**Criteria for elevation of obligations to progress SAICM Issues of Concern (IoCs)in the post 2020 multilateral regime: The case of Per and Poly Fluoroalkyl Substances (PFASs)**

## Introduction

At the Second International Conference on Chemicals Management (ICCM2) in 2009, perfluorinated chemicals (PFCs) were recognised as an issue of concern (IoC), through the adoption of Resolution II/5 on Managing perfluorinated chemicals and the transition to safer alternatives.[1]

Resolution II/5 invited the Inter-Organization Programme for the Sound Management of Chemicals (IOMC), in cooperation with the Organization on Economic Cooperation and Development (OECD), together with governments and other stakeholders to develop national and international stewardship programmes and regulatory approaches to reduce emissions of perfluorinated chemicals of concern in products *and to work towards global elimination* (emphasis added).

The perfluorinated chemicals are also known by the term “PFASs” – short for per- and polyfluoroalkyl substances. The OECD Portal on Per and Poly Fluorinated Chemicals defines PFAS as a fully (per) or partly (poly) fluorinated carbon chain connected to different functional groups. It distinguishes between long chain PFASs such as PFOA, PFOS and their precursors, and short chain PFASs. The length of the carbon chain affects the substances’ physicochemical properties, including their bioaccumulability and their toxicity. However, all PFASs share the property of extreme persistence.

Some efforts have been made to phase out long-chain PFASs such as PFOS and PFOA. PFOS was included in the Stockholm Convention in 2009, though many uses were exempted. In 2019 PFOA was added to the list of chemicals to be eliminated under Stockholm, and some of the exemptions for uses of PFOS were closed. PFHxS is now also being considered for inclusion in the Stockholm regime. However, while production and use of PFOA and PFOS has dropped in the USA and Europe, they continue to be produced in countries such as China and India and to be applied to products in the global supply chain. Moreover, at least 4500 other PFASs have been identified as on the global market.

The problem of PFASs has been compounded by the development of short chains marketed today by the chemical industry as “environmentally preferable” alternatives. While the short chains may not be as bioaccumulative as the long chains, they pose many of the same health concerns.

Meeting just one of the nine criteria proposed in the IP3 information document[2] should be sufficient for moving the issue of PFASs to an increased level of obligation. However, as this paper shows, PFASs as a class meet all nine of the criteria. The paper concludes that it is time to think about how to bring about a global phase-out of all non-essential uses of PFAS. It also provides suggestions for how to start such a phase-out.

## The criteria applied to PFAS

### 1. Failure to reduce acute poisoning and/or chronic effects by PFAS

Virtually all persons on the planet have some PFASs in their bodies today. Even if a country does not have facilities producing PFASs or manufacturing PFAS-treated products, the extreme persistence and

[1] http://www.saicm.org/Portals/12/Documents/saicmtexts/New%20SAICM%20Text%20with%20ICCM%20resolutions_E.pdf
[2] Information document for IP3 (http://www.saicm.org/Portals/12/documents/meetings/IP3/stakeholders/NGO-Information-doc-on-IoC-criteria.pdf)

mobility of PFASs means that these chemicals will be present at background levels. As a result, exposure of its citizens and natural resources will occur.

PFASs are a diverse group of substances with diverse sources, properties, fate and transport behavior, exposure pathways and effects. However, all PFASs are extremely persistent in the environment. Like plastics, they will be on the planet for eons to come.
For many people, the main sources of exposure are contaminated food and PFAS-containing products. Contamination of food may occur  through uptake of PFASs by crops or other food sources, e.g. fish, or via contact with PFAS-treated food packaging.. Exposure also occurs through contact with consumer products treated with PFASs, including water- and stain-repellent textiles and carpets, cosmetics, and cleaning products.

Higher levels of exposure occur to workers in the chemical factories producing PFAS as well as at the manufacturing sites where goods are treated with PFAS or where PFAS-containing products are made or used. Communities may receive higher levels of exposure due to contamination of drinking water, e.g. via the release of industrial pollution or of fluorine-based aqueous fire-fighting foams.

