2966991

PlasticsEurope
Association of Plastics Manufacturers
Fluoropolymers Product Group

Fluoropolymers Product Group comments to the summary reports

Contents

PlasticsEurope
Association of Plastics Manufacturers
Fluoropolymers Product Group

Introduction

Preparing our response for the second consultation, the PlasticsEurope Fluoropolymers Product Group[1] (FPG) has assessed the summary reports provided within the consultation.

FPG wants to point-out positively points raised by these summary reports:

1. The segmentation of PFAS with a distinction between fluoropolymers, F-gases and other PFAS. FPG believes that this segmentation is important in the development of the proposed restriction.

2. The recognition of the significant lower PFAS emissions related to fluoropolymerscompared to F-gases and other PFAS

3. The acknowledgement that fluoropolymers are used in critical application where mostly no alternatives exist without technological regression, higher carbon footprint and safety concerns.

4. In the discussion of fluoropolymers, we welcome the citation of the PlasticsEurope socioeconomic analysis raising the point that a forced transition to alternatives could put Europe's goals for the Green Deal and the EU's digital agenda at risk.The contribution of fluoropolymers to the achievement of key EU policies such as the Green Deal and digitalization of the EU economy is indispensable.

5. The indication that fluoropolymers market is expected to increase, while PFAS emissions related to fluoropolymers are expected to decrease.

Besides these positive points, we would like to provide our comments and concerns onmissing or incomplete information of these summary reports.

As general comments on the summary reports:

1. The summary reports are unclear whether several usages of fluoropolymers are being cover or not. For example, the chemical process industry usage of fluoropolymer seems not be cover by the reports. This fluoropolymer usage covers stock shapes, tubes, pipes used in extreme environment: hot and/or corrosive fluids and high purity water transportation, especially in semi-conductors manufacturing allowing less waste and lower carbon footprint. Also, it is unclear where and if the water filtration membranes and medical filtration membranes volumes are covered. Therefore, it is difficult to confirm if the assess volumes are correct and if alternatives are correctly identified.

[1] The Fluoropolymers Product Group is the voice of the fluoropolymer industry in Europe and members include 3M, AGC, Arkema, Chemours, Daikin Chemicals, DuPont, Gujarat Fluorochemicals, Honeywell, W. L. Gore & Associates, and Solvay. We are a sector group ofPlasticsEurope, which counts over 100 member companies, producing over 90% of all polymers across the EU27 plus the UK, Norway, Switzerland and Turkey. Together PlasticsEurope members directly employ 1.6 million workers in the EU27.

2. The term PFAS does seems having the same use in all summary reports. Therefore,we would suggest for clarification to use the term polymeric PFAS and non- polymeric PFAS.

3. Some use in the chemical Production does not appear clearly on the summary reports; Fluoropolymers in particular are used is a multitude of applications related to chemical manufacturing to seal equipment and containers to prevent the release of hazardous chemicals or for filtration applications to prevent air or water emissions during industrial processes. These sealant and filtration products are used during the manufacturing of many chemical and other materials, like acids, chlorine, carbon black, cement, TiO2, catalysts, mineral, polymers, fertilizers, pesticides, industrial & household cleaners, pulp & paper manufacturing, and many others.

Food contact materials & packaging

On page 4 of the summary report, it is important to notice that f Polyvinylidene fluoride (PVDF) is used in fabrication of cookware equipment for his mechanical properties and chemical resistance.

On the same page 4, on cookware applications, the summary report indicated "
Polyvinylidene fluoride (PVDF) – based
- *o Perfluoroalkyl vinyl ethers e.g. PFMVE;*
- *o Copolymers of hexafluoropropylene;*
- *o PTFE copolymers"*

PVDF based PTFE copolymers and PFMVE does not exist. PTFE and PFMVE are a differentcategory of polymer. This misinterpretation is repeated on page 5.

