Cii REACH OSH
Cross-Industry Initiative
for better regulation in chemicals management

POSITION PAPER ON RMOAs

CII recommendations for a more effective and consistent RMOA process

The CII encourages an open and inclusive discussion between authorities and stakeholders on how to further improve RMOAs

May 2020

Executive summary

I. Background:

- Regulatory / Risk Management Option Analyses (RMOAs) contribute to better informed and proportionate decisions on chemicals risk management, identifying the most appropriate measures to address a concern.
- Authorities, including the Commission in the 2nd REACH Review, the Council, the Government Group of the Refit Platform, have identified areas for further improvement of the RMOA process.

II. Recommendations:

- To enhance consistency and effectiveness of RMOAs, the CII recommends that:
  - the existing authorities' template for RMOAs should be transformed into Guidance and published;
  - the Guidance clearly determines the scope of RMOAs and enables industry to proactively gather the data sought by authorities during RMOAs;
  - RMOAs clarify whether there is a risk (or in the absence of sufficient data whether there is a relevant concern) before determining that a risk management option is necessary;
  - socio-economic data and the impact of chemicals management measures on other policy objectives be considered consistently;
  - the Guidance includes recommendations for Member States to consult with relevant stakeholders during the development of RMOAs;
  - criteria be developed to support consistency in choosing the most appropriate Risk Management Option (RMO) – particularly in the overlapping area of REACH and OSH the development of criteria has been called for by authorities and stakeholders and appears to be possible based on experience gathered in RMOAs so far.

III. Call:

- The CII calls upon the Commission, ECHA and Member States to start an open exchange with stakeholders on how consistency and effectiveness of RMOAs can be promoted further.

1. Introduction

The concept of Risk / Regulatory Management Option Analyses (RMOAs) was introduced in 2013 with the SVHC (substances of very high concern) Roadmap. As per the European Chemicals Agency (ECHA) website, the purpose of RMOAs "*is to help authorities clarify whether regulatory action is necessary for a given substance and to identify the most appropriate measures to address a concern*".

The present paper analyses the status of what has already been achieved by means of RMOAs and **identifies areas where**, after several years of positive experiences with RMOAs, **there may be opportunities for enhancing** their **consistency and effectiveness**. This would make regulatory measures more efficient and targeted.

2. RMOAs – An overview

The second REACH Review recognises the positive contribution of the RMOA process as an essential part of the system that ensures the consistent application of REACH[1].

For its part, the CII welcomes the introduction of a tool that has enabled a better consideration of whether and how to best manage or regulate risks caused by uses of substances. **Through** the conduct of **RMOAs, authorities comply with** their obligation to abide by **the proportionality principle**. When a risk is identified, they should choose the most proportionate risk management option for swiftly addressing this regulatory concern. While RMOAs are meant to propose an EU-wide approach on how to address concerns, they can be conducted by different authorities (ECHA or Member State Competent Authorities) and therefore naturally face a **challenge in terms of consistency**.

Mechanisms have already been put in place to promote consistency as well as predictability of RMOAs:

- Mechanisms promoting consistency in RMOAs: The Risk Management and Evaluation Platform (**RiME+**) facilitates coordination and discussion on RMOAs. It **promotes consistency** both **in general terms and through the discussion of specific RMOAs**. Furthermore, a template for RMOAs has been developed, which in its most recent version (Version 2.1 of October 2015) is not a mere template, but provides basic, though non-binding, guidance on RMOAs to authorities. This **existing unpublished guidance on RMOAs is a steppingstone for promoting consistency of RMOAs**.
- Mechanisms promoting predictability of RMOAs: Through the ECHA Public Activities Coordination Tool (**PACT**) as well as transparency on screening criteria, **stakeholders are informed ahead of time when they can expect an RMOA** to be started for a substance or group of substances. PACT does not yet provide clarity on what data will be needed during the RMOA and what industry can effectively do to prepare for it.

[1] European Commission, Commission staff working document accompanying the document *"Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee, Commission General Report on the operation of REACH and review of certain elements*", SWD 2018(58), part 6/7, p.6.

