Alliance for Telomer Chemistry Stewardship

Alliance for Telomer Chemistry Stewardship's 2nd Response to ECHA Public Consultation to the PFHxA Restriction Proposal

Executive Summary

The Alliance for Telomer Chemistry Stewardship (ATCS) represents the world's leading producers of short-chain fluorotelomer-based chemistry. We welcome the opportunity to submit our opinion on the proposal to restrict PFHxA, its salts and related substances through this consultation.

The ATCS does not believe that PFHxA meets the criteria for restriction under REACH or that the proposed restriction is the most efficient way to address the potential presence of PFHxA in the environment. As discussed below, other instruments that could address the concerns raised in the Restriction Dossier (hereinafter RD) already exist and/or are under preparation. Moreover, the ATCS believes the potential costs of the restriction have been largely under-estimated, which demonstrates that the RD lacks any assessment of the restriction's environmental benefits in comparison to incurred socio-economic costs. In addition, the RD lacks an evaluation of the availability of alternatives and their respective environmental and health profiles. This is evident, especially when the underestimated restriction costs are coupled with much overestimated PFHxA emission estimates. Furthermore, the RD does not provide harmonized analytical methods to ensure product compliance and enforceability of any threshold. In case the restriction proposal is adopted in its current form, this would pose serious implementation and enforceability challenges to both industry and regulators.

In the present document, we wish to complement our previous input by strengthening some of the points made in our first submission, as well as by sharing additional information and concerns.

First and foremost, we provide revised data and calculations on the release potential of PFHxA. We believe the RD contains serious errors that are based on incorrect assumptions and simple omissions that lead to an over-estimation of the emissions, up to 40 times overall. In this submission we include a more complete assessment, compared to our previous contribution which focused on certain applications only.

Second, we stress that persistence as such is not sufficient to restrict a substance. Since persistence is not necessarily an intrinsic hazard, it does not in itself imply an adverse effect. We also reinforce that the persistent nature of the substance enables high performance and durability for key applications. Additionally, we reiterate our support to the use of Best Available Technologies (BAT) and Best Environmental Practices (BEP) combined with continued development of innovative technologies to effectively monitor

and minimize emissions to the environment from C6 fluorotelomer chemistry (defined as "PFHxA related substances" in the restriction proposal). ATCS further supports these techniques to be applied during production and throughout the lifecycle.

Third, we emphasize that an evaluation of critical performance attributes or essentiality must be based on the viability of alternative technologies with the required functional performance and an improved environmental and health footprint.

Fourth, we list various regulatory instruments and legal frameworks that could be used as an alternative to a REACH Restriction, particularly when only a limited number of applications of C6 fluorotelomer-based substances can be substituted with non-fluorinated alternatives.

Fifth, we highlight that the cost of restriction and substitution in relation to the environmental benefits shows the proposal's ineffectiveness. For instance, the SEA data from the ECHA/DG ENV document "The use of PFAS and fluorine free alternatives in fire-fighting foams" shows the high costs of replacing C6 fluorotelomer chemistry in this application, while there is also no evidence of existing alternatives with an improved environmental and health footprint.

Finally, we have included an updated list of requested derogations, which may be complemented with the third contribution we will submit by 25 September.

Section III – General concerns

1. The release potential of PFHxA is over-estimated, up to 40 times overall

The RD contains serious errors that are based on incorrect assumptions under many sections. We have therefore provided revised data and calculations which are explained in detail below.

Contrary to the view of the RD we can estimate with high accuracy the amount of PFHxA, its salts and related substances used in the EU. We will provide corrected estimations and calculations which show the emissions by subsector. As described in our previous submission these emission quantities are very low which demonstrates that PFHxA does not present an unacceptable risk, supports the current derogations and justifies further vital additions to the list of derogations.

Further, it demonstrates that actual emissions from PFHxA and precursors are much lower than is imagined and this has a further impact on the cost analysis of transition which has been vastly underestimated. Updated calculations for this will be shown together with the impact on proportionality.

The total emissions of PFHxA lie in a range of 2.3 – 6.8 t/a, more than 40x lower than claimed by the Submitter.

The RD contains a series of tables (Tables 24 a-d, p. 120) which show the environmental releases assumed for PFHxA and its precursors. There are a number of serious errors in the calculations and underlying assumptions which mean that these values are 20x higher than reality.

