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Standardisation of Emission Factors for the Exposure Assessment under REACH

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Standardisation of Emission Factors for the Exposure Assessment under REACH

by

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Abstract

The project analyzed the process of different industry associations of developing and documenting specific environmental release categories (spERCs). Issues regarding the information structure and type of justification provided in the fact sheets documenting the derivation of spERCs were described and analyzed at a general level. For selected spERCs, more in-depth analyses were conducted. In addition, specific aspects such as the derivation of release factors for emissions to water based on measured data collected by industry surveys or the adaptation of the regional use amounts based on market data of consumer products were evaluated. The quality of information of specific assumptions and default values of the spERCs, i.e. the correctness of these values, was not assessed in detail.

In the context of evaluating spERCs and the pertaining fact sheets, phone conferences were held with the representatives of the industry associations and the related documents were analyzed, compared and assessed using specific examples.

The results of the evaluation are the following:

Industry understands spERCs as a specification of ERCs; however, according to the representatives of the industry associations it is not intended that they are used by the registrants directly and without adaptation to his (a single registrants) specific situation. This intention of the organizations that have developed spERCs differs from the general expectations of the REACH actors (authorities, downstream user etc.), which have not been involved in the development of spERCs, regarding the degree of specification of information.

The conditions of use are described at a general level in most of the fact sheets. There is little concrete advice to the registrant, which specific conditions of use should be assumed and communicated. The covered uses are frequently rather broadly defined, respective descriptions are spread over several sections in the fact sheets and are partly inconsistent. The default values of the spERCs are derived using different methods and different information sources. In many cases the documentation of the justification of values is regarded as not sufficient.

An essential aspect of the further development of spERCs is the clear and precise derivation of whether or not release factors apply before or after risk management measures and a respective unambiguous and understandable description in the fact sheets. In addition, information on the coverage of spERCs should be shortened and presented in a better structured way. The documentation of justifications of values and assumptions should be improved.

Kurzbeschreibung

Im Rahmen des durchgeführten Vorhabens wurde das Vorgehen verschiedener Industrieverbände zur Entwicklung und Dokumentation von specific environmental release categories (spERCs) analysiert. Dabei wurden übergeordnete Fragestellungen bezüglich der Struktur der Informationen in den Fact Sheets und der Begründungen zur Ableitung der einzelnen spERCs auf einer allgemeinen Ebene analysiert und beschrieben. Für ausgewählte spERCs wurden die Analysen vertieft. Außerdem wurden spezielle Fragestellungen wie z.B. die Ableitung der Werte für Emissionsfaktoren ins Wasser anhand von in Branchenerhebungen ermittelten Messdaten oder die Ableitung regionaler Verwendungsmengen von Verbraucherprodukten geprüft. Die Informationsqualität einzelner Aussagen und Zahlenwerte der spERCs, d. h. die Richtigkeit der Werte wurde nicht vertieft bewertet.

Im Rahmen der Prüfung der spERCs und der Fact Sheets wurden Telefonkonferenzen mit Vertretern der Verbände abgehalten, die Dokumentationen analysiert und verglichen, sowie anhand von Beispielen untersucht. Im direkten Gespräch mit Branchenexperten wurden weitere Fragen vertiefend diskutiert.

Die Prüfung führte zu den folgenden Ergebnissen:

Die spERCs werden seitens der Industrie zwar als Konkretisierung der ERCs verstanden. Es ist lt. Auskunft der befragten Verbandsvertreter aber nicht beabsichtigt, dass die spERCs durch die Registranten direkt und ohne Anpassungen auf die spezifische Situation des Registranten genutzt werden können. Dieser Anspruch der Organisationen, die die spERCs entwickelt haben unterscheidet sich von den allgemeinen Erwartungen der REACH Akteure (Behörden, nachgeschaltete Anwender etc.), die nicht an der Entwicklung der spERCs beteiligt sind in Bezug auf den Grad der Konkretisierung der Informationen zu den Verwendungen.

In den Fact Sheets werden die Verwendungsbedingungen meist sehr allgemein formuliert. Es gibt kaum konkrete Hinweise für den Registranten, welche spezifischen Bedingungen angenommen werden und zu kommunizieren sind. Die Verwendungen selbst sind häufig sehr breit definiert, wobei beschreibende Informationen in den verschiedenen Abschnitten der Fact Sheets z.T. uneinheitlich präsentiert werden. Die Standardwerte werden aus unterschiedlichen Quellen und mit unterschiedlichen Methoden abgeleitet, vielfach ist allerdings die Begründung für die Werte nicht ausreichend dokumentiert.

Ein zentraler Aspekt für die zukünftige Weiterentwicklung der spERCs ist es, eindeutig abzuleiten und darzulegen, ob Emissionsfaktoren mit oder ohne Risikomanagementmaßnahmen gelten. Dies ist in den Fact Sheets konsistent und verständlich zu beschreiben. Des Weiteren sollten die Informationen zur Beschreibung der Abdeckung der spERCs gekürzt und übersichtlicher strukturiert und präsentiert werden. Die Dokumentation der Begründungen für Werte und Annahmen sollte verbessert werden.

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List of Abbreviations

A.I.S.E.	Association for Soaps, Detergents and Maintenance Products
ATIEL	Technical Association of the European Lubricants Industry
BAT	Best Available Techniques
BREF	Best Available Techniques Reference Document
CEFIC	European Chemical Industry Council
CEPE	European Council of the Paint, Printing Ink and Artists' Colours Industry
COLIPA	European trade association for the cosmetic, toiletry and perfumery industry
CONCAWE	Research association of European Petroleum industries CSR Chemical Safety Report
DU	Downstream user
E	Release rate = daily/annual amount of substance emitted into a single environmental compartment
ECPA	European Crop Protection Association
EFCC	European Federation for Construction Chemicals
ECHA	European Chemicals Agency
EUROMETEAUX	European Association of metals
ESIG	European Solvents Industry Group
ETRMA	European Type & Rubber Manufacturers Association
ERC	Environmental Release Category
ES	Exposure Scenario
ESD	Emission scenario document
EU TGD	European Union Technical Guidance Document on risk assessment
Fmainsource	largest fraction of registered substance, used by one single user
FEICA	Association of European Adhesives and Sealants Manufacturers FS Fact Sheet
GES	Generic exposure scenario
IR/CSA	ECHA-Guidance on Information Requirements and Chemical Safety Assessment
MT	Amount of registered substance (CEFIC guidance) [indices: total = amount of substance registered by a single legal entity, EU = total amount of substance for a single use, regional = amount of substance, used at regional scale during one year); the amount of substance corresponds to the term Q (for calculations at regional scale Q has to be multiplied with the factor 0.1 to consider equal regional distribution)

M	Consumption rate (CEFIC guidance); (Indices: use, region = consumption rate at regional scale; use, site = Consumption rate at a point source, spERC = specific consumption rate, mentioned in the spERC as default value)
OC	Operational Condition
PBT/vPvB	Persistent bioaccumulative and Toxic substances / very persistent, very bioaccumulative substances
PC	Physical-chemical
PROC	Processing Category
Q	Amount of substance according to ECHA-TGD (Indices: total = amount of substance manufactured/imported; use = amount of substance per use; regional = amount of substance, which is used in a specific region; daily = amount of substance used at a point source.
RF	Release Factors
RL	Richtlinie / Directive
RMM	Risk Management Measures
SDB	Safety Data Sheet
STP	Sewage treatment plant
spERC	Specific Environmental Release Category
SVHC	Substance of very high concern
Temission	Emission days
TEGEWA	German industry association „Verband der Hersteller von Textil- und Lederhilfsmitteln und Waschrohstoffen “
VOC	volatile organic compound

1 Introduction

1.1 Objective and framework conditions

This report describes the operational process and the results of an examination of several spERCs, carried out by Oekopol at the order of the Federal Environment Agency (UBA) between September and November 2010. This opinion does not represent a factual/functional quality assurance or any deeper-reaching scientific evaluation of the spERCs available so far. The derivations of default values as well as the assumptions regarding specific processes underpinning those spERCs were not checked on in detail. Rather, this is a **first probe** into the approach chosen by industry when deriving spERCs and completing relevant spERC Fact Sheets.

