

Final report

**ECHA SERVICE CONTRACT
“ASSESSMENT OF RELIABILITY
OF SPERCS”**

FRAMEWORK CONTRACT NO ECHA/2011/01;
SERVICE REQUEST SR16

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1 SUMMARY

The project on the “Assessment of Reliability of SpERCs” should support the European Chemicals Agency and the REACH stakeholders in ensuring a high quality of environmental emission estimates under REACH in cases where specific environmental release categories (spERCs) are used.

In the first project phase, the quality of 19 spERCs was assessed at a screening level. The screening experience was used to develop a spERC Best Practice Format (factsheet). In addition it was suggested to streamline spERC factsheets and provide explanatory information and justifications in a separate background document. Based on the Best Practice Format and indications on the expected content of the background document, best practice examples were developed by four industry associations. The draft spERC examples developed during the project could be further reviewed and discussed by ECHA and industry with Member States Competent Authorities (MSCAs).

The Best Practice Format was revised three times during the project taking account of the opinions of ECHA as well as the industry associations participating in the exemplification work. However, Member States’ views are not yet taken into account and a respective discussion process should be started, too.

The majority of sections headings and the expected content of the current Best Practice Format version are consensual. Open questions relate to the split of information between factsheet and background document (substance use rate, optional RMMs) and don’t relate to the information content. The only unresolved issue regards the need to derive a release factor to waste.

The general content of the background document appears to be clear and there is consensus among ECHA and the associations participating in the project. However, the transparency of release factor documentation remains yet to be discussed based on the examples.

It is recommended to further discuss the Best Practice Approach with industry and the Member States, clarify the remaining issues and continue work on the examples with industry also after the end of the project to ensure that an illustration of how the factsheets and background documents should look like is available.

2 INTRODUCTION

The project on the “Assessment of Reliability of SpERCs” aimed at supporting the European Chemicals Agency (ECHA) and the REACH stakeholders in ensuring a high quality of environmental emission estimates conducted in chemical safety assessments (CSAs) under REACH in cases where specific environmental release categories (spERCs) are used.

It should in particular facilitate checking whether a given spERC or groups of spERCs are:

- applicable to an industry sector and a particular use of chemicals, including typical operational conditions (OCs) and risk management measures (RMMs);
- plausible regarding the release factors (RFs) proposed in relation to the OCs and RMMs and
- transparent and sufficiently well documented to allow all stakeholders to unambiguously select and use and/or check the use of spERCs in exposure assessments as well as to implement them as communicated by exposure scenarios (ESs) or respective information in the safety data sheet (SDS)¹.

The project was divided into two phases:

The aim of the first project phase conducted in May and June 2014 was to develop an overview of the status quo regarding the quality of existing spERCs. Information on 19 spERCs was compiled from earlier projects or generated by a screening assessment. The results are presented in the first project report.

In addition a proposal for best practice regarding the content of factsheets was developed in the form of a table having the same main structure as CEFIC’s factsheet format. It was suggested to streamline the factsheet content by complementing it with a background document. The background document should contain details on the justification of release factors and other default values as well as give contextual information on the sector, the State-of-the-Art of application processes and risk management measures and main emission points. The proposal of a “Best Practice Format²” was further developed during the second project phase.

¹ The focus of the second project phase is shifted towards transparency and sufficient documentation to allow the evaluators checking the plausibility of the spERC. This focus is set because the requirement of spERCs to be sufficiently well documented and justified may be in conflict with the requirement for simple and concise communication. Hence, in the second phase the main question is whether or not the information in the spERC (which is transferred to the CSR) is sufficient to demonstrate safe use of a substance.

² The term “Best Practice Format” evolved during the work and seems to be more accepted and understandable than the term “spERC requisites” that was applied in the terms of reference and at the beginning of the project. In this report the term Best Practice Format will be used to take account of the most common way how the table listing the factsheet content is addressed.

The main objectives of Phase II conducted between June and October 2014 were to:

- Further develop the Best Practice Format so it could be used by associations as a structure and orientation for the improvement of existing or development of new spERCs and
- to accompany the process of industry associations developing Best Practice Examples of spERC factsheets and background document. The examples should be based on the Best Practice spERC Format

The overall work process is described in Section 3 and is differentiated according to the development process of the spERC Best Practice Format and the development of best practice examples.

Section 4 of the report presents a summary of the exemplification results at the time of writing the report³. For each spERC the individual work process is outlined, the current version is briefly described (form and content) and it is compared to the spERC Best Practice Format and expected content of the background document (c.f. Annexes, Section 1 and 2). For each spERC an evaluation by the consultants regarding the strengths and weaknesses of the spERC factsheet and background document is provided.

The results from the further development of the Best Practice Format are described in Section 4. This includes a summary of industry's feedback after having worked with the spERC Best Practice Format in exemplification and an evaluation and recommendations by the consultants.

Conclusions and recommendations regarding the Best Practice Format are provided in Section 6.

A separate document is provided including several annexes to this report which are:

- Introduction to the Best Practice Format (Annex, Section 1)
- Best Practice Format agreed before and after exemplification (Annex, Section 2)
- Overview table of the feedback collected from industry on the spERC Best Practice Format (Annex, Section 3) and

³ A final version of the Best Practice Examples could not be delivered by the industry associations due to overall time constraints (part of exemplification took place over the summer break, associations need time for internal discussions and resources to revise the document).

