REACH Review Action 3: Development Plan

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Glossary

Chemical Safety Assessment (CSA): In the context of the current Development Plan, CSA refers to single substances, and consists of hazard assessment, building exposure scenarios for identified uses, making corresponding exposure estimates, and characterising the risks. The principles and method for the CSA are laid down in Annex I and XII of REACH.

Mixture Assessment: In the context of the current Development Plan, mixture assessment means the tasks a mixture formulator carries out in order to ensure that the hazard characteristics of the mixture's ingredients (as received from their suppliers) and the expected exposure under the foreseeable conditions of use are appropriately taken into account when deriving the SDS for the mixture. This includes i) exposure estimation and (combined) risk characterisation for the hazardous ingredients at the concentration level relevant for the mixture and (ii) the subsequent application of the mixture classification rules for determining additional safety measures (if relevant).

Conditions of use are the operational conditions and risk management measures as described in an exposure scenario.

Conformity check *means* comparing the actual uses and conditions of use in a downstream company with the exposure scenario information (= safe use advice) received with the safety data sheet. As an outcome, the downstream user decides whether his activities with the chemical are covered by the supplier's safety data sheet.

Contributing activity means the activities (tasks) carried out with a chemical during an identified use. For example, the use of a coating may include stirring the paint, pouring it into application equipment, application itself by various techniques, drying (film building) and cleaning of equipment.

Chemical is used within this document to cover both substances and mixtures.

End user is a person or body using substances or mixtures in an industrial or professional activity (e.g. not a consumer or distributor) who does not supply it further downstream.

Exposure Scenario: Set of information in an SDS describing the operational conditions and risk management measures per use, under which a hazardous substance can be safely used (safe use advice). Exposure scenarios result from the REACH Chemical Safety Assessment, and one substance can have multiple exposure scenarios, depending on the broadness of the identified uses. Usually various contributing activities are differentiated in one ES. For a mixture, the safe use advice (in future called for example exposure scenario information) can be usually limited to one or few uses, however differentiating according to the contributing activities within a use may be still needed. *Note: There is no consensus yet on terminology in the context of a mixture and whether the safe use advice for a mixture should be an attachment or incorporated in sections 7 and 8 of the SDS..*

Derived no-effect level (DNEL) is the level of exposure to the substance, below which no adverse effects are expected to occur. It is therefore the level of exposure to the substance above which humans should not be exposed.

Industry: In the context of this document the term "industry" means mostly all economic actors in the supply chain, in order to differentiate from "authorities". In various places of the document further differentiation among actors is made.

Minimum requirements for presence of certain information in the SDS: In the context of the current Development Plan, this concerns data/information usually needed

- by formulators or end-users to carry out an assessment of occupational, environmental or consumer risks resulting from the use of a chemical (hazard information, substance properties, % of hazardous substance in mixture)
- by formulators to carry out mixture assessment (hazard information, substance properties, % of hazardous substance in a mixture used as such or as ingredient of another mixture)
- by downstream users when largely relying on supplier's assessment, and thus comparing the safe use advice in the SDS with the actual conditions of use in place e.g.at a workplace (= ES minimum requirements]

Minimum requirements define the information type required (e.g. *General Room Ventilation)* and how the conditions are to be specified (e.g. *Mechanical ventilation ensuring at least 5 air exchanges per hour*).

Occupational exposure limit (OEL) is a value set by competent national authorities or other relevant national institutions as the limit for concentrations of hazardous compounds in work-place air.

Predicted no-effect concentration (PNEC) is the concentration of the substance below which adverse effects in the environmental sphere of concern are not expected to occur.

Recipient of a substance or a mixture means a downstream user or a distributor being supplied with a substance or a mixture.

Registrant means the manufacturer, importer or the only representative of a substance in quantities of 1 tonne or more per year, or the producer or importer of an article submitting a registration for a substance.

Safe use advice: Information in sections 7 and 8 of a SDS (substance or mixture) or attached to it aiming, to inform the recipient on appropriate (operational) conditions or (risk management) measures for safe handling and exposure controls.

Safety Data: Information in the safety data sheet supporting risk assessment and the safe use of hazardous chemicals. This includes information on chemical-physical properties, hazard characteristics, percentage of hazardous ingredients in mixtures, as well as advice on safe use (including exposure scenarios).

Specific environmental release category (SPERC) is a set of realistic exposure values that can be used in environmental exposure models to assess chemical safety.

Supplier means any registrant (substance manufacturer or importer), downstream user or distributor placing on the market a substance or a mixture.

1 Introduction

This document sets out a multi-year plan of work to improve the way **safety data** on hazardous chemicals is generated, communicated and applied in Europe[1]. The safety data, generated through Chemical Safety Assessment, is transmitted via the SDS, and includes inter alia the information on hazards (classification, Derived No-Effect Levels [DNEL], Predicted No Effect Levels [PNEC]), chemical-physical properties, and safe use advice for the chemical. This *Plan* has been prepared by the European Chemicals Agency (ECHA) and the Commission, for endorsement by CARACAL.[2] Stakeholders drawn from chemical and non-chemical business sectors, policy domains (occupational, environmental, product safety) and Member State authorities were consulted in its preparation. It is a collaborative programme that demands the commitment and investment of industry and authorities alike. The *Plan* draws on learnings from work carried out during a REACH Review scoping phase with stakeholders in 2019[3], and consultations with CARACAL[4]. Stakeholders have given broad support in terms of the proposed development towards a better means to generate and communicate safe use information to end users and the steps that need to be carried out by suppliers. An important conclusion from all this work has been that **no viable alternative approach** was identified. Despite support for the envisaged direction of the development, there is an ongoing discussion how to best motivate broad implementation by industry (once all the system elements are worked out). The development plan includes a brief analysis of the options from the legislative perspective, which however does not yet preclude that other mechanisms could be found.

For companies/employers, the **safety data sheet** (SDS) has been an essential, principal source of information for the past quarter of a century. The basis is laid down in the UN GHS standard and the minimum requirements for the countries where REACH applies are detailed in Annex II of REACH. REACH introduced a requirement for hazardous substances registered in quantities of 10 tonnes or more per year (and PBT/vPvB substances)[5] to extend the SDS with an **exposure scenario** annex, delivering safe use advice determined by means of a Chemical Safety Assessment, and differentiated among the various uses foreseen with the chemical. A second area of extension concerns the inclusion of **DNELs/PNECs** into the SDS (section 8), providing every downstream actor with benchmark values for his own risk assessment.

However, the **quality of the information** provided in the registrant's SDS is not yet at an appropriate level to serve as a good source of information for downstream users (and distributors) at all levels in the supply chain. This concerns various aspects originating from the current implementation of REACH and/or CLP:

- the hazard characteristics of the substance as expressed by classification and DNEL/PNEC,
- the way how classification and DNELs are utilised to drive risk management (i.e. a lack of integration between the two ways to characterise hazards),
- the predictive exposure estimates for risk characterisation (i.e. conflicting exposure estimates between the applied modelling tools),
- the advice on safe use which frequently does not fit into the practical reality of downstream users
- the understandability, relevance and amount of information arriving at the different recipients in the supply chain

[1] The Plan refers to safety data sheets for REACH registered substances (as such or in mixtures), and is focussed on the substances registered in amounts of 10 t/y or more. The methods for formulators and end-users however will take into account safety data sheet information for substances with lower tonnage.

[2] CARACAL is an expert group which advises the European Commission and ECHA on questions related to REACH and CLP.

[3] CARACAL – Call for support on REACH Review Action 3 – Transition from scoping phase to development phase

[4] CARACAL – Call for support on REACH Review Action 3 – Transition from scoping phase to development phase

[5] See ECHA's web page: Management of PBT/vPvB substances under REACH

Also, the uptake of the exposure scenario concept as a means to support safe use of hazardous chemicals (substances as such and substances in mixtures) along the supply chain is still limited, as evidenced by the second REACH Review[6]. Some of the quality issues observed with safety data sheets for mixtures are not related to REACH, but to mistakes in applying the CLP classification rules and determining the corresponding safe use advice.

This *Plan* responds only to some of the quality issues, namely: i) better integration between classification-based and DNEL based hazard conclusion, ii) more realism in the conditions of use assumed for the assessment, and iii) making the information received via the SDS more understandable, more relevant and less overwhelming. The correctness of substance classification and DNEL derivation itself (based on the data required under REACH) and the reliability of exposure estimates across the various exposure estimation modelling tools are outside the scope of this *Plan*. The same applies to the correctness of the mixture classification itself according to CLP rules.

A major driver for the proposed development is to meet the needs of micro-, small- and medium-sized enterprises, who represent 99% of businesses (i.e. companies) in Europe, who produce as well as utilise chemicals[7,8]. At its core, *the Plan* concentrates on the safety of chemicals by design and by safe- use advice. Specific attention is given to improving and simplifying the authoring and the utilisation of the **SDS for the mixture**, given that mixtures represent vast majority of hazardous chemicals in the European market. One key target is that the mixture SDSs are equipped with one **single block of safe use advice**, covering all the hazardous ingredients contained in the mixture[9]. Another key target is the better integration between classification-driven safe use advice for substances and mixtures, and the DNEL-driven safe use advice for the individual ingredients.

An equally important driver is the need to ensure that the safe use information delivered via the SDS can be directly used by employers and site managers in terms of occupational safety and health (OSH) and environmental emission controls, and this will be a principal focus of the current development work. The utilisation of the SDS information by other actors such as article producers and waste operators (and then further synergies with European product legislations) are known areas for attention and further development; these areas are part of a longer term goal for supply chain communication but are not under the direct focus of this document.

2 The system for enhancing supply chain communication

2.1 Vision

The Commission's REACH Review[10] recognised there has been a continued increase in the information passed through the supply chain over recent years. However it needs to be made more effective (delivering useful and relevant safe use advice) and efficient (e.g. reduce costs

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[6] COM, General Report on the operation of REACH, SWD(2018) 58 final. Action 3 *Improving the quality & workability of the extended SDS*, and Action 12 *REACH-OSH interface* (including REACH tools like SDS + ES).

[7] According to Eurostat's statistics [2015], enterprises employing fewer than 250 persons represent 99% of all enterprises in the EU.

[8] Micro: <10 employees and ≤2 million euro annual turnover; Not SME: >250 employees and >50 million euro annual turnover (reference: Commission Recommendation 2003/361/EC)

[9] No consensus yet on how this single block of information should be called (*exposure scenario*, or *safe use of mixture information* or *safe use advice* or *safe handling and exposure controls*), and how it would appear in printed SDS documents (attachment or incorporated in the main body of the SDS).

[10] See footnote 5

of producing and supplying safety data sheets), especially for SMEs[11]. Furthermore, improvement is also needed in the ability of companies to develop specific safe use advice, in particular for mixtures. To that end, the Commission recommended a suite of inter-related actions to improve the quality and workability of the extended safety data sheet, identifying roles for different actors to make those improvements.