A corrected version of the table is shown below, and we provide accurate calculations by subsector. We also demonstrate that these emissions of PFHxA represent a definitive endpoint in the breakdown process. Therefore, there is no need to include additional precursor volumes in the Restriction as all precursors break down to PFHxA which 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 1 – Current environmental release of PFHxA [t/a]:

Sector of Use	Subsector	Current release PFHxA and salts		*Table 24d Figures release PFHxA and salts*	
		min	max	*min*	*max*
1. Polymers	1.1 Mfr of SC SFP	-	0.006	*-*	*0.003*
	1.2 Mfr of F-Elastomers with APFHxA	-	-	*0.100*	*1.030*
2. Textiles	2.1 Consumer Clothing EU manufacture	0.537	1.344	*0.340*	*59.35*
	2.2 Consumer Clothing EU imported	1.611	4.032	*0.850*	*158.41*
	2.3 Consumer Outdoor clothing	0.013	0.063	*0.030*	*5.540*
	2.4 Occupational wear	0.064	0.080	*0.020*	*3.510*
	2.5 Carpets & other text floor coverings	0.002	0.006	*-*	*0.150*
	2.6 Technical textiles	0.002	0.005	*0.001*	*0.004*
3. Paper & C'board	3.1 Grease-proof papers	0.002	0.004	*0.005*	*0.580*
4. Extinguish agents	4.1 Use by Professional firefighting	0.033	0.427	*0.020*	*0.520*
	4.2 Use by Voluntary fire fighting brigades	-	0.030	*4.600*	*143.84*
5. Chrome plating	5.0 Chrome plating	0.016	0.160	*0.780*	*7.800*
6. Inks	6.0 Inks	0.059	0.585	*0.310*	*3.130*
	TOTAL release of PFHxA	**2.339**	**6.742**	*7.056*	*383.87*

It is important to stress that these are total amounts of PFHxA in each of the individual usage sectors and of interest that approximately 50% of these emissions arise from imported articles.

Section 1. Polymers

- Subsection 1.1 Short chain surface active agents and side-chain fluorinated polymers

The indirect release of PFHxA can arise from the manufacture and use of products based on 6:2 FTOH and related intermediates, either as surface-active agents or in the formation of side-chain fluorinated polymers (SFP). The typical manufacturing route is described in Figure 7, E.2.1.1, p.135. Short chain surface active agents are used in the Extinguishing Agents, Paints and Coatings, Chrome plating and Inks sectors while the SFP grades are used in the Textile and Paper sectors.

We agree with the statement that these substances (i.e. SFP) are used between 1 000 to 10 000 t/a and the assumption of a maximum release of these SFP at manufacture of either precursors or articles containing these substances of 0.15 t/a. We can further assume, using the findings of several authors (e.g. Liu 2010, Zhao 2013) that this translates into a maximum emission of 0.0059 t/pa PFHxA using the degradation of 6:2 FTOH to PFHxA as a surrogate for the degradation of precursors.

- Subsection 1.2 Fluoropolymers

The discussion in the RD about the ammonium salt of perfluorohexanoic acid (APFHx) demonstrates some confusion about the definition of the products it is used to make.

APFHx and related substances are used as polymerisation and processing aids to produce certain fluoropolymers which include both fluoroplastics and fluoroelastomers. These fluoropolymers are incapable of forming PFHxA in the environment or via biota, given their stability and inertness. It is therefore incorrect to estimate any emission volumes for this application, except during the manufacturing where emissions can be controlled.

Section 2. Textiles

The textile industry covers a broad range of applications with different technical requirements. For technical textiles there is a vital need for oil in addition to water repellency to meet several regulations and norms, e.g. EU 2016/425 Annex I and Annex II 3.7.2, EN 469, ISO 14419. Reviewing the emissions for these applications we can see that the calculations made in the RD are overstated based on errors in the assumptions. The corrected values show that releases range from 2.23 – 5.53 t/a PFHxA.

- Subsection 2.1 Consumer Clothing manufactured in the EU.

Using the data provided in Table 24 we agree that the range of C6 fluoropolymers (i.e. SFP) is in the range of 3200 – 8000 t/a. As stated in the RD (p. 98) "the release of PFHxA from the side chain fluoropolymers is considered very low during the textiles service life of about five years". This figure is further quantified on p. 100 with the following statement, "The release of PFHxA from polymer degradation is assumed with < 6 kg at service life and from landfills."

To calculate loss of the treatment during the life span of the garments we have used the environmental release category ERC 10a (outdoor products with low release). This assumes that the majority of use will be for outdoor wear and that 100% of the breakdown of the side chain product occurs as 6:2 FTOH to calculate the subsequent volume of PFHxA produced. This gives a range of losses of the SFP of 13.76 – 34.4 t/a with subsequent degradation giving a total of 0.54 – 1.34 t/a PFHxA.

Using the same calculations as the DS, emissions from landfill at end of life can be calculated in a range of 0.0008 – 0.002 t/a. This is consistent with the finding in the RD which states that "from landfills an emission of PFHxA up to 2.55 kg/a could be expected from the 10 000 t of C6 side chain acrylate polymer used in the EU" (Section B.9.4.2.1 , p. 97).

On this basis we can state that the total emissions due to the Consumer Clothing subsegment are in a range of 0.537 – 1.344 t/a PFHxA.