Lubricants

- o The "Uncertainties" section of the summary report points out important gaps and shortcomings to CfE efforts that should be considered when moving to the next steps of the policy making. Specifically, under "Substances, uses and applications"it is noted that the inventory of commercially essential PFAS substances used, and the identification of essential use categories is incomplete. It is recognised that the CfE market data is incomplete and structured in a way that makes estimates of usageand market size highly uncertain. The uncertainties of the conclusions regarding emissions were linked to data gaps on the nature of uses (consumer, professional or industrial), numbers of workers and users exposed. Ultimately, although the volume of use and types of use are clear gaps, the conclusion that the gaps would impact the calculations of emissions and exposure is incorrect. Regarding emissions and exposures, proper consideration of the physical properties of the materials, especially the lack of water solubility or volatility of PFAS used in lubricants, greatly overestimate emissions to air and water regardless of the physical volumes or types of uses.

- The summary report section 4 Emissions, Table 3 estimates that 35 tonnes of PTFE (Micropowder) are emitted to air annually and 31 tonnes to water. As PTFE is not volatile and insoluble in water, it is unclear how the report could reach this conclusion. Similar partitioning is applied to PTFE (granulates) and PFPE which raised comparable questions regarding the conclusion of this section.

- Section 4.1, Table 5 notes that the justification for application of emission factors during filling of lubricants in sealed articles says, "*Formulation of lubricants is likely to happen at elevated temperature, (...)*". Use of elevated temperatures in formulation is unknown from our experience and appears not be a reasonable assumption. The justification indicates that "*it is possible during filling of articles that there may be spillages/leaks which would further contribute to emissions*." This statement is not a reasonable assumption due to the lack of volatility of these substances and lack of water solubility. Spills or leaks in filling are manageable and are unlikely to result in uncontrolled emissions to air or water as noted in the table.

- High molecular weight backbone fluoropolymers are the vast majority of fluorinated lubricants. The lack of volatility and water solubility of most of the higher molecular weight backbone fluoropolymers lead to emissions estimates that are overestimated and appear to be too widely distributed in air and water. Use of general Environmental Release Categories (ERC) are not applicable to PFAS lubricants considering their lack of volatility and solubility. It would be appropriate to develop Specific Environmental Release Categories (SPERCs) for subsets of PFAS containing lubricants that better consider the uses and material characteristics for PFAS lubricants to improve the estimates of emissions.

Construction products

- Glass - fiber impregnation by PTFE-Dispersion is missing in the current report. The main use of this product is roofing applications as an alternative for glass. According to market intelligence the demand of this products should be > 500 mt /y.

- In the questionnaire, PTFE should be divided in sub-categories molding powder, fine-powder, and dispersion.

- On page 7 of the summary report, the author mentions that PVDF growth is linked to durability and weather resistance and is anti-abrasion resistance.

Medical devices

- The specific use of fluoropolymers in pharmaceutical packaging is hardly mentioned in the Summary report. E.g., PCTFE (CAS:9002-83-9), a polymer used in pharmaceutical packaging gets one single mention (in Table 1 of the Report summary medical devices), but it is not mentioned in the breakdown of usage/volumes of production in Table 4 or anywhere else in the Report.

- In pharmaceutical packaging, fluoropolymers are used in numerous critical applications. However, no mention is made of the contribution of fluoropolymers in the supply and preservation of safe drugs. Fluoropolymer- based medicine packaging is characterized by, among other things, best moisture barrier (highest WVTR protection), bio-chemical inertness (very low leaching/migration), chemical-resistance (practically to any chemicals), high crystal clarity (if required) and non-flammability. Typically, these materials also have very good machineability and can be used without retrofitting packaging machinery. There are no acceptable chemical or functional alternatives for many fluoropolymers-based pharmaceutical packaging that could meet the above characteristics and existing marketing authorization specifications.

