

Appendix 1: ECHA progress report on technical work

A.1 Progress made since the end of the scoping phase

In November 2019, ECHA summarised the key outcomes arising from the scoping phase for REACH Review Action 3 in which potential solutions to the issues of workability and quality of extended Safety Data Sheets (SDS) were gathered, including a schematic workflow for risk management information through the supply chain, and an overview on seven building blocks of the technical system to be developed.¹ The overview provided also initial thoughts on development actions required and potential actors best placed to lead these actions.

The current document is a progress report for CARACAL towards a development plan, describing the emerging directions since the November 2019, suggesting the way of working with stakeholders (development platform) and providing a tentative timeframe for development and implementation.

Emerging directions

The seven building blocks referred to in the report (CA/75/2019) from the scoping phase have been further integrated with each other into five blocks (see Figure 1 and Table A.1 in the Annex). They are now also more consistently/systematically connected to i) minimum requirements for exposure scenarios, ii) the suite of methods for formulators (formulators toolbox) for deriving SDSs for mixtures, and iii) the workflows/methods of end users to process the received information, in particular the integration with the risk management tasks under occupational and environmental legislation.

This led to further shaping of the vision for a coherent system for generating, transferring, and using/processing safety data² for chemicals, which can be summarised in the following points:

- Develop one common solution for the SDS related to both substances and mixtures. Thus, build a systematic link between the REACH-generated data (exposure scenarios, DNELs/PNECs, other data on substance properties) and the corresponding sections of the existing SDS system. The solution should facilitate easy access to all data required for risk/safety assessments by any actor in the supply chain.
- Therefore, an XML schema for exchanging the data contained in the SDS (called SDSxml in the further text) would form the backbone of a communication flow from registrants down to end users of mixtures. This XML schema would not only include the safe use advice for substances and mixtures, but also the data on substance hazards and chemical-physical properties required to carry out, in case needed, exposure/risk assessment at any point in the supply chain. The aim is to fully integrate the REACH concept of (i) DNEL/PNEC-based hazard characterisation and risk-based exposure scenarios with (ii) the information in the relevant sections of the SDS core body (1, 2, 3, 7, 8, 9, 11, 12) for substances and mixtures.³

¹ Appendix to CA/75/2019.

² In the bullets that follow, “safety data” are the data expected to be contained in a safety data sheet.

³ The development of an XML for this purpose would take account of experience existing already on such exchange standards.

- Minimum requirements will define the core set of mandatory fields, with regard to both substance properties and safe use advice. Together with the fields, standard phrases are to be defined to express the measures for safe handling and exposure controls. Those could e.g. be deployed as drop down menus in corresponding software.
- ENES put the emphasis for use map development on a method for supporting the interaction between formulators and registrants. However, for the holistic system envisaged for generating, communicating and receiving safe use advice for hazardous chemicals the profile and coverage of sector use maps would need to be extended. Sector use maps should form the common reference for the whole supply chain, in order to synchronise the communication and checks on foreseen uses (including tasks at workplaces, products and article types) at the various levels in the supply chain.
- Toolboxes for formulating companies and for end-using companies should enable processing the safety data conveyed by the exchange standard,⁴ to support a number of standard processes: (i) Check whether actual uses (and/or conditions of use) on site are in conformity with the information received from supplier; (ii) take into account the safe use advice from supplier for own OSH/site risk management or own product safety information; (iii) carry out own safety/risk assessment for workplace, site or product.

The emerging directions expressed above also respond to an increased, wider focus on OSH-REACH interaction (and related work in terms of environmental legislation e.g. under IED). A common safety data exchange standard (SDSxml) is meant to support data processing; in particular to enable the conformity check and assessment (when needed). It is expected:

- to increase efficiency of data transfer (electronic transfer instead of retyping) and data access (single actors can easily find the information needed),
- to prevent errors (due to manual copy/paste of data),
- to promote consistency (same substance/same composition/same property profile/same hazard/same risk management under same use conditions),
- to enable enforcement (presence of required information; implementation of required risk management down to the bottom of the supply chain),
- to feed the end users' information needs on the hazardous chemical they use (inventories) and on which measures are to be taken to control exposure.

