

SPERCs Quality Criteria

SPERCs describe the conditions of use and related release factors for a specific use. They do not depict emission situations at concrete sites but address generic emission situations such as related to relevant practices in industry and in particular in the downstream industries. They attempt to be applicable to compute typical emission situations during the use of a substance or mixture for environmental exposure analysis. To that end, SPERCs strike a balance between the degree of detail needed for describing a given use situation and the generic character of a safety assessment under REACH. To that end a SPERC represents the level of conservatism in the derivation of the release factors matching the scope of its coverage.

Hence, SPERCs that describe a broad range of uses must depict a larger variance of release rates, which results in less realism for each single use covered but a higher conservatism overall. On the other hand, a SPERC that describes a narrow application scope, can be more realistic towards the specific use and the release factors; the derivation of emission relevant factors therefore deserves less conservatism

Purpose

According to the 2019-2020 ENES working programme, a review of SPERCs is expected to be conducted by both industry (internal review) and by authorities (external review). To ease this review, the industry SPERC TF has developed a set of quality criteria. The purpose of the quality criteria is **to support and document a quality assessment** of the SPERC background document and, where relevant, the corresponding fact sheets by considering following topics:

- Is the scope of the SPERC clear in terms process-types and/or product-types covered?
- Are the main Conditions of Use (CoU), including Operative Conditions (OC) and risk Management Measures (RMMs) driving the environmental release clearly identified, understandable and verifiable?
- Are the factors resulting from the key drivers for environmental emissions (water, soil, air) adequately quantified, and is it sufficiently explained how the release fractions were estimated?

The quality criteria are to be seen as a mean to assess quality, not as an objective on its own.

Who are the end-users of this template?

The quality criteria, in first instance, are to be used by the SPERC developers to check the completeness and quality of their own SPERCs as a self-assessment tool. External reviewers (industry, consultants or Member States) are encouraged to use the quality criteria to provide a focussed feedback to the SPERC developers on their SPERCs.

How to use the quality criteria template?

The quality assessor is asked to answer all relevant quality criteria questions by means of a score 1 (good) to 3 (insufficient) or indicate “not applicable” (4). A justification of the selected score shall be reported in the field ‘explanation of evaluation’. Especially where the scoring is “insufficient” the assessor should provide a thorough explanation in order to enable a focussed review of potential gaps. In addition, the quality assessor is asked to provide an overall score to the SPERC. When conducting the quality assessment, information present in both the factsheets and the background documents should be considered.

Scoring - Legend:

1 - Good	No need for further improvement
2 - Acceptable	OK, but room for improvement or aspects to be verified
3 - Insufficient	Improvement is required.
4 – Not applicable	Criteria not applicable to the specific SPERC under review

Glossary:

- CoU: Condition of Use
- Key condition of use drivers: CoU that are not key drivers for release can be considered to be removed from the SPERC.
- OC: Operational Condition
- RF: Release Fraction
- RMM: Risk Management Measure
- SPERC: Specific Environmental Release Category

ASSESSOR IDENTIFICATION	
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Documents evaluated	SPERC for the widespread use of household care and professional cleaning and hygiene products; A.I.S.E. ERC 8a
Date of the evaluation	July 10, 2020

1 – TITLE

1.1 Is the SPERCs title simple, concise, unambiguous, understandable?

The title of the SPERC is important to facilitate the selection of the most appropriate SPERC to be used to estimate environmental emissions when running a chemicals safety assessment.

EVALUATION	GOOD
Explanation of evaluation	Widespread use includes professional and consumer use. Relevance of professional use is explained in the document and clearly distinguished from industrial use.
Remarks on improvements	Further considerations on professional use might help to understand the role of this sector with regard to the temporal equalization of releases.
Feedback from A.I.S.E.	To clarify the scope of ERC 8 related to the professional uses, based on the feedback of the review, a short paragraph was added to the document giving a brief explanation of the professional aspects and how they differ from industrial uses covered by the A.I.S.E. SPERC document covering ERC 4 on <i>Specific Environmental Release Categories (SPERCs) for the Industrial use of Water-borne Processing Aids</i> . More information on the distinction can be found in the ERC 4 document. Regarding the role of the professional sector and temporal equalisation, this is in part inherently considered for detergents in the study by Fox et al. (2002), as releases from professional would be recorded in the WWTP measurements made. However, further investigations differentiating between products used in a consumer or professional context and the patterns of use e.g. higher use during 9-5 working hours, could allow development of an even more accurate picture of product usage.

