

Report from SPERC Workshop on May 13, 2016

Abstract

On May 13 2016, a workshop was held in Brussels to discuss and review the improvements of the documentation of specific environmental release categories (SPERCs). SPERCs are an instrument for lower tier assessments of environmental emissions in the REACH chemical safety assessment. The workshop was part of joint activities of ECHA, the EU Member State authorities and European industry sector associations in the framework of the CSR/ES Roadmap. The workshop participants acknowledged the revised factsheet format and two worked SPERC background documents as best practice examples. Likewise, a brief guidance document was approved. The combination of this guidance and the best practice examples will support the further improvement of the quality of the documentation of the use conditions and the justification of SPERC release factors in factsheets and background documents. A common understanding was achieved of the need to match the level of detail of the description of the use conditions with the risk to be controlled (i.e. the expected release rates and the hazard profile of the substances) and with the level of conservatism of the SPERC release factors. The complete and transparent documentation of the derivation of the release factors and of their conservatism is conceived crucial for the credibility of the SPERCs as a resource provided by industry such that they can be trusted by partners in the chemicals supply chain and by regulators. To that end, background documents will include a dedicated section describing the conservatism of the SPERC. The workshop concluded with an outline of the practical way forward for the improvement of the SPERC documentation.

The workshop and its objectives

On May 13 2016, a workshop was held in Brussels to discuss the improvement of specific environmental release categories (SPERCs). SPERCs are an instrument for lower tier assessment of environmental emissions in REACH chemical safety assessments (Reihlen et al, 2016). They describe the generic conditions of use in a sector of industry and the related release factors to the environment. The workshop was part of the joint activities involving ECHA, the Member State authorities and European substance manufacturers' associations, formulating sectors and end-use sectors. These stakeholders have established the Exchange Network for Exposure Scenarios (ENES) and launched the Chemical Safety Report / Exposure Scenario (CSR/ES) Roadmap (ECHA 2013) to foster good quality information on the safe use of chemicals. Roadmap item 2.4 addresses the further development of SPERCs. To support this, ECHA launched the so-called "SPERC Best Practice Project" (Reihlen, Bakker 2014). The project report is available online under the following link:

https://echa.europa.eu/documents/10162/13628/assessment_of_reliability_of_sperc_final_report_en.pdf

In this project, the quality of SPERCs was assessed and best practice examples were developed for a limited number of uses in four industry sectors. The workshop was held to feed the results of this project into the CSR/ES Roadmap discussion. Its objective was to finalize the discussion on improving the SPERC documentation. This encompasses agreeing on a factsheet format for the presentation of the core information set for emission estimation and communication on conditions of safe use in the supply chain. In addition, this includes developing a common understanding of adequate background documentation of SPERCs. To that end, representatives of all stakeholders named above attended the workshop.

The Background

By providing an overview of the history of the SPERCs, A. Reihlen informed about the background of the workshop. SPERCs describe the generic conditions of use in a sector of industry and the related release factors to the environment. They were initially developed prior to 2009 by several industry sector associations for their use or the uses of their products by their customers. As discussed in a previous workshop (Sättler et al, 2012), the SPERCs were widely used in the first wave of registrations in 2010 and they have continued to be heavily relied on since then. A comprehensive overview of SPERCs has become available recently (Reihlen et al, 2016).

Since their introduction, SPERCs have been subject to three reviews by regulatory agencies (Lüskow et al, 2010, Reihlen 2013, Reihlen and Bakker, 2014). The major conclusions of these reviews relate to the release factors and their justification and to the documentation of the SPERCs. It was observed that the justification of the release factors needs to be improved, that more detailed information on operational conditions and risk management measures is needed, that the references used, the assumptions made need to be provided and that the approach used in deriving the release factors needs to be presented. In addition, it was found difficult to assess the reliability of the individual release factors based on the available documentation. The recommendation was to provide a clearer and more consistent documentation across sectors to enhance reliable use of SPERCs and overall credibility.