Human health impacts linked to exposure to long-chain perfluoroalkyl acids (PFAAs) via epidemiological studies include chronic diseases such as kidney and testicular cancer, liver damage, increased serum cholesterol levels (related to hypertension), increased risk of thyroid disease, obesity, decreased immune response (higher risk of infection), and decreased fertility. Acute impacts include higher risk of pre-eclampsia in pregnancy and low birth weight. Less information is available for short-chain PFAAs, but results from animal testing indicate similar health impacts could occur.

In light of new scientific knowledge about how PFAS exposure can harm human health, regulatory authorities in Europe and the USA are setting health-based limit values for PFAS in drinking water lower and lower. In 2016, the US Environmental Protection Agency (US EPA) set the lifetime health advisory limit for PFOA and PFOS in drinking water at 70 ppt. In 2018, the US Agency for Toxic Substances and Disease Registry (US ATSDR) published draft findings indicating that limit values for drinking water should be 7 ppt for PFOS and 11 ppt for PFOA. Studies are finding immunosuppressive effects (e.g. failure to respond to childhood vaccinations) at background levels of exposure, resulting in calls by some scientists for limits as low as 1 ppt.

Because of the extreme persistence of PFAS, without a phase-out, these background exposures and the resulting health impacts will continue to increase.

## 2. Failure to reduce the levels of PFAS in human and environmental samples

While levels of PFOA and PFOS in human serum are lower than a decade ago, due to the phase-out of production in the US of the long chains, at the same time levels of short chain fluorinated alternatives are rising.[3]

In 2013-2015 the US EPA monitored PFAS concentrations in publicly supplied drinking water. A review of the data found that drinking water supplies for at least 6 million U.S. residents exceeded the US EPA's

[3] Danish EPA: Short-chain Polyfluoroalkyl Substances (PFAS) A literature review of information on human health effects and environmental fate and effect aspects of short-chain PFAS, p.25. https://www2.mst.dk/Udgiv/publications/2015/05/978-87-93352-15-5.pdf.

health advisory limits of 70 ppt for PFOS and PFOA[4]. A similar study estimated that at least 3% of the Swedish population have received drinking water higher than the Swedish action level of 90 ppt.

Significant predictors of PFAS concentrations in US public water supplies included the number of industrial sites manufacturing or using these compounds, the number of military and civilian fire training areas, and the number of wastewater treatment plants. The short chain PFAAs especially tend to be highly mobile and pose threats to groundwater and other drinking water sources wherever they are released into the environment.

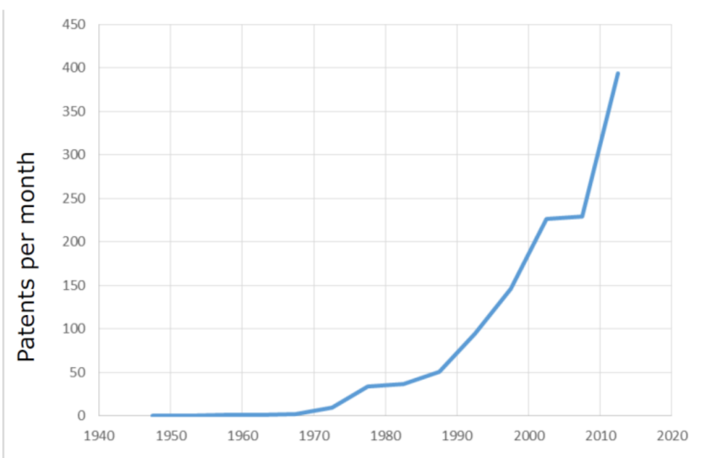
Extensive PFAS contamination of groundwater resources has been found in Australia, North America, South America and Europe. Investigations by the International POPs Elimination Network (IPEN) carried out in Bangladesh, India, Indonesia, Japan, Malaysia, Nepal, Sri Lanka, Thailand, and Vietnam indicate widespread PFAS pollution in Asia as well.[5]

### 3. Failure to reduce the volume of the production, use and disposal of PFAS

The number of different PFASs on the global market keeps growing. In 2007 around 3,000 different PFAS were identified as available for commercial use. Today the number of PFAS compounds identified as on the global market for commercial use is estimated at over 4,700[6]. Other compounds may also be produced but their identities are protected for confidential business reasons.

