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Bundesanstalt für Arbeitsschutz
und Arbeitsmedizin

Risk Management Option Analysis Conclusion Document

Substance Name: Undecafluorohexanoic acid (PFHxA) including its salts and precursors

EC Number: 206-196-6

CAS Number: 307-24-4

Authority: Germany

Date: 29.09.2017

Version 2.1
October 2015

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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

This document focuses on perfluorohexanoic acid (PFHxA, C6-PFCA) and its precursors. These substances are representatives of the group of per- and polyfluoroalkyl substances (PFASs). They all represent the same structural element; a perfluorinated carbon chain. PFASs are pragmatically divided into long and short-chain representatives, depending on the length of the perfluorinated carbon chain.
Long-chain perfluoroalkyl acids share similar properties, besides their persistence they accumulate in organisms and some of the representatives show toxic effects to humans. Therefore, PFOS, a representative of the long-chain perfluoroalkane sulfonic acids (PFSAs) has already been identified as a persistent organic pollutant (POP) and is thus internationally regulated via the Stockholm Convention. Regulatory activities under REACH for further PFSAs are on the way.

In Europe, three long-chain perfluoroalkyl carboxylic acids (PFCAs) with 8-10 carbon atoms[2] are included in Annex VI of the CLP-regulation, i.a. as reprotoxic substance of category 1B. Under REACH the long-chain PFCAs containing 8-14 carbon atoms and C9 PFSA have been identified as SVHCs because of their PBT or vPvB properties and were added to the Candidate List. Restriction proposals for long-chain PFCAs are implemented (for C8 PFCA, its salts and related substances) or under preparation (for C9-C14 PFCAs).

Because of the regulatory pressure, industry is moving to PFASs with shorter chains. These PFASs are as persistent as long-chain representatives and have in addition a high mobility, especially in the aqueous environment. Already today, short-chain PFASs are increasingly detected in different environmental media, in remote places far from any obvious sources and in drinking water resources including ground water. Even advanced techniques for drinking water treatment are ineffective in removing short-chain PFASs. Therefore, it is of importance to reveal concerns and adverse effects related to their presence in different environmental compartments in order to assess the need for measures to protect the environment.

PFHxA itself is neither registered under REACH nor is it used. However, PFHxA-related substances (precursors), which can be degraded to PFHxA are registered and used within the EU. For grouping purposes of PFASs, the properties of the final degradation products, e.g. PFHxA, are in the focus of the hazard assessment. However, risk management should address all potential precursors as well.

Two precursors of PFHxA, fluorotelomer acrylate (6:2 FTA) and fluorotelomer methacrylate (6:2 FTMA), were listed on the CoRAP for the year 2016, due to potential endocrine disrupting properties, suspected PBT properties and concerns regarding exposure. The process of substance evaluation is not yet finished. Open points from SEV are not targeted by the RMOA.

[2] *perfluorooctanoic acid, (PFOA C8-PFCA), perflurononanoic acid, (PFNA, C9-PFCA), and perflurodecanoic acid (PFDA, C-10 PFCA)*

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:	X
Harmonised classification and labelling	
Identification as SVHC (authorisation)	X
Restriction under REACH	X
Other EU-wide regulatory measures	X
Need for action other than EU regulatory action	X
No action needed at this time	

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

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

PFHxA is a man-made substance without any known natural source. It is very mobile in the aqueous environment given by its high water solubility and low sorption coefficients. PFHxA does not degrade under environmentally relevant conditions and is regarded as very persistent. The high mobility and extreme persistence leads to an effective transport of PFHxA to raw water and to a transport of PFHxA into remote regions. This is demonstrated by environmental monitoring data showing ubiquitous findings of PFHxA in the environment, e.g. in surface waters including rivers and oceans, in groundwater, in drinking water and in biota. The raw water contamination results also in a contamination of drinking water. Once water resources are contaminated, PFHxA cannot be eliminated sufficiently with common measures or even modern technologies. PFHxA is found in remote regions, as for example in the arctic or snow in the European Alps. Besides the distribution of PFHxA itself, also long-range transport of potential precursors of PFHxA could be responsible for these findings of PFHxA.

