FluoroCouncil
Global Industry Council for FluoroTechnology

18 February 2015

Submitted via online form at:
https://comments.echa.europa.eu/comments_cms/AnnexXVRestrictionDossier.aspx?substancename=Perfluorooctanoic acid

Re: **Annex XV Restriction Report: Proposal for a Restriction for Perfluorooctanoic acid (PFOA), PFOA salts and PFOA-related substances (17 October 2014)**

To Whom It May Concern -

The Global Industry Council for FluoroTechnology (FluoroCouncil) appreciates this opportunity to provide comments on the "Annex XV Restriction Report: Proposal for a Restriction for Perfluorooctanoic acid (PFOA), PFOA salts and PFOA-related substances" (PFOA restriction proposal) published by the European Chemicals Agency for public comment.

The FluoroCouncil is a global membership organization representing the world's leading manufacturers of fluoropolymers, fluorotelomers, and other fluorinated surfactants and surface property modification agents.[1] The FluoroCouncil has a fundamental commitment to product stewardship and, as part of its mission, addresses science and public policy issues related to FluoroTechnology, including PFOA and related long-chain substances.

All members of the FluoroCouncil were early adopters of the 2010/2015 PFOA Stewardship Program, the global partnership between the U.S. Environmental Protection Agency (EPA) and industry based on voluntary corporate goals to reduce human and environmental exposure to PFOA and higher homologues by globally eliminating those chemicals from facility emissions and product content by the end of 2015. The FluoroCouncil has also been focused on facilitating the successful transition from long-chain fluorinated chemicals, including PFOA and related long-chain substances, to alternative fluorochemistries at a global level.

For a broad range of applications, short-chain chemistry presents the only alternative providing the same performance properties. The transition to alternative short-chain chemistry is ongoing for downstream users, and even though not fully completed, the remaining economic cost of the transition will therefore be manageable. An effective restriction of PFOA and PFOA-related substances would be a useful tool for completion of this process.

[1] The FluoroCouncil's members are Archroma Management LLC, Arkema France, Asahi Glass Co., Ltd., Daikin Industries, Ltd., DuPont Company, and Solvay Specialty Polymers.

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In order to allow for an effective restriction, however, the following principles must be applied:

- Restriction should cover the target substances but not have consequences outside its intended scope.
- Threshold should be set on a level which eliminates the manufacturing, use and placing on the market of long-chain substances while still allowing manufacturing, use and placing on the market for the essential alternatives.
- The threshold must be compatible with standardised, robustly repeatable, analytical techniques that minimise false positives available in Member States to allow a proper enforcement of the restriction. In this regard, FluoroCouncil believes that multiple thresholds are essential with a clear distinction between PFOA and PFOA-related substances. Limits of quantification that are possible vary from product to product.

FluoroCouncil is of the view that the above mentioned principles are not applied in the draft restriction proposal, for the reasons elaborated in our response to the four specific information requests.

The threshold of 2 ppb applicable for all substances in scope and all types of products would mean a *de facto* ban of all short-chain alternatives and fluoropolymers made without PFOA. With current analytical technology, it would show false-positive results against "clean" products, and would even catch certain products that were made without fluorochemicals at all but were contaminated somewhere in the logistics chain, causing great reputational and economic damage to European industry. For more information on FluoroCouncil's concerns with the proposed threshold, see the more detailed comments provided in response to Question 4.

In addition, there needs to be further clarification on the scope in order to avoid the inclusion of substances not intended to be restricted.

If the restriction would be implemented as currently proposed, it would cause severe damage to the European manufacturing industry without any additional benefits for the environment and human health.

The FluoroCouncil commends Germany and Norway for developing the PFOA restriction proposal to build upon the progress of the Stewardship Program by regulating the manufacture, use, and commerce of PFOA and related long-chain substances. Below please find the FluoroCouncil's specific comments offered to improve the restriction proposal. Additional comments are provided in the online comment form in response to specific information requests in Questions 1-4 and attached as an appendix.

