Alliance for Telomer Chemistry Stewardship's Response to ECHA Public Consultation

Introduction

The Alliance for Telomer Chemistry Stewardship (ATCS) represents the following companies: AGC, Daikin, Dynax Corporation, and Johnson Controls.

The hereby submission is an initial one, in which the ATCS wishes to share its serious concerns with respect to the scientific and legal validity of the restriction proposal due to the many factual inaccuracies, contradictions and overall lack of technical data on which it is based.

A summary of our concerns follows, and these will be discussed in more detail in this document.

1. Legal basis: the pre-requirement of unacceptable risk is not fulfilled.
2. The release potential of PFHxA is over-estimated, up to 40 times overall and 1000 times in the AFFF example based on our calculations.
3. The restriction disregards the availability of technologies capable of removing C6 fluorotelomer chemistry (the "related substances" as defined in the restriction proposal) from water.
4. The relevance of C6 fluorotelomer chemistry in the context of EU climate and circular economy ambitions has been overlooked.
5. There is a fundamental confusion throughout the document between fluoropolymers and side-chain fluorinated polymers.
6. Analytical methods do not exist to ensure product compliance and enforceability of any threshold (see question 13).

The ATCS wishes furthermore to draw European Chemicals Agency (ECHA) Committees' attention to the insufficient analysis provided in the dossier with respect to derogation needs related to C6 fluorotelomer chemistry. An initial list of additional derogation needs is provided in the section on specific concerns. This provisional list will be further detailed in a subsequent contribution.

Section III – General concerns

1. Legal basis: the pre-requirement of unacceptable risk is not fulfilled

Under Article 68 of the REACH Regulation, in order to be restricted, substances have to pose an unacceptable risk to human health or the environment. Instead of relying on the established criteria for the identification of PBT (persistent, bioaccumulative, toxic) and vPvB (very persistent, very bioaccumulative) substances, laid down in REACH Annex XIII, **the restriction proposal relies on the persistent and mobile properties of PFHxA and considers them as equivalent to PBT/vPvB properties, with any release being a proxy for unacceptable risk** (p.9):

> 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.

However, in order to analyse the presence of “an unacceptable risk to human health or the environment” as set out by Article 68 of REACH, one cannot simply rely on the alleged vPvM properties of a substance and consider any release to the environment as a proxy for unacceptable risk as it is the case for PBT/vPvB substances.

First, such an approach dismisses the outcome of previous discussions on the proposal to identify PFHxA as SVHC, precisely on the basis of alleged equivalent level of concern to PBT/vPvB properties. It should be reminded that this proposal raised serious concerns within the ECHA Member State Committee (MSC) and was ultimately withdrawn by the SVHC dossier submitter.

Further, in the framework of Article 57(f) of REACH, the European Court of Justice (hereinafter “CJEU”) has already determined the criteria which shall be fulfilled in order for a substance to be of an “equivalent level of concern” to PBT or vPvB substances. In case C 323/15 P, the CJEU stated that Article 57(f) REACH requires that it be established, on a case-by-case basis and on the basis of scientific evidence, and that **two cumulative** criteria are fulfilled:

i) it must be probable that the hazards arising from the substance’s intrinsic properties have **serious effects on human health or the environment**, and

ii) there must be **scientific evidence** that these effects give rise to an equivalent level of concern to those of CMR, PBT or vPvB substances.

This principle was further clarified in a more recent case, T-636/17 of 20 September 2019 concerning endocrine disruptors, in which the Court once more reiterated that the equivalent level of concern requires*:*

> **An actual analysis** of the hazards linked to the intrinsic properties of the substance under consideration, and **the demonstration** that the serious effects on human health or the environment of the substance under consideration give rise to an equivalent level of concern to those of other substances referred to in Article 57(a) to (e) of the same regulation.

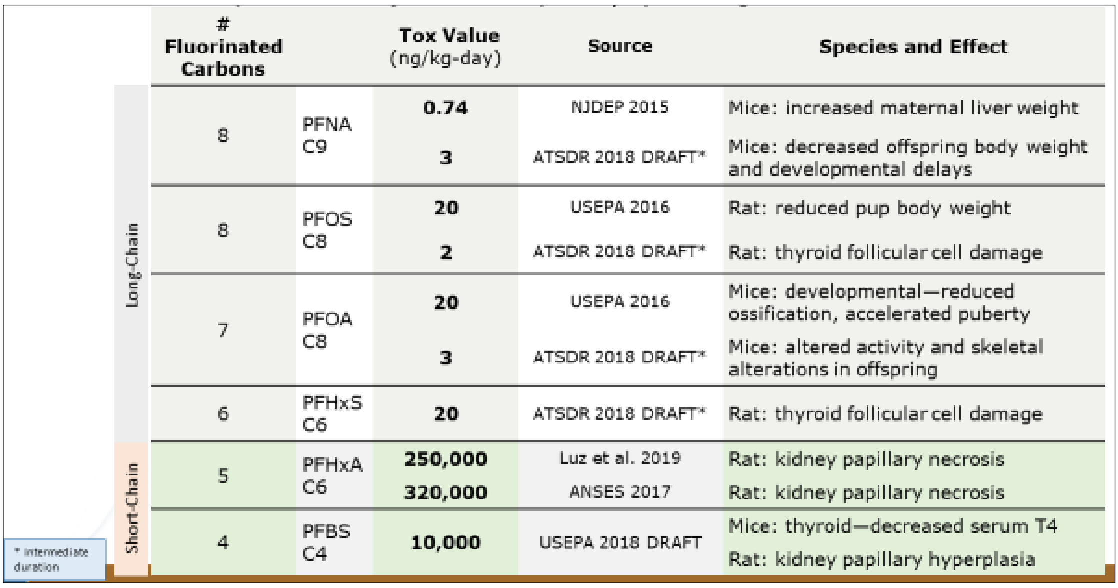
Instead, the dossier itself recognises the following with respect to PFHxA (p. 73):

> […] to date no indications of serious human health risks are documented. […] 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.

This is substantiated by the fact that national agencies which have assessed the toxicity of PFHxA have found high safety levels for PFHxA. In 2015 the French Agency for Food, Environmental and Occupational Health & Safety (ANSES) published an opinion on PFHxA, establishing a chronic toxicity reference value (TRV) of 0.32 mg/kg bw per day. In 2017, the German Human Biomonitoring (HBM) Commission established drinking water guide values (TWLW, Trinkwasser-Leitwerte) for PFHxA at 6 µg/L.

As a matter of comparison, the toxicity value of PFHxA is several orders of magnitude higher (i.e. safer) than for PFOA, as also shown in Table 1. The study conducted by Luz et al (2019; noted in Table 1) also emphasizes the low toxicity of PFHxA:

Table 1 – Example of Toxicity Values (or R_fD): Long and Short-Chains



	# Fluorinated Carbons		Tox Value (ng/kg-day)	Source	Species and Effect
Long-Chain	8	PFNA C9	**0.74**	NJDEP 2015	Mice: increased maternal liver weight
			3	ATSDR 2018 DRAFT*	Mice: decreased offspring body weight and developmental delays
	8	PFOS C8	**20**	USEPA 2016	Rat: reduced pup body weight
			2	ATSDR 2018 DRAFT*	Rat: thyroid follicular cell damage
	7	PFOA C8	**20**	USEPA 2016	Mice: developmental—reduced ossification, accelerated puberty
			3	ATSDR 2018 DRAFT*	Mice: altered activity and skeletal alterations in offspring
	6	PFHxS C6	**20**	ATSDR 2018 DRAFT*	Rat: thyroid follicular cell damage
Short-Chain	5	PFHxA C6	**250,000**	Luz et al. 2019	Rat: kidney papillary necrosis
			320,000	ANSES 2017	Rat: kidney papillary necrosis
	4	PFBS C4	**10,000**	USEPA 2018 DRAFT	Mice: thyroid—decreased serum T4 Rat: kidney papillary hyperplasia

* intermediate duration

Not only do these data cast doubt on the scientific and legal validity of the restriction proposal, they also directly dispute the proportionality of the proposal to have similar concentration limits as those adopted for PFOA (i.e. 25 ppb and 1000 ppb).

With regard to potential hazards to the environment, it is stated that the “environmental risks from the emission of PFHxA cannot be quantified with sufficient certainty.” (p. 73). This statement does not reflect available scientific evidence. The SVHC proposal for PFHxA, issued in 2018, stated that “no adverse effects have been observed in the various tests conducted on ecotoxicity for algae, daphnia and fish covering acute as well as chronic toxicity” (p. 31).

