



Workshop on REACH Review Action 3

Improving the workability and quality of extended Safety Data Sheets

18 March 2019

Breydel building, Avenue d'Auderghem, Brussels

Summary of the feedback collected from the workshop participants and material used

Disclaimer:

This Workshop Report has been prepared by members of staff of ECHA and the European Commission, based on notes taken by individual note-takers during the break-out and plenary sessions of the Workshop. The participants of the Workshop have checked the report for completeness and possible errors in the representation of the messages given by the participants. Comments received have been taken into account when preparing the final version of the Report.

It must be noted that the Report has not been adopted or endorsed by the European Commission or ECHA. The views collected and summarised are the views of the participants to the Workshop and may not in any circumstances be regarded as stating an official position of the European Commission or ECHA.

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Glossary

APF	Assigned Protection Factor
CARACAL	Competent Authorities for REACH and CLP
CSA	chemical safety assessment
CSR	chemical safety report
DNEL	derived no-effect level
DU	Downstream user
ENES	Exchange Network on Exposure Scenarios
ES	Exposure scenario
ESCom	Exposure scenario for communication
LEV	local exhaust ventilation
OC	operational condition
OEL	occupational exposure limit
OSH	occupational safety and health
OSOR	one substance one registration
PNEC	predicted no effect concentration
PPE	personal protective equipment
PROC	process category
LCID	Lead Component IDentification methodology
SUMI	Safe Use of Mixtures Information
RCR	risk characterisation ratio
RMM	risk management measure
SDS	safety data sheet
SLIC	Committee of Senior Labour Inspectors
SME	small- and medium-sized enterprise
SVHC	substance of very high concern
SWED	sector-specific workers exposure description

1. Executive Summary

This document summarises the discussions at the Workshop on REACH Review Action 3 (Improving the workability and quality of extended safety data sheets) that took place in Brussels on 18 March 2019. The European Commission (DGs GROW, DG ENV and DG EMPL) organised the event together with the European Chemicals Agency (ECHA).

REACH Review Action 3 requests the Commission to encourage more industry sectors to develop and use harmonised formats and IT tools that would provide more user-targeted information and simplify the preparation and use of extended Safety Data Sheets as well as facilitate their electronic distribution. It also includes the request to ECHA to develop a methodology for generating safety data sheets for mixtures and the consideration by the Commission of the potential definition of minimum requirements for exposure scenarios. In addition, the expectations for safety data sheets as an information source for occupational safety and health and for industrial emission control were issues covered in the Workshop.

The one-day workshop had three objectives:

- a) To discuss the issues raised in the paper to the Competent Authorities for REACH and CLP (CARACAL) CA/98/2018 (dd.6 November 2018) and the feedback received from Member States and other stakeholders.
- b) To improve the understanding of the scope of REACH Review Action 3, including its link to Action 12 on clarifying the interface between REACH and occupational safety and health (OSH) legislation.
- c) To harvest options for solutions that may be further explored in the follow-up process.

Forty eight experts took part, from Member States' authorities (REACH and OSH), industry, Trade Unions, from the European Commission and ECHA.

The main outcomes of the **plenary** and **breakout** sessions were:

- a. The participants expressed a **clear demand for "safe use" information** regarding hazardous chemicals in the supply chains. The demand is partly driven by legal obligations (compliance) and partly by practical information needs of chemicals users. Unfortunately, many users of chemicals observe that the provided information in the extended safety data sheets does not meet their needs.
- b. More emphasis should be placed on the **opportunities and legal obligations for upstream communication** on uses and use conditions to make exposure scenarios more realistic and tangible, so that ultimately downstream users can effectively use the information they receive from their suppliers. Downstream users should express the demand for relevant safety information more clearly e.g. via sector use maps. Action is also needed in sectors where organisations have not yet developed sector-specific use map information.
- c. **Extending the SDS for mixtures** can, compared to the current SDS, provide more explicit and specific advice on the engineering controls. A method for extending the safety data sheet (SDS) for **mixtures** should:
 - Enhance the visibility of the included exposure scenario information so that the receiving downstream user can respond to it. Attaching the safe use advice for mixtures seems to support better visibility.
 - Improve communication of use/activity specific measures for safe handling and exposure controls, respecting the OSH hierarchy of controls.
 - Support (as far as possible and as far as not already existing in current CLP and SDS rules) addressing the behaviour and effects of all (hazardous) substances in a mixture, or even reactions that take place when producing the mixture.

It is important that authors of extended Safety Data Sheets have the readers in mind (**user targeting**). User targeting includes a number of key aspects:

- Different types of users require different type of information, level of detail or presentation;
 - Readers should be able to identify information relevant to them in a quick way;
 - Information content should be relevant and helpful for the task/business of the reader;
 - The presentation of information should be optimised, “technical language” and pictograms should match the readers’ needs and knowledge.
 - At the same time, the number of options to express and present information must be restricted, i.e. a balance is needed between user targeting and harmonisation.
- d. Various **linguistic challenges** need to be tackled – different terminology used under REACH and OSH, recipients of information not being able to understand technical terminology used in extended SDSs and translation issues. To be considered:
- Develop phrases for safe use advice having the OSH background of recipients in mind.
 - Use maps expressing the conditions of use that have to be communicated in the technical language of the sector.
 - Dictionary and translation tables between the REACH and OSH worlds.
- e. Currently, exposure scenarios are generated mainly by upstream suppliers and there is no proportionality check, unless the scenarios are based on downstream sector use maps. Therefore, **end users of chemicals** need to get involved more actively in the development and the update of exposure scenarios. More involvement may, for example, help avoiding situations at single recipient’s level where exposure scenarios for worker protection are unrealistic and /or go beyond what is required under OSH.
- f. The participants expressed **legal minimum requirements** for the exposure scenarios are needed to support consistency and enforcement. Minimum requirements should cover/define the content and include a (harmonised) structure of headings/subheadings.
- g. At present, there is too much multiplication of identical information elements in the exposure scenario. Therefore exposure scenario **information should be rationalised** for presenting to readers.
- h. Consistency and harmonisation in use-descriptions can already be achieved via Chesar and the Exchange Network on Exposure Scenarios’ (ENES’) tools as a starting point (use maps, LCID, SUMIs & ESCom). These existing approaches should be better known and more commonly used.
- i. **Information exchange** should become fully **electronic** and options made available by modern Information Technology (e.g. QR-codes, interactive documents) should be explored for a more efficient and targeted flow of information. Information Technology (IT) should follow the minimum requirements, not the other way round. This may require establishing a standard that IT solutions can implement.
- j. A solution is to be found to **integrate the employer’s role and downstream user’s (DU) role** regarding compliance under **REACH and OSH**. One could consider combined REACH/OSH guidance for companies on how to use information from (extended) SDS for assessing and managing safe use at the workplace. This

could also include how a single company can handle situations when exposure scenario information is unrealistic and/or goes beyond the OSH requirements.

- k. For **fitting SDS information to OSH expectations**, it would be desirable that Member State OSH authorities align and clearly express their expectations, e.g. through an iterative process by commenting on illustrative examples.
- l. Though the focus at the workshop was on the interface between REACH and OSH, some degree of practical integration is also desirable regarding **other roles**. For example: the extended SDS may, for example, also provide valuable information to **product** or **environmental safety managers**.
- m. There is a need to continue the **close cooperation** between industry and authorities to align eSDS information with requirements under other legislation (e.g. OSH & environment).
- n. There is a particular need to closely coordinate and address the interlinks between REACH Review Action 3 and Action 12.

2. BACKGROUND

On 5 March 2018, the European Commission published a Communication, reporting for the second time on the operation of REACH and the review of certain elements ([the 'Second REACH review'](#)). In that Communication, the Commission identified 16 concrete actions to improve further the implementation of REACH, through joint efforts with national authorities, ECHA and stakeholders. Among the measures put forward was an action to improve the workability and quality of the extended safety data sheets (SDS).

Action 3: Improving the workability and quality of extended Safety Data Sheets

(1) The Commission encourages more industry sectors to develop and use harmonised formats¹ and IT tools that would provide more user-targeted information and simplify the preparation and use of extended Safety Data Sheets as well as facilitate their electronic distribution.