Based on work with stakeholders carried out on these inter-related actions in scoping and pre-development phases during 2019-2020, a **vision** has emerged for improving the way the safety data on hazardous chemicals (substances as such, or in a mixture) is generated by a supplier and communicated to downstream users in the supply chain via the safety data sheet (SDS), and then utilised by the recipient. The primary objective is that the knowledge on chemicals generated under REACH (i.e. information on substance properties and related conditions of safe use), reaches all the actors down the supply chain. This enables them to confirm that their practices are within the safety information received from their supplier(s) or, if needed, carry out an assessment themselves, including to ensure that appropriate safe use advice is available to their customers when relevant. This will lead to increased safety in the use of chemicals in the EU, underpinned by effective company risk management, as well as to a more cost effective way of handling SDS information, and a better integration with other legislations such as worker protection and the environment. These improvements, in parallel, would over time improve the information available to authorities on the use of chemicals.

Implementing such a vision into practice is complex and requires a careful balancing between the different interests and needs of different actors down the supply chain (and authorities), as well as the different cost impacts on them. In essence, implementing the vision requires three key strategies which affect fundamentally the way economic operators generate and communicate safety information via the safety data sheet: Firstly, refinement (and some extension) of the existing **mandatory minimum requirements** for the content of the safety data sheet[12] is envisaged. Secondly, it is proposed to put in place a **common XML format** for company-to-company electronic communication of the safety data in the supply chain. Based on this, suppliers of hazardous chemicals would provide the safety data for their products not only in paper format, but also in the electronic exchange format[13]. This would enable electronic checks of completeness and consistency, and would provide customers with the opportunity to electronically process the safety data of the purchased chemicals, including targeted extraction for certain tasks at company level, e.g. risk assessment under OSH legislation. To make use of this opportunity, a recipient would need to get equipped with tools to process/"read" the xml.
Based on a common SDS-xml, the market can develop tools for generating and processing the safety data sets. As a third strategy, such **tool development** in the market could be supported by authorities. For example, ECHA does foresee the further development of Chesar into a tool for exposure/risk assessments by actors further down the supply chain[14] .

A common data exchange standard could be a means [driver] for improved workability (including simplification) of supply chain communication. However, providing an xml standard as such will not motivate investments by companies to systematically generate the SDS information in the common electronic data-format. Further accompanying measures may be necessary, including demonstrating the practical benefits to companies (i.e. convincing the market), and potentially introducing the legal obligation to provide the safety data in an electronic data format.

Most importantly, the **content quality** of the information communicated down the supply chain

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[11] See Commission's REACH Review Report 2018 (footnote 4), section 2.2, page 3 at https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52018DC0116&from=EN

[12] Note: For many areas of the main body of the SDS, already the current Annex II sets clear minimum requirements. However minimum requirements are missing in other areas, for example the content of exposure scenarios, the inclusion of DNELs and PNECs, and also specification of engineering controls as required under section 8 of the main body of the SDS.

[13] Whether maintaining a paper document transfer as a routine service or on request only can be clarified at a later stage. While aiming at electronic safety data transfer as the routine in the long term, the present proposal however explicitly foresees to keep transfer on paper as an option.

[14] Chesar is ECHA's Chemical Safety Assessment and Reporting tool.

needs also to be improved. The development plan is expected to contribute to such an improvement via i) the minimum requirements for the communicated exposure scenario content, ii) the integration of the classification- and DNEL-based hazard assessments towards a coherent driver for risk management, and iii) further development and uptake of sector use maps.

The practical benefits expected from the proposed development and the costs for its implementation will be illustrated [substantiated] by means of examples and case studies in the first development phase (see section 3.2.)

2.2 Interface between OSH, REACH and environmental legislation

The **OSH legislation** places full responsibility upon the employer to make a site-specific risk assessment in relation to various hazards (including but not limited to chemical hazards) at the workplace. The resulting site-specific safety [*preventive and protection*] measures should guarantee worker protection, including measures to control exposure where necessary. OSH sets the obligation for the employer to carry out their risk assessment. But the actual tools and methods may differ from Member State to Member State. Nevertheless, there are good examples in place that these existing aids have shown to be useful and accepted by end users, especially SME. The safety data sheet is defined as a key source of information required for the risk assessment. REACH reinforces the role of the SDS, and adds specifically i) the exposure scenarios and ii) the threshold values for exposure below which no adverse effects are expected.

The safety data sheet (SDS) is/should be the principal source of information to an employer.[15] This is both in the context of (i) substances, where the SDS and related safe use advice come directly from the REACH registrant, and (ii) for mixtures (which represents a much higher part of the market than for substances) where the hazard information and safe use advice needs to be consolidated, by the supplier .

However, as stated earlier, the quality of the information provided through the SDS is not yet at an appropriate level and the uptake of the exposure scenario concept is still limited.[16]

In very simple terms, the main shortcomings experienced by actors who operate within and/or service the OSH community have been:

- The hierarchy of exposure control is not respected.
- The amount of information received is overwhelming, not well structured and often contradictory.
- The language for the descriptions of use and conditions of use is not understandable, including the problem that the same content is expressed in various different ways.
- The risk management advice included in the exposure scenarios received via the SDS is often not realistic or too generic to be sufficient for OSH.
- Recipients, in particular downstream end users, do not understand on what basis the advice is given.

The vision and mechanisms set out in this Plan serve collectively to address these shortcomings. Addressing these shortcomings and improving the quality of the information, e.g. completeness and consistency, that then flows down the supply chain should thus help recipients, and in particular micro- and small-enterprises **(MSEs) and SMEs** in the management of risk (under OSH) to fulfil their tasks more easily and improve worker protection. Safety data in an electronic format can bring benefits through facilitating the targeted extraction of information

[15] ECHA's REACH database also provides in-depth information on substances and their functions. However, the principal source of data in the safety data sheet should be derived from the chemical safety assessment carried out by an upstream supplier. In some situations, the author of a safety data sheet may choose to draw upon information or data from ECHA's database, but ultimately the author remains responsible for the information content of their safety data sheet.

[16] See footnote 5.

from a SDS which is needed as an input to a workplace risk assessment. Such benefit however can only materialise when at the same time the quality of the extracted information is appropriate.

The ready availability of appropriate safety data can also benefit those responsible for the design of the machinery used in the workplace e.g. in the production/fabrication of articles, that hazards due to the chemicals which are intended to be used in the process are either eliminated or the risks reduced by changing the design or operating characteristics of the machinery.

Environmental legislation

Similar to the Chemical Agents Directive 98/24/EC (CAD), the Industrial Emissions Directive (IED) is to be transposed through national legislation for setting requirements for companies. Different from the occupational arena, the main mechanism to set requirements is the environmental permitting system. Up to now, there is no standard requirement for site operators to carry out a risk assessment for the hazardous chemicals used on site under IED. Hence at present, the environmental information added into the SDS via REACH (environmental exposure scenarios and PNECs) has no legally defined addressee, except for the REACH downstream user referred to in REACH Article 37 (4)-(6). However, in the current update of the BREF (Best Available Technique Reference Document) for textile processing there is a discussion between the Commission's Joint Research Centre (JRC), Member States and ECHA on whether setting a Best Available Technique (BAT) conclusion making environmental risk assessment for hazardous chemicals used at site a standard condition in the environmental permit. Once this is set up, operators of industrial sites to which IED applies would start using the data input from SDS for their site assessment, and largely benefit from the availability of the data in xml format.

The development work to be carried out at this interface differs from the work related to occupational risk management:

- Methods and tools to predict releases from sites need to be newly developed, as the demand for such tools (also from authorities) was so far quite limited.

- Environmental risks are driven by the total load of a substance entering into the eco-systems from all the various sources. This means that the environmental assessment needs to combine the single site perspective with the regional perspective.

2.3 Safety data supporting safe design and use of articles

A significant fraction of the hazardous chemicals placed on the EU market becomes part of materials from which articles are made or are used in coating of article surfaces. This concerns for example rubber and plastic products, paper, leather and textile products. Some article producers have to comply with specific EU product legislation, for example for food-contact materials, toys, or construction products. Releases of hazardous substances and subsequent exposure and risk from articles are to be assessed by suppliers of chemicals, and the outcome of this assessment should be communicated in the safety data sheet for substances and mixtures (e.g. safe concentration). Correct and complete information on the hazardous ingredients of mixtures and an indication of the measures required to control the releases from the article will help article producers to improve and document the safety of their products.

2.4 The System Described

The principal actors in the system [inside the blue box] for generating, communicating and utilising "safety data" on hazardous chemicals are shown in Figure 1: suppliers, formulators, end users. Distributors, as a supplier of substances and mixtures, are an additional important actor at any point in that system, in particular in forwarding information between the other actors, but for simplicity they are not shown in this Figure. Authorities, whilst not active players in the

communication of information, enforce the relevant legal requirements, and also utilise the information for their regulatory work under REACH to identify, set priorities and control substances of concern.

