

# Specific Environmental Release Categories—A Tool for Improving Chemical Safety Assessment in the EC—Report of a Multi-Stakeholder Workshop

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## ABSTRACT

In April 2011, experts from industry and authorities met for a workshop to discuss experience and future developments regarding the use of specific environmental release categories (SPERCs) in chemicals safety assessment (CSA) under the European Chemicals Regulation Registration, Evaluation and Authorization of Chemicals (REACH). This article provides a summary of the workshop. It briefly explains what a SPERC is, why SPERCs are needed, where the challenges of the concept are, and what improvements are needed to make SPERCs a useful tool for assessments under REACH. Integr Environ Assess Manag

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## INTRODUCTION

In 2006, the European Union (EU) implemented legislation (EC) 1907/2006 (Registration, Evaluation, and Authorization of Chemicals; REACH) (EU 2006). This legislation requires that manufacturers and importers of substances in amounts greater than 1 ton per year (t/a) register the substances they place on the market in the EU. By establishing the “No Data—No Market” principle, the EU requires that manufacturers and importers provide data on physical-chemical, toxicological, and ecotoxicological properties. If the marketed amount exceeds 10 t/a, the manufacturers or importers are required to carry out chemical safety assessments. For substances that meet the criteria for classification as dangerous according to Directive 67/548 EC (EU 1967) or that meet the EU criteria for persistent, bioaccumulative, and toxic, or very persistent and very bioaccumulative, an exposure assessment and a risk characterization is required. Substances may only be marketed for applications for which their use has been demonstrated to be safe. Furthermore, the conditions of safe use must be communicated to the users of the substances in the supply chain. With some 30 000 substances expected to be registered, REACH requires thousands of environmental risk assessments, a task hitherto not attempted. Similarly, the communication of the outcome of these assessments in the supply chain has not been tested previously. Both

challenges require a standardized approach to address this enormous task.

### Estimating emissions under REACH

The environmental assessment includes 4 elements: 1) a description of operational conditions and risk management measures (RMM) suitable to ensure safe manufacture and use, 2) an estimation of resulting emissions for all uses covering the entire life cycle of the substances, 3) an estimation of exposure resulting from these emissions, and 4) a risk characterization demonstrating that the estimated exposure in the environment is below the predicted no-effect concentrations.

Chapters R.12 and R.16 of the Guidance on Information Requirements and Chemical Safety Assessment (ECHA 2010) introduce the environmental release categories (ERC) as a standardized way to describe uses from an environmental perspective. The default worst case in Guidance Chapter R.16 provides release factors (to the water, air, and soil environmental compartments) for each ERC, enabling TIER 1 emission estimations. The ERC release factors are broadly applicable, but they often lead to significant overprediction of releases and, hence, of environmental exposure.

In response, a number of groups in the chemical industry sector and their downstream customer industries have refined the emission estimates by developing specific environmental release categories (SPERCs). SPERCs are intended to be advanced tier instruments (TIER 1.5) in environmental safety assessments, which increase the accuracy of the emission estimate while ensuring that the same release factors can be used for operations characterized by similar operational conditions. Thus, the sector knowledge is used to provide standardized release information in the form of SPERCs.

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SPERCs are used for 2 purposes: defining the requirements of safe use in the REACH chemical safety assessment and communicating the conditions corresponding to safe use.

### *The SPERC workshop*

Although SPERCs have been used extensively to generate the dossiers of the 2010 REACH registrations, only limited public discussion has occurred on the development and scope of SPERCs. Early in 2011, the German Federal Environmental Agency issued the report “Standardization of Emission Factors for the Exposure Assessment under REACH” (Umweltbundesamt 2011). To open the discussion on SPERCs, the European Chemical Industry Council (CEFIC) organized a multistakeholder workshop on April 14, 2011 in Brussels, with participation from industry representatives, EU member state authorities, the European Chemicals Agency (ECHA), the EU commission, and the OECD (Organisation for Economic Cooperation and Development). The goals of the workshop were to review SPERCs in light of the outcome of a recent publication by the German Federal Environment Agency (UBA), to develop a common understanding of the usefulness and limitations of SPERCs, and to identify areas for improvement.

