EUROPEAN CHEMICALS AGENCY

Committee for Risk Assessment (RAC)

Committee for Socio-economic Analysis (SEAC)

Background Document

to the Opinion on the Annex XV dossier proposing restrictions on

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
ARC	anti reflective coatings
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
NaPFHx	sodium perfluorohexanoate
NGP	naturally greaseproof paper
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/ perfluoroalkyl 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	wastewater 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 by the Dossier Submitter for confidential information.

This Background Document is based on version 1.0 of the Annex XV report published on the ECHA website in March 2020 to coincide with the beginning of the six-month consultation on the proposal. The Background Document incorporates revisions to the proposal made by the Dossier Submitter in response to the consultation comments and to discussions in RAC and SEAC plenaries. The Background Document also includes RAC and SEAC 'boxes' in the text to highlight important elements of the Committees' evaluation of the proposal, specifically where the opinions of RAC or SEAC deviate from the Dossier Submitter's conclusions.

RAC and SEAC box

RAC and SEAC noted several inconsistencies between different sections and between the Background Document and its annexes. These inconsistencies concern the information and values presented (e.g. release estimates differ between sections), as well as the terminology used. For example, categories of use are named differently across the Background Document (e.g. paper and board vs. food contact materials and other paper, clothing in general vs. apparel). Moreover, reference to fluoropolymers and side-chain fluorinated polymers is sometimes inaccurate.

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 PFHxA-related substances and by the following degradation of the related substances. Releases occur particularly 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 to centuries, 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 and transplacental transfer.

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 related substances 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.

RAC and SEAC box

RAC and SEAC proposed changes to the scope and conditions of the restriction.

The details of these changes are reported in the RAC and SEAC opinion, together with the justification for these changes.

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 (including polymers) (a) 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; (b) 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 in the production of or placed on the market in or used 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.

2. The following substances shall be derogated from this designation: (a) C_6F_{14}; (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). (c) Any substance having a perfluoroalkyl group C_6F_{13}- directly attached to a sulphur atom.	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. 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, papers, printing plates and inkjet photo media coatings; (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 for cases of class B fires; this shall not apply to: (i) use of fire-fighting foam for training; and (ii) use of fire-fighting for testing unless all emissions to the environment are minimised and effluents collected are safely disposed of. 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 to latex printing inks until XX XX XXXX [seven years after the entry into force] 8. Paragraphs 1 and 2 shall not apply until XX XX XXXX [12 years after the entry into force] to: (a) concentrated fire-fighting foam mixtures for cases of class B fires in tanks with a surface area above 500

	m^2; (b) semiconductors and semiconductor related equipment. 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), (g), (h), (l); (c) High visibility clothing fulfilling the requirements of EN ISO 20471 Class 3 (d) impregnation agents for re-impregnating of articles referred to in paragraph 9(b), (c), (g); (e) textiles for the use in engine bays in the following usage groups: Automotive and aerospace industry (f) epilames used in watches (g) medical devices as specified in Regulation 2017/745 of the European Parliament and of the Council; (h) filtration and separation media used in high performance air and liquid applications that require a combination of water- and oil-repellency; 10. From (entry into force + 12 months), a natural or legal person placing a mixture or an article specified in paragraph 9(b)-9(h) on the market for the first time and benefitting from the derogation therein shall provide by 31 January of each calendar year a report to the European Chemicals Agency 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. The European Chemicals Agency shall forward the data to the Commission by 31 March every year.

	11. The concentration limit referred to in paragraph 2 shall be (a) 2000 ppb for the sum of PFHxA and its salts in fluoropolymers; (b) 150 ppm for the sum of PFHxA and its salts in fluoropolymers used in the following usage groups: Engine parts in automotive, aerospace and shipping industry. (c) 10 ppm for the sum of PFHxA and its salts in fluoropolymers used in coating of electronic devices until XX XX XXXX [7 years after entry into force]. (d) 100 ppm for the sum of PFHxA related low molecular substances in fluoropolymers. (e) 2500 ppm for the sum of PFHxA related low molecular substances in fluoropolymers used in the following groups: Engine parts in automotive, aerospace and shipping industry. (f) 500 ppm for the sum of PFHxA related substances in fluoropolymers used in coating of electronic devices until XX XX XXXX [7 years after entry into force]. 12. From (entry into force + 12 months), a natural or legal person benefitting from the derogation in paragraph 6 or paragraph 8(a) shall provide by 31 January of each calendar year a report to the European Chemicals Agency containing: (a) A description of their efforts on substitution of fire-fighting foams that contain PFHxA, its salts and PFHxA-related substances; (b) quantities they used in the previous year of fire-fighting foams that contain PFHxA, its salts and PFHxA-related substances per sector specifying: (i) share in training and in operation (ii) whether emission was contained, collected and disposed safely or emitted into the environment. The European Chemicals Agency shall consolidate and forward the data to the Commission by 31 March each year. 13. By (entry into force + 6 years), the

	Commission shall carry out a review of paragraph 6 and paragraph 8(a) in the light of new scientific information, including the availability of alternatives for articles referred to in paragraph 6 and paragraph 8(a), and proposing amendments if indicated by the outcome of the review. As long as the Commission concludes that there is still need for these derogations this review shall be carried out every three years.

Explanatory notes:

Column 1:

Paragraph 2(a): This paragraph refers to any linear and/or branched perfluorinated hydrocarbon with a total carbon number of C6. It is not degraded to the corresponding PFCA given the stability of the carbon fluorine bond.

Paragraph 2(c): This paragraph refers to any substance having a perfluoroalkylgroup C_6F_{13}- directly attached to a sulfur atom. These substances are already covered by the restriction with the arrowhead substance perfluorohexane-1-sulfonic (PFHxS) acid including its salts and related substances. The Dossier Submitter notes that the derogation could also be placed in the right column of the table above. It would be up to the Commission to ultimately decide whether the left or the right side of the entry is the most appropriate to address the derogation of PFHxS, its salts and related substances.

Column 2:

Fire-fighting foam:
Paragraph 5(c): For fire-fighting foam mixtures for cases of class B fires 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 (c) (i) and (ii) derogates fire-fighting foam mixtures that contain or may contain PFHxA, its salts and PFHxA-related compounds that are used for training and for testing unless emissions to the environment are minimised and effluents collected are safely disposed of. 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. Class B fires are fires of liquid substances or substances becoming liquid as specified in the European standard EN2 Classification of Fires.

Paragraph 6: While some armed forces (e.g. Denmark cf. Annex E2.3.4 Table 31) already reported transitions to fluorine free foams (FFF) and positive experiences with these foams, other armed forces reported challenges regarding a complete transition due to missing appropriate aqueous film forming foam (AFFF) alternatives in the defence sector. One of the challenges reported is, that the available FFF do not fulfil the requirements of some defence-specific applications for fire-fighting foams. Due to some exceptionally high risks of defence-specific fire-scenarios (e.g. fire-fighting on seagoing units) a switch to FFF is currently not possible. Generally, the use of FFF for defence applications is desired and new alternatives are being investigated regularly. However, at the moment a restriction of the use of AFFF for defence-applications would lead to unacceptable constraints for fire-fighting in some defence-specific scenarios (information received by the Federal Ministry of Defence (Germany) and confirmed by another national authority in the public consultation).

For defence applications a derogation 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 (i.e. incinerated at temperatures > 1400 °C).

Paragraph 8: Furthermore, a derogation 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 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 derogations 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 articles or mixtures covered by Paragraph 9 (b) to 9(h): 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 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. In the case of fire-fighting foams emissions to the environment occur mainly in the use phase. For this reason, the reporting requirement is linked to the actual application of FFF (i.e. the applicants benefitting from the derogation) and not the placing on the market. This is further supported by the fact, that FFF have a long shelf life of up to 30 years (see B.9.7).

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.

Persistence:

- PFHxA is extremely persistent and by far exceeds the trigger of being vP. Once PFHxA is released, PFHxA will remain in the environment for decades to centuries
- Exposure to PFHxA increases if releases are not minimized.
- Effects related to environmental exposure with PFHxA might occur with delay and are not limited to the present time
- PFHxA causes long-term and intergenerational exposure of humans and biota – even if releases cease. Future generations will be faced with these contaminations.

Mobility:

- PFHxA is efficiently distributed throughout the aquatic environment (incl. ground water and drinking water) whereas none of the environmental compartments acts as a removal pathway for the substance.
- There is no natural barrier to prevent PFHxA from being distributed to oceans and to groundwater
- Exposures and emissions are difficult to regulate with end-of-pipe solutions. It is difficult to remove PFHxA from wastewater, drinking water and contaminated sites
- 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, its salts and PFHxA-related substances do not occur naturally. However, PFHxA is already ubiquitously present in the environment and drinking water shown by monitoring data.
- PFHxA effects will not only occur on the point of release of PFHxA but also far away from its point of release and will affect a very large number of people.
- Drinking water is a source of direct exposure of humans to PFHxA as drinking water is contaminated with PFHxA

Long range Transport potential

- PFHxA is transported over long distances and contaminates remote regions indicated by modelling data and confirmed by monitoring, showing the occurrence of PFHxA in remote regions
- Vulnerable populations and ecosystems in remote regions are likely to be affected by this.

Enrichment in Plants:

- Because of its high water solubility, PFHxA enriches in plants, especially in edible parts.
- Via plants, PFHxA enters the food chains of humans and animals.

Effects on Human Health and environmental species:

- PFHxA may cause adverse effects on human health and environmental species such as reduced levels of thyroid hormones and developmental toxicity.
- Co-exposure of PFHxA with other relevant PFAS could synergistically increase injuries of cell or tissues, for example based on protein binding, increased peroxisomal oxidation or impaired membrane barrier functions
- Due to an increased permeability of cell membranes, PFHxA might increase the adversity of other toxicants.
- PFHxA enters biota and humans via several routes. Humans are continuously exposed via drinking water. Plants accumulating PFHxA are another route for human exposure.
- 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
- PFHxA is already present in humans (general population), as shown by findings in breast milk, urine, and blood. Experimental studies in animals and studies investigating humans indicate a placental transfer.

PFHxA-related substances share one structural element with PFHxA: the perfluorinated carbon chain. 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 although the T criterion might be fulfilled using toxic effects relevant to human health. 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 long-range transport potential of PFHxA facilitate the unpredictable and irreversible adverse effects over time.

With regard to the extreme persistence of PFHxA and its remains in the environment for decades to centuries, 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 articles cannot 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 enters 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 derogations have been proposed for socio-economic reasons. The derogated uses will constitute relevant emission sources. However, the emissions of PFHxA, its salts and PFHxA-related substances will be reduced by more than 50 percent over 20 years in comparison to a non-restriction scenario. However, large quantities of releases refer to releases from deposit. Due to its short service live, mainly grease prove-papers and clothing only emit smaller quantities of PFHxA, its salts and PFHxA-related substances during its service live. In contrast, large quantities of PFHxA, its salts and PFHxA-related substances are emitted for many years from landfills. The current uses already contribute considerably to emissions that occur over 20 years. So, this restriction reduces the emissions substantially in larger time frames than 20 years.

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 important 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.

Uses that are addressed by the restriction but for which no alternatives are available at the moment are e.g. in the production of semi-conductors or in textiles to generate dirt and oil repellency of a certain standard.

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

SEAC box

SEAC notes that the RAPEX (Rapid Exchange of Information) system has been replaced by Safety Gate.

A joint approach for different enforcement activities such as inspections and testing for the occurrence of several 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, substances with perfluorinated sections in their molecules (PFASs) have been used in the manufacture of several products and articles. Common to all these substances is the substitution of the carbon-hydrogen-linkage in organic compounds by a carbon-fluorine-linkage. This linkage is extremely stable. Not only smaller PFAS molecules are important resources for the production of products and articles. Large quantities of the low molecular PFASs are used to produce specifically designed polymers. In general, these polymers belong to two different polymer classes: fluoropolymers and side-chain fluorinated polymers (SFPs). Fluoropolymers, such as polytetrafluoroethylene (PTFE), have a carbon-only polymer backbone where fluorines are directly attached to the backbone carbon atoms. SFPs consist of a non-fluorinated polymer backbone with fluorinated side-chains. Non-fluorinated side-chains can be present as well. The fluorinated side-chain is typically composed of a terminal perfluoroalkyl moiety, a spacer and a linker (Buck et al., 2011; Henry et al., 2018). PFAS and the different polymers made thereof 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 persistence 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 and 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 related substances. 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 non-essential uses of PFASs. The European Commission published a chemicals strategy for sustainability on 14 October 2020 in which it stressed that the use of per- and polyfluoroalkyl substances (PFAS) in the EU needs to be phased-out, unless their use is essential.

1.2. Manufacture and Uses

The majority of PFHxA, its salts and related substances is used for the production of fluoropolymers and side-chain fluorinated polymers (SFPs), either as monomers or as processing aids to control polymerisation processes. About 51 000 t/a of fluoropolymers and SFPs 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 and SFPs are also important in manufacturing of articles which are used in automotive- and aviation industries or in industrial plant building.

Large quantities especially of clothing are imported into the EU. According to the report from the EC-DG environment, up to 17 000 000 t of clothing are imported into the EU. According to TEGEWA, about 75% of clothing used in the EU are imported into the EU. About 65 000 t/a of low molecular PFHxA-related substances like 6:2 acrylates are applied in textiles used in the EU.

PFHxA-related substances are used in large quantities in several other textile applications, e.g. personal protective equipment (PPE, for example for fire-fighting or in the medical sector), filtration media, medical textiles, carpets and rugs, upholstery and building materials.

An estimated tonnage of 105 – 563 t PFHxA-related substances is used annually in fire incidents, testing and training of fire-fighting foams. 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 fire-fighting 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.

For the use in food contact materials large quantities of PFHxA-related substances are used in the paper pulp as well as for surface refining. They are applied to create water- and grease-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, tablecloths, microwave popcorn bags, cupcake forms and sandwich papers.

6:2 FTS (up to 100 t/a) is used as well in hard chrome plating as in decorative and plastics chrome plating processes. The substance serves 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.

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.

Fluorinated polymers are used in a coating process to achieve high levels of water repellency to protect electronic devices from water and corrosion damage and to achieve electrical resistance of printed circuit boards (PCB) during immersion in liquids.

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.

Several additional uses where reported in the public consultation. PFHxA-related substances are used in smaller quantities e.g. in the manufacture of watches, optical fibres and PTFE micro-powders.

Information from REACH registrations and CLP-notifications was also used, and on the basis of those, more than one hundred substances within the scope of the proposal were found to be manufactured and/or imported to the EU/EEA, however the majority of them in quantities below 1 t/a.

The end-uses of low molecular PFHxA related substances are described in Figure 1. For several uses the use quantities are very uncertain. With this in mind it can be stated that treated paper and board products is the dominating sector of use. The second largest sector is textiles. It is important to note, that about 75% of clothing that come to the European market is imported into the EU. The bulk of garments is imported from the Asia-Pacific region, e.g. from China, Vietnam or from Indonesia. These textiles significantly contribute to environmental releases of PFHxA, its salts and related substances. This figure is based on median values from min/max data summarized in Table 25 c in part II.

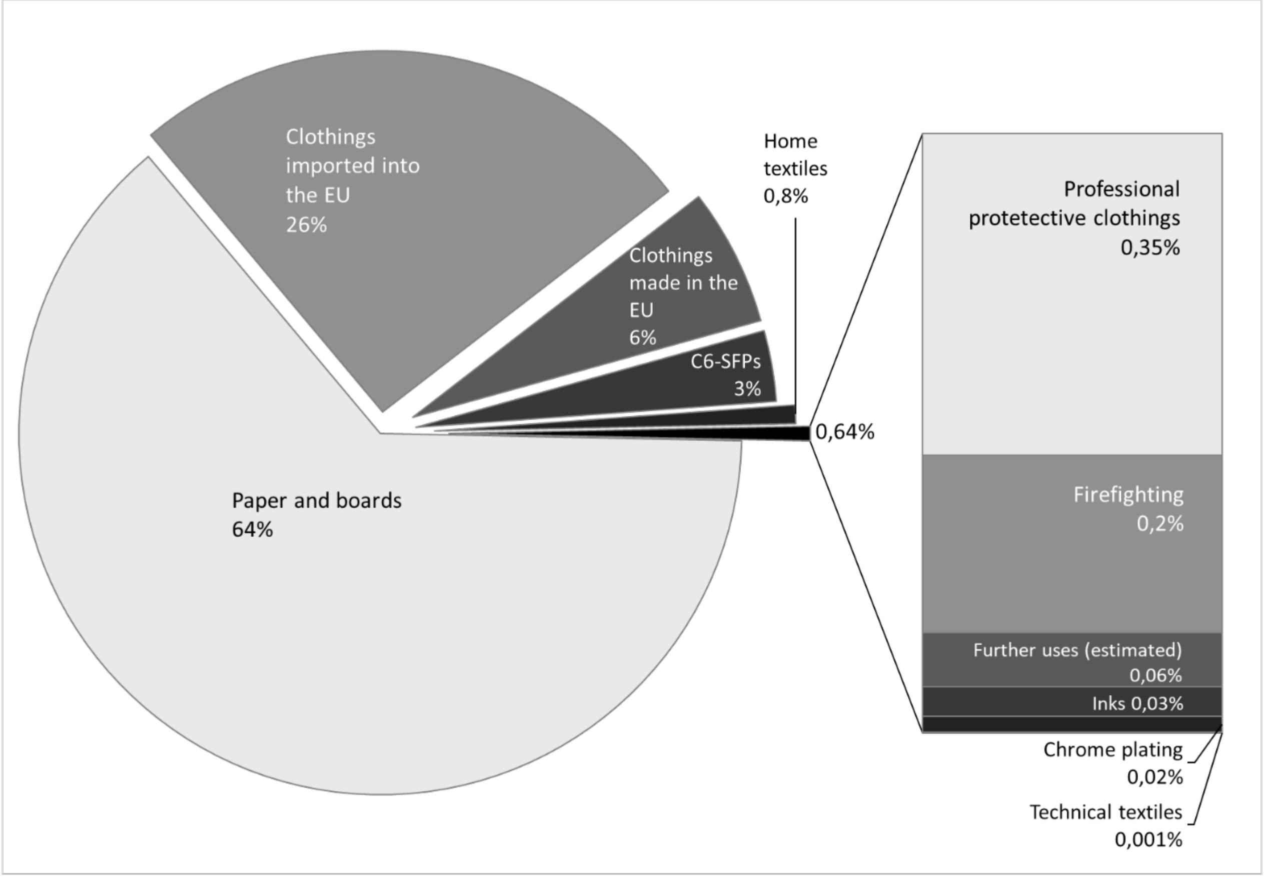


Figure 1: Current end use of low molecular PFHxA-related substances itemized to the sectors of use in the European Union.

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 derogated from this proposal for restriction:

- — C_6F_{14};
- — 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);
- any substance having a perfluoroalkyl group C_6F_{13}- directly attached to a sulphur atom.

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 regulatory 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.

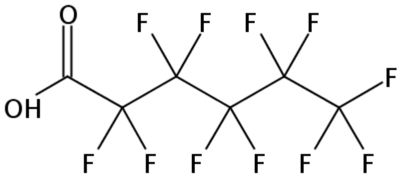
EC number:	206-196-6
EC name:	undecafluorohexanoic acid
CAS number (in the EC inventory):	307-24-4
CAS name:	hexanoic acid, 2,2,3,3,4,4,5,5,6,6,6-undecafluoro-
IUPAC name:	undecafluorohexanoic acid
Molecular formula:	$C_6HF_{11}O_2$
Molecular weight range:	314.05 g/mol
SMILES notation:	C(=O)(C(C(C(C(C(F)(F)F)(F)F)(F)F)(F)F)(F)F)O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

Table 2: Substance identity of APFHx.

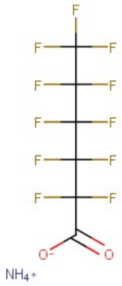
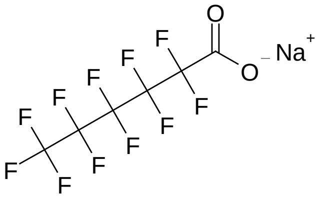
EC number:	244-479-6
EC name:	ammonium undecafluorohexanoate
CAS number (in the EC inventory):	21615-47-4
CAS name:	hexanoic acid, 2,2,3,3,4,4,5,5,6,6,6-undecafluoro-, ammonium salt (1:1)
IUPAC name:	ammonium undecafluorohexanoate
Molecular formula:	$C_6H_4F_{11}NO_2$
Molecular weight range:	331.08 g/mol
SMILES notation:	[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 notation:	[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 degradation is 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 related substances (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 related substances, 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.

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. It is not possible to estimate the point of time in the future when effects would be encountered as PFHxA is also formed from PFHxA-related substances, which complicates the prediction of exposures. Problems with PFHxA exposure however do already occur today (e.g. contamination of soil in Rastatt, Germany and uptake of PFHxA in plants).

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.

In the following summaries are given of the chapters B.4.1.1.-B.5 where properties of PFHxA are discussed in regard to the concerns they evoke for environment and human health.