1. Derogation for the Production of Short-chain Alternatives

While the FluoroCouncil supports a ban on the manufacturing of PFOA and PFOA-related substances, we are concerned that the restriction proposal may also ban the manufacturing of short-chain fluorotelomer alternatives due to the unavoidable occurrence of a residual fraction of C8 substances – as an on-site isolated intermediate - during the production process of short-chain alternatives. FluoroCouncil welcomes the fact that the restriction dossier envisages a derogation for the production of short-chain alternatives under strictly controlled conditions (RMO1b). This

derogation for the production of short-chain fluorotelomer alternatives under strictly controlled conditions is needed; otherwise the restriction would result in the production of short-chain fluorotelomer alternatives in the EU having to stop.

2. DNEL Derivations

FluoroCouncil comments on the DNEL calculations in this section focused on the quality of the underlying study and the consistency with other available studies. We make no proposal for a specific DNEL at this time; however, as detailed in the below analysis, the DNEL derivation is not appropriate and extremely conservative. Of the studies selected for DNEL calculation, two were human health studies and three were toxicological studies in animals. The selected human health studies are inappropriate for DNEL derivation based on further comments below. The selected toxicological study by Macon et al. (2011) is based on a method that has not been validated for regulatory risk assessment, hence inappropriate for DNEL derivation. Other studies, including studies using humanized mouse models, did not support the finding by Macon et al. (2011) even though the dose level was substantially higher (Albrecht et al., 2013). The calculation for DNEL and human health exposure assessment are conservative. An important controlled phase I clinical trial in humans reported no effect on liver and kidney function at doses ranging from 50–1,200 mg, and other human exposure data for general population were not considered.

a) Current epidemiological evidence is limited and to date data is insufficient for DNEL derivation for PFOA and the health outcomes of concern.

A study by Steenland et al. (2009) is one of the two selected human health studies for DNEL derivation based on a positive association between PFOA and cholesterol increase. This is a cross-sectional study; therefore, causal inference is limited. A more recent review by the same first author (Steenland et al. 2010) concluded that to date data, mostly cross-sectional, are insufficient to draw firm conclusion that PFOA increases cholesterol. The strength of the association between PFOA and cholesterol varies by study, and there is no monotonic response. Studies with lower range of exposure levels have larger change in cholesterol per unit change in PFOA. For example, Nelson et al. (2010) reported 10 mg/dL change in cholesterol per 5 ng/mL change in PFOA in a cross sectional study of a representative sample of the U.S. population. On the other hand, Sakr et al. (2007) reported 1 mg/dL change in cholesterol per 1,000 ng/ml change in PFOA in a longitudinal study of occupational exposure. Besides, the associations between PFOA and increased cholesterol in humans contradict with animal studies from multiple species where PFOA decreases serum lipids, not increases (Lau et al. 2007). In addition, an important controlled phase I clinical trial in humans (Macpherson et al., 2010) was not included in this report in which oral dose equivalent to plasma PFOA level ranging from 30,000-600,000 ppb results in a reduction in LDL-cholesterol at the highest exposure level of PFOA.

The second study for DNEL derivation is by Fei et al. (2007) based on an inverse association between birth weight and PFOA. This is also a cross-sectional study; therefore, causal inference is limited. The authors reported a decrement of 10.6 g (95%

CI: 0.5-20.8) in birth weight per 1 ng/mL change in PFOA exposure. Given a wide confidence interval of the effect estimate, this cross-sectional study lacks precision. Two review studies that included the study by Fei et al. (2007) concluded that there is not sufficient evidence to suggest a possible decrement in birth weight associated with PFOA exposure (Steenland et al., 2010; Olsen et al., 2009). A more recent review study by Johnson et al. (2014) that was discussed in this report concluded there is "sufficient" evidence that developmental exposure to PFOA reduces fetal growth, but do not cite data sufficient to this conclusion. These authors reviewed 9 studies in which 7 (80%) of them are cross-sectional studies. Results from 5 (60%) of these 9 studies were not statistically significant, which included two recent studies that were not included in the two previous reviews, a nested case-control study by Whitworth et al. (2012) and a cross-sectional study by Chen et al. (2012). This review did not evaluate the pharmacokinetics of PFOA among pregnant women. The inverse association between birth weight and PFOA reported in the current literature may be confounded by maternal glomerular filtration rate (Morken et al., 2014), as mentioned in the report. In addition, the review approach by Johnson et al. (2014) is a new method, and its utility has not been validated for different environmental chemicals or for regulatory risk assessment.

