



4 December 2019

Dear Sir/Madam,

Thank you for the opportunity to provide feedback on the [draft](#) amendment of Annex I to Regulation (EU) 2019/1021 of the European Parliament and of the Council as regards the listing of perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds.

Overall, the signing organizations are pleased to see the tightening of the EU PFOA regulation to reflect the PFOA listing in the Stockholm Convention which was more rigorous in terms of allowed derogations. However, we have concerns with some of the proposals in the draft PFOA regulation (see details and supporting references in Annex A).

The proposed unintentional trace contaminant level of 25 ppb is not consistent with sensitive modern analytical methods or updated scientific information on the extreme toxicity of PFOA and actions taken by EFSA to sharply lower permissible intakes of the substance. This level should be set substantially lower at 2 ppb.

The proposed derogation for PFOA use in photographic coatings applied to films should not be granted because it is an obsolete use of PFOA which has been replaced by digital imaging – even in developing country uses such as healthcare.

Alternatives exist for PFOA uses in textiles including in healthcare and therefore the proposed derogation for PFOA use in textiles for oil- and water-repellency should not be granted. In addition, it would be ironic to provide a derogation for the purpose of worker protection for a substance associated with diagnosed high cholesterol, ulcerative colitis, thyroid disease, testicular cancer, kidney cancer and pregnancy-induced hypertension in humans.

The industry rationale for proposing exemptions for PFOA use in invasive and implantable medical devices was that unnamed medical devices might contain PFOA as a result of its use to make PTFE. However, modern methods of PTFE manufacturing have eliminated use of PFOA as a surfactant and zero-PFOA PTFE medical products are approved and widely available on the market. For these reasons, no derogation for these uses should be granted.

None of the proposed derogations for manufacture of PTFE and PVDF were recommended by the Stockholm Convention POPs Review Committee. Furthermore, at the 9<sup>th</sup> Conference of the Parties, one of the strongest opponents of these proposed exemptions was FluoroCouncil – an industry association of manufacturers of fluorinated substances. For these reasons, this derogation should not be granted.

Use of PFAS-containing fire-fighting foams is a direct route into the environment that has already contributed to contamination of soil, groundwater, drinking water, humans and the environment in the EU and in countries all over the world. Due to the costly remediation required and the presence of alternative fluorine-free firefighting foams and non-combustion methods of destruction, these derogations should not be granted.

No derogation for PFOA use for pharmaceutical products is currently present in Annex XVII to Regulation (EC) No 1907/2006, indicating that none was required. The new PFOA law should not open a new loophole, especially since it involves PFOA (a PFOA-related substance) and because a wide variety of pharmaceutical porous carriers are approved and on the market.

More detailed comments on these proposals can be found in Annex 1. Thank you for consideration of our views.

Yours faithfully,

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# Annex 1 Detailed comments on the draft amendment of the listing of perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds

## Proposed unintentional trace contaminant level

The draft amendment includes a proposal to exempt concentrations of PFOA or any of its salts equal to or below 0,025 mg/kg (0,0000025% by weight or 25 ppb) where they are present in substances, mixtures or articles. However, the restriction dossier developed by Germany and Norway submitted in 2014 puts forward a threshold of 2 ppb for PFOA and PFOA related substances in order to ensure that these substances were not intentionally applied in these uses. The final limit of 25 ppb that was finally adopted by the Commission was the result of the RAC and SEAC Committees who, following claims by industry stakeholders on the lack of availability of EU standardized testing methods, changed their opinion on the scope of the PFOA restriction proposal. However, the dossier included a summary of test methods showing that it was possible already at that time to achieve quantification limits for PFOA and some PFOA-related substances of 2 ppb.<sup>1</sup> It was also noted in the dossier that, “Given that methods exist, the absence of an EU standard analytical method is not considered as a hindrance to the enforceability of the proposed restriction.” In addition, at least one new PFOA EU standard is under development for construction products and includes “...analytical methods for all matrices except metals.”<sup>2</sup> A 2015 study of PFAS in consumer products obtained limits of quantification for PFAAs such as PFOA of 0,1 – 0,5 ppb – well below the proposed 25 ppb limit and consistent with the 2 ppb limit proposed by Germany and Norway.<sup>3</sup>

During the past years, scientific evidence for effects of exposure to PFOA of increasingly low concentrations have emerged. This has led the European Food Safety Agency (EFSA) to recently establish a Provisional Tolerable Weekly Intake (TWI) level for PFOA at 6 nanograms per kilogram of body weight per week. EFSA has also expressed concerns that a large portion of the European population already exceeds these new safety levels.<sup>4</sup> A 2018 study of mother-child cohorts found that a considerable proportion exceeded the HBM1 value for PFOA established by The Human Biomonitoring Commission of the German Federal Environment Agency.<sup>5</sup> Also, the recent assessment from the HBM4EU project under European Union's Horizon 2020 research and innovation programme estimated that median intake levels for PFOA range between 19 ng/kgbw/d (Norway) and 37 ng/kgbw/d (Denmark)<sup>6</sup>, i.e. already above the TWI levels.

