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Alliance for Telomer Chemistry Stewardship's Response to the Call for Evidence on all PFAS

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Executive Summary

The Alliance for Telomer Chemistry Stewardship (ATCS) represents the world's leading producers of C6 short-chain fluorotelomer-based chemistry. We welcome the opportunity to submit our opinion to the call for evidence on all poly- and perfluoroalkyl substances (PFAS).

In the present document, ATCS wishes to share its serious concerns with respect to the forthcoming restriction on all substances containing either the -CF2- or -CF3 moiety. The concerns that are dealt with are the following:

1. Persistence is not sufficient to support the claim that only "essential uses" of PFAS should be allowed.

In the first section we highlight that persistence, in and of itself, is not a hazard and does not eliminate the need for a risk assessment, based on evidence of adverse effects and releases. In order to manage and limit any potential releases, ATCS members implement emission minimization techniques as part of their commitment to sustainable production and promote the use of Best Available Techniques down the value chain. We also highlight the importance of exceptionally stable chemicals in a range of strategic sectors.

2. The "essential uses" concept is not supported under REACH, and any potential consideration of this concept should only be applied according to well established criteria once the REACH restriction conditions are fulfilled.

Secondly, we raise our concern over the increased employment of the "essential use" concept as a basis for justifying potential derogations to future restrictions. We note that this concept is not defined in EU law and does not form part of the REACH process, which puts into question its legitimacy within the current legislative framework. The "essential use" concept should not be used to undermine the need to establish an unacceptable risk and should be part of a hierarchy of responses, to be used only once other risk management approaches have been exhausted. If applied, it shall be used according to well established criteria once the REACH conditions for a restriction are fulfilled. Additionally, we underline the strategic importance of ensuring a chemical production capacity in Europe, particularly in the context of the COVID-19 recovery.

3. Any proposed restriction measures need to be balanced against actual emissions and socio-economic implications.

We state that the assumption of there being a potentially increasing presence in the environment needs to be balanced against actual emissions, associated costs, and socio-economic implications. We believe that a proper assessment of these factors should be conducted to design suitable measures and ensure proportionality. For this

purpose, we provide the examples of the textile and the firefighting foam sectors, which would be strongly affected by any potential restriction of C6 fluorotelomer-based chemistry.

4. The call for evidence uses a new definition of PFAS substances and significantly overestimates the number of PFAS in commerce.

We also believe that the proposed definition of PFAS including any and all CF_3 and/or CF_2 containing compounds is not scientifically justified since it encompasses substances that vary widely in their physical and chemical properties and their health and environmental profiles. Furthermore, many of these compounds are already subject to specific regulations. This call provides a new and broader definition of PFAS substances, under which any substance containing a CF_2 and CF_3 group would be included. As a result, more than the 4730 substances covered under the current definition (OECD, 2018) would be expected to be affected.

5. A ban of all PFAS opens the way for restrictions without proper risk justification.

In addition, we question the legal basis of a potential restriction of all PFAS substances, based on their persistency and potential accumulation in the environment. We contend that such an approach does not fulfil the requirements set by the REACH Regulation, nor the jurisprudence of the European Court of Justice. We believe that such an approach would be the start for future restrictions without proper risk justification. Instead we propose that other, more appropriate, regulatory means be pursued to manage and limit emissions of PFAS substances into the environment such as the Industrial Emissions Directive, the Drinking Water Regulation and a sound waste management in line with the circular economy principles.

6. The availability of harmonised analytical methods should be a prerequisite to any regulatory action.

We raise our concern over the lack of harmonised analytical methods to accurately assess current and future emissions of PFAS to the environment. ATCS members contribute to the development of methods to analyse PFAS in textiles and aqueous film forming foams and we believe that such methods should be the prerequisite to any regulatory action and certainly before restriction.

7. Fluorotelomer chemistry plays a key role in many strategic sectors in Europe.

Finally, we provide a list of applications where C6 fluorotelomer chemistry plays a critical role, particularly in providing the required levels of water- and oil-repellence, barrier properties and unmatched surface-active capabilities.

