Submitted on 20th July 2023

HEAL response to the public consultation on the universal PFAS (uPFAS) restriction

Introduction:

HEAL thanks the authorities of Germany, Denmark, the Netherlands, Norway, and Sweden for their proposal for a restriction on per- and polyfluoroalkyl substances (PFASs) and supports its unprecedented broad and comprehensive scope.

In particular, we support employing the OECD 2021 definition for PFAS and using persistence as a sufficient justification for restricting PFAS (the P-sufficient approach).[1] We also fully support the inclusion of fluoropolymers and perfluoropolyethers under this definition, as they are widely used, are increasingly being found in the environment, and are associated with widespread pollution.[2] We further commend the dossier submitters for the concrete measures proposed to promote transparency through the inclusion of information requirements tied to derogations.

To improve the effectiveness of the proposed restriction, we urge the ECHA risk assessment committee (RAC) to minimise derogations for any non-essential PFAS uses and to reduce the time frames of derogations as much as possible. Evidence of cumulative high levels of many different PFAS in humans, demonstrated in the joint European research programme HBM4EU, highlight the urgent need to take, "...all possible measures to prevent further contamination of the European population."[3] In the context of the restriction proposal under discussion, this includes limiting derogations to only those PFAS uses that are essential for health, safety and the functioning of society and for which there are currently no safer alternatives.[4] [5]

Areas where the restriction may be strengthened can be summarised as follows and more detailed information is also provided later in this public consultation response.

1. **Proposed time unlimited derogations:**
   HEAL does not support time unlimited derogations, as those currently proposed are not well justified and it is unclear how PFAS exposure through the derogated uses will effectively be minimised. Furthermore, enforceable regulatory timelines provide market predictability and innovation in replacing extremely persistent chemicals with safer alternatives.

2. **Time unlimited derogations for plant protection products (PPP) and biocidal products (BP):**

Plant protection products (PPP) and biocidal products (BP) are proposed for exclusion from the restriction, yet they contribute to direct PFAS emissions into the environment and the use of PFAS is utilised for the mass production of pesticides in particular. We are therefore concerned by the proposed time unlimited derogations. How concretely coordination between regulatory bodies will take place to minimise environmental and human health impacts of these PFAS emissions remains unclear from the dossier and other available public information, potentially creating a huge regulatory loophole resulting in further human exposure.

3. **Proposed derogations linked to direct human exposures from food contact materials (FCMs) and drinking water applications:**
   Derogations for FCMs and drinking water applications may unnecessarily pose ongoing and increasing hazards to human health and the environment throughout their life-cycle. Recently published evidence demonstrates the presence and migration of various PFAS from drinking water pipes[6] and FCMs[7] that lead to direct human exposure in water and food via ingestion. The dossier submitters note the pitfalls of the increasing stock of PFAS stating that "...even if further releases of PFASs were immediately prevented, existing environmental stocks as well as technical stock (stock of PFASs in existing articles) and PFAS-containing waste would continue to be a source of exposure for generations." Therefore, in order to minimise future cumulative exposures and potential harm to people and the natural environment, bans should be implemented as soon as possible. This is especially critical in instances where the public may be directly exposed via products such as drinking water applications and FCMs.

4. **Information requirements and mandatory management reports:**
   Although reporting requirements are proposed for derogations with a duration of 12 years (13.5 years after entry into force, or EiF) as well as for all applications of fluorinated gases, all derogations (even those with a 5-year time limit or 6.5 years after EIF) should have the same reporting requirements, or sufficient justification for the lack of such requirements should be provided. Information requirement reports are also the first step towards implementation of the polluter pays principle as they provide information on the sources and quantity of potential pollution, which can be used to hold industry accountable in the future.

5. **Mechanisms for oversight and review of the restriction implementation:**
   The wide scope of this restriction necessitates a clearly established process for regulatory action and oversight of implementation grounded in up-to-date science and technology. These mechanisms can be employed to review restriction implementation, ensure compliance, and hold industry accountable for pollution and clean up. Specifically, we suggest:
   - Regular review of the restriction's implementation at the 5 (6.5 years after EiF) and 12-year (13.5 years after EiF) deadlines for derogation phase out and ban of uses. This would provide more oversight to ensure compliance with bans and safer

substitution. Such a mechanism would also trigger proactive updates, guaranteeing that the restriction is fit for the future.
    - Regular incorporation of new analytical methods as they become available and standardised for regulatory use.
    - Industry accountability for derogations through an obligation for industry to provide analytical methods and technology necessary for environmental assessment for any PFAS use, in addition to covering the costs for abatement.

Strengths of the restriction proposal:

HEAL recognises and supports the strength of this comprehensive restriction proposal, specifically:

1. **The broad P-sufficient scope and approach**
2. **The reliance on a scientifically justified definition of PFAS that includes fluoropolymers and perfluoropolyethers**
3. **The inclusion of information requirements for derogations**

1. **Broad P-sufficient scope and approach**

The restriction's P-sufficient scope is based on wide scientific consensus on the approach to regulate PFAS as a chemical class and offers a comprehensive regulatory framework for better protecting present and future generations' health and the environment from irreversible, increasing harm.[8] [9] [10] We welcome the aim to regulate all PFAS that meet this criteria of highly persistent intrinsic properties exceeding the very persistent (vP) criterion under Annex XIII, which constitutes an efficient and effective grouping approach (also demonstrated in the restrictions on intentionally added microplastics, PFHxA, and PFAS in firefighting foams) to minimise the potential for future regrettable substitution.