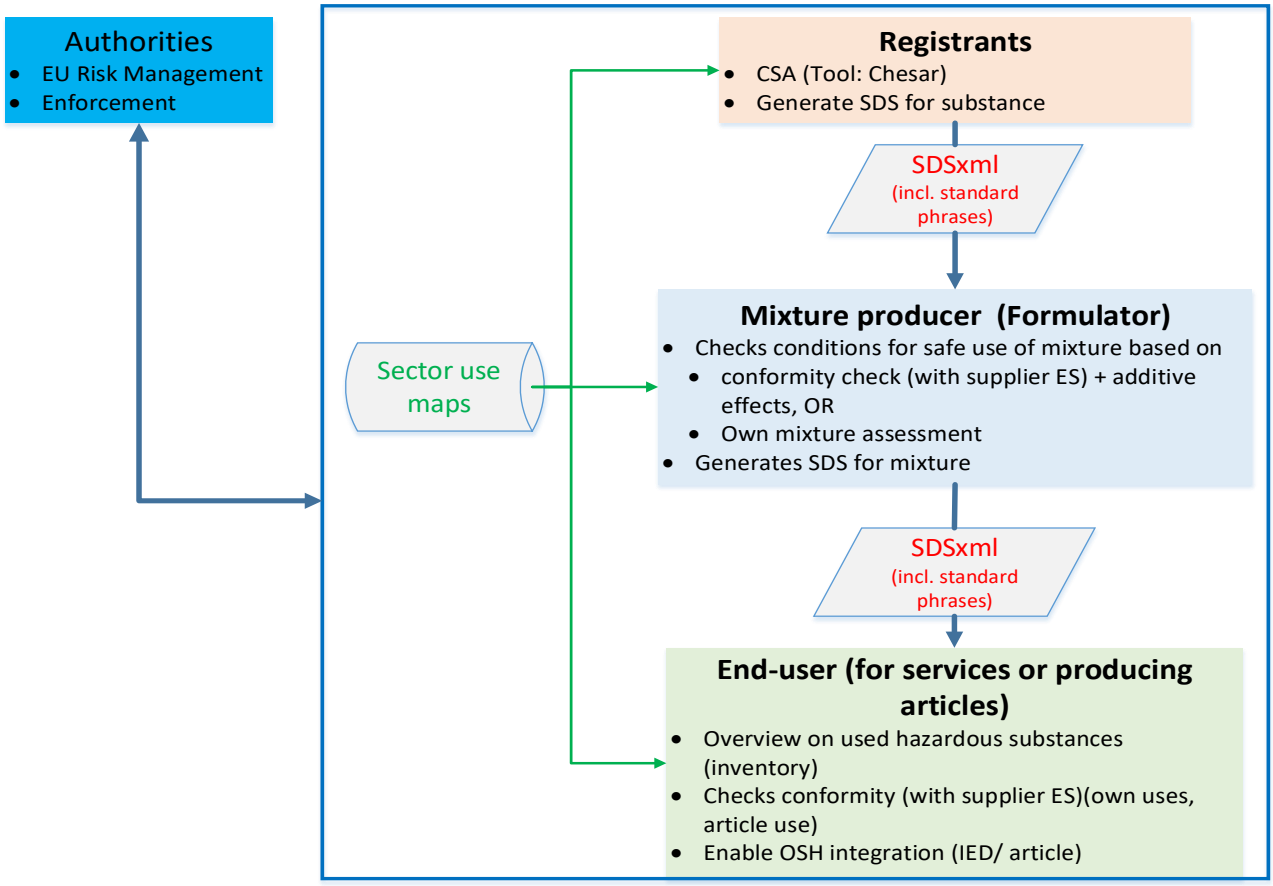

Figure 1: Generation, communication and use of safety data

Figure 1 concentrates on the main stages where safety information is generated and communicated between actors and utilised by them; the bullet points identify the relevant tasks/responsibilities in the scope of this *Plan*.

In Figure 1, the **starting point** of the system is the Chemical Safety Assessment for the whole life cycle of the registered hazardous substances, carried out by the **registrants**. If available, they utilise **sector use-maps**, ideally drawn up by (downstream) sectors, to provide registrants with structured information on the actual uses of chemicals in a sector or supply chain, the operational conditions (OC) and the related risk management measures (RMM) actually in place in the EU market.. The OC/RMM ensuring safe use are expressed in **standard phrases** for communicating down the supply chain via the **safety data sheet** (SDS). The SDS also contains all information on the substance's hazards (classification, DNELs, PNECs, similar parameters to characterise the substances hazard, and other properties required for any assessments further down the chain. All these CSA outputs are contained in the **SDSxml**[17].

Based on their business data on mixture recipes, mixture classification and product types, **formulators** build an **inventory** of their hazardous mixtures, including the description of expected uses and the related conditions of use**. Use maps** compiled by their sector organisation will help

[17] ECHA's Chesar tool currently generates an ESComXML which can be uploaded into a company's SDS generation system which has implemented the format. A number of IT providers are known to have implemented the upload functionalities but currently, do not generate the SDS using ESCom.

the single formulator to compile a consistent inventory in an efficient way. Subsequently, formulators check [assess] whether the actual (expected) conditions of use of their mixtures are safe for all the hazardous ingredients. Such a task can be based on a) a conformity check against the suppliers' exposure scenarios, potentially completed with an assessment on the additivity of risk across substances or b) on an own mixture assessment. For both assessment routes, the outcome of the mixture hazard assessment according to CLP rules needs to be integrated.

a. Formulators check in the received SDS whether or not their actual use(s) of the purchased chemical match with the uses identified and assessed by their suppliers. This check addresses both, the use of the chemical during all the production steps of the mixtures, and the use of the (final) mixture by the direct customers and potentially further down the chain.[18] In Figure 1, these (two) operations are called "**conformity checks**".

b. The **assessment for the whole mixture** is based on the exposure assessment methods for the single hazardous ingredients in the mixture. In addition, it includes a combined risk characterisation across all substances in the mixture (where relevant), and the check whether the CLP based hazards of the mixture are sufficiently addressed in the risk management determined by the REACH assessment.

The **output from these assessments** can be i) "demonstration of safe use, no further action", ii) potential adjustments of the mixture composition or use pattern, iii) communication of uses to supplier for assessment, iv) reporting of uses not covered in supplier's assessment to ECHA and/or v) adjustments in the advice to customers. As the last step, formulators determine the safe use advice for their customers, industrial or professional end users; this safe use information is a single piece of information for the whole mixture, provided in the **SDSxml**. This file also contains the classification of the mixture as a whole, and all the information on the single hazardous ingredients that may be needed for assessments further down the chain (e.g. DNELs, PNECs, vapour pressure) including by those customers who themselves are formulators[19].

End users will receive SDS (SDSxml and document) that contain the safe use advice for the mixture, differentiated according to the activities/tasks involved in using the mixture, as well as the relevant information on hazard and fate for all the individual hazardous ingredients. The information feeds into the companies' **inventory** of hazardous chemicals, which also includes the characterisation of the workplaces where the chemicals are used. Such characterisation will be based on a common REACH-OSH terminology (to be developed). Once built, the inventory can serve as a regularly updated basis for assessments under REACH, OSH and environmental legislation, with largely automated routine **conformity checks** for received SDS. If the use does not conform, the end user may choose one of the following options: find an alternative to the chemical used; apply the recommended [risk management] measures as prescribed in the SDS, request supplier to assess use as an intended use; check via an **own safety assessment** (possibly already existing as required by OSH), that the existing practice is safe. In case of actual uses significantly deviating from the use as determined in the SDS, the end-user will report this fact to ECHA. Receiving the SDS information in an **xml format** may support in particular smaller users of hazardous chemicals (who usually have no own risk assessment capacity), for using simple IT-tools to compare the risk management profile of the company with the risk management needs determined in the safety data sheet. The system outlined above may also serve as a basis for safety assessments related to produced articles.

Authorities will gain knowledge and support for enforcement from the systems:

[18] The term formulator here is used to include the formulation of mixtures for supply from ingredient substances or (intermediary) mixtures, sometimes called "mixtures-in-mixtures".
[19] The foreseen SDSxml will also transport other SDS information.

- Binding minimum requirements and a structured way of providing the required information (i.e. numeric values, selecting items from drop down lists) will make enforcement of SDS completeness/quality easier.
- Reference to a harmonised methodology for downstream users (potentially laid down in a REACH Annex) regarding the utilisation of SDS information for identifying the appropriate measures for safe handling and exposure control at workplace, will help OSH and REACH inspectors to check whether companies have the right systems and documentation in place.
- Updated and extended sector use maps, in combination with an improved use description system (with a focus on streamlining product categories and potentially reducing the granularity in describing worker activities), and a robust use-conformity check method downstream, aim to provide better information to the authorities. This would arrive via the update of IUCLID dossiers and registrants' CSRs or via downstream user reporting on uses not covered by suppliers.

More description on the technical aspects which underpin the actors' tasks shown in Figure 1 can be found in Section 3, *Technical Development Plan*.

2.5 Considerations on potential legal changes

Implementing the system in an effective, consistent and synchronised manner is likely to require binding rules. This section therefore describes the options for legislative actions in case the Commission comes to the conclusion that binding rules are required. There are four main areas of considerations on potential legal changes, if deemed appropriate:

- If a prescribed mandatory electronic data exchange format (SDSxml) is considered to be the best way forward, the legal basis for such a requirement would need to be identified or created. The current REACH Articles 31(8) and Article 111 do not seem to provide such basis. Article 31(8) explicitly leaves the choice between paper and electronic SDS format to the supplier, and Article 111 only covers data submitted to ECHA, but not B2B information in the supply chain. A mandatory format for electronic exchange of the SDS, to be followed by those suppliers preferring the electronic form rather than the paper form, may be set up via an Implementing Act, but making the provision of the SDS in electronic exchange format mandatory would need a change in Article 31(8).
- Minimum requirements regarding the content of safety data sheets (including exposure scenario information) for hazardous substances and mixtures could be specified via the relevant REACH Annexes (I, II, XII).
- A method for mixture safety assessment as referred to in Article 31(2) is not prescribed in the legal text. Such method would need to integrate the principles of REACH Annex I and Annex XII with the classification rules for mixtures according to CLP (and the corresponding safety advice triggered)[20]. Such integrative method for mixture assessment could be laid down in one of the relevant REACH Annexes (I, II, XII).
- The harmonised method for conformity check, supporting implementation of Articles 37 (4) and (5) regarding the comparison between the SDS information received and the actual practice by DU company could be laid down via an Implementing Act. This could also cover a clarification when and what to report to ECHA according to Article 38.

[20] While the REACH Annexes contribute the concept of exposure scenarios based on quantitative risk assessment for single substances, the CLP classification rules contribute the concept of cross-substance hazard characterisation of a chemical.

2.6 Note on supporting MSEs and SMEs in the management of risk

The supply chain system improvements described in this Plan seek to help small businesses both in terms of the content of the information that flows down the supply chain e.g. a single piece of safe use advice for a hazardous mixture, and the opportunity to utilise information technology to handle that information to do their work more easily and improve worker protection. It helps to integrate REACH and OSH and support the single companies' OSH risk management by REACH safety assessment outcomes. To that end, engagement and consultation with stakeholders, serving the small business communities on both the industry and authority sides, will be important components of the development work.

3 Technical development plan

3.1 Overview, contribution and timing

The next sections describe 5 different work packages meant to support the development work for the system described in section 2. They cover the needs for development of:

- Registrants' chemical safety assessment (WP1).
- Sectors' use maps (WP2).
- Safety Data Exchange Standard (XML schema definition) (WP3).
- Formulators' methods and tool (WP4).
- End users' methods and tool (WP5).

It should be noted that there are a large number of interdependencies between the work packages, as illustrated by Figure 1. In particular:

- The content of the SDS exchange standard (WP 3 in section 3.5) will be driven by the needs of the end user (WP 5 in section 3.7) and formulators (WP 4 in section 3.6), and all suppliers should be able to generate such content (WP 1 in section 3.2 and WP 4 in section 3.6).

- Use maps (WP 2 in section 3.4) should contain the data needed by registrants, formulators and even possibly end users, and be provided in a structured data format which is compatible with SDSxml.

Development phases

It has been agreed among the ENES stakeholders that case studies should be developed in a **first phase**, starting in 2021, to illustrate the proposal for the formulators' method and for the end users' method by examples. This exemplification aims to increase the understanding of what is proposed, to get feedback from companies and from authorities whether the proposal has the potential to solve the experienced practical problems, to identify unexpected impacts, to get aware of any feasibility issues, and to trigger ideas to improve the proposed solution. Together this should form a proof of concept, as a basis for carrying the development into the second phase.

