



# 2<sup>nd</sup> Workshop on REACH Review Action 3 Improving the workability and quality of extended Safety Data Sheets

23-24 September 2019

ECHA, Helsinki

#### Summary report of the discussions

Final Version, 11 November 2019

#### Disclaimer:

This Workshop Report has been prepared by ECHA staff, 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 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**

CARACAL Competent Authorities for REACH and CLP

Cefic European Chemical Industry Council

CSA chemical safety assessment

CSR chemical safety report

DNEL derived no-effect level

DU downstream user

DUCC Downstream Users of Chemicals Coordination Group

ENES Exchange Network on Exposure Scenarios

ES exposure scenario

ESCom exposure scenario for communication

LEV local exhaust ventilation

OSH occupational safety and health

PNEC predicted no effect concentration

PPE personal protective equipment

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

SWED sector-specific workers exposure description

The Forum Forum for Exchange of Information on Enforcement

VCI German Chemicals Industry Association

IUCLID software to record, store, maintain and exchange data on

chemical substances

OECD Organisation for Economic Co-operation and Development

#### 1. Introduction

Improving the workability and quality of extended safety data sheets (SDS) is the aim of Action 3 under the <u>second REACH Review</u>. The work on this Action's scoping phase was kicked off in a stakeholder workshop the European Commission and ECHA organised in Brussels on 18 March 2019. A summary report of the March workshop is available in the REACH Review Action 3 section of the ECHA website.

As a follow-up to the March event, the second workshop on *Improving the workability and quality of extended Safety Data Sheets* organised by ECHA and the Commission took place in Helsinki on 23-24 September 2019. It reviewed the outcome of the first event and discussed the information ECHA had collected during the scoping phase. In addition, the lessons learned during industry testing of ENES tools were shared.

The main part of the workshop was dedicated to discussions in breakout groups. The objective of the discussions was to collect the participants' views on:

- a) the overall approach towards workability and quality described in the workshop documents:
- b) the different building blocks and the identification of actions needed; and
- c) the priorities of the identified actions.

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

The 87 participants of the September workshop represented different actors in the supply chain, companies providing SDS authoring systems and services, Member State authorities (REACH, OSH and Environment), industry associations, the European Commission and ECHA. Two thirds (58) of the participants were from industry and 10 were from Member State authorities, four from the Commission and 15 from ECHA. The 67 organisations that attended the event are listed in **Appendix 2**. The plenary sessions of the workshop were web streamed. On Monday 23 September, 61 and on Tuesday 24 September, 16 people followed the web streaming.

Prior to the workshop, the participants received pre-reading documents on the *Potential Building Blocks for Solutions* and the *End User Needs for Safe Use Information*, draft background documents on the *Minimum Requirements for Exposure Scenarios* and the *Mixture Methodology* as well two *examples of how exposure scenario information could be attached to a mixture SDS*. These documents provided the participants with a framework for the workshop discussions. They were intended to be thought-provoking and open the floor for brainstorming and new inputs.

The slides presented and documents used during the workshop are available on the workshop page of the ECHA website.

#### 2. Workshop discussions

The first afternoon of the workshop provided the participants with an update on the outcomes of the March workshop and shared progress made under the scoping phase on four topic areas:

User-targeting of information,

- Methodology for generating SDSs for mixtures,
- Minimum requirements for exposure scenarios, and
- Supporting communication of safety information with IT tools.

The scoping work on user-targeting had focused on information for workplace safety. Environmental and product safety related aspects are foreseen to be considered at a later stage. The proposed methodology for extending SDSs for mixtures is exploring how relevant exposure scenario information from substances can be included in the mixture SDS. The proposed approach for minimum requirements for exposure scenarios is considering the content, structure and layout related elements both for substances and mixtures. And the scoping actions on IT tools had focused on better understanding of the SDS authoring systems and how their development might facilitate the implementation of building blocks for the enhanced supply chain communication.

Sections 2.1 - 2.4 of this report provide an overview of the information shared and discussions carried out during the workshop.

#### 2.1. Welcome by the European Commission and ECHA

*Sylvain Bintein*, a Commission representative from DG ENV opened the workshop, welcomed the participants and thanked the ECHA staff for organising the event. He was impressed by the amount of work that had been carried out since March and encouraged everybody to express their views actively to make the workshop a success.

Kevin Pollard, Head of the Exposure and Supply Chain Communication Unit, welcomed the participants on behalf of ECHA. He underlined the importance of this workshop as a good opportunity to influence the direction of Action 3 work that is currently foreseen to be based on the guiding principles and building blocks explained in the workshop material.

#### 2.2. Setting the scene and reports from recent work

This session included five presentations that provided the participants with background information on ECHA's proposals, the Forum's feedback from enforcement projects and the lessons learned during industry's pilot projects.