Particular attention is needed with regard to the skills, experience and resources available in SMEs. The form of received information (i.e. the output of the formulators' toolbox) and the methods (tools) to use this information should be simple and flexible enough to add value in practice. The investment required to adapt practices and company systems should be proportionate to the value added. Further analysis is needed on this aspect.

Updated schema for the system to generate, communicate and receive safe use advice for hazardous chemicals

The schema/workflow presented in the document for CARACAL-32 (CA/75/2019 Appendix) on the steps, the tools and the actors involved in the supply chain for hazardous chemicals has been updated based on the emerging directions of work. This updated schema is shown in Figure 1. An explanation on the building blocks and corresponding actors can be found in the Annex to this Appendix.

⁴ See footnote 2 on page 1.

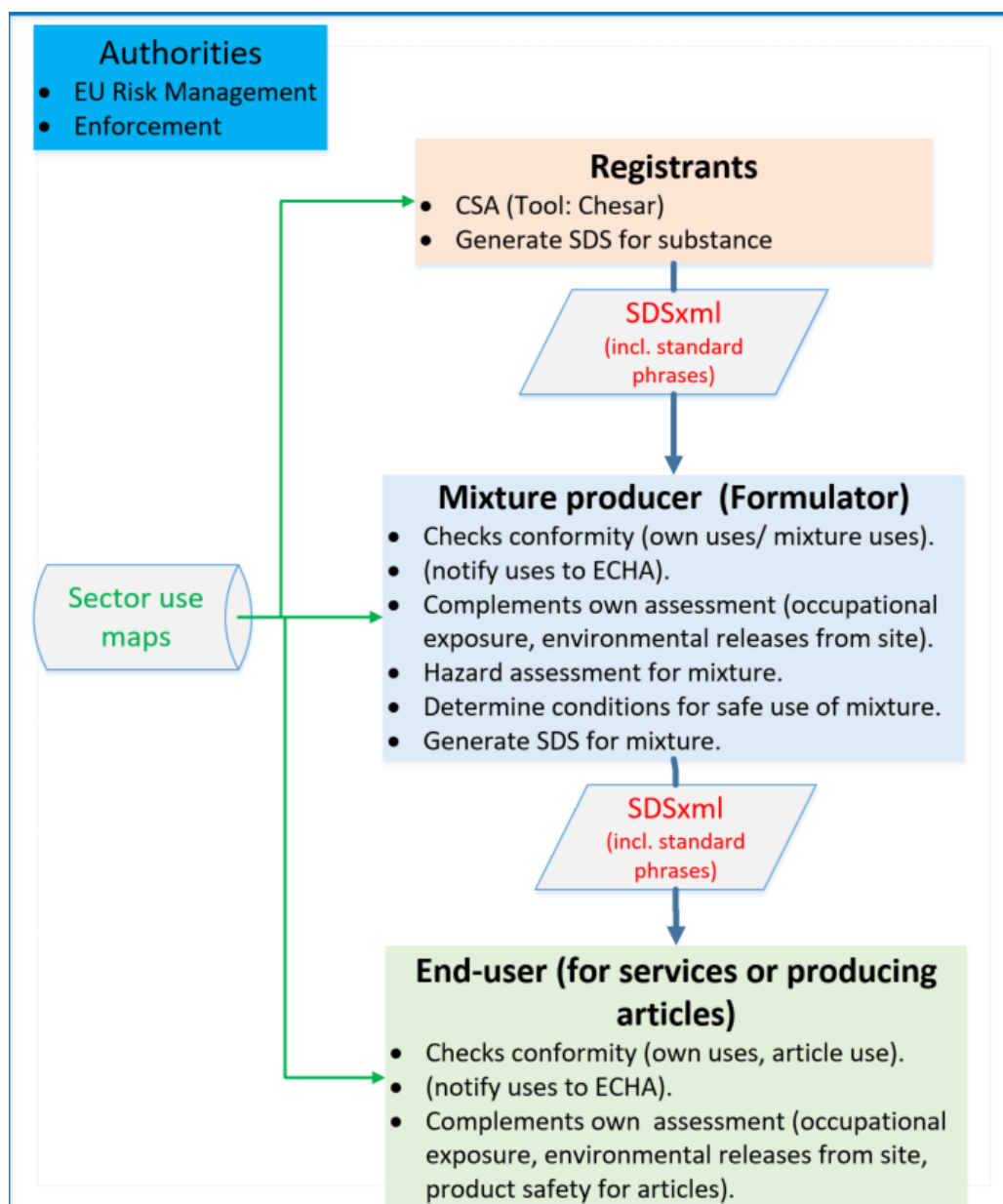


Figure 1. [Updated] Schema showing the coherent system for generating, communicating and receiving safe use advice for hazardous chemicals (See Annex, Table A.1 for details on each building block in the workflow.)