1. Persistence is not sufficient to support the claim that only "essential uses" of PFAS should be allowed.

The ATCS acknowledges that persistent chemicals can be a possible concern under certain circumstances, due to a potentially increasing presence in the environment from emissions. However, it must be noted that, while it is considered an intrinsic property, persistence in and of itself is not justification for chemical regulation. In fact, it can be a benefit as persistent substances are often used in product design to enable critical performance, durability and functionality. Moreover, persistence of a substance does not eliminate the need for a risk assessment based on evidence of adverse effects and environmental releases. Therefore, it is critical to work towards acceptable conditions for a continued use of short chain fluorotelomer chemistry, based on monitoring and further reduction of emissions as well as the required analytical methods.

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

1.1. Potential PFAS emissions can and should be managed

While persistence is not an intrinsic hazard, as it does not in itself imply an adverse effect, appropriate emission minimization techniques should be in place for persistent substances as has been done with many other types of chemicals.

ATCS members have been implementing such emission minimization techniques as part of their commitment to sustainable production. ATCS members have also actively promoted the use of Best Available Techniques for minimizing emissions by users, especially in the textile and AFFF segments.

1.1.1. Emissions to water

The ATCS would like to highlight that proven full scale water treatment technologies are currently available for the removal of short-chain fluorotelomer-based chemistry 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.

- 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).

- 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 to below reportable quantities (Dickenson 2016). Additionally, reverse osmosis techniques have been designed for household undersink and residential well water PFAS treatment (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). For instance, nanofiltration was shown to reject PFHxA at greater than 95% removal rates in bench scale testing of the Dow FILMTEC^{TM} 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).

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.

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, 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.

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. The ozofractionation columns were effective at removing PFOA and PFOS and precursors from influent wastewater, and subsequent polishing steps with engineered sorbent removed certain residual PFAS (Evocra 2017).

1.1.2. Emissions to soil

Recent research demonstrates that it is possible to remove PFAS from contaminated soil. The work conducted in the Royal Australian Airforce Base in Townsville (Australia)

shows that PFAS leachability can be reduced via in-situ immobilisation by more than 99%, using RemBind®, a powdered product that permanently binds up PFAS. This project demonstrated the way for the safe, sustainable, and economical management of PFAS contaminated soil (RemBind, 2019).

In addition, tests carried out in the Moose Creek Facility North Pole (Alaska) demonstrated that it is possible to thermally remediate contaminated soil. The analytical results showed the successful removal of regulated PFAS-compounds from contaminated soil to levels below the target clean-up levels set by the Alaska Department of Environmental Conservation (ADEC). The facility consisted of a British thermal unit per hour (Btu/hr) refractory-lined rotary kiln primary combustion unit that exposed waste material to temperatures of up to 815°C. In order to further control emissions, released gasses were treated in a secondary combustion unit with temperatures up to 1200°C, sufficiently high temperatures that break down residual PFAS to a non-detect level (Organic Incineration Technology, Inc. 2019).

1.2. Exceptional chemical stability enables high performance, stability, and durability for key applications

It should be recognised that for substances like fluorotelomers, the intrinsic property of chemical stability 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, fluorotelomer chemistry plays a key role in many strategic sectors in Europe. 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 – for more information on the uses, please refer to section 7.

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.

One should also consider the disruptive effects of restricting chemicals based on their persistence. This will not only curb a wide range of existing chemistries but will limit the innovative potential of industry to develop new applications in the future. In this context

it is important 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 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.

2. The "essential use" concept is not supported under REACH, and any potential consideration of this concept should only be applied according to well established criteria once the REACH restriction conditions are fulfilled.

To restrict a substance under Article 68 REACH, EU authorities have to demonstrate that the substance presents "an unacceptable risk to human health or the environment. on an EU-wide basis" Restrictions should be based on the risk of a substance associated with a given use and should only take place if an unacceptable risk has been identified by the authorities. Article 68 of REACH mandates the Commission to take into account the socio-economic impact of the restriction and the availability of alternatives, as two key elements essential for determining the content 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 forthcoming restriction on PFAS substances. However, it is worth noting that the concept of 'essential uses' is not defined under EU law. We would like to note that essentiality as a criterion for evaluating/restricting/authorizing substances under REACH could lead to restrictions of substances that do not represent a risk as other solutions exist to mitigate their emissions (e.g. chemicals used in closed systems). There are significant consequences to impose a scientifically unjustifiable restriction of all PFAS.

