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Concerns: **REACH REVIEW ACTION 3 – ECHA Appendix**
ECHA summary report on outcome of RRA3 Scoping Phase

Agenda Point: **4.4 REACH**

Action Requested: **For discussion**

Appendix 1: ECHA summary report on outcome of RRA3 Scoping Phase

A.1 Outcomes from the scoping phase

This Appendix summarises key outcomes arising from the scoping phase for REACH Review Action 3. These outcomes have been endorsed by participating stakeholders as being necessary to enable the delivery of improved safe use advice to end users of chemicals.

Section A.1 of this document outlines the key learning in terms of the overall system that needs to be implemented in order to deliver appropriate safe use advice in the supply chain. Section A.2 and A.3 outline the more detailed learnings in terms of Action 3.2: minimum requirements for exposure scenarios and methodologies for extended Safety Data Sheets (eSDS) for mixtures.

The scoping phase of REACH Review Action 3 (January to September) has involved two stakeholder workshops (in March and September) [1], interviews and bilateral discussions with stakeholders, in particular IT Providers, and a number of projects organised within the framework of the Exchange Network on Exposure Scenarios (ENES) to test "in real life" selected tools for generating and/or communicating safe use information. The workshops involved stakeholders drawn from industry (companies, sector organisations, IT providers), Member State authorities, DGs GROW, ENV and EMPL, and ECHA.

A.1.1 The system required[2]

Based on our learnings from all of the work carried out during this scoping phase, our stakeholders have given broad support in terms of the technical system necessary to enable the generation of appropriate safe use advice to end-users; including the steps that need to be carried out by registrants and formulators. This system is based to a large extent on tools which have already been (partially) developed and tested under the ENES work programmes, but also identifies significant gaps and proposes how to address them. At the high level, the proposed system is based on the following vision for the generation of safe use advice:

1. **End-users** of chemicals would receive meaningful advice on operational conditions and risk management measures to ensure safe use of chemicals.

[1] A detailed report on the March stakeholder workshop can be found here. The report from the September workshop is currently undergoing consultation with the workshop's participants; a draft can be found at https://echa.europa.eu/documents/10162/13563/190923-24_Action-3_Workshop_Draft-Report_Consultation.pdf/d258a32b-0d79-f5d6-a85f-688da0095525

[2] Whilst the scoping process was focussed on delivering meaningful safe use information for mixtures to end users to control occupational and environmental risk (at/from the workplace), the utilisation of mixtures by end users in producing articles and the associated advice on safe design of articles is another type of assessment covered in the schema.

This information would directly support compliance with REACH, OSH and Environmental legislation. Improved availability of appropriate information on the safe use of chemicals will, for instance facilitate workplace level dialogue between employers and workers thus contributing to improved levels of OSH compliance.

2. **Formulators** of mixtures would be equipped with tools for enabling the processing of information received from registrants via the SDS and exposure scenarios. These tools would enable the formulators to confirm or update i) the site assessment for their workers protection and environmental protection, ii) the product safety assessment for their mixtures and the safe use advice for their customers (end-users of chemicals).
3. Based on the enhanced implementation of use maps and the corresponding phrase libraries, **registrants** would be enabled to perform their Chemical Safety Assessment (CSA) based on more relevant and representative information on use, operational conditions and corresponding risk management measures, and to communicate the output of their CSA (highest safe use concentration, or use advised against under existing conditions of use) directly to downstream users. In this way the system would enable a clear distinction between substances that can be safely used under existing good practice conditions (reflected in use maps) and those substances where more in depth assessment, refinement of operational conditions/risk management measures (or use advised against) is required.

These elements have the potential to ensure a better functioning system for safe use advice on chemicals. In addition, there would be corresponding benefits to the work of the authorities:

4. Improved basis for enforcement of safe use advice for REACH, OSH and Environment inspectors.
5. Better overall information for the REACH authorities in terms of uses on the European market (type of use and implemented risk management measures), thus being in a better position to (i) prioritise and implement EU-wide Regulatory Risk Management under the Integrated Regulatory Strategy and (ii) for substances not being considered for EU-wide RRMs, national CAs would have better information for identifying the need for national-level action in terms of company risk management.

The steps involved, the tools and the actors in the supply chain for hazardous chemicals are shown in the workflow at Figure 1. This workflow was one of the elements tabled and discussed in the second stakeholder workshop in September. An important conclusion from the workshop was that **no viable alternative approach** was identified.