Persistence

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 persistence 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 greater than 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, PFHxA is considered to exceed by far the trigger of being very persistent and expected to clearly exceed the threshold values for being “very persistent” (vP) defined in REACH Annex XIII. (for more details see chapter B.4.1.1).

Therefore, once PFHxA is released it will remain in the environment for decades to centuries (Cousins et al., 2016). Even if PFHxA emissions will be stopped, background concentrations of PFHxA, e.g. in surface water, oceans as well as groundwater, will remain.

As long as PFHxA emissions to the environment – also from degradation of related substances - 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.

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.

Mobility

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).

Its environmental distribution properties 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 a 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.

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).

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 wastewater 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.

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 fire-fighting foam containing PFHxA or related substances.

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)).

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., 2021); (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).

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)).

The combination of the extreme persistence 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 related substances 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.

Enrichment in plants

Due to its high water solubility, PFHxA enriches in plants, especially in edible parts of plants (see chapter B.4.5). 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).

Food consumption, more in detail vegetables, function as source of PFHxA to humans. This is of relevance for example when agricultural soil is contaminated with PFHxA (and/or some related substances), leading to the contamination of agricultural plants. Via plants, PFHxA enters the food chains of humans and animals.

Effects on Human Health

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, urine might be a more appropriate matrix for biomonitoring of PFHxA.

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. Additionally, other PFASs are continuously introduced into aquatic ecosystems and are ubiquitously present in complex mixtures. PFHxA could be involved in a synergistic effect due to increase of cell membrane permeability.

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.

In a 28-day gavage study, treatment-related changes associated with PFHxA were observed on the amount of thyroid hormones in rats, namely reduced levels of 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. Furthermore, increased relative organ weights of kidney and liver of rats have been noted (NTP, 2018). This effect was also observed in a subchronic toxicity study in male rats (200 mg/kg bw/d) showing further a significant reduction in body weight at doses of 50 and 200 mg/kg bw/d (Chengelis et al., 2009).

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).

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 developmental 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.

PBT Assessment

As described above 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 for forward to reason that safe concentrations of PBT/vPvB substances in the environment cannot be established with sufficient reliability which can be found in detail in chapter 1.3.7. In the following summaries are given for the bioaccumulation potential as well as the effects on the environment.

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 muscle tissue, kidney, liver and blood ((Gannon et al., 2011), (Numata et al., 2014)). 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, 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).

The Bioaccumulation potential of a substance is often described as its potential to partition into lipids. In case of PFASs protein binding is however an important portioning property. 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). Interactions of PFHxA with biological matrices in plasma and tissues contribute to their tissue distribution and bioaccumulation patterns (Kudo, 2015). Protein binding is one mechanism among others that explains the wide distribution of PFHxA to most organs in the body of pigs (Numata et al., 2014) (see chapter B.4.4.4).

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 to centuries 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. Endocrine disrupting properties in the environment are currently investigated in the frame of the substance evaluation of two related substances of PFHxA: 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl acrylate (EC-No. 241-527-8; CAS-No. 17527-29-6; 6:2 FTA) and 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluorooctyl methacrylate (EC-No. 218-407-9; CAS-No. 2144-53-8; 6:2 FTMA).

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 related substances. Overall, the extreme persistence in combination with the formation from related substances makes it very difficult to reliably estimate environmental long-term co-exposure with different PFASs.

1.3.6. Exposure/Emissions assessment

RAC box

Based on the information available in the Background Document and submitted during the consultation, RAC performed a qualitative evaluation of the releases and effectiveness in view of the need to minimise the releases. This is because RAC concludes that the reported quantitative release estimates are unreliable due to numerous inconsistencies between different sections of the Background Document, insufficient justifications for the assumptions made and significant gaps in the information presented or in the reporting of the underlying calculation methodology for the different use sectors. Therefore, RAC concludes that the Background Document provides insufficient information to draw firm conclusions on the central estimates and ranges of releases to the environment. At the same time, RAC notes that measured data in various environmental matrices convincingly demonstrates that emissions to the environment occur.

The details of RAC's qualitative evaluation and of these concerns are reported in the RAC opinion, together with the respective justifications.

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 as well import as export of the substances and the substances included in products 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/centuries ahead.

PFHxA is formed in the environment as a degradation product of several related substances (see chapter B.4.1.2). The yield of PFHxA formation strongly depends on the type of related substances 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 related substances available on the market is unknown, but known related substances cover a broad range of uses and possible release patterns into the environment.

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.

The challenges for exposure assessment are:

- The extreme persistence of PFHxA (see chapter B.4.1 and above).
- Emissions already occurred in the past have to be considered in the same way as new releases.
- Emissions and subsequent transformation of PFHxA-related substances have to be considered 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

Import in the EU/EEA of PFHxA itself takes place at low level only (six CLP-notifications, no REACH registrations), therefore only a limited 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 65 kg/a of the ammonium salt may be released to water and soil, during service life. Assuming, a low release of APFHx by leachate from landfills up to 390 kg may be released into the environment annually. Due to the only known use of PFHxA and its salts in fluoroelastomers, **the only direct release of 0.1 to 1 t/a is assumed by this use**. However, the estimated number of unreported releases could be much higher. The remaining share of PFHxA and its salts releases (up to 569 t/a) is considered as indirect releases by the degradation of related substances.

Indirect sources

The release of PFHxA from indirect sources mainly occurs by degradation of the related substances. For the assumption it does not matter whether the formation of PFHxA occurs already at/directly after manufacturing of the related substances or later in products and articles. Therefore, the measured amount of PFHxA in various products and articles like in textiles is considered as transformation product from the used PFHxA related substances.

6:2 Fluorotelomer iodides are used to manufacture 6:2 fluorotelomer alcohols. These are intermediates to produce 6:2 acrylates (like 6:2 fluorotelomer acrylate (FTA) as of 6:2 fluorotelomer methacrylate (FTMA)) subsequently. The 6:2 acrylates are monomers for manufacturing of acrylate polymers with C6 fluorinated side chains (SFPs).

Above that, the low molecular PFHxA-related substances are further used as surface-active agents. Therefore, these substances are manufactured and used between 1 000 to 10 000 t/a. The release of C6 fluorochemicals into the environment at manufacture of the related substances and at manufacture of articles containing these substances is assumed to be low (< 10 t /a). Several stakeholders reliable demonstrated strong mitigation measures at production to prevent the release of low molecular C6 fluorochemicals via WWTP and into the air. The majority of substances is regained and recycled at the manufacturing process. Therefor only 10% of standard release factors for manufacturing processes were assumed.

However, an uncountable number of different low molecular C6 fluorochemicals are used for manufacturing products and articles. The exact number and the used quantities are unknown. Due to its properties these substances may be released into air, water and soil at service life and from deposition of the articles containing these substances in large quantities. These substances are very soluble in water and they accumulate in water. Based on the evaluated data, it is assumed that about 1 349 to 14 425 t of related substances currently released into the environment annually (see Table 25 c, Part II).

By degradation these substances contribute to the indirect emission of PFHxA and other PFAS into the environment. Many low molecular PFHxA related substances degrade very quickly to the acid. But, compared to the large amount of (unknown) PFHxA related substances, there are only few data on fate and behaviour of the related substances. Often 6:2 FTOH is formed as intermediate. Above that, there are some publications available describing the fate and behaviour of 6:2 FTOH and 8:2 FTOH in the environment. Therefore, the degradation of 6:2 FTOH to PFHxA is used as surrogate for the degradation of related substances in general. In compiling the dossier two different approaches were used. As the worst-case approach it is assumed that 100% of low molecular PFHxA related substances are transformed into PFHxA at some time. The molecular masses of the fluorotelomer alcohol was proportioned to the molecular mass of PFHxA (86%). For a more realistic worst-case scenario the data gained by several authors in degradation experiments are used. On this basis, about 70 kg PFHxA are emitted by one tonne 6:2 FTOH (e.g. Liu 2010, Zhao 2013).

Taking the worst-case approach, currently between 1 160 and 12 406 t/a of PFHxA could be released in sum theoretically. This number seems to be overestimated, because in degradation of related substances not only PFHxA is formed. In contrast, the realistic worst-case numbers (94 – 1 010 t/a PFHxA) are an underestimation of PFHxA formation due to the use of 6:2 FTOH as surrogate.

Due to the large amount of treated paper and board products used in the EU, the release of PFHxA related substances from such products is the highest from all considered uses. Currently up to approximately 9 445 t/a of related substances are released into the environment. This results annually in 8 123 t/PFHxA (worst case) / 661 t/PFHxA (realistic worst case).

The second large sector of use 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 of clothing in general and of home textiles (e.g. furniture, carpets, curtains, awnings). Because only one quarter of garments is manufactured in the EU, three quatre of PFHxA released into the European environment originates from imported clothing. Therefore, the release estimation is based on the used tonnage of clothing in the EU and the share of 75% of imported clothing. From clothing used in the EU up to 4 034 t/a of low molecular substances could be released into the environment. Thereof, only about 1 000 t/a result from clothing are manufactured in the EU. The releases of PFHxA related substances from EU clothing manufacture with up to 122 t/a is included in this number. That yields in a release of PFHxA of about 8.5 t/a (realistic worst-case) from clothing manufacturing. From all emitted related substances up to 3 500 t/PFHxA (worst case) / 285 t/PFHxA (realistic worst case) could be released into the environment, annually.

Up to 1 800 000 t of home textiles were used in Europe in 2018. From these textiles up to about 132 t/a of related substances are released. In summary, during the life cycle of home textiles up to 114 t/a (worst case) / 9 t/a (realistic worst case) of PFHxA are released.

In Europe up to 194 000 t/a of professional apparel are used. It is assumed that up to 59 t/a of low molecular related substances are released into the environment. The release of up to 4 t/a /PFHxA (realistic worst case) / 48 t/a/PFHxA (worst case) is assumed.

An important textile sector is technical textile fabrics, like truck tarpaulins. Up to 520 000 t/a were used in Europe in 2018. Technical textiles only contain low volumes of low molecular related substances. Only about 3 t/a of related substances are used. The related emission of low molecular substances is assumed to be below 200 kg/a.

One important sector of use of C6 fluorochemicals is the manufacture of polymers with C6 side chains (SFPs) 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 an underestimation of releases from C6 SFPs. A more realistic approach is the annual release of about 1% from the SFPs.

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.

About 12 000 - 20 000 t AFFF concentrate are placed on the market per year. However, it is assumed that only 10% thereof is used on fire (represents the minimum value). On the other hand, about 75 000 t AFFF are be stockpiled. From this stock it is assumed that about 15% is used on fire (represents the maximum value). Fluorinated fire-fighting foams concentrates in general contain up to 5% fluorosurfactants (about 0.15% in ready to use foams). It is assumed that 100% of the on fire used foam is released into the environment. This results in an annual release of PFHxA related substances between 100 and 563 t. From these related substances between up to 39 (realistic worst case) and up to 480 t (worst case) of PFHxA could be released into the environment.

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 60 t/a 6:2 FTS is assumed. About 20% of the used 6:2 FTS has to be replaced annually. Therefor the amount of 12 t is considered as annual release into the environment. This yields in a release of about 0.8 to 10 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 up to 100 t/a of fluorinated substances are probably used in inks (this value is not reliable because there were lots of uncertainties in the statements of stakeholders). It is assumed that up to 80 t/a of related substances are released into the environment in applying and using these inks. This results in 8 to 80 t/a PFHxA.

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 semiconductor 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.

Looking at the data for different lifecycle steps, it is obvious that **about 80 % of the releases of PFHxA, its salts and related substances occur from deposit** of products and articles. Paper and board or textiles have a relatively short average service life, because large quantities of these products and articles are use-and-throw items. In conclusion, there are no known uses of PFHxA itself in the EU. Large quantities of PFHxA-related substances are used in and for manufacturing of paper and board, textiles and of fluorinated polymers and SFPs. 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 (888 t/a - realistic worst case to 12 900 t/a (worst case) of PFHxA) is released into the European environment (mainly into water) and results from degradation of low molecular related substances 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 related substances. The exact number of PFHxA-related substances available on the market is unknown, but known related substances 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 to centuries, 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 persistence 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.

<u>Persistence</u>: 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 greater than 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. 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 effective 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[1].

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 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

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[1] *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.

drinking water from raw water, for the treatment of wastewater 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 persistence 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 related substances 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 as well 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 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 chapter B.4.2.4) regarded as a proxy for an unacceptable risk to the environment and human health.

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 PFHxA-related substances 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 related substances 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 enrichment 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 related substances with chemicals containing shorter perfluoroalkyl chains and the global market for fluoropolymers and SFPs 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.

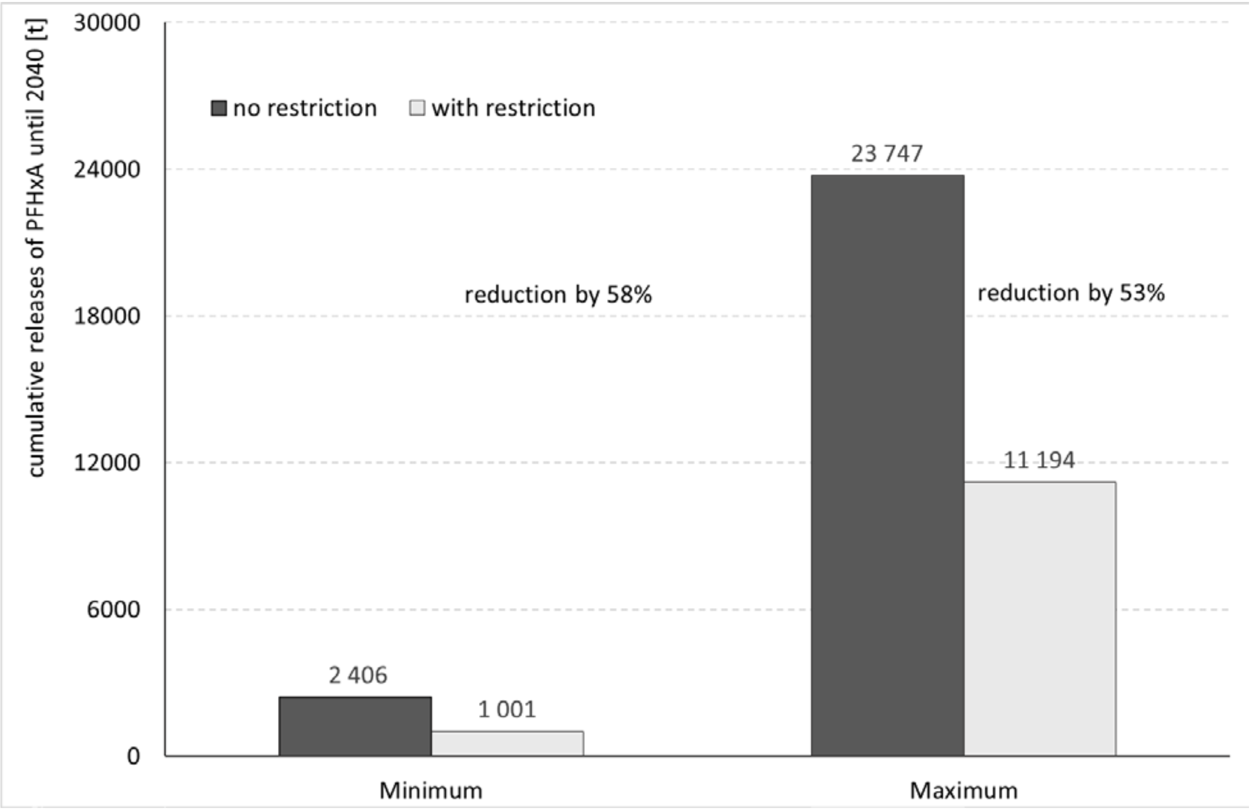

Figure 2: Estimated cumulative releases of PFHxA over 20 years.
The values also include the assumed minimum and maximum amount of PFHxA which is formed by degradation of related substances and SFPs. In both bars the release delay due to the article's life span is considered, too.

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 potentially 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 persistence 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 related substances 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 related substances 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. labelling;

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 6 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.

RAC and SEAC box

RAC and SEAC proposed changes to the scope and conditions of the restriction proposal presented in Table 5.

The details of these changes are reported in the RAC and SEAC opinion, together with the justification for these changes.

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

1. Undecafluorohexanoic acid (PFHxA), its salts and related substances (including polymers) (a) 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; (b) 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 in the production of or placed on the market in or used 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.

2. The following substances shall be derogated from this designation: (a) C_6F_{14}; (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). (c) Any substance having a perfluoroalkyl group C_6F_{13}- directly attached to a sulphur atom.	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. 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, papers, printing plates and inkjet photo media coatings; (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 for cases of class B fires; this shall not apply to: (i) use of fire-fighting foam for training; and (ii) use of fire-fighting for testing unless all emissions to the environment are minimised and effluents collected are safely disposed of. 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 to latex printing inks until XX XX XXXX [seven years after the entry into force]

	8. Paragraphs 1 and 2 shall not apply until XX XX XXXX [12 years after the entry into force] to: (a) concentrated fire-fighting foam mixtures for cases of class B fires in tanks with a surface area above 500 m^2; (b) semiconductors and semiconductor related equipment. 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), (g), (h), (l); (c) High visibility clothing fulfilling the requirements of EN ISO 20471 Class 3 (d) impregnation agents for re-impregnating of articles referred to in paragraph 9(b), (c), (g); (e) textiles for the use in engine bays in the following usage groups: Automotive and aerospace industry (f) epilames used in watches (g) medical devices as specified in Regulation 2017/745 of the European Parliament and of the Council; (h) filtration and separation media used in high performance air and liquid applications that require a combination of water- and oil-repellency; 10. From (entry into force + 12 months), a natural or legal person placing a mixture

	or an article specified in paragraph 9(b)-9(h) on the market for the first time and benefitting from the derogation therein shall provide by 31 January of each calendar year a report to the European Chemicals Agency 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. The European Chemicals Agency shall forward the data to the Commission by 31 March every year. 11. The concentration limit referred to in paragraph 2 shall be (a) 2000 ppb for the sum of PFHxA and its salts in fluoropolymers; (b) 150 ppm for the sum of PFHxA and its salts in fluoropolymers used in the following usage groups: Engine parts in automotive, aerospace and shipping industry. (c) 10 ppm for the sum of PFHxA and its salts in fluoropolymers used in coating of electronic devices until XX XX XXXX [7 years after entry into force]. (d) 100 ppm for the sum of PFHxA related low molecular substances in fluoropolymers. (e) 2500 ppm for the sum of PFHxA related low molecular substances in fluoropolymers used in the following groups: Engine parts in automotive, aerospace and shipping industry. (f) 500 ppm for the sum of PFHxA related substances in fluoropolymers used in coating of electronic devices until XX XX XXXX [7 years after entry into force]. 12. From (entry into force + 12 months), a natural or legal person benefitting from the derogation in paragraph 6 or paragraph 8(a) shall provide by 31 January of each calendar year a report to

	the European Chemicals Agency containing: (a) A description of their efforts on substitution of fire-fighting foams that contain PFHxA, its salts and PFHxA-related substances; (b) quantities they used in the previous year of fire-fighting foams that contain PFHxA, its salts and PFHxA-related substances per sector specifying: (i) share in training and in operation (ii) whether emission was contained, collected and disposed safely or emitted into the environment. The European Chemicals Agency shall consolidate and forward the data to the Commission by 31 March each year. 13. By (entry into force + 6 years), the Commission shall carry out a review of paragraph 6 and paragraph 8(a) in the light of new scientific information, including the availability of alternatives for articles referred to in paragraph 6 and paragraph 8(a), and proposing amendments if indicated by the outcome of the review. As long as the Commission concludes that there is still need for these derogations this review shall be carried out every three years.

Explanatory notes:

Column 1:

Paragraph 2(a): This paragraph refers to any linear and/or branched perfluorinated hydrocarbon with a total carbon number of C6. It is not degraded to the corresponding PFCA given the stability of the carbon fluorine bond.

Paragraph 2(c): This paragraph refers to any substance having a perfluoroalkylgroup C_6F_{13}-directly attached to a sulfur atom. These substances are already covered by the restriction with the arrowhead substance perfluorohexane-1-sulfonic (PFHxS) acid including its salts and related substances. The Dossier Submitter notes that the derogation could also be placed in the right column of the table above. It would be up to the Commission to ultimately decide whether the left or the right side of the entry is the most appropriate to address the derogation of PFHxS, its salts and related substances.

Column 2:

Fire-fighting foam:
Paragraph 5(c): For fire-fighting foam mixtures for cases of class B fires 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 (c) (i) and (ii) derogates fire-fighting foam mixtures that contain or may contain PFHxA, its salts and PFHxA-related compounds that are used for training and for testing unless emissions to the environment are minimised and effluents collected are safely disposed of. 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. Class B fires are fires of liquid substances or substances becoming liquid as specified in the European standard EN2 Classification of Fires.

