ANNEX XV RESTRICTION REPORT

PROPOSAL FOR A RESTRICTION

SUBSTANCE NAMES:
Undecafluorohexanoic acid (PFHxA), its salts and related substances

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Abbreviations

AF	assessment factor
AFFF	aqueous film forming foams
ALP	Alkaline phosphatase
ALT	alanine aminotransferase
APFHx	ammonium salt of perfluorohexanoic acid
ASAT	aspartate aminotransferase
BAF	bioaccumulation factor
BCF	bioconcentration factor
BDD	boron doped diamond
BMF	biomagnification factor
CEA	cost effectiveness analysis
CEN	European Committee for Standardization
CMF	ceramic membrane filtration
decaBDE	decabromodiphenyl ether
diPAP	polyfluoroalkyl phosphoric acid diesters
DMEL	derived minimum effect level
DNEL	derived no-effect level
DOC	dissolved organic carbon
DWR	durable water repellent
ECF	edible part concentration factor
EEA	European Economic Area
ERC	environmental release category
EtOH	ethanol
FOD	frequency of detection
FT	fluorotelomer
FT(M)A	fluorotelomer (meth)acrylate
FTAL	fluorotelomer aldehyde
FTCA	fluorotelomer carboxylic acid
FTI	fluorotelomer iodide
FTO	fluorotelomer olefin
FTOH	fluorotelomer alcohol
FTS	fluorotelomersulfonic acid
FTTAoS	fluorotelomer thioether amido sulfonate
FTU	fluorotelomer urethane
FTUCA	fluorotelomer unsaturated carboxylic acid
FTUI	fluorotelomer unsaturated iodide
GAC	granular activated carbon
LC-PFCA	longchain-perfluoroalkyl carboxylic acid
LOAEL	lowest observed adverse effect level
LOD	limit of detection
LOEC	lowest observed effect concentration

LOQ	limit of quantification
MDL	method detection limit
monoPAP	polyfluoroalkyl phosphoric acid monoesters
NaPFHxA	sodium perfluorohexanoate
NOAEC	no observed adverse effect level
NOEC	no observed effect concentration
OCRA	ozofractionative catalysed reagent addition
PAC	powdered activated carbon
PBT	persistent, bioaccumulative and toxic (substance)
PEC	predicted environmental concentration
PFAA	perfluoroalkyl acid
PFAB	polyfluorinated alkyl betaine
PFAL	perfluoroalkyl aldehyde
PFAS	per- and polyfluoroalkyl substance
PFBA	perfluorobutanoic acid, C4-PFCA
PFBS	perfluorobutansulfonic acid
PFCA	perfluoroalkyl carboxylic acid/ perflouroalkyl carboxylate
PFDA	perfluorodecanoic acid, C10-PFCA
PFHpA	perfluoroheptanoic acid, C7-PFCA
PFHxA	perfluorohexanoic acid, C6-PFCA
PFHxS	perfluorohexasulfonic acid
PFNA	perfluorononanoic acid, C9-PFCA
PFOA	perfluorooctanoic acid, C8-PFCA
PFOS	perfluorooctansulfonic acid
PFPA	perfluoralkyl phosphonic acid
PFPeA	perfluoropentanoic acid, C5-PFCA
PFPiA	perfluoroalkyl phosphinic acids
PFPrA	Perfluoropropanoic acid, C3-PFCA
PFSA	perfluoroalkyl sulfonic acid
PFUnDA	Perfluoroundecanoic acid, C11-PFCA
PND	postnatal days
PNEC	predicted no effect concentration
PoD	point of departure
RCR	risk characterisation ratio
Related substance (to PFCAs)	Substances that may degrade to PFCAs (e.g. fluorotelomers and side-chain fluorinated polymers) …
SFP	side-chain fluorinated polymers
sFTOH	secondary fluorotelomer alcohol
SPAC	super-fine powder activated carbon
sRV	standard respiratory volume
TFA	Trifluoroacetic acid, C2-PFCA
TOF	total organic fluorine
TOP assay	total oxidisable precursor assay

vPvB	very persistent and very bioaccumulative (substance)
WWTP	waste water treatment plant
ZVO	German national metal plating assosciation

About this report

The proposal has been prepared using version two of the Annex XV restriction report format and consists of a summary of the proposal, a report setting out the main evidence justifying the proposed restriction and a number of Annexes with more detailed information and analysis as well as details of the references used.

This report has been reviewed for confidential information.

Summary

Due to their unique properties, perfluorinated substances like perfluorohexanoic acid (PFHxA) are used for manufacturing of articles and products in large quantities in the EU. As C8 to C14 perfluorinated substances are or will be soon restricted, manufacturers have shifted to the use of perfluorinated short chain substances (C6 and lower) and perfluorinated ethers, in addition to their already existing uses (e.g. use of the ammonium salt of PFHxA in manufacturing of fluoroelastomers).

PFHxA itself is not registered and used in the EU, therefore no direct release of the acid into the environment is expected. Several PFHxA related substances (substances which have the potential to degrade or be transformed to PFHxA) as well as the ammonium salt of PFHxA are registered with tonnage bands from one to more than 1000 tonnes per annum. Use and manufacture of these PFHxA related substances are taking place in Europe. The sectors of use are broad and release into the environment can be expected. The release of PFHxA from indirect sources occurs among others from impurities of PFHxA in products and articles treated with the precursors and by the following degradation of the precursors. Releases occur particulary during service life and from deposition of the articles. Therefore, a large variety of emission sources contribute to the exposure of humans and the environment to PFHxA. Monitoring data for PFHxA and knowledge from other per- and polyfluoroalkyl substances (PFASs) demonstrates that release into the environment is occurring in reality.

PFHxA, its salts and related substances have a combination of hazardous properties. The PFHx-anion is extremely persistent and by far exceeds the trigger of being vP, it is also mobile in the aquatic environment, can be distributed easily within and between environmental compartments by aqueous media, has a long-range transport potential and has the potential to enrich in plants. Plants are an important source for nutrition. Additionally, due to its mobility PFHxA is found in drinking water. Therefore, nutrition and drinking water are important routes of exposure for humans via the environment. In addition, the substance shows adverse effects in developmental toxicity studies.

For human health impacts standardised risk assessments (DNEL vs. exposure) can be carried out. These suggest that current exposures and emissions to the environment from manufacture and use do not pose a risk for human health at the moment. However, the extreme persistency of PFHxA and any release that occurs contributing to the environmental stock over time, imply uncertainties regarding long-term risks to human health and for the environment. At the point of time the effects are triggered, it will be very difficult to negate the consequences due to the irreversibility of the exposure.

In regard to the extreme persistence of PFHxA and its presence in the environment for decades, the results of standardised (eco)toxicity tests may be of limited value as they do not consider intergenerational effects. This complicates an adequate prediction of toxicity and risks.

Once PFHxA has been released, it will stay in the environment, be distributed on a wide scale and removal is difficult (e.g. for contamination of ground water aquifers, surface water and oceans on a wide scale). As a consequence, future generations will be faced with these contaminations and are already exposed via breast milk.

If emissions of PFHxA into the environment continue, concentrations in the environment and environmental media relevant for human nutrition (e.g. vegetables and drinking water) will increase. In consequence, PFHxA may affect the health of the general population in the future. This has many outcomes for society and the ecosystem, e.g. in the water cycle.

All these concerns also apply to PFHxA-related substances, which can degrade to PFHxA in the environment. Therefore, the hazard profile of PFHxA applies to these substances as well. An EU wide restriction will prevent and reduce the emissions of PFHxA, its salts and related substances within the EU in a harmonised manner. Moreover, a restriction within the EU may be the first step for global action. In order to minimise the exposure of the environment with PFHxA, PFHxA related substances and its salts need to be substituted where technically and economically feasible.

The Dossier Submitter has considered the risk assessment of PFHxA using threshold, non-threshold and 'case-by-case' approaches outlined in Annex I of REACH. The Dossier Submitter concludes that PFHxA should be treated as a non-threshold substance for the purposes of risk assessment, similar to PBT/vPvB substances under the REACH regulation, with any release to and exposure of the environment and environmental monitoring data regarded as a proxy for an unacceptable risk. On the basis of this conclusion the releases of PFHxA, its salts and precursors are considered to pose a risk to the environment that is not sufficiently controlled. National regulatory actions will not adequately manage the risks of PFHxA and related substances. An EU wide restriction would create a more level playing field amongst companies operating on the EU market. A restriction on PFHxA, its salts and related substances is the most appropriate way to limit the risks for human health and the environment on an EU level. On the basis of the analysis of the effectiveness, practicability and monitorability of the risk management options, the following restriction is proposed:

1. Undecafluorohexanoic acid (PFHxA), its salts and related substances[1] (a) Any PFHxA-related substance (including its salts and polymers) having a linear or branched perfluoropentyl group with the formula C_5F_{11}- directly attached to another carbon atom; (b) Any PFHxA-related substance (including its salts and polymers) having a linear or branched perfluorohexyl group with the formula C_6F_{13}-. 2. The following substances are excluded from this designation: (a) C_6F_{13}-X, where X= F;	1. Shall not be manufactured, used or placed on the market as substances on their own; 2. Shall not be used or placed on the market in: (a) another substance, as a constituent, (b) a mixture, (c) an article in a concentration equal to or above 25 ppb for the sum of PFHxA and its salts or 1000 ppb for the sum of PFHxA- related substances. 3. Paragraphs 1 and 2 shall apply 18 months from entry into force of the restriction. 4. Paragraph 2(c) shall not apply to articles placed on the market before the date referred to in paragraph 3.

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[1] PFHxA-related substances are substances that, based upon their structural formulae, are considered to have the potential to degrade or be transformed to undecafluorohexanoic acid.

(b) C_6F_{13}-C(=O)OH, C_6F_{13}-C(=O)O-X′ or C_6F_{13}-CF_2-X′ (where X′ = any group, including salts).	5. Paragraphs 1 and 2 shall not apply until XX XX XXXX [five years after the entry into force] to: (a) hard chrome plating; (b) photographic coatings applied to films; (c) concentrated fire-fighting foam mixtures that were placed on the market before [date – 18 months after the entry into force of this Regulation] and are used or are to be used in the production of other fire-fighting foam mixtures; (d) Paragraph 5 (c) shall not apply to use of fire-fighting foam for training; (e) Paragraph 5 (c) shall not apply to use of fire-fighting for testing unless all releases are contained. 6. Paragraph 1 and 2 shall not apply to concentrated fire-fighting foam mixtures for defence applications – as long as no successful transition to military operable fluorine free foams can be achieved: (a) for seagoing units, air traffic facilities and storage of fuel; (b) for training purposes provided that emissions occur in enclosed areas and wastewater is collected and disposed of safely. 7. Paragraphs 1 and 2 shall not apply until XX XX XXXX [seven years after the entry into force] to: (a) photolithography or etch processes in semiconductor industry; (b) latex printing inks. 8. Paragraphs 1 and 2 shall not apply until XX XX XXXX [12 years after the entry into force] to concentrated fire-fighting foam mixtures for cases of class B fires in storage tanks with a surface area above 500 m^2. 9. Paragraphs 1 and 2 shall not apply to any of the following: (a) a substance that is to be used, or is used as a transported isolated intermediate, provided that the conditions in points (a) to (f) of Article 18(4) of this Regulation are met; (b) personal protective equipment intended to protect users against

	risks as specified in Regulation (EU) 2016/425 of the European Parliament and of the Council, Annex I, Risk Category III (a), (c), (d), (e), (f); (c) non-woven medical textiles; (d) impregnation agents for re-impragnating of articles referred to in paragraph 9(b). 10. From (entry into force + 12 months), a natural or legal person placing an article specified in paragraph 9(b), 9(c) or 9(d) on the market for the first time and benefitting from the derogation therein shall provide by 31 Januar of each calender year a report to the competent authority in the Member State concerned containing: (a) the identity of the substance(s) used in the previous year; (b) the quantity of PFHxA, its salts and PFHxA-related substances used in the previous year. Member States shall forward the data to the Commission by 31 March every year. 11. The concentration limit referred to in paragraph 2 shall be 150 ppm for the sum of PFHxA and its salts in fluoroelastomers used in the following usage groups: Automotive and aerospace industry. This derogation shall not apply to articles referred to in paragraph 2(c). 12. By (entry into force + 6 years), the Commission shall carry out a review of paragraph 6 in the light of new scientific information, including the availability of alternatives for articles referred to in paragraph 6, with a view to proposing amendments. From (entry into force + 12 months), a natural or legal person benefitting from the derogation in paragraph 6 shall provide by 31 January of each calendar year a report to the competent authority in the Member State concerned containing: (a) efforts on substitution of fire-fighting foams that contain PFHxA, its salts and PFHxA-related substances; (b) used quantities in the previous year of fire-fighting foams that contain PFHxA, its salts and PFHxA-related substances per sector specifying:

	(i) share n training and in operation (ii) information on whether emission was contained, collected and disposed safely or emitted into the environment. Member States shall forward the data to the Commission by 31 March every year.

Explanatory notes:

Column 1:

Paragraph 2(a): This is a perfluorinated substance with only fluorine atoms attached and as such is not degraded to the corresponding PFCA as the carbon fluorine bond is known to be very stable.

Column 2:

Fire fighting foam:
Paragraph 5(c), (d), (e): For fire-fighting foam mixtures for a period of time of five years after entry into force of the restriction paragraph 2 shall not apply. After this period of time use, production and placing on the market of fire-fighting foam mixtures shall not be allowed. The specification in 5 (d) and (e) excludes fire-fighting foam mixtures that contain or may contain PFHxA, its salts and PFHxA-related compounds that are used for training and firefighting foams that contain or may contain PFHxA, its salts, and PFHxA-related compounds that are used for testing unless all releases are contained. Thereby only allowing use of fire-fighting foams in cases of emergency and under specific conditions use in testing. If all releases are contained when testing, paragraph 2 shall not apply to fire-fighting foam mixtures used in testing for a period of time of five years after entry into force of the restriction.

Paragraph 6: While some armed forces already transitioned to fluorine free foams and report positive experiences with these foams, other armed forces reported challenges regarding a complete transition due to missing alternatives in the defence sector.

For defence applications an exemption applies as long as a transition due to missing alternatives is not possible for the use in fire-fighting foam mixtures for seagoing units, air traffic facilities and storage of fuel, furthermore, for training purposes provided that emissions occur in enclosed areas and wastewater is collected and disposed of safely.

Paragraph 8: Furthermore, an exemption applies for twelve years after entry into force of the restriction for the use in fire-fighting foam mixtures for cases of class B fires in storage tanks with a surface area above 500 m^2.

The dossier submitter is aware of the project by ECHA and the European Commission, which studies the use of PFASs in fire fighting foams, analyses the alternatives and the impact assessment to provide a basis for the decision on an appropriate regulatory measure and gains information for a possible restriction report. The restriction for PFHxA, its salts and

PFHxA-related substances and respective exemptions for fire-fighting foam mixtures are based on an extensive literature research and stakeholder consultation. However, the respective project might lead to further information that were not taken into account in the present dossier and might lead to different conclusions.

Paragraph 10: Annual reporting on the use of PFHxA, its salts and PFHxA-related substances in the production of personal protective equipment (PPE), non-woven medical textiles and impregnation agents (see Paragraph 9 (b), 9(c) and 9(d)): This will help the European Commission to gather data on the use of these substances in these sectors and to monitor any changes. In the event that the data reveals any concerns for the sector, further actions under REACH can be initiated. The reporting requirement will help to monitor whether there are any changes to uses and quantities which may be an indication to changes in the emissions. The proposed action sends a signal that substitution of PFHxA, its salts and PFHxA-related substances is desirable.

Paragraph 11: Fluoroelastomers used in automotive and aerospace industry are mainly related to proper, efficient and safe engine operating. Fluoroelastomers are used in cases of extreme conditions. They are fuel resistant, tolerate high temperatures and the abrasion during usage is lower than by other elastomers. Accordingly, machine parts like seals, dampers and hoses for fuel-, oil and hydraulic liquids have to be manufactured with fluoroelastomers.

Paragraph 12: The market of fluorine free foams is rapidly developing and testing requirements for fire fighting foams are already being reviewed, regarding changing requirements when assessing fluorine free foams. Therefore, the feasibility of a transition to fluorine free foams in the defence sector shall be possible for all armed forces in the future. That is why the efforts on substitution will be closely monitored.

Annual reporting on the quantities and efforts of substitution of fire-fighting foams that contain PFHxA, its salts and PFHxA-related substances will allow the European Commission to also gather data on the used quantities of these substances and to monitor the developments of alternatives for fire-fighting foams. The reporting requirement will not only help to monitor whether there are any changes to uses and quantities which may be an indication to changes in the emissions, but it will also allow a facilitated re-evaluation of paragraph 6 by the European Commission. The proposed action sends the signal that substitution of PFHxA, its salts and PFHxA-related substances is desirable in the field of fire-fighting foams as well.

Identified hazard and risk

From its intrinsic properties and additional elements relevant for the assessment, various concerns can be described.

- PFHxA is very persistent and mobile and efficiently distributed throughout the aquatic environment (incl. ground water) whereas none of the environmental compartments acts as a removal pathway for the substance.
- PFHxA is transported over long distances and contaminates remote regions.
- PFHxA enters biota and humans via several routes. Humans are continuously exposed via drinking water. Plants accumulating PFHxA are another route for human exposure.
- Exposures and emissions are due to the intrinsic properties difficult to regulate with end-of-pipe solutions. It is difficult to remove PFHxA from wastewater, drinking water and contaminated sites.
- PFHxA, its salts and PFHxA related substances do not occur naturally. However, PFHxA is already ubiquitously present in the environment as shown by monitoring data.
- PFHxA is already present in humans (general population), as shown by findings in breast milk, urine and serum. Experimental studies in animals indicate a placental transfer.
- PFHxA causes long-term and intergenerational exposure of humans and biota – even if releases cease.
- Exposure to PFHxA increases if releases are not minimised.
- PFHxA is also formed from precursors, which complicates the prediction of exposures.
- PFHxA is due to its intrinsic properties causing co-exposure with similar PFASs. PFHxA could be involved in a synergistic effect due to increase of cell membrane permeability.
- PFHxA may cause adverse effects on human health such as relevant reduction in thyroid hormones.
- Problems with PFHxA exposure already occur today (e.g. contamination of soil in Rastatt, Germany and uptake of PFHxA in plants).

PFHxA related substances share one structural element with PFHxA: the perfluorinated carbon chain. PFHxA-related substances additionally contain a moiety which is as a whole non-fluorinated, or has a non-fluorinated part attached to the PFHx-moiety. PFHxA related substances can degrade to the persistent PFHxA in the environment. Therefore, the hazard profiles of PFHxA apply to these substances as well.

PFHxA fulfils the P-criterion and vP-criterion and even by far exceeds these criteria. The data on bioaccumulation and ecotoxicity do not fulfil the B and T criterion in order to identify PFHxA as a PBT or vPvB substance. Nevertheless, PFHxA shows characteristics which do comply with the concerns which are put forward to reason that safe concentrations of PBT/vPvB substances in the environment cannot be established with sufficient reliability. This is due to unpredictable and irreversible adverse effects on the environment or human health over time. For vPvB substances this applies even if no toxicity is demonstrated. This similarity is in particular justified on the extreme persistence of PFHxA. Mobility and longe range transport potential of PFHxA facilitate the unpredictable and irreversible adverse effects over time.

With regard to the extreme persistence of PFHxA and its remain in the environment for decades, the results of standardised (eco)toxicity tests may be of limited value as they do not regard cross generational effects. This complicates an adequate prediction of toxicity. The Dossier Submitter has considered the risk assessment of PFHxA using threshold, non-threshold and 'case-by-case' approaches outlined in Annex I of REACH. There is currently insufficient information and no appropriate tool to:

1. Derive a robust predicted no effect concentration (PNEC).
2. As well as a predicted environmental concentration (PEC) that could be used to underpin a conclusion that risks are adequately controlled, either now or on the future.

Furthermore, its mobility and long-range transport potential are reasons for applying a non-threshold approach to the assessment of these substances.

Based on these considerations, the Dossier Submitter concludes that PFHxA should be treated as a non-threshold substance for the purposes of risk assessment, similar to PBT/vPvB substances under the REACH Regulation, with any release to the environment and environmental monitoring data regarded as a proxy for an unacceptable risk.

Justification that action is required on a Union-wide basis

The risks associated with the uses and imported articles containing PFHxA, its salts and related substances need to be addressed on a Union-wide basis because of two main facts:

- Exposure takes place in all Member States and
- the free movement of goods within the Union.

The restriction on PFOA, PFOA-related substances and its salts will become binding in 2020 with certain derogations. This so called C8-chemistry represents the preferred choice of chain length for almost all fluorinated applications due to its superior properties with regard to quality and cost. A large part of the industry has already substituted C8-based chemicals towards C6-technology (e.g. PFHxA and PFHxA-related substances) or fluorine free alternatives. It can be assumed that the vast majority of the remaining companies using C8-chemistry will substitute to C6 (e.g. PFHxA and PFHxA-related substances) or fluorine free alternatives. Moreover, a restriction within the EU may be the first step for global action.

Effectiveness

Emissions of PFHxA and PFHxA-related substances arise during every lifecycle step of the substances, including manufacture, industrial use, use in consumer products, service life and the disposal phase. PFHxA-related substances significantly contribute to human and environmental exposure of PFHxA since they can be degraded to PFHxA in the environment. Furthermore, imported mixtures and articles, emitting PFHxA and PFHxA-related substances during the service life, constitute relevant emission sources. Imported articlescannot be targeted by other risk management measures than restrictions. Voluntary agreements might contribute to emissions reduction. However, it is questionable whether voluntary measures can be implemented effectively for companies importing into the EU. A restriction covering all emission sources is considered to be the most appropriate union-wide measure that can effectively reduce emissions of PFHxA and PFHxA-related substances. The proposed restriction will ban the manufacturing, placing on the market, and use of PFHxA and PFHxA-related substances after a transitional period of 18 months from the entry coming into force. The restriction will cover PFHxA, its salts and PFHxA-related substances on their own, as a constituent of another substance, in a mixture or in articles. After the restriction comes into force, products containing PFHxA and PFHxA-related substances will not be manufactured in the EU and the substances will not be placed on the EU market, except for the uses where exemptions have been proposed on socio-economic grounds. The exempted uses will constitute relevant emission sources. However, the emissions of PFHxA, its salts and PFHxA-related substances will be reduced by over 95 percent over 20 years in comparison to a non-restriction scenario.

Practicality

The proposed restriction is practical because it is affordable, implementable, enforceable and manageable.

Implementability

The proposed restriction is considered to represent an implementable option for the actors involved within the timeframe of 18 months for most uses. As described in Annex E.2 it appears that for the most part the necessary technology, techniques and alternatives are available and economically feasible. However, for some essential uses alternatives are not available. For other uses alternatives are available but a longer timeframe than 18 months is needed for the adjustment to new technology, techniques and alternatives.

Enforceability

Enforcement authorities can set up efficient supervision mechanisms to monitor industry`s compliance with the proposed restriction. Methods can be easily adapted from the methods to analyse PFOA and longer-chain PFASs. Given that methods exist, the absence of an EU standard analytical method is not considered as a hindrance to the enforceability of the proposed restriction.

Manageability/Monitorability

A joint approach for different enforcement activities such as inspections and testing for the occurrence of serveral regulated PFASs as PFOS, PFOA, C9-C14 PFCAs and PFHxA, its salts and related substances at the same time would lower costs. Thereby, cost effectiveness is enhanced and enforcement costs for PFHxA, its salts and related substances are reduced. Regarding imported articles, border authorities can control compliance using the RAPEX system (Rapid Exchange of Information System) to report any violation of the restriction. A time trend monitoring can be performed with samples from the environment, from animals or from humans. Methods and instruments available in (environmental) specimen banks could be used for such a monitoring.