PFOA is a persistent, bioaccumulative and toxic chemical with numerous direct and indirect sources of PFOA and PFOA-related compounds that contribute to concentrations of PFOA in the environment. Direct sources include releases from the production of the raw substance, during the processing, use and disposal of the chemical and of products containing the chemical. Indirect releases occur due to the formation of PFOA from PFOA-related substances that are released to air and wastewater during manufacture of the substances themselves, from side-chain fluorinated polymers and during use and disposal of consumer articles treated with PFOA-related compounds.<sup>7</sup> It is

1 See Annex E, Table A.E.2-1: Example of analytical methods for measurement of PFOA in articles and mixtures <https://echa.europa.eu/documents/10162/e9cddee6-3164-473d-b590-8fcf9caa50e7>

2 [https://www.techstreet.com/standards/bs-pd-cen-ts-17331-2019?product\\_id=2073089#jumps](https://www.techstreet.com/standards/bs-pd-cen-ts-17331-2019?product_id=2073089#jumps)

3 Kotthoff M, Muller J, Jurling H, Schlummer M, Fiedler D (2015) Perfluoroalkyl and polyfluoroalkyl substances in consumer products, Environ Sci Pollut Res 22:14546-14559

4 EFSA CONTAM Panel (EFSA Panel on Contaminants in the Food Chain), Knutsen HK, Alexander J, Barregard L, Bignami M, Brüschweiler B, Ceccatelli S, Cottrill B, Dinovi M, Edler L, Grasl-Kraupp B, Hogstrand C, Hoogenboom LR, Nebbia CS, Oswald IP, Petersen A, Rose M, Roudot A-C, Vleminckx C, Vollmer G, Wallace H, Bodin L, Cravedi J-P, Halldorsson TI, Haug LS, Johansson N, van Loveren H, Gergelova P, Mackay K, Levorato S, van Manen M and Schwerdtle T, 2018. Scientific Opinion on the risk to human health related to the presence of perfluorooctanesulfonic acid and perfluorooctanoic acid in food. EFSA Journal 2018;16(12):5194, 284 pp. <https://doi.org/10.2903/j.efsa.2018.5194>

5 Haug LS, Sakhi AK, Cequier E, Casas M, Maitre L, Basagana X, Andrusaityte S, Chalkiadaki G, Chatzi L, Coen M, de Bont J, Dedele A, Ferrand J, Grazuleviciene R, Gonzalez JR, Gutzkow KB, Keun H<sup>1</sup>, McEachan R<sup>1</sup>, Meltzer HM, Petravičienė I, Robinson O<sup>1</sup>, Saulnier PJ, Slama R, Sunyer J, Urquiza J, Vafeiadi M, Wright J, Vrijheid M, Thomsen C (2018) In-utero and childhood chemical exposure in six European mother-child cohorts, Environ Int 121 (Pt1) 751-763

6 Deliverable Report AD12.5 WP 12 - From HBM to exposure Deadline: December 2018 <https://www.hbm4eu.eu/deliverables/>

7 Risk Profile Pentadecafluorooctanoic acid (PFOA, Perfluorooctanoic acid), its salts and PFOA-related compounds.

therefore crucial to put strong provisions in place to keep exposure to a minimum. A limit of 2 ppb would help minimize environmental releases of PFOA at all stages of its life-cycle, e.g. at manufacturing sites, during use of mixtures and articles, and during waste management.

The trace contaminant level should also take into consideration a recent assessment from the HBM4EU project under European Union's Horizon 2020 research and innovation programme. There it was estimated that median intake levels for PFOA range between 19 ng/kgbw/d (Norway) and 37 ng/kgbw/d (Denmark)<sup>8</sup>, i.e. already above the TWI levels. In addition, PFOA is a persistent, bioaccumulative chemical. It is therefore crucial to put strong provisions in place to keep exposure to a minimum.

A 2 ppb limit would also support a phase out of all PFAS, which is necessary for the transition to a non-toxic circular economy in the EU. The FluoroCouncil states that the *“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.”*<sup>9</sup>

Finally, an exemption is proposed for concentrations of any individual PFOA-related compound or a combination of PFOA-related compounds equal to or below 1 mg/kg (0,0001 % by weight) where they are present in substances, mixtures or articles. It should be noted that a PFOA-related substance is any substance that degrades to PFOA.

**Therefore, the limit for PFOA-related compounds should be the same as for PFOA itself, i.e. 2 ppb**

### **Proposed derogation for photographic coatings applied to films**

In Decision SC-9/12, the Stockholm Convention includes an exemption for production and use of PFOA for photographic coatings applied to films.

This is an obsolete use of PFOA since it has essentially been replaced by digital imaging – even in developing country uses such as healthcare. As noted by the International Atomic Energy Agency (IAEA) and the World Health Organization (WHO), medical diagnostic imaging began in the 1970s and the momentum has grown to the extent that *“digital image management is currently the preferred method for medical imaging.”*<sup>10</sup> IAEA and WHO note that the rapid adoption of digital technology in healthcare results from *“efficiencies inherent in digital capture, storage and display and the competitive cost structures of such systems when compared to alternatives involving film.”*<sup>11</sup> Some drawbacks of film-based imaging include use of chemicals that require careful handling, certain storage and use conditions, and environmentally sound waste management. Advantages of digital imaging in healthcare noted by IAEA and WHO include<sup>12</sup>:

- (1) Efficient information dissemination and increased access to images.
- (2) Significantly better dynamic range of digital image acquisition systems.
- (3) Improved reliability, error free retrieval of images without loss.
- (4) Ease of use.
- (5) Potential for multimodality, composite imaging.
- (6) Retention of dynamic diagnostic information.
- (7) Simultaneous transmission and display of images to multiple geographical areas.
- (8) Image manipulation and processing, feature extraction and enhancement.
- (9) Ease of interaction between specialists, e.g. between radiologists and referring physicians.
- (10) Expertise in subspecialties of diagnostic imaging can be widely disseminated.