(2) The Commission will consider including minimum requirements for the exposure scenarios for substances and mixtures in Safety Data Sheets and request ECHA to develop a methodology for Safety Data Sheets of mixtures.

After an initial discussion in the CARACAL meeting of November 2018, the member state authorities and stakeholders agreed with the proposal of the Commission and ECHA to organise a dedicated workshop on REACH Review Action 3. The Commission and ECHA decided to organise a first workshop as an opportunity for representatives from authorities (Member States, Commission and ECHA), industry sector organisations and other stakeholders, to share their experience, exchange views and provide concrete ideas for scoping Action 3 and to identify potential solutions to meet the aims of Action 3.

A brief summary of the topics discussed is provided in the following section 3.

The Workshop programme is available in **Appendix 1**.

The 48 organisations represented at the event are listed in **Appendix 2**.

Appendix 3 and **Appendix 4** collect all supplementary documents and all presentations given at the Workshop, respectively.

¹ As those developed by the Exchange Network on Exposure Scenarios (ENES).

Prior to the workshop the automotive industry submitted their Position Paper on exposure scenarios and extended safety data sheets for mixtures. The Dutch competent authority (RIVM) provided a discussion note on "Use of exposure scenario (ES) information in Occupational Safety and Health". Both documents were circulated to the participants. The papers were not discussed explicitly during the Workshop, but the ideas they contain, or similar ones, were raised in the break-out and plenary sessions.

3. THE WORKSHOP DISCUSSION

3.1. Introduction

A Commission representative from DG GROW opened the workshop, introduced the day's programme, and thanked the ECHA staff for their active contributions in organising the event. He explained that the workshop was one of the follow-up actions to move forward with REACH Review Action 3, as proposed in paper CA/98/2018 sent to the CARACAL members in November 2018. The Commission services expect to provide CARACAL with an interim report in July and a full report on the outcomes of the Workshop and follow-up actions in November 2019.

Prior to the workshop, the registered workshop participants had received a Background Document.² This document provided the framework for the workshop and included proposals for the four main themes around which the scoping of Action 3 will develop further. The Workshop kicked-off this scoping exercise. The topics of the breakout sessions were chosen to gather the ideas and views of the participant organisations towards that scope.

ECHA then reiterated the importance of the extended safety data sheet (ext.SDS) within the whole supply chain communication for hazardous chemicals, as illustrated by ECHA's support in the preparations for this workshop.

ECHA emphasised the role of supply chain communication as an integral part of the "safe use" of chemicals.

The collaborative work done so far, for example within the Exchange Network on Exposure Scenarios (ENES), was acknowledged. A suite of tools for the generation and communication of exposure scenarios (ESs) is available, however their uptake remains at a low level. Market studies undertaken by ECHA confirmed that many of the practical problems affecting efficient supply chain communication identified five years ago in the first REACH Review remained. ECHA's Strategic objectives for the next five years complemented well the outcomes expected from REACH Review Action 3. The year 2021 represented a reasonable period in which to make progress and effective change. Organisations were encouraged to make the commitment to support Action 3 and get involved to improve supply chain communication, also because 2021 provided the opportunity to take stock when celebrating ten years of the collaborative work of ENES.

ECHA then reminded participants of the REACH principles and the related tasks on communication through the supply chain, including tasks of REACH downstream users under other legislations. More detail was provided on the main ENES tools developed in recent years to support registrants and downstream users, in particular formulators, to transfer and process the conditions of use in ESs, namely sector use maps, ECom standard phrases and XML, and for hazardous mixtures, the lead component identification method (LCID) and S.U.M.I. selection method. The state-of-play on a series of on-going beta-testing projects that embrace sector use maps, LCID and S.U.M.I. selection methods was given. These beta-tests serve to demonstrate how these tools can function together

² REACH Review Action 3. Joint COM-ECHA Workshop with stakeholders to scope Action 3. Background Document for Participants.

and where adjustments are still needed.

ECHA highlighted that the legal requirements for ESs leave room for flexibility, and that this leads to great variability in the way safe use advice is communicated down the supply chain. This diversity is an obstacle for efficient processing of the information by recipients and also for effective enforcement. Another observation highlighted was the fact that companies mostly have not yet changed their existing safety data systems for the systematic integration of information generated in the REACH chemical safety assessment. The consequence is inefficient and error-prone manual transfer of information. The obstacles and consequences highlighted in the presentation served as the framework for the topics to be discussed further with participants in the workshop to harvest potential solutions.

To conclude the introduction session DG-GROW then summarised the feedback received from Member States and stakeholder organisations, who participated in the November 2018 meeting of CARACAL; a document summarising the feedback had been distributed to participants beforehand.³ The feedback received had been supportive of the proposals for follow up action in 2019. It also reinforced the major issues for which attention was necessary: more user-targeted information through the supply chain, more emphasis on electronic safety data sheets as a means to convey safe use information, taking inspiration and potential solutions already available from the work of ENES, and the need for synergy between SDS and workplace safety rules. There were high expectations from more harmonisation and standardisation of requirements and from use of electronic tools (e.g. ECom). Minimum ES requirements were viewed as a way to facilitate the 'logistics' of supply chain communication and to improve quality and comprehensibility of ext.SDS. In respect of the ext. SDS, the Commission services are open to consider further development of REACH Review Action 3 and what mechanism(s) it may take forward to improve their workability and quality.

3.2. Breakout Group Discussions

The participants were then divided into six evenly sized groups each including representatives of industry sectors and authorities. They discussed in sessions of ca. 45 minutes the following three topics: (1) *User-targeted information*, (2) *Minimum requirements for ESs* and (3) *Methodology for mixture safety data sheets*. The groups had a facilitator and a note taker.

A range of reference documents were prepared to stimulate discussion and these are collected in Appendix 3.

A summary of the key points made during each group discussion is given below.

3.2.1. Breakout Discussion Topic 1: User-targeted information

Introduction: Companies using chemicals vary from large well-resourced ones to small firms of a few entrepreneurs operating in different sectors. Such a diverse pool of companies has varying needs for safety information. The legislation requires all companies to comply with the same requirements. The participants discussed how the targeting of information can be done in a way that meets the information needs of the user and the legal requirements, without overburdening the actors and systems generating, processing and receiving the chemical safety information.

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Response of the European Commission and ECHA to comments from CARACAL Members provided during or after the 21/11/2018 meeting to Document CA/98/2018 'Second REACH Review Action 3: Improving the workability and quality of safety data sheets', CA/19/2019, 14/03/2019.

Desired Outcome from breakout:

- Stakeholders' views on what user-targeted information means.
- Better understanding on how user-targeting relates to simplification, harmonisation and IT support (conflicts and synergies).
 - Identification of contributors to the further scoping process in 2019.

Key points from discussion

- User targeting means having the recipient in mind when generating ES information, while at the same time, for the sake of harmonisation, limiting the options on how information can be expressed and presented (i.e. balancing needed). This should take into account:
 - the capacity of the recipient to handle the information received
 - translation and terminology issues
- Targeting includes a number of key aspects:
 - Different types of users require different types of information, level of detail and presentation;
 - Recipient should be able to identify information relevant to him in a quick way (e.g. issue of 'how to label')
 - Information content to be relevant and helpful for the task/business of the recipient
 - Information presentation optimised, "technical language" plus pictograms meeting the recipient's task and ability.
- User targeting also means that the information in the ES or SDS should support the needs of recipients under other legislation, in particular OSH.
- ECHA to map out the main assessment points in the supply chain, propose the specific information needs of each user at that assessment point and then calibrate this with the stakeholder community (ensure sufficient coverage possibly beyond current ENES community)
- Information needs have to be correlated with minimum requirements topic, i.e. which info from the chemical safety report is needed, and where in the extended SDS should it be found.
- Activate upstream communication and sectors who have not yet determined (via use maps), how registrants should address the conditions in their sector in their ESs (content, realism, terminology)
- IT solutions from an information recipient perspective, implementing the mapping outcomes, to enable users to filter information received according to their needs

What do you consider the key aspects of user-targeted information for the different REACH roles & authorities?