2 –SCOPE

2.1 Is the scope of the SPERC clear, verifiable and consistent with underlying ERCs?

Is the scope of the SPERC (in factsheet and background document) clear and verifiable for a user in terms of i) process-types, ii) product-types, and iii) substance properties covered?

Are the boundaries of the scope sufficiently clear and explicit, indicating what is not covered, for example where misunderstanding may arise, or where the SPERC developer has chosen not to cover a particular use situation because it is exceptional for the sector. For example, where SpERCs relate to the scale of operation or the volatility of substances, quantitative benchmarks should be provided.

(*) The use-map developer needs to build use names and names for the contributing activities that i) correctly match the scope of the applicable SPERC and ii) are easily verifiable for the companies receiving exposure scenarios.

EVALUATION	GOOD
Explanation of evaluation	Product types are clearly described and specified. With regard to the hazard profile of compounds, reference to applicable legislation is provided. Explanation is given why ERC 8a is selected for the scenario. Specific aspects like reactivity of bleaches and transformation of compounds are addressed.
Remarks on improvements	
Feedback from A.I.S.E.	The consultant review outlined the need for an explanation as to why ERC 8a is still suitable for products with a certain reactivity, like bleaches. Thus, further explanation was added in the document on the applicability of reactive substances.

2.2 Is the scope described as substance and/or process domain consistent with the OC/RMM identified as driving the release?

The Scope section is to understand the relationship between substance type, product and process, including RMMs/abatement techniques, on the one hand and the environmental release on the other hand. Does this relationship become adequately clear and transparent?

For example:

- If SPERC refers to products and processes where no water is involved, absence of water contact should be made explicit in the conditions of use, and it should be made clear whether this refers to the process as such or also to cleaning operations (equipment cleaning, floor cleaning). Hence, the process domain should hint towards the relevant sections in the process (i.e. conditions of use). The scope of the SPERC is driven in this case by the process domain and to a lesser extent by the substance domain;
- If a SPERC refers to volatile substances that are used as process aids leading mainly to emissions to air, the combination of substance and process domain will equally describe the scope of the SPERC. Certain substances (e.g. defined by a boiling point threshold) will be prone to air emissions as specified within the process domain (closed or open processes). Further conditions affecting the release into the environment is given in the CoU and is not part of the scope section.

EVALUATION	GOOD
Explanation of evaluation	The main purpose is to clarify the route of release. All products covered by SPERCs a and b are supposed to go 'down the drain' directly or indirectly. Description provides sufficient information to exclude substantial releases to air or soil. All products covered by SPERC c are released to air. No RMMs are applicable for this kind of use. Release rate is assumed to be 1 (100 %) for either water or air, with no ambiguity.
Remarks on improvements	

3 – OPERATIONAL CONDITIONS**3.1 Are the OCs clearly described and practically verifiable?**

Together with the substance properties, the operational conditions determine the initial release of substances from the use-process. For example, elevated temperature (temperature benchmark needed) and abrasive processes usually increase the release of a substance to air, water contact during the process (water based process steps) or during cleaning (equipment or room cleaning) drives the presence of the substance in waste water. For the mentioned examples, it should be possible to communicate the operational conditions in a clear and verifiable way. However, it is not always possible in a generic SPERC (or in the resulting exposure scenario) to describe and communicate the (complex) operational conditions in the industrial processes of a sector driving the initial releases of the substance into exhaust air, waste water -or residue streams. In such cases, the SPERC best makes reference to a documented best/good practice or a Best Available Technique (BAT), provided such sector “standard” can be connected to (substance related) release factors. For example, generic phrases in SPERCs factsheet such as “high degree of automation” or “efficient use of raw materials” should be referenced (or exemplified) to what this means in practice in the background document.

EVALUATION	GOOD
Explanation of evaluation	Use as aqueous solution and release to the aquatic route for products covered by SPERC a and b is quite evident and does not require further description. The same applies for products covered by SPERC c. No further verification is required.
Remarks on improvements	

3.2 Do the OCs properly reflect the main drivers for release potential of substances into the environment?

Note - On this purpose, operational conditions mentioned shall be linked to the environmental releases covered by the SPERC. For example, if release to water is set to 0, CoU should reflect that cleaning operation needs to be performed without water and no water used in process or water is completely recycled and water containing residues (from cleaning the water-cycle) are disposed of as waste.