3 OVERALL WORK PROCESS

3.1 Best practice examples

Four industry associations participated in the exemplification: FEICA (Johannes Tolls), ACEA (Thomas May), ETRMA (Lorenzo Zullo) and EUROMETAUX (Frederick Verdonck)⁴. In addition, AISE (Thorsten Wind) provided factsheets according to the first Best Practice Format to broaden the basis of factsheets and allow a wider view on the usefulness of the Best Practice Format⁵.

The current factsheet and background document versions are

- based on the spERC Best Practice Format agreed between ECHA and the associations (c.f. below)
- commented by the consultants according to the Best Practice Format and
- partly revised as industry associations

It is expected that ECHA will comment the examples provided with this report and a further revision may take place.

3.2 Development of Best Practice Format

The first version of the Best Practice Format, which was developed in the first project phase, was discussed with the industry representatives in the exemplification kicking-off meeting. Non-controversial comments were directly implemented whereas potentially controversial aspects were compiled for further discussion.

The so derived second version of the Best Practice Format was discussed between industry, ECHA and the consultant in a conference call. In the conference call several aspects could be clarified whereas others remained open either to await the results of the exemplification (e.g. regarding the segmentation of information in the section “operational conditions”) or because no agreement could be found (e.g. on the need to derive release factors to waste).

The resulting third version of the Best Practice Format was used as basis for the exemplification work. This version of the Best Practice Format is provided in in Section 1 of the Annexes.

⁴ Eurometaux approached the project team with interest to participate. They stepped in later in the work process.

⁵ AISE did not develop their examples further during the project but their feedback to the Best Practice Format was taken into account.

4 BEST PRACTICE EXAMPLES

4.1 ACEA

4.1.1 Work process

The following work steps were performed by industry and the consultants:

- initial meeting on July 7th,
- drafting of first revised version of a factsheet covering 5 spERCs on the industrial use of liquid spray coatings with wet scrubbers
- written commenting by the consultant and telephone discussion
- provision of ACEA background document and factsheets after the common conference call,
- written commenting by the consultant,
- partial revision of the ACEA factsheet for draft final report.

4.1.2 Description of current version of the example

The ACEA factsheet is adapted to the most recent Best Practice Format and information is provided for all aspects. The information is less abbreviated than e.g. in the FEICA factsheets.

The background document is still work in progress. It is provided in the same format as the factsheet and explanation is elaborated in the table directly next to the factsheet information. An excel-sheet is provided in addition outlining that RFs to water were derived based on measured data from companies of the automotive industries.

4.1.3 Comparison of current spERC version with best practice format and observations on content

In the following the content of the factsheets is described. If relevant, differences to the format, inconsistencies and doublings are pointed out. In addition, issues which are specific for the factsheets are described as well.

As the background document is still in an early stage, only general comments regarding its organization and content are made in the respective section.

4.1.3.1 Title and scope

Due to the coverage of different spERCs in the factsheet, the scope sections are partly differentiated according to volatile and non-volatile compounds.

A new line is inserted with the title "hazard profile". Here, CM and PBT/vPvB substances as well as "non-reactive" and "non-easily biodegradable" volatile compounds are excluded from the scope.

The types of covered spray coatings are further explained in the scope section.

4.1.3.2 Operational conditions

The information on the operational conditions is relatively detailed in the various sections and several aspects are specified in each field.

The information in the sections “conditions of cleaning” and “conditions of auxiliary processes” do not fully explain if emissions to the environment occur. Some information is not relevant to environmental emissions of substances, e.g. that sludge is dewatered to achieve a high caloric value for incineration.

The section on “emission prevention” includes (additional) and comparatively extensive information on the obligatory RMMs and how they are implemented.

4.1.3.3 Substance use rate

No justification / information source of the substance use rate is provided in the factsheet. The value is a worst case estimate rather than a realistic use amount.

4.1.3.4 Emission days

Different emission days are specified for the volatile and the solid substances, which is explained in the factsheet and background document. However, a clear justification of the number of emission days is not provided in the factsheet or background document (yet).

4.1.3.5 RFs and justifications

The release factors are justified with one sentence in the factsheets. A detailed justification is under development; the current version of the background document contains the same information as the factsheet.

An excel file exists outlining the rationale and the values used to derive the transfer rates from the paint overspray to water. The values are averages of information provided in an industry survey.⁶

4.1.3.6 Background document

The background document is provided in the same structure as the factsheet (table). General information on the sector, the use and the processing steps are included but not provided as coherent text. No justification of emission days is provided. A justification why the release factors and emission days derived from information of the automotive industry can be read-across to all the other sectors listed in the spERC's scope as being covered is not contained.

⁶ Further details on the justification were provided in the first project phase (screening assessment of ACEA spERC).

4.1.4 Consultant's evaluation of the spERC regarding best practice

The ACEA spERCs are, in contrast to e.g. the FEICA spERCs, rather specific and information is provided at a higher level of detail; consequently also the release factors to water are comparatively low. The language and technical terms are not always understandable and could be simplified.