Report

1 The problem identified

1.1 Introduction

Since the 1950ies, per- and polyfluorinated substances (PFASs) are used in several products and articles. These substances and the polymers containing perfluorinated (side-) chains have unique and valuable physical properties. Articles made of these substances combine high water and grease repellence with a high resistance against environmental influences like against UV-radiation. They are good lubricants and form stable foams. However, some substances like PFOA and PFOS are hazardous to human and environment. Due to their enormous persistency and the difficulties in removal of perfluorinated substances from the environment, these substances enrich in environmental compartments. A long-range transport by water and air to remote areas already was proven. Therefore, some PFASs like PFOS and its derivates or PFOA, its salts and related substances are already restricted or restriction proposals for other PFASs are currently being compiled.

PFHxA, its salts and related substances partially were used as replacement for the restricted substances. However, these substances are also very persistent, mobile and difficult to eliminate from (waste-) water. PFHxA is formed by many precursors. So, PFHxA and its salts are already ubiquitously present in water although there are no natural emission sources. PFHxA and related substances have the potential of long-range transport by e.g. rivers into oceans and by their currents into remote areas. PFHxA was also detected in groundwater. The risk to the environment is currently not adequately controlled.

Due to their listed properties the whole group of PFASs are of increasing concern and currently critically looked at. In the European Council conclusions of June 2019 the council called on the European Commission to develop an action plan to eliminate all no essential uses of PFASs.

1.2 Manufacture and Uses

The majority of PFHxA, its salts and related substances is used for the production of (per-) fluorinated polymers, either as monomers or as processing aids to control polymerisation processes. About 45 000 t/a of fluoropolymers are currently used in Europe. More than 75 percent of these polymers are used for several applications as finishing agents or as repellents e.g. in treating paper, textiles, leather or hard surfaces. Fluoropolymers are also important in manufacturing of machine parts which are used in automotive- and aviation industries or in industrial plant building.

About 55 000 t/a of PFHxA precursors like 6:2 acrylates are used in textile treatment. Thereof, about 75 % of the used precursors could be found in imported textiles. Finishing agents are applied in functional clothing such in outdoor textiles, which provide weather protection and body moisture management to the wearer.

About 3 000 t/a precursors are used in fire extinguisher products. Foams containing perfluorinated substances are used for class B fires (flammable liquids) as well as in special cases for class A fires (combustible materials). The fluorinated surfactants contained in firefighting foams lower the surface tension and allow the formation of an aqueous film between fuel and foam. Especially in aviation, petrochemical industry or for defence applications foams with perfluorinated substances are used.

6:2 FTS (up to 1 000 t/a) is used in hard chrome plating processes as well as in decorative chrome plating processes as surfactant to lower the surface tension of the plating solution. The aim of hard chrome /functional chrome plating is to provide e.g. hardness, corrosion and wear resistance, lubricity and high resistance against chemicals. Hard metal plated parts are used e.g. in automotive industry, aircraft construction, shipbuilding and engineering like hydraulic cylinders and rods, railroad wheel bearings and couplers.

PFHxA related substances are used in different building materials. Fluorinated substances for example are added in paints to improve flow, wetting, and levelling. In coatings, fluorinated substances are used to achieve water, oil or dirt repellent properties and protect building materials from weather influence. Special glass or transparent polymer panels which are used in the solar sector or in transparent building construction are coated with perfluorinated substances.

Perfluorinated substances are used in cosmetic products like in sun lotions to reduce surface tension. These are often mixtures of fluoroalkyl substances with different lengths of the polyfluoroalkyl chain.

The semiconductor industry uses PFASs as processing agents for the photolithography process, etching process and furthermore in cleaning fluids.

PFHxA related substances are detected in floor waxes, stone or wood sealants and wood insulation materials, too.

A small amount of PFHxA related surfactants is used in semiconductor industry for the photolithography process, etching process and furthermore in cleaning fluids. Besides surface activity, also purity and stability of PFASs are relevant properties for semiconductor industry.

Perfluorinated surface active substances are used in inkjets to improve the working of modern printers as well as enhancing picture quality with different media. C6-based fluorinated surfactants are used in small tonnages in photographic equipment or in coatings when manufacturing conventional photographic films.

A general overview is summarized in Figure 1.

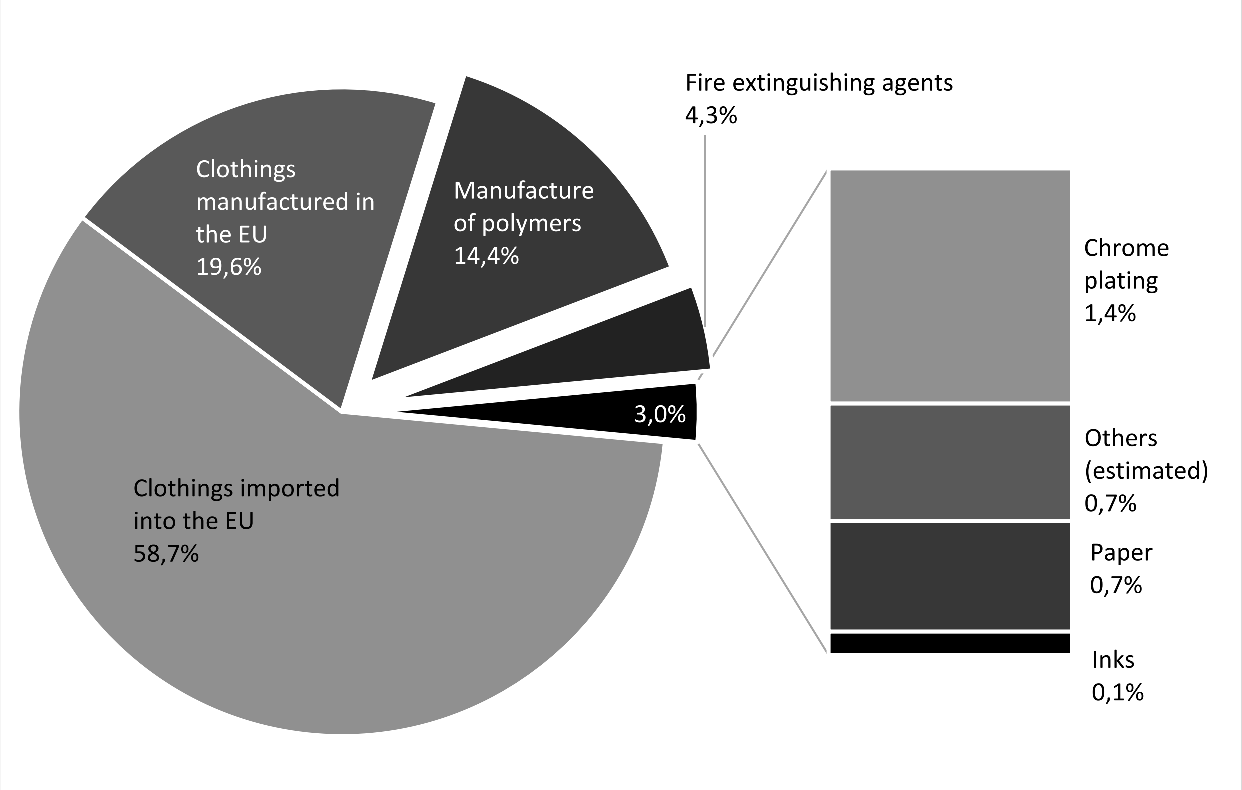


Figure 1: *Current use of PFHxA related substances itemized to the sectors of use in the European Union.*

1.3 Hazard, exposure/emissions and risk

1.3.1 Identity of the substances, and physical and chemical properties

This proposal for restriction covers the substances undecafluorohexanoic acid (PFHxA), its salts and related substances. Related substances mean any related substance (including its salts and polymers) having a linear or branched perfluoropentyl group with the formula C_5F_{11}- directly attached to another carbon atom, as one of the structural elements. In addition, related substances also cover any related substance (including its salts and polymers) having a linear or branched perfluorohexyl group with the formula C_6F_{13}- as one of the structural elements. However, the following substances are excluded from this proposal for restriction:

- — C_6F_{13}-X, where X = F;
- — C_6F_{13}-C(=O)OH, C_6F_{13}-C(=O)O-X′ or C_6F_{13}-CF2-X′ (where X′ = any group, including salts)

The perfluorinated substance with a fluorine atom attached to the C_6F_{13}-group is not degraded to the corresponding PFCA as the carbon fluorine bond is known to be very stable.

Table 1 summarizes chemical and regulative identifiers of the substance PFHxA. The physicochemical properties of PFHxA are listed in Table 4. PFHxA has not been registered yet. Thus, the physical-chemical data rely on publicly available databases, which do neither provide detailed information on the software package nor on which form of the substance (dissociated vs. non-dissociated) or which relevant parameters were used for the calculation.

Table 1: Substance identity of PFHxA.

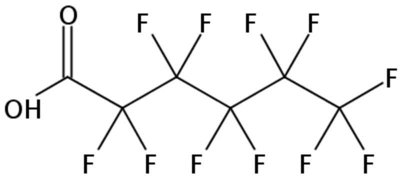
EC number:	206-196-6
EC name:	undecafluorohexanoic acid
CAS number (in the EC inventory):	307-24-4
CAS name:	hexanoic acid, 2,-2,-3,-3,-4,-4,-5,-5,-6,-6,-6-undecafluoro-
IUPAC name:	undecafluorohexanoic acid
Molecular formula:	$C_6HF_{11}O_2$
Molecular weight range:	314.05 g/mol
SMILES Code:	C(=O)(C(C(C(C(C(F)(F)F)(F)F)(F)F)(F)F)(F)F)O
Synonyms:	PFHxA perfluorohexanoic acid
Structural formula:	

Table 2: Substance identity of APFHx.

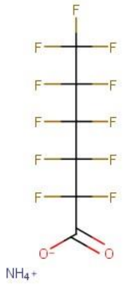
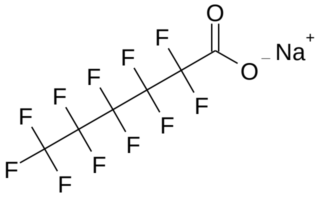
EC number:	244-479-6
EC name:	ammonium undecafluorohexanoate
CAS number (in the EC inventory):	21615-47-4
CAS name:	hexanoic acid, 2,-2,-3,-3,-4,-4,-5,-5,-6,-6,-6-undecafluoro-, ammonium salt (1:1)
IUPAC name:	ammonium undecafluorohexanoate
Molecular formula:	$C_6H_4F_{11}NO_2$
Molecular weight range:	331.08 g/mol
SMILES Code:	[NH4+].[O-]C(=O)C(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)F
Synonyms:	APFHx ammonium perfluorohexanoate
Structural formula:	

Table 3: Substance identity of NaPFHx.

EC number:	220-881-7
EC name:	sodium undecafluorohexanoate
CAS number (in the EC inventory):	2923-26-4
CAS name:	hexanoic acid, 2,-2,-3,-3,-4,-4,-5,-5,-6,-6,-6-undecafluoro-, sodium salt (1:1)
IUPAC name:	sodium undecafluorohexanoate
Molecular formula:	$C_6F_{11}NaO_2$
Molecular weight range:	336.04 g/mol
SMILES Code:	[Na+].[O-]C(=O)C(F)(F)C(F)(F)C(F)(F)C(F)(F)C(F)(F)F
Synonyms:	NaPFHx sodium perfluorohexanoate
Structural formula:	

The free undecafluorohexanoic acid (PFHxA) is in equilibrium with undecafluorohexanoate (PFHx), the conjugate base, in aqueous media in the environment as well as in the laboratory. The physico-chemical properties of PFHxA and PFHx are different. Therefore, the expected environmental fate will depend on the environmental conditions, which influence the equilibrium between base and acid (pH and pKa).

The ammonium salt (APFHx), which is for example used in some animal experiments, is very soluble in water. In aqueous solution it is present as the anion PFHx and the ammonium cation. The dissolved anion PFHx will stay in equilibrium with the corresponding acid in aqueous media. With currently available analytical methods it is not possible to distinguish between PFHx and PFHxA in samples. In the literature reporting human and environmental monitoring studies the concentrations are referred to as PFHxA or APFHx, but always both species (PFHx and PFHxA) are included in the given concentration.

In the following PFHxA refers to the acid (PFHxA) as well as to its conjugate base PFHx. Only in cases where it is important to distinguish between both species and where species specific knowledge is available it is clearly indicated that either the acid PFHxA or the conjugate base PFHx is meant.

Table 4: Overview of physicochemical properties of PFHxA.

Property	Description of key information	Value [Unit]	Reference/source of information
Physical state at 20 °C and 101.3 kPa		liquid	
Melting/freezing point	experimental	12-14 °C	Huang, Bing Nan; Journal of Fluorine Chemistry 1987, V36(1), P49-62
Boiling point	experimental	157 °C	Savu PM; Fluorinated Higher Carboxylic Acids. Kirk-Othmer Encyclopedia of Chemical Technology (1999-2015). New York, NY: John Wiley & Sons. On-line Posting Date: 4 Dec 2000
Vapour pressure	estimated (no experimental value available, unknown reliability of estimated value)	1.98 mm Hg = 264 Pa at 25 °C	US EPA; Estimation Program Interface (EPI) Suite. Ver. 4.11. Nov, 2012. Available from, as of Jan 11, 2015
Density	experimental	1.762 g/mL at 20 °C	Kauck, E. A.; Industrial and Engineering Chemistry 1951, V43, P2332-4
Water solubility	experimental	15.7 g/L (ambient temperature)	Zhao L et al; Chemosphere 114: 51-8 (2014) (Zhao et al., 2014)
Partition coefficient n-octanol/water	estimated	log K_{OW} = 4.06	calc., COSMOtherm (temp. not specified) (Wang et al., 2011)
Dissociation constant	comparison of the sorption behaviours and mechanisms of perfluorosulfonates and perfluoro-carboxylic acids on three kinds of clay minerals.	pK_a = -0.16	Zhao L., Bian J., Zhang Y., Zhu L. and Liu Z.; Chemosphere 114, 51-58 (2014) (Zhao et al., 2014)

1.3.2 Justification for grouping

A grouping of substances in the scope of this restriction proposal is needed to eliminate the risks resulting from the exposure of humans and the environment to PFHxA. There is experimental evidence on degradation of many PFHxA-related substances into PFHxA (Ruan et al., 2013; Zhang et al., 2016; Zhao et al., 2013) (for more details see chapter B.4.1.2). Therefore, these PFHxA-related substances also contribute to the exposure of humans and the environment of PFHxA. Besides such PFHxA-related substances, for which their degradation to PFHxA has already been shown in different studies, other substances (for examples see chapter B.1.1 and Appendix B.4.1) show similarities in their molecular structures compared to PFHxA and related substances for which degradation to PFHxA was shown. This similarity and the nature of the chemical binding of the perfluorinated alkyl moiety to other parts of the molecules lead to the hypothesis, supported by modelling evidence, that formation of PFHxA as result of degradationis very likely, but has simply not yet been investigated in detail. Besides the substances registered under REACH (see chapter A.1.1), further PFHxA-related substances are known which could be used within the EU and may also be imported into the EU via articles and mixtures. A grouping approach via chemical sum formula is therefore the most appropriate way to cover all relevant substances.

1.3.3 Classification and labelling

PFHxA as well as their salts are not listed in Annex VI of CLP Regulation.

For PFHxA, its ammonium salt and some precursors (e.g. 6:2 FTOH, 6:2 FTA, 6:2 FTMA) industry self-classification(s) and labelling for e.g. skin corrosion/irritation, eye irritation, specific target organ toxicity, acute toxicity or hazardous to the aquatic environment are available. Please see chapter B.3 for further information.

1.3.4 Approach to risk assessment

The following sections will summarise the available information on the hazard and risk of PFHxA, its salts and precursors, principally from an environmental perspective. Hazard and risks will be presented in form of a 'weight of evidence'.

This approach is further described in section 1.3.7 (risk characterisation) but as the hazard properties of PFHxA are complex and in many instances uncertain (e.g. a DNEL/PNEC approach nor identification as PBT/vPvB are appropriate) a case-by-case assessment according to para 0.10 of Annex I of REACH will be investigated, underpinned by what can be referred to as their 'extreme' persistence in the environment and the potential for this to result in a non-reversible pollution stock associated with potential for environmental risks. The risk assessment has been supported by an assessment of the releases.

1.3.5 Hazard assessment

Perfluorohexanoic acid (PFHxA) and its salts have a combination of hazardous properties. The substance is extremely persistent and by far exceeds the trigger of being vP, mobile in the aquatic environment, can be distributed easily within and between environmental compartments by aqueous media, has a long-range transport potential and the potential to enrich in plants. In addition, the substance shows adverse effects in developmental toxicity studies.

All these concerns also apply to PFHxA-related substances which can degrade to PFHxA in the environment (see chapter B.4.1.2). Therefore, the hazard profile of PFHxA applies to these substances as well.

From its intrinsic properties and additional elements relevant for the assessment, various concerns can be described:

- PFHxA is very persistent and mobile and is efficiently distributed throughout the aquatic environment (incl. ground water) whereas none of the environmental compartments acts as a removal pathway for the substance.
- PFHxA is transported over long distances and contaminates remote regions.
- PFHxA enters biota and humans via several routes. Humans are continuously exposed via drinking water. Plants accumulating PFHxA are another route for human exposure.
- Exposures and emissions are due to the intrinsic properties difficult to regulate with end-of-pipe solutions. It is difficult to remove PFHxA from wastewater, drinking water and contaminated sites.
- PFHxA, its salts and PFHxA-related substances do not occur naturally. However, PFHxA is already ubiquitously present in the environment as shown by monitoring data.
- PFHxA is already present in humans (general population), as shown by findings in breast milk, urine and serum. Experimental studies in animals indicate a placental transfer.
- PFHxA causes long-term and intergenerational exposure of humans and biota – even if releases cease.
- Exposure to PFHxA increases if releases are not minimized.
- PFHxA is also formed from precursors, which complicates the prediction of exposures.
- PFHxA is due to its intrinsic properties causing co-exposure with similar PFASs. PFHxA could be involved in a synergistic effect due to increase of cell membrane permeability.
- PFHxA may cause adverse effects on human health such as developmental toxicity.
- Problems with PFHxA exposure do already occur today (e.g. contamination of soil in Rastatt, Germany and uptake of PFHxA in plants).

Due to these concerns it is evident that increase of exposure of humans and the environment is unavoidable in the future as well as hardly reversible unless further releases of the substance are prevented by minimisation. Due to the concerns listed above it is not possible to estimate the point of time in the future when effects would be encountered. Additionally, today’s ubiquitous exposure of drinking water is a societal concern. Also future generations will be faced with these contaminations. Furthermore, due to the potential for wide spreading of PFHxA effects will not only occur on the point of release of PFHxA but also far away from its point of release. It will affect a very large number of people.

Degradation

Due to the high stability of the carbon-fluorine bond (Siegemund et al., 2000) PFHxA is considered to be persistent. Structurally similar perfluorinated carboxylic acids with longer carbon chains, e.g. PFOA or C9-C14 PFCAs, were already identified as being (very) persistent fulfilling the persistency criteria of REACH Annex XIII. From the data available for PFOA it can be concluded that no degradation is observable during the test-duration (e.g. 259 days in (Liou et al., 2010)). The hydrolytic half life of 92 years in water was calculated for the structurally similar substance, PFOA (European Chemicals Agency, 2013). Based on read-across also PFHxA is considered being "very persistent". PFCAs including PFHxA do not show any degradation in respective studies and it is not possible to derive half-lives. Therefore, they are considered to by far exceed the trigger of being very persistent (for more details see chapter B.4.1.1).

PFHxA-related substances can degrade to PFHxA in the environment (see chapter B.4.1.2). Therefore, the hazard profile of PFHxA applies to these substances as well.

Removal from the environment, decontamination and purification

The removal of PFHxA from different (environmental) media (e.g. soil and water) is important for example in the following scenarios:

- Purification of wastewater, e.g. in wastewater treatment plants also for industrial plants.
- Production of drinking water from raw water. Often PFHxA is present in raw water (see chapter B.4.2.4) in so-called background concentrations.
- Remediation of contaminated sites, e.g. removal of PFHxA from soil and groundwater after the use of firefighting foam containing PFHxA or its precursors.

Wastewater treatment plants were shown to be a source of PFHxA into the environment via their effluents and sludge (e.g. (Loos et al., 2013), see section B.4.2.4). The usually applied techniques in wastewater treatment plants are not capable of removing PFHxA from the environment. For water treatment plants different studies show that even though different techniques are applied, they do not effectively remove PFHxA from the water (e.g. (Appleman et al., 2014)). Studies investigating more advanced treatment techniques also show a lack of removal of PFHxA ((Lundgren, 2014); (Rahman et al., 2014)).

Exposure

Currently, no exposure model is available which with sufficient granularity and reliability would predict environmental concentrations several years and decades ahead. The challenges for such calculations are:

- The extreme persistence of PFHxA (see chapter B.4.1 and above).
- Emissions already occurred in the past have to be taken into account in the same way as new releases.
- Emissions and subsequent transformation of precursors have to be taken into account as well (see chapter B.4.1.2).

Considering the irreversibility of the exposure and the lack of appropriate tools for estimation, it is very difficult or even impossible to reliably estimate with sufficient certainty current and future environmental concentrations and indirect human exposure of PFHxA.

Environmental distribution

Log K_{OC} values for PFHxA reported in the literature range from 1.3 to 3.6. Also studies under semi-natural (Vierke, 2014) as well as under laboratory condition (Gellrich et al., 2012) show a low to moderate adsorption potential of PFHxA (see chapter B.4.2.1). The water solubility of PFHxA is 15.7 g/L (see chapter 1.3.1). PFHxA has a low to moderate tendency to volatise from water to air (Henry's Law constant of PFHxA is 5.279 Pa m^3 / mol). Based on these properties it can be expected that – once emitted - PFHxA predominantly stays in the aqueous compartments of the environment like surface water, oceans and ground water. In a municipal sewage treatment plant the predominant compartment is water (81 %) followed by primary sludge (8 %) (see chapter B.4.2.3).

Potential for long-range transport

Modelling data indicate a high long-range transport potential for PFHxA (see chapter B.4.3). The calculated atmospheric half-life is 20.57 days, the calculated characteristic travel distance of PFHxA is 9 598 km. This high long-range transport potential is confirmed by findings of PFHxA in remote regions ((Benskin et al., 2012); (Kirchgeorg et al., 2013)).

Bioaccumulation

In oceanic plankton and fish the bioaccumulation observed was low. PFCAs are known to be more bioaccumulative in air-breathing organisms compared to aquatic organisms and elimination half-lives have been proven to be of importance for long-chain PFASs. (ECHA, 2013). Likewise for PFHxA with its high water solubility bioaccumulation in fish may not be the most relevant endpoint to look at. As other PFAS, PFHxA does not accumulate to a large extent in fat but distributes primarily to kidney, liver and blood ((Gannon et al., 2011), (Numata et al., 2014)). Unlike the accumulation in adipose tissue, binding to proteins and accumulation in organs has a higher potential to cause adverse effects. Half-lives of PFHxA in mammals range between 2 - 5 hours for monkeys and rats. The half-life of PFHxA in humans was estimated with a range between 7 and 28 days based on monitoring data of humans (ski wax technicians). Based on the considerably lower half-life reported for PFHxA in comparison to the half-lives of PFOA and PFHxS it is concluded that PFHxA is less bioaccumulative (see chapter B.4.4). However, independent of the half-lives and regardless of the half-life in mammals the non-reversible environmental background concentrations lead to long-term continuous exposure. Substances that have a low bioaccumulation potential could potentially reach similar levels in biota to substances that are known to bioaccumulate, provided that they are sufficiently persistent and mobile in the environment (Peter Fisk Associates Ltd, 2018).

Protein binding

The protein-water distribution coefficient, log K_{PW}, is 4.05 based on BSA (bovine serum albumin) (Bischel et al., 2011). This coefficient is comparable to the distribution coefficient of perfluorooctanoic acid (PFOA). The binding potential to BSA might lead to facilitated tissue distribution of PFHxA – once taken up into the body. This is supported by findings demonstrating that PFHxA is effectively distributed to most organs in the body of pigs (Numata et al., 2014) (see chapter B.4.4.4).