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Persistent Organic Pollutants Review Committee September 2016 ([UNEP/POPS/POPRC.12/11/Add.2](#))

8 Deliverable Report AD12.5 WP 12 - From HBM to exposure Deadline: December 2018

<https://www.hbm4eu.eu/deliverables/>

9 FluoroCouncil Comments on the Annex XV Restriction Report, February 2015

<https://fluorocouncil.com/wp-content/uploads/2017/02/PFOA-Restriction-Dossier-Comments.pdf>

10 IAEA, WHO (2015) Worldwide implementation of digital imaging in radiology, IAEA Human health series No. 28, <http://www-pub.iaea.org/MTCD/Publications/PDF/Pub1647web.pdf>

11 IAEA, WHO (2015) Worldwide implementation of digital imaging in radiology, IAEA Human health series No. 28, <http://www-pub.iaea.org/MTCD/Publications/PDF/Pub1647web.pdf>

12 IAEA, WHO (2015) Worldwide implementation of digital imaging in radiology, IAEA Human health series No. 28, <http://www-pub.iaea.org/MTCD/Publications/PDF/Pub1647web.pdf>

- (11) Studies are available to authorized viewers immediately after image acquisition.
- (12) Examination sequencing and tailoring and the integration of diagnostic data are possible.
- (13) Elimination of environmental problems caused by film-based imaging.

While established companies making film products claim that price points dictate the ability of developing countries to use digital technologies, in practice developing countries are leapfrogging over the film stage and rapidly adopting digital technology. In fact, some physicians note that instead of viewing digital technology as too high-tech for developing country settings, digital imaging in particular allows for transfer over long distances thus permitting advice and diagnosis that otherwise would not be available.<sup>13</sup>

Technology-based mobile health is rapidly increasing in developing countries.<sup>14 15 16</sup> For example, the entire healthcare system in Gabon is rapidly becoming digital.<sup>17</sup> Furthermore, alternatives to instruments using film are being rapidly adopted. For example, 3D digital mammography systems are already available across South Africa.<sup>18</sup> In Bolivia, digital photos are used as an appropriate tool for dietary assessment.<sup>19</sup> In rural Kenya, mobile digital x-ray equipment serves patients that cannot travel to Nairobi for this service and the images are uploaded into the patient's electronic medical record.<sup>20</sup> In Latin America, the market for digital dental x-rays is projected to increase from USD\$100 million in 2016 to USD\$149 million by 2021.<sup>21</sup> Kazakhstan began moving to install digital radiography devices for national breast cancer screening in all public hospitals in the country in 2013.<sup>22</sup> Advanced telemedicine with the use of digital imaging has become a standard practice for healthcare in remote Arctic Indigenous communities, giving healthcare providers the ability to *"share images and consult with specialists in real-time...In the past, film images had to be shipped hundreds of miles to the hospital. Now they're forwarded from the workstation to a server, transmitted via satellite or microwave and read by clinicians in the territorial capital within 10-15 minutes."*<sup>23</sup> The PFOA Risk Management Evaluation notes that, *"Digital imaging will replace the need for PFOA in photo-imaging and the transition is occurring rapidly."*<sup>24</sup>

There is no justification for continuing this archaic use of PFOA when it has already been replaced by digital technologies. The final PFOA law should not contain this proposed derogation.

## Proposed derogation for textiles for oil- and water-repellency

In Decision SC-9/12, the Stockholm Convention includes an exemption for production and use of PFOA for textiles for oil and water repellency for the protection of workers from dangerous liquids that comprise risks to their health and safety. It is ironic that a substance associated with diagnosed high cholesterol, ulcerative colitis, thyroid disease, testicular cancer, kidney cancer and pregnancy-induced hypertension is described as a worker protection mechanism.<sup>25</sup>

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13 Andronikou S, McHugh K, Abdurahman N, Khoury B, Mngomezulu V, Brant W, Cowan I, McCulloch M, Ford N (2011) Paediatric radiology seen from Africa. Part I: providing diagnostic imaging to a young population, *Pediatric Radiology* 41:911-825 DOI 10.1007/s00247-011-2081-8

14 <https://www.theguardian.com/sustainable-business/technology-mobile-health-developing-countries>

15 <https://www.economist.com/news/special-report/21731035-how-get-smarter-health-care-technology-can-make-scarce-medical-resources-go-further>

16 Mayes J, White A (2017) How smartphone technology is changing healthcare in developing countries, *Journal of Global Health*, 1 April 2017 <http://www.ghjournal.org/how-smartphone-technology-is-changing-healthcare-in-developing-countries/>

17 <http://www.worldbank.org/en/news/feature/2016/06/21/using-digital-technology-to-improve-gabons-health-care>

18 <http://www.goodhousekeeping.co.za/health/the-mammogram-that%E2%80%99s-30-more-effective-in-picking-up-cancer/>

