Comments for Annex XV restriction report
Substance Name: Per- and polyfluoroalkyl substances (PFAS)

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SECTION III. Non-confidential comments and further specific information requests

Planned regulation

Through the definition of “PFAS” chemicals, with CF2 and CF3 groups as chemical building blocks, fluorinated polymers have also been included in the current restriction process for "PFAS", because these polymers (about 30 in total) have the same building blocks as the materials referred to as "eternity chemicals" (up to 10000).

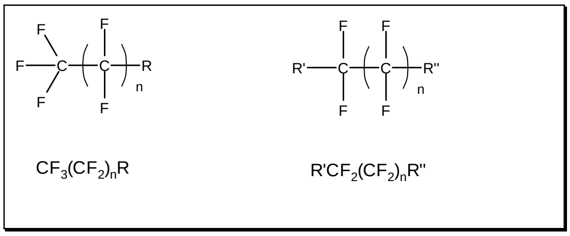

Fig. 1: Definition of PFAS via CF2 and CF3 groups.
Source: “Information document accompanying the call for evidence 2020”

Although the polymers concerned are no hazardous chemicals in the sense of ANNEX XIII REACH, not mobile (not soluble in water), not bioaccumulative and not toxic, but on the contrary safe materials proven by testing, they are to be regulated without weighing their active hazard.
Test certificates on leaching tests with different substances according to FDA 21 and EC 1935, as well as cytotoxicity tests and in-vivo-tests for medical applications according to USP Class VI, confirm the safety of PTFE Fluoropolymer Products. Please refer to the attached documents for results and certificates.

Latest tests on various PFAS substances have shown that all tested PTFE products do not contain, do not release and do not emit volatile, soluble, mobile, bioaccumulative or toxic PFAS substances. Specific fluorinated processing aids (emulsifiers) like HFPO-DA (Gen-X), ADONA and 6:2 FTS could not be found in the test samples, although the raw materials used for these products had been produced using these processing aids. Please refer to the attached certificates where you can find specific information on raw material grades in context to our different product codes.

According to the Annex XV report, the background of this proposed regulation, which is intended to ban the production, marketing and use of fluoropolymers, is solely the persistence of these substances, which is assessed as a "key hazardous property" in section 1.1.4, the hazard assessment of the Annex XV Report.

This definition of the "PFAS" substances concerned is thus also intended to regulate materials that are absolutely necessary for the operation and maintenance of industrial plants. The connection with environmental protection, e.g. through minimized emission values when using PTFE seals and membranes, was not taken into account, and the dossier even calls into question the necessary use of fluoropolymers by naming “supposed alternatives”.

For the proposed restriction options (RO1 and RO2), reference is also made to the possibility of developing alternatives, and for the proportionality assessment, to the fact that functional alternatives would already be available for a high number of applications.

This means that all fluoropolymers would be banned after 18 months if restriction option 1 (RO1) would come into force. In the case of RO2, extended transition periods would be possible for various applications, from 6 ½ years to 13 ½ years.

The problem here, however, is that fluorinated polymerization aids used for the production of PTFE, PVDF and FKM should generally be regulated under RO1 and may no longer be used after 18 months. This means that PTFE, PVDF and FKM could still be used in special applications for a few years, but in practice they would no longer be available from European producers after 18 months.

Emissions in the End-of-Life phase

Although fluoropolymers, such as PTFE, are considered safe because, as explained earlier, they do not have emissions during their use phase, it is paradoxically assumed that emissions occur after end-of-life.

Considering the possible degradation mechanisms:
- biological degradation
- degradation by decay under environmental influence
- degradation during waste incineration

the formation of PFAS emissions can be completely ruled out, since fluoropolymers are considered to be very persistent because they do not degrade, and in the case of waste incineration there are to be no PFAS emissions, proven by studies (Gehrmann et al.; Pilot-Scale Fluoropolymer Incineration Study: Thermal Treatment of a Mixture of Fluoropolymers under Representative European Municipal Waste Combustor Conditions, 2023).
If uncontrolled incineration is used as an argument for possible hazardous emissions, we would like to point out that e.g. all domestic waste also has hazardous emissions when incinerated uncontrolled. For this reason waste is regulated separately in the EU and therefore cannot be the subject of this Annex XV report.