Results on the examinations of spERCs refer both to the process for working out spERCs according to the CEFIC Guidance[1], including the Fact Sheet Format, and to the questions of comprehensibility and transparency of deriving default values. Proposals are submitted to improve information contained in the Fact Sheets and their documentation. These might serve to increase both their acceptance and the applicability of spERCs.

This opinion provides hints on where work done so far may be followed and be used by the responsive experts in industry and in the authorities. But it also contains references to what aspects need to be critically challenged, and, where required, should be reworked at the level of guidance and documentation structures (CEFIC Guidance on development of spERCs / Fact Sheet Format). The different approaches by single industry sectors, which were subject to closer analysis in the examples chosen, might offer suggestions for developing spERCs in other sectors. The results of this opinion might be used for a refinement of assumptions in future.

When the examination was carried out, Fact Sheets were not available for all sectors for which spERCs are mentioned in the CEFIC overview table.[2] From several sectoral associations fact sheets were available, which were not listed in the CEFIC overview table. Numerous associations stressed that the development of spERCs was not yet concluded and will be continued. Those spERCs already published would probably have to be reworked in future.

1.2 spERCs under REACH

In the context of emission evaluations under REACH spERCs are meant to specify ERCs. They are being developed by sectoral associations on a voluntary basis, using a standardised format and considering the directions laid down in the CEFIC Guidance. Such an approach was also foreseen in the ECHA Guidelines for Chemical Safety Assessment.

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[1] Guidance on spERCs is available at CEFIC website (http://www.cefic.be/Documents/IndustrySupport/REACH%20Implementation/SPERC%20Guidance%20100707%20FINAL.pdf)

[2] This overview table may be downloaded from http://cefic.org.templates/shwPublications.asp?HID=750&T=806. The Excel file contains spERCs for the following sectors, which, however, had not published any Fact Sheets at the time this check was run (September until October 2010): cosmetics, building chemicals, glues and sealants, textiles, and plant protective agents (a background documentation was made available. This, however, did not follow the structure of the Fact Sheets).

In the context of carrying out a chemical safety assessment of substances (CSA) as well as submitting a chemical safety report (CSR), spERCs are seen as an instrument to use. By reference to both the spERC used and the documentation in the accompanying Fact Sheet, a registrant shall be able to meet his duties of documenting for a registration in those cases, where safe use was proven, thus no additional specification of assumptions will be required for the spERC. Fact Sheets, therefore should offer in a transparent way both the derivation of assumptions (such as conditions of use and risk management measures) and the derivation of standard values for the calculation of emitted quantities of a substance. This includes the description of methods and sources of information used in such a way that both registrants and the examining authorities view them as comprehensible and plausible. Should any iterative steps be required, these must be documented additionally to the reference to the spERC.

SpERCs represent one further step towards a generic exposure assessment and they are not appropriate for an evaluation of substances of very high concern ([SVHC], such as substances with PBT or vPvB properties).

SpERCs are not part of the communication within the supply chain. However, according to the instructions of the REACH regulation and of the ECHA Guidelines, information from the exposure scenario, by which the manufacturer or importer identified the safe use, must be communicated to downstream users. Specifically, this means that assumptions in the exposure scenario regarding the processes covered, the quantities of substance used, the conditions of use, as well as the required measures for risk management have to be passed on in the supply chain (see REACH, art. 31 (7), together with Appendix I, section 5.1.1, as well as the ECHA Guidelines regarding chemical safety assessment, part D and the ES format).

The emission factors, applying exactly under the operational conditions (OCs) and the risk management measures that are indicated as necessary (RMMs)[3] will usually NOT be communicated as such[4]. Therefore, the correctness of emission factors regarding to the specified conditions of use is of central importance.

1.3 Central questions for this opinion

The main subject of analyses carried out was the approach taken by industry sectors and their understanding of spERCs when developing their Fact Sheets. In addition, some selected spERCs as well as a number of specific questions from individual sectors were subject to deeper analysis. The CEFIC Guidance for development of spERCs was evaluated to consider, to what extend the instructions for developing and documenting spERCs are sufficiently precise.

This examination of spERCs was oriented on the following central questions:

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[3] In the following, this situation will be reviewed in more detail, as it is unclear in many cases, whether emission factors are related to emission before or after risk management measures

[4] Also, the communication of emission factors is not binding for specific evaluations. Of course, voluntary communication will always be possible. As a matter of principle, however, any downstream user should not (have to) re-examine emission factors, but should be able to rely on that risk evaluation applies to his use once he meets application conditions.

1. What was the reason for sectoral associations to develop a spERC?
2. What should this spERC cover? All uses, the "best eighty per cent of users", or Good Practice? How will it be ascertained that there is clarity regarding which uses / which conditions of use are covered / not covered?
3. How was the process to develop the spERCs? Who (which player from the supply chain) was involved? Which documents were evaluated? Were any specific application processes considered when working out spERCs?
4. How are the headings in the Fact Sheets understood and filled in with information?
5. Which processes are covered by the spERC, and which are not? Were specific processes considered when spERCs were worked out? Were (all) side processes considered? How were emissions from side processes considered or used for calculations of the emission factors?
6. How (by way of documents, calculations, sectoral knowledge) were assumptions made or how were values derived?
7. Does the spERC examined meet demands regarding transparent documentation of assumptions and methods for deriving values? Would this spERC be sufficient for documentation in the context of a dossier evaluation of the registrant?
8. Are values and assumption plausible and may they be tested[5]?
9. Does data on scaling make sense, and do the "adjustment factors" given make sense? Is this data sufficient for use by downstream users and was relevant scaling data entered into the ES?

Based on this examination, conclusions were drawn as regards strengths and weaknesses of spERCs tested. Such conclusions also referred to instructions by CEFIC Guidance.

[5] This did not include any detailed research regarding examinations of figures for emission values. The deviation of factors between ERCs and spERCs, however, were used as indicators for a test on both plausibility and consistency.

2 Evaluation of spERCs

2.1 General Approach

Examinatory tests were based on available Fact Sheets, which describe the range of applications and the processes covered by one or several spERCs as well as the emission factors derived. In addition, and in part, they include the reasons for such derivations. Also included in these examinations were the information documents used by industry associations as well as any additional background documents prepared and describing the approach or the methods to derive values.

The central source of information, however, were direct contacts with the members of industry associations involved in working out spERCs, as written information alone was not sufficient to run the examination. Telephone conferences were held with CEFIC's[6] spERC core team as well as individual sectoral associations working on development of spERCs (CEPE[7], ETRMA[8], ECPA[9], and EUROMETAUX[10]).

For general research on methodology, the CEFIC Guideline was analysed and compared with the approach following the ECHA Guidelines. The CEFIC Guidance includes a format for documentation in the fact sheets, as well as examples on how to fill the formats. Some of these are being varied by branches.

The following table shows the format of the Fact Sheets. Chapter 3.3.8 offers a description of the types of information included in the Fact Sheets

Table 1: Format for spERCs from CEFIC Guidance

General Information				
Title of Specific ERC				
Applicable ERC				
Responsible				
Version				
Code				
Scope				
Coverage				
	Characteristics of specific ERC		**Type of Input Information**	**Processing of Information**
Operational Conditions				
Substance Use Rate				
Days Emitting				
Environmental Parameters for Fate Calculation				
Emission Fractions (from the process)				Justification

[6] CEFIC: European Chemical Industry Council

[7] CEPE: European Council of producers and importers of paints, printing inks and artists' colours

[8] ETRMA: European Tyre and Rubber manufacturers' association

[9] ECPA: European Crop Protection Association

[10] EUROMETAUX: European Association of Metals

Air			
Water			
Soil			
Appropriate Risk Management Measures (RMM) that may be used to achieve required emission reduction			
	Type of RMM		Typical Efficiency
Air			
Water			
Narrative Description of / Justification for specific ERC			
Safe Use Communication in SDS Scaling			

As a first step, the available Fact Sheets as well as the spERCs overview table offered by CEFIC were subjected to an initial outline examination.

In a second step, experts of the various sector associations were interviewed to find out about framework conditions and their understanding of the status of spERCs. Information gathered was considered and compared to written documentation. If any question raised afterwards it was taken up directly with the members of the association involved.