19 Lazarte CE, Encinas ME, Alegre C, Granfeldt Y (2012) Validation of digital photographs, as a tool in 24-h recall, for the improvement of dietary assessment among rural populations in developing countries, *Nutrition Journal* 11:61

<https://nutritionj.biomedcentral.com/articles/10.1186/1475-2891-11-61>

20 <http://www.rsna.org/NewsDetail.aspx?id=14696>

21 <https://www.statista.com/statistics/790691/digital-dental-x-ray-market-value-latin-america/>

22 <http://www.ehealthnews.eu/agfa/3619-public-hospitals-in-kazakhstan-move-to-digital-mammography-with-agfa-healthcare>

23 <http://www.healthcareitnews.com/news/telemedicine-drives-image-sharing-around-world>

24 UNEP (2017) Risk management evaluation on pentadecafluorooctanoic acid (CAS No: 335-67-1, PFOA, perfluorooctanoic acid), its salts and PFOA-related compounds, Stockholm Convention POPs Review Committee, UNEP/POPs/POPRC.13/7/Add.2



There are alternatives for these uses in healthcare that are applicable to other industries, obviating the need for a derogation. Alternatives exist for medical products such as operation scrubs, medical gowns, surgical drapes, and surgical face masks.<sup>26 27 28 29 30</sup> In addition, non-fluorinated water-repellent textile finishes that are based on high molecular weight and highly branched polymers known as dendrimers have been commercialized for use in textile pre-treatment, coating, sizing, and finishing.<sup>31</sup>

## Proposed derogation for invasive and implantable medical devices

In Decision SC-9/12, the Stockholm Convention includes an exemption for invasive and implantable medical devices. The industry rationale for proposing these exemptions was that unnamed medical devices might contain PFOA as a result of its use to make PTFE. However, modern methods of PTFE manufacturing have eliminated use of PFOA as a surfactant. Furthermore, during the Stockholm Convention POPs Review Committee evaluation, not one example of a medical device requiring or containing PFOA or a PFOA-related substance was demonstrated.

As noted in the Stockholm Convention PFOA Risk Management Evaluation, the “*main fluoropolymer manufacturers have already developed several alternatives to replace PFOA. These alternatives are often exclusively manufactured and used by each company.... Industry stated that there is no change in quality of the PTFE manufactured with the alternatives (ECHA, 2015a).*”<sup>32</sup> Commercially available Zero-PFOA PTFE coatings for medical devices approved by US FDA<sup>33</sup> are a feasible and effective alternative to the use of PFOA.<sup>34</sup> Many companies manufacture these PFOA-free products.<sup>35 36 37 38 39</sup> For example, Boyd Coatings Research has developed a proprietary chemistry and application process for zero-PFOA PTFE coatings. Their solvent-based coating systems (PC 4006 and PC 8-403) are zero-PFOA and chromic acid free.<sup>40</sup> In the US, four companies with 54 hospitals and USD\$4 billion in purchasing power formed Greenhealth Exchange in 2016. In a 2018 letter to the Stockholm Convention POPs Review Chair and PFOA Working Chairs, Greenhealth Exchange noted that “*Granting an exemption to allow PFOA for these uses would penalize those companies that have made the effort to produce products without PFOA.*”<sup>41</sup> The US medical products industry also noted that, “*Given the harmful impacts of PFOA in manufacturing communities, we find also find arguments about ‘small amounts’ of use to be unconvincing. Finally, we think it is extremely disingenuous to imply that patient safety will be jeopardized if an exemption is not granted. Our products have passed all regulatory approvals and provide patient safety.*”<sup>42</sup>

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25 UNEP (2016) Risk profile on pentadecafluorooctanoic acid (CAS No: 335-67-1, PFOA, perfluorooctanoic acid), its salts and PFOA-related compounds, UNEP/POPS/POPRC.12/11/Add.2

26 Healthcare Without Harm (2019) Alternatives to PFOA used in medical textiles, [https://noharm-europe.org/sites/default/files/documents-files/6013/2019-10-02\\_PFOA\\_medical\\_alternatives.pdf](https://noharm-europe.org/sites/default/files/documents-files/6013/2019-10-02_PFOA_medical_alternatives.pdf)

27 [http://multimedia.3m.com/mws/mediawebservlet?mwsId=SSSSSu9n\\_zu8l00xm8mBl8t94v70k17zHvu9lxtD7xt1evSSSSSS-](http://multimedia.3m.com/mws/mediawebservlet?mwsId=SSSSSu9n_zu8l00xm8mBl8t94v70k17zHvu9lxtD7xt1evSSSSSS-)

28 <https://www.daikinchem.de/products-and-performance/water-oil-repellency>.

29 <https://products.halyardhealth.com/surgical-solutions/surgical-gowns/breathable-high-performance-gowns/halyard-microcool-breathable-high-performance-surgical-gown-with-secure-fit-technology.html>.

30 <https://www.agcchem.com/news/2016/june-1-2016-asahiguard-ag-e600-repellent-provides-sustainable-solution-for-nonwoven-medical-textiles>.

