routes of exposure (inhalation, ingestion, dermal), thereby reducing uncertainties. In addition, measured data published in literature may also be used, as well as measured data from a similar substance and/or workplace in an analogous data (read-across) approach. Detailed guidance can be found in the ECHA guidance R14.

A brief description of the most frequently used modelling tools for human health and environment exposure assessment has been included in the glossary section.

### METALS tip



Note that several metal-specific tools have been developed to enable good exposure estimates to be derived for metals:

#### Occupational exposure:

Tier 1 tool: [MEASE](#) (more on MEASE on: <http://www.ebrc.de/ebrc/ebrc-mease.php>)

Tier 2 tool: [ART](#) (FOR COLD PROCESSES only) (more on ART: <http://www.advancedreachtool.com/> (under development)

#### Environmental exposure:

The Downstream User Scaling tool can be found on: <http://www.arche-consulting.be/Metal-CSA-toolbox/du-scaling-tool> (please note that this tool contains some default settings that are metal-specific.)

### Short ES tip



This section might be deleted in the short version of the ES, as Section 8 of the SDS/full ES usually already includes the information on the assessment method. The assessment method is also often mentioned in the Introduction or Section 3 of the ES.

### Scaling tip



The indication of the assessment method used is for your information only. As the DU you are free to assess exposure with any suitable method (please see above for a short description of possible assessment methods) if you need to re-assess exposure in a potential scaling process. In most cases, however, this would involve the use of more sophisticated methods (i.e. higher tier methods) than those originally used by the registrants. Please note that, for an exposure assessment based on measured data, strict quality criteria have to be applied to the data sets used (e.g. minimum number data points, documentation of the sampling methodology, etc.).

### Link with SDS

Section 8: Exposure controls/personal protection



BACKGROUND: [ECHA Chapter R14 Occupational exposure estimation](#),  
[ECHA R16 "Environmental exposure estimation," May 2010.](#)

## Section 2: Operational conditions and risk management measures

### 2.1 Control of workers' exposure

**REASONING:** The ES is intended to prescribe conditions under which a substance can be handled safely. This means addressing all factors that could potentially (under realistic assumptions) modify the emission into the workplace atmosphere as relevant for inhalation exposure, or modify the dermal exposure potential. Modifying factors for occupational exposure may be grouped in (i) substance (or material) intrinsic, (ii) process intrinsic or (iii) emission/exposure reduction measures (such as local exhaust ventilation). Additionally, personal protective equipment may be worn by workers to reduce personal exposure.

#### **METALS tip**



Monitoring and biomonitoring datasets may be available for your workplace. If you do not meet compliance in one of the following sections because of differences in one or several parameters, reliable and good quality measured data could be used to show compliance. Alternatively, the MEASE tool can be used for scaling.

#### **Scaling tip**



If specific parameters are not addressed in an ES, they were considered as being of marginal relevance for that specific ES and exposure assessment, respectively. Thus, not listed parameters are not limiting any potential scaling of the exposure scenario. It should be noted, however, that some relevant parameters are potentially mentioned in other sections of the ES - for example, the scale of operation (industrial vs. professional settings) is often described in the short text title of the ES or inherently defined in the use descriptors.

### Product characteristics

**REASONING:** The product characteristics need to be defined for each (contributing) ES developed, because substance characteristics such as the molecular weight, the melting point, vapour pressure, and physical form define the substance's intrinsic emission potential. The substance's intrinsic emission potential could be one of the key exposure modifiers, depending on the ES to be assessed. It should be noted that, for exposure assessment modelling, and in the absence of precise information on the substance's intrinsic emission potential (e.g. dustiness), the "worst-case" physical form of the substance - i.e. the powder form - has been taken forward for exposure modelling, as this will represent the worst case in terms of emission potential. In other cases, the physical form of the substance that is actually used is used. It should also be noted that, in the absence of a designated field in the standard ES format, the "fugacity class" is reported here. This fugacity class is used in MEASE and in the ECETOC TRA tool and could also depend on the process temperature or level of abrasion.

**METALS tip**



In the MEASE tool, the physical form and factors such as the type of operation and temperature related to it (ambient or furnace temperature), dustiness, abrasion, etc. will assign a so-called fugacity class. MEASE can be used as scaling tool.

The product specifications, such as the concentration/percentage of the substance in a preparation or an article, may directly be linked to the exposure of humans and the environment. For example, the concentration in the product multiplied by product amount per activity will determine the amount of substance present in that activity.

**DU-mmies tip**



If the substance that you are using is supplied to you in a form that reduces emission potential (granular solids, agglomerated powders), you may consider that the RMMs recommended in the ES section 'Personal Protection' are not appropriate or too worst-case. To be able to adapt these RMM to your situation, you need to demonstrate the reduced emission potential by collecting appropriate measured data/use of scaling tools.

**Short ES tip**



In the short version of the ES some data have been deleted as considered as not relevant (e.g. if the parameter is not used in metal-specific tools). You can find this information in the full ES if need be.

**Scaling tip**



The substance intrinsic emission potential could be a crucial limiting factor for the scaling of ES. In such cases, the intrinsic emission potential of the reported substance has to be seen as a maximum limit value, not to be exceeded. The use of materials with a lower emission potential could be assumed as being covered on a "worst-case basis" or could be re-assessed in a scaling exercise. For modelling exposure in MEASE, it should be noted that ES also exist in which the substance intrinsic emission potential may be "overwritten" by the emission potential resulting from the processes conducted. For example, for the use of a massive metal in a highly abrasive task, the very low emission potential from the massive object itself is "overwritten" by the amount of generated process dust resulting from the task conducted.

It should be noted that inhalation DNELs may have been derived, also considering the particle size of the substance used or process dust generated. If finer particles are likely to be involved than as those determined by the reported physical form (or emission potential), you should urgently contact the supplier of the SDS.

Link with SDS

Section 3: Composition/information on ingredients



**DECISION: You need to answer two questions here:**

- 1) Does the physical form as defined in this section correspond to the form of the substance you are using in the process/workplace covered in this section?
- 2) Is the content (%) of the substance in the preparation at or below the value within the ranges proposed in this section?

YES	NO
<p><b>OK</b> please proceed to the next section.</p>	<p>Please run the MEASE tool in order to scale the ES according to your product characteristics. With the outcome, please fill in the <a href="#">template</a> in Annex I. Measured can also be used. If the physical form of your substance does not correspond to the physical form as defined in this section, please contact the supplier of your ES.</p>
<p><i>BACKGROUND: <a href="#">ECHA R13 "Risk management measures and operational conditions", May 2008.</a></i></p>	

### **Amounts used**

REASONING: Depending on the [ES](#), the amounts used at the workplace will or will not be reported here. In some cases, an exact value may be reported, considered as defining the threshold of a substance that can be used onsite per year or per shift. For others, the actual tonnage per shift will not be considered as relevant for exposure determination, as other parameters like the scale of the operation (industrial vs. professional), level of containment/automation (as reflected in the [PROC](#)), etc. will be the main determinants of the emission potential of the process.

#### **Scaling tip**



If an amount used is stated in the ES, this amount has to be seen as the potential limiting maximum value for occupational exposure. Scaling beyond reported amounts is often not appropriate and measured data are most likely to be used for demonstrating adequate control.

**DECISION: If "amounts used" are reported in this ES, please check if you use the substance in comparable amounts.**

YES

NO

**OK**  
please proceed to the next section.

Please contact the supplier of your ES to determine with him if this factor is critical for the exposure assessment.

*BACKGROUND: [ECHA R13 "Risk management measures and operational conditions", May 2008.](#)*

### **Frequency and duration of use/exposure**

REASONING: In this section you should be able to identify the recommendations with regard to the use of the substance in terms of duration and frequency/day. More specifically, you need to identify whether the ES defines a time limit on the use of the substance at a certain workplace (or activity). The duration of exposure per hour/day/week is a very important factor that will determine the exposure over a working shift. The duration and frequency of use related to the human health and safety assessment should be a realistic worst-case combination of the duration and frequency of use for one worker.



**Scaling tip**



Any values reported here have to be considered as maximum scaling limits. It should be noted that most available exposure models use the duration of exposure as a parameter to refine exposure estimates, particularly for inhalation exposure. However, such refinements are only appropriate when comparing derived exposure levels with long-term effects. If acute effects are involved, refinements via exposure duration are usually not appropriate. This is also true for exposure estimates derived from measured data: exposure levels should usually not be expressed as time-weighted averages (TWAs) when comparing with acute effects.

