



EUROPEAN COMMISSION  
ENVIRONMENT DIRECTORATE-GENERAL  
Circular Economy and Green Growth  
Sustainable Chemicals

DIRECTORATE-GENERAL INTERNAL MARKET, INDUSTRY, ENTREPRENEURSHIP AND SMES  
Consumer, Environmental and Health Technologies  
**REACH**  
Chemicals

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## **34<sup>th</sup> Meeting of Competent Authorities for REACH and CLP (CARACAL)**

**Open session**

**31 March - 1 April 2020**

**Room: ..**

**Centre Albert Borschette**

**Rue Froissart 36**

**1040 Brussels, Belgium**

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

**Agenda Point:** 4.1

**Action Requested:** Competent Authorities and observers are invited to comment on the summary of inputs presented in this document. Written comments should be sent by 8 May 2020 to:

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

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# CARACAL PAPER

## ON REACH REVIEW ACTION 3

### INTRODUCTION OF 1<sup>ST</sup> 'DEVELOPMENT PLAN'

#### **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**

At its meeting of 21 November 2018, CARACAL discussed a first proposal by the Commission and ECHA outlining steps towards the implementation of RRA3. One year later, following workshops and discussions at various levels, the Commission and ECHA presented a short overview of the outcome of the 'Scoping Phase' and called on the CARACAL members for more involvement in order to achieve the objectives laid down in RRA3 (CA/75/2019).

This current paper by the Commission intends to summarise the responses received from CARACAL members on the outcome of the 'Scoping Phase' and the presented 'Call for support' document and proposes next steps. The Appendix prepared by ECHA highlights the first steps within the 'Development Phase' and presents a progress report towards a development plan for RRA3 with division of tasks, timeframes as well as rough estimation of resources needed from the different actors, seeking their further commitment and involvement.

## 2 MAIN CONCLUSIONS OF CARACAL-32 FEEDBACK

CARACAL members were invited to express their views on the 'Scoping Phase' findings in order for the Commission and ECHA to better understand the actions necessary within the 'Development Phase'.

In general, the **principles for a coherent system are accepted** and there is an overall agreement on the main findings of the RRA3 'Scoping Phase'. CARACAL members support the proposed approach to establish an enhanced system for extended Safety Data Sheets to improve the information flow in the supply chain.

There is a strong signal from the respondents requesting a deeper **involvement of the Occupational Safety and Health (OSH) 'community'**, as their participation is indispensable for the targeting of user information. Apart from this, there is a strong request to address the needs and concerns of **micro- and SME companies**, as registrants and formulators falling into this range are particular prone to lack awareness, resources and knowledge to meet certain regulatory requirements. Bringing (micro- and SME) end user companies, their advisors (e.g. occupational hygienists), OSH authorities and representatives from workers' organisations on board, and establishing good cooperation between them seems to be essential.

It has also been emphasised that discussion on REACH downstream user duties for recipients of **mixture** SDSs at end user level is needed.

In the responses received, CARACAL members did not point to **viable alternatives** to the system described by the ECHA document (Appendix to CARACAL-32) and the system's basic building blocks were deemed appropriate. (Some of the building blocks exist already e.g. tools of the **Exchange Network for Exposure Scenarios (ENES)**, others need to be refined or developed).

As regards **digitalisation** of the flow of information in the supply chain, CARACAL members indicated that further work is needed in order to better understand the implications of the proposed changes/improvements. CARACAL members broadly accept that digitalisation is necessary, however, more thought should be put on what it means in practice and what are the pros and cons. There are certain concerns for example on potential administrative and cost burden for SMEs.

CARACAL members were asked whether **resources** could be made available for the future work in the 'Development Phase', e.g. in the form of a dedicated CARACAL subgroup. Although CARACAL members support the approach and the findings of RRA3 'Scoping Phase', they could unfortunately not commit to provide the resources required for a new CARACAL subgroup.

On the other hand, ENES is considered by most CARACAL members to be a suitable platform taking forward the necessary technical development work, involving all relevant interest groups.

### 3 PROPOSED WAY FORWARD

The 'Development Phase' will require significant efforts from all actors involved. In this phase, ECHA and the Commission would work closely with industry, MS Competent Authorities and workers' representative organisations in order to propose a more detailed development/implementation plan, based on the 'Building blocks' identified earlier by ECHA. During this phase, the basis for the potential new, more efficient and workable solutions would be developed and tested so in the future, consultations on the selected solutions could be carried out.

#### ➤ **Technical work**

ENES is considered to be the most appropriate platform to take forward the necessary technical development work. However, due to the extent and complexity of the work ahead, there is an urgent need to involve the relevant key actors more actively, especially as regards representatives of the OSH 'community' and SMEs but also Member States would need to play a more active role

ENES has devoted significant efforts into this work already (e.g. developing tools and concepts) and is ready to face the challenges of the technical work, but its functioning needs to be reinforced through improved participation of all relevant actors.

#### ➤ **Policy validation**

As the creation of a dedicated CARACAL subgroup was not supported by MS Competent Authorities due to their resource constraints, policy validation will have to be carried out at CARACAL level.

Short discussion and information points will therefore be included systematically in the agenda of the CARACAL meetings, in order to validate the directions and check the deliverables of the work carried out on RRA3 by the ENES platform.

### 4 NECESSARY INPUT AND COMMITMENT

As already identified in the last CARACAL 'Call for support' document (CA/75/2019), the key actors should play an active role during the 'Development Phase' in order to find potential solutions that have the broadest possible support.

**MS Competent Authorities** shall assess whether new requirements can, in principle, enable REACH compliance for manufacturers/importers and formulators whilst delivering relevant and fit-for-purpose safe use advice to the end user via simplified extended SDS, as well as corresponding enforcement. Representatives from the relevant authorities should participate in ENES discussions and be ready to review draft documents.

**Industry** (including SMEs), producers, manufacturers and industrial associations potentially would need to adjust to new working methods and therefore have a vital role in helping to assess the impact of proposed measures, comparing the short term burden with long term intended benefits. Increased involvement by representatives of SMEs in ENES would assist in considering their specific needs during the development of tools and concepts.

IT tool providers would also be important partners to determine which of the suggested solutions would be feasible from a technical point of view. Also, some of the tools requiring development in the implementation phase would rely on investments from industry to contract development work to the IT tool providers. They should be ready to contribute to relevant actions.

**Occupational Safety and Health (OSH) ‘community’** (including employers, workers and their representative organisations and Member State ‘OSH’ authorities) need to play an active role as well, being an important end-user of the information in the extended SDS. Therefore, action should be taken to engage with workers and their representative organisations to ensure that the information to be communicated in the extended SDS can be effective in improving the protection of workers’ health and safety. Both Member States and Industry should look into options to create connections and synergies between the relevant units dealing with the two domains.

In addition, other relevant policy areas, for example the Industrial Emissions Directive (IED) or the Waste Framework Directive (WFD) should also be taken on board in order to ensure coherent and effective legislation as well as exploring synergies and mutual benefits.

### **Questions to MS Competent Authorities and interest groups at CARACAL**

- 1) Do you agree that policy validation should be carried out at CARACAL?
- 2) Do you agree that the main technical work should be carried out by the reinforced ENES platform and if so, how do you foresee to be (more) involved in this work?
- 3) How do you intend to reach out to your OSH (and environmental) experts to involve them in the RRA3 discussion?
- 4) Do you agree with the directions now emerging for further conceptual development as expressed in ECHA’s Appendix (section A.1)?