Even if these selected health outcomes are proved to be causal, they are not clinically significant. In the study by Fei et al. (2007), a decrement of 10.6 g (95% CI: 0.5-20.8) in birth weight per 1 ng/mL change in PFOA exposure was reported. However, this study did not find the same association for low birth weight (LBW; <2,500 g), a significant clinical outcome that has direct consequences for infant mortality and morbidity compared to that of birth weight (Wilcox 2001). In a community-based study with high exposure to PFOA, Savitz et al. (2012) did not find a statistically significant association between 100 ng/mL increased in PFOA exposure and term LBW. Birth weight is measured on a continuous scale; therefore, any moderate-size studies would have sufficient statistical power to detect small decrements, and the results reflect only the normal distribution range of birth weight (Savitz, 2007).

Steenland et al. (2009) reported 11 mg/dL change in cholesterol per 340 ng/mL change in PFOA among workers. However, in another occupational cohort study including 3 different manufacturing sites, Olsen et al. (2007) did not find any statistically significant association between PFOA exposure and total cholesterol (≥ 200 mg/dL) or low-density lipoproteins (LDL≥130 mg/dL). Olsen et al. (2007) expressed total cholesterol and LDL based on clinical identification of metabolic syndrome in their study; therefore, the study has the advantage of addressing the significant clinical implication of the results. In addition, PFOA is not lipophilic, and any potential mechanism by which PFOA might be related to cholesterol in humans is not known (Steenland et al., 2009).

Taking all these together, the current epidemiologic evidence is limited and, to date, data is insufficient for DNEL derivation.

b) A selected toxicological study for DNEL derivation by Macon et al. (2011) is based on a method that has not been validated for regulatory risk assessment.

Although the mammary gland effect is important, this effect has only been reported in mice and not rats or primates. Use of the LOAEL dose descriptor (0.01 mg/kg/d; mammary gland development) and the corresponding internal concentration (285 ng/mL) from Macon et al. (2011) for DNEL derivation is inconsistent with another key risk assessment from the US EPA (February 2014, draft). The U.S. EPA's review of the human health effects of PFOA, which will inform its safe drinking water guidance, does not support the use of the Macon et al. study in consideration of its point of departure in determining a RfD due to the lack of evidence in other studies such as Albrecht et al. (2013) (U.S. EPA (2014)). In order to calculate a more appropriate DNEL, a thorough review of all toxicological endpoints should be conducted.

The findings of Macon et al. (2011) are inconsistent with those of White et al. (2009), which reported effects at a much higher dose level (≥3 mg/kg), and Albrecht et al. (2013), which found no differences in the average length of mammary gland ducts and the average number of terminal end buds per mammary gland per litter in female pups following a maternal dose of 3 mg/kg.

Based on these differences among three researchers, and the fact that this effect has not been reported in other species, using the LOAEL from Macon et al. (2011) for derivation of DNEL is invalid. The study by Albrecht et al. (2013) is particularly notable, since that study examined mice with a humanized PPAR alpha receptor. The lack of effect in the humanized mice, as well as the lack of effect in the wild type mice, indicates that using the Macon et al. (2011) study to calculate a DNEL is not appropriate.

c) Rodent studies are not relevant for DNEL derivation for PFOA for liver and kidney function endpoints.

