EUROPEAN CHEMICALS AGENCY

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

DIRECTORATE-GENERAL INTERNAL MARKET, INDUSTRY, ENTREPRENEURSHIP AND SMES
Chemicals and Consumer Industries
**REACH**
**Chemicals and Plastics Industries**

Brussels, 12/06/2020

Doc. **CA/41/2020**

# 35th Meeting of Competent Authorities for REACH and CLP (CARACAL)

## Open session

## 30 June - 1 July 2020

## WebEx meeting

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| **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 15 August 2020 to:** <br> **GROW-CARACAL@ec.europa.eu** <br> **ENV-CARACAL@ec.europa.eu** |

# CARACAL PAPER

# ON REACH REVIEW ACTION 3

## SUMMARY OF RESPONSES AND VISION FOR NEXT STEPS

## - 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

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, a second discussion was held by CARACAL (CA/75/2019), where the Commission and ECHA presented a short overview of the outcome of the 'Scoping Phase' and called on CARACAL members for more involvement in order to achieve the objectives laid down in RRA3. In the last (WebEx) CARACAL meeting in April 2020 the Commission outlined the next steps within the 'Development Phase' and ECHA prepared a report proposing 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 (CA/14/2020).

The current document summarises the responses received from CARACAL members on document CA/14/2020 and provides suggestions and vision for the next steps. The feedback given by CARACAL will also be further analysed by the Commission services and ECHA when further preparing the draft Development Plan for RRA3. In that next step (mid-June to mid-October 2020), the Commission and ECHA expect further dialogue with various CARACAL members and observers to help toward the concrete action(s) and process needed for the Plan.

In addition to CARACAL, paper CA/14/2020 and its Appendix were distributed to the following bodies, who were invited to comment over the same timeframe:

- DG EMPL's Advisory Committee on Safety and Health at Work (ACSH) via its Working Party on Chemicals (WPC)
- DG EMPL's Committee of Senior Labour Inspectors (SLIC) via its Chemex Working Group
- ECHA's Forum for Exchange on Information on Enforcement (Forum)
- The two REACH Member State fora: REACH Exposure Expert Group (REEG) and the Risk Management Evaluation platform (RiME+).
- Sector organisations who are members of the ENES Coordination Group but not (currently) observers at CARACAL.

## 2 MAIN CONCLUSIONS OF CARACAL-34 FEEDBACK AND PROPOSED WAYS FORWARD

CARACAL members and other recipients were invited to express their views on the planned steps within the development phase as described in CA/14/2020. Feedback was collected through four targeted questions and written comments were received from 12 Member States and Norway, from the subgroups of DG EMPL's two advisory Committees (the ACSH and SLIC responded via the Working Party on Chemicals and Chemex, respectively), and from a number of sector organisations, such as AISE, Cefic, Concawe, DUCC and SME United.

The Commission and ECHA thank CARACAL members and others who responded for sharing their constructive views.

The summary of responses to each questions and the proposed way forward is explained below.

**Policy validation**:

***Question 1: Do you agree that policy validation should be carried out at CARACAL?***

Background:

From earlier consultations with experts it was understood that the creation of a dedicated CARACAL subgroup is not supported by the majority of the MS Competent Authorities due to their resource constraints. Therefore, policy validation was proposed (in document CA/14/2020) to stay at CARACAL level.

CARACAL members' feedback:

CARACAL responders unanimously supported the approach that policy validation is carried out at its meetings, which means regular feedback and discussion on the progress of the RRA3 dossier.

In addition, a structured process was proposed to involve the Advisory Committee on Safety and Health (ACSH) via its Working Party on Chemicals (WPC) in order to officially represent the OSH community, as information provided in the extended SDS relates to the workplace to a large extent. In this involvement/consultation/approval process the Forum, REEG and RIME+ could also play an important role.

