Risk Management Option Analysis Conclusion Document

Substance Name: Tetrafluoroethylene

EC Number: 204-126-9

CAS Number: 116-14-3

Authority: The Health and Safety Authority

Date: October 2018

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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

EU Regulation 1907/2006; Directive 98/24/EC

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	
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

3.1 Harmonised classification and labelling

Tetrafluoroethylene is registered in the 10,000-100,000 p.a. tonnage band. It is used primarily in polymer manufacture (intermediate). Currently it does not have a harmonised classification but there is sufficient evidence to support a harmonised classification as Carc. 1B. Harmonisation of its classification is also important since more than two thirds of the Classification & Labelling Inventory notifications have not self-classified it as Carc 1B.

A harmonised classification of Tetrafluoroethylene would ensure coherent communication in the supply chain and trigger additional and improved risk management actions by all operators utilising this substance. In particular, classification of the substance as Carc. 1b will ensure its inclusion within the scope of Directive 2004/37/EC governing carcinogens and mutagens at work.

As a primary step in improved worker safety, it is concluded to submit a CLH dossier for a harmonised classification for this substance.

4. TENTATIVE PLAN FOR FOLLOW-UP ACTIONS IF NECESSARY

An Annex VI CLH dossier for harmonised classification and labelling has been prepared by the IE Member State Competent Authority.

Follow-up action	Date for follow-up	Actor
Annex VI dossier for harmonised classification and labelling	August 2018	Ireland