Figure 1. Workflow: Risk management communication through the supply chain for REACH registered substances (based on ENES tool set). [3]

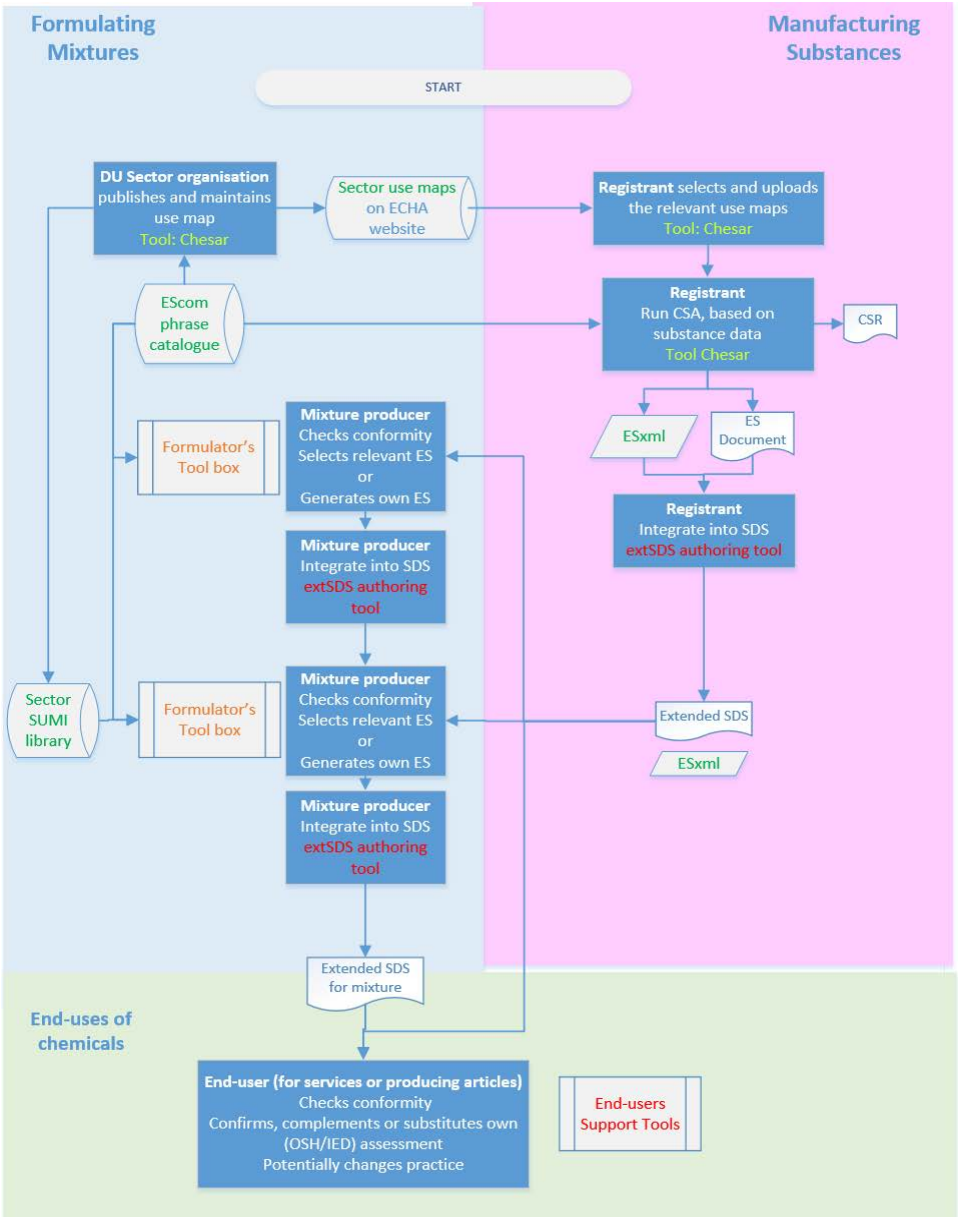

Figure 1 highlights the various steps and tools required in order for an improved system. Green text indicates tools that already exist (but may need to be extended e.g. some sectors have not developed use maps), orange text for tools/methods which are under development and red text for tools that are not currently in place. The following text highlights some of the main elements of the workflow.

The starting point of the workflow is the transmission of Sector use maps to the registrant. The use maps provide registrants with structured information on the actual uses, operational conditions and related risk management measures that are being followed by formulator and end-users on the EU market. In the downstream sector use maps, suitable

[3] ENES is the ECHA-stakeholder Exchange Network for Exposure Scenarios

phrases from the EScom catalogue (if available) are already assigned to these conditions of use. The registrant determines then for his substance the highest safe concentration under use map conditions. The EScom phrases (largely imported already with the use map information) are used to convert the CSA conclusions into an xml output for direct inclusion in the resulting extended safety data sheet.