Andreas Ahrens from ECHA presented the <u>Draft Guiding Principles and Building Blocks</u>. He also briefly summarised the written comments received from the European Chemical Industry Council (<u>Cefic</u>) and the European Automobile Manufacturers' Association (<u>ACEA</u>) on the March workshop summary.

The presentation underlined that REACH Review Action 3 aims at ensuring that the extended SDS will in the future better meet the information needs of users of chemicals under various pieces of legislation. The potential solutions that have been identified include e.g. that i) registrants use sector use maps in their Chemical Safety Assessment, ii) minimum requirements are set for exposure scenarios and iii) SDS authoring/processing systems are developed to enable exchange and handling the exposure scenario information electronically. These building blocks are expected to resolve many of the challenges companies currently face in using the information received in inconsistent PDF/paper-documents and in a language that is difficult to understand. ECHA's proposals are described in detail in the workshop document on the <u>Potential Building Blocks for Solutions</u>.

Abdulqadir Suleiman from the Norwegian Labour Inspection Authority explained the <u>Lessons Learned from Forum</u>'s enforcement actions on the supply chain communication. He noted that the four first REACH enforcement (REF) projects had inspected SDSs and found shortcomings in sections 1, 2, 3, 8 and 15. The Forum's fifth project (REF-5) focused on extended SDSs, exposure scenarios and Chemical Safety Reports. It concluded that there is still lots of room for improvement in the quality and consistency of information as well as in translations into national languages. The recommendations of the REF-5 project are well in line with the aims of REACH Review Action 3.

Evelyn Tjoe Nij from the Dow Chemical Company gave an introduction to the projects on <u>Testing the Use-map-SUMI Approach and the LCID Method</u> that had been carried out by seven industry sectors under the ENES Network. These projects covered both upstream and downstream communication in the supply chain.

Laura Portugal from DUCC (Downstream Users of Chemicals Co-ordination group) explained the SUMI approach and provided an overview of the <u>Testing the Use map SUMI approach by CEFIC-DUCC</u> that covered registrants in 2018 and formulators in 2019. The objective of these projects was to learn how formulators process exposure scenarios that are based on sector use maps or generic exposure scenarios (GES) and how such information can be used for selecting an appropriate SUMI for a mixture.

The main findings of the projects include that the Chemical Safety Assessment based on sector use maps works well and provides consistent outcomes. For formulators, the use maps-SUMI approach is easy to use, provided that the user is familiar with the concept. Use of Chesar in generating exposure scenarios was considered to be very helpful in producing harmonised, easy to navigate exposure scenarios. The benefits at formulator level materialised when all exposure scenarios were based on sector use maps.

Laura concluded her presentation by noting possible areas for improvement in the tested approach. These include e.g. the need for harmonised and improved formats for the exposure scenario; the potential inclusion of parameters for higher tier assessments within sector use maps; the normalisation of assessments<sup>1</sup>; and the development of further guidance.

*Nursulu Davrenova* from Verisk 3E introduced the LCID methodology and explained the project that was carried out in 2018/2019 on the *Testing the LCID Method* of seven mixture examples, and included a decision tree when embedding and when attaching the exposure scenario information in/to the mixture-SDS is the better solution. This approach, developed by Cefic and VCI, is based on the basic premise that if the risks are controlled for the most hazardous substance in a mixture, then the risks from the other substances in it are also likely to be controlled. A Practical Guide on the LCID method is available on the VCI website.

The project concluded that the LCID method is an efficient way to focus the assessment work on the risk driving ingredients. Annexing of safe use advice was considered to be the preferred option, e.g. for a mixture with multiple uses or when different risk management measures are needed per activity as well as when the recipient of the mixture SDS is a

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<sup>&</sup>lt;sup>1</sup> Use maps should be used as input for the assessment; the assessment should be done against an RCR of 1; and the outcome of the registrants' assessment should be by default be expressed as highest safe concentration in mixture under the conditions described in the sector use map.

formulator. On the other hand, embedding safe use advice might be more appropriate when a mixture is only classified for local effects related to skin and eye and/or has limited/specific end uses.

The findings of the LCID project will be published on Cefic's and VCI's websites.

#### 2.3. Breakout Discussions

The participants were divided into six evenly sized groups (11-12 people) each including representatives of industry sectors, SDS authoring system/service providers and authorities. The groups discussed in sessions of 45 minutes to 2 hours the four topics explained in Sections 2.3.1-2.3.4.

The material used to support the discussions is indicated in the description of the breakout session. The key points made in the six parallel groups were consolidated. The participants in each group indicated the topics raised in their group that they considered most important by marking them on the flip charts. These key points are reported below for each breakout session under the *Key points from discussion* heading. A flash report of them was shared with the participants during the plenary Session 2.4 on the *Building Blocks to be carried forward* on Day 2.

