September 24, 2023

Non-confidential comments for Annex XV restriction report: Health-related socioeconomic costs linked to PFAS exposure

Dear Madame or Sir,

We welcome the opportunity to provide input on the restriction proposal regarding per- and polyfluoroalkyl substances (PFAS). This submission was prepared by Gretta Goldenman (Milieu Ltd, retired) and Dr. Juliane Glüge (ETH Zürich), with input of other members of the Global PFAS Science Panel (GPSP). The GPSP is a collaborative partnership among academic researchers, regulatory scientists and policy analysts dedicated to enhancing understanding of PFAS and to protecting human and environmental health from potentially adverse effects associated with PFAS through better informed decision-making. The scientific work of the GPSP in the last five years has considerably advanced the understanding of PFAS and the GPSP would like to take the opportunity to also give input to the PFAS restriction proposal.

We see the restriction proposal as a very important initiative and good way forward to counteract the ongoing emissions of PFAS in Europe (and in part even worldwide). Our submissions should therefore be seen as a support of the restriction proposal to make it even stronger and more fully complete. This submission is on the health-related socioeconomic costs linked to exposure of PFAS. A separate submission will cover non-health (environment-related) socioeconomic costs. The following topics are covered:

1) A general note on costs to society from externalized impacts of PFAS exposure
2) How “The cost of inaction” report estimates for health-related costs linked to PFAS were developed and why we consider them as low
3) The Obsekov study on annual US costs of health impacts from PFAS exposures
4) The USEPA benefit-of-action study to back up proposed parameters for PFAS in drinking water
5) Not yet quantifiable health related costs of PFAS
6) Concluding remarks

1) A general note on costs to society from externalized impacts of PFAS exposure

We are pleased that the Annex XV report cites the health cost figures calculated for "The cost of inaction” report (published by the Nordic Council of Ministers) as one of the bases for its strong proposal to restrict uses of PFAS. “The cost of inaction” report estimated the costs to society of health harm linked to PFAS exposure at **between EUR 52 and EUR 84 billion a year** for 520 million people in the European Economic Area (EEA) (Goldenman 2019).

The OECD defines inaction in terms of the lack of regulatory progress, i.e., “no new policies beyond those which currently exist” (OECD 2008). The cost of inaction is therefore the cost that society will pay now and in the future, if action is not taken to limit PFAS exposure.

“The cost of inaction" report considered only the socioeconomic costs incurred by society at large. It did not look at possible costs to industry such as costs of substitution due to the phase-out of PFAS.

A benefit-of-action analysis is a complementary approach that can be used to justify the costs of taking a proposed action. If measures to reduce exposure to PFAS are implemented, e.g., clean-up of contamination, the health risks due to potential exposure are reduced. The resulting savings (reduced health costs, less costs of the remediation) are considered the benefits of implementing the action.

Most assessments of socioeconomic costs associated with PFAS have narrowly focused on costs to industry if uses of PFAS were restricted (Gabbert 2018). Studies quantifying and monetizing the societal costs associated with the very high persistence of PFAS, e.g., chronic disease linked to long-term exposure and environmental clean-up to reduce human exposure, are rare.

This note reviews how the quantitative estimates in “The cost of inaction” report were developed, and how these figures compare to other estimates of long-term societal costs linked to PFAS. It also considers non-quantifiable categories of costs, to further highlight the potential gains of reducing sources of PFAS exposure.

2) How “The cost of inaction” estimates for health-related costs linked to PFAS were developed and why we consider them as low

“The cost of inaction” estimates of EUR 52 and EUR 84 billion a year for the EEA are very large figures. The short paragraph in the Annex XV report gives no further details on costs. In contrast, Annex E (the Impact Assessment) goes into considerable detail (400+ pages) concerning potential costs to businesses (company closures, job losses) and consumers (higher prices) if proposed derogations to certain sectors of industry are not granted. Meanwhile, the fluorochemical industry has alleged that restricting the use of PFAS will endanger the energy transition and impose even larger costs on society (Keating 2023).