Enrichment in plants

Several studies investigate the uptake of PFHxA from the surrounding environment into plants showing the uptake of PFHxA in plants, especially in the edible parts of plants. The uptake factors range from one to ten for uptake of PFHxA from the nutrient solution into edible parts and roots of lettuce, tomatoes, cabbage and zucchini ((Felizeter et al., 2012); (Felizeter et al., 2014)). Also for maize PFHxA concentrations in shoots were more than two times higher than in roots (Krippner et al., 2014). Also if plants were grown on biosolid amended soils, which contained PFHxA, accumulation factors were up to 12 for lettuce and 6.8 for tomatoes (Blaine et al., 2014) (see chapter B.4.5).

Effects on Human Health

General Remark: It is of note that information on toxicity after repeated administration was obtained mainly from published literature and only occasionally from original study reports.

Based on currently available non-human toxicity studies some effects of PFHxA relevant for human health can be observed. In particular, PFHxA showed some adverse effects in subacute, subchronic and chronic toxicity studies.

Treatment-related changes associated with PFHxA were observed on the amount of thyroid hormones in rats, namely T3 and T4. Furthermore, treatment related mild to minimal degeneration/atrophy of the olfactory epithelium in male and female rats at doses from 250 mg/kg bw/d was observed. Furhtermore, increased relative organ weights of kidney and liver of rats can be noted (NTP, 2018).

In histopathological investigations of kidneys and livers of female rats renal papillary necrosis and renal tubular degeneration were shown at dose 200 mg/kg bw/d (Klaunig et al., 2015).

Toxicity in rats was observed in reproductive toxicity testing with a reduction in body weight at doses of 50 mg/kg bw/d (Chengelis et al., 2009). A developmental toxicity study with mice showed a significant increase in the number of stillborn pups and pups dying on day 0 postpartum at a dose of 500 mg/kg bw/d Hoberman (2011a). There was a significant reduction of the average pup weight per litter on day 0 postpartum observed at 175 mg/kg bw/d and higher doses (Hoberman, 2011b); the reduction showed a dose-related effect. The effects on reproductive toxicity are considered adverse. For further details please see chapter B.5 as well as Appendix B 5.

The combination of extreme persistence in the environment with high protein binding potential might lead to toxicologically relevant systemic exposure. In addition to PFHxA humans are already exposed to several other per- and polyfluorinated substances. Effects resulting from combined exposure are unknown.

Effects in the environment

Studies on aquatic organisms show no effects at environmentally relevant concentrations of PFHxA. In regard to the extreme persistence of PFHxA and its remain in the environment for decades the results of these studies may be of limited value as they do not involve cross generational effects. The presence of other PFASs in the environment that are also highly persistent and act in a similar manner makes it very hard to adequately predict the toxicity. Additionally, PFASs are continuously introduced into aquatic ecosystems and are ubiquitously present in complex mixtures which are not covered by a single substance test. PFHxA could be involved in a synergistic effect due to increase of cell membrane permeability.

Studies assessing endocrine disrupting properties of PFHxA show a concern for PFHxA interaction with the HPT axis based on in vitro data supported by in vivo fish data on homologues (e.g. (Liu et al., 2011); Weiss et al. (2009)), but these data are not sufficient to draw a definite conclusion on whether or not PFHxA is an endocrine disruptor in the environment.

PFHxA is extremely persistent and mobile and efficiently distributed throughout the aquatic environment

Its environmental distribution properties (see previous section) make PFHxA mobile in the aquatic environment. Due to the global water cycle, the aqueous compartments are all well connected, e.g. rivers and oceans. Once PFHxA has entered the environment, e.g. in a surface water body, there is no natural barrier to prevent PFHxA from being distributed to oceans and to groundwater. If PFHxA enters soil, it will be transported further to ground water. Sediment and soil do not function as sink for the substance in similar manner as for, e.g., heavy metals or most of persistent organic pollutants (see chapter B.4.2.3). To summarise, PFHxA releases to the environment are of relevance on a great spatial scale even though sources would be geographically limited.

PFHxA contaminates remote regions

The combination of the extreme persistency and the high mobility of PFHxA also leads to long distance transport processes in the environment. Transport is taking place via the atmosphere or with ocean currents and not only PFHxA itself but also its precursors are subject to transport (see chapter B.4.3). That transport is taking place is proven by data from monitoring, showing the occurrence of PFHxA in remote regions. Therefore, PFHxA might affect humans and the environment far away from its point of emission into the environment. Vulnerable populations and ecosystems in remote regions are also affected by this.

PFHxA enters the biosphere and humans via several routes

Biota are exposed to PFHxA mainly via food web (especially plants) and surface water, and to lesser extent via air. PFHxA concentrations in biota are often reported below the limit of detection or mainly in the low nanogram per gram range. However, there is a significant increasing trend for some short-chained perfluoroalkyl acids (PFAAs) from 2002 to 2014 (Lam et al., 2016). For instance, the ratio of perfluorobutansulfonic acid (PFBS) as an alternative to perfluorooctansulfonic acid (PFOS) has significantly increased. Hence, PFHxA concentrations in biota may increase in the future if used as an alternative for restricted PFAAs.

Drinking water is a source of direct exposure of humans to PFHxA as drinking water is contaminated with PFHxA ((Gellrich et al., 2012); (Llorca et al., 2012); (Ullah et al., 2011); (Eschauzier et al., 2012)). Monitoring data show that drinking water tested within the EU contains PFHxA up to 40 ng/L (see chapter B.4.2.4).

Furthermore, food consumption, more in detail vegetables, function as source of PFHxA to humans. Because of its high water solubility, PFHxA enriches in plants, especially in edible parts of plants (see chapter B.4.5). This is of relevance for example when agricultural soil is contaminated with PFHxA (and/or some precursors), leading to the contamination of agricultural plants. Via plants, PFHxA enters the food chains of humans and animals.

Independent of the half-life in humans, the non-reversible environmental background concentrations, e.g. in drinking water and nutrition, lead to long-term continuous human exposure.

Exposures and emissions are due to the intrinsic properties difficult to regulate with end-of-pipe solutions

It is very difficult to remove PFHxA from water due to its properties summarised in chapter B.4.6. Techniques for purification of water installed today are mostly not able to remove PFHxA from water. This is of relevance for the production of drinking water from raw water, for the treatment of wastewaster as well as for the remediation of contaminated sites. Once drinking water resources are contaminated with PFHxA it is technically very difficult and currently not economically feasible to remove PFHxA from water. Therefore, if a human activity causes a release of PFHxA, the exposure of the environment and humans via the environment is difficult to prevent and is irreversible.

PFHxA is already ubiquitously present in the environment

There is no natural source known for PFHxA in the environment; nevertheless PFHxA is found ubiquitously in the aqueous environment, like groundwater (e.g. (Gellrich et al., 2012); (Eschauzier et al., 2013); (Houtz et al., 2013)) and surface waters and oceans (e.g. (Benskin et al., 2012); (Ahrens et al., 2010); (Zhao et al., 2012); (Gellrich et al., 2012)) (see chapter B.4.2.4).

Humans (general population) are already exposed to PFHxA

In human tissue PFHxA can already be found, proving that exposure is taking place. PFHxA has been found in humans (serum, urine, breast milk and/or hair) from the US, Canada, China, Germany, Sweden, Poland, Italy, South Korea and Austria (see chapter B.4.4.2). PFHxA concentrations in human serum are often reported below the limit of detection. However, there are indications that higher concentrations could be found in urine and hair than in serum.

PFHxA causes long-term and intergenerational exposure of humans and biota – even if releases have ceased

Once PFHxA is released, PFHxA will remain in the environment for decades to centuries (Cousins et al., 2016). This is because of the extreme persistence of PFHxA. Half-lives of PFHxA in the environment are not known, but are expected to clearly exceed the threshold values for being “very persistent” (vP) defined in REACH Annex XIII. The hydrolytic half-life of 92 years in water was calculated for the structurally similar substance, PFOA. Therefore, even if PFHxA emissions will be stopped, background concentrations of PFHxA, e.g. in surface water, oceans as well as groundwater, will remain.

Taken together this leads to the fact, that all effects related to environmental exposure with PFHxA might occur with delay and are not limited to the present time, but will also be an issue for future generations. In addition, future generations are exposed to PFHxA via human breast milk.

Exposure to PFHxA increases if releases are not minimised

As long as PFHxA emissions to the environment – also from degradation of precursors - continue, concentrations in the environment will increase. These new emissions will be cumulative to what is already there, leading to a built-up of the substance in the environment over time.

Formation of PFHxA from precursors

PFHxA is formed in the environment as a degradation product of several precursors (see chapter B.4.1.2). The yield of PFHxA formation strongly depends on the type of precursor as well as type of degradation (e.g. biotic or abiotic). In some cases degradation pathways are very complex, covering many degradation intermediates, partly leading to a slow formation rate of PFHxA. The exact number of precursors available on the market is unknown, but known precursors cover a broad range of uses and possible release patterns into the environment.

Co-exposure of the environment with other PFASs

Environmental media are not only exposed to PFHxA but also to other PFASs. For example in groundwater used for the production of drinking water several different PFASs are present (see chapter B 4.2.4). Many of those measured PFASs (e.g. PFOA and other long-chain perfluoroalkyl acids) are also known to be very persistent. Some of them also have toxic effects (e.g. toxic for reproduction). Similar to PFHxA also these PFASs are degradation products of several different precursors. Overall, the strong persistency in combination with the formation from precursors makes it very difficult to reliably estimate environmental long-term co-exposure with different PFASs.

1.3.6 Exposure/Emissions assessment

Due to its inherent properties large amounts of the salts of PFHxA and PFHxA-related substances are manufactured and used in the EU. The used tonnage covers import and export of the substances and articles. The release of PFHxA, its salts and related substances into the environment by the various uses is in general wide dispersive. Currently no exposure model is available, which with sufficient granularity and reliability would predict exposures several years and decades ahead. The challenges for such calculations are:

- The extreme persistence of PFHxA (see chapter B.4.1 and above).
- Emissions already occurred in the past have to be taken into account in the same way as new releases.
- Emissions and subsequent transformation of precursors have to be taken into account as well (see chapter B.4.1.2).

Considering the irreversibility of the exposure and the lack of appropriate tools for estimation, it is very difficult if not impossible to reliably estimate with sufficient certainty current and future environmental concentrations and indirect human exposure of PFHxA.

Direct sources

PFHxA itself is not registered and used in the EU, therefore no direct release of the acid into the environment is expected. The ammonium salt of perfluorohexanoic acid (APFHx) is used as processing aid in fluoroelastomer manufacture at industrial sites (10 -100 t/a). APFHx is imported as a watery solution into the EU. The release by manufacturing the fluoroelastomers is considered as very low (below 10 kg/a). The ammonium salt may occur as impurity in these fluoroelastomers. Applying the default release factors, up to 300 kg/a of the ammonium salt may be released to water and soil, respectively. Assuming, a low release of APFHx by leachate from landfills up to 200 kg may be released into water annually. However, the estimated number of unreported releases could be much higher.

Indirect sources

The release of PFHxA from indirect sources occurs among others from impurities of PFHxA in products and articles treated with the precursors and by degradation of the precursors. 6:2 Fluorotelomer iodides as well as 6:2 fluorotelomer alcohols are intermediates to produce 6:2 acrylates (like 6:2 fluorotelomer acrylate (FTA) as of 6:2 fluorotelomer methacrylate (FTMA)). These 6:2 acrylates are monomers for manufacturing of acrylate polymers with C6 fluorinated side chains. These PFHxA precursors are further used as surface-active agents. Therefore, these substances are used between 1 000 to 10 000 t/a. The release of C6 fluorochemicals into the environment at manufacture of the precursors and at manufacture of articles containing these substances is assumed to be low (< 150 kg /a). The majority of substances is regained and recycled at the manufacturing process (according to statements of manufacturers).

However, the C6 fluorochemicals are released at service life and from deposition of the articles containing these substances in large quantities. Due to its properties these substances may be released into air, water and soil. These substances are very soluble in water and they accumulate in water. By degradation these substances contribute to the indirect emission of PFHxA into the environment. Many precursors of 6:2 fluorotelomer alcohol (FTOH) degrade very quickly to the acid. Therefore, the degradation of 6:2 FTOH to PFHxA is used as surrogate for the degradation of precursors. Using data gained by several authors, about 39 kg PFHxA are emitted by one tonne 6:2 FTOH (e.g. Liu 2010, Zhao 2013).

The largest sector of use of C6 fluorochemicals is the manufacture of polymers with C6 side chains and the following use of these copolymers: The polymers may contain C6 fluorochemicals as impurity. At aging process of these polymers, the fluorinated sidechain may be dissociated from the backbone. However, this process is very slow. According to the investigations from Lang et al. 2010, per tonne acrylate polymers containing C6 side chains, up to 425 mg PFHxA /a are released mainly into water in average. This amount seems to be very low. However, considering an average service life of ten years of the polymers in connection with the article it contains and a following deposit of 60 % of the articles and products, surface soils and landfills constitute a major global reservoir for PFAS for decades.

The C6 fluorochemicals itself and the polymers containing C6 side chains are used in various sectors of uses. A large sector is the textile sector. In the European Economic Area (EEA) there are more than 61 000 installations that may use or emit PFAS in this sector (Goldenman, 2019). The most important uses in the textile sector are uses for household textiles (e.g. furniture, carpets, curtains, awnings) for occupational and outdoor wear and for clothing in general. From overall textile articles manufactured in the EU, about 430 t/a 6:2 FTOH may be released into air and water during the service life, which results in an indirect release of PFHxA of 17 t/a. By the following deposition in landfills, about 10 t/a PFHxA may be released into the environment by textiles in general.

Several textile subsectors contribute to the emission of PFHxA, its salts and related substances into the environment. One of the largest sectors is the manufacture of clothing. Only one third of garments is manufactured in the EU. The bulk of garments is imported from the Asia-Pacific region, e.g. from China, Vietnam or from Indonesia. Therefore, two thirds of PFHxA released into the European environment originates from those textiles.

Of 150 000 t/a of outdoor clothes used in Europe, about 37.5 t/a of 6:2 FTOH are released into the environment. Finally, together with direct releases of PFHxA, in summary 5.5 t/a of PFHxA are released during the service life of outdoor clothes. From in landfill deposited outdoor clothes a release of about 3.3 t/a PFHxA could be assumed.

In Europe about 95 000 t/a of occupational wear are used. It is assumed that 14 t/a of 6:2 FTOH are released into the environment, resulting in a release of 0.5 t/a PFHxA. In summary, 0.9 t/a of PFHxA are released into the environment during the service life of occupational wear by direct and indirect emission. About 0.6 t/a PFHxA are released from landfills by occupational wear.

About 200 000 t of textile floor coverings were used in Europe in 2018. From these textiles 59 t of 6:2 FTOH were released. In summary, during the life cycle of floor coverings 3 t/a of PFHxA are released by indirect and direct sources. The release from landfills is about 3 t/a.

An important textile sector is industrial textile fabrics, like truck tarpaulins. About 100 000 t/a were used in Europe in 2018. Summarising the directly and indirectly emitted quantity of PFHxA, during the service life of industrial fabrics about 132 kg/a are released into air, and 8 t/a are released into water and soil, respectively. From deposited industrial fabrics a release of 5 t/a into water and soil, respectively could be expected.
Due to the uncertainties and due to data gaps, it is not justified to simply summarise the individual contributions of different subsectors.

Evaluating data from the UN comtrade database, about 47 000 t of grease proof paper were used in Europe in 2018. From grease proof paper 1.4 t/a PFHxA are released from direct and indirect sources during its life cycle in Europe. Via landfills about 2.5 t/a PFHxA are released into the environment.

For firefighting foams in general fluorosurfactants like PFHxA and 6:2 FTOH are in use. Only in few cases polymeric substances may be added to the foam concentrate. For professional firefighting an annual use of fluorosurfactant containing firefighting foam concentrate of about 11 000 t was estimated in Europe (personal communication Blunk, University of Cologne 2017). About 14.6 t of PFHxA are released into the European environment annually by professional firefighting operations and about 5.5 t/PFHxA are released at fire operations by volunteer brigades.

Fluorinated substances are applied via laqueurs, coatings and paints to a large amount of very different building materials to improve flow, wetting, and levelling. Primarily water-based paints require these properties and PFASs can be present at concentrations of about 0.05

percent here (European Chemicals Agency, 2018). There are currently no sufficient data available on tonnages used in those applications and for the release of perfluorinated substances from building and construction. Therefore, a quantitative exposure assessment is not feasible. The main use of coatings with fluorosurfactants especially is on roofs and on frontages of buildings. So, a direct release of significant amounts of perfluorinated surfactants from the sector building and construction into the environment is considered as very likely.

For chrome plating 6:2 FTS is used as surfactant mainly as a mist suppressing agent. Emissions of 6:2 fluorotelomer sulfonic acid (FTS) during plating processes originate e.g. from the rinsing steps between the electrolytes and from replacement of used solutions (Blepp et al., 2017). Chromate solution containing the most suppressing agent has a limited usage lifetime and has to be changed regularly. In the EU a use of about 800 t/a 6:2 FTS is assumed. About 160 t/a 6:2 FTS are released by chrome plating into water via waste water treatment plants (WWTP). This yields in a release of about 6 t/a of PFHxA into water.

Perfluorinated substances are added to printing inks for hydrophobisation of surfaces, for example for textiles, papers, glasses, building materials, and adsorbents. In addition, it is possible that perfluorinated surfactants are used as interface promoters, emulsifiers or viscosity reducers in paints, coatings or adhesives (UNEP, 2012b). Mainly C6 based short-chain fluorinated surfactants are used in some water based inkjet inks and latex inks. In Europe about 15 t/a of these substances are probably used (this value is not reliable because there were lots of uncertainties in the statements of stakeholders). Based on this worst case assumption 330 kg/a of the precursors (= 13 kg PFHxA) are released to air at formulation, 150 kg/a of the precursors (= 6 kg PFHxA) are released into the air during application process and, during the imprinted paper service life, about 7.3 t/a of the precursors, resulting in about 280 kg/a PFHxA, are released into air and from air into water. From the deposited imprinted paper the release of about 3 t of the C6 based short-chain fluorinated surfactants (= 175 kg/a PFHxA) into water could be assumed.

C6-based fluorinated surfactants are used in small tonnages in photographic equipment or in coatings when manufacturing conventional photographic films (Stakeholder Consultation, 2018). For this sector no data is available. However, due to the small used tonnage in this sector the release of PFHxA and its related substances is considered as very low.

The overall amount of PFASs used in semi conductor industry is assumed to be < 10 t/a (Stakeholder Consultation, 2018). PFHxA and its related substances represent only a considerable small amount from the total PFASs that are in use. In the effluents from a semiconductor plant in Taiwan the measured concentration of PFHxA was 71.5 ± 16.5 ng/L. In contrast to the concentrations of other PFASs, e.g. PFOS, the following concentration was measured: 5663.3 ± 427.4 ng/L (Lin et al., 2010). An increase in use of PFHxA, its salts and related substances due to the restriction of PFOA is currently not likely. Thus the possible emissions of PFHxA from the process of semiconductor manufacture and by the subsequent service life of microchips is considered as very low.

Concluding, there are no known uses of PFHxA itself in the EU. Large quantities of PFHxA precursors are used in and for manufacturing of fluorinated polymers. These polymers are mainly used in textile and paper treatment. Together with the articles, the polymers are deposited in landfills. Polymers may degrade to a certain extent over very long timescales. The annual release of PFHxA from polymer degradation is in the range of milligram per year. However, the articles and products containing these polymers deposited in landfills are a major global reservoir for PFASs for centuries. In contrast, the majority of PFHxA (about 1 000 t/a) is released into the European environment (mainly into water) and results from degradation of precursors like 6:2 FTOH that are used in several products and articles.

1.3.7 Risk characterisation

Risk assessment of chemicals under REACH can be performed in several ways, depending on the hazard properties of the substance. A range of risk assessment paradigms will be considered in this report, specifically.

'Conventional' (eco)toxicological risk assessment based on the derivation of an effects threshold (PNEC) and a quantitative risk characterisation (PEC/PNEC or RCR approach)

Considering the irreversibility of the exposure, the lack of appropriate tools for estimation, it is very difficult if not impossible to reliably estimate with sufficient certainty current and future environmental concentrations and indirect human exposure of PFHxA. Furthermore, PFHxA is formed in the environment as a degradation product of several precursors. The exact number of precursors available on the market is unknown, but known precursors cover a broad range of uses and possible release patterns into the environment. Therefore, derivation of an acceptable amount of release into the environment is not possible.

With regard to the extreme persistence of PFHxA and its expected presence in the environment for decades, the results of standardised (eco)toxicity tests may be of limited value as they do not cover cross generational effects. This complicates an adequate prediction of toxicity.

For human health impacts standardised risk assessments can be carried out. These suggest that exposure does not pose a risk for human health at the moment. However, the extreme persistency of PFHxA and that any releases that occur contribute to the environmental stock over time imply uncertainties regarding risks to human health that are similar to the long-term risks for the environment. It is not possible to reliably estimate the point of time when effects are triggered. At the point of time the effects are triggered, it will be, however, very difficult to reverse the effects due to the irreversibility of the exposure.

In conclusion there is currently insufficient information on cross generational ecotoxicological effects to derive a robust predicted no effect concentration (PNEC) as well as a predicted environmental concentration (PEC) that could be used to underpin a conclusion that risks are adequately controlled, either now or in the future.

PBT /vPvB perspective

PBT/vPvB substances give rise to specific concerns due to their potential to lead to unpredictable and irreversible adverse effects on the environment or human health over time. In this respect, the hazard of PFHxA appears similar to that posed by PBT/vPvB substances.

Specifically, exposure to PBT/vPvB may lead to an impact in a manner which is difficult to predict and difficult to prove by testing, regardless of whether there are specific effects already known or not. In the case of vPvB substances, there is concern that even if no toxicity is demonstrated in laboratory testing, long-term effects might be possible since being very persistent, high levels with unpredictable effects may be reached in humans or the environment over extended time periods.

Recognising these concerns, the REACH Regulation established that 'safe' concentrations of PBT/vPvB substances in the environment cannot be established with sufficient reliability for undertaking quantitative risk assessment. Therefore, registrants of PBT/vPvB substances are obliged to implement, and recommend to downstream users, risk management measures (RMMs) which minimise releases to environmental compartments throughout the lifecycle of the substance. Risk management, such as authorisation or restriction, may be required to ensure that the minimisation of releases is achieved.

Persistency: The stability of organic fluorine compounds has been described in detail by Siegemund et al.: "When all valences of a carbon chain are satisfied by fluorine, the zig-zag-shaped carbon skeleton is twisted out of its plane in the form of a helix. This situation allows the electronegative fluorine substituents to envelope the carbon skeleton completely and shield it from chemical attack. Several other properties of the carbon-fluorine bond contribute to the fact that highly fluorinated alkanes are the most stable organic compounds. These include polarizability and high bond energies, which increase with increasing substitution by fluorine. The influence of fluorine is greatest in highly fluorinated and perfluorinated compounds. Properties that are exploited commercially include high thermal and chemical stability" (Siegemund et al., 2000).

Based on their molecular properties perfluorinated compounds can be expected to be poorly degradable.

Half-lives of PFHxA in the environment are not known. However, considering the organic chemistry of the substance group of perfluorinated carboxylic acids, it seems to be very likely that PFHxA is as resistant to degradation as PFOA. For PFOA a half life of 92 years in water was calculated (European Chemicals Agency, 2013).

In summary, PFHxA is very persistent according to the criteria of Annex XIII to REACH (see also section B.4.1.1). Moreover, its rate of abiotic or biotic degradation under relevant environmental conditions is expected to be slow. The degradation half-life is expected to clearly exceed the triggers for being vP.

