Risk Management Option Analysis Conclusion Document

Substance Name: tert-butyl-4-methoxyphenol (BHA)

EC Number: 246-563-8

CAS Number: 25013-16-5

Authority: France

Date: January 2015

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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

2. Table: Completed or ongoing processes

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[2]
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

[2] Please specify the relevant entry.

Other processes/ EU legislation	☒ Other (provide further details below)

No ongoing activity other than this RMOA.

A justification document has been produced by Sweden after ECHA proposed BHA for manual screening in 2014.

The table below indicates for each known use of BHA which one is already regulated by specific EU legislation.

Different uses of BHA	**Non REACH regulations**	
food products or feedingstuffs (food additive)	Regulation (EC) No1333/2008	Following EFSA opinions (EFSA, 2011, 2012), BHA is authorized in food produect as a antioxidant preservative (European Parliament and Council Directive 95/2/EC (1995) on food additives other than colours or sweetener). The TDI is set at 0.5 mg/kg/d
food products in animal nutrition	Regulation (EC) No 1831/2003	BHA is authorized in feed produect for animal nutrition, with a maximal concentration set at 150 mg/kg
Food contact material	Regulation (EC) No. 1935/2004	BHA is authorized in food contact material
cosmetics	EU Cosmetic Products Regulation (EC) No 1223/2009	BHA is listed in the EU database of cosmetic ingredient. (CosIng) for its functions as a maskant and ontioxidant.
pharmaceuticals	Regulation (EC) No726/2004,	BHA is listed in the lsit of excipient in medicines with notable effets.

3. 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.

For each conclusion selected in the table below a justification needs to be provided in section 3 of this document. Reasons outlining why a particular risk management option was not considered appropriate can also be included in the relevant section; otherwise subsections can be left blank/deleted if not relevant.

Conclusions	Tick box
Need for follow-up regulatory action at EU level:	
Harmonised classification and labelling	
Identification as SVHC (authorisation)	
Restriction under REACH	X
Other EU-wide regulatory measures	
Need for action other than EU regulatory action	
No action needed at this time	

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

Based on all information available and the uncertainty remaining concerning the reprotoxicity potential and the ED characteristics of the BHA, the recommended management options are the following:

- Propose the substance for targeted evaluation for its ED potential for next year Community Rolling Action Plan.

If the additional information confirm the effects on reproduction and the ED character of the substance:

- Draft a SVHC-57(f) dossier
- Prepare a CLH dossier for reprotoxicity and aquatic toxicity

Depending on the outcome of discussion at the RAC level regarding the relevance of pre-stomach carcinogenic lesions for human:

- Prepare a CLH dossier for carcinogenicity

Finally, it should be noted that it would be worth evaluating/ performing the same analysis of the risk management options on BHT (CAS 128-37-0, 10 000-100 000 t/y) in order to evaluate in which way a grouping approach could be appropriate.

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
Substance evaluation	2015	France