Factsheet

The factsheet includes the relevant information for emission estimation and allows selection of the correct spERC by the registrants. It is comparatively detailed and evaluators can get a good impression of the process covered. Nevertheless, some issues could be improved:

- 1) Further shortening (and standardization) of information⁷
- 2) Removal of information not relevant regarding the environmental emission of substances, e.g. on dewatering of sludge to achieve high caloric values in sludge incineration
- 3) Further adaptation to Best Practice Format (e.g. use of full row titles)
- 4) "Filters" are mentioned in several places in the factsheet but not explicitly described as RMM. Either removal or explicit coverage of filtering systems should be implemented.

Background document

The current version of the background document lacks an introduction and a general overview of the covered use. Although a lot of information is provided on the processing details, a coherent and easy to understand overview description of the substance flows (and emission points) from the various steps and particularly the risk management measures is missing. This hinders a clear understanding of where emissions could occur.

Some parts of the background document (as in the factsheet) are not relevant regarding emission estimation to the environment. Although helpful details to run the processes they may cause confusion.

At present, the information in the background document is not yet well sorted and e.g. the justification on the use amount is included in the section on emission events.

The background document does not contain a justification of release factors.

Whereas the use of the values in calculating release factors is documented in a separate excel-file, neither the raw data is presented nor information on the number and type of information providers are given (c.f. assessment of the spERC in the first project phase). It is furthermore not intuitively clear from the

⁷ E.g. in the section "containment" it is specified: "Spray-booths and spray stands provide a certain level of containment but cannot be considered as closed due to openings for material transfer, for ventilation and for application devices and due to doors for operators and maintenance staff". This could be shortened in the factsheet to "open" and explanation be given only in the background document.

excel-sheet what RFs finally are to be applied and to which spERCs they relate. The release factors to air and soil are not justified in detail, either.

4.2 ETRMA

4.2.1 Work process

4.2.2 Work process

- ETRMA was first contacted in June to be invited to work on best practise examples.
- After further clarification on the expectations and timing issues ETRMA expressed their willingness to work on the best practise examples.
- ETRMA indicated that they would start their work on the examples after the major holiday season by the end of August beginning of September.
- Identified issues from the screening assessment and points of interest to work on have been provided and communicated by writing and during telephone discussion.
- ETRMA commented on these identified issues and response to their comments was provided by the consultant by the end of September.
- A first version of the best practice spERC factsheet was provided beginning of November but after submission of the draft final report.
- The spERC factsheet was commented twice by the consultant and sent back to ETRMA for revision. The second revision is included in the final report.

4.2.3 Description of current version of the example

The ETRMA spERC factsheet is not based on the factsheet format presented in this report. The factsheet contains a narrative description. A background document describing the derivation of release factors and underlying data and guidance on the use of emission factors is also provided.

The factsheet covers the industrial use of chemicals used in the production of tires and other rubber goods both during compounding and processing of rubber.

The background document contains the background information used to derive the release factors and the identification of relevant operational conditions. A tiered approach is presented in the background document. Emission factors for water have been derived from measured data. Average and 90th percentile values have been calculated. For air the release factors from the A-tables in the TGD are used and reference is made to a measured air emission factor for ZnO, which is in line with the value provided in the A-table.

4.2.4 Comparison of current spERC version with best practice format and observations on content

In the following the content of the factsheets is described. If relevant, differences to the format, inconsistencies and doublings are pointed out. In addition, issues which are specific for the factsheets are described as well.

4.2.4.1 Title and scope

The title mentions that both formulation (compounding) and industrial use of substances used in the production of tires and general rubber goods are covered.

Further specification of substance types covered and processes involved is provided in the scope. The spERC refers to plants that cover the whole process of formulation and processing.

The domain of substances included in the scope is consistent with the applicable ERCs that refer to formulation into a matrix (ERC 3) and ERC6d, referring to processing of rubber chemicals.

4.2.4.2 Process description

Further specification of the processes involved is provided in the scope. The spERC refers to plants that cover the whole process of formulation and processing.

Reference is made to the Generic Exposure scenarios for a description of the main activities and operations where emissions occur.

4.2.4.3 UDs

The (supplementary) sector of use and the process codes are provided. The related article category AC 10 is not included. The article category could be included to indicate the link with the service life stage.

4.2.4.4 Operational conditions

Standard qualitative phrases are used to describe the operational conditions, differentiating three categories. The description of the operational conditions in the factsheet is undefined and terms like efficient and optimal material use should be further specified especially the difference between the three categories. Reference is made to the Generic Exposure Scenarios for tyres and general rubber goods for further specification of operational conditions and risk management measures.

Some information on the common cleaning processes and conditions related to potential emission to (waste)water is provided.

Types of waste from cleaning operations, processes and waste from RMMs are not reported. General undefined statements on releases to soil are included as justifications in the sections release fractions. ETRMA included a note on a project to collect waste data for tyre manufacturing to be included in the factsheet

4.2.4.5 Obligatory RMMs

Reference is made to the Generic Exposure scenarios (web link included) for a description of the typical RMMs by process activity.

4.2.4.6 Substance use rate

A rather detailed calculation for the substance use rate is provided, which preferably should be placed under a specific heading.

4.2.4.7 Emission days

The number of emission days is provided for the three categories of OCs based on a survey of facilities used to derive the emission factors. Additional information is provided in the background document.

4.2.4.8 RFs and justifications

The release factors for water are based on the results of a survey and wastewater effluent data collection. Release factors have been derived for three different types/categories of substances and relevant operational conditions have been identified. Average and 90th percentile values have been calculated. The emission factors relate to the situation before biological treatment.

