Risk Management Option Analysis Conclusion Document

Substance Name: Nonadecafluorodecanoic acid (Perfluorodecanoic acid, PFDA) and its sodium and ammonium salts.

EC Number: 206-400-3, -, 221-470-5

CAS Number: 335-76-2 (acid), 3830-45-3 (sodium salt), 3108-42-7 (ammonium salt)

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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

The Swedish Chemicals Agency has submitted a CLH dossier in November 2014 that concludes that PFDA and its salts should have a harmonized classification as reprotoxic in Category 1B based on Regulation (EC) No 1272/2008. The proposed harmonized classification will be discussed at RAC 35 in December 2015 and, based on public consultation, no major deviations to the conclusions in the CLH proposal are expected. PFDA and its sodium and ammonium salts therefore fulfil the criteria for article 57c in the REACH Regulation.

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 (later stage)	√
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

A CLH dossier has been submitted that concludes that PFDA and its sodium and ammonium salts fulfil the criteria for classification as reprotoxic in Category 1B. The proposed harmonized classification will be discussed at RAC 35 in December 2015.

3.2 Identification as a substance of very high concern, SVHC (first step towards authorisation)

The proposed harmonized classification for PFDA and its sodium and ammonium salts as reprotoxic in Category 1B will be discussed at RAC 35 in December 2015. Based on public consultation, no major deviations to the conclusions in the CLH proposal are expected. PFDA (and its sodium and ammonium salts) can therefore be considered as a substance of high concern for inclusion in the Candidate List according to Article 57c of the REACH Regulation. The persistent and bioaccumulative properties of PFDA are considered to fulfil the P- and B- criteria in accordance to Annex XIII to REACH. Hence, PFDA fulfils the criteria for Article 57d too.

Although PFDA does not fulfil the relevancy criteria according to the SVHC roadmap 2020

(no full registration yet), the identification of PFDA as a PBT substance and also as a possible replacement for PFOA are reasons for inclusion in the Candidate List. Furthermore, an inclusion of PFDA in the Candidate List would clearly establish that the substance has PBT properties and should therefore be substituted wherever possible.

After the inclusion of PFDA and its sodium and ammonium salts in the Candidate List, a restriction of a group of long-chain (C9-C14) PFCAs and their precursors might be considered as a next step, provided that sufficient information on e.g. occurrence in articles and exposure of humans and the environment is available. Experience and the outcome of the ongoing restriction proposal on PFOA will be important to take into account before deciding that a restriction on PFDA and its potential precursors is appropriate.

4. 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 intention**	**Actor**
Annex XV dossier for SVHC	2016 (when harmonized classification adopted by REACH Committee)	Sweden (Swedish Chemicals Agency) and Germany (German Environment Agency)