Table 2 – Current environmental release of PFHxA [t/a] for consumer clothing manufactured in the EU

	Subsector 2.1		
	t/a min	t/a max	comments / references
Quantity SC SFP t/a	3200	8000	table 24 b p 121
Life Span SC SFP	13.76	34.40	Quantity x ERC 10a
convert to PFHxA	0.54	1.34	39 kg PFHxA from 1t 6:2 FTOH
End of Life: Landfill	1920	4800	60% of Quantity
convert to PFHxA	0.0008	0.002	425 mg/t PFHxA
	0.537	**1.344**	total emissions PFHxA

Note that, for Consumer Clothing applications the assumption that "4300 t are substances that fairly easily degrade to PFHxA, like 6:2 FTOH or polyfluoroalkyl phosphate esters" is not valid. This assumes that while the information states that "up to 10 000 t/a" are used then ALL of this 10 000 t/a must be used. There is no justification for this assumption. This also conflicts with the 8000 t/a Max used tonnage of C6 fluoropolymers stated in Table 24b.

Additionally, the products postulated (6:2 FTOH or polyfluoroalkyl phosphate esters) do not exhibit repellency effects on textile substrates and could not be used for the application described. As these account for almost all of the emissions described for this subsegment it is important that the details for this section are updated.

- Subsection 2.2 Clothing imported into the EU.

This has been calculated based on the proportion of quantity of goods imported into the EU vs. manufactured in the EU. Using the same calculation as in the RD we can update the range from 1.059 to 4.057 t/a PFHxA.

- Subsection 2.3 Consumer Outdoor Clothing.

The RD assumes that 100% of the 150 000 t/a weight of the outdoor clothes are treated with SC SFP protection. This is not a valid assumption. Outdoor clothing is typically multi layered and only the outermost layer is protected with a fluorinated or non-fluorinated durable water repellence (DWR), as described on p. 181. It is certainly not the case that all outdoor clothing is protected with fluorinated SC SFP technologies.

Instead, we assume that 50% of the weight of outdoor clothing is protected and use the maximum BfR (2012) value of 0.2 – 0.5 % (w/w) of fluorinated polymers (i.e. SFP) applied to the fabric (ATCS is in the process of confirming this assumption with downstream user associations). ERC 10a is applied for outdoor wear during service life. This gives a range of losses of the SFP of 0.323 – 1.61 t/a with subsequent degradation giving a total of 0.013 – 0.063 t/a PFHxA.

Using the same calculations as the DS, emissions from landfill at end of life are <0.001 t/a. On this basis we can state that the total emissions due to the Consumer Clothing subsegment are in a range of 0.013 – 0.063 t/a PFHxA.

Table 3 – Current environmental release of PFHxA [t/a] for consumer outdoor clothing

	Subsector 2.3		
	t/a min	t/a max	comments / references
Quantity SC SFP t/a	75	375	50% of total mkt at 0.05% w/w treat rate
Life Span SC SFP	0.3225	1.61	Quantity x default release factor ERC 10a
convert to PFHxA	0.013	0.063	39 kg PFHxA from 1t 6:2 FTOH
End of Life: Landfill	45	225	60% of Quantity
convert to PFHxA	0.0000	0.000	425 mg/t PFHxA
	0.013	**0.063**	total emissions PFHxA

- Subsection 2.4 Occupational Wear including Professional Outdoor Wear.

The DS seeks to exempt two categories of use that they have identified as "essential uses" where alternatives do not meet the properties needed with regard to oil and/or dirt repellence. These are certain PPE applications identified under Regulation (EU) 2016/425 and Nonwoven Medical Textiles. We would also propose to add Regulation (EU) 2016/425 Annex I Risk Category III (l) and further include PPE used by military and law enforcement which are exempt from Regulation (EU) 2016/425. The following calculations include quantities covering these additions.

We have assumed that a range of 80-100% of these items are protected using SC SFP. The use of the outdoor ERC used reflects a harsher wearing environment which is also reflected in the shorter life span of these garments.

On this basis we can state that the total emissions due to the Occupational Wear including Professional Outdoor Clothing subsegment are in a range of 0.064 – 0.080 t/a PFHxA. We assume that this subsegment will be covered by the exemption described on p. 51 of the main document.

Table 4 – Current environmental release of PFHxA [t/a] for occupational wear

	Subsector 2.4		
	t/a min	t/a max	comments / references
Quantity SC SFP t/a	380	475	80% or 100% total mkt at 0.05% w/w treat rate
Life Span SC SFP	1.634	2.04	Quantity x default release factor ERC 10a
convert to PFHxA	0.064	0.080	39 kg PFHxA from 1t 6:2 FTOH
End of Life: Landfill	228	285	60% of Quantity
convert to PFHxA	0.000	0.000	425 mg/t PFHxA
	0.064	**0.080**	total emissions PFHxA

- Subsection 2.5 Carpets and other Textile Floor Coverings.