The case studies will have to be worked out on the basis of the draft concepts proposed by ECHA for each of the five system elements described in this document. The initial input to be provided by ECHA is described beneath for each work package as a subset of the overall development work.

In addition, a series of (small scale) cost benefit case studies will be carried out during this first phase, to better understand the impacts on the different types of actors in the supply chains.

The plan for this is described in section 3.2.

Depending on the outcome of these studies, the further development work (**second phase**) will be (re)directed and decision be made at CARACAL on how to best set incentives for the supply chain actors for implementing the foreseen change.

In the following sections, the initial ideas for the development work are described including both (i) the work for the initial method description and illustrative examples (first phase) and (ii) the further foreseen development work (second phase). The latter will be revised after the first phase for potential modifications from the learnings made during the first phase.

Contribution and consultation

Dedicated technical working groups (sometimes with subgroups) will have to be set in place to carry out the work. This will require that all stakeholders, in particular industry, but also member states, dedicate sufficient resources to bring their experiences and their ideas for developing the new system, and to test it with real life situations. The consultation will also be made via those development groups. Therefore, it is important that experts contributing to the work also have the capacity to consult other representatives.

The detailed tasks and planning will be developed at the kick-off stage of those working groups.

It is important that all contributors of expertise, experience and views under the various work packages have a good understanding of how the whole system is meant to work. The following specificity should be taken into account:

For WP 1, it is suggested to set up a working group in close connection with the development of ECHA's Chesar tool. Therefore, it is important that experts covering both workers[21]' and environment assessment expertise, with experience in SDS management contribute to the work. It is suggested that the work is led by the ECHA team in charge of Chesar development.

For WP 2, a group of use map developers, led by ECHA already exists within ENES. This group may form a basis for the future working group. Nevertheless, it will be important that the participants contribute more extensively to the work than what is currently done. The update of the use map template could be carried out by ECHA in consultation with this group, while the update of the (sector) use maps should be led by the corresponding industry groups. For identification of gaps in the use map landscape and for the potential refinement of the product category system (PC) input from Cefic and DUCC will be required.

For WP 3, 2 subgroups focused on i) business aspects and ii) IT aspects could be put in place. The existing industry led ESCom group could be a starting point.

For WP 4, 2 subgroups[22] could focus on (i) the workers' aspects and ii) the environmental aspects). It is essential that experts with industry (various types: from MSE to multinational companies) and authorities' (inspectors') perspectives contribute to the work.

For WP 5, 2 subgroups could focus on i) workers' aspects (and the link to OSH) and ii) environmental aspects (and the link to IED). It is essential that experts with industry (various types: from MSE to multinational companies) and authorities' (inspectors') perspective contribute to the work.

More details on the governance will be described in section 4.

For the phase 1, not all the groups will be put in place. First ECHA will further develop its proposal for the methods for formulators and end users, with an initial illustration (examples). Two groups of stakeholders (corresponding to WP 4 and 5) will be set up to digest and further

[21] Consumer assessment should also be covered.
[22] To see how to cover consumers.

work out those examples so that they can be made available to the full ENES+ community as an illustration of the methods (proof of concept). This work may also include workshops/webinars with MS authorities and/or industry to broaden understanding and feedback.

In addition, an initial analysis of the requirements for an SDS XML will be carried out (WP3).

Overall timing

The current ideas for planning the work are provided in Figure 2. For each WP a more detailed planning will be set up to kick off the work. The setting of legislative requirements is displayed in light colours to indicate that the right means to provide sufficient incentives for broad implementation are still to be discussed, also in the light of the proof of concept phase.

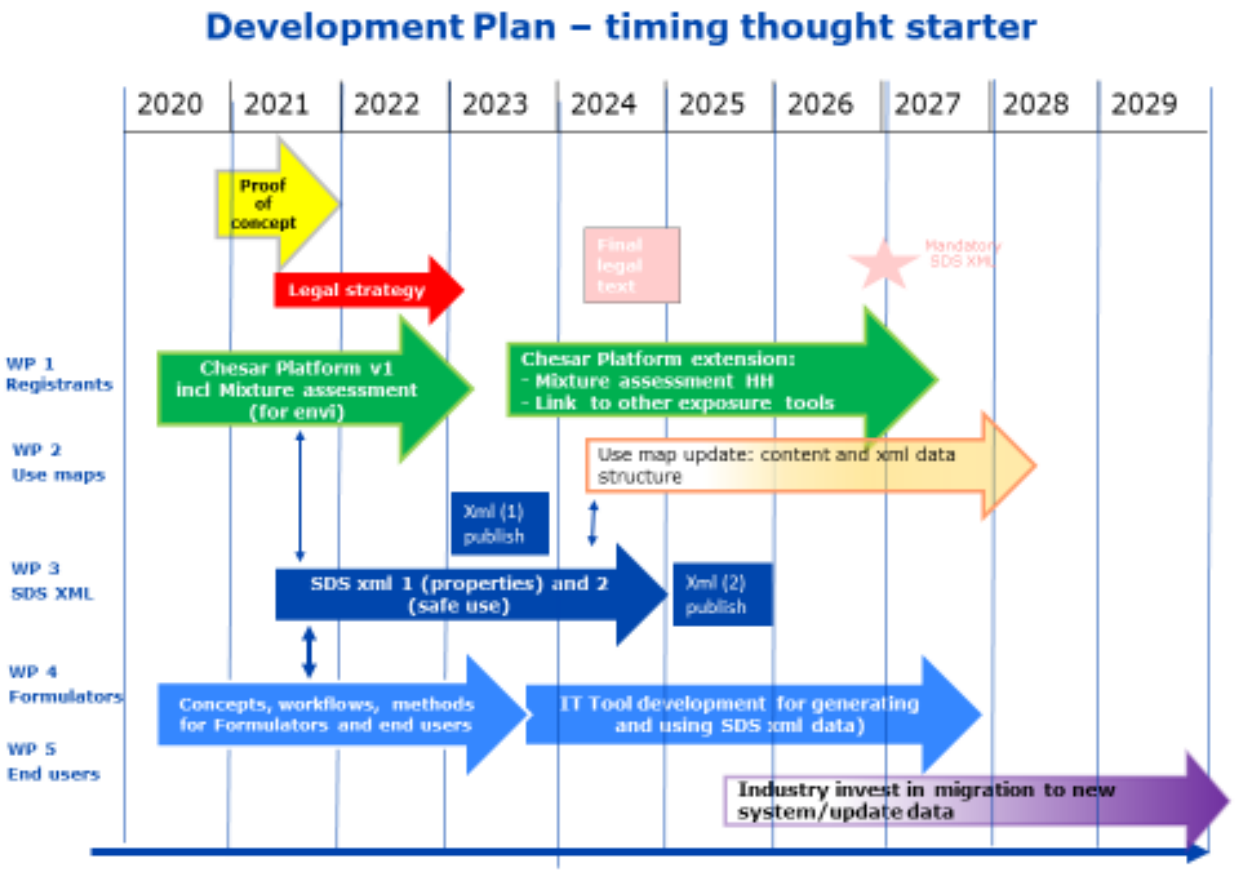

Figure 2: Overall timing for the development

3.2 Considerations on benefits and costs

The proposed system is anticipated to generate significant benefits (including long-term cost savings), a hypothesis which is though subject to proof of concept in the first development phase.

One of the expected benefits is related to data **quality improvements contained in the suppliers' SDS**:

- The consistency [integration] between the classification of a substance and the DNELs/PNECs for being used as a trigger/benchmark for risk management are likely to increase due to an improved Chesar workflow support. For the development work required see WP 1 in section 3.

- The usefulness and consistency of exposure scenarios across markets will increase when setting the right minimum requirements in the system. This includes limiting the exposure scenario information to aspects that are necessary for and can be verified by a formulator or an end user, when carrying out their conformity check (see section 3.6 and 3.7 beneath). With the setting of minimum requirements, it will also be possible for engineering controls to get a higher profile in the safe use advice, thereby supporting the hierarchy of exposure control principle.
- The exposure scenarios should become more realistic and consistent across registrants of hazardous substances, provided the registrants utilise the information available from sector use maps when updating their CSRs.
- Data in the SDS will become more consistent and complete due to its direct extraction from the CSR (i.e. avoiding copy and paste mistakes) and the possibility to use tools for completeness and consistency checks on the SDS xml.

The provision of the safety data in a standard electronic format provides **opportunities for the recipients to use electronic tools** for:

- Checking the consistency and completeness of the SDS
- Ideally, the information can be used directly for the risk assessment under OSH legislation
- Targeted extraction of information that may reduce resources for manual transfer and will facilitate documentation
- Generation of paper versions, as needed
- Digital processing of information for substances and mixtures (e.g. for assessment purposes)
- Simple tools to check conformity with the safe use advice (serving both REACH and OSH needs). In particular, small companies can be enabled to meet their duties under the OSH and environmental legislation.

With further specified, minimum requirements in areas of the SDS where they have been missing so far (for example the safe use advice in terms of engineering controls; discriminating the advice according to tasks/activities; provision of DNEL/PNEC information for hazardous ingredients in mixtures) and an electronic format for the safety data, it is expected that **enforcement becomes easier**, as it will clearly defined which information is expected where and inspectors could check completeness and plausibility with IT support.

REACH authorities may benefit through getting **better information on the uses of substances**, as a basis for efficient regulatory work.

The investment costs for industry to generate the above benefits are driven by:

- Suppliers need to re-wire their SDS systems, which are often closely interconnected with their business management systems.
- The recipient of an SDS making the choice to benefit from the provision of safety data in an electronic format needs to invest in using tools to "read" and process the data.

The anticipated benefits, the feasibility and the proportionality of costs will be further explored by means of a suite of practical examples and case studies (business cases), which together will form the proof of concept. The technical development plan below (section 3.3 to 3.7) therefore includes a proof of concept phase at its start.

Approach to Business Case Studies (by industry drafting group)

Note that this section has not been integrated with the rest of the text of the development plan. A more detailed plan for the business case studies is expected to be developed in the first part of 2021. Whether a platform different from the ENES+ one is needed will be identified

then. Also the relationship between the pilot project mentioned below and the illustrative example described in the sections 3.6 and 3.7 is to be clarified.

Safe handling or use of chemical products across all actors of the supply chain, from substance producers to users of articles, rely on information conveyed through Safety Data Sheets (SDSs). SDSs are also instrumental in providing measures and recommendations to minimize the impact on environment as these products are stored and transported. The spectrum of uses of substance and mixtures varies. It includes transformation of one substance into another, the formulation of a mixture, the handling of an article or an end use like painting a surface. In this respect, the information contained in an SDS will be utilized differently in the supply chain. Each actor in the supply chain may have different needs and expectations what the content of an SDS should be.

