MINISTÈRE
DE LA TRANSITION
ÉCOLOGIQUE
ET DE LA COHÉSION
DES TERRITOIRES

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Regulatory Management Option Analysis Conclusion Document

Substance Name: MTBE (tert-butyl methyl ether)

EC Number: 216-653-1

CAS Number: 1634-04-4

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

There are several ongoing or completed processes under REACH and CLP regulations for MTBE.

ECHA has conducted an assessment of regulatory needs in 2020 on branched/cyclic dialiphatic ethers (excluding alpha, beta-unsaturated ethers) that includes MTBE but ECHA was not able to conclude since the substance evaluation for MTBE was ongoing.

France has finalised the substance evaluation in 2021, the corresponding conclusion document[2] was published on the ECHA website in March 2022.

MTBE has also a harmonised classification under CLP as flammable liquid and skin irritant (both category 2).

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)	

[2] https://echa.europa.eu/documents/10162/dbafd544-5671-8b03-980c-37a2bc9291b0

(UNEP) Stockholm convention (POPs Protocol)	☐ Assessment
	☐ In relevant Annex
Other processes / EU legislation	☒ Other (provide further details below)

MTBE is also concerned by the two following EU directives:

o Directive 2009/161/EU establishing a third list of indicative occupational exposure limit values in implementation of Council Directive 98/24/EC and amending Commission Directive 2000/39/EC

Indicative occupational exposure limits are set for MTBE:

Long-term Exposure (LTEL)Values		Short-term Exposure Limit (STEL) Values	
mg/m^3	ppm	mg/m^3	ppm
183.5	50	367	100

o Directive 2009/30/EC amending Directive 98/70/EC as regards the specification of petrol, diesel and gas-oil and introducing a mechanism to monitor and reduce greenhouse gas emissions and amending Council Directive 1999/32/EC as regards the specification of fuel used by inland waterway vessels and repealing Directive 93/12/EEC

A maximum concentration of MTBE for market fuels to be used for vehicles equipped with positive ignition engines is set at 22%.

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	

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

The assessment performed by the French Agency for Food, Environmental and Occupational

Health Safety (ANSES) concludes to the high persistency and the high mobility of MTBE that could lead to a long term and not remediable contamination of drinking water, given the high production volumes.

The regulatory processes for the identification of the hazards of MTBE have been assessed.

Taking into account the recent amendment of the CLP regulation, the identification of the vPvM properties is now possible through a CLH dossier and ANSES considers that MTBE could fulfil the criteria. This will have to be assessed with the upcoming guidance on the new hazard classes in CLP in preparation by ECHA.

The SVHC identification has also been evaluated. The hazardous properties of MTBE are considered to trigger a level of concern equivalent to the PBT/vPvB substances considering the potential of long term and not remediable contamination of drinking water. However, the inclusion of a substance in the candidate list is often a first step towards authorisation and the authorisation provisions do not apply to uses of a substance as fuel, which is the main use of MTBE. Therefore the authorisation process will not be an effective measure to address the risks. For the objective to address the identification of hazards, the CLH process appears to be more appropriate than SVHC.

ANSES has also identified MTBE as a suspected endocrine disruptor for human health according to their own methodology developed through the French national strategy on endocrine disruptors. The opportunity to include this supplemental hazard to the CLH dossier will be evaluated once the updated guidance on the CLP hazard classes will be made available.

As a first step, FR considers that the revision of the harmonised classification of MTBE is relevant for the acknowledgement of the hazards which would imply their consideration in the registration dossiers and information of users.

4. NEED FOR ACTION OTHER THAN EU REGULATORY ACTION

In view of the above, the update of the registration dossiers would now be required already.

Moreover, as ANSES assessment also shows that according to modelisation, environmental risks cannot be excluded for the aquatic compartment in relation to industrial and professional uses, further monitoring data would be useful. The update of the registration dossiers should thus contain recent monitoring data and refined exposure scenarios.

On that basis FR would be able to further assess the appropriateness of a restriction proposal at a later stage.

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
CLH dossier	2024 or 2025	France

France would consider the opportunity to submit a CLH intention when the guidance documents from ECHA on the new hazard classes will be made available.