Bioaccumulation: The biomagnification as well as the bioconcentration of short-chain PFAS in laboratory studies with fish is low. According to the bioconcentration factor (BCF) criteria outlined in REACH Annex XIII (see section B 4.4) the B criterion is not fulfilled. This approach, however, only addresses one compartment, i.e. water, and water breathing organisms, i.e. fish. Elimination half-lives have been proven to be of importance for long-chain PFASs such as PFOA. In general, the reported half-lives for PFHxA in mammals are considerably lower when compared to PFOA. Based on the considerably lower half-life reported for PFHxA in comparison to the half-lives of PFOA and perfluorohexansulfonic acid (PFHxS), it is concluded that PFHxA is less bioaccumulative. However, independent of the half-lives and regardless of the half-life in mammals the non-reversible environmental background concentrations lead to long-term continuous exposure. Additionally, PFHxA has a strong binding potential to proteins, which may facilitate tissue distribution. Toxicokinetic studies show that PFHxA becomes well distributed within the organisms, mainly plasma, kidney and liver in rats and mice, but in comparison to long-chain PFAAs PFHxA is rapidly eliminated via the urine. It should however be noted that PFHxA represented the highest median PFAS-concentrations in brain and liver in humans.

In conclusion, PFHxA shows properties of concern such as strong binding potential to proteins and an effectice distribution within organisms. However, it does not fulfil the bioaccumulation criteria of Annex XIII to REACH.

Ecotoxicity**:** Standard tests on ecotoxicity are available for algae, daphnia and fish covering acute as well as chronic toxicity. In the study of (Hoke et al., 2012) no effects on fish and daphnia in the acute toxicity tests were observable up to > 99.2 mg/L and > 96.5 mg/L respectively. No effects were observable for algae up to 100 mg/L.

(Barmentlo et al., 2015) report an EC_{50}-value of 1048 mg/L for acute toxicity on daphnia. The acute toxicity of PFHxA on Baltic microalgae investigated by (Latala et al., 2009) is 998.7 mg/L for *Geitlerinema amphibium* and 4032 mg/L for *Chlorella vulgaris. Scenedesmus subspicatus* seems to be considerably more sensitive as an EC_{50}-value of 86 mg/L and a NOEC of 50 mg/L is reported (ENVIRON, 2014). Long-term effects on hatching success, survival, length and weight of *Oncorhynchus mykiss* were not observable up to > 9.96 mg/L (Burke, 2008). The reported EC_{50} (21d) value based on reproduction of daphnia is 776 mg/L. The EC_5 (21d) value is not considerably lower (724 mg/L) (Barmentlo et al., 2015). Likewise there is no considerable difference between EC_{50} (21d) and EC_5 (21d) based on population growth rate (853 mg/L and 779 mg/L).

Based on standard ecotoxicity the toxicity criteria according to Annex XIII to REACH are not fulfilled (see also section B.7.1).

Additionally, PFHxA is neither classified as carcinogenic (category 1 or 2), mutagenic (category 1 or 2), or toxic for reproduction (category 1, 2, or 3) (see sections B.5.3, B.5.4 and B.5.5).

Conclusion: Though PFHxA does fulfil the P- and vP criterion and even by far exceeds these criteria, the data on bioaccumulation and ecotoxicity are not sufficient to identify PFHxA as a PBT or vPvB. Nevertheless, as already noted, PFHxA shows characteristics which do comply with the concerns which are put forward to reason that a safe concentration of PBT/vPvB substances in the environment cannot be established with sufficient reliability due to unpredictable and irreversible adverse effects on the environment or human health over time. For vPvB substances this applies even if no toxicity is demonstrated. This similarity is in particular founded on the extreme persistence.

Case-by-case assessment according to para 0.10 of Annex I of REACH[2]*.*

When considering an appropriate risk assessment, the 'extreme', arguably permanent, persistence in the environment should be born in mind. This property will lead to a

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[2] *para 0.10 of Annex I of REACH:* In relation to particular effects, such as ozone depletion, photochemical ozone creation potential, strong odour and tainting, for which the procedures set out in sections 1 to 6 are impracticable, the risks associated with such effects shall be assessed on a case-by-case basis and the manufacturer or importer shall include a full description and justification of such assessments in the chemical safety report and shall be summarised in the safety data sheet.

contribution by any occurring release to the environmental stock over time, which would eventually exceed any effect threshold in the future.

Further additional concerns reason a non-threshold approach.

Mobility: Studies show a low to moderate adsorption potential and high water solubility for PFHxA. These environmental distribution properties make PFHxA mobile in the aquatic environment. Due to the global water cycle the aqueous compartments, e.g. rivers and oceans are all well connected. Therefore, once PFHxA has entered the environment, e.g. in a surface water body, there is no natural barrier to prevent PFHxA from being distributed to oceans and to groundwater. If PFHxA enters soil, it will be further transported to ground water. Sediment and soil do not function as sink for the substance in similar manner as for, e.g., heavy metals or most of persistent organic pollutants. As a consequence, PFHxA releases into the environment are of relevance on a great spatial scale even if sources are geographically separated.

PFHxA is difficult to remove: Additionally, due to its low to moderate adsorption potential and its mobility, it is difficult to remove PFHxA. Techniques for purification of water installed today are mostly not able to remove PFHxA from water. This is of relevance for the production of drinking water from raw water, for the treatment of wastewaster as well as for the remediation of contaminated sites.

Exposures and releases are due to the intrinsic properties and are difficult to regulate with end-of-pipe solutions and contaminations are likely to be irreversible.

Long-range transport potential: Modelling data indicate a high long-range transport potential for PFHxA. In combination with the extreme persistency and the high mobility of PFHxA this leads to long distance transport processes in the environment. Transport is taking place via the atmosphere or with ocean currents and not only PFHxA itself but also its precursors are subject to transport. That transport is taking place is proven by data from monitoring, showing the occurrence of PFHxA in remote regions such as the Canadian Arctic Ocean or snow in the European Alps ((Benskin et al., 2012); (Kirchgeorg et al., 2013)).

In consequence PFHxA might affect humans and the environment far away from its point of emission into the environment. Also vulnerable populations and ecosystems in remote regions are affected by this.

Therefore, the extreme persistence, the mobility and the long range transport potential of PFHxA aswell as the difficulty to remove PFHxA lead to unpredictable and irreversible adverse effects on the environment and human health over time.

The Dossier Submitter has considered the risk assessment of PFHxA using threshold, non-threshold and 'case-by-case' approaches outlined in Annex I of REACH. There is currently insufficient information and no appropriate tool to

1. derive a robust predicted no effect concentration (PNEC)

2. as well as a predicted environmental concentration (PEC) that could be used to underpin a conclusion that risks are adequately controlled, either now or on the future.

PFHxA is not a PBT substance but the concerns of PFHxA compare with the concerns of PBT/vPvB substances.

Based on these considerations, the Dossier Submitter concludes that PFHxA should be treated as a non-threshold substances for the purposes of risk assessment, similar to PBT/vPvB substances under the REACH regulation, with any release to the environment (see chapter B.9) and environmental monitoring data (details in chapter B.4.2.4) regarded as a proxy for an unacceptable risk.

This is consistent with recent restrictions on substances where it is not possible to derive a threshold, such as decabromodiphenyl ether (decaBDE), PFOA and lead (in PVC and in gunshot).

1.4 Justification for an EU wide restriction measure

Due to their unique properties, perfluorinated substances are used for manufacturing of articles and mixtures in large quantities in the EU. Because of the restriction of C8 to C14 perfluorinated substances, manufacturers shifted to using short chain perfluorinated substances (C6 and lower) and perfluorinated ethers, in addition to the existing uses for short chain perfluorinated substances and perfluorinated ethers.

Several of its potential precursors as well as the ammonium salt are registered with tonnage bands from one 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 occurring.

A large variety of emission sources contributes to the exposure of the environment and humans to PFHxA (see chapter B.9). Wide spreading and enrichement of the extremely persistent substance PFHxA in the environment, e.g. via aqueous compartments or via the atmosphere, potentially leads to spatial effects. Thus, effects will not only occur at the point of release of PFHxA but also far away from its point of release. At the same time it may affect a very large number of people. Human biomonitoring shows that the EU population is exposed to PFHxA (see chapter B.4.4.2) and monitoring studies show the ubiquitous presence of PFHxA and other perfluorinated substances (e.g. PFOA and other long chain perfluorinated substances) in all environmental media including groundwater and tap water (see chapter B.4.2.4). Thus, co-exposure of PFHxA and other perfluorinated substances to humans and the environment takes place in all EU-Member States. Furthermore, PFHxA has been shown to be involved in synergistic effects due to co-exposure with other substances, such as PCBs. A restriction on PFHxA, its salts and related substances is the most appropriate way to limit the risks (due to further releases into the environment) for human health and the environment.

National regulatory actions will not adequately manage the risks of PFHxA and related substances. An EU wide restriction will prevent and reduce the releases of PFHxA, its salts and related substances within the EU in a harmonised manner. Moreover, a restriction within the EU may be the first step for global action. To minimize the exposure of the environment with PFHxA, its salts, and related substances need to be substituted where technically and economically feasible.

In addition, Union-wide action is proposed to avoid trade and competition distortions, thereby ensuring a level playing field in the internal EU market as compared to action undertaken by individual Member States.

1.5 Baseline

Since 2002, there is a trend amongst manufacturers in the USA, Canada, Europe and Japan to replace long-chain PFCAs and their potential precursors with chemicals containing shorter perfluoroalkyl chains and the global market for fluoropolymers is growing.

Monitoring data show that PFHxA is already ubiquitously present in the environment. There is no natural source known for PFHxA in the environment, nevertheless PFHxA is found ubiquitously in the aqueous environment, like groundwater (e.g. (Gellrich et al., 2012); (Eschauzier et al., 2013); (Houtz et al., 2013)) and surface waters and oceans (e.g. (Benskin et al., 2012); (Ahrens et al., 2010); (Zhao et al., 2012); (Gellrich et al., 2012)) (see chapter B.4.2.4).

Furthermore, PFHxA is already present in humans (general population). In human tissue PFHxA can already be found, proving that exposure is taking place. PFHxA has been found in humans (blood, serum, urine, breast milk) from the US, Canada, China, Germany, Sweden, Poland, Italy, South Korea and Austria (see chapter B 4.4.2). PFHxA concentrations in human serum are often reported below the limit of detection. However, higher frequencies of detections are found in urine and hair than in serum.

If releases are not minimised, the circumstances that (1) exposure will increase due to extreme persistence and (2) humans are exposed to the substance via drinking water and food (and prenatally) lead to the fact that the effects will be unavoidable. It is, however, not possible to reliably estimate the point of time when effects are triggered. At the point of time the effects are triggered, it will be, however, very difficult to reverse the effects due to the irreversibility of the exposure. A restriction will minimise the emission of PFHxA, its salts and related substances considerably (see Figure 2).

Once PFHxA has been released it will stay in the environment, be distributed on a wide scale and removal is difficult (e.g. for contamination of ground water aquifers, surface water and oceans on a wide scale). Future generation will be faced with these contaminations. Therefore, it is important to avoid emissions by replacing the current uses of PFHxA, its salts and related substances.

The potential for wide spreading of PFHxA, e.g. via aqueous compartments or via the atmosphere leads to spatial effects. Effects will not only occur on the point of release of PFHxA but also far away from its point of release. At the same time, it will affect a very large number of people. There are some hints e.g. from Dauchy et al. and Larsson (Dauchy et al., 2017; Larsson, 2018) and from unpublished studies that PFHxA and the related substances could bind to proteins. Substances that have a low bioaccumulation potential could potentially reach similar levels in biota to substances that are known to bioaccumulate, provided that they are sufficiently persistent and mobile in the environment (Peter Fisk Associates Ltd, 2018), please see section B.4.4.5. Hence, even though it is still unclear if PFHxA bioaccumulates, the continuous exposure of humans with relevant concentrations could lead to toxic effects comparable to those for bioaccumulative perfluorinated substances.

If emissions of PFHxA into the environment continue, concentration in environmental media relevant for human nutrition (e.g. vegetables and drinking water) will increase even further. In consequence, PFHxA may affect the health of the general population in the future by consumption of contaminated food and water.

PFHxA exposure does affect the functioning of ecosystems including humans. If drinking water or (agricultural) plants are contaminated, these resources cannot be used for human consumption anymore. Waterworks have to close and households need to be supplied from other sources. This has a lot of consequences, for the society, not only for the people directly affected, but also for the whole ecosystem, e.g. the water cycle.

Problems with PFHxA occur already today

Many of the above given arguments are proven by studies from the environment, not only by theoretical considerations or laboratory studies. There are already today cases (e.g. Rastatt in Germany) known, where the environmental contamination with PFHxA is causing substantial problems with the supply of drinking water and with agricultural products. There is a big societal concern, because of resources are needed to handle such problems. These actions also occur with delay, because such contaminations at first need to be uncovered.

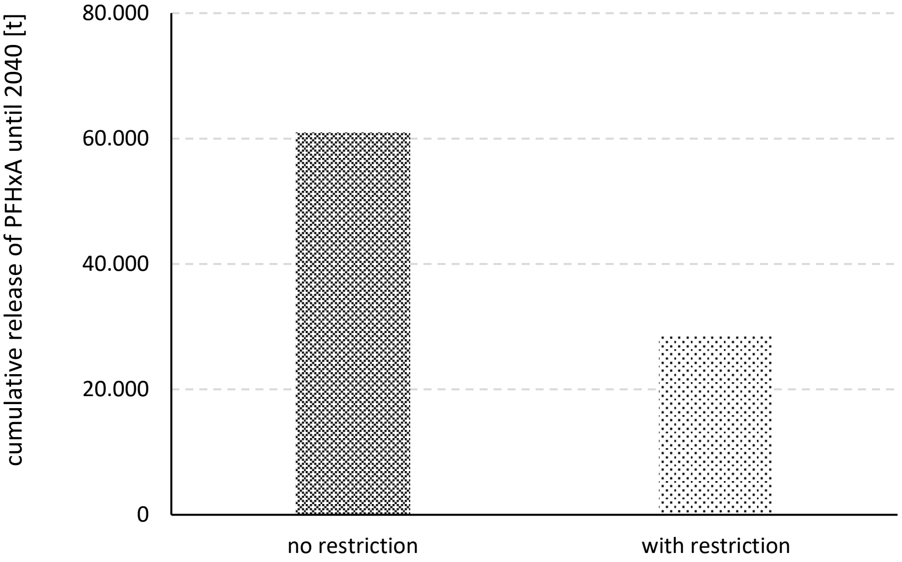

Figure 2: *Cumulative release of PFHxA until 2040.*

The estimated maximum values were used as worst case. The values include the assumed maximum amount of PFHxA which is formed by precursor degradation. In both bars the release delay due to the articles life span is considered.

2 Impact assessment

2.1 Introduction

The main concern regarding PFHxA is related to its potential to persist in the environment for a very long time. It does not degrade under normal environmental conditions (see more details in chapter B.4.1.1). This extreme persistence in conjunction with the described concerns and uncertainties regarding other potential unfavourable properties of PFHxA pose an unacceptable risk.

Considering the uncertainty associated with the exposure estimation of PFHxA in the environment and owing to lack of knowledge and data (in particular of long-term intergenerational effects), it is very difficult if not impossible to reliably estimate with sufficient certainty current and future environmental concentrations and indirect human exposure of PFHxA. The Dossier Submitter has therefore concluded that a conventional threshold-based environmental risk assessment cannot be carried out for PFHxA with sufficient reliability. In conclusion, there is currently insufficient information on cross generational ecotoxicological effects to derive a robust predicted no effect concentrations (PNECs) as well as a predicted environmental concentration (PEC) that could be used to underpin a conclusion that risks are adequately controlled, either now or in the future.

PFHxA shows characteristics which do compare with the concerns which are put forward to reason that a safe concentration of PBT/vPvB substances in the environment cannot be established with sufficient reliability due to unpredictable and irreversible adverse effects on the environment or human health over time. For vPvB substances this applies even if no toxicity is demonstrated. This similarity is in particular founded on the extreme persistence.

Therefore, the Dossier Submitter considers that PFHxA should be treated as a non-threshold substance for the purposes of risk assessment, similar to PBT/vPvB substances under the REACH regulation. This means that the magnitude and extent of the risks to the environment remain uncertain. To inform risk management, the risks have to be qualitatively assessed taking into account release patterns and exposure pathways.

For human health impacts standardized risk assessments can be carried out. These suggest that exposure does not pose a risk for human health at the moment. However, one should keep in mind that the extreme persistency of PFHxA implies uncertainties regarding risks to human health that are similar to the long-term risks for the environment. It is not possible to reliably estimate the point of time when effects are triggered. At the point of time the effects are triggered, it will be, however, very difficult to reverse the effects due to the irreversibility of the exposure.

2.2 Risk management option

On the basis of the conclusions of the risk assessment reported in section 1.3.7, the releases of PFHxA, its salts and precursors are considered to pose a risk to the environment that is not adequately controlled.

In response to the identification of this risk the Dossier Submitter has conducted an analysis of diverse risk management options (RMOs) to identify the most appropriate risk management measure to address these risks.

As a first step, the possibility to address the risks posed by PFHxA, its salts and precursors under other REACH regulatory measures, existing EU legislation and other possible Union-wide RMOs was examined. Whilst it was recognised, and taken into account when developing the scope of the proposed restriction, that some existing or proposed EU legislation or other measures could have an impact on the risk management of certain sectors these were assessed as inappropriate to address *all* of the sectors and products contributing to risk.

Therefore, the option to use a restriction under REACH to address the identified risks was investigated further. The following restriction options, alone and in combination, were considered in addition to the proposed option:

Restriction with concentration limit and specific derogations

1. restriction with no concentration limit
2. restriction on selected products
3. restriction on specific sectors
4. labeling;

Each of the options possible under REACH was assessed against the main criteria for restriction identified in Annex XV of REACH: effectiveness, practicality and monitorability.

As a result of this assessment, the restriction option presented in Table 5 is proposed, whilst those summarised in Table 5 were discarded. The detailed rationale for not proposing the discarded restriction options is presented in Annex E.1. In summary, the proposed restriction, was found to fulfil the criteria for effectiveness, practicality and monitorability better than the other evaluated restriction options.

Table 5: Proposed restriction on PFHxA, its salts and PFHxA-related substances.

1. Undecafluorohexanoic acid (PFHxA), its salts and related substances[3] (b) Any PFHxA-related substance (including its salts and polymers) having a linear or branched perfluoropentyl group with the formula C_5F_{11}- directly attached to another carbon atom; (b) Any PFHxA-related substance (including its salts and polymers) having a linear or branched perfluorohexyl group with the formula C_6F_{13}-.	1. Shall not be manufactured, used or placed on the market as substances on their own; 2. Shall not be used or placed on the market in: (a) another substance, as a constituent, (b) a mixture, (c) an article in a concentration equal to or above 25 ppb for the sum of PFHxA and its salts or 1000 ppb for the sum of PFHxA- related substances. 3. Paragraphs 1 and 2 shall apply 18 months

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[3] PFHxA-related substances are substances that, based upon their structural formulae, are considered to have the potential to degrade or be transformed to undecafluorohexanoic acid.

2. The following substances are excluded from this designation: (c) C_6F_{13}-X, where X= F; (d) C_6F_{13}-C(=O)OH, C_6F_{13}-C(=O)O-X′ or C_6F_{13}-CF_2-X′ (where X′ = any group, including salts).	from entry into force of the restriction. 4. Paragraph 2(c) shall not apply to articles placed on the market before the date referred to in paragraph 3. 5. Paragraphs 1 and 2 shall not apply until XX XX XXXX [five years after the entry into force] to: (a) hard chrome plating; (b) photographic coatings applied to films; (c) concentrated fire-fighting foam mixtures that were placed on the market before [date – 18 months after the entry into force of this Regulation] and are used or are to be used in the production of other fire-fighting foam mixtures; (d) Paragraph 5 (c) shall not apply to use of fire-fighting foam for training; (e) Paragraph 5 (c) shall not apply to use of fire-fighting for testing unless all releases are contained. 6. Paragraph 1 and 2 shall not apply to concentrated fire-fighting foam mixtures for defence applications – as long as no successful transition to military operable fluorine free foams can be achieved: (a) for seagoing units, air traffic facilities and storage of fuel; (b) for training purposes provided that emissions occur in enclosed areas and wastewater is collected and disposed of safely. 7. Paragraphs 1 and 2 shall not apply until XX XX XXXX [seven years after the entry into force] to: (a) photolithography or etch processes in semiconductor industry; (b) latex printing inks. 8. Paragraphs 1 and 2 shall not apply until XX XX XXXX [12 years after the entry into force] to concentrated fire-fighting foam mixtures for cases of class B fires in storage tanks with a surface area above 500 m^2. 9. Paragraphs 1 and 2 shall not apply to any of the following: (a) a substance that is to be used, or is used as a transported isolated intermediate, provided that the

	conditions in points (a) to (f) of Article 18(4) of this Regulation are met; (b) personal protective equipment intended to protect users against risks as specified in Regulation (EU) 2016/425 of the European Parliament and of the Council, Annex I, Risk Category III (a), (c), (d), (e), (f); (c) non-woven medical textiles; (d) impregnation agents for re-impragnating of articles referred to in paragraph 9(b). 10. From (entry into force + 12 months), a natural or legal person placing an article specified in paragraph 9(b), 9(c) or 9(d) on the market for the first time and benefitting from the derogation therein shall provide by 31 Januar of each calender year a report to the competent authority in the Member State concerned containing: (a) the identity of the substance(s) used in the previous year; (b) the quantity of PFHxA, its salts and PFHxA-related substances used in the previous year. Member States shall forward the data to the Commission by 31 March every year. 11. The concentration limit referred to in paragraph 2 shall be 150 ppm for the sum of PFHxA and its salts in fluoroelastomers used in the following usage groups: Automotive and aerospace industry. This derogation shall not apply to articles referred to in paragraph 2(c). 12. By (entry into force + 6 years), the Commission shall carry out a review of paragraph 6 in the light of new scientific information, including the availability of alternatives for articles referred to in paragraph 6, with a view to proposing amendments. From (entry into force + 12 months), a natural or legal person benefitting from the derogation in paragraph 6 shall provide by 31 January of each calendar year a report to the competent authority in the Member State concerned containing: (a) efforts on substitution of fire-fighting foams that contain PFHxA, its salts and PFHxA-related substances; (b) used quantities in the previous year of

	fire-fighting foams that contain PFHxA, its salts and PFHxA-related substances per sector specifying: (i) share n training and in operation (ii) information on whether emission was contained, collected and disposed safely or emitted into the environment. Member States shall forward the data to the Commission by 31 March every year.

Explanatory notes:

Column 1:

Paragraph 2(a): This is a perfluorinated substance with only fluorine atoms attached and as such is not degraded to the corresponding PFCA as the carbon fluorine bond is known to be very stable.

Column 2:

Fire fighting foam:
Paragraph 5(c), (d), (e): For fire-fighting foam mixtures for a period of time of five years after entry into force of the restriction paragraph 2 shall not apply. After this period of time use, production and placing on the market of fire-fighting foam mixtures shall not be allowed. The specification in 5 (d) and (e) excludes fire-fighting foam mixtures that contain or may contain PFHxA, its salts and PFHxA-related compounds that are used for training and firefighting foams that contain or may contain PFHxA, its salts, and PFHxA-related compounds that are used for testing unless all releases are contained. Thereby only allowing use of fire-fighting foams in cases of emergency and under specific conditions use in testing. If all releases are contained when testing, paragraph 2 shall not apply to fire-fighting foam mixtures used in testing for a period of time of five years after entry into force of the restriction.

Paragraph 6: While some armed forces already transitioned to fluorine free foams and report positive experiences with these foams, other armed forces reported challenges regarding a complete transition due to missing alternatives in the defence sector.

For defence applications an exemption applies as long as a transition due to missing alternatives is not possible for the use in fire-fighting foam mixtures for seagoing units, air traffic facilities and storage of fuel, furthermore, for training purposes provided that emissions occur in enclosed areas and wastewater is collected and disposed of safely.