As mentioned above, a controlled phase I clinical trial in which humans were dosed orally with 50 - 1,200 mg equivalent of PFOA given once per week resulted in nominal plasma PFOA levels ranging from 30,000 – 600,000 ppb (Macpherson, 2010). Even at these elevated plasma concentrations there were no changes in normal liver function and kidney function. These data indicate that the rodent biological response is greatly exaggerated relative to the human biological response and calls into question the results of the DNEL calculations and their relevance to humans.

d) DNEL derivation for human studies is inappropriate.

As discussed above, evidence from human studies on PFOA is limited for DNEL derivation. Even if there is sufficient evidence from human studies, the approaches for DNEL derivation for human studies are conservative. The DNEL derivation for increase in total cholesterol and low density lipid protein (Table B.5-6) is based on human adults >18 yrs (Steenland et al., 2009). The assessment factors (AFs) applied for the intra-species difference of 6 for general population and 3 for workers are extremely conservative since the study is representative of the workers. The AF of 3 for workers was chosen for workers based on the fact that this subpopulation does not cover the very young, the very old or the very ill. Worker subpopulation would normally not include the

very young (<18), the very old or the very ill; therefore, an AF of 1 is recommended for workers. The AF for general population is typically 2 times that of the worker. This would result in the sum AF of 3 for workers and 6 for the general population instead of 9 and 18, respectively.

The DNEL derivation for decrease in foetal birth weight (Table B.5-7) is based on human adults >18 yrs (Fei et al., 2007). The assessment factors (AFs) applied for the intra-species difference of 6 for the general population is extremely conservative since the study is representative of the general population. Therefore, no assessment factor is needed for the general population or the worker. This would result in sum AF of 3 for both workers and general population instead of 9 and 18, respectively.

e) Human health exposure assessment is inappropriate.

The exposure estimates from both external dose and internal dose approaches are based on PFOA manufacturing processes (Kaiser et al., 2010) which do not reflect the current exposure scenario in the EU where there is no PFOA manufacturing facility as indicated in the Dossier. Therefore, the exposure estimate for PFOA manufacturing workers is irrelevant in the EU.

If applied, exposure estimates based on manufacturing processes only reflect an extreme worst case exposure scenario, and the exposure assessment approaches are conservative (Section B.5.3.2.1, Table B.5-10). Kaiser et al. (2010) indicates that waste sumps should be kept above pH 7 to avoid the vaporization of PFOA; therefore, the monitoring data from the sump pump area with pH adjusted to 7 (0.001 mg/m^3) would be a reasonable worst case exposure scenario for PFOA manufacturing today. In addition, workers would not be expected to spend 6 hrs/day standing near the sump, and the concentration would dissipate as one moves away from the sump assuming adequate ventilation in the processing areas. Assuming a worst case scenario of 4 hrs standing near the sump (0.001 mg/m^3) with an inhalation rate of 1.4 m^3/hr, the equivalent intake from inhalation of occupational air is 0.006 mg/day (or 86 ng/kg bw/day) which is considerably less than the range of 490-7900 ng/kg bw/day stated. In addition, arithmetic mean of serum/plasma concentrations was used for exposure estimate instead of geometric mean which is less influenced by extreme values. For example, if geometric mean of serum/plasma concentrations (1,130 ng/mL) was used for Decatur and Antwerp locations (Olsen et al, 2003), the equivalent overall mean intake of PFOA is 131 ng/kg/day which is less than half of the 298 ng/kg/day stated.

f) Other available biomonitoring data for general population were not considered.

Biomonitoring data for general U.S. and Canadian populations were not considered for human exposure assessment. In the U.S., there is a declining trend of PFOA exposure among the general population from 1999 to 2010 (U.S. DHS, 2009). For the 2009-10 survey with the highest PFOA exposure level, the geometric mean and 95th percentile for PFOA are 3.07ng/mL and 7.5 ng/mL, respectively. Even at the 95th percentile of this

highest exposure level for PFOA, it is still lower than the high internal serum value (21 ng/mL) used to calculate the RCR for general adult population (Table B.5-15).

