

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 formulation of household care and professional cleaning and hygiene products; A.I.S.E. ERC 2
Date of the evaluation	August 12, 2021

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	The term formulation is quite clear for communication in the supply chain. It is evident that the SPERC deals with formulation of products for end-users (and not with semi-finished raw materials inside the chemical industry supply chain).
Remarks on improvements	

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	Main product types, application areas and production processes are clearly specified and described. ERC 2 applies for processing of solid, liquid and volatile compounds. It is clarified that ERC 3 would not be appropriate for the vast majority of products (candle manufacturing is explained elsewhere).
Remarks on improvements	As some of the underlying documents are dealing with compounding, i.e. formulation of semi-finished raw materials like fragrances, it might be useful to underline explicitly that this stage is not in scope.
Feedback from A.I.S.E.	Following this feedback we have stated that “Individual compounding steps (= formulation of intermediate products) are not treated in this document. Compounding steps are only in scope if relevant for on-site formulation.” The rationale is that most compounding is performed off-site, however this may be an exception for some sites and at the end we are looking at figures on site emission.

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: <ul style="list-style-type: none"> 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	Especially, the description of production processes is helpful to understand risk reduction measures and release fractions for different product groups. The impact of viscosity on release factors is well explained. The focus is clearly on risk reduction measures by process-integrated techniques (subsumed under operational conditions) rather than subsequent risk management measures.
Remarks on improvements	With regard to substances listed in annex 2 it would support the understanding of release routes when their status (solid, liquid, volatile) would be included. As REACH is a substance related regulation, it would be helpful for other stakeholders to get further information on typical substances of compounds, as e.g. provided by the PEF Category Rules on household laundry detergents for machine wash.
Feedback from A.I.S.E.	This information would have no impact on the outcome of the SPERCs exposure parameter. Moreover, it is not possible (with the exception of fragrances) to make generalisation on form (solid/liquid/volatile) by ingredient class and product type. A.I.S.E. therefore decided not to follow the recommendation.

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	The description of production processes for different product groups is appropriate for a good understanding by external stakeholders. The focus is clearly on risk reduction measures by process-integrated techniques.
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	The impact of viscosity on release factors might be explained more specifically. As there is a certain overlap with cosmetics for high viscosity products, it might be helpful to explain why conclusions on release factors are different for A.I.S.E. and CE (CE takes RF for creams and lotions from the Royal Haskoning report as reference for high viscosity products).
Feedback from A.I.S.E.	A distinction has been made for liquid products of low vs high, with their respective release factors in Section 5.3 Table 3 of the document, along with the rationale behind this distinction explained in Section 2.1.

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	GOOD
Explanation of evaluation	The industry sector provides reliable information on manufacturing volumes of different product groups which allow a derivation of substance use rates in combination with reference formulations as displayed in annex 2. Explanation is provided how volume bands as proposed by A.I.S.E. match with information from underlying documents.
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	As detergents are in scope of a European regulation which requires sufficient biodegradability, it might help to agree that no specific on-site WWTP is mandatory. An indication of typically achievable reduction rates by waste water treatment plants as described in literature (PEF Category Rules on household laundry detergents for machine wash) might be valuable.
Feedback from A.I.S.E.	We added a clarifying sentence as response of the remark to Ch 4 that states: “Biological treatment of wastewater by municipal sewage treatment plants (STP) is generally required but are outside the scope of the SPERCs exposure parameter, i.e. release factor.”

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	GOOD
Explanation of evaluation	Measured data have been evaluated and published by a couple of accessible documents (emission scenario reports, guidance documents, articles in journals). Measured data mainly refer to large plants. The background document explains appropriately how this information is considered in the SPERC context.
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	ACCEPTABLE
Explanation of evaluation	Modelling is required in order to derive release factors for medium and small installations, and to distinguish between low and high viscosity detergents.
Remarks on improvements	The data available from literature and chemical monitoring by some companies were pooled to derive release factors. The data indicated a factor of two between small, medium and large production scales. We therefore allowed for data gaps of certain product types, the same correlation as a generalized rule. A.I.S.E. could not find reasons of disproof.

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	ACCEPTABLE
Explanation of evaluation	Multiple literature sources are available. Published release factors are representative and robust for product groups at certain volume bands. Royal Haskoning and OECD have considered a release factor/fraction of 0.001 or 0.1 % for large sites and 0.002 or 0.2 % for medium sites (granular and liquid detergents) and half of these values for soaps. AISE is proposing lower release factors to water for certain product groups and production scales.
Remarks on improvements	Recent data input from companies should be displayed in a transparent way to provide sufficient evidence.
Feedback from A.I.S.E.	Table 3 highlights the values where company data was also included, however due to competition law, company data can only be displayed transparently if over three companies have provided data. As this threshold was not reached, it is not possible for the data to be laid out.

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 90%ile, 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
Explanation of evaluation	A.I.S.E. is proposing lower release factors to water for certain product groups and production scales (granular detergents, large and medium scale; liquid detergents with low viscosity, large and medium scale; soaps, large scale) compared to underlying reports by Royal Haskoning and OECD. This is justified by recent data collection from members. As the difference is expressed by a factor of 2, this seems to be realistic.
Remarks on improvements	Recent data input from companies should be displayed in a transparent way to provide evidence.
Feedback from A.I.S.E.	See comment above.

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	ACCEPTABLE
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Title	Scope	OCs	RMMs	RELEASE FACTORS	CONSERVATISM
GOOD	GOOD	GOOD	Not applicable	ACCEPTABLE	GOOD

Overall evaluation	Document provides a good structure and describes process-integrated risk reduction measures as preferred concept for the minimization of releases from formulation.
Overall remarks on improvements	Recent improvements achieved by this approach may require some further explanation.