**DECISION: If the ES restricts the duration of the substance use in a certain workplace, are your workers compliant with this work timeframe limitation?**

**YES**

**NO**

**OK**

please proceed to the next section.

Please run the MEASE tool in order to scale the prescribed ES according to your workplace-specific parameters. With the outcome, please fill in the [template](#) in Annex I. Alternatively measured data could be used as outlined above.

*BACKGROUND: [ECHA R13 "Risk management measures and operational conditions", May 2008.](#)*

**Human factors not influenced by risk management**

REASONING: This is a set of parameters that are presented in case they were relevant for modelling the exposure estimates. Examples of such parameters are: respiration volume under conditions of use, ventilation rate, exposed skin surface, body weight, etc.

**Scaling tip**



Reporting these data is for your information only. These factors have been used for the exposure assessment and are typically values accepted in several risk assessments.

### Other given operational conditions affecting workers' exposure

REASONING: In this section, other factors influencing exposure to the substance, like indoor or outdoor use, process temperature, and process pressure are specified if identified as relevant. If the substance is used indoors, the room volume (and ventilation) may be further defined. The process temperature and pressure may be defined, depending on the relevancy to the specific exposure assessment.

Link with SDS

Section 7: Handling and storage



#### **DECISION: Do I comply with the defined and relevant parameters in this section?**

**YES**

**NO**

**OK**

please proceed to the next section.

If the ES does not represent your situation (and especially a worst-case situation) please collect exposure monitoring data that show that safe use can be ensured or run MEASE with your specific parameters like process temperature. With the outcome, please fill in the [template](#) in Annex I.

BACKGROUND: [ECHA R13 "Risk management measures and operational conditions", May 2008.](#)

### Technical conditions and measures at process level (source) to prevent release

REASONING: Depending on the type of process and the level of possible exposure, different technical measures including process design and conditions to prevent release will be defined. The type of measures proposed here will either be measures to avoid any kind of manual manipulation during the process (e.g. through automated control of closed process equipment), or to encapsulate relevant handling areas by e.g. ventilated booths or glove boxes (also referred to as "containment"). This section may also entail guidance on assessment of the performance of the containment.

#### **Scaling tip**



It is important to note that some PROCs inherently define a specific level of containment: for example, PROC1 would require a closed system. If such PROCs are to be re-assessed in a scaling effort by using MEASE or the ECETOC TRA tool, the level of containment cannot be modified, as both tools inherently reflect the level of containment in their exposure estimates. In such cases, the level of containment could only be modified by selecting a different PROC, requiring this PROC to be covered by the ES (please see also under "Systemic title based on use descriptor").

Link with SDS

Section 8: Exposure controls/protection



**DECISION: Am I compliant with the measures recommended here to prevent release from the source?**

**YES**

**NO**

**OK**  
please proceed to the next section.

Please run the MEASE tool with your conditions at the site and, with the outcome, please fill in the form in [Annex I](#). Alternatively, measured data could be used as outlined above (please consider that a change of the “level of containment” could lead to the assignment of a different PROC).

**BACKGROUND:** [ECHA R13 “Risk management measures and operational conditions”, May 2008.](#)

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

**REASONING:** Depending on the descriptions in the previous section, you should by now know the exact parameters defining the process area requirements and the process itself. In this section, further details are provided on technical conditions and measures to control residual emissions escaping from the process as described in the previous subsections of the ES (either defined by a [PROC](#), workplace, tasks or [contributing scenario](#)).

The type of control measures proposed here will be to further reduce exposure after the technical measures put in place in the subsection technical conditions and measures proposed to prevent release: e.g. proposing local controls like local exhaust ventilation, etc. The effectiveness of such control measures can vary depending on the technique and operation of the setup. You will therefore probably be given a numerical value representing the effectiveness of the chosen RMM to be achieved in order to efficiently reduce exposure.

#### **Scaling tip**



It is noted that the reported efficacy values for specific RMMs usually reflect those achieved with standard, properly designed and regularly maintained equipment. However, certain efficacy values for RMMs could be refined in a scaling exercise, depending on the assessment method used. For measured data, the efficacy could be overwritten according to additional measured data, whereas for modelled exposure levels the given efficacy should be seen as a limiting maximum value that may only be increased based on scientific justification (e.g. by consulting the product specification/manual).

Link with SDS

Section 8: Exposure controls/personal protection



**DECISION: Do the chosen technical measures correspond to the ones implemented at my workplaces?**

**YES**

**NO**

**OK**

Please run the MEASE tool and, with the

please proceed to the next section.

outcome, please fill in the form provided in [Annex I](#).

BACKGROUND: [ECHA R13 “Risk management measures and operational conditions”, May 2008.](#)

### **Organisational measures to prevent /limit releases, dispersion and exposure**

REASONING: In this section, specific organisational measures are listed for supporting the functioning of particular measures, such as training and supervision of workers in terms of, for example, personal hygiene. A reference to the following core SDS sections could be made here:

- 7.1.2: “Advice on general occupational hygiene”,
- 8.2.2.2: “Individual protection measures, such as personal protective equipment” and
- 11: “Toxicological information”.

In general, the main aim of this section is to describe the general organisational measures necessary for the health and safety of workers, based on obligatory standards such as the “reduce-to-a-minimum” principle and the hierarchy of RMM prescribed in the EU Chemical Agents Directive.

Apart from substance- or process-specific risk management measures, good industrial hygiene practice could be mentioned and special requirements (e.g. when oral exposure significantly contributes to occupational exposure, special requirement for personal hygiene may be given)) could be defined in this section.

Personal hygiene procedures (e.g. washing hands after handling of substances, changing contaminated cloths) and organisational settings (e.g. separation between exposure areas (black) and non-exposure areas (white)) should be supported by regular training / instruction of workers and consequent supervision. Application of personal protective equipment should be based on acceptance and a high level of comfort to achieve effective implementation.

#### **Short ES tip**



In the short version of the ES, the text will be probably reduced. You can find the complete text in the following core SDS Sections 7, 8, 11 or in the introduction of the ES.

#### **Scaling tip**



Because of their generic nature, the requirements as prescribed in this section should be seen as minimum limiting values. Omitting of the measure would have to be justified on a scientific basis. It should also be noted that some measures may have been set by the registrant in order to further justify the negligible nature of specific exposure routes (e.g. the oral route). Thus, although some of the reported measures may seem to be over-cautionary, careful consideration of their implications is needed if the DU wishes to deviate.

#### **Link with SDS**



Section 7.1.2: “Advice on general occupational hygiene”, 8.2.2.2: “Individual protection measures, such as personal protective equipment” and 11: “Toxicological information”.

**DECISION: Are you applying the organisational measures as prescribed in this section or as defined in the core section of the safety data sheet?**

**YES**

**NO**

**OK**  
please proceed to the next section.

You need to start a discussion with the supplier of your ES and justify why you are not applying these measures, or what you propose as an alternative. Please fill in the form provided in [Annex I](#).

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

REASONING: Personal Protective Equipment ([PPE](#): gloves or masks) is also a type of [RMM](#). What is recommended by the supplier in terms of PPE will be detailed in this section when required to control worker exposure. This will entail recommendations on the efficiency to be achieved by the

**Scaling tip**



It should be noted that the use of PPE has to be minimized, and other measures to reduce exposure have to be taken first, before using PPE (STOP principle). This is particularly important for RPE: If the DU considers the wearing of RPE in a re-assessment, he has to ensure that a RPE policy is implemented in parallel addressing the training of workers to ensure good practices of use of RPE. As a re-assessor, the DU should also keep in mind that RPE cannot usually be worn comfortably during an entire working shift due to increased breathing resistance. In contrast, if a DU wants to implement less restrictive RPE or even to completely avoid the use of RPE, this could be done by considering the assigned protection factors (APFs). These APFs are specific to individual types of RPE and could be obtained from the manufacturer of the RPE.

masks, gloves, or working clothes.

Link with SDS      Section 8: Exposure controls/personal protection



**DECISION: Are you compliant with the recommendations made in this section? Do you achieve comparable efficiencies?**

**YES**

**NO**

**OK**  
please proceed to the next section.

You need to start a discussion with the supplier of your ES and justify why you are not applying these measures or what you propose as an alternative. Please fill in the form provided in [Annex I](#).

**General note on RMMs in controlling occupational exposure:**

For the ES you are re-assessing in a scaling exercise, it may happen that the recommended RMM are not appropriate for the type of substance you are using, for example:

\*If the recommended RMM are overprotective.