2. **The reliance on a scientifically justified definition of PFAS that includes fluoropolymers and perfluoropolyethers**

The inclusion of fluoropolymers and perfluoropolyethers in the proposed restriction is absolutely crucial due to their extreme persistence, growing life-cycle cumulative emissions, high likelihood of human exposure, and their wide uses.[11] As the dossier and independent peer-reviewed scientific evidence clearly demonstrate, fluoropolymers and perfluoropolyethers pose unacceptable risks to human health and the environment during their manufacturing, use and disposal. During manufacturing, fluoropolymers and perfluoropolyethers release low molecular weight PFAS used as raw materials, processing agents, additives, or generated as intermediates, all of which contaminate air and water waste streams. Thus far, industry public consultation responses to the proposed restriction have not provided evidence to the contrary. These other PFAS are also released during some uses, such as PFCA in personal care products that contain PTFE.[12] During disposal PFAA can also be generated and released, such as during incomplete incineration, which is common.[13] [14] [15]

In addition, contrary to findings from studies on fluoropolymers with declared conflicts of interest (where the authors work for manufacturers of fluoropolymers),[16] [17] experts and much of the independent peer-reviewed scientific literature to date have found evidence that fluoropolymers, perfluoropolyethers, and processing aids used in fluoropolymers' manufacturing may not be of low concern for human health and the environment due to their persistence and growing detection in the environment. [18] [19] [20] [21] As the dossier submitters point out, the evidence of fluoropolymers' life-cycle impacts from production to end-of-life (EoL) pose additional concerns specific to emissions of low-molecular weight PFAS and fluoropolymer microplastics, which have been detected even in remote areas.[22]

The dossier submitters also highlight that some producers have already announced a transition to non-fluorinated polymerisation aids, suggesting that safer alternatives are available. [23] [24] [25] [26] [27] It is important to note here though that caution should be taken in evaluating any potential substitutes. However, the literature indicates that safer non-fluorinated polymerisation aids do exist and are already being used. As part of the available literature, a study looking at non-fluorinated alternatives found that, polyolefin glycol emulsifier presents a likely reduction in human-health and environmental hazard.[28]

Thus, the inclusion of fluoropolymers and perfluoropolyethers within the scope of the restriction preemptively avoids regrettable substitution, which is the most effective regulatory strategy for reducing long-term, cumulative harmful exposures to humans and the environment.

3. **Transparency through information requirements for derogations**

We support the dossier submitters' proposed information requirements for derogations of 12 years (13.5 after EiF), in line with REACH legal requirements that industry bears the burden of proof regarding the lack of safer alternatives for a specific use. [29] [30] This is a very important mechanism to strengthen industry accountability and transparency, but we are concerned that the proposal only requires annual reporting for 13.5-year time-limited derogations and for fluorinated gases (which have a proposed time-unlimited derogation). Meanwhile, no information requirements for 5-year (6.5 after EiF) derogations are included. We discuss this further in the next section on key areas to strengthen.

Key areas to strengthen the uPFAS restriction

In considering the unprecedented, highly ambitious restriction currently proposed, we would like to provide further scientific justification for strengthening the key areas of concern that we have highlighted above and cover the following:

1. **Proposed time-unlimited derogations**
2. **Active substances in plant protection products (PPP), biocidal products (BP) excluded from restriction scope**

3. **Proposed derogations linked to direct human exposures from food contact materials (FCMs) and drinking water applications**
4. **Reporting requirements and mandatory management reports**
5. **Mechanisms for oversight and review of the restriction implementation**

1. Proposed time-unlimited derogations

HEAL does not support any time-unlimited derogations with the exception of the "use of PFASs in calibration of measurement instruments and as analytical reference materials (because this is necessary for the targeted analysis of PFASs in the monitoring of these substances in various matrices)."[31] Applying a time limit to derogations provides both market predictability and incentives for safer substitution or use of effective non-chemical interventions. Therefore, we recommend placing a time limit on the two proposed time unlimited derogations relevant to:

- Use of refrigerants in HVACR-equipment in buildings where national safety standards and building codes prohibit the use of alternatives;
- Use of PFASs as active ingredients (but not as co-formulants) in plant protection products (PPP) and biocidal products (BP).

Furthermore, in order to reduce regulatory gaps, clear coordination measures with other respective pieces of legislation (e.g. Regulation (EC) No 1107/2009 (PPPR), Regulation (EU) No 528/2012 (BPR), and (EU) 2019/1937 (recently proposed F-gas restriction)) must be explicitly detailed in the restriction proposal in order to avoid regulatory gaps. We make further recommendations below regarding the proposed time unlimited derogation of the use of PFASs as active ingredients (but not as co-formulants) in PPP and BP.

We urge RAC to consider recommending a time-limited derogation for, "use of PFASs in refrigerants in HVACR-equipment in buildings where national safety standards and building codes prohibit the use of alternatives." Since safer alternatives exist, there is no scientific justification for a delay in the transition to safer substitutes. Given what is now known about environmental effects of F-gases, it is not logical for current building codes to require their use or prohibit alternatives. Indeed, according to the Evaluation Final Report for (EU) 517/2014 such safety standards at the international level, EU wide, and in most Member States already support the use of natural refrigerants or are currently being adjusted to do so. Any remaining barriers are unjustified on the grounds of flammability safety.[32] A related report states that the problem "lies outside the scope of the Regulation and hence changes to the Regulation alone cannot fully resolve this issue."[33] A time limit on the derogations in the current PFAS restriction proposal would support this important transition and fill the current regulatory gaps.