Considering the above, good quality SDS will serve several purposes. Manufactures and/or formulators need good quality SDSs for their purchased raw material not only have the right input to produce sustainable products under safe conditions, but also to compile good quality SDS to ensure customers are provided with the required and comprehensible information to handle the product in a safe way. End users also need SDS data as input for workplace risk assessments. The variety of actors along the supply chain is not only role related, but also company size related (from large enterprises to SME's and micro-companies). Nevertheless, the size does not necessarily determine their level of expertise related to SDS.

Therefore, for a realistic assessment of the benefits that a more digitalised information flow can bring, it will be fundamental to assess to what extend such benefits would materialise to whom and at what cost.

Such an assessment needs to look at different tiers of a supply chain and find out:

- Who the actual actors are and if and how they can be grouped,
- what are their concrete data needs?
- Are there already XML IT solutions in the supply chain and how can we benefit from those?
- Are there already working software solutions and databases at receivers' end and how can we benefit from those?
- Does the Development Plan offer a good alternative to the current system for communication in supply chain?

A platform, consisting of all organisations representing stakeholders in the supply chain and companies with experience in electronic SDS data transfer, should organise the gathering of intelligence, but also monitor if developments go in the right direction, and manage change among their members.

A workshop and/or an EU-wide questionnaire could be possible tools for the collection of intelligence. Based on this, more refined business cases could be developed. In particular, cases should provide insight on the following elements:

- size and characteristics of different actors / actor-groups,
- data needs of different actors / actor-groups,
- anticipated investments required for different actors / actor-groups,
- estimation of current manual work that could be replaced by digital means,
- opportunities where SDS information could lead to other savings (e.g. less work on workplace risk assessments),
- options for sponsorship,
- estimated time needed for implementing changes,

- obstacles foreseen, including costs, awareness-raising and building up of expertise.

The outcomes of the Business Cases should determine to what extent the new approach is sustainable, meets different needs in the supply chain and provides added value. The outcomes can also provide information to adjust the development plan if needed.

The business cases should support the answers to the following questions:

- Where will major investments be needed, and can they be quantified?
- What and where are the major benefits?
- What and where are the major disadvantages (incl. for impact on global players with benefits in EU only so far)?
- What are the most relevant data elements for end users regarding safe use (e.g. CLP classification, composition, classical section 7+8 information, DNELs, PNECs, ES, SWED codes + max safe use concentration) and would electronic communication improve the quality of such data?
- Assessment of benefits and disadvantages of changing the current approach to a full XML-based approach.
- How and by whom could a change-process be managed?
- What is a realistic time frame for a change-process?
- Pros and cons of managing the XML standard by the market.
- What type of applications would need to be developed (particularly EU wide coverage for SME/micro enterprises) and who could sponsor those?
- How can existing solutions be leveraged or adapted to meet the objectives?

Pilot project

In addition to the business cases, a pilot study could make the anticipated benefits and weaknesses visible on the content of the safe use information. Such a pilot could assist in defining minimum ES requirements and generate examples to use in communication with stakeholders.

Iterative steps to define data needs on safe use:

Step 1: Set minimum ES requirements for substances, focusing primarily on formulators'/distributors' needs for mixtures.
Step 2: Review if the ES information received is sufficient to integrate in mixture SDS. Review if the formulator/distributor has methods to process the information received. It should also be considered that mixtures are also used in formulations (mixture in mixture issue).
Step 3: Evaluate whether the recipient of the product receives meaningful information about safe handling and to carry out his own risk assessment.
Step 4: Align and balance the different needs for substances and mixtures based on the evaluation of step 3 and go back to step 1 (iterative process)

3.3 WP1: Registrant's chemical safety assessment

3.3.1 Description

Methods for chemical safety assessment have been developed over the last decade and implemented in tools, for example Chesar, developed by ECHA and available for free to all registrants. Data exchange formats to Chesar (to automatically transfer data from IUCLID) and from Chesar (towards IUCLID for the registration dossier or SDS generating system using the Chesar and/or ESCom standard) have been developed.

The proposed system may lead to adaptation needs at the level of the registrant's CSA, to better serve the needs of the downstream users. In addition, it should be noted that some of the

principles (and tool features) will be the same for assessing substances and mixtures. Therefore consistency between methods is to be ensured (link to WP 4). The elements to be worked out identified up to now are explained below.

It should be noted that ECHA is currently developing a new tool which will merge Chesar and EUSES[23] and replace the current Chesar in a few years' time. This development aims to better support the environmental part of assessment[24] for biocides. As part of it, a first implementation of assessment of mixtures (at least for the environment) is expected to be implemented to cover the biocides' needs.

3.3.2 Development work

3.3.2.1 Foreseen development work

Adaptation of existing substance assessment methods and tools will have to take place, in particular for the following:

- Clarify the relationship between the classification (driven by CLP) and the PNECs/DNELs (driven by REACH Annex I), both expressing the conclusions from the hazard assessment (hazard characteristics), and both serving as a trigger and reference for the chemical safety assessment (identification of adequate risk management). The impact on ECHA guidance extension (and possibly changes), modification of IUCLID and Chesar will have to be analysed. Also, the necessary corresponding information needs in the SDS regarding the DNEL should be developed. Such work should contribute to the improvement of the quality of the hazard information derived at the top of the supply chain and communicated via the SDS.

- Implement the minimum requirements for safe use advice and the corresponding set of conditions of use in the SDS XML. It should be noted that a mapping between the conditions of use determining exposure in the various occupational modelling tools took place in 2018-2020 within ENES.[25] This led to harmonisation of a number of core exposure determinants. But this mapping also revealed some difficulty for a further harmonisation: Currently 23[26] different conditions of use with their respective values are needed to run the following tools: ECETOC TRA, ART, Stoffenmanager, MEASE and EMKG Expo-Tool). Further integration and possibly simplification depend on the interest and cooperation of the various tool owners.

The deliverables of the development work done within this work package are:

- Workflow for assessment (to be adapted in Chesar and possibly in IUCLID for the hazard assessment conclusions. Such workflow should be available in 2021 for implementation in the Chesar platform). Proposals for adaptation of ECHA guidance on hazard characterisation.
- Proposal for data structure for the SDS regarding the hazard characterisation (DNELs, PNECs)

3.3.2.2 Development work for the first phase (initial method description and illustrative examples)

An initial proposal regarding the relationship between the two hazard assessment conclusions -

[23] Reference to be added.
[24] The human health integration has not yet been decided at this point in time but would probably follow.
[25] Reference to be added.
[26] Plus sometimes up to 4 activity specific conditions for ART or MEASE.

classification and DNELs/PNECs - will be developed by ECHA to feed into the mixture assessment method which should be developed and illustrated during the first phase of the development (WP4).

3.4 WP2: Sectors' use maps

3.4.1 Description

The use maps may serve registrants, formulators and the end user for describing their own uses or uses further down the supply chain. They aim at describing realistic conditions of use in a standardised way. As such they can improve the quality of the safe use advice provided via the SDS by an assessor to his customer.

The information provided via the use map should support the generation of the "minimum requirements" on safe use advice. Consequently, a strong link with those (developed in WP 4 and 5) will have to be ensured. If needed, the use map format will have to be adapted. If the "minimum requirements" become mandatory, the uptake of use map supporting the generation of those will be naturally promoted.

An electronic (XML) use map format should be developed so that the information can be automatically plugged in to exposure/chemical safety assessment tools as well as to support the building of the use inventories of formulators and end users for the conformity check (see WP 4 and 5). A similar format may be used by formulators or end users for reporting to a supplier a use which is not covered by the SDS received. At the moment, the use maps are provided in a readable format (excel or Word) as well as in an XML format, defined as a "Chesar file", as those files are created in Chesar. ECHA considers developing a specific platform for the library of elements that may serve as input to the chemical safety assessment, mainly use maps, but also biocide emission scenarios. Such a library will be used by Chesar users but could be accessible by any other tools. This format should be similar/mappable to the relevant parts of the SDS XML format (use description and conditions of use within the exposure scenarios).

The main advantage of use maps is that the effort of the use description is carried out at sector level and can be reused by many actors, both upstream and downstream. Nevertheless this requires that each actor making use of the use maps can i) easily find the "right" use map (i.e. overlaps and gaps between sector use maps to be removed) ii) easily identify the relevant uses (i.e. clear structure needed in differentiating uses and contributing activity; harmonisation of terminology needed across markets).

3.4.2 Development work

3.4.2.1 Foreseen development work

The development work will consist in two types of activity:

- Adaptation of existing use map template if needed, and of mechanism to generate a use map XML fitting the overall system.

- Update of current use maps, if needed, taking the learnings from the first phase of this development work (i.e. illustration of formulators' and end users' methods), for example extending them to the use of more hazardous mixtures which require a higher level of control, by including information required to run higher tier exposure estimation models

- Harmonisation and rationalisation of all use maps over time, including across sectors. This may result in a revision of ECHA's product category system (PC) in order to serve as a common reference to structure the use map landscape, to support the use conformity by downstream users, and ultimately also improves the use related information in the registrants' dossiers.

In parallel an approach needs to be developed to increase the coverage of (sector) use maps, i.e. to activate sector organisations that have not invested in use maps yet.

The deliverables of the development work done within this work package are:

- An updated template (together with phase 2 of the SDS XML, see WP 3).
- A number of updated use maps by industry sectors
- Potential refinements to product category lists.

3.4.2.2 Development work for the first phase (initial method description and illustrative examples)

The example developed in WP 4 and 5 may rely on current use maps. Consequently, some learnings may be made from those examples. In addition, as a new SWED template[27] containing all the harmonised conditions of use for workers will have been published (publication planned before the end of 2020 together with the release of Chesar 3.6), some sectors may decide already to expand their current use maps to account for higher tier exposure determinants. Such example may also be used for the illustration of the formulators' and end users' method in the first phase.

3.5 WP3: Safety Data Exchange Standard (XML schema definition)

3.5.1 Description

The objective of the work is to develop an XML schema for exchanging SDS information (in the widest sense: for substances and mixtures and including the exposure scenario Annex to the SDS), together with the catalogue of standard phrases adapted to the XML (see section 2).

The XML schema defines the information that can be conveyed between actors in the supply chain. This should enable a receiving IT tool to "understand" and process the information after automated upload of the incoming information. The XML schema itself does not ensure consistency of the included information. Nevertheless "validation rules" can be made available and implemented in generating/receiving systems. Also, the XML schema does not preclude where the information will be printed (e.g. in section 7 of the SDS or in the Annex). Each printing system can decide on its own layout. It is nevertheless possible to define and to agree on a recommended layout.

It is suggested that this development takes place in 3 steps for the following reason:

- To develop the specifications in a stepwise manner, taking into account the various existing SDS systems, and the development of the methods for the providers and recipients of SDSs (see WP 1, 4 and 5).

- Making the substance information (step 1) generated during the REACH registration process readily available to downstream users as soon as possible (in particular formulators), to enable them to run their own assessments.