For example: if due to a different physical form of the substance compared to the form described in the ES, exposure is reduced to a minimum. You are requested to demonstrate that your operational conditions and implemented RMMs are appropriate. You will need to demonstrate that exposure of the worker is below the respective [DNEL](#). If measured data are not available, you may make use of an appropriate scaling tool such as MEASE to estimate the associated exposure.

\*If the recommended RMM relate to irrelevant exposure routes.

For example, if it were to be recommended that dust masks be worn when in-fact no aerosols are formed because the substance is provided as a massive and hot processes or abrasive tasks are not performed, then inhalation exposure is unlikely and masks do not need to be worn.

\*The recommended RMM conflict with existing environmental, workers or installation-related legislation:

For example, if a certain RMM is triggered by specific workplace legislation, and the RMM under Heading 8 of the SDS are clearly contradictory, this is an obvious case of inappropriateness.

## 2.2 Control of environmental exposure

### Product characteristics

REASONING: The concentration or percentage of the metal in an article or preparation is important to determine the amount of metal being used (i.e. tonnage), since the concentration/percentage of metal will be directly linked to exposure to the environment.

Further information on the tonnage is provided below under “amounts used”.

Please note that product characteristics are likely to vary from one site to the other in a given sector. Typically, a generic exposure scenario (GES) will include a concentration/percentage range in order to cover the sector and be based on the worst case (i.e. highest percentage in the range).

#### **Short ES tip**



This section might be deleted in the ES if the detailed tonnage information has already been provided in the human health part of ES.

Link with SDS

Section 3: Composition/information on ingredients



**DECISION: Do my product characteristics match the value /range provided in the (G)ES?**

**YES**

**NO**

OK

If your metal concentration is higher than the

please proceed to the next section.

value or range provided in the GES, then you can still show compliance with the (G)ES depending on the amount you use. You can move on to the next section on amounts used to check compliance once again.

BACKGROUND: [ECHA R13 "Risk management measures and operational conditions", May 2008.](#)

### **Amounts used**

REASONING: The tonnage reported (daily and annual) in the (G)ES reflects only one hypothetical situation which demonstrates safe use of the substance. This tonnage value may represent a typical site in a sector or may be a worst-case tonnage value that demonstrates safe use for all environmental compartments. This value is of particular importance for environmental exposure modelling, since it feeds into the metals DU Scaling Tool.

#### **METALS tip**



In some cases, the tonnage value is reported as tonnage of *free metal ion* used on site and not as a tonnage of the total substance. For example, if you were using NiCl, NiS, NiNO<sub>3</sub> on a same site, you would need to add the tonnages (based on Ni ion - calculated using the molecular weight of the substance) of all substances, since the assessment of environmental exposure on a same site usually does not make a distinction between the different substances or processes.

#### **DECISION: is my tonnage equal to or below the tonnage specified in the (G)ES?**

**YES**

**NO**

**OK**  
please proceed to the next section.

If your tonnage is above the tonnage reported in the (G)ES, please check compliance of your site-specific tonnage (whether you are out of risk) with the DU Scaling tool.

BACKGROUND: [ECHA R16 "Environmental exposure estimation," May 2010. DU Scaling tool](#)

### **Frequency and duration of use**

REASONING: This subsection refers to the number of days during which the substance is released to the environment from a single site. The number of release days is used in conjunction with the tonnage to estimate maximum daily use at a site, which is in turn used to calculate exposure concentrations in the environment. Continuous release refers to release on every production day (e.g. 300 days/year). Intermittent release refers to <12 days /year (e.g. during cleaning and equipment).

**DU-mmies tip**



The maximum number of release days per year is 365.

**METALS tip**



The number of release days is an input parameter in the DU Scaling tool to calculate your site-specific Local Environmental Concentrations. As you decrease the number of release days with the same operational conditions (e.g. tonnage and emission rates), exposure to the environmental compartments will increase.

**Link with SDS**



Section 8.2.3: Environmental exposure controls

**DECISION: is my number of release days equal to or below the reported release days in the (G)ES?**

**YES**

**NO**

**OK**

please proceed to the next section.

If the number of release days is higher, please use the DU Scaling tool. This is another operational condition that can be scaled either up or down.

BACKGROUND: [ECHA R16 "Environmental exposure estimation," May 2010.](#) [DU Scaling tool.](#) [ECHA R13 "Risk management measures and operational conditions", May 2008.](#)

**Environmental factors not influenced by risk management**

REASONING: Default dilution factors are generally applied in the (G)ES. These dilution factors ([DF](#)) are:

- Freshwater: default dilution factor = 10 (effluent flow of 2000 m<sup>3</sup>/day, river flow rate 18000 m<sup>3</sup>/day)
- Marine water: default dilution factor = 100

If you know the site-specific river and/or effluent flow rates, these can be used in the Metals DU Scaling tool.

Your site-specific dilution factor is calculated as follows:

$$\text{Dilution factor} = (\text{Effluent discharge rate of } \text{STP} + \text{low flow rate of receiving waters} -) / (\text{Effluent discharge rate of STP})$$

**DECISION: is my surface water volume the same as, or lower than, the one reported in the (G)ES?**

**YES**

**NO**

**OK**

please proceed to the next section.

If your surface water volume is lower than the one reported in the ES, then you can still demonstrate compliance with more effective RMMs or lower release rates. Known river and/or effluent flow rates can be entered into the Metal DU Scaling tool to scale your



exposure up or down.

BACKGROUND: [ECHA R16 "Environmental exposure estimation," May 2010. DU Scaling tool](#)

### **Other given operational conditions affecting environmental exposure**

This section may in some ES indicate some information deemed relevant by the Registrant like e.g. if it is a wet or dry process, closed or open...

**Short ES tip**



This section might be deleted in the short version of the ES, as this information might not be deemed relevant

Link with SDS

Section 8.2.3: Environmental exposure controls



### **Technical conditions and measures at process level (source) to prevent release**

REASONING: This is for processes where conditions ensure rigorous containment to prevent exposure to the environment. Performance (efficiency) of the containment is to be included as a release factor that can be used in the DU Scaling tool to scale to your site specific conditions.

**METALS tip**



Rigorous containment is a site-specific condition and cannot (or rarely) be included in a GES to represent the whole sector. Thus, this section is typically left as "NONE" or "NOT RELEVANT" in the (G)ES.

**Short ES tip**



This section might be deleted in the short version of the ES, as this information might not be deemed relevant.

Link with SDS

Section 8.2.3: Environmental exposure controls



BACKGROUND: [ECHA Part D4 "exposure scenario format" May 2010](#)

### **Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil**

REASONING:

- Waste water: By default, the (G)ES considers the wastewater that is treated on-site and the wastewater that is treated off-site in a municipal STP. An environmental ES for the absence of a municipal [STP](#) may also be provided in the (G)ES. One or more of the following measures (as set out in the Best Available Technique ([BAT](#)) Reference Document on Non-Ferrous Metal

Processes), is taken to reduce emissions to water.

- Chemical precipitation: used primarily to remove metal ion;
  - Sedimentation;
  - Filtration: used as final clarification step;
  - Electrolysis: for low metal concentrations;
  - Reverse Osmosis (extensively used for the removal of dissolved metals);
  - Ion exchange: final cleaning step in removal of heavy metal from process waste water.
- **Air:** One or more of the following measures (as set out in the Best Available Technique (BAT) Reference Document on Non-Ferrous Metal Processes), is/are taken to reduce air emissions:
    - Fabric or bag filters: high efficiency in controlling fine particulate (melting): achieve emission values that Membrane filtration techniques can achieve;
    - Electrostatic precipitators using wide electrode spacing;
    - Wet electrostatic precipitators;
    - Wet scrubbers;
    - Cyclones, but as primary collector;
    - Ceramic and metal mesh filters, PM 10 particles are removed.
  - **Soil:** measures to reduce emissions to soil are related to measures to reduce atmospheric emissions/deposition, and measures to reduce substance concentration in waste waters going to STP.

**Short ES tip**



This section might be deleted in the short version of the ES; please check Section 8 of SDS

Efficiency of RMMs and Calculation of Release factors:

The RMM efficiency (or range of efficiencies) is reported here for a given use or production process. The efficiency of your site-specific RMM should be documented with reasonable certainty (documenting the source of information). Further information on how to determine the efficiency of your RMM can be found in the ECHA guidance for Downstream Users. This efficiency is the percentage of reduction in exposure (or release to the environment) that can be used in conjunction with an Environmental Release Category ([ERC](#)) to calculate a release factor (for input in the Metal EUSES tool). If you are using a metal Specific ERC (SPERC; <http://www.arche-consulting.be/Metal-CSA-toolbox/sperc-tool-for-metals>), then this already considers on-site treatment.