The SPERC Best Practice Project constitutes the latest review commissioned by a regulatory agency (i.e. ECHA) of the SPERCs. In this project, it was observed that providing the SPERC information for the chemical safety assessment and the underlying justifications in a single document (i.e. the SPERC factsheet) may create confusion as values for emission estimation are mixed with justifications and explanation. To overcome this, it was recommended to separate the documentation of SPERCs into two documents. One is a factsheet, which presents a limited set of information in a thoroughly structured, standardized and short document. It is complemented with a background document, which provides justification of the release factors and details on their derivation including references, etc.

The workshop preparation

In the follow up to the SPERC Best Practice Project and in preparation to the workshop, the proposed factsheet format and the concept of a background document were tested. Two sets of SPERCs covering industrial uses of adhesives and the industrial spraying of coatings were put forth by the sector organisation for adhesives (FEICA) and a cooperation of the sector organisations of the coatings and paints industry (CEPE) and the automotive industry (ACEA) for the automated coating applications in the manufacturing of cars. This led to further development of the factsheet format through factsheet examples, examples of background documents and a first draft guidance for extracting the essential information from the background document to the factsheet. This set of documents was sent to the authority representatives (February 24, 2016), who provided more than 120 individual comments by March 31. About half of these related to the structure of the documents or to a combination of content and structure. They were addressed by revising the factsheet structure and/or by making the guiding document clearer. The remainder concerned the content of the factsheets and/or background documents. These were accounted for by revising the content of factsheets or background documents or in the discussion on the level of detail in the SPERC documentation.

Prior to the workshop, the participants received the revised documents and the presentations. The latter addressed the history of the SPERCs (by A. Reihlen), ECHA's reflection on SPERCs and how they facilitate a better REACH process (A. Ahrens), overview of the comments and how they were addressed

in the revision (T. Wind), and a reflection by industry (F. Verdonck & T. May) on the national authority comments asking for more detailed information on SPERCs.

Improving the Factsheet Structure

The SPERC factsheet contains five sections along with the subdivision into the individual fields. For each of the fields an explanation of the field content is provided and instructions are given as to whether the content is to be provided as phrases from picklists, numerical values, or as free text. It also indicates whether the information is meant to be communicated with the CSR to the authorities (“Y” in Column ‘CSR’) or with the extended Safety Data Sheet to the downstream users (“Y” in Column ‘eSDS’).

The workshop resolved a number of structural issues in the factsheet format. The sections on “scope” and “operational conditions” have been revised to bring forth a clearer separation of the respective information. In addition, several factsheet fields have been better delineated from each other in order to avoid duplication of information. This was accompanied by a clarifying description in the guidance document. Under “conditions of use” a new field has been introduced to indicate whether a SPERC describes a process operated with rigorous containment with minimized releases in order to flag that the use is of low priority for potential regulatory action.

It was agreed that the release factor to waste should be expressed as numerical values (or ranges thereof) with a common understanding that these values bear uncertainties and do not aim at representing an accurate element of a substance’s mass balance.

The concept of sub-SPERCs was clarified as an option of documenting emission situations, where the same conditions of use apply to different substance types or properties. They allow for defining multiple release factors for one SPERC to reflect the influence of substance properties and/or technical functions on the emissions. To that end, the SPERC factsheet format provides repeatable blocks of release factors. These allow for defining as many sets of release factors as considered relevant for one set of identical operational conditions (Section 5, framed in bold), for instance to define release factors in dependence of the physical-chemical properties. It was also agreed that the sub-SPERCs in one factsheet can relate to different environmental release categories (ERCs) as defined in the relevant guidance (ECHA 2016). This facilitates representing the emission estimation of e.g. solvents and the solid constituents of a coating in a single SPERC factsheet with one set of operational conditions, even though their emission patterns are different.

As indicated in the column ‘eSDS’, some information is to be communicated to downstream users. Where available, a standard phrase may be selected from the ECom catalogue and the corresponding phrase ID should be provided in the factsheet. For several factsheet fields comprehensive picklists of standard phrases are available. These fields are marked with a single asterisk. For a second set of fields (marked with two asterisks), the content may already be adopted from existing ECom phrases. However, at present, the list of standard phrases is incomplete, particularly for operational conditions and risk management measures. Hence, when standard phrases are not available yet, concise free texts (one or two sentences) should be included into the factsheet. These may be the basis for later phrase development.