#### 2.3.1. Safety data for chemicals – user needs

The first breakout session focused on companies' information needs at the bottom of the supply chain for ensuring workers' safety and health. To structure the discussion three user audiences<sup>2</sup> were considered. Their information needs to assess and take decisions on the control of exposure to hazardous substances in the workplace are presented in Table 1 (page 7) of the *End User Needs for Safe Use Information* document. In addition, two examples on how the exposure scenario information could look when attached to a mixture SDS were reviewed to assess the suitability of the information contained and the language used for the three user audiences. They included an *Exposure Scenario* for application of coatings at industrial sites and *SUMIs* covering application of coatings in professional construction work.

#### Key points from discussion

There was an agreement that the proposed three user audiences are relevant. It was felt that it can be helpful to group companies based on their awareness of chemical legislation, capacity to carry out workplace chemical risk assessments and on their information needs. However, there were some differing views on how the audiences should be grouped: e.g. Group 2 was considered to be a sub-group of Group 1. The criteria (awareness or capacity or combination of these) for including companies in a group also requires further thought and the terminology used in the user audience table could be made clearer (e.g. in relation to equivalence check).

It was emphasised that all companies have same obligations under the OSH legislation

<sup>&</sup>lt;sup>2</sup> **User audience 1:** Company with full assessment capacity carries out quantitative assessment against OEL or DNEL, **User audience 2:** Company with full assessment capacity carries out qualitative assessment (except for substances with OEL) and **User audience 3:** *Company benefits from supplier's assessment, and checks only applicability to their activity.* 

and companies large and small in any sector that use chemicals should actively fulfil their duties. The participants expressed a need to align exposure scenario requirements and what is expected under the OSH legislation, so that the ES information would contribute to the workplace risk assessment and does not generate duplicate work. Therefore, a strong request was made to better coordinate the REACH and OSH legislation. The participants also underlined that as long as this is not done, the risk is that the use of exposure scenarios remains limited.

The discussions also indicated that there is a need to clarify what conformity check means for different user audiences. Development of clear examples on how exposure scenario information could be used for workplace risk assessment was considered necessary.

The two examples on how to communicate exposure scenario information were considered workable and value-added. There are, however, areas for further development such as the criteria for deciding when to use an exposure scenario attachment versus a SUMI, or to embed the information in the main body of the SDS. In addition, some participants expressed a desire for a single harmonised template for the safe use information for a mixture that would combine the best elements of the two discussed approaches. Or alternatively, the user of a chemical should receive the information in an electronic format that would allow the recipient to select the information that is relevant. The listing of the conditions of use per activity in one document was considered to possibly be a space efficient way to provide information.

When information from an exposure scenario or a SUMI is used, it needs to be reviewed against the conditions in the company receiving it. It was suggested to develop examples and method for that.

It was agreed that the language used and advice given in a SUMI/ES need to be as clear and explicit as possible. Abbreviations or codes should be avoid when information is provided to end users and technical terms e.g. what is "closed system" or "level II" should be explained.

The new approach should give a consideration to an option where a condition of use can be expressed both in a more generic way to allow higher flexibility for the user audience 1 and in a more specific manner suitable to derive concrete instructions for recipients in the user audience 3.

The participants deemed the SUMI example interesting and visually clear with the pictograms supporting the information. Development of further communication aids – e.g. additional pictograms, drawings of engineering controls and video clips – was also suggested, especially to illustrate required risk management measures to user audience 3. An indication of the RMM level in a SUMI was considered a good way to support awareness raising about hazardous chemicals.

#### 2.3.2. Methods for generating safety data for mixtures

This breakout session discussed a proposal for a methodology explained in the Methodology for Including Exposure Scenario Information in the SDS for Mixtures as presented in the supply chain scheme (page 14 of the pre-reading document on <u>Building Blocks for Solutions</u>) of the overall system. The discussions focused on the process of how a SUMI is derived and communicated with the SDS and how the LCID method is used to

complement the toolbox.

The participants provided their views on the workability of the proposed approach. No alternative approaches were suggested to those already discussed under the ENES Network.

#### Key points from discussion

The participants agreed that time and resource should not be spent in developing completely new or alternative systems but efforts should focus on further development and refining of what is already available. It was felt that currently the main problems for mixtures include the lack of harmonisation of approaches and limited implementation of the tools available.

The LCID method was considered practical, workable and available for any company to use. However, the method also has limitations e.g. it does not support the consolidation of ES information for two or more risk-driving substances in a mixture.