EVALUATION	GOOD
Explanation of evaluation	See 3.1
Remarks on improvements	

3.3 If a use rate has been provided: Is it transparent, how the use rate has been derived and how representative it is?

Note: a use rate is generally site specific and cannot be provided as definite by a SPERC. Therefore, in general, SPERCs may provide indicative use rates that are based on conservative assumptions (i.e. high end of daily use rates) from industry use data. These use-rates are meant to serve as a starting point or benchmark for the registrant’s assessment. It is for example important to explain, whether the indicative value is based on statistical figures on daily consumption of chemicals at single sites, or whether the indicative value is extrapolated from an annual market/sector tonnage, distributed over a number of users and/or a number of use-days. In this respect it may also play a role whether the activity is carried out as i) small scale operation and ii) large scale operation, and or under optimal or suboptimal conditions and thus whether several SPERCs may be needed (with a corresponding indicative use-rate), e.g. one with onsite emission controls and the other without onsite emission controls. For uses where process waters are retained and environmental releases potentially occur discontinuously, it need to be transparently explained to what use rate the SpERC emission factors are applicable. For example, the emission factors of such a SPERC can be a reflection of the continuous flow-through situation (with daily compensation of losses) and/or a situation where the whole bath is exchanged (and fractions of it are released on a day).

EVALUATION	Not applicable
Explanation of evaluation	
Remarks on improvements	

4 – RISK MANAGEMENT**4.1 Are the RMM described in a clear manner?**

Are the RMM (in factsheet and background document) described in a clear manner (required effectiveness and technical possibilities to achieve it), so that a DU or an authority could practically verify whether such techniques or equivalents are in place?
In case RMMs are linked to good/best practices/techniques, have the corresponding references been provided (e.g. BAT, BREF documents)? Note, that a link to good/best practices may subsume an array of alternative techniques that lead to similar results of emission reduction.

EVALUATION	Not applicable
Explanation of evaluation	
Remarks on improvements	

4.2 Are RMMs adequate for the substance/product domain?

Is it plausible that the reported RMMs are effective to substances within the described domain and /or to the product types within the scope of the SPERC? Is this linkage adequately described in the background document? For example, mechanical oil/water separation may not effectively work where emulsions occur.

EVALUATION	Not applicable
Explanation of evaluation	
Remarks on improvements	

4.3 Are RMMs clearly linked to release sources?

Are the main sources/pathways of release from the process described in the background document, and is it clear to which of these the RMM refer? For complex air treatment systems (e.g. wet scrubbing), is it sufficiently clear, on which pathway and at which rate the substances removed from air leaves the site (for example via waste-water or waste)?

In case alternative RMMs can be applied to achieve similar end-of-pipe effectiveness, are concrete examples/options provided? Note, that good/best practices may subsume an array of alternative techniques that lead to similar results of emission reduction.

EVALUATION	Not applicable
Explanation of evaluation	
Remarks on improvements	

5 – RELEASE FACTORS**5.1a MEASURED DATA - Are measured data representative and well documented?**

In case a set of measured data for the process/products covered in the SPERC, and taken under the conditions of use as described in the SPERC, is the number of data points, the number of companies and the substances analysed documented or referenced? Are measured data related to reasonable and documented use rates in order to derive representative release factors? Where available, provide a data analysis (e.g. distribution %ile) to identify representativeness of the data for the respective purpose (e.g. determination of release rate).

EVALUATION	Not applicable
Explanation of evaluation	
Remarks on improvements	

5.1b MODELLED DATA - Is the documentation on the model and the modelling report available?

In case release factors are determined based on a model developed for the processes and products covered in the SPERC, is the documentation of the model and a modelling report available? Are modelled releases related to representative use rates in order to derive reasonable release factors?

EVALUATION	Not applicable
Explanation of evaluation	
Remarks on improvements	

5.1c LITERATURE DATA - Is the literature source provided and assessed to be representative/robust?

In case the release factors are extracted from published literature referring to the process/products and conditions of use covered in the SPERC, is the literature referenced and is a short summary provided in the background document? Is the number of data points, the number of companies, the conditions of use and the substances analysed clearly documented in the publication? Are the conditions of use referred to in the publication consistent with the conditions identified in the SPERC.