Paragraph 6: While some armed forces (e.g. Denmark cf. Annex E2.3.4 Table 31) already reported transitions to fluorine free foams (FFF) and positive experiences with these foams, other armed forces reported challenges regarding a complete transition due to missing appropriate AFFF alternatives in the defence sector. One of the challenges reported is, that the available FFF do not fulfill the requirements of some defence-specific applications for fire-fighting foams. Due to some exceptionally high risks of defence-specific fire-scenarios (e.g. fire-fighting on seagoing units) a switch to FFF is currently not possible. Generally, the use of FFF for defence applications is desired and new alternatives are being investigated regularly. However, at the moment a restriction of the use of AFFF for defence-applications would lead to unacceptable constraints for fire-fighting in some defence-specific scenarios (Information received by the Federal Ministry of Defence (Germany) and confirmed by another national authority in the public consultation).

For defence applications an derogation 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 (i.e. incinerated at temperatures > 1400 °C).
Paragraph 8: Furthermore, an derogation 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 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 derogations 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 considered 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 articles derogated from the restriction (Paragraph 9 (b) to 9 (h)): 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 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. Critical 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-critical	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.

	uses + proportionate			
3. restriction on specific sectors	negative impacts - ongoing emissions from non-critical uses - restriction of critical uses	positive impacts: + restriction would be practical	positive impacts: + restriction would be monitorable	most sectors with broad uses also comprise one or more critical uses. New uses and uses currently unknown to the Dossier Submitter would not be covered by the restriction.
4. labelling	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. operational conditions implemented and recommended by the manufactures and/or importers	mixed impacts: + addresses emissions from manufacturing - emissions from service-life and waste phase not adressed	negative impacts: - not enforceable	unclear impacts	measures such as improved containment in manufacture and use and increased use efficiency are mostly associated with some level of discharge and do not influence contamination outside manufacturing or processing sites. Furthermore, relevant emission sources are not addressed by this measure.
7. EU Drinking Water Directive	Negative impacts: - addresses past emissions - uncertain, how fast and how effective memberstates	positive impacts: + restriction would be practical	positive impacts: + restriction would be monitorable	not yet adopted. As this regulatory measure focusses on a sum parameter in drinking water and addresses the consequences of an already passed emission the enforcement of the

	take actions needed			EU Drinking Water Directive will have a different effect than the restriction of PFHxA, its salts and related substances.
8. 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.
9. 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.[2]

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, public consultation and publicly available information is highly aggregated. While the collected facts sufficiently demonstrate that a general ban would not be proportionate it is on the other side difficult to determine the justified derogations from a general ban.

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

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 when alternatives cannot be implemented immediately resulting in disproportionate socio-economic impacts.

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 terminate the emission of PFHxA, its salts and PFHxA-related substances to the environment by further uses. Nevertheless, this threshold is not feasible and enforceable e.g. due to detection limits, due to the available methods for sample extraction and processing and due to an increased error rate the lower the measured concentrations are.

2.5. Assessment of the proposed restriction

2.5.1. Economic impacts

SEAC box

SEAC noted that a conclusion on the magnitude of the overall socio-economic costs related to the restriction proposal is difficult to achieve and uncertain.

The justification for this consideration is explained in the SEAC opinion.

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 fire-fighting 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 and SFPs, semiconductors and electronic devices, fire-fighting-foams, printing inks, chrome plating, building material, photographic applications, mixtures for consumer use, cosmetic products, textiles, food contact materials, watches, medical devices, optical fibres and filtration media.

Where the available information permits, the analysis is performed at 'use-specific' level rather than at sector level. For example, within the fire-fighting foams sector, the availability of safe alternatives varies between uses. The information gathered demonstrates 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 a derogation 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 Member States 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.

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 when enough data is available.

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 behaviour. 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 socio-economic 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 discusses in Annex E.8. Proportionality how the missing information might influence the proportionality assessment.

The following markets have been assessed:

- manufacture of fluoropolymers and side-chain fluorinated polymers,
- textiles,
- fire-fighting foams,
- electronic devices (including semiconductors, coatings, batteries and flat panel displays)
- surface treatment of food contact materials,
- printing inks,
- chrome plating,
- building material,
- photographic applications,
- fragrances and flavour industry,
- mixtures for consumer use,

- cosmetic products,
- medical devices,
- mechanical watches,
- filtration membranes,
- PTFE Micro powders,
- optical fibres.

2.5.1.1. Manufacture of fluoropolymers and side-chain-fluorinated polymers

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 and SFPs provide vital performance characteristics to products or production processes. Fluoropolymers and SFPs are used in a wide range of sectors and a restriction would impact uses e.g. in building materials, FCM, electronic devices and cables, gaskets, seals, etc. – mainly as processing aid in the production of PTFE, ETFE and fluoroelastomers.

Structurally, fluorinated polymers belong to different polymer classes: side-chain fluorinated polymers (SFPs) and fluoropolymers. SFPs consist of a non-fluorinated polymer backbone with fluorinated side-chains. Non-fluorinated side-chains can be present as well. Several low molecular PFHxA-related substances are used as intermediate and as monomers for polymerisation. Fluoropolymers as such do not contain structural moieties like FTOHs and PFCAs. A potential source, however, could be residues of fluorinated processing aids.

Aqueous based products on the basis of side-chain-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). For side-chain-fluorinated polymers some information is available on uses from the public literature, too. For example, textiles are one of the use areas of side-chain-fluorinated polymers.

The fluorinated side-chains comprise an alcohol moiety which is bonded *via* ester linkage or other (e.g. urethane) linkages to the non-fluorinated polymer backbone Polymer degradation and related breakage of the linkages can release the fluorinated alcohols as cleavage products. Degradation half-lives for fluorotelomer-based SFPs in soil and water are on the time scale of decades or longer. However, the ester linkages could be cracked partially, so that the polymeric structure itself seems to be a source for the occurrence of FTOHs and PFCAs, too. Most relevant sources are, however, residuals from production such as unreacted monomers and derivatives thereof. Impurities from the production process could be another source.

Polymers are an extremely large family of very different materials with different characteristics, properties and uses. These materials offer specialized solutions to a wide range of requirements in numerous products, applications and sectors. Among the polymers, fluoropolymers are high-performance materials. The overall trend in global manufacturing and consumption of fluorotelomer and fluorotelomer-based polymers is a shift from ≥ C8 to C6 fluorotelomer chemicals.

SEAC box

SEAC considered that the reported estimate "52 000 t of fluorinated polymers [...] sold in the EU in 2015" refers only to fluoropolymers, not to fluorinated polymers in general.

The justification for this conclusion is reported in the RAC and SEAC opinion.

According to industry 52 000 t of fluorinated polymers (fluoropolymers, perfluoropolyether polymers and SFPs) were sold in the EU in 2015. A constant polymer production is assumed for the next 20 years. According to estimates, the share of SFPs is about 10% thereof. The Dossier Submitter estimates that 90% (46 800 t) of the fluorinated polymers are considered as "fluoropolymers" (containing fluoropolymers itself, fluoroelastomers and perfluoropolyether polymers). As worst case estimate it is assumed here, that the whole amount of extractable related substances is released via the average service life for polymers of about 10 years. On that basis it could be assumed that about 9.36 t of related substances are released by the use of fluoropoymers within 20 years.

The share of fluoropolymers used in engine parts in automotive, aerospace and shipping industry is unknown. However, due to information from stakeholders a majority of fluoropolymers used in engine parts are fluoroelastomers. It is estimated that currently 4 680 t of fluoroelastomers are used in the EU and 3 276 t of fluoroelastomers are used in engine parts in automotive, aerospace and shipping industry annually. 16.4 t of PFHxA related substances could be released within 20 years from fluoropolymers in engine parts.

Manufacturing of polymers with perfluorinated C6 side chains is one of the most important uses of low molecular PFHxA-related substances. These polymers are used in the EU in quantities from 1 000 to 10 000 t/a. Further, the ammonium salt from PFHxA is used as processing aid for manufacturing of fluoroelastomers from 10 – 100 t/a. It is estimated that 10 to 100 t/a of PFHxA-related substances are released into the environment via C6 side chain (co-) polymers at manufacturing.

However, with regard to the whole life cycle the Dossier Submitter notes that the partial degradation of C6 side chains from the acrylic polymers could be a source for release of PFHxA into the environment that should not be underestimated especially if large timeframes are investigated.

Fluoroelastomers are rubbery materials based on several of the same monomers as used for manufacturing fluoropolymers. The APFHx containing rubbery material is used to produce e.g. seals and tubes in transportation sector like in automotive or aviation. So, a wide dispersive outdoor use of these articles with a low release of APFHx could be assumed. Up to 0.65 t/a of the ammonium salt from the 10 to 100 t APFHx used in the EU are released to the environment. Assuming, a low release of APFHx by leachate from landfills (60 % of articles are deposited in landfills) up to 390 kg may be released into water annually. However, the estimated number of unreported releases could be much higher. The number of articles imported into the EU containing fluoroelastomers or other products with APFHx as impurity is unkown.

Several stakeholders submitted information in the public consultation that PFHxA, its salts and related substances are required as process media to produce certain Fluoropolymers.

Fluoropolymers are manufactured in various forms (resins, films, powders) and further processed by customers. Processing includes extrusion, molding, etc.

Based on the information from the public consultation no information is available which share of the approximately 52 000 t of fluoropolymers are manufactured with PFHxA, its salts and related substances. However, several uses are mentioned by the stakeholders.

Stakeholders mention inter alia the production of ETFE, PTFE micro-powders and certain fluoroelastomers as important applications where a derogation is justified with a view to societal benefits of continued use.

Stakeholders claim that fluoropolymers display outstanding chemical and temperature resistance, combined with mechanical and electrical properties. They are used in specific, high reliability/safety critical applications.

ETFE resins are used for coating of cables and wire. Some stakeholders cite data from a report by Plastics Europe to illustrate the importance of fluoropolymers (Group, 2017).

Stakeholders in general did not provide detailed information on restriction scenarios. They did not provide information on alternatives for certain applications or detailed information on uses where costs from functional losses (when not using PFAS) are affordable. The Dossier Submitter is not aware of further information that would help in identifying applications where technically and economically feasible alternatives are available or in development.

The Dossier Submitter notes that for several uses alternatives might be available (e.g. cookware, textiles, food processing) and for other uses it is prima facie not evident that society values the benefits of continued use as highly as stakeholders claim (e.g. construction materials, textiles). No information is available to differentiate for certain sub-uses whether a derogation is justified for all applications.

One manufacturer claimed that a restriction would lead to complete reorganisation of his business and could entail a closure of the production site. The Dossier Submitter lacks information on whether the proposed derogations would enable the manufacturer to continue at least part of his business.

Fluoroelastomers are fluoropolymers that are produced with PFHxA-related substances and 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. A stakeholder provided information that PFHxA-related substances remain as impurities in the product.

According to stakeholder information fuel lines, fuel hoses and turbochargers, o-rings, gaskets and seals play a vital role in boosting engine performance and reducing emissions in automotive and aerospace/aircrafts. They also contribute to the reliability of articles that have to withstand high temperatures and aggressive fluids. Stakeholders argue that standards in automotive industry can only be fulfilled by using high performance fluoroelastomers. The Dossier Submitter proposes a derogation on the basis of the submitted information but notes that he could not verify whether information submitted by one manufacturer is generalizable and therefore justifies a general derogation.

In sum, the Dossier Submitter notes that societal benefits of continued use of PFHxA, its salts and related substances are evident for some uses but ambivalent for others. Emissions from the use phase are significant but most likely very small in comparison to the positive impacts.

Cost-effectiveness cannot be calculated with the available information. The Dossier Submitter notes that reasonable worst-case scenarios in case of a restriction imply high societal costs.

With regard to the production of fluoroelastomers the Dossier Submitter recognizes the high costs in relation to the emissions reduction, the impacts on international competitiveness for the impacted European industries and the environmental benefits of using fluoroelastomers that are produced with PFHxA-related substances and therefore proposes a separate derogation with higher thresholds for the use of PFHxA, its salts and related substances.

In sum, cost-effectiveness cannot be calculated. Risks from further use (continuing emissions to the environment) and from a restriction are both poorly understood. The Dossier Submitter proposes to first act and then learn (see 2.5.5 on this concept) by granting derogations (i.e. higher concentration limits) that enable the continued manufacture and use of fluoropolymers, including fluoroelastomers.

The Dossier Submitter proposes higher concentration limits and considers these concentration limits as adequate for continuing use in critical applications and also assumes that further emission reduction can be reached when all manufacturers have to consider identical limit values.

The European Commission and Member States should take note of the very high uncertainties with regard to the justification for the derogations and should consider revaluation and further regulation in the future.

The Dossier Submitter notes the ongoing discussions with regard to the question whether there is a scientific rationale for concluding that fluoropolymers are of low concern for environmental and human health. Recently, a group of scientists presented concerns with regard to the hypothesis that fluoropolymers are polymers of low concern (Lohmann R. et al., 2020). Discussing the whole group of fluoropolymers and not just those using PFHxA, its salts and related substances they conclude that:

- concluding that some specific fluoropolymer substances are of low concern for environmental and human health can only be achieved by narrowly focusing on their use phase;
- ideally, the assessment and management of fluoropolymer products would consider the complete life cycle;
- mapping of all industrial activities that produce, process, and dispose/incinerate fluoropolymers is required to target protection of potentially exposed communities;
- It would anyway be impossible to verify if all fluoropolymer products were of low concern or not with the information available in the public domain. Assessment should be performed on a product-by-product basis because various grades and commercial products of fluoropolymers may or may not meet the polymer of low concern criteria. For example, a PTFE product made in China cannot be assumed to be equivalent to PTFE product from other regions.

The authors recommend moving toward the use of fluoropolymers in closed-loop mass flows in the technosphere and in limited use categories, unless manufacturers and users can eliminate PFAS emissions from all parts of the life cycle of fluoropolymers.

For more detailed information on this use see B.9.4. Polymers and plastic material and E.2.1. Fluoropolymers and side-chain fluorinated polymers.

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. In 2015 approximately 6.4 million t of clothing (estimated range 4.8 -14.6 million t) were used in the EU of which approximately 75 percent were imported (Rijkswaterstaat, 2017). In addition, about 95 000 t professional apparel (76 000 – 194 000 t/a), 1.2 million t home textiles and 400 000 t technical textiles were placed on the market in Europe (central estimates).

The Dossier Submitter estimates (see Background Document section B.9.5) that the use of PFAS remains constant in the future. Without a restriction, constant releases of PFHxA-related substances from textiles amount to 1 229 –4 225 t/a. Accordingly, emissions over 20 years are expected to add up to 24 592 – 84 502 t. Additionally release of C6 related fluoropolymers and SFPs of approximately 74 – 222 t/a (1406 – 4414 t over 20 years) has to be considered. These numbers are highly uncertain.

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).

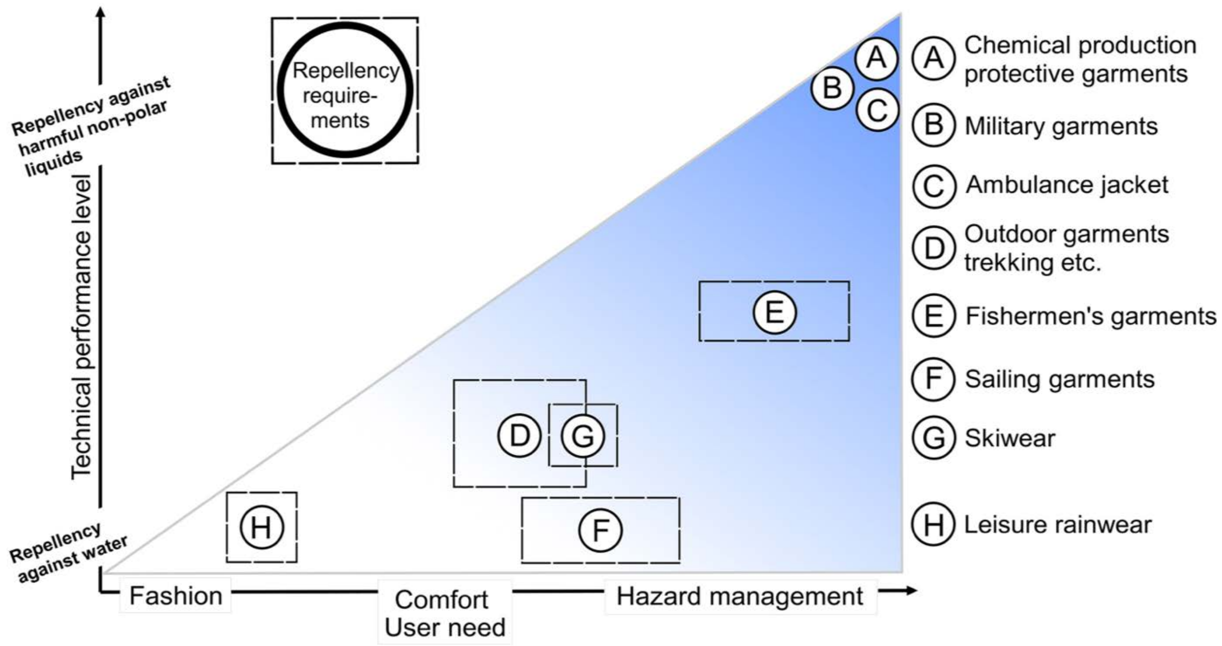

Figure 3: Illustration of the increased need for technical performance (in terms of oil repellency and durability of oil- and water repellency) with more advanced user needs; advancing from fashion to comfort to hazard management (Holmquist et al., 2016). Examples of garments meeting user needs within 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.[3]

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[3] 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).

Alternatives are available that provide good water repellency. These include alternative technologies (woven fabrics) and alternative substances. European Comission – DG Environment (2020) analyzes alternatives according to chemical groups: dendrimers, hybrids (silicon/carbon), hydrocarbon, nanotechnologies, polyurethanes, silicones and other alternatives without substance information are available. Human health and environmental hazards and risks of most alternatives are not fully understood. However, according to the European Commission report the properties of some substance groups (e.g. dendrimers, hydrocarbons) are most likely less hazardous than PFAS.

Limited information is available with a view to the cost of the alternatives. Alternatives might be similarly priced as PFHxA-related substances. The purchasing costs for some alternatives are up to 50 percent lower. However, some sources claim that certain alternatives might use 30-50 percent more volume compared to C6-related chemicals. The majority of available stakeholder information suggests that additional use quantities are required when cheaper products are used. Therefore, the Dossier Submitter assumes comparable cost for the use of alternatives and PFHxA-related substances.

Minor uncertainties concern required machinery and equipment alterations. The available information suggests that application methods are similar with only minor modifications and therefore no additional costs are expected.

Alternatives to provide equivalent oil and dirt repellence properties are not available. The loss or reduction of these properties might induce a 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). However, more specific information on impacts is not available. During the public concultation stakeholders repeatedly claimed such impacts but failed to discuss possible alternatives like for example washable or replaceable slip-covers.

Some categories of use have been identified as uses where alternatives might not meet the properties needed with regard to oil and/or dirt repellence.

Some personal protective equipment (PPE) protects against risks where reduced oil, dirt and soiling properties might endanger the needed protective function. In the medical sector repellency to bodily fluids is necessary to avoid the transmission of diseases. In other sectors (e.g. defence, fire-fighting, oil and gas industry) repellency towards non-polar stains is also part of the hazard management (Schellenberger et al., 2019).

The lack of these properties might lead to unacceptable health risks for certain groups, possibly leading to high societal costs. Therefore, derogations 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), (g), (h), (l).[4]

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[4] 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

Category III includes the risks that may cause very serious consequences such as death or irreversible damage to health. Only qualitative information is available on the probable effects of a restriction. Information submitted by stakeholders suggests that Cat. III(a), (c), (d), (e), (h), (l) are required for uses where water repellency is not sufficient to substantially mitigate the risks. No further quantitative information is available. According to information from the public consultation a derogation for Cat. III(g) is needed for belts and ropes where UV-resistance and strong resistance against weathering are important safety concerns. No further information on the availability of alternatives has been provided. Cat. III(f) includes the risks caused by very low-temperature environments. Stakeholders argue that maximum water-repellency is required to effectively protect the wearer from such risks. In absence of any further information the Dossier Submitter notes that he agrees with this argument in general. However, he also notes the risk that this derogation might become a legal loophole for uses where in his view no derogation is justified, e.g. seasonal clothing or sports clothing. No further information is available to better understand this risk.

An additional risk with regard to PPE is the visibility of a wearer in certain situations. Again, no quantitative information is available, but the Dossier Submitter agrees that soiling of high visibility PPE can impair the intended function severely. Therefore, a derogation is proposed for

- High visibility clothing fulfilling the requirements of EN ISO 20471 Class 3.

Class 3 high-visibility clothing is mandatory when visibility in the dark is required at traffic speeds up to 90 km/h. The norm stipulates minimum areas of visible material in m^2 for reflective tape, fluorescent material and contrast material.

Several other derogations for PPE have been proposed by stakeholders in the public consultation. A non-exhaustive list of requests has been provided with confidential comment 3133. The Dossier Submitter will not propose further derogations. In contrast to the proposed derogations there is no serious risk to be expected when alternatives are used. Not using C6-related substances might lead to functional losses comparable to those for apparel, i.e. shortened service-life or reduced ease of use might be possible. But in order to consider such costs the Dossier Submitter needs more evidence that they could be significant.