SUMIs that are based on sector specific use maps were regarded very useful to end users when choosing RMMs (such as the right PPE) but its reliance on DNELs<sup>3</sup> was noted to be a potential issue if the values received by formulators are not reliable or they vary between suppliers. It was also noted that the SUMIs do not provide sufficient details for formulators to develop safety instructions to their downstream users (i.e. mixtures in mixtures). The importance of sector use maps for SUMIs was underlined and it was stressed that additional sectors should be activated to develop them. A question about who is checking the correctness of use map information (e.g. that they follow the hierarchy of controls under OSH) was also raised.

The breakout discussion also indicated a need for automation to keep the workload manageable and to reduce errors in data handling. It was felt that information should be communicated between companies in an XML-format (at least down to formulator level) and SDS authoring tools for generating mixture SDSs should support integration of ES information in XML format from supplier's extended SDS. The participants felt that there should be more support for implementing the existing XML-exchange-standards for the ES and the body of SDS. In addition, a harmonised catalogue of quality phrases that are translated into all EU languages would be beneficial. The development of such a catalogue and its maintenance should be explored.

It was also noted that end users prefer to receive safe-use information for mixtures in a harmonised layout/format, irrespective of the type of mixture they use. They are not so interested in the upstream machinery but only the extended SDS output they receive. Therefore it would be beneficial to consider harmonising the output of different approaches used.

During this breakout session ECHA was asked to reflect on the role of distributors in the proposed workflow for risk communication in the supply chain schema. Furthermore, the participants would like further work to be carried out on inputs/output for mixtures versus mixtures in mixtures as well as how the hierarchy of control principle is considered in the extended SDS information and how changed information in updated extended SDSs could

<sup>&</sup>lt;sup>3</sup> In the CEPE approach.

be indicated to facilitate recipients in finding it.

The tools that the breakout discussions suggested for further work are:

- Chesar for mixtures
- Conformity/equivalence checking tool (should address the needs of formulators and end users)
- o upstream communication tool for company to company transfer of information on uses

#### 2.3.3. Minimum requirements for exposure scenario methodology

The breakout group discussed a proposal for minimum requirements as presented in the <u>Minimum Requirements for Exposure Scenarios</u> document. Draft minimum requirements are outlined in its Appendix 1 (pages 7-11). The discussion focused on the need for minimum requirements. The participants were also invited to consider which elements (i.e. content, structure and layout) the requirements should cover.

#### Key points from discussion

Minimum requirements were seen to be beneficial both for substances and mixtures e.g. to improve consistency, rationalise information, enable automatic processing in SDS software and minimise repetition. It was generally agreed that the minimum requirements should define the content and structure of the ES information but not all supported a predefined layout. However, even those who were not in favour of including a layout requirement, considered page and version numbering as well as a table of contents to be essential. In addition, a common data exchange standard (XML and phrases) was suggested to be included in the requirements.

The participants were of the opinion that there should be differentiated requirements for substance ESs and ES information included into mixture SDSs. For example they felt that for mixtures, it is questionable to include exposure estimates and it was debated if RCR and highest safe concentration for each substance in the mixture should be specified.

The participants felt that minimum requirements should be implemented first for substances and a sufficient transition period should be given for the implementation. It was also stressed that the rules should not be complex and that content requirements should be conditional for example for Tier 1/Tier 2 assessment information, codes, exposure estimates, physical form etc. It was suggested that the requirements should treat Section 7 and 8 of the SDS and the annexed ES information as one system. The supplier's assessment should be based on the "highest safe concentration" approach (plus "normalisation" of assessment).

Minimum requirements should cover the outcomes of the CSA to the extent that the corresponding exposure drivers are under control of the user and include what are the assumptions which have led to the safe use advice that has been provided. Although minimum requirements should not cover good practice advice (provided independent from the CSA), it was suggested that the updated system should still allow the communication of such advice in the extended SDS. In addition, it was noted that environmental aspects should be considered.

The minimum requirements should:

- include a manageable volume of information;
- be actionable by the recipient;
- be relevant for the role of the recipient; and
- be consistent within ESs in measures required (e.g. outdoor use and LEV are not compatible control measures).

There were differing views on how to report information indicated in the minimum requirements. Two approaches were considered i) to list all exposure determinants by default and indicate "not relevant" for those that are not applicable and ii) to limit the listed information to those aspects where exposure controls are needed. The discussions also covered how minimum requirements based on the most common determinants for exposure modelling tools should work for CSAs based on measured data.

The participants indicated that any proposed minimum requirements should be tested before they are implemented. The testing should also cover the ease of understanding of the terminology used.