The numbers of possible applications are also growing rapidly. The figure below shows an increasing trend in the number of patents with “perfluor” in the patent text that are approved in the USA each month[7]. A large proportion of these compounds are polymers and therefore exempted from registration in some jurisdictions.

**Figure 1: Number of approved patents in US with “perfluor” in the patent text[8]**




[4] Hu, X.C. *et al.* (2016). Detection of Poly- and Perfluoroalkyl Substances (PFASs) in U.S. Drinking Water Linked to Industrial Sites, Military Fire Training Areas, and Wastewater Treatment Plants. Environ. Sci. Technol. Lett. 3, 344−350 .
[5] https://ipen.org/sites/default/files/documents/pfas_pollution_across_the_middle_east_and_asia.pdf
[6] OECD (2018). Summary Report on Updating the OECD 2007 List of Per- and Polyfluoroalkyl Substances (PFASs), ENV/JM/MONO(2018).
[7] KEMI, 2015. *Occurrence and use of highly fluorinated substances and alternatives: Report from a government assignment,* https://www.kemi.se/global/rapporter/2015/report-7-15-occurrence-and-use-of-highly-fluorinated-substances-and-alternatives.pdf
[8] Fischer, S., 2017. ‘Known uses of PFASs’, presentation at Nordic workshop on joint strategies for PFAS, 5.04.2017.

Very little information is available on quantities of PFASs produced globally but they are clearly growing. A recent market research report estimated that production of PFAS used primarily in aqueous firefighting foams (AFFFs), in textiles to provide stain resistance and surface finishing, and as surfactants would more than double between 2013 and 2020, for a 2020 value of USD 539.3 million (EUR 466 million)[9]. The main drivers of growth are expected to be an increased demand from the textile sector (34.8% of total demand in 2013) and government norms leading to use of AFFFs in firefighting systems. These uses are not essential, in that functionally equivalent alternatives are available and thus these uses of PFAS could be phased out without major consequences for society.

## 4. Insufficient monitoring of human and environmental impacts from PFAS

Most environmental and bio-monitoring for PFASs focuses on the long chain perfluoroalkyl acids such as PFOA and PFOS which are already known to be harmful.[10] The environmental levels and health impacts of the other thousands of PFASs on the global market are not adequately tracked.

Dozens of unknown PFAS compounds were found by USEPA scientists during monitoring on the Cape Fear River in North Carolina, where Dupont/Chemours operate a major PFAS production facility. Downstream residents such as in the city of Wilmington were unknowingly drinking PFAS-contaminated water for decades.[11] PFAS compounds were also found upstream due to releases of PFASs to air during production.

Widespread PFAS contamination of drinking water has also been found close to hundreds of US military bases due to the use of PFAS-based firefighting foams used in training. Similar contamination near airports and military sites has also been found in Sweden, Denmark and Australia. However, few other countries around the world have carried out systematic testing of public water supplies near possible sources of PFASs to identify if contamination is present.

With the shift in production to China, India and Brazil, it is particularly important to start monitoring in other parts of the world for PFAS in drinking water and in the blood serum of exposed communities, in order to take action where significant releases to the environment may be occurring.

## 5. Significant costs for society in the absence of action to address PFAS

The failure to curb PFAS production, use and exposure is leading to a range of costs, from PFAS-related health impacts to the clean-up of PFAS contamination of drinking water and other natural resources, such as air and soil. It should be noted that these costs are ”externalities”, borne not by the producers of PFAS but by governments and their taxpayers.