A.2 IT tools to support companies

IT tools can support companies where large amount of information need to be processed or where documentation is needed that a certain workflow or check has been applied and what the outcome was. Once the workflows and methods for conformity checks and assessment at formulator's level and at end user's level have been defined more specifically, it will be explored how and to which extent they can be supported by IT tools for companies. This will

result in requirements for IT tools to be built. One clear requirement is for tools that support SMEs in their management of safety, with minimum administrative burden and cost. Such tools need to be developed with keeping the necessary integration into existing IT-infrastructures in mind.

In addition, discussion is required on the pros and cons of leaving the development of tools to the market, to ECHA, or to other options.

A.3 Working structures/fora supporting the development phase

In terms of the REACH/OSH interface, discussions are foreseen, amongst others, with DG EMPL's Advisory Committee on Safety and Health at Work's Working Party on Chemicals⁵ to increase (i) the common understanding between OSH and REACH community how a coherent system for exchange of chemicals' safety data in supply chains can bring added value to health and safety at the workplace and (ii) their active contribution to the development phase. In parallel, there is the need to explore how to engage with the environmental authorities.

The system's elements to be developed need proper piloting/testing to ensure that they deliver added value to companies, in particular considering the size of the company, and that these values will outweigh the cost of implementation. The main fora foreseen for practical piloting/feedback are:

- Forum under Article 86 of REACH (network of inspectors having participated in the various SDS quality and supply chain projects); confirm the enforceability of the system and the building blocks to be developed from REACH and OSH perspectives.
- REACH Member State fora such as the REACH Exposure Expert Group (REEG) and the Risk Management Evaluation platform (RiME+).
- ENES (network of industry with currently a few Member States contributing):
 - Pilot/test and confirm the usefulness and practical feasibility of the system to be developed. In particular, sector organisations, either from among their members or their supply chains, bring in the SME perspective.
 - Explore and analyse the implementation challenges of the new system on industry side.

It should be noted that the current ENES has 'gaps' in terms of its contributing profiles. Good contribution and commitment have been made by industry so far. However for the future development plan and its success, representation that ensures a broad coverage of business types and sizes (especially SMEs) for the foreseen consultations, pilot projects, and tool development, as well as competencies e.g. OSH practitioners. In this regard, the current ENES platform needs to be boosted and resourced.

Given that CARACAL considered ENES to be the most appropriate platform to take forward the necessary technical work, Member States too need to indicate their involvement. For example, either through expressing interest to participate directly in the technical development work or in ENES' stakeholder coordinating function/group, and/or support via the types of Member State fora mentioned above.

⁵ Originally scheduled for the Working Party on Chemicals' meeting in March, now rescheduled to June.

Beyond providing the testing/piloting environment, ENES will continue to work in a number of areas:

- Share and discuss the learnings from BAuA's *REACH2SDS* research project⁶ with a broad community, including interested Member States. The learning will be feeding all the five building blocks.
- Further develop the use maps: Improve existing use maps; map the market to identify existing but not published use maps/GES and to identify gaps; progress GES/DU use map alignment; explore how end users work with SUMIs.

These two roles (piloting/testing/analysing implementation challenges on the system **and** continued work on the two specific projects mentioned above) of ENES will lead to a new ENES work programme contributing to the development plan under RRA3 (to be agreed by Q4 2020).

A.4 Sequencing and timing

As highlighted above, the development plan is still to be prepared. However, Table 1 beneath serves to illustrate at "high level" how the development plan for REACH Review Action 3 might be realised, breaking down the development phase into a series of compartments and a tentative timing on which further discussion can take place.