- The Primary Users are formulators and end users
 - Within that there are companies and workers
 - A further consideration is the capacity of the companies, and the role of the company "safety manager" (where existing) who needs to assess the information and ensure both worker and environmental safety
- The Secondary users are authorities
 - REACH authorities take regulatory action based on information provided in the registrations (e.g. on uses)
 - Authorities indicate information coming down the supply chain is not fit for purpose both in terms of workplace health and safety and the environment

- Avoid one-size-fits-all approach – targeting is not in line with the harmonisation approach
- The information should cover the use conditions and support workplace risk assessment
 - Information has to be understandable for end users + needs to be presented in a simplified format
 - Which info is most relevant and for whom?
 - Which information is really needed, under which scenario
 - For the SDS: which parts are really needed by each actor and how to calibrate this
 - For the ES: how does a user identify their use or ES, then which information is really needed, how can this be improved
 - Which users need exposure estimates (that have to be reliable): mainly formulators but end users could also require this information, especially if they are doing their own assessments (DU CSR or workplace risk)
 - Different sector solutions could be considered
 - Could there be options to provide info based on the quantity purchased, or distinguishing between closed/open systems?
- Very important is to consider other legislation, especially OSH
 - Industry frustration with having to deal with legislation separately, better integration needed
 - Industry questions added value of REACH if they already fulfil their OSH requirements, and the information provided by REACH is not useful
 - There was consensus that it would be useful to clarify and align which information (both core SDS and ES) is needed by which actor for which purpose (including OSH and environment legislation).

How could/should these needs be addressed under Action 3?

- Firstly the real needs have to be identified by consulting the users of the substance/mixture
 - Safety managers or workers
 - This should be done using a structured approach, i.e. by mapping out some scenarios using examples of existing/adapted extended SDS or SUMI, and identifying whether the needed information is present (or not) for that role or type of hazard, finding out if the information as provided is understandable/useful, and if not then how to improve it
 - For end-users, the example scenarios should be simple, i.e. information about what to do or not to do
- Who should be asked?
 - Use maps may be a good start but is it the real users that provide that information (are workers providing input?)
 - What about the sectors that are not even doing use maps?
 - What about SMEs that are not even members of the sector organisations?
 - We should map out the main assessment points in the supply chain, propose the needs of each user at that assessment point and then calibrate this with the stakeholder community

- Having established and calibrated the needs of each user at each relevant point in the supply chain, these could lead to the development of a method, or standard, for targeting (or navigating to) the relevant information according to the user and their needs.
- Role of enforcement – different in different MS, some provide guidance, others rather look for non-compliances and fine.
- Responsibility of employers to make sure workers are aware of SDS contents (both under REACH and OSH).

Where/How can simplification, harmonisation and IT support more user-targeted information?

- Assuming that we can map, identify and reach consensus on the needs of the users at each step in the supply chain, a standard could be developed which would allow the users to navigate to the information they need. This standard could, in principle, be implemented via IT into a 'dynamic' SDS which delivers information according to the user and the type of assessment being performed.
- Simplification is not simple – very difficult to reduce an assessment of 20-30 of pages to 2-3 pages of information to be communicated, while at the same time ensuring compliance with legal requirements
 - Selection of only the right information to share, shorter SDS, easier to find information
 - Should not be whole CSR, message on what the user should implement should be clear, new tool needed
 - For some, simplification means a 2-page SDS, each step separated, pictograms
- Can there be one assessment that covers both REACH and OSH requirements?
 - If there is a conflict is it an indication that one of them doesn't work?
 - Improve harmonisation between REACH-OSH
- Too much flexibility for ES – harmonised template(s)?
 - Harmonisation conflicts with user-targeting
 - Defined minimum requirements (on uses and conditions) should incorporate the needs
 - Take the right info from the CSR
 - Different sectors use different terminology
 - Minimum requirements for ES for formulators
 - Minimum requirements for end users
- IT solutions from a user perspective – dynamic SDS: users could input their role/use and filter the SDS to indicate applicable information only for their needs
- Free IT tools for SMEs (developed by ECHA?)
- Gaps in the existing systems:
 - Bottom-up communication to get information i.e. use maps – who is missing, can we expand coverage?
 - Can we improve the granularity of information:
 - ES library developed by ECHA, possibly as a 2nd tier to fill gaps or where the sector is not active
- Language and terminology remains a problem: both translation, and using REACH language that is not understood by others
- Conflicting costs/resources

- Defined method needs to be supported and accepted by authorities.

What follow-up actions do you consider necessary (and by whom)?

- Need to map information needs by user (as described in point 2)
- Need to develop profiles of users and calibrate with their needs
- ECHA Guidance on ES for communication?
 - Guidance on SDS exists, Guidance on CSR exists, but how to get info from the CSR to the eSDS? Guidance/methodology/decision tree on how to handle incoming information
 - Leading to a possible IT standard when that information has to be converted to a mixture SDS
 - ECHA takes a more active role in ensuring that information is fit for purpose
- User-targeted tools towards specific groups: e.g. formulators, professional users etc.
 - Sufficient for the obligations that the user has to fulfil
- More, clear and workable measures have to be communicated in the SDS for every (hierarchy of) control level. OSH has to check which level of measure has to be taken. Raise awareness that ES can be user targeted
- Less administrative work for REACH because an assessment has to be done for OSH
- Responsibility and active involvement of the end users, change mentality/culture
 - Raise awareness of duties and active role when using safety information
 - Training needs for companies, workers and authorities
 - Build capacity of/within companies
 - Companies ensure their workers are trained etc.
- "Efficiency" can be gained at all levels by investing in learning and dissemination of information
- EU funding to build capacity of companies - at our level we should take care that companies understand what they need to do, and in turn companies need to take care that their workers are trained etc.

3.2.2. Breakout Discussion Topic 2: Minimum requirements for exposure scenarios

Introduction: Annex II of REACH prescribes the structure of the SDS (i.e. 16 sections and subsections including titles) and specifies the required content. For "attaching" or "including" ESs into the SDS such requirements do not yet exist. The discussion focused on identifying currently known problems for which minimum requirements would provide a solution. In addition, the participants provided their views on what these requirements should cover to make the eSDS communication more efficient and effective.

Desired Outcome from breakout:

- Understanding stakeholders' expectations and concerns related to minimum requirements
- Better understanding of which of the identified problems could be solved and what kind of draw backs there might be
- Collect views on what such requirements should cover and how they could be set.

Key points from discussion

- General agreement among stakeholders and Member States that minimum requirements for ESs are needed.
- Minimum requirements should include a (harmonised) template. Such standardisation serves to support all supply chain actors in their obligations, including enforcement authorities.
- A number of templates already exist as a starting point to define minimum requirements, e.g. ECHA's Chesar tool, ENES examples, including for mixtures (S.U.M.I. template).
- Further work is required to define the actual content of the requirements and if/how user targeting should be considered in setting minimum requirements.
- Minimum requirements should serve a wider purpose and stretch beyond the REACH related obligations and processes.
- Must involve target recipient(s) upfront (i.e. OSH, environment, product safety,...) to establish that the minimum requirements meet their needs.

Expectations - what should minimum requirements cover?

- General agreement that minimum requirements are needed.
- Avoid overload of ES. State also what an ES should not cover.
- Set template/format. Template: Simple. Standardised. Stable.
- Harmonised table of content with harmonised titles and page numbering
- A short explanation of what ES are for (e.g. with table of content, not with each ES)
- Technical function of the substance should be in the ES title (also important for substitution)
- Differing views on the actual specific content to be required:
 - full content of ES in CSR
 - not too detailed
 - as simple as possible
- Use-specific information:
 - Use descriptors.
 - Concentration; Physical state; Temperature range(s): to match the subsequent steps in a process.
 - Exposure estimation: not risk characterisation ratio (RCR), as this requires a "back calculation from DNEL (if found)".
 - Information on the exposure estimation tool used: for formulators only.
- Chesar (already) provides a list of requirements: Draw inspiration from and utilise Chesar list as the starting point for defining the minimum requirements.
- User targeting to be considered. Recognition that different content may be required depending on recipient (e.g. formulator vs end user), on chemical (substance vs mixture) and on combination of both (substance/mixture for formulation vs substance/mixture for end use). Note: not discussed whether hazard type should be considered (e.g. SVHC vs skin irritant).
- Type of chemical safety assessment done: quantitative or qualitative. Flag the information derived from a qualitative assessment, to avoid recipient demanding DNELs, RCR information etc.
- For quantitative assessment: mention the modelling tool used and the input parameters needed for the assessment (possibility for checking assessment and scaling if necessary).