A 2019 study for the Nordic Council[12] estimated annual costs to Europe for just a few health endpoints linked to PFAS exposure. Annual costs were calculated for the elevated risk of kidney cancer due to occupational exposure, increased rates for all-cause mortality for communities with PFAS-contaminated drinking water, and the additional hypertension in the general adult population from background

[9] Production of fluorotelemers was predicted to increase from 21.3 million kg in 2013 to 47.9 million kg by 2020. Hexa Research, 2018. Press release available at: http://www.digitaljournal.com/pr/3601419 . Conversion to euro made based on exchange rate on 9 Sept 2018.
[10] The US National Health and Nutrition Examination Survey (NHANES) tracks PFAS levels in humans. The EU has a similar biomonitoring project that also tests for PFASs.
[11] https://factor.niehs.nih.gov/2019/3/feature/2-feature-pfas/index.htm
[12] *The Cost of Inaction: A socioeconomic analysis of environmental and health impacts linked to exposure to PFAS.* http://urn.kb.se/resolve?urn=urn:nbn:se:norden:org:diva-5514.

exposure. The total cost came to EUR 52-84 billion each year. These costs are likely to be underestimates due to the lack of epidemiological studies calculating the risks of other health endpoints.

The Nordic Council study also compiled information on direct costs incurred by communities taking measures to reduce PFAS exposure, such as remediation of drinking water by capital investment in granulated activated carbon (GAC) or reverse osmosis technologies. These estimates did not include other costs related to PFAS contamination such as loss of property value, reputational damage to a polluting company, ecological damage, and the costs incurred by public authorities in responding to affected communities.

Significant costs linked to PFAS contamination have also incurred in the USA and Australia. The US Department of Defense estimates it will cost at least USD 2 billion to clean up drinking water around the 400+ military bases where PFAS-based firefighting foams were used.[13] Lawsuits against 3M and Dupont/ Chemours have been settled for huge sums (USD 800 million and USD 670 million respectively), and more liability suits are pending.

Figures are not available for other geographical regions where PFAS contamination is building up, such as China (now a major producer and exporter of PFAS and of PFAS-treated products), India and Brazil.

## 6. National regulations have failed to achieve sufficient improvement with respect to PFAS-related problems

Some Parties to the Stockholm Convention have set in place national regulations to implement the inclusion of PFOS and PFOA in the Convention's annex B and A respectively. But the Stockholm restrictions cover some 200 compounds, [14] compared to the 4700+ PFASs on the global market today.

The Scandinavian countries and a few US states are taking some interesting steps to reduce human exposure. For example, Denmark has just banned the use of food contact materials that contain PFASs. However, most countries have not yet recognised the need to put controls in place to curb the release of PFASs into the environment and to minimize human exposure.

The lack of effective national regulations means that the global production and release of PFASs, including of the short chain PFAA, continues to rise. The global dimensions of the production and use of PFAS in international trade means that the problem of human and environmental exposure to the class of PFAS cannot be addressed efficiently by national regulatory measures.

## 7. Regional regulations for addressing an IoC are in place, or under development

The regional organisation known as the European Union has set in place a number of regulatory measures aimed at reducing exposure to PFAS. The Stockholm Convention restrictions on PFOS and PFOA are implemented. A proposal submitted by Germany and Norway to restrict the production and use of six long chain PFAAs (PFNA, PFDA, PFUnDA, PFDoDA, PFTrDA and PFTeDA) is pending approval. Moreover, in mid-2019, HFPO-DA (a short chain also known as GenX) was designated as a Substance of Very High Concern under the REACH Regulation, due to its extreme persistence and high mobility in the environment. This designation is expected to lead to a restriction or ban on the production and use of the GenX technology within the EU.

[13] https://www.militarytimes.com/news/pentagon-congress/2019/03/07/2-billion-cost-to-clean-up-water-contamination-at-military-bases-defense-official-says/

[14] The restrictions cover perfluorooctane sulfonic acid (PFOS), its salts and perfluorooctane sulfonyl fluoride (around 165 compounds) and perfluorooctanoic acid (PFOA), its salts and PFOA-related compounds (around 30 compounds).

Additional measures are also under way within the EU, including a proposal to restrict PFHxS. A proposed revision of the EU Drinking Water Directive is likely to include a group parameter for PFASs in drinking water, and restrictions on PFASs in food contact materials is also under consideration.

In June 2019 the European Council issued conclusions concerning EU chemicals policies that *inter alia* called for the Commission to develop a PFASs action plan, including elimination of all "non-essential" uses. This call for action mirrored the thinking in a recent peer-reviewed article[15] on how the concept of essential use could help to determine when non-essential uses of PFAS can be phased out without undue impact on society as a whole.

