Risk Management Option Analysis Conclusion Document

Substance Name: Melamine
EC Number: 203-615-4
CAS Number: 108-78-1

Authority: DE CA (aMSCA)
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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 assess whether further regulatory management measures are needed.

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. OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

RMOA		☐ Risk Management Option Analysis (RMOA) other than this RMOA
REACH Processes	Evaluation	☒ Compliance check, Final decision
		☒ Testing proposal
		☐ CoRAP and Substance Evaluation
	Authorisation	☐ Candidate List
		☐ Annex XIV
	Restri -ction	☐ Annex XVII
Harmonised C&L		☒ Annex VI (CLP) (see section 3.1)
Processes under other EU legislation		☐ Plant Protection Products Regulation Regulation (EC) No 1107/2009
		☐ Biocidal Product Regulation Regulation (EU) 528/2012 and amendments
Previous legislation		☐ Dangerous substances Directive Directive 67/548/EEC (NONS)
		☐ Existing Substances Regulation Regulation 793/93/EEC (RAR/RRS)
(UNEP) Stockholm convention (POPs Protocol)		☐ Assessment
		☐ In relevant Annex

Other processes/ EU legislation	☒ Other (provide further details below) REACH: Assessment of ED properties is currently ongoing by the French CA. Plastic food contact materials Regulation (EU) No 10/2011 (Annex I; to be used as additive or monomer, specific migration limit: 2.5 mg/kg food)

2. CONCLUSION OF RMOA

This conclusion is based on the REACH and CLP data as well as other available relevant information.

Conclusions	**Tick box**
Need for follow-up regulatory action at EU level:	x
Harmonised classification and labelling	x
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

In the course of this RMOA process, the aMSCA identified relevant human health and environmental hazards of melamine and subsequently gathered information under REACH and in a public consultation on uses, exposure and emissions to describe the risk for environment, consumer and workers for the use of melamine.

The aMSCA concludes that melamine meets the criteria to be identified as substance of very high concern (SVHC) according to Art. 57 f) under REACH because of its PMT properties.

Further, the aMSCA suggests to address the reproductive toxicity of melamine by a proposal for harmonised classification for Repr. 2, H361f under CLP.

3.1 Harmonised classification and labelling

Based on the proposal by the aMSCA, RAC adopted an opinion to classify melamine as STOT RE 2, H373 and Carc. 2, H351 on the 10th of December 2020. The respective

harmonised classification of melamine was considered within the 18th ATP of the CLP Regulation and will be included in Annex VI to Regulation (EC) 1272/2008 in due course.

Subsequently, the results of an Extended One-Generation Reproductive Toxicity Study (EOGRTS; EU B.56./OECD TG 443) have been made available, enabling the aMSCA to assess the newly generated data on adverse effects on sexual function and fertility (toxicity to reproduction). Conducted under the respective OECD TG and in compliance with GLP, the EOGRTS data are considered reliable and of high quality. Because of the histopathological changes and altered sperm cell morphology observed in F0/F1 animals, the aMSCA feels confident that classification for effects on fertility is warranted. It is, therefore, the intention of the aMSCA to address the reproductive toxicity of melamine in a proposal for harmonised classification for Repr. 2, H361f under CLP. A respective self-classification (Repr. 2, based on specific effects on male reproductive system [testis, sperm]) has been notified to ECHA by industry.

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

The aMSCA concludes that the substance is very persistent in the environment, is very mobile in aquatic environment and is toxic. Due to the consequence resulting from these substance properties for drinking water resources, drinking water and the remediation, melamine can be considered a relevant substance of very high concern from the environmental perspective. Based on these hazardous properties the aMSCA considers that melamine fulfils the criteria of being of equivalent level of concern (ELOC) according to Art 57 f) of the REACH Regulation.

Candidate Listing will lead to a formal recognition of the SVHC properties and will also support potential subsequent risk management options, if needed. Industry has to acknowledge the SVHC status of melamine and to minimize emissions of this substance to the environment by the help of substance tailored operational conditions and RMMs. Furthermore, Candidate Listing triggers information rights for consumers and the duty to report certain information in the supply chain for industry. SVHC identification as such is considered to encourage substitution of the substance. In several industrial supply chains specific conditions of purchase are already in place for substances of concern. These conditions might include terms like "absence of SVHC in the delivered product" with thresholds for residual SVHC lower than the regulatory triggers.

3.3 Restriction under REACH

Restriction of specific uses of melamine and melamine resins is possible.

According to the risk assessment by the aMSCA, worst-case assumptions point towards a health risk from dermal exposure to melamine used as flame retardant in polyurethane foam mattresses. However, due to significant uncertainties of this risk assessment resulting from insufficient data available together with uncertainties regarding the relevance of this risk for the European market, further confirmation is needed before proceeding to a specific restriction. Moreover, the aMSCA expects that the harmonised classification and labelling of melamine and its identification as SVHC will lead to market changes and a certain pressure towards substitution of melamine also in mattresses. Only if these substitution effects prove to be insufficient, a specific restriction might be required.

3.4 Other Union-wide regulatory measures

3.4.1. Setting an Occupational Exposure Limit for the workplace

The aMSCA identified a risk for the worker, specifically for uses associated with the handling of pure melamine or mixtures with a high amount of unreacted melamine. The aMSCA, taking into account the conservative derivation of the DNEL for risk assessment, assumes on the basis of exemplary measurement data from the public consultation, that worker exposure can be sufficiently reduced by risk management measures (RMM) at the workplace in most cases. Considering the high volume tonnage and wide-dispersive use of melamine, the aMSCA concludes that setting of a specific IOELV for melamine as an union-wide action is the most appropriate regulatory option for protection of the worker. An IOELV at workplaces where pure melamine is handled will draw the attention to RMM for the worker in the scope of an obligatory risk assessment for every use, where melamine is applied (independent of the type of use, e.g. as an intermediate) or even expected to be released. The aMSCA would like to stress that for an efficient implementation of an OEL, practical guidelines for selection of the appropriate RMM are required. In the case of melamine, it could push the selection of RMM according to the S-T-O-P principle and by this way avoiding PPE in cases where technical and organisational measures are clearly preferable. As an EU-MS cannot initiate but bring forward a proposal for an OEL setting, the final decision of setting of an IOELV for melamine would lie in the responsibility of the European Commission.

3.4.2 Release Reduction by Obligations under the Industrial Emissions Directive (2010/75/EU) and Downstream Legislative Provisions

Melamine might qualify as polluting substance for the water compartment according to Annex II, number 4 of the Industrial Emissions Directive due to the adopted opinion for a harmonised classification as STOT RE 2, H373, and Carc. 2, H351.

However, addressing measures for reduction of melamine in BREFs is currently not seen as a profound way forward for risk management by the aMSCA. This is because abatement measures would have to be specified per industrial sector and BREF, respectively. Each individual BREF has an interval of several years for reviewing the current level of processing and abatement techniques applied in the related industrial sector. By following this pathway, risk management may not be able to tackle the most relevant emitters of melamine. In the case that the respective BREF for the major melamine emitters has just been revised, a new revision would not take place for several years and thus emission reduction measures would come into effect very late.

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
Annex XV SVHC dossier	August 2022	DE CA
IOELV		EU-Kom
CLH Dossier	2023	DE CA