EVALUATION	GOOD
Explanation of evaluation	Evaluation of literature is not related to the release factor, but to the geographical and temporal distribution of consumption. The background document is targeted at challenging the standard model assumptions on regional distribution and the applicable safety factor. Detergents are expected to be an example for a relatively even distribution across regions. The assessment of geographical regions according the standard model (200 km x 200 km grid) is combined with an assessment of population density, showing that only very few regions may exceed the threshold of 20 million inhabitants. The temporal aspect is addressed by reference to a study based on measurements for a reference compound.
Remarks on improvements	The temporal aspect might be further assessed by describing changes in use pattern over the last decades and the relevance of professional use.
Feedback from A.I.S.E.	Based on feedback from the external review an additional explanation was added to the background document to better explain the work by Price et al. (2010). The EUSES model is a hypothetical model and remains the same regardless of the countries in the EU, in addition the Price et al. (2010) work accounted for all countries that are now in the EU. Refinement of Fprodregion Within all three SPERCs defined here, the fraction of EU tonnage used in a region is set to 0.04 (4%) as opposed to the default of 0.1 (10%) set within ECHA Guidance document R16 (ECHA 2016). This revision is based on an empirical/statistical work performed by (Price et al. 2010b). The work by Price et al. (2010b) presented a novel approach that allows the coupling of population density and country-specific usage statistics for a range of home and personal care products. Spatially explicit usage estimates were generated for hypothetical EU regions (200 × 200-km grid). Recent sales and population density data were combined to assess the relevance of the default assumption that

	<p>10% of a product will be used in an EU hypothetical region that is inhabited by 20 million people. The results of this analysis suggest that environmental exposure estimates conducted for regulatory risk assessments under REACH, for ingredients used in home and personal care products, are not a “representative worst-case”. Fprodregion is usually lower than 10%.</p> <p>For the study, five large cleaning and maintenance product categories representing ERC 8a were included in the assessment (laundry care, surface care, toilet care, dish washing, bleach). The average per capita use values for the default region containing 20 million people, as a proportion of the total EU27 (+ Croatia, Norway and Switzerland) product usage, were derived for each product type (see Table 4). An inter-country analysis was performed that identified two primary regions in the EU27+3 with maximum use of home and personal care products (the UK and a transboundary region). EU regions containing 20 million people had maximum product usage (99.5th percentile) ranging from 3.6 to 5.11% (of the total EU product usage) for the sub categories (as shown in Table 4) with the mean PCC (per capita consumption) typically less than a factor of three lower than the maximum country PCC. It is important to note that whilst the maximum usage of products such as bleach within the homecare category are much higher than their mean, these products make up a relatively small percentage of the overall usage of the homecare product category. For example, the usage of bleach in Spain is 6.3 times greater than the mean usage of bleach across the EU, however bleach makes up only 10.04% of the home care product category usage i.e. the volume of bleach used across the EU is a factor of 6 smaller than the laundry care sub-category. In addition, the 99.5th percentile results in just 5.11% of the total EU tonnage. A weighted average over all analyzed home care product categories is therefore deemed sufficiently conservative and appropriate to provide a generic refinement to ERC8a for chemicals used over all cleaning and maintenance product categories. The weighted average Fprodregion was calculated to be 0.0402 (as shown in Table 4). This value is considered conservative as it is based on product usage per category and not per substance usage. In other words, the assumption is made that all products are similar and the same ingredient would always be used in every product across the home care category and each product sub category e.g. the same ingredient would be used across every laundry care product and every bleach product. It is considered that this fact inherently includes a large conservative safety factor for the home care category.</p> <p>For a local risk assessment, a factor of 4 is generally applied to the per capita consumption to take into account geographical or temporal peaks (e.g. night-day, behavioral). For high production chemicals in detergents and cosmetics the EU TGD (2003; cf. B-Table B4#) already diminished this variability completely to a factor of one by realizing wide-spread uses of these products occur with much less variability, this would result in a less conservative Fmainsource of 0.0005. Here a more conservative approach is taken based on the work by Fox et al. (2002) who measured influent concentrations of boron from 48 sewage treatment plants (STP) within the UK, Germany, Italy and the Netherlands. As a common ingredient in detergents at that time, boron was chosen as a representative marker for environmental monitoring, due to its lack of absorption or biodegradation in the sewer system. Freights of boron indicated that 90% of the STPs never received more than 1.5 times of the average predicted boron input by using regional detergent sales volumes. As discussed further in Price et al. (2010), the default assessment factor of 4 is considered overly conservative and it has been deemed appropriate that an assessment factor of 1.5 provides a ‘reasonable worst case’ for all uses of this category. Moreover, Fox et al. could not draw correlations between the local and regional variations of product usage. Hence, the factor of 1.5 appears to be applicable to local situations of all regions in the EU.</p> <p>Using an assessment factor of 1.5 instead of 4 means $F_{mainsource} = 10,000 / 20,000,000 * 1.5 = 0.00075$. Therefore, for the purpose of the SPERCs defined in this document the ‘fraction of regional tonnage used locally’ (Fmainsource) has been set to 0.00075.</p>
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5.1d READ-ACROSS DATA – Is the read-across sufficiently robust and well explained?