Canada has a similar biomonitoring program as in the U.S., beginning in 2007 (Health Canada, 2013). For the 2009-11 survey, the geometric mean and the 95th percentile for PFOA are 2.5 ng/mL and 5.5 ng/mL, respectively.

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p. 113-116; Tables B.5-12 – B.5.14: Please consider including human biomonitoring data and trends from Canada and the USA:

Canadian Health Measures Survey 2 (CHMS 2): http://www.hc-sc.gc.ca/ewh-semt/contaminants/human-humaine/index-eng.php

Assembly of First Nations [AFN] – 2013: First Nations Biomonitoring Initiative - National Results (2011): http://www.afn.ca/index.php/en/news-media/latest-news/AFN-Study-Tracks-Contaminants-in-First-Nation-Population

National Report on Human Exposure to Environmental Chemicals (NHANES). Updated data tables for the 2011-2012 NHANES data have been published in August 2014: http://www.cdc.gov/exposurereport/

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Thank you for your consideration of these comments. Please contact me at +1-202-249-6737 or jessica_steinhilber@fluorocouncil.com with any questions.

Sincerely,

Jessica S. Bowman

Jessica S. Bowman (Steinhilber)
Executive Director

APPENDIX

FluoroCouncil Responses to Specific Information Requests

Question 1

FluoroCouncil member companies believe that they have introduced alternatives, based on short-chain chemistry, that are suitable for substantially all applications. Similarly, FluoroCouncil member companies have developed processing aids alternatives allowing for the manufacturing of fluoropolymers without PFOA. Based on our understanding, absent short-chain chemistry, there are broad industrial sectors that do not have acceptable alternatives.

Since the year 2000, this industry has seen an increased effort in developing new products that can deliver the same performance as the products they replace. For example, in 2006 eight chemical companies joined the global voluntary US EPA Product Stewardship Program [http://epa.gov/oppt/pfoa/pubs/stewardship/index.html] committing to phasing-out of PFOA, precursor chemicals that can break down to PFOA, and related higher homologue chemicals. FluoroCouncil member companies invested over €500 million in the development of alternative products that offer the same high-performance benefits with improved environmental and human health profiles (See, *e.g.*, Environ report, available at http://fluorocouncil.com/PDFs/Assessment-of-POP-Criteria-for-Specific-Short-Chain-Perfluorinated-Alkyl-Substances.pdf). The investments also include the deployment of state-of-art emission control equipment to minimize any potential impact on workers and the environment. The new fluorinated alternative offerings went through extensive testing and qualification steps in the value chain and gained market acceptance.

In addition, FluoroCouncil member companies have engaged in an extensive dialogue with downstream users to encourage the application of best environmental practice and the use of best available technologies when applying the alternatives. Considering all efforts taken to deploy the alternatives, the total cost to the value chain can be estimated as many multiples of that investment.

In parallel, non-fluorinated alternatives entered the market but, according to feedback from our downstream users, these do not bring all the unique performance attributes of fluorinated products and can only be used in a limited number of non-demanding applications.

The table C.1-1 lists non-fluorinated alternatives for several industry branches, such as: construction, fire-fighting, textile, polymerization processing aids. Non-fluorinated alternatives have particularly been promoted for use in textiles and firefighting foam. However, only the fluorinated alternatives are fully assessed while the non-fluorinated alternatives are only listed as "exist". We would suggest that the authorities perform a full assessment of all available alternatives according to the REACH guidance document. Data on availability, functionality, toxicology and environmental impact, and economic feasibility of non-fluorinated alternatives are available and should be taken into account in the assessment of alternatives to PFOA and PFOA-related substances.