Although covered under the F-gas regulation and Montreal Protocol, regrettable substitution of HFCs with HFOs is growing due to the latter's lower global warming potential. However, these HFOs have been associated with atmospheric degradation to TFA, which is persistent and highly mobile in the environment. [34] [35] In fact, HCFCs, HFCs, and HFOs are associated with the >10-fold increase in the level of Arctic deposition of TFA since the Montreal Protocol.[36] There is

growing consensus that policies and standards supporting low-GWP fluorinated refrigerants are transitional tools to be used only until large scale usage of natural refrigerants is achieved. [37] It is important to signal that F-gases will at some point be completely banned in order to motivate standard setting bodies to revise their codes and companies to transition to natural alternatives.

As noted in the restriction proposal, “For specific applications of fluorinated gases, the market is assumed to grow considerably in the coming 30 years.”[38] The restriction proposal also points out that, “...it is expected that the standards and codes over time are allowing more use of PFAS-free refrigerants.”[39] It is important that safer alternatives are developed and implemented quickly to meet this demand. Contrary to industry claims, viable non-fluorinated refrigerants exist and are growing in use already. [40] [41] [42] Time limited derogations are an important tool to incentivise updates to national safety standards and building codes based on current science, and to minimise regrettable substitution.

2. Active substances in plant protection products (PPP) and biocidal products (BP) excluded from restriction scope

We strongly concur with the dossier submitters that PFAS emissions and exposure through PPP and BP need to be addressed. Further, we support the dossier submitters in including co-formulants in PPP and BP within the scope of the restriction. We also acknowledge the legal rationale for addressing PFAS active substances in PPP and BP under their respective legislative frameworks. However, the restriction dossier is unclear on a number of points that are extremely important for these PFAS uses to be adequately restricted as soon as possible.

A recent US report investigating the prevalence of PFAS in PPP has shed light on the potential dangers of this PFAS exposure pathway. This study found that 40% of the most popular agricultural pesticides widely used in the US were laden with PFAS, some at levels as high as 1500 ppt.[43] Another recent investigation found that 500 tonnes of PFAS pesticides, specifically diflufenican and fluopyram, were sprayed over agricultural land in Denmark over the past decade. [44] [45] Scientists caution that more accurate EU data is needed to determine the true extent of PFAS used in pesticides in the EU and globally.[46] This new data from the US and Denmark, not included in the dossier, suggests that the problem may be larger than the restriction presumes and should be investigated to get a more accurate understanding of the extent of PFAS pesticide use in the EU. In fact, some of the industry responses to the public consultation on the restriction proposal also suggest that PFAS exposure through PPP is a significant issue that will not be solved solely through the PPP regulation. For instance, according to the submission of Central Glass, "70% of synthetic pesticides developed in the last five years are fluorine organic compounds" and "fluorinated intermediates and fluorine raw materials have been an enabling mass production of pharmaceuticals and agrochemicals"[47] - arguments that they use to unduly request another derogation for fluorinated intermediates and fluorine raw materials under the proposed restriction. In any case, this line of argument together with its supporting figures illustrate the need for a more comprehensive approach to the risk management of PFAS pesticides than through the sole PPPR and at least call for changing the currently proposed time unlimited derogation into a limited one for PPPR active substances.

PFAS active substances used in PPP and BP must be considered a priority for immediate regulatory action. Thus, PFAS active substances must be regulated under the universal PFAS restriction until other legislation offers a more protective framework to address these persistent substances. This is the only way to address the unacceptable risks stemming from PFAS pesticide emissions and exposures in a comprehensive, coherent way at the EU level in order to minimise them over the long term.

Several points that require clarifications in the dossier include:

- A more accurate baseline estimate of the number of current active substances in PPP and BP is needed. Dossier submitters reference data sources as, "roughly based on ratio of PFAS PPP/total PPP in NL times total PPP in EU." [48] We recommend cross referencing these data estimates with registration records under REACH and the EU Pesticides database. As per exchanges between HEAL and the European Commission Directorate General in charge of food safety, the number of substances mentioned in the restriction dossier neither comes from the European Commission, nor seems to have been discussed with them.
- The dossier submitters acknowledge the need for more complete data in these sectors. Thus, they rightly suggest setting up a mechanism in the restriction in which, "the proposed derogation includes reporting requirements for the placing on the market, applicable to manufacturers and importers of PFAS active substances in PPP, BP and human and veterinary MP."[49] We recommend an automatic reporting mechanism to the relevant authorities in charge of the risk management of PPP and BP.
- The dossier is even less clear about actual coordination between authorities to make sure that the uses of PFAS are effectively restricted in PPP and BP, simultaneously to the development of the REACH restriction. There is a high risk of regulatory gap at the moment. Since the REACH restriction process covers these uses as long as it remains the most protective legislative framework, PP and BP should be included in the universal PFAS restriction to fill this gap.

3. Proposed derogations linked to direct human exposures

Food contact materials (FCMs) and drinking water applications:
Allowing continued use of fluoropolymers and perfluoropolyethers for use in food contact materials for industrial and professional food and feed production (including for drinking water applications) and the potential derogation for non-stick coatings in industrial and professional bakeware may both pose unacceptable risks from a human health and environmental perspective. Although there is limited scientific literature on this topic, there is evidence of PFAS migration from some sources of industrial food contact materials such as water pipes.[50] [51] In a review of the literature, researchers found that pipe material was associated with contaminant migration of five groups of substances including PFAS.[52] As contaminated drinking water poses a primary human exposure pathway, more critical evaluation of the necessity of PFAS use in drinking water applications such as filtration and separation media and piping and tubing is warranted. The very

intent of these uses is to distribute safe drinking water and remove contaminants such as PFAS, but use of PFAS in these materials may pose both direct and downstream contamination and further avoidable exposures.