- Even if the entire SDS content is not structured at first (the sixteen sections), a first step will enable industry to start its implementation in various company IT systems (and thus implementation of the second step could be quicker).

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[27] SWED stands for 'sector-specific workers exposure descriptions'. SWEDs contain information on operational conditions and risk management measures for activities by workers. Registrants can use the information as an input to their exposure assessments (SWED)

As a consequence, a scoping of the various sections of the SDS which should be covered has to be agreed first. At the high level, the current proposal would be to:

1. In the first step, start with the data related to the characteristics of the substance/mixture, i.e. relevant parts of SDS sections 1, 2, 3, 8, 9, 11, 12.

2. Then cover the information related to safe handling, i.e. parts of SDS sections 1, 7, 8 and the annex.

3. Complete the SDS.

3.5.2 Development work

3.5.2.1 Foreseen development work

The development work will consist of two types of activity:

- Identifying the data that need to be included in the schema and defining their format (e.g. label, picklist items or possible units, in the form of standard phrases). This should be based on the data needs identified for formulators in WP4 and for end users in WP5 as well as in Annex II of REACH and the Globally Harmonised System (GHS). Existing SDS systems/architectures should be taken into account: various SDS formats on the market, as well as ESCom for the annex of the SDS[28]. The scoping to phase the work should be done first.

- Agreeing on an XML format, which is more an IT aspect. In particular, an analysis of the pros and cons of using the IUCLID format should be carried out together with all stakeholders.

Finally, the development of the XML schema combining the 2 points above will be carried out by ECHA.

In addition, a technical proposal should be made concerning the hosting and maintenance of the SDS XML schema and related standard phrases, including their translations. Such a proposal will have to be discussed. As a starting point it could be considered whether ECHA should host the catalogue of standard phrases and their translations as well as the XML schema. Regarding the phrases' translation a strong involvement of member states and/or national industry organisations would be discussed.

The deliverables for this WP will be:

- The specifications for the XML schema (both content- and IT-wise):
    - Data requirement for step 1
    - Format; pros and cons of using the IUCLID format.
    - Data requirement for step 2 and then step 3.
- "Validation rules" for the XML to support "quality" of the conveyed information

[28] ESCom is an ENES project. Information can be found on https://cefic.org/guidance/reach-implementation/escom-package-guidance/.

- The XML schema (publication), including the catalogue of standard phrases and their translations for the three steps.

- A proposal for the governance for the management of the update of the XML schema and the phrase catalogue (2023).

3.5.2.2 Development work for the first phase (initial method description and illustrative examples)

The detailed specifications of the XML schema will not be developed in the first phase as it is expected that business cases for the cost/benefit analysis will be developed during that phase, in order to better understand the impact of the availability (and potential mandatoriness) of such a format. Nevertheless, in order to inform the further decision on the way forward, some initial work should take place together with stakeholders, in particular industry and their IT providers, but also with the authorities. The following should be done during the first phase:

- Agree on a format for the XML and define its relationship to the IUCLID format

- Develop an initial list of requirements for the XML schema

- Make a proposal for the development steps for the XML with a clear scope related to the SDS sections.

3.6 WP4: Formulators' methods and tool (including methodology for mixture assessment and mixture SDS generation).

3.6.1 Description

The objective of this work package is to develop concepts and methods to enable the mixture producers (formulators) to meet their obligations under the REACH Regulation as described in section 2, in particular checking that their mixtures are safe to use, either based on the safe use information received from their suppliers for all the substances in their mixture, and/or based on an own mixture assessment. For mixtures for industrial or professional uses, safe use information for the mixture will have to be provided as part of their SDS. Although no SDS is produced for consumer mixtures, its safety is to be checked based on the incoming information (in the SDS) or an own assessment and, if necessary, safety measures are to be provided via the inherent design of the product and its label.

In this work package it is assumed that both incoming SDSs (for substance and mixtures) and the generated SDS, for the produced mixture when relevant (mixture for occupational use) will be provided in an electronic format (following the SDS XML format). The ultimate aim would be that IT tool(s) are developed to support the mixture producer to implement the proposed workflow.

This work package concentrates on the formulator's tasks related to the further life cycle of their mixture, and not on the handling of substances and mixtures at the formulator's site (for producing new mixture). Since the technical tasks related to the mixture production are generically similar to mixing, transfer and cleaning operations expected to be carried out by an end user (generally a formulator falls into the group of users of a high number of substances). Therefore, it is suggested that for the methods for formulators related to their own activities to rely on the methods developed in WP 5.

The principles assumed in this system, for formulators to deliver conditions for safe use for their mixture, are the following:

- The formulator identifies himself the relevant conditions of use for his mixture. He will

describe those in an ES format. He may base such conditions of use on his sector use map[29] or describe it himself.

- Before putting his product on the market he should check that his assumed conditions of use are indeed safe. For that he may:
    - Check that the advice for safe use provided in the SDS for each ingredient covers the conditions of use for the mixture, or
    - Carry out his own mixture assessment.

Note that when relying on the advice for safe use received, the formulator will still have to cross check, that the effects related to the classification of the mixture (derived by the formulator himself on the basis of the classification of each substances in the mixture) are still controlled by the mixture's safe use advice. Whether and to which extent combined effects across the substances in the mixture should be taken into account via the quantitative assessment based on the DNELs is expected is to be clarified in this WP.

Also, if the formulator decides to carry out his own assessment, he may have to report to ECHA in some situations (when a report would be expected and when not is to be clarified5).

As a consequence, this WP aims at describing in detail the workflows and the methods for carrying out the tasks described above. As a starting point for the development of those methods the following steps have been identified that need to be carried out by a formulator. The relationship between those steps (the formulator's workflow) is illustrated in Figure 3 beneath. Those steps are:

1. Build **an inventory** of their hazardous mixtures (including their recipe in terms of hazardous substances and percentages[30]). The properties of the hazardous substances contained can be automatically extracted from the SDS received. The formulator should then describe for each mixture the expected uses (and related conditions of use). As explained above such description may be done on the basis of existing use maps developed by the sectors, or by entering information into a standard template by the single formulator.

For each mixture:

2. Identify and check whether the foreseen uses are "covered by" the use assessed by the supplier and provided in the SDS for each substance in the mixture[31], and if the expected conditions of use by customers, conform with (are covered by) the conditions of use which are described in the incoming SDS. In addition, it should be checked within conformity whether the safe concentration indicated in the ingredient substances' ES is equal to or higher than the concentration in the mixture's recipe for each of the relevant uses. If the use does not conform (i.e. is not covered by incoming SDS of some ingredients), there are options that the formulator can take:
    a. Not use the substance in the mixture, i.e. change the mixture's recipe.
    b. Adapt the mixture recipe (change the percentage of the various ingredients for safety reasons) or consider whether the use conditions assumed (in step 1) could be adapted, possibly leading to instructions for a stricter level of control.

[29] The advantage of using a use map as a starting point is that his suppliers may have assessed their substance against the conditions of use described in the use map.
[30] Such inventory is expected to be available for all mixture producers, but the proposal here is to clarify which (additional) data may be relevant and necessary to carry out (preferably supported by IT as far as possible) the further tasks of the formulator such as conformity check.
[31] Slight modifications needed if the purchased mixture ingredient is already a mixture.

c. Assess the use (with its assumed conditions of use, as described in 1) to check whether it is safe although such assessment has not initially been carried out by the supplier. Such assessment can be carried out:

   i. On request by the supplier. In such situation the formulator should provide the description of his use to the suppliers of the various substances for which the use was not covered, so that his supplier(s) assess it. When providing a description of the use to his supplier(s) this should be done in an appropriate format for easy transfer of information between IT systems. The outcome of the assessment is then received by an update of the SDS. Or

   ii. by the formulator himself for one or more ingredient substances. In such case the next step is (3) below. Or

   iii. By the formulator himself for the mixture as a whole

   In the later two cases, a DU report according to REACH Article 38 may be needed for some or all substances part of the mixture.

Note that the LCID method is also to be taken into account for this development step.

3. If the expected use of the mixture conforms (is "covered" by) with the ES for all the substances part of the mixture, the formulator still needs to apply the CLP classification rules for the mixture and determine where the safe use of the mixture requires measures going beyond those ensuring safe use of each single substance in the mixture. Indeed, additivity of effects is partly taken into account in the classification rules for a mixture. In addition, how to address the additivity of systemic effects (when assessed using a DNEL reference) is to be clarified. In case the assumed conditions of use (in step 1 and for which conformity has been checked) are not sufficiently protective on the basis of the mixture classification, then the mixture recipe may need to be modified (in particular for consumer products) or additional measures need to be advised in the SDS for the mixture.

4. As a last step the formulator should generate an SDS for the mixture providing conditions for safe use for all industrial and professional uses.

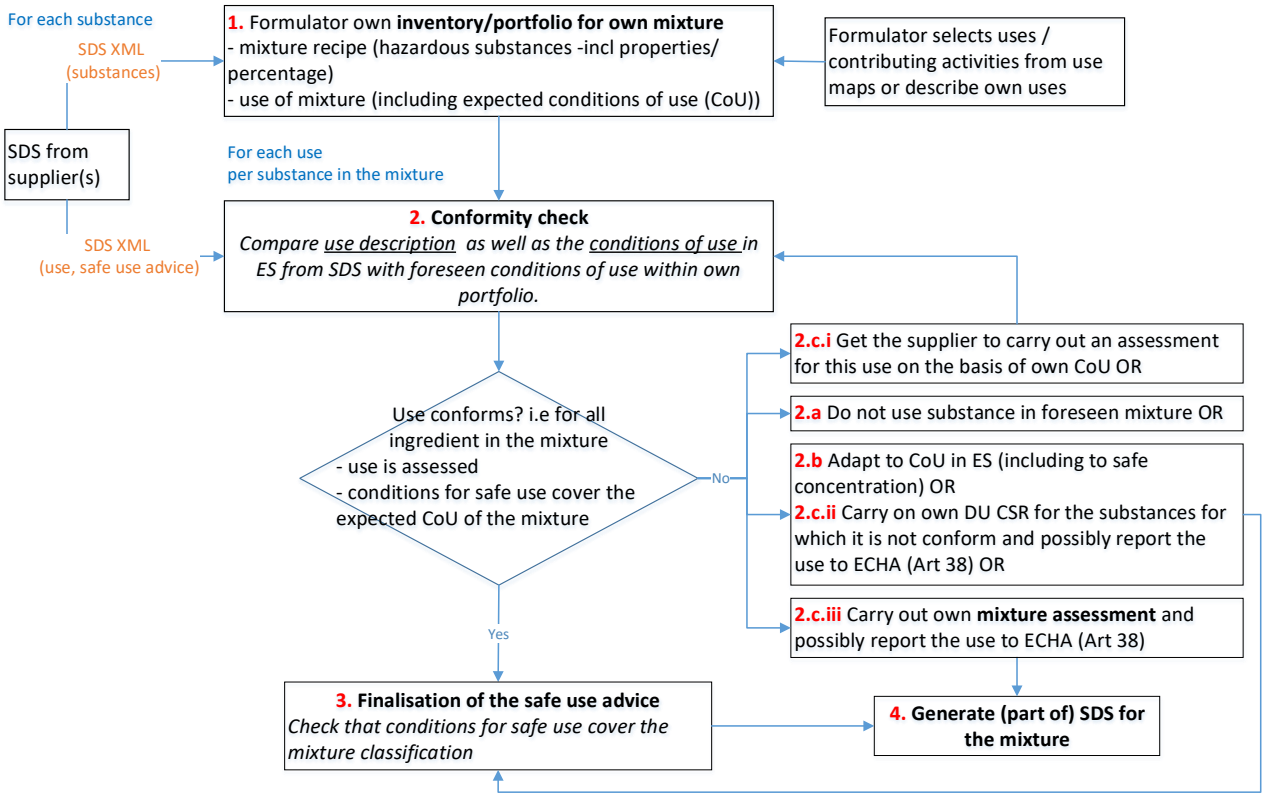

Figure 3: High level workflow of the formulator's tasks under REACH for his own mixture's uses. [Note: The box numberings refer to the steps described in the preceding paragraphs.]