If demonstration of safe use under use map conditions fails, the registrant has a number of options to refine his assessment (before concluding that he cannot support the use as being safe): He may refine the exposure estimate and risk characterisation (possibly switching to another exposure estimation method/tool), or may determine – in dialogue with downstream sector – the required changes in the conditions of use.

The next key step is the mixture formulator (and downstream formulators of 'mixtures in mixtures'), who confirms or updates i) their site assessment for workers protection and environmental protection, ii) the product safety assessment for their mixtures and modifies/generates the safe use advice for their customers (end-users of chemicals). This step relies on further development of the methodologies for mixtures (see section A.3) plus the development of an IT tool to implement the methodologies in extended SDS processing tool(s).

The final step is the receipt of safe use advice by the end-users of chemicals, who would require tools for checking conformity with the safe use advice and using this information in terms of confirming, complementing or substituting their OSH/IED compliance documentation.

The next section of this document gives a high level summary of the type of work needed to implement the system holistically and proposes the actors in the supply chain who would be in the lead for this work.

A.1.2 The development phase - building blocks

Together, the tools outlined in Figure 1 make up a series of building blocks. The status of the major building blocks depicted in Figure 1 are summarised in Table 1, below, with the primary "actor" responsible and a description of the actions that would be needed. This gives an indication of the scale of work and would (subject to agreement and commitment from CARACAL participants) form the basis to develop, together with the corresponding stakeholders a more detailed Development and Implementation plan for the next phases in 2020 and 2021.

Table 1: Building blocks for workability and quality of safe use advice in extended Safety Data Sheets

Building block	Description how it is intended to work	Status and action needs	Actor(s)[4]
Registrant's Chemical Safety Assessment	Registrants must assess all uses of their substance (they are aware of) during its lifecycle. The assessment is to be carried out with the method laid down in Annex I of REACH. Based on this assessment, registrants extend their Safety Data Sheets with an annex of exposure scenarios, describing the required risk management per use and its contributing activities. The outcome of the assessment is also sent as part of the registration dossier to the authorities in form of the Chemical Safety Report (CSR).	• **Available and taken up**: ECHA's Chemical Safety Assessment and Reporting Tool for registrants (**Chesar**) is used for more than 60% of new or updated CSRs received at ECHA. • **Action**: Maintenance of tool is required; includes adaptations for further harmonisation of the registrant's assessment output.[5] • **Action**: Update registrations when new information becomes available following the further development and implementation of the tools for improving the workability and quality of the extended SDS.	ECHA Registrant
Sector use maps	Use maps provide a systematic compilation of activities with chemicals and the related conditions of use in a market sector. The information is structured, and contains the information needed by registrants to carry out their Chemical Safety Assessment (CSA) with the available exposure modelling tools. A use map also contains the phrases for the communication of the required risk management measures with the extended safety data sheet. Where based on sector use maps, the exposure scenarios formulators receive for their ingredient substances will be more realistic and consistent across suppliers.	• **Available** for various market sectors but uptake is slow. • **Action**: use in CSAs for new registrations and dossier updates.	Registrant
		• **Action**: For significant parts of the market, use map development still to be initiated.[6] • **Action**: Some existing use maps to be aligned to the common principles. In particular, this is required for generic exposure scenario (GES)-based use maps (i.e. use maps from upstream sectors).	Sector organisations

[4] "Action" here refers to task(s) of leading actor identified e.g. updating means the updater. For tools and method development, these are foreseen as collaborative exercises.
[5] Chesar or an equivalent chemical safety assessment tool that enables an xml output.
[6] A high level status among (downstream) sectors and use map development was given at the March workshop (see 1st Workshop Report: Appendix 4 - Presentations, pages 50-51 https://echa.europa.eu/documents/10162/13563/20190318_workshop_summary_report_appendix-4_en.pdf/53daaebf-a75c-df74-1320-3e186a636f42).