To bring some balance to these discussions, this summary explains how the health cost estimates were developed, and why the true costs to society from PFAS exposure are probably considerably higher. In 2018-19, when the research for “The cost of inaction” study was carried out, considerable debate still existed about which health endpoints, if any, were linked to PFAS exposure (Note: 3M still denies that PFAS causes harm). There was also little information about who was exposed to PFAS and whether this exposure was at concentration levels that could lead to disease.[1]

Given the limited information available, the study constructed three scenarios that corresponded to the main known pathways of PFAS exposure: (a) persons exposed to PFAS at high levels in the workplace; (b) communities exposed because of proximity to PFAS production or manufacturing sites or with PFAS in their drinking water due to the use of AFFF; (c) the general population exposed to PFAS because of its

[1] The methodology for estimating the health-related costs was developed by Dr Meena Fernandes.

presence in foods and consumer goods, and its ubiquity in the environment. We then estimated the size of the populations exposed under each scenario.

The next stage was to estimate the risk or probability that exposure to PFAS via one of these three scenarios would lead to a disease. The research team carried out a review of epidemiological studies of populations exposed to PFAS where risk ratios or odds ratios (basically, risk-response relationships) had been estimated. These ratios were used to calculate the percentage of the exposed population that suffered from a disease because of the exposure to PFAS, compared to the general population with that disease. Confidence intervals of the ratios were reflected in the lower and upper bounds of the estimated number of people who developed a disease linked to PFAS exposure. The analysis then investigated the potential number of deaths resulting from diseases that could be linked to PFAS exposure. Conservative estimates were used in the assumptions supporting the analysis.

Scenario (a) Occupational exposure. Exposure to PFAS due to working in a facility where PFAS is being produced or used in a manufacturing process can lead to higher levels of exposure than reference populations (Christensen 2023). To determine how many workers were exposed to PFAS in occupational settings, we estimated the total number of PFAS production plants operating in Europe at between 12 and 20. Using Eurostat data, we searched for how many manufacturing and commercial facilities could be found across Europe where PFAS might be in use. Relevant categories included textiles, leather, metal plating, paper and paper products, paints and varnishes, soaps and detergents, and plastics and resins, for a total of 352,764 small plants (less than 500 employees) and 780 large plants (more than 500 employees). We further assumed that 3% to 10% of these facilities used PFAS in their activities, the number of exposed workers in small facilities would average 30, and the number of exposed workers in large plants would average 300. With these assumptions we estimated that a range of 334,508 to 1,091,692 persons could be exposed to higher levels of PFAS in Europe, through their occupations.

The literature review identified an epidemiological study of workers in a fluoropolymer-production facility in West Virginia. The study found an elevated risk of death due to kidney cancer from occupational exposure to PFOA (Steenland 2012). We made a conservative assumption that in Europe only a quartile of exposed workers would have an elevated risk of kidney cancer mortality. This further reduced the size of the exposed population. We then calculated that 3.6 to 11.8 workers in Europe died each year from kidney cancer linked to occupational PFAS exposure. This was monetized using the ECHA lower bound value of life at EUR 3.5 million, at EUR 12.7 - EUR 41.4 million a year.

Scenario (b) Exposure of affected communities. Our research had identified several communities in Europe where drinking water or local food supplies were contaminated by emissions from a nearby PFAS production or manufacturing facility, or from releases of aqueous firefighting foams (AFFFs), and where residents had higher levels of PFAS in their bodies due to ongoing exposure to PFAS. We assumed that 3% of Europeans (12.5 million) were affected by contaminated drinking water on the basis of two studies: a study that estimated 3% of Swedish residents were drinking water with levels of PFAS over the Swedish advisory limit value, then 90 ppt (Holmström 2014); and a US study that estimated 6 million US residents (around 5% of the total) received publicly supplied drinking water exceeding US lifetime health advisory levels for PFAS, then 70 ppt (Hu 2016). This was combined with an increased risk factor for all-cause mortality that came from a study of residents exposed to PFAS from a manufacturing plant in the Veneto Region (Mastrantonio 2017). On this basis, the annual number of adult deaths linked to heightened PFAS exposure in affected communities was estimated at between 11,746 to 13,843. The ECHA lower bound value of life at EUR 3.5 million was again used to value the cost of lives lost at EUR 41.1 to 48.5 billion annually.