3. RMOAs – What aspects of the RMOA-process could be further improved?

The CII believes, now that authorities have gained experience in applying RMOAs, it is the right moment to further strengthen the positive mechanisms described in the previous section of this paper. The nature of the data considered, and the procedure followed during the RMOA often differ between authorities. This leads to challenges in terms of consistency of conclusions. A **more coherent approach**, however, is **important in relation to more general principles of risk management, i.e. proportionality, non-discrimination, consistency, the need to examine the benefits and costs of action or lack of action**.[2] With the existing level of different approaches to RMOAs, it is very difficult to achieve consistency. Without the consideration of socio-economic aspects, the benefits and costs of action will be completely unknown when the regulatory route is chosen.

The CII encourages authorities to review their experience and compare their different approaches as well as their best practices in conducting RMOAs. Based on such a review, consistency, effectiveness and predictability could be further enhanced. Predictability, in terms of what will be assessed and how conclusions will be drawn from the assessment, is crucial.

We acknowledge that EU authorities have made relevant proposals in this direction. Examples are:

(1) Action 7 of the **2nd REACH Review provides that ECHA** in co-operation with the Commission and Member States **will consider options to** further develop and **use available socio-economic information** for consideration **at the RMOA stage**;

(2) The **Government Group of the REFIT Platform** referenced the RMOA process as the appropriate way to decide when OSH/OELs should be given preference over REACH RMOs and **suggested** the **development of criteria** for making that choice[3];

(3) The **Council concluded on 10 December 2019** in relation to the interface of OSH and REACH **that transparent procedures and criteria should be developed and used when selecting** the most appropriate **substance-specific regulatory options**;[4]

(4) A study conducted by Ökopol and RPA on behalf of the German Ministry of Economy recommends developing criteria to help choose the most suitable different risk management option (an example of how the criteria to choose between authorisation and restriction was included. It also referred to the possibility to develop further criteria that would include other risk management options outside of REACH).[5]

---

[2] See section 6.3 of the Communication from the Commission on the precautionary principle of 2 February 2000 (COM(2000) 1 final), which can be accessed here: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52000DC0001&from=EN

[3] REFIT Platform Opinion on the submission by the CII on the interface between REACH and the EU Occupational Safety and Health (OSH) legislation (27/28 June 2016), page 6. The Opinion can be found here: https://ec.europa.eu/info/sites/info/files/opinion_chemicals.pdf

[4] See paragraph 40 of the Council Conclusions 14942/19. The Council Conclusions are available here: https://data.consilium.europa.eu/doc/document/ST-14942-2019-INIT/en/pdf

[5] See Ökopol/RPA study conducted on behalf of the German Ministry of Economy, 'REACH beyond 2018 – Restriction and authorisation as regulatory alternatives' Summary, p. 11, 15. The document can be found here: https://www.bmwi.de/Redaktion/EN/Publikationen/Studien/reach-after-2018-complete-report.pdf?__blob=publicationFile&v=7

In the eyes of the CII, the following aspects could be improved, while further details are developed in the section 4 of the present paper:

- The current template for RMOAs, which contains only basic guidance, could be revised and updated to a more detailed **Guidance for RMOAs that ensures the consistent application of EU chemicals management legislation**. Currently, most RMOAs are conducted by a small number of Member States. Member States have a different degree of experience with RMOAs and they would be enabled to share the regulatory challenge better if they had clearer guidance on how to conduct an RMOA.
- The **RMOA Guidance (for the time being the 'template') should be published.** This would enhance transparency and **contribute to the effectiveness of RMOAs**: More transparency and clarity about what authorities will consider during their RMOA would give industry an early chance to organise itself and motivate value chains to gather and prepare information that authorities need.[6] This would improve the quality of the data-base for RMOAs, reduce authorities´ workload, improve communication and possibly speed up RMOAs.

4. CII recommendations for refining the RMOA process

As described prior in Section 3 of this paper, the CII recommends the development and publication of more detailed Guidance on RMOAs. In this section, the CII gives recommendations and arguments for what would be useful to include in the RMOA Guidance. It would also welcome **alternative ideas that would address the aspects of the RMOA process that could be improved**.