In case of read-across from any of the type of sources above (to other processes, other products, other conditions of use) the , is the read-across sufficiently explained, for example by comparing the processes, the release driving factors and the properties of the chemicals involved. For example, releases to water from any kind of formulation processes will have very similar drivers, independent of the concrete product category: It will depend on i) dustiness or viscosity of the chemicals to be mixed, ii) whether cleaning of machinery is carried out with water, iii) whether the equipment is run continuously or in batch-mode with intermediate cleaning and iv) which techniques are used to minimise the residues in the equipment before cleaning. Thus read-across from formulation of one product category to another one may be straight forward.

EVALUATION	Not applicable
Explanation of evaluation	
Remarks on improvements	

6 – CONSERVATISM

6.1 – Is the level of conservatism appropriate?

Does the scope of the SPERC cover sufficiently all uses described by the CoU and RMMs? Is the level of conservatism, i.e. the conservative derivation of release factors, etc., sufficiently described in the background document? Is the level of conservatism balanced compared to the scope? (i.e. broader scope requires more conservatism and vice versa). Conservatism can result from different aspects, e.g. from the mathematical analysis of data (e.g. taking a 90th percentile, summing up from individuals to a category, etc.), the read across from different processes and/or a worst case approach, where assumptions were taken from the process with the worst emission aspects.

EVALUATION	GOOD
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Explanation of evaluation	<p>EU + EEA consist of more than 100 regions according the standard model with a 200 km x 200 km grid. Average population per region is around 3.6 million. Taking regional variations of consumption and typical compounds used across all product types into account, an F (prodregion) of 0.04 (4 %) is well justified. It is demonstrated that this covers more than 99 % of all regions when considering population density.</p> <p>Due to transfer to waste and substance transformation, a release rate of 100 % to water is clearly conservative. The assessment factor of 1.5 for local release is justified by studies and anyhow envisaged by standard models for high volume compounds with relatively even distribution.</p>
Remarks on improvements	
Feedback from A.I.S.E.	<p>It was clarified in the review more information was required on the conservatism derivation of the $F_{\text{prodregion}}$ and assessment factor used to derive the $F_{\text{mainsource}}$. This has been more thoroughly explained in the document:</p> <p>The use rates identified in this background document and reported in the relevant SPERC factsheets are based on the subject matter expertise of AISE members in addition to peer reviewed scientific publications. Release factors were chosen in a conservative manner (100% release), since the product uses are intended for its release into the environment after use.</p> <p>The $F_{\text{prodregion}}$ and $F_{\text{mainsource}}$ for the regional and local exposure assessment have been revised in a conservative manner. For the $F_{\text{prodregion}}$ this was done by using the weighted average of maximum regional use rates (99.5%iles) of laundry and home care products to derive a reasonable worst-case figure. The $F_{\text{mainsource}}$ was altered by the adjustment of the AF which accounts for spatial and temporal fluctuations of home care product use found by Fox et al. (2002). By these approaches a two-fold worst-case representation of the widespread emissions of household care and professional cleaning and hygiene products is reached.</p> <p>In combination, the values provided are considered to be a reasonable worst-case scenario for input into exposure assessments.</p>

7 – SUMMARY and OVERALL JUDGEMENT

7.1 - Overall judgement of the reviewer

Based on the documented information, are the release factors considered representative and reliable for the conditions of use described in the SPERC and the type of substances (by chemical-physical properties) contained in products/processes covered by the SPERC?

Overall score		GOOD			
Title	Scope	OCs	RMMs	RELEASE FACTORS	CONSERVATISM
GOOD	GOOD	GOOD	Not applicable	GOOD	GOOD
Overall evaluation	Aspects of geographical and temporal distribution are described in a comprehensive manner.				
Overall remarks on improvements	The standard format for quality assessment is not exactly suitable for the description of widespread uses with regard to considerations about distribution.				