Paragraph 8: Furthermore, an exemption applies for twelve years after entry into force of the restriction for the use in fire-fighting foam mixtures for cases of class B fires in storage tanks with a surface area above 500 m^2.
The dossier submitter is aware of the project by ECHA and the European Commission, which studies the use of PFASs in fire fighting foams, analyses the alternatives and the impact

assessment to provide a basis for the decision on an appropriate regulatory measure and gains information for a possible restriction report. The restriction for PFHxA, its salts and PFHxA-related substances and respective exemptions for fire-fighting foam mixtures are based on an extensive literature research and stakeholder consultation. However, the respective project might lead to further information that were not taken into account in the present dossier and might lead to different conclusions.

Paragraph 10: Annual reporting on the use of PFHxA, its salts and PFHxA-related substances in the production of personal protective equipment (PPE), non-woven medical textiles and impregnation agents (see Paragraph 9 (b), 9(c) and 9(d)): This will help the European Commission to gather data on the use of these substances in these sectors and to monitor any changes. In the event that the data reveals any concerns for the sector, further actions under REACH can be initiated. The reporting requirement will help to monitor whether there are any changes to uses and quantities which may be an indication to changes in the emissions. The proposed action sends a signal that substitution of PFHxA, its salts and PFHxA-related substances is desirable.

Paragraph 11: Fluoroelastomers used in automotive and aerospace industry are mainly related to proper, efficient and safe engine operating. Fluoroelastomers are used in cases of extreme conditions. They are fuel resistant, tolerate high temperatures and the abrasion during usage is lower than by other elastomers. Accordingly, machine parts like seals, dampers and hoses for fuel-, oil and hydraulic liquids have to be manufactured with fluoroelastomers.

Paragraph 12: The market of fluorine free foams is rapidly developing and testing requirements for fire fighting foams are already being reviewed, regarding changing requirements when assessing fluorine free foams. Therefore, the feasibility of a transition to fluorine free foams in the defence sector shall be possible for all armed forces in the future. That is why the efforts on substitution will be closely monitored.

Annual reporting on the quantities and efforts of substitution of fire-fighting foams that contain PFHxA, its salts and PFHxA-related substances will allow the European Commission to also gather data on the used quantities of these substances and to monitor the developments of alternatives for fire-fighting foams. The reporting requirement will not only help to monitor whether there are any changes to uses and quantities which may be an indication to changes in the emissions, but it will also allow a facilitated re-evaluation of paragraph 6 by the European Commission. The proposed action sends the signal that substitution of PFHxA, its salts and PFHxA-related substances is desirable in the field of fire-fighting foams as well.

2.3 Discussion on disregarded risk management options

Other restriction options under REACH and alternative risk management options outside REACH are summarized in Table 6. As has been demonstrated, the proposed restriction with concentration limit and specific derogations addresses the main criteria for restriction adequately. All other risk management options fail to meet the demands of one or more main criteria (indicated by a minus sign).

Table 6: Summary of management options assessment.

	Effectiveness **(risk reduction/ proportionality)**	**Practicality** **(implementability, enforceability, manageability)**	**Monitorability**	**Comment**
Other restriction options				
1. restriction with no concentration limit	mixed impacts: + very high potential for risk reduction - disproportionate	negative impacts: - enforcement problems	negative impacts: - monitoring difficult	in theory this option would bring all emissions to an end, however the option is disproportionate in terms of potential cost. Essential uses like the use of AFFF for large liquid fires for which no alternatives are available would no longer be possible. Also very small impurities would fall under this restriction which also raises questions of practicality and monitorability.
2. restriction on selected products	mixed impacts: - potential for ongoing emissions from non-essential uses + proportionate	positive impacts: + restriction would be practical	positive impacts: + restriction would be monitorable	new uses and uses currently unknown to the Dossier Submitter would not be covered by the restriction.
3. restriction on specific sectors	negative impacts - ongoing emissions from non-essential uses - restriction of essential uses	positive impacts: + restriction would be practical	positive impacts: + restriction would be monitorable	most sectors with broad uses also comprise one or more essential uses. New uses and uses currently unknown to the Dossier Submitter would not be covered by the restriction.
4. labeling	negative impacts - low risk reduction	positive impacts: + restriction would be practical	positive impacts: + restriction would be monitorable	visible Label on articles for endconsumers: ‘Contains PFAS’. No evidence that labelling would be an effective RMM for the uses considered in this dossier.
Other Union-wide risk management options than restriction				
5. voluntary industry activities	negative impacts: - low risk reduction	negative impacts: - not enforceable	unclear impacts	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 related substances during its whole life-cycle. Releases 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.
6. Stockholm Convention	mixed impacts: - risk reduction uncertain (time and scope of restriction) + worldwide regulation	positive impacts: + restriction would be practical	positive impacts: + restriction would be monitorable	PFHxA might be proposed as POP in the future. At the moment it is unclear whether PFHxA would be considered as POP under the Stockholm Convention. Therefore it seems to be more effective to start with a REACH Regulation first.
7. further international regulatory activities	not clear	not clear	not clear	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.

See also Risk Management Option Analysis Conclusion Document for PFHxA, its salts and precursors.[4]

2.4 Restriction scenario(s)

An extensive stakeholder consultation has been undertaken by the Dossier Submitter to obtain detailed information on uses of the substances in the scope of this restriction proposal (see Annex G). The consulted stakeholders stated that there are no intentional uses of PFHxA within the EU. However, the ammonium salt and related substances are used extensively within the EU and for imported articles. Publicly available information has also been extensively considered. Therefore, the Dossier Submitter is confident, that the general information presented on the use of the substances in different sectors is exhaustive. However, the Dossier Submitter had to consider large uncertainties which regard to:

- Specific uses within larger fields of use.
- Use quantities.
- Release quantities.
- Availability and applicability of alternatives.
- Affordability of alternatives.

Most of the information received during the stakeholder consultation and publicly available information is highly aggregated. While the collected facts sufficiently demonstrate that a

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[4] https://echa.europa.eu/documents/10162/e7a9d441-417d-1eb1-6afb-80f175b18b3e
(last access: 01.10.2019)

general ban would not be proportionate it is on the other side difficult to determine the justified derogations from a general ban.

It has been demonstrated that for certain uses alternatives are available. Hence a transitional period of 18 months after entry into force is reasonable. A rather short transitional period is important to reduce the ongoing releases into the environment which continuously increase the environmental stock. The dossier submitter proposes longer transitional periods for specific uses where alternatives cannot be implemented immediately but the uses are essential.

Threshold:

It is concluded that the following thresholds are feasible for mixtures and articles placed on the market:

- **25 ppb for PFHxA and its salts,**
- **1 000 ppb for the sum of PFHxA related substances.**

A restriction with a threshold of zero would be most effective, as this would end the exposure of PFHxA, its salts and PFHxA-related substances to the environment. Nevertheless, this threshold is not feasible and enforceable (e.g. due to detection limits).

2.5 Assessment of the proposed restriction

2.5.1 Economic impacts

C6-PFAS have various applications in consumer, professional and industrial products. These products have various modes of use, which lead to releases of C6-PFAS into the environment via various pathways. Furthermore, the availability of suitable alternatives varies (and their market share) for different uses, as also the anticipated resources required to substitute current uses do. In many sectors stakeholders stated that the substitution potential is limited, when special properties must be met. These are:

- Oil grease or dirt repellency,
- film-forming effects,
- special durability of treated materials or in a specific process under harsh conditions.

Examples stated are working protection apparel (e.g. in hospitals), the AFFF firefighting foams and engine isolation membranes in cars.

Because of the variations in key factors, different impacts are expected for separate uses of C6-PFAS. Recognising these variations, the socio-economic impacts and the proportionality of the proposed restriction are assessed on a per-sector basis, i.e., separately for fluoropolymers, semiconductors, fire-fighting-foams, printing inks, chrome plating, building material, photographic applications, mixtures for consumer use, cosmetic products, textiles and food contact materials.

Where the available information permits, the analysis is performed at 'use-specific' level rather than a sector level. For example within the fire-fighting foams sector, the availability of safe alternatives varies between uses. The information gathered shows that for some uses like fighting fires at large liquid tanks, not enough evidence is available that fluorine free fire-fighting foams perform as well as fluorinated products. Considering the risks arising from this uncertainty the Dossier Submitter proposes an exemption for this use.

Recognizing the difficulties to obtain and consider all relevant information, the Dossier Submitter attempted to obtain data for quantitative analysis for all uses and especially those where the largest quantities of PFHXA, its salts and related substances have been identified. However, for most uses it is necessary to rely on qualitative information as well to fully understand the projected impacts from the proposed restriction.

The geographical scope of the impact assessment is the European Economic Area (EEA), meaning the memberstates of the EU plus Norway Iceland and Liechtenstein) as the proposed restriction would take effect over the territory of the EEA, recognizing that there is considerable uncertainty related to the future status of the United Kingdom. Whenever this dossier refers to the EU, it should be read to cover the three additional EEA countries too. The temporal scope of the analysis is 2023 (as the first potential full year of entry into force of the proposed restriction) plus 20 years. Unless otherwise specified all costs are in 2019 price levels, discounted with 4 % discount rate to the study reference year of 2019, in Net Present Value (NPV) or annualized costs over the study period.

PFHxA, as defined in this restriction proposal, is extremely persistent and therefore accumulative in the environment. As discussed in chapter 1.3.5 and Annex B.4, the Dossier Submitter argues that PFHxA shows characteristics which do comply with the concerns which are put forward to reason that a safe concentration of PBT/vPvB substances in the environment cannot be established with sufficient reliability. This is due to unpredictable and irreversible adverse effects on the environment or human health over time. This similarity is in particular founded on the extreme persistence. Therefore, PFHxA must be analyzed in the same way as a non-threshold substance. Quantification of benefits is typically not possible for PBT/vPvB substances or substances of similar concern (such as PFHxA), which makes it difficult to demonstrate quantitatively whether the benefits of a proposed restriction outweigh its costs. Instead, the Dossier Submitter has adopted a cost-effectiveness approach as recommended by SEAC for evaluating restriction proposals for PBT/vPvB (-like) substances.

The approach rests on the assumption that emission reduction is a reasonable proxy of the benefits of the restriction.

Economic impacts of the proposed restriction have been assessed for the uses and supply chains, representing the major current applications of PFHxA, its salts, and related substances in terms of volumes used. It must be stressed that the Dossier Submitter could not obtain enough quantitative information to undertake reliable cost-effectiveness analyses for all uses. For most markets it is necessary to consider qualitative information and large uncertainties:

- For most uses the known alternative non-fluorinated substances will not fully replace the functional properties provided by PFHxA, its salts and PFHxA-related substances.

Functional losses are therefore expected. However, the Dossier Submitter is not aware of studies that systematically evaluate the value of such losses, for example studies that measure the hypothetical willingness to pay for certain functions or studies on actual market behavior. For example, neither does the Dossier Submitter know what consumers in Europe are hypothetically willing to pay for stain-resistant workaday clothes nor whether stain-resistency influences their actual buying decisions for such products.

- The Dossier Submitter is not aware of any studies that analyze quantitatively direct impacts of functional losses from not using fluorinated substances in articles. For example, no information is available on the cost of the loss of oil-resistant properties in fast food wrappers, i.e. how many cases of soiling of consumer clothes can be expected.
- Information on market sizes is often not available. For example, the large group of mixtures for consumer use contains articles for a variety of polishes, waxes, impregnations and paints. Several studies show that PFHxA-related substances are present in some articles. However, the differences between the samples, the low number of samples with comparable product types and methods and the lack of data for many products and countries make it impossible to deduct general information on market sizes and use quantities within this large group of products. In addition, it must be considered that due to the ongoing changes in PFAS uses, it is not possible to deduce future concentrations of PFHxA in consumer products from studies that are two to ten years old.

In absence of a lot of the aforementioned information the cost-effectiveness assessments for the majority of uses mainly considered the difference in market prices between PFHxA, its salts and related substances and the alternatives available on the market. For most uses the costs for the alternatives are expected to be slightly less expensive to slightly more expensive. The resulting very low cost-effectiveness ratios are then underestimations not accounting for functional losses. In addition, they do not represent total but relative societal costs of the restriction proposal. In order to be as transparent as possible about these shortcomings of the socio-economic assessment the Dossier Submitter gives detailed qualitative and - where available - quantitative information on missing costs for the different uses and illustrates in Annex E.8. Proportionality how the missing information might influence the proportionality assessment.

The following markets have been assessed:

- manufacture of fluoropolymers,
- textiles,
- fire fighting foams,
- semiconductors,
- surface treatment of food contact materials,
- printing Inks,
- chrome Plating,
- building material,
- photographic applications,
- fragrances and flavour industry,
- mixtures for consumer use,
- cosmetic products.

2.5.1.1 Manufacture of fluoropolymers

PFHxA, its salts and related substances are used for the production of (per-)fluorinated polymers, either as monomers or as processing aid to control the polymerisation process. Fluoropolymers provide vital performance characteristics to products or production processes. These polymers are used for several applications as finishing agents or as repellents. Several precursors of PFHxA are used as intermediates and as monomers for polymerisation. Aqueous based products based on fluorinated polymer dispersions are used to impart functional oil and water repellency when applied to textile, leather, hard surfaces or paper fabrics (industrial and consumer application). A large quantity of the fluoropolymers is further processed into a variety of specialized articles (fibers, tubes, sheets and tapes). Those articles are then further processed into the final products and offered for sale.

According to information received from industry, emissions to water from the manufacture process only result from water contact of the C6 alcohol and the C6 monomer. Emissions from water are sent to the waste water treatment plant and the sludge is incinerated at high temperature.

Additionally, emissions are in the off-gases which are incinerated. It is assumed that in general no emissions are generated into the air. Relying on this information it is estimated that emissions into the environment from production of fluoropolymers are in the low kilogram-range for the manufacturers identified in the EU. Therefore, the Dossier Submitter (DS) assumes that emissions from production of fluoropolymers are in general low. Even considering that there may be production sites with less effective waste water treatment plants the DS estimates that emissions into the environment are not larger than 1 t/a.

The production sites using PFHxA-related substances that are known to the Dossier Submitter rely heavily on fluorinated compounds.

One manufacturer claims that a restriction would lead to complete reorganisation of his business. According to his claims a considerable number of direct jobs would be at stake in case of a restriction. This number could not be verified but is likely to be an overestimation (see E.2.1.4 Economic and other impacts).

One additional manufacturer contacted the Dossier Submitter late in the preparation process for this dossier asking for a derogation for the use of PFHxA-related substances in the production of fluoropolymers, fluorinated polymers and fluoroelastomers at his manufacturing facilities in the EU. The manufacturer did not provide case specific data on possible socio-economic consequences in case of a restriction. The Dossier Submitter asked him to submit more detailed information in the public consultation of the restriction process.

According to information received during the consultation from downstream users, PFAS-free mixtures are not more expensive than fluorinated products. Therefore, it is expected that downstream users will not face high costs when they have to substitute with fluorine-free mixtures and that the fluorine-free mixtures will fully replace fluorinated products.

The Dossier Submitter has not enough information on the manufacturers that are already producing alternatives.

In case of a restriction, downstream users will shift their demand to alternative products which are expected to be similar in cost as their fluorinated counterparts. The Dossier Submitter cannot evaluate whether the demand can be met by the manufacturers that are currently producing (acrylic) polymers with C6 side chains or whether distributional impacts will occur in the EU with other manufacturers taking over the demand.

Uncertainties have to be considered regarding the availability of alternatives for all downstream users. There is not one drop-in alternative available for all applications by downstream users. For example, for textile applications other alternatives will be needed than for food contact materials. And in the production of food contact materials it might be necessary to use different alternatives for the various applications. Therefore, it is not possible to predict whether alternatives will be produced in sufficient quantities for all applications in time.

Proposed exemption for the use of APFHx in the production of fluoroelastomers:

Fluoroelastomers are predominantly used in highly critical combustion engine vehicles (gasoline, diesel). Their excellent heat and chemical resistance are necessary for smaller, higher performance engines to meet the EU car emission standards. Typical products are turbo charger hoses, fuel hoses, seals and gaskets.

The Dossier Submitter received information that the EU market for fluoroelastomers with C6 polymerization aids is served by two producers. One of them demonstrated that emissions from the production process are in the very low kilogram-range. Emissions from the service life of articles containing fluoroelastomers into water and soil have been calculated according to the expected use in automotive and aviation applications and are estimated to be to be in the range of 100 – 1 000 kg/a, with a central estimate of 300 kg/a based on information by one manufacturer.

The Dossier Submitter estimates a loss of profit of the European (C6-)fluoro-elastomer manufacturers in case of a restriction in the range between 2 - 16 million €/a with a central estimate of 9 million €/a. This also is based on information from one manufacturer. Cost-effectiveness ratio would be 2 000 - 160 000€/kg. A central estimate of approximately 30 000 €/kg has been considered to determine whether the costs are proportionate. Considering CEAs from previous restrictions an exemption as stated in the restriction proposal might be justified based on these costs alone. In addition, the Dossier Submitter was informed by the manufacturer that automotive and aerospace industries rely on these specific fluoroelastomers to comply with international safety standards, i.e. they cannot use alternative materials arbitrarily. Therefore, the Dossier Submitter proposes the derogation for the use of AFPHx in the production of fluoroelastomers.

For more detailed information on this use see B.9.4. Polymers and plastic material and E.2.1. Fluoropolymers.

2.5.1.2 Textiles

The occurrence of fluorotelomer alcohols (FTOHs) and PFCAs in textiles is (primarily) related to the DWR finishing that imparts water, oil and stain resistance to the textile. DWR finishing finds important application in functional clothing such as performance outdoor textiles, which provide weather protection and body moisture management to the wearer (Schellenberger et al., 2018). This is achieved by a multi-layered fabric system, in which a water-repellent outer fabric is combined with a waterproof breathable membrane inside.

Information on relevant uses and their quantities in the textile sector is scarce. The Dossier Submitter obtained only some basic information. Without a restriction, constant releases of PFHxA-related substances from textiles amounts to 162 – 3 420 t/a. Accordingly, emissions over 20 years are expected to add up to 3 240 – 68 400 t. Additionally release of C6 fluoropolymers of approximately 36 – 91 t/a (724 – 1 814 t over 20 years) has to be considered. These numbers are highly uncertain.

Estimates for the releases from major sub-uses are as follows:

Table 7: Releases from use in textiles.

Subsector	**Release of C6 fluoropolymers (min – max t/a)**	**Release of C6-related substances (min – max t/a)**
clothing and textiles except outdoor and occupational	26.6 – 66.5	152.9 – 3 249.2
outdoor clothing	2.3 – 5.8	4.1 – 86.2
occupational wear	1.4 – 3.7	2.6 -54.6
carpets and other textile floor coverings	3.1 -7.7	2.3 – 29.7
industrial textile fabrics	2.8 – 7.0	0 – 0.1

According to present knowledge, no alternatives allow an encompassing replacement with a performance of equivalent quality. Especially development of alternatives for properties such as oil and dirt repellency, is challenging.

For DWR a progress in development of alternatives can be observed. Several chemical processes are available, which show comparable results for water repellency. In the field of industrial textiles, which are designed and produced for professional uses and have to withstand harsher conditions, limitations might exist for specific uses. For clothes a high performance level is required when the clothes are an integral part of the hazard management and repellency against harmful non-polar liquids is necessary (see Figure 3).

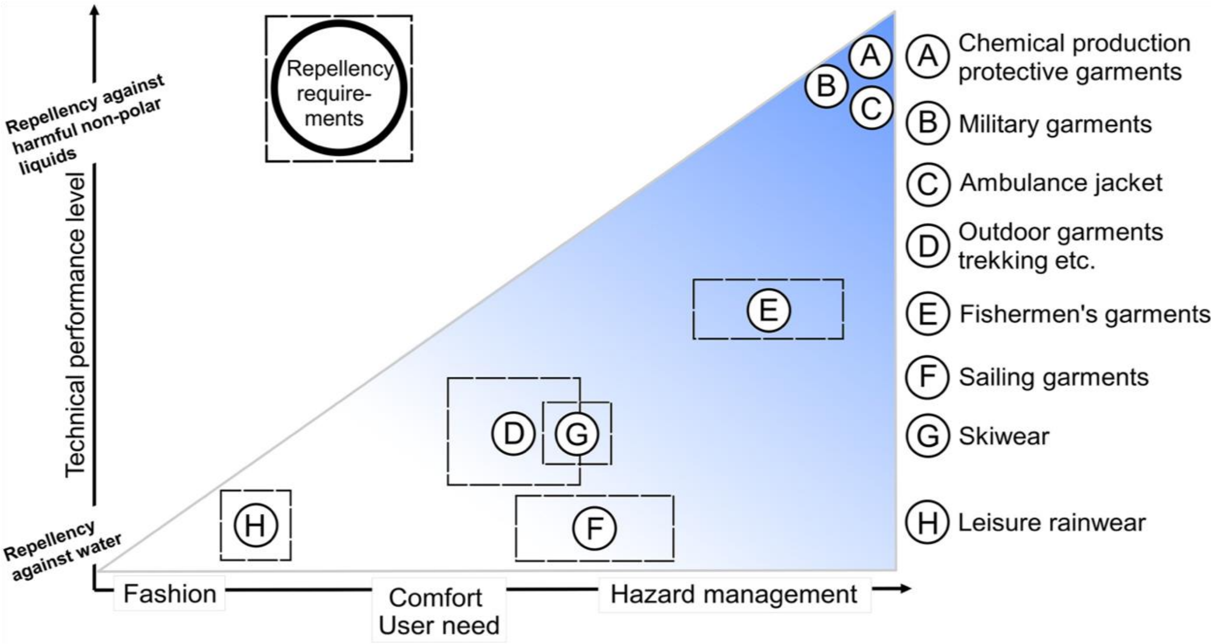

Figure 3: *Illustration of the increased need for technical performance (in terms of oil repellency and durability of oil- and water repellency) with more advanced user needs; advancing from fashion to comfort to hazard management (Holmquist et al., 2016). Examples of garments meeting user needs within the fashion segment are e.g. jackets primarily chosen based on looks (design, colour etc.) and never or seldom used in weather conditions requiring water repellency. Garments within the comfort segment could be e.g. jackets often used in weather conditions requiring water repellence to stay warm and dry but where the user can find shelter within a reasonable time and thus is unlikely to experience a life-threatening situation due to failing water repellency. Finally, garments in the hazard management segment must be water (and sometimes oil) repellent for protecting the life of the wearer.*

Reprinted from Environment International 94, H. Holmquist,S. Schellenberger,I. van der Veen,G.M. Peters,P.E.G. Leonards,I.T. Cousins, Properties, performance and associated hazards of state-of-the-art durable water repellent (DWR) chemistry for textile finishing, 251-264., Copyright (2016), with permission from Elsevier.

The products produced range from outdoor fashion, worker protection clothes, uniforms for the military, police etc. to textiles that are not intended for wearing by consumers but can be considered to be home textiles (e.g. carpets, awnings etc.) or are integrated in other products (e.g. aeroplane /car seats, automotive headliners). Other applications that can be included in this group of products are impregnation agents for leather. Furthermore, some special applications were reported, e.g. mixtures for the treatment of non-woven textiles for uses in the medical sector (chemical resistance of work wear in operating theatres) and non-woven for automotive sector (e.g. resistance of components in motor to oil and diesel /gasoline).

A general trend in the textile industry and notably in the sportswear and outdoor industry to phase out PFAS-related substances and move to fluorine-free alternatives can be observed, that is due to increasing pressure from the public to phase out hazardous substances.[5] This

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[5] PFAS Central provides a list of PFAS-free products that also links to the manufacturers product policies regarding PFAS: https://pfascentral.org/pfas-basics/pfas-free-products/ (last access: 13.12.2019).

demonstrates that substitution is technically and economically feasible for a lot of uses. Alternatives can be used without specific new investments (unchanged machinery) at costs at the same level as the costs of using the PFAS-based agents.