Regarding the assessment of alternatives, substantial scientific data clearly shows that 6:2 FTOH, the short-chain methacrylate and acrylate and short-chain PFCAs, such as PFHxA are not

bioaccumulative in aquatic ecosystems, For example, PFHxA has been shown to rapidly eliminate in multiple mammalian species and is not detected in the vast majority of human biomonitoring studies conducted. (Martin et al., 2003a,b; Conder, et al., 2008; Russell et al., 2013) These facts show unequivocally that short-chain PFCAs are very different from PFOA in their biology.

In addition, we would encourage authorities to take account of a report conducted by ENVIRON International Corporation evaluating the persistent organic pollutant (POP) characteristics of several short-chain fluorinated chemicals. The conclusions of the report read as follows:

"Based on the data reviewed for each substance (i.e., the raw materials, the commercial product, and the potential degradation products), none of the substances meet all of the criteria required to be classified as a POP and none of the substances meet more than one criterion. […] In the case of the Methacrylate Polymer, although there was very little pertinent data, because polymer molecules in general are too large to cross biological membranes, they are of low toxicity, and would, therefore, not be expected to trigger the toxicity criterion for identification of a POP. More data were available for the fluorotelomer raw materials (i.e., 6:2 FTOH, 6:2 FTAC, and 6:2 FTMAC) and their degradation product, PFHxA. While PFHxA may persist in the environment, PFHxA, 6:2 FTOH, 6:2 FTAC, and 6:2 FTMAC are rapidly metabolized and eliminated from mammalian systems. None of these materials appear to bioaccumulate or biomagnify based on laboratory data and available field monitoring data, and none show severe toxicity of the types that would warrant designation as POPs. Lastly, although 6:2 FTOH may be subject to long-range atmospheric transport, 6:2 FTAC and 6:2 FTMAC are not likely to be transported long distances in the environment. Additional data are necessary to determine if PFHxA meets the Annex D 1 (d) (ii) persistence criteria based on concentrations of "potential concern" in remote environments."

Therefore, to state that the short-chain PFCAs "differ only in the number of fluorinated carbon atoms" (p. 129) from PFOA is not supported by the available scientific data.

Relevant references:

- ENVIRON, 2014. "Assessment of POP Criteria for Specific Short-Chain Perfluorinated Alkyl Substances", 3, available here: http://fluorocouncil.com/PDFs/Assessment-of-POP-Criteria-for-Specific-Short-Chain-Perfluorinated-Alkyl-Substances.pdf
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Furthermore, in table C.2.1, properties of an organic acid are compared to properties of an alcohol. It would be more appropriate to compare the alcohols 8:2 FTOH to 6:2 FTOH, and the acids PFOA to PFHxA.

Question 2

Because leading manufacturers proactively and voluntarily prompted the phase out of PFOA and related long-chain chemicals years before this restriction proposal, significant research, development, and capital expenditures associated with the alternatives have already been invested. While these expenditures have already been made and, therefore, will not be impacted by this proposal, it is important that the total costs associated with this transition are recognized.

FluoroCouncil member companies have invested over €500 million of R&D and capital expenditures into the development of alternative polymerization aids and short-chain products and emission control technology. This figure does not include the transition and qualification costs for downstream users to replace PFOA and its related substances, which varied significantly up to over €1,000,000 per use per company, depending on the application. While the FluoroCouncil cannot provide specific costs per use, we believe the total costs to downstream customers for testing, recalibration, etc. are many times greater than the investment made by FluoroCouncil member companies.

It is important that the proposal portrays the full costs associated with the transition to alternatives to PFOA and related chemicals, even if all of those costs will not be an outcome of the proposed restriction because industry worked proactively to address these chemicals of concern in advance of regulation. The transition to alternative short-chain chemistry is ongoing for downstream users, and even though not fully completed, the remaining economic cost of the transition will therefore be manageable. An effective restriction of PFOA and PFOA-related substances would be a useful tool for completion of this process.

It is critical that thresholds are set at levels allowing the use of fluorinated alternatives, and yet preventing the placing on the market of articles treated with long-chain chemistry as well as unprocessed fluoropolymers manufactured with PFOA. The currently proposed single threshold of 2ppb covering PFOA and PFOA-related substances would severely limit the use of fluorinated alternatives and therefore lead to a demand for derogations for a majority of uses from the restriction. To the best of our knowledge, there exist no other alternatives providing the required performance.