Suggested way forward:

In order to validate the directions and check the deliverables of the work carried out on RRA3 by the Exchange Network for Exposure Scenario (ENES) platform (see feedback to Question 2), a discussion or information point will be included systematically in the agenda of the CARACAL meetings.

Although the main instance for policy validation will be at CARACAL level, the following fora (that are normally outside the remit of CARACAL work), will also be systematically involved to the extent necessary. Their involvement is necessary mainly in order to facilitate the policy validation by CARACAL and to provide input to ensure that the suggestions are technically feasible and compatible with existing implementation measures. The involvement of these following fora will be carried out in a coordinated manner (subject to alignment, as it deems appropriate) and their opinions will be communicated to CARACAL:

- DG EMPL's Advisory Committee on Safety and Health at Work (ACSH) via its Working Party on Chemicals (WPC)
- DG EMPL's Committee of Senior Labour Inspectors (SLIC) via its Chemex Working Group
- ECHA's Forum for Exchange on Information on Enforcement (Forum)
- REACH Exposure Expert Group (REEG)
- Risk Management Evaluation platform (RiME+)

Consultations carried out with the above listed platforms will be conducted primarily in writing, however if necessary, presentations and discussion on RRA3 with participation of COM/ECHA representatives, will be added to the agenda of the various meetings.

**Technical work**

***Question 2: Do you agree that the main technical work should be carried out by the reinforced Exchange Network for Exposure Scenario (ENES) platform and if so, how do you foresee to be (more) involved in this work?***

Background:

The Commission and ECHA have proposed to use ENES as the most appropriate platform to take forward the necessary technical development work related to RRA3. However, it was also noted that due to the extent and complexity of the work ahead, there is an urgent need that some of the relevant actors become more actively involved/engaged, especially representatives of the OSH 'community' and SMEs, as well as some additional Member States.

ENES developed concepts, approaches and methods already in the preceding years and devoted significant efforts in the 'Scoping Phase' of RRA3. ENES is ready to face the challenges of the technical work, however, its functioning needs to be reinforced through improved participation of all relevant actors.

CARACAL members' feedback:

ENES was unanimously viewed as the appropriate platform for the technical work on RRA3, provided:

- its role (and mandate) is adapted to suit the task ahead;
- its composition is adapted to better reflect/involve the range of stakeholder interests, including occupational and environmental expertise and SMEs; and
- the role of Member States is clearly defined and more targeted, to facilitate their engagement, not least so that Member States can earmark resources towards this work. The work should focus on safety/risk assessment and communication of safety data (including safe use advice) through the supply chain.

Suggested way forward:

The Commission and ECHA support the reinforcement of the ENES platform (*e.g. named 'ENES+' platform*) within the developmental phase of RRA3 in order to enable it to provide a solid and coherent (technical) basis for subsequent policy validation. The Commission and ECHA is currently discovering possibilities how to ground/formalise the expected new engagement with the relevant actors, while in the meantime the ongoing work at current ENES-level is continued.

The Commission and ECHA expect ENES to be *the* platform to identify needs of key players, develop new interfaces, exchange practical experience, share learnings and develop solutions in order to improve the efficiency (workability) and effectiveness of the supply chain communication. Therefore, all ENES activities are expected to be synchronised to effectively communicate safe work practices to occupational health professionals and workers.

## OSH and environmental community

***Question 3: How do you intend to reach out to your OSH and environmental experts to involve them in the RRA3 discussion?***

Background:

The Occupational Safety and Health (OSH) 'community' (employers, workers or their representative organisations as well as Member State OSH authorities) and the environmental 'community' is very closely linked to the success of RRA3.
Being important end-users of the information in the extended SDS, an increased participation of these 'communities' in the current discussions is indispensable and their active role during the development phase of RRA3 is expected.

Consequently, 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 find ways to establish connections and synergies between the relevant departments dealing with the REACH/CLP and OSH domains and with environmental experts.