- Consider adding modelling assumptions that would be necessary to run assessment of same use/contributing scenario with another tool.
- For mixtures, start from S.U.M.I. template.
- ES minimum requirements should mirror the elements to be taken into consideration to perform workplace risk assessment (Article 4 of the Chemical Agents Directive, [CAD](#))
 - hazardous properties of the chemical,
 - information on safety and health that shall be provided by the supplier (e.g. the relevant safety data sheet in accordance with Regulation (EC) No 1907/2006 of the European Parliament and of the Council (1)),
 - the level, type and duration of exposure,
 - the circumstances of work involving such agents, including their amount,
 - any occupational exposure limit values or biological limit values established on the territory of the Member State in question,
 - the effect of preventive measures taken or to be taken,
 - where available, the conclusions to be drawn from any health surveillance already undertaken.
 - In the case of activities involving exposure to several hazardous chemical agents, the risk shall be assessed on the basis of the risk presented by all such chemical agents in combination.
- Expand OSOR concept to OSOROSE (One Substance – One Registration – One Starting Set of ES)
- Support better/understandable upstream communication.

Obstacles – what could be solved with minimum requirements?

- Legal certainty will help enforcement by authorities and compliance by industry.
- Clarifying legal uncertainty: ESs exist for substances, and “safe use” information exists for mixtures (not the ES for mixture).
- Will bring alignment across industry sectors.
- IT tools development will be easier once the minimum requirements are set (clarity on what to develop).
- No repetition of SDS main body information in Annex.
- Provide the same level of information to “users” and “inspectors”. More structured information via a template helps enforcement.
- Converting substance properties in moving from substance(s) to mixture(s) e.g. change in physical form(s).

Challenges – which additional challenges will minimum requirements bring?

- Too many requirements may be difficult to handle.
- Too few requirements may not be sufficient to ensure clear value added for other legislative obligations (e.g. OSH workplace risk assessment).
- More (user-targeted) specificity in the ES (template) will increase the number of ESs in the Annex: a balancing act!
- Industry consortia and consultants use Chesar, not SMEs; as a consequence there is a knowledge gap in this segment of industry.
- Depending on content/level of details of requirements, upstream communication

- needs to work properly (so that registrants get the information needed).
- Currently, too much variation in what downstream users ask of upstream suppliers (registrants): it needs standardisation. Downstream users CSR (Annex XII) too onerous if additional identified use(s) not taken up by registrant.
- There is a clear demand for “safe use” information regarding hazardous chemicals in the supply chains. The demand is partly driven by legal obligations (compliance) and partly by practical information needs of chemicals users. Unfortunately, many users observe that the provided information in the extended safety data sheets does not meet their needs

Implementation – how should minimum requirements be set?

- In addition, guidance, training and awareness raising needed (all actors need to be aware of their duties and rights).
- Provide training on ES and tools used for CSA to authorities and EHS managers. Education of recipients / inspectors.
- Also make sure HelpDesks are aware and trained so they can answer questions.
- Summarise uses and process categories (PROCs) with same risk management measures; avoid duplication of information in the ES.
- Put generic information e.g. dermal protection, into the SDS main body.
- Prepare standard template. NB: Both industry and Member State participants believed an ES “template” was necessary; guidance alone is not considered enough.
- Utilise “ENES template” as starting point for template; divide template into ‘Obligations’ and ‘For Information Only’ sections.
- More specific description(s) of what is required for the user.
- Smarter use of IT tools e.g. scannable QR codes to download relevant SDS & ESs.
- Smarter procurement:
 - IT tool(s) to enable the selection of relevant use(s) needed by recipient.
 - Prepare a “standard” as a benchmark against which IT providers can develop IT solutions (without inhibiting their business development).
- A gradual transition to minimum requirements template will be needed.
- More emphasis on existing legal requirements for upstream communication: not well known in industry / not easily enforceable.
- Presentation on “ENES tools”, raise awareness that information on exposure is being harmonised there: use the ENES tools!

Further scoping and commitment

- Point of view of OSH (SLIC; DG EMPL) should be taken on board in the work.
- Ensure dialogue with Env & OSH users of the information i.e. it meets their needs and purpose.
- Allow “flexibility” in how the REACH information is utilised at the workplace locally.
- Also consider environment, nanomaterials, product safety elements.
- HelpNet, ECHA, sector associations.
- European Association of Chemical Distributors (Fecc) is an active partner in ENES. Interest in nanomaterials question.
- European Crop Protection Association (ECPA) is interested in the nanomaterials question and links with plant protection products regulation.

Other – wish list

- Create a glossary of all acronyms used in legislation related to chemicals.

3.2.3. Breakout Discussion Topic 3: Mixture methodology

Introduction: European companies have been producing SDSs for mixtures for the past 20 years, and sectors, companies and service providers have continuously developed their corresponding methodologies. Nevertheless, Action 3.2. requests ECHA to develop a methodology for SDS for mixtures. It is therefore crucial to define in which way such development could add value to what is already in place or what is under development. The discussion focused on harvesting the participants' views on what should ECHA's work deliver and how could it contribute to solving the identified problems as well as on how should the contribution/consultation with stakeholders be organised on this topic.

Desired outcome from breakout:

- Understanding of the stakeholders' expectations and concerns
- Collect ideas on the scope that ECHA's development work could have
- Information on activities that could be complementary to the overview on ongoing developments
- Identification of contributors to the further scoping process in 2019

Key points from discussion

- The method should support (as far as possible) addressing the behaviour of substances in a mixture, or even reactions that take place when producing the mixture.
- The method should support narrowing down the various ingredients of a mixture to the risk driving components.
- The method should support generation of user-targeted information for different user groups (e.g. formulator and end-user companies, work place risk assessor and workers).
- The method should enable clear indication what information comes from the components' ESs. Attaching the included ES information may be clearer in this respect than integration into Sections 7 and 8 of the SDS⁴. However there are also industry groups expressing their preference for the ES information to be integrated into the main body of the ES.
- The method should support cascading relevant information down the supply chain.
- The method should support selection of component specific information relevant to the recipient - How to integrate relevant DNELs, OELs and PNECs and certain physico-chemical properties in the mixture SDSs.
- OSH concern - How to inform about process generated materials in the SDS (e.g. dust & reaction products during use).

Ideas on the scope of the mixture methodology development work

- Do not reinvent the wheel but further develop and promote what has already been developed by industry and ECHA (Chesar, use maps, LCID, SUMIs & ESCOM)
- Strengthen mechanisms that bring more reality into the ES: bottom-up use map and SWED reference in the extended SDS; provide RCR and exposure values so

⁴ However ACEA indicated in their written input that automotive industry would prefer all information to be integrated in the main body of the SDS.

that DU can see at which level of exposure/risk the supplier has concluded his assessment.

- The method should support (as far as possible and as far as not already existing in current CLP and SDS rules) addressing the behaviour and effects of all (hazardous) substances in a mixture, or even reactions that take place when producing the mixture.
- The method should support narrowing down the substances in a mixture to the risk driving components.
- For end-users of mixtures, the method should generate consolidated information in a simple and clear document that uses standard phrases (information in the body of the SDS or attached);
- The method should support the provision of targeted information to different user groups, as their needs may vary: worker instruction card type for micro-companies on the one hand, and data supporting an own assessment at a user's site on the other hand. The latter may also include the needs of formulators to receive the information in disaggregated form for the substances in raw materials that are used for mixtures. Possibly a case study is needed to better understand this need.
- Make it clear in mixture eSDSs which information comes from ESs and ensure that relevant information is cascaded down in the supply chain; under this perspective, attaching the ES information to the mixture SDS may be clearer than integration into Sections 7 and 8 of the SDS.
- Ensure that REACH information provided will support the workplace risk assessment requirements and be suitable for commonly used OSH tools e.g. Stoffenmanager. Remember to consider also environmental information in the eSDS.
- Move to electronic information exchange and use of modern ways of passing information, for example QR-codes (i.e. digitalisation of the information flow and not only PDF-documents)
- Formulator sectors to support and take a more prominent role in targeted downstream communication by activating inactive sectors to take part in the use map development and other related activities.
- Authorities to indicate acceptable methods for measuring exposure.

