



EUROPEAN COMMISSION

Directorate-General for Environment  
Circular Economy and Green Growth  
**Sustainable Chemicals**

Directorate-General for Internal Market, Industry, Entrepreneurship and SME's  
Chemicals and Consumer Industries  
**REACH**  
**Chemicals and Plastic Industries**



Brussels,

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**37<sup>th</sup> Meeting of Competent Authorities for REACH and CLP  
(CARACAL)  
Open session  
17-18 November 2020 (WebEx meeting)**

**Concerns:** REACH REVIEW ACTION 3 (extended Safety Data Sheets)

**Agenda Point:** 4.2

**Action Requested:** Competent Authorities and Observers are invited to take note of the assessment presented in this document. Written comments should be sent by 1 December 2020 to:

[GROW-CARACAL@ec.europa.eu](mailto:GROW-CARACAL@ec.europa.eu)  
[ENV-CARACAL@ec.europa.eu](mailto:ENV-CARACAL@ec.europa.eu)

**CARACAL PAPER**  
**ON REACH REVIEW ACTION 3**  
**- CURRENT STATE OF PLAY -**

**REACH REVIEW ACTION 3 (RRA3):**  
**Improving the workability and quality of extended Safety Data Sheets (eSDS)**

*Action 3(1): The Commission encourages more industry sectors to develop and use harmonised formats and IT tools that would provide more user-targeted information and simplify the preparation and use of extended Safety Data Sheets as well as facilitate their electronic distribution;*

*Action 3(2): The Commission will consider including minimum requirements for the exposure scenarios for substances and mixtures in Safety Data Sheets and request ECHA to develop a methodology for Safety Data Sheets for mixtures.*

## **1. INTRODUCTION**

The first proposal by the Commission and ECHA outlining steps towards the implementation of REACH Review Action 3 (RRA3) was discussed at CARACAL in November 2018. In the following two years, extensive dialogue took place in various forms between the Commission, ECHA and many actors identified as crucial partners to help achieve the objectives of RRA3.

The ‘Scoping Phase’ oriented our attention to the most viable directions and called for more involvement of CARACAL members. This was followed by the outline of the next steps within the ‘Development Phase’, where the envisaged division of tasks, timeframes as well as rough estimation of resources needed by the different actors were presented by the Commission and ECHA (CA/14 and 41/2020).

This document reports the progress on RRA3 since CARACAL-35, June 2020. Since then, ECHA, together with the stakeholders who make up the Exchange Network on Exposure Scenarios (ENES), and the Commission have worked to define a Development Plan, which describes in more detail the system changes and enhancements required to improve the workability and quality of extended Safety Data Sheets to better serve the whole supply chain. For these discussions, the ENES group has been expanded to include additional representatives drawn from REACH and/or occupational safety and health (OSH) authorities from the Member States (currently France, the Netherlands, Norway, and Sweden), hereafter referred to as

ENES+.<sup>1</sup> DG EMPL's advisory bodies, the Advisory Committee on Safety and Health at Work (ACSH) via its Working Party on Chemicals and the Working Group Chemex of the Committee of Senior Labour Inspectors (SLIC) have also been briefed.

The Development Plan (see Annex) represents the state-of-play in describing the aims, drivers and (elements of) the technical tools currently considered and discussed with ENES+.<sup>2</sup> It builds upon, and is consistent with, the system design ideas on which CARACAL has been consulted previously.<sup>3</sup> The Plan includes a technical section in which a series of interconnected work packages are described. The final section includes ideas on governance and communication. The document as it stands today reflects the current planning and is shared with CARACAL to inform them on how the development is foreseen to take place.

CARACAL is asked to take note of the progress in defining the technical work underpinning REACH Review Action 3 and to respond to the questions concerning the next steps (see section 4 beneath).

## 2. MAIN CONCLUSIONS OF DISCUSSION WITH ENES+

The process of defining a Plan (Annex) over the last few months has been a beneficial exercise in identifying those areas where greater clarification with stakeholders on the system's elements/building blocks and their implications for them have been required (as well as articulating concerns); overall, this process has resulted in a stronger buy-in toward the Plan and its aims. That said, these discussions identified several major points raised by ENES+ stakeholders, which are included in the Plan; these are summarised beneath.