The release factor to air is based in the EU TGD A-tables for the polymer industry. These factors have also been used in the OECD emission scenario document on additives in the rubber industry. The appropriateness is only indicated by measured data for one substance (ZnO).

Release factors for soil and waste are not provided and it is stated that release to soil are not to be expected.

4.2.4.9 Optional RMMs

Optional RMMs are not provided in the spERC factsheet.

4.2.4.10 Background document

The background document provides a tiered approach on release factors for air and water, starting with the standard RF for the ERCs, to sector specific values obtained from the EU TGD A-tables to release factors based on measured data. The background document contains the summary information collected and used to derive the release factors. Besides release information the background document contains the characteristics of plants participating in the study like production volume, number of emission days, discharge fate and effluents flow rates.

4.2.5 Consultant's evaluation of the spERC regarding best practice

The spERC document is consistent with respect to the title, scope and the ERCs referred to. Three general categories of operational conditions are included in the factsheet which contradicts the principle that there should only be one set of operational conditions per spERC factsheet.

A description of the operations and process steps is provided in the Generic Exposure Scenarios (GES). This description of OCs needs further specification especially with respect to the difference between the three categories.

Release factors to water are based on measured data on a set of three substances. There is no consideration on the applicability of the measured data to the whole range of chemicals (within the scope of the spERC) used in the rubber industry. Release factors to air are based on the EU TGD A-tables, which are considered not to be appropriate. In the GES process activities are linked to exposure routes and RMMs. Releases to waste and soil are not or insufficiently substantiated. Limited information on the conditions of cleaning is provided. Information on waste streams has not been provided yet, but will be in the near future. The narrative description contains relevant information on operational conditions, which have not been mentioned before in the spERC factsheet.

4.3 EUROMETAUX

4.3.1 Work process

- EUROMETAUX joined in later in the process and expressed interest to provide a best practice example because since September EUROMETAUX is working on an update of their spERC factsheet and background document.
- On the 1st of October EUROMETAUX was invited to work on the best practise examples
- A first draft spERC factsheet and background document on “Manufacture and recycling of massive metal and metal powder” was provided in October
- The draft was commented in writing by the consultant and discussed by telephone
- The spERC factsheet was partially adjusted for the draft final report with some issues left that could not be solved on short notice.
- The spERC factsheet was revised taking account of the comments by ECHA submitted with the feedback to the draft final report.

4.3.2 Description of current version of the example

In the EUROMETAUX factsheet the most recent factsheet format and layout is implemented, as well as the content proposal for the background document.

The factsheet covers the manufacture and recycling of metals and was not part of the initial screening assessment (a factsheet covering another life stage of metals was screened). However, the main issues identified in the screening assessment also applied to the factsheet for manufacturing and recycling.

The background document contains the justification of the release factors and the identification of relevant operational conditions. The release factors are based on a statistical analysis of the data from a large database that contains

the release factors to air and water for the manufacture, recycling and industrial use of metals. The factsheet covers the three basic processes in metal manufacturing and recycling: pyrometallurgy, hydrometallurgy (electrowinning) and metal recycling.

4.3.3 Comparison of current spERC version with best practice format and observations on content

In the following the content of the factsheets is described. If relevant, differences to the format, inconsistencies and doublings are pointed out. In addition, issues which are specific for the factsheets are described as well.

4.3.3.1 Title and scope

The title mentions that both manufacture and recycling are covered.

Further specification of substance types covered and excluded by the factsheet is provided in the scope (list of compounds understood as “metals and metal powders”).

In the section “substance types / functions” the scope is limited to metals within a specific range of solid water partition coefficients for suspended matter.

4.3.3.2 Process description

The first paragraph in the section repeats information from title and scope.

The process description contains a rather detailed but not an exhaustive summation of the processes that can be applied in metal manufacturing and recycling. It is indicative to show that all metal manufacturing and recycling process are covered by the factsheet instead of indicating that only these processes are covered. The measured data used to derive the release factors are integrative of all processes on-site, releases from all these processes are included.

The main emission sources within metal manufacturing and recycling have been indicated in the fact sheet for both air and water but not for soil.

4.3.3.3 UDs

The sector of use is provided and the product codes are stated to be not relevant.

4.3.3.4 Operational conditions

Standard phrases are used to describe the operational conditions. The conditions of equipment cleaning and the conditions of auxiliary processes are not provided because they were not specifically collected. The common cleaning processes and conditions could be added in a later stage if desired.

The section “Emission prevention” was interpreted as to mention additional (then specified elsewhere) measures to prevent emissions.

As a worst-case assumption waste water is not directed to a municipal STP.

Types of waste from cleaning operations, processes and waste from RMMs should be reported separately. General information on how to handle waste residues is provided. Different types of waste like slags and filter dust were not mentioned in the first draft but are included now.

4.3.3.5 Obligatory RMMs

Common RMMs that are generally applied within metal manufacturing and recycling are mentioned. Common techniques and general accepted efficiencies are provided as well but not substance specific.

4.3.3.6 Substance use rate

A substance use rate is not provided but it is recommended to use a realistic value in the iteration process.

4.3.3.7 Emission days

The number of emission days is provided and additional information is provided in the background document (value derived from the database).