Missing Uses

PTFE membranes and their applications

1. expanded PolyTetraFluoroEthylene (ePTFE) membranes for filtration applications

ePTFE membranes are used in various configurations for air filtration systems as HEPA or ULPA filters, e.g. in clean room ventilation systems in the pharmaceutical industry, as well as a component of high-quality exhaust air filters in industrial dust filtration.

Using industrial dust removal as an example, the following explanation illustrates how effectively fabric filters coated with ePTFE membranes work.

Background: Until the 1980s, exhaust air from industrial plants often entered the environment completely unfiltered. Gravity separators or scrubbers were mainly used for exhaust air purification. After their introduction, electrical separators significantly increased the efficiency of exhaust air purification systems. Nevertheless, very high levels of toxic and carcinogenic particulate matter were released into the environment from industrial plants. Filtration separators were already state of the art in other applications, but the standard materials could only be used to produce depth filters, which saturated very quickly at very high levels of fine dust and then had to be replaced - which was not feasible for high continuous dust levels due to the maintenance effort involved with constant downtime.

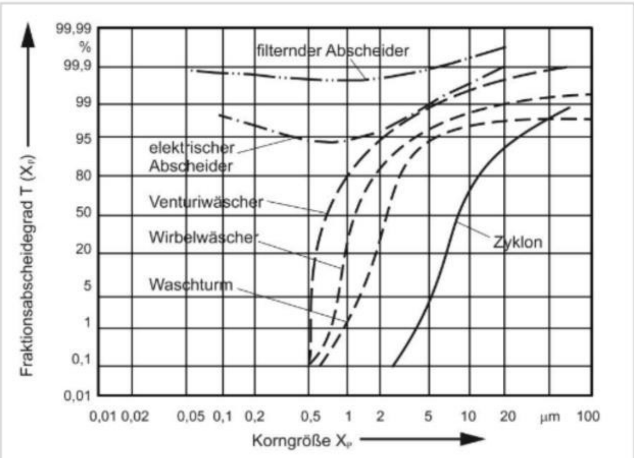

Fig 2: Separation efficiencies of different dust collectors.
(Dr. Matthias Bank, Basiswissen Umwelttechnik, 2006)

With the development and introduction of highly effective filter systems equipped with surface filters made of ePTFE membranes that were fully regenerable, a breakthrough in industrial dust removal was achieved.

Since the 2000s, a large proportion of industrial plants have been equipped or retrofitted with this technology, significantly curbing particulate emissions.

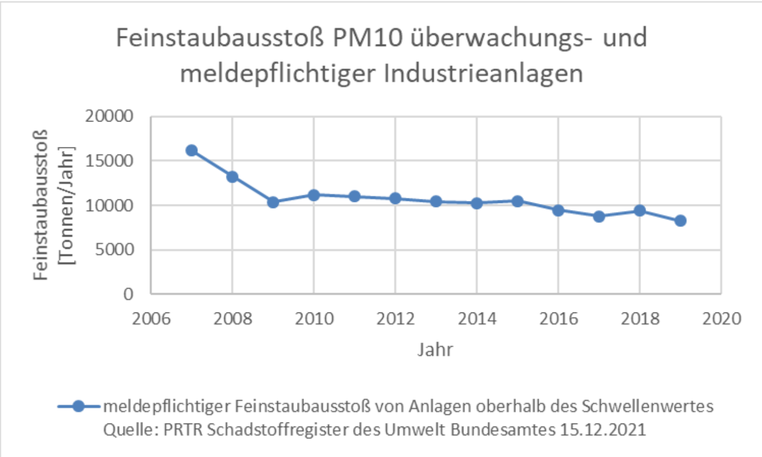

Fig 3: Particulate matter PM10 emissions from industrial facilities that were subject to mandatory reporting due to emission levels. (PRTR Pollutant Register UBA, 2021)