Afterwards, and in a feedback process with the Federal Environment Agency, a proposal for selecting spERCs to be subject to a deeper evaluation as well as concerning matters of detail for the examination was submitted. The selection of examples was confirmed. -

Essential insights from all those steps were summarized (see chapter 4 and chapter 5). Appropriate conclusions were drawn and recommendations were derived (chaper 6).

2.2 Availability of spERCs during the project period and selected examination examples

The following table offers an overview over the documents examined and the activities conducted in the project for the different sectoral associations

Table 2: A survey of Fact Sheets available and of project activities

Association	data source	activities
CEFIC	overview table Guidance	examination of Guidance
		Telephone conference with CEFIC core team regarding the understanding of spERCs
AISE	Fact sheets	General description
	„Industrial use of water-borne processing aids“	detailed examination
	„wide dispersive use of cleaning agents“	examination of method for modification of $F_{mainsource}$
ESIG	Fact sheets	General description
	„Lubricants – Industrial (solvent –borne)“	detailed examination of example
ETRMA	Fact sheets	General description
	“Formulation and industrial use of materials resulting in inclusion on a matrix”	detailed examination derivation TIER 2 and use of A/B-tables from EU TGD for TIER 1
EUROMETAUX	Fact sheets	General description
	“Use of metals & metal compounds in coating”	detailed examination
CEPE	partially available	General description

Association	data source	activities
	"Manufacture of water-borne coatings & inks"	detailed examination comparsion with other spERCs developed for formulation processes
ECPA	spERCs table	Discussion with ECPA
FEICA	First version of Fact sheets	No examination
COLIPA	No Fact sheets	No examination
EFCC	No Fact sheets	No examination
TEGEWA	No Fact sheets	No examination
ECCA	No Fact sheets	No examination

3 General understanding of spERC concept by CEFIC

The concept and the understanding of the development approach of spERCs have been discussed with representatives of the CEFIC Core Team. The core team on spERCs consists of representatives of the following sector groups of CEFIC: A.I.S.E., CEPE, COLIPA, EFCC, ESIG (ATIEL, CONCAWE), FEICA, TEGEWA. Input was obtained from downstream users in most cases.

The members of the core team share the same understanding of the role of spERCs and the approach towards their development. Therefore, **the overall approach in the development of spERCs is the same in the different sectors represented in the CEFIC core team. However**, depending on the availability of background information, industry structure, complexities of processes or the possibility to specify spERCs based on substance groups and their properties, **there are sector specific differences in the design and reasoning for individual spERCs.**

ETRMA, EUROMETAUX and ECPA are not represented in the core team but have used the CEFIC guidance and Fact Sheet format to document their spERCs.

3.1 Concept and role of spERCs in chemical safety assessment from industries point of view

The core team stated the following intentions and roles of spERCs in exposure assessment:

1. spERCs are more specific than ERCs but still range on a generic level ("Tier 1.5")
2. spERCs will let more substances pass the safety assessment but they are still conservative and will trigger "further assessment" in many cases[11]
3. spERCs are no "static boxes" that can be implemented 1:1 "without thinking" in the emission estimate by the registrant but are meant to support the assessment by narrowing the frame of conditions[12]. Therefore it is not possible to unambiguously define which specific processes are covered by a spERC.
4. spERCs do not intend to provide "ready to use" information for DU communication. According to the CEFIC core team, it is the explicit demand towards the registrants to identify the relevant information for DU communication and respective standardization tools like the catalogue of standard phrases and other instruments are still under development.
5. spERCs rather narrow the assessment conditions by detailing emission factors according to the substance properties (vapour pressure, water solubility) and the sizes of enterprises (related to the efficiency of raw materials use and hence the assumed "losses" in the processes) than by specifying operational conditions in terms of specific processes, operating times or temperatures etc.

[11] The associations haven't assessed which number of substances would „pass" an assessment with a spERC in comparison to an ERC. They expect that in many cases registrants using spERCs will still have to iterate their assessment by introducing risk management measures in order to document safe use.

[12] In the past, spERCs have been discussed as defining more specific conditions of use than an ERC. This expectation of authorities and other actors is not met and will result in difficulties for authorities and downstream users to decide whether or not a process is covered or not and which particular activities are taken into account (e.g. cleaning).

6. The binding information in a spERC Fact Sheet is contained in the "middle part" and comprises the headings "operational conditions[13]", "substance use rate", "days emitting" and "environmental parameters for fate calculation". If these conditions are fulfilled, the emission factors specified are valid.
7. The current version of the spERCs and the Fact Sheets are work in progress. There is a lot of information available on different issues relevant for emission estimation but it requires time and resources to bring it together for further refining spERCs[14].

The above overall approach and understanding of spERCs is in principle shared also by the sectors that are not part of the core team of CEFIC and which have been interviewed during the project. In addition, some sectors have developed further tools to support registrants and downstream users (e.g. generic exposure scenarios and scaling tool by ETRMA), in addition to the spERCs.

3.2 Consequences of industry's understanding of spERCs

The consultants observe that the general perception and expectation towards spERCs both by industries not involved in the spERC development as well as in authorities and by other actors differ from the above outlined understanding of the concept and the role of spERCs in chemical safety assessment with regard to two fundamental issues. These actors expect that:

1. spERCs are "ready to use models" for emission estimation which can be easily and unambiguously assigned to specific industrial processes.
2. clearly highlight which information, in particular regarding the operational conditions of use, should be communicated downstream.

It is important that all actors - the registrants using spERCs in exposure assessment, the authorities discussing content and documentation of spERCs regarding compliance with REACH requirements for CSRs and DUs using spERCs and Fact Sheets when receiving and checking compliance of their conditions of use – keep in mind the explicit different intention and scope of spERCs that is stated by the CEFIC core team and the associations having published their fact sheets.

3.3 Development process of spERCs by industry

The following description of the development process of spERCs applies – with slight modification – to all sector associations of the CEFIC core team; i.e. in the context of this report

[13] As discussed also in the later sections of this report, the information in the section operational conditions is not very specific and normally does not enable a direct comparison between spERC information and the processing conditions at DU site. Nevertheless are these conditions regarded as "binding". How they are specified by the registrant in the DU communication (and the CSR in case of refinements or iterations of the conditions of the spERC), is the decision of the individual registrant.

[14] The version number of a spERC is very important in the light of further development of the spERC Fact Sheets in order to enable authorities to check compliance with the used information and derived default values. Therefore, all versions of Fact Sheets need to be available at all times and the version numbers are essential references in the registration dossier and DU communication.

to A.I.S.E., CEPE and ESIG. Eurometaux, ETRMA and ECPA have also followed the outlined process. Some examples of the approaches are mentioned in this section.

3.3.1 Definition of generic processes underlying the spERC

According to the core team, a spERC is the description of a generic process. The CEFIC guidance does not specify how these generic processes should be established. In practice, the different sector groups have chosen similar and iterative approaches to defining generic processes:

Experts of the sector associations have listed the main and relevant activities along the supply chain and listed the pertaining processes in their own member companies and of downstream users. Information from the use mapping and discussions with DU associations and individual companies has sometimes been used as well. Based on this, the experts have discussed which processes could be grouped because the emission characteristics are similar. Finally the processes have been given a title. In most cases the discussions and decision basis is not documented and published in the fact sheets but is sometimes part of other background documentation (e.g. CEPE).

Based on the lists of main processes the sections “title”, “scope”, “coverage”, “narrative description” were filled, further detailing information on the processes covered. The level of detail in documenting the coverage of process steps, side activities or e.g. cleaning and maintenance differs across the spERCs have been assessed.

ECPA has assessed which aspects of the use of crop protection products are not normally covered under plant protection legislation and would therefore require support under REACH. They identified two scenarios that should be used to assess exposures of “man via the environment” and “secondary poisoning”.

ETRMA has not discussed and defined specific operational conditions for their processes but their spERCs address the entire rubber processing plant “as such” and distinguishes between large and small installations and installations having water pre-treatment on site. This is due to the fact that the release factors have been developed from the perspective of emissions “from sites”. In addition, a generic exposure scenario, which contains detailed information on processing steps, operational conditions and their exposure relevance, exists. The two tools – generic exposure scenario and spERC – are not connected, because the definition of specific conditions of use within the conditions of the spERC is seen as task of the registrant that should not be standardized in the fact sheets.