For assessing the bioaccumulation potential it is known from the assessment of PFOA that BCFs in fish are not the relevant endpoint to consider. PFHxA has non-negligible half-lives in organisms, even though they are shorter compared to those of long-chain PFASs. The protein binding potential of PFHxA is comparable to long-chain PFASs. Due to the extreme persistence, organisms may be permanently and nearly irreversibly exposed, once PFHxA has been emitted. Based on this a final conclusion cannot be drawn, whether PFHxA is bioaccumulative or not. Data on enrichment in food chains is rare. Nevertheless, laboratory studies as well as field studies show enrichment of PFHxA in plants. Overall, it can be concluded that PFHxA is frequently observed in organisms.

Standard data for ecotoxicity of PFHxA does not give reason for concern. However, long-term effects cannot be excluded. Exposure via background concentrations of short-chain PFASs may affect sensible population groups or development stages (Health effects for the human population and environmental endocrine disrupting properties are potentially of concern, but not subject of this evaluation).

In summary, the following concerns regarding PFHxA have been identified in a first assessment:

➔ PFHxA is very persistent.

- ➔ PFHxA is very mobile.
- ➔ Once emitted, PFHxA can only hardly, if at all, be removed from water.
- ➔ PFHxA has a potential for long-range transport.
- ➔ Organisms may be permanently exposed to PFHxA, resulting in continuous exposure to organisms and poorly reversible internal concentrations.
- ➔ There is a high level of uncertainty, if the permanent exposure causes adverse effects in organisms. Due to the prognosticated increasing use of short-chain PFASs (based on substitution of long-chain PFASs), background concentrations might reach toxic levels.
- ➔ PFHxA can enrich in water-rich edible parts of plants.

Considering the precautionary principle (Article 1(3) of the REACH Regulation), the release of very persistent chemicals, resulting in continuous and poorly reversible concentrations in organisms, is considered as of high concern.

The concerns regarding PFHxA match the characteristics of a PBT substance according to guidance R.11 (2014): “What distinguishes the PBT and vPvB substances from other substances is that i) the level of uncertainty in identifying long-term risk cannot be estimated with sufficient accuracy and ii) consequences of an underestimation of adverse effects are not easily reversible by regulatory action, i.e. the effect is occurring or is likely to occur at a certain point in time and, even if there is immediate regulatory action to prevent further emission, the adverse effects will continue.” Due to the extreme persistence and mobility, PFHxA is poorly reversible from the environment, even if regulatory action is taking place. Furthermore, in case of PFHxA, there is a high uncertainty about long-term effects. In conclusion, the above described behaviour of PFHxA in the environment is considered to be of very high concern.

The detailed assessment of these concerns is going to be subject to the next step after the RMOA. The aim of the assessment is to justify that PFHxA is of equivalent level of concern to a PBT or vPvB substance according to Article 57(f).

The relevance of PFHxA is shown by its occurrence in the environment. Even though PFHxA itself is not registered under REACH, several of its potential precursors are registered with tonnage bands from 1 to more than 1000 tonnes per annum. Use and production of these precursors are taking place in Europe. The use areas are broad and release into the environment cannot be excluded. Monitoring data for PFHxA and knowledge from other PFASs show that release into the environment is taking place.

To minimize the exposure of the environment with PFHxA, PFHxA, its salts, and its precursors need to be substituted were technically and economically feasible. The first appropriate risk management option is to assess the concerning intrinsic properties of PFHxA in order to assert that PFHxA raises equivalent level of concern to a PBT or vPvB substance according to article 57(f). An in-depth discussion at MSC-level on the properties of concern of PFHxA will decide on the SVHC status and will facilitate e.g. a restriction process.

Restriction under REACH

Scope of the restriction:

In order to minimize the exposure of the environment to PFHxA the precursors need to be in the scope of risk management. They are used for several applications whereas PFHxA itself has no known use. Therefore, a grouping approach seems appropriate for managing the risk.

Restriction as the most appropriate risk management measure:

In line with risk management for other representatives out of the PFASs group we suggest a restriction as the most appropriate measure to minimize concentrations in the environment. The advantages of the restriction are:

- The possibility to address a group of substances, in this case all potential precursors.
- The possibility to cover imported articles, which in this case is assumed one potential source into the environment.