A “**proof of concept**” through the development of illustrations of how the methods for formulators and end users process the REACH-generated information in practice. This is now explicitly foreseen as a first development phase to be started in 2021. (See Annex, section 3)

Closely connected with the “proof of concept”, the development of **case studies**, with industry in the lead, is foreseen to better understand the costs and benefits of the system design proposed and whether simplification is achieved (see Annex, section 3.2.). Such study(ies) are deemed appropriate in particular for the proposed **common/harmonised safety data exchange standard** (e.g. in XML<sup>4</sup>).

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<sup>1</sup> Member State representatives from AT, NO, SE also participated on behalf of the Forum for Exchange of Information on Enforcement (the Forum)

<sup>2</sup> Note: ECHA's future involvement in supply chain-related development work will be discussed at an ECHA Management Board in December 2020 and may affect ECHA's resource availability for this work.

<sup>3</sup> See CA/14/2020 and CA/14/2020 Annex, dated 17/03/2020, CARACAL-34, 21 March – 1 April 2020.

<sup>4</sup> Extensible Markup Language (XML) is a text-based markup language that is commonly used for encoding data in structured way that is suitable for production and consumption by computer programmes but can still be authored and verified by humans if the need arises.

Whilst ENES+ stakeholders view the advantages of a common standard when information is exchanged/communicated electronically between supplier and recipient, divergent views exist whether it should be **obligatory** for all suppliers to provide the SDS in that electronic format. It is noted that a (fully digitalised) safety data exchange standard to communicate relevant safety data does not preclude a recipient at any point in the supply chain to access and/or print (the information as) a full safety data sheet. To this end, the Plan notes that mechanisms do need to be put in place to synchronise the market actors along the supply chain, in the way that they generate and exchange safety information on hazardous chemicals, and to trigger investment (to change) by them. However, the means to achieve that e.g. via guidance, market forces or legal changes, remain open for the time being.

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).

A voluntary system would probably be less powerful and require more time to bring significant changes/improvements to the current practice. The Commission is committed to find the most appropriate legal tools/framework to facilitate any options; clearly, the case studies and proof of concept phase(s) will serve as one source of information for the Commission to consider the most appropriate means.

ENES+ also identified that improving the workability of the (extended) Safety Data Sheet through technical improvements in information flows does not necessarily mean that quality in terms of content will improve e.g. regarding hazard information or more understandable and concrete safe use advice (especially on engineering control measures). The Plan (see Annex, Introduction) explains which quality issues are foreseen to be addressed in the development work, and which issues are expected to remain out of scope. One of the anticipated outcomes of the proof of concept phase is a confirmation that the proposed scope is likely to significantly improve the quality of the SDS information arriving at end users, including making it clear, concrete and simple.

### 3. PROPOSED WAY FORWARD

The Development Plan in the Annex is for information and represents the state-of-play in terms of describing the technical development needs for REACH Review Action 3 and in documenting the common understanding reached among ENES+ stakeholders/representatives.

The next step is a proof of concept phase for the main system elements. This would include illustrative examples [pilots] how the various system elements would work and business case studies on the corresponding value (cost benefit) to the supply chain. Defining and organising the work will start in 2021, and the learnings will be reported to CARACAL once available (potentially 2022).

#### **4. QUESTIONS TO MS COMPETENT AUTHORITIES AND INTEREST GROUPS AT CARACAL**

- a) Is the overall direction on REACH Review Action 3 sound?
- b) Do you support that the REACH Review Action 3 work moves to a 'proof of concept' phase and industries' business case studies, as the next step?
- c) Do you see the added value of defining a uniform exchange standard (e.g. XML-based) for conveying relevant safety data electronically along the supply chain?
- d) Do you agree that taking a decision on the best means/strategy to ensure the uptake of this standard in the market should await the learnings from the proof of concept phase, including industries' business case studies?

#### **Annex**

#### **RRA3 Development Plan draft v.3.2.** *{to be attached}*