EUROMETAUX followed an approach corresponding to EU risk assessment practices consisting of viewing at installations at a whole without differentiating between processes. Hence, the development of spERCs started from “generic installations“ and used integrated emission factors (integrated over the entire plant and including RMMs).

3.3.2 Derivation of operational conditions

The CEFIC core team and the other sector associations[15] did not intend to define specific operational conditions that bind the downstream users in their way of processing. In most

[15] ETRMA, EUROMETAUX and ECPA

cases, the information in this section is rather general and either relates to the descriptions of PROCs or the initial conditions of the ERC (open/closed process, wet/dry etc.).

Types of entries narrowing the scope of the operational conditions are:

1. differentiating by the used amounts (CEPE): the associations assume that larger companies more efficiently use raw materials or have better risk management measures in place than SMEs[16]
2. existence of pre-treatment (ETRMA)
3. types of products or processes (e.g. ESIG: solvent based; A.I.S.E. water borne)
4. main emission pathways, in particular for spERCs on wide dispersive uses (A.I.S.E. volatility and emission to water)

The above listed variations either narrow down the conditions described in the ERC or define sub-spERCs. Some of them can be very easily applied, e.g. the differentiation between a solvent based product. Some of them however lack concrete details to compare with, for example when differentiations are made based on the high efficient use of raw materials but no specification of "efficient use" is given. Specification of "efficient use" could consist in providing the percentage of raw materials ending up in the products or in a specific description of operational conditions and risk management measures to be in place.

3.3.3 Derivation of defaults for M_{spERC}, $T_{emission}$, the safety factor for wide dispersive uses and environmental fate parameters

The CEFIC guidance does not provide any methods for deriving the listed default values but explains how they are related according to the equations of the ECHA guidance.

The substance use rates (M_{spERC}) are specified by most sectors (except EUROMETAUX) based on sector knowledge and given either as fixed values or as variable parameter. In the latter cases (A.I.S.E, CEPE, ETRMA) equations are provided to derive M_{spERC}. The CEPE approach for example allows registrants to calculate M_{spERC} based on the production volume of their clients and the concentration of the substance in the products.

The emission days ($T_{emission}$) are either not specified (some spERCs of ESIG) or given as fixed values. They are always derived from sector knowledge.

The fraction of products used in a region is modified e.g. by A.I.S.E. In the fact sheet, a detailed description of the method of identifying the used amount in a region is given based on data on market penetration of household chemicals and reference made to recent studies and related methodological approaches. A.I.S.E. furthermore has refined the safety factor for assessing wide dispersive uses.

Sector knowledge is either derived from literature, such as BREFs or related to surveys among member companies of the associations. References to the information sources are provided in the fact sheets directly with the respective values or are quoted in an Annex to the fact sheets.

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[16] The better risk management practices or technologies assumed in larger companies create difficulties and confusion on whether or not the emission factors relate to the release from the process only (before RMM) or include the use of RMMs (release from plant). This is also a matter of defining the differences of RMMs and OCs. The issue is further elaborated and discussed in the following sections.

The values M_{spERC} and $T_{emission}$ are documented via the spERC in the CSR and are relevant for the identification of safe use. They should both be communicated as binding conditions of use to the downstream user and need to be checked in order to determine whether DU complies or not. Scaling equations providing rules to check compliance are based on the used amounts and emission days by DU[17] in most Fact Sheets assessed.

The environmental fate parameters are not changed in any of the spERCs but are adopted from the ECHA guidance.

3.3.4 Derivation of release factors

The release factors (RF) of the ERCs are refined in most of the spERCs for water and air. Factors for releases to soil are frequently not changed.

Refined RFs are based on literature information (mostly use of ESDs and EU TGD as well as risk assessment reports), on qualitative argumentation (substance properties, operational conditions) or on data from surveys or measurement campaigns conducted by the associations (ETRMA, EUROMETAUX). In some cases, the associations (e.g. ETRMA) have checked whether the release factors given in literature are valid by comparing with sector knowledge, risk assessment reports etc. Other sector associations have not conducted an assessment of applicability of the default values. Assessments of literature information are documented only in the case of ETRMA.

None of the associations has stated to have checked in detail whether and to which extent risk management measures are integrated in release factors of ESDs or A/B-tables and in how far this fits the conditions described in the spERC fact sheet. The default values have been discussed and agreed among experts at EU level and are systematically addressing "plants as such"; hence they can be regarded as integrating a certain level of risk management on-site; however also here no specific information on what was assumed is available. Hence, the use of these factors, although being accepted at EU level and most likely being very conservative, leaves it to the registrant to decide whether or not he must recommend risk management measures as obligatory and if yes, which measures these should be and which efficiency they should have.

The release factors of ERCs are all either > 0 or are stated as not applicable, because they regard wide dispersive uses. In the spERCs, some release factors have been set to the value of "0". Industry interprets this as "mathematical translation" of irrelevant or insignificant emissions rather than a scientific statement of zero emission. Argumentation for assigning the value "0" to release factors to soil is not provided by any of the associations. Argumentation for assigning the value of "0" to release factors to water and air is, if provided at all, based on the physico-chemical properties of the substances in relation to the processing conditions (e.g. no emissions to air of metals in water based processing aids used at low energy conditions and excluding spray applications).

[17] Consequently, risks could only remain undetected in case DUs have different use amounts / emission days than communicated and are not obliged to take action, because he is (they are) exempted from the conduction of a DU CSR (c.f. REACH article 37.4).

3.3.5 Risk management measures

It is not always clear or explicitly stated in the fact sheets whether the release factors to air, water and soil apply before or after risk management measures; hence it is not always evident if the efficiency of RMMs is included in the release factor or not. Although in the general understanding, the release factors apply BEFORE risk management measures, this is not the case for all of the spERCs.

The risk management measures are described in the last section of the fact sheet in different ways:

- no measures are described at all; this is logical for wide dispersive (consumer) uses and is intended for some industrial uses, e.g. by ETRMA, which provides more specific information on RMMs in their separate generic exposure scenarios independent of the spERCs and Fact Sheets
- measures are described as “possible additional options” with or without specification of their efficiency; this is intended as first support to the registrant for iterating his assessment in case safe use is not ensured with the standard conditions. As these conditions are not part of the emission estimation (RF relate to emissions before RMMs), the registrant is required to identify the appropriate measures, identify their (necessary) efficiency and document both in the CSR and in the communication with DUs, as stated in the section on "communication with the safety data sheet" of the fact sheets. In these cases, no RMM were integrated in the release factors derivation.
- Measures are described as a binding condition for being covered by the spERC; this is the case e.g. in the fact sheets of EUROMETAUX. As the release factors integrate the use of RMMs (explicitly stated as applying including RMMs) a specification of efficiency is necessary for compliance checking.

In some fact sheets reference is made to the CEFIC RMM-library which lists for several risk management measures the associated efficacy.

3.3.6 Safe use: communication with the safety data sheet

In the examined fact sheets of CEFIC sector groups, a fairly standardized text is included in this section, stressing that the registrant has to define the set of conditions to be documented in the CSR and communicated to DU. In doing so he may adopt information from the spERC and must include any additional information or assumptions made in his assessment and possible iteration of RMMs. EUROMETAUX does not include specific information on DU communication in this section and ETRMA also stresses communication as task of the registrant that is not provided in the fact sheets.

3.3.7 Safe use: scaling

Information on scaling is standardized in the spERCs fact sheets of the sector groups of CEFIC as well. A general equation for scaling is given in the fact sheets based on the CEFIC guidance and it is explained which values DU need to check compliance. The parameters needed for scaling are in all cases the used amounts, the efficiency of risk management measures, the effluent volume from the sewage treatment plant (STP) and the dilution volume in the receiving surface water.

The release factors are included in the scaling options only by A.I.S.E. All other sectors either explicitly state for their spERCs that modifications of the release factors are part of a DU CSR and are not supported by the scaling rules. EUROMETAUX does not provide scaling rules and ETRMA has developed a separate excel – tool for scaling operations, which is referenced in the fact sheet.