Recent research looking at food, beverage, and feedstock processing facility wastewater also demonstrates both the potential risk of environmental contamination and exposure through the food chain.[53] This research suggests that either the food source or the manufacturing process itself may be the source of PFAS contamination.

The more general body of evidence looking at consumer FCMs such as food packaging and PFAS migration into food suggests the need for a precautionary approach to FCMs in the industrial sector as well due to the same potential route of direct exposure via ingestion.[54] [55] Studies have found that FCMs for consumer use may contribute substantially to individuals tolerable weekly intake (TWI) of PFAS.[56] [57] [58] [59] Vulnerable populations including infants and children are particularly susceptible to greater exposures due to multiple factors including consuming more food and fluids per body weight. [60] [61] As dossier submitters point out, plastic food packaging known to contain PFAS, especially fluoropolymers and perfluoropolyethers**,** is expected to grow quickly in the near future along with a steady growth of paper food packaging and use in industrial food and feed production equipment.[62] In order to slow growth of fluoropolymer and perfluoropolyethers, in addition to other PFAS use in the industrial and professional FCMs sector and encourage a shift to safer, more sustainable alternatives, derogations should be shortened (e.g. 18 months after EiF).

Thus, HEAL urges authorities not to grant these derogations and potential derogations unless more evidence is provided on the different types of uses within the subsectors demonstrating their essentiality and lack of safer viable alternatives.

4. Reporting requirements and mandatory management reports

While the proposed restriction establishes important reporting requirements for derogations with a duration of 12 years (13.5 years after EIF) and all applications of fluorinated gases, it fails to do so for 5-year derogations (6.5 years after EIF). We disagree with the restriction's rationale for this gap in the reporting requirements. The dossier submitters state, "the reporting requirement is mainly applicable for larger, generally more knowledgeable stakeholders (manufacturers and formulators) and require only annual reporting for 13.5 year time-limited derogations and for one of the time-unlimited derogations, making the administrative burden for both stakeholders and authorities manageable."[63] On the contrary, all of the granted derogations must have the same information requirements to incentivise more complete data collection and transparency, and to relieve the burden on authorities in collecting this data. We see the introduction of harmonised reporting requirements for all derogations as a concrete means to force industry to provide more data in order to ensure that REACH legal requirements are met. This will help to ascertain whether the safe use of these chemicals is also met. Thus, for 5-year derogations (6.5 years after EIF), we recommend that the same reporting requirements also apply.

5. Mechanism for scientific updates, review, and oversight of restriction implementation

In order to be truly fit for the future and remain relevant, this restriction proposal must take into account the latest state of the science on PFAS as it evolves. Therefore, we recommend including:

- Two monitoring milestones tied to the expiration of derogations: A 5-year (6.5 year after EiF) and a 12-year (13.5 years after EiF) monitoring milestones for authorities to assess the overall effectiveness of the restriction. The results of such monitoring exercises could be used to trigger enforcement measures to check compliance and progress towards safer substitution that the restriction aims to serve. These monitoring milestones would also support the obligation to take into account new, state-of-the art science on analytical methods for enforcement and compliance as they develop in the context of the restriction implementation.
- Linking directly the granted derogations to industry obligations to:
    - Provide analytical methods and technology that adequately detect and remove PFAS, PFAS precursors, and their degradation products from the environment (water, air, and soil);
    - Contribute fees to a fund (to be established and managed by public authorities) to cover the costs of environmental monitoring and remediation in order to be able to continue producing PFAS for a particular use that is derogated.

Conclusion

The uPFAS restriction's unprecedented and ambitious scope sets a strong environmental and health protective framework for the future of EU citizens and the world. HEAL supports its P-sufficient approach as a basis for the efficient and effective regulation of PFAS of concern for human health and the environment.

---

[1] OECD. (2021). Reconciling Terminology of the Universe of Per- and Polyfluoroalkyl Substances: Recommendations and Practical Guidance, OECD Series on Risk Management. *OECD Publishing*. 61. Retrieved 12 July 2023 from https://www.oecd.org/chemicalsafety/portal-perfluorinated-chemicals/terminology-per-and-polyfluoroalkyl-substances.pdf

[2] Kwiatkowski, C.F., Andrews, D.Q., Birnbaum, L.S., Bruton, T.A., DeWitt, J.C., Knappe, D.R U., Maffini, M.V., Miller, M.F., Pelch, K.E., Reade, A., Soehl, A., Trier, X., Venier, M., Wagner, C.C., Wang, Z., and Blum, A. (2020). Scientific Basis for Managing PFAS as a Chemical Class. *Environ. Sci. Technol. Lett.* 7(8), 532–543. DOI: 10.1021/acs.estlett.0c00255

[3] Uhl, M., Schoeters, G. Govarts, E., Bil, W., Fletcher, T., Haug, L.S., Hoogenboom, R., Gundacker, C., Trier, X., Fernandez, M F., Calvo, A.C., López, M.E., Coertjens, D., Santonen, T., Murínová, L.P., Richterová, D., De Brouwere, K., Hauzenberger, I., Kolossa-Gehring, M., and Halldórsson, Þ., I. (2023). PFASs: What can we learn from the European Human Biomonitoring Initiative HBM4EU. Int J Hyg Environ Health. 250, 114168. DOI: 10.1016/j.ijheh.2023.114168