It was also generally agreed that the communication of exposure scenario information involves large amounts of data that is not practical to manage unless it can be transferred electronically between IT-systems. This was considered to be a solid reason, in addition to harmonisation of communication (incl. translations), for using ESCom standard phrases. For a standard phrase system to be workable, there should be flexibility for using /suggesting new phrases and a quick process to get them approved.

The discussions also acknowledged that an electronic data transfer and processing would need to include a functionality to print documents for own use or for customers and the needs of SMEs should not be overlooked when the system is developed.

## 2.3.4. Expectations for SDS authoring software in the short- and long-term

The March workshop findings and discussions with stakeholders during the scoping phase have indicated that various IT solutions, tools and methods have been developed over the years and could facilitate the flow of information. However, until now they have not been widely implemented. It has also been commonly noted that if the communication of safety information would move from "fixed documents" (paper/PDF) to an electronically transferrable format, this could make the handling of the information in the extended SDS much easier.

The breakout session collected participants' views on the value of the different tools, methods and standards listed in the *supply chain workflow scheme* (page 14 of the prereading document on the *Building Blocks for Solutions*). The focus was placed on the longer-term development of extended SDS authoring and the flow of safety information between and within companies. The discussions explored where the tools and methods add value, what are the challenges of electronic handling of extended SDS information and what steps would be necessary to enable all companies (large and small) to benefit from the electronic exchange of safe use information between companies.

#### Key points from discussion

The participants felt that the logic underpinning the presented workflow schema for risk communication in the supply chain is in general acceptable (especially for formulators and authorities), and it is positive that testing of building blocks has already started.

There are two critical regulatory aspects of the supply chain communication that require further discussion and agreement for Action 3 to be a success. These are i) how information can be transmitted (paper/PDF documents versus electronic data objects) and ii) what is required on one hand under REACH and on the other for the workplace risk assessment under OSH legislation in Member States. Therefore, REACH and OSH authorities should establish together the requirements for an enhanced extended SDS system. It is also essential that authorities and industry work together during the development (e.g. testing/piloting of tools) and transition phase of REACH Review Action 3. A formally established platform/working group of authorities and industry could be a way to organise the work. In addition, benefits that the changes are expected to bring should be understood and communicated.

The discussions in this breakout session agreed that there is still work to do in further developing available tools. There were however differences in opinion on the priorities. Some wanted downstream user tools to be further developed including Chesar for mixtures while others would focus on ESCom/XML or a conformity check tool (including "equivalence" assessment or "scaling"). It was strongly emphasised that information coming from registrants should be harmonised as the first step. And to enable this to happen, the ESCom catalogue and its updating should be explored. It was noted that it would be logical to start from the top of the supply chain and then move downwards because without quality incoming information the system cannot deliver useful information to the next step.

The participants considered that enabling a system-to-system data transfer is a must for a well-functioning future system. The implementation of such a system could start from registrants making available their exposure scenarios (and other SDS information) in a data exchange format (XML). Over time the extended SDS information would flow in XML-format through the whole supply chain, with interactive tools available for extracting information that is relevant to the recipient (ability to request/select information). Therefore, all tools used for supply chain communication should communicate with each other, i.e. work like a toolbox, and be easy to operate. In addition, it was noted that SDS authoring tools need to be developed to support the SUMI and LCID methods.

The workshop also discussed how the harmonised system for the communication of safe use information could be established. Discussed options included industry standards, guidance by authorities and legal minimum requirements.

The participants also repeatedly noted that it is essential to promote the tools that are already available and to organise training sessions for authorities and companies on the new approaches to facilitate the acceptance, change in behaviour and to unlock investment at company level. In addition, it was felt that guidance e.g. on how to read the information provided in extended SDS (main body versus attachment) would be beneficial. And last but not least, it was underlined that it is critical that enforcement authorities understand and agree on the building blocks that are chosen to ensure they are accepted across Europe.

#### 2.4. Building blocks to be carried forward

The final plenary session provided a flash report of the ideas expressed during the breakout sessions (Solution elements to be carried forward by ECHA). A more detailed report on the discussions is available above in Sections 2.3.1-2.3.4 of this report. Ideas on further work on the building blocks that was identified during the workshop is listed in **Appendix 3**.

During the plenary, the participants were invited to indicate their level of agreement with the core guiding principles presented in the workshop. There was a high-level of agreement (>80% agreeing or strongly agreeing) with the chosen approach for six of the guiding principles. The only one for which the level of agreement was lower (60%) is the consolidation of exposure scenario information for mixtures in one piece of advice. The outcome of the online poll is summarised in **Appendix 4**.