CARACAL members' feedback:

A number of Member States indicated that they were already putting in place resources to support the next stages of the work, and infrastructure for dialogue at national level with the authorities for the different spheres of responsibility: REACH-CLP, occupational and environmental law.

DG EMPL's advisory Committees, via their relevant topic specific subgroups, confirmed their willingness to participate in the technical work. They acknowledge that the extended SDS is a key source of information for workplace risk assessment, and that the aim is to achieve an efficient and enforceable system for exchanging chemicals' safety data which brings added value to health and safety in the workplace. In their view, this information does not yet meet the needs of employers, especially SMEs, in terms of content, form and clarity, and to be adaptable to specific local conditions, so that it can be used effectively and appropriately by an employer to protect his workers. DG EMPL noted that it may be necessary to seek a formal Opinion of the Advisory Committee on Safety and Health at Work (ACSH) and this will need to be taken into account when planning any joint future activities.

Suggested way forward:

It was pleasing to note that a number of Member States were already putting in place resources to support the next stages of the work, and that dialogue has been established at national level between the various authorities responsible for REACH-CLP, occupational and environmental policies. This should serve as a good example and encouragement to all other Member States.

The Commission and ECHA commit to involve DG EMPL's advisory Committees in the work ahead on RRA3 (see *Question 1*) and provide the OSH 'community' the necessary support/information to enable the best cooperation. The same level of good collaboration is expected with the environmental 'community'. The most effective way of cooperation needs to be seen and adjusted, as the development phase evolves.

**Emerging directions**

***Question 4: Do you agree with the directions now emerging for further conceptual development as expressed in ECHA's Appendix (section A.1)****?*

This issue relates to the document 'ECHA's Appendix to CA/14/2020' and is addressed in the Annex to this cover paper (ECHA's Appendix to current note).

**Annex**

# Summary of responses to the Annex to CA/14/2020

## *Appendix 1: ECHA progress report on technical work*

This document provides a summary of the responses received from CARACAL-34 in connection with paper CA/14/2020 Annex, *Appendix 1: ECHA progress report on technical work.*[1] A comment-by-comment response is not provided here. The full text of all responses received are available on s-CIRCABC.

## Brief reminder

ECHA's Appendix to CA/14/2020 described the following aspects:

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

This section explained the **emerging directions** towards **a vision** for a coherent system for generating, transferring, and using/processing safety data[2] for chemicals, comprising 5 core building blocks (see bullets beneath). One **common solution** for the Safety Data Sheet (SDS) related to both substances and mixtures that links REACH-generated data (exposure scenarios, DNELs/PNECs, other data on substance properties) and the corresponding sections of the existing SDS system. The solution should facilitate easy access to all data required for risk/safety assessments by any actor in the supply chain.

- **Minimum requirements** that define the core set of mandatory information, with regard to both substance properties and safe use advice.
- An **XML schema** for exchanging the data contained in the SDS (called SDSxml) as the backbone of a communication flow from registrants down to end users of mixtures, with standard phrases to be defined to express the measures for safe handling and exposure controls.
- **Sector use maps** form a common reference for the whole supply chain, to synchronise the communication and checks on foreseen uses (including tasks at workplaces, products and article types) at the various levels in the supply chain.
- **Toolboxes** for **formulating companies** and for **end-using companies** should enable processing the safety data conveyed by the SDSxml exchange standard, to support a number of standard processes: on-site use conformity checks, utilising the supplier's safe use advice for own site/product risk management, and carry out own safety/risk assessment for workplace, site or product.

### A.2 IT tool support for companies

This section explained that once the workflows and methods for conformity checks and assessment at formulator's level and at end user's level have been defined more specifically, it will be explored how and to which extent they can be supported by IT tools for companies.

[1] See https://echa.europa.eu/documents/10162/13563/caracal_mar_2020_reach_action_3_extended_sds_annex-1_en.pdf/c9037570-ff50-98c0-4e43-1ea87647bc93

[2] In the bullets that follow, "safety data" are the data expected to be contained in a safety data sheet.