31 <http://www.rudolf.de/en>

32 UNEP (2017) Risk management evaluation on pentadecafluorooctanoic acid (CAS No: 335-67-1, PFOA, perfluorooctanoic acid), its salts and PFOA-related compounds, Stockholm Convention POPs Review Committee, UNEP/POPS/POPRC.13/7/Add.2

33 For example, [https://www.accessdata.fda.gov/cdrh\\_docs/pdf14/K140608.pdf](https://www.accessdata.fda.gov/cdrh_docs/pdf14/K140608.pdf)

34 <http://www.medicaldesignandoutsourcing.com/pfoa-free-ptfe-ready-for-catheter-applications/>

35 <http://www.surfacesolutionsgroup.com/site/files/785/69121/273265/759549/no-pfoa-ptfe-coatings-guidewires-brochure.pdf>

36 <https://meritoem.com/composite-reinforced-coatings-the-future-of-medical-device-coatings/>

37 <http://store.tegrammedical.com/zero-pfoa-green-ptfe-wire/>

38 <http://www.cambusmedical.com/PTFE-Coating-New.html>

39 <https://wytech.com/wire-components/>

40 <https://precisioncoating.com/>

41 <https://www.greenhealthexchange.com/sites/default/files/2018-09/GX%20PFOA%20Letter%20180830.pdf>

42 <https://www.greenhealthexchange.com/sites/default/files/2018-09/GX%20PFOA%20Letter%20180830.pdf>

Based on the substantial number of PFOA-free medical products already on the market, no derogation for PFOA use in medical devices or implantable medical devices should be granted.

## **Proposed derogation for manufacture of polytetrafluoroethylene (PTFE) and polyvinylidene fluoride (PVDF)**

In Decision SC-9/12, the Stockholm Convention includes an exemption for manufacture of polytetrafluoroethylene (PTFE) and polyvinylidene fluoride (PVDF) for the production and use of:

- o High-performance, corrosion-resistant gas filter membranes, water filter membranes and membranes for medical textiles
- o Industrial waste heat exchanger equipment
- o Industrial sealants capable of preventing leakage of volatile organic compounds and PM2.5 particulates

None of these proposed exemptions were recommended by the POPRC after a multi-year investigation. Ironically, at COP9, one of the strongest opponents of these proposed exemptions was FluoroCouncil – the association of companies manufacturing fluorinated chemicals.<sup>43</sup>

During the evaluation of PFOA, the POPRC considered a possible exemption for membranes intended for use in medical textiles, filtration in water treatment, production processes and effluent treatment, but rejected it. The Committee noted that, “*Several potential alternatives for use in textiles such as short-chain fluorinated alternatives, non-fluorine containing alternatives and non-chemical alternatives have been identified in the RME, including those that meet regulatory requirements and are in current use. In addition, no specific application has been identified that requires C<sub>8</sub> chemistry. Based on the evaluation of available information a specific exemption for use in membranes intended for use in medical textiles, filtration in water treatment, production processes and effluent treatment is not recommended.*”<sup>44</sup> Despite this rejection by the Committee, the EU undermined by the scientific process by re-proposing the exemption at COP9.<sup>45</sup>

Ironically, there were several EU Member States represented on the POPRC that arrived at the consensus decision to reject these proposed exemptions. In addition, the EU itself proposed PFOA for listing and led the drafting process in the Committee. In developing its PFOA law, the EU should opt for the recommendation of the Convention’s expert committee and not include this proposed derogation.

## **Proposed derogation for fire-fighting foam**

Use of PFAS-containing fire-fighting foams is a direct route into the environment that has already contributed to contamination of soil, groundwater, drinking water, humans and the environment in countries all over the world. Therefore, DG Environment launched a background study in preparation of a restriction dossier on all PFAS in fire-fighting foam in 2019.<sup>46</sup> The proposed derogations in the draft amendment to the POPs regulation is therefore inconsistent with other ongoing measures in the EU.

Any firefighting foam containing PFOA should not be derogated but be destroyed in an environmentally sound manner, preferably through industry-funded recall programs. For developing countries, UNIDO has recommended a variety of effective non-combustion techniques, including methods suitable for PFAS destruction such as gas phase chemical reduction and ball milling.<sup>47</sup> These methods are also highly applicable in the EU. The updated general technical guidelines for the environmentally sound management of wastes consisting of, containing or contaminated

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43 “FluoroCouncil stressed that PFOA is no longer used to manufacture the products included in the exemptions.” Earth Negotiations Bulletin (2019) Summary of the Meetings of the Conferences of the Parties to the Basel, Rotterdam and Stockholm Conventions <http://enb.iisd.org/vol15/enb15269e.html>

44 UNEP (2018) Addendum to the risk management evaluation on perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds, Stockholm Convention POPs Review Committee, UNEP/POPs/POPRC.14/6/Add.2

45 Napierska D (2019) NGO Platform: Unnecessary EU exemption permits toxic chemicals in healthcare, Chemical Watch 17 June 2019 <https://chemicalwatch.com/78694/ngo-platform-unnecessary-eu-exemption-permits-toxic-chemicals-in-healthcare#overlay-strip>

46 According to information in background paper “The use of PFAS and fluorine-free alternatives in fire-fighting foams” disseminated in preparation for the stakeholder workshop on Tuesday 24 September 2019 at ECHA, Helsinki

47 UNIDO (2007) Non-combustion technologies for POPs destruction, <http://capacitydevelopment.unido.org/wp-content/uploads/2014/11/23.-Non-combustion-Technologies-for-POPs-Destruction-Review-and-Evaluation.pdf>

with persistent organic pollutants (POPs) under the Basel Convention lists Gas Phase Chemical Reduction as capable of destroying all POPs. Electrochemical oxidation has been demonstrated to destroy C4 – C8 PFAAs.

