

Strengthening RMOAs to better manage chemical risks while maintaining the competitiveness of the European industry

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A wide and dynamic membership, active since 2015

Overview of presentation

- Introduction: Status and role of RMOAs
- Proposal: Further Harmonisation of RMOAs
- Specific example: Criteria for considering OSH/OELs in choice of appropriate RMOs
- Conclusion

Status of RMOAs

- Recognised to be useful / necessary
- Voluntary?
(not explicitly foreseen in REACH)

Or

- Required?
→ **principle of proportionality** requires a process that allows to make an informed regulatory choice

Status of Harmonisation of RMOAs

Existing tools for enhancing consistency:

- SVHC Roadmap 2020
- Template for RMOAs
- RiME

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More Guidance: Why and what needs to be considered?

- Guidance will enable more MS to contribute
 - Predictability (procedure, data needs and outcomes)
- Guiding principles:
- RMOAs need to remain manageable
 - Industry needs to know what data to prepare for RMOAs

What to address by Guidance

- When is a substance not a 'relevant' SVHC
- Procedure
- Assessment per use:
 - Exposure and/or risk(s);
 - Information on alternatives;
 - Preliminary socio-economic considerations (including contributions to other policy objectives)
- Criteria for choosing amongst RMOs; e.g.:
 - REACH Authorisation or Restriction (BMW Study)
 - Criteria for choosing RMOs outside REACH

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Date of Adoption: 27/28 June 2016

REFIT Platform Opinion on the submission by the Cross Industry Initiative on the interface between REACH and the EU Occupational Safety and Health (OSH) legislation

3.2 Considerations of the REFIT Platform Government group

Excerpts: “REACH Authorisation may not be necessary **where OSH legislation** is shown to provide an **appropriate, targeted, proportionate and mandatory regulatory control of risks**. This **should be decided on a case-by-case basis using defined criteria**. [...]

[M]ore needs to be done to raise awareness of OSH legislation as an appropriate risk management measure. Appropriate risk management measures (RMMs) under REACH are considered case-by-case in the Risk Management Expert Group (RiME). Here experts from Member States routinely consider whether OSH or other controls are better able to manage risks than authorisation or restriction under REACH. This is done as part of a Risk Management Options Analysis (RMOA) which is undertaken for substances of concern, particularly those under consideration for REACH restriction or authorisation. **Although OSH is now helpfully part of the discussions regarding the appropriate RMMs** for substances, the **awareness of OSH** as a robustly enforced and rigorous control regime **amongst those more acquainted with the requirements of REACH could be enhanced.**”

CII: Criteria for choosing OSH/OELs

OSH (incl. OEL) should be chosen as RMO when:

- SVHC property causes risks only at the workplace;
(not for environment, consumers or man via the environment)
- No feasible alternative to uses in the near to mid-term future.

Where the above does not apply for all uses, combinations with other RMOs can be foreseen (e.g. restriction for uses leading to consumer exposure)

Way forward and conclusion

➤ **Further harmonization is needed!**

- Interface of REACH and OSH = priority of 2nd REACH

Review:

- Caracal Doc. CA/MS/87/2018 of 5 November does not reflect on recommendation of the REFIT Platform Gvmt Group → Element to be added
- Common Understanding Paper on REACH & OSH → Should include criteria for OSH/OEL
- German study and criteria for OSH/OELs can serve as building blocks of future RMOA Guidance

Thank you!

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