Building block	Description how it is intended to work	Status and action needs	Actor(s)[4]
		• **Action:** Sector use maps potentially to be equipped with input information for higher Tier assessment.	
ESCom Phrase catalogue	The catalogue of harmonised phrases is meant to ensure consistent "translation" of the chemical safety assessment outcomes into risk management advice for the industrial and professional users of chemicals. The catalogue is regularly updated with new or modified phrases. The catalogue of harmonised phrases is also the basis for exposure scenario electronic data transfer (digitalisation).	• **Available:** The catalogue is available in English and managed by a Cefic-led working group. Downstream sector organisations have started to make proposals for improved phrases that better support their membership when receiving exposure scenarios. • **Action:** Better resourcing of the maintenance of the catalogue. • **Action**: Make use of the harmonised phrases. • **Action**: Consider options for making one "official" quality translation in all EU languages available.	Catalogue owner Industry ESCom Steering Group
ESCom xml standard	The XML standard for exposure scenario data transmission has been developed to facilitate the electronic transfer of use-specific risk management advice from the registrant's CSA via the SDS authoring systems to the formulators of mixtures (and potentially further down the supply chain).	• **Available:** XML standard published on Cefic's web-site and maintained by a group of IT providers represented in a Cefic working group. • **Uptake lacking**: Minimal uptake by industry yet due to the hurdles in making synchronised changes to their existing SDS authoring systems. Also electronic transfer not yet broadly accepted by authorities. • **Action**: Adapt once exposure scenario minimum requirements have crystallised.	Industry
SDS authoring for registered substances	The outcome of the CSA is imported into the SDS authoring system, equipped with the functionalities to ensure consistency between C&L, DNELs/PNECs, SDS sections 7/8 and the exposure scenario annex. At the same time, the SDS authoring tool supports the transfer of exposure scenarios (and related information) to the next level in the supply chain in a form that it can be efficiently processed by the recipient.	• **Available:** Chesar provides an xml output. However, only a minority of registrants have equipped their SDS system with the corresponding import and processing functions. • **Action:** Enable SDS authoring tools to import data from the chemical safety assessment and to provide exposure scenarios in xml format to downstream users.	Registrants/SDS IT providers
Formulator's exposure scenario processing and assessments	Formulators may produce mixtures for supply to another formulator or for supply to end users (industrial or professional). For the safety assessment of their mixture, they either check conformity with the exposure scenarios received from suppliers, or carry out a downstream user chemical safety	• **Available**: An initial suite of tools is available to support formulators, in particular where downstream sector use maps exist but uptake is slow by IT providers and formulators. • **Action**: Implement available tools.	Formulator

Building block	Description how it is intended to work	Status and action needs	Actor(s)[4]
	assessment themselves. Subsequently the formulator compiles activity-specific advice on safe use to be included into the extended safety data sheet for the mixture.	• **Action**: A number of gaps are still to be closed, including: a common workflow for a conformity check; an exposure scenario consolidation tool where no use maps exist; exposure scenario transfer for mixtures in mixtures; a tool for assessing aggregated exposure for mixtures.	ENES Member State authorities
End users processing of safe use advice for chemicals[7]	End users of chemicals (e.g. industries producing articles, construction and building companies or cleaning/repair services) need to assess/check whether or not their practice in the different activities with the chemical is in line with the risk management advice they receive in the safety data sheet. The supplier's risk management advice may significantly contribute to the OSH workplace risk assessment of the chemicals user.	• **Not available**: Methodology (including workflows) and corresponding tools not available at present. • **Actions**: Requirements and cases for testing to be developed (understanding of terminology; visualisation of risk management; formats supporting easy access to the information). • **Action:** Broad testing with companies of different size and business to be carried out.	ENES as platform Downstream (end) users COM and OSH Member State competent authorities National enforcement authorities

[7] Requires engagement from OSH community. Examples from Forum's SDS quality improvement initiative and ENES projects can provide test cases.

A.2 Minimum requirements for exposure scenarios

In addition to the overall conclusions and resulting workflow outlined in Section A1, this section highlights the more detailed learnings in terms of Action 3.2: minimum requirements for exposure scenarios.

There was an agreement in the workshops that minimum requirements for exposure scenarios would be beneficial for improving the workability and quality of extended Safety Data Sheets (eSDS) for substances and mixtures. Stakeholders agreed in general that the minimum requirements should ideally define content and structure and include a common data exchange standard (XML & phrases).

Key points on the scope, coverage and development process collected from stakeholders are summarised beneath. These elements would all need to be considered further, exemplified and tested to define ultimately a set of minimum requirements for an exposure scenario (for both human health and the environment).

- There is broad agreement on the goals for setting minimum requirements for exposure scenario information (being an element in safety data sheets for substances or mixtures):
  - Increase the usefulness of the exposure scenario information for the recipients, in particular for those duty holders at the bottom of the supply chain.
  - Synchronise the activities of the actors in the market to improve the workability of the SDS.
  - Create a solid basis for support via IT tools. *Note: Digitalisation is a pre-requisite for managing safety data relevant for the control of risk through the whole life cycle of a substance.*
  - Increase legal certainty on all sides, consistency and enforceability.