[4] Cousin, I. T., Goldenman, G., Herzke, D., Lohmann, R., Miller, M., Ng, C. A., Patton, S., Scheringer, M., Trier, X., Vierke, L., Wang, Z., & Dewitt, J. C. (2019). The concept of essential use for determining when uses of PFASs can be phased out. *Environmental Science: Processes & Impacts*, *11*. 10.1039/C9EM00163H

[5] Cousins, I. T., De Witt, J. C., Glüge, J., Goldenman, G., Herzke, D., Lohmann, R., Miller, M., Ng, C. A., Patton, S., Scheringer, M., Trier, X., & Wang, Z. (2021). Finding essentiality feasible: common questions and misinterpretations concerning the "essential-use" concept. *Environ Sci Process Impacts.*, *23*(8), 1079-1087. 10.1039/d1em00180a

[6] Mohammadi, A., Dobaradaran, S, Schmidt, T.C., Malakootian, M., and Spitz, J. (2022). Emerging contaminants migration from pipes used in drinking water distribution systems: a review of the scientific literature. Environ. Sci. and Pollution Research. DOI: 10.1007/s11356-022-23085-7

[7] Geueke, B., Groh, K.J., Maffini, M.V., Martin, O.V., Boucher, J.M., Chiang, Y., Gwosdz, F., Jieh, P., Kassotis, C.D., Łańska, P., Myers, J.P., Odermatt, A., Parkinson, L.V., Schreier, V.N., Srebny, V., Zimmermann, L., Scheringer, M., and Muncke, J. (2022) Systematic evidence on migrating and extractable food contact chemicals: Most chemicals detected in food contact materials are not listed for use. *Critical Reviews in Food Science and Nutrition*. DOI: 10.1080/10408398.2022.2067828

[8] Cousins I.T., DeWitt J.C., Gluge J., Goldenman G., Herzke D., Lohmann R., Miller M., Ng C.A., Scheringer M., Vierke L., and Wang Z. (2020a): Strategies for grouping per- and polyfluoroalkyl substances (PFAS) to protect human and environmental health. *Environ. Sci. Technol.* Processes & impacts 22 (7), 1444-1460. DOI: 10.1039/d0em00147c.

[9] Cousins I.T., DeWitt J.C., Gluge J., Goldenman G., Herzke D., Lohmann R., Ng C.A., Scheringer M., and Wang Z. (2020b): The high persistence of PFAS is sufficient for their management as a chemical class. *Environ. Sci Technol.* Processes & impacts 22 (12), 2307- 2312. DOI: 10.1039/d0em00355g

[10] Cousins I.T., Ng C.A., Wang Z., and Scheringer M. (2019): Why is high persistence alone a major cause of concern? Environ. Sci. Technol. Processes & impacts 21(5), 781-792. DOI: 10.1039/c8em00515j

[11] Lohmann R., Cousins I.T., DeWitt J.C., Glüge J., Goldenman G., Herzke D., Lindstrom A.B., Miller M.F., Ng C.A., Patton S., Scheringer M., Trier X., and Wang Z. (2020): Are Fluoropolymers Really of Low Concern for Human and Environmental Health and Separate from Other PFAS? Environ. Sci. Technol. 54 (20), 12820-12828. DOI: 10.1021/acs.est.0c03244.

[12] Ministry of Environment and Food of Denmark. (2018). Risk assessment of fluorinated substances in cosmetic products, The Danish Environmental Protection Agency. Retrieved on 12 July 2023 from https://www2.mst.dk/Udgiv/publications/2018/10/978-87-93710-94-8.pdf.

[13] Lohmann R., Cousins I.T., DeWitt J.C., Glüge J., Goldenman G., Herzke D., Lindstrom A.B., Miller M.F., Ng C.A., Patton S., Scheringer M., Trier X., and Wang Z. (2020): Are Fluoropolymers Really of Low Concern for Human and Environmental Health and Separate from Other PFAS? Environ. Sci. Technol. 54 (20), 12820-12828. DOI: 10.1021/acs.est.0c03244.

[14] Kwiatkowski, C.F., Andrews, D.Q., Birnbaum, L.S., Bruton, T.A., DeWitt, J.C., Knappe, D.R U., Maffini, M.V., Miller, M.F., Pelch, K.E., Reade, A., Soehl, A., Trier, X., Venier, M., Wagner, C.C., Wang, Z., and Blum, A. (2020). Scientific Basis for Managing PFAS as a Chemical Class. *Environ. Sci. Technol. Lett.* 7(8), 532–543. DOI: 10.1021/acs.estlett.0c00255.

[15] Brandsma, S.H., Koekkoek, J.C.,van Velzen, M.J.M., and de Boer, J. (2019). The PFOA substitute GenX detected in the environment near a fluoropolymer manufacturing plant in the Netherlands. *Chemosphere.* 220, 493-500. DOI: 0.1016/j.chemosphere.2018.12.135.