Further scoping work and contributors in 2019

- The outputs of LCID and SUMI methods need to be tested with end users of chemicals. The test should also include SMEs (i.e. go beyond the current ENES pilot studies; see <https://echa.europa.eu/about-us/exchange-network-on-exposure-scenarios>).
- Explore how the new approaches can be made better known in sectors not yet actively participating in ENES work.
- Explore how SUMI approaches can be made more transparent (i.e. from a sector-developed to a generally understood and accepted way to communicate, incl. public guidance to the recipients on the approach).
- Continue the close cooperation between industry and authorities.

ECHA's role

- Guidance: identify and develop what is still missing.
- Stimulate downstream users to generate use maps.
- Bring industry sectors together for harmonisation.
- Endorse industry templates/methods.
- Provide a tool for formulators for processing ES information.
- Provide databases that support eSDS creation (e.g. European Union Chemical Legislation Finder (EUCLEF) that has information on national OELs etc.).
- Provide a library of good practice examples of eSDS for various product types (should also include difficult cases).

- Explain how the available methods/tools (LCID & SUMI) can help formulators to comply with the extended SDS requirement for mixtures (e.g. simple guidance).
- Contribute to the SUMI phrase translation activities.
- Compile a list of ongoing national activities of relevance.
- Harvest experience and expertise from
 - Member State enforcement experts,
 - Member State helpdesks,
 - IT providers (SDS services and software providers).

REACH and OSH

- Close coordination and interlinks between REACH Review Action 3 and Action 12.
- Alignment of REACH information with the OSH work place chemical risk assessment requirements.
- Develop a “translation table” that links REACH and OSH terminology, information requirements etc.
- Consider “educational” enforcement activities (i.e. to enhance the understanding of the eSDS requirements and benefits the new information may bring).
- Member States should be clearer (and preferably more aligned) on how to determine safe use at the workplace and which information is needed for that. Such alignment of expectations would help making REACH information more targeted.

3.2.4. Plenary roundtable reactions

The following are comments or reactions from individual participants, noted during the plenary sessions (mostly after the breakout sessions).

- Cefic: If changing REACH Annex II or other Annexes, will there be implications for GHS?
- ACSH WPC⁵ (DE): What is expected from end users? What are their duties in respect of mixtures (ES information)?
- EuPC: Responding to the report from breakout session Topic 3 – Consolidation is not always needed. If there is only one hazardous substance in masterbatch or plastic compound for example, there is no need for consolidation.
- Dept. for Labour Inspection (CY): Standardisation in format and content is priority.
- ECPA: REACH and Plant Protection Products legislation to be taken together.
ECHA and EFSA to tackle mixture issue → common strategy is necessary. ECHA mentioned “co-formulants” being discussed between ECHA and DG SANTE, but ESs have not yet featured in discussions.
- CONCAWE: Regarding IT service providers: companies buy IT services but then customise them further. Need to talk to companies about IT tools as well.
- Cefic: Important to look at the electronic distribution of SDS and the positioning of ECom and EuPhraC; buy in and take up of solutions by IT providers is necessary but content/quality needs to be right first.
- DUCC: Chemical safety report situation for downstream users not addressed in workshop or scope discussions. Obligation of DUs to attach ES to SDS of the mixture when they have carried out a DU CSR causes confusion – need to make obligations clearer.
- SMEUnited: Focus needed on communication flow. Acknowledge a challenge to i)

⁵ Advisory Committee for Safety and Health at Work, Working Party on Chemicals (ACSH WPC)

make information flow work and ii) having good quality information flowing. Put more emphasis on making technology work for communication of safe use of substances. Get DUs to respond to what they receive i.e. motivate more upstream communication.

- EuPC: Different target groups have different needs; IT solution should help.
- DUCC: Which sectors/companies will be interviewed in the further scoping process? DUCC willing to support discussions.
- RIVM (NL): REACH is also meant to improve workplace safety. It is worrying if authorities have more trust in the workplace risk assessment of a DU SME than in the ES of a large registrant. Member State OSH authorities should make clearer/more concrete what they expect in terms of workplace risk assessment and corresponding input via REACH ESs.
- ACSH WPC (DE): The Chemical Agents Directive says that the SDS is the first information source for workplace risk assessment. WPC has a problem with the concept that the "risk assessment (ES) from the supplier has priority over the workplace risk assessment by the employer". ECHA: REACH provides a mechanism to allocate assessment responsibility in the supply chain (either supplier or customer) rather than giving priority to the suppliers.

4. Conclusions and follow up

The main outcomes of the discussion can be found in Section 1 (Executive Summary).

The participants at the workshop agreed with the basis for the work on Action 3 described in the Background Document, namely that an *extended* Safety Data Sheet is an SDS into which DNELs/PNECs and ESs resulting from a chemical safety assessment (CSA, according to REACH Annex I or Annex XII) have been included. DNEL/PNECs complement the information in Section 8.1 of the SDS, ESs complement information in Sections 1.2, 7 and 8 of the SDS. For registered substances as such, the ESs must be included in the form of an Annex to the SDS. For substances in mixtures, the legal text leaves it open how the ESs received at formulator's level are included into the SDS for mixtures.

Within the scope of REACH Review Action 3, four main themes need to be addressed:

- (i) The information needs of the actors in the supply chain, to be satisfied by the eSDS,
- (ii) How that information can be generated by the suppliers,
- (iii) How that information can be transferred between actors in an efficient and effective way, and
- (iv) Suitable mechanisms and means to support implementation of the solutions.

For the next steps, the workshop considered a 3-stage process that involved

1. A scoping phase to identify issues/problems/potential solutions,
2. A development phase for working out solutions, making choices between options and testing their impacts, and
3. A consultation phase on whether the eventually proposed solutions are appropriate.

For 2019, efforts would concentrate on harvesting proposals for solutions from different stakeholder groups, drawing upon the ideas shared at this workshop. A stakeholder workshop on 23 and 24 September 2019 (ECHA, Helsinki) will provide the opportunity to review and agree upon the priority areas and potential solutions for development that would form the basis of a Commission-ECHA paper to CARACAL in November 2019.

Appendix 1 Programme of the workshop

REACH Review Action 3 - Joint COM-ECHA Workshop with stakeholders to scope Action 3

18 March 2019, Brussels

9h00-9h30 Registration

9h30-9h40 Welcome by Commission and ECHA

9h40-10h40 Set the scene: Why is Action 3 needed?

- The state of supply chain communication 10 years after REACH (Jack de Bruijn, ECHA)
- ECHA's analysis on shortcomings (Andreas Ahrens, ECHA)
- Current status of REACH Review Action 3 and main comments received from CARACAL (Gert Roebben, COM)
- Discussion/Reaction to opening remarks

10h40-10h50 Explanation and set-up of workshop approach (breakout group format)

10h50-11h10 Coffee break

11h10-12h50 Discussion in small groups, rotating (Part 1)

12h50-13h50 Lunch break

13h50-14h35 Discussion in small groups, rotating (Part 2)