Scenario (c) The general population. The US NHANES (National Health and Nutrition Examination Survey) survey has found measurable PFAS in the bodies of 99% of US residents and levels of PFAS in US blood serum are comparable to findings in Europe (Kato 2011). It was therefore safe to assume that almost all Europeans have measurable PFAS in their bodies simply from exposure to PFAS in food, drinking water, consumer products, etc. Several studies based on the NHANES data suggested that PFAS exposure at low levels increased the risk of developing cardiovascular disease. Our valuation was based on a study that looked at the relationship between serum PFOA concentrations and the risk of developing hypertension, based on blood samples of 2,208 adults provided to NHANES (Min 2012). The calculation assumed that half of European adults had levels of PFAS associated with a higher risk of developing hypertension and that half of the 6.1 million new cases of cardiovascular disease diagnosed in the EU in 2015 were specifically related to hypertension and a higher risk of mortality. This worked out to an estimated 3,066 and 10,035 deaths attributable to PFAS-related hypertension, which was valued at EUR 10.7 -35 billion.

Table 1: Summary of the health-based "cost of inaction" estimates for the three exposure scenarios

Exposure scenario	"Exposed" population & source	Health endpoint	Size of population at risk	Annual costs
Occupational (high)	Workers at chemical production plants or manufacturing sites	Kidney cancer	84,000 – 273,000	EUR 12.7 – 41.4 million
Elevated (medium)	Communities near chemical plants, etc. with PFAS in drinking water	All cause mortality	12.5 million	EUR 41-49 billion
General population (low)	Adults exposed via food, consumer products, water, etc.	Hypertension	207.8 million	EUR 10.7 – 35 billion
Totals				**EUR 52 – 84 billion**

These estimates were calculated based on a very limited number of health endpoints for which risk or odds ratios were available. Given the mounting evidence on links between PFAS and other diseases, and the careful assumptions made about size of affected populations, the estimates seemed conservative. For example, we only estimated the losses due to mortality. But there are other costs of living with a disease which we did not include – health care costs, reduced productivity, and lower quality of life. Our analysis also does not account for impacts on children and future generations.

In response to informal queries, we carried out simple calculations to find US equivalents to the health-related costs of PFAS exposure, accounting for differences in population size and currency values in 2019.

*Table 2: US equivalencies to "The cost of inaction" health-related estimates**

	Overall population	Annual overall costs	Cost per capita
EEA+CH	522,000,000	EUR 52 – 84 billion	At least EUR 1,056
USA	325,000,000	USD 37 – 59 billion	At least USD 1,213

* EUR to USD = 1.1482, at 31.12.2018.

3) The Obsekov study on annual US costs of health impacts from PFAS exposures

Annex XV notes that a 2022 study on US health-related costs linked to PFAS exposure found annual costs in the same range as the cost of inaction estimates (Obsekov 2022). The Obsekov study aimed to quantify the disease burden for the entire US population associated with routine, low-level environmental PFAS exposure.

To counter peer review concerns about possible bias in data selection, the Obsekov study used only meta-analyses and systematic reviews of epidemiologic studies with statistically significant associations between PFAS exposure and disease outcomes.[2] Figures for the population at increased risk were drawn from the 2017-2018 US National Health and Nutrition Examination Survey (NHANES) dataset on PFAS concentrations in blood serum in a sample of the US population (NHANES 2017-2018).

The Obsekov study also used exposure-response relationships, e.g., risk ratios or odds ratios, for its estimates of disease burdens and costs. The low range of the cost estimates ($5.52 billion a year) were based on meta-analyses that had calculated the risk ratios for five (5) diseases. An additional eight (8) PFAS-attributable diseases identified in systematic and scoping reviews (but not meta-analyzed) were used for a sensitivity analysis that then became the high range ($62.6 billion) estimate. The table below summarizes the study's estimates for each disease outcome considered.

Table 3: Summary of estimated costs of 13 disease outcomes linked to PFAS exposures

	Disease outcome	Low	High
From meta-analyses			
1	Low birth weight due to prenatal exposure	$1,420,000,000	$13,700,000,000
2	Childhood obesity due to prenatal exposure	$2,650,000,000	$9,600,000,000
3	Kidney cancer due to lifetime exposure	$184,000,000	$184,000,000

[2] A systematic review asks a specific research question and then identifies, assesses, and synthesizes the empirical evidence, according to pre-set criteria aimed at eliminating bias. A meta-analysis is a quantitative study design used to mathematically combine outcomes from multiple studies so as to obtain a more precise estimate than when considering studies individually.