The carpet and flooring market has moved away from water and stain protection, following market changes, towards PP (polypropylene) and PET (polyethylene terephthalate) based fibres which have reduced requirement for these treatments. Our assumption of the range of treatment therefore covers 30 – 80% of the market. The ERC used reflects indoor usage.

We can therefore state that the total emissions due to the Carpets and other Textile Floor Coverings subsegment are in a range of 0.002 – 0.006 t/a PFHxA.

Table 5 – Current environmental release of PFHxA [t/a] for carpets and other textile floor coverings

	Subsector 2.5		
	t/a min	t/a max	comments / references
Quantity SC SFP t/a	300	800	30% or 80% total mkt at 0.05% w/w treat rate
Life Span SC SFP	0.06	0.16	Quantity x default release factor ERC 11a
convert to PFHxA	0.002	0.006	39 kg PFHxA from 1t 6:2 FTOH
End of Life: Landfill	180	480	60% of Quantity
convert to PFHxA	0.0001	0.000	425 mg/t PFHxA
	0.002	**0.006**	total emissions PFHxA

- Subsector 2.6 Industrial Textile Fabrics.

This is a broad subsector which includes nonwoven filtration and separation media used in critical applications in the medical and transportation markets. Emissions are small throughout the service life of the articles and the end of life process is managed through regulation, e.g. the "ELV Directive" 2000/53/EC, so waste to landfill is low. In spite of this we have used the ERC calculation and assumption of 60% of quantities going to landfill as a worst-case calculation. This subsector is the subject of a request for a derogation.

This shows that total emissions due to the industrial textile subsector account for 0.002 – 0.005 t/a PFHxA, in line with the original estimate.

Table 6 – Current environmental release of PFHxA [t/a] for industrial textile fabrics:

	Subsector 2.6		
	t/a min	t/a max	comments / references
Quantity SC SFP t/a	300	600	30% or 80% total mkt at 0.05% w/w treat rate
Life Span SC SFP	0.06	0.12	Quantity x default release factor ERC 11a
convert to PFHxA	0.002	0.005	39 kg PFHxA from 1t 6:2 FTOH
End of Life: Landfill	180	360	60% of Quantity
convert to PFHxA	0.0001	0.000	425 mg/t PFHxA
	0.002	**0.005**	total emissions PFHxA

Section 3. Paper and Cardboard.

In addition to food contact applications there is a market of paper additives for medical disposables which should be included in the exemption for medical applications. The products consist of single-use disposable medical bowls which require treatment to be detergent proof. As the SFP is incorporated into the mass of the bowl and not applied topically there are no losses during service life and disposal is controlled so there are no losses due to landfill.

For the calculation we have assumed the same overall quantity of paper is protected as the DS with quantities updated to reflect a range of usage between 30 – 70% of the market. On this basis the emissions due to this Paper and Board market are in a range of 0.002 – 0.004 t/a. We expect that approx. 50% of this market will be subject to an exclusion from the restriction.

Table 7 – Current environmental release of PFHxA [t/a] for paper and cardboard:

	Subsector 3		
	t/a min	t/a max	comments / references
Quantity SC SFP t/a	212	494	30% or 70% total mkt at 1.5% w/w treat rate
Life Span SC SFP	0.0424	0.10	Quantity x default release factor ERC 11a
convert to PFHxA	0.002	0.004	39 kg PFHxA from 1t 6:2 FTOH
End of Life: Landfill	127.2	296.4	60% of Quantity
convert to PFHxA	0.0001	0.000	425 mg/t PFHxA
	0.002	**0.004**	total emissions PFHxA

Section 4. Extinguishing Agents

The RD significantly overstates the expected future discharge rate of foam stocks. The combination of the ban on testing and training with legacy foams going into effect on 4 July, together with current industry best practice calling for the elimination of virtually all testing and training with fluorinated foams, the future discharge rate is likely to drop to 5% or 3 125 t/a. This is in line with the estimate in the Restriction Dossier of an EU-wide stock of AFFF of 62 500 t/a. As a minimum case we have used the Submitter's central estimate of 2 000 t/a (Table 8 p. 70).

The Dossier 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. However, this methodology is flawed as the test conditions do not reflect environmentally relevant conditions. Instead, we have calculated the maximum fluorosurfactant content based on the formulation of a typical 3% firefighting foam concentrate.

- Subsection 4.1 Professional firefighting brigades.