[16] Henry B.J., Carlin J.P., Hammerschmidt J.A., Buck R.C., Buxton L.W., Fiedler H., Seed J., and Hernandez O. (2018): A critical review of the application of polymer of low concern and regulatory criteria to fluoropolymers. *Integrated Environmental Assessment and Management.* 14 (3), 316-334. DOI: 10.1002/ieam.4035

[17] Korzeniowski, S.H., Buck, R.C., Newkold, R.M., El kassmi, A., Laganis,E., Matsuoka,Y., Dinelli, B., Beauchet, S., Adamsky, F., Weilandt, K., Soni, V.K., Kapoor, D., Gunasekar, P., Malvasi, M., Brinati, G., Musio, S. (2023). A critical review of the application of polymer of low concern regulatory criteria to fluoropolymers II: Fluoroplastics and fluoroelastomers .*Integrated Environmental Assessment and Management.* 19(2), 326–354.DOI: 10.1002/ieam.4646

[18]Lohmann R., Cousins I.T., DeWitt J.C., Glüge J., Goldenman G., Herzke D., Lindstrom A.B., Miller M.F., Ng C.A., Patton S., Scheringer M., Trier X., and Wang Z. (2020): Are Fluoropolymers Really of Low Concern for Human and Environmental Health and Separate from Other PFAS? Environ. Sci. Technol. 54 (20), 12820-12828. DOI: 10.1021/acs.est.0c03244

[19] Brandsma, S.H. (2019). The PFOA substitute GenX detected in the environment near a fluoropolymer manufacturing plant in the Netherlands. *Chemosphere.* 220, 493-500. DOI: 0.1016/j.chemosphere.2018.12.135

[20] Wouter A. Gebbink, Laura van Asseldonk, and Stefan P.J. van Leeuwen. (2017). Presence of Emerging Per- and Polyfluoroalkyl Substances (PFASs) in River and Drinking Water near a Fluorochemical Production Plant in the Netherlands. *Environ. Sci. Technol.* 2017, 51, 19, 11057–11065.DOI: 10.1021/acs.est.7b02488

[21] Kwiatkowski, C.F., Andrews, D.Q., Birnbaum, L.S., Bruton, T.A., DeWitt, J.C., Knappe, D.R U., Maffini, M.V., Miller, M.F., Pelch, K.E., Reade, A., Soehl, A., Trier, X., Venier, M., Wagner, C.C., Wang, Z., and Blum, A. (2020). Scientific Basis for Managing PFAS as a Chemical Class. *Environ. Sci. Technol. Lett.* 7(8), 532–543. DOI: 10.1021/acs.estlett.0c00255

[22] Member States Germany, Denmark, Netherlands, Norway, and Sweden. (2023). Proposal for a restriction of Per- and polyfluoroalkyl substances (PFASs): Annex B. Pg. 219. Retrieved on 13 July 2023 from https://echa.europa.eu/documents/10162/bc038c71-da3e-91a8-68c1-f52f8f0974dd.

[23] Gujarat Fluorochemicals Limited.(2022). Company Announcement. Retrieved 12 July 2023 from https://www.gfl.co.in/assets/pdf/Announcement-9th-March-2022.pdf

[24] Solvay. (2022) .Retrieved on 12 July 2023 from https://www.solvay.com/en/press-release/solvay-phase-out-use-fluorosurfactants-globally.

[25] 3M. (2022). 3M to Exit PFAS Manufacturing by the End of 2025. Retrieved on 12 July 2023 from https://news.3m.com/2022-12-20-3M-to-Exit-PFAS-Manufacturing-by-the-End-of-2025#:~:text=Exit%20all%20PFAS%20manufacturing%20by,and%20PFAS%2Dbased%20additive%20products

[26]Chemours. (2022). *Advanced Performance Materials leads the industry by developing the first non-fluorinated surfactant to produce APA grade fluoroelastomers. Retrieved on 12 July 2023 from* https://www.chemours.com/en/news-media-center/all-news/press-releases/2022/chemours-announces-process-innovation-with-new-viton-fluoroelastomers-advanced-polymer-architecture

[27] Cousins, I.T., Goldenman, G., Herzke, D.,Lohmann, R., Miller, M., Ng, C.A., Patton, S., Scheringer, M., Trier, X., Vierke, L., Wang, Z., and DeWitt, J.C.. (2019). The concept of essential use for determining when uses of PFASs can be phased out - Environmental Science: Processes & Impacts. *Environ. Sci.:Processes Impacts*, 21:1803-1815. DOI:10.1039/C9EM00163H

[28] Glüge, J., London, R., Cousins, I.T., Jamie DeWitt, Goldenman, G., Herzke, D., Lohmann, R., Miller, M., Ng, C.A., Patton, S., Trier, X., Wang, Z., and Scheringer, M. (2022). Information Requirements under the Essential-Use Concept: PFAS Case Studies. *Environ. Sci. Technol. 56* (10), 6232-6242 DOI: 10.1021/acs.est.1c03732

[29] European Chemical Agency. Understanding REACH. Retrieved 16 May 2023 from https://echa.europa.eu/regulations/reach/understanding-reach..

[30] European Commission. (2020). Chemical Strategy for Sustainability. Cited 16 May 2023.

[31] Member States Germany, Denmark, Netherlands, Norway, and Sweden. Proposal for a restriction of Per- and polyfluoroalkyl substances (PFASs): Annex XV. Pg. 77. Retrieved on 13 July 2023 from https://echa.europa.eu/documents/10162/1c480180-ece9-1bdd-1eb8-0f3f8e7c0c49.