3.3.8 Summary of information in the fact sheets

The following table complies and presents the information explained in the previous chapters in a summarizing manner in the format of the fact sheets.

Table 3: Types of information that is presented in the fact sheets by the different sectors

<table>
<tr><td colspan="5">General Information</td></tr>
<tr><td>Title of specific ERC</td><td colspan="4">Title spERC</td></tr>
<tr><td>Applicable ERC</td><td colspan="4">Reference to the ERC to which the spERC relates. In some cases, more than one ERC is specified.</td></tr>
<tr><td>Responsible</td><td colspan="4">Sector association which has developed the spERC. The information is not provided in all fact sheets.</td></tr>
<tr><td>Version</td><td colspan="4">Number of the version of the fact sheet</td></tr>
<tr><td>Code</td><td colspan="4">Short title and description of spERCs which are covered by the fact sheet. The information is not provided in all fact sheets.
The code is structured: 1st digit= ERC; 2nd digit = number of spERC, a/s… = differentiation within spERCs; vx = version number</td></tr>
<tr><td>Scope</td><td colspan="4">Description of covered processes. Partly shorter, partly longer than title. Frequently limitations by specifying substances covered or the size of installations. Few limitations relate to specifications of processes.</td></tr>
<tr><td>Coverage</td><td colspan="4">Listing of uses, frequently by making reference to PROCs in order to enable the registrant to connect the ES with his use mapping.
Eurometaux provides in this section information on the representativity of background data which has been used to derive release factors related to metals compounds.</td></tr>
<tr><td></td><td colspan="2">Characteristics of specific ERC</td><td>Type of Input Information</td><td>Processing of Information</td></tr>
<tr><td>Operational Conditions</td><td rowspan="4">Differentiations are made in case more than one spERC is described</td><td>Quotation of the characterization of ERCs, general descriptions using the EU phrase catalogue or provision of efficiencies of processes / size of installations</td><td rowspan="4">Quotation of information source / method of deriving values
a) Reference to ECHA defaults
b) EU TGD (A and B-Tables), ESDs
c)sector knowledge or expert decision without further documentation
d) own studies or surveys</td><td rowspan="4">Information if data can be used as it is or needs to be processed. Frequently not used or deleted from format.</td></tr>
<tr><td>Substance Use Rate</td><td>Maximum used amount in a typical process (M_{SPERC} kg/d)
Some FS don’t contain an MspERC. The values are derived in different ways, always based on sector knowledge</td></tr>
<tr><td>Days Emitting</td><td>Emission days (days/year)
Either according to ECHA guidance or derived from sector knowledge.</td></tr>
<tr><td>Environmental Parameters for Fate Calculation</td><td>In all cases defaults of ECHA guidance are used.</td></tr>
<tr><td colspan="3">Emission Fractions (from the process)</td><td></td><td>Justification</td></tr>
<tr><td>Air</td><td colspan="2" rowspan="3">Frequently it is not clear if release factors actually apply before or after RMMs.
Those conditions of use that determine the values of the release rates cannot be identified from the fact sheet section describing the OCs.
Partly the values and the reasoning for the values are not differentiated sufficiently.</td><td>Value %</td><td rowspan="3">Reasoning and information sources</td></tr>
<tr><td>Water</td><td>Value %</td></tr>
<tr><td>Soil</td><td>Value %</td></tr>
</table>

Appropriate Risk Management Measures (RMM) that may be used to achieve required emission reduction		
	Type of RMM	Typical Efficiency
Air **Water**	In many cases it is not fully clear if the RMMs are to be implemented because their use is assumed in the release factors of if the RMMs are included to support the registrant in iterating his assessment. In case release factors apply explicitly AFTER RMM: Information on minimum efficiency of RMMs (e.g. ETRMA) and list of possible measures (not connected to values). In cases release factors apply explicitly BEFORE RMM: RMMs are understood as information for iteration (not integrated in the emission factors but to be used by the registrant for identifying measures) that consists of lists of possible measures which are not connected to concrete efficiencies. Partly there are references to the CEFIC library, some fact sheets don't contain information at all (e.g. for wide dispersive use)	
Narrative Description of / Justification for specific ERC	In most cases another description of processes. Partly emphasizing the efficiency of resource use (e.g. CEPE, ETRMA). More references to information sources.	
Safe Use Communi-cation in SDS	SpERCs developed by sectors that are members of the CEFIC core team have included relatively standardized text, emphasizing that the registrant is to develop a set of conditions of use. In doing so the registrant may adapt the conditions of use of the spERC and provided information on the extent and efficiencies of risk management measures, if these are necessary to ensure safe use. It is indicated that in the CSR and DU communication reference can be made to the information in the fact sheet and that specific RMMs are to be described separately. In the spERCs of Eurometaux no information is given on communication; ETRMA describes that the development of information is the task of the registrant and also does not provide respective support.	
Scaling	The spERCs of the sector associations of the CEFIc core team more or less contain standardized texts on scaling including one or more equations for compliance check with the conditions of the ERC $[M_{sperc} X (1-RE_{total,spERC})]/(G_{eff,spERC} X q_{spERC}) \geq [M_{site} X (1-RE_{total,site})]/[G_{eff,site} X q_{site})$ M (sperc/site) = use amount in spERC / of DU RE_{total} (spERC/site) = efficiency of RMM on-site and off-site acc. spERC / DU G_{eff} (spERC/site) = amount of water in STP acc. spERC / DU q_{spERC} = dilution volume in surface water acc. spERC / DU A.I.S.E. allows to also change the release factors; CEPE and ESIG see this as part of a DU CSR. EUROMETAUX does not provide support for scaling and ETRMA makes reference to its respective instrument (Excel-Table).	

4 General observations and conclusions

The following observations relate to issues and challenges that are discovered in all or in the majority of fact sheets. The issues discussed concern the development approaches and the general understanding of spERCs by the sector associations. Besides that specific issues and challenges related to items that should be included in the fact sheets are discussed in the following. Some observations and conclusions on specific approaches and aspects are described in Section 5 where observations from the evaluation of examples are described.

4.1 Expectations to spERCs and the role of spERCs

The general expectations towards spERCs and the level of detail provided in the fact sheets don't match the understanding and intention expressed by CEFIC and its sector organizations at present (c.f. Section 3). It is generally expected that:

- spERCs are narrower in scope than the majority of the currently existing spERCs,
- the operational conditions of use are described in more detail and hence are directly comparable to actual processes at DU
- specific information on appropriate risk management measures including their respective efficiency are provided and that
- support regarding the communication down the supply chain is given in the fact sheets.

In addition, authorities and other actors expect a higher degree of transparency in the derivation of the default values and the documentation of methods and information sources as currently observed in the fact sheets.

It is important that CEFIC and the sector associations clearly communicate their understanding of spERCs, explain their approaches and process of derivation of spERCs and define in what situations spERCs can be used. For example it should be clarified to authorities and other actors that it is not intended to unambiguously define the coverage of a spERC but only to give respective indications. Registrants should be made aware of the fact that they are responsible for defining more specific conditions of use and will not get "ready to use" DU communication instruments. The sector organizations are aware that the current state of fact sheets should be revised and stated that related feedback is welcome.

4.2 Information on processes in the fact sheets

In all of the examined fact sheets the descriptions of covered processes in the different sections "title of spERC", "applicable ERC", "spERC code", "scope", "coverage", "narrative description", and "safe use" are ambiguous. The information of the coverage sometimes is redundant, is provided in different forms and words and is split between the beginning and the end of the fact sheet. The different ways of providing information on processes under the different headings frequently causes confusion, as the information is doubled, not always consistent and sometimes even contradicting. The sectors have partly provided information in different formats in the same sections (e.g. free text information and PROCs in the section "coverage").

CEFIC should consider restructuring the fact sheet format and providing more detailed information on which information to include in the different sections. One possible option to

make the sections relating to the coverage of the spERC consistent and comprehensible is provided in Section 6, Table 4.