14h35-14h55 Coffee break

14h55-15h30 Reports of rapporteurs

15h30-16h30 Plenary round-table discussion

16h30-17h00 Conclusions and discussion on next steps

Appendix 2 List of participating organisations

Ministry of Health, Spain	Norwegian Labour Inspection Authority, Norway	SMEUnited	European Federation for Construction Chemicals (EFCC)
Ministère du Travail, France	Inspectorate SZW, Ministry of Social Affairs and Employment, Netherlands	Downstream Users of Chemicals Coordination group (DUCC)	Orgalim - Europe's Technology Industries
Swedish Work Environment Authority (KEMI), Sweden	National Institute for Public Health and the Environment (RIVM), Netherlands	The European Chemical Industry Council (Cefic)	European Plastics Converters (EuPC)
Ministry of Health, Croatia	Chemikalia, Poland	European Tech & Industry Employers (CEEMET)	IMA-Europe (Industrial Minerals Association Europe)
National Health Centre, Hungary	Federal Public Service (FPS), Health, Food chain safety and Environment, Belgium	European Trade Union Institute (ETUI)	International Association for Soaps, Detergents and Maintenance Products (A.I.S.E.)
Ministry of Economy, Slovakia	Danish Working Environment Authority (WEA), Denmark	The European Crop Protection Association (ECPA)	CONCAWE
Health & Safety Authority, Ireland	Environmental Protection Agency (EPA), Lithuania	The European Council of the Paint, Printing Ink and Artists' Colours Industry (CEPE)	European Commission (DG GROW)
Ministry of Environment, Romania	Federal Institute for Occupational safety and Health (BAuA), Germany	EUROMETAUX	European Commission (DG ENV)
Agency for Competitiveness and Innovation (IAPMEI), Portugal	Department of Labour Inspection, Cyprus	European Association of Chemical Distributors (Fecc)	European Commission (DG EMPL)
State Secretariat for Economic Affairs (SECO), Switzerland	Austrian Federal Economic Chamber (WKO)	Confederation of Danish Industries (DI)	European Chemicals Agency (ECHA)
	ACSH Working Party on Chemicals ⁶ (German national authority member)		

⁶ Advisory Committee for Safety and Health at Work (ACSH)

Appendix 3. Breakout discussions: Supplementary documents

3.1 Topic 1: User-targeted information

Document A

Types of needs

The information need refers to:

- I. The information **content**
- II. The technical language/terminology and graphical support intended for **human readers**

Different needs according to:

- **Role** in the supply chain
 - Formulator
 - Distributor
 - End-user delivering services
 - End-users producing articles
- **HSE** capacity of company
 - Companies with no or limited HSE management
 - Companies with full HSE management
- **Destination/use** of information e.g.
 - Workplace risk assessment (OSH)
 - Chemicals safety assessment (REACH)
 - Obtaining / complying with environmental permit
 - Generating SDS for mixture
 - Product safety assessment under particular legislation
 - **Enforcement** perspective (e.g. REACH/CLP, OSH, environment, market surveillance)
- **Type and extent of hazard** (may determine required granularity and specificity of exposure scenarioES information)

Document B

Example for a task/contributing scenario (worker part), addressing "Charging and discharging of substances" for a solvent

Contributing Scenario(s)			
Use descriptors covered	PROC 8b: Transfer of substance (charging and discharging) at dedicated facilities. Use domain: Industrial		
Operational conditions			
Concentration of the substance	up to 100 %		
Physical state	liquid		
Process temperature	20°C	100°C	100°C
Resulting vapour pressure of substance	32 Pa	10,000 Pa	10,000 Pa
Duration and frequency of activity	480 min daily	60 min daily	480 min daily
Indoor/Outdoor	indoor		
Risk Management Measures			
Room ventilation	Provide a good standard of controlled ventilation (5 to 10 air changes per hour)	Provide a good standard of controlled ventilation (5 to 10 air changes per hour)	N/A
Local exhaust ventilation	N/A	N/A	Provide specifically designed and maintained LEV (fixed capturing hood type, on-tool extraction or enclosing hood type)
Gloves	Wear chemically resistant gloves in combination with basic employee training. For further specification refer to section 8 of the SDS.		
Eye protection	Use suitable eye protection. For further specification refer to section 8 of the SDS.		
Exposure Assessment			
Assessment Method	EASY TRA v4.2, ECETOC TRA v3.0 Worker, Room ventilation assumed effectiveness 70% LEV: assumed effectiveness 95% Gloves: assumed effectiveness 90%		
Exposure estimate - Dermal, long-term - Inhalation, long-term	1.3714 mg/kg bw/day 6.1957 mg/m ³	0.2743 mg/kg bw/day 6.1957 mg/m ³	1.3714 mg/kg bw/day 5.1631 mg/m ³
Risk Characterisation Ratio (RCR) - Dermal - systemic - Inhalation - systemic	0.285714 0.430257	0.057143 0.430257	0.285714 0.358547

Document C

Example for an exposure scenario (worker part) addressing use in coatings at industrial sites for an aromatic solvent

Not all of the 16 contributing scenarios listed here.

Measures applicable to all contributing scenarios

Product (Article) characteristics
Covers concentrations up to 100.0 % except for PROC 10 (range between 2 and 50%)
Technical and organisational conditions and measures
For measures to control risks from physicochemical properties, refer to main body of the SDS, section 7 and/or 8. Assumes process temperature up to 40.0 C, except for film formation by forced drying (PROC 2) Assumes indoor use
Conditions and measures related to personal protection, hygiene and health evaluation
Ensure that direct skin contact is avoided; Identify potential areas for indirect skin contact; Wear suitable gloves; For further specification, refer to section 8 of the SDS.

Specific measures

Contributing scenario	Specific measures
Mixing operations; Closed systems; (PROC 3)	Covers use up to 8.0 h/day
Preparation of material for application; Mixing operations; Open systems (PROC 5)	Covers use up to 8.0 h/day Provide a good standard of general ventilation (not less than 3 to 5 air changes per hour).
Material transfers; Dedicated facility (PROC 8b)	Covers use up to 1.0 h/day Provide a good standard of general ventilation (not less than 3 to 5 air changes per hour). Provide specifically designed and maintained LEV (fixed capturing hood type, on-tool extraction or enclosing hood type) Drain down system prior to equipment break-in or maintenance.
Material transfers; Drum/batch transfers; Transfer from/pouring into containers (PROC 9)	Covers use up to 1.0 h/day Provide a good standard of general ventilation (not less than 3 to 5 air changes per hour). Provide specifically designed and maintained LEV (fixed capturing hood type, on-tool extraction or enclosing hood type) Use suitable eye protection. For further specification, refer to section 8 of the SDS.
Spraying; Automated task (PROC 7)	Covers use up to 8.0 h/day Provide specifically designed and maintained LEV (fixed capturing hood type, on-tool extraction or enclosing hood type). Carry out in a vented booth or extracted enclosure. Wear suitable gloves in combination with specific activity training; For further specification, refer to section 8 of the SDS.

Spraying; Manual (PROC 7)	Covers use up to 8.0 h/day Provide a good standard of controlled ventilation (10 to 15 air changes per hour). Wear a respirator providing APF 10; for further specification, refer to section 8 of the SDS.
Roller, spreader, flow application (PROC 10)	Covers use up to 8.0 h/day Provide a good standard of general ventilation (not less than 3 to 5 air changes per hour). Provide specifically designed and maintained LEV (fixed capturing hood type, on-tool extraction or enclosing hood type)
Dipping, immersion and pouring (PROC 13)	Covers use up to 8.0 h/day Provide a good standard of general ventilation (not less than 3 to 5 air changes per hour). Provide specifically designed and maintained LEV (fixed capturing hood type, on-tool extraction or enclosing hood type)
Film formation - force drying, stoving and other technologies (PROC 2)	Covers use up to 8.0 h/day Provide specifically designed and maintained LEV (fixed capturing hood type, on-tool extraction or enclosing hood type) Closed systems Assumes process temperature up to 100.0 °C
Film formation - air drying (PROC 4)	Covers use up to 8.0 h/day

Document D

SUMI
Safe Use of Mixtures Information



AISE_SUMI_IS_7_1

Version 1.1, August 2018

Industrial spraying; Automated task; Open systems; Long term (LEV)

This document is intended to communicate the conditions of safe use for the product and should always be read in combination with the product's Safety Data Sheet and labels.


General description of the process covered

The SUMI applies to industrial spraying products. This Safe Use Information is based on the AISE_SWED_IS_7_1.

Operational Conditions

Maximum duration	480 minutes per day.
Range of application / Process conditions	Indoor Use.
	Process carried out at room temperature.
	In case of dilution, tap water at a maximum temperature of 45°C is used.
Air exchange rate	LEV required.

Risk Management Measures

Measures related to personal protective equipment (PPE), hygiene and health evaluation	Wear suitable gloves. See section 8 of the SDS of this product for specifications. 
	Training of workers in relation to proper use and maintenance of PPEs must be ensured.
Environmental measures	Prevent that undiluted product reaches surface waters.
	If appropriate AISE SPERC 8a.1.a.v2 may apply: wide dispersive use resulting in release to municipal sewage treatment plant.