**METALS tip**



Eurometaux developed SPERCs for industrial uses of metals and metal to replace the more conservative ERCs. Realistic worst-case default release factors to air and wastewater (intended to cover >90% of the sector) are proposed. When using a SPERC, it is important to check whether your OCs and RMMs are compliant with the OC and RMMs of the SPERC. More information on the SPERCs can be found in their fact sheets on <http://www.arche-consulting.be/Metal-CSA-toolbox/sperc-tool-for-metals>.

TO DEMONSTRATE COMPLIANCE:

You must have at least one of the above RMM in place (documented in the BAT reference document under the [IPPC](#) directive) for both wastewater and air. Proper documentation is also required to back up the efficiency of the RMM you implement on-site

Link with SDS      Section 8.2.3: Environmental exposure controls



**DECISION: Do my RMM reflect what is reported in the (G)ES?**

**YES**

**NO**

**OK**  
please proceed to the next section.

You need to start a [discussion](#) with the supplier of your ES.

**BACKGROUND:**

[Best Available Technique \(BAT\) Reference Document under the IPPC Directive. Dec 2001.](#)

[ECHA R16 "Environmental exposure estimation," May 2010.](#) [ECHA R13 "Risk management measures and operational conditions", May 2008.](#) [ECHA R12: "User descriptor system" version 2, March 2010](#)

**Organisational measures to prevent/limit release from site**

REASONING: This section in particular needs to be filled out in order to demonstrate strictly controlled conditions. Typically left as "NONE" in the metals industry GES for intermediates.

**Short ES tip**

This section might be deleted in the short version of the ES



Link with SDS      Section 8.2.3: Environmental exposure controls



**BACKGROUND:** [ECHA Part D4 "exposure scenario format" May 2010.](#)

**Conditions and measures related to municipal sewage treatment plants**

REASONING: By default, it is assumed in the (G)ES that the wastewater is connected to a municipal sewage treatment plant (STP). As a result, two additional exposure scenarios are described in the (G)ES:

- The first is exposure to the micro-organisms in the municipal [STP](#). The default effluent discharge rate for calculating exposure in the Metal DU Scaling is 2000 m<sup>3</sup>/day (=2000000 l/d), serving 10000 inhabitants.
- By default, it is also assumed that discharge into municipal sludge is spread to agricultural land; consequently, this is considered in the exposure estimation to soil.

The DU Scaling tool can be used to estimate exposure to STP and subsequently to soil via sludge spread over agricultural land (if applicable). The DU needs to calculate this exposure if this has not been done in the GES. In this case, contact your supplier to update the GES accordingly so as to include the relevant environmental compartments.

**METALS tip**



For site-specific scaling, the removal rate of the STP can be included in the DU Scaling tool, if known - otherwise, metal-specific removal rates are included where available.

Link with SDS

Section 8.2.3: Environmental exposure controls



BACKGROUND: [ECHA R16 "Environmental exposure estimation," May 2010. DU Scaling tool](#)

**Conditions and measures related to external treatment of waste for disposal**

REASONING: It is the duty of Downstream Users:

- i) to consider the waste life-stage related information received with the exposure scenario,
- ii) to take action if the internal handling of waste and the chosen route for recovery or disposal is outside the conditions set in the ES, and
- iii) to communicate the relevant information to further downstream users. As a matter of principle, ES and recommended RMM cannot be used to reduce or modify any obligations arising under waste legislation. Any user of the substance for which the exposure scenario was prepared will have to comply with all requirements from waste legislation. In order to assist downstream users, ES should, as far as possible, describe legal requirements under waste legislation, but there is a limit to the amount of details that can go into ES. It should be noted that it is impossible to cover all national and local provisions as well as all possible indirect implications of waste legislation in the ES.

**Short ES tip**



This section might be deleted in the short version of the ES; please check Section 13 of SDS.

**METALS tip**



New guidance is now available (since December 2010 – after registration) for estimating environmental exposure from the waste life stage. This new guidance should be considered by the different registrants/consortia for updating the (G)ES in 2011/2012.

Link with SDS

Section 13: Disposal considerations



BACKGROUND: [ECHA R13 "Risk management measures and operational conditions", May 2008.](#)

[ECHA R.18: Exposure scenario building and environmental release estimation for the waste life stage, Dec 2010](#)

**Conditions and measures related to external recovery of waste**

REASONING: This is the fraction of the used amount transferred to external waste treatment for recovery. This section is normally left as “NONE” or “NOT RELEVANT”, since it differs widely across different sites within a sector.

BACKGROUND: [ECHA Part D4 "exposure scenario format" May 2010](#)

## Section 3: Exposure estimation and reference to its source

This section will communicate the information related to exposure estimation and risk characterisation. Such information can be reported as numerical data (e.g. calculated exposure level and/or risk characterisation ratio ([RCR](#))), or as a reference to where these data can be found (e.g. web-link, reference to specific subsections and/or appendices of the [CSR](#)). You should also find information on which methods and/or tools the supplier has been using for generating the exposure estimates when he has had no measured data.

This section is sometimes shortened to one sentence in the eSDS stating e.g. the assessment method, the DNEL, the calculated RCR < 1 and that safe use is demonstrated.

### 1.1 Occupational exposure

#### REASONING:

This section will report the workplace exposure levels that relate to the described [OC](#) and [RMMs](#) in the [ES](#).

Ideally, *actual measurements* for the use of the substance have been used to estimate exposure levels. However, actual measurements are not always available. In that case, the ES supplier has most often used models to derive estimates. These estimates could be generated by Tier 1 and/or higher tier tools. Tier 1 tools aim to provide a 'reasonable worst-case' exposure for the conditions of use described in the ES on a conservative basis to reflect associated uncertainties. They require only a limited amount of knowledge about the actual conditions of use, as defined for example by certain process or product categories in the UDS. Tier 1 tools referred to in the ECHA guidance R14 are the (ECETOC) [TRA](#), the *Easy-to-use Workplace Control Scheme*, [Stoffenmanager](#), and [MEASE](#).

Higher tier tools like [ART](#) and [RISKOFLDERM](#) could provide more refined exposure estimates, but require more input parameters and knowledge about actual conditions of use. A brief introduction to these models is provided in the glossary.

Whether based on actual measurements or on modelled estimates, the available exposure dataset should be evaluated to assess whether it is adequate to derive an exposure estimate that reflects the conditions of use described in the ES. When it is the case, the appropriate percentile shall be selected to represent a 'reasonable worst case'. Such a reasonable worst-case level will only occur in a minority of cases within the ES, but it is realistic. Cases that are clearly outside the scope of the ES, such as exposures after serious accidents or exposures in situations where workers do not follow the instructions or do not use the required RMM, should be excluded from the dataset used before calculating exposure levels.

The ECHA guidance recommends selecting the 90<sup>th</sup> percentile of an exposure distribution reflecting the whole spectrum of conditions of use described in a particular ES. However, under particular conditions (well defined, high quality dataset, referring to homogeneous exposure conditions, ...) other percentiles (like the 75<sup>th</sup>) may appear appropriate as well. In these latter cases, a justification should have been included in the CSR.

Exposure should normally be understood as external exposure that can be defined as the amount of

substance ingested, the total amount in contact with the skin and/or either the amount inhaled or the concentration of the substance in the atmosphere, as appropriate. The exposures may be differentiated into short-term (usually less than or about one hour) or longer-term exposures. For some metals, biological monitoring data can be used to assess occupational exposure. Biological monitoring can add value to the exposure assessment process by providing information that enables a better understanding of the nature and extent of the total exposure, as it considers the internal dose, summing all exposure routes.

Exposure levels will be compared with the respective effect levels ([DNELs](#)) to calculate a risk characterisation ratio (RCR). The effect levels and RCRs are usually also reported in this section of the ES. A RCR will be calculated for the relevant exposure routes and exposure durations (long-term and/or short-term exposures).

It is stated in the REACH Regulation text (Annex 1, 6.4) that, for any ES, the risk to humans can be considered to be adequately controlled if exposure levels do not exceed the relevant DNEL, i.e. if the RCR <1. It should be noted that in the ECHA guidance document R14, it is specified that the RCR level to be achieved also depends on the specificity of the used data to the ES and the number of data points.

#### Short ES tip

This section might be deleted in the short version of the ES.