Derogations for woven and non-woven medical textiles are discussed in the chapter on medical devices.

A derogation is proposed for certain textile uses in the transportation sector, like automotive and aerospace. It has been reported that products are used for sound absorption, climate regulation within vehicles and reduction of fuel among other things. The Dossier Submitter proposes a derogation with a view to the potentially life-saving functions the treatment with C6-related substances provides:

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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, III(g) falling from a height, III(h) electric shock and live working; III(l) bullet wounds or knife stabs;.

- Textiles for the use in engine bays in the following usage groups: automotive and aerospace industry

No derogations are proposed for further transport-related uses. Not using C6-related substances might lead to functional losses, e.g. shortened service-life or reduced ease of use. But in order to consider such impacts the Dossier Submitter needs more evidence that they could be significant. More information on the impact of using alternatives like slip-covers would also be needed.

In the public consultation derogations have been requested inter alia for the use in carpets and rugs, textile wallcovers, upholstery, curtains and blinds, outdoor cushions and seatings. The information provided did not demonstrate significant impacts from a restriction for these uses.

Emission estimates resulting from the proposed automotive and aerospace derogations are not available. No further information is available on end-of-life treatment of the derogated articles. The Dossier Submitter notes that stakeholders proposed to ensure proper disposal of derogated articles via the EU Directive on End-of Life Vehicle 2000/53/EC.

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.

(European Commission DG Environment and European Chemicals Agency, 2020) reports regarding the cost of substitution: “Regarding the effective price of alternatives, manufacturers of alternatives consider that the overall price is more or less the same. In some cases, the unit price of the fluorine-free alternatives that provide water repellency is lower but the amount required during application can be up to 50% more compared to the C6 technologies to achieve comparable water repellence”.[5]

Based on this expert opinion, the Dossier Submitter expects that during application more product is required when using cheaper products. Non-fluorinated products in a similar price range as fluorinated products most probably do not require larger use quantities. In sum, the cost of substitution will be negligible.

A yearly reporting requirement is 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 (see 2.5.1.17).

In sum it is expected that costs related to the restriction proposal for textiles will mainly be direct substitution costs. The Dossier Submitter assumes that these costs are negligible considering various information that cost for alternatives and PFAS substances are comparably high. Uncertainties remain whether different product groups face different substitution costs, i.e. whether costs for e.g. apparel are considerably lower than for e.g. awnings.

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[5] However, there is uncertainty over what exact level of performance is really needed in some applications (whether it is the level currently provided by PFAS or it can also be lower).

Filtration and separation media

Filtration and separation media treated with C6 fluorinated polymers consist primarily of non-wovens or paper composed of manmade fibres, natural fibres (or a combination of both), with resins that contribute to the structural or physical properties of the media. Filtration and separation media manufactured with C6 fluorinated polymers play a critical role in the following applications, among others: medical devices, PPE, heating, ventilation, air conditioning (HVAC), Air Pollution Controls (APC), dust collectors, hydraulic systems, coalescers, gas turbines, and fuel systems.

Several stakeholders submitted information on the wide range of applications and requested derogations from the restriction. The Dossier Submitter agrees that several applications fulfill important functions and proposes a derogation.

Several stakeholders submitted information demonstrating very small release from production. However, very limited information on the waste phase is available. The Dossier Submitter also notes that EU-wide use quantities and therefore potential for releases from end of life are unknown.

The scarce available information suggests that significant quantities, possibly several hundred tonnes per year of PFHxA related substances are used in the European Union.

Some stakeholders state that for some uses substitution could be possible within 10 – 15 years. Some stakeholders claim that longer transition periods are needed.

Stakeholders requested derogations for ‘all industrial uses’ or ‘high-performance applications’. The Dossier Submitter does not fully understand the consequences regarding implementability and enforceability of the different scope definitions.

Some cost estimates from manufacturers are available. In the Dossier Submitter’s view substantial costs of not using PFAS are demonstrated and if technical claims from manufacturers are valid no alternatives are available at the moment. A restriction would lead to a large loss of effectiveness and potentially large societal costs.

However, no robust comparative analysis has been submitted on the consequences of using alternatives instead of PFHxA-related substances. Therefore, the magnitude of negative impacts remains unclear.

Considering information from the public consultation the Dossier Submitter proposes a derogation for filtration and separation media used in high performance air and liquid applications that require a combination of water- and oil-repellency.

The Dossier Submitter notes high uncertainties with regard to the broad scope of the derogation. It might be possible that alternatives are already available for some applications (e.g. when mainly water-repellent properties are needed) or that substitution is available in the near future for applications.

For more detailed information on the textile uses see B.9.5 and E.2.11. For filtration and separation media see B.9.19 and E.2.13.4. For medical textiles see B9.19 and E2.13.6.

2.5.1.3. Fire-fighting foams

Fire-fighting 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 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 fire-fighting 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 related substances. 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 fire-fighting foams are estimated to contain PFHxA-related substances in the range of 480 - 560 t/a. Results from a study by the European Commission and ECHA (European Commission DG Environment and European Chemicals Agency, 2019) suggest a market split as follows: Military 6 %, civil aviation 9 %, municipal fire brigades 13 %, chemical/petrochemical 59 %, marine applications 12 %.

Within the last years, a shift from AFFF to fluorine-free foams (FFF) happened.
This trend (a decreasing share of AFFF in the market) will be counteracted when 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. Considering these divergent trends, the Dossier Submitter expects a stable demand for AFFF in the future for the non-restriction scenario.

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 Dossier Submitter 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. During the public consultation, the Dossier Submitter was informed by several stakeholders that the originally proposed derogation for the use of AFFF in cases of class B fires in storage tanks with a surface area > 500 m^2 is not feasible. It was claimed that also some process facilities have tanks with a similar size that are not used for storage but for processing of liquid fuels. Therefore, the word "storage" was removed from the original derogation proposal. Furthermore, the Dossier Submitter received information, that a derogation is needed as well for class B fires in secondary containment areas (or so called bunded areas). The Dossier Submitter was informed by fire-fighting experts that such incidents are very rare. In the view of the Dossier Submitter, proposing a derogation for the use of AFFF in secondary containment area would undermine the intended narrow scope of the proposed derogation for large tanks, since it would also allow the use of AFFF for cases of fires in smaller tanks (< 500 m^2) or spill fires within a secondary containment area. Furthermore, the Dossier Submitter is of the opinion that a fire which started in a tank > 500 m^2 which than extends to a secondary containment area can still be extinguished with AFFF as the incident started as a tank fire.

Some armed forces report challenges regarding a complete transition due to missing alternatives in the defence sector. A derogation 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. 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 the substances in these sectors and to monitor the developments of alternatives. The Dossier Submitter proposes that the European Commission shall review the derogations six years from entry into force of the restriction.
The Dossier Submitter could not calculate total impacts of the proposed restriction. 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). Some sources claim that fluorine-free foams have to be used in higher quantities to achieve stable performance.

European Commission DG Environment/European Chemicals Agency (2020) reports exactly the same weighted average prices for PFAS containing and fluorine free foams of 3 000 €/t. The Dossier Submitter calculates on average an increase in volumes required of 30 % for the concentrate when fluorinated foams will be restricted. A 30 % increase in volume therefore would result in substitution costs of 0.9 €/kg foam concentrate when taking prices from the EC/ECHA study. For professional fire-fighting an annual use of fluoro-surfactant containing fire-fighting foam concentrate of 12 000 - 20 000 t/a has been estimated, resulting in additional procurement cost of roughly 15 million €/a (central estimate) when all uses of AFFF are replaced with FFF. This number does not consider that some uses are derogated, i.e. it might be an overestimate.

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

Estimates for the EU-wide stock of AFFF foams are highly uncertain. Several considerably different estimations have been taken into consideration (see Annex E2.3.). To be able to give at least an idea on the possible procurement costs it is assumed that the stock in the EU is 75 000 t (see Annex E2.3.5 for a discussion of this assumption).

It is estimated that nearly half of the stock will be used or has to be replaced during the five-year transitional period.

At a 10.5 % use rate stocks would be reduced by 43 % after five years (see Annex E2.3.5 for explanation).

In that case transition from AFFF to FFF still would result in considerable replacement costs of nearly 130 million € when all foams that are placed on the market are replaced as a consequence of this restriction (which is an overestimate, considering that not all AFFF are PFHxA-related). The numbers are very uncertain, but still demonstrate that replacement of PFHxA-related AFFF in stock with fluorine-free fire-fighting foams might be expensive.

However, stocks always have to be replaced after expiry. Therefore, replacement with new foams is just an early replacement.

But the main argument why replacement costs related to this restriction will be considerably lower is the expectation that a large share of AFFF-users must replace their stocks latest in 2025 as a consequence of the amended Annex I to Regulation (EU) 2019/1021.

According to information from stakeholders this results in the necessity to dispose of the large majority of foam stocks. An unknown but large share of existing stocks are mixtures containing PFOA-related and PFHxA-related substances. One stakeholder commented during the consultation for the POP listing: “A ban on the use of existing stocks of fluorotelomer-based foam with long-chain fluorosurfactant content would require more than 90% of the existing foam stocks in the world to be removed from service and disposed.”

Based on this information from industry and users the DS expects that a large part, likely to be more than half of the existing stock of AFFF containing PFHxA-related substances has to be disposed of as the mixtures contain PFOA and PFOA-related substances. Equipment must be decontaminated to ensure the concentration limits for PFOA and PFOA-related substances, which are identical to the limits proposed for PFHxA. If users act rationally, they will switch to non-fluorinated alternatives where possible to avoid additional costs resulting from this restriction a few years later.

Availability of foams may be an issue. But the risk of supply constraints in chemical/petrochemical industry is lower, when the time-limited derogation for large atmospheric tanks is granted, which has been proposed by the Dossier Submitter.

The conclusion on procurement costs for replacement of AFFF in stock with fluorine-free fire-fighting foams is as follows: without substitution activities resulting from the the listing of PFOA in the Stockholm Convention the Dossier Submitter estimates replacement costs of less than 130 million €. Up to 90 percent of these costs will not apply because fire-fighting foam will be disposed of as a result of requirements resulting from the Stockholm Convention.

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.

The available information suggests a cost of 1 €/L AFFF. Not included are transportation and other handling costs. No information on the magnitude of these costs is available. Accordingly, for 42 750 t of stock the costs would amount to approximately 43 million €.

The Dossier Submitter expects that a share of up to 90 percent will already be replaced when mixtures with PFOA and PFOA-related substances must be replaced.

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.

Quantitative information on the number of stationary fire extinguishing systems, fire-fighting vehicles and foam tanks affected is uncertain. European Commission DG Environment/European Chemicals Agency (2020) cite the following numbers for exemplary purposes: for chemicals/petrochemicals, more than 10 000 establishments covered under the EU's Seveso III Directive; more than 600 offshore oil and gas platforms; more than 400 airports in the EU; more than 50 000 public fire brigades in the EU, more than 1 200 commercial seaports, more than 230 military airbases.

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.

Due to the PFOA-related requirements decontamination costs resulting from the restriction on the use of PFHxA and related substances will be reduced. It is not possible to give a reliable estimate. Additional inconclusive information is discussed in annex E.2.3.5.

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. It might be necessary for some users to install additional tanks to store larger amounts of foam. Some older equipment maybe needs to be replaced. No detailed information is available.

The Dossier Submitter assumes that for most users these costs are small in comparison to other substitution costs considered. It cannot be exluded, that a minority of users will face significant difficulties and costs when they need to adjust their infrastructure.

Administrative issues, training with alternative foam

Additional costs are connected to the 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 but are expected to be minor in comparison to other costs.

Administrative costs for the reporting requirements will most likely be comparatively low. It is expected that procurement of fire-fighting foams for the derogated 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. Only an unknown share of the extinguishers will be affected by the restriction. Replacement costs are unknown but considering that handheld fire extinguishers are available for considerably less than 100 € the replacement would be affordable for consumers and SME.

Calculation of avoided emissions

The Dossier Submitter estimates that without a restriction, emissions to the environment amount to 48 – 280 t of PFHxA-related substances. With a restriction, emissions from military uses will continue and from chemical/petrochemical uses will continue for 12 years. Considering that not all uses in these industries will be derogated but also considering that these make up 65% of the current market a considerable amount of emissions will not be avoided. But most probably more than half of the emissions of PFHxA-related substances into the environment can 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 cost 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 fire-fighting would all be financially prepared to afford substitution. However, a large share of users will face the costs already when they need to comply with the amended regulation (EU) 2019/1021.

Large parts of the costs will not be incurred when users act rational and replace AFFF with FFF when restrictions for PFOA come into effect. Other parts of the expenses are most probably just early replacement costs. Some users that are not affected by the POPs regulation and purchased foams recently will face higher costs resulting from a restriction on the use of PFHxA and related substances, especially for the replacement of existing foams.

However, in the case of PFOA it already has been agreed that costs for the replacement of existing foams are affordable and proportionate.

On the other hand, very high direct emissions of PFHxA-related substances into the environment would be avoided when all existing stock of AFFF will be replaced by FFF.

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.

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.

No additional information was submitted by stakeholders in the public consultation.

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 crucial uses in specialized products.
For more detailed information on this use see B.9.13 and E.2.9

2.5.1.5. Electronic devices

There are several uses of PFAS in the production of electrical devices and their components (e.g. semiconductors or printed circuit boards). In the following section the applications that the DS is aware of will be described. It should be noted, that there most likely are more applications that the DS was not informed about during the public consultation.

2.5.1.5.1. Semiconductors

The semiconductor industry uses PFASs as process agents for the photolithography process, etching process and furthermore in cleaning fluids and fluoroelastomers, which serve as seals. 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 - 100 t/a (Stakeholder Consultation, 2018). Short-chain perfluorinated substances are used in very small quantities as ingredients at low concentrations in photoresist and anti reflective coatings (ARC) chemical formulations in semiconductor photolithography.

Stakeholders commented that 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. They assume that this process will take more than five years.

Limited information is available on chemical and technological alternatives. It has been reported that the replacement of PFOS has been achieved through a variety of means, incl. C9-C4 PFAS, non-fluorinated substitutes and the elimination of the surfactant function within the photo-resist ((EU, 2016), see also the additional information in E.2.2.4 Uses, functions and alternatives).

It has been reported, that in the US the cost of developing a new photo-resist represents 0.3 % of annual sales. This indicates that cost is not a barrier to develop a new photo-resist system (UNEP 2018b).

Short-chain perfluorinated substances are sometimes becoming part of the final product (the microchip). According to stakeholder information PFHxA containing materials remain in the final product in some cases.

Limited information suggests that the societal costs resulting from profit losses, the closure of manufacturing sites and release of workforce result in a very high cost-effectiveness ratio that indicates unproportionately high costs of a restriction. Semiconductors are integral parts of electronics, integrated circuits, computer industry and various other products. Obviously, not being able to manufacture or import these articles would lead to unacceptable socio-economic cots.

Therefore, one stakeholder (comment 3066) requests a derogation for semiconductors (including compound semiconductor) itself and no-time-limited derogation for the various uses of semiconductor manufacturing processes such as process agents for the photolithography process, etching process and cleaning fluids.

The benefit of a restriction would be < 10 t/a emissions avoided.

In summary the Dossier Submitter proposes a time limited derogation for twelve years for semiconductors. Drop in alternatives are not available at the moment. Several stakeholders asked for a general derogation for semiconductors including manufacturing processes. The submitted information suggests a large variety of uses and it is not clear from the information which of these uses can be substituted in general and how long it would take to find suitable alternatives. The Dossier Submitter is aware that use quantities and emissions are comparatively low in comparison to the economic impacts that are possible when EU manufacturing would no longer be possible.

Therefore, the Dossier Submitter expects the Commission to monitor the situation closely after entry into force of the restriction. In the Dossier Submitters view an extension of the twelve-year derogation is only justified when manufacturers provide more detailed information on substitution efforts and prepare detailed substitution plans.

2.5.1.5.2. Electronic grade coating

A C6 fluorinated polymer is used in a coating process to achieve high levels of water repellency to protect electronic devices from water and corrosion damage and to achieve electrical resistance of printed circuit boards (PCB) during immersion in liquids.

With regard to the amount of PFAS used for this application, one stakeholder provided confidential information on the tonnage of a C6 based monomer in Europe and worldwide.

The stakeholder also informed about his assessment of possible alternatives and reported that of the available non-fluorinated technologies none can mimic the full range of desirable properties found in their fluorinated counterparts. The main problem reported was water- and oil-repellency, the latter being particularly important for in-ear devices. Additional confidential information on the analysis of alternatives was provided. The Dossier Submitter considered this information in their analysis.

As alternatives are expected to not perform as good as current technology, it is estimated by stakeholders that a higher number of devices will break down due to water damage with a restriction of the use and manufacture of PFHxA and related substances. Therefore, a time limited derogation for at least 7 years is requested to allow for the development and synthesis of alternative chemicals able to deliver an acceptable performance. A derogation for this use may not be necessary as alternatives to achieve water repellency seem to be already available, although they may not perform as well as the current technology. On the other hand, a time limited derogation for seven years might be justified under the consideration that for the use and production of fluoropolymers a general derogation threshold of 2000 ppb and 150 ppm for specific applications in engine parts in automotive, aerospace and shipping industry is proposed. Emissions from this use are expected to be low considering the closed loop recycling of electronic articles and the low amounts of C6 fluorinated polymers that are used for this application in Europe. It should be kept in mind though, that the worldwide use of C6 fluorinated polymers in this application was reported to be higher than the European one and that a restriction for the European market could also influence the amounts used worldwide.

During the public consultation one stakeholder presented economic evidence that suggests that a time-limited derogation for seven years is justified. The dossier submitter notes uncertainties with regard to the justification for this derogation.

Alternatives are available in general, but the stakeholder presented limited information that substitution is not economically feasible at the moment. The Dossier Submitter does not understand how competitors treat their electronic devices for water and oil resistance. No information is available if other devices are treated similarly or whether other manufacturers use PFAS-free alternatives and what the respective impacts would be.

In absence of further information, the Dossier Submitter proposes a time limited derogation for seven years. The expected emissions in the EU most likely will be comparably low. Equally effective alternatives are only available for upscale articles, making it likely that these substitutes are not economically feasible as general substitute at the moment. Relying on the information from the stakeholder the socio-economic costs resulting from the use of less effective (cheaper) alternatives are potentially high (see E2.2).

2.5.1.5.3. Others

Further uses of PFHxA and related substances in electronic devices that DS was informed about during the public consultation are different applications of fluorosurfactants. Fluorosurfactants are used due to their anti-corrosion and electrostatic properties in applications such as zinc batteries, plating bath aids, photoresists and low foam. Concerning the used amounts of fluorosurfactants for these applications, one stakeholder commented on individual use quantities, however gave no information regarding the overall market. The Dossier Submitter assumes that this use will be covered by a derogation for semiconductors.

Amorphous fluoroplastics, are applied in electronic devices due to their ability to dissolve and their high transparency. A visible light transmission ratio of more than 95% can be achieved.

Furthermore, DS was informed that fluorosurfactants are used as photoresists and coating solutions for polarization films in the production of Flat Panel Displays (FPD). In the view of the DS these uses are covered by the proposed derogation for semiconductor manufacturing and related equipment. However, due to missing information on this view is fraught with some uncertainties.

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 food contact materials (FCM) 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). It has been reported that PFAS in general also might be used for non-food applications (folding cartons, containers, glossy papers, carbonless forms and masking papers) (Federal Office for the Environment, 2009). No further information is available from manufacturers, users or scientific literature.

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, tablecloths, 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.

OECD (2020) estimates that 13.8 million tonnes of paper and board are produced annually in the EU for food contact from three main sectors: folding box board, corrugated boxes and paper sacks. According to industries, the content of side-chain fluorinated polymers is about 0.3 – 1.5 % by weight of the paper, depending on the specific purpose of the treated material (stakeholder consultation, OECD (2020) states a similar range of 0.2-1.5 % by weight of the paper) (OECD, 2020). The Dossier Submitter estimates that up to 70 percent of all FCMs are treated with PFHxA-related substances.
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,
- paper refinement by micro- or nanofibrillated cellulose,
- paper refinement by intensive pulp treatment resulting in the formation of naturally greaseproof paper (NGP),
- natural materials with dense surfaces such as bamboo, elefant gras and palm leaves.

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. Quite contradictionary to that, a recent report of on paper FCM concludes, that efficient PFAS-free alternatives are available for all applications, though higher costs for the paper production of approximately 10 – 30% might result.

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.[6] 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. In July 2020 the ban entered into force.

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”.

Recently the argument on the availability of alternatives has been strengthened by the OECD (OECD, 2020). The level of grease resistance of paper or paperboard can be measured by industry accepted methods in a ‘Kit value or rating’. Low grease resistance is indicated by a Kit value of 1, high resistance has a value of 12. OECD lists applications requiring low grease and water performance (with paper requiring low Kit values of 3, e.g. bread, nuts) to requiring paper with high Kit values (Kit value 12, e.g. pet food). For all applications alternatives are commercially available based on short-chain PFAS, physical alternatives and chemical alternatives.

