Risk Management Option Analysis Conclusion Document

Substance Name: Beryllium
EC Number: 231-150-7
CAS Number: 7440-41-7

Authority: German CA
Date: November 2016

DISCLAIMER

The author does not accept any liability with regard to the use that may be made of the information contained in this document. Usage of the information remains under the sole responsibility of the user. Statements made or information contained in the document are without prejudice to any further regulatory work that ECHA or the Member States may initiate at a later stage. Risk Management Option Analyses and their conclusions are compiled on the basis of available information and may change in light of newly available information or further assessment.

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

1.1 Other processes under REACH

Beryllium has already been subjected to an RMO-Analysis. Within this process the German CA concluded that detailed data on occupational exposure were lacking for a number of uses. As a consequence the substance was selected for substance evaluation. During this evaluation data on the exposure situation for the uses under discussion has been provided by industry. As a result an update of the original RMOA became necessary.

1.2 OSH legislation

In August 2016 SCOEL has proposed a value of 20 ng/m³ as a time weighted 8-hours average occupational exposure limit. A short term exposure limit at 200 ng/m^3 is also proposed. The setting of a (B)OEL is still ongoing.

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)	
Restriction under REACH	(x)
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

The data found both during the SEv and the RMOA activities show that, based on the DNEL of 60 ng/m³, a risk for workers exists at a lot of metal working processes. On the other hand, the beryllium industry has set their RMM based on an (voluntary) exposure limit of 200 ng/m³. This limit, in contrast to the 60 ng/m³, has been implemented at a lot of companies.

To handle the risk for workers, a two-step approach is proposed.

Firstly, SCOEL and DG Employment are highly encouraged to set an community-wide OEL for beryllium in order to harmonise the minimum level of safety. In the meantime the DNEL may serve as a point of reference. In August 2016, SCOEL has proposed a value of 20 ng/m³ for the setting of the (B)OEL, which is in the same range as the derived DNEL.

The change to the new and lower exposure limits might take time, but industry is willing to already work on best practice examples (as a result of the RMOA consultation process in Germany) while the (B)OEL is being set.
Secondly, a labour inspection activity throughout the EU (or at least in the countries with a great amount of beryllium industry) is proposed. Some preliminary discussions on such

an activity have been conducted in the SLIC-meeting of the WPC and the idea was favourably received.

In case this system does not yield useful results, a restriction process to set a minimum requirement on risk reduction measures might be an alternative to the proposed way forward.

3.1 Restriction under REACH

Although a general or even a partial ban will undoubtedly reduce risks, the societal impacts would be disproportionate. Beryllium is used in many high-technology processes and articles, and in most cases it is unclear, whether suitable alternatives exist currently. This makes it questionable, whether a meaningful case for a restriction could be created. A restriction based on the setting of specific risk management measures might be a way forward.

3.2 Other Union-wide regulatory measures

3.2.1 Setting a harmonised OEL

Setting of an OEL by the Scientific Committee on Occupational Exposure Limits (SCOEL) is seen as a necessary step forwards for the regulation of beryllium. While it is a non-threshold carcinogen, the CBD (or even sensitisation) is the leading health effects and can be regulated through an OEL. The implementation of an OEL in the range of the DNEL should significantly lower the risk of CBD and will possibly also have an effect of lowering the risk of cancer. Such an OEL may serve as a basis for further regulatory measures.
This regulatory option indicates the high potential for risk reduction capacity and equivalent high health benefits for the workers. On the other hand additional costs for the measures for exposure reduction may incur e.g. plants with encapsulated equipment. However, taking into account the investment for the continuous improvement, the additional costs would be proportional to the benefits arising from exposure reduction. Therefore, SCOEL and DG Employment are encouraged to prioritize setting an OEL for beryllium.
Note: In August 2016 SCOEL published its opinion on Beryllium. The document can be found at:
https://circabc.europa.eu/sd/a/bc187180-1f4e-4bd1-ba9d-8bcaa4a7d697/2016-09-05_REC-175%20v11%20Beryllium%20and%20compounds_for%20PUBLIC%20consultation.pdf

3.2.2 Labour inspector activity

Considering that the exposure levels regularly exceed the DNEL of 60 ng/m³, a health risk for workers has been identified. New risk reduction measures to reach the DNEL of 60 ng/m³ have to be developed by the industry. Additionally, the compliance with the DNEL has to be checked. Therefore, a community-wide activity of labour inspectors to evaluate the risks of beryllium at workplaces and the implementation of appropriate risk managing measures seems to be a good way forward.

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**
Proposing a value for the setting of an OEL	ASAP	SCOEL, Done in August 2016
Setting of an OEL	ASAP	DG EMPL
Labour inspections		
Annex XV dossier for restrictions	tbd	Germany