Alternatives to provide equivalent oil and dirt repellence properties are not available. The loss or reduction of these properties might induce a significantly reduced service life and increased cleaning efforts for home textiles (e.g. carpets, awnings, seating furniture), textiles used in automotive and aerospace sectors and other public places (e.g. seats and carpets). Information on impacts is not available. The Dossier Submitter assumes that functional losses might lead to significant costs, mainly caused by a reduced service life of textiles that are used in strongly frequented public places. On the other hand, the Dossier Submitter calculates that emissions from these product groups into the environment are comparatively high (see B.9.5.2.1). Therefore, in absence of further information on the magnitude of societal impacts no derogation is proposed.

No derogation is proposed for non-woven textiles used in the automotive and aerospace sector. It has been reported that products are used for sound absorption, climate regulation within vehicles and reduction of fuel among other things. Stakeholder commenting was too generic to be able to determine the necessity for derogations. This might change if stakeholders come up with more detailed analyses in the future.

Two categories of use have been identified as essential uses where alternatives do not meet the properties needed with regard to oil and/or dirt repellence. The lack of these properties would lead to unacceptable health risks for certain groups, most likely leading to high societal cost. Therefore, for two categories of use exemptions are proposed by the Dossier Submitter:

- Personal protective equipment intended to protect users against risks as specified in regulation (EU) 2016/425 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL, Annex I, Risk Category III (a), (c), (d), (e), (f).[6]
- Non-woven medical textiles.

Emissions are estimated to be in the range of 2 - 4 t C6-fluoropolymers and 25 – 533 t PFHxA-related substances for derogated personal protective equipment over 20 years. For non-woven medical textiles emission estimates are not available.

In the medical sector repellency to bodily fluids is necessary to avoid the transmission of diseases. In other sectors (e.g. defence, firefighting, oil and gas industry) repellency towards non-polar stains is also part of the hazard management (Schellenberger et al., 2019).

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[6] REGULATION (EU) 2016/425 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 9 March 2016 on personal protective equipment and repealing Council Directive 89/686/EEC. Category III includes risks that may cause very serious consequences such as death or irreversible damage to health. The categories mentioned above relate to the following: III(a) substances and mixtures which are hazardous to health, III(c) harmful biological agents, III(d) ionising radiation, III(e) high-temperature environments the effects of which are comparable to those of an air temperature of at least 100 °C, III(f) low-temperature environments the effects of which are comparable to those of an air temperature of – 50 °C or less.

Owing to the vast number of textile and leather products and applications, in which PFHxA-related substances are used, it is not possible to give a robust estimate of substitution costs, which is representative for the entire industry.

The cost change per unit has been estimated based on industry information from the consultation and review of publicly available information. Respondents confirmed that treatment with PFHxA-related substances in general is more expensive than with non-fluorinated alternatives. Additional information from publicly available ressources confirms that the cost change when using non-fluorinated alternatives is negligible.[7]

Considering the various applications and the confidentiality of price information, it was not possible to identify generalizable market prices. However, the Dossier Submitter estimates that industry will not face higher cost when substituting from PFHxA-related substances to fluorine-free substances. The non-fluorinated substances are cheaper in general. However, considering the information from industry that it might be possible that for some treatments slightly higher use volumes are needed, steady costs are assumed.

Some information from industry claims that certain functional properties will not be available for end users any longer when articles are not treated with fluorinated substances. Especially the loss of stain and oil repellent properties might lead to higher costs for textile cleaning and a reduced service life for textiles. The severity of this impact is unknown, but substitution costs will be underestimated when not considering the cost of functional losses.

A yearly reporting requirement has been proposed for the derogated uses. Information on the derogated use quantities is scarce and monitoring future use quantities will lead to sufficient information if further EU action is required. The costs associated with this requirement are expected to be affordable. Costs include:

- A one-time cost to develop the reporting format and software to submit and process the information for regulators;
- ongoing costs for industry to gather the required information and submit it annually.

The costs for industry are difficult to estimate as it would depend on the complexity of company structure and the number of products with reporting requirements. The one-time costs to ECHA are unlikely to exceed 50 000 €, especially when considering the possibility to develop the functionality under existing tools such as REACH-IT or Article 66 notifications. Considering the comparatively low costs for reporting requirements a yearly reporting is proportionate, providing detailed information for possible further actions.

For more detailed information on this use see B.9.5 and E.2.11

2.5.1.3 Fire fighting foams

Fire extinguishers based on foams are used for class B fires (flammable liquids) as well as in special cases for class A fires (combustible materials). Socio-economic impacts of a regulatory action under REACH on the use of PFHxA and related substances in fire fighting foams are

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[7] See for example information provided by the company Levi-Strauss (2016): http://www.levistrauss.com/wp-content/uploads/2016/05/160311_Case-Story_Levi-Strauss_May252016final.pdf (last access: 13.12.2019).

studied for five broad categories of uses: aviation, petrochemical industry, defence applications, other industrial uses and other uses.

Different fire-fighting foams exist. Fire-fighting foams can be assigned to protein foams (P) and synthetic foams (S) as well as to their respective alcohol-resistant (AR) versions: P(AR) and S(AR), which are fluorine-free and the following foams which are fluorinated fire-fighting foams: Aqueous film-forming foams (AFFF, AFFF (AR)), fluorprotein foams (FP (AR)) and film-forming fluoroprotein foams (FFFP, AR-FFFP). The listed fluorinated fire-fighting foams are often referred to as Class-B-foams.

Fluorinated fire-fighting foams for extinguishing hydrocarbon-based fuel fires include fluorosurfactants to reduce the surface tension of the aqueous solution. AFFFs are especially used for hydrocarbon fuel fires occurring in defence, industrial, aviation and municipal applications, but can also be used in firefighting trainings, in households and in public buildings. Different concentration ranges of fluorosurfactants in foam concentrates are reported, e.g. 0.6 – 1.5 wt% of total weight (Kempisty et al., 2018) or 1.5- 6.5 wt% (Moody and Field, 2000).

In recent years a shift from long-chain PFASs to short-chain PFASs used in AFFF formulations could be observed (Houtz et al., 2016) due to several regulations regarding long-chain PFCAs, PFSAs and their precursors. Most fire-fighting foams are now manufactured with fluorochemicals /fluorotelomers based on a perfluorohexane (C6) chain (UNEP, 2016).

The application of fire-fighting foams will in most cases lead to considerable amounts released to the environment.

Surfactants placed on the market in the area of firefighting foams are estimated to contain PFHxA-related substances in the range of 1 000 – 3 000 t/a. The Dossier Submitter received information that a large share of the emissions from AFFFs is caused by volunteer fire brigades (see Annex B.9.7 Firefighting Foams). However, preliminary results from an ongoing study by the European Commission and ECHA (European Commission DG Environment and European Chemicals Agency, 2019) suggest a market split as follows: Military 29 %, civil aviation 16 %, municipal fire services 14 %, petroleum refineries 20 %, petrochemical manufacturing 21 %. Neither EU/ECHA nor the Dossier Submitter included handheld and mountable fire extinguishers and uses in other industrial manufacturing sites and both estimates are highly uncertain.[8]

Within the last years, a shift from AFFF to fluorine-free foams (FFF) happened. Some airports already substituted AFFF with FFF. Personal information from an alternatives supplier suggests that substitution processes are also taking place in industrial manufacturing sites. These trends might lead to a decreasing demand for AFFFs containing PFHxA-related substances.

But another trend might counteract this decrease. It is expected that foams containing PFOA-related substances have to be replaced when the restriction under REACH becomes effective and the PFOA-related requirements from the Stockholm Convention are implemented in the EU. Without a restriction on PFHxA-related substances the Dossier Submitter expects

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[8] At the time of writing this restriction dossier the joint project by EU and ECHA on the use of PFAS in fire-fighting foam was still ongoing. Preliminary data (European Commission DG Environment and European Chemicals Agency, 2019) suggests that the estimations used for this restriction proposal are plausible, i.e. of the same order of magnitude as what can be expected to be calculated by EU/ECHA. Possibly EU/ECHA will present less uncertain data during 2020 that can be used by RAC and SEAC additionally.

substitution of PFOA with C6 foams. Considering these divergent trends, the Dossier Submitter expects a stable demand for AFFF in the future for the non-restriction scenario.

AFFFs are used in several classes of fires and by several different actors. Main users according to information received by the Dossier Submitter are airport rescue and firefighting, industrial firefighting, petrochemical industry firefighting, defence sector firefighting and private users. In recent years several fluorine-free fire fighting foams meet the requirements of Class-B standard fire fighting performance certifications (see Table 6 in UNEP/POP/POPRC.14/6) as alternatives to AFFF were developed. Therefore, AFFF are no longer necessary for the use in most classes of fire.

The Dossier Submitter intends to restrict the use of PFHxA-related substances in fire-fighting foams that are already placed on the market five years after entry into force of this restriction. Considering the large stocks held and the emissions of PFHxA-related substances when the stocks are used this provision is justified.

The Dossier Submitter further identified two uses where temporary derogations from the restriction on PFHxA-related substances are necessary. The DS proposes derogations for certain uses in the petrochemical industry and for certain uses in defence applications. Alternatives are currently not available which results in unacceptable risks for human health and the environment. The Dossier Submitter expects that alternatives will become available within twelve years for the derogated uses in the petrochemical industry.

At the Stakeholder Workshop on firefighting foam (24.09.2019, Helsinki) several experts confirmed, that alternatives are available for critical applications, like for example for aviation. The Dossier Submitter is aware of two EU members, where the defence sector shifted to FFF: Denmark and Norway (IPEN 2018). The Dossier Submitter was informed by the fire-fighting services of the Royal Danish Airforce that alternatives were available to them on short notice and that extinguishing of JP-8 fuel (which is used by defence sector) is possible.

Other armed forces report challenges regarding a complete transition due to missing alternatives in the defence sector. An exemption shall therefore apply for the use in fire-fighting foam mixtures for seagoing units, air traffic facilities and storage of fuel, furthermore, for training purposes relevant for these sectors provided that emissions occur in enclosed areas and wastewater is collected and disposed of safely. The market of fluorine free foams is rapidly developing and testing requirements for fire fighting foams are already being reviewed, regarding changing requirements when assessing fluorine free foams. Therefore, the feasibility of a transition to fluorine free foams in the defence sector might be possible for all armed forces in the foreseeable future. That is why the efforts on substitution will be closely monitored. Annual reporting on the quantities and efforts of substitution of fire-fighting foams that contain or may contain PFHxA, its salts and PFHxA-related substances will help the European Commission to gather data on the use of these substances in these sectors and to monitor the developments of alternatives. The proposed action sends a signal that substitution of PFHxA, its salts and PFHxA-related substances is desirable.

Experts at the workshop also explained that the market for FFF is expanding very fast and that new (and better products) are developed constantly. Therefore, it is likely that solutions for the derogated uses in the petrochemical industry will be available within the next years.

The Dossier Submitter expects industry to monitor the developments closely and to inform the Commission in time in case no acceptable FFFs are available within twelve years.

The Dossier Submitter could not calculate total impacts of the proposed restriction. However, stakeholders provided extensive comments and additional information was obtained from publicly available resources. Relevant costs for users of fire fighting foams arise from the following substitution activities:

Price differences for fluorine-free fire fighting foams

According to expert information "the price of F3 doesn't differ significantly compared to other foams like AFFF used in Western Europe" (IPEN 2018). However, AFFF foam concentrate is available in different qualities and concentrations. It has been reported that users in some parts of the EU are very price sensitive, resulting in higher cost for them if they are forced to buy fluorine-free products. Some sources claim that fluorine-free foams have to be used in higher quantities to achieve stable performance. Further details are not available.

Considering the above information, on average a slight increase in prices from 0-20 % for the concentrate is calculated when fluorinated foams will be restricted. For further use a central estimate of an increase by ten percent is calculated considering that possibly some foam users active in the lower price segment face higher procurement costs.

Market research by the Dossier Submitter resulted in an assumed price range for 1 kg AFFF from less than 1 €/kg to more than 4 €/kg. A central price of 2 €/kg is estimated.

A 10 % increase therefore would result in substitution costs of 0.2 €/kg foam concentrate. For professional firefighting an annual use of fluoro-surfactant containing firefighting foam concentrate of about 125 000 t/a has been estimated, resulting in additional procurement costs of 2.5 million €/a.

Procurement costs for replacement of AFFF in stock with fluorine-free fire fighting foams

The Dossier Submitter is not aware of any reliable estimates for the EU-wide stock of AFFF foams However, to be able to give an idea on the possible procurement costs it is assumed that stock is five times the annual use of AFFF, i.e. 62 500 t. Not all stock has to be replaced. The dossier submitter assumes that a share of the stock will be used during the five year transition period proposed for fire-fighting foam mixtures that are placed on the market before entry into force of the regulation. Again, just to give an indication on the possible costs for replacement it is assumed that fifty percent of the stock will be used during the five-year transitional period and fifty percent have to be replaced, i.e. 31 250 t.

In that case transition from AFFF to FFF would result in considerable replacement costs. Using the price of 2 200 €/t for replacement of the foams replacement costs would amount to nearly 69 million € when all foams that are placed on the market are replaced as a consequence of this restriction. The numbers are not backed by any real evidence. However, this example numbers illustrate that replacement of AFFF in stock with fluorine-free fire fighting foams will be comparatively expensive.

Incineration cost for replaced AFFF

Fluorinated foams that are no longer usable must be disposed via a safe method. It is assumed that disposal happens via high-temperature incineration. Cost estimate for high-temperature incineration in Europe amounts to 0.83/kg (in 2019 prices) (Klein, 2013). Again, using the numbers from above for illustrative purposes, incineration would result in costs of approximately 26 million €. This number is illustrative and only indicates that incineration costs could be very high.

Cleaning of existing fire fighting installations and vehicles

Substantial costs are connected to the decontamination of fire extinguishing systems. Both, for mobile and stationary fire extinguishing systems, it is difficult to remove contaminations after the fluorinated foam concentrate is discharged and before the fluorine-free concentrate can be used. Relevant parts have to be flushed and decontaminated flush water has to be disposed of safely.

Due to lack of quantitative information on the number of stationary fire extinguishing systems, fire fighting vehicles and foam tanks affected it is not possible to derive an estimated cost for clean-up. These costs might be substantial. Personal information from one stakeholder suggests that, for example, the cost for fire engine clean-up might amount to 50 000 € per vehicle. Another relevant information from the ECHA stakeholder workshop in Helsinki (Chatham House Rules) is that total costs for the substitution at one petrochemical plant amounted to 200 000 - 300 000 €.

Cleaning of stationary fire fighting systems depends among other things on size, configuration and location. Therefore, average costs (per litre or per apparatus) cannot be estimated.

The Dossier Submitter expects that as a result from the listing of PFOA under the Stockholm convention a phase-out process for foams already installed in systems will be implemented. Stored foams would have to be disposed of by 2025. Depending on the then existing stocks and also depending on the limit value implemented by the EU users of AFFF might be obligated to clean their equipment from remaining PFOA-containing stocks or from contaminations that were caused by previous use of PFOA-containing AFFFs. During preparation of this dossier details were not available on how PFOA will be added to the EU Regulation on persistent organic pollutants. Therefore, it is uncertain if there will be an opportunity for users to share cleaning costs, incineration costs and procurement costs for the replacement of C8-containing and C6-containing AFFFs.

Adjustments to existing extinguishing infrastructure

The costs for the adjustment of existing extinguishing systems are expected to be comparatively low. According to information from a distributor of fluorine-free foams minor costs for example for the installation of different nozzles, pressure gauges etc. have to be considered depending on the existing system.

The Dossier Submitter assumes that these costs are small in comparison to other substitution costs considered.

Administrative issues, training with alternative foam

Additional costs are connected to the slightly different properties of fluorine-free foams. It might be possible that some users have to consult external experts to prepare the conversion to fluorine-free foams. It might be possible that additional training is necessary to acquaint firefighters with the new foam. Costs cannot be estimated.

Administrative costs for the reporting requirements will most likely be comparatively low. It is expected that procurement of fire fighting foams for defence applications is highly centralized. The existing centralized structures most likely can be used when reporting to ECHA on uses of fire fighting foams.

Handheld fire extinguishers

The Dossier Submitter received information that in handheld fire extinguishers, fixed foam fire suppression systems and trolley units AFFF cannot be replaced by fluorine free foams. Consequently, users must replace handheld fire extinguishers. It is expected that the fire extinguisher has to be decontaminated before being disassembled for recycling. No statistics on hand held fire extinguishers in use in the EU are available. But it is estimated that EU-wide 40-80 million devices are in use (see Annex E.2.3.5). Only an unknown share of the extinguishers will be affected by the restriction.

Calculation of avoided emissions

For the restriction proposal the use of 12 500 t/a AFFF concentrate is estimated. The Dossier Submitter estimates that without a restriction emissions into the environment of 99 – 3 037 t of PFHxA and salts will happen. Considering the derogations for articles placed on the market, defence aplications and petrochemical industry 8 – 230 t emissions over 20 years are expected in case the proposed restriction takes place, i.e. that 91 – 2 807 t of emissions of PFHxA and salts will be avoided. In case that alternatives for the derogated uses become available sooner than expected even more emissions can be avoided.

It is not possible to calculate cost-effectiveness because important details on costs like the amount of fire-fighting equipment installations affected and the cost for cleaning are unknown. It is not known whether affordability could be an issue. Obviously larger airports, some manufacturers and the defence sector in general can afford the costs associated with substitution to FFF. No information is available if SME, smaller airports or municipal firefighting would be financially prepared to afford substitution. However, the Dossier Submitter takes into consideration that some SME might face difficulties when forced to replace or clean-up their fire-fighting installations. As well it might be possible that smaller professional firefighting units still use very old equipment that is not suited for the use of FFF. Hence, such units would have to replace equipment to be able to replace AFFF with FFF.

It is not possible to determine whether a restriction would be proportionate. Costs are high, especially for the replacement of existing foams. On the other hand, unknown but very high emissions of PFHxA-related substances into the environment would be avoided over 20 years.

For more detailed information on this use see B.9.7 and E.2.3

2.5.1.4 Mixtures for consumer use

PFAS are used in various mixtures intended for end-use by consumers. These include impregnating agents, ski or floor wax, cleaning products, car care and polishes (Jensen et al., 2008; KEMI, 2015; Knepper et al., 2014; Posner et al., 2013). Only limited information is available regarding the use of PFHxA related substances in these products. However, information is available that suggests the availability of alternatives.

While the composition of the mixtures for consumer use (hereafter referred to as "consumer mixtures") is difficult to uncover due to lack of information in SDS and due to business confidentiality (BfR, 2014; Knepper et al., 2014), several studies have analyzed the composition and contents of PFAS in these products. Several authors reported on shorter chain PFAS content in consumer mixtures (see Annex E.2.9.2).

Information on current and future uses of PFHxA related substances in mixtures for consumer use is highly uncertain. Only one manufacturer took the opportunity to present information on uses of PFHxA and related substances. This company reported that it produces mixtures that contain or are produced with fluorinated substances as well as fluorine free alternative products. The production costs, when fluorinated substances are used compared to their non-fluorinated alternatives, are "somewhat higher costs than fluorine free alternatives (11 - 25 %)" (Stakeholder Consultation, 2018). This information is no sufficient basis to develop a general baseline of current and future uses in the EU.

The Dossier Submitter is in contact with manufacturers and hopes that additional information will be available later in the restriction process.

Currently, the Dossier Submitter can only refer to uncertain and incomplete information regarding the market for mixtures for consumer use. The studies that are summarized in Annex E.2.9 Mixtures for Consumer Use suggest that products are available with and without shorter chain PFAS content. Publicly available information (e.g. from Nordic ecolabel certification "Nordic Swan") indicates that fluorinated as well as fluorine-free products are available to consumers for impregnating agents, ski or floor wax, cleaning products, car care and polishes. However, the information is not sufficient to derive robust information on the general availability and current quantities of fluorinated and non-fluorinated alternatives for all product groups affected by this restriction proposal. Information is not only missing on current market-shares and quantities for fluorinated and non-fluorinated mixtures but also it is unclear whether quantities will change in the future.

Emissions to the environment by consumer mixtures can be significant due to the assumed large quantities and qualities of several consumer mixtures used in the EU. The Dossier Submitter additionally assumes that a large share of quantities used will be emitted into the environment.

Fluorinated and non-fluorinated products are available in a similar price range. Several manufacturers produce fluorinated products as well as non-fluorinated alternatives. It is likely that direct economic impacts for manufacturers and consumers will be low because alternatives are available in a price range similar to the fluorinated substances. It is unknown what the respective market-shares are and if quantities will change in the future.

However, impacts resulting from reduced or lost functionality of the mixtures are possible. For example, fluorine-free impregnating agents and floor polish might be less effective in protecting textiles and floors against oil and grease stains leading to a reduced service life or a loss of consumer-friendly cleaning properties. Fluorine-free ski waxes are less effective in optimizing the sliding properties of skiers. Such impacts cannot be further qualified or quantified, but not monetarizing the reduced functionality leads to an underestimation of societal cost.

In absence of more detailed information the Dossier Submitter argues that a restriction on the use of PFHxA, its salts and related substances in mixtures for consumer use will be proportionate. Currently a lot of emissions of PFHxA-related substances in this product groups are directly released into the environment. Alternatives are most likely less costly or similar priced and already available on the market. However, information is scarce on the possible impacts of functional losses and in addition it is possible that the Dossier Submitter is unaware of essential uses in specialized products.
For more detailed information on this use see B.9.13 and E.2.9

2.5.1.5 Semiconductors

The semiconductor industry uses PFASs as process agents for the photolithography process, etching process and furthermore in cleaning fluids. Besides surface activity, also purity and stability of PFASs are relevant properties for semiconductor industry. Furthermore, usage of PFASs in photo-acid generators (PAGs) allows the creation of strong acids and non-diffusive, highly soluble and non-agglomerating PAG molecules (Stakeholder Consultation, 2018).
The overall amount of PFASs used by the semiconductor industry is assumed to be < 10 t/a (Stakeholder Consultation, 2018). Short-chain perfluorinated substances are used in very small quantities as ingredients at low concentrations in photoresist and ARCs chemical formulations in semiconductor photolithography. Short-chain perfluorinated substances are not becoming part of the final product (the microchip).

No single “drop-in” replacement is possible for all semiconductor applications where substitutes exist. Every use has to be re-engineered to see if a replacement material will meet the technology requirements. Moreover, even within the semiconductor industry technologies are not consistent. Alternatives that work for one application or one company, will not necessarily work for another application or another company.

Currently the semiconductor industry does not see an option to substitute the fluorine chemistry from their processes immediately. It is assumed that this process will take more than five years.

If uses in the manufacturing of semiconductors are included in the scope of the restriction, severe economic impacts are expected. Detailed information on impacts for European industry could not be obtained during the consultation or from research. Some general information is available: Global revenue of the semiconductor industry amounted to around 470 billion US $ in 2018. The share of Europe based manufacturers is estimated to be roughly nine percent.[9]

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[9] https://www.zvei.org/fileadmin/user_upload/Presse_und_Medien/Pressebereich/2018-89_Deutscher_Halbleitermarkt/2018-12_Pressekonferenz_Fachgruppe_Halbleiter_ZVEI.pdf (last access: 13.12.2019).

However, it is unknown to the Dossier Submitter how many products from European manufacturers are produced within the EU.

It is important to consider that PFHxA-related substances are used as manufacturing chemicals and are not present in the final articles. Therefore, if production is no longer possible in the EU, it is expected that production will take place outside the EU and articles will be imported. The benefit of a restriction would be < 10 t/a emissions avoided.

The Dossier Submitter therefore proposes a time limited derogation for seven years for semiconductors. Alternatives are not available at the moment but the Dossier Submitter received information that efforts are undertaken by industry to identify fluorine-free alternatives and to integrate them into production processes.

For more detailed information on this use see B.9.12 and E.2.2.

2.5.1.6 Food contact materials and other paper

For the use in FCMs PFHxA-related substances possess valuable properties. They are chemically stable, heat resistant as well as water- and oil-repelling. In addition they are cost-effective because low amounts are sufficient to achieve the desired effect (Begley et al., 2005; UBA, 2018).