The Table includes a pre-development phase (Phase 2, the current position), which serves as a bridge between the outcomes of the 2019 Scoping phase and the building, with stakeholders, of a meaningful and resourced development plan. This pre-development phase encompasses considerations on how a future, coherent supply chain system will function, both from a technical perspective and from the perspective of implementation (i.e. synchronisation of the actors, clarification of legal obligations). Preparing a development plan for Q4 2020 which is endorsed by CARACAL and for which ECHA, industry, Member States etc. are resourced and committed to deliver, are prerequisites before moving to Phase 3.

Table 1. Phases and Stages foreseen toward implementation of REACH Review Action 3.

	Phase	Stage	What is done	Output	Timeframe
Scoping	1	Scoping	Gather potential solutions to SDS workability and quality; determine where potential technical developments are needed.	Report to CARACAL	Q4 2019 (Completed.)
Developme	2	Pre-development	To prepare a development plan and validate it via CARACAL, with the corresponding resources in order to be launched.	Development plan	est.Q4 2020
		3	Concept development	Defining the concepts that support a coherent system; setting out the	Requirements for the various

⁶ The BAuA REACH2SDS project determines the availability of information on workplace exposure and risk management measures (RMMS) in the Chemical Safety Report (CSR) and the extended Safety Data Sheet (eSDS). It investigates the quality of information transfer from CSR to eSDS and examines the applicability of the given information for risk assessment in the workplace. More information, see: <https://www.baua.de/EN/Tasks/Research/Research-projects/f2415.html>

	Phase	Stage	What is done	Output	Timeframe
			requirements for the tools; piloting tools' requirements to make refinements. Option analysis for implementation (including pros and cons of making all or certain parts of the system elements mandatory).	tools.	est.4-5 years
	4	Tool building	Converting requirements into IT tools, testing prototypes to make refinements. Legislative process to enable system changes, as necessary.	Set of robust tools (built and tested). Legislation in place	
Implementation	5	Implementation	Implementation by actors in the supply chain (Registrant, Formulator, Distributor, End user), potentially with differing transitional arrangements depending on the actor's position in the supply chain. Arrangements for tool maintenance in place.	Improved compliance, ideally with reduced administrative burden	est.2025

Annex

*Table A.1: System building blocks for enhancing workability and quality of safety data transferred in the supply chain
[updated from Appendix to CA/75/2019]*

Building block	Description how it is intended to work	Action needs	Actor(s) ⁷
Registrant's Chemical Safety Assessment (generation and communication)	Registrants must assess all uses of their substance during its lifecycle. The Chemical Safety Assessment (CSA) 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 DNELs and PNECs, and 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).	<ul style="list-style-type: none"> • Action: Identify specific aspects of the chemical safety assessment that need review for the system to deliver consolidated advice to the formulator.⁸ • Action: Maintenance of Chesar is required; includes adaptations for further harmonisation of the registrant's assessment output.⁹ • 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 SDS. • Action: Adapt SDS authoring systems to the foreseen safety data exchange standard which will also impact on the SDS core body. 	ECHA ECHA Registrant Registrant / IT providers.
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	<ul style="list-style-type: none"> • Action: Use in CSAs for new registrations and dossier updates. 	Registrant
		<ul style="list-style-type: none"> • Action: For significant parts of the market, use map development still to be initiated 	Sector organisations

⁷ "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.

⁸ For example, exploring the options to simplify the interface between DNEL-driven risk management and classification-driven risk management.

⁹ Chesar or an equivalent chemical safety assessment tool that enables an xml output.

