Risk Management Option Analysis Conclusion Document

Substance Name: Lead and its compounds

Authority: European Chemicals Agency on behalf of the European Commission

Date: 28/01/2016

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Foreword

The purpose of Risk Management Option analysis (RMOA) is to help authorities decide whether further regulatory risk management activities are required for a substance and to identify the most appropriate instrument to address a concern.

RMOA is a voluntary step, i.e., it is not part of the processes as defined in the legislation. For authorities, documenting the RMOA allows the sharing of information and promoting early discussion, which helps lead to a common understanding on the action pursued. A Member State or ECHA (at the request of the Commission) can carry out this case-by-case analysis in order to conclude whether a substance is a 'relevant substance of very high concern (SVHC)' in the sense of the SVHC Roadmap to 2020[1].

An RMOA can conclude that regulatory risk management at EU level is required for a substance (e.g. harmonised classification and labelling, Candidate List inclusion, restriction, other EU legislation) or that no regulatory action is required at EU level. Any subsequent regulatory processes under the REACH Regulation include consultation of interested parties and appropriate decision making involving Member State Competent Authorities and the European Commission as defined in REACH.

This Conclusion document provides the outcome of the RMOA carried out by the author authority. In this conclusion document, the authority considers how the available information collected on the substance can be used to conclude whether regulatory risk management activities are required for a substance and which is the most appropriate instrument to address a concern. With this Conclusion document the Commission, the competent authorities of the other Member States and stakeholders are informed of the considerations of the author authority. In case the author authority proposes in this conclusion document further regulatory risk management measures, this shall not be considered initiating those other measures or processes. Since this document only reflects the views of the author authority, it does not preclude Member States or the European Commission from considering or initiating regulatory risk management measures which they deem appropriate.

[1] For more information on the SVHC Roadmap: http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/svhc-roadmap-to-2020-implementation

1. OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

Lead is heavily regulated in the EU and internationally but there is no harmonised legislation in the EU on lead in shot.

2. CONCLUSION OF RMOA

This conclusion is based on the current available information.

Conclusions	**Tick box**
Need for follow-up regulatory action at EU level:	✓
Harmonised classification and labelling	
Identification as SVHC (authorisation)	
Restriction under REACH	✓
Other EU-wide regulatory measures	
Need for action other than EU regulatory action	
No action needed at this time	

3. NEED FOR FOLLOW-UP REGULATORY ACTION AT EU LEVEL

The Commission has requested ECHA to prepare an Annex XV dossier to demonstrate that action on the use of lead in shot in wetlands beyond any measures already in place is necessary on a Union-wide basis.

The harmonisation of the conditions of use of lead in shot in wetlands is a priority at EU level, as national legislation has already been enacted by some Member States (or regions in some Member States) further to international action through the Agreement on the Conservation of African-Eurasian Migratory Waterbirds (AEWA) under the auspices of the UN Environment Programme (UNEP) to which the EU is a Party.

4. TENTATIVE PLAN FOR FOLLOW-UP ACTIONS IF NECESSARY

Indication of a tentative plan is not a formal commitment by the authority. A commitment to prepare a REACH Annex XV dossier (SVHC, restrictions) and/or CLP Annex VI dossier will be made via the Registry of Intentions.

Follow-up action	**Date for follow-up**	**Actor**
Submission of an Annex XV dossier for restrictions	April 2016	ECHA upon request/on behalf of Commission