Similarly, PFHxA shows no bioaccumulation potential. **PFHxA constitutes a non-biopersistent substance and is rapidly eliminated from all mammals** (Conder 2008; Han 2011). This is illustrated by the low-level frequency of detection (FOD) (Kim et al. 2014; Kang et al. 2016; Lee et al. 2018) and low levels in human serum (Frisbee et al. 2009; Mannetje et al. 2013; Olsen et al. 2017; Lee et al. 2017; Canadian Ministry of Health 2013; Japan Ministry of the Environment 2016; Li et al. 2017; Ingelido et al. 2018; Kärrman et al. 2006; Falandysz et al. 2006; First Nations Biomonitoring Initiative, 2013).

Further, there is no commonly agreed approach with regard to mobility. At the workshop on “PMT substances, a challenge for analytical chemistry and water quality control” organised in January 2020 in Leipzig, Germany, it was clear that there was not a single, commonly agreed approach to mobility, therefore it is unclear how the Dossier Submitter definitively concludes that PFHxA is “very mobile” (p. 74; p. 79). The restriction proposal concludes that “PFHxA is mobile in the aquatic environment” (p. 18) without giving clear and consistent criteria of the mobility concept.

According to ECHA’s guidance on information requirements and chemical safety assessment, chapter R.7b (v4.0; June 2017; p.146; first paragraph), substances with “log Koc > 3” are considered “strongly adsorbing”. Therefore, it is scientifically irrelevant to consider substances with log Koc just below 3 as very mobile. A clear description of mobility should be established so that any line of evidence can be confronted to the definition. Additionally, it should be noted that, unlike for bioaccumulation, there is **no legal basis to address mobility under REACH nor under any international chemical legislation**. As such, mobility lacks scientifc and legal validity to jusify a restriction.

Furthermore, exposure data presented in the Restriction Dossier contain serious errors and are based on incorrect assumptions under many sections. The ATCS therefore provides revised data and calculations which are explained in detail in point 2). In this respect we would highlight that total emissions of PFHxA can be calculated based on the data provided and that these are in a range of 1.77 – 7.81 t/a, **40x lower than stated by the Submitter**.

Based on this, there is no scientific basis to refer to potential “unpredictable and irreversible adverse effects over time” (p. 9). Such vague assumptions **do not constitute a demonstration of unacceptable risk** as required by REACH, **nor a sufficient basis to justify the use of the precautionary principle** (p.73):

> 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. [...] Environmental risks from the emission of PFHxA cannot be quantified with sufficient certainty. […] Information on current spatial effects from releases is uncertain and future effects are impossible to predict.

Finally, to the best of our knowledge, it is the first restriction proposal based on concerns related to persistence and mobility. The Dossier Submitter’s approach, in defining PFHxA related substances as “non-threshold” substances simply due to their mobility and persistence would set unacceptable legal and scientific precedent, possibly leading to grave legal uncertainty. Not only does the approach disregard the existing legal framework, it could be used to justify the restriction of any new mobile and persistent chemistry without having to prove unacceptable risk. Yet, substances with persistence and a certain mobility as intrinsic properties cover a large number of chemicals. The current restriction proposal, as it stands, would mean that any substance, based on these properties represents a risk and should be restricted.

In line with the principle of Better Regulation, alternatives to a REACH restriction should be considered that could address concerns such as the potential contamination of water. As an alternative regulatory instrument, ATCS members suggest that instead of an EU REACH restriction, water legislation should be considered, first to monitor and gather evidence and second to define safety levels, if necessary. The Industrial Emissions Directive could also be an effective instrument to evaluate and control C6 fluorotelomer releases to the environment from facilities handling C6 fluorotelomer chemistries. Furthermore, ATCS members recommend a sound management of waste products in line with the EU Circular Economy. Separate collection and proper treatment of waste containing fluorinated products should be extended and harmonised at the European level. Finally, a voluntary initiative between industry and authorities in the form of a stewardship programme, which could involve producers and downstream users, remains a promising path forward.

2. The release potential of PFHxA is over-estimated, up to 40 times overall and 1000 times in the AFFF example based on our calculations

In addition to concerns over the legal basis, the data presented in the Restriction Dossier contains serious errors and are based on incorrect assumptions under many sections. We have therefore provided revised data and calculations which are explained in detail below.

There is only one facility in Europe where the entire process of fluorotelomer production takes place, from initial telomerisation to production of C6 fluorotelomer-based products. Other members of the ATCS import C6 fluorotelomer-based products for direct sales to customers. The assumption of increasing levels, a priori to levels that would represent a concern for human health or the environment, are completely inconsistent with present-day industry manufacture, use, and best management practices.

As discussed in the following sections, the manufacturing of fluorochemicals and customer usage have both become more efficient, thus limiting environmental releases and potential future contamination levels.

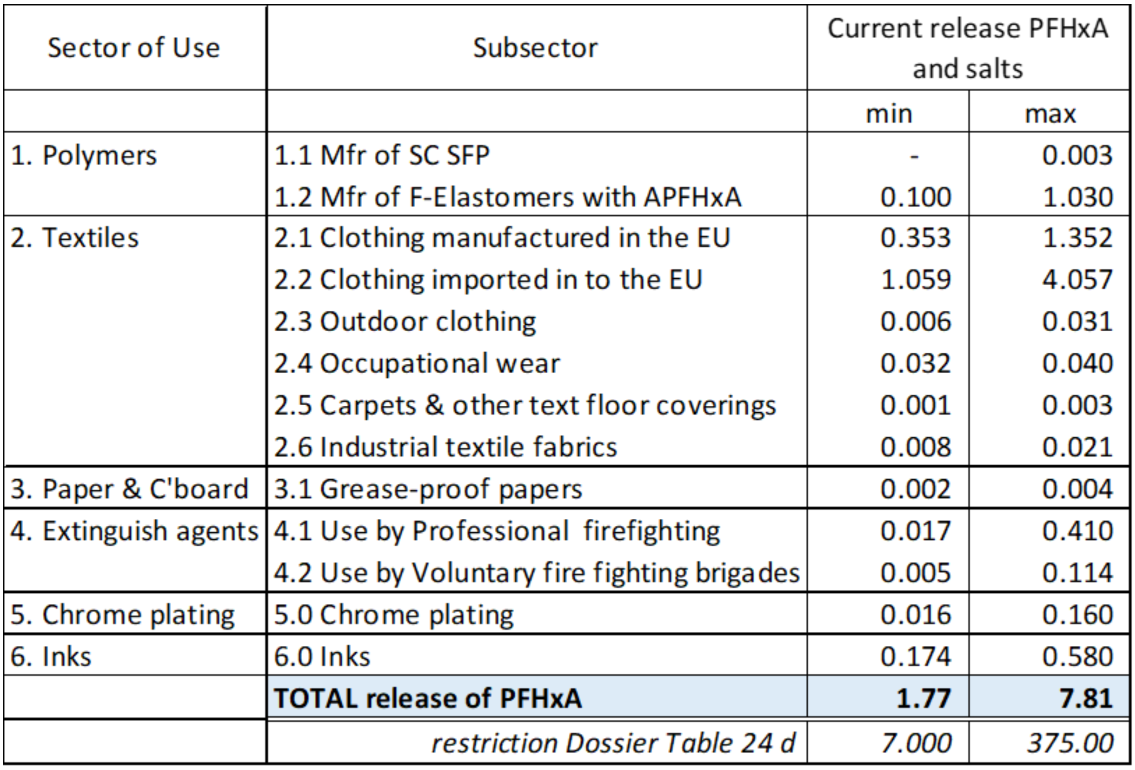
Levels of PFHxA in the environment

Following a detailed analysis of the exposure scenarios outlined in the Restriction Dossier we can show that the total emissions of PFHxA lie in a range of 1.77 – 7.81 t/a, 40x lower than claimed by the Submitter. These values correspond to emissions of 5.3 – 43 ng/L into the European body of water, using the same calculations as the Dossier. This throws into serious doubt the understanding of the market and the assumptions made in the whole Dossier.

To illustrate this, we will focus on two sectors of use: extinguishing agents and chrome plating. The first of these will demonstrate the errors used in calculation and the second the errors in assumptions to boost the PFHxA emissions numbers.

The Restriction Dossier contains a series of tables (Tables 24 a-d, p. 120) which show the environmental releases assumed for PFHxA and its precursors. A corrected version of the table is shown below, based on analysis by subsector. PFHxA represents a definitive endpoint in the breakdown process. Therefore, there is no need to include additional precursor volumes in the Restriction as all breakdown to PFHxA can be directly calculated. In spite of this we have also recalculated the precursor quantities and these range between 27 – 182.3 t/a, again 20x lower than the estimations in the report.