4.3.3.8 RFs and justifications

The release factors are based on a statistical analysis of the data from a large database that contains the release factor to air and water for the manufacture, recycling and industrial use of metals. A release factors for waste is also provided. This release factor is also based on site specific release factors from manufacturing sites. Summary information is provided and reference has been made to the background document for additional information on the applied method for deriving release factors. The release factor for soil is based on the ERC default.

4.3.3.9 Optional RMMs

Considered not to be relevant because for iteration purposes (if SPERC default release factors do not demonstrate safe use), it is recommended to measure/monitor the air and/or water releases as a first refinement step. In case further iterations are required, a combination of multiple obligatory on-site measures can be considered.

4.3.3.10 Background document

The background document contains a general overview of the sector. For specific sector information on RMMs it refers to the Best Available Techniques Reference Document for the non-ferrous metal industries. For the derivation of release factors, RMM efficiencies and number of emission days reference has been made to the confidential database containing site specific data and the additionally published paper on the applied method has been included in the background document.

4.3.4 Consultant's evaluation of the spERC regarding best practice

The spERC document is considered to be rather complete with some minor additions that could be added for completion (e.g. conditions of cleaning and auxiliary processes) or further explanation and some doubling that could be shortened (e.g. repetition of coverage in the section "process description").

The use descriptors should be completed by adding the product category 7 (metals and alloys); this is relevant also in the case of substance manufacturing.

A release factors for waste based on site specific release factors from manufacturing sites was also provided. OC and RMMs were provided in detail to stress the broad coverage of processes within metal manufacturing and recycling. Besides the standard OCs, additional OCs were provided for which there was a relation with the release factor water. The factsheets covers three basic processes in metal manufacturing and recycling that have not been considered separately with respect to the release factors. This is intrinsic to the applied method to derive the release factors because measured data used are integrative of all processes on-site, and therefore releases from all these processes are included.

The assessment of the reliability of the data included in the confidential database is an issue of concern. One option would be to provide an anonymised database containing the site specific data and indicate the setting or context within which the data have been established, like for instance PRTR reporting obligations etc. This kind of information could then serve as a kind of data quality indication.

4.4 FEICA

4.4.1 Work process

The following work steps were performed by industry and the consultants:

- initial meeting on June 30th,
- drafting of first revised version of 3 spERCs on the industrial use of substances in adhesives / sealants by FEICA and two spERCs on the formulation of detergents by AISE,
- written commenting by the consultant; written reply by FEICA / AISE followed by a telephone conference for further discussion,
- commenting of the FEICA publication on the derivation of release factors by read-across of ESDs from the paint sector,
- provision of FEICA background document and factsheets after the common conference call,
- written commenting by the consultant and written reply by FEICA followed by a phone conference,
- partial revision of the FEICA background document and factsheets for draft final report
- provision of comments by ECHA to the spERCs provided with the draft final report,
- revision of the spERCs according to comments.

4.4.2 Description of current version of the example

FEICA developed a background document with a general introduction to spERCs, their role in tiered exposure assessment and how they were developed, including the rationale for selecting default values. The release factors are derived by reading-across emission rates from the OECD ESD on the coatings industry⁸. The rationale of that read-across is explained in the background document, also. The details of the read-across approach are described in a separate publication which is currently in the review process. In addition it is explained why the OECD ESDs on adhesives are not appropriate for use in the spERC RF-derivation.

In addition to the general and introductory information, the background document contains specific information and justification on the spERCs for industrial uses of adhesives.

Each factsheet covers one spERC without sub-spERCs. The factsheets are provided in the Best Practice Format agreed in the common telephone conference (c.f. Annex, Section 2, Table 1) and contain short and standardized information. All sections are filled with concise and standardized information / phrases.

4.4.3 Comparison of current spERC version with best practice format and observations on content

In the following the content of the factsheets is described. If relevant, differences to the format, inconsistencies and doublings are pointed out. In addition, issues which are specific for the factsheets are described as well.

4.4.3.1 Title and scope

The product type is already mentioned in the title.

The background document includes a list of available spERCs linked to ERCs but without reference to a use map.

4.4.3.2 Process description

The process description is short and generic in the factsheet and includes a list of application techniques.

The background document provides a brief explanation of how the different application techniques work (general principles) and information on cleaning and waste handling is provided as well. Information on the process and emission sources from the activities is provided in different sections and tables.

⁸ EMISSION SCENARIO DOCUMENTS ON COATING INDUSTRY (Paints, Laquers and Varnishes), ENV/JM/MONO(2009)24, 08-Jul-2009

4.4.3.3 Use descriptors

In the use descriptors the main user group is mentioned (SU3) as well as the construction sector (SU 19) although the title and explanations specify that any manufacturing could be covered⁹.

4.4.3.4 Operational conditions

In the process description the basic steps in the use of adhesives are listed, including an enumeration of application techniques. No details are provided on individual activities or how the steps are performed.

The application techniques are explained regarding the basic functional principle in the background document. The main emission points from the processes are explained in table form. Parts of the operational conditions, such as the handling of waste are described as well. The information on the operational conditions is provided in different sections of the document.

The same information is provided in the section “measures to achieve efficient use of chemicals” and “emission prevention”. Furthermore, information on how waste from cleaning is handled is provided in the section “conditions of equipment cleaning” and “information on how waste from equipment cleaning is handled”.