### A.3 Working structures/fora supporting the development phase

This section emphasised the need to strengthen the REACH-OSH interface through dialogue with DG EMPL's Advisory Committee on Safety and Health at Work (ACSH) and other OSH fora to increase (i) the common understanding between OSH and REACH community how a coherent system for exchange of chemicals' safety data in supply chains can bring added value to health and safety at the workplace and (ii) their active contribution to the development phase. In parallel, there is the need to explore how to engage with the environmental authorities.

To achieve that, the system's elements to be developed need proper piloting/testing to ensure that they deliver added value to companies, in particular considering the size of the company, and that these values will outweigh the cost of implementation. The paper identified certain fora through which practical piloting/feedback should be done e.g. Member State groups like the Forum, RiME+ and REEG, and through an Exchange Network on Exposure Scenarios (ENES) platform boosted and resourced.

### A.4 Sequencing and timing

This section illustrated at "high level", how the development plan for REACH Review Action 3 might be realised, breaking down the development phase into a series of compartments and a tentative timing on which further discussion can take place, spanning the years 2020-2025.

## Summary

Consistent/constructive support was received for the **emerging directions** and associated building blocks described in section **A.1** of ECHA's Appendix to CA/14/2020 document, from the Member State and other stakeholder organisations that responded. When approaching the further development of (all) the building blocks, distinguishing clearly the technical requirements from legal aspects and communication was deemed important.

CARACAL's feedback reinforced many of the issues that require attention and organisation in preparing a future RRA3 Development Plan described in sections **A.2** and **A.3** of ECHA's Appendix. In addition, constructive, complementary feedback was received from members on individual elements/building blocks of the holistic system. **Table 1** beneath consolidates and paraphrases this feedback as a means to focus on areas where attention is required, in the short term.

Certain organisational aspects were highlighted in the responses. For instance, the need to clarify which forum is in charge of directing the project [programme] on a regular basis. Furthermore, there may be the need to incorporate "policy decisions" at certain points in the programme, and also to work out more interim milestones. Examples mentioned where such a "policy validation" or "strategic decision" might be required were:

- Coverage of the minimum requirements regarding substance safe use advice in the SDS (content, layout, data format)? Confirming that the requirements are principally the same regardless of whether the chemical is a substance or a mixture.
- Whether the SDSxml (data format) should cover all elements of the SDS and whether it would be made mandatory and if not, whether different implementations by companies would inhibit workability.
- Expectations how SDS recipients should respond to the safe use advice received with the SDS.
- Tool development by ECHA or the market.

Whilst CARACAL's comments supported the holistic system and associated building blocks, the following points were made:

- Ensure that the proposed change opens opportunities rather than leading to additional burdens. In particular, the ambiguities at the interface to other legislation need to be resolved. Member States need to play an important role in that.
- Ensure that SMEs benefit from the system proposed.
- Clarify that the "common solution" for the substance and mixture SDS targets the digitalisation and the content of the safe use advice for a chemical, but at the same time respects the existing differences from technical and legal perspective.