- There is no mention of the existing regulatory framework applicable for this use: Fluoropolymers used in the pharmaceutical packaging sector are subject to stringent requirements of the EU legislation on regulation of medicinal products for human or veterinary use (i.e., Regulation (EC) 726/2004, Directive 2001/83/EC, Directive 2001/82/EC). These materials are explicitly excluded from the scope of most REACH requirements and procedures because all components of pharmaceutical products, including packaging/containers, are subject to comprehensive and stringent safety/quality assessments procedures and data requirements, including those relating to traceability and testing. Their safety for humans, animals and environment, including the production and waste phases, is vigorously scrutinized and approved by the European Medicines Agency (EMA) and the EU Member States medicines authorities prior to the marketing authorization of each drug.

- In addition, pharmaceutical packaging is subject to the EU regulations on packaging and packaging waste (Directive 94/62/EC) and Directive 2008/98/EC on waste, which set comprehensive requirements on safety and eco-design of packaging materials and their environmentally friendly waste treatment (collection, disposal, recycling, etc.).

- Finally, the report does not mention any alternatives. The primary packaging of any pharmaceutical product directly affects one of its key properties: the "stability characteristics" stipulated in the marketing authorization conditions specified by the EMA or national drug authorities. The use of substitutes (such as PVC, PVDC, COC, COP, etc.) will inevitably lead to increased packaging weight, reduced storage and use periods of pharmaceuticals, which are crucial characteristics for many drugs.

- Reading the summary report, it is not clear if membranes for life sciences applications were look at by the author of the report.

Pharmaceutical Manufacturing

- Processes to make pharmaceuticals require a high degree of cleanliness, purity, chemical stability, and thermal resistance necessitating the use of fluoropolymers. They are commonly used in a variety of containers, tubing, filters and other processing equipment.

Metal plating & manufacturing of metal products

- For this summary report, it is again unclear which PVDF applications are covered. Is the use of PVDF for "manufacture of metal products" and "metal plating" are covered? For example, PVDF can be used for metal protection, for example in manufacturing of chemical industry vessels.

PFAS production (manufacturing)

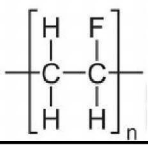
- The summary report does make distinction between the different PFAS sub-categories (see Buck, et al. "Perfluoroalkyl and Polyfluoroalkyl Substances in the Environment: Terminology, Classification, and Origins" Integrated Environmental Assessment and Management (2011) 7(4), 513 – 541). This distinction is important especially for emissions assessment based on persistence, mobility and toxicity. Grouping PFAS gives the impression that the emissions of a non-persistent, non-toxic HFO refrigerant, or inert fluoropolymer, are equivalent to those of a bio persistent surfactant.

- It is not sure that the report includes peer-reviewed publications such as Henry et al Integr Environmental Assessment and Manag (2018) 14(3). This paper indicates that high molecular weight backbone fluoropolymers should be treated as a different category of materials with a substantially lower inherent risk than other PFAS.

- The Buck paper could be use as guidelines to correct some inconsistencies in the terminology used in the summary report. For example, the mention of side chain perfluoroether polymers is unclear (see page 5). If the sentence is referring to perfluoroalkoxy alkane polymers (PFA) the comment about the hydrocarbon backbone is incorrect. If the reference is about side chain fluorotelomer polymers, this is technically incorrect. The side chains are not generally perfluorinated and not always connected to hydrocarbon backbones through ether linkages (see FPG document send).

- While polyvinyl fluoride (PVF) is a fluoropolymer, it does not meet the current OECD[2] or proposed EU restriction definition[3] of a PFAS and as such should not be "genericized" as a PFAS at this time in this report. Overall, greater consistency in defining the correct chemical structures and nomenclature of PFAS is needed for all parties involved in the development of future regulatory measures.

  Polyvinyl fluoride:



[2] OECD Report: Reconciling Terminology of the Universe of Per- and Polyfluoroalkyl Substances: Recommendations and Practical Guidance Series on Risk Management No.61; ENV/CBC/MONO(2021)25; July9, 2021

[3] https://www.reach-clp-biozid-helpdesk.de/SharedDocs/Downloads/DE/REACH/Verfahren/PFAS_RMOA_Supplementary_document.html

We therefore suggest updating the report, with a note below figure 2 stating that while PVF is a fluoropolymer, it is not a PFAS.