Table 2 – Current environmental release of PFHxA [t/a]:



Sector of Use	Subsector	Current release PFHxA and salts	
		min	max
1. Polymers	1.1 Mfr of SC SFP	-	0.003
	1.2 Mfr of F-Elastomers with APFHxA	0.100	1.030
2. Textiles	2.1 Clothing manufactured in the EU	0.353	1.352
	2.2 Clothing imported in to the EU	1.059	4.057
	2.3 Outdoor clothing	0.006	0.031
	2.4 Occupational wear	0.032	0.040
	2.5 Carpets & other text floor coverings	0.001	0.003
	2.6 Industrial textile fabrics	0.008	0.021
3. Paper & C'board	3.1 Grease-proof papers	0.002	0.004
4. Extinguish agents	4.1 Use by Professional firefighting	0.017	0.410
	4.2 Use by Voluntary fire fighting brigades	0.005	0.114
5. Chrome plating	5.0 Chrome plating	0.016	0.160
6. Inks	6.0 Inks	0.174	0.580
	TOTAL release of PFHxA	**1.77**	**7.81**
	restriction Dossier Table 24 d	*7.000*	*375.00*

It is vital to stress that these are total amounts of PFHxA emitted in each of the individual usage sectors and we note that approx. 50% of these emissions arise from imported articles.

- <u>Extinguishing Agents (Section 4)</u>

A careful analysis of the exposure scenarios of PFHxA and its precursors showed many confusing and contradictory uses of input data and information. For example, page 27 of the report states that PFHxA and 6:2 FTOH are used as fluorosurfactants in firefighting foam. It is also stated on p.28 that “there are no known uses of PFHxA itself in the EU.” The statement about the use of PFHxA in firefighting foam is clearly incorrect. 6:2 FTOH to our knowledge has never been used as a fluorosurfactant in foam and is generally not considered useful for that purpose. PFHxA has not been used as an intentionally added fluorosurfactant in foam. Instead it is an unintended by-product of manufacture, present in impurity levels in C6 fluorotelomer-based products.

The Dossier Submitter developed the following environmental release scenarios for PFHxA and its precursors (see B.9.7 Firefighting Foams/B.9.7.2 Environmental exposure, p.103-104): 4.6 (PFHxA itself) to 144.4t/a (precursors). The same results are also presented as: 5 – 145t/a (Table, p.70) and 4.60 – 143.84t/a (Annex Table 24d, p.123).

Throughout the derivation of this release range the Dossier Submitter made it clear that these large release volumes are due to the foam use by volunteer fire brigades in Europe. The release volumes by professional firefighters are not even considered significant, because unlike volunteers, professional firefighters can manage the fire water properly.

In estimating the total volume of AFFF foam used by the German volunteer fire brigades, an input data, 1150kg which was supposed to be the volume of 0.1% "ready to use" AFFF foam solution was instead used as the volume of AFFF concentrates in the calculation, an error by a factor of 1000. This error, stating that 4.6 t/a instead of the actual 0.0046 t/a, leads to the absurd conclusion that in Europe the volunteer firefighters deploy 280x more AFFF foam than the 16.6 kg/a of their professional counterparts (4.6t/16.6 = 277). Correcting the error shows that the professional firefighters in fact use 3.6x more foam than the volunteer firefighters.

In addition to the arithmetic error, it was found that input data that the Dossier Submitter used are based on old foam samples that contain significant amounts of long chain (C8 and higher) fluorosurfactants. For example, the Submitter used as the average concentration of PFHxA in AFFF, 1328µg/kg, a value quoted from a reference in which commercial foams on the market in Sweden in 2014 were analysed for PFHxA.

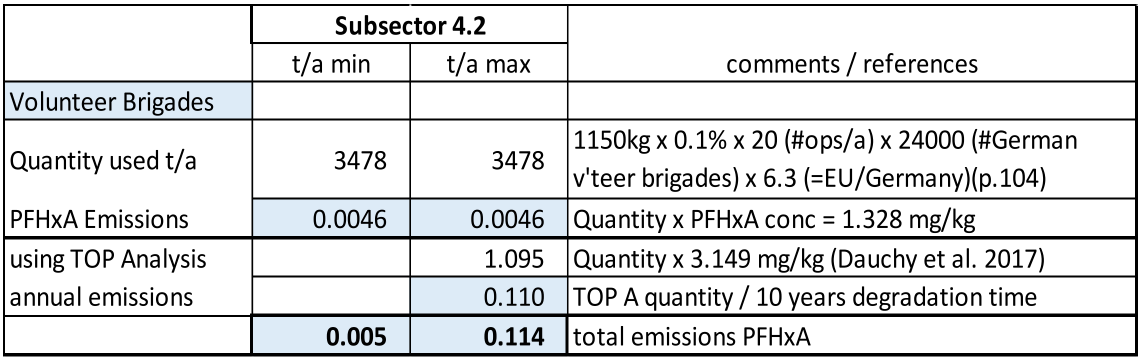
The Submitter also considers two sources of PFHxA: (a) as impurity in the firefighting foam concentrate and (b) as degradation product based on TOP Assay studies. Updating the same calculations on the 12 500 t/a usage and the PFHxA concentration of 1328µg/kg we arrive at the minimum emissions. Adding the calculations based on the TOP Assay time averaged over ten years gives the maximum.

Table 3 – Current environmental release of PFHxA [t/a] for extinguishing agents used by professional firefighting

	Subsector 4.1		comments / references
	t/a min	t/a max	
Professional Brigades			
Quantity used t/a	12500	12500	20% total market stock (62500 t p. 55)
PFHxA Emissions	0.0166	0.0166	Quantity x PFHxA conc = 1.328 mg/kg
using TOP Analysis		3.936	Quantity x 3.149 mg/kg (Dauchy et al. 2017)
annual emissions		0.394	TOP A quantity / 10 years degradation time
	0.017	**0.410**	total emissions PFHxA

The same calculation for the Volunteer Brigades gives the following:

Table 4 – Current environmental release of PFHxA [t/a] for extinguishing agents used by volunteer fire fighting brigades



	Subsector 4.2		
	t/a min	t/a max	comments / references
Volunteer Brigades			
Quantity used t/a	3478	3478	1150kg x 0.1% x 20 (#ops/a) x 24000 (#German v'teer brigades) x 6.3 (=EU/Germany)(p.104)
PFHxA Emissions	0.0046	0.0046	Quantity x PFHxA conc = 1.328 mg/kg
using TOP Analysis		1.095	Quantity x 3.149 mg/kg (Dauchy et al. 2017)
annual emissions		0.110	TOP A quantity / 10 years degradation time
	0.005	**0.114**	total emissions PFHxA

These recalculations of the Submitter's data show that the total emissions are in a range of 0.022 – 0.524 t/a PFHxA.

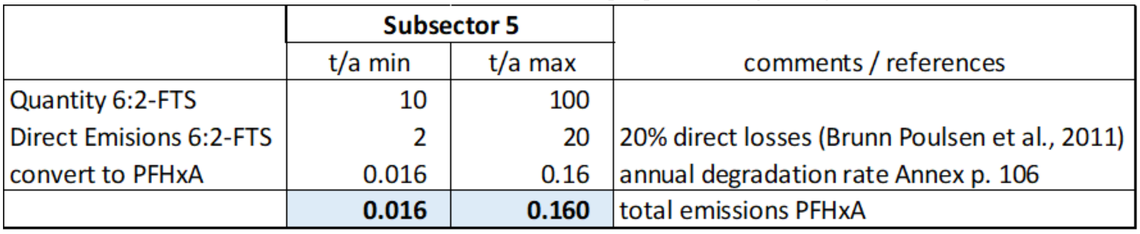
While these highlight the error in calculation from the original values of 4.62 – 144.36 t/a we believe that they are further overstated for the following reasons: (a) The foams currently on the market in Europe are formulated with high-purity C6 fluorotelomer surfactants that contain far less PFHxA, in the range of 50 – 100µg/kg (mean 75µg/kg). This would reduce the minimum emissions value; (b) the TOP Assay technique is flawed as the test conditions do not reflect real world or environmentally relevant conditions. Instead, TOP is a useful technique to help determine what precursors might become under excessively harsh oxidative conditions. This would reduce the maximum emissions value.

- Chrome Plating (Section 5)

Table 1 Section A.1.1 (Annex p. 1) REACH registrations states that the annual usage for 6:2 FTS (6:2 Fluorotelomer Sulfonate) lies in a band between 10 and 100 t/a. This can be verified on the ECHA's website (ECHA, 2020). However, the Dossier Submitter ignores this fact and states in Section B.9.10, p. 106 that "In Germany about 150 t/a of fluorosurfactants are used as well for decorative as for hard chrome plating. Based on Germanys share of the European GDP, for the EU a use of about 800 t/a was derived (tonnage band 100 – 1000 t/a)."