Changes in the background document and the guidance.

The objective of a background document is providing justification of the release factors and details on their derivation including references and methods. With this in mind, the structure of the background document examples was aligned with the factsheet sections such that a direct correspondence

between the two documents is achieved. This facilitates the development of the background documents, as the explanation / justification needs are clearly addressed. In addition, users of the SPERCs or evaluators can more easily trace information pertaining to the factsheets.

The background documents include a reference to the newly developed extended use maps. These support the selection of the proper SPERC per use. Furthermore, the degree of conservatism underlying the derivation of the release factor is characterized in a separate section. This could relate to the selection of (worst case) release factors from literature, the use of measured data or logical argumentation related to the conditions of use and the substance properties, to show that the SPERCs cover all uses and use situations described in the scope. Another section of the background document should provide those references, which were used in the derivation of the SPERC(s). Finally, the mass flows in a process are to be outlined in an annex to the SPERC background document.

Many comments indicated that the draft document on including the essential information from the background document into the factsheet was insufficient. As a consequence, this document was thoroughly revised and expanded. It is now considered a guidance for filling the factsheet format with information such that SPERC factsheet of sufficient quality can be obtained.

[Addressing the main comments on content of factsheets and background documents.](#)

The 61 comments on content were grouped according to main issues. Specific comments on the content of the example factsheets and background documents were addressed by implementing respective changes. Comments related to the level of detail in both types of documents were not implemented but put up for discussion in relation to the question of how conservatism could be taken into account in the documentation. Table 1 displays the main comments on content along with the respective responses.

[Comments requesting more detail](#)

The requests for more detail in the SPERC documentation constitute the largest group of comments on the content. They can be further subdivided into three groups. One group are requests for summaries of information, which is provided via a link or via a reference in the factsheets or background documents. Generally, it was avoided to replicate justifying / supporting literature in the background document. However, in some instances the information provided in the factsheets was found incomplete and included into the revised background documents.

A second group of requests related to moving detailed information from the background document to the factsheet. This set of requests was not followed because this would reverse the outcome of the SPERC Best Practice Project (i.e. the separation of the concise presentation of SPERC information in the factsheet from the detailed description and justification in the background documents).

The third group of comments asked for more detail on the content in the factsheets or background documents. Most of these were directed towards the FEICA SPERCs. These SPERCs were found to provide little detail, and to define the operational conditions very broadly. More information on charging the equipment and the application process was deemed useful. The comments touch the crucial issue of balancing the level of detail required for a SPERC in relation to its conservatism and applicability domain. Since this issue had not yet been discussed previously, the workshop was the forum for presenting the underlying considerations in more detail.

Level of detail of documentation vs conservatism of emission estimation

At the workshop, a general discussion took place on the relationship between the level of detail required for a SPERC and the degree of conservatism in the release estimates. It was emphasized that the SPERCs' purpose is to support lower tier environmental exposure assessment. Hence, they represent generic emission situations based on good practice. From that perspective, it was underlined that SPERCs need to be conservative. The SPERC conservatism is rooted in the release factors, including the fact that many SPERCs are based on historic data reflecting 'old' technology. In addition, the background documents may provide worst case estimates of the substance use rates. These are recommended conservative values for starting exposure assessments and may be refined if the registrants can justify the use of lower use rates. This was exemplified for SPERCs for spray application of coatings and industrial uses of adhesives and sealants.

The examples can be seen as models of SPERCs with a rather narrow application domain (spray coating with wet scrubber in automotive industry) and with a broad application domain (industrial use of adhesives and sealants). This may explain why the majority of comments requesting more detail addressed the FEICA SPERCs. The differences in the required degree of detail in SPERCs usually are driven by the emission intensity of a process, the hazard profile of the substance, and whether a substance is included into a product matrix or is used as (constituent of) a processing aid, which, after use, is disposed.

