



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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**32nd Meeting of Competent Authorities for REACH and CLP
(CARACAL)
Open session
6-7 November 2019**

**Room: 2D
Centre Albert Borschette
Rue Froissart 36
1040 Brussels, Belgium**

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

Agenda Point: 4.4 REACH

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 5 December 2019 to:

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CARACAL – ‘CALL FOR SUPPORT’

ON REACH REVIEW ACTION 3

TRANSITION FROM ‘SCOPING PHASE’ TO ‘DEVELOPMENT PHASE’

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.

A more detailed plan, consisting of a ‘Scoping Phase’ (covering most of 2019), a ‘Development Phase’ and a formal ‘Consultation Phase’ was discussed at a first Workshop in Brussels (18 March 2019). This plan and the Workshop findings were reported to CARACAL in June (CA/40/2019).

This paper by the Commission and ECHA and its Appendix prepared by ECHA is supposed to give a short overview of the outcome of the ‘Scoping Phase’ and present a ‘Call for support’ by CARACAL members for future involvement, so that the objective of RRA3 can be achieved.

2 KEY OUTCOMES FROM THE SCOPING PHASE

The ‘Scoping Phase’ was defined as the period in which ECHA and the Commission would collect as many realistic ideas as possible for potential solutions to the issues of workability and quality noted in the REACH Review. There were two major events (workshops) organised in this context. The second Workshop was recently held at ECHA in Helsinki on 23-24 September 2019.

During the ‘Scoping Phase’, interest groups emphasised and called for particular action on some of the concerns already noted during the REACH Review (in 2018):

✓ **Strong need for digitalisation**

Most interest groups believe that there is a strong need for a digitalisation of (extended) Safety Data Sheets ((e)SDS), in order to improve the flow of safety information in the supply chain and to facilitate a more user-targeted presentation of the safety information. In addition, this would reduce administrative burdens and have a positive impact on the environment.

✓ **Mandatory regulatory requirements**

Most interest groups believe that mandatory regulatory requirements (e.g. for minimum requirements for exposure scenarios) are needed. This will improve enforceability and harmonise communication between the supply chain actors.

Other key outcomes of the Scoping Phase are the following:

✓ **Holistic approach**

Feedback was collected on a workflow of a possible future system (‘System required’ and corresponding ‘Building blocks’, see Appendix ‘*Summary report on RRA3 Scoping Phase, section A.1*’) that would implement, in a holistic manner, methods and tools, some of which have already been proposed (e.g. by ENES) and some of which still need to be developed. The workflow illustrates how these tools and methods are interdependent and cannot function in isolation. The proposed system is based on a vision outlined in Appendix ‘*Summary report on RRA3 Scoping Phase*’ for the generation of safe use advice. So far, no viable alternatives to this holistic system have been identified.

✓ **End user needs**

Many end-users, who are probably the ones that should benefit the most of a concise and fit-for-purpose risk management advice identified via exposure scenario, either received massive and raw exposure scenario and therefore too much information, or no information at all. This practice could challenge the real added value of eSDS requested under REACH. To remedy this, some industrial sectors developed use maps and exposure scenarios, however some important sectors are still missing.

3 NECESSARY INPUT AND COMMITMENT FROM KEY ACTORS

As indicated in RRA3, the Commission will consider legal measures imposing *minimum requirements for exposure scenarios for substances and/or safe use information for mixtures*. This could for example be achieved through a revision of REACH Annexes I and II and XII, or by a dedicated regulatory measure. The aim would also be to facilitate the introduction of a more digitalised system.

However, the introduction of a digitalised system and mandatory minimum requirements for exposure scenarios would have important practical consequences for all actors in the supply chain. In order to find potential solutions that have the broadest possible support, the Commission is seeking input and support, in particular, from the following interest groups:

1) Member States (MS)

Member States play an important role in assessing whether new requirements can, in principle enable:

- (a) REACH compliance for manufacturers/importers and formulators whilst delivering relevant and fit-for-purpose safe use advice to the end user via simplified eSDS; and
- (b) corresponding enforcement.

The current rate of non-compliance of extended Safety Data Sheets (eSDS) is rather high (around 50%¹). Therefore the Forum has established an active Working Group dedicated to improving the quality of SDS to achieve a higher compliance level. Nevertheless, participation by the MS Competent Authorities during the ‘Scoping Phase’ was not as strong as expected, in particular at the 2nd Workshop. The Commission is now considering ways to facilitate the participation of Member States in the ‘Development Phase’ of RRA3, for example through the creation of a dedicated CARACAL subgroup.