The Submitter then further states that "The ZVO (German national metal plating association) states that in the case of Germany only 20 % of the applied surfactant is lost (Brunn Poulsen et al., 2011). Applying this share of 20 % 6:2 FTS is lost to the in the EU used amount of the surfactant, about 160 t/a (min 20, max 1 000 t/a) are released by chrome plating into water. Calculating with the assumed surrogate for the annual degradation of precursors to PFHxA, it is assumed that about 6 t/a of PFHxA (min 1 t/a, max 8 t/a) are released into water."

Table 5 – Current environmental release of PFHxA [t/a] chrome plating



	Subsector 5		
	t/a min	t/a max	comments / references
Quantity 6:2-FTS	10	100	
Direct Emisions 6:2-FTS	2	20	20% direct losses (Brunn Poulsen et al., 2011)
convert to PFHxA	0.016	0.16	annual degradation rate Annex p. 106
	0.016	**0.160**	total emissions PFHxA

This statement thereby overstates both the precursors value with the estimation of 160 t/a emissions into water and the estimate of PFHxA which would arise from this.

Further, it implies that the chemical companies supplying 6:2-FTS are supplying up to 10x more than permitted under their REACH registration. The Submitter needs to provide details that confirm their assumption that up to 10x the registered volumes are being used or recognize that this is a gross over-estimation and that neither the volume for the precursors, nor the volume for the PFHxA emissions are valid and correct.

- Summary of the findings

The analysis of these two market sectors has shown that the emissions of PFHxA have been overestimated by >150 t/a and the precursors by >320 t/a. Equivalent analysis shows that the total overestimate is >360 t/a PFHxA and >3 600t/a precursors. These findings cast doubt on the validity of all of the assumptions and claims being made by the Dossier Submitter.

The detailed analysis of the exposure scenarios outlined in the Restriction Dossier shows that the total emissions of PFHxA lie in a range of 1.77 – 7.81 t/a, 40x lower than claimed by the Submitter. These values correspond to emissions of 5.3 – 43 ng/L into the European body of water.

3. The restriction disregards the availability of technologies capable of removing C6 fluorotelomer chemistry from water

Unlike what is claimed in the restriction proposal, according to which “techniques for purification of water installed today are mostly not able to remove PFHxA from water” (p. 24; p.32), proven full scale water treatment technologies are currently available for the removal of PFHxA from water. These technologies usually employ treatment trains which include ion exchange resins and/or membrane filtration. These ex situ treatment technologies have been applied to drinking water supplies, groundwater remediation, and industrial wastewater treatment plants.

These technologies are able to remove PFHxA and its related substances effectively and efficiently (AECOM 2018, AWWA 2016, Lindegren 2015, ITRC 2018, Evocra 2017, Liu 2019).

Ion exchange resins

Ion exchange resins are an established treatment technology for many common contaminants in both municipal drinking water and groundwater, including sulphate, chromate, nitrate, chloride, and perchlorate. Full scale ion exchange resin systems engineered to treat PFAS impacted water are currently in operation in Australia and the United States (ITRC 2018). The resins utilize both adsorption and ion exchange, which effectively remove long and short-chained PFAS compounds by attraction of both the polar and non-polar properties of PFAS compounds (ECT2 2018a). Ion exchange resins designed to selectively remove PFAS are not subject to the same degree of fouling as carbon-based sorbents (ITRC 2018).

Ion exchange resins are designed to be regenerable or disposed of after breakthrough of target compounds (single use). Resin regeneration is typically performed within the ion exchange treatment vessel, and results in a highly concentrated regenerant waste that requires further treatment and disposal. Currently available literature regarding PFAS removal has focused on regenerable ion exchange resins, however, single use resins are gaining traction in the remedial market as they have lower initial capital costs and the used resin can be disposed of by incineration (ITRC 2018).

The regenerable ion exchange resin Sorbix LC1 was designed to treat an array of PFAS compounds, specifically short-chain PFAS, and is currently in use in multiple full-scale ion exchange groundwater treatment plants in Australia and the United States (ECT2 2018a,b). United States-based company Emerging Compounds Treatment Technologies (ECT2) developed designed, fabricated, and oversaw the installation of ion exchange resin groundwater treatment plants at two separate Australian Government Department of Defence (Defence) sites formerly used for fire-fighting training (ECT2 2018a,b). The two Australian plants have a similar design to one another: each are capable of operating at 192 litres per minute (50 gallons per minute), and each contain two vessels filled with Sorbix A3F resin followed by polish vessels containing Sorbix LC1 (ECT2 2018a, 2018b). Influent PFAS concentrations range from 1-120 µg/L and both plants have demonstrated removal of three regulated target PFAS compounds, including perfluorohexane sulfonic acid (PFHxS), below reportable limits of 10 parts per trillion (ppt) (ECT2 2018a, 2018b; Defence 2018). ECT2 is currently building a second, larger PFAS removal and resin regeneration system capable of treating 750 litres per minute (200 gallons per minute) at an identified source area on one of the Defence sites (ECT2 2018a).

Additional commercially available ion exchange resins have demonstrated short-chain PFAS removal at the bench scale. Purolite Purofine® PFA694E is a single use resin being marketed for point of entry and point of use systems for removal of both long and short-chain PFAS (Purolite 2018). Bench-scale results from treatment of municipal well water with PFA694E showed 100% removal of PFHxA, reducing concentrations below 1 part per trillion, as compared with less than 10% by a bituminous granular activated carbon sorbent (Purolite 2018). Separately, bench-scale experiments tested the removal efficacy of PFHxA from synthetic and fluorochemical plant wastewater using five different commercially available Purolite resins; Purolite resin BA103 was found to have the highest PFHxA adsorption capacity of the five tested resins, with removal rates ranging from 101-320 mg/g/hour (Karnwadee 2015).

Membrane filtration

Two commercially available membrane filtration technologies, reverse osmosis and nanofiltration, have demonstrated effective removal of PFAS regardless of chain length (Dickenson 2016). In each of these technologies, impacted water is forced via high pressure through a filter membrane with a high contact area, producing a high concentration rejectate while allowing the treated filtrate to pass through. Dickenson and Higgins (2016) evaluated fifteen full-scale water treatment systems and concluded reverse osmosis was the most effective PFAS treatment method evaluated in the study: reverse osmosis systems at two California potable reuse treatment plants demonstrated removal of all PFAS analyzed, including PFHxA, to below reportable quantities (less than 0.50 ng/L for PFHxA) (Dickenson 2016). Additionally, reverse osmosis techniques have been designed for household undersink and residential well water PFAS treatment with removal rates greater than 90% for PFHxA (AWWA 2016).

It is to be noted that though full-scale implementation of nanofiltration has not yet been demonstrated for PFAS removal, commercially available nanofiltration membrane systems could evolve to be just as effective as reverse osmosis (ITRC 2018). Nanofiltration was shown to reject PFHxA at greater than 95% removal rates in bench scale testing of the Dow FILMTECTM NF270, NF200, and NF90 membranes (Steinle-Darling 2008) and field pilot-scale testing of two NF270 membranes in series at a Swedish drinking water treatment plant (Lindegren 2015).

Water treatment technologies capable of complete destruction of PFHxA are in development and may eventually evolve to commercial full-scale applications.

Current commercially available treatment technologies (e.g. ion exchange resin, membrane filtration) do not destroy PFAS but rather concentrate PFAS in the spent media, rejectate water, or regenerant solution. Ongoing research is being performed to develop advanced chemical oxidation techniques that are capable of complete PFAS destruction. AECOM (2018) developed the DE-FLUOROTM electrochemical oxidation technology, a proprietary electrode capable of PFHxA destruction. The manufacturer is currently identifying trial sites for the treatment of groundwater and commercialization of this technology is underway (AECOM 2018). Heat activated persulfate chemical oxidation has shown promise at the bench scale for PFAS destruction in waters impacted by fire-fighting foams: at the start of the experiments PFHxA concentrations increased due to precursor degradation, but ultimately PFHxA further degraded and eventually mineralized (Bruton 2017).

Combinations of remedial technologies into treatment trains show potential to be an efficient method for removal of a wide array of PFAS from water.

The development of a treatment technology that can effectively treat the full suite of PFAS, including precursors, has been challenging given the varying physical and chemical characteristics within this class of compounds. However, available scientific and product literature highlight the possibility of combining remedial technologies in treatment trains for the efficient removal of a wide array of PFAS compounds, including short-chain PFAS such as PFHxA, from impacted waters.

Recent research has demonstrated the potential for electrochemical oxidation technologies to effectively treat highly-concentrated PFAS waste streams generated during remediation, such as the rejectate from membrane filtration or ion-exchange regenerant waste.

Bench-scale testing for the electrochemical oxidation technology DE-FLUOROTM demonstrated a 99.66% removal rate of PFHxA from ozone oxidation treatment effluent (AECOM 2018).