4.1. A clearly defined scope of RMOAs

RMOAs can be conducted by a Member State or ECHA. It is at the discretion of those authorities to decide what information should be considered during the RMOA. These RMOAs are then the basis for a decision-making process at EU-level. Therefore, it is necessary that RMOAs are as consistent as possible.

The current RMOA template provides a very basic framework for RMOAs and is voluntary. The template suggests that authorities conducting an RMOA should reflect on:

- Substance identity and grouping;
- Completed or ongoing regulatory processes regarding the substance;
- Hazard information (including classification);
- Information on (aggregated) tonnage and uses (or use-specific tonnage, if available and not confidential).

For the following type of information, the RMOA template suggests that authorities may *optionally* provide a short description:

- Emission, exposure and risk(s) per use;
- Information on alternatives, including on R&D;

[6] Not all data that authorities use during the conduct of an RMOA is necessary for a REACH registration dossier. For example, to implement the 2nd REACH Review and consider Socio-Economic data during the conduct of RMOAs, other data than the one contained in REACH registration dossiers is needed. This kind of information is not readily available and takes time and resources to be gathered.

- Preliminary socio-economic considerations; if possible;
- Other information;
- Identification of missing information / uncertainties, which could affect the justification for the proposed RMO.

It is evident that the conclusions from an RMOA on a substance can be completely different, if the currently optional aspects are not considered. However, the optional elements are usually essential for assessing proportionality of regulatory measures, e.g.: If there is no risk caused by the uses of a hazardous substance, but its uses provide benefits which cannot be achieved by alternatives, then a costly RMO cannot be justified.

Hence, the CII **recommends that all the above elements – including those that are currently considered as optional – should be systematically considered in RMOAs**.

The CII recognises that in the absence of sufficient data on exposure, socio-economic aspects and alternatives (or the lack thereof), uncertainties can drive towards more conservative conclusions in the RMOA.

With regard to socio-economic considerations, the **CII also raises the importance of considering the benefits of the use and the functions of substances for other EU policy objectives outside the limited perspective of chemicals management.** RMOAs give the opportunity for a holistic and integrated view on EU legislation. Where information on societal impacts and benefits of the use of a substance are made available to authorities conducting the RMOA, this information should be taken into account in order **to find the best balance from a societal perspective between key EU policy objectives** (e.g. Circular Economy, decarbonisation) and **to prevent unintended negative impacts of chemicals management regulation on them**.

The CII notes that the RMOA template refers to information on risks per use. We explicitly support this use-specificity, as it enables targeted risk management. The **CII recalls that also the Analysis of Alternatives needs to be use-specific**.

4.2. Enhancing the effectiveness of RMOAs

4.2.1. Enabling industry to provide data that is relevant for RMOAs

Authorities conducting RMOAs frequently seek data from industry that would enable them to better conclude whether there is a risk / concern and its extent, as well as other information that may help them determine the appropriate RMO. As the **information that authorities frequently seek during RMOAs goes beyond the REACH information requirements, not all of this data is available in REACH registration dossiers**[7]. In a study for the German Ministry of Economy, the consultancies Ökopol and RPA concluded that "active participation of market players within the framework of an RMOA is a prerequisite for the timely acquisition of information and, more

[7] Ökopol and RPA found in their study conducted on behalf of the German Ministry of Economy that "the challenge is that in most cases, the authorities have limited access to the relevant market and supply chain information". See Ökopol/RPA, Sct. 3.1, page 9.

generally, for the ability to draw informed conclusions"[8]. However, **this requires an extensive data-gathering exercise for the industry**.

Currently, the collection of relevant information happens *ad hoc* during the conduct of RMOAs. There is no common standard regarding which data is considered (see previous subsection 4.1) for the scope of RMOAs. Consequently, authorities and industry jointly struggle to gather the data that the individual authority would want to take into consideration for the RMOA. This often leads to either delays (because authorities give time to gather the data *ad hoc*) or to a very limited data basis for the RMOA (which is less reliable).

