KEMI
Swedish Chemicals Agency

Risk Management Option Analysis Conclusion Document

Substance Name / EC Number / CAS Number:

C9-C14 PFCAs including their salts and precursors

Substance name	Acronym	CAS-Number	EC-Number
Perfluorononan-1-oic acid (C_9-PFCA)	PFNA	375-95-1	206-801-3
Nonadecafluorodecanoic acid (C_{10}-PFCA)	PFDA	335-76-2	206-400-3
Henicosafluoroundecanoic acid (C_{11}-PFCA)	PFUnDA	2058-94-8	218-165-4
Tricosafluorododecanoic acid (C_{12}-PFCA)	PFDoDA	307-55-1	206-203-2
Pentacosafluorotridecanoic acid (C_{13}-PFCA)	PFTrDA	72629-94-8	276-745-2
Heptacosafluorotetradecanoic acid (C_{14}-PFCA)	PFTDA	376-06-7	206-803-4

Authority:

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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 perfluorinated carboxylic acids (PFCAs) with a chain length of 9 to 14 carbon atoms (C_9-C_{14} PFCAs) have been identified as SVHC-substances under REACH according to their PBT or vPvB properties and are listed in the candidate list. PFNA and PFDA are harmonised classified as Carc Cat 2 and Repr. 1B.

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

3.1 Restriction under REACH

Based on the PBT or vPvB properties of the C_9-C_{14} PFCAs a restriction is needed to minimize the emissions of C_9-C_{14} PFCAs and their related substances to the environment and reduce human exposure to a minimum.

Humans and the environment are exposed to PFASs due to their wide dispersive uses and ubiquitous dispersion in the environment due to their persistence, potential for long range transport and bioaccumulative properties. Taking also into account the available European temporal trend studies, showing increasing levels in human populations and in the environment, and the present registrations under REACH, an EU wide regulation is necessary to minimise the emissions of these substances to the environment

Human exposure to C_9-C_{14} PFCAs via food and drink intake and through exposure to house dust. Food intake is assumed to be a main source of exposure for the general population. The human exposure to these substances can be confirmed via their occurrence in e.g. blood (serum) and breast milk. Temporal trend studies show that the levels of C_9-C_{14} PFCAs are increasing in human populations in the EU, though some recent data indicate a levelling off of the increasing trend.

C_9-C_{14}-PFCAs are ubiquitously distributed in the environment which is confirmed by a large number of studies. Temporal trend studies show increasing levels of these substances in the environment (including biota).

C_9-C_{14} PFCAs have been detected in e.g. water and stain resistant textiles (such as child storm suits), outdoor-jackets, sport clothes and tablecloth. Since 2002, there has been a trend amongst global manufacturers to replace long-chain PFCAs and their potential precursors with chemicals containing shorter perfluoroalkyl chains or non-perfluoroalkyl products. In general, C_9-C_{14}-PFCAs related substances can be replaced with shorter chain fluorinated substances based on C_4 or C_6 chemistry that cannot transform into C_9-C_{14} PFCAs. Alternatives to C_9-C_{14} PFCAs are:

- substances with shorter per- or polyfluorinated chains (e.g. fluorotelomers)
- Perfluoropolyethers (PFPE),
- non-fluorine-containg substances, and
- non chemical techniques

The main concerns of the precursors to C_9-C_{14} PFCAs are that they degrade to C_9-C_{14} PFCAs and shall thus be included in the restriction since they can be regarded as a considerable source of exposure to the PFCAs. According to REACH, Annex XIII, if a substance transforms and/or degrades to a substance with PBT- or vPvB-properties, the substance itself must be regarded as a PBT- or vPvB-substance. Therefore, the hazard profile of C_9-C_{14} applies to these substances as well. A similar grouping procedure has already been used for the restriction of PFOA, its salts and precursors.

Authorisation would not be an optimal risk management option because of the relatively low manufacturing volume in the EU of the C9-C14 PFCAs, their salts and related substances, which suggest a low priority for inclusion in Annex XIV of the REACH Regulation. Moreover, an inclusion in Annex XIV would not include C9-C14 PFCAs, their salts and related substances in imported articles or uses in concentration below 0.1%.

A socioeconomic analysis will be conducted. In light of the PBT/vPvB properties of C_9-C_{14} PFCA we regard a restriction benefit as an insurance against future health- and environmental costs. Future health and environmental damage might be very difficult and costly to reverse once C_9-C_{14} PFC has been released into the environment due to their PBT/vPvB properties.

In conclusion, a restriction on C_9-C_{14} PFCAs, their salts and related precursors is the most appropriate way to limit the risks for human health and the environment on an EU level. Particularly import of articles containing these substances can be regulated this way.

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 follow-up	Actor
Annex XV dossier for restrictions	07 / 2017	DE & SE