The main conclusions from the workshop are:

- a. There was a broad consensus on the guiding principles and building blocks proposed.
- b. The dialogue with stakeholders needs to continue in setting a common vision for the future flow of safe use advice in the extended SDS, and the role of different actors in achieving it.
- c. There was an agreement that minimum requirements for exposure scenarios would be beneficial for improving the workability and quality of extended SDSs for substances and mixtures.
- d. Further work e.g. on terminology and missing elements is needed.
- e. It is necessary to better coordinate the REACH and OSH legislation.
- f. A possible future system as presented in **Appendix 5** would need to be implement in a holistic manner so that methods and tools, some of which have already been proposed (e.g. by ENES) are complemented with those that still need to be developed. The workflow illustrates how these tools and methods are interdependent and cannot function in isolation.

The findings of the workshop will be reported to the Member States at the CARACAL meeting in November 2019 and presented to DG EMPL's Working Group on Chemicals. That report will summarise the workshop findings and the overall outcome of the REACH Review Action 3 scoping phase in 2019. It will highlight areas of consensus on the proposed approach and indicate where further development work and investment of resources are needed.

Shortly after the workshop, the participants received an online survey to provide feedback on the workshop. A summary of the feedback, that is very positive, is available in **Appendix 6**. The feedback form also allowed the respondents to highlight anything they consider particularly important for REACH Review Action 3. The points raised include the importance of REACH authorities to work together with OSH authorities in defining the requirements, training and helping of SMEs as well as a call for communicating a clear vision on this complex and highly technical matter as well as the importance of ensuring that inspectors' views are not overlooked.

#### **Appendix 1 Programme of the workshop**

## Workshop on REACH Review Action 3 Improving the workability and quality of Extended Safety Data Sheets

23-24 September 2019 ECHA, Annankatu 18, Helsinki

**Timing:** Monday 13:00-17:30 and Tuesday 9:00-16:00.

**Purpose:** This  $1^{1}/_{2}$ - day workshop has three principal aims:

- 1. To **highlight the outcomes** of the stakeholder workshop organised jointly by the European Commission and ECHA on 18 March 2019 and share progress on four topic areas:
  - User-targeted information (with a focus on information for workplace safety);
  - Minimum requirements for exposure scenarios;
  - Methodology for extending Safety Data Sheets for mixtures with relevant exposure scenario information, DNELs and PNECs;
  - Expectations regarding development of *SDS authoring tools* and elements of a long-term vision for disseminating "safety data" for chemicals.
- 2. To **gather feedback** from stakeholders on the building blocks of solutions identified so far under Action 3 for the above mentioned topic areas and their workability.
- 3. **Identify building blocks to be carried forward**. The outcome of the discussions will be used as input to proposals the Commission and ECHA will make to CARACAL in November 2019. The building blocks endorsed by CARACAL may form the basis for defining a work programme to improve the workability and quality of extended safety data sheets in the European Union.

#### **Programme**

This workshop will comprise both plenary sessions and breakout group discussions.

Chair: Kevin Pollard Monday - Day 1

	<u> </u>	
Time	Session	Web streamed
12:00 - 13:00	1.0 Registration	
13:00 – 13:10	1.1 <b>Welcome</b> by ECHA and the European Commission	Yes
13:10 – 13:20	1.2 <b>Practicalities &amp; objectives</b> of the workshop by ECHA	Yes
13:20 – 15:00	<ul> <li>1.3 Setting the scene and reports from recent work</li> <li>ECHA: Development since March workshop</li> <li>FORUM: Learnings from enforcement on the supply chain and extended safety data sheets</li> <li>ENES: Projects on use map/SUMI testing and the LCID testing</li> </ul>	Yes
15:00 – 15:30	1.4 Introduction to the group work and moving	-

	to the breakout rooms – coffee on the go	
15:30 – 17:30	<ul> <li>1.5 Safety data for chemicals – user needs</li> <li>User audiences and their potential needs for exposure scenario information</li> <li>Example of safe use advice in a SDS</li> </ul> Discussion in 6 breakout groups	-
17:30-18:30	Reception	

Tuesday - Day 2

Time	Session	Web stream
8:30 – 9:00	2.1 Debriefing from the session on user needs	-
9:00 – 10:45	<ul> <li>2.2 Methods for generating safety data for mixtures:</li> <li>Formulators' SDS authoring task under REACH</li> <li>Methodologies for the inclusion of exposure scenario information in a mixture SDS</li> <li>The role of exposure quantification in the authoring of a mixture SDS</li> </ul> Breakout discussions in 6 groups	-
10:45 – 11:15	Coffee break	
10.45 - 11.15		
11:15 – 12:30	<ul> <li>2.3 Minimum requirements for exposure scenarios and SDS Sections 7/8.</li> <li>The role of minimum requirements in the SDS authoring – Would they be beneficial for exposure scenarios?</li> </ul> Breakout discussions in 6 groups	-
12:30 – 13:30	Lunch	
13:30 – 14:30	<ul> <li>2.4 Expectations for SDS authoring software in the short/ and long-term</li> <li>• IT support needed to implement the identified building blocks</li> <li>• Longer-term goals for the flow of safety information and related SDS authoring developments</li> </ul> Breakout discussions in 6 groups	-
14:30 – 15:00	Coffee break	
15:00 – 15:45	2.5 Building blocks to be carried forward	Yes
15:45 – 16:00	2.6 Wrap-up - Conclusions & next steps	Yes