It is expected that a clear harmonised method for the formulator will increase the average quality of the information provided to end users.

3.6.2 Development work

3.6.2.1 Foreseen development work

The development work will consist of describing the methods (data and workflows) for the different tasks as described above. Those methods should take into account existing practice/systems of formulators. Note that while developing the method, the elements currently described above may change if alternative, workable and more adapted proposals emerge. Based on the current analysis by ECHA the development work will cover:

a. Requirements for an inventory of hazardous mixture, as described above, in particular identifying which information on substance properties and use description (including conditions of use) are needed to support both a mixture assessment (step 2ciii above) [(c) below] or a conformity check (step 2 above) followed by the complementary assessment (step 3 above) [(b) below]

b. Conformity check (from an occupational and environment perspective, but also covering the use of mixtures by consumer). Note that it is expected that the basis for the conformity check should be developed within WP 5 and that only the aspects specific to the formulator (e.g. related to the percentage of substance in the mixture or physical form of the product) will have to be addressed here. Also, a method for the complementary assessment step to address the mixture classification and, possibly, the combined effects that are assessed quantitatively via a risk characterisation ratio, will have to be worked out. This last step will have to be consistent with the method for mixture assessment ((c) below)

c. Mixture assessment methodology, including the method to ensure that mixture classification is properly addressed.

The deliverables of the development work done within this work package (WP) are:

- Requirements for an inventory for a formulator, identifying how each data is used in the further processes.
- Method for conformity check for the uses by customers of own mixture and method for complementary assessment step to cover the combined effect (mixture classification or quantitative assessment) across the substances in the mixture.
- Method for mixture assessment.

From the above deliverables a list of data/information needs within the formulator workflow can be drawn up. The information generated by a formulator in a mixture SDS will also be defined. This will serve for defining and developing the **minimum requirements** (including the definition for the **SDSxml** schema, WP 3) for the substance properties and the safe use advice in the safety data sheet, thereby ensuring that i) all the relevant information needed by the formulator to perform their conformity checks and where necessary, chemical safety assessments will be provided to them electronically and ii) that they can provide the outcome of their assessment (according to what an end user needs, see WP 5) in an electronic format as well.

In addition the methods developed can be converted into requirements for IT tool(s) for formulators to support them in their tasks. Note that features supporting a mixture assessment are intended to be implemented in the future Chesar platform. It is not yet decided whether ECHA would extend its IT tools to also support other functionalities for formulators.

3.6.2.2 Development work for the first phase (initial method description and illustrative examples)

One key element is the illustration of how a formulator could handle the information received in SDS on the ingredient substances/mixture in order to generate the SDS for his mixture, including the safe use advice for his customers. The examples will be based on an initial definition of minimum requirements. The following would be developed:

- Initial method for a conformity check regarding the uses foreseen for the produced mixture, and the method for the complementary assessment step to accommodate the mixture classification. This will rely on a proposal for the:
  - Minimum requirements and related data intended to be provided via an SDS XML
  - Initial proposal on how to deal with both the classification and DNELs as a basis for risk management (see WP 1)
- Initial method for the mixture assessment. This will also rely on the methods proposed to handle the classification and the DNELs in a combined and systematic way (WP1)

Subsequently, for a few examples of mixtures (to be defined), it will be illustrated how the above methods could be applied. For that, the relevant parts in the SDS for i) each of the ingredient substances/mixture and ii) for the produced mixture would be illustrated.

Those examples will be used for illustrating the content of the SDS XML (WP 3) and the methods developed in WP 5.

3.7 WP5: End users' methods and tool[32]

3.7.1 Description

The objective of this work package is to develop concepts and methods to enable the downstream end user [*employer, site manager*] to make optimum use of the information they receive in the safety data sheet (SDS) for a hazardous chemicals, both to meet their obligations under the REACH Regulation and responsibilities under worker protection and environmental legislations, as described in the system (section 2.4). In particular, it is assumed that the SDS will be provided in an electronic format (SDS XML) and that IT tool(s) will be developed to support the end user to implement the proposed workflow. Such SDS will contain a set of safe use advice for the mixture as well as the information on hazard and fate for all the hazardous substance ingredients contributing to the hazard of the mixture. The methods to be developed should take into account a variety of situations, in particular differentiating between industrial and professional end users of hazardous substances and mixtures, as well as small and large workplaces or installations (especially with respect to the number substances and/or mixtures expected to be handled). The methods for an end user who is foreseen to handle low numbers of substances and/or mixtures, and therefore few SDSs, can nevertheless be tested in an equivalent manner to those end users who opt for an IT-based system, based on their manual processing of a hardcopy paper SDS.

As a starting point for the development of the methods the following tasks are identified that need to be carried out by an employer (downstream end user). Their relationship is illustrated in Figure 4 beneath[33]. Those tasks are:

1. Build an inventory of the hazardous substances as such and in mixtures used at the work-place[34]. Such an inventory can be automatically built from the SDS received (and therefore the properties of the substances will also be available to the end user). The end user will then connect each substance/mixture (and the related substances in the mixture) to his use/workplace, including information about amounts handled. The uses in the inventory may be described from the beginning by the end user considering his site[35], using a template for use description[36], or described step by step based on the safe use advice in the SDSs, if corresponding to his site situation. Consequently, depending on the stage of development of the inventory of the end user, it may be used as a starting point for the conformity check (see next bullets) or it may be built automatically while carrying out the conformity check, the latter being possibly easier for small companies using few substances/mixtures.
2. Identify and check whether the use is "covered by"/conforms to the uses in the SDS. In Figure 4 this step is called "conformity check". It covers both whether the use description is covered but also whether the conditions of use (CoU) described in the information received from the supplier are equivalent to those in place at the workplace. If the use does not conform, there are options that the end user can take: do not use the substance/mixture; apply the recommended [risk management] measures as prescribed in the SDS, request supplier to assess use as an intended use; check, via an assessment (possibly already carried out under worker protection legislation (OSH)), that the existing [risk management] measures ensure that the hazardous substance/mixture is used safely (and, if needed, report

[32] No specific account of producers of articles have yet been included in this Plan. Although ECHA recognises that this is a very important aspect, additional resources would be needed to further develop a specific methodology. At the moment it is anticipated that a large part of what is developed for the use of a mixture will be applicable for the production of an article.

[33] For the current guidelines see Guidance for downstream users, section 4.2.

[34] Note that this is also an important starting point for an OSH workplace risk assessment.

[35] Possibly making use of the information in the sector use maps.

[36] A template following the data structure of the information in the SDS (in particular the exposure scenario part) to enable automated comparison with the received information will have to be provided. Such template will be very close (or a subset of) the use map template.

the fact to ECHA according to Article 38). The criteria triggering a report to ECHA are to be worked out in this WP.

3. Utilise the information received from the supplier (in the SDS) to review/revise the local, site-specific risk assessment for worker protection. Note that the workplace risk assessment as such is not part of the Development Plan, but it is the reference to determine the REACH information meant to feed into it.

4. Utilise the information received (in the SDS) as an input to a local site assessment for the environment. As for the workplace risk assessment, the environmental site assessment is not part of the Development Plan, , but it is the reference to determine the REACH information meant to feed into it.

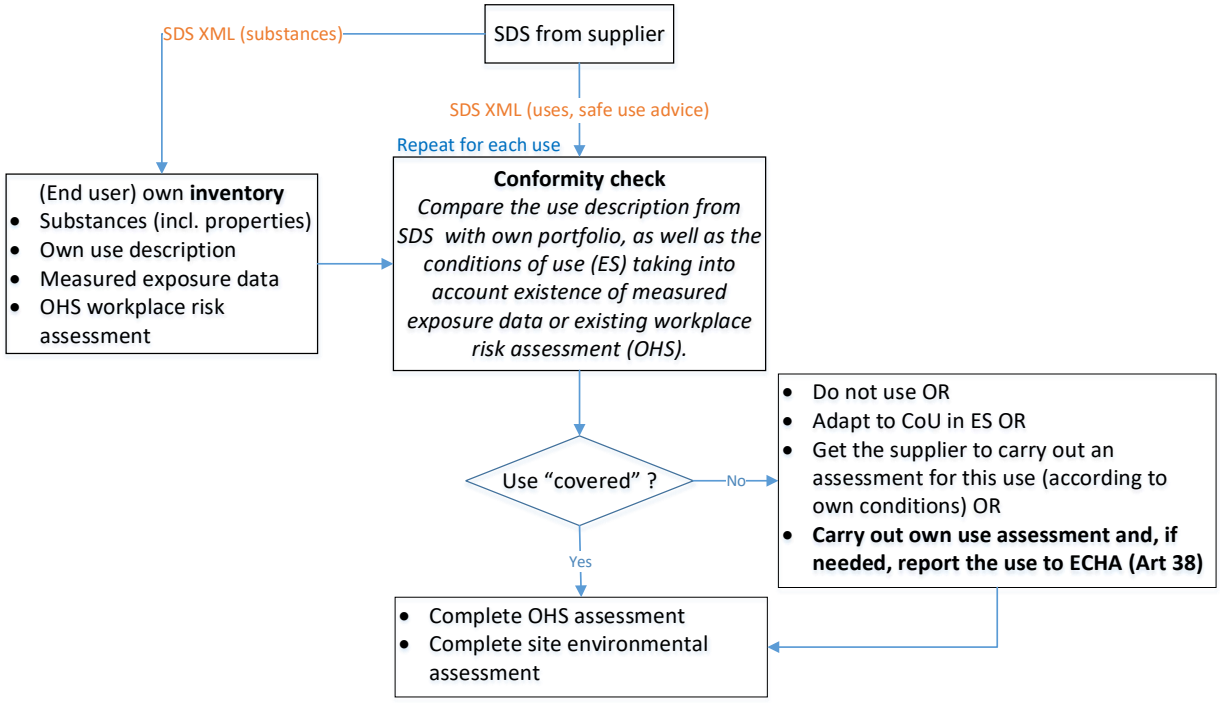

Figure 4: High level workflow of the end user's tasks under REACH and their links to worker protection and the environment.