Additional good practice advice

Don't eat or drink. Don't smoke. Don't use in proximity of open flame.	
Wash hands after use. Avoid contact with damaged skin. Do not mix with other products.	
Spillage instructions	Dilute with fresh water and mop up.
Hygiene practices	Follow the product instructions as specified on the label or in the product information sheet and use good occupational hygiene practices as specified in Section 7 of the product SDS.

Additional information depending on product composition

The label and (when required) the Safety Data Sheet contain additional, product specific information crucial for working safely with mixtures. Please refer to the product label and SDS for information including, but not limited to: product hazard classification, potentially allergenic fragrances, notable ingredients and threshold limit values (when available).

Disclaimer

This is a document for communicating generic conditions of safe use of a product. It is the responsibility of the formulator to link this SUMI to the SDS of a specific product that he is selling.


If a SUMI (or associated SWED) code is mentioned in the SDS of a product, the formulator of that product declares that all substances in the mixture are present in such concentration, that the use of the product within the conditions of the SUMI is safe. When available, this safe use is ensured by evaluating the results of the chemical safety assessments as performed by the raw material suppliers. When no chemical safety assessment has been carried out by the supplier for an ingredient that contributes to the classification of the mixture, the formulator has performed a safety assessment himself.

Following Occupational Health legislation, the employer of workers that use products that are assessed as safe following SUMI conditions remains responsible for communicating relevant use information to employees. When developing workplace instructions for employees, SUMI Sheets should always be considered in combination with the SDS and the label of the product.

This document is provided by A.I.S.E. for general information purposes only. The formulator uses the content of this document at its sole risk.

A.I.S.E. disclaims any liability to any person or entity for any loss, damage no matter of what kind (actual, consequential, punitive or otherwise), injury, claim, liability or other cause of any kind or character based upon or resulting from the use (even partly) of the content of this document.

Document E

SUMI Safe Use of Mixtures Information for end-users	
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Title: Industrial spray painting, no booth	CEPE_IS_03
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This document is intended to communicate the conditions of safe use for the product and should always be read in combination with the product's Safety Data Sheet and labels.

General description of the process covered

Paint application on industrial line with no enclosure (only local exhaust ventilation)

This safe use information is linked to SWED CEPE_IS_03

Operational Conditions

Indoor use

Maximum duration of individual exposure: covers daily use up to 8 hours, 225 days per year

Risk Management Measures

Contributing activity	Ventilation	Ventilation - air changes/hr
Preparation of material for application	Enhanced (mechanical) room ventilation	5-10
Loading of application equipment and handling of coated parts before curing	Enhanced (mechanical) room ventilation	5-10
Application	Local exhaust ventilation	Refer to relevant technical standards
Drying/curing	Enhanced (mechanical) room ventilation	5-10
Application equipment cleaning	Enhanced (mechanical) room ventilation	5-10
Waste management	Enhanced (mechanical) room ventilation	5-10

Contributing activity	Respiratory	Eye	Hands
Preparation of material for application	None	Use eye protection according to EN 166	Wear suitable gloves tested to EN374
Loading of application equipment and handling of coated parts before curing	None	Use eye protection according to EN 166	Wear suitable gloves tested to EN374
Application	Wear a respirator conforming to EN140 with an assigned protection factor of at least 10	Use eye protection according to EN 166	Wear suitable gloves tested to EN374
Drying/curing	None	None	None
Application equipment cleaning	None	Use eye protection according to EN 166	Wear suitable gloves tested to EN374
Waste management	None	Use eye protection according to EN 166	Wear suitable gloves tested to EN374

See chapter 8 of this Safety Data Sheet for specifications.



<http://www.ducc.eu/Publications.aspx>

Disclaimer

The information in this Safe Use of Mixtures Information sheet is based on the data provided by the substance supplier for the substances in the product for which a chemical safety assessment has been carried out at the time of issue. It does not guarantee safe use of the product and does not replace any occupational risk assessment required by legislation. When developing workplace instructions for employees, SUMI sheets should always be considered in combination with the SDS and the label of the product.

No liability is accepted for any damage, no matter of what kind, which is the direct or indirect consequence of acts and/or decisions (partly) based on the contents of this document.

Page 2/2

SUMI CEPE_IS_03_v1 2017-02-01

3.2 Topic 2: Minimum requirements for exposure scenarios

Document A

Obstacles identified

Lack of demand for safe use advice from the bottom of the supply chain
(=> market forces do not properly work)

- Confusing and not sufficiently targeted information
- Unclear value of ES information for other obligations
- Lack of capacity to use/work with information
- Lack of trust from Member State OSH authorities in modelling based REACH ES
- Recipients of mixture SDS don't recognise the "status" of exposure scenario information, and associated duties

Upstream communication mechanisms don't deliver No established mechanisms for one to one communication; DUs unaware of duties, don't know how or reluctant to communicate own conditions; when communicating, no response from suppliers => registrants (and authorities) lack full overview of uses and use conditions of substances

Current legal requirements on exposure scenarios **difficult to enforce**
(=> market forces do not properly work; => insufficient driver for harmonisation)

Inertia of existing SDS systems and underlying IT global players reluctant to change running SDS systems

Available solutions are not used

- by registrants for CSR and SDS update
- by downstream sectors still absent from making use-information available to registrants in an organised way
- in a way that duplication of information is avoided (e.g. over-differentiation of uses).

Document B

Existing base line (REACH regulation) for content of exposure scenarios, and first ideas for amendment

Generic requirement on content	Specific	Existing requirement laid down ...	Additional condition	Details to be specified ⁷
Provide brief general description of identified use:		Annex VI, 3.5 Annex 1,		
	Briefly describe what the substance is intended to do (technical function)	Annex II, 1.2 Via IUCLID		
	Specify life-cycle stage	Via IUCLID		
	Specify category for process and related workers activity	via IUCLID		
	Specify category of mixture	Via IUCLID		
	Specify category article	Via IUCLID		
	Specify environmental release category	Via IUCLID		
	Specify sectors of use	Via IUCLID		
Give exposure scenario a title consistent with description of use		Annex 1		
	Specify to which life cycle stage and products the exposure scenario refers		x	x
Describe operational conditions (<i>to which precautions and exposure controls apply</i>)	Type of process and related workers activity	Annex 1 via IUCLID		
	Activity of consumers	Annex 1		
	Concentration of substance in the material processed		x	x
	Physical form of chemical	Annex 1		x

⁷ Preferably the details/values that can be specified are defined in a drop down list. For example: For the condition type "Extent of room ventilation" one may want to specify the following details: [*no particular room ventilation measures required*] [*good mechanical room ventilation of least 3 air changes per hour*]; [*enhanced mechanical room ventilation of at least 5 air changes per hour*]; [*specialised room ventilation of at least 10 air changes per hour*]; [*specialised room ventilation of at least 30 air changes per hour*].

Generic requirement on content	Specific	Existing requirement laid down ...	Additional condition	Details to be specified ⁷
	Room size		x	x
	Duration of exposure	Annex 1		x
	Frequency of exposure	Annex 1		x
	Temperature of process		x	x
Recommend precautions for safe handling	Specify (degree) of Containment	Annex 1, Annex II, 7.1		x
	Specify Measures to prevent dust and aerosol generation	Annex II, 7.1		x
Describe appropriate engineering controls		Annex II, 8.2.1		
	Specify extent of room ventilation		x	x
	Specify local exhaust ventilation		x	x
	Specify in detail eye/face protection	Annex II, 8.2.2		
	Specify in detail Hand protection	Annex II, 8.2.2		
	Specify in detail other skin protection	Annex II, 8.2.2		
	Specify in detail Respiratory protection	Annex II, 8.2.2		
Environmental exposure controls	Provide summary of risk management measures controlling exposure	Annex II, 8.2.3		
	Identify daily amount that can be used without onsite RRM at industrial site		x	x
	Identify whether or not the identified use implies release to water		x	x
	Specify type of suitable onsite treatment technique with required efficiency		x	x
Summarise exposure estimation in Annex to SDS, where required		Annex I, 5.2.1		