## Appendix 2 List of participating organisations

- A.I.S.E. (International Association for Soaps, Detergents and Maintenance Products)
- 2. Anthesis on behalf of the Cefic Resin Technical Platform
- 3. Arkema France
- 4. Atlantic Copper
- BASF A/S
- 6. BAuA: German Federal Institute for Occupational Safety and Health
- 7. Borealis Polymers Oy
- 8. BorsodChem Zrt.
- 9. Bureau Veritas
- 10. Caldic Benelux
- 11. Cefic
- CEPE (European Council of the Paint, Printing Ink and Artists' Colours Industry) / DUCC (Downstream Users of Chemicals Coordination Group)
- 13. Chemler
- Clariant Produkte (Deutschland)
   GmbH
- 15. CONCAWE
- 16. Confederation of Danish Industry
- 17. Covestro Deutschland AG
- 18. Daimler AG
- 19. Danish Working Environment Authority
- 20. DOW Benelux B.V.
- DUCC (Downstream Users of Chemicals Coordination Group)
- 22. Dutch Labour Inspectorate/SLIC Chemex
- 23. EBRC Consulting
- 24. EcoMole Compliance LTD.
- 25. ECPA (Crop Protection) /
- 26. Essenscia
- 27. Eurometaux
- 28. European Association of Chemical Distributors Fecc
- 29. European Chemicals Agency, ECHA
- 30. European Commission, DG EMPL
- 31. European Commission, DG ENV

- 32. European Commission, DG GROW
- 33. ExxonMobil
- 34. FIEC Swedish Construction Federation
- 35. Finnish environmental supervisors KEHYS group
- 36. Finnish Institute of Occupational Health
- 37. Finnish Safety and Chemicals Agency
- 38. French Helpdesk Ineris
- 39. Givaudan
- 40. Hempel A/S
- 41. Janssen PMP, a Division of Janssen Pharmaceutica NV
- 42. Knoell Germany GmbH
- 43. LANXESS Deutschland GmbH
- 44. Logscale oy
- 45. MCF-Consultancy GmbH
- 46. Neste Oyj
- 47. Norwegian Labour Inspection Authority
- 48. Qualisys GmbH / eSDScom Alliance UG
- 49. ReachSpektrum, s.r.o.
- 50. RIVM Netherlands National Institute for Public Health and the Environment
- 51. Saint-Gobain
- 52. Selerant
- 53. Shell
- 54. Solvay
- 55. Sweco Industry
- 56. Swedish Work Environment Authority
- 57. Symrise AG
- 58. TIB Chemicals AG
- 59. Tikkurila Oyi
- 60. Treibacher Industrie AG
- 61. UL
- 62. Valmet Technologies
- 63. Venator Pigments UK Limited
- 64. Verband der Chemischen Industrie e.V.
- 65. Verisk 3E
- 66. Versalis S.p.A.
- 67. Yara Suomi

## Appendix 3. Listing of further work on the building blocks that was identified during the workshop (suggestions in blue italics)

- Sector Use maps
  - DU sector maps; SUMIs
- >>> Broaden availability
- Registrant's use maps (GES type)
- >>> Consider Adaptation

ESCom

>>> Consider better resourcing

- Phrase catalogue
  - · Xml exchange standard
- · Chesar for registrants
- Formulator's tools

>>> Integrate into tool box

- SUMI selection (based on sector use maps)
- Lead Component Identification (LCID) + Consolidation rules
- Exposure estimation and risk characterisation (CSA)
- Extended SDS authoring and processing tools
- DU Conformity check tool
- Sector Use maps (by industry, not ECHA)
  - DU sector maps; SUMIs >>> Broaden availability across the market
  - Registrant's use maps (GES type)
     >> Consider Adaptation
  - All:
- Close gaps in coverage;
- Assess relevance of including Tier 2 inputs and relevant actions where necessary; ensure that conditions conform with hierarchy of control;
- consider cross sector harmonisation (across different types of mixtures) for the benefit of end-users;
- ensure that setting short duration of activity (assessed by registrant against RCR=1) does not lead to uncontrolled risk across due to aggregate exposure to the substance across all the activities over the shift;
- ESCom