### *What is a SPERC?*

A SPERC characterizes the typical release parameters and scenarios resulting from good practice in operating specific on-site activities, or processes, or in designing chemical products for widespread use by professional users and consumers. It describes the operational conditions that determine the release of a substance from the activity or process. Furthermore, a SPERC may specify the risk management measures (and their associated effectiveness, if available) applied before release into the environment or the sewage system. If applicable, the release to off-site waste treatment operations is also addressed in a SPERC.

All of the release parameters established by a SPERC, their justification, and a description of the corresponding conditions of use are compiled in SPERC factsheets. By promoting standardization, SPERCs contribute to transparent assessments and efficient communication in the supply chain, with information on environmental exposure scenarios conveyed in the annexes of extended safety data sheets.

Release factors are currently available for more than 150 SPERCs. This information was used in environmental risk assessments for the first registration deadline under REACH.

## **CURRENT ISSUES IN SPERC DEVELOPMENT**

### *Overview of the sector approaches*

The UBA reports that various sources of information on typical processes and emission rates were used by the sector associations as a starting point for the development of SPERCs (Umweltbundesamt 2011). In most cases, emission values from the OECD emission scenario documents (ESDs), Tables A and B in the Technical Guidance Document on Risk Assessment (EU 2003), and Best Available Technology Reference Documents (BREFs) were used. In addition, measured release data, market research data, and information collected via questionnaires were employed to derive SPERCs. Independent from the industry initiative, the European Chemicals Agency (ECHA) and the Dutch

Institute of Public Health and the Environment investigated the development of SPERCs. Table 1 provides an overview of the SPERC development activities discussed in the workshop. The following sections present a short description of several approaches to SPERC development and provide a web link for assessing the SPERC factsheets.

### *Specific observations made during the development of SPERCs*

The European Sector Group of the producers and users of paints, printing inks, industrial coatings, and artists' colors (CEPE), used the emission factors of the OECD's ESD “coatings industry” (OECD 2009a) as a starting point. This information was evaluated by experts, leading to the conclusion that the data in the ESD are outdated in some areas. Therefore, the technical requirements of the VOC Directive (EC 1999) were used to define a conservative “typical worst-case” scenario covering all installations subject to this directive. Other types of installations remain uncovered by the SPERCs developed by CEPE.

Like CEPE, the federation of the textile chemical industry (TEGEWA), and the federation of the textile finishing industry developed their SPERCs based on the OECD ESD for their industries (OECD 2004). Several R&D projects and measurements were carried out in textile finishing companies to refine the release fractions for the textiles industry (Kohla et al. 2008).

The Dutch National Institute for Public Health and the Environment (RIVM) developed a sample SPERC for paper-making using the OECD ESD for the “Pulp, Paper and Board Industry” (OECD 2009b) as a starting point. The ESD was found to provide insufficiently detailed information, and the BREF document for the paper industry was consulted. This document provided information on sector-specific RMMs and estimated their efficiency using the input of sector experts. RIVM found it necessary to specify the SPERC for the type of chemical used and to create subSPERCs for the 3 main chemical groups.

The federation of adhesive and sealant manufacturers (FEICA) judged the ESD on adhesives (OECD 2009c) to be inappropriate because it was not based on empirical data. Instead, the OECD ESD for Coatings (OECD 2009a) was used as starting point to develop SPERCs for adhesives. FEICA argued that the conditions for adhesive and sealant application and use are similar to coatings; thus, the emissions can be read across. In addition, FEICA found the applications to be too specific. Hence, individual applications were aggregated to define broader application types, and worst-case release factors were assigned.