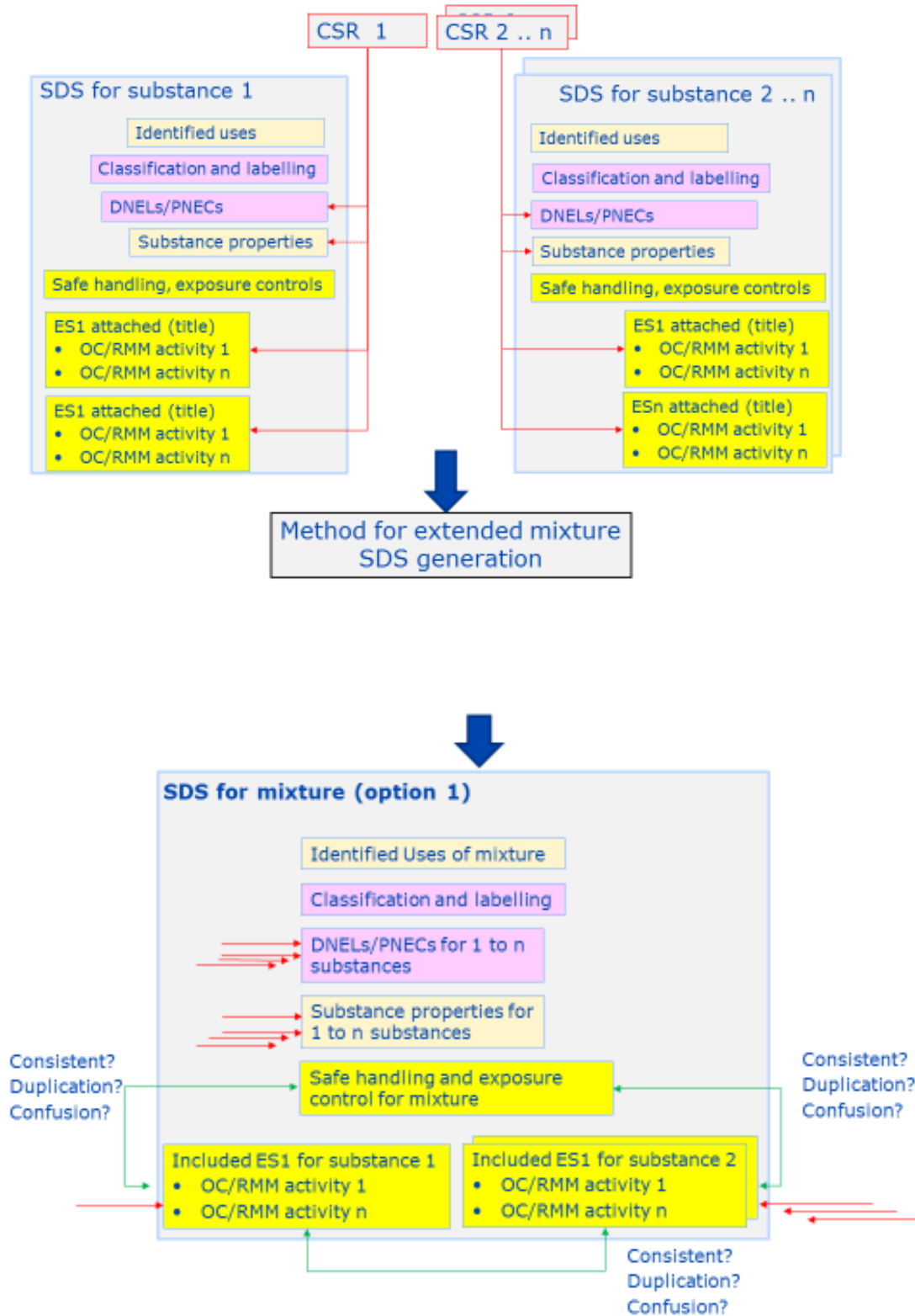
Other ideas for amending/clarifying the requirements

- Provide table of content (index) for ES attachment
- Attach included ES to the SDS for mixture
- Indicate per hazardous substances in mixture whether safe use advice for the mixture is based on exposure scenario for that substance.

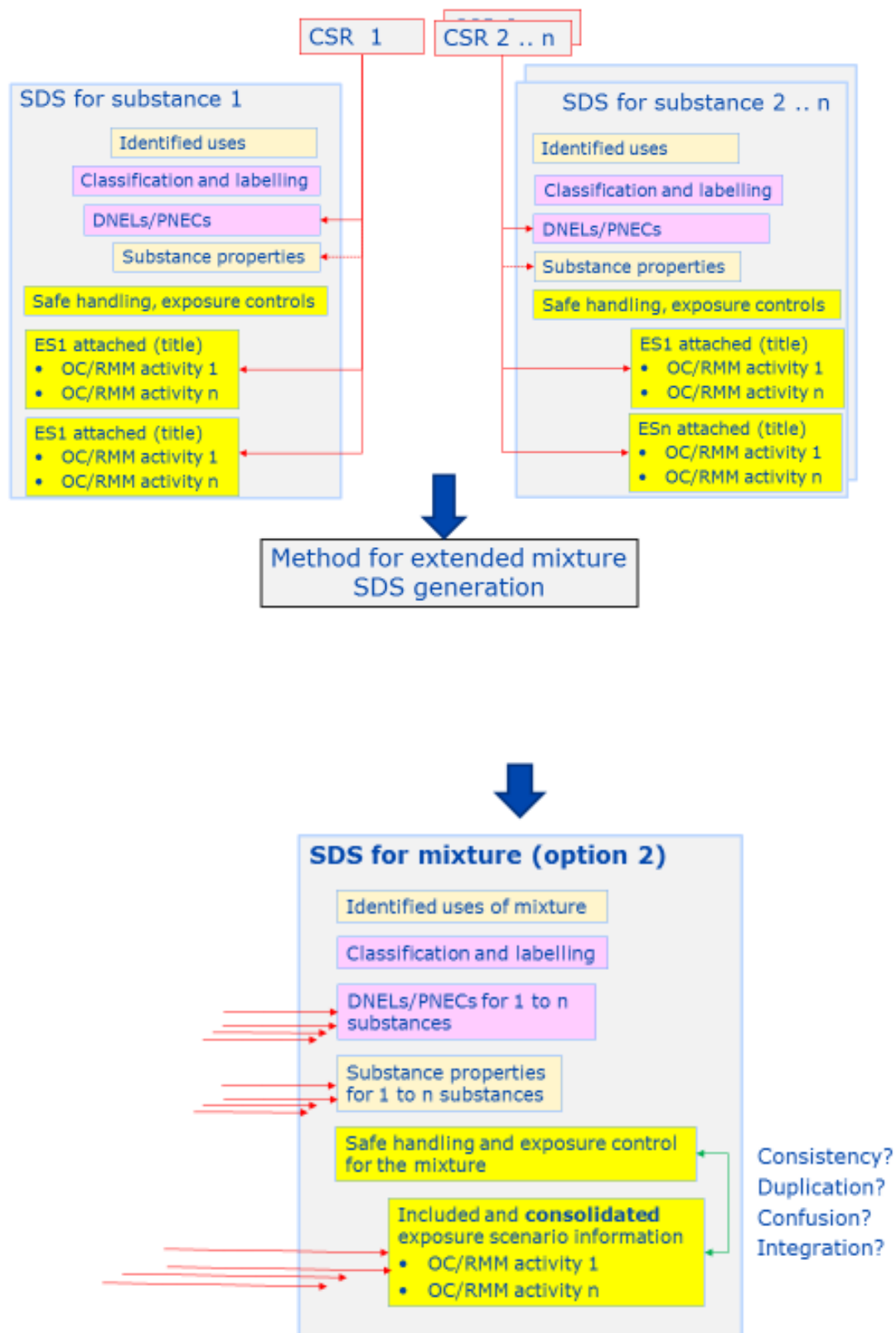
Topic 3: Mixture safety data sheet

Document A

Method for extending the Safety Data Sheet for Mixtures



Method for extending the Safety Data Sheet for Mixtures



Appendix 4. Presentations

See separate pdf files for slide set available online at:

<https://echa.europa.eu/reach-review-action-3>