[32] Birchby, D., Dubey, J., Johansen, B., Hekman, J., Gschrey, B., Behringer, D., Kleinschmidt, J., Jörß, W., Liste, V., Ludig, S., Wissner, N. (2022). Support contract for an Evaluation and Impact assessment for amending Regulation (EU) No 517/2014 on fluorinated greenhouse gases. See section 5.1.7.1 https://climate.ec.europa.eu/system/files/2022-04/f-gas_evaluation_report_en.pdf

[33] Gschrey, B., Behringer, D., Kleinschmidt, J., Jörß, W., Liste, V., Ludig, S., Wissner, N., Birchby, D., Dubey, J., Hekman, J., (2022). Support contract for an Evaluation and Impact assessment for amending Regulation (EU) No 517/2014 on fluorinated greenhouse gases. https://climate.ec.europa.eu/system/files/2022-06/f-gases_external_preparatory_study_en.pdf

[34] Kwiatkowski, C.F., Andrews, D.Q., Birnbaum, L.S., Bruton, T.A., DeWitt, J.C., Knappe, D.R U., Maffini, M.V., Miller, M.F., Pelch, K.E., Reade, A., Soehl, A., Trier, X., Venier, M., Wagner, C.C., Wang, Z., and Blum, A.. (2021). Response to "Comment on Scientific Basis for Managing PFAS as a Chemical Class." Environ Sci and Technol Lett. 8(2): 195–197. DOI: 10.1021/acs.estlett.1c00049

[35] Lerner, S. (2018, August 25). *How a Dupont Spinoff Lobbied the EPA to Stave Off the Use of Environmentally Friendly Coolants*. The Intercept. Retrieved July 13, 2023, from https://theintercept.com/2018/08/25/chemours-epa-coolant-refrigerant-dupont/

[36] Pickard, H. M., Criscitiello, A. S., Persaud, D., Spencer, C. S., Muir, D. C. G., Lehnherr, I., Sharp, M. J., De Silva, A. O., and Young, C. J. (2020). Ice Core Record of Persistent Short-Chain Fluorinated Alkyl Acids: Evidence of the Impact From Global Environmental Regulations. Geophys. Res. Lett. 47 (10), e2020GL087535. DOI:10.1029/2020GL087535

[37]ECOS (2021). Briefing: One step forward, two steps back. A deep dive into the climate impact of modern fluorinated refrigerants. Retrieved on 13 July 2023 from https://ecostandard.org/wp-content/uploads/2021/11/ECOS-briefing-on-HFO-production-and-degradation_final.pdf

[38] Member States Germany, Denmark, Netherlands, Norway, and Sweden. (2023). Proposal for a restriction of Per- and polyfluoroalkyl substances (PFASs): Annex E. *ECHA*. Pg 242. Retrieved on 13 July 2023 from https://echa.europa.eu/documents/10162/8de11d7c-c56f-e204-5072-e89f11071219

[39] Ibid, Pg. 10

[40] Kwiatkowski, C.F., Andrews, D.Q., Birnbaum, L.S., Bruton, T.A., DeWitt, J.C., Knappe, D.R U., Maffini, M.V., Miller, M.F., Pelch, K.E., Reade, A., Soehl, A., Trier, X., Venier, M., Wagner, C.C., Wang, Z., and Blum, A.. (2021). Response to "Comment on Scientific Basis for Managing PFAS as a Chemical Class." Environ Sci and Technol Lett. 8(2): 195–197. DOI: 10.1021/acs.estlett.1c00049

[41] Lerner, S. How a Dupont Spinoff Lobbied the EPA to Stave Off the Use of Environmentally Friendly Coolants. The Intercept; August 25, 2018.https://theintercept.com/2018/08/25/chemours-epa-coolant-refrigerant-dupont/.

[42] European Commission. Climate-friendly alternatives to HFCs (europa.eu). Retrieved 5 June 2023 from https://climate.ec.europa.eu/eu-action/fluorinated-greenhouse-gases/climate-friendly-alternatives-hfcs_en#:~:text=In%20chillers%2C%20hydrocarbons%20and%20ammonia,is%20available%20on%20the%20market

[43] Donley, N. and Bennet, K. (2023). High Levels of Dangerous 'Forever Chemicals' Found in California's Most-Used Insecticide *40% of Tested Agricultural Pesticide Products Contain PFAS.* Retrieved on 13 July 2023 from https://biologicaldiversity.org/w/news/press-releases/high-levels-of-dangerous-forever-chemicals-found-in-californias-most-used-insecticide-2023-05-02/

[44] Sonne, C., Jenssen, B.M., Rinklebe, J., Lam, S.S., Hansen, M., Bossi, R., Gustavson, K., Dietz, R. (2023). EU needs to protect its environment from toxic per- and polyfluoroalkyl substances. *Sci. of Total Environ.* 876(10), 162770. DOI: 10.1016/j.scitotenv.2023.162770

[45] Farmers' use of PFAS pesticides could be a ticking time bomb. *Nyheder.dk.* (2023, February 9). Retrieved 13 July 2023 from https://nyheder.dk/landmaends-brug-af-pfas-pesticider-kan-vaere-en-tikkende-bombe/

[46] Pesticide Action Network Europe. Insecticides contaminated with Per- and polyfluoroalkyl substances (PFAS) need to be urgently addressed. Insecticides contaminated with Per- and polyfluoroalkyl substances (PFAS) need to be urgently addressed | PAN Europe (pan-europe.info). (2022, December 22). Retrieved 13 July 2023 from https://www.pan-europe.info/blog/insecticides-contaminated-and-polyfluoroalkyl-substances-pfas-need-be-urgently-addressed

[47] Central Glass Public Consultation. Public Consultation. RCOM, Part 11, pp.24-26. https://echa.europa.eu/registry-of-restriction-intentions/-/dislist/details/0b0236e18663449b

[48] Member States Germany, Denmark, Netherlands, Norway, and Sweden. Proposal for a restriction of Per- and polyfluoroalkyl substances (PFASs): Annex A.3.17.2 Volumes, Pg. 153. Retrieved on 13 July 2023 from https://echa.europa.eu/documents/10162/d2f7fce1-b089-c4fd-1101-2601f53a07d1

