Risk Management Option Analysis Conclusion Document

Substance Name: Lead

EC Number: 231-100-4

CAS Number: 7439-92-1

Authority: Swedish Chemicals Agency

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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

Since lead metal is classified as Repr. 1A it fulfils the criteria for Article 57 (c) in REACH and since it is widely used in large volumes the substance also fulfils the SVHC Roadmap for 2020 relevance criteria.

The harmonised classification of lead (Index no 082-013-00-1 lead powder and 082-014-00-7 lead massive) is Repr 1A and Lact. Since lead is reprotoxic in category 1A it will also be covered by entry 30 in Annex XVII of REACH. This means that it will be restricted as such and in mixtures placed on the market for sale to the general public.

Lead is listed under entry number 63 in Annex XVII of REACH, which includes restrictions of lead in jewellery and in articles supplied to the general public that can be placed in the mouth by children.

Lead and lead compounds are also regulated in several other EU legislations, such as the RoHS directive, cosmetic regulation, toy safety directive, batteries directive, chemical agents directive (for workers) and pregnant workers directive, etc.

2. CONCLUSION OF RMOA

This conclusion is based on the REACH and CLP data as well as other available relevant information taking into account the SVHC Roadmap to 2020, where appropriate.

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

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

3.1 Identification as a substance of very high concern, SVHC (first step towards authorisation)

At present there are 31 lead compounds included in the Candidate list, however not yet metallic lead. Although already heavily assessed and regulated, the assessment in this RMOA leads to the conclusion that there is a need to prepare an Annex XV dossier with the intention of inclusion of lead metal in the REACH candidate list, and eventually in Annex XIV.

Candidate listing would also be useful for providing further information on the potential presence of lead in articles that are not already restricted. Further, as the ultimate aim would be to substitute lead in all uses where this is possible, inclusion in Annex XIV would force industry to more actively look for substitutes and phase out the use of lead metal wherever possible.

Identification of metallic lead as an SVHC will lead to increased knowledge about the presence of lead in articles which are produced in or imported to the EU, due to the information requirements in REACH article 33. Such information could be useful when assessing whether a restriction of lead in certain imported articles is justified as an additional risk management measure.

Since lead metal is classified as Repr. 1A it fulfils the criteria for Article 57 (c) in REACH and since it is widely used in large volumes the substance also fulfils the SVHC Roadmap for 2020 relevance criteria.

Owing to the hazardous properties of the substance there is a need for regulatory risk management for lead. Identification as SVHC and subsequent inclusion in Annex XIV is considered the preferred risk management option, in line with previous regulation of other lead compounds.

3.2 Other Union-wide regulatory measures

One major concern is the potential for occupational lead exposure considering the high volumes being used in the EU. Taking the type and severity of the health effects into account, a lowering of the current occupational exposure limit and biological limit value to protect workers appears to be justified.

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 should be made via the Registry of Intentions.

Follow-up action	Date for follow-up	Actor
e.g. Annex XV dossier for restrictions	Month / Year	Member State
Candidate list	February 2018	Sweden