The **described difficulty could be resolved by defining a clear scope of RMOAs and ideally by publishing an RMOA Guidance**, including recommendations for consulting with stakeholders during the RMOA process. A clearer framework would enable industry to better and more proactively prepare for RMOAs. Data could be gathered from a wider audience and not only from REACH registrants. In particular, Downstream Users should be more closely involved. The **current approach**, however, **discourages** such **proactive preparations**. Without a guarantee that their submitted data will be considered, companies do not have a high incentive to contribute. Such a data-collection is usually resource intensive. SMEs, in particular, do not have sufficient resources to collect data without some degree of certainty that authorities will use it.

4.2.2. Clarity about stakeholder involvement

The **CII recommends that the Guidance on RMOAs foresees an early and iterative public consultation process.** This means relevant data is gathered at an early stage and refined along the way.

The CII also acknowledges that after a public consultation, some Member States have had follow-up meetings with contributors. The CII recommends this as a best practice and a great tool to address potential ambiguities of public contributions.

4.3. Enhancing consistency of RMOA conclusions

4.3.1. Consistent identification of risks or their absence

The **Guidance on RMOAs should include** as a standard element **an assessment whether the use of a substance presents a risk**. Authorities should only adopt risk management options based on the precautionary principle if the available data is not sufficient to conclude whether or not there is a risk. This assessment in the RMOA should follow a **standardised risk assessment framework,** which **can be included in the Guidance.** The DNEL/PNEC-concept and the risk characterisation ratio system could serve as a basis for determining whether there is a risk. The CII notes that DNELs and PNECs are determined by industry and authorities may disagree with them. Consequently, the **standardised risk assessment framework should also set some basic standards for how to deal with such disagreements**. It is crucial, that the relevant level of the DNEL is not determined from a national perspective, since the RMOA conclusions are meant to be implemented at the EU-level.[9] The common risk determination framework could for

[8] See Ökopol/RPA study conducted on behalf of the German Ministry of Economy, 'REACH beyond 2018 – Restriction and authorisation as regulatory alternatives' Summary, p. 13.

[9] An example why the determination of a risk on the basis of national perspectives is not appropriate in the context of RMOAs: If two different jurisdictions carried out an RMOA for the same substance and they used

example recommend that a European limit value has priority. In the absence of such a value, existing and up-to-date limit values in different EU Member States could be used jointly for the risk-assessment. If that is not the case, a consultation in a relevant committee could help to ensure that the identified concern is shared by authorities other than the one conducting the RMOA.

4.3.2. Choosing the best RMO

Once the **RMOA** has assessed risk per use of a substance, it **should consistently determine the most appropriate Risk Management Option(s) for the different uses**. It may be that the same risk management option is the most appropriate for all uses. However, in many cases, uses, or different types of use, may need to be treated differently. The RMOA should also consider that the most appropriate Risk Management Measures could be through other sectorial regulatory frameworks including for instance OSH or EQS.

The **CII recommends building upon the Ökopol/RPA study conducted on behalf of the German Ministry of Economy as well as upon lessons learned from RMOAs**. On this basis, authorities (in a transparent process that involves a public consultation) **could develop Guidance criteria for choosing the best RMO(s)**. These criteria should include socio-economic aspects. A common set of criteria would also strengthen acceptance of RMOA conclusions drawn by a particular Member State among other authorities, reducing the risk of competing and sometimes divergent risk management decisions. **When RMOs that promote substitution of the use of a substance are considered, technical and economic feasibility of substitution should be taken into account**. Specialist knowledge of the use, the function of the substance and the limitations of alternatives is needed. The assessment should consider whether the substitution of the substance can be reasonably expected, or whether R&D data shows that no alternative can feasibly be implemented.

The CII recalls that the **Council and the REFIT Platform recommended** the **development of criteria for when a** Binding Occupational Exposure Limit Value (**BOELV**) **is the best RMO**. **This recommendation can be implemented with the RMOA Guidance.** Based on the proposals of the REFIT Platform, the CII recommends the following criteria for choosing a BOELV:
A BOELV is the best suited risk management option for uses where:

- the substance presents a risk related to an SVHC-property limited to the workplace only (i.e. not for consumers, man via the environment or the environment); and
- the substance cannot be reasonably expected to be substituted in that use in the near to mid-term future.