Current top-quality Class B fluorine-free firefighting foams are capable of meeting all the standard firefighting performance certifications applicable to AFFF and related foams.<sup>48</sup> Recent independent test results published in 2017 by the Southwest Research Institute found that the fluorine-free foam Re-Healing RF3 (manufactured by Solberg) met the Performance Level B Fire Test Standard of the International Civil Aviation Organization (ICAO).<sup>49</sup> Tests at the Dallas-Fort Worth Airport in the US demonstrated that the extinction efficiency of fluorine-free foam was indistinguishable from that of AFFF. The report noted that “criticisms from some parts of the industry that fluorine-free products suffer from fuel pickup with foam flammability and poor burn-back resistance or drainage characteristics proved to be unfounded.” The tests confirm that fluorine-free foam is “totally suitable for aviation firefighting.”<sup>50</sup> Testing at research facilities in France with participation of regulators, manufacturers, and firefighters showed that fluorine-free foam was just as efficient as AFFF.<sup>51</sup> At the Copenhagen Airport, fluorine-free Solberg RF Re-Healing Foam was used to replace AFFF for environmental and aviation safety reasons, as well as for the occupational health and safety of firefighters.<sup>52</sup> The London Heathrow Airport in the UK switched to fluorine-free foam in 2012 after extensive public testing that were independently evaluated by representatives of the civil aviation authority. “The Norwegian and Danish air forces now use fluorine-free foam, as does the oil and gas sector in the North Sea; countless firefighting brigades around the world; as well as 47 corporations including 3M, Exxon Mobil, Statoil, and ConocoPhillips; and at least 77 airports.”<sup>53</sup>

Fluorine-free firefighting foams have considerable financial, socio-economic, public health and environmental advantages over persistent fluorochemical-based firefighting foams. They are non-persistent, biodegradable with only short-term, localized and self-remediating effects versus highly persistent PFAS in aqueous film forming foams which are all toxic and bio-accumulative to varying degrees for the environment and human health, as well as exhibiting extreme long-range transport that has resulted in worldwide contamination. Barzen-Hanson<sup>54</sup> demonstrated the complexity of AFFF mixtures, indicating that more than 240 individual per- and polyfluoroalkyl substances (PFAS) can now be associated with AFFF, with the discovery of forty novel classes of PFAS and additional detection of 17 classes of previously reported PFAS. The authors stated that these newly discovered PFAS will pose challenges for effective remediation due to the presumed wide range of solubilities. Systems designed to capture PFOS and PFOA (such as granulated active carbon) will not be effective because shorter-chained substances will likely break through.

The PFOA Stockholm Convention Risk Management Evaluation acknowledges non-fluorine containing alternative firefighting foams are readily available.<sup>55</sup> A variety of fluorine-free Class B foams are on the Swedish market indicating the technical feasibility of this alternative. “The firefighting foam Moussoll-FF 3/6 was introduced at a Swedish airport and is degraded to carbon dioxide and water in the environment. It is considered effective in fire suppression required at airports where high safety standards have to be fulfilled.”<sup>56</sup> The Swedish Armed Forces began phasing out the use of perfluorinated substances in firefighting foam in Sweden in 2011. All Swedish and

48 Allcorn M, Bluteau T, Corfield J, Day G, Cornelsen M, Holmes NJC, Klein RA, McDowall JG, Olsen KT, Ramsden N, Ross I, Schaefer TH, Weber R, Whitehead K (2018) Fluorine-free firefighting foams (3F) – Viable alternatives to fluorinated aqueous film-forming foams (AFFF), IPEN F3 Panel, [https://ipen.org/sites/default/files/documents/IPEN\\_F3\\_Position\\_Paper\\_POPRC-14\\_12September2018d.pdf](https://ipen.org/sites/default/files/documents/IPEN_F3_Position_Paper_POPRC-14_12September2018d.pdf)

49 Huczek, JP. 2017. Fire Testing of RF3 Synthetic Foam Concentrate, Per International Civil Aviation Organization (ICAO) Fire Test Standard, Airport Services Manual (Doc. 9137-AN/898) Part 1. A Report by the Southwest Research Institute.

50 Industrial Fire Journal – Fire and Rescue – Hemming Group Ltd.: Solutions in Foam. December 5, 2017.

51 Thorbjorn Olsen, T. 2012. CAFs and Fluorine-Free Foam in ARFF. Fire and Rescue, Third Quarter.

52 Thorbjorn Olsen, T. 2012. CAFs and Fluorine-Free Foam in ARFF. Fire and Rescue, Third Quarter.

53 Lerner, S. 2018. The US Military is Spending Millions to Replace Toxic Firefighting Foam with Toxic Firefighting Foam. The Intercept February 10, 2018. <https://theintercept.com/2018/02/10/firefighting-foam-afff-pfos-pfoa-epa/>

54 Barzen-Hanson, KA et al. 2017. Discovery of 40 Classes of Per- and Polyfluoroalkyl Substances in Historical Aqueous Film-Forming Foams (AFFF) and AFFF-Impacted Groundwater. Environ. Sci. Tech. 51 (4): 2047-2057.