Furthermore, contrary to the assumption made in the restriction dossier on page 166, the current restriction proposal will only induce change for fluoropolymer dispersions that are shipped to Europe in an unsintered form. Therefore, further action needs to be taken to ensure that fluoropolymers made with PFOA outside Europe, are not allowed into the EU market. Such actions are needed to eliminate the EU demand for fluoropolymers made using PFOA, which remain the major sources of global environmental releases of PFOA. One option could be to require documentation confirming that PFOA was not used in the production.

With reference to the substances listed in Appendix B.1, FluoroCouncil member companies are committed to phase out the use of these substances by the end of 2015. Some of these (8:2

FTOH, 8:2 FTAC, and 8:2 FTMAC) are commonly used in the manufacture of long-chain fluorinated polymers and will most probably continue to be used by non-FluoroCouncil members mainly in China, India and Russia.

Question 3

C_7F_{15}-COOH is PFOA and is already covered by the restriction (same CAS Number 335-67-1).

There has been no showing that any other C7 substance can degrade to PFOA and, therefore, they should be outside the scope. C8F17- as a structural element, including its salts, degrades to PFOA and should remain in scope.

As an additional comment, C8F17-CF2-X' describes fluoropolymers that are end capped with fluorine. If the polymer chain has a different terminal group, then the formula for those fluoropolymers would not start with C8F17.

In order to avoid any confusion, we would suggest that all fluoropolymers with fluorine in their backbone be expressly excluded from the scope of the restriction dossier.

Question 4

While it is possible to identify products where a 2 ppb threshold for PFOA-only could apply, FluoroCouncil has not identified any applications where this threshold could be applied for PFOA-related substances. A single threshold cannot be applied to all fluoropolymer and fluorotelomer products. These products may have a range of detection and quantification limits, which could span several orders of magnitude. As a result, thresholds for substances within scope must be developed on a product by product basis, such as:

- Short-chain products (intermediates and fluorinated polymers mixtures)
- Articles treated with short-chain products
- Fluoropolymers

The reasons why a 2 ppb threshold for PFOA and PFOA-related substances is not acceptable are:

- A threshold of 2 ppb applicable for all substances in scope and all types of products would mean a de facto ban of all short-chain alternatives and fluoropolymers made without PFOA.
- Under current state-of-art manufacturing practice, it is not possible to ensure a level below 2ppb for all substances to be restricted.
- The threshold should be set at a level of quantification that must be applicable and enforceable by Member States.
- Analytical methods are matrix dependent.

- Such a low threshold would increase probability of encountering false positives.
- As we have been informed by one of our customer groups, for articles in commerce, trying to certify an absence of contamination at the 2 ppb level would be impossible.
- No single methodology available to detect such a low threshold for all substances within the scope of the dossier. However, of the 16 methods listed in table A.E.2-1 only 5 have a LOQ of less than 2 ppb, despite the quoted results relating only to PFOA. In addition, it is misleading to compare the work needed to develop standardized methods for PFOA to the method under development for PFOS where the threshold is substantially higher (i.e. 100.000 times higher in articles).
- The proposed threshold is inconsistent with approaches proposed in Norwegian PFOA restriction and existing PFOS POP restriction.

The proposed threshold would result in a significant economic burden for authorities and on the value chain for implementation and ongoing monitoring.FluoroCouncil supports the development of a European standardized method for the enforcement of the restriction.

Given the current lack of data on the different substances in scope for the various matrices, it is not possible to identify suitable thresholds at this point.

FluoroCouncil will continue to assess the possibility to define workable thresholds that would allow an efficient restriction of PFOA (and related substances) without limiting the use of short-chain alternatives.

FluoroCouncil members aim to submit further information within the six months period of the public consultation.