4.3 Coverage of uses

Although real processes were kept in mind in the definition of generic processes underlying a spERC (c.f. Section 3.3.1) this is in most cases not illustrated and documented in detail (e.g. in form of operational conditions and specific descriptions of processes or processing conditions or exemption of specific processes) in the fact sheets or in other background documents[18]. Such information would be very helpful for registrants to better understand whether the process they intend to assess with the spERC is covered (including side activities and cleaning). This information is regarded as essential for evaluation processes by authorities. Hence, respective documentation should be provided on how assumptions are justified and which processes are covered in a transparent manner for those, who need to work with the spERCs in more detail.

Recurring to the list of PROCs is helpful, as it connects to the use descriptor system, which should be familiar to all REACH actors by now and which has been used already in use mapping and other tasks of registration. It should be ensured that the references are up to date.

4.4 Operational conditions

The information provided in the section “operational conditions" is in many cases not more specific than the general characteristics of the ERCs, which corresponds to the intention of spERCs as stated by CEFIC and its sector groups. In some cases, specifications are introduced using terms such as “optimized processing conditions” but which are not further defined.

The lack of detailed conditions of use makes it difficult for authorities and registrants to understand and check the reasonability of emission factors in the fact sheets and for DUs to decide whether or not their conditions of use are covered (provided the operational conditions are not further specified by the registrants in their DU communication). This is particularly important for the registrants who should define a “set of conditions of use” for which it is ensured that they are covered by the operational conditions of the fact sheet.

The conditions of use are an essential element of the emission estimate and the DU communication. At present, the way conditions of use are specified is not sufficient to allow checking the plausibility of emission factors. If literature values are quoted, it is not possible to compare the conditions of use under which release factors are defined in literature with the conditions defined in the spERC. If release factors are derived by other methods, it cannot be determined if all possible processes covered by the spERC would show emissions below the established factors.

In the short term it could be an option to explicitly exclude processes or conditions from the scope, of which it is known that they are not covered by the spERC. In the longer term, a common understanding of core information needed by registrants for selecting a spERC, by authorities for checking plausibility and by DUs for determining coverage of their processes should be developed. This specific information could be collected in the sectors and the

[18] Some associations, like ETRMA and CEPE provide information on the processes by reference to background documents or tools on their websites.

feedback from downstream users to the conditions described in real exposure scenarios. Based on this sector knowledge and actual experience with ESs, this spERC section could be improved. With view to the near registration deadline, these activities are not likely to begin before next year. In order to be able to learn from the first registration phase, an evaluation of information submitted to assess uses could inform that work.

4.5 Default values for substance use rates and emission days

Almost all sectors have provided information on emission days and specific substance use rates in the spERC fact sheets. Both parameters significantly influence the outcome of the local safety assessment as they determine the input amount of substance to a point source. If the registrant calculates with unrealistic assumptions the resulting emission rate would be lower as actually occurring at point sources. Hence, the situation in the CSR would not reflect the reality. In addition, DUs would have to apply the scaling rules in their compliance checking and may identify risks, in case e.g. the use amounts are higher than assumed. This would lead to the need for DU CSRs.

As the safety assessment should ensure that risks are identified by the registrants (and not the downstream users) and the responsibility for identifying RMMs should be on the registrant, the assumption of realistic input amounts to point sources is within the intention of REACH.

The refinement of the values for substance use rates and emission days is in most of the cases based on sector knowledge but the methods and information basis is not always documented and provided in a transparent way. It is assumed that sector associations have used the best information and judgment available; however, plausibility checking is not always possible due to the lack of underlying data or information sources.

4.6 Default values of release factors

4.6.1 Scope of release factors

In the CEFIC guidance and the fact sheet format it is explained that the release factors describe the initial release from the process (before application of risk management measures). However, in some spERCs the release factors apply only under the condition that RMMs are in place (e.g. EUROMETAUX) and in other cases it is not clear if RMMs are included or not (e.g. ETRMA where the method and information suggests that RMMs are integrated but the fact sheets only state that the factors apply before municipal wastewater treatment).

It would be optimal if the release factors to air, water and soil would always relate to the emission before RMMs, as this would provide for a direct relationship between release factor and operational conditions, enable the registrant to iterate the assessment only on the side of risk management measures and avoid any misunderstandings of how the factors should be understood.

Due to the different ways of deriving the release factors this seems not always possible and it should therefore be

- explicitly stated in the row title (RF_{air}, RF_{water}, RF_{soil}) if the RFs include the use of RMMs and
- if the factors include the use of RMMs, the measures which hereby become a binding condition for DU communication should be included in the fact sheet section on operational conditions. They should be listed to a degree of detail that the registrant is

aware[19] of what to communicate to the downstream users and the downstream user is able to adapt the operational conditions to his situation in case of scaling. Besides that the risk of including a risk management measure twice in the emission estimation could be avoided. Alternatively a new row could be inserted in the fact sheet with the row title "obligatory RMMs", in order to work with the current definitions of terms in the ECHA guidance.

This should be explained in more detail in the CEFIC guidance and should be reviewed by all associations that have already presented spERC fact sheets.

4.6.2 Release factors from literature

Many release factors used in the fact sheets have been derived from existing literature, namely the TGD and the OECD ESDs. This approach is useful and regarded as valid in principle; however, in most cases neither the TGD nor the ESDs specify the operational conditions underlying the emission factors and it is frequently not clear, if they integrate the use of risk management measures.

In order to decide whether or not the values are applicable, they should be compared with the scope and operational conditions of the spERC and compared with other available information, if possible. ETRMA for example checked the ESD values using BREFs, existing risk assessment reports and own measured data, concluded on the applicability of values and documented the procedure and results in their background information to the spERCs.

The associations using existing values for release factors in their spERCs should make an assessment of applicability of information and document their considerations for the sake of transparency. This could also contribute to getting a better feeling for the degree of conservatism of the values and the chances of decreasing the default value by collecting own information in the future.

4.6.3 Release factors based on survey information

EUROMETAUX and ETRMA have collect data on input amounts and emissions from companies in their sector and used it to derive release factors. Although it was not possible to check the background studies and the information collection and processing in detail due to resource constraints of the project, the overall approach is evaluated as useful, and providing a good basis for deriving release factors. But using monitoring data for the derivation of release factors always require an evaluation of the applicability of the data to the situation / processes covered with the spERC.

EUROMETAUX and ETRMA, obtained information on the state of the art risk management measures (because they are to be implemented because the release factors apply AFTER onsite RMM) and a rough appraisal of what percentage of companies would be covered by the conditions of the spERC in their survey for deriving release factors.

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[19] If the efficiency of the measures and the total release factor are known either the release factors before risk management measures could be calculated and the two factors given separately in the fact sheet, indicating that RMMs are a condition for safe use or the efficiencies could be provide in relation to the possible RMMs identified in the section of operational conditions.

4.6.4 Values of "0"

In many spERCs, the release factors to soil, but also some release factors to air and water are set to "0". The lowest release factors of the ERCs in the ECHA guidance R16 are to soil: 0.01% (ERC 1 and 2), to air: 0.05% (ERC 11a) and to water: 0.005% (ERC 6d). For wide dispersive uses, release factors to soil are not applicable.

The approach to assigning the value of "0" to release factors relating to emission pathways which are "insignificant" is in principle regarded as valid by the consultants. However, reasoning should be given and it should be made transparent why an emission is regarded as insignificant.

The argumentation should not be based on exposure considerations but relate to the negligibility of emissions, in order to be systematically consistent (spERCs as part of emission estimation and not as part of exposure assessment). This argumentation is important for the registrant to ensure that the processes he aims to assess are covered by the spERC, in particular because the operational conditions are rather openly worded.

4.6.5 Justification of release factors

It should be transparently documented how the release factors were derived. If possible all related information, e.g. any equations used or assumptions made, all information sources evaluated as well as any considerations of expert judgment or qualitative arguments should be included in the fact sheet. If information is too extensive, separate background documentation is advisable. A clear link to the specific documents should be provided in the fact sheet.

If background information consists of references to other documents, this could be directly included in the section "justification" of the release factors. If more information is necessary to explain the background of the factors, it should be included in an Annex to the fact sheet and a reference to that should be included in the section "justification". In any case should the justification be clearly separated from the default values in order to avoid misunderstandings[20].

4.7 Risk management measures

The information on risk management measures differs in level of detail and form across the sectors and hence different levels of support are provided to the registrant.