#### Link with SDS

Section 8: Exposure controls/personal protection and section 11: Toxicological information



BACKGROUND: [ECHA Chapter R14 Occupational exposure estimation](#), [ECHA Part D, May 2010](#)

## 1.2 Environmental exposure

### REASONING:

For the environment, the (G)ES describes the general conditions under which the environmental risks associated with an identified use(s) or production process of a substance can be controlled. REACH states that, for any exposure scenario, the risk to the environment can be considered to be controlled if exposure levels do not exceed the appropriate PNEC, i.e. if the [RCR](#) <1.

The OC and emission estimates that provide the basis for the determination of risk in the (G)ES were derived by using either statistically representative values (e.g. 90 percentile) from the aggregated data for a particular sector or estimated assuming default assumption (e.g. release factors ([ERCs/SPERCS](#)), dilution factors, presence of [STP](#)). A safe use scenario is developed for each relevant environmental compartment (e.g. soil, freshwater, marine, sediments, STP and air, which is used in the Man via the environment assessment). In some instances, the (G)ES are based on the maximum representative tonnage that can be produced or used before being at risk for a particular environmental compartment. In some instances, there is one environmental compartment that is the most sensitive, and which is therefore the driver of the selected tonnage in the (G)ES.

The environmental exposure assessment is typically based on total emissions (from several sites) to the various environmental compartments from all operations and processes related to production or a particular downstream use of the substance. It is not possible to attribute specific emission loads to a distinct activity or process, as emissions are normally treated in a central treatment plant and discharged at a single point source (e.g. wastewater emissions).

The environmental exposure estimates in the (G)ES are directly related to the reported operational conditions and RMM. If your operational conditions and/or RMM are different, then you must scale the (G)ES according to your site-specific conditions by either 1) using the DU scaling Tool to estimate your local predicted environmental concentrations (PEC) related your site-specific OC and RMM, or 2) if monitoring data exist for your site, use this information to compare to the PNEC in the SDS to calculate your RCR ( $RCR = \frac{PEC}{PNEC}$ ).

**Short ES tip**

This section might be deleted in the short version of the ES.



**Link with SDS**

Section 8: Exposure controls (section 8.1.2) and Section 12: Ecological information



BACKGROUND: [ECHA Chapter R14 Occupational exposure estimation](#), [ECHA Part D, May 2010](#)



## Section 4: Guidance to DU to evaluate whether he is working inside the boundaries set by the ES

### Environmental emissions

**REASONING:**

You are working inside the set boundaries by the (G)ES that you are checking if:

- a) You can demonstrate with your own site-measured data that the emissions are equal to, or lower than, the emissions to air or water and that you operated under the same, or more conservative, operational conditions as reported in Section 2 of the (G)ES.
- b) Available monitoring data from the local environment demonstrates that concentrations are below the PNEC that is specified in Section 8 of core Safety Data Sheet.

If you do not have any monitoring data, then please use a scaling tool such as the DU Scaling Tool.

**DECISION: Based on the checks carried out in Sections 1, 2 and 3, can you prove compliance with this (G)ES?**

**YES**

**NO**

**OK**

you can finalise the check and proceed to other exposure scenarios.

You need to start a discussion with the supplier of your ES and justify why you think this specific GES is not applicable and needs further refinements. Please fill in the form provided in [Annex I](#).

**BACKGROUND:**

[DU Scaling tool](#)

### Occupational exposure

**REASONING:**

You are working inside the set boundaries by (G)ES that you are checking if:

- a) You are working inside the proposed risk management measures as described in Section 2 above
- b) You can demonstrate with your own occupational measured data that your operational conditions and implemented risk management measures are adequate

This has to be done by showing that you limit the inhalation and dermal exposure to a level below the respective DNEL provided in core Section 8 of the Safety Data Sheet, taking into account the fact that processes and activities on your site are covered by the PROCs listed in Section 1 or 3 in the (G)ES.

If measured data are not available, you may make use of an appropriate scaling tool such as MEASE ([www.ebrc.de/mease.html](http://www.ebrc.de/mease.html)) to estimate the associated exposure. The dustiness of the substance used can be determined according to the MEASE glossary.

**DECISION: Based on the checks carried out in Sections 1, 2 and 3, can you prove compliance with**

this (G)ES?

**YES**

**NO**

**OK**

you can finalise the check and proceed to other exposure scenarios.

Have you tried to do scaling with MEASE?

You need to start a discussion with the supplier of your ES and justify why you think this GES is not applicable and needs further refinements. Please fill in the form provided in Annex I.

BACKGROUND:

[MEASE](#)



## Annex I

### Template for DU - supplier - consortia communication

<p>Based on the assessment done when using the DU-mmes Guidance you can provide your comments back to your supplier and/or consortia via the standardised 'blank' template presented below.</p> <p><b>Send back to: xxxxxxxxxxxxxxxxxxxxxx</b></p>	
<b>1. Free short title</b>	
<i>(add missing identified use if identified as necessary)</i>	
<b>Systematic title based on use descriptor</b>	<i>(add missing user descriptors if needed)</i>
<b>Processes, tasks and/or activities covered</b>	<i>(add short description per process stage and assign the relevant user descriptors per process step)</i>
<b>Assessment Method</b>	
<b>2. Operational conditions and risk management measures</b>	
<b>2.1 Control of workers exposure</b>	
<b>Product characteristic</b>	
<i>(add reasoning explaining your concerns and/or available data you have to back your arguments)</i>	
<b>Amounts used</b>	
<i>(add reasoning explaining your concerns and/or available data you have to back your arguments)</i>	
<b>Frequency and duration of use/exposure</b>	
<i>(add reasoning explaining your concerns and/or available data you have to back your arguments)</i>	
<b>Human factors not influenced by risk management</b>	
<i>(add reasoning explaining your concerns and/or available data you have to back your arguments)</i>	
<b>Other given operational conditions affecting workers exposure</b>	
<i>(add reasoning explaining your concerns and/or available data you have to back your arguments)</i>	
<b>Technical conditions and measures at process level (source) to prevent release</b>	
<i>(add reasoning explaining your concerns and/or available data you have to back your arguments)</i>	
<b>Technical conditions and measures to control dispersion from source towards the worker</b>	
<i>(add reasoning explaining your concerns and/or available data you have to back your arguments)</i>	
<b>Organisational measures to prevent /limit releases, dispersion and exposure</b>	
<i>(add reasoning explaining your concerns and/or available data you have to back your arguments)</i>	

<b>Conditions and measures related to personal protection, hygiene and health evaluation</b>
<i>(add reasoning explaining your concerns and/or available data you have to back your arguments)</i>
<b>2.2 Control of environmental exposure</b>
<b>Product characteristics</b>
<i>(add reasoning explaining your concerns and/or available data you have to back your arguments)</i>
<b>Amounts used</b>
<i>(add reasoning explaining your concerns and/or available data you have to back your arguments)</i>
<b>Frequency and duration of use</b>
<i>(add reasoning explaining your concerns and/or available data you have to back your arguments)</i>
<b>Environment factors not influenced by risk management</b>
<i>(add reasoning explaining your concerns and/or available data you have to back your arguments)</i>
<b>Other given operational conditions affecting environmental exposure</b>
<i>(add reasoning explaining your concerns and/or available data you have to back your arguments)</i>
<b>Technical conditions and measures at process level (source) to prevent release</b>
<i>(add reasoning explaining your concerns and/or available data you have to back your arguments)</i>
<b>Technical onsite conditions and measures to reduce or limit discharges, air emissions and releases to soil</b>
<i>(add reasoning explaining your concerns and/or available data you have to back your arguments)</i>
<b>Organisational measures to prevent/limit release from site</b>
<i>(add reasoning explaining your concerns and/or available data you have to back your arguments)</i>
<b>Conditions and measures related to municipal sewage treatment plant</b>
<i>(add reasoning explaining your concerns and/or available data you have to back your arguments)</i>
<b>Conditions and measures related to external treatment of waste for disposal</b>
<i>(add reasoning explaining your concerns and/or available data you have to back your arguments)</i>
<b>Conditions and measures related to external recovery of waste</b>
<i>(add reasoning explaining your concerns and/or available data you have to back your arguments)</i>

<b>3. Exposure estimation and reference to its source</b>
<b>Occupational exposure</b>
<i>(if you have the occupational monitoring data which could help to further refine the assessment please contact your supplier)</i>
<b>Environmental emissions</b>
<i>(if you have the site monitoring data which could help to further refine the assessment please contact your supplier)</i>
<b>4. Guidance to DU to evaluate whether he works inside the boundaries set by the ES</b>
<b>Occupational exposure/ Environmental emissions</b>