55 UNEP (2017) Risk management evaluation on pentadecafluorooctanoic acid (CAS No: 335-67-1, PFOA, perfluorooctanoic acid), its salts and PFOA-related compounds, Stockholm Convention POPs Review Committee, UNEP/POPs/POPRC.13/7/Add.2



Norwegian commercial airports have recently replaced PFAS-based AFFFs with fluorine-free foams because of environmental safety concerns.<sup>57</sup> A number of oil and gas corporations employ the use of the Solberg Re-Healing formulation, including Statoil, Shell, Exxon Mobil, Conoco Phillips, BP, Maersk Drilling, Total, Fina, Songa Offshore, and others.<sup>58</sup>

Considering the wide availability of technically feasible, certified alternatives, no derogations for PFOA use in firefighting foams should be granted and a rapid transition to fluorine-free firefighting foams should be mandated.

### **Proposed derogation for perfluorooctyl bromide (PFOB)**

In Decision SC-9/12, the Stockholm Convention includes an exemption for production and use of perfluorooctyl iodide (PFOI) for the production of perfluorooctyl bromide (PFOB) for the purpose of producing pharmaceutical products that expires in 2036 at the latest. The exemption includes a review at COP13 and every second ordinary meeting thereafter. The exemption originated from a proposal by a single Japanese company, Daikin, at the POPs Review Committee (POPRC). The lack of rigorous examination of alternatives for this use undermines the integrity of Convention at the behest of a single company. The EU should not support this approach.

In the EU, no derogation for PFOB use is currently present in Annex XVII to Regulation (EC) No 1907/2006, indicating that none was required. However, the draft law opens a new loophole in the PFOA regulation to allow the derogation. This should not be permitted in the final law.

The derogation proposal is for use of a likely persistent, bioaccumulative substance (PFOB) contaminated with a PFOA-related substance (PFOI) which is predicted to become an Arctic contaminant and appears to be an endocrine disruptor. Both substances are by-products of 6:2 telomer manufacturing including 6:2 fluorotelomer alcohol – a substance which is present both in both the Arctic and Antarctic indicating long-range transport; appears to be an endocrine disruptor; is transformed to other PFAS substances in the environment; and pollutes factory air, indoor air, house dust, and food packaging materials. A regulation which aims to protect EU residents from POPs and other harmful substances should not allow a derogation for substances with POPs properties.

At issue is the use of porous materials for drug delivery due to their high surface area and subsequent enhancement of drug bioavailability. A wide variety of porous carriers can be used, indicating a variety of alternative processes and processing aids.<sup>59 60 61</sup> The porous materials are delivered via metered dose inhaler systems, however this is not the only effective medication delivery system, as indicated by alternatives for medication delivery which are approved, on the market, and used by patients including dry powder inhalers among others.<sup>62</sup>

At the Fourth International Conference on Chemicals Management (ICCM4) the EU led more than 100 countries to recognize the potential adverse effects associated with exposure to environmentally persistent pharmaceutical pollutants on human health and the environment, and the need to protect humans and ecosystems and their constituent parts that are especially vulnerable.<sup>63</sup> It would not be appropriate for the EU to undermine its own

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56 UNEP (2017) Risk management evaluation on pentadecafluorooctanoic acid (CAS No: 335-67-1, PFOA, perfluorooctanoic acid), its salts and PFOA-related compounds, Stockholm Convention POPs Review Committee, UNEP/POPS/POPRC.13/7/Add.2

57 **Norström, K., Viktor, T., 2011. Årsrapport för projektet RE-PATH.** IVL rapport B2060, 2011 (in Swedish). Available at: [http://repath.ivl.se/download/18\\_488d9cec137bbdef94800056018/1350483917062/B2060.pdf](http://repath.ivl.se/download/18_488d9cec137bbdef94800056018/1350483917062/B2060.pdf).

58 Blum, A. and T. Bruton. 2018. Understanding PFAS: For Healthy Drinking Water and Fire Safety. Green Science Policy Institute [www.greensciencepolicy.org](http://www.greensciencepolicy.org).

59 Ahuja G, Pathak K (2009) Porous carriers for controlled/modulated drug delivery, *Indian J Pharm Sci* 71:599-607

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63 UNEP (2015) Report of the International Conference on Chemicals Management on the work of its fourth session, SAICM/ICCM. 4/15

advocacy for reducing threats posed by environmentally persistent pharmaceutical products by allowing a derogation to produce them.