There is an error in the calculation used by the Dossier Submitter. A synthetic foam concentrate intended for dilution at 3 % into water contains 0.045% fluorosurfactants, not 0.45%. The correct calculation is as follows:

Table 8 – Current environmental release of PFHxA [t/a] for professional firefighting brigades:

	Subsector 4.1		
	t/a min	t/a max	comments / references
Professional Brigades			
Quantity used t/a	2000	3250	Dossier central estimate or 5% total mkt
PFHxA Emissions	0.0027	0.0043	Quantity x median PFHxA conc = 1.328 mg/kg

This shows that Professional Brigades emit 3 – 4 kg/a PFHxA due to impurities in the foam concentrates that they use.

- Maximum content of Fluoro-based products

The total content of fluorosurfactants in the AFFF concentrates can be calculated and considered instead of the TOP Assay to determine other components in the formulation. Further details of the typical composition can be found in Korzeniowski, S.H. et al. (2019).

Table 9 – Current environmental release of fluorosurfactants in AFFF concentrates by Professional Brigades:

	Subsector 4.1		
	t/a min	t/a max	comments / references
Professional Brigades			
Quantity used t/a	12500	12500	20% total market stock (62500 t p. 55)
PFHxA from Impurities	**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
total PFHxA from precursors	**0.017**	**0.410**	total emissions PFHxA

The maximum value of 0.410 t/a PFHxA chemically bound in several precursors is in alignment with the RD calculation of 0.520 t/a (annex p.104). We can conclude that the emissions arising from use of extinguishing agents by professional fire brigades is in a range of 0.020 – 0.414 t/a when the PFHxA impurities and the precursors are combined.

- Subsection 4.2 Volunteer firefighting brigades.

There are two major errors with the analysis in this section. The first involves the value of 1328 µg/kg which is incorrect as it does not account for the reduced strength described as the “0.1% ready to use solution”. This indicates that the standard, 1% solution has

been diluted 10x, so we need to do the equivalent modification to the impurity level. The correct calculation is: 1328 µg/kg x 0.1% x 1150 kg = 0.0015 g per event, not 1.5 g.

The DS has then scaled this amount for the whole region. However, this scaling assumes that all of the volunteer fire brigades use fluorine-based foams whereas the paper cited (Keutel and Koch, 2016) states clearly that 75% (15 out of the 20) of the volunteer fire brigades interviewed use only fluorine-free foaming agents. On this basis we can calculate (Table 10) that the overall emissions for volunteer fire brigades is up to 0.0012 t/a PFHxA as impurities.

The equivalent volume arising from the analysis of the precursors using the TOP method on the foams used by Voluntary Brigades is calculated as: 314.9 mg/kg x 0.1% x 1150 kg = 0.362 g per event. Once again, the scaling operation needs to reflect that 75% of fire brigades use fluorine free foams, i.e. only 25% of fire brigades use fluorine-based foams.

Table 10 – Current environmental release of fluorosurfactants in AFFF concentrates by Volunteer Brigades:

	Subsector 4.2		
	t/a min	t/a max	comments / references
Volunteer Brigades			
Quantity used t/a	869.4	869.4	1150kg x 0.1% x 20 (#ops/a) x 0.25 x 24000 (#German v'teer brigades) x 6.3 (=EU/Germany)(p.104)
PFHxA from Impurities	**0.0001**	**0.0012**	Quantity x PFHxA conc = 0.075 or 1.328 mg/kg
using TOP Analysis		0.274	Quantity x 3.149 mg/kg (Dauchy et al. 2017)
annual emissions		0.027	TOP A quantity / 10 years degradation time
total PFHxA from precursors	**0.000**	**0.029**	total emissions PFHxA

Scaling for the whole region gives a total amount of 0.029 t/a PFHxA precursors.

Extinguishing Agents total emissions.

Combining all of these results for both the professional and volunteer brigades gives an updated range for the extinguishing agents of 0.033 - 0.457 t/a of PFHxA or PFHxA precursors. The socio-economic costs compared to the environmental benefits of the proposed restriction are further discussed under Question 12.

Section 5. Chrome Plating

Table 1 Section A.1.1 (Annex p. 1) REACH registrations states that the annual usage for 6:2 FTS (Fluorotelomer Sulfonate) lies in a band between 10 and 100 t/a. This implies that the maximum usage should be assumed as 100 t/a. There is no justification for an 800 t/a usage assumption.

Using the calculation of losses described in the RD, the actual emissions lie in a range of 0.016 – 0.16 t/a PFHxA.

Table 11 – Current environmental release of PFHxA [t/a] for 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

Section 6. Inks

A significant proportion of the 15 t/a estimated usage is for medical imaging (X-ray, etc.) applications which is covered by a derogation for five years after entry into effect of the restriction. The emissions calculations have been updated to include this.

Table 12 – Current environmental release of PFHxA [t/a] for inks:

	Subsector 6		
	t/a min	t/a max	comments / references
Quantity 6:2-FTS	10	100	
Direct Emisions 6:2-FTS	1.5	15	15% direct losses
convert to PFHxA	0.006	0.059	39 kg PFHxA from 1t 6:2 FTOH
	0.006	**0.059**	total emissions PFHxA

Overall Emissions

Concluding, the current emissions of PFHxA are 2.343 – 6.74 t/a. Total emissions of short chain C6 side groups during service life and landfill which do not degrade to PFHxA are 23.7 – 181.5 t/a.