## Annex II

### Glossary

<b>AC</b>	Article Category, element of the Use Descriptor System (UDS) characterising the type of article in which a substance is contained
<b>AF</b>	Assessment factor
<b>ART</b>	<p>Advanced REACH Tool: is a Tier 2 tool, making use of mechanistically modelled estimates of exposure and any relevant measurements of exposure. The tool provides estimates of the whole distribution of exposure variability and uncertainty, allowing the user to produce a variety of realistic and reasonable worst-case exposure estimates, dependent upon the requirements of the particular risk assessment.</p> <p>The model takes into account several operational conditions and risk management measures throughout the whole exposure pathway from source to worker. Amongst its strengths, it shall be noted that ART provides the choice of several percentiles of the resulting exposure distribution, provides an indication of the uncertainty of the mechanistic model result and there is the possibility to estimate exposure during a number of consecutive activities</p> <p>ART is a web-tool that is free to use following registration. Registration can be easily done via the website <a href="http://www.advancedreachtool.com">http://www.advancedreachtool.com</a>.</p> <p><b>WARNING:</b> ART can be used for cold metal processes: significant inputs on the mechanistic model and data have been provided to the ART developers to make it usable by the metals. This could not be finalised for hot metal processes. Therefore ART shall not be used as Tier 2 tool to estimate exposure in hot metal processes, measured data shall be collected if need so</p>
<b>Assigned protection factor</b>	<p>Means the workplace level of respiratory protection that a respirator or class of respirators is expected to provide to employees when the employer implements a continuing, effective respiratory protection program.</p> <p><a href="http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_id=12716&amp;p_table=standards">http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_id=12716&amp;p_table=standards</a></p>
<b>BAT</b>	<p>Best Available Techniques Reference Document on Non-Ferrous Metal Processes</p> <p><a href="http://eippcb.jrc.es/reference/nfm.html">http://eippcb.jrc.es/reference/nfm.html</a></p>
<b>Bioavailability</b>	<p>The rate and extent to which a substance can be absorbed by an organism and is available for metabolism or interaction with biologically significant receptors. Bioavailability (biological availability) involves both release from a medium (if present) and absorption by an organism.</p>
<b>Bioavailable fraction of a metal</b>	<p>Bioavailability is a combination of factors governing metal behaviour and the biological receptor (such as route of uptake, duration and frequency of exposure). As such the bioavailable fraction is dependent on the metal forms that prevail under specific environmental conditions and the biological receptors and can be defined as the metal fraction that can be taken up and that can interact with the organism's specific metabolic machinery</p>
<b>BLM</b>	<p>Biotic Ligand Model. The Biotic Ligand Model (BLM) is a predictive tool that can account for variations in metal toxicity using information on the chemistry of local water sources</p>
<b>BREF</b>	Reference Document for Best Available Techniques



<b>Brief description of uses</b>	Description of identified uses in the registration dossier (see REACH Annex VI, point 3.5) <a href="http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_r20_en.pdf?vers=20_08_08">http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_r20_en.pdf?vers=20_08_08</a>
<b>CBI</b>	Confidential business information
<b>Conditions of Use</b>	Conditions of Use include the operational conditions (OC) and risk management measures (RMM) as described in an ES
<b>ConsExpo</b>	Software model to calculate consumer exposure <a href="http://www.rivm.nl/en/healthanddisease/productsafety/ConsExpo.jsp">http://www.rivm.nl/en/healthanddisease/productsafety/ConsExpo.jsp</a>
<b>Contributing ES</b>	<p>Briefly, in the exposure scenario, the conditions driving exposure to humans and to the environment are to be consistent. OC and RMM relative to 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. One ES can thus include different contributing scenarios: one contributing scenario related to the environment and one or more contributing scenarios related to human exposure. For example:</p> <p>ES X for metal Y includes the following contributing ES, corresponding to several workplace activities/processes:</p> <ul style="list-style-type: none"> <li>- Raw material handling</li> <li>- Formulation and mixing</li> <li>- Melting</li> <li>- Packaging</li> <li>- Cleaning and Maintenance</li> </ul> <p>Each of these processes or activity is associated with different PROC codes, OC and RMM, leading to different degrees of human health exposure and explaining the conditions under which the task is safe to be carried out.</p> <p>ES will also include one contributing ES for each environmental compartment, since exposure to the environment cannot be divided by process.</p>
<b>CSA</b>	Chemical Safety Assessment. Process aimed at determining the risk posed by a substance and, as part of the exposure assessment, develop exposure scenarios including risk management measures to control the risks.
<b>CSR</b>	Chemical Safety Report. It documents the chemical safety assessment (CSA) for a substance on its own, in a preparation or in an article or a group of substances. In other words the chemical safety report (CSR) is a document, which details the process and the results of a chemical safety assessment (CSA). Annex I of the REACH Regulation contains general provisions for performing CSAs and preparing CSRs.
<b>Dermal route</b>	Dermal exposure is usually short-term from splashing or spilling the chemical during use or from contact with treated surfaces. It can result in damage to the skin or absorption through the skin into the body. Dermal exposure can also be chronic if it occurs repeatedly over a long period of time.
<b>Determinants of emissions/exposure</b>	Factors determining the exposure and or release when a sub-stance is manufactured or used (including the subsequent life cycle stages: service life and waste disposal). These factors include the characteristics of the substance, the operational conditions and risk management measures.
<b>DF</b>	Dilution Factors, by default = 10 for freshwater, 100 for marine water

<b>DMEL</b>	Derived minimum effect level
<b>DNEL</b>	Derived no effect level
<b>DU</b>	Downstream User: who uses a substance, either on its own or in a preparation, in the course of his industrial or professional activities. A distributor or a consumer is not a downstream user.
<b>DU-CSA</b>	Downstream user chemical safety assessment
<b>EASE</b>	Estimation and assessment of substance exposure, modelling tool to estimate exposure when measured data are not available. It has been demonstrated that for several metals, EASE produces produce significant overestimates (compared to measured data). EASE has been used in the previous Existing Substances Regulation.
<b>ECETOC-TRA</b>	Tier 1 software tool' that can be used to generate exposure/emissions estimates in the absence of (measured) data. It is provided in an integrated version which allows the user to perform worker, consumer or environmental assessment via one interface. It can be downloaded free of charge, after completing the download request form from <a href="http://www.ecetoc.org/tra">http://www.ecetoc.org/tra</a> . For occupational exposure the ECETOC approach uses established exposure prediction models (EASE with documented modifications by industry experts). The model provides the user with the risk assessment methodology that selects the Process Categories (PROCs) for the broad sector of use (either industrial or professional) of a substance, and then enables further modifications by selecting exposure control (Risk Management Measures). For guidance on the type of RPE leading to the required reduction in exposure the tool refers to COSHH Essentials sheets, available at: <a href="http://www.oehc.uchc.edu/news/Control_Guidance_Factsheets.pdf">http://www.oehc.uchc.edu/news/Control_Guidance_Factsheets.pdf</a> . The assessment as an output is a simple description of the type and basic conditions of use which can then be translated into a calculated exposure using an exposure model.
<b>ECHA</b>	European Chemicals Agency
<b>Eco-region</b>	In the context of carrying out a CSA/CSR for metals, the eco region concept is used to allow to correct for differences in abiotic parameters (present in the different ecoregions) that are potentially affecting (bio)availability. As such the ecoregions proposed in the questionnaire should be considered as representative typical examples of specific EU conditions for which the critical parameters needed to run the (bio)availability model are readily available. This allows to parameterize the (bio)availability models without the effort of collecting an extensive database on site/region specific abiotic factors. This approach would in essence still allow the REACH registrant to set region-specific PNECs for a set of default example scenarios represented by various abiotic factors.
<b>Emission potential</b>	For operations conducted with solid substances at ambient temperature the emission potential is considerably dependent upon the dustiness of that substance, therefore the exposure assessment is based on the emission potential associated with the conducted process. Thus, any PROC selection should be based on the main driver of the emission potential of a process.
<b>EMKG</b>	Einfaches Massnahmens-Konzept Gefahrstoffe. Generic model for exposure estimation at the workplace worked out by the BAuA. This tool, also known as the COSHH-BAuA tool can only be used for inhalation exposure calculations. It can be downloaded from <a href="http://www.reach-helpdesk.de/en/Exposure/Exposure.html">http://www.reach-helpdesk.de/en/Exposure/Exposure.html</a> .This exposure predictive model is based on the assumption that the workplace exposure is determined by two principal factors: the exposure potential of the handled substance and the applied control strategy. While the exposure potential has a positive or enhancing effect on the exposure level, the control strategy has a negative or decreasing effect. More

information in ECHA Guidance R14:  
[http://guidance.echa.europa.eu/docs/guidance\\_document/information\\_requirements\\_r14\\_en.pdf?vers=27\\_05\\_10](http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_r14_en.pdf?vers=27_05_10)