Building block	Description how it is intended to work	Action needs	Actor(s) ⁷
	<p>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 safety data sheet. Based on sector use maps, the exposure scenarios formulators receive for their ingredient substances will be more realistic and consistent across suppliers.</p> <p>Beyond that, use maps provide the actors in the whole supply chains (manufacturers, formulators, end users) with a common reference for use identification, activity/task definitions and conditions of use description.</p>	<p>(gap analysis required).¹⁰</p> <ul style="list-style-type: none"> Action: Existing use maps to be aligned to common principles and terminology. Overlaps and inconsistencies to be minimised. In particular, this is required for generic exposure scenario (GES)-based use maps (i.e. use maps from upstream sectors). Action: Sector use maps potentially to be equipped with input information for higher Tier assessment. 	
<p>Safety Data Exchange Standard (including minimum requirements for exposure scenarios)</p>	<p>The Safety Data Exchange Standard (e.g. via an XML schema) facilitates transfer and processing of the relevant safety data (hazard information, substance property data and safe use advice) along the supply chain. At the same time it defines the minimum of data to be provided, including the minimum requirements for exposure scenarios. The SDS XML schema is expected to cover both the SDS core body and an Annex (ES/SUMI). It should be the same for substances and for mixture. Some fields may be relevant only for substances or only for mixtures.</p> <p>Structuring the XML fields will focus on the information required to run the needed by the formulators' or end users' toolbox (sections 1, 2, 3, 7, 8, 9, 11, 12, Annex of the SDS).</p> <p>The SDS XML schema will make use of existing</p>	<ul style="list-style-type: none"> Action: Develop and test minimum requirements regarding the information to be contained in the XML schema. Test the information requirements regarding usefulness and enforceability. Action: Develop SDS XML schema. Action: Adapt SDS content once exposure scenario minimum SDS XML schema requirements have crystallised. Action: Enable SDS authoring tools to import and export SDS according to the SDS XML schema. Action: Consider options for making one "official" quality translation of the standard phrase catalogue in all EU languages 	<p>ECHA</p> <p>All interest groups via ENES</p> <p>Potentially ECHA (if resources available).</p> <p>Registrants/Formulators.</p> <p>Registrants/ SDS IT providers.</p> <p>ECHA</p>

¹⁰ A high level status among (downstream) sectors and use map development was given at the March workshop (see [1st Workshop Report: Appendix 4](https://echa.europa.eu/documents/10162/13563/20190318_workshop_summary_report_appendix-4_en.pdf/53daaebf-a75c-df74-1320-3e186a636f42) - 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	Action needs	Actor(s) ⁷
	standard phrases from ESCom (and possibly SDSCom, if needed).	available.	
Formulator's toolbox (methodology for mixture SDS generation)	<p>Formulators may produce mixtures for supply to another formulator or for supply to end users (industrial or professional). The toolbox supports two tasks:</p> <ul style="list-style-type: none"> Conformity check with the uses/activities covered in the received SDS (and DU use notification when relevant). Determination of the conditions for safe use for the mixture. <p>The safe use advice can be based on:</p> <ul style="list-style-type: none"> The received information for the various classified substances and the mixture hazard (C&L), or The formulator's own mixture assessment, which may also include considerations on additivity for systemic endpoints. 	<ul style="list-style-type: none"> Action: Develop the requirements for a tool to support the formulators (formulating substances or mixtures into new mixtures) in their tasks. Action: Piloting requirements and potentially testing of early tool versions. 	<p>ECHA</p> <p>ENES network of companies. Member State authorities.</p>
End users' toolbox (processing of safe use advice for chemicals ¹¹ , for feeding SDS information into occupational and environmental risk management).	<p>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 chemicals is in line with the risk management advice they receive in the safety data sheet (conformity check). The supplier's risk management advice may significantly contribute to the OSH workplace risk assessment of the chemicals user.</p> <p>When the own practice is not covered by the supplier's advice, the end user may decide to carry out/amend his own assessment.</p>	<ul style="list-style-type: none"> Actions: Identify tasks for broader alignment between OSH-REACH, as necessary. Actions: Develop the requirements for a tool to support the end users in their tasks. Actions: Broad testing: <ul style="list-style-type: none"> Workability and usefulness for companies of different size and business. Enforceability of the resulting information. 	<p>Actors, as appropriate.</p> <p>ECHA</p> <p>ENES network</p> <p>National enforcement</p>

¹¹ Requires engagement from OSH community at company and Member State side. Examples from Forum's SDS quality improvement initiative and ENES projects can provide test cases.

Building block	Description how it is intended to work	Action needs	Actor(s) ⁷
		<ul style="list-style-type: none"> ○ Usability of the information under OSH/IED. 	<p>authorities (REACH)</p> <p>National enforcement authorities (OSH/IED).</p>