The most important application field is the production of paper and board for the packaging and preparation of food. The PFHxA related substances are used in the paper pulp as well as for surface refining. They are applied to create water- and grease- /oil-repellent paper products, which can be used at higher temperatures without burning and adherence to food or other materials. Typical articles are baking paper, packaging for pet food, packing of take away food, table cloths, microwave popcorn bags, cupcake forms and sandwich papers (Blom and Hanssen, 2015; Borg and Ivarsson, 2017; Jensen et al., 2008; UBA, 2018).

In addition, perfluorinated substances are used as emulsifiers during the production of temperature resistant polymer coating systems (e.g. polytetrafluoroethylene) for frying, cooking and baking utensils. Currently, the Dossier Submitter has no reliable information on the total amount of PFHxA used for FCM or the consumption volume of PFHxA containing FCM-products.

Evaluating Data from UN comtrade database about 47 000 t of grease proof paper were used in Europe in 2018. According to industries, the content of side-chain fluorinated polymers is about 0.3 – 1.5 %, depending on the specific purpose of the treated material (stakeholder consultation).

The production of water- and oil- /grease-repellent paper and board products is predominantly based on fluorine technology (UBA, 2018). Apart from that, water repelling properties can be achieved (amongst others) by applying the following techniques (BfR, 2017a; BfR, 2017b; UNEP, 2012a):

- Plastics (films, melts, solutions, lacquers, dispersions), e.g. polyacrylates or polyvinylalcohols with fatty alcohol sidechains, polyamides, modified polyethylenterephthalates and others,
- silicon oils /resins or silicon elastomers,
- paraffins, microcrystalline waxes, low-molecular polyolefins and polyterpenes,
- chromium-, aluminium-, calcium-, sodium- or potassium-salts of saturated straight fatty acids.

Some potential alternatives are identified as substances of very high concern and some might not be desirable due to other considerations (e. g. plastics, nanomaterials).

According to information from industry alternatives for PFHxA and related substances that provide similar oil- /grease-repelling properties (for FCM from paper and board as well as other materials) are scarce or less effective (UBA, 2018). This is even truer when stability at higher temperatures is needed – e.g. as packaging material in contact with hot foods or during baking or frying.

In sum, information on the use of fluorinated substances is very scarce. Several requests to discuss the issue of a potential restriction were not answered by paper producers. Industry claims that potential alternatives for paper applications do not reach an equivalent performance. On the other hand, with the information collection as well as with publicly available information it was demonstrated that some fast food companies already are substituting all fluorinated compounds from their packaging material. So most likely partial substitution processes are taking place and at least some alternatives for substitution are available in the field of short-term use and avoidance of oil migration.

In general, the literature suggests use of PFAS in FCM but on the other hand it also suggests that FCM from the same product categories are available with and without PFAS. Therefore, it seems reasonable to assume that alternatives are available for certain uses and that therefore PFAS are not essential for all applications.

In a recent report on PFAS in paper and board for food contact (Trier, 2017), the authors claim that non-fluorinated alternatives "are available and functional for all uses of paper and board" and that market research demonstrates that "these are cost neutral for retailers and hence most likely for manufacturers".

The authors argue that Danish retailer COOP successfully substituted PFAS-containing FCM with non-fluorinated alternatives in their own brands in a cost-effective way: "COOP estimates that substitution to non-fluorinated alternatives is not more expensive than the fluorinated coatings, and is aiming to expand the phase-out of non-fluorinated alternatives to all of COOP Nordic" (Trier, 2017).

However, the authors suggest that there might be some additional cost in the production process of alternatives. They suggest that one alternative, natural greaseproof paper, might be more expensive because its content of dry solids is low compared to paper containing PFAS which leads to slower machine speed.

The Danish Ministry of Environment and Food announced in September 2019 that Denmark intends to ban the use of all PFAS in paper and cardboard used in FCM by July 2020.[10] The ministry states that alternatives with similar greaseproof and water-repellent properties are available. It is unknown to the Dossier Submitter whether the Danish authorities have gathered any additional information on impacts of this proposed ban or whether they relied on information available.

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[10] Miljø- og Fødevareministeriet, 2019: Fødevareministeren er klar til at forbyde fluorstoffer (https://mfvm.dk/nyheder/nyhed/nyhed/foedevareministeren-er-klar-til-at-forbyde-fluorstoffer/ (last access: 13.12.2019)).

In the Dossier Submitters view the information available is not fully sufficient to conclude on the availability of alternatives in FCM with certainty.

The information on the affected quantities is also uncertain. The Dossier Submitter estimates that approximately 47 000 t/a greaseproof paper are used in the EU. The articles contain 141 - 705 t of C6 fluoropolymers resulting in emissions into the environment of 235 - 470 kg/a PFHxA-related substances during service life and an additional release of about 2.5 t/a PFHxA via landfills. Accordingly, the restriction will result in an emission reduction of 4.7 – 9.4 t PFHxA-related substances and approximately 50 t PFHxA over 20 years.

To estimate the substitution costs the Dossier Submitter uses the information from the literature, i.e. that substitution is cost neutral. However, it is uncertain whether additional machinery is needed when fluorinated products are replaced by natural greaseproof paper.

Data from UN COMTRADE and Eurostat suggest that EU manufacturers export large quantities of greaseproof paper to non-EU countries. The Dossier Submitter has no information on quantities affected by this restriction proposal. No information is available on the share of the quantities that is re-imported as part of finished products. Further, it is not known whether the demand from non-EU buyers will change when greaseproof papers are coated with alternative materials. Therefore, exports represent a major uncertainty for the Dossier Submitters assumption that the restriction will have small impacts on paper manufacturing in the EU.

However, unless additional information to the contrary is provided during the public consultation in the restriction process the Dossier Submitter assumes that economic impacts of a restriction are small.

A major uncertainty with regard to the restriction of PFHxA-related substances in FCM is the potential for functional losses. In case the alternatives are less greaseproof products could be less durable with reduced shelf-life. The potential for burns from hot oil migration and the potential for soiling could be increased. However, no information is available on the likelihood or potential magnitude of such effects.

Some potential alternatives have or might have undesirable impacts. Substitution with siloxanes, plastics or C4-perfluorinated substances could be regrettable substitutions as for food contact materials these potential alternative substances should be avoided. No information is available which substitution strategies would be pursued by the impacted industries in case of a restriction.

2.5.1.7 Printing inks

Adding fluorinated surface active substances to inkjets improves the working of modern printers as well as enhancing picture quality with different media. The surface active fluorinated substance improves surface wetting during the printing process (UNEP, 2012b). During stakeholder consultation it was confirmed that C6 based short-chain fluorinated surfactants are used in some water-based inkjet inks and latex inks. The main function is the reduction of the water surface tension, when applied on nonporous substrates. (Stakeholder Consultation, 2018).

Little data on the volumes of PFHxA related substances used in inks is available. But results from the consultation with industry indicate that short chain PFAS are still commonly used in printing inks applications.

Various non-fluorinated surfactants were tested as alternatives. Only the C6-based fluorinated surfactants provided the required performance, but research on non-fluorinated alternatives surfactants continues. Alternative technologies are solvent based or UV-curable mixtures (Stakeholder Consultation, 2018).

According to industry, fluorinated products are used in applications that require exceptional technical performance such as industrial coatings. In many coatings, siloxanes are commonly used instead, also because fluorine-based additives are comparatively expensive. It has been reported that C4 PFAS have partially replaced the long-chain PFAS. The dossier submitter therefore believes that alternatives are available.
Considering the lack of additional information, a calculation of substitution costs was not possible but the following aspects have been considered:
Information from industry suggests that printing inks are mainly produced outside the EU.

- A very uncertain estimate for the tonnages used is 10 – 100 t/a of PFHxA-related substances.
- Approximately 80 percent emissions from the use of PFHxA-related substances is estimated, i.e. 8 - 80 t/a.
- Companies already undertake R&D irrespective of this restriction proposal. Therefore, these costs must not be counted as direct impact from the restriction proposal.
- Siloxanes and C4 PFAS have partially replaced longer chain PFAS. The Dossier Submitter assumes that this group of substances can be used as direct substitute. The Dossier submitter notes that this might pose a case of regrettable substitution.
- Industry stated that slightly higher costs for the substitute substances in latex printing inks are expected.

Latex printing inks
For latex printing inks the dossier submitter proposes a temporary derogation. During the stakeholder consultation information was submitted that PFHxA-related substances are used in latex printing inks. One manufacturer claimed that a simple "drop in" substitution is not possible and a more extensive reformulation will be necessary to develop competitive products. The manufacturer estimated the time needed for substitution with five to ten years. Considering that research for substitution according to information submitted has already started, the dossier submitter assumes that alternatives will be available shortly after the proposed entry into force of this restriction.
However, printers in use have to be equipped with the current generation of printing inks. These printers are expected to have a 7 – 10-year service life. Hence, printing inks for the current printer generation need to be available after 2024 to avoid early replacement of the printers. The proposed exemption of seven years ensures that printer hardware can be used until the expected service life expires. Therefore, impacts from early replacement are expected to be negligible. The environmental impacts from continued emissions caused by the proposed derogation cannot be calculated because no separate information on the market for latex printing inks is available.

2.5.1.8 Chrome plating

Identification of PFOS as persistent organic pollutant (POP) and the inclusion in Annex B of the POP regulation (EC No 850/2004) led to the substitution of PFOS with 6:2 fluorotelomer sulfonate (6:2 FTS also known as H4-PFOS) in chrome plating processes (UNEP, 2018a).

6:2 FTS is used in hard chrome plating processes as well as decorative chrome plating processes as surfactant to lower the surface tension of the plating solution. The differences between both chrome plating processes are reflected in thickness, hardness and deposition of the chrome layer on the plated object.

PFASs (e.g. 6:2 FTS) are used as wetting agents for numerous wet-chemical processes of surface finishing due to their properties with regard to process safety (Blepp et al., 2017). The wetting agents are used for chrome baths to lower the surface tension of the plating solution. The surfactants are also used to decrease aerosol emissions especially to reduce emissions of chromium VI (carcinogen) to the air (UNEP, 2018a; Willand et al., 2019).

Based on an extrapolation (see B.9.10.2) approximately 100 – 1 000 t/a 6:2 FTS are used for chrome plating in the EU, resulting in 20 - 200 t/a emissions of PFHxA-related substances into the environment. This extrapolation is highly uncertain. Therefore, estimates for the emissions from the specific chrome plating processes are equally uncertain. Without a restriction 400 – 4 000 t will be emitted into the environment over 20 years. Considering a five-year derogation for hard chrome plating emissions would be reduced to 69 – 687 t over 20 years as a result of the restriction.

For plastic electroplating non-fluorinated and non-toxic surfactants are available if the production line is very constant. As a precondition, the plastic goods have to be dipped into the surfactant liquid before the etching process (UNEP, 2015).

Fluorine-free substances/products are not considered equally effective to fluorinated surfactants. Furthermore, additional risks with respect to safety, process stability and device preservation are mentioned by the German electroplating industry association (UNEP, 2018a). Nevertheless, these substances have been used successfully in bright (decorative) chrome electrolytes (Blepp et al., 2017).

An economic assessment for PFOS has been undertaken. The POP Review Committee concluded: "Non-fluorinated surfactants are used during the production process for hard metal plating and decorative metal plating. Although they are degraded in the chromium electrolyte or etching bath and must be constantly dosed, the costs are not higher than using fluorinated surfactants" (UNEP/POPS/POPRC.12/INF/15/Rev.1).

For decorative plating a shift to other electrolytes that are Cr(III) based is an available alternative. This would mean that the demand on surfactants and process fluids is considerably lower, and that PFAS are not required.

It has to be considered that in contrast to fluorinated products the fluorine-free products often have to be added diluted and in smaller dosages throughout the day. To achieve comparable surface tensions, higher amounts of wetting agents are necessary (Willand et al. unpublished). Therefore, it is possible that production processes need to be changed.

If an alternative is used where the goods have to be dipped into the surfactant liquid, an additional bath has to be installed into the production facility. This means additional cost for the procurement of equipment as well as cost related to a reorganization of the production facilities for some companies.

The information that is available at the moment is not sufficiently detailed to derive a cost-effectiveness estimate. Therefore, the following information was taken into account to consider the economic impacts qualitatively:

- PFHxA-related substances are used in large quantities in the EU (estimated 100 - 1 000 t/a)
- It is estimated that approximately 20 percent of the quantities used are emitted into the environment. The Dossier Submitter estimates that without a restriction 400 – 4 000 t of PFHxA related substances will be emitted to water in the EU within 20 years.
- Alternatives are available and used for decorative chrome plating and plastic electroplating.
- Alternatives for hard metal plating have been identified but not tested sufficiently by the industry.
- Of the various alternatives available some seem to have issues regarding performance, health and environmental impacts.
- Some alternatives proposed cannot be used without additional cost. For example, control devices for air flow, additional baths or additional waste water treatment could be needed. It is possible that manufacturing routines have to be changed.
- The chrome plating industry is characterized by heterogeneity and a large share of small and medium enterprises.
- It is not possible to derive a realistic restriction scenario for this diversified industry.
- The automobile industry is an important customer of hard metal plated parts and relies on these products.
- PFHxA-related substances are not present in the chromium-plated article. Therefore, no impacts are expected for imported articles.

Considering the admittedly scarce information the Dossier Submitter proposes a temporary five-year derogation from the restriction for hard metal plating. The information suggests that an immediate substitution of substances falling under this restriction proposal is not possible. The European manufacturers of hard chromium plated articles would no longer be able to participate in the market and most likely their products would be replaced by imported articles. This could lead to supply shortages for downstream users who, like the automotive industry, depend on these products heavily. Five years also is realistic to install the necessary production processes for continued manufacturing in the EU.

For decorative chrome plating and plastic electroplating, alternatives are available and scarce information suggests that the cost of substitution is affordable.

2.5.1.9 Building material

This use covers the treatment of hard surfaces like e.g. stone, ceramics, glass, tile ground etc. with either solvent or aqueous based fluorinated polymer solutions or dispersions and paints to impact functional oil and water repellency. Such finishes are applied to the surfaces via spray, roller or brush applications and are available for industrial and professional users and for consumers, too. The estimated tonnage range for this application area is < 1000 tons per year. Sufficient information on specific uses is not available. But it is assumed that coatings with fluorosurfactants especially are used outdoors. So, a direct release of perfluorinated surfactants from the sector building and construction into the environment is considered as very likely in significant amounts.

There is little data on the volumes of PFHxA related substances used in paints. Comments from stakeholders indicate that short chain PFAS are still commonly used in paint applications (paints and varnishes). Suppliers in the paint industry commented that surface-active fluorinated substances are generally significantly more expensive than alternative surface-active substances. They are only used if a very low surface tension is required which cannot be achieved with a fluorine-free alternative (UNEP, 2013).

For water repellency the use of fluorine-free alternatives is possible. Considering that fluorinated substances are more expensive, fluorine-free alternatives would be cost effective and available if only the water-repellent properties are needed and considered.

The industry submitted information that dirt and oil repellent properties might have considerable benefits: longer useful lifetime, lower repairing interval, reduced paint waste from recoat preparation. It might also be possible that the protective properties of anticorrosive paints can be enhanced by perfluorinated urethanes. Thus, it is possible that some benefits of the current use of PFHxA-related substances would be lost in case of a restriction. No information is available on the magnitude of such effects.

However, considering that coatings with fluorosurfactants especially are used outdoors, i.e. with potentially significant emissions of perfluorinated surfactants into the environment, the Dossier Submitter proposes a restriction on PFHxA-related substances in building materials. Benefits include possibly lower-priced products and cessation of direct emissions into the environment from outdoor applications.

2.5.1.10 Photographic applications

PFASs are used in the production of photographic material or x-ray material, where the substances can be contained as wetting agents in very small concentrations.

Here some PFAS are essential for the application of coating layers during the manufacture of some remaining conventional photographic products.

According to a stakeholder for some specific applications suitable non-fluorinated alternatives have not been found. Substances to be used in photographic applications require specific properties, e.g. lack photoactivity or colloidal stability.

Nevertheless, information has been submitted that for specific photographic applications (photographic coatings applied to paper and for use in printing plates) non-fluorinated alternatives are used and that in conjunction with the move to digital imaging these substances have successfully replaced the use of PFAS. These alternatives and alternative techniques should also be useable for the remaining applications with C6-based fluorinated surfactants (UNEP, 2018b).

According to information received during the consultation for the PFOA restriction proposal, remaining products are mainly used by professional or hobby photographers, in medical or defence applications. Digital techniques will completely replace traditional photographic film within the coming years. Owing to this strongly decreasing market demand and the significant investment that would be needed to switch to alternatives (0.5 – 1 million € for a single photographic material), it is likely that the manufacture of the photographic film could cease in response to the proposed restriction. It is reasonable to assume that costs would be high compared to the volumes of PFOA and PFOA-related substances used given the probability that no traditional photographic film might be available to consumers/downstream users anymore. The dossier submitter assumes that this business will phase out within the next years. Therefore, an exemption for five years after entry into force of the restriction is justified after which no more production is expected anyway.

2.5.1.11 Cosmetic products

Per- and polyfluorinated alkylated substances (PFAS) are used in various cosmetic products. To quantify the vast amount of PFAS, substances containing perfluorinated (side-)chains often are derivatised to their corresponding perfluoroalkyl acids (PFAA), which are measured thereafter. After a derivatisation step, PFHxA concentrations have been reported in concentrations up to 6 500 µg/kg in cosmetic products. PFAS serve as emulsifiers and surfactants and are added to cosmetic products for binding, bulking and skin /hair conditioning purposes. Studies suggest that PFAS are used in higher concentrations only in some product groups. Market research suggests that PFAS-free alternatives are available for all cosmetic products.

CosIng, the European Commission database for information on cosmetic substances and ingredients (which lists cosmetic ingredients and their intended functions), comprises more than 70 perfluorinated substances. According to the database, substances like polyfluoroalkyl phosphonic acids (PAPs) serve as emulsifiers and surfactants. Other PFAS (e.g. perfluorinated polymers, ethers and esters) are added to cosmetic products for binding, bulking and skin /hair conditioning purposes. According to a recent study from the Danish Environmental Protection Agency, 0.7 % (78 out of 11108) cosmetic products had declared contents of fluoroalkyl substances or other fluorinated compounds (Brinch et al., 2018).

The highest concentrations of PFAS have been found in foundations, concealers and sun screen. Emissions from these uses are at least partly emitted directly into the environment and wastewater.

In general, it would be feasible to model use quantities and emissions for individual products by using the default values for individual daily use amounts proposed by the Scientific Committee on Consumer Safety[11]. However, no information is available on the share of products placed on the market that would be impacted by a restriction on PFHxA-related substances. Accordingly, the Dossier Submitter cannot estimate total use quantities and emissions into the environment of PFHxA-related substances that are used in cosmetic products.

Market research indicates that PFAS-free alternatives are available for all cosmetic products: Some large producers have announced a phase-out of all PFAS from their products: L'Oréal,

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[11] SCCS NfG, 2018SCCS NfG, 2018. The SCCS Notes of Guidance for the Testing of Cosmetic Ingredients and Their Safety Evaluation. 10th revision. SCCS/1602/18. Available from: https://ec.europa.eu/health/sites/health/files/scientific_committees/consumer_safety/docs/sccs_o_224.pdf (last access: 13.12.2019).

H&M, Lumene, the Body Shop, Isadora and Kicks. L'Oréal announced in 2018 that the reformulation processes are completed for all their trademarks (Chemical Watch, 2018).

The Danish retailer Coop eliminated all cosmetics containing PFAS from their product range.

No cosmetics producer submitted information during the stakeholder consultation. However, the phase-out activities by the mentioned companies suggest that affordable alternatives are easily available and functional losses of products are not to be expected. It can be assumed that alternatives are available for the whole scope of cosmetics on the market. For example, L'Oréal is the world's largest cosmetics company and serving various market segments with different brands (e.g. mass, professional, luxury, and active cosmetics markets).

The voluntary phase-out activities demonstrate that the transition to a PFAS-free production is affordable and therefore the Dossier Submitter proposes to restrict the use of PFHxA-related substances in cosmetic products.

Uncertainties regarding functional losses are minor. The manufacturers that have agreed to voluntary substitution serve large parts of the cosmetics market and have alternatives available for all their products.

Some uncertainties remain regarding the affordability of a restriction on PFHxA-related substances. According to information from the restriction proposals on microplastics and D4, D5 and D6 several participants on the cosmetic market are small and medium enterprises. No information is available how these companies would be affected by a restriction on PFHxA-related substances. Uncertainties remain on whether such companies are prepared to reformulate at affordable cost, i.e. whether scientific expertise and financial resources are always available to reformulate their products without functional losses.

2.5.1.12 Other special uses of fluorinated compounds

A number of applications of fluorinated compounds have been reported in the information collection or are mentioned in the literature that do not completely fit in one of the areas described in more detail:

- Products made by PFHxA, its salts and precursors have properties that are essential for handling of fragrance and odor compounds in products and articles, such as they are surface-active and inert to different chemicals. However, the use of PFHxA, its salts and precursors in this field of use is not clear so far.
- One company reported that a side chain PFSA C6 product is used for the production in proton exchange membranes for the fuel cell industry.
- One company uses perfluoropolyethers in an aerosol application during their in-house quality control of other fluoropolymer products. They recognised that such laboratory applications might be sources of potential emissions (untreated off air) and they will reduce these emissions in the future.
- One company uses polymethylacrylates in optical fibres.
- One company uses C6 fluorosurfactants in the production of polyester films as anti-fog coatings for face shields for surgeons. Probably this use would be covered under the exemption for personal protective equipment (2.5.1.2).

- One company uses fluorinated substances in special glass for:
  - Construction (external glazing and interior decorative glass),
  - automotive (original and replacement glass),
  - solar sector.

For some applications they see a potential for substitution by fluorine-free alternatives if only water repellence is needed. In other sectors they do not consider this option.

For all this uses no further socioeconomic information has been submitted. The Dossier Submitter concludes that in order to determine whether exemptions are needed the companies need to submit additional information during the SEAC consultation.

2.5.1.13 Administrative cost

Testing costs might be incurred to some importers to test the occurrence of PFHxA, its salts and related substances through unintended use. This will induce some costs for the companies. Part of these testing costs most probably can be shared with the testing needed to comply with the PFOA and C9-C14 PFCAs restrictions. No further information is available.

2.5.1.14 Enforcement cost

Average enforcement costs have been identified in connection to the restriction on lead compounds in PVC for all of the EU 28 Member State Agencies to ensure compliance with EU regulation, with reference to Milieu (2012) and RPA (2012). In these reports ECHA assessed the administrative cost of all member states to comply with restrictions to be approximately 55 600 € per year in total. This number should only be seen as an indication of the magnitude of the enforcement costs, since a variation in costs is observed for different restrictions. It might be possible that enforcement cost can be reduced when some of these costs are shared with the enforcement costs associated with the PFOA restriction (and most probably the C9-C14 PFCAs restriction).

2.5.1.15 Summary of the costs

Table 8 summarises the volumes of PFHxA, its salts and PFHxA-related substances that will have to be replaced in response to the proposed restriction. Cost estimates are missing or incomplete for most uses.