4.4.3.5 Substance use rate

Information on the substance use rate is only provided in the background document¹⁰. Based on expert judgement average use rates of adhesives / sealants and the concentrations of the main ingredients were compiled to derive use rates per component type by multiplication of the concentration of the component with the daily use rate.

4.4.3.6 Emission days

The emission days are specified in the factsheet and background document.

4.4.3.7 RFs and justifications

The release factor derivation method is described in the background document: The literature assessed (three OECD ESDs) is described and the approach for read-across is explained:

- the product ingredients and manufacturing and use processes are assessed as similar,
- the OECD ESD on adhesives is characterised as less appropriate to derive RFs than the OECD ESD on paints (focus on air emissions, calculations rather than emission rates),
- the manufacturing and use scenarios of paints in the OECD ESD are grouped and assigned to spERCs for adhesives and sealants; the use

⁹ Here the concept of using the lifecycle indicator and the product category only could be useful due to the broad range of users; c.f. proposal for a revised Best Practice Format in the Annexes, Section 2, Table 2.

¹⁰ According to the final proposal of the factsheet structure as included in the Annex, Section 2, information on the daily use rates should also be included in the factsheet.

- in automotive and marine coating is not considered as the application techniques are not relevant in the use of adhesives and sealants,
- the worst case emission rates of each group of OECD ESD scenarios is selected as release factor for the respective spERCs; expert judgement is applied in the case of water emissions for industrial uses.

The details of the process and a demonstration of which ESD emission rates were used to conclude on the spERC release factor are described in a separate publication.

4.4.3.8 Additional information on the background document

The background document contains several chapters in the beginning which explain the (development and) use of spERCs in general as well as general information and the sector and the used products.

There is no description of the State-of-the-Art regarding risk management measures to air, water and soil included. The spERCs are hence applicable without specific RMMs in place with one exception: In the case of spraying, wash water from spray booths is to be disposed of as waste. This is explained in the background document.

4.4.4 Consultant's evaluation of the spERC regarding best practice

In the following, an overall assessment of the spERC factsheet and background document is contained. Differentiated feedback was provided to the industry association in writing but here only the main aspects are included.

Factsheet

The spERC factsheet conforms to a large extent to the expectations regarding a best practice spERC as it contains concise and easily understandable information. The process description appears sufficiently detailed taking into account the broad coverage of the spERC and the fact that application techniques are listed (and briefly explained in the background document).

FEICA argues in favour of having substance use rate information in the background document and not in the factsheets based on the following arguments¹¹: FEICA defines substance use rates as indicative values for guiding registrants to specify substance use rates that are relevant for their dossiers. The factsheet contains defaults, which in combination constitute a set of binding conditions. Including the indicative values into the factsheet would make them part of the binding conditions. This is in contradiction with the indicative nature of the substance use rates and not supported by FEICA. Alternatively, the substance use rates could be included as indicative values in the factsheet without being binding. Inclusion of binding and non-binding values in a factsheet would create confusion and is therefore not supported by

¹¹ The consultant shares FEICA's opinion and suggests excluding the section "daily substance use rate" from the factsheet.

FEICA. In addition to the above, presenting multiple values of substance use rates (FEICA specifies several use rates for different component types in a factsheet per one spERC) in a factsheet creates ambiguity, which should be avoided.

Background document

The background document contains several sections putting spERCs into context. These are regarded helpful if registrants are not familiar with spERCs and how to use them but may become superfluous over time.

The background document lacks a clear and coherent description of the processing steps and technologies and the main emission sources. Most of that information, including on equipment cleaning and waste handling, is provided in the document but in different sections and tables, which makes it difficult to get the full picture.

The derivation of release factors is documented in detail (read-across approach) in a separate publication¹². The underlying principles are described in the background document at a general level. The concrete and specific justifications of the release factors in the factsheets are not provided in the background document; i.e. it is not transparent which scenarios of the OECD ESD were allocated to a spERC and which OECD emission rates were used to derive a (worst case) release factor for the spERC.

The derivation of RFs is included in more detail in the publication which is yet under review; however, the organization of information is difficult to follow and several aspects are not fully transparent.

The derivation of substance use rates is systematic and transparently documented, so that the approach could be applied also by other associations. The listing of substance use rates according to adhesives/sealant components is useful to provide registrants with a realistic starting point for the use amounts. Due to the transparent derivation of values, the values can be well understood (and modified, if necessary). The base data from the survey / expert judgement is not provided. Given that the substance use rate is an indicative value, this is not regarded as necessary.

In conclusion, the FEICA spERC factsheet and background document can be regarded as Good Practice with a few issues, namely the level of detail and coherence of the process description in the background document and the allocation of daily emission rates in the factsheet or background document, to be further discussed and resolved.

¹² The publication was provided to and commented by the consultant.

5 BEST PRACTICE FORMAT

The Best Practice Format was revised several times during the project. After the exemplification, interviews were held with the industry association representatives to collect feedback on the current version of the format.

In the following, the industry feedback is summarised and suggestions for improving the spERC Best Practice Format as well as regarding the content of the background documents are provided. Afterwards the consultants' view on potential revision needs of the Format is provided. These potential revision needs are indicated in a track changes version of the Best Practice Format in Annex 1 to this report.

5.1 Industry feedback after exemplification

The overall feedback on the spERC Best Practice Format is positive. It is stated to facilitate the compilation of spERC information due to its detailed structure and thereby also supports supply chain communication. Furthermore, the split into a factsheet and background document is regarded as useful to present information on spERCs.