The deliverables of the development work within this work package (WP) are:

- List of data/information needs within the end user workflow. This will serve for defining and developing the **minimum requirements** (including the definition for the **SDSxml** schema, WP 3) for the substance properties and the safe use advice in the safety data sheet, thereby ensuring that all the relevant information needed by the end user to perform their conformity checks and where necessary, chemical safety and workplace risk assessments will be provided to them electronically, in a form that they can process in an automated manner.
- Requirements for the IT tool(s) for the end user to support them in their tasks (end user workflow). At the time of writing, it is open whether ECHA may develop a demo-version of such an IT tool, to support in particular small end user companies, or whether this is completely left to the market.

3.7.2 Development work

3.7.2.1 Foreseen development work

The development work will consist of describing the methods (data and workflows) for the different tasks as described above. Those methods should take into account the methods used for occupational workplace risk assessment to ensure worker protection and for a site environmental assessment so that they serve those purposes as much as possible[37] (to prevent duplicated work across legislation). Note that while developing the method, the elements currently described below may change if alternative, workable and more adapted proposals emerge. Based on the current analysis by ECHA the development work will cover:

- Requirements for an inventory of hazardous substances.
- Conformity check (both from a worker's and environment perspective)
    - Develop and agree on the criteria to be applied to determine that the use description "conforms" to the use description described in the SDS received.
    - Define a core set of conditions of use which needs to be present systematically (minimum requirements) in the safe use advice section(s) of the SDS, as well as the conditions of use that may be relevant for certain activities, in particular when handling more hazardous substances/mixtures. All those conditions of use will define the data needs for the SDS XML. They will be used for the data structure of the inventory of the uses conditions (description of the workplaces) by the end users.
    - Describe the method(s) that should be utilised by the end user (tool) to check the conformity of their conditions of use (possibly documented in their inventory), with the information in the SDS. Availability of an existing workplace risk assessment (potentially based on own measured data) will have to be taken into account.
    - Describe the options for the end user in the case of a non-conformity and how to carry them out, in particular i) how to report a use to a supplier for him to assess it ii) how to carry out an own downstream end user chemical safety assessment (the link is to be made with the method developed in WP 4), and iii) how to report to ECHA when needed.

3.7.2.2 Development work for the first phase (initial method description and illustrative examples)

The second key element of the first phase (see WP 4 for first one) is the illustration of how an end user could handle the information in an SDS. For creating examples, the following should be developed:

- Initial method for conformity check. This will rely on a proposal for the minimum requirements and related data intended to be provided via an SDS XML
- Initial description on how to use the SDS information for a workplace risk assessment and what limitation may be encountered.

Subsequently, for a few examples of mixtures (same as the ones selected for WP 4) it will be illustrated how the above initial method could be applied.

Successful exemplification will largely depend on the extent to which the OSH community in authorities and industries will get engaged.

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[37] For this purpose, it may be needed to identify which information and process are jointly covered for developing methods serving all purposes, but also which information may be specific to the one or the other legislation.

4 Governance

REACH Review Action 3 development work has a multi-level governance structure. The Commission is responsible for the policy orientation and ensuring that views of different interest groups (e.g. industry sectors, company sizes and authorities responsible for different pieces of legislation) are appropriately reflected in the chosen direction. CARACAL[38] on the other hand is providing consensus and endorsing decisions affecting the technical solutions. The technical development work is carried out under ENES[39] that is given a clear mandate and reinforced through improved participation of relevant actors[40] as agreed at CARACAL[41] (hereafter referred to as ENES+).

To realise the vision and benefits through this *Plan*, it is essential that Member State **authorities** are actively involved in development of the XML standard, and the closely related minimum requirements, which will bring harmonisation to the way relevant safety data is communicated in the supply chain. Practice shows that industry implements/operates a wide spectrum of formats and architectures in their generation of safety data sheets, leading to many of the system shortcomings summarised in this document. So, to achieve greater consistency and control, authorities should lead in the establishment of a harmonised standard, thereby providing (i) industry with a clear(er) frame and level playing field for creating and communicating their safety data regarding substances and mixtures and (ii) a consistent point of reference for their regulatory work, including enforcement.

Although competent authorities attending CARACAL have arrangements to consult with their national occupational safety and environmental counterparts, the need for "formal" opinions from equivalent groups which advise the Commission services was recognised. DG EMPL has indicated that EU level consultations on topics related to workers' safety should be carried out through its Advisory Committee on Safety and Health at Work[42] (via its Working Party on Chemicals). A working relation with an equivalent EU level body for the environmental legislation needs to be established. Enforcement and technical platforms will be consulted in writing and stakeholders at large will be able to provide comment through consultations via online forms. ECHA will play a central role in ENES+ and in day-to-day management and support of activities at all levels.

The Terms of Reference for the ENES+ platform to oversee and undertake the (assigned) technical development work (see section 3), its composition and the mechanism for its establishment will be proposed by the current ENES. It is Member State competent authorities and industry to provide the specific resources to make the ENES+ platform deliver.

A high-level overview of organisations/bodies foreseen to be involved in development activities is given below (Table 1). Their roles are also briefly explained.

Table 1. Roles and responsibilities in the governance of executing the REACH Review

[38] CARACAL is an expert group which advises the European Commission and ECHA on questions related to REACH and CLP.

[39] Exchange Network on Exposure Scenarios (ENES) –A collaborative network that has identified good practices on preparing and implementing exposure scenarios and developed effective supply chain communication tools since 2011.

[40] Representation, both from Member States and from industry stakeholders, covering the necessary spheres of interest e.g. OSH, environment, REACH, SDS authoring systems and SME companies

[41] CARACAL-34, April 2020

[42] Advisory Committee on Health and Safety at Work https://ec.europa.eu/social/main.jsp?catId=148&intPageId=683&langId=en

1 **Action 3 Development Plan.**

Organisation	Role
European Commission (GROW, ENV, EMPL)	• Take policy decisions, monitor objectives of RRA3 and report on progress (including the next REACH Review). • Consolidate key actors' inputs: gather opinions via established mechanisms e.g. on OSH, environmental and SME aspects. • Manage legal processes, where required, including (formal) consultation. • Inform UN GHS and WTO about the changes in the EU SDS requirements. • Monitor progress and report to CARACAL.
ECHA	• Support Commission and provide secretariat for ENES+. • Provide project management for the work packages. • Support the technical work plans by providing expertise/ experts and taking lead on selected development tasks and contributing to others. • Organise and coordinate contacts to widen the contributing/participating industry sectors and authorities to the development work. • Lead the awareness raising activities about the new system and coordinate communication efforts with industry and Member States. This includes maintaining web pages to timely publish information on RRA3 and ongoing development work.
CARACAL	• Discuss, build consensus and endorse decisions affecting the technical solutions to be developed. • Endorse the Development Plan (including communication activities) prepared jointly by the Commission, ECHA and ENES+. • Endorse the deliverables from the ENES+ technical work.
ENES+	• Prepare an annual technical work plans and ensures their timely implementation. • Ensure appropriate resourcing and composition of working groups that carry out the development work and decide who is leading them. • Report progress and update technical work plans to the Commission (this includes CARACAL). • Prepares a multi-annual plan on awareness raising, communication and training activities on the new SDS system.
EU level OSH and environmental bodies (Working Party on Chemicals[43] & …..)	• Discuss, build consensus and provide feedback on aspects relevant to workers' safety/the environment, primarily in writing.
Enforcement networks (REACH - the Forum[44]; OSH –	• Provide input on aspects relevant to enforceability of the new system, primarily in writing.

[43] DG EMPL's Advisory Committee on Safety and Health at Work (ACSH) via its Working Party on Chemicals (WPC).

[4444] The Forum for Exchange of Information on Enforcement of REACH and CLP – ECHA will coordinate contacts.

Organisation	Role
SLIC[45] and Environment – …	
Technical platforms (e.g. REEG46, RiME+47 and industry organisations not part of ENES+)	• Provide input on the technical "soundness" of approaches included in the new system, primarily in writing.
Member State authorities (REACH, OSH & Env.)	• Support the technical work by providing expertise/experts, specifically in respect of the development of the XML standard, based on specified minimum requirements, and as necessary to support the ENES+ work plan activities. • Carry out awareness raising, communication and training activities on the new SDS system, at national level.
Industry actors (Sector organisations and companies)	• Support ENES+ in aspects of the technical work plans by providing expertise/experts and taking the lead on selected development tasks and contributing to others. • Carry out awareness raising, communication and training activities on the new SDS system, in their sector/supply chain.

Organisations nominating "experts" are responsible for the resources needed to participate and deliver their contributions.

5 Communication

ECHA will lead awareness raising activities on the enhanced SDS system. However, this multi-year activity is foreseen to be a joint communication effort with Member States and industry stakeholders. A communicators' network will contribute to the planning and preparation of awareness raising activities and material. It will also ensure that information is efficiently distributed to companies in different industry sectors and relevant authorities across Europe. The network may also participate in the identification of training needs and how they could be best met.

The main channel for publishing information about REACH Review Action 3 (in English) will be a REACH Review Action 3 web section on ECHA's website. RRA3 documents that provide policy direction[48] for the development work will be made available on the main page and ongoing work pages will explain the progress made on the building blocks. The main page will also have links to calls of expression interest in participating and to consultation forms.

Information about key milestones will be announced in ECHA Weekly and the European Commission, ECHA and ENES+ will organise information events/webinars to ensure good flow of information. The communication network members and other organisations are expected to customise centrally produced material and/or further distribute it through their networks so that all impacted will be informed about the new system and how it works well before it enter in to force.

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The communication on the RRA3 activities via ECHA's website, sectorial associations and some

[45] DG EMPL's Committee of Senior Labour Inspectors – DG EMPL will coordinate contacts.
[46] REACH Member State fora: REACH Exposure Expert Group – ECHA will coordinate contacts.
[47] Member State authorities' Risk Management Evaluation platform

[48] Progress updates to the Competent Authorities of REACH and CLP (CARACAL).

individual companies will require an intensive effort. The communication needs to target and reach a wider audience – in particular, more actors at the bottom of the supply chain, including end users throughout the EU. This audience should be better informed about the ongoing work and ideally give feedback on the suggested developments and what their needs are in relation to a better communication and data quality.

To reach a wider audience and create communication platforms in the Member States, it is desirable to add roles for the national authorities, national REACH helpdesks, the national chemical industry associations and national sector organisations in the communication plan.