Separately, Soriano et al. (2017) performed a series of bench scale experiments to remove and degrade PFHxA from industrial process waters using a combination of nanofiltration and electrochemical oxidation. Initial PFHxA concentrations ranged from 60 – 200 mg/L: under a range of operating pressures, they found that the Dow FILMTECTM NF270 membrane rejected PFHxA at a rate of 96.6 – 99.4%. The nanofiltration step concentrated PFHxA in the rejectate solution to 870 mg/L, which was then subjected to electrochemical degradation to reduce PFHxA by 98% (Soriano 2017).

Some companies are specifically marketing their remedial technologies for use in treatment trains for comprehensive PFAS removal. At an Australian demonstration treatment plant for a former fire-fighting training facility, Evocra verified the efficacy of its patented ozofractionation column technology combined with sorbent polishing steps (Evocra 2017). The ozofractionation columns were effective at removing PFOA and PFOS and precursors from influent wastewater, and subsequent polishing steps with engineered sorbent removed PFHxA and other residual PFAS. **The overall PFHxA removal rate in the combined ozofractionation and sorbent treatment train was 99.8%, reducing influent wastewater PFHxA from 5.16 µg/L to 0.0114 µg/L** (Evocra 2017).

4. The relevance of C6 fluorotelomer chemistry in the context of EU climate and circular economy ambitions has been disregarded

We would like to highlight that C6 fluorotelomer chemistry can contribute to achieving the objectives of the European Green Deal and help the EU on its trajectory to a carbon-neutral economy. This economic transition demands technological breakthrough that relies on access to substances with high performance. C6 fluorotelomer chemistry lies at the heart of components for green transportation (electric- and hydrogen-powered vehicles), solar power optimisation, lubrication for offshore wind generation, and carbon capture and storage. It is also key to components used in computers and mobile phones in addition to its key role in semiconductor manufacture.

As part of the Green Deal the EU is aiming to become a Circular Economy, reducing the use of resources and creation of waste. This will necessitate longer lasting products, made from substances with durable properties. Thanks to their persistence, C6 fluorotelomer chemistry contribute to these objectives as an element of durable products. Restriction of C6 fluorotelomer chemistry due to its persistence is in a sense contradictory to these environmental objectives. Other ways to control environmental releases should therefore be considered such as efficient production and mandatory collection and waste management for products containing persistent substances.

Following the COVID-19 crisis, some of C6 fluorotelomer traditional applications, such as medical barrier fabrics for masks and surgical gowns and drapes, have shown the importance of this chemistry. The ongoing issues sourcing personal protective equipment (PPE) has stressed the need for localised manufacturing and revealed the strategic importance of maintaining a production capacity in Europe. Although the restriction dossier provides for an exemption for nonwoven medical textiles, the breadth of the restriction would put in jeopardy the only production facility in Europe.

5. There is a fundamental confusion throughout the document between fluoropolymers and side-chain fluorinated polymers

ATCS is concerned that the restriction proposal constantly uses fluoropolymers and side-chain fluorinated polymers –belonging to fluorotelomers– interchangeably. These two groups of polymers are different in terms of chemical structure, uses, and potential releases, and a separate assessment for each is therefore is required. Fluoropolymers are high molecular weight polymers with a carbon-only backbone to which the fluorine atoms are directly attached. In contrast, C6 side-chain fluorinated polymers are polymers with fluorinated side chains intermittently attached to a non-fluorinated organic polymer backbone.

For example, the Dossier Submitter states that fluoropolymers are used as finishing agents or as repellents in treating paper, textiles, or hard surfaces, while these uses refer to side-chain fluorinated polymers instead (p.11; p. 47).

Section III – Specific concerns

Question 1 – Additional uses: Are you aware of any other present or future intentional uses, or uses where impurities are above the concentration limit proposed?

Textiles

Significant efforts were conducted by the sector over the past years to reduce emissions, including from PFHxA related substances. Best Available Techniques (BREF/BATs) for the Textile sector are currently being revised under the EU Industrial Emissions Directive. BATs set requirements regarding emissions that industrial plants must meet in order to be allowed to operate. A review of the BREF/BATs for the textile sector is underway, with specific provisions on C6 fluorotelomer chemistry being developed.

It is also worth highlighting that ATCS members contributed to the development of best practice guidance for the textile sector that provides guidance to minimize emissions of fluorinated – e.g. closed loop water management to avoid discharges to water. This is reflected in industry-based frameworks for responsible and sustainable manufacturing of textile consumer products, such as the bluesign® programme.

Regarding emissions from use, textiles treated with C6 fluorotelomer chemistry substances are expected to be in contact with water (e.g., rain, laundry). A certain amount of abrasion during lifetime has been reported (Gremmel et al., 2016; Knepper et al., 2014), resulting in PFHxA related substances on textiles separating from the article and ending up being released to the environment. Nonetheless, these emissions have been shown to be minimal. In a study focusing on PFOA and conducted by the German Environmental Agency, it was estimated that 80 million outdoor jackets sold in Germany represent 0,27 kg of emissions of PFOA (Knepper et al., 2014).

Treatment of textile with PFHxA-related substances increases durability, extending product's lifetime and thus reducing textile waste. Additionally, textile articles will be subject to a separate collection scheme under the EU Waste Framework Directive as of 2025. This obligation should allow for appropriate treatment of most textile articles, including those treated with C6 fluorotelomer chemistry.

In the following subsections, we describe some of the most relevant uses of textiles treated with C6 fluorotelomer chemistry. In addition, we share the concerns identified by TEGEWA regarding the following applications: home textiles and technical textiles used for mobility, industrial food manufacturing, building and construction, and earthworks and road building.

- Medical textiles

We welcome the exemption for professional protective equipment and medical nonwovens. However, it is not clear at this stage if medical textiles fall under the exemption mentioned in paragraph 9. It is worth noting that C6 side-chain fluorinated polymers are also used in medical textiles to protect doctors, nurses and researchers against contact with microbiological contaminants, such as viruses or bacteria. Typical uses include surgical gowns, drapes, or curtains (Schellenberger et. al., 2019).

Textiles are also used for medical devices, which share the same requirements in terms of protection against chemical and microbiological contaminants, as well as water-, oil- and stain-resistance.

Additionally, it must be noted that the current wording of the exemption could put at risk the existence of the only EU manufacturing location for C6 fluorotelomer technology used for medical barrier fabrics, among other medical applications. Given the huge importance of being able to access local production of these items for the foreseeable future, it is concerning that this industry is at risk of closure.

We therefore believe that this exemption should also cover medical textiles other than nonwoven, including those used for medical garments and medical devices.

- Outdoor textile applications

The European Union has a strong high-performance textile industry, which relies on C6 fluorotelomer chemistry. A recent study showed that there are certain niche applications for which no alternatives are available yet, such as outdoor professional and consumer apparel intended for adverse environmental conditions (Schellenberger et al., 2019).

We would therefore suggest that, in addition to the listed personal protective equipment, an exemption for textile should be extended to other applications. In addition to the fire fighters and defence that are already listed, TEGEWA has identified the following applications for which alternatives are currently not available:

- Indoor and outdoor wear useable for both public and professional uses;
- Sportswear and footwear for which special requirements are necessary;
- Protective gloves;
- Apparel (PPE) for Oil and Gas workers, law enforcement and military authorities, and emergency responders, including mountain rescue and lifeboat crews and volunteers working;
- Respiratory protective devices;
- Apparel (PPE) for workers in production of liquid acids;
- Protective suits in agriculture application of pesticides;
- Apparel - gas-tight chemical protective suit, survival suits for passengers on ships, etc.;
- Apparel for worker suits flammable fuel transportation;
- Apparel (PPE) for production of dust forming pesticides, allergenic products;

  - Apparel (PPE) for wastewater workers;
  - Apparel for decontamination workers;
  - Apparel for high voltage electricity worker suits, suits for fuel tanker driver; and
  - Protective clothing used in the welding industry.

Textiles and nonwovens used in transport

Textiles treated with C6 fluorotelomer-based products are used in the transport sector – including the automotive, aviation and railway industries– for an array of applications. For instance, it is used in the automotive industry for divers, convertible tops, engine bonnets, and carpets and rugs. For divers, C6 fluorotelomer chemistry provides the required water- and oil-repellence properties as well as high heat resistance. In the case of convertible tops, it allows maximum repellence against dry soil and white spirit, heavy dynamic rain repellence, and maximum resistance against high impact (> 200 km/h) of raindrops.

Nonwovens treated with C6 fluorotelomer-based products are used in transport for engine compartment interior/cushion. This constitutes a safety feature in case of fire and allows maximum fuel rejection. Moreover, the C6 fluorotelomer chemistry plays a critical role in nonwoven/PU-foam motor compartment sound cushions. The impregnation with this chemistry prevents, fuel being absorbed by the PU-foam in case of an accident. In case of fire, there is more time to rescue people before the vehicle starts to burn out.