Using the calculations shown in B.9.17 “Overall environmental exposure assessment”, this gives a European PFHxA concentration of 7.0 ng/L to 38 ng/L. This is entirely in agreement with the cited example of Ahrens et al. (2009) who measured a maximum concentration of PFHxA of 9.56 ng/L in the German Bight’s surface water. It is also two magnitudes of scale lower than the drinking water guide values for PFHxA (TWLW 6 µg/L) established by the German Human Biomonitoring (HBM) Commission in 2017, (Bundesgesundheitsblatt 2017).

2. The focus on persistence is not enough to restrict a substance

Persistence in and of itself is not necessarily a concern. In fact, it can be a benefit as persistent substances are often used in product design to enable critical performance and functionality. However, the ATCS acknowledges that persistent chemicals can be a

potential concern, due to a potentially increasing presence in the environment from emissions. Despite this, we wish to underline that while persistence is considered an intrinsic property it is not necessarily an intrinsic hazard. Persistence of a substance does not eliminate the need for a risk assessment based on evidence of adverse effects and releases.

In the case of PFHxA, the substance has been detected in the environment at low levels. However, this should not be assumed to equal harm. In fact, the RD states that "no indications of serious human health risks are documented" and "there are currently no impacts to be expected" (p. 73). Indeed, the overwhelming weight of scientific evidence indicates that PFHxA does not cause cancer; does not disrupt endocrine (hormone) activity; has not been shown to cause reproductive or developmental harm; does not build up in the human body, and does not become concentrated in the bodies of living organisms. This, in combination with the significantly overestimated level of emissions, as noted in Section III, reinforce that PFHxA is not anticipated to present a significant risk to human health or the environment.

In order to prevent the increasing presence of PFHxA in the environment, the ATCS supports and is interested in the continued development of innovative technologies to effectively monitor and minimise emissions to the environment of short-chain fluorotelomer-based substances and any potential break down products during production and throughout their lifecycle.

Potential PFHxA emissions can be managed

ATCS members have been implementing and promoting best practices and techniques to manage and minimize potential emissions as part of their commitment to sustainable production. ATCS members have also actively promoted the use of Best Available Techniques for minimising emissions by users. In this respect, the ATCS would like to reiterate that a.) any actual emissions are extremely low and b.) that proven techniques and practices are available to minimize potential emissions. 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.

Advancing BAT/BEP and more precise monitoring and analytical methods are critical to assess more accurately current and future emissions to the environment. Such efforts should be the prerequisite to any regulatory action and certainly before restriction.

Persistence enables high performance, stability, and durability for key applications

It should be recognised that for substances like fluorotelomers, the intrinsic property of persistence confers the desirable properties of high durability and unique functionality to products made and treated with this chemistry. This results in significant durability, contributing to product design that saves resources and reduces waste in line with the EU's objectives for a circular economy.

Furthermore, combined with other properties, high durability and unique functionality remain crucial for high performance applications without suitable alternatives. For instance, C6 fluorotelomer chemistry plays a key role in many strategic sectors in Europe, including medical applications, transport, energy, electronics, and construction, among others. For example, C6 fluorotelomer chemistry is used in medical textiles – e.g. surgical gowns, drapes, or curtains – because of its water-, oil- and stain-repellence. These properties provide the chemical barrier necessary to protect healthcare personnel against contact with microbiological contaminants (blood-bourne pathogens), including viruses or bacteria.

Textiles and nonwovens treated with C6 fluorotelomer-based products are used in the transport sector to avoid the penetration of oil, as well as to provide the levels of heat resistance and flame retardancy required by the industry. The properties mentioned herein constitute key safety features for transport applications and cannot be ensured by other chemistries.

Finally, in the energy industry C6 fluorotelomer chemistry is used, for instance, in the production of filtration media intended to purify the air before entering turbines for energy generation purposes. These filter media provide high levels of particulate removal efficiency, protecting gas turbines against fine pollutants. Additionally, high level of hydrophobicity prevents liquid water ingress and reinforces filters' resistance under humid environmental conditions. The absence of these properties would lead to engine stops and generate serious risks in terms of energy supply and gas transport.

It is also worth noting that the increased focus on persistence alone is likely to lead to restrictions of potential alternatives as they would require similar properties in order to fulfil the abovementioned critical performance and functions. Loss of durability (of materials) would lead to frequent maintenance or disposal of treated materials. That would consume energy of production, likely increase the price of materials, and also increase the amount of waste in the overall supply chain.

3. An evaluation of "essential use" should be comprehensive in nature and consider all relevant factors including the core principles of circularity and sustainability.