## Table 1. Commentary on some specific feedback received.

| **Building block** | *Suggestions / Observations received*[3] | *How being taken into account [in the next stage]* |
|---|---|---|
| Registrant's Chemical Safety Assessment (generation and communication) | The existence of multiple SDS (or CSR) for a same substance from various suppliers/registrants makes problems for formulators and end users (and authorities); make registrants agree on content of sections of the SDS e.g. on hazard and exposure scenario content as much as possible, to limit to a maximum the number of SDS/CSR available for a same substance. | • *Yes, the IUCLID hazard data set from joint submission should be the basis for all registrants covered. A future system should facilitate the use of registration data as the source for SDS.*<br>• *However, same substance may have different composition and different hazard profile as a result; the SDS will naturally need to reflect that. Future system aims for more transparency in this respect.*<br>• *Use maps as a help to streamline safe use advice across registrants.* |
| | A prerequisite to develop SDS for mixtures is to ensure that SDS for substances (i.e. registered boundary compositions) are reliable, which is currently not the case and cannot be as CSR are currently not targeted by any regulatory processes. A proposal could be to improve/extend the completeness check so as to ensure that substances SDS are sufficiently correct. ECHA could afterwards disseminate these SDS for registered substances. | *Agree with first sentence. Our planned work incudes improving the REACH CSA and reflecting these improvements in ECHA's Chesar tool. ECHA can consider, in the future, further improvements to the registration dossier technical completeness check (TCC) in respect of substance data which is destined for the SDSxml. Furthermore, the xml approach to SDS might enable a "validation (quality) assistant". This could ensure completeness and consistency of substance data including hazard characteristics, and to a certain extent the adequacy of the safe use advice. At present ECHA does not have any plans or mandate to receive and disseminate SDS.* |
| | The notions of "operational conditions" (OC) and "risk management measures" (RMM) within exposure scenarios need to be clarified. Indeed, a condition of use could be an OC or a RMM depending on the context. | *Clarity on terminology and their relevance to exposure control are essential, not least in communicating meaningful information to serve other legislations. We* |

[3] Examples received from Member States and observers e.g. AT, DE, FR, NL, SE, Cefic, Concawe, SME United.

| **Building block** | *Suggestions / Observations received*[3] | *How being taken into account [in the next stage]* |
|---|---|---|
| | | *agree that delivery of appropriate OC and RMM are essential to the proposed system.* |
| Sector use maps | For use maps to become reference tools, a key issue is that registrant have to know which use map to utilise. The link between a substance and sector use maps is the knowledge of the sectors of use (SU), of the types of products (PC)/articles (AC) where a substance is used, and of the technical function (TF) of the substance. Therefore it is proposed to include SU, PC, AC and TF (as reported in the R12 Guidance), into the minimum set of requirement for exposure scenarios. | *Planned work on use maps includes broadening the availability for product types not yet covered, streamlining the category system for products (PC) and better linking to Technical Function.*<br><br>*Nevertheless, also registrants have market knowledge available (otherwise difficult to market the substance). The use maps are a tool providing complementary information to registrants, but cannot replace the registrant's own knowledge on the use of their products.* |
| **Safety Data Exchange Standard** (including **minimum requirements** for exposure scenarios) | Analyse, build on, adapt and/or take learnings from existing tools, schemas and phrase libraries, such as Chesar, the biocidal products "SPC editor" ESCom, EuPhraC, SDScom, SDBtranfer. | *An integral part of the development work will be to evaluate to what extent features of existing "tools" provide a basis for a workable solution, also drawing upon experience of current levels of implementation.* |
| | Address potential non-technical barriers to an SDSxml implementation. E.g.:<br><br>- Diverging stakeholders interests.<br>- Agreement on formats and terminology.<br>- Barriers should be analysed and subject to a policy discussion which changes forced upon stakeholders = costs to industry (IT providers, duty holders)<br>- Servicing/Supporting those companies where "digital" is not an (easy) option. | *The identification non-technical barriers such as these are valuable in assuring the benefits and impacts are (clearly, fully) addressed when developing a SDSxml for consultation with stakeholders. Developing a common understanding on burdens and opportunities connected with digitalisation for SMEs will be an important part of the stakeholder dialogue.* |
| | Assess if an increased standardisation of the information in the SDS and extended SDS (eSDS) is:<br><br>- in line with the goal to give the downstream user clear information on safe use; standardised phrases (often) lead to less specific, more general information on safe use;<br>- in line with REACH Art.31, that a supplier provides a SDS to the downstream user for the identified use that the downstream user actually has; a downstream user should not have to find this information himself from a SDSxml. | *Agree: The key objective is to deliver easily accessible and activity-specific advice. "Standardisation" is a means for that rather than an objective in itself. It is anticipated that such assessment will come in the development and piloting stages with (all) relevant stakeholders, industry and Member States. The SDSxml would be 'driving' the technical system but downstream users would receive activity specific safe use advice.* |