Alternatives:

There are three types of alternatives to C6 PFCAs (related to the alternatives to long-chain PFASs):

1) substances with shorter per- or polyfluorinated chains e.g. 4:2 fluorotelomer based chemicals and perfluoropolyethers (PFPE) used as alternative processing aids for fluoropolymer manufacturing
2) non-fluorine-containing substances, and
3) non chemical techniques

Table 1: Alternatives to C6 PFCAs

Alternative substances	**Uses**
4:2 fluorotelomer-based chemicals	Replaces especially their higher homologues
Perfluorobutane sulfonyl fluoride (PFBS) or substances based on C-4 perfluorocompounds	Replaces chemicals based on perfluorooctane sulfonyl fluoride
Perfluoropolyethers, PFPE	Fluoropolymer manufacturing
Fluorinated oxetanes	
Other fluorinated polymers	
Fatty alcohol polyglycol ether sulphate	Levelling and wetting agents
Silicone polymers	Impregnation of textiles, leather and carpets
Sulfosuccinates	Wetting agent for paints and coatings
Propylated aromatics (naphtalenes and biphenyls)	Water repelling agents for *e.g.* corrosion protection systems, marine paints, resins, printing inks, electrical and mechanical applications
Other hydrocarbon surfactants	Photographic industry
Stearamidomethyl pyridine chloride	Impregnation of textiles, leather and carpets
Paraffins	Increased water repellence of textiles
Siloxans	
Melamin-resins	

Dendrimers	
Polyurethans	

The technical and economic feasibility of an alternative is heavily influenced by the specific requirements of the user (a company, an industry or sector) of the alternative and the conditions prevailing in the country where the user operates. In addition, determining the technical feasibility of an alternative requires detailed information about the performance for the specific use and expertise to assess this information. Industry points out that even though fluorine-free substances are available for some applications they may not work as well as PFASs in all cases. For example, when durable water and oil repellence or very low surface tension is needed, it is, according to industry, difficult to replace PFASs with a non-fluorine alternative.

However, alternatives have been discussed already in the course of the restriction for PFOA and other long-chain PFASs. Short-chain PFASs persist in the environment and are already ubiquitously distributed in the environment. Because of their mobility, they easily reach water resources and are of concern for drinking water. Therefore, the use of short-chain PFASs as alternatives should be avoided, where possible. Substances/techniques with less concern are already available for a majority of uses or need to be developed.

Socio-economic consequences of the envisaged restriction:

A socioeconomic analysis will be conducted within the process of the restriction. In light of the concerning properties of PFHxA a restriction is seen as a beneficial contribution to avoid future health- and environmental costs. Future health and environmental damage might be very difficult and costly to reverse once precursors of PFHxA have been released into the environment.

In conclusion, a restriction on PFHxA, its salts and related precursors is the most appropriate way to limit the risks for the environment on an EU level. Particularly import of articles containing these substances can be regulated in this way.

3.2 Other Union-wide regulatory measures

Further possible EU-wide regulatory measures have been evaluated. In result these individual measures can due to the wide dispersive uses of PFHxA and respective precursor substances not effectively reduce the overall emissions and are therefore evaluated to be not sufficient.

4. NEED FOR ACTION OTHER THAN EU REGULATORY ACTION

Table 2: Other instruments

Other relevant Instruments	Community wide option for risk management
Stockholm Convention	PFHxA might be proposed as POP in the future. However, it seems to be more effective to start with the assessment of concerns on PFHxA in the frame of an SVHC identification under REACH regulation first.
Further international regulatory activities	Given PFHxA might be present in imported articles, and due to its ubiquitous presence in environmental compartments, it is important to consider initiating world-wide risk management measures.
Voluntary industry activities	Voluntary measures to be initiated by industry might cover phase out of PFHxA and related substances from certain product categories and industrial uses. Furthermore, it might comprise the education of manufacturers, downstream users and consumers regarding the proper use of articles with PFHxA and precursors during its whole life-cycle. Emissions during manufacture might be as far as possible prevented. However, voluntary industry activities might address only certain sectors and applications, therefore they cannot completely prevent emission of PFHxA into the environment.

5. TENTATIVE PLAN FOR FOLLOW-UP ACTIONS IF NECESSARY

Indication of a tentative plan is not a formal commitment by the authority.

Follow-up action	Date for follow-up	Actor
Annex XV dossier for SVHC identification	08 / 2018	DE
Annex XV dossier for Restriction	Following SVHC identification	DE