The essential use concept is used in the global Montreal Protocol agreement. The agreement is a phase out plan for production and consumption of ozone-depleting substances and it contains a methodology to allow the utilization of these substances for essential uses. Industry experience shows that the essential use methodology of the Montreal Protocol has been difficult to apply and not sufficiently clear as an objective in granting an essential use. We believe it is a methodology that is not applicable under the current REACH regulations and not to such a large chemical group as PFAS due to the large variation of chemical compositions within that group. Should the essential use concept be considered further, it should only apply once a proper risk-evaluation has been done according to the REACH requirements. Furthermore any further consideration of this concept should be based on the following principles:

- chemical safety on a life-cycle basis;

- the substance's ability to deliver critical functionality and output to the normal functioning of society;
- the substance's essentiality to the functioning of 'critical infrastructure' sectors for the benefit of society;
- regional and "sub-populational" differences to allow a holistic consideration of what is 'essential';
- 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.

2.1. The EU needs to ensure a manufacturing capacity for critical products

In the roadmap on the Chemicals Strategy for Sustainability, the European Commission highlights the strategic importance of a chemical production capacity and its potential for economic growth and job creation as part of a post COVID-19 recovery.

The experience during the COVID-19 crisis – e.g. issues sourcing personal protective equipment (PPE) – has demonstrated the need to be able to significantly increase its production capacity for critical products within short lead times by European industries. A rapid increase in production capacity can only be ensured with a robust domestic chemical industry.

It is worth noting that there is only one facility in Europe where the entire process of fluorotelomer production takes place, from initial telomerization to production of fluorotelomer-based products. This location therefore represents the only fully integrated EU facility to manufacture repellent products for Medical Barrier Fabrics and Face Mask Fabrics to protect against microbiological contaminants, including virus or bacteria. Although these applications could be regarded as essential, the upcoming restriction would put in jeopardy the only integrated fluorotelomer production facility in Europe as well as other fluorotelomer repellent product producers.

3. Any restriction measures need to be balanced against actual emissions and socio-economic implications.

As discussed, the forthcoming restriction aims at applying a precautionary grouping approach to phase out PFAS based on their high persistence.

The European Commission's Communication on the precautionary principle (EC, 2000) states that, when action is deemed necessary, measures based on such principle "must

not be disproportionate to the desired level of protection and must not aim at zero risk." The Communication also states that the application of the precautionary principle requires the following preliminary conditions:

(1) identification of potentially adverse effects,
(2) evaluation of scientific data available, and
(3) extent of scientific uncertainty.

We therefore believe that, in order to justify a restriction, a comprehensive quantitative assessment should be conducted to provide evidence that would support the claim that increasing and long-term exposure could reach a level of concern that could represent an unacceptable risk.

3.1. Emissions from fluorotelomer chemistry

C6 fluorotelomers and products made from them provide extensive protection for workers in a variety of work environments. These extend from those exposed to harsh weather conditions, durable and functional performance for medical gowns and drapes, filtration units used in ventilators and other breathing equipment, and the highest level of fire-fighting performance for chemical, petroleum and industrial sites. Scientific research on specific types of PFAS substances shows that current exposures and emissions to the environment from manufacture and use do not pose an unacceptable risk for human health.

For instance, in the textile sector, significant efforts have been conducted by the industry over the past years to reduce emissions from PFAS. 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 to be allowed to operate. A review of the BREF/BATs for the textile sector is underway, with specific provisions on C6 side chain fluorinated polymer (C 6 SFP) chemistry being developed.

This has helped optimise the use of C6 fluorotelomer treatments to support employers meet their duty of care and meet the requirements of standards such as EU 2016/425, ISO 14419 and EN 343 for durable oil and water repellency. A certain amount of abrasion during lifetime has been reported (Gremmel et al., 2016; Knepper et al., 2014), resulting in PFAS substances on textiles separating from the article and ending up being released to the environment. Nonetheless, these emissions have been shown to be minimal.

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, reducing the potential for emissions even further.

Another related example is the use of C6 SFPs in nonwoven substrates for medical applications. One major example is the use of medical barrier fabrics, for example surgical gowns, drapes, and masks. It will be vital to maintain access to these items in the future to respond to future medical situations, such as COVID-19. It will also be vital to have access to these technologies in the EU and not be reliant on imports from other continents.