- The report mentions "There is no clear demonstration whether fluoropolymers produced using emulsion polymerization can indeed be produced without the PFAS-based processing aids. There has been development of emulsion polymerization processes with much reduced PFAS use, or even without PFAS-based aids, but it is not yet clear whether these will be implemented at industry level". Some public information on the industrial usage of on fluorinated surfactant in emulsion process can found at https://www.kynar500.com/en/product-information/fluorosurfactant-free/

TULAC (textiles, upholstery, leather, apparel and carpets)

- On page 12 of the summary report, the author mentions the use of PVDF in membranes. PVDF based membranes are used in water purification and in life sciences filtration (for production of medicinal products for example). Reading the summary report, it unclear if these applications were look at especially as there are no relation between the use of these products with "TULAC" applications. There are no clear mention of these two important applications (water purification and life sciences membranes) in the summary report.

Petroleum & mining

- The summary report mentions that PFAS use in petroleum refining is "expected", no data are collected on this use. None of the summary reports present use of PFAS in the Chemical Processing Industries (CPI) which also extensively use PFAS, and particularly backbone fluoropolymers (such as FKM, FFKM and PVDF) in equipment like uses in Petroleum and Mining such as seals, linings and coatings.

- The summary report "PFAS in mining and petroleum industry – use, emissions and alternatives" should list FKM and FFKM as examples of fluoroelastomers used in seals, liners, valves, O-rings, gaskets, and packer elements in the petroleum industry (Table 2.2).

- There are limitations to apply ERC approaches to calculate the emissions due to the lack of volatility and water solubility of most of the higher molecular weight backbone fluoropolymers. It will be appropriate to develop Specific Environmental Release Categories (SPERCs) for subsets of PFAS used in Petroleum and Mining that better consider the applications and material characteristics for PFAS materials or subsets of PFAS (i.e., fluoropolymers, fluorinated tracers, …). Therefore, the ERC analysis report should be adjusted taking in consideration the physical properties and use conditions of PFAS.

Electronics & energy

- On battery (table 2, page 3), FPG does not understand the logic to separate lithium-Ion batteries and batteries. Does the term "batteries" mean only "alkaline batteries"? The author of the summary report forgot the use of fluoropolymers for binder in the lithium-Ion batteries section.

- Page 5: 8% of fluoropolymer in batterie seems overestimated.

- PTFE filters are used throughout the energy sector to improve performance and reduce environmental emissions. Turbine filters are used to improve the efficiency and reduce downtime of natural gas turbines. Mercury filters are used at coal-based power plants to remove mercury from exhaust gases. PTFE filter bags, including some with catalytic functionality, are used to reduce particulate and chemical emissions from waste-to-energy plants.

- Fluoropolymers enables electronic components used for oil & gas exploration such wire and capacitors for downhole well applications. All of these applications require materials that can withstand harsh chemical and temperatures while remaining strong and air permeable.

✓ Electronics

- In the Electronics sector, fluoropolymers are used for wire and cable insulation due to their very low diaelectric constant, strength, flexibility, temperature stability, UV resistance, and low particulation. This allows cables that use fluoropolymers to achieve unmatched performance in highly demanding applications such as aerospace, test & measurement, clean room production, extreme environments, and high-speed data transmission.

- For semiconductors, the use of PVDF piping for high purity water transportation does not seem to be covered in the summary report. In addition, fluoropolymer filters are used to process the aggressive chemicals needed to process like chemical etching and photolithography.

- Fluoropolymers are also used as component in electronic devices beyond semiconductors themselves. They are used for thermal and electrical insulation gaskets.