C6 fluorotelomer chemistry is also used in perfluorosulfonic membranes in fuel cells, providing the necessary water- and oil-repellence, high heat resistance, and maximum resistance to hydrolysis and acid conditions.

In aviation, C6 fluorotelomer chemistry is also used for membrane textiles in mould injection processes of carbon fibre composite parts. C6 fluorotelomer chemistry enables these products to comply with high performance requirements established in legal normative regulations – i.e. maximum release properties, air permeability, maximum durability performances, and high temperature/humidity/defences.

Pulp-based repellent medical equipment

Apart from textiles, C6 fluorotelomer chemistry is also critical for other medical applications, such as medical equipment – e.g. wash bowls. These products require high repellence against water and oil in order to protect healthcare personnel and patients from the risk of infection transmission due to the reuse of improperly cleaned/sterilised bowls. The products are used in hospitals to prevent transmission of e.g. COVID-19, Clostridium difficile and methicillin-resistant staphylococcus aureus (MRSA).

We therefore assert that medical equipment requiring this barrier protection must also be covered by an exemption.

High-performance air and liquid filtration and separation media that require a combination of water- and oil-repellency

Durable water and oil repellencies are essential properties for high performance filtration and separation media. These media are used in equipment intended for various safety critical sectors, such as hospitals, personal protective equipment, and medical devices, pharmaceutical, energy, food, chemical, transport etc.

C6 fluorotelomer chemistry, due to its highly hydrophobic and oleophobic nature, provides various benefits according to applications such as protection against airborne harmful pollutants and microbial contaminants, optimal pressure drop, dust holding capacity, prevention of microbiological growth, high mechanical strength even in highly humid or rainy environments as well as protection against corrosion and damages. This results in long life and efficient filtration and separation media.

Question 5 – Fire-fighting foams (all relevant sectors, including defence sector)

A) Have you already shifted from PFHxA, its salts and/or related substances to fluorine-free foams or are you planning to shift to those alternative foams?

Class B fluorinated firefighting foams protect life and critical infrastructure where significant volumes of flammable and combustible liquids are involved. Firefighting foams based on C6 fluorotelomer chemistry remain the most effective agents currently available to fight high hazard flammable liquid fires. They provide a rapid extinguishment and help to prevent re-ignition to protect firefighters working in the area as part of rescue and recovery operations.

ATCS members promote the use of best practices in order to minimise emissions of firefighting foams to the environment. Best practices include the containment and treatment of foam discharges and the use of non-fluorinated foams for training and equipment testing (Fire Fighting Foam Coalition, 2016). The appropriate use, containment, and disposal measures can minimize emissions of fluorinated firefighting foams. Several commercially available remediation techniques to concentrate PFAS from firewater run-off, surface or groundwaters exist and allow a small volume of PFAS-enriched waste to be sent for appropriate disposal by incineration (Willson Consulting 2018).

Fluorine-free foams are increasingly being used by municipal fire departments and some airports, and for firefighter training and system testing, which are generally welcomed to avoid unnecessary dispersive uses of fluorosurfactants. However, recent discussion in some forums suggest that life safety protection at airports may require C6 fluorosurfactant-based foam to meet the performance requirements specific to the climate conditions in Australia. (Australian Senate inquiry, 2019).

Fluorine-free firefighting foams show lower performances and carry additional constraints for their use compared to fluorinated firefighting foams (Hinnant et al. 2017). For example, different types of fluorine-free foams may need to be used depending on the fire. Many existing foam systems are designed for lower application rates of the most effective firefighting agents and cannot be easily re-designed. Detailed risk assessments and duty of care reviews should be undertaken before embarking on replacing fluorinated foams with alternatives, without the same fire performance levels, to avoid compromising life safety and critical infrastructure protections. The selection of suitable fluorine-free foams for any application requires a careful risk assessment as well as additional logistics, in terms of storage, proportioning, delivery devices, and deployment in case of fire.

Furthermore, only limited information is available on the components of fluorine-free mixtures and their hazard profiles. It is reported that they are often based on polymers, as well as hydrocarbon or silicone surfactants. Besides considerations of performance and practicability during use, further hazard information on alternative foams should be gathered before they can be considered as suitable substitutes.

B) Are you using aqueous film-forming foams (AFFF) containing PFHxA, its salts and/or related substances for training purposes? If yes, please specify why

Best practices guidance for Class B firefighting foams, developed by some members of the ATCS (please see www.FFFC.org), recommends that fluorinated fire-fighting foams be used only for high hazard Class B fires and applications such as military, airports, storage tanks, terminals, and petroleum/chemical processing and industrial facilities. Containment and disposal measures should be in place to limit releases to the environment. It also indicates that **wherever possible fluorinated fire-fighting foams should not be used for training, testing and calibration purposes** (Fire Fighting Foam Coalition, 2016; Fire Protection Association Australia 2017).

The use of “modern” short chain C6 fluorinated substances has been significantly curtailed due to elimination of testing, training and calibration of equipment in most countries. And in addition, there has been and continues to be substitution of AFFF with fluorine-free foams. All these actions significantly lower the potential use of modern AFFF unless there is an emergency Class B high hazard fire.

There are specially designed training foams available from most foam manufacturers that simulate Class B foam during live training and do not contain fluorosurfactants. These foams are normally biodegradable and usually with advanced approval can be safely sent for treatment to the local wastewater treatment plant. Because they do not contain fluorosurfactants, training foams produce no film thereby allowing for more repeat fire training sessions and a more challenging training environment. During training evolutions fire fighters must be aware of the trade off in performance with training foams resulting in longer extinguishments and little burn-back protection compared with Class

B foams. Firefighters and other foam users should work with the Authority Having Jurisdiction (AHJ) to ensure that the use of training foams meets all local and application-specific live training requirements. In some cases, training foams can also be used as a substitute for Class B foams in vehicle and equipment testing

Training should be conducted under conditions conducive to the collection of spent foam. Training facility design should include a containment system. Some fire training facilities have elaborate systems designed and constructed to collect foam solution, separate it from the fuel, treat it, and in some cases re-use the treated water. In general, advanced training and education on the products, hazards and applications are critical. This alone will significantly contribute to the most efficient and safe use of Class B firefighting foams.

C) *Are you using AFFF containing PFHxA, its salts and/or related substances for testing purposes? If yes, please specify why.*

The Best practices guidance for Class B firefighting foams, prepared FFC with some shared members of ACTS, recommends that, wherever possible, fluorinated fire-fighting foams should not be used for training, testing and calibration purposes. However, many Authority Having Jurisdictions (AHJ) and third-party approval organizations require periodic testing of installed foam fire protection systems to assure reliable performance in an actual fire event. Typically, these tests involve full discharge of the system usually through fire hose lines connected to test outlets that are part of the system installation. Testing primarily involves engineered, fixed foam fire extinguishing systems. Two types of tests are conducted on foam systems: acceptance tests, conducted pursuant to installation of the system; and maintenance tests, usually conducted annually to ensure the operability of the system.

- Surrogate Liquid Test Methods

The major focus when evaluating foam system performance is to confirm proper function of the foam proportioning system. This is done by conducting a foam injection rate test. **This testing can now be done using surrogate non-foaming environmentally acceptable test liquids in lieu of Class B foam if the AHJ permits such substitutions**. The surrogate test liquids are specifically formulated to simulate the flow behaviour (viscosity characteristics) and approximate conductivity or refractive index of the foam concentrate used in the system. If these alternatives are used, users must put in place proper procedures to guarantee the systems can be returned to emergency ready status without issue. A common mistake can be not opening the main foam supply valve after testing.

- Water Equivalency Method

In some cases, water can be used as a surrogate liquid in place of foam. This is generally called the “water equivalency method” since a correction factor (to account for viscosity differences between foam and water) is applied to the water flow rate to make it equivalent to the foam concentrate flow rate. When using this method, flow meter measurements on the water and foam concentrate sides of the system are compared to determine the injection rate. The simulated foam concentrate (using water in place of foam) flow rate is multiplied by a correction factor to account for the flow rate difference between foam concentrate and water. This corrected flow rate is divided by the total system flow rate to determine the foam injection rate percentage. While this practice may work on some systems, water equivalency is not accurate when representing the viscosity characteristics of most alcohol resistant (AR) foam concentrates due to their thixotropic nature. Users should consult with the foam manufacturer to determine if they have appropriate test data to support the water equivalency testing method.

Question 6 – Other uses (cleaning, cosmetics, waterproofing agents, polishing products, floor waxes, food contact materials, etc.) including uses in consumer products

Paper-based grease repellent food packaging/wrapping

The OECD is currently finalising the review “PFASs and alternatives in food packaging (paper and paperboard): Report on the commercial availability and current uses,” which gives a detailed overview of the market. Once published, this document could serve as a source to assess these applications.