The REACH restriction process allows for addressing the criticality of a use, as well as the risk associated with a given use. Furthermore, Article 68 of REACH mandates the Commission to consider the socio-economic implications of the restriction and the availability of feasible alternatives, as the two key factors in determining the scope of a restriction.

Today, EU regulators are considering applying the concept of "essential uses" as a basis for justifying potential derogations, as is the case for the restriction proposal on PFHxA, its salts and related substances (pp. 10-11, 42, 51, 59). However, it is worth noting that the concept of "essential uses" is not clearly defined under EU law and is not part of the REACH process. Therefore, it is not clear how the concept of (non-)essential use can be legitimately used under the current legislative framework. Under REACH, a restriction is triggered by an unacceptable risk for a specific use. The REACH restriction process does not allow for the regulation of substances on the basis of 'essential use'.

Furthermore, the essential use concept, as currently proposed, could undermine overall product safety and product performance, while also undercutting the EU's efforts to advance circularity and sustainability. An evaluation of "essential use" should be part of a hierarchy of responses, to be invoked only when other risk management approaches or regulatory measures are insufficient to address any identified risks.

If the preconditions are met that a substance is likely to cause adverse effects and warrants restriction, any consideration of essential use would benefit from a well-established set of criteria to assess the essentiality of a use in the restriction process. For this purpose, evaluations of 'essentiality' are not and should not be limited to just one factor. This extends well beyond the chemical that may be substituted and requires a holistic approach to product design.

We therefore believe that key factors to consider in evaluating essential use include:

- chemical safety on a life-cycle basis;
- the availability of alternative technologies which provide equivalent functional performance;
- the technical and economic feasibility of deploying an alternative technology;
- the safety and efficacy of alternatives;
- an improved overall environmental and health footprint; and
- products' contribution to other key EU policy objectives such as the Green Deal and Circular Economy.

This approach, which is aligned with the REACH restriction process and other existing international agreements to which the EU is a Party (e.g. Montreal Protocol, Stockholm Convention), would allow for a proper justification of the exemption of specific uses to a restriction and ensure that the restriction is not based entirely on the hazard profile of the substance.

Finally, we would like to note that the experience during the COVID-19 crisis – e.g. issues sourcing personal protective equipment (PPE) – has demonstrated that European industry needs to be able to significantly increase its production capacity for essential products within short lead times. A rapid increase in production capacity can only be ensured with a robust domestic chemical industry.

As explained in our initial contribution, there is only one facility in Europe where the entire process of fluorotelomer production takes place. This location therefore represents the only EU facility to manufacture protectors for Medical Barriers and Face Mask Fabrics. Although these are regarded as essential uses under the RD, the breadth of the restriction would put in jeopardy the only production facility in Europe.

4. There are alternative instruments and legal frameworks for addressing issues related to PFHxA to REACH Restrictions.

The ATCS has analysed various regulatory management measures, including the EU REACH Restriction and other EU environmental legislation. As discussed in our previous contribution, the ATCS believes that the conditions for a restriction of uses of PFHxA, its salts and related substances are not met. According to Article 68 of EU REACH Regulation, in order to be restricted, substances would have to pose an unacceptable risk to the environment and/or human health, which is not the case for PFHxA.

Furthermore, a limited number of current applications of C6 fluorotelomer-based substances can be substituted with non-fluorinated alternatives. Most applications reported by participating ATCS members remain without alternatives and fulfil critical purposes. In line with the principle of Better Regulation, alternative ways to a REACH restriction should be considered.

As an alternative regulatory instrument, the ATCS suggests that water legislation should be considered, first to monitor and gather evidence and second to define safety levels. At present, there is EU water legislation in place to address concerns about water pollution from chemicals, including PFAS. For example, the EU Drinking Water Directive (Council Directive 98/83/EC) establishes very ambitious thresholds for this type of substances.

Moreover, the Industrial Emissions Directive could also be an effective instrument to evaluate and control C6 releases to the environment from facilities handling C6 fluorotelomer-chemistry. This legislative instrument establishes requirements for the

reduction of emissions into air, water and soil and the prevention of waste generation in industrial plants.

Furthermore, the ATCS recommends a sound management of waste products in line with the EU Circular Economy. The EU is currently revising its waste policy framework in order to achieve the EU's zero-pollution ambition. This is a key opportunity for policymakers to also look at products treated or made with C6 fluorotelomer chemistry. Separate collection and proper treatment of waste containing fluorinated products should be extended and harmonised at the European level.

Finally, the ATCS believes that 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 to continue to advance BAT/BEP for minimizing any potential emissions.