OECD argues that efficient PFAS-free alternatives for paper FCM are available for all applications, though higher costs for the paper production might result. But due to the low share of costs for FCM in the finished articles, these higher costs for paper production are not relevant for the final (food) product. As an example, costs for a single muffin cup are estimated to rise by less than 0.5 cents (OECD, 2020).

Using the information provided by OECD (2020) costs of a restriction on PFHxA, its salts and related substances can be derived. The Dossier Submitter estimates a use of 13.8 million t/a paper in the EU and that up to 70% of the paper is treated with PFHxA-related substances. This usage results in emissions of 235 – 1 760 t/a of C6 side-chain fluorinated polymers, 1 –

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[6] 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)).

9 445 t/a PFHxA-related substances and 1 – 170 t/a of PFHxA as impurities. Central estimates are 1 000 t/a side-chain fluorinated polymers and 4 720 t/a PFHxA-related substances.

In case of a restriction the central estimate for substitution costs is 1.45 billion €/a for the cheapest alternative, i.e. chemical alternatives. Emissions reduction would amount to 5 726 t (central estimate), resulting in an average cost of 250 €/kg (central estimate) for every kg avoided emission. This cost-effectiveness estimate confirms OECD's argument (with the cupcake example) that the additional costs lead to affordable price increases for the individual articles affected.

With regard to the affordability of the restriction, average costs of <4 €/a (chemical alternative) to <100 €/a (physical alternative) per EU citizen are very likely affordable.

Considering all the studies discussed in section E.2.12.2 the assumption that 70% of the 13.8 million t/a are treated might be an overestimation as for several product categories smaller percentages are reported. The Dossier Submitter notes that regarding cost-effectiveness and affordability such an overestimation makes no difference: additional costs and emissions are both dependent on the use quantities.

Some uncertainties have to be considered:

- Use quantities and therefore costs and emissions might be overestimated.
- No information is available on the share of articles that are re-imported as part of finished products.
- Further, it is unknown whether the demand from non-EU buyers will change when greaseproof papers are coated with alternative materials. 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.According to information available no additional machinery or other equipment is needed when chemical alternatives are applied to the paper. However, no information is available if the producers of the alternatives can meet increased demand.
- Emissions might be severely underestimated because potentially large direct emissions to the environment are possible from pulp and paper mill sludge that is produced during the treatment of wastewater derived from a paper mill.
- Some potential alternatives have or might have undesirable impacts. Stakeholders claimed in the public consultation that alternatives are not available when high KIT values are required. No robust information was submitted as evidence.

Although uncertainties remain the Dossier Submitter assumes that economic impacts of a restriction as well as avoided emissions of PFHxA and related substances are substantial. The costs in relation to the avoided emissions are therefore likely to be proportionate. The Dossier Submitter's central estimate for additional costs resulting from this restriction is 250 €/kg avoided emissions when chemical alternatives are used. With regard to the affordability of the restriction, average costs of less than 4 €/a per consumer are very likely to be affordable.

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. Some alternative technologies are solvent based or UV-curable mixtures (Stakeholder Consultation, 2018).

Stakeholders expect that a simple “drop in” substitution will not be possible.

Regarding cost of substitution, some companies indicate similar ranges from 0.1 -10 million Euro. Others assume higher costs of >10 million Euro (Stakeholder Consultation 2018). It was not possible to derive general substitution costs for the whole industry from this company related information.
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. It is not clear for which products and why fluorosurfactants are needed instead of siloxanes.

The Dossier Submitter regards the information as highly uncertain evidence that alternatives might be 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 up to 15 t/a of PFHxA-related substances.
- Approximately 80 percent emissions from the use of PFHxA-related substances is estimated, i.e. up to 12 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 (for example PFBS) have partially replaced longer chain PFAS. The Dossier Submitter assumes that this group of substances can be used as direct substitute.
- Other Alternative technologies are solvent based or UV curable mixtures which are in the evaluation of one company. They are even less recommendable with regard to human health and environmental properties (during production and in final use) (Stakeholder Consultation 2018).

- 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 derogation 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.

In summary, the Dossier Submitter proposes a temporary derogation for the latex printing inks. A manufacturer claims that alternatives are not available at the moment but in the process of development. No contrary information is available. For the remaining printing inks, no derogation has been proposed. Stakeholders claim that for some applications (for example inkjet inks) printing inks with fluorosurfactants are needed to reduce the water surface tension. However, considering that printing inks without fluorosurfactants or with C4-fluorosurfactants are available, the Dossier Submitter would need more information to evaluate whether additional derogations are proportionate in general and for which specific applications.

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) up to 57 t/a 6:2 FTS (2 – 57 t/a; central estimate 30 t/a) are used for chrome plating in the EU, resulting in a central estimate of 5.9 t/a emissions (0.5 – 11.4 t/a) of PFHxA-related substances into the environment. This extrapolation is uncertain, however, within the registered band for annual usage of 10 – 100 t/a. Accordingly, estimates for the emissions from the specific chrome plating processes are uncertain, too.

20% of the applied surfactant is lost in the plating processes over time (Brunn Poulsen et al., 2011). Without a restriction 9 – 228 t/a PFHxA-related substances will be emitted into the environment over 20 years. Considering a five-year derogation for hard chrome plating emissions would be reduced to approximately 0.27 - 13 t/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).

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., 2019). 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 costs related to a reorganization of the production facilities for some companies. Information from industry suggests that 'the costs of phasing-in alternatives varies per company. Tests with alternative products may cost a company €50 000 to €150 000 per test and a test cycle has a minimum length of at least 1 year. However, the representatives indicate that the costs are mainly related to the costs of phasing in the alternative in practice and not in the costs of testing. Most relevant for the cost is whether the alternative is a drop-in alternative or that new installations (tanks, baths, etc.) are required' (EU, 2016).

For decorative plating a shift to other electrolytes that are Cr(III) based is an available alternative. The Norwegian association of electroplaters (NGLF) has estimated the cost of replacing Cr-VI in plating baths with Cr-III to be approximately NKR 100 000 (US$ 15 000–16 000) per bath (UNEP, 2013).

The information that is available at the moment is not sufficiently detailed to derive a cost-effectiveness estimate. Information from Germany suggests that manufacturers in the sector of plastic product chrome plating have already started to replace Cr(VI) in plating baths with Cr(III). This substitution process has been set off by the listing of Cr(VI) as an SVHC under REACH Annex XIV.

However, for decorative chrome plating some users claim that Cr(III) use is not possible when high technical performance and strict aesthetic standards have to be met, as for example in automotive industry (Steinhausen, 2019).

One main missing information to derive costs for the chrome plating industry from this restriction proposal is the number of baths per manufacturer. The chrome plating industry is characterized by heterogeneity and a large share of small and medium enterprises.

The cost estimate from the Norwegian association of electroplaters suggests that substitution of Cr(VI) with Cr(III) is affordable. Substitution costs mainly consist of one-time replacement costs that amount to less than 1 000 €/a (750-800 €/a) per bath when considering a time period of 20 years.

But this information is not sufficient to evaluate proportionality of a restriction as information on emissions per bath are not available. Emissions depend on bath size, type of use and operating time.

For hard chrome plating where it is not possible to use Cr(III) a cost estimate cannot be derived. It is not clear to the Dossier Submitter how the quoted costs of 50 000 – 150 000 € translate into costs per bath or costs for avoided emissions.

Therefore, the following information was taken into account to consider the economic impacts qualitatively:

- PFHxA-related substances are used in non-negligible quantities in the EU (central estimate 30 t/a).
- approximately 20 percent of the quantities used are emitted into the environment.
- Alternatives are available for decorative chrome plating and plastic electroplating. The substitution is likely to be economically feasible.
- As a response to the listing of Cr(VI) as an SVHC on Annex XIV manufacturers already prepare to use Cr(III) for plastic electroplating and when possible for decorative chrome plating.
- Alternative wetting agent fume suppressants for hard metal plating have been identified but not tested sufficiently by the industry. A time-limited derogation is needed to complete testing and procure new installations.
- Some alternatives proposed for hard metal plating might be costly. For example, control devices for air flow, additional baths or additional wastewater treatment could be needed. It is possible that manufacturing routines have to be changed.
- Of the various alternatives available some might have issues regarding performance, health and environmental impacts. Additional information is not available.
- The chrome plating industry is characterized by heterogeneity and a large share of small and medium enterprises.
- It is not possible to derive a generalizable restriction scenario for this diversified industry.

- The automobile industry is an important customer of hard metal plated parts. Suppliers have to deliver parts according to specifications over long time-periods (up to 20 years).
- PFHxA-related substances are not present in the chromium-plated article. Therefore, no impacts are expected for imported articles.
- In a recent report on technical and economical feasibility of alternatives for chromium trioxide it was questioned whether alternatives are available for all applications in decorative chrome plating and and plastic electroplating (Müller A. et al., 2020). No additional information has been provided in that regard in the public consultation.

No additional information was submitted by stakeholders in the public consultation.

Considering the scarce information, the Dossier Submitter proposes a temporary five-year derogation from the restriction for hard metal plating. 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 fluoropolymer or side-chain 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.

The following further information regarding the use of PFHxA-related substances was submitted during public consultation:

One company mentioned the use of coated C6 fabric in reinforcement of roofing membranes to avoid any water absorption. Further information was not submitted.

The use of PFHxA-related substances for protection of surfaces and facades against water, molds, mosses, soil, solvents and oil-based stains (e.g. graffiti) was also mentioned in some comments.

Furthermore, C6 is used in non-wovens fabrics for construction to bring weathering resistance. It was reported that C6 substances are not expected to be released during use.

Fluorinated polymers (not further specified) are used to make water- and oil-repellent penetrating sealers for natural stone, porous tile, grout and masonry. C6 fluorocarbons are used because of stain resistance, easy clean-up properties, hydro-repellence, protection from atmospheric agents, UV rays and pollutions.

Another use of C6 fluorinated substances is in textiles for flexible civil construction (e.g. flexible textile roofs or ceiling panels). It was mentioned that with fluorine-free alternatives a maximum dynamic water repellency and dirt repellency cannot be achieved and manufacture standards are failed to meet.

C6 fluorinated substances are also used in reinforcement fabric for wall plaster to ensure water and UV-resistant effects (e.g. for effective outdoor durability and low suscreptibility). The company stated that no fluorine-free alternative is suitable for this use.

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.

Stakeholders commented in the public consultation in this regard. The information provided was not sufficient to draw any conclusions.

As stated above several other stakeholders commented on various applications in the construction sector. However, no stakeholder provided sufficient information as a basis to calculate the impacts of a restriction.

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 required 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, a derogation for five years after entry into force of the restriction is justified after which no more production is expected anyway.

During Public Consultation representatives of the European photographic industry mentioned that PFHxA-related substances are still used in photographic coatings in some printing plates and in photographic paper. PFHxA-related substances are used as an alternative of the C8 based substances but research to replace PFHxA-related substances is ongoing. The Dossier Submitter supports the request for derogations.

Another stakeholder requested a longer transition period for coated inkjet photo papers to find, test and implement a non-fluorinated alternative. The stakeholder provided details on the reasons why short-chain perfluorinated surfactants (e.g. PFHxA-related substances) are used in certain water-based inkjet media coatings.

For inkjet photo media coatings, the stakeholder reported confidential information on their use of PFHxA-related substances. Based on this information, the Dossier Submitter assumes that total use quantity for this use in the EU is <10 t/a. The stakeholder provided confidential information on their search for alternatives and concluded that it would not be possible to substitute within the 18 months transitional period. The stakeholder claims that premature obsolescence of these products would impact the ability of small businesses and consumers to produce photo quality prints possibly leading to early replacement of a large number of printers.

Based on information available the Dossier Submitter assumes that a restriction would not result in any direct cost to manufacturers or users but mainly in functional losses, i.e. impaired visual quality. The Dossier Submitter has no information on how this functional loss would impact professional users or private users.

Considering the assumption that emissions will be comparatively small and that the derogation will be time-limited a derogation for five years is proposed. However, impacts are very poorly understood. Therefore, it is very uncertain whether this derogation would be justified.

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. PTFE, 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 sunscreen. 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[7]. 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, 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,

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[7] 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).

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.

No additional information was provided during the public consultation.

2.5.1.12. Watches

PFHxA-related substances are used by the watchmaking industry as epilames. Epilames are applied as coating on mechanical watch-parts that need lubrication due to their movement (e.g. wheels, pivots, escapements, stones). The epilame coating is required to obtain a low surface tension in order for the lubricant (oil) to stay in place and not spread through the movement of the mechanical watch-parts. Furhtermore, the epilame coating must be chemically compatible with the substrate on which it is deposited and must also not react with the components of the lubricant. Therefore, watch production processes rely on epilames having a structure on the basis of C6 fluorinated polymers and alternatives are not available (information received from stakeholder). The overall mass of C6 fluorinated polymers used in watchmaking processes lies within the lower, one-digit kg/a area. As epilame coating takes place through immersion of the to-be-coated parts in a bath of the epilame mixture, a proportion of around 80 % of the epilame mixtures goes to waste. According to stakeholder information the waste is collected as industrial chemical waste and is properly disposed of (i.e. high temperature incineration). So, emission of PFHxA related substances from watchmaking processes can be considered as low. The watches themselves only contain a small amount of C6 fluorinated polymers (< 1 kg/a on a global scale) and the coated parts are inside the hermetic watch case. So exposure of consumers through the use of watches is not expected. Furthermore, mechanical watches usually are expensive products with a long service life. They are not likely to be disposed through household waste, but rather are resold or dismantled for their parts. But still, emissions to the enviroment will eventually occur at the end of the products life. During the public consultation DS was informed, that historically stearic acid was used for epilamisation. When asking stakeholders about this as a possible alternative, DS received information, that stearic acid does not fulfill current industry standards due to its poor oil repellency and wash resistance. Considering the low amounts of PFHxA related substances used in the production of epilame mixtures for watchmaking processes, the low emissions to the enviroment and neglible exposure of consumers, a derogation for this use could be considered. It could, however, also be questioned whether the production of mechanical watches should be considered as a crucial use that needs a derogation, as there are other watches available. DS is of the opinion, that a derogation for this use should be proposed only if all available risk reduction measures (in this case reduction of emissions) were taken by the manufacturer and downstream users. So far the relevant stakeholders demonstrated that the amounts of PFHxA related substances produced and used are already very small but no information on possibilities to further reduce the used amounts or substitution plans were provided.

A derogation is justified when just considering the low emissions and the potential impact for companies of no longer being able to produce mechanical watches according to international standards. Exports might be affected when standards can no longer be fulfilled.

However, with a view to information that alternatives do not fulfill industry standards the Dossier Submitter does not know what these standards are. If the only effect of using PFHxA-related substances is more precise functioning of watches the proportionality of a derogation could be questioned. If more precision means less maintenance and longer service life than it is highly likely that a derogation is justified. The Dossier Submitter deems information provided by stakeholders as sufficient to propose a derogation but notes that stakeholders did not provide detailed information on future substitution plans.

2.5.1.13. Medical Devices

In the medical sector there are different applications for PFHxA and its related substances. Uses of PFHxA and PFHxA related substances, that were brought to the DSs attention during the public consultation, are the following and described in further detail in Annex E.2.13.6.

Production of detergent proof, one-use, washbowls

These single-use and disposable washbowls are used in the medical sector to prevent cross infections and hospital acquired infections (e.g. Methicillin-resistant Staphylococcus aureus (MRSA)). There seem to be fluorine-free alternatives which allow the production of detergent-proof washbowls.

Non-active medical devices in ophthalmic applications

In ophthalmic applications PFAS serve as non-active medical device in the application of eye drops for the treatment of dry eyes symptoms. It remains unclear to the DS (and the manufacturer of this product) whether a derogation for this use is needed as the claim is made, that the semifluorinated alkane is inert and does not undergo degradation unless exposed to high temperatures (i.e. incinerated). Still the substance is listed as PFHxA related substance in Table 5 of Appendix B of the restriction dossier.

Specialty compounds blended with polymers for implantable and non-implantable medical devices

For the use in implantable and non-implantable medical devices, PFHxA related substances are used in specialty compounds blended with polymers. A derogation for this use should be considered as there are clear health benefits and emissions can be considered as low.

Coating for hearing aid devices

In the production of hearing aids PFHxA related substances are used as coating to provide hydrophobic and oleophobic properties. These properties are important, so that water, sweat and ear wax will not enter the interior of the device. The Dossier Submitter was informed that finding a suitable alternative and replacing the production processes will take approx. ten years. So at least a time limited derogation for this use could be justified.

Non-woven medical textiles

Non-wovens are used in hospitals to avoid cross-contamination from re-using of woven gowns, masks or similar articles. Non-woven articles are considered as cost-effective and disposable alternative. They are considered to have have good barrier properties, good performance characteristics (comfort, thickness and weight, water vapor transmission, air permeability etc.) and provide increased protection (tensile, tear resistance, abrasion resistance etc.).

Non-woven medical textiles are used in the following applications:

- Personal health care/hygienic products: Bedding, clothing, surgical gowns, cloths, wipes surgical curves, surgical hosiery, diapers, etc.
- Non-implantable material or medical dressings and auxiliaries: Wound dressing, bandage, plasters, gauge, lint wadding, etc.
- Implantable materials: Sutures, vascular grafts, artificial ligaments, and artificial joints.
- Extra corporal devices: Artificial kidneys, liver & lungs, etc.

The non-wovens are used for the given applications in different forms and are used in ambulances, consultation couches, ICUs, laboratory, operating rooms, wards etc.

Woven medical textiles

Woven medical textiles are used similarly in the following applications:

- Protective and healthcare textiles,
- external devices,
- implantable materials,
- hygiene products,
- extracorporeal devices.

In the public consultation stakeholders submitted information that there is rising demand for reusable woven medical textiles which are considered as sustainable alternative to some disposable non-woven articles. Stakeholders claim that in order to avoid contamination issues the use of PFHxA-related substances is necessary.

The Dossier Submitter proposes a general derogation for medical devices as specified in Regulation 2017/745 of the European Parliament and of the Council. Some information on costs and benefits have been provided by stakeholders for the uses mentioned above. The Dossier Submitter considered analysing socio-economic information from the public consultation. However, he argues that this information is not relevant when he proposes a general derogation for medical devices. Only when no general derogation is proposed detailed information for individual uses needs to be assessed.

The Dossier Submitter argues that there are most probably current (and future) uses not identified in the public consultation. In two different personal meetings with stakeholders who submitted information he was informed that a) the stakeholders became aware of the restriction proposal more or less by chance and b) that it is very unlikely that there are no additional uses for medical devices.

Whether cost information submitted in the public consultation is representative for all uses is unknown. E.g. if there are several additional uses it is highly unlikely that the sample from the public consultation represents reliable information in regard to all uses for medical devices.

That said, the Dossier Submitter proposes a very broad derogation that might not be justified. However, considering possible negative impacts from limited use-specific derogations this seems to be a proportionate approach under uncertainty.

Uncertainty remains especially with a view to textiles regarding the necessity of the proposed derogations. The Dossier Submitter has no information on actual risk reduction from using C6-treated textiles. Considering that the risks of equipment failure, need of early replacement, and other unwanted consequences could be potentially high, precautionary use of textiles treated with PFHxA-related substances might be justified. The Dossier Submitter notes that most probably the derogation covers articles where the continued use of PFHxA-related substances is not justified. However, without further information the large variety of articles and uses makes it impossible to identify use categories for exclusion.

Emissions from this use might be up to 100 t PFHxA-related substances over 20 years.

In sum, the Dossier Submitter argues that not enough evidence is available to assess the proportionality of a broad derogation.

In order to assess proportionality and implementability in the future for a narrower restriction proposal more information is needed. The Dossier Submitter argues that stakeholders from the textile industry often failed to provide well-balanced information in the public consultation claiming essentiality for a large variety of uses without providing information on alternatives or impacts of not using C6-related substances.

2.5.1.14. PTFE (Polytetrafluoroethylene) micro-powders

Polytetrafluorethylene is a fine, inert, white micro-powder with desired mechanical, thermic, electrical and chemical characteristics. PTFE itself does not consist of C6 related substances, but it is still related to PFHxA because impurities of PFHxA are components of the PTFE micropowder. These impurities are unintentionally created while producing PTFE. Therefore, it is linked to the restriction proposal of PFHxA and its related substances. PTFE micro-powders are used in the medical sector, in electronics, in the field of tribology, mechatronics and serve as an additive to different substances and liquids to enhance their attributes. Hence, it has a broad scope of applications.

In the following, the scope of application will be limited to the usage of PTFE micro-powders brought to the DSs attention during the public consultation.

PTFE is used in printing inks as an additive in toner, powder for laser or fax and in liquids. PTFE has to be added to 1-5 % in weight to the product to reach desired aspects, for instance scuff-resistance, improved image protection and higher efficiency. Printing inks are commonly used for wrappings and similar products with a short functional life. With present data it cannot be determined in which quantities PFHxA is currently present in products and therefore released into the environment.

Similar characteristics (e.g. scratch resistance, slipping, matting effects and rubbing) are aspired for paints and coatings where 5-15 w% needs to be added. The PTFE lubricant powder can be used for a wide scope of industrial coating formulations like powder coating, wood coating, as well as can and coil coating. DS received information on the amount of sold product (t/a) from one stakeholder. A statement of the purchased quantity of PTFE and its content of PFHxA is not given.