- In terms of scope and coverage, the following key elements were identified:
  - Sections 1.2, 7 and 8 of the SDS and the annexed exposure scenarios should be treated as one system i.e. they should be aligned and complimentary
  - The minimum requirements should as much as possible support the rationalisation of the information in the exposure scenarios annexed to a SDS in particular, minimising repetition of information and avoiding listing actions with the remark/phrase “not relevant”.
  - The requirements should be differentiated between the eSDSs for substances and the eSDSs for mixtures.

Next steps will include:

- Working out the technical requirements regarding contents, and the related phrases more in detail.

- Testing examples of exposure scenario information following the draft "minimum requirements" with the recipient user audiences; testing also the terminology utilised

in the exposure scenarios to determine the nature of the descriptions/phrases that are best understood.

- Testing examples with registrants in terms of updating existing Chemical Safety Assessments and providing updated advice via xml.

A.3 Methodology for mixture Safety Data Sheets

In addition to the overall conclusions and resulting workflow outlined in Section A1, this section highlights the more detailed learnings in terms of Action 3.2: methodology for mixture SDSs.

Developing a methodology for eSDSs for mixtures with exposure scenario-related information is a specific element of REACH Review Action 3, and was also addressed in the scoping phase in 2019.

Mixture SDS may refer to products that are used (i) as an ingredient mixture in another mixture, or (ii) as a mixture for end use (e.g. producing an article, carrying out construction work, or providing cleaning and repair services). In order to initiate the stakeholder dialogue on the SDS recipient's needs from the OSH perspective, the current scoping phase had its focus on mixtures for end use. Particular methods potentially required for generating/processing safe use advice for mixtures in mixtures is foreseen to be part of the future work.

The formulator of a mixture for end use has to check the conformity of the mixture for each ingredient substance for which an exposure scenario has been received. In addition, relevant safe use advice for the whole mixture, based on the inclusion of the relevant exposure scenario information, needs to be prepared so that the mixture SDS is complete, use-specific and understandable to the recipient.

The discussions with stakeholders have been supported by two initiatives in 2019 under the umbrella of the Exchange Network on Exposure Scenarios (ENES) to test two approaches with "real life" information: (i) the bottom-up Safe Use of Mixtures Information (SUMI) approach, which has been developed (and is now being rolled out) by a number of downstream formulating sectors, and (ii) the top-down Lead Component IDentification method (LCID), developed by Cefic and the German Chemical Industries Association (VCI). The SUMI is an integral part of the sector use map tool, as it conveys the risk management for the end use of a mixture based upon the registrant's chemical safety assessment that has utilised/imported the relevant sector use maps.

The **lessons learnt** from these projects and the two scoping workshops can be summarised as follows:

- Stakeholders prefer the current tools to be further refined and gaps to be closed rather than developing alternative approaches.

- At present, there is no common understanding how the formulators should assess the conformity of their mixture composition and the foreseen conditions of use against the exposure scenarios received. This needs to be developed further.
- The Safe Use of Mixtures Information (SUMI) selection methodology works quite well where the registrant makes use of available use map information and respects the basic principles of the downstream user sector use maps.
- Where the received exposure scenarios are not based on downstream sector use maps (current majority of the cases), the Lead Component IDentification (LCID) method is an efficient support to focus the formulator's assessment on the risk-driving substances in the mixture. However, the LCID does not provide a solution for consolidating the information from various exposure scenarios (which are diverse in format, content and phrases) into one consistent piece of safe use advice for the mixture, and this implies further work.
- The relationship between the exposure scenario information included into the SDS for a mixture and the exposure controls referred to in sections 7 and 8 of the main body of the safety data sheet is a major source of confusion; advice should be developed in order to ensure that sections 7 and 8 are complementary to the corresponding exposure scenarios.
- Automation is essential to keep the workload manageable and to reduce errors in data handling. Information should be communicated between companies in an XML-format (down to the formulator's level) and the SDS authoring tool for generating a mixture SDS should support the integration of exposure scenario information in XML format from supplier's extended SDS.

Next Steps:

Further development is consequently needed in the following areas:

- Develop criteria and workflows for the formulator conformity check.
- Complement the LCID method with a method or rules for consolidation across exposure scenarios.
- Integrate tools for the downstream user safety assessment and for aggregated exposure assessment for mixtures into the suite of tools for formulators.
- Develop particular approaches to support the receiving/processing and the communication of safe use advice for mixtures to be used as ingredients of another mixture.