The association representatives mentioned that considerable resources were needed to compile and restructure information in the new format which may be discouraging to other sectors. However, no major difficulties were encountered in developing the (revised) spERC factsheets and background document.

Opinions on whether or not a factsheet covers only one or more spERCs are divided and no clear recommendation can be derived from the industry interviews.

The section "scope" of the factsheet is regarded as sufficiently detailed and appropriate. It was suggested by ACEA to include an opportunity to limit the scope, e.g. to exclude the assessment of PBTs using the spERC.¹³

The level of detail of the process description was viewed critically by all associations. In the factsheet generic information with little details on the activities was recommended. The description should not be too specific and the process rather viewed as a whole (no differentiation of individual activities). Furthermore, and particularly with view to the general information in the background document, it was stated that information available in other sources (e.g. ESD or BREFs) should not be duplicated.

The current section "emission prevention" was commented as

- confusing because it suggests to list risk management measures in the section on operational conditions
- causing doublings as information included here was also included in the section on obligatory or optional RMMs

¹³ As this can already be done in the section „substance types functions included or excluded“ the suggestion is not taken further.

However, it was commented useful to have a place to include information on operating conditions which do affect the level of emissions to the environment. There were two suggestions:

- rename the section to „additional emission prevention“ and explain how it relates to OCs and RMMs
- change the section “measures to achieve efficient use of chemicals” to “measures to achieve efficient use of chemicals affecting releases to air/water/soil” and delete the section emission prevention.

The information types on obligatory risk management measures requested in the factsheet format were commented as generally acceptable by the associations. There were questions on why RMMs to soil for industrial sites should be specified¹⁴.

There are several ways information on the daily substance use rate is derived (equation, worst case based on information of large customers, differentiated use rates per mixture component, not provided at all) and it is partly included in the factsheet and partly in the background document.

The release factor to waste is controversial between industry and ECHA. The arguments why a release factor to waste (and an estimation of substance amounts in waste) is not necessary are that

- There is no legal basis to do so
- Waste is not an environmental compartment
- Emissions from waste treatment occur at different facilities
- Information is not used within or outside REACH

Nevertheless, some associations have provided release factors to waste either based on mass balances (difference between 100 and the sum of emissions to water, air and soil) or based on company data on wastes.

Industry’s feedback showed that there is still some confusion on regarding the obligatory risk management measures regarding whether or not their efficiency is already to be included in the release factors or not. In addition, the relation between obligatory and optional risk management measures is evidently not clear from the factsheet format which leads to confusion by the spERC developers and potentially also the registrants.

5.2 Consultants’ evaluation of the Best Practice Format

The Best Practice Format and the complementing Background Document appear a useful way to structure spERC information. The exemplification showed that this approach is generally acceptable for industry and ECHA and should therefore be further developed. Whereas the structured format of the factsheet is recommended and necessary to standardise information (also for the use in IT-tools), for the background document only the minimum information

¹⁴ As the factsheet format should, apart from industrial processes should also cover professional and consumer (outdoor) uses it makes sense to include a part where respective information can be placed. If this is not relevant, this can be specified in the spERC. Therefore, this comment is not further discussed.

content should be specified. Due to some misunderstandings voiced in the feedback by industry, it should be assessed if further explanation of the information to be included in the factsheet is needed in addition to the illustration that the examples should provide.

Recommendation

- The results of the project should be further discussed in a wider audience, including spERC users (registrants) and downstream users (assess usefulness of communicated information).
- It should be assessed, e.g. from associations deciding to update their spERCs according to the new spERC format, if the Best Practice Format needs further explanation regarding the type of information to provide. If so, respective guidance should be developed, e.g. by CEFIC or by ECHA.

As there is no agreement in industry on the question of whether or not one or more spERCs should be covered in one factsheet it does not appear useful to exclude either way of presenting spERCs.

Recommendation

- It should not be regulated how many spERCs can be covered by a factsheet.
- ECHA should communicate to industry how information needs to be provided for inclusion into CHESAR independent of whether a factsheet relates to one or more spERCs (with sub-spERCs).

It is observed that spERCs relating to products being used in several sectors may require listing a large number of SUs in the Section use descriptors. In addition, the “main user group” has been included in that section by all associations. Industry proposed to include the IUCLID lifecycle stages in the section “use descriptors” so that for cross – sector uses the product type and the lifecycle stage could be provided. This suggestion is supported as it avoids listing of a large number of sectors of use. This is implemented in the revised factsheet format in the Annex.

The level of detail of the process description is still a difficult issue, as it depends on the scope of the spERC as well as the type of process. In the exemplification it can be observed that spERCs with a specific scope (e.g. ACEA and Eurometaux) have a more detailed process description than those with a rather broad scope (e.g. FEICA). It may therefore not be possible to define objective criteria for the content of information in the section “process description” and “main emission points”.

The background document is an opportunity to support the overall understanding of registrants and evaluators of the sector, the products used and processes described in the spERCs. Although information may be available in other sources already, it is still regarded useful to present it in a targeted way and with view to what is necessary to know to use or evaluate the spERC.

