Regulatory Management Option Analysis Conclusion Document

Substance Name:	**Per- and polyfluoroalkyl substances, PFAS**
EC Number:	**-**
CAS Number:	**-**
Authority:	**Germany, the Netherlands, Sweden, Norway, Denmark**
Date:	**June 2021**

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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 assess whether further regulatory management measures are needed.

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 authorities. In this conclusion document, the authorities consider 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 authorities. In case the author authorities propose in this conclusion document further regulatory management measures, this shall not be considered initiating those other measures or processes. Since this document only reflects the views of the authorities, it does not preclude Member States or the European Commission from considering or initiating regulatory risk management measures which they deem appropriate.

1. OVERVIEW OF OTHER PROCESSES / EU LEGISLATION

REACH:

For several specific PFAS other processes under REACH are either on-going or have already been completed, including substance evaluation (21 PFAS), RMOA (9 PFAS), SVHC-identification (10 PFAS, including PFOA/APFO, C9 – C14 PFCAs, GenX), restriction (5 restriction proposals submitted so far covering PFAS, including PFOA, C9 – C14 PFCAs, PFHxS, PFHxA including their salts and related substances, respectively).

CLH:

51 CLH proposals for PFAS in the scope of this RMOA (covering 43 active substances in pesticides and/or biocides as well as 8 industrial chemicals registered under REACH) have been submitted to ECHA so far. All of the active substances in plant protection and biocidal products have been classified as Aquatic Acute 1 and Aquatic Chronic 1 or are proposed for this classification. In addition, for the majority an additional classification as toxic for reproduction, carcinogenic, acute toxic or specific target organ toxicity has been adopted or suggested.

Stockholm Convention/POP-Regulation:

Perfluorooctane sulfonic acid (PFOS) and perfluorooctanoic acid (PFOA), their salts and precursors are already regulated in the Stockholm Convention and included in the POP Regulation. Furthermore, PFHxS, its salts and related substances have also been nominated as candidates to be included into the Stockholm Convention and thus into the POP Regulation.

F-gases Regulation:

Regulation (EU) No 517/2014 aims to reduce emissions from industry by 70% in 2030 compared to those in 1990. This reduction is to be realised by three means:

1. Gradual phase-down of the quantities of HFCs used by means of quota. The phase-down only applies to HFCs and not to perfluorocarbons (PFCs) or sulphur hexafluoride (SF6).

2. Prohibitions on use and placement on the market, insofar as technically feasible and more climate friendly alternatives are available.

3. Continuation and expansion of the scope of regulations concerning leak tests, certification, disposal and labelling.

Non-EU legislation:

In addition to EU legislation, relevant regulations for PFAS are in place in other countries, e.g. USA, Canada, New Zealand and Australia.

2. CONCLUSION OF RMOA

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

PFAS in the scope of this RMOA have the following structural formula:

$X\text{-}(\text{-}CF_2\text{-})_n\text{-}X'$ with $n \geq 1$ and X, X' not being H (thus including $X\text{-}CF_3$).

meaning fluorinated substances that contain at least one aliphatic carbon atom that is both, saturated and fully fluorinated, i.e. any chemical with at least one perfluorinated methyl group ($\text{-}CF_3$) or at least one perfluorinated methylene group ($\text{-}CF_2\text{-}$), including branched fluoroalkyl groups and substances containing ether linkages fluoropolymers and side chain fluorinated polymers.

PFAS are a large family of thousands of man-made chemicals that are widely used throughout society. The general and common concern for all PFAS is persistence. PFAS will remain in the environment for ages. All PFAS are, or ultimately transform into, persistent substances. For instance, according to UNEP, perfluorooctanoic acid (PFOA) does not undergo any further abiotic or biotic degradation under relevant environmental conditions. Substances that are transformed into stable PFAS are called PFAS-precursors or "related substances". The extreme persistence of PFAS leading to irreversible environmental exposure and accumulation is a reason for major concern.
Due to their water solubility and mobility, contamination of surface, ground-, and drinking water and soil has occurred in the EU as well as globally and will continue. It has been proven very difficult and extremely costly to remove PFAS when released to the environment.
In general it can be stated that PFAS may cause harm, although exposure levels that are linked to adverse effects show wide variations for individual substances. Some PFAS have been documented as toxic and/or bioaccumulative substances, both with respect to human health as well as the environment.
Without taking action, their concentrations will continue to increase, and their toxic and polluting effects will be difficult to reverse[1]. Actions taken so far have not sufficiently addressed these concerns. This is why a coherent and coordinated EU strategy to address PFAS through regulatory and non-regulatory actions is urgently needed. The goal is to minimise environmental and human exposure to PFAS, at all stages of their life cycle.

3.1 Restriction under REACH

A restriction under the chemicals legislation (REACH) is considered the most effective tool to manage the risk from substances, such as PFAS, that are used in industrial processes but also in products (mixtures and articles). A restriction can ban or include other requirements to address risks (such as use of RMM) during the manufacture, placing on the market or use of a chemical substance, or for a group of substances. It applies also to imported articles and it is flexible, because it can include derogations, unlimited in time or time limited. Therefore, a REACH restriction is an appropriate EU instrument to address PFAS concerns at the source.

In addition, restriction is considered to be the most effective and efficient way to manage such a large and complex group of substances that are used in numerous applications. A broad restriction is, therefore, preferable to authorisation.

A broad restriction under REACH covering all PFAS as a group:

- would be the preferred option, in order to limit as many (non-essential) uses as practically possible. This would have the greatest impact on minimising human and environmental exposure to PFAS,

[1] https://sverigesmiljomal.se/miljomalen/giftfri-miljo/miljogifter-i-modersmjolk-och-blod/

- would also include currently unknown PFAS and uses,
- would prevent regrettable substitution of restricted PFAS by other PFAS.

In the final Annex XV restriction proposal the restriction, including the derogations will be worked out in detail.

4. TENTATIVE PLAN FOR FOLLOW-UP ACTIONS IF NECESSARY

Indication of a tentative plan is not a formal commitment by the authorities. 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	July 2022	Germany, the Netherlands, Sweden, Norway, Denmark