<b>Env</b>	Environment
<b>EoL</b>	End of Life
<b>ERC</b>	<p>Environmental release categories [ERC] label the characteristics of a use based on several aspects relevant from the environmental perspective. Firstly the intended technical fate (purpose) of the substance during use determines to what extent a substance is consumed on use, is expected to be released with discharges, air emissions or waste or is expected to enter into the next life cycle stage. Secondly the general conditions of use, for example: the life cycle stage at which a use takes place, the dispersiveness of the use and emission, whether the substance is contained by definition during use, whether the use takes place indoors or outdoors, whether substances in articles are used under release-promoting conditions...</p> <p><a href="http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_r20_en.pdf?vers=20_08_08">http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_r20_en.pdf?vers=20_08_08</a></p>
<b>ES</b>	<p>Exposure scenario: Set of conditions, including operational conditions and risk management measures, that describe how the substance is manufactured or used safely during its life-cycle and how the manufacturer or importer controls, or recommends downstream users to control, exposures of humans and the environment.</p>
<b>eSDS</b>	Extended Safety Data Sheet
<b>EUSES</b>	European System for the Evaluation of Substances
<b>Exposure assessment</b>	<p>Exposure assessment aims to make a quantitative or qualitative estimate of the dose / concentration of the substance to which humans and the environment are or may be exposed. Exposure assessment under REACH consists of two steps: 1) Development of Exposure Scenarios and 2) Exposure Estimation, which have to be iterated until it can be concluded that the resulting exposure scenarios would ensure adequate control of risks upon implementation.</p> <p><a href="http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_r20_en.pdf?vers=20_08_08">http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_r20_en.pdf?vers=20_08_08</a></p>
<b>Exposure estimation</b>	<p>Quantification of exposure related to the operational conditions and risk management measures as described in an exposure scenario. Exposure scenario building and the related exposure estimate together build the exposure assessment.</p>
<b>GES</b>	<p>Generic Exposure Scenarios are ES for the typical conditions of use(s) of a certain type of substance (e.g. solvents, pigments, resins, detergents) within a certain sector industry (area of use), suitable to control risks for substances with a certain generic hazard profile (e.g. low toxicity , low volatility). Such GES aims to cover the whole life cycle of the type of substance.</p> <p>In the metals sector GES have been defined:</p> <ul style="list-style-type: none"> <li>- by substance intrinsic emission potential/physical form</li> <li>- by processes: those GES describe the OCs and related RMMs which should be implemented to control the risks to human health and the environment associated with the use of a substance/product in a given similar process (e.g. mechanical treatment, packaging/unpacking of metal powder.</li> </ul>
<b>HH Identified use</b>	<p>Human Health</p> <p>Means a use of a substance on its own or in a preparation, or a use of a preparation, that is intended by an actor in the supply chain, including his own use, or that is made</p>

known to him in writing by an immediate downstream user.

<b>Inhalable fraction</b>	Sampling convention: as defined in EN481 (1993), the mass fraction of particles which can be inhaled by nose or mouth
<b>Inhalation route</b>	Route of exposure. One is exposed to e.g. gases, fumes, dust...by the act of inhaling, breathing. Inhalation exposure can be acute, for example breathing a chemical during short-term use, or chronic, for example longer-term inhalation of chemicals at the workplace.
<b>IC</b>	Industry category
<b>IPPC</b>	Industrial production processes account for a considerable share of the overall pollution in Europe (for emissions of greenhouse gases and acidifying substances, wastewater emissions and waste). The EU has adopted in 1996 a set of common rules for permitting and controlling industrial installations in the IPPC Directive (Directive 96/61/EC). More on: <a href="http://ec.europa.eu/environment/air/pollutants/stationary/ippc/summary.htm">http://ec.europa.eu/environment/air/pollutants/stationary/ippc/summary.htm</a>
<b>LC50 / LD50</b>	Median lethal concentration. The concentration causing 50 % lethality /Median lethal dose. The dose causing 50 % lethality.
<b>LEV</b>	Local exhaust ventilation
<b>Level of containment</b>	Determinant related to exposure of humans and environment and for example in MEASE the processes for which the exposure potential is driven by the level of containment rather than process itself is defined by 4 categories.
<b>Localised controls</b>	Risk management measures represent implemented (locally installed) devices or any personal protective equipment to reduce workers' exposure. In MEASE, there are several different localized controls with corresponding efficiencies as reported by Fransman et al.(2008) See also: <a href="http://www.ebrc.de/ebrc/ebrc-mease.php">http://www.ebrc.de/ebrc/ebrc-mease.php</a>
<b>M/I</b>	Manufacturer / importer
<b>MEASE</b>	Is a Tier 1 tool to estimate dermal and inhalation exposure at the workplace, which could be used in the absence of adequate measured data. This tool generates conservative estimates that can be further refined with Tier 2 tools (like ART, for cold metal processes) or by initiating measurements campaigns. MEASE has been developed to address specifics of metals/inorganic substances and uses peer-reviewed monitoring data collected for EU metal risk assessments: MEASE is a user-friendly Excel tool freely downloadable from <a href="http://www.ebrc.de/ebrc/ebrc-mease.php">http://www.ebrc.de/ebrc/ebrc-mease.php</a> , accompanied by a glossary and manual.
<b>Method used for dermal exposure assessment in MEASE</b>	This is based on the categorisation system of the EASE tool (Estimation and Assessment of Substance Exposure): pattern of use, pattern of exposure control and level of contact. Exposure estimates are based on measured data from several metal commodities, which have been collated and assigned to the EASE categories (more information can be found in the HERAG Fact Sheet" Assessment of occupational dermal exposure and dermal absorption for metals and inorganic metal compounds". The exposed skin surface is defined by ECETOC and/or HERAG. HERAG fact sheets: <a href="http://www.ebrc.de/ebrc/ebrc-projects.php">http://www.ebrc.de/ebrc/ebrc-projects.php</a> see also: <a href="http://www.ebrc.de/ebrc/ebrc-mease.php">http://www.ebrc.de/ebrc/ebrc-mease.php</a>
<b>Method used for inhalation exposure assessment in MEASE</b>	MEASE follows the PROC-specific approach of the TRA tool and selects initial exposure estimates from so called "fugacity classes". In contrast to the TRA tool, the initial exposure estimates in MEASE are based on measured data from the metals industry which have previously been validated in EU RA procedure under the Existing Substances Regulation for metal-specific PROCs.

See also: <http://www.ebrc.de/ebrc/ebrc-mease.php>

<b>MMQ</b>		Multi-Metallic Questionnaire
<b>MoE /MOS</b>		Margin of exposure/Margin of Safety
<b>NACE</b>		NACE stands for 'Nomenclature générale des activités économiques dans les Communautés Européennes', which is the standard for classification of economic activities in the EU. The latest NACE codes (Revision 2) are based on the Regulation (EC) No 1893/2006 of the European Parliament and of the Council, establishing the statistical classification of economic activities. The complete list can be found following the link: <a href="http://ec.europa.eu/competition/mergers/cases/index/nace_all.html">http://ec.europa.eu/competition/mergers/cases/index/nace_all.html</a>
<b>NAEC/ /NOAEL/ NOEL</b>	<b>NAEL</b>	No adverse effect concentration /No adverse effect level /No observed adverse effect level/ No observed effect level.
<b>OC</b>		Operational conditions: those include e.g. physical appearance of preparation, duration and frequency of use/exposure, amount of substance, room size and ventilation rate. More general: The operational conditions include any action, use of tool or parameter state that prevails during manufacture or use of a substance (either in a pure state or in a preparation) that as a side effect might have an impact on exposure of humans and/ or the environment.
<b>Oral route</b>		Oral exposure can be direct (eating or drinking) or indirect such as from hand to mouth contact after touching a chemical. It can be either acute or chronic.
<b>P90 or percentile</b>	<b>90<sup>th</sup></b>	The 90th percentile tells you the value for which 90% of the data points are lower and 10% higher
<b>PC</b>		Chemical product category: Element of the use descriptor system characterizing the type of chemical product in which the substance is (finally) used. Includes also intermediates and single substances marketed as chemical product.
<b>PBT</b>		Persistent, bioaccumulative, toxic
<b>PEC/PNEC</b>		Predicted environmental concentration /Predicted no effect concentration
<b>phys-chem</b>		Physico-Chemical
<b>Physical form in MEASE</b>		Whereas the molecular weight is exclusively used to re-calculate the exposure estimates for liquid and gaseous substances to mg/m <sup>3</sup> , all other substance characteristics may have direct impact (based on their relevance) on the selected fugacity class, which is one of the key input parameters for MEASE. Therefore knowledge on physical form of the substance is very crucial and in MEASE the following list is included: <ul style="list-style-type: none"> <li>- Massive object: non-dusty, massive objects with negligible potential for (unintended) abrasion during the process of interest. Objects have a very low emission potential (90% reduction of "low fugacity" estimate). For tasks involving abrasion (e.g. grinding), "low", "medium" or "high dusty solid" should be selected according to the level of abrasion</li> <li>- Solid, low dustiness: Granules, pellets, wetted powders, etc. with little potential for dust emissions (dustiness is less than 2.5% according to the Rotating Drum Method (RDM))</li> <li>- Solid, medium dustiness: powders and dust consisting of relatively coarse particles with moderate potential to become (and stay) airborne (dustiness is less than 10% (RDM))</li> <li>- Solid, high dustiness: fine powders having high potential to become and stay airborne</li> <li>- Aqueous solution: typically solid substance (at room temperature) dissolved in</li> </ul>