- Fluoropolymer vents are used in a wide variety of electronic components ranging from computers, mobile phones and smart watches to telecommunications infrastructure such as base stations. Fluoropolymers are necessary to create durable, breathable barriers which prevent water entry and resist chemical, thermal and ultraviolet degradation.

Transportation

- This summary did not have a separate section noting important gaps or uncertainties compared to other sector summary reports.

- It seems that the summary report uses the term "fluoroelastomers" incorrectly throughout the document. It appears that "fluoropolymers" or "backbone fluoropolymers" should replace most, if not all, uses of the term "fluoroelastomer". For example, in several parts of the document (e.g., Table 2), PTFE is listed as a fluoroelastomer, which is not correct. PTFE is a backbone fluoropolymer. Typical fluoroelastomers include FKM, FFKM etc.

- An important subgroup of `fluid-handling` applications like turbo-charger hoses, exhaust gas return-lines, hoses for fuel/gasoline needs to be added. This sub- group has an important influence to meet the current and future EU emission regulations on vehicles. Based on market intelligence, the estimated demand in Europe for this sub-group is about 2000-2500 mt in 2020.

- 111,104 mt for PFAS sealing applications must corrected. We assume that this number includes the weight of the final parts but is an incorrect number (by far too high) for the PFAS content. This will lead to totally wrong calculation of PFAS – emissions.

- It seems that the summary report forgets to mention the additional applications in aerospace that require temperature and chemical resistance, thermal stability and high strength. Such applications include insulation for cables or gasket materials used in aircraft, spacecraft and satellites which are exposed to extreme conditions and require exceptional reliability. The same for many components and systems in automobiles require protective vents made from fluoropolymers. These vents are used to seal critical systems like headlamps, drive trains, or batteries from dirt, oils and water while allowing gases to pass through for safe, reliable performance.

Waste

- The summary report does not segregate the PFAS mentioned into any sub-categories (see Buck, et al. "Perfluoroalkyl and Polyfluoroalkyl Substances in the Environment: Terminology, Classification, and Origins" Integrated Environmental Assessment and Management (2011) 7(4), 513 – 541), and in so doing, assuming they all behave the same in the waste treatment facilities mentioned. It does not consider:
  - ✓ that some PFAS are not persistent and treats all PFAS as equivalently persistent in most situations apart from incineration
  - ✓ any volatile PFAS except for those that might be formed by thermolysis of PFAS
  - ✓ the different mobility of different PFAS (e.g., mobility of PFAS from landfills into leachate is assumed to take place in all cases) or the temporal course of mobile PFAS generation in landfills and waste treatment plants

- ✓ differences in hazard or toxicity of different PFAS
- ✓ differences in potential for exposure to different PFAS

- o On incineration (page 19, paragraph 4.3) might be revised based on the additional references and comments below:

  - The publication of Aleksandrov et al (Aleksandrov, K.; Gehrmann, H-J.; Hauser,M.; Matzing, H.; Pigeon, D.; Stapf, D.; Wexler, M. "Waste incineration of Polytetrafluoroethylene (PTFE) to evaluate potential formation of per- and Poly- Fluorinated Alkyl Substances (PFAS) in flue gas" Chemosphere (2019), 226, 898 – 906.) demonstrates that the PFAS expected to be the most common recalcitrant PFAS (fluoropolymers) are effectively mineralized even at lower temperatures in a prototypical municipal waste incinerator pilot plant.

  - The comments in the summary relating to the Tsang 1998 publication are not representative of PFAS incineration. Tsang provided calculations suggesting the entropic thermal destruction (aka pyrolysis) of CF4 would require temperatures more than 1400 °C based on its symmetry. However, thermo-oxidative combustion in the presence of fuel is a different process than pyrolysis and, inany case, virtually all other PFAS were expected to be much easier to destroythan CF4, even entropically.

  - The cited English papers (by Garcia and Huber) have been evaluated and thetwo in English relate to pyrolysis processes, not incineration.