2) Industry (including SMEs)

a) Producers, manufacturers and industrial associations

The Commission and ECHA are aware that a new and integrated digital eSDS system would initially require significant efforts from industry to adjust to new working methods. Endorsement of the new proposals would mean that industry has to invest further in:

- (a) development of the corresponding tools;
- (b) development of new use maps for missing industrial sectors, updated phrase libraries etc. and;
- (c) implementing and updating the corresponding information in their registration dossiers and eSDSs (e.g. newly available use maps, updated phrase libraries etc.).

Industry would therefore have a vital role in helping to assess the impact of proposed measures, comparing the short term burden with long term intended benefits.

¹ https://echa.europa.eu/documents/10162/13577/forum_report_ref2_en.pdf/6ae12cf0-a24d-4263-a30f-3dabf9928aed

b) IT tool providers

IT tool providers would 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 the development work to the IT tool providers. During the ‘Scoping Phase’, IT tool providers expressed a positive opinion about increased digitalisation. However, they do not seem to believe that the transfer from ‘paper to digital’ would work out, or even take place, unless requirements and specific obligations are imposed at EU level.

3) Occupational Safety and Health (OSH) ‘community’

As an important end-user of the information in eSDS, the input of this community (including both employers, workers and their representative organisations) would be valuable to confirm that the proposed measures will make REACH more useful for them, in terms of REACH information supporting both:

- (a) OSH site assessments together with the implementation of proportionate and effective site specific RMMs,
- (b) as well as the corresponding enforcement activities.

In addition, action should be taken to engage with workers and their representative organisations to ensure that the information to be communicated in the eSDS can be effective in improving the protection of workers’ health and safety.

In this context, ECHA is invited by DG EMPL to give a presentation to outline current activities and to seek the engagement and active support of relevant OSH interest groups on RRA3 at the next meeting of the Working Party on Chemicals in Luxembourg, March 2020.²

4) Other policy areas

The Commission should coordinate with other relevant policy areas such as the Industrial Emissions Directive (IED) or the Waste Framework Directive (WFD) in order to ensure coherent and effective legislation as well as exploring synergies and mutual benefits.

² The Working Party on Chemicals is a tripartite group (Member States/employers/ workers) mandated by DG EMPL’s Advisory Committee for Safety and Health at Work (ACSH).

4 PROPOSED WAY FORWARD:

- In CARACAL-32 we aim to find out whether MS Competent Authorities and interest groups agree with the conclusions of the RRA3 ‘Scoping Phase’, so as to conclude this phase.
- As a next step, ECHA and the Commission would work with industry/MS Competent Authorities (via ENES and/or dedicated CARACAL subgroup) to propose a more detailed development/implementation plan, based on the ‘Building blocks’ identified by ECHA’s *‘Summary report on RRA3 Scoping Phase’, section A.1.2.*
- At the next CARACAL meeting, ECHA and Commission would propose a more elaborate plan on task division, time frame as well as rough estimation of resources needed from the different actors, seeking their commitment and investment.
- During the ‘Development Phase’, the basis for the potential new, more efficient and workable solutions would be developed, so we can make more informed choices between different possibilities, and for identifying the impact of the different options.
- After the ‘Development Phase’, consultations on the selected solutions would be carried out.

Questions to MS Competent Authorities and interest groups at CARACAL

- 1) Do you agree with the main findings of the RRA3 ‘Scoping Phase’?
 - (a) Are there important elements missing? If so, please provide the corresponding evidence.
 - (b) Do you agree with the ‘System required’ as identified by the ECHA document? Can you identify viable alternatives?
 - (c) Do you agree with the corresponding ‘Building blocks’? Do you find missing elements?
- 2) Should the Commission and ECHA initiate the transformation of the eSDS process to a fully digital system?
- 3) Would you provide resources as and when needed to develop the identified building blocks, and/or encourage/stimulate sectors where necessary to get engaged?
- 4) Do you support the creation of a dedicated CARACAL subgroup?
- 5) Do you agree that ENES should be asked to be the central platform taking forward the necessary developmental work, involving relevant interest groups?
- 6) What would assist you in participating more actively compared to the previous phase?