water. For most of the existing PROCs, the use of aqueous solutions is assumed to be associated with a very low emission potential (90% reduction of estimate for "low fugacity"). However, when assessing spray applications (PROC 7, 11), a medium fugacity is chosen by default to reflect the involved higher inhalation exposures due to the intended emission (i.e. spraying). Since droplets tend to join together with spatiotemporal progress this fugacity class is assumed to be appropriate

- Liquid: liquid substance, fugacity class is defined by vapour pressure
- Gaseous: gaseous substance, fugacity class is defined by vapour pressure

<b>PPE</b>	Personal protective equipment
<b>PROC</b>	Process category: Element of the use descriptor system describing the type of technical processes applied during manufacturing and use.
<b>RA /VRA</b>	Risk Assessment /Voluntary Risk Assessment
<b>RDM</b>	Rotating drum method
<b>Respirable fraction</b>	Respirable dust approximates to the fraction of airborne material that penetrates to the gas exchange region of the lung.
<b>RMM</b>	Risk management measure: Measures that control the emission of a substance and/or expo-sure to it, thereby controlling the risks to human health or the environment. Risk management measures include e.g. containment of process, local exhaust ventilation, gloves, waste water treatment, exhaust air filters. More general: risk management measures include any action, use of tool, change of parameter state that is introduced during manufacture or use of a substance (either in a pure state or in a preparation) in order to prevent, control, or reduce exposure of humans and / or the environment.
<b>RCR</b>	Risk characterization ratio. Outcome of hazard identification and risk estimation applied to a specific use of a substance or occurrence of an environmental health hazard: the assessment requires quantitative data on the exposure of organisms or people at risk in the specific situation. The end product is a quantitative statement about the proportion of organisms or people affected in a target population.
<b>RISKOFDERM</b>	The RISKOFDERM Dermal Exposure Model is a model for estimating <a href="#">potential dermal exposure</a> , i.e. the total amount of a substance coming into contact with the protective clothing, work clothing and exposed skin. It is based on statistical analysis of data gathered in the RISKOFDERM project, a European project on dermal exposure. The model originally consists of a set of equations as reported in the deliverables of the RISKOFDERM project.
<b>RPE</b>	Respiratory Protection Equipment. Those are defined by their "assigned protection factor" as given in BS EN 529:2005. Any respiratory protective equipment (RPE) as defined below shall only be worn if the following principles are implemented in parallel: the duration of work exposure should reflect the additional physiological stress for the worker due to the breathing resistance and mass of the RPE itself, due to increased thermal stress by enclosing the head. In addition, it shall be considered that the worker's capability of using tools and of communicating are reduced during the wearing of RPE. For reasons as given above, the worker should therefore be (i) healthy (especially in view of medical problems that may affect the use of RPE), (ii) have suitable facial characteristics reducing leakages between face and mask (in view of scars and facial hair). The recommended devices above which rely on a tight face seal will not provide the required protection unless they fit the contours of the face properly and securely. The employer and self-employed persons have legal responsibilities for the maintenance

and issue of respiratory protective devices and the management of their correct use in the workplace. Therefore, they should define and document a suitable policy for a respiratory protective device programme including training of the workers.

<b>RWC</b>	Reasonable Worst Case
<b>SDS</b>	Safety data sheet
<b>Segregation</b>	Isolation of the source from the work environment
<b>Separation</b>	Personal enclosure within a work environment
<b>Short title of ES</b>	Describes the uses and/or subsequent life cycle stages of a dangerous substance addressed in an exposure scenario. The short title of the ES should be consistent with the brief general description of use (see Annex I, point 5.1.1). The building blocks for the short title can be obtained from the use descriptor system (UDS).
<b>SPERC</b>	SPecific Environmental Release Categories: Eurometaux developed SPERCs to replace the more conservative ERCs. They were developed for several sectors of industrial uses of metals and metal compounds based on an extensive dataset of measured release factors of >700 sites, >6 metals and multiple sectors. Realistic worst-case default release factors to air and wastewater (intended to cover >90% of the sector) are proposed. When using a SPERC, it is important to check whether your OCs and RMMs are compliant with the OC and RMMs of the SPERC. More information on the SPERCs can be found in their fact sheets on <a href="http://www.arche-consulting.be/Metal-CSA-toolbox/spercs-tool-for-metals">http://www.arche-consulting.be/Metal-CSA-toolbox/spercs-tool-for-metals</a> .
<b>Stoffenmanager</b>	The “Stoffenmanager” tool (version 4.0) includes a quantitative model for estimating inhalation exposure to vapours, aerosols of low volatility liquids and inhalable dusts (including comminuting activities such as grinding and sawing). The web-based tool ( <a href="http://www.stoffenmanager.nl">www.stoffenmanager.nl</a> ) has a specific REACH section and a section for exposure calculations in which e.g. full shift time weighted averages can be calculated. The Stoffenmanager 4.0 exposure model tool is currently somewhere between first Tier and higher Tier models. The rationale of the underlying exposure algorithm is based on work of Cherrie and Schneider (1999) but is adapted in several ways. The model uses process information, physicochemical characteristics, and mass balance to assess exposure situations. More information in ECHA Guidance R14: <a href="http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_r14_en.pdf?vers=27_05_10">http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_r14_en.pdf?vers=27_05_10</a> .
<b>STP</b>	Sewage treatment plant
<b>SU</b>	Sectors of use: Element of the use descriptor system describing the sector of economy (industry, professional service, private) a substance is used in, as such or in a preparation.
<b>TRA</b>	See ECETOC TRA
<b>TWA</b>	Time-weighted average exposure
<b>UC</b>	Use category: Means an exposure scenario covering a wide range of processes or uses, where the processes or uses are communicated, as a minimum, in terms of the brief general description of use.
<b>UDS</b>	Use descriptor system: Set of 4 descriptors which can be used i) to briefly describe identified uses in a brief general way and ii) to build the short title of an exposure scenario. The four descriptors are: sectors of use (SU), preparation/product category (PC), process category (PROC), article category (AC).

<b>UEC</b>	Use and exposure categories
<b>UVCB</b>	Substances of unknown or variable composition, complex reaction products or biological materials as defined in the Guidance on substance identification.
<b>vPvB</b>	very persistent very bioaccumulative
<b>WMM</b>	Waste Management Measures
<b>WWTP</b>	Waste Water Treatment Plant



## Annex III

### References

ECHA Guidances:

- ECHA R12: "User descriptor system" version 2, March 2010.  
[http://guidance.echa.europa.eu/docs/guidance\\_document/information\\_requirements\\_r12\\_en.pdf](http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_r12_en.pdf)
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Other legislative documents:

- *Best Available Technique (BAT) Reference Document under the IPPC Directive. Dec 2001.*  
[ftp://ftp.jrc.es/pub/eippcb/doc/nfm\\_bref\\_1201.pdf](ftp://ftp.jrc.es/pub/eippcb/doc/nfm_bref_1201.pdf)

Metal's tools:

- *DU Scaling tool* <http://www.arche-consulting.be/Metal-CSA-toolbox/duscaling-tool>
- *MEASE* [www.ebrc.de/mease.html](http://www.ebrc.de/mease.html)

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