Recommendations:

- The current version of the Best Practice Format is not changed in relation to the section “process description” as it provides opportunities to include information at different levels of detail
- The best practice examples should be used to illustrate the level of detail required by ECHA. Hence, ECHA and industry associations should pay particular attention to that this section is well commented and revised so that both sides can agree on the level of detail.
- There should be a list of information that is expected in a background document (but no structure proposal) including
 - General information on the sector, products and processes relevant for the spERCs and environmental emission estimation
 - General information on risk management measures applied in the sector
 - Explanation of (specific) operational conditions described in the factsheet, if relevant
 - Specific justification of release factors and other default values

The various information types to be provided in the sub-section relating to the operational conditions were commented as being relevant and useful. The segmentation was regarded as useful in general. However, it may be discussed in the further work process on spERCs if the headings should be aligned to the ES headings.

The only section which was commented by all associations as critical regards the “emission prevention”. This section is understood as misleading (allocation under “operational conditions”) and lead to duplication of information provided in other places of the factsheet. The industry suggestion (c.f. above) to provide this information in the section “measure to ensure efficient use of chemicals affecting emission to air/water/soil” is supported as it enables specification of OCs which as a side effect also will lead to emission reduction¹⁵. This is implemented in the revised factsheet format in the Annex.

The three separate lines regarding conditions of waste handling are recommended to be maintained, although there was some critical feedback that they seemed to be doubling.

The information types requested in the section “obligatory RMMS” are currently envisaged as relevant and should hence not be changed. However, it is as yet not fully elaborated whether it is strictly necessary to derive (substance-)specific efficiencies. In particular for process integrated measures there may not be a need to specify substance-specific efficiencies; e.g. if integrated release factors are derived from measurements after risk management measures.

The factsheet currently includes RMMS to soil. These may be relevant in case of professional and/or consumer outdoor uses but not for industrial applications.

¹⁵ Examples are e.g. recovery of substances from processing water for reuse in the process or specific application techniques that ensure minimum losses (e.g. specific nozzles).

It should hence be further discussed whether the section is necessary and relevant or if it could be deleted from the format.¹⁶

There are differing opinions on how and where the daily substance use rate should be provided.

ECHA is of the opinion that the daily substance use rate should be included in the factsheet and the CHESAR file of the spERC so it is directly available to the registrants. This would not only simplify the use of the spERC but also ensure a high degree of harmonization of the assessments.

Industry and the consultants regard the daily substance use rate as an indicative value which can be used by the registrants as starting point for an assessment. It systematically differs from the other spERC defaults because it can be iterated in the assessment without leaving the scope of the spERC. Furthermore, there are various approaches to providing the information which can hardly be compared or harmonized.

Recommendation for further work

- Discuss with industry and the Member States if the daily substance use rate should be provided in the factsheet or only in the background document.

The release estimation to waste is stated as required according to REACH and its Annex I¹⁷. Therefore, a release factor to waste should be provided in the spERCs.

Recommendation

- ECHA should clarify the legal requirement to assess emissions to waste and provide information on the clarification results to industry
- ECHA should communicate why the release estimation to waste is important and explain how the information may be used in the future

There are different opinions on how and where information on the optional risk management measures should be included in the background document:

ECHA prefers including examples of optional RMM techniques and their efficiencies in the factsheets. This would ensure iterations are standardized and registrants would get maximum support in getting respective information.

It was stated by FEICA that if an assessment is iterated, the registrant goes beyond the spERC's scope, which is evident from that additional information is to be communicated. In addition, the content of two different sections on risk management measures appears to cause confusion, which would be avoided if this information were provided in the background document only.

¹⁶ There is no possibility to enter this information into CHESAR / IUCLID at the moment.

¹⁷ It was not the tasks of the consultant to interpret the legal text in this regard. Here, the opinion of ECHA is supported assuming their REACH interpretation is correct.

Recommendation for further discussion

- It should be discussed if the optional risk management measures should be described in the factsheet (and hence integrated into CHESAR) or if they should only be specified in the background document

6 OVERALL CONCLUSIONS

The spERC project resulted in a revised approach for documenting spERCs that is consisting of a factsheet and a background document. The different information in the factsheet has been assigned to specific destinations ensuring that chemical safety reports and downstream user communication are based on the same set of data. The revised approach is generally accepted by the participating associations, while some issues remain to be clarified and agreed, such as the need to derive a release factor to waste and whether information on substance use rates and optional RMMS should be included in the factsheet or the background document.

The level of detail of information in the factsheets and the background document is difficult to define at an abstract level. The best practice examples should therefore support the overall understanding of which information is expected by ECHA in order to evaluate a spERC (and accept its quality). If ECHA could thoroughly evaluate a spERC factsheet and background document, further assessments for individual registration dossiers could become superfluous, except when iterations were performed. Hence, large resource savings could be expected for all actors if the process of defining Best Practice and illustrating it with examples were finalized.

The Best Practice Examples could not be finalized, during the project among others due to the following reasons:

- The work on the examples started before summer break cutting the already short time available for example development
- The Best Practice Format was developed in an iterative process requiring 2 revisions of the spERC factsheets and background document within a very short time;
- ECHA and Industry were developing common views on the structure and content of the spERC during the project and did (still do) not completely align; hence the spERC format and the examples are work in progress.
- Associations needed internal discussion time
- ECHA feedback was provided to one example before the draft final report was delivered. Further feedback was provided after the draft final report was delivered on two additional examples (as well as a second feedback to the one already provided before).

Consequently, further work is necessary to accompany industry in finalizing the examples.