It should also be mentioned that, based on our assessment, the total emissions of PFHxA in the Paper and Cardboard are between 2 – 4 kg/a. We therefore believe that the cost increase of moving away from C6 fluorotelomer chemistry protection is highly disproportionate.

Question 10 – Alternatives for uses where substitution would be possible but is expected to lead to a lower quality of products or lower performance

Textiles

Side-chain fluorinated polymers’ properties include dirt, oil, grease and water repellence, which are imperative to the manufacture the high-performance textile applications mentioned above in this document.

The Danish Environmental Protection Agency reported that many different agents providing water repellence are marketed –including wax-based repellents consisting of paraffin-metal salt formulations, silicone repellents, resin-based repellents consisting of fatty modified melamine resins, and hydrophobic modified polyurethanes–, but none of the identified agents provide efficient repellence against oil, alcohol and oil-based dirt (2015).

Moreover, as discussed above, certain of the abovementioned free alternatives have a less favourable hazard profile compared to PFHxA.

Finally, it is worth mentioning that each industry has specific performance standards not only regarding repellence against fluids but also in terms of heat resistance, stain protection, etc. This information is available in TEGEWA's contribution to the public consultation.

- Medical textiles

For professional textile applications, studies have concluded that there is an absence of suitable non-fluorinated alternatives (Hill et. Al., 2017). Medical garments –including white coats, surgical clothing gowns or surgical covers– and devices need a combination of durable water, oil and stain repellence to protect healthcare personnel and ensure patients' safety. In particular, repellence towards non-polar liquids (such as body fluids) is part of hazard management, such as preventing transmission of infectious agents. As discussed above, dirt, oil, grease and water repellence properties cannot be reached by existing non-fluorinated alternatives –i.e. wax-based repellents consisting of paraffin-metal salt formulations, silicone repellents, resin-based repellents consisting of fatty modified melamine resins, and hydrophobic modified polyurethanes (Danish Environmental Protection Agency, 2015).

Another important property is the breathability of the fabric. It is possible to create a non-fluorinated barrier with repellence, but then the fabric will lose all breathability, which for some work environments may result in an unacceptable level of worker discomfort. Furthermore, a barrier type effect will result in large quantities of unwanted substances adhering to the textile or nonwoven, which may create more risks for workers (Schellenberger et. al., 2019).

It is also relevant to consider that the mentioned products have to meet higher requirements due to legal normative regulations. Please, find below some of the most relevant standards and test methods:

Table 6 – Standards and analytical methods for medical garments

Standard/Test	Scope
DIN EN 13795 (39/42/EEC)	Medical-product legislation.
EN 14216	Protective textiles against infection.
DIN EN 14126	Protective clothing – performance requirements and test methods for protective clothing against infective agents.
DIN EN 14786	Protective clothing – determination of resistance to penetration by sprayed liquid chemicals, emulsions and dispersions –Atomizer test.

Textiles used for medical devices necessitate, in addition to the abovementioned requirements, high hydrolyses stability since they undergo hot steam disinfection (130 °C) and often repeated laundry. The performance of these products is also covered by specific regulations. Please, find below some of the most relevant standards and test methods:

Table 7 – Standards and analytical methods for medical devices

Standard/Test	Scope
EN 943 Protective clothing against liquid and gaseous chemicals, including liquid aerosols and solid particles – Part 1 and 2.	Part 1: Performance requirements for ventilated and non-ventilated 'gas-tight' (Type 1) and 'non-gas-tight' (Type 2) chemical protective suits Part 2: Protective clothing against liquid and gaseous chemicals, including liquid aerosols and solid particles - Part 2: Performance requirements for "gas-tight" (Type 1) chemical protective suits for emergency teams (ET)
EN14605 Protective clothing against liquid chemicals	Performance requirements for clothing with liquid-tight (Type 3) or spray-tight (Type 4) connections, including items providing protection to parts of the body only (Types PB [3] and PB [4])
EN 13982 Protective clothing for use against solid particulates - Part 1	Performance requirements for chemical protective clothing providing protection to the full body against airborne solid particulates (type 5 clothing)
EN 13034 Protective clothing against liquid chemicals	Performance requirements for chemical protective suits offering limited protective performance against liquid chemicals (Type 6 equipment)

- <u>Outdoor textile applications</u>

For these applications, studies have concluded that some non-fluorinated alternatives can provide a sufficient level of water repellence, although they are not effective for oil and grease protection. Therefore, there are certain niche applications for which no alternatives are available yet, such as outdoor apparel intended for adverse environmental conditions (Schellenberger et al., 2019).

These properties are relevant for the applications mentioned under this subsection in Question 1 and are subject to specific industry standards – please, refer to TEGEWA's contribution in this regard.

Textiles and nonwovens used in transport

Like for the abovementioned applications, C6 fluorotelomer chemistry plays a crucial role in providing transport applications with the required levels of water repellence and oil repellence, as well as the other specific requirements – e.g. heat high temperature and humidity resistance.

It is worth noting that these applications, given their safety implications, are subject to strict normative legislations. Please, see a summary of the relevant standards and tests in the following table:

Table 8 – Standards and analytical methods for transport applications

Transport applications	Stands/tests
Divers	VW-PV 3353 (soiling and cleaning characteristics)
	GMW 4726 (Water Repellent Properties of Automotive Textiles)
	GMW 4726 (Water Repellent Properties of Automotive Textiles)
Convertible tops automotive	Audi-Standard LAH 893-800 – Technical development specification book materials textiles"
Nonwoven engine compartment interior/cushion and nonwoven/PU-foam motor compartment sound cushions	Standard of automotive industry – 96 hours fuel rejection according to AATCC TM 118-oil repellency – Hydrocarbon resistance test.
Perfluorosulfonic membranes used in fuel cells	Safety Standards of International Electro-technical Commission (IEC)
	Certified carbon fibre nonwoven for fuel cells (Innovations Plug in hybrid, alternative energy sources/energy efficiency)

High-performance air and liquid filtration and separation media that require a combination of water- and oil-repellency

There are at present no viable substitutes capable of providing the required level of water and oil repellency. As a result, the absence of derogation would represent significant risks for the many safety-critical applications that rely on high performance filtration and separation media and would be disproportionately costly.

Paper-based grease repellent food packaging/wrapping

C6 fluorotelomer chemistry enhances the surface properties of paper and cardboard by delivering water, oil and grease repellence for food packaging. Any restriction would require a switch to plastics, laminated constructions, or silicones.

Furthermore, in line with sustainable chemistry principles, it is necessary that alternatives are also assessed based on their environmental footprint along their entire life cycle. In the production for paper-based applications, ATCS members have assessed the alternatives in terms of energy and recyclability:

Table 9 – Assessment of alternatives: Energy and recyclability

Refined fibres	**Polyethylene coating**	**Bioplastics, clays, and alternative polymer coatings**	**Short chain fluorochemicals**
High energy costs from refining process	High add-on weight ~10-20 g/m²	High add-on weight ~10-20 g/m²	Low add-on weight ~0.1-0.3 g/m²
High energy costs from increased dry time	Non-renewable, fossil fuel-based	Alternatives like PLA are very expensive	Can be used with recycled fibers
Requires use of virgin fibres vs recycled	Slow to biodegrade and not easily recycled	Not easily recycled	Repulpable and recyclable

C6 fluorotelomer chemistry enables the use of paper and cardboard as alternatives to plastics and plastic coatings, materials which are subject to increasing restriction requirements in the context of the EU circular economy policy.

As for plastic packaging, these materials are subject to increasing restriction requirements in the context of the EU circular economy policy. In 2019, the European institutions adopted a legislation to ban certain single-use plastic food containers, such as fast food boxes and plastic cups for beverages. The Packaging and Packaging Waste Directive sets recycling targets for plastic packaging. The European Commission is currently working on the revision of the Packaging Directive to ensure 100% re-use or recycling of plastic packaging by 2030. In view of the expected measures on plastics and plastic packaging, it is unclear whether plastic will be considered an appropriate alternative to paper-based food packaging treated with C6 fluorotelomer chemistry.

Additives in paints and varnishes

Paints and varnishes in which C6 fluorosurfactants are used as additives are mainly intended for building materials. These products must display, amongst other properties, high durability. Downstream users have reported that alternatives based on C4 fluorotelomers are available, but that they display a lower performance and raise similar concerns regarding persistence. Moreover, the substances' hazard profile must also be assessed for these applications.

For further information on the socio-economic impact of the exemption, refer to question 12.

Question 12 – Costs: Do you agree with the assumptions and costs used?