PFOI is a persistent PFOA-related compound and is one of 120 substances predicted to become an Arctic contaminant based on modeling studies.<sup>64</sup> PFOI has an OH  $t_{1/2}$  greater than 2 days and matches the structural profile of known Arctic contaminants. In vivo studies in male medaka fish show that PFOI upregulates estrogenic genes in a dose-dependent manner indicating that it is an endocrine disruptor.<sup>65</sup> In human adrenocortical cells in vitro, PFOI upregulates 10 steroidogenic genes at  $\mu\text{M}$  levels of PFOI.<sup>66</sup> GHS hazard statements for PFOI note that it “*may cause long lasting harmful effects to aquatic life.*”<sup>67</sup> EU precautionary statement codes include P273 “*avoid release to the environment*”.<sup>68</sup> PFOI producers also include hazard code H413 “*May cause long lasting harmful effects to aquatic life.*”<sup>69</sup>

AstraZeneca admits that publicly available data on environmental fate and effects of PFOB in the aquatic environment is limited. However, the company notes the persistence of PFOB and concludes that “*PFOB is not readily or rapidly biodegradable.*”<sup>70</sup> Furthermore, AstraZeneca notes that “*the octanol-water partition coefficient is above the bioaccumulation screening criterion established by ECHA. Therefore, it is concluded that PFOB may be potentially bioaccumulative.*”<sup>71</sup> AstraZeneca claims that there is, “*no risk to the health of staff involved in the manufacture of porous particles using PFOB.*” However, there is no monitoring data, health surveillance data, or independent studies that support this statement.

PFOI and PFOB are produced by Japanese company, Daikin, during manufacture of an unnamed 6:2 fluorotelomer substance. An increasing body of scientific research raises concerns about the POPs properties of these substances including the following for commonly-produced 6:2 fluorotelomer alcohol:

Found in the Arctic<sup>72 73 74</sup>

Found in the Antarctic<sup>75</sup>

Impairs growth of *Tetrahymena thermophila*<sup>76</sup>

Endocrine disruption in zebra fish<sup>77</sup>

Effects on estrogen receptor in male medaka (*Oryzias latipes*)<sup>78</sup>

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64 Brown TN, Wania F (2008) Screening chemicals for the potential to be persistent organic pollutants: A case study of Arctic contaminants, *Environ Sci Technol* 42:5202-5209

65 Wang Y, Zhou Q, Wang C, Yin N, Li Z, Liu J, Jiang G (2013) Estrogen-like response of perfluorooctyl iodide in male medaka (*Oryzias latipes*) based on hepatic vitellogenin induction, *Environ Toxicol* 28: 571-578

66 Wang C, Ruan T, Liu J, He B, Zhou Q, Jiang G (2015) Perfluorooctyl iodide stimulates steroidogenesis in H295R cells via a cyclic adenosine monophosphate signalling pathway, *Chem Res Toxicol* 28: 848-854

67 [https://pubchem.ncbi.nlm.nih.gov/compound/Perfluorooctyl\\_iodide#section=Hazards-Identification](https://pubchem.ncbi.nlm.nih.gov/compound/Perfluorooctyl_iodide#section=Hazards-Identification)

68 [https://pubchem.ncbi.nlm.nih.gov/ghs/#\\_prec](https://pubchem.ncbi.nlm.nih.gov/ghs/#_prec)

69 [https://pubchem.ncbi.nlm.nih.gov/compound/Perfluorooctyl\\_iodide#section=Safety-and-Hazards](https://pubchem.ncbi.nlm.nih.gov/compound/Perfluorooctyl_iodide#section=Safety-and-Hazards)

70 AstraZeneca (2018) Chemical safety report for the use of PFOB containing up to 200 ppm PFOI

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72 Bossi R, Vorkamp K, Skov H (2016) Concentrations of organochlorine pesticides, polybrominated diphenyl ethers and perfluorinated compounds in the atmosphere of North Greenland, *Environ Pollut* 217:4-10

73 Shoeb M, Hamer T, Vlahos P (2006) Perfluorinated Chemicals in the Arctic Atmosphere *Environ Sci Technol* 40:7577-7583

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76 Wang Z, Ud-Daula A, Fiedler S, Schramm KW (2010) Impact of fluorotelomer alcohols (FTOH) on the molecular and macroscopic phenotype of *Tetrahymena thermophila*, *Environ Sci Pollut Res Int* 17:154-164

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78 Ishibashi H, Yamauchi R, Matsuoka M, Kim JW, Hirano M, Yamaguchi A, Tominaga N, Arizono K (2008) Fluorotelomer alcohols induce hepatic vitellogenin through activation of the estrogen receptor in male medaka (*Oryzias latipes*), *Chemosphere* 71:1853-1859

Estrogenic activity in cultured tilapia hepatocytes<sup>79</sup>  
 Estrogenic effects on human estrogen receptor<sup>80</sup>  
 Estrogen activity revealed in mcf-y breast cancer cell proliferation<sup>81</sup>  
 Biotransformation to other perfluorinated substances in the environment<sup>82</sup>  
 Released from textiles and found in indoor air<sup>83</sup>  
 Found indoor air in office environments<sup>84</sup>  
 Found in factory air manufacturing fabric in China<sup>85</sup>  
 Found in food contact materials and their migration<sup>86</sup>  
 Found consumer products<sup>87 88 89 90</sup>  
 Found in indoor air in Japanese homes<sup>91</sup>  
 Found in residential and non-residential house dust in South Korea<sup>92</sup>  
 Found in indoor dust and packaging materials in Egypt<sup>93</sup>  
 Can be converted to PFHxA in sewage sludge<sup>94</sup>

Taken together, the available data indicates that both PFOB and PFOI have some POPs properties along with the 6:2 fluorotelomers that are used to make them. A regulation banning a POP such as PFOA should not include a derogation for substances that have POPs properties or depend on substances that have POPs properties. If a derogation for this use is included, then it should be for five years, ending in 2025, not 2036.

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