The International Association for Soaps, Detergents, and Maintenance Products (AISE) used another approach to developing a SPERC factsheet for the wide dispersive use of cleaning products, all of which are released to the municipal wastewater. The focus was on replacing the default value of 0.2% of a substance used in the unit town according to the ECHA Guidance Document R.16 (ECHA 2010) with a realistic estimate. To that end, market survey data, geographically resolved population density data (Price et al. 2010), and environmental monitoring data (Fox et al. 2002) were used to determine an estimated value of 0.075%.

Table 1. Overview of SPERC development activities discussed in the workshop

Developer	Type of information used	Applications covered	Focus of SPERC	Web link to SPERC factsheets
CEPE	OECD ESD on coatings and paints, VOC Directive 99/13/EC	Formulation of coatings and inks, industrial applications	Refinement of ERC release fractions	<a href="http://www.cepe.org/EPUB/easnet.dll/ExecReq/Page?eas:template_im=100087&amp;eas:dat_im=101AED#SPERCs">http://www.cepe.org/EPUB/easnet.dll/ExecReq/Page?eas:template_im=100087&amp;eas:dat_im=101AED#SPERCs</a>
FEICA	OECD ESD on adhesives, on coatings and paints	Formulation of adhesives, industrial applications	Refinement of ERC release fractions	<a href="http://www.feica.com/ehs-sustainability/reach/feica-use-descriptors">http://www.feica.com/ehs-sustainability/reach/feica-use-descriptors</a>
RIVM	OECD ESD for "Pulp, paper and board industry" BREF on paper industry	Industrial application of chemicals in paper making	Refinement/validity of RMM efficiency	No factsheets produced
Eurometaux	Measured data from EU risk assessments	Manufacturing, formulation and industrial use	Refinement of ERC release fractions	<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>
AISE	Georeferenced population density data, market research data	Wide dispersive application	Refinement of the default amount of substance used at local level as specified in the REACH Guidance Document R16	<a href="http://www.aise.eu/reach/?page=exposuressub4">http://www.aise.eu/reach/?page=exposuressub4</a>
TEGEWA	OECD ESD on Textiles, measured data	Industrial applications of textile treatment chemicals	Refinement of ERC release fractions	Factsheets will be available by mid 2012 at <a href="http://www.textil-bekleidung.de">http://www.textil-bekleidung.de</a> and <a href="http://www.tegewa.de/">http://www.tegewa.de/</a>
European chemicals Agency (ECHA)	OECD ESD on textiles	Industrial applications of textile treatment chemicals	Development of SPERC data model for ECHA's IT-tool CHESAR	No factsheets produced

SPERC = specific environmental release category; ERC = environmental release category; CEPE = European sector group of the producers of adhesives and sealants; RIVM = Dutch National Institute for Public Health and the Environment; Eurometaux = The European Association of Metals; AISE = The International Association for Soaps, Detergents and Maintenance Products; TEGEWA = Federation of Textile Chemical Industry; OECD = Organization for economic cooperation and development; ESD = Emission scenario document; CHESAR = Chemical Safety Assessment and Reporting tool.

The European Association of Metals (Eurometaux) decided to use measured data from air and wastewater releases, which were considered more realistic than estimated values. These data integrate all on-site processes per life cycle stage. The 90th percentiles were established as the realistic worst-case rates of substance release into the environment. It was noted that the presentation of the information does not allow the determination of whether the release fractions are driven by the process and/or operational conditions or whether they are the result of the implementation of risk management measures.

## FEEDBACK FROM AUTHORITY AND INDUSTRY ON SPERC DEVELOPMENT

In the study “Standardization of Emission Factors for the Exposure Assessment under REACH” (Umweltbundesamt 2011), SPERC examples were analyzed in terms of their coverage of processing steps, information sources for the derivation of release factors, and the plausibility of the derivation processes. Furthermore, the CEFIC guidance document on SPERC (CEFIC 2010) and the structure, completeness, and transparency of the documentation in the SPERC factsheets were analyzed. It was determined that it is difficult for nonexperts to understand SPERCs because there is often only a vague description of processes and a weak relationship between operational conditions and release factors. This makes it difficult for users to determine whether the SPERC covers the process and whether the release factor is applicable. Another area of uncertainty in the application of SPERCs is whether the release factor takes risk management measures into account, and whether emissions from cleaning and maintenance operations are covered. Information sources are not always accessible to SPERC users or well referenced in the factsheet. In the case of the evaluation of the registration dossiers, the mentioned aspects make it difficult for authorities to determine the plausibility of the exposure assessment. Some actors expect SPERC factsheets to provide more standardized information for downstream user communication, a more detailed description of the conditions of use, and fewer adaptation requirements.