A proper socio-economic assessment has not been conducted because there has not been a sufficient assessment of the scope of products that would fall under the restriction. For instance, non-woven medical textiles are exempt under the restriction proposal, while other non-woven applications have neither been exempt or specifically mentioned.

Although a proper socio-economic assessment could not be conducted, we can provide an estimation of substitution costs, including implications for downstream users, by looking at previous experiences of transitioning from C8 fluorotelomer chemistry to C6 fluorotelomer chemistry. ATCS membership includes leading producers of FluoroTechnology in Europe, the United States and Asia, who are committed to sound stewardship of FluoroTechnology and the safe use of chemicals. This commitment has been demonstrated in past years through the US Environmental Protection Agency (EPA) PFOA Stewardship Programme, which resulted in the phase-out of PFOA and other long-chain substances by the end of 2015. The ATCS members that produce either fluoropolymers and/or fluoroelastomers use alternatives to PFOA as polymerisation aids, as well as C6/short-chain substances instead of C8/long-chain substances, which are potential precursors of PFOA in the fluorotelomer-based product business. During the stewardship programme, ATCS member companies invested over €500 million of R&D and capital expenditures into the development of alternatives. This figure does not include the transition and qualification costs for downstream users to replace PFOA and its related substances, which vary significantly depending on the application (e.g. historically up to over €1,000,000 per use per downstream user in some instances.

On aqueous film forming foams (AFFF), the proposed restriction would ban the manufacture and import of the C6 fluorosurfactants used in fluorinated foams 18 months after entry into force. The Restriction Dossier does not take into consideration the substantial cost and complications required to transition. First, the fluorine free options are still evolving and many of the needed design criteria for hazards have not been established. These include, but are not limited to, application densities (application rates) and times. Secondly, once guidelines are established, it will possibly be years before complete transition can occur. This will result in major capital expenditures, infrastructure changes and substantial downtime for most industries that handle large quantities of flammable liquids.

Requiring a technology change (from AFFF to FFF) will demand significant investments on equipment and product by the EU chemical industry, the EU oil and gas industry and any EU company handling large volumes of flammable liquids. The cost to changes in the tank farm alone would be significant. In addition, any change to the system of a site also triggers additional testing and calibration costs to ensure full functionality. No doubt that the global competitiveness of the aforementioned EU industries will be affected to some degree. This loss in competitiveness could negatively impact EU employment and

GDP. The Fire Fighting Foam Coalition, in its submission to this public consultation, estimates that the restriction as proposed would cost EU foam manufacturers and users more than € 200 million.

Finally, it is worth noting that there is only one facility in Europe where the entire process of fluorotelomer production takes place, from initial telomerisation to production of C6 fluorotelomer-based products. This location therefore represents the only EU facility to manufacture protectors for Medical Barrier Fabrics and Face Mask Fabrics to repel contaminated sneezes and droplets. Although Medical Barrier Fabrics are exempt under the Restriction Dossier, the required production capacity cannot be secured if other applications are restricted. The strategic importance of this production facility should be considered instead of threatening its closure, as acknowledged in the Restriction Dossier (p. 136).

Such a far-reaching restriction as proposed by the Dossier Submitter would force the production of products with C6 fluorotelomer chemistry to relocate outside the EU. Nonetheless, many uses for these products will remain essential in the EU, leading to an increased dependency of the EU on imported products. However, due to a lack of available analytical methods, the import of products cannot be properly controlled. This difficulty has already manifested among Member States' authorities who are facing difficulties in preventing the import of products containing PFOA, following its restriction. The PFHxA restriction would therefore not lead to environmental improvement while the cost of enforcement would be very high in an already difficult economic climate where public finances are limited.

Question 13 – Analytical methods: Are you aware of a method for chemical analysis of PFHxA, its salts and related substances present in a matrix relevant for the restriction proposal? Do you develop or intend to develop such a method?

The dossier does not provide harmonized analytical methods to ensure product compliance and enforceability of any threshold. The few analytical methods provided do not cover the array of products falling under the scope of the restriction proposal. Additionally, in case the restriction proposal is adopted in its current form, the absence of a standard analytical method would pose serious implementation and enforceability challenges to both industry and regulators.

Much of the PFAS analysis work has been on PFOS and PFOA (ISO 2009; National Standards Authority of Ireland 2010), although more recently, analytical methods are starting to be applicable to more PFASs. For example, the USA EPA has published details of analytical methods for measuring PFAS in water that includes the analysis of PFHxA (2020):

- **Method 537.1**: Determination of Selected Per- and Polyfluorinated Alkyl Substances in Drinking Water by Solid Phase Extraction and Liquid Chromatography/Tandem Mass Spectrometry (LC/MS/MS) (USA EPA 2018).
- **Method 533**: determination of per- and polyfluoroalkyl substances in drinking water by isotope dilution anion exchange solid phase extraction and liquid chromatography/tandem mass spectrometry (USA EPA 2019a).
- **Validated Test Method 8327**: Per-and Polyfluoroalkyl Substances (PFAS) Using External Standard Calibration and Multiple Reaction Monitoring (MRM) Liquid Chromatography/Tandem Mass Spectrometry (LC/MS/MS) (USA EPA 2019b).

However, analysis of PFHxA in solid materials is much more challenging due to the sample preparation and extraction stages. Although methods do exist for the extraction and analysis of PFOS and PFOA (ISO 2018), **no standards have yet been published for the extraction of PFHxA**. While total fluorine detection techniques and methods (e.g., TOP assay technique) are useful for general screening, they are not suitable for compliance certification or enforcement unless they are validated and certified methods (Houtz and Sedlak 2012).

It should also be noted that measurements on PFHxA related substances is much more difficult than measuring PFHxA, particularly when they are bound to larger molecules, in environmental media, in biota, etc. Precursors by definition, are significantly more complex than just PFHxA or any PFCA for that matter. This leads us to believe that substance specific tests are required.

To develop validated and certified methods, the Fluoropolymer industry (through the trade association PlasticsEurope) has proposed test methods based on ultrasonic extraction and LC-MS-MS analysis of the resulting liquid to ECHA for PFOA in 2019. These methods have not yet been adopted in the ECHA Compendium of Methods. A similar analytical approach as used for PFOA could be used for PFHxA analysis from solids. Furthermore, the ATCS members are contributing to the development of methods for the analysis of PFAS, including PFHxA in textiles with CEN –e.g. CEN/TC 248 WG 26, CEN/TC 309 WG2, CEN/TC 289 WG1/IUC– (CEN 2020a; 2020b; 2020c) and a method for PFHxA and other PFCAs and PFAS (29 analytes in total) in AFFF concentrates is in the final validation process (FFFC 2019).

Table 10 – Comparison of PFAS analytical methods (Schultes et al 2019; Field 2019)

Method/Technique	Advantages	Limitations/Issues
LC-MS/MS	Commercially available; Extensive QA/QC Quantifies individual PFAS UCMR3/Method 537/SW-846 Differentiates branched/linear (Br/L)	Expensive Equipment Limited number of PFAS Generally good for targeted analyses
TOP Assay (LC-MS/MS) Total Oxidizable Precursor	Commercially available technique QA/QC improving Some chain length and Br/L info	Twice as Expensive (LC-MS/MS - 2X) No Information on Individual PFAS Conservative estimate of PFAS presence Limited comparative data at this time Aggressive lab oxidation: no real environmental relevance TOP is not a validated analytical method
EOF/AOF Extractable / Adsorbable Organic Fluorine	Quantifies Extractable / Adsorbable Organic Fluorine	Not commercial in US No information on individual PFAS Limited comparative data at this time
PIGE Particle Induced Gamma Emission	Quantifies total fluorine atoms Faster - quick screening; less expensive Non-destructive technique	Not commercially available in us (1 lab - ND). Units being develop for commercial use Not as sensitive as MS-based methods Limited comparative data at this time Does not speciate - just Fluorine presence Sample preconcentration needed to increase sensitivity

Method/Technique	Advantages	Limitations/Issues
LC-QTOF Quadrupole Time of Flight. Can also include HRMS: high resolution mass spec and Orbitrap MS here	Unlimited number of PFAS – good for non-targeted PFAS analyses Stored data can be searched in future	Instruments but not analysis commercially Available in US Expensive; skill; time consuming; lots of data generated which need analyses; Sample confirmation difficult as no authentic standards in many cases
CIC Combustion Ion Chromatography	Used for fluorine mass balance Determine total fluorine in environmental Samples and consumer products Better sensitivity and versatility vs PIGE/INAA	Possible matrix effects that impact peak separation CIC does not speciate and give you individual PFAS identification
INAA Instrumental Neutron Activation Analysis (Gamma Rays)	Measurement of fluorine in biological And environmental matrices Non-destructive technique Quick screening Compared to XRF - often used side-by-side	Better for solids than liquids Sensitivity depends on sample matrix

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