Restricting the use of C6 SFPs will lead to increased imports from jurisdictions with less strict regulations, where long-chain PFAS (many of which are PBT substances, compared to short-chain substances which do not bioaccumulate) are still allowed. Due to a lack of sufficiently robust analytical methods, to detect the PFAS content of imported products, and a lack of resources among regulators for enforcement purposes, there is a significant risk of importing longer chain PFAS compounds.

Medical applications also include the C6 SFP-treated filtration units used in ventilators and other breathing equipment. Here too the C6 SFPs play a vital role in protecting medical staff and patients in a role that can only be played by fluorochemistry. Management of the treated items at end of life also ensures that emissions are kept to a very low level.

In this context it should be noted that C6 fluorotelomer chemistry fulfils a range of critical functions for society which cannot readily be substituted. The socio-economic cost of developing new alternative chemistries for all these applications would be enormous. Producers of fluorotelomers, represented in ATCS, have developed and are committed to using the emissions management techniques and technologies explained previously. Similar measures would need to be undertaken again, at significant cost, to ensure the proper stewardship of alternative chemistries.

3.2. Socio-economic implications

In order to ensure proportionality, the risks of the substances should be balanced against the associated costs and other socio-economic impacts of their restriction. A proper socio-economic assessment should therefore be conducted for the scope of products that would fall under the restriction.

One application which highlights the fundamental value of the fluorotelomer chemistry is in the area of fire-fighting based on aqueous film forming foams (AFFF). In their best estimate of total annual costs plus annualised one-off costs of transition, the EC / ECHA report into “The use of PFAS and fluorine-free alternatives in fire-fighting foams” proposes that these will range from € 100 - 200 million per year (p.175) with one-off costs running into € billions.

These huge replacement costs reflect the outstanding performance of fluorotelomer based foams which are unmatched by other technologies. It also emphasises their

importance in protecting the thousands of industrial locations and tank storage depots throughout Europe.

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 along with vapor suppression. 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. Additionally, one should note that fluorine free foams are not compatible with each other, requiring the use and stock of multiple types of foam. Therefore, establishing a potential sole source situation does not lend the flexibility needed for mutual aid or available restock at larger events. As a consequence, higher levels of foam and dilution water at added cost are required on site.

Requiring a technology change (from AFFF to FFF) will demand investment of several billions of euro in equipment and product by the EU chemical industry, the EU oil and gas industry and any EU company handling large volumes of flammable liquids. Adding these crippling costs with no demonstrated increase in fire protection as well as to reduce emissions by less than 1 t/a makes neither economic nor environmental sense.

An additional cost of using a non-fluorinated foam, which is an inferior product for class-B fires, would be the financial repercussions from slow or uncontrolled extinction of the fire and inferior vapour suppression that could result in preventable escalations of an event causing added injury, death, equipment destruction, downtime, evacuations and unforeseen, potential environmental disaster.

Best practices guidance for Class B firefighting foams, developed by some members of the ATCS, 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 fluorinated fire-fighting foams should not be used for training, testing and calibration purposes (Firefighting Foam Coalition, 2016; Fire Protection Association Australia 2017).

In each of these cases we have demonstrated that emissions are controlled and minimised throughout the life cycle of the applications. This reduces any possible environmental impact while enabling the unique attributes offered by fluorotelomer based C6 SFP products.

4. The call for evidence uses a new definition of PFAS substances and overestimates the number of PFAS in commerce.

Until recently, some, but not all, PFAS had been the focus of regulators for nearly two decades (Buck et al. 2011). The first non-polymer, long-chain perfluoroalkyl substance to be restricted was perfluorooctane sulfonate, PFOS (Annex I, Part A. Regulation (EU) 2019/1021 of the European Parliament and the Council), followed by perfluorooctanoic acid, PFOA (Commission Regulation (EU) 2017/1000). Additionally, long-chain (C9-C14) perfluorocarboxylic acids, such as perfluorononanoic acid, PFNA, and long-chain perfluoroalkane sulfonic acids, such as perfluorohexane sulfonate, PFHxS, are currently subject to restriction proposals under REACH after having been identified as Substances of Very High Concern (SVHCs).