In the above diagram Fig. 3, a significant reduction of the reportable particulate matter emissions from 2007 approx. 16000 tons to approx. 8000 tons in 2019.
A reduction of about 50%, corresponding to about 8000 tons of PM10 particulate matter, within 12 years, which would not have been possible without the use of modern membrane technology using fluoropolymer membranes.
In recent years, ePTFE membrane technology has been further developed in Germany and optimized for use in industrial dust collection, thus reducing fine dust emissions by a further 95%.

Example: Conversion of a cement plant from electrostatic precipitator to ePTFE surface filter
Waste gas quantity mill operation: 520000 m³/h at 95°C
Waste gas quantity kiln operation: 490000 m³/h at 170°C

a a) Electrostatic Precipitator
Total dust emission with electrostatic precipitator: approx. 10 mg/m³, => 22780 kg/year during mill operation
Fine dust emission with electrostatic precipitator: approx. 10 mg/m³, => 21460 kg/year during kiln operation
Total emission during operation with electrostatic precipitator at 50% utilization: **44240 kg/year**

a b) ePTFE Membrane Filter
Fine dust emission with ePTFE filter: approx. 1 mg/m³, => 2280 kg/year at mill operation
Fine dust emission with ePTFE filter: approx. 1 mg/m³, => 2150 kg/year during kiln operation
Total emission during operation with membrane filter at 50% utilization: **4430 kg/year**

a c) new type of ePTFE Membrane Filter
Fine dust emission with ePTFE filter: approx. 0.04 mg/m³, => 91 kg/year during mill operation
Fine dust emission with ePTFE filter: approx. 0.04 mg/m³, => 86 kg/year during kiln operation
Total emission during operation with high-tech membrane filter at 50% utilization**: 177 kg/year**

Sources for calculation:
Fundamental study on the determination of particle size distribution in the exhaust gas of various emitters (< PM 2.5 and < PM 10), Bavarian State Office for Environmental Protection (LfU), December 2000.
Installation of a fabric filter in the cement plant "El Alto", Angel Bartolomé de Pedro, Ernesto Ferrer, John Jespersen, ZKG 09/2010
Development-accompanying investigations of the project partner

Cost / benefit:
The total fluoropolymer need is approx. 250kg for a complete filter unit of 1 cement oven, with a filter area of approx. 8300 m², when using ePTFE filter membranes on glass fabric supports.

The usual service life of ePTFE membrane filters is between 2 and 4 years, assuming a conservative service life of 2 years, which results in a requirement of max. 125 kg of fluoropolymer to save approx. 44000 kg of particulate matter per year compared to not using them.

2. expanded PolyTetraFluoroEthylene (ePTFE) membranes for fuel cells

ePTFE membranes are used as support materials for sulfonated fluorinated ionomers or sulfonated pentablock terpolymers for use as proton-selective membranes in low-temperature fuel cells (PEM).

The highly open-cell ePTFE membranes, with porosities up to 85%, take over the function of the strength support, allowing the formation of much thinner membrane layers of the sulfonated polymers.

This significantly favors the proton flux through the PEM membranes and leads to power densities that are currently not achievable with other membrane systems.

In the field of mobile power generation, e.g. in vehicle construction or space travel, this fuel cell variant is unavoidable, since fuel cells with high-temperature technology have proved unsuitable for this area of application.

(Bertram, Björn (2011). "Innovation processes of knowledge-based technologies, example of the PEM fuel cell." Dissertation, Karlsruhe Institute of Technology, ISBN 978-3-86644-728-8).

3. PTFE and ePTFE gasketing materials and their applications

For decades, gaskets made of PTFE and expanded PTFE have represented the state of the art in sealing flanges in the chemical process industry, the pharmaceutical industry, the power generation and electronics industries, and in all other industries where chemical resistance to process media and the purity of the processed products are important.