5. Any proposed restriction limits should be based on established scientific data.

The RD claims that out of the four management options under restriction, the "restriction with no concentration limit" is discarded because this option does not meet the proportionality in terms of potential cost in cases for essential uses such as the use of AFFF for large liquid fires, and the RD states that the unavoidable impurity of PFHxA has issues with practicality and monitorability (Table 6 Summary of management options assessment, p. 42).

For these reasons, the restriction option with no concentration limit was discarded. The RD therefore proposes as the best option the restriction with concentration limits, 25ppb for PFHxA and its salts and 1000ppb (1ppm) PFHxA-related substances. This chosen option, however, has exactly the same set of issues as the discarded option. These issues arise mainly because of the fact that all C6 fluorotelomer-based products, such as C6 fluorotelomer surfactants, are PFHxA-related substances (precursors) by the definition in the RD.

To illustrate the problem, the proposed limit concentration of PFHxA precursors is: 1000ppb = 1ppm = 0.0001%. At this limit concentration, there are practically no C6 fluorotelomer-based products that can be useful in providing their intended functions, such as oil repellency, low surface tension, in any applications including paper, textile, firefighting foams and all others.

This demonstrates that the proposed limits are not based on scientific data and reasoning. Instead, the values chosen appear to be copied directly from the threshold concentrations for PFOA and its related substances. This implication of equivalent concern is contrary to peer-reviewed studies (Luz et al. 2019, Anderson et al. 2019).

Section III – Specific Information Requests

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?

The use of C6 fluorotelomer chemistry remains without suitable functional alternatives for an array of applications for which the level of impurities might be above the proposed concentration limit. ATCS is concerned about the absence of derogations for the following uses and would request the below uses to be derogated from the restriction proposal due to its lack of alternatives with equivalent functional performance:

- Woven medical textiles;
- Outdoor technical textile applications (e.g. awnings, high-performance sports equipment);
- Professional apparel, including apparel (PPE) for Oil and Gas workers, law enforcement and military authorities, and emergency responders;
- Interior textiles, including its uses in transport;
- Nonwovens used in transport;
- Pulp-based repellent medical equipment;
- High-performance air and liquid filtration and separation media that require a combination of water- and oil-repellency;
- Paper-based grease repellent food packaging/wrapping;
- Class B high-hazard Fire-fighting foams;
- Paints and coatings; and
- Floor finishing.

Regarding medical applications, it is our understanding that products such as chirurgical drapes and gowns or sterile barrier systems having a non-woven structure are covered by the exemption 9 (c) non-woven medical textiles. These applications would therefore not require an additional derogation.

For further information on environmental releases from these applications, please refer to *Section III – General Concerns*.

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

The RD references that previous restrictions have been rejected because the Cost Effectiveness Analysis (CEA) gives a value that is too expensive. In addition, the fluorotelomers section states the following (p. 48):

> A central estimate of approximately 30 000 €/kg has been considered to determine whether the costs are proportionate. Considering CEAs from previous restrictions an exemption as stated in the restriction proposal might be justified based on these costs alone.

In the case of Extinguishing Agents, we have shown in the Emissions section that the amount of PFHxA emitted by firefighting foams is up to 0.457 t/a. The SEA data from the ECHA/DG ENV document "The use of PFAS and fluorine free alternatives in fire-fighting foams" details the annualised cost of replacing short chain firefighting foams for two scenarios.

Scenario one represents a restriction (ban) on the placing on the market of PFAS-based AFFF. The use of legacy foams, i.e. foams already in stock at producers' or users' sites, would still be permitted. For the second scenario the ban would be identical, but the legacy foams would need to be disposed of safely. In this second case not only would new sales be prevented, but existing stocks would need to be disposed of and replaced with new volumes of fluorine-free foams.

Their best estimate for the two scenarios is ~100 € Million/a for the first scenario and ~200 € Million/a for the second scenario. Using these values in a CEA using the emissions value for PFHxA calculated gives values of 219 000 €/kg of PFHxA and precursor emissions for scenario 1 or 438 000 €/kg for scenario 2. This is 7x - 14x higher than the CEA for the fluoroelastomers business (30 000 €/a) that justified the granting of exemption for that sector. We will discuss this further in response to Q 12.

The ECHA/DG ENV review also highlights that fluorine free foams are not a drop-in replacement for AFFF, particularly in petrochemical processing and large storage tank farms.

Since fluorine free foams (F3) are not direct drop-in replacements, there are concerns about their effectiveness in unchanged existing installations for large surface tank fires, practicability and need for technical changes in existing installations. These may not be easy to do while maintaining the required fire safety. There is lack of experience with changes in application techniques for F3 for these fire scenarios. Against this background, the proposed transitional periods appear too short.

We therefore propose a derogation for fire extinguishing applications using the same argumentation as the DS has used for fluoroelastomers. Considering CEAs from previous restrictions an exemption as stated in the restriction proposal might be justified based on these costs alone. This combination of factors requires the granting of a derogation for the fire extinguishing market.

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