MINISTÈRE
DE LA TRANSITION
ÉCOLOGIQUE
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DES TERRITOIRES

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Regulatory Management Option Analysis Conclusion Document

Substance Name: Melamine

EC Number: 203-615-4

CAS Number: 108-78-1

Authority: France

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FOREWORD

The purpose of Regulatory 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].

A 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: https://echa.europa.eu/en/svhc-roadmap-to-2020-implementation

1. OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

Several processes have been completed and are still ongoing under REACH and CLP regulations for melamine.

Regulatory Management Option Analysis

Germany has published a RMOA in June 2022 following an assessment of melamine for its concern regarding persistence, mobility and toxicity properties in order to decide whether further regulatory risk management activities were required for this substance and to identify the most appropriate instrument to address a concern.

The RMOA concluded to the need to identify melamine as a substance of very high concern (SVHC) under REACH Regulation and to revise the harmonised classification under CLP Regulation.

SVHC identification

On the basis of a German dossier, melamine has been identified in January 2023 as a SVHC under article 57(f) (Equivalent level of concern having probable serious effects to human health and the environment) for its properties of very high persistence, high mobility in water, potential for being transported in the water phase over long distances and toxicity.

Discussions at EU level are ongoing to include melamine in the 12th recommendation of ECHA for inclusion in the Authorisation List.

Harmonised Classification

Melamine has a harmonised classification under CLP for its carcinogenicity and its specific toxicity on the urinary tract after repeated exposure (both category 2).

Germany has submitted in September 2023 an intention to update the harmonised classification to address the endpoint of reproductive toxicity and of persistent, mobile, toxic / very persistent, very mobile character.

Endocrine disruptor assessment

In parallel to the work performed by Germany and in the framework of the second National Strategy on Endocrine Disruptor (SNPE 2), the French Competent Authority requested the French Agency for Food, Environmental and Occupational Health Safety (ANSES) to assess the endocrine disrupting profile of melamine in 2019.

The subject of the RMOA is to share the analysis and conclude on this assessment at this point in time.

Table: Completed or ongoing processes

RMOA	☒ Regulatory 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)	

Melamine is also concerned by Regulation n°10/2011 on plastic materials and articles intended to come into contact with food where a specific migration limit is set at 2.5 mg/kg food for the substance.

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:	
Harmonised classification and labelling	X*
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	

* Based on the analysis conducted by ANSES in the RMOA, the French authorities support the intention made by Germany for the revision of the harmonised classification regarding the reproductive toxicity of melamine.

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

Endocrine disruptor assessment

The assessment of ANSES concludes that the endocrine disrupting properties of melamine can't be confirmed with the available dataset.

According to the human health assessment, melamine is able to alter reproductive functions by impairing spermatogenesis but the present set of data display alternative mode of action than endocrine disruption. For the environmental part, in the absence of a demonstrated endocrine mode of action, melamine does not meet the criteria for endocrine disruption as defined by the WHO/IPCS (2002).

The French authorities share the conclusions of ANSES and have therefore no follow-up regulatory action to propose at EU level regarding the endocrine disruptor concern for melamine.

Harmonised Classification

ANSES concludes to the need to classify melamine for the toxic effects on the sexual function which is in line with the German intention to revise the harmonised classification of melamine for this specific endpoint.

The French authorities support the intention made by Germany for the revision of the harmonised classification regarding the reproductive toxicity of melamine.

Tolerable Daily Intake

A Tolerable Daily Intake (TDI) for melamine was determined by EFSA in 2010. In its assessment, ANSES observed deleterious effects on the reproductive function at doses lower than the BMDL10 used for the derivation of the current TDI. These effects were observed in three studies published after the determination of the current TDI.

The French authorities would recommend EFSA to analyse the new available data pointed out by ANSES to possibly consider the revision of the tolerable daily intake

value.

4. NEED FOR ACTION OTHER THAN EU REGULATORY ACTION

No need for action other than EU regulatory action.

5. 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
No Follow-up action		France

The French authorities have no follow-up regulatory action to propose at EU level regarding the endocrine disruptor concern for melamine at this point in time.