The **CII reiterates that exposure limits at the workplace should always be implemented as OELVs**, and **not as a restriction**, which would circumvent the legally foreseen procedure for the adoption of OELVs.

5. Conclusion

Many authorities and stakeholders have called for refinements of RMOAs and the consistent consideration of OSH in RMOAs. Against this background, we **call on the Commission, ECHA and**

their different national limit values, one of the two jurisdictions may conclude that there is no risk and no need for action, whereas the second jurisdiction with a lower national limit value may come to the contrary conclusion.

the Member States to start an open and inclusive exchange with stakeholders on how to further promote the consistency and effectiveness of RMOAs. In the framework of such an exchange, authorities and stakeholders could generate further ideas, establishing an approach that is viable for all involved parties.

Annex: List of signatory organisations

Annex: List of signatory organisations

European and global associations and platforms

1. ACEA – European Automobile Manufacturers' Association
2. ADCA Taskforce
3. AmCham EU
4. BSEF – The International Bromine Council
5. Cadmium Consortium
6. CAEF – European Foundry Association
7. CI – The Cobalt Institute
8. CECOF – The European Committee of Industrial Furnace and Heating Equipment Associations
9. CEMBUREAU – The European Cement Association
10. CEPE – European Council of the Paint, Printing Ink and Artists' Colours Industry
11. Cerame-Unie – The European Ceramic Industry Association
12. CETS – European Committee for Surface Treatment
13. CheMI – European Platform for Chemicals Using Manufacturing Industries
14. ChemLeg PharmaNet
15. CIRFS – European Man-made Fibres Association
16. CPME – Committee of PET Manufacturers in Europe
17. EAA – European Aluminium Association
18. EBA – European Borates Association
19. ECFIA – Representing the High Temperature Insulation Wool Industry
20. ECGA – European Carbon and Graphite Association
21. ECMA – European Catalyst Manufacturers Association
22. EPMF – European Precious Metals Federation
23. ETRMA – European Tyre & Rubber Manufacturers' Association
24. Euroalliages – Association of European Ferro-alloy Producers
25. EUROBAT
26. EUROFER
27. Eurometaux
28. Euromines
29. FEPA – Federation of European Producers of Abrasives products
30. Frit consortium
31. Glass Alliance Europe
32. I2a – The International Antimony Association
33. ICdA – International Cadmium Association
34. IIMA – International Iron Metallics Association
35. IMA Europe, the Industrial Minerals Association – Europe
36. IMAT – Innovative Materials for Sustainable High-Tech Electronics, Photonics and Related Industries
37. Ipconsortium
38. Lead REACH Consortium
39. MedTech Europe
40. Nickel Institute
41. PRE – The European Refractories Producers Federation
42. RECHARGE – European Association for Advanced Rechargeable Batteries
43. SMEunited
44. UNIFE – The European Rail Industry

National associations

45. A3M – Alliance des Minerais, Minéraux et Métaux (French Ores, Minerals and Metals Association)

46. ASSOGALVANICA – Associazione Italiana Industrie Galvaniche (Italian Plating Industry Association)
47. BCF – British Coatings Federation
48. BVKI – Bundesverband Keramische Industrie e.V. (German Association of the Ceramic Industry)
49. ION – Vereniging Industrieel Oppervlaktebehandelend Nederland (Dutch Association for Industrial Surface Treatment)
50. NFA – Non-Ferrous Alliance
51. SEA – Surface Engineering Association
52. VDA – Verband der Automobilindustrie (German Automotive Industry Association)
53. VDFFI – Verband der Deutschen Feuerfest-Industrie e.V. (German Association of the Refractory Industry)
54. VdL – Verband der deutschen Lack- und Druckfarbenindustrie e. V.
55. VDS – Verband Deutscher Schleifmittelwerke e.V. (German Abrasives Association)
56. WKÖ – Wirtschaftskammer Österreich (Austrian Federal Economic Chamber)
57. WVM – Wirtschaftsvereinigung Metalle (German Metals Trade Association)
58. ZVO – Zentralverband Oberflächentechnik e.V. (Central Association of Surface Technology)

Corporations

59. Colorobbia
60. DALIC
61. Esmalglass itaca
62. Ferro
63. Smalticeram