Nonetheless, the regulatory focus is no longer limited to long-chain substances. Short-chain substances are now also subject to various initiatives under REACH, notably under this call for evidence on all PFAS. This call provides a new and broader definition of PFAS substances, under which any substance containing a CF_2 and CF_3 group would be included. As a result, more than the 4730 substances covered under the current definition (OECD, 2018) would be expected to be affected.

The ATCS believes that the proposed scope is not scientifically justified since it encompasses substances that vary widely in physio-chemical properties – including gases, liquids, and solids – and their health and environmental profiles. We therefore believe it is not accurate to make general statements about the health and environmental impacts of the proposed group.

In addition, it should be noted that certain groups covered under the current scope of the Call for Evidence are already addressed by targeted regulation. For instance, F-gases have been regulated by the Montreal Protocol (Kigali Amendment) on ozone-depleting substances, as well as by the EU F-Gas Regulation. We wish to highlight that this Call for Evidence seeks to address PFAS mainly due to their persistence, something which most F-gases are not.

4.1. Evolution of the PFAS definition

The term PFAS was first described and used by Hekster et al (2002 and 2003) as a perfluoroalkyl(ated) substance. Buck et al (2011) describes the scientific community also used PFC's in the 2000's for the same overall chemistry thereby creating further confusion for this group of substances.

For this reason, Buck et al (2011) further elaborated on the definition of PFAS for the group of perfluoroalkyl and polyfluoralkyl substances. Their goal was to create a unified lexicon. These authors defined PFAS as "aliphatic substances for which all hydrogen (H) atoms attached to at least one carbon atom (C) have been replaced by fluorine (F) atoms." For polyfluorinated species they would then contain the following structure: CnF2n+1-. In this case n = 1. For perfluoroalkyl substances, all of the H on C have been

replaced by F on the aliphatic substance from which they derived. This publication excludes aromatic compounds and compounds that have scattered multiple F atoms. It appears to also exclude refrigerants, blowing agents, F-gases etc. See Buck et al (2011) for full details.

ITRC in 2018 and updated April 2020 proposed a definition modification where a PFAS substance must include CnF2n+1- where n > 2.

OECD in 2018 (OECD 2018) further modified the PFAS definition to include CnF2n+1- where n = 3 or more. And they included a perfluoroalkylether moiety with 2 or more carbons (-CnF2nOCmF2m-, where n and m are equal or greater than 1). As a result, 4730 substances were included under this new definition of PFAS.

The present Call for Evidence further re-defines PFAS substances to include any and all "substances that contain at least one aliphatic -CF2- or -CF3 element" in its structure with no apparent exclusions. Therefore, this casts a significantly larger net on fluorine-containing compounds and affected sectors.

4.2. The amount of PFAS in commerce is vastly overstated

The list of 4730 PFAS chemicals was published in a 2018 OECD Report titled "Toward A New Comprehensive Global Database of Per- and Polyfluoroalkyl Substances (PFASs): Summary Report on Updating the OECD 2007 List of Per- and Polyfluoroalkyl Substances (PFASs)." Thereafter, the Report was cited by many to highlight and raise concern regarding the large, diverse, and expanding world of PFAS Chemicals in commerce and/or on the market.

In the 2018 OECD Report, the authors acknowledged they were trying to do a bottom up compilation of PFAS compounds from various global regulatory lists. The goal was to try to reflect what compounds were in commerce. This was not successful as the authors clearly noted. However, the 4730 compounds still ended up being perpetuated as "4730 Items in commerce" when in fact this is not true. The 4730 compounds is a compilation from lists and has no bearing whatsoever on what compounds are actually in commerce today. In addition, a more recent analyses indicate that the OECD list vastly overstates the number of PFAS compounds that are actually in commerce today. For example, in the US, the TSCA Inventory (one of the lists from which the OECD list was derived) includes approximately ~1200 chemicals that the US Environmental Protection Agency (USA EPA 2019) identifies as PFAS substances. However, a recent update of the TSCA Inventory revealed that only ~600 of the substances on the Inventory have been in commerce since 2006. Further analysis shows that, because of the phase-out of long-chain compounds in 2015, the actual number of PFAS substances in US commerce is substantially lower than 600.