[49] Member States Germany, Denmark, Netherlands, Norway, and Sweden. Proposal for a restriction of Per- and polyfluoroalkyl substances (PFASs): Annex XV. Pg.74. Retrieved on 13 July 2023 from https://echa.europa.eu/documents/10162/1c480180-ece9-1bdd-1eb8-0f3f8e7c0c49

[50] Mohammadi, A., Dobaradaran, S, Schmidt, T.C., Malakootian, M., and Spitz, J. (2022). Emerging contaminants migration from pipes used in drinking water distribution systems: a review of the scientific literature. Environ. Sci. and Pollution Research. DOI: 10.1007/s11356-022-23085-7

[51] Zimmermann, Lisa. (2022). Contaminants migrate from pipes into drinking water worldwide. Food Packaging Forum. https://www.foodpackagingforum.org/news/contaminants-migrate-from-pipes-into-drinking-water-worldwide.

[52] Mohammadi, A., Dobaradaran, S, Schmidt, T.C., Malakootian, M., and Spitz, J. (2022). Emerging contaminants migration from pipes used in drinking water distribution systems: a review of the scientific literature. *Environ. Sci. and Pollution Research*. 29(50), 75134-75160. DOI: 10.1007/s11356-022-23085-7

[53] Hubbard, L. E., Kolpin, D. W., Givens, C. E., Blackwell, B.R., Bradley, P.M., Gray, J.L., Lane, R.F., Masoner, J.R., McCleskey, R.B., Romanok, K.M., Sandstrom, M.W., Smalling, K.L., and Villeneuve, D.L. (2022). Food, Beverage, and Feedstock Processing Facility Wastewater: a Unique and Underappreciated Source of Contaminants to U.S. Streams. *Environ. Sci. Technol*. 56, 1028−1040. DOI: 10.1021/acs.est.1c06821

[54] Lurch, M., Fengler, R., Mbog, G., Nguyen, K.H., and Granby, K. (2023). Food simulants and real food – What do we know about the migration of PFAS from paper based food contact materials? *Food Packaging and Shelf Life.* 35, 100992. DOI: 10.1016/j.fpsl.2022.100992

[55] Zabaleta,I., Blanco-Zubiaguirre, L., Baharli, E.N., Olivares, M., Prieto, A., Zuloaga, O., and Elizalde, M.P. (2020). Occurrence of per- and polyfluorinated compounds in paper and board packaging materials and migration to food simulants and foodstuffs. *Food Chemistry,* 321: 126746, DOI: 10.1016/j.foodchem.2020.126746

[56] Lurch, M., Fengler, R., Mbog, G., Nguyen, K.H., and Granby, K. (2023). Food simulants and real food – What do we know about the migration of PFAS from paper based food contact materials? *Food Packaging and Shelf Life.* 35, 100992. DOI: 10.1016/j.fpsl.2022.100992

[57] Zabaleta,I., Blanco-Zubiaguirre, L., Baharli, E.N., Olivares, M., Prieto, A., Zuloaga, O., and Elizalde, M.P. (2020). Occurrence of per- and polyfluorinated compounds in paper and board packaging materials and migration to food simulants and foodstuffs. *Food Chemistry,* 321: 126746, DOI: 10.1016/j.foodchem.2020.126746.

[58] Geueke, B., Groh, K.J., Maffini, M.V., Martin, O.V., Boucher, J.M., Chiang, Y., Gwosdz, F., Jieh, P., Kassotis, C.D., Łańska, P., Myers, J.P., Odermatt, A., Parkinson, L.V., Schreier, V.N., Srebny, V., Zimmermann, L., Scheringer, M., and Muncke, J. (2022) Systematic evidence on migrating and extractable food contact chemicals: Most chemicals detected in food contact materials are not listed for use. *Critical Reviews in Food Science and Nutrition*. DOI: 10.1080/10408398.2022.2067828

[59] Whitehead, H.D. and Peaslee, G.F. (2023). Directly fluorinated containers as source of perfluoroalkyl carboxylic acids. *Environ. Sci. and Technol Lett*. 10(4), 350−355. DOI: 10.1021/acs.estlett.3c00083

[60] Lurch, M., Nguyen, K.H., and Granby, K. (2022). Is the use of paper food contact materials treated with per- and polyfluorinated alkyl substances safe for high-temperature applications? – Migration study in real food and food simulants. *Food Chemistry.* 393: 133375. DOI: 10.1016/j.foodchem.2022.133375

[61] EFSA Panel on Contaminants in the Food Chain (EFSA CONTAM Panel). (2020). Risk to human health related to the presence of perfluoroalkyl substances in food. *EFSA Journal.* 18(9) e06223. DOI: 10.2903/j.efsa.2020.6223.

[62] Member States Germany, Denmark, Netherlands, Norway, and Sweden. Proposal for a restriction of Per- and polyfluoroalkyl substances (PFASs): Annex XV. Pg. 58-59. Retrieved on 13 July 2023 from https://echa.europa.eu/documents/10162/1c480180-ece9-1bdd-1eb8-0f3f8e7c0c49

[63] Member States Germany, Denmark, Netherlands, Norway, and Sweden. Proposal for a restriction of Per- and polyfluoroalkyl substances (PFASs): Annex XV. Pg. 182. Retrieved on 13 July 2023 from https://echa.europa.eu/documents/10162/1c480180-ece9-1bdd-1eb8-0f3f8e7c0c49