Regulatory Management Option Analysis Conclusion Document

Substance Name: Hazardous chemicals in single use baby diapers

EC Number: -

CAS Number: -

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: http://echa.europa.eu/addressing-chemicals-of-concern/substances-of-potential-concern/svhc-roadmap-to-2020-implementation

1. OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

There is no completed or ongoing processes on hazardous chemicals in single use baby diapers.

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[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
Other processes / EU legislation		☐ Other (provide further details below)

[2] Please specify the relevant entry.

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	
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	

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

Single use baby diapers can contain hazardous chemicals which may cause diseases in susceptible individuals. The quantitative health risk assessment (QHRA) performed by the French Agency for Food, Environmental and Occupational Health Safety (ANSES) showed that health thresholds have been exceeded for several substances, after having applied a refined scenario and reasonably conservative assumptions.

The diseases that may be caused by the use of single use baby diapers may have a significant impact on a person's quality of life, partly because some of the chemicals have CMR properties and because it is a massively adopted practice to use these articles before three years of age, without widely accepted alternatives.

Moreover, to be free of potential symptoms, babies should not wear single use baby diapers containing hazardous substances at a level that can not be demonstrated as safe.

Based on the available scientific literature, it is impossible to estimate how many people in Europe would suffer from diseases that could be attributed to the regular wearing of single use baby diapers until the age of 3.

Considering the elements described above, ANSES considers that there is a need for risk management.

Several RMOs to address the risks identified in this RMOA from chemicals in single-use baby diapers have been discussed and considered by ANSES.

Based on available data, ANSES considers that the most efficient way to regulate hazardous chemicals in single-use baby diapers is to address chemicals at risks using relevant legal instruments available in REACH, namely a restriction under article 68.1. EU wide legally binding restriction in REACH will address the risk for all babies all over Europe, will impose equal conditions for the entire EU market and will make it easier for the companies to set demands on the suppliers.

FR considers restriction under REACH Article 68.1 to be the most appropriate RMO to address the risk from chemicals in single-use baby diapers. Such an option enables regulation of groups of substances at once, applies to EU products as well as imported baby diapers and allows covering different types of hazard endpoints.

TENTATIVE PLAN FOR FOLLOW-UP ACTIONS IF NECESSARY

Follow-up action	Date for follow-up	Actor
Restriction dossier	2020	France