    - o Garcia describes pyrolysis in fuel-rich scenarios with increasing amounts of oxygen that are still sub-stoichiometric. They report some F-gas formation that decreases with the amount of oxygen present.

    - o Huber describes pyrolysis; although the title of the article is incineration all the data presented is related to pyrolysis except for one entry which is listed as pyrolysis in air.

- o On page 20, the assumptions on PFAS in fly ash are not supported by the references provided (Abis, M., Bruno, M., Kuchta, K., Simon, F.-G., Grönholm, R., Hoppe, M., & Fiore, S. (2020) and Sandblom, O. (2014). It is far more likely any fluorine present in fly ash is in the form of inorganic fluorides. Substances such as PFCAs are known to decarboxylate at temperatures as low as 160°C.

  - Abis describes the general treatment of municipal solid waste and the comments on incineration, which are quoted as providing ~3% ash, are not specific to PFAS containing materials. PFAS is likely mineralized, and the ash is most likely heavy metal and other solid oxides which may also contain metalfluorides (e.g., CaF2).

  - Sandblom (Master Thesis) states:" The main conclusion of this study is that waste incineration in Sweden is not a significant source of PFAAs to the atmosphere or to the environment in general". Moreover, the single digit ng/g levels found inash and volatiles were below the level of quantification and within the method uncertainties.

- Fluoropolymers also are used for the transformation of non-hazardous organic residues from households, industrial or agricultural generators into products which close the natural cycle to return valuable nutrients to soils contributing to soil health sustainably while supporting the carbon capture in the ground, addressing global challenges like climate change and food security.

- Additional comments on specific pages:

  - **Page 5:** The source of the selected value of 0.2 – 1.0 m3/year for generation of leachate per ton of landfilled waste is not clear as the Brennan paper was not specific to PFAS (see Brennan et al 2016[4]).

  - **Page 7:** It is not clear what fraction of textiles are assumed to be treated with PFAS or what loading of PFAS per unit of textile or household waste are assumed or where these assumptions came from.

  - **Pages 8 - 9 and 10 - 11.** The figures show the assumptions used but do not indicate where they came from (e.g., calculated PFAS concentrations in wastes).

  - **Page 10:** the discussion of globalization of waste is important and we would recommend adding the following aspects:
    - discuss, whether regulations can be more effective at managing wastes than an EEA ban in preventing illegal disposal in other regions,
    - discuss unintended consequences of bans in the EEA which simply drive manufacturing and use elsewhere (e.g., industry shifts to Asia)
    - discuss the impact of global distributions of PFAS into the EEA from manufacture and use in other countries.

  - **Page 16:** It is not clear the assumptions inherent in the seven studies used for Table 3 (mean and median concentrations for the PFAS groups in influent and effluent streams). For example, is the influent to WWTPs really containing nearly 800 ppt of PFAS? Also, what are PFPAs? Finally, the means and medians are quite different (by more than a factor of 3 in many cases) suggesting widespread heterogeneity in the assumptions.

  - **Page 17:** Part of the reason some PFAS are destroyed in WWTP operations is that not all PFAS are persistent. This fact is not taken sufficiently into account in the presented summary report.

  - **Page 17:** The assumption that some types of wastes, specifically carpets, are a disproportionately higher source of PFAS is not necessarily correct. Topic treatments may contribute in the relatively short-term, but the side-chain

[4] Brennan, R. B., Healy, M. G., Morrison, L., Hynes, S., Norton, D., & Clifford, E. (2016). Management of landfill leachate: The legacy of European Union Directives. Waste Management, 55(October), 355–363. https://doi.org/10.1016/j.wasman.2015.10.010

polymeric "mill applied" finishes are very inert, with decomposition taking place on the order of decades to centuries (see for example Russell, M. H.; Berti, W. R.; Szostek, B.; Buck, R. C. "Investigation of the Biodegradation Potential of a Fluoroacrylate Polymer Product in Aerobic Soils" Environ. Sci. Technol. (2008), 42, 800 – 807 and references contained therein.