| **Building block** | *Suggestions / Observations received*[3] | *How being taken into account [in the next stage]* |
|---|---|---|
| | Need for a user friendly interface and to consider didactic concepts because the more information is shared electronically, the less the information is read. | *To be addressed in the design and/or piloting of software which implements a SDSxml exchange standard. (Interfaces may vary depending upon the software developer that implements the standard.)* |
| | When looking at new digital solutions, important to find a good balance between the initial burden of implementing them and generated benefits. To this end, the reasons why the current safety data on the eSDS are not being propagated through the supply chain should be clearly understood before developing a "new" solution. | *Agree, regarding the need to find a balance. Many reasons have already been identified as part of the Commission's REACH review exercise, leading to the action 3.* |
| | The Global Harmonised Standard (GHS) is the basis and framework for REACH Annex II and the CLP Regulations, so must consider when changing requirements for SDSs. | *Agree. Important to be considered in further development.* |
| | The current communication style of the information in the annex of the eSDS (not appropriate for the target group), communication barriers within supply chains, and the lack of (or lack of quality of) eSDS for mixtures are problematic. Further formalisation of the eSDS will not solve the problems occurring in the real world. Approaches such as e.g. guidelines, trainings, workshops are needed. Whilst recognising a need to promote electronic solutions, the eSDS should remain available in paper/pdf-format and in the national language. | *The problems are acknowledged, hence the initiative behind REACH Review Action 3. "Formalisation", digital solutions and the extent to which the approaches mentioned complement or serve as the primary means for improving the workability and quality of the eSDS will be analysed and consulted upon during the Development Phase.* |
| Formulator's toolbox (methodology for mixture SDS generation) | The process to formulate requirements for IT tools needs further elaboration. It should be a stakeholders' process in which:<br>- Downstream (end) users (or their sector organisations) describe the minimum information requirements that they need to fulfil their duties with regards to OSH and other legislation; and<br>- Authorities describe the minimum requirements which would make exposure scenario methodology meaningful. | *It is anticipated that such process will come in the development and piloting stages with the stakeholders mentioned, potentially through ENES and/or other fora, for which industry and Member States will need to provide resource.* |
| | Analyse how IT providers and their clients can be motivated or encouraged to adapt their tools to the new requirements. | *Such analysis will form the basis for the policy decision on whether and to which extent the minimum requirements and the xml schema will be mandatory and what the required transition period would be.* |

| **Building block** | *Suggestions / Observations received*[3] | *How being taken into account [in the next stage]* |
|---|---|---|
| | Include software producers for risk assessment into toolbox development for toolbox(es) to carry out own safety/risk assessment for workplace, site or product. | *The option for own risk/safety assessment instead of, or complementary to, following the supplier's advice in the SDS is a key element of the anticipated system. IT software providers are a discrete stakeholder group with which dialogue and consultation is foreseen.* |
| | Involve scientists and experts involved in mixture assessment, to develop a science-based, but operational and pragmatic way, to utilise safe use information of substances to derive safe use information for mixtures. | *It is anticipated that such expertise will come in the development and piloting stages, potentially through ENES and industry's input, for which industry and Member States will need to provide resource.* |
| End users' toolbox (processing of safe use advice for chemicals, for feeding SDS information into occupational and environmental risk management). | *(Some) Suggestions/Observations received on the Formulators' toolbox are also relevant to an end users' toolbox, as well as the need to differentiate requirements for specific target groups.* | *Agree. One important feature regarding the requirements for the end user "toolbox" is that the extreme diversity of companies in terms of business, size and structure need to be addressed. A stakeholder process will aim to identify a common "minimum".* |