If the release factors apply under the condition that RMMs are implemented, it is suggested to include that information in the section "operational conditions" or an additional section "obligatory RMMs" (c.f. Section 4.6.1). As a consequence it would be structurally clear that the section "risk management measures" includes information that supports the registrant in iterating his assessment in case risks are identified by providing starting information on which RMMs could be recommended and which efficiencies of risk reduction could be achieved.

Considering that registrants might be not well aware of risk management measures applied at the end of the supply chain in industrial end-uses of substances and mixtures, it is regarded as valuable input information for the registrant if in the spERCs more specific RMMs with average efficiencies are suggested. In the future it may be possible to either refine the information in

[20] In the fact sheet by EUROMETAUX for example, the average emissions of the sector are quoted next to the release factor of the spERC in the fact sheet. Here, the average emissions could be mistaken for a release factor.

the CEFIC library with more specific information or to develop sector specific lists of risk management measures to support both registrants and downstream users (who may select measures in order to meet a given efficacy of emission reduction).

If the registrant iterates the assessment by adding risk management measures to his emission estimation, he should be aware that this has to be documented in the CSR and communicated to DU in addition to reference to the spERC.

4.8 Downstream communication

4.8.1 Information in the safety data sheet

As stated in the beginning, it is not the intention of spERCs and its fact sheets to provide standardized information for DU communication. However, it may be useful if CEFIC revises the guidance section on DU communication. The following is recommended:

- Separating the description of documentation needs from the communication needs to DUs
- Identifying which information from the fact sheets could be quoted for DU communication and which should be further specified (e.g. operational conditions)
- Identifying which information is necessary for compliance checking (OCs and RMMs) and which can be provided in addition (release factors).

The text blocks explaining the obligations of the registrant in relation to the CSR and DU communication should not be part of the fact sheet but discussed in the CEFIC guidance, if possible (c.f. for example fact sheets of A.I.S.E or CEPE).

4.8.2 Scaling

Up to now the scaling rules and equations provided in the examined fact sheets are similar and provide modification of the same parameters. This is an indication that general guidance on scaling could be provided by CEFIC on how to communicate scaling rules to downstream users. This way the registrants could refer directly to the CEFIC guidance and the fact sheets could be significantly shortened by including a respective reference.

5 Observations from the evaluation of examples

5.1 Clarity on the application of on-site RMMs

The most significant issues discovered in the overall assessment of spERCs development and documentation as well as in the detailed assessments of the examples are the difficulties and intransparencies related to the inclusion of risk management measures in the release factors of the spERCs.

In the majority of the assessed fact sheets it is not fully clear whether or not on-site risk management measures are to be implemented in order to achieve the emission factor specified in the fact sheet. The uncertainties result from the following

- On-site risk management measures are sometimes mentioned in the description of spERCs (e.g. ETRMA classification of small sites with or without pre-treatment) but are not found explicitly in the description of operational conditions, release factors or risk management measures
- The operational conditions are not clearly described (in the relevant section or other sections of the fact sheet)
- The emission factors are in almost all cases given without specification if they apply before or after RMMs.
- The information sources of release factors suggest that RMMs are integrated in the factors, but this is frequently not explicitly described. If it is mentioned, the type and efficiency of on-site treatment is not given.
- The section RMMs is headed: RMMs that may be applied, which is interpreted as support for iterating an assessment but not detailing RMMs that are obligatory due to the applied emission factors.

Clarification of this issue is of highest priority at all levels, as it contributes significantly to

- Misunderstanding or wrongly using the application of the emission factors (registrants),
- Lack of understandability and possibility to evaluate the appropriateness of release factors (registrants, authorities) and
- Lack of certainty which conditions of use have to be communicate downstream

5.2 Coverage and scope – operational conditions

In the evaluation of examples of spERCs fact sheets from different sectors the initial assumption was confirmed that the spERCs define rather broad processes or uses. This corresponds to the understanding of the sectors that it is not possible or not intended to provide a precise and unambiguous description of uses in the spERCs fact sheets.

The operational conditions of use are hardly more specific than for the ERCs and the main modification is limiting either the company sizes or the types of products that are covered by a spERC.

The general expectation towards spERCs was that in particular the operational conditions, which are communicated along the supply chain to enable the downstream user to check

compliance with the risk assessment, would be worded more precise. CEFIC and the sector associations should consider ways of implementing more precise operational conditions in the spERCs fact sheet in order to facilitate standardization to a higher degree and support registrants better in "defining a set of conditions", as stated in the section on safe use in many fact sheets.

5.3 Derivation of emission factors for water by ETRMA

ETRMA has documented how they have checked the emission factors of the A-Tables of the TGD (2003) and the OECD ESDs by explaining the review process and naming documents and information used to assess the correctness and applicability of value. They have documented the outcome of the evaluation in a transparent way. It is regarded as a good practice example in spERC development and transparent documentation.

ETRMA has derived the emission factors to water based on a survey in the sector. In a background document the following information of the survey is documented in a transparent and structured manner: the work process of the survey, the number of participating installations, the methods of data-evaluation and the methods / calculation for deriving emission factors. Although not all information could be evaluated during the project, the overall impression is that a scientifically sound approach had been chosen and a transparent documentation is provided. It is seen as a good way of deriving emission factors in lack of better information by a sector.

5.4 Factors for the assessment of wide dispersive uses

For some spERCs A.I.S.E. has derived values for the distribution of their products in the region ($F_{prod,region}$), based on information on the use rates of products by consumers and the average population in a region. The method of derivation of the factor is described in the fact sheet[21] and specific reference is made to the documentation of the methodology and underlying data base.

In addition, the safety factor for deriving the fraction at main source for wide dispersive uses has been set to "1.5" instead of "4". The ECHA guidance explicitly mentions the possibility to do so, but also mentions that good justification is needed. This justification is missing in the fact sheet but was provided by the experts: Based on measurements it was shown that under worst case conditions an STP would as a maximum receive 1.5 times the average amount of a substance contained in home care products. This is used as justification for the lower factor.

The process chosen by A.I.S.E. of collecting information on market penetration and derive use amounts for the region are evaluated as viable, although not detailed assessment of data could be performed. In reducing the safety factor it should be ensured that the factors are applicable to the region where the product is used (if this is not limited, this means across all Europe) and that data from monitoring and measurements have to be appropriate for the assessed use.

[21] The underlying survey on use of products as well as details on the market penetration could not be evaluated during the project due to resource constraints.

6 Recommendations

From our evaluation of the CEFIC spERC guidance, spERC development approaches from the sectors A.I.S.E., CEPE, ESIG, ECPA, EUROMETAUX and ETRMA and detailed spERC fact sheets it can be concluded that a lot of effort has been invested by industry to provide support for registrants in estimating emissions from the use of their substances. Whereas some actors may be disappointed of the level of detail provided in the current available spERCs fact sheets, it should be acknowledged that in many cases a substantial specification of the scopes of ERCs and related decreases of release factors has been achieved and that - as many other processes under REACH - the development of spERCs is a continuous learning and improvement process; hence, the current recommendations and proposals are hopefully taken up in future revisions and new development work of spERCs.

Recommendations to CEFIC and the guidance on spERCs development

CEFIC should start clearly communicating its understanding of the concept and role of spERCs and communicate what spERCs are used for: generic emission estimation ("Tier 1.5"). Communication should prevent future misunderstandings and enable better understanding of how to use spERCs in registration as well as how to view them in compliance checking.

The main focus of attention in any revision of fact sheets or in recommendations by CEFIC to its member associations should relate to the transparent and clear communication of the relationship between the operational conditions and the risk management measures. It is necessary to distinguish between risk management measures that are precondition for applying the release factors of the spERCs and those, which are mentioned as possibilities for iterating the assessment by including additional measures.

The following table summarizes the recommendations related to the fact sheet format and its content. The issues discussed in relation to the fact sheet format and a respective revision of the overall structure of fact sheets as shown in the following table and discussed in sections 4.2, 4.6.1, 4.7 and 4.8 should be discussed by the CEFIC core team and implemented, if regarded helpful. In addition, it is recommended to provide more guidance on which type of information at which level of detail should be included in the fact sheets.