In lubricant and greases PTFE micro-powder is added up to 15 % in oils and 25-40 % in greases to adjust the viscosity and to obtain lubricity during a wide temperature range (-190 °C to +260 °C). It also reduces the static and dynamic coefficient of friction, does not absorb water and improves the thermal and corrosional resistance. In consequence, a good non-stick and sliding property is achieved. PTFE micro-powder is an additive which is used instead of graphite and molybdenum disulphide because of higher chemical resistance and the higher temperature range needed for specific applications.

PTFE can be used in a wide variety of materials like thermosets and thermoplastic (e.g. polyesters, polyacetals, polyamides, polycarbonates, polysulfides, melamine resins, polysulfones/epoxy, phenol-formaldehyde), as well as elastomers (e.g. silicones, nitriles, neoprenes and fluoroelastomers). Regarding thermoplastics, PTFE is added to 10-15 w% to improve tribological properties, such as reducing friction and abrasion. PTFE is added to elastomers with 15-25 w% to improve the abrasion resistance and tear strength. The micro-powder can be used to minimize drip and propagation of flame while fibrillating in the melt and blending process. Additionally, it is claimed to improve anti-fingerprint, anti-dust and has a flame-retardant effect. Similarly, it can be used in food and beverage cans. The necessary quantities of PTFE for the mentioned improvements are unclear, as well as the contained amount of PFHxA.

In the production of PTFE industrial film laminating for the automotive sector and other sectors, PTFE micro-powder can be also applied. The PTFE glide layer is combined with different materials to improve durability. The data from the public consultation neither shows how much PTFE is needed nor the amount of PFHxA that is contained.

Furthermore, PTFE can be used to insulate cables. These cables, as the manufacture claims, are used in aerospace application under therefore very harsh environmental conditions (e.g. wide temperature range, chemical forces). The materials for the cable have to be inert to their environment and guarantee functionality at different temperatures. The manufacturer also states that 100% of the wiring installed in an aircraft is based on fluoropolymers (e.g. PTFE, FEP, PFA, ETFE and PVDF). The only quantity given is the complete global amount (100-1000 tons) of fluoropolymers purchased by the company per year. There is no information about the quantity of PTFE and PFHxA. The manufacturer requests a derogation based on major standards of cables used in aerospace and the need to sustain a high level of performance to guarantee the safety of passengers and aircraft.

Generally, there are alternative substances or alternative manufacturing processes for PTFE that create impurities of PFHxA lower than 25 ppb. As there is no openly available knowledge concerning the efficiency, availability for companies or potential risks with regard to regrettable substitution a derogation for use and manufacture of PTFE might be necessary. DS is of the opinion that this will be covered by the derogation for fluoropolymers (see section E.2.1 Floropolymers and side-chain fluorinated polymeres). Even though more companies are looking for alternative production processes to reduce the amount of PFHxA produced, there is no clear timetable for completion. As a result, it remains unclear how many companies could replace their PTFE quantity or adjust their production in time for the sun set date. It should also be noted that a derogation for PTFE micro-powders used in industrial and commercial applications is already included in the draft delegated act implementing the POP Regulation on PFOA. This entered into force on 04 July 2020 and grants a derogation for two years until July 2022. Furthermore, the use of PTFE is accompanied by economic and societal advantages, such as improved properties of medical devices, cost savings and emission reductions due to reduced friction and improved tribiological properties..

2.5.1.15. Optical fibres

The Dossier Submitter was informed about uses of PFHxA related substances for optical fibres during the public consultation.

In the telecommunications sector, ETFE is used for special optical cable applications called “buffer tubes”, these tubes hold and carry the actual fibre optics. Protecting them from the adjacent environment (public consultation, comment 3002).

Mainly, the optical fibres are used for transmission media for in-vehicle data communication. Especially, to achieve safe driving or auto-pilot system (Advanced Driver Assistance Systems, ADAS, and self-driving cars), higher data rate transmission media will be mandatory in the near future. If optical fibres using fluorinated cladding were prohibited by a REACH restriction, there would be no suitable transmission medium which could the technical requirements for the noise resistance, mechanical properties and costs (comment 3002). The Dossier Submitter does not fully understand what is meant by fluorinated polymers in the content. However, if SFPs are used a derogation is not justified by the information provided. More information on comparison between other materials and C6 fluorinated polymers regarding the refractive index properties would be needed. In order to evaluate the request for a derogation it also would be helpful to receive more specific information on the claim that higher data rate transmission media will be mandatory in the near future, e.g., how many years from now this can be expected? What data rate would be required and what can alternatives achieve in that regard?

2.5.1.16. Other special uses of PFHxA related substances

A number of applications of PFHxA related substances 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 related substances have properties that are used 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 related substances in this field of use is not clear so far and no additional information was submitted in the public consultation.

- 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 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 derogation 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. No additional information was submitted in the public consultation.

For these uses no further socioeconomic information has been submitted. No additional information has been submitted during the public consultation.

2.5.1.17. 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.

Administrative costs will be incurred to the users reporting use quantities and/or substitution efforts to ECHA.

The Dossier Submitter proposes for articles and mixtures (except concentrated fire-fighting foam mixtures) to which paragraphs 1 and 2 shall not apply a reporting requirement:

> From (entry into force + 12 months), a natural or legal person placing a mixture or an article specified in paragraph 9(b)- 9(h) on the market for the first time and benefitting from the derogation therein shall provide by 31 January of each calendar year a report to the European Chemicals Agency containing:
>
> (c) the identity of the substance(s) used in the previous year;
>
> (d) the quantity of PFHxA, its salts and PFHxA-related substances used in the previous year.
>
> The European Chemicals Agency shall forward the data to the Commission by 31 March every year.

For concentrated fire-fighting foam mixtures for certain defence applications paragraph 1 and 2 shall not apply. For concentrated fire-fighting foam mixtures for cases of class B fires in tanks with a surface area above 500 m^2 paragraph 1 and 2 shall not apply until 12 years after the entry into force of the restriction. A natural or legal person benefitting from the derogations shall provide by 31 January of each calendar year a report to the European Chemicals Agency containing:

(c) A description of their efforts on substitution of fire-fighting foams that contain PFHxA, its salts and PFHxA-related substances;

(d) quantities they used in the previous year of fire-fighting foams that contain PFHxA, its salts and PFHxA-related substances per sector specifying:
    (iii) share in training and in operation
    (iv) whether emission was contained, collected and disposed safely or emitted into the environment.

The European Chemicals Agency shall consolidate and forward the data to the Commission by 31 March each year.

The main purpose of the reporting requirement is to provide information for decision-makers to facilitate further action. Based on incomplete information the Dossier Submitter assumes that the proposed derogations are justified with a view to socio-economic considerations and assumes that the continuing emissions resulting from the derogations will not impact the effectiveness of the restriction fundamentally. However, in order to minimise the current large uncertainties with regard to the potential emissions better data on use quantities is required. This data can be used to reassess the effectiveness of the restriction and to reconsider the proportionality of derogations in the future.

While the Dossier Submitter has not quantified the total cost of the reporting requirement, he notes that the costs associated with reporting would consist of a one-time cost to develop the reporting format and software to submit and process the information for regulators and ongoing costs for industry to gather the required information and submit it once a year.

According to information provided for the restriction proposal on microplastics 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 (similar to the existing system for Article 66 downstream user notifications). Such an approach would also minimise costs for annual compiling and disseminating of the information. The Dossier Submitter notes that costs might be smaller when a similar system for microplastics has already been installed.

Ongoing costs for industry are difficult to estimate as they would depend on the complexity of the structure of companies and supply chains and the number of products/materials/mixtures for which reporting requirements hold. However, the Dossier Submitter notes that all derogations proposed and the associated reporting requirements concern uses where specific industry norms have to be fulfilled by the manufacturers and/or their supply chain. Hence, it should be possible to identify the link in the supply chain where the necessary oil-, water, dirt- or grease-repellent properties are provided. There, the required information should be available on substances and quantities used to provide the properties required by the industry norms.

For concentrated fire-fighting foam mixtures the Dossier Submitter proposes a more complex reporting requirement. In order to evaluate the impacts resulting from the derogations not only the quantities placed on the market are of interest. In order to better understand the effective emissions to the environment more information is required with regard to quantities not only stored but actually emitted to the environment via training, testing, accidental spills and fire incidents. Secondly, more information on substitution activities is needed to better understand when some or all uses of AFFF for defence purposes can be substituted with non-fluorinated foams. Thirdly, the European Commission needs detailed information to closely monitor the availability of non-fluorinated alternatives for fire-fighting foams for tanks with a surface area above 500 m^2 in order to assess in sufficient time whether effective alternatives will be available after 12 years for all tank sizes.

2.5.1.18. 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 costs 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 and PFHxS restrictions).

2.5.1.19. Summary of the costs

Table 7 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. Missing data means that only incomplete quantitative information is available that is no basis for any meaningful quantification of costs. However, sometimes this incomplete data (e.g. very specific data provided by individual manufacturers) is a basis for a qualitative discussion and qualitative conclusions with regard to the uses. No data means that no meaningful discussion of the costs in case of a restriction is possible.

The proposed derogations have not been considered in this table because impacts are very uncertain with regard to costs and benefits. Continuing emissions from derogated uses are discussed in Annex B9.19. Benefits resulting from the proposed derogations are discussed in Annex E.

Table 7: 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 million €
fluoropolymers	use quantities, manufactured articles and mixtures, emissions and societal costs unknown or very uncertain					
manufacture of (acrylic-) polymers with C6 side chains	1 000 – 10 000 (5 500) 1 000 – 10 000 (5 500)	7 – 68 (37.5) 11 – 110 (60)	94 – 945 (519.5) 210 – 2 100 (1 155)	missing data	missing data	reorganization of business unemployment effects of reorganization
manufacture of fluoroelastomers (APFHx)	12 – 16 (14)	0.1 – 1 (0.55)	1.8 – 18.5 (10.1)	40 – 320 (180)	2 160 – 177 780 (17 820)	Cost for automotive and aerospace industries and supply chain, semiconductor manufacturing
clothings used in the EU	24 000 – 73 000 (32 000) 21 360 – 64 970 (28 480)	50 – 174 (67) 1 161 - 4034 (1 548)	919 – 3 223 (1 225) 10 879 – 37 779 (14 505)	0 when substituting with alternatives that provide water repellent properties	(0)	loss of stain and oil repellency: reduced service life cleaning convenience reduced water repellency possible for some applications reduced protective functions
professional apparel (complete restriction!)	380 – 970 (475) 338 - 863 (423)	2 - 5 (3) 23 - 59 (29)	36 – 91 (45) 237 - 602 (296)	0 when substituting with alternatives that provide water repellent properties	(0)	loss of stain and oil repellency: reduced service life cleaning convenience reduced water repellency possible for some applications reduced protective functions
home textiles	3 100 – 9 000 (6 050) 735 – 2 133 (1 430)	6 -18 (12) 45 - 132 (89)	115 – 163 (139) 417- 2 232 (1 325)	0 when substituting with alternatives that provide water repellent properties	(0)	loss of stain and oil repellency: reduced service life cleaning convenience

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 million €
						reduced water repellency possible for some applications reduced protective functions
technical textiles (complete restriction!)	1 350 – 2 600 (1 975) 2 – 3 (3)	13 – 25 (19) 0.1 – 0.2 (0.2)	114 – 223 (169) 0.6 – 1.4 (1)	0 when substituting with alternatives that provide water repellent properties	(0)	loss of stain and oil repellency: reduced service life reduced filtration properties increased energy consumption
fire-fighting foams	(480 - 560)	105 – 563	1 442 – 6 825 (4 134)	additional procurement costs: (< 280)	data too uncertain	all additional costs too uncertain due to missing information and unknown impact of PFOA-regulation: replacement foam (13 – 130 million €) Incineration costs (4.3 – 43 million €) cleaning of fire-fighting apparatus adjustments to extinguishing infrastructure: Administrative issues, training handheld fire extinguishers export losses
greaseproof paper	27 600- 207 000 (117 300) 18 – 220 800 (110 400)	235 – 1 760 (998) 1 – 9 445 (4 723)	4 430 – 33 223 (18 827) 8 – 97 629 (48 819)	28980 – 86 940 (57 960)	221 – 19 590 (856)	additional machinery increasing grease and oil spillage causing cleaning costs and possibly injuries

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 million €
mixtures for consumer use	missing data for emissions estimate			no additional costs for manufacturers (no additional information in PC)	0	reduced service life, e.g. of textiles, floor covers and cars convenience losses (cleaning) reduced desired effects (ski waxes)
printing inks	10 – 100 (15)	8 – 80 (12)	147 – 1 473 (221)	missing data		Premature obsolescence of hardware less precise printing R&D expenditure availability of alternatives in time
chrome plating	2 – 57 (30)	0.5 – 11.4 (6)	8.7 – 215 (112)	missing data		additional chrome baths additional air ventilation conversion and reorganization of manufacturing installations
building material	missing data for emissions estimate			missing data		reduced service life faster soiling higher repairing intervals reduced energy efficiency
photographic applications	missing data	< 5	< 100	missing data		loss of remaining production when phase-out to digital photographic applications takes longer
semiconductors	missing data	< 10	< 200	missing data		identification and implementation of alternatives cessation of production in Europe

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 million €
cosmetic products	missing data for emissions estimate			negligible additional costs for manufacturers (no additional information in PC)	0	loss of aesthetic functions decreased water repellency loss of convenience (application of product) reformulation costs
filtration	missing data for emissions estimate			missing data		loss of stain and oil repellency: reduced service life reduced filtration efficiency (HH and environmental risks) export losses → future manufacturing outside EU
watches	< 0.002	< 0.002	< 0.04	missing data		reduced service life increased maintenance less precision export losses
medical devices	missing data for emissions estimate			missing data		for textiles: Less hygienically reliable Switch to disposable articles For other medical devices: Therapeutical advantages
optical fibres	missing data for emissions estimate			missing data		impact on possible future uses in driverless vehicles

*red: C6 side-chain fluorinated polymers; 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 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. Serious health concerns related to PFHxA-exposure are expected to rise in future due to prospectively increased exposure, as described below. 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 serious human health impacts cannot be excluded.

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 wastewater 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 5 700 – 38 000 t C6-related fluoropolymer and SFPs and 13 300 – 148 000 t PFHxA-related substances. Some uses are not included in this estimate. See B.9 Exposure Assessment and Table 7 for uncertainty ranges and further information.It can be questioned whether emissions reduction is an adequate proxy of risk reduction when substitutes are SVHCs or otherwise of substantial concern. The risk profile of potential alternatives sometimes is poorly understood or unknown. Often it is not known which of the potential alternatives will be used in case of a restriction. Therefore, it is not possible to predict where regrettable substitution will happen. In Annex E2 known alternatives for the different uses are listed. Some potential alternatives are substances of very high concern (for example some silicons which are PBT or vPvB). Other potential alternatives might have detrimental effects on other environmental policy goals (for example the use of plastics or nanomaterials as an alternative).

Considering previous restrictions on PFAS-substances, where substitution with shorter-chain alternatives was possible, it might be possible that the same happens here, namely the substitution by C4 substances taking place due to the proposed restriction. In the Dossier Submitters view this would be a case of regrettable substitution as the hazard profile of these substances is similar to PFHxA, they are extremely persistent and mobile in the environment.

Not much information is available on the likelihood and extent of substitution with C4 substances. There are some minor indications that substitution with C4 substances might be possible for some consumer mixtures, printing inks, building materials or cosmetics. This is based on information from the consultation that it might be possible that for some products in these use groups substitution from PFOA-related substances to C4 substances happened in the past. Stakeholder consultations by Dossier Submitter and the public consultation during the restriction process did not produce any evidence that broad substitution with C4-related substances (or other fluorinated substances) can be expected for the concerned uses.

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 and 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. 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 and SFPs. Production facilities affected will need restructuring for alternative production purposes. Several stakeholders claimed in the public consultation that the restriction would endanger the production facilities in the European Union for fluoropolymers and substances covered by the restriction. It might be possible that due to the limited derogations and resulting limited uses production in the EU might no longer be economically viable. Stakeholders claim that this might be a strategic disadvantage in situations of crisis. 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 cannot be ruled out by the Dossier Submitter and therefore is an uncertainty.

The Dossier Submitter notes concerns with regard to PFAS in general in several countries outside the EU. Early research and development activities and manufacturing of alternatives might be an advantage if other countries decide to regulate C6 substances in the future.

Also, considering the concerns with regard to persistence and transboundary mobility of the substances the restriction will encourage other countries to further regulate PFHxA, its salts and related substances.

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 similarly priced as fluorinated substances. Some properties of the products will be lost or reduced. Potential impacts of functional losses include loss of convenience and associated additional costs like reduced service life or increase in cleaning processes.

However, in general, no information on distributional effects of the proposed restriction could be identified.

2.5.5. Proportionality

SEAC box

SEAC reached different conclusions than the Dossier Submitter concerning the proportionality of the restriction proposal for some sectors or sub-sectors. Moreover, SEAC considered that it is not possible to conclude whether the overall restriction is proportionate, although there are arguments in favour of proportionality, i.e. irreversibility of the accumulating stocks of PFHxA in the environment and the extreme persistence of PFHxA.

Details of the SEAC assessment are reported in the SEAC opinion, together with the justification for conclusions on proportionality.

The restriction proposal for microplastics[8] 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."

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

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

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 PFHxA is of equivalent level of concern to the above mentioned PFAS (see additional information in Annex E.5 Proportionality) and 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, 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 several uses.

The Dossier Submitter notes that very limited additional robust information has been submitted in the public consultation.

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 in the microplastics restriction proposal) 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 harmful 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.

However, this restriction also faces additional large uncertainties with regard to possible functional losses. Although far from certain, there is the distinct possibility of negative consequences for human health and the environment when certain uses of PFHxA-related substances are no longer possible. In order to be consistent, the Dossier Submitter proposes to favour the “first act, then learn” approach, too, when impacts from not using PFHxA-related substances are uncertain but potentially irreversible (e.g. additional deaths or chronic illnesses).

Additionally, it has to be considered that the “first act, then learn” approach imposes sunk costs on society. These costs have been described quantitatively and qualitatively by the Dossier Submitter.

Costs and benefits of a restriction are uncertain and both environmental emissions and policy costs are irreversible. However, most 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.

Table 8 summarizes arguments for the restriction of the specific uses and arguments for derogations. Obviously, some uses face large uncertainties with regard to costs as well as benefits: The level of emissions is unknown but might be high. Functional losses might lead to severe consequences for human health and the environment in some cases. The Dossier Submitter argues that in such cases a cost-effectiveness analysis is not productive. Instead the Dossier Submitter proposes to consider reasonable worst-case scenarios for costs and benefits and evaluate whether consequences from reasonable worst-case scenarios are affordable to society as a whole and impacted individuals or subgroups. When information is incomplete and informed optimal decision-making is not possible an adequate strategy is to minimise future regret.

For some uses this approach leads to distinct and intuitively understandable conclusions what action should result from adopting the "first act, then learn" approach: In the first place the approach suggests to ban all uses of PFHxA, its salts and related substances because the effects of the substance are uncertain but irreversible. However, when considering reasonable worst-case consequences from the restriction for human health and the environment (e.g. from less effective PPE or not being able to effectively extinguish large fires) it might be necessary to act first by granting a derogation for certain uses to prevent possibly disproportionate irreversible consequences for human health and the environment.

Facing very large uncertainties and few reliable data this balancing of worst-case costs and benefits of a restriction is challenging. However, the decision if PFHxA, its salts and related substances shall be restricted needs to take into account the socio-economic impacts. In the Dossier Submitters' view for this restriction proposal socio-economic impacts need to be described mostly qualitatively. However, if cost-benefit or cost-effectiveness cannot be described in quantitative terms it seems reasonable to discuss the proportionality mostly in terms of affordability and potential regret.

Table 8: Justifications for proportionality of restriction and derogations for certain uses.

Use	Derogation proposed	Justification
Fluoropolymers	yes (higher limit values)	Uncertain emission quantities, but believed to be comparably low. Emissions from waste phase are very uncertain. Very broad use (several applications, some of them affecting large parts of everyday life). Alternatives are most probably available for some uses; however, information is scarce. Uses with very high societal benefits (e.g. in transportation, medical devices, semiconductors). It is likely, that for some uses a restriction would be cost-effective and/or affordable. It is very likely that for certain uses limited benefits (reduced emissions) would result in disproportionate costs (very low cost-effectiveness on societal level, e.g. semiconductors; very high (i.e. unaffordable) costs for some individuals (e.g. with regard to certain health and security related issues). → As long as no new information regarding the resulting emissions from the manufacture, use and waste phase become available a restriction is most likely not proportionate for several uses. The Dossier Submitter does not possess detailed enough information with regard to all uses to propose a more precisely tailored and more limited derogation for certain uses only.
Semiconductors	yes (time-limited)	Emissions are comparably low. Very high societal benefits of use. Several applications, for which substitution potential is not very clear.