The broad applicability domain of SPERCs, i.e. the coverage of several use situations, implies a generic description of the operational conditions and thus a low degree of detail. The ERCs as defined in ECHA's guidance (ECHA 2016) are at the most extreme end of very low level of detail on conditions of use and justification but very broadly defined. Conversely, there is a need for more narrowly defined SPERCs whenever emission situations with high exposure intensity and/or substances with high hazard are to be covered. The ACEA SPERCs are one example of such SPERCs with a narrow applicability domain in order to be able to adequately address the emissions of substances from the industrial coatings process to the wastewater. The SPERCs for the use of metal salts (zinc, nickel, chromium and copper) in conversion coating are a second example.

More narrow SPERC definitions in general would lead to increasing the number of SPERCs beyond the more than 200 SPERCs, which are already available (Reihlen et al. 2016). It was therefore concluded at the workshop that the generic nature of SPERCs is acceptable if it goes along with conservative assumptions. These in turn correspond to conservative release factors that are higher than those in more specific assessments. The conservatism in release factors can compensate the relatively low degree of detail in the description of the conditions, still qualifying the SPERCs for lower tier exposure assessments. In view of the importance of conservatism in the credibility of SPERCs it was concluded that it is necessary to explicitly describe in the background document how this conservatism is achieved for a SPERC.

Way forward

In the follow-up to the workshop, the individual sector organisations will transform the existing SPERC documentation into revised factsheets format and into background documents, using the formats and guidance agreed in the workshop. Once this is completed, the sector organisations will generate SPERC files for use with ECHA's chemical safety assessment tool (CHESAR, CHESAR 2015). The timing for these activities will be decided in due course. This will include the planning for the development of phrases to communicate conditions of environmentally safe use. Moreover, for a minority of the current SPERCs for uses with discontinuous emissions the representation of the releases needs to be developed further. Finally, there is agreement that there is a need to increase the stakeholders' trust

in the reliability of SPERCs as a basis for regulatory acceptance. To that end, a review of the revised SPERCs needs to take place, preferably with national authorities being involved.

Workshop results

The workshop approved the revised factsheet format and the model background documents as best practice examples to give orientation to the further development of SPERCs. Similarly, the guidance document coming forth from the review process was accepted to guide the further development of SPERC factsheets and background documents. A common understanding was achieved of the need to match the level of detail of the description of the use conditions with the risk to be controlled (i.e. the expected release rates and the hazard profile of the substances) and with the level of conservatism of the SPERC release factors. The complete and transparent documentation of the derivation of the release factors and of their conservatism is conceived crucial for the credibility of the SPERCs as a resource provided by industry such that they can be trusted by partners in the chemical supply chain and by regulators. To that end, background documents will include a dedicated section describing the conservatism of the SPERC. The workshop concluded with an outline of the practical way forward for the improvement of the SPERC documentation.

References

CHESAR 2015. CHESAR software and guidance by ECHA downloadable under <https://chesar.echa.europa.eu/web/chesar/chesar-tool>, European Chemicals Agency, Helsinki, Finland.

ECHA 2010. Guidance for intermediates. European Chemicals Agency, Helsinki, Finland.

ECHA 2012. Guidance on information requirements and Chemical Safety Assessment, Chapter R.18: Exposure scenario building and environmental release estimation for the waste life stage, European Chemicals Agency, Helsinki, Finland.

ECHA 2013. The CSR/ES roadmap - A cross-stakeholder plan of actions to 2018. Helsinki, Finland. <https://echa.europa.eu/regulations/reach/registration/information-requirements/chemical-safety-report/csr-es-roadmap>

ECHA 2014 Exchange Network on Exposure Scenarios (ENES) <http://echa.europa.eu/about-us/exchange-network-on-exposure-scenarios>

ECHA 2016. Guidance on information requirements and Chemical Safety Assessment, Chapter R.16: Environmental exposure assessment, European Chemicals Agency, Helsinki, Finland.