Table 8: Summary of use volumes and substitution costs estimates of PFHxA, its salts and related substances.*

PFHxA and PFHxA-related substances in …	**used tonnages t/a (central estimate)**	**current release t/a (central estimate)**	**emissions avoided estimate 20 years cumulative t (central estimate)**	**costs 20 years cumulative million € (central estimate)**	**cost effectiveness based on emissions €/kg**	**uncertain/unknown cost**
manufacture of (acrylic-) polymers with C6 side chains	1 000 – 10 000 (5 500)	3.5 – 33.9 (18.7)	50 – 475 (263)	unknown	unknown	reorganization of business unemployment effects of reorganization
manufacture of fluoroelastomers (APFHx)	10 – 100 (30)	0.1 – 1 (0.3)	2 – 20 (6)	40 – 320 (180)	2 000 – 160 000	
clothing and textiles except outdoor and occupational	5 910 – 30 780 (18 345) 2 460 – 52 310 (27 385)	26.6 – 66.5 (47) 152.9 – 3 249.2 (1 701)	495 – 1 236 (866) 1 427 – 30 306 (15 867)	no additional costs for manufacturers	0	loss of stain and oil repellency: reduced service life cleaning convenience reduced water repellency possible for some applications
outdoor clothing	300 – 750 (525) 60 – 1 275 (668)	2.3 – 5.8 (4.1) 4.1 - 86.2 (45.2)	43 – 109 (76) 41 – 883 (462)			
occupational wear	190 – 475 (333) 38 – 808 (423)	1.4 – 3.7 (2.6) 2.6 – 54.6 (28.6)	27 – 69 (48) 26 – 559 (293)			
carpets and other textile floor coverings	400 – 1 000 (700) 34 – 440 (237)	3.1 -7.7 (5.4) 2.3 - 29.7 (16)	58 – 143 (101) 24 – 303 (164)			
industrial textile fabrics	300 – 500 (400) 0.1 – 1.2 (0.7)	2.8 – 7.0 (4.9) 0 – 0.1 (0.1)	40 – 100 (70) 0.1 – 2.5 (1.3)			
fire fighting foams	1 000 – 3 000 (2 000)	5 – 145 (75)	91 – 2 807 (1449)	price change: 0 – 100 (50) other data not available	missing data	replacement of foam on the market incineration cost for replaced foam cleaning of fire fighting apparatus

						adjustments to extinguishing infrastructure: Administrative issues, training handheld fire extinguishers
paper	141 – 705 (423) 0 – 470 (235)	1 – 6 (3.5) 0 – 32 (16)	23 – 113 (68) 0 – 326 (163)	no additional costs for manufacturers	0	additional machinery increasing grease and oil spillage causing cleaning costs and possibly injuries
mixtures for consumer use	no data for emissions estimate			no additional costs for manufacturers	0	reduced service life, e.g. of textiles, floor covers and cars convenience losses (cleaning) reduced desired effects (ski waxes)
printing inks	10 – 100 (55)	8 – 80 (44)	147 – 1 473 (810)	missing data		less precise printing R&D expenditure availability of alternatives in time
chrome plating	100 – 1 000 (800)	20 – 200 (160)	331 – 3 313 (2 650)	missing data		additional chrome baths additional air ventilation conversion and reorganization of manufacturing installations
building material	no data for emissions estimate			no data		reduced service life faster soiling higher repairing intervals
photographic applications	no data	< 5	< 75	no additional costs for manufacturers	0	loss of remaining production when phase-out to digital photographic applications takes longer
semiconductors	no data	< 10	< 130	missing data		identification and implementation of alternatives cessation of production in Europe

cosmetic products	no data for emissions estimate	negligible additional costs for manufacturers	0	loss of aesthetic functions decreased water repellency loss of convenience (application of product)

*red: C6 fluoropolymers; blue: PFHxA-related substances; green: PFHxA and salts

When no additional information was available the median from min-max represents the central estimate.

2.5.2 Human health impacts

The human exposure to PFHxA, its salts and related substances has the potential to cause adverse health effects. The toxicological profile of PFHxA is described in Annex B.5. Studies suggest that PFHxA might cause risks with regard to developmental and reproductive toxicity.

To date no indications of serious human health risks are documented. Human exposure to PFHxA is limited and the studies available suggest a considerable gap between effect levels and measured exposure levels and the current state of research suggests that human exposure to PFHxA is unlikely to increase to levels that cause risks to the human health. But since PFHxA is extremely persistent and the releases are not reversible the magnitude of future exposure cannot be predicted conclusively. The extreme persistence means that the exposure via environment is intergenerational, and inevitably increasing, in case the releases are not minimised. It may thus be possible that serious health concerns related to PFHxA-exposure may be documented in the future. It is important that releases are reduced to a minimum and possible future uses of the substances are prevented.

Considering the absence of clear evidence regarding human health impacts from exposure to PFHxA, the Dossier Submitter concludes that there are currently no impacts to be expected. However, with a rising environmental concentration of PFHxA this may change in the future.

2.5.3 Environmental impacts

Environmental risks from the emission of PFHxA cannot be quantified with sufficient certainty. As discussed in section 1.3.7 releases from PFHxA are distributed on a wide scale in the environment. Full removal from the environment is difficult for point source pollution and virtually impossible for widespread releases. Information on current spatial effects from releases is uncertain and future effects are impossible to predict. Effects will not only occur on the point of release of PFHxA but also far away from its point of release. Even though it is unclear if PFHxA bioaccumulates, the continuous exposure via the environment could lead to toxic effects in the same way as for vPvB substances. Due to the similarity of the concern, PFHxA can be considered as a non-threshold substance for biota and man via environment.

In principle, it might be possible to monetise at least some of the environmental impacts of PFAS emissions. The willingness to pay for environmental or groundwater remediation of contaminated sites could be estimated from a number of cases where contaminated sites already have been remediated and where cost estimates are available. However, although there is some information available it is too uncertain and too related to specific damage events to derive generalised cost information from it.

For example, one study analysed reported remediation cost and estimated costs for environmental remediation of all PFAS in the EU totalling 821 million € to 170 billion € (Goldenman, 2019). This cost estimate does not differentiate between various PFAS and its upper bound estimate is more than two orders of magnitude higher than the lower bound estimate. Furthermore, these numbers only reflect contaminated sites where remediation is possible. Widespread emissions that contaminate large areas in low concentrations are not covered by this cost estimate. However, the evidence presented in this study illustrates that remediation is very costly and incomplete, because it is not possible for widespread emissions.

EurEau, the European federation of national associations of drinking water suppliers and waste water services, estimates that effective treatment of contaminated drinking water resources from very mobile substances would be very expensive. According to their calculation the cost for reverse osmosis, a treatment technique against most polar compounds would raise the price of water treatment by more than 1 €/m^3, resulting in circa 200 €/year additional cost for the average household. Other societal cost which are not considered in this estimate would be impacts from additional waste (approximately 25 percent of the treated water) or the potential consumer losses in terms of taste when natural ground and spring water is replaced by treated (artificial) water that needs to be re-mineralised (EurEau, 2019). The cost estimates are for the treatment of very mobile substances in general, but EurEau singles out short-chain per- and polyfluoroalkyl substances as substances that need to be addressed to avoid such additional cost.

In sum, while monetisation of some environmental impacts would be possible, the cost estimates would be extremely uncertain and only reflect an unknown fraction of the total cost. Therefore, partial cost estimates are meaningless.

A derivation of an acceptable amount of release into the environment is also not possible. Any releases that occur contribute to the environmental stock over time, which would eventually exceed any effect threshold in the future.

Therefore, and as PFHxA, its salt and related substances are non-threshold substances, for the purpose of this restriction proposal, releases of these substances are considered as a proxy for risk. The benefits of this restriction can only be measured in its capacity to reduce emissions. The central estimation for emissions reduction over 20 years resulting from this restriction proposal is approximately 1 500 t C6-related fluoropolymers, 20 600 t PFHxA-related substances and 1 450 t PFHxA. Some uses are not included in this estimate. See B.9 Exposure Assessment and Table 8 for uncertainty ranges and further information.

2.5.4 Other impacts, practicability and monitorability

Social and wider economic impacts:

The proposed restriction is not expected to have major effects on employment because for the majority of uses alternatives are available implementable at a reasonable cost. For most of the articles concerned, the use of PFHxA, its salts and related products is only one step in the production process. Some of the alternatives do not provide all the functions that are resulting from the application of fluorinated substances. However, for consumer articles oil and stain repellency is just one additional function of the product. Consumers still have incentives to buy them for their remaining properties. The identified alternatives are available and affordable. It is expected that production processes will not be interrupted. For some uses, derogations have been proposed because alternatives are not available immediately. For some industries (i.e. hard chrome metal plating and semiconductors) major employment effects are possible when no derogation is granted. Because PFHxA-related substances are only used in manufacturing and are not present in the final product, it would be reasonable to expect that parts of the production would be replaced by imported articles. The Dossier Submitter expects alternatives to be available within the next years and therefore the proposed derogations are time-limited.

For other uses, imported articles and mixtures will also be covered by the restriction. Relocation of production facilities to countries outside the EU is not a likely response by the industry concerned.

In sum, closing down of business, relocation of business activities and employment effects are not expected. One uncertainty in this regard is the manufacturing of fluoropolymers. Production facilities affected will need restructuring for alternative production purposes. Manufacturers have not provided sufficient information to substantiate the claim that a shutdown of a manufacturing plant is the most probable outcome of a restriction. However, this scenario is considered as possible by the Dossier Submitter and therefore an uncertainty.

Distributional impacts:
Distributional impacts are difficult to predict. It might be possible that in some sectors first movers that are already developing and marketing fluorine-free alternatives take over market shares from other market actors. However, stakeholder consultation and market review suggest that most companies affected are actively pursuing research on alternatives.

Any costs of the proposed restriction to EU and non-EU businesses are likely to be passed on along the supply chain. Most of the costs will consist of functional losses. As has been demonstrated, monetary effects will be low (except for the replacement of AFFF) considering the fact that non-fluorinated alternatives are less expensive than fluorinated substances. Some properties of the products will be lost or reduced. Consumers could value these functional losses as reduced convenience or functionality.

However, in general, no detailed information on distributional effects of the proposed restriction surfaced in the preparation of this report.

2.5.5 Proportionality

The restriction proposal for microplastics[12] states on proportionality: "In order to assess the proportionality of the proposed restriction, the comparison of the cost-effectiveness with the cost-effectiveness of former measures to avoid PBT(-like) substances can provide some indication. A recent study has looked into this issue more closely. It concludes that, although cost estimates of previously adopted actions do not allow deriving a value for society's willingness to pay to reduce PBT presence, use, and emissions, roughly speaking, the available evidence suggested that measures costing less than €1 000 per kilogram PBT use or emission reduction would usually not be rejected for reasons of disproportionate costs, whereas for measures with costs above €50 000 per kilogram PBT such a rejection is likely (Oosterhuis et al., 2017).

When looking at the data, it is obvious that there is a large grey area where it is unclear whether society is willing to spend the amount needed for reduction of emissions. Much higher costs than 1 000 € per kg have been spent in the past to reduce or avoid PBT substances implying that there is a large range of cost-effectiveness that can be considered proportionate."

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[12] https://echa.europa.eu/de/restrictions-under-consideration/-/substance-rev/22921/term (last access: 13.12.2019).

The willingness to pay for emission reductions for other fluorinated substances and substance groups could be considered as relevant comparison points. This restriction proposal examines properties similar to the specific properties of PFOA, PFOS and C9-C14 PFCAs. However, those restrictions might not be totally adequate points of reference in the Dossier Submitter's view. For those substances, short-chain PFAS were considered as the most likely substitute and substitution costs were calculated on the basis of that assumption. However, short-chain PFAS were considered only as less hazardous to an unknown degree.

This restriction proposal, however, assumes that PFAS will be replaced by non-fluorinated alternatives where it is assumed that hazard and risk will be reduced to a larger degree. In the Dossier Submitter's view, the risk reduction capacity of this restriction proposal is larger, resulting in the assumption that society's willingness to pay should be expected to be larger than for previous regulatory measures on fluorinated substances.

Looking only at the costs where monetization is possible with the limited information that is available, the restriction is proportionate. For most uses identified costs are low due to the fact that non-fluorinated alternatives are expected to be less expensive than or similar priced as the restricted substances. However, the Dossier Submitter has identified uses where he expects significant substitution costs that cannot be quantified. Further it has to be considered that functional losses are a cost to society that also cannot be monetized by the Dossier Submitter.

Subjectively valued attributes like loss of convenience or modified physical attributes of a product might impact the cost-effectiveness of this restriction. Examples would be textiles with reduced water repellency, cosmetics that are more difficult to apply evenly or paint coatings that are soiled faster. Other functional losses might lead to impacts that theoretically have market values, but crucial information is missing. Examples include reduced service life of textiles when stain and oil repellency functions are missing or higher repairing intervals for constructions. The Dossier Submitter is not aware of any studies or statistics that provide a scientifically sound basis to estimate the magnitude of such effects for this restriction proposal.

Cost-effectiveness estimates highly depend on the assumptions on substitution costs as well as on emission factors. The data basis to derive cost as well as emission estimates is very limited. The costs are underestimated.

The Dossier Submitter is considering the information and evidence available and finds it plausible that the missing costs are not unproportionately high when compared with previous restrictions. However, the DS emphasizes large uncertainties regarding the uses for fire fighting foams, photographic applications, printing inks and chrome plating:

- Fire fighting foams: the costs associated with the replacement of fluorinated foams with fluorine-free fire fighting foams are expected to be high. The central estimate for avoided emissions is 1449 t over 20 years. For illustrative purposes it is assumed that the average costs for the cleaning of stationary and mobile fire fighting apparatus will be 50 000 €/unit. In this case case cost-effectiveness of a restriction would be >1 000 €/kg if >28 980 cleaning procedures are necessary. Both assumed numbers for average cleaning costs and the number of cleaning procedures are illustrative but cannot be dismissed by the Dossier Submitter as completely implausible. Other costs, e.g. for replacement and incineration of foams, have to be considered, too. Therefore,

uncertainties remain regarding the proportionality of the proposed restriction for the use and placing on the market of AFFF that contain PFHxA-related substances.
- Photographic applications: phase-out of traditional photographic may take longer than five years.
- Printing inks: Alternatives might not be available as soon as expected by the Dossier Submitter meaning that the market for latex printing inks cannot be served.
- Chrome Plating: Loss of business to non-EU manufacturers is possible. Restructuring of the manufacturing plants might be very expensive considering that a few thousand manufacturing companies in Europe might be affected.

The Dossier Submitter expects these industries to present additional information during public consultation if the cost effectiveness of the proposed restriction is uncertain.

In sum, the proportionality of this restriction proposal is difficult to determine for some uses. Uncertainties regarding the costs are large. However, the same can be said for the benefits. Negative properties of PFHxA have been described in this dossier, among others it:

- Is extremely persistent,
- is mobile in the aquatic environment,
- can be distributed easily within and between environmental compartments,
- has a long-range transport potential,
- has the potential to enrich in plants,
- is very difficult to remove from the environment in case of point source pollution,
- is impossible to remove from the environment in case of widespread emissions,
- has the potential to contaminate drinking water.

Most of these properties and possible effects are still poorly understood. Additionally, there is a high uncertainty regarding its long-term effects and future use quantities. Thus, future effects may be underestimated.

Other restriction proposals under REACH have faced large uncertainties, too. The Dossier Submitter of the restriction proposal for intentionally added microplastics (see footnote 12) demonstrates that immediate regulatory action might be justifiable whenever effects of a substance are uncertain but irreversible and when learning about a possible harm is expected to happen. In this case a "first act, then learn" approach might be preferred over a "first learn, then act" approach.

The dossier submitter expects that learning on the quantities and effects of PFHxA emissions to the environment will take place in the future. Currently there is considerable uncertainty about effects but high certainty regarding the irreversibility of emissions. Society places a value on preserving nature and therefore on the reduction of harmfull emissions. In case of uncertainty society also places a value on the reduction of possible effects. This value will be higher when the possible effects are irreversible because then future options to avert negative impacts are constrained.

On the other hand, the "first act, then learn" approach imposes sunk costs on society. These costs have been described quantitatively and qualitatively by the Dossier Submitter.

To summarise, costs and benefits of a restriction are uncertain and both environmental emissions and policy costs are irreversible. However, costs of a restriction on PFHxA, its salts and related substances are most likely affordable for society and the impacted industries. The possible impacts of continued emissions on the environment and human health are largely unknown but might be extremely severe. Hence, it is likely that society's willingness to pay for risk reduction is high and a restriction as proposed is proportionate.

3 Assumptions, uncertainties and sensitivities

Assumptions relevant for the socio-economic analysis of the individual sectors in the scope of the restriction proposal are detailed in their respective sector-specific assessment presented in Annex E. The main uncertainties in the analysis are due to knowledge gaps regarding the tonnages of PFHxA, its salts and related substances affected by the proposed restriction and where relevant, the availability and or functionality of alternatives. Knowledge gaps are especially large with regard to the impact of this restriction proposal on imports and exports. On the basis of available statistical data (from EU and OECD) it is not possible to derive quantities of imports and exports for articles that contain PFHxA or related substances. Product groups are often broad and do not differentiate between fluorine-free and fluorinated articles. Additionally, the Dossier Submitter lacks information on the nature of international commodity chains. Therefore, he has no information on whether exported /imported articles are further processed and then imported /exported again. For example, information is available that EU-manufacturers export significant amounts of food contact materials. However, no information is available on whether these articles re-enter the EU incorporated in other articles.

The information on amounts of PFHxA, its salts and related substances used in the EU and imported in articles is limited. Therefore, only rough estimates are possible. Limited data is available on amounts used and on environmental emissions, especially from downstream user sites. Therefore, only rough emission estimates are presented in this restriction proposal. The risk assessment of PFHxA is complicated by several uncertainties in relation to toxicity, potential for accumulation in organisms, fate and exposure. These uncertainties are described in the respective sections of this report. Not much is known about fate. The non-threshold-based approach to risk assessment (and the minimization approach to risk management) was adopted in response to these uncertainties.

Furthermore, it is very uncertain whether all related substances with relevant uses have been identified.

As summarized in the preceding sections, the conclusions on the proportionality of the proposed restriction hold for the majority of uses also when plausible worst-case costs for key assumptions are applied.

4 Conclusion

It has been demonstrated that perfluorohexanoic acid (PFHxA) is characterized by a negative combination of properties. The substance is extremely persistent, mobile in the aquatic environment, can be distributed easily within and between environmental compartments by aqueous media, has a long-range transport potential and the potential to enrich in plants. Once released, it is very difficult to remove PFHxA from the environment. Therefore, PFHxA has the potential to contaminate drinking water. In addition, there is a high uncertainty regarding its long-term effects. Thus, future effects may be underestimated. Based on this, there is scientific evidence of probable serious effects to the environment.

Information to derive a robust predicted no effect concentration (PNEC) as well as a predicted environmental concentration (PEC) is currently insufficient. Therefore, it is not possible to conclude whether risks are adequately controlled, either now or in the future.

PFHxA is not a PBT substance but the concerns raised for PFHxA compare with the concerns for PBT/vPvB substances. Additional concerns regarding mobility and long-range transport potential of PFHxA reason a non-threshold approach. The Dossier Submitter therefore concludes that PFHxA should be treated as a non-threshold substance for the purposes of risk assessment, similar to PBT/vPvB substances under the REACH regulation, with any release to the environment (see chapter B.9) and environmental monitoring data (details in annex B.4.2.4) regarded as a proxy for an unacceptable risk.

In accordance with previous restriction proposals on non-threshold substances, the Dossier Submitter argues that every emission to the environment increases the likelihood of adverse effects. Therefore, current and future emissions have to be minimized.

The proposed restriction is considered to be proportionate to the risk: Emissions to the environment are irreversible and alternatives are available and affordable. Its cost-effectiveness is expected to be similar to REACH restrictions that have been decided previously. Furthermore, the proposed restriction is considered affordable for the impacted supply chains. The Dossier Submitter considers that the proposed restriction is also justified for the following reasons:

- PFHxA can be regarded as extremely persistent. This extreme persistence is regarded as an incalculable hazard itself, as PFHxA will stay in the environment for decades to centuries. Furthermore, several studies show that PFHxA is the ultimate degradation product of several precursors.
- The available data on physicochemical properties of PFHxA show that it is a very mobile substance preferentially distributing to aquatic systems. Thus, once emitted to soil, PFHxA leaches into underlying water bodies easily.
- This high mobility leads to a ubiquitous distribution of PFHxA in the environment. PFHxA has been found in several compartments such as in surface waters and in marine waters. Also, some drinking water resources and drinking water itself are already contaminated with PFHxA.
- Once emitted, PFHxA can only hardly, if at all, be removed from water. The high mobility in combination with the persistency lead to difficulties in removing PFHxA from the environment. It is difficult to filtrate out PFHxA and PFHxA does not degrade during standard treatment processes.
- Due to persistency and mobility, PFHxA has the potential for long-range transport via the aqueous environment, e.g. in oceans. This is proven by findings of PFHxA in remote areas as for example in the Arctic Ocean and Arctic biota.
- Continuous emissions of PFHxA (and its potential precursors) into the environment will lead to the enrichment of PFHxA in the environment including increased background concentration levels, especially in the aquatic systems.
- PFHxA enriches in plants especially in leaves and fruits and thus in edible parts of plants. This enrichment can pose a risk regarding distribution along the food chain as

plants, e.g. fruits and vegetables, are important human nutritions and therefore are a source for human exposure.
- Numerous direct and indirect sources of PFHxA, its salts and related substances contribute to the overall environmental emissions of PFHxA.
- PFHxA, its salts and related substances are used in large quantities wide dispersively. Furthermore, many products and articles containing these substances are imported into the EU. The release of PFHxA and its related substances from imports significantly contributes to the environmental increase of these substances. Thus, an EU-wide restriction seems reasonable to prevent future uses in products made in the EU or abroad to prevent increasing releases into the environment.

For the sectors where specific transitional arrangements are proposed, the measure is justified in the following manner:

- Fluoroelastomers: The measure is justified for fluoroelastomers with C6 polymerisation aids. Emissions to the environment are in the very low kilogram-range while costs are very high. This leads to a cost-effectiveness ratio that is unproportionate to justify a restriction.
- Personal protective equipment intended to protect users against risks from hazardous liquids and substances and respective impregnation agents for re-impregnation: A general exemption is justified because no alternative products are available that ensure the same performance as products on the market in the foreseeable future.
- Non-woven medical textiles: A general exemption is justified because no alternative products are available that ensure the same performance as products on the market in the foreseeable future.
- Fire-fighting foams: Alternatives are largely available but for transition to and testing of alternatives a transitional period of five years is proposed to ensure capacity for action in case of emergencies. To minimize additional release into the environment no such arrangement applies for training and testing unless all releases are contained for latter. For defence uses in airports, ships, fuel depots and for training purposes in enclosed areas an exemption applies in combination with an annual requirement to report and a revision clause. Thereby taking into account advances in the field of fluorine free foams and knowledge about already performed transitions in the defence sector as well as reports from the defence sector on current challenges regarding transition to fluorine free foams.
  For non-defence uses: For cases of class B fires in storage tanks with a surface area above 500 m^2 a transitional period of twelve years has been proposed because with current testing methods no conclusive evidence can be produced whether non-fluorinated foams perform adequate in environments where very large liquid based fires can break out.
- For semiconductors alternatives are not available at the moment but some efforts are undertaken by industry to identify fluorine-free alternatives and to integrate them into production processes. A transitional arrangement of seven years is considered appropriate to give industry sufficient time to substitute and enable industry to continue production in the EU.
- For latex printing inks a transitional period of seven years has been considered to account for the service life of related printer hardware.

- Hard metal chrome plating: Alternatives are available but have not been tested sufficiently. To ensure steady performance of hard plated products a transitional period of five years is proposed.
- Photographic applications: With the move to digital imaging the use of PFAS in photographic applications has decreased. Companies with remaining niche applications have small turnover and emissions. Costs of substitution would be too high to be affordable. Therefore, a transitional period of five years should be enough to phase-out these uses.

Analytical methods to enforce the restriction and to monitor the effect are under development.

National regulatory actions will not adequately manage the risks of PFHxA and related substances. An EU wide restriction would create a more level playing field amongst companies operating on the EU market. A restriction on PFHxA, its salts and related substances is the most appropriate way to limit the risks for human health and the environment on an EU level.

Based on the information provided, it is concluded that the following thresholds are feasible for mixtures and articles placed on the market:

- **25 ppb for PFHxA and their salts,**
- **1 000 ppb for the sum of PFHxA related substances.**

The costs for industry and enforcement agencies were assessed to be affordable. A transitional period of 18 months seems to be manageable because alternatives for current uses are widely available. The proposal gives sufficient time to the impacted supply chains, which are not ready to transition to alternatives within 18 months.

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