>>> Consider better resourcing

• Phrase catalogue *translations:* 

>>>Consider harmonised

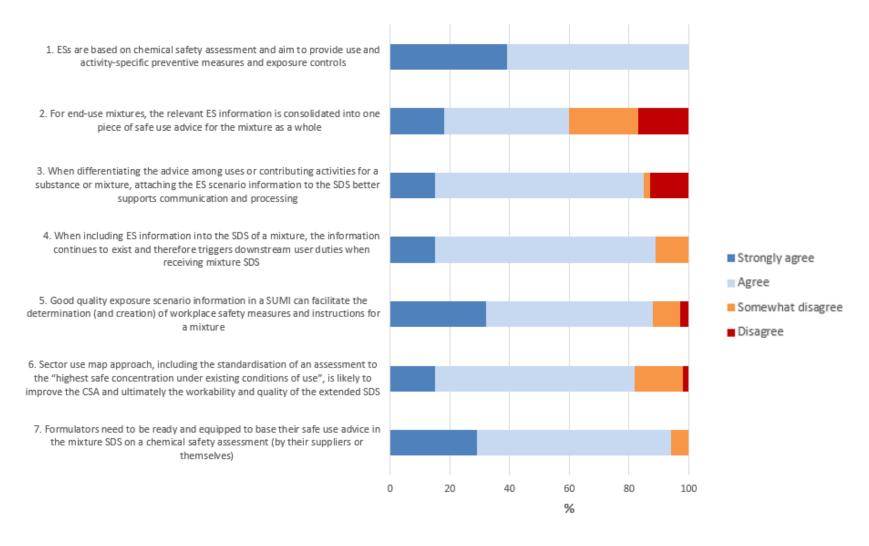
official

- Xml exchange standard
- Consider integration with SDScom, regarding (SDS section 7/8 and/or whole SDS main body;
- Chesar for registrants
- Formulator's tools

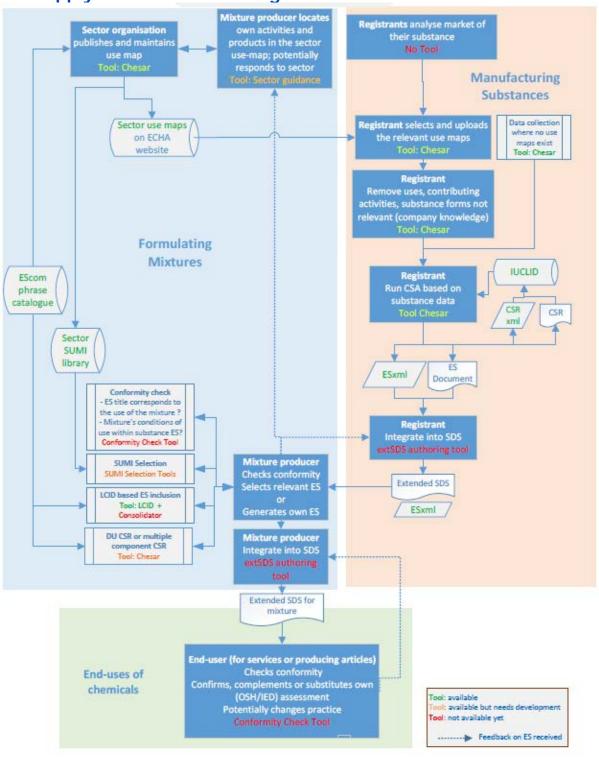
>>> Integrate into tool box, workflow, guidance

- SUMI selection (based on sector use maps); better explain selection mechanisms; develop rules; develop tool
- Lead Component Identification (LCID); (note: covers substances < 10 t; applicable also to mixtures for mixtures to reduce the complexity of information to be further communicated) + Consolidation rules for end-use mixtures;
- Exposure estimation and risk characterisation; note: for single substance assessment DU can use Chesar for that by end of 2019; for multiple substance assessment (=mixture assessment; aggregated risk), some adaptations (but no fundamental new development) needed in Chesar
- Mixture for Mixture method/tool [note: clarification what really is needed here, if anyway by default the single substance ESs are forwarded with the SDS for the mixture; possibly more a legal issue regarding substances placed on the market in form of mixtures, where one substance has a CSR by the registrants and the other substances are sourced externally (i.e. only ES available).
- Extended SDS authoring and processing tools (substance SDS and mixture SDS)
- Agree on DU Conformity check principles (equivalence assessment ES/OSH risk management) at the different levels in the supply chain; develop corresponding tool

#### Appendix 4. Participants' level of agreement on core guiding principles



## Appendix 5. Workflow: Risk management communication through the supply chain for REACH registered substances



## Appendix 6. Participants' level of satisfaction with the pre-reading material and workshop sessions