	Disease outcome	Low	High
4	Testicular cancer due to lifetime exposure	$6,850,000	$6,850,000
5	Hypothyroidism in females due to lifetime exposure	$1,260,000,000	$5,180,000,000
	Low estimate	**$5,520,850,000**	$28,670,850,000
	From systematic reviews (sensitivity analysis)		
6	Adult obesity due to exposure over the lifespan	$17,000,000,000	$17,000,000,000
7	T2D (adult Type II diabetes) in females due to lifetime exposure	$140,000,000	$140,000,000
8	GDM (gestational diabetes) due to exposure measured in pregnancy	$414,000,000	$852,000,000
9	Endometriosis due to exposure over the lifespan	$397,000,000	$10,200,000,000
10	PCOS* due to exposure over the lifespan	$10,500,000	$10,500,000
11	Couple infertility due to lifetime exposure in females	$37,600,000	$1,660,000,000
12	Female breast cancer due to lifetime exposure	$555,000,000	$4,080,000,000
13	Pneumonia in children due to prenatal exposure	$1,490,000	$22,500,000
	Subtotals	$18,555,590,000	$33,965,000,000
	High estimate		**$62,635,850,000**

- *Polycystic ovarian syndrome*

Note that several disease outcomes also associated with PFAS exposure were not included, such as pediatric dyslipidemia, reduced age at menarche, adult high cholesterol (linked to high blood pressure), and reduced response to childhood vaccination.

The Obsekov study's high estimate of USD 62.6 billion is similar to the calculation based on "The cost of inaction" figures that US health-based costs of PFAS exposure could be between USD 37 – 59 billion a year. However, there are also significant differences between the two studies. The Obsekov study aimed to capture the costs of low-level exposure across the US population and did not look at instances of high or medium exposure. In addition, in 2022, more studies were available on health endpoints associated with PFAS exposure, including syntheses in the form of systematic reviews and meta-analyses. The Obsekov study was thus able to consider more disease endpoints and in greater detail. Nonetheless the two studies arrive at overall estimates that suggest an analogous scale of health-based costs due to population-wide exposures to PFAS.

4) The USEPA benefit-of-action study to back up proposed parameters for PFAS in drinking water

In March 2023, economists at the US Environmental Protection Agency (USEPA) carried out a benefit-of action analysis to justify proposed federal standards for six PFAS in drinking water. The proposed National Primary Drinking Water Regulation (NPDWR) would set maximum contaminant levels (MCLs) for PFOA and PFOS at 4 ppt (parts per trillion). Four other PFAS (PFNA, HFPO-DA, PFHxS and PFBS) would be regulated as a mixture using a hazard index calculation (USEPA 2023a).

The USEPA analysis assessed benefits as avoided cases of illness and deaths associated with exposure to PFAS, while costs were the expenses incurred by public water systems to (1) monitor for PFAS, (2) inform consumers, (3) install and operate remediation technologies, and (4) comply with reporting provisions (USEPA 2023b).

The benefits assessment quantified the avoided morbidity and mortality due to cardiovascular disease (CVD), low birth weight, and renal cell carcinoma (RCC) if PFOA and PFOS were reduced in drinking water in compliance with the proposed rule. To quantify benefits from reductions in cardiovascular disease incidents, USEPA carried out a meta-analysis based on 14 studies, 12 of which were used to develop exposure-response relationships for the potential effects of PFAS in blood serum. It then used standardized values of statistical life to estimate the benefits of reducing mortality, and cost of illness-based valuations to cover the medical costs of treating a disease incidence.

If the proposed MCLs were implemented, USEPA calculated that the expected health benefits from reductions in illness and death from cardiovascular disease, low weight births and kidney cancer would be USD 1.23 billion a year. USEPA then subtracted the anticipated cost of compliance (estimated at USD 771 million a year, over an 80-year period) to arrive at a net annualized benefits-of-action of USD 460 million a year, at a 3% discount rate.