Industry (the members of the Performance Fluoropolymer Partnership) has assessed the list of 4730 to identify substances that are in or related to products in commerce today, in 2020. The group is currently developing a manuscript (publication in preparation)

whereby these global manufacturers identify items in commerce today and classify them in the categories set forth in the original publication that established the nomenclature and terminology for per- and poly-fluoroalkyl substances (Buck et al. 2011) and in the categories presented in the 2018 OECD Report. This is a 'bona-fide bottom-up' current compilation of compounds in commerce that also includes intermediates, degradation products, etc. Upon completion of the current project, this industry group will show that the active list in commerce is hundreds not thousands of compounds which is more in line with the recent US EPA values noted above.

5. A ban of all PFAS opens the way for restrictions without proper risk justification.

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 criteria for the restriction initiative on all PFAS substances are persistency and potential accumulation in the environment; clearly not the criteria outlined in Article 68 of the REACH regulation for restriction.

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 persistent 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.

In the framework of Article 57(f) of REACH, the European Court of Justice (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 based on 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.

We understand that certain PFAS substances might fulfil the abovementioned criteria. However, this is not the case for all substances covered under the scope of the call for evidence. We therefore believe that the conditions for a restriction of uses of all PFAS substances are not met.

5.1. Alternative instruments and legal frameworks to REACH Restrictions for addressing issues related to PFAS

The ATCS has analyzed other regulatory management measures, including EU environmental legislation. It should be noted that a series of EU instruments and legal frameworks that could address the concerns related to PFAS and other substances covered under the scope of the call for evidence already exist and/or are under preparation.

As an alternative regulatory instrument to REACH restriction, 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 releases to the environment from facilities handling 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 to achieve the EU's zero-pollution ambition. This is a key opportunity for policymakers to also look at products treated or made with 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.

6. The availability of harmonised analytical methods should be a prerequisite to any regulatory action.

In addition to advancing BAT/BEP, 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.

ATCS members are contributing to the development of methods for the analysis of PFAS, including PFHxA in textiles with CEN (CEN 2020a; 2020b; 2020c). A method for other PFCAs and PFAS (29 analytes in total) in AFFF concentrates is in the final validation process (FFFC 2019).

ATCS members are aware of the ECHA's consultation on the analytical methods (including PFOA) and are considering a response to the consultation.

The table below summarises the main advantages and limitations of currently available analytical methods to monitor PFAS substances.

Table 1 – 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

Method/Technique	Advantages	Limitations/Issues
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
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

7. Fluorotelomer chemistry plays a key role in many strategic sectors in Europe.

7.1. Critical properties

Side-chain fluorinated polymers based on C6 fluorotelomers are both hydrophobic and oleophobic, featuring outstanding properties in terms of grease, water and oil repellence

and stain release properties including resistance to liquids and body fluids while minimizing the amount of fluorotelomer used.

While many different agents providing water-repellence are marketed (including wax-based repellents, resin-based repellents) none of these provide efficient repellence against oil, alcohol, and oil-based dirt.

7.2. Key applications

7.2.1. Woven medical textiles

Fluorotelomer chemistry is used in medical textiles – e.g. surgical gowns, drapes, or curtains – because of its water-, oil- and stain-repellence (Schellenberger et. al., 2019). These properties provide the chemical barrier necessary to protect healthcare personnel against contact with microbiological contaminants, including blood-bourne pathogens. FFP2/3 masks are one example of current relevance due to the COVID-19 epidemic, which will accompany global societies for the foreseeable future. Nonwovens for hygiene outside of clinical uses will also likely become increasingly more relevant where population densities rise and climate change forces wildlife more and more into human habitats or vice versa.

7.2.2. Textiles and nonwovens used in transport

Textiles and nonwovens treated with fluorotelomer-based products are also 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.

For example, treated nonwovens 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.

7.2.3. Outdoor technical textile applications

The EU has a strong high-performance textile industry, which relies on C6 fluorotelomer chemistry. There are certain niche applications for which no alternatives are available yet, such as outdoor professional and consumer apparel intended for adverse environmental conditions. Furthermore, treatment of textile with C6 fluorotelomer chemistry increases durability, extending the product’s lifetime and thus reducing textile waste.