Use	Derogation proposed	Justification
		→ As long as no alternatives are available the use of PFHxA-related substances in semiconductors and the manufacturing of semiconductors is clearly justified. → A time-limited derogation is justified as long as semiconductor industry does not demonstrate that substitution is technically and economically not feasible for all uses.
Electronic grade coating	yes (time-limited)	Information is available that emissions from manufacturing and use are low. Emissions from the waste phase are very uncertain. Information is available that the societal benefits of the use of PFHxA-related substances could be substantial. Alternatives will be available within seven years. Whether economically feasible alternatives are already available is uncertain. → If information provided in the public consultation is correct (i.e. limited emissions, no alternatives available now but soon, high benefits with regard to protection of electronic equipment and a resulting extended average service life) a derogation is justified. The Dossier Submitter notes that information on emissions and benefits is limited and clearly overestimates societal benefits. The Dossier Submitter cannot evaluate whether alternatives are already available in general.
Fire-fighting foams (general)	no	Emission quantities are uncertain but estimated to be substantial. Alternatives are available, technically and economically feasible and already in use. Direct substitution costs (price of AFFF in comparison to price of FFF) are affordable. Costs for stock replacement and cleaning of equipment are very uncertain. Up to 90 percent of replacement costs can be saved when PFOA containing stocks are replaced with fluorine-free foams. Costs for equipment adjustments and administrative issues are most likely affordable in general but according to anecdotal information from industry might be substantial in some cases. → A restriction is justified because alternatives are technically feasible. A restriction is justified because replacement of stocks is economically feasible when a large share of the costs can be shared with the obligations concerning PFOA in fire-fighting foams. → The Dossier Submitter notes uncertainties reported in the public consultation with regard to economic feasibility when extensive adjustments to existing equipment are necessary. The Dossier Submitter agrees that some users

Use	Derogation proposed	Justification
		might face high costs however notes that a) the share of such users is unknown and b) that, considering information from the public consultation, mostly large tanks could be impacted which will benefit from a longer transition period. Hence, users have more time to prepare for the technical challenges and economic investments.
Fire-fighting foams (certain defence applications)	yes	Emission quantities are uncertain but estimated to be significant. Stakeholders claim that alternatives are not available. The Dossier Submitter cannot evaluate the claims that available non-fluorinated alternatives do not meet standards required for certain defence applications. The Dossier Submitter notes information from stakeholders that existing non-fluorinated foams do not meet standards required to extinguish certain fuels used in the defence sector. The Dossier Submitter does not fully understand why fluorine-free foams meeting the requirements of Class-B standard fire-fighting performance certifications are no suitable alternative. → However, a restriction is justified because no substantial information was submitted during the public consultation to challenge information from the defence sector. Severe impacts are likely to occur when no foams are available to extinguish fires reliably. The Dossier Submitter proposes that the European Commission monitors the situation and acts when alternatives become available.
Fire-fighting foams (large tanks)	yes (time-limited)	Emission quantities are uncertain but estimated to be significant. According to stakeholder information fluorine-free foams are available to extinguish fires in tanks <500m^2. For larger tanks only inconclusive information is available. According to stakeholders non-fluorinated alternatives for large tank fire-fighting might become available within a few years. The magnitude of the resulting risk when non-fluorinated foams are used is unknown but potential for irreversible and high negative impacts on human health and the environment is large. → Considering uncertainties with regard to performance of FFF and considering irreversible negative impacts in case large fires cannot be extinguished fast enough a time-limited derogation is justified. The development of better performing FFF has been very dynamic in the recent past. If developments continue alternatives will be available in 12 years in general or at least for tanks larger than 500m^2 but smaller than very large tanks of a defined size.

Use	Derogation proposed	Justification
Mixtures for consumer use	no	Unknown emissions. Limited evidence that alternatives are available and economically feasible. No information to the contrary was submitted in the public consultation. → No reasonable worst-case scenario that suggests unaffordable costs in case of a restriction.
Printing inks (general)	no	Unknown but significant emissions from use. Stakeholder information suggests that alternatives are available in general. Stakeholders informed in the public consultation that alternatives are available in general and that costs to develop and manufacture printing inks without PFHxA-related substances are significant but affordable. Some stakeholders claim that time-limited derogations for all/certain inkjet inks are needed to sort out performance issues. The magnitude of these performance issues is completely unknown. Stakeholders did only provide very basic information that performance issues might be a problem and gave broad numbers of printers that might be affected. No information on frequency of problems and possible/probable reaction by printer owners is available. Stakeholder information does not demonstrate sufficiently that a restriction would result in disproportionate costs. However, the Dossier Submitter cannot rule out a scenario where early obsolescence of a large number of printers results in disproportionate costs for society. → Considering that it seems very unlikely that affordability will be an issue in case of early obsolescence of printers a derogation is not justified.
Latex printing inks	yes (time-limited)	Emissions from this use are unknown. Stakeholder information was submitted that for printers already placed on the market no latex printing inks will be available in case of a restriction, resulting in early obsolescence of all latex ink printers. Alternatives are available for new printer generations. → If stakeholder information regarding the availability of alternatives for printers in use is correct early replacement of printers will happen. It is likely that this results in disproportionate costs. A time-limited derogation for latex printing inks is justified to extend service life of existing printers.
Chrome plating (decorative, plastic)	no	Unknown but significant emissions from use. Information that alternatives are available and substitution processes partly ongoing.

Use	Derogation proposed	Justification
		However, information available that costs resulting from substitution process can be significant. Voluntary substitution progress suggests affordability. No further information in the public consultation. → No stakeholder presented new information to contradict the initial assumption from the Dossier Submitter that no derogation is necessary.
Chrome plating (hard)	yes (time-limited)	Unknown but significant emissions from use. Information that alternatives are available in general but substitution processes still need more time. Information available suggests that costs resulting from substitution process can be significant. No further information in the public consultation. → No stakeholder presented additional information in the public consultation to contradict the initial assumption from the Dossier Submitter that substitution is possible within 5 years and that the process is economically feasible.
Building materials	no	Unknown but significant emissions from uses. Derogation requests for different applications. Stakeholders provided very general information. No estimation of future emissions and cost is possible. In case of a restriction alternative products are available albeit functional losses and increased costs are likely. No information has been provided that suggests severe impacts to society. Therefore, the Dossier Submitter proposes no derogation.
Photographic coatings in printing films, plates and paper	yes (time-limited)	Unknown but most likely negligible emissions from use. Small niche applications but probably some health and safety related uses (defence and medical). Phase out and switch to digital photography need approximately five years. Substitution process is not economically feasible. → In order to enable a smooth phase-out and transition to digital photography the Dossier Submitter proposes a longer transition period. In comparison to overall emissions, the emissions from this use are negligible.
Inkjet photo media coatings	yes (time-limited)	Unknown but most likely small emissions from use. Wide professional and consumer use. According to stakeholders, substitution processes is economically feasible but needs additional time. In case of restriction no direct additional costs are expected but functional losses. Impacts are very poorly understood. Therefore, it is very uncertain whether a longer transition period is justified. → Considering the small emissions and that functional losses could lead to early obsolescence of more expensive

Use	Derogation proposed	Justification
		large format printers for professional uses a derogation might be justified.
Cosmetic products	no	Unknown emissions. Limited evidence that alternatives are available and economically feasible. No information to the contrary was submitted in the public consultation.
Textiles (apparel)	no	Very high emissions. Alternatives that provide water repellence are available and economically feasible. Functional losses from reduced dirt and oil repellence might lead to additional societal costs. No information is available that substantiates the claim by some stakeholders that functional losses lead to significant societal costs. → No information is available that suggests that affordability might be an issue in case of a restriction. Considering the very high emissions of PFHxA resulting from this use derogations are not justified.
Textiles (Personal protective equipment)	yes (some uses)	Unknown but significant emissions. Alternatives that provide water repellence are available and economically feasible. Stakeholders claim that PFHxA-related substances are required to ensure important health and security related functions of PPE. No evidence is available regarding the actual risk reduction resulting from the use of PFHxA-related substances. The Dossier Submitter notes that although the impact is unknown it is likely that PFHxA-related substances sometimes function as important part of the risk management in several applications. → A general restriction might result in very high societal costs. Therefore, the Dossier Submitter proposes derogations for uses with risks that may cause very serious consequences such as death or irreversible damage to health and when water repellence is not sufficient to substantially mitigate the risks. For these uses it is likely that a derogation from the restriction is justified. → The Dossier Submitter notes that he does not fully understand if the proposed derogation presents a loophole whereby manufacturers (e.g. for apparel) can fulfil certain norms and manufacture textiles in accordance with the proposed derogations although the additional functionality is not required to prevent death or damages to health. Considering the emissions in such case the proposed derogation might not be justified.

Use	Derogation proposed	Justification
Technical textiles (without medical and filtration)	yes (some uses)	Unknown emissions but possibly significant. Textiles are used in the transportation sector in the engine bay area and it has been reported that treatment with C6-related substances provides potentially life-saving functions. No evidence is available regarding the actual risk reduction resulting from the use of PFHxA-related substances. The Dossier Submitter notes that although the impact is unknown it is likely that PFHxA-related substances function as important part of the risk management in these applications. → A general restriction might result in very high societal costs. The Dossier Submitter therefore proposes derogations for the uses with risks that may cause very serious consequences such as death or irreversible damage to health. It is unknown whether a derogation is justified however the potential costs to society are very high. → No derogations are proposed for further transport-related uses. Not using C6-related substances might lead to functional losses, e.g. shortened service-life or reduced ease of use. No information is available that suggests impacts could be unaffordable.
Home textiles (incl. outdoor and awnings)	no	Unknown but probably significant emissions. Derogations have been requested inter alia for the use in carpets and rugs, textile wallcovers, upholstery, curtains and blinds, outdoor cushions and seatings. → Information provided does not demonstrate significant negative impacts from a restriction for these uses.
Paper (food contact materials)	no	Very large emissions. Alternatives are available. Some stakeholders claim that alternatives are not available when very high grease-repellence is required, e.g. for pet food. Costs are affordable. → The Dossier Submitter does not propose a derogation. Some empirical evidence is available that substitution with non-fluorinated alternatives is available for all applications. Worst-case for high-KIT packaging would be regrettable substitution (e.g. a switch to plastics packaging). However, the Dossier Submitter is not aware of any information that suggests a serious risk increase from such regrettable substitution.
Filtration and separation media	yes	Unknown emissions. Significant use quantities of PFHxA-related substances suggest that significant emissions are possible when considering the complete article life cycle. Stakeholder information suggests high societal value with

Use	Derogation proposed	Justification
		regard to the protection of human health and environment. Stakeholder information suggests high societal value with regard to additional aspects (e.g. CO_2-reduction, longer service life of articles, etc.). Limited information with regard to actual risk reductions and other benefits. Limited information on substitution activities and perspectives. High uncertainties with regard to the broad scope of the derogation. It might be possible that alternatives are already or in the future available for some applications. → Information from the public consultation suggests significant societal benefits from using PFHxA-related substances in filtration and separation media that require a combination of water- and oil-repellency. A broad derogation is justified as long as not enough information is available to identify uses where substitution is possible.
Watches	yes	Negligible emissions. No alternatives are available that provide the same functionality. The Dossier Submitter does not fully understand the impacts that could result from functional losses. Stakeholder information suggests increase in maintenance cost and shorter service life. Exports might be affected when international standards can no longer be fulfilled. → Impact on consumers in the EU is very uncertain and it is uncertain whether a restriction is justified when just considering these impacts. Limited evidence provided by stakeholders suggest the possibility for disproportionate impacts when exports to non-EU markets are affected significantly. The Dossier Submitter deems information provided by stakeholders as sufficient to propose a derogation but notes that stakeholders did not provide detailed information on future substitution plans.
Medical devices	yes	Unknown emissions but most probably significant. Stakeholders provided information for medical applications that suggest that derogations are justified. Limited information is available that PFHxA-related substances are relevant for the manufacture of additional but unknown medical devices. Limited information suggests that the use of PFHxA-related substances in some non-woven and woven medical textiles is justified. The Dossier Submitter has no information on actual risk reduction from using C6-treated textiles. Considering that the risks of equipment failure, need of early replacement and other unwanted consequences

Use	Derogation proposed	Justification
		could be potentially high, precautionary use of textiles treated with PFHxA-related substances might be justified. → most probably a broad derogation for all medical devices covers articles where the continued use of PFHxA-related substances is not justified. However, without further information the large variety of articles and uses makes it impossible to identify use categories for exclusion.
Optical fibres	no	Unknown current emissions. Probably significant emissions in the future. Stakeholders claim that a derogation is necessary for future uses. Information is very limited so that no estimation is possible on current or future emissions, on when the technology will become mandatory and what the current and future impacts are in case of a restriction. → A derogation is not justified by the information provided. The Dossier Submitter notes that a derogation could be justified in case more detailed information becomes available.

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.

In the public consultation stakeholders suggested longer transitional periods for several uses, either because alternatives are not available yet or because a longer transitional period would lower costs of the substitution process significantly. The Dossier Submitter considered these arguments accordingly and proposes prolonged transition periods for several uses.

A longer general transition period of 36 or 48 months for this restriction to reduce the number of necessary derogations is not proportionate. The Dossier Submitter notes that up to 90 percent of all emissions result from the use of PFHxA, its salts and related substances in textiles and paper. According to the available information and empirical evidence substitution is possible on short notice for food contact materials from paper and for apparel. In the Dossier Submitter’s view, it is disproportionate to allow continued emissions from these high emission uses for 18 – 30 months when the continued use and the accompanying unacceptable risk to the environment cannot be justified by socioeconomic considerations.

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, serious effects to the environment are probable.

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 for many uses, alternatives are available and affordable. Where this is not the case, derogations from the restriction have been proposed. 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, as PFHxA will stay in the environment for decades to centuries. Furthermore, several studies show that PFHxA is the ultimate degradation product of several related substances.
- 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 persistence 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 persistence 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 related substances) 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.

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.

References

Ahrens L., Xie Z., and Ebinghaus R. (2010): Distribution of perfluoroalkyl compounds in seawater from northern Europe, Atlantic Ocean, and Southern Ocean. Chemosphere 78 (8), 1011-1016. DOI: 10.1016/j.chemosphere.2009.11.038

Appleman T.D., Higgins C.P., Quinones O., Vanderford B.J., Kolstad C., Zeigler-Holady J.C., and Dickenson E.R. (2014): Treatment of poly- and perfluoroalkyl substances in U.S. full-scale water treatment systems. Water Res 51, 246-255. DOI: 10.1016/j.watres.2013.10.067

Barmentlo S.H., Stel J.M., van Doorn M., Eschauzier C., de Voogt P., and Kraak M.H.S. (2015): Acute and chronic toxicity of short chained perfluoroalkyl substances to Daphnia magna. Environmental Pollution 198 (0), 47-53. DOI: 10.1016/j.envpol.2014.12.025

Begley T.H., White K., Honigfort P., Twaroski M.L., Neches R., and Walker R.A. (2005): Perfluorochemicals: Potential sources of and migration from food packaging. Food Additives & Contaminants 22 (10), 1023-1031. DOI: 10.1080/02652030500183474

Benskin J.P., Muir D.C., Scott B.F., Spencer C., De Silva A.O., Kylin H., Martin J.W., Morris A., Lohmann R., Tomy G., Rosenberg B., Taniyasu S., and Yamashita N. (2012): Perfluoroalkyl acids in the Atlantic and Canadian Arctic Oceans. Environ Sci Technol 46 (11), 5815-5823. DOI: 10.1021/es300578x

BfR (2014): Per- and Polyfluorinated Alkyl Substances (PFAS): Status Quo of consumer health assessment on PFAS - Abstracts. BfR symposium on the status quo of the health assessment of PFAS, Berlin, DE, Federal Institute for Risk Assessment (BfR). https://www.bfr.bund.de/cm/343/per-and-polyfluorinated-alkyl-substances-pfas-status-quo-of-consumer-health-assessment-on-pfas-abstracts.pdf (last accessed 2019-02-27)

BfR (2017a): BfR Recommendations on Food Contact Materials - Recommendation XXXVI. Paper and board for food contact. German Federal Institute for Risk Assessment (BfR). https://bfr.ble.de/kse/faces/resources/pdf/360-english.pdf

BfR (2017b): BfR Recommendations on Food Contact Materials - Recommendation XXXVI/2 . Paper and Paperboard for Baking Purposes. German Federal Institute for Risk Assessment (BfR). https://bfr.ble.de/kse/faces/resources/pdf/362-english.pdf

Bischel H.N., Macmanus-Spencer L.A., Zhang C., and Luthy R.G. (2011): Strong associations of short-chain perfluoroalkyl acids with serum albumin and investigation of binding mechanisms. Environ Toxicol Chem 30 (11), 2423-2430. DOI: 10.1002/etc.647

Blaine A.C., Rich C.D., Sedlacko E.M., Hyland K.C., Stushnoff C., Dickenson E.R., and Higgins C.P. (2014): Perfluoroalkyl acid uptake in lettuce (Lactuca sativa) and strawberry (Fragaria ananassa) irrigated with reclaimed water. Environ Sci Technol 48 (24), 14361-14368

Blepp M., Willand W., and Weber R. (2017): Use of PFOS in chromium plating – Characterisation of closed-loop systems, use of alternative substances, German Environment Agency, TEXTE 95/2017, Project No. 55 567, Report No. (UBA-FB) 002369/ENG). https://www.umweltbundesamt.de/sites/default/files/medien/1410/publikationen/2017-11-01_texte_95-2017_pfos_en_0.pdf

Blom C. and Hanssen L. (2015): Nordic Working Papers: Analysis of per- and polyfluorinated substances in articles. ISSN 2311-0562. Nordic Council of Ministers, Copenhagen K, DK. DOI: 10.6027/na2015-911

Borg D. and Ivarsson J. (2017): Analysis of PFASs and TOF in Products. TemaNord 2017:543, ISSN 0908-6692. Nordic Council of Ministers, Copenhagen, DK. DOI: 10.6027/TN2017-543

Brinch A., Jensen A.A., and Christensen F.M. (2018): Risk assessment of fluorinated substances in cosmetic products

Brunn Poulsen P., Gram L.K., Astrup Jensen A., Alsted Rasmussen A., Ravn C., Møller P., Ree Jørgensen C., and Løkkegaard K. (2011): Substitution of PFOS for use in nondecorative hard chrome plating, Environmental Project No. 1371 2011, Danish Ministry of the Environment - Environmental Protection Agency

Burke J.S., A (2008): PFH Ammonium Salt: Fish, Early Life Stage Toxicity Test to Oncorhynchus mykiss (Rainbow Trout). Daikin Industries

Chemical Watch (2018): Cosmetics giant L'Oréal to eliminate PFASs in products. https://chemicalwatch.com/68795/cosmetics-giant-loreal-to-eliminate-pfass-in-products#overlay-strip

Chengelis C.P., Kirkpatrick J.B., Myers N.R., Shinohara M., Stetson P.L., and Sved D.W. (2009): Comparison of the toxicokinetic behavior of perfluorohexanoic acid (PFHxA) and nonafluorobutane-1-sulfonic acid (PFBS) in cynomolgus monkeys and rats. Reproductive Toxicology 27 (3–4), 400-406. DOI: 10.1016/j.reprotox.2009.01.013

Cousins I.T., Vestergren R., Wang Z., Scheringer M., and McLachlan M.S. (2016): The precautionary principle and chemicals management: The example of perfluoroalkyl acids in groundwater. Environment international 94, 331-340

Dauchy X., Boiteux V., Bach C., Rosin C., and Munoz J.-F. (2017): Per-and polyfluoroalkyl substances in firefighting foam concentrates and water samples collected near sites impacted by the use of these foams. Chemosphere 183, 53-61

ECHA (2013): Member State Committee support document for identification of pentadecafluorooctanoic acid (PFOA) as a substance of very high concern because of its CMR and PBT properties. European Chemicals Agency. https://echa.europa.eu/candidate-list-table/-/dislist/details/0b0236e1807db2ba

ENVIRON (2014): Assessment of POP Criteria for Specific Short-Chain perfluorinated Alkyl Substances. Report prepared for FluoroCouncil, Washington, DC. Project Number: 0134304A. ENVIRON International Corporation, Arlington, Virginia, January 2014

Eschauzier C., Beerendonk E., Scholte-Veenendaal P., and De Voogt P. (2012): Impact of treatment processes on the removal of perfluoroalkyl acids from the drinking water production chain. Environ Sci Technol 46 (3), 1708-1715. DOI: 10.1021/es201662b

Eschauzier C., Raat K.J., Stuyfzand P.J., and De Voogt P. (2013): Perfluorinated alkylated acids in groundwater and drinking water: identification, origin and mobility. Sci Total Environ 458-460, 477-485. DOI: 10.1016/j.scitotenv.2013.04.066

EU (2016): Assessment of the continued need for PFOS, Salts of PFOS and PFOS-F (acceptable purposes and specific exemptions), Brussels

EurEau (2019): Moving Forward on PMT and vPvM Substances.Briefing Note. http://www.eureau.org/resources/briefing-notes/3934-briefing-note-on-moving-forward-on-pmt-and-vpvm-substances/file

European Chemicals Agency (2013): Member State Committee support document for identification of pentadecafluorooctanoic acid (PFOA) as a substance of very high concern because of its CMR and PBT properties. https://echa.europa.eu/candidate-list-table/-/dislist/details/0b0236e1807db2ba

European Chemicals Agency (2018): Background document to the Opinion on the Annex XV dossier proposing restrictions on C9-C14 PFCAs including their salts and precursors. https://echa.europa.eu/documents/10162/f17a38ac-62a8-ae9d-a011-0e98b6d36a9c

European Commission DG Environment and European Chemicals Agency (2019): The Use of PFAS and fluorine-free alternatives in fire-fighting foam. Stakeholder workshop background paper.