European Commission 2003. Technical Guidance Document on Risk Assessment in support of Commission Directive 93/67/EEC on Risk Assessment for new notified substances, Commission Regulation (EC) No 1488/94 on Risk Assessment for existing substances, Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market Part II. Italy: European Commission. EUR 20418 EN/2

European Commission 2006. REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

Lüskow H, Wirth O, Reihlen A, Jepsen, D. 2010. Standardisation of Emission Factors for the Exposure Assessment under REACH. Dessau, Germany: Federal Environment Agency Germany. FKZ 363 01 300.http://reach-info.de/dokumente/exposure_assessment.pdf

Reihlen A, 2013. Standardisation of release factors for the exposure assessment under REACH - Developments since 2010. Dessau, Germany: Federal Environment Agency Germany. Report No. 001915/E

Reihlen A, Bakker J, 2014. Assessment of reliability of SPERCs. Final Report. Helsinki, Finland: European chemicals Agency. Contract No ECHA/2011/01; Service request SR16. Report downloadable under https://echa.europa.eu/documents/10162/13628/assessment_of_reliability_of_sperc final_report_en.pdf.

Reihlen A, Bahr T, Boegi C, Dobe C, May T, Verdonck F, Wind T, Zullo L, Tolls J. 2016. SPERCS—A Tool for Environmental Emission Estimation, *Integrated Environmental Assessment and Management*. In press.

Sättler D, Schnöder F, Aust N, Ahrens A, Bögi C, Traas T, Tolls J. 2012. Specific Environmental Release Categories—A Tool for Improving Chemical Safety Assessment in the EC—Report of a Multi-Stakeholder Workshop. *Integrated Environmental Assessment and Management*. 8, 580-585.

Tolls J, Gomez D, Guhl W, Funk T, Seger E, Wind T. 2016. Estimating emissions from adhesives / sealants uses and manufacturing for use in environmental risk assessment. *Integrated Environmental Assessment and Management*. 12, 185-194.

Verdonck FAM, Van Assche F, Hicks K, Mertens J, Voigt A. 2014. Development of Realistic Environmental Release Factors Based on Measured Data: Approach and Lessons from the EU Metal Industry. *Integrated Environmental Assessment and Management*. 10, 529–538.

Table 1. The main comments on content and the responses provided.

Comment	Response
<p>Provide more detail in describing content i.e. processes and operational conditions, in justification of data.</p> <p>Avoid using poorly defined phrases such as (negligible, small, etc.) to address low releases.</p>	<p>The request for more detail in describing processes, in providing justification and for avoiding phrases which are perceived as poorly defined are addressed in the discussion on „Detail/Conservatism“. The discussion led to agreement that the level of detail in the SPERC documentation should be matched with the level of conservatism in the derivation of the SPERC release factors.</p>
<p>Make background documents easier to read for non-experts.</p>	<p>The primary objective of background documents is to provide explanation and justification on technical processes. The target audience are risk assessors that want to understand emission estimation. Generally, technical jargon was avoided. In certain instances, however, brevity of the document was preferred over presenting the facts.</p>
<p>RF of solvents in water borne adhesives in question (FEICA)</p>	<p>FEICA addressed this comment by generating a separate SPERC for solvents in water borne adhesives / sealants.</p>
<p>Harmonize wording between FS and BD</p>	<p>This comment was adopted by changing the factsheet and background documents.</p>
<p>Summary of information in links or in references to justifying / supporting literature in BD</p>	<p>This comment was addressed by adding relevant information. Generally, however, it was avoided to replicate justifying / supporting literature in the background document.</p>
<p>Add advice for treatment of substance waste</p>	<p>Advice on waste treatment is considered beyond the scope of the SPERCs. Hence, this is not included.</p>
<p>Amend factsheets with information on optional risk management measures (RMMs).</p>	<p>The optional RMMs were part of the earlier SPERC factsheet. They were subject to discussion in the SPERC ‘Best Practice’ project. That discussion concluded that SPERCs need to define an unequivocal set of conditions and corresponding release factors. This requirement cannot be met with optional RMMs.</p>