7.2.4. Apparel (PPE) for Oil and Gas workers, law enforcement and military authorities, and emergency responders

This type of apparel is treated with C6 fluorotelomer chemistry to both prevent absorption of oils/fuels and provide protection against fire. As explained above, C6 has greater oil repellency on woven textiles than non-fluorinated repellents. Additionally, these substances do not provide oil repellency when applied to non-woven textiles. As a result, textiles treated with non-PFC can easily catch fire when used in these applications.

7.2.5. Class B fluorinated firefighting foams (AFFF)

This class of 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 rapid extinguishment and help to prevent re-ignition while better protecting firefighters working in the area as part of rescue and recovery operations. Fluorinated foams are proven on large scale events and have great versatility covering many variables with their well-established safety factor including different levels of aspiration, high temperature, wide range of fuel types, mutual aid compatibility, etc.

Fluorine-free firefighting (F3) foams, on the other hand, do not contain persistent fluoro-surfactants and play an important role in fire protection and training. However, they provide lower performance than either the legacy C8 or the so-called “modern” C6 foams. Typically, F3 foams do not provide the same fuel shedding, film forming characteristics, vapour sealing or burnback resistance, which can be vitally important to rapid extinguishment of fires in some applications, especially in the industrial and petrochemical fields (Fire Protection Association Australia, 2017). In these uses, F3 foams do not provide the necessary suppression of toxic vapors associated with crude oils or other petroleum-based products.

Additionally, F3 carry additional constraints for their use compared to fluorinated firefighting foams (Hinnant et al. 2017). F3 foams attract hydrocarbon fuels, require aspiration, need gentle application, and have difficulty with multiple fuel types and limited performance at high ambient temperatures. They are not compatible with each other, so introduce a major obstacle for mutual aid assistance. Unlike fluorinated foams, fire performance scalability from small qualifying fire tests to actual large fires has not been proven for fluorine free foams.

Furthermore, F3 foams have been shown to be an order of magnitude higher in short-term aquatic toxicity than C6 foams. Evidence suggests, when unsuited to the application, they are slower to extinguish volatile fuels, so more foam is likely to be used, increasing BOD (Biochemical Oxygen Demand) issues (Fire Protection Association Australia, 2017). Detailed risk assessments and duty of care reviews should be therefore undertaken before embarking on replacing fluorinated foams with alternatives to avoid compromising life safety and critical infrastructure protections.

7.2.6. Semiconductors/electronics

Fluorotelomer chemistry is used in the manufacturing of numerous electronic components, including as etching agents for wet and dry fluorine types for semiconductor manufacturing. When used in the intended applications, C6 fluorotelomer chemistry provides improved permeability and reduces particle adhesion onto silicon wafers.

7.2.7. 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, which enables the use of paper and cardboard as alternatives to plastics and plastic coatings. Any restriction would require a switch to plastics, laminated constructions, or silicones – materials which 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 European Commission is currently working on the revision of the Packaging Directive, which sets recycling targets for plastic packaging, 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.

7.2.8. Pulp-based repellent medical equipment

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).

In addition, due to its durable water and oil repellence, C6 fluorotelomer chemistry is used in high performance filtration and separation media. These media, which are protected against microbial contaminants and microbiological growth, are used in equipment intended for various safety critical sectors, such as hospitals, pharmaceutical transport, and medical devices. There are at present no viable substitutes capable of providing the required level of water and oil repellency.

7.2.9. High-performance air and liquid filtration and separation media

There are at present no viable substitutes capable of providing the required level of water and oil repellency for high-performance filtration and separation applications. 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.

In the energy industry, these filtration media are 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.

7.2.10. Metal plating

Many metal coating processes rely on the use of fluorotelomer based chemistry. Due to its specific properties, which allow it to be used in electroplating baths, fluorotelomer chemistry can be used for soft chrome plating, where other chemistries would not survive.

7.2.11. Paints and varnishes

Paints and varnishes in which C6 fluorosurfactants are used as additives are mainly intended for building materials. These coating products must display, amongst other properties, high durability, anti-block functionality, anti-orange peel capability, good open-time and recoatability. C6 fluorosurfactants provide further benefits as terrific wetting and leveling agents. There are no non-fluorinated alternatives that provide equivalent functionality and although downstream users have reported that alternatives based on C4 fluorotelomers are available, they display a lower performance and raise similar concerns regarding persistence.

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