### 8. Failure to establish an effective, transparent multi-stakeholder working platform on PFAS

A multi-stakeholder platform on PFASs has been established, i.e., the OECD/UNEP Global PFC Group. The OECD has established a Portal on Per and Poly Fluorinated Chemicals, [16] and published several studies of PFASs. It has also compiled a global database on PFASs.

However, the question arises as to whether it has been effective in achieving the goals set forth in Resolution II/5. That resolution called for the development of national and international stewardship programmes and regulatory approaches to reduce emissions of perfluorinated chemicals of concern in products and to work towards global elimination.

As already documented above, emissions of PFAS have not been reduced, nor are we on a path towards global elimination. It is therefore important to re-examine whether more elevated obligations are necessary in order to achieve the goals set in Resolution II/5.

### 9. Failure to make available the information necessary for addressing the class of PFAS

It is extremely difficult to get an overview of which PFAS are on the market, which companies produce them and where, where manufacturing of PFAS-related products takes place and what are the downstream uses for PFAS.

Much of the information concerning which PFAS are on the market is considered confidential business information (CBI). The result is that scientists, public authorities and the general public are in the dark about how the 4600+ PFAS on the market are being used and which of these uses are truly essential.

Given that all PFAS are extremely persistent and will be on the planet for eons to come, it is critical to begin to consider how the various PFASs are being used, and whether such uses can be eliminated because they are not essential and/or because safer alternatives are available.

## The Concept of Essential Use as a way forward

The Montreal Protocol's definition of "essential use" provides a way forward.[17] The two elements are that a use is "necessary for health, safety or is critical for the functioning of society" and that "there are no available technically and economically feasible alternatives".

[15] Cousins, I. et al. "The concept of essential use for determining when uses of PFAS can be phased out", *Environmental Science: Processes & Impacts* (2019). DOI: 10.1039/c9em00163h.
[16] https://www.oecd.org/chemicalsafety/portal-perfluorinated-chemicals/
[17] Decision IV/25. https://ozone.unep.org/treaties/montreal-protocol/meetings/fourth-meeting-parties-montreal-protocol/decisions/decision-4.

Under that definition, if a use is not essential for health and safety or the functioning of society, it is "non-essential". Examples of non-essential uses of PFAS include dental floss, cosmetics, and easy use textiles. Uses that have come to be regarded as essential because they perform important functions may cease to be essential because alternatives have been developed that have equivalent functionality. For instance, fluorine-free substitutes are now available for such uses as durable water repellency for textiles and firefighting foams, indicating that these uses of PFAS can now be phased out without significant impacts to modern society.

This leaves some uses considered important for health and safety but where no fluorine-free alternatives are yet available, e.g. protective clothing for first responders. For those uses, research and development is needed to come up with suitable alternatives, in order to reduce the production and use of PFAS as a class as much as possible.

It is encouraging to know that a number of manufacturers and retailers – IKEA and H&M in Sweden, COOP in Denmark, Vaude in Germany, L'Oreal in France – have decided to voluntarily phase out the use of certain PFASs because of their persistence and the risk of adverse health and environmental impacts. They provide positive examples of how uses of PFAS can be phased out successfully.

**Conclusion**

As stated above, meeting just one of the above criteria should be sufficient to trigger global action. However, the class of highly persistent compounds known as PFASs meet all nine proposed criteria for moving Issues of Concern to an increased level of obligation.

The unchecked growth in production and use of PFASs needs to be turned around, and a global phase-out initiated. If emissions are not reduced, they will continue to accumulate in the environment and to be sources of exposure for us and our descendants far into the future.

The Montreal Protocol's concept of essential use provides a way forward. Analysis of the various uses of PFASs can help us determine which uses may be non-essential and phased out or substituted without endangering society.[18] It will be complicated to carry out analyses for the many different uses of PFAS, but it will also provide us with a number of starting points for working towards global elimination of PFAS, as per the ICCM's Resolution II/5 adopted in 2009.

[18] Cousins *et al.* (2019)