Table 4: Proposal for restructuring information in the Fact Sheets

Section	Content	Comment / reasons
Title of spERC	short title of spERC	
spERC code	Structured Code of spERCs (e.g. A.I.S.E. 8a.1a.v1)	Code identifies: responsible sector association (e.g. A.I.S.E.); ERC that is specified (8a); spERC number (1a) and version number (v1)
Responsible	Could be omitted	Information part of code
Applicable ERC	Could be omitted	Information part of code
Version	Could be omitted	Information part of code
Scope	Limitations of coverage compared to ERC relate to: • User groups (if not already obvious from Title) • Substance groups or functions (e.g. solvents, additives) • Types of products (e.g. coatings, water borne mixtures) • Size of installations (e.g. defined by use amounts) • Processing conditions (e.g. dry processing, no high temperatures) Conditions or processes explicitly not covered	Repetition of information in the title is avoided. It is made obvious in which way the spERC is more specific than the ERC. This enables registrants, authorities and other actors to get a better feeling for the coverage. For many spERCs it was stated by the sector associations that their spERCs don't cover all downstream users / processes. It would be helpful to explicitly list conditions of use or other related information to enable the user of spERCs to check if their uses are covered and to enable them to easily identify the non-covered uses. The registrants could include this information in their DU communication.
Related use descriptors	SU, PCs, PROCs or ACs if relevant	Section title replaces the title "coverage" Relation to the use descriptors is regarded helpful and should be included unambiguously.
Operational conditions	Clear description of the operational conditions that determine the emission. Specification of concepts such as "efficient resource use" by quantified indicators (e.g. % of raw materials use) or qualitative conditions (e.g. processing techniques)	The relation between the release factors and the operational conditions of use determining should be explicit and clear to the registrant using the spERC. The coverage should not be misunderstood; hence any words or definitions which are not explained should be avoided.
NEW section: obligatory onsite RMMs	Clear description of risk management measures that are to be applied and the existence of which is assumed in the release factors. "no RMMs needed" to be explicitly stated, if release factors apply without any RMM	This section would unambiguously clarify to the registrant and any other actor if the release factors require the implementation of risk management measures. The type of measure should be specified. If efficiencies are available, they should be given as well to enable scaling by DU.
Substance use rate	No recommendations	
Days emitting	No recommendations	

Section	Content	Comment / reasons
Release factors (air, water, soil)	Numeric value Justification of value by reference to literature or methods. Direct link to related documents.	The justification of values should be easy to find. In order to keep the fact sheet short, the links to reference documents should be given. If emission factors are set to 0, the justification should be given here, in order to enable the registrant to check, if the conditions of "no emission" apply to his use
Optional risk management measures for iteration	Extended title of the row If possible and available, risk management measures should be named and efficiencies in relation to substance groups should be provided.	It should be made clear that in this section support for iteration is provided and that the measures are not obligatory, if the release factors are used.
Narrative description	Short and concise flow text description. Relevant items to be specified: Abstract description of full process (e.g. storage, automated pumping of substances to mixing vessels, continuous or batch wise processing, automated packaging, cleaning of equipment, local exhaust ventilation) Explicit mentioning of whether or not cleaning of equipment and side activities are covered. Unambiguous description of conditions regarding waste management and wastewater discharges (e.g. if there are no restrictions in scope, statement that any type of waste disposal is covered). No justification should be included.	It is important that registrants, authorities, and DU get a better picture of the covered processes in order to decide on the applicability of the spERC. If existing processes have been kept in mind in the spERC development, these could be made transparent here. Some sectors have process descriptions in their background documentation, which could be either included here or made reference to illustrate the coverage. The abstract description of the process would allow for specification of process characteristics without limiting themselves to sectors. The coverage of cleaning steps and side activities would be made explicit and avoid uncertainties. Waste water and waste management information is frequently included here (and helpful) but in many cases confusing or contradicting. The justification of default values and assumptions should be provided directly in the respective sections. A general justification (e.g. processes are optimized for resource efficiency and therefore have low emissions) does not add to transparency or understandability of the fact sheet.
Safe use	No information on the processes should be given. Could be omitted	It is not the intention to provide support for DU communication. The overall responsibilities of the registrant regarding his DU communication are described in the ECHA guidance. How to use spERCs in relation to DU communication should be specified in the CEFIC guidance. Information on processes is already provided in other sections. The fact sheet would be shortened and the possibilities of inconsistency are reduced.
Scaling	Reference to the CEFIC guidance on how to communicate scaling rules to DU Only Scaling information that is specific to the sector / spERC should be provided	The general equation for scaling should be described and explained in the CEFIC guidance, so all registrants could implement it. Specific scaling parameters of the sector should be explained and how they can be integrated in the general equation. This way fact sheets would be shortened.

CEFIC should consider revising its guidance document on spERCs with regard to the following aspects: inclusion of

- a separate section explaining carefully the concept, role, and intended use of spERCs with respect to the gap of the expected and realized level of detail
- a separate section on the derivation of release factors
  - outlining different methods to derive release factors, such as using literature values, qualitative argumentation and own data collection and processing
  - providing rules for documentation of derivation methods and information sources of release factors that ensure transparency and enable plausibility checking by authorities and
  - highlighting the importance on differentiating between release factors from the process and release factors that integrate the use of RMMs
- revised information on communication to downstream users, including an explanation of which information to quote from fact sheets and which to further specify, methods to specify the information as well as general guidance on scaling that could replace the respective paragraphs in the fact sheets

It should be discussed whether information on „emission factors to waste“ should be included in the spERCs and related fact sheets. This information could complement the spERCs and would increase their usefulness for the registrant.

Recommendations to industry associations

The associations developing spERCs should keep all versions of spERCs available at all times on their websites to ensure compliance checking over time.

The associations should consider the following recommendations when developing new or revising existing spERCs:

- Exclude processes, processing conditions or other characteristics of a use explicitly from the scope, if it is known that certain processes or types of installations are not covered (in analogy to a use advised against)
- Check all information in the spERC for consistency. The more different ways are used to describe the covered processes the higher the risk of inconsistencies and contradictions.
- Carefully document all information sources and describe methods and assumptions directly in the fact sheet that were used to derive default values. If the information is too extensive, it should be included as an annex.
- Clearly separate information related to the spERC as such and information that documents how values or conditions were derived.
- Avoid the use of undefined terms like “optimized processing” and be as specific as possible
- Try to provide release factors and efficiencies of risk management measures separately. Be explicit on whether or not release factors apply under the condition that risk management measures are applied or not.

- If risk management measures are recommended, give indications on their efficiencies

In the longer term, experience from the actual use of spERCs, the development of exposures scenarios and the feedback from downstream users should be collected and evaluated to refine the spERCs. In this, further information from sector publications could be included and targeted surveys be started in member companies to close knowledge gaps and derive more specific values. The method of ETRMA could be used as example. Contribution of further information on risk management measures and their efficiencies to the CEFIC library should be considered of high priority, as it is expected that many registrants will have to iterate their assessments.

It is advisable to start a well prepared communication with authorities on their expectations towards spERCs.

Recommendations to authorities

Authorities should seek a discussion with CEFIC and its sector group on their requirements to the documentation and transparency of information in spERCs based on the available examples from different sectors. They should in particular clarify in which aspects they regard the current spERCs as insufficient to fulfill the documentation requirements of a chemical safety report. This report is a first step in that direction.

Authorities could support industry on increasing the level of detail in spERCs by providing information from their enforcement activities on risk management measures of downstream users or by initiating projects for developing operational conditions in certain sectors or evaluating the development of exposure scenarios along the supply chain as REACH implementation moves forward.

7 References

CEFIC (July 2010): CEFIC Guidance Specific Environmental Release Categories (SPERCs) Chemical Safety Assessments, Supply Chain Communication and Downstream User Compliance, Brussels.

ECHA (January 2008): Guidance for downstream users, Helsinki.

ECHA (March 2010): Guidance on information requirements and chemical safety assessment – Chapter R.12: Use descriptor system, Helsinki.

ECHA (May 2010): Guidance on information requirements and chemical safety assessment – Chapter R.16: Environmental Exposure Estimation, Helsinki.

European Commission; Joint Research Center (2003): Technical Guidance Document (TGD) 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, Brussels.

REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006, Brussels.