Table 3: Total Net National Annualized Benefits-of-Action ($2021) over 80 years, at 3% Discount Rate

Option	Expected annualized benefits	Expected annualized costs	Total annualized net benefits-of-action per option
Proposed option	$1,232,980,000	$771,770,000	$461,210,000
Option 1a	$1,216,080,000	$755,820,000	$460,260,000
Option 1b	$1,046,910,000	$611,010,000	$435,900,000
Option 1c	$584,800,000	$292,570,000	$292,230,000

The key take-away from the USEPA benefit-of-action analysis was that the most stringent drinking water standards proposed for PFAS were expected to produce the highest reduction in PFAS-associated illnesses and deaths, and therefore represented the best overall value.

The USEPA's expected annualized benefits of USD 1.23 billion a year over 80 years are much lower than the Obsekov study's low estimate of USD 5.52 billion a year. There are at least two explanations for this. First, the USEPA study calculated reductions in three disease endpoints (cardiovascular disease, low weight births, and renal carcinoma). The Obsekov study considered two of these disease endpoints (low weight births and kidney cancer); and in addition, it also looked at childhood obesity, testicular cancer, and hypothyroidism in females due to lifetime exposure. Second, drinking water is considered to contribute only 20% of a person's overall daily exposure to PFAS (USEPA 2018) and the USEPA's benefits-of-action analysis takes this into account. So, the anticipated reduction in PFAS exposure through treatment of PFAS-contaminated water would not reduce exposure to PFAS from other sources, such as contamination of food from PFAS used in food packaging materials or other uses in consumer goods.

Note that the USEPA economists also carried out a qualitative assessment of potential benefits where information needed for a quantitative analysis was lacking. They concluded that "the non-quantifiable human health benefits associated with reductions in drinking water PFAS exposure are substantial and may reasonably exceed the benefits the Agency was able to quantify for this regulatory proposal."

5) The not yet quantified health-related costs of PFAS

Since the 2019 study, awareness has grown concerning many other societal impacts linked to PFAS contamination, many of which cannot be quantified:

- Stressors on communities affected by PFAS drinking water contamination, e.g., uncertainty over health, distrust of community institutions, and financial burdens (Calloway 2020);
- Health and social concerns in communities affected by PFAS contamination (Banwell 2021);
- Burdens on local and state governments, e.g., monitoring for contamination and related health impacts, interactions with concerned citizens to address their health concerns.

"The True Cost of PFAS and the Benefits of Acting Now" is a 2021 commentary that gives a fuller picture of the many costs to society from PFAS contamination (Cordner 2021). These costs are routinely and disproportionately externalized to society at large.

6) Concluding remarks

Efforts to quantify the long-term health-related costs to society of PFAS exposure aim to highlight how reducing exposures will lead to significant savings in health-related costs. For while the costs of cleaning up contaminated drinking water are substantial, the costs of *not* acting to reduce PFAS exposure are much greater.

It is important to note that many of the costs cited above, particularly health-related costs of PFAS exposure, are already a burden to society due to current impacts from exposure to legacy PFAS and to the PFAS still used in industrial processes and consumer products. To cap these costs at current levels, it is urgent to limit the derogations in the REACH restriction proposal to as few as possible.

References

Andrews DQ and Naidenko OV (2020). Population-Wide-Exposure to Per- and Polyfluoroalkyl Substances from Drinking Water in the United States. *Environ. Sci. Technol. Lett.* 2020, 7, 12, 931–936, https://doi.org/10.1021/acs.estlett.0c00713

Banwell C et al. (2021). Health and social concerns about living in three communities affected by per- and polyfluoroalkyl substances (PFAS): A qualitative study in Australia, PLOS ONE, 16(1), p. e0245141. doi: 10.1371/JOURNAL.PONE.0245141.

Calloway, E. E. et al. (2020) 'Exploring Community Psychosocial Stress Related to Per- and Poly-Fluoroalkyl Substances (PFAS) Contamination: Lessons Learned from a Qualitative Study', International Journal of Environmental Research and Public Health 2020, Vol. 17, Page 8706, 17(23), p. 8706. doi: 10.3390/IJERPH17238706

Christensen, B.T., Calkins, M.M. Occupational exposure to per- and polyfluoroalkyl substances: a scope review of the literature from 1980–2021. *J Expo Sci Environ Epidemiol* (2023). https://doi.org/10.1038/s41370-023-00536-y.