CEFIC conducted a survey among SPERC users (industry companies and consultants) to collect feedback on their experiences using SPERCs in environmental risk assessments. Approximately 50% of the questionnaires ( $n=14$ ) were returned by individual companies, with the remainder divided almost equally between consultants and companies acting as consortium representatives. SPERCs have been widely used for emission assessments as an intermediate and/or final approach (>50%) to the REACH registration dossiers.

## MAIN PRACTICAL CHALLENGES IDENTIFIED IN THE WORKSHOP

### *Defining the coverage of a SPERC*

The boundaries of SPERCs must be defined clearly. To that end, clear criteria are desirable to determine whether a SPERC covers a specific use. Such criteria may be based on substance function, groups of substances with similar physicochemical properties under the same process conditions, or grouping of activities according to “good practice.” The scope of a SPERC must be clearly identified.

### *Providing SPERCs with information at an appropriate level of detail*

The available SPERC factsheets differ considerably in the degree of detail used to describe operational conditions, risk management measures, and good practice. This differentiation is the result of case-by-case decisions made in the process of defining each SPERC. These decisions considered the hazard profile of the substances used, the typical amounts of substances used, the sector-specific processes or activities and their variation, the corresponding variation in release factors, and the need to cover the majority of sites. Hence, in defining SPERCs, a balance must be achieved between standardization and efficient communication in the supply chain. At the same time, a sufficient level of differentiation is required so that the SPERC defaults allow an appropriate level of environmental protection to be defined for the majority of operations while avoiding the implementation of measures that cost more but do not offer added protection.

### *Sources and quality of information for deriving SPERCs*

It is apparent from Table 1 that OECD ESDs were a preferable starting point for SPERC development in most sector organizations. Expert judgment has proven to be an important element in the development of SPERCs and has been applied, for example, in selecting, discarding, or aggregating information in ESD, estimating release factors, and assigning operational conditions and risk management measures to release factors. Qualitative justification is especially needed if release factors are set to zero. The experts’ considerations that lead to specific release factors should be documented in the corresponding SPERC factsheet.

Measured data can also be the departure point for SPERC development, as exemplified by Eurometaux. The measured data for metals integrate all on-site processes, including risk management measures. As a result, they can generally be considered realistic. In a more general discussion, the prerequisites for obtaining valid measured emission data were identified, such as appropriate sampling and analytical procedures.

## IMPROVING SPERCs

### *Suggestions from feedback*

Proposals for improvements were collected based on the feedback to SPERCs provided in the study by Umweltbundesamt (2011), the CEFIC survey, and the workshop discussions. Table 2 summarizes these suggestions. The UBA and industry respondents agree on many suggestions for improving SPERCs, including improvements to the plausibility and traceability of SPERC release factors and the requirements for the factsheet formats.

The UBA has emphasized that guidance on SPERC development must be revisited and identified a number of specific items to be addressed. The industry-specific suggestions relate to specifying the scope of SPERCs, particularly for those that address downstream uses. The suggestions in Table 2 will be included in the revision of the SPERC guidance to develop SPERC quality criteria.