European Commission DG Environment and European Chemicals Agency (2020): The use of PFAS and fluorine-free alternatives in textiles, upholstery, carpets, leather and apparel, Brussels

Federal Office for the Environment (2009): Substance flow analysis for Switzerland - Perfluorinated surfactants perfluorooctanesulfonate (PFOS) and perfluorooctanoic acid (PFOA), 22/09. Federal Office for the Environment FOEN, Bern, 2009. http://www.bafu.admin.ch/publikationen/publikation/01066/index.html?lang=en

Felizeter S., McLachlan M.S., and de Voogt P. (2012): Uptake of perfluorinated alkyl acids by hydroponically grown lettuce (Lactuca sativa). Environ Sci Technol 46 (21), 11735-11743. DOI: 10.1021/es302398u

Felizeter S., McLachlan M.S., and De Voogt P. (2014): Root uptake and translocation of perfluorinated alkyl acids by three hydroponically grown crops. J Agric Food Chem 62 (15), 3334-3342. DOI: 10.1021/jf500674j

Gannon S.A., Johnson T., Nabb D.L., Serex T.L., Buck R.C., and Loveless S.E. (2011): Absorption, distribution, metabolism, and excretion of [1-14C]-perfluorohexanoate ([14C]-PFHx) in rats and mice. Toxicology 283 (1), 55-62. DOI: 10.1016/j.tox.2011.02.004

Gellrich V., Stahl T., and Knepper T.P. (2012): Behavior of perfluorinated compounds in soils during leaching experiments. Chemosphere 87 (9), 1052-1056. DOI: 10.1016/j.chemosphere.2012.02.011

Goldenman G.F., M.; Holland, M.; Tugran, T.; Nordin, A.; Schoumacher, C.; McNeill, A. (2019): The cost of inaction - a socioeconomic analysis of environmental and health impacts linked to exposure to PFAS. TemaNord 2019:516. DOI: 10.6027/TN2019-516

Group P.E.F. (2017): Socio-economic Analysis of the European Fluoropolymer Industry – Executive Summary

Hoberman A.M. (2011a): Oral (Gavage) Combined Developmental and Perinatal/ Postnatal Reproduction Toxicity Study of PFH Ammonium Salt (Ammonium salt of Perfluorinated Hexanoic Acid) in Mice Laboratory Project ID 20005045. Charles River Laboratories, Final Report 26 July 2011

Hoberman A.M. (2011b): Oral (Gavage) Combined Developmental and Perinatal/Postnatal Reproduction Toxicity Study of PFH Ammonium Salt (Ammonium salt of Perfluorinated Hexanoic Acid) in Mice, UZS00010 Charles River Laboratories, Final Report 25 August 2011

Hoke R.A., Bouchelle L.D., Ferrell B.D., and Buck R.C. (2012): Comparative acute freshwater hazard assessment and preliminary PNEC development for eight fluorinated acids. Chemosphere 87 (7), 725-733. DOI: 10.1016/j.chemosphere.2011.12.066

Hollins S. (2020): Second draft: PFASs and alternatives in food packaging (paper and paperboard) – report on the commercial availability and current uses. Exponent International Ltd., Prepared for: OECD. Project number: 1908200.UK0, Task number: A0F0, Document number: EWC 0736.

Holmquist H., Schellenberger S., van der Veen I., Peters G.M., Leonards P.E.G., and Cousins I.T. (2016): Properties, performance and associated hazards of state-of-the-art durable water repellent (DWR) chemistry for textile finishing. Environment international 91, 251-264. DOI: 10.1016/j.envint.2016.02.035

Houtz E.F., Higgins C.P., Field J.A., and Sedlak D.L. (2013): Persistence of perfluoroalkyl acid precursors in AFFF-impacted groundwater and soil. Environ Sci Technol 47 (15), 8187-8195. DOI: 10.1021/es4018877

Houtz E.F., Sutton R., Park J.S., and Sedlak M. (2016): Poly- and perfluoroalkyl substances in wastewater: Significance of unknown precursors, manufacturing shifts, and likely AFFF impacts. Water Res 95, 142-149. DOI: 10.1016/j.watres.2016.02.055

Jensen A.A., Poulsen P.B., and Bossi R. (2008): Survey and environmental/health assessment of fluorinated substances in impregnated consumer products and impregnating agents. Survey of Chemical Substances in Consumer Products, No. 99. Danish Environmental Protection Agency. https://mst.dk/service/publikationer/publikationsarkiv/2008/okt/survey-and-environmentalhealth-assessment-of-fluorinated-substances-in-impregnated-consumer-products-and-impregnating-agents/ (last accessed 2019-02-26)

KEMI (2015): Occurrence and use of highly fluorinated substances and alternatives. Report from a government assignment. ISSN 0284-1185. Swedish Chemicals Agency, Stockholm, SE. https://www.kemi.se/global/rapporter/2015/report-7-15-occurrence-and-use-of-highly-fluorinated-substances-and-alternatives.pdf (last accessed 2017-01-09)

Kempisty D.M., Xing Y., and Racz L. (2018): Perfluoroalkyl substances in the environment: theory, practice, and innovation. CRC Press. ISBN: 0429945035

Kirchgeorg T., Dreyer A., Gabrieli J., Kehrwald N., Sigl M., Schwikowski M., Boutron C., Gambaro A., Barbante C., and Ebinghaus R. (2013): Temporal variations of perfluoroalkyl substances and polybrominated diphenyl ethers in alpine snow. Environ Pollut 178, 367-374. DOI: 10.1016/j.envpol.2013.03.043

Klaunig J.E., Shinohara M., Iwai H., Chengelis C.P., Kirkpatrick J.B., Wang Z., and Bruner R.H. (2015): Evaluation of the chronic toxicity and carcinogenicity of perfluorohexanoic acid (PFHxA) in Sprague-Dawley rats. Toxicol Pathol 43 (2), 209-220. DOI: 10.1177/0192623314530532

Klein R. (2013): The cost - and still counting! Fire-fighting foam - disposal, remediation, and lifetime costs. Industrial Fire Journal Q4, 36-40

Knepper T.P., Frömel T., Gremmel C., van Driezum I., Weil H., Vestergren R., and Cousins I. (2014): Understanding the exposure pathways of per- and polyfluoralkyl substances (PFASs) via use of PFASs-Containing products – risk estimation for man and environment. ISSN 1862-4804, date: July 2014. Federal Environment Agency (Umweltbundesamt), Dessau-Roßlau, DE. https://www.umweltbundesamt.de/en/publikationen/understanding-the-exposure-pathways-of-per (last accessed 2019-02-25)

Krippner J., Brunn H., Falk S., Georgii S., Schubert S., and Stahl T. (2014): Effects of chain length and pH on the uptake and distribution of perfluoroalkyl substances in maize (Zea mays). Chemosphere 94, 85-90. DOI: 10.1016/j.chemosphere.2013.09.018

Kudo N. (2015): Toxicological Effects of Perfluoroalkyl and Polyfluoroalkyl Substances. Metabolism and Pharmacokinetics, 151-175. DOI: https://doi.org/10.1007/978-3-319-15518-0_6

Lam J.C., Lyu J., Kwok K.Y., and Lam P.K. (2016): Perfluoroalkyl Substances (PFASs) in Marine Mammals from the South China Sea and Their Temporal Changes 2002 - 2014: Concern for Alternatives of PFOS? Environ Sci Technol. DOI: 10.1021/acs.est.5b06076

Larsson P. (2018): A study to understand the information gap between total organofluorine analysis and total oxidizable precursor assay on polyfluoroalkyl/perfluoroalkyl substances (PFASs). Student thesis. http://urn.kb.se/resolve?urn=urn:nbn:se:oru:diva-71047 (last accessed 2018-12-28t09:27:40.103+01:00)

Latala A., Nedzi M., and Stepnowski P. (2009): Acute toxicity assessment of perfluorinated carboxylic acids towards the Baltic microalgae. Environ Toxicol Pharmacol 28 (2), 167-171. DOI: 10.1016/j.etap.2009.03.010

Li F., Mascheroni E., and Piergiovanni L. (2015): The Potential of NanoCellulose in the Packaging Field: A Review. Packaging Technology and Science 28 (6), 475-508. DOI: 10.1002/pts.2121

Lin A.Y.-C., Panchangam S.C., and Ciou P.-S. (2010): High levels of perfluorochemicals in Taiwan's wastewater treatment plants and downstream rivers pose great risk to local aquatic ecosystems. Chemosphere 80 (10), 1167-1174

Liou J.S., Szostek B., Derito C.M., and Madsen E.L. (2010): Investigating the biodegradability of perfluorooctanoic acid. Chemosphere 80 (2), 176-183. DOI: 10.1016/j.chemosphere.2010.03.009

Liu Y., Wang J., Fang X., Zhang H., and Dai J. (2011): The thyroid-disrupting effects of long-term perfluorononanoate exposure on zebrafish (Danio rerio). Ecotoxicology 20 (1), 47-55. DOI: 10.1007/s10646-010-0555-3

Llorca M., Farre M., Pico Y., Muller J., Knepper T.P., and Barcelo D. (2012): Analysis of perfluoroalkyl substances in waters from Germany and Spain. Sci Total Environ 431, 139-150. DOI: 10.1016/j.scitotenv.2012.05.011

Lohmann R. , Cousins I.T., DeWitt J. C. , Glüge J., Goldenman G., Herzke D., Lindstrom A. B., Miller M. F. , Ng C. A., Patton S., Scheringer M., Trier X, and Z W. (2020): Are fluoropolymers really of low concern for human and environmental health and separate from other PFAS? Environmental Science and Technology 54, 12820-12828

Loos R., Carvalho R., Antonio D.C., Comero S., Locoro G., Tavazzi S., Paracchini B., Ghiani M., Lettieri T., Blaha L., Jarosova B., Voorspoels S., Servaes K., Haglund P., Fick J., Lindberg R.H., Schwesig D., and Gawlik B.M. (2013): EU-wide monitoring survey on emerging polar organic contaminants in wastewater treatment plant effluents. Water Res 47 (17), 6475-6487. DOI: 10.1016/j.watres.2013.08.024

Lundgren S. (2014): Evaluation of the efficiency of treatment techniques in removing perfluoroalkyl substances from water, http://www.w-program.nu/filer/exjobb/Sandra_Lundgren.pdf. 2016-12-01

Moody C.A. and Field J.A. (2000): Perfluorinated surfactants and the environmental implications of their use in fire-fighting foams. Environ Sci Technol 34 (18), 3864-3870

Müller A., Nicolai H., and W. L. (2020): Survey on technical and economic feasibility of the available alternatives for chromium trioxide on the market in hard/functional and decorative chrome plating. . Bundesanstalt für Arbeitsschutz und Arbeitsmedizin, Dortmund, Survey. DOI: DOI: 10.21934/baua:report20200331

NTP (2018): Perfluorohexanoic acid (307-24-4). Chemical Effects in Biological Systems (CEBS). Research Triangle Park, NC (USA) : National Toxicology Program (NTP). Accessed 2019-03-28. https://manticore.niehs.nih.gov/cebssearch/test_article/307-24-4

Numata J., Kowalczyk J., Adolphs J., Ehlers S., Schafft H., Fuerst P., Müller-Graf C., Lahrssen-Wiederholt M., and Greiner M. (2014): Toxicokinetics of Seven Perfluoroalkyl Sulfonic and Carboxylic Acids in Pigs Fed a Contaminated Diet. Journal of Agricultural and Food Chemistry 62 (28), 6861-6870. DOI: 10.1021/jf405827u

OECD (2020): PFASs and Alternatives in Food Packaging (Paper and Paperboard) Report on the Commercial Availability and Current Uses,OECD Series on Risk Management, No. 58, Environment, Health and Safety, Environment Directorate, OECD

Peter Fisk Associates Ltd (2018): Evaluation of using mobility of chemicals in the environment to fulfil bioaccumulation criteria of the Stockholm Convention. PFA.882.000.002, confidential

Posner S., Roos S., Poulsen P.B., Jörundsdottir H.Ó., Gunnlaugsdóttir H., Trier X., Jensen A.A., Katsogiannis A.A., Herzke D., Bonefeld-Jörgensen E.C., Jönsson C., Pedersen G.A., Ghisari M., and Jensen S. (2013): Per- and polyfluorinated substances in the Nordic Countries: Use, occurence and toxicology. TemaNord 2013:542. ISBN 978-92-893-2562-2. Nordic Council of Ministers, Copenhagen K, DK. DOI: 10.6027/tn2013-542 (last accessed 2019-02-26)

Rahman M.F., Peldszus S., and Anderson W.B. (2014): Behaviour and fate of perfluoroalkyl and polyfluoroalkyl substances (PFASs) in drinking water treatment: a review. Water Res 50, 318-340. DOI: 10.1016/j.watres.2013.10.045

Rijkswaterstaat (2017): ECAP European Textiles & Workwear Market - The role of Public Procurement in making textiles circular, http://www.ecap.eu.com/wp-content/uploads/2018/10/ECAP-Workwear-Report.pdf

Ruan T., Szostek B., Folsom P.W., Wolstenholme B.W., Liu R., Liu J., Jiang G., Wang N., and Buck R.C. (2013): Aerobic soil biotransformation of 6:2 fluorotelomer iodide. Environ Sci Technol 47 (20), 11504-11511. DOI: 10.1021/es4018128

Schellenberger S., Gillgard P., Stare A., Hanning A., Levenstam O., Roos S., and Cousins I.T. (2018): Facing the rain after the phase out: Performance evaluation of alternative fluorinated and non-fluorinated durable water repellents for outdoor fabrics. Chemosphere 193, 675-684. DOI: 10.1016/j.chemosphere.2017.11.027

Schellenberger S., Hill P.J., Levenstam O., Gillgard P., Cousins I.T., Taylor M., and Blackburn R.S. (2019): Highly fluorinated chemicals in functional textiles can be replaced by re-evaluating liquid repellency and end-user requirements. Journal of Cleaner Production 217, 134-143. DOI: https://doi.org/10.1016/j.jclepro.2019.01.160

Siegemund G., Schwertfeger W., Feiring A., Smart B., Behr F., Vogel H., and McKusick B. (2000): Fluorine Compounds, Organic. In: Ullmann's Encyclopedia of Industrial Chemistry. Wiley-VCH Verlag GmbH & Co. KGaA. ISBN: 9783527306732. DOI: 10.1002/14356007.a11_349

Staff I.R.E. (2018): Enabling Fabrication Beyond 7nm. IBM. https://www.ibm.com/blogs/research/2018/11/fabrication-beyond-7nm-scale/ (last accessed 19.07.2019)

Stakeholder Consultation (2018): Questionnaire and interviews with stakeholders on PFHxA and PFHxA-related substances, Report published as Wirth O., Bliklen R., Rödig L., Wichmann P., Zimmermann T., Posner S., and Hildenbrand J. (2019): Potential SVHC in environment and articles - information collection with the aim to prepare restriction proposal for PFAS, German Environment Agency, TEXTE 144/2019

Steinhausen M. (2019): Perspektiven der Substitution für Chrom (VI) – Funktionieren die Alternativen und sind sie bezahlbar? Gefahrstoffe - Reinhaltung der Luft 79 (4), 125-127

Trier X.T., Camilla ; Rosenmai, Anna Kjerstine; Alsing Pedersen, Gitte (2017): PFAS in paper and board for food contact - options for risk management of poly- and perfluorinated substances. 573. National Food Institute. Ministers N.C.o., Copenhagen, Denmark. DOI: 10.6027/TN2017-573

UBA (2018): Stakeholder Consultation (2018): Questionaire and interviews with stakeholders on PFHxA and PFHxA-related substances.

Ullah S., Alsberg T., and Berger U. (2011): Simultaneous determination of perfluoroalkyl phosphonates, carboxylates, and sulfonates in drinking water. J Chromatogr A 1218 (37), 6388-6395. DOI: 10.1016/j.chroma.2011.07.005

UNEP (2012a): Stockholm Convention on Persistent Organic Pollutants - Technical paper on the identification and assessment of alternatives to the use of perfluorooctane sulfonic acid in open applications. United Nations Environment Programme. https://www.informea.org/en/technical-paper-identification-and-assessment-alternatives-use-perfluorooctane-sulfonic-acid-open

UNEP (2012b): Technical paper on the identification and assessment of alternatives to the use of perfluorooctane sulfonic acid in open applications. UNEP/POPS/POPRC.8/INF/17, http://chm.pops.int/Convention/POPsReviewCommittee/POPRCMeetings/POPRC8/POPRC7WorkingDocuments/tabid/2801/Default.aspx

UNEP (2013): Guidance on alternatives to perfluorooctane sulfonic acid, its salts, perfluorooctane sulfonyl fluoride and their related chemicals. UNEP/POPS/POPRC.9/INF/11/Rev.1, http://chm.pops.int/Convention/POPsReviewCommittee/LatestMeeting/POPRC9/POPRC9Documents/tabid/3281/Default.aspx

UNEP (2015): Revised draft guidance on best available techniques and best environmental practices for the use of perfluorooctane sulfonic acid and related chemicals listed under the Stockholm Convention. UNEP/POPS/COP.7/INF/21

UNEP (2016): Consolidated guidance on alternatives to perfluorooctane sulfonic acid and its related chemicals. UNEP/POPS/POPRC.12/INF/15/Rev.1

UNEP (2018a): Draft report on the assessment of alternatives to perfluorooctane sulfonic acid, its salts and perfluorooctane sulfonyl fluoride. UNEP/POPS.POPRC.14/INF/8

UNEP (2018b): Report of the Persistent Organic Pollutants Review Committee on the work of its fourteenth meeting - Addendum to the risk management evaluation on perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds. UNEP /POPS/POPRC.14/6/Add.2

Vierke L. (2014): Environmental Mobility of Short Chain Perfluoroalkyl Carboxylic Acids-Partition Behaviour and Resulting Environmental Concern, Universitätsbibliothek der Leuphana Universität Lüneburg

Wang Z., MacLeod M., Cousins I.T., Scheringer M., and Hungerbühler K. (2011): Using COSMOtherm to predict physicochemical properties of poly- and perfluorinated alkyl substances (PFASs). Environmental Chemistry 8 (4), 389-398. DOI: 10.1071/en10143

Weiss J.M., Andersson P.L., Lamoree M.H., Leonards P.E., van Leeuwen S.P., and Hamers T. (2009): Competitive binding of poly- and perfluorinated compounds to the thyroid hormone transport protein transthyretin. Toxicol Sci 109 (2), 206-216. DOI: 10.1093/toxsci/kfp055

Willand W., Blepp M., Baron Y., and Weber R. (2019): Best available techniques for the substitution of PFOS in surface treatment of metals and plastics and analysis of alternative substances to PFOS for use in chrome plating and plastic etching. Research project on behalf of German Environment Agency, unpublished (published in German language as: Willand W., Blepp M., Baron Y., and Weber R. (2019): Beste verfügbare Techniken für die PFOS-Substitution in der Oberflächenbehandlung von Metallen und Kunststoffen sowie Analyse der alternativen Substanzen zu PFOS beim Einsatz in Anlagen zur Verchromung und Kunststoffbeize. Abschlussbericht Im Auftrag des Umweltbundesamtes, Dessau.)

Zhang S., Lu X., Wang N., and Buck R.C. (2016): Biotransformation potential of 6:2 fluorotelomer sulfonate (6:2 FTSA) in aerobic and anaerobic sediment. Chemosphere 154, 224-230. DOI: 10.1016/j.chemosphere.2016.03.062

Zhao L., Bian J., Zhang Y., Zhu L., and Liu Z. (2014): Comparison of the sorption behaviors and mechanisms of perfluorosulfonates and perfluorocarboxylic acids on three kinds of clay minerals. Chemosphere 114, 51-58. DOI: http://dx.doi.org/10.1016/j.chemosphere.2014.03.098

Zhao L., Folsom P.W., Wolstenholme B.W., Sun H., Wang N., and Buck R.C. (2013): 6:2 fluorotelomer alcohol biotransformation in an aerobic river sediment system. Chemosphere 90 (2), 203-209. DOI: 10.1016/j.chemosphere.2012.06.035

Zhao Z., Xie Z., Moller A., Sturm R., Tang J., Zhang G., and Ebinghaus R. (2012): Distribution and long-range transport of polyfluoroalkyl substances in the Arctic, Atlantic Ocean and Antarctic coast. Environ Pollut 170, 71-77. DOI: 10.1016/j.envpol.2012.06.004