Cordner A, Goldenman G, Birnbaum LS, Brown P, Miller MF, Mueller R, Patton S, Salvatore DH, and Trasande L (2021). The True Cost of PFAS and the Benefits of Acting Now, *Environmental Science & Technology* **2021** *55* (14), 9630-9633. DOI: 10.1021/acs.est.1c03565.

Gabbert S. 2018. Economic assessment and valuations of environmental and health impacts caused by Perfluorooctanoic acid (PFOA) and its salts - OECD Environmental Working Papers No. 128.

Goldenman G, Fernandes M, Holland M, Tugran T, Nordin A, Schoumacher C, et al. 2019. The cost of inaction - A socioeconomic analysis of environmental and health impacts linked to exposure to PFAS.; doi:10.18146/soima2015.2.06.

Holmström et al. (2014). Nationell screening av perfluorerade föroreningar (PFAA) i dricksvatten. Rapport no 2014/20 (In Swedish)

Hu X, Andrews DQ, Lindstrom AB, Bruton TA, Schaider LA, Grandjean P, Lohmann R, Carignan CC, Blum A, Balan SA, Higgins CP and Sunderland EM (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. 2016, 3, 10, 344–350. https://doi.org/10.1021/acs.estlett.6b00260.

Kato K et al. (2011). Trends in exposure to polyfluoroalkyl chemicals in the US population: 1999 – 2008. *Environmental Science & Technology,* 45(19), pp.8039-8045.

Keating D (2023). "Health vs climate? How an EU chemical ban could hinder the energy transition," *Energy Monitor*, June 15, 2023. Available at: https://www.energymonitor.ai/sectors/industry/health-vs-climate-pfas-how-an-chemical-ban-could-hinder-the-energy-transition/.

Mastrantonio M *et al*. (2017). Drinking water contamination from perfluoalkyl substances (PFAS): an ecological mortality study in the Veneto Region , Italy. *European Journal of Public Health*, 28(1). doi: 10.1093/eurpub/ckxo66.

Min JY, Lee KJ, Park JB, Min KB. Perfluorooctanoic acid exposure is associated with elevated homocysteine and hypertension in US adults. *Occup Environ Med*. 2012 Sep;69(9):658-62. doi: 10.1136/oemed-2011-100288.

NHANES (2017-2018). National Health and Nutrition Examination Survey Data (NHANES), National Center for Health Statistics (NCHS), Centers for Disease Control and Prevention (CDC), https://wwwn.cdc.gov/Nchs/Nhanes/2017-2018/PFASJ.htm.

Obsekov V, Kahn LG, Trasande L. 2022. Leveraging Systematic Reviews to Explore Disease Burden and Costs of Per- and Polyfluoroalkyl Substance Exposures in the United States. Expo Heal; doi:10.1007/s12403-022-00496-y.

OECD (2008). OECD Environmental Outlook to 2030, OECD Publishing, Paris, https://doi.org/10.1787/9789264040519-en.

Steenland K and Woskie S (2012). Cohort mortality study of workers exposed to perfluorooctanoic acid. American journal of epidemiology. 176(10) pp.909–917

US EPA (2023a). EPA's Proposal to Limit PFAS in Drinking Water, EPA Fact Sheet, March 2023. Accessed at: https://www.epa.gov/system/files/documents/2023-04/Fact%20Sheet_PFAS_NPWDR_Final_4.4.23.pdf.

USEPA (2023b). Economic Analysis for the Proposed Per- and Polyfluoroalkyl Substances National Primary Drinking Water Regulation (draft for public comment). EPA Document No. EPA-822-23-001.

USEPA (2023c). Chemical Lists that contain "PFAS" in their list name. Available at https://comptox.epa.gov/dashboard/chemical-lists.

USEPA (2023d). Presentation by the USEPA Office of Water. See "General Overview Webinar Presentation: Proposed PFAS NPDWR (pdf). Available at: https://www.epa.gov/sdwa/and-polyfluoroalkyl-substances-pfas.