Ministry of Environme
and Food of Denmark
Environmental
Protection Agency

Risk Management Option Analysis Conclusion Document

Substance Name: Toluene
EC Number: 203-625-9
CAS Number: 108-88-3

Authority: **Denmark**
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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

See Section Background section (Extisting legal requirements) of the RMOA document and section 2 of the Danish LOUS survey for toluene:
http://www2.mst.dk/Udgiv/publications/2014/11/978-87-93283-18-3.pdf

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.

The Danish EPA has conducted a survey of all substances and substances groups listed on the Danish List of Undesirable Substances (LOUS): www.mst.dk/lous (click further for English).

The survey carried out for toluene provides an overview of the use and the environmental and human health aspects of the substance. The report can be found here: http://www2.mst.dk/Udgiv/publications/2014/11/978-87-93283-18-3.pdf

The results of the survey have been used as the main background information for the RMOA as well as feedback from the Dutch and German Competent Authorities.

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	✓

Toluene is a high product volume chemical and has a wide dispersive use by both workers and consumers. It is mainly used as an intermediate in the chemical industry and as a solvent. A harmonised CLP classification has been agreed upon for toluene due to, among other effects, its negative effects on the central nervous system and reproductive toxicity where toluene is suspected to cause damage to the unborn child. Toluene is restricted in adhesives and spray paints intended for sale to the general public. It is also restricted in nail polish and in paints and other film-forming products for indoor and outdoor use on buildings.

Based on a study published in February 2016 the Danish EPA concluded that the emissions of toluene and other volatiles from children´s room-related products do not generally occur at levels causing concern for chronic neurotoxic effects in children. This is supported by a number of measurements performed in children´s rooms in private homes, where the levels of the neurotoxic substances were generally low.

Denmark supports the conclusions in the 2013 substance evaluation report that the Commission Scientific Committee on Occupational Exposure Limits (SCOEL) takes into account results from the EU risk assessment from 2003 in the current review on IOEL values for toluene.

Considering the risk reduction measures already implemented and on their way in the EU, the analysis concludes that toluene does not represent additional unacceptable risk to workers, consumers or to the environment. The Danish EPA considers therefore that there is no need for further regulation for toluene for the time being.