### *The way forward*

Industry representatives have committed to revising the SPERC factsheets and the guidance on SPERCs to enhance

**Table 2.** Overview on suggested improvements

Suggestions for improvement	UBA	CEFIC
<b>SPERC coverage</b>		
In each SPERC it should be clearly identified what processes and/or activities are covered	X	
SPERCs and corresponding release factors need to be more use specific		X
Exposure scenario titles should include a reference to the relevant SPERCs	X	
<b>Representation of RMMs in SPERC release factors</b>		
Systematically differentiate between operational conditions driving the initial release (loss) from a process and onsite risk management (with specified effectiveness) applied before release to environment or sewage system “release” to off-site waste treatment and waste management	X	
Clarification is required on whether risk management measures (including their effectiveness) are accounted for in release factors given in the factsheet		X
<b>Documentation of rationale for choice of release factors</b>		
Transparency regarding the derivation of SPERC parameter values should be improved by better and more detailed documentation of the justifications of the release data	X	X
<b>Define relationship between operational conditions, risk management, and release factors</b>		
Release factors alone are not enough. The conditions of use leading to the release factor need to be made explicit for each SPERC. Avoid the use of undefined terms like “optimized processing” and “RMM with high efficiency”	X	
Improvement of the structure and content of SPERC factsheets should facilitate extraction of OC/RMMs and additional information		X
<b>Making SPERCs available to the stakeholders</b>		
Industry associations should maintain and update the SPERCs (all versions of SPERCs should be kept available)	X	
Better communication on SPERC updates (new or revised factsheets and implementation in exposure estimation and risk assessment tools)		X
SPERC release factors should be always published together with the underlying documentation in the factsheets	X	
<b>Harmonized and structured format</b>		
A structured and harmonized format for SPERCs and SPERC fact sheets is essential for supporting IT based efficiency in generating, communicating, processing, and evaluating exposure scenarios	X	
A need to make SPERCs available for use in CHESAR was identified, including e.g., upload function (exchange format)		X
<b>Guidance on derivation of SPERCs</b>		
Clearly communicate the understanding of the concept and role of SPERCs. This could prevent future misunderstandings regarding the expected and realized level of detail and could help to clarify of “how-to-use” SPERCs in registrations	X	
Outline different methods for deriving release factors	X	
Provide rules for documenting the information source and the method how a release factor was determined in a transparent manner	X	
Define which information from a SPERC factsheet should be regularly communicated to downstream users	X	

UBA = Federal Environment Agency (Umweltbundesamt), Germany; CEFIC = European Chemical Industry Council; SPERCs = specific environmental release categories; RMMs = risk management measures; OC = operational condition; CHESAR = Chemical Safety Assessment and Reporting tool.

the usefulness and credibility of SPERCs for registrants, evaluators, and enforcement bodies. The suggestions summarized in Table 2 provide a good start to achieving this goal. The detailed commitments for the short-term to mid-term future are provided in Table 3. In view of the registration deadline of May 31, 2013, it was agreed that the process of revising the SPERCs should be completed in spring 2012 so

that all stakeholders have sufficient time to familiarize themselves with the revised SPERCs.

In the longer term, acceptance of SPERCs among the stakeholders requires a discussion about the plausibility of SPERCs and a consensus on their applicability.

From a practical point of view, the efficient generation and processing of SPERC information is necessary. To that end, a



**Table 3.** Overview of the commitments made at the workshop to improve the usefulness and credibility of SPERCs

Committed item	Who committed?
Clarify under which operational conditions release factors apply and whether or not release factors account for risk management measures	Sector groups and trade associations
Document SPERCs in revised factsheets formats to improve readability and structure of SPERCs	
Improved description of using SPERCs in assessments	CEFIC
More elaborate rules for using SPERCs in the communication to downstream users	
Follow-up multistakeholder workshop on SPERCs	CEFIC

SPERCs = specific environmental release categories; CEFIC = European Chemical Industry Council.

standard data format should be defined that can be exchanged between IT systems that support chemical safety assessments and communicate exposure scenarios in the supply chain. To promote harmonization, ECHA announced that it would make available an example of a SPERC factsheet with a data model definition that aligns with ECHA's Chemical Safety Assessment and Reporting Tool (CHESAR) in Fall 2011. ECHA will also test the SPERC functionalities planned for availability in CHESAR 2.

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