In addition to chemical resistance, which is a fundamental prerequisite for the permanent tightness of flanged joints, sealing properties such as leakage rate have increasingly come into focus since the 1990s.

Since PTFE gaskets are used in most cases where outstanding sealing properties against chemically aggressive media are required, not only the loss of products due to leakage plays an important role, but rather the protection of the environment and health from fugitive emissions of hazardous substances.

In the course of the amendments to the Technical Instructions on Air Quality Control (TA Luft), the requirements for industrial plants and the sealing systems used have therefore been continuously increased.
See also: Umwelt-Bundesamt (2020). "Harmonization of requirements for sealed connecting elements such as flange connections to limit fugitive volatile organic emissions (VOC)." ISSN 1862-4804.

PTFE gaskets significantly contribute to meeting the requirements on workers and environmental safety and cannot be substituted in modern industrial plants.

With regard to PTFE gasketing materials used in pharmaceutical plants, the requirements are much stronger, as not only the above-mentioned targets have to be met, but additional special requirements are placed on the materials, which, for example, need an evaluation of the possible implantability of the gaskets in order to be allowed to use them in the intended applications.

Alternatives to Fluoropolymers that comprehensively fulfil all technical and medical-pharmaceutical requirements are currently not available.

Non-PFAS alternatives for flange gaskets in chemical and pharmaceutical applications:
- Metallic gaskets (e.g. weld ring, ring joint, kammprofile, spiral wound gaskets)
- Mineral gaskets (e.g. graphite, mica, ceramic, glass)
- Fiber gaskets (e.g. aramid, glass, ceramic fiber), elastomer bonded – persistent non-fluorinated polymers
- Rubber gaskets (e.g. elastomer, rubber-steel) – persistent non-fluorinated polymers

Particularly in the case of metallic gaskets (kammprofile, spiral), fluoropolymers (PTFE) are often used as overlays or inserts in order to achieve the required tightness with correspondingly required chemical resistance.

In accordance with the largely overlapping requirements for chemical resistance, temperature resistance (low, or high) and sealing properties (EN13555 / EN1591) in the intended applications, the use of non-fluorinated polymers as alternatives is often not possible, taking into account the minimization requirement for emission protection as well as for maintaining the highest possible operational safety.

This is evidenced by the large number of PTFE-based gasketing products that have to be used to cover the required properties, despite much more favorable non-PFAS alternatives, following the Annex XV dossier.

Indicated Alternatives in the Annex XV dossier

In order to be able to enforce such restrictions at all, the existence and usability of alternatives must be ensured. For this purpose, the dossier submitters were essentially dependent on information from manufacturers, processors, users and their own research.

The alternatives for fluoropolymers mentioned in the dossier are essentially non-fluorinated polymers such as polyethylene (PE), polyetheretherketone (PEEK), or, in the case of elastomers, ethylene-propylene-diene (monomer) rubber (EPDM).

Based on this, an evaluation of the alternatives must be carried out to ensure that "regrettable substitutes", i.e. substances with similar hazards to those of the substances to be regulated, will not be used.

However, at no point in the restriction proposal the polymers specified as alternatives are subjected to a necessary risk assessment.

In ANNEX E, Appendix E2, with regard to all non-fluorinated polymers mentioned, only "No data found" is stated for the PBT / vPvB assessment, or "Not sufficient data available for evaluation" for Additional Information, although sufficient meaningful data are publicly available on this topic.

It is precisely this fact that leads to the fact that the fluorine-free polymers listed as alternatives in the ANNEX XV Report must not be used as substitutes for fluoropolymers, since precisely these non-fluorinated polymers are also considered very persistent according to Annex XIII REACH, since their degradation half-lives in marine, fresh or estuarine water are > 60 days or in sediments > 180 days.

For example, mean degradation half-lives of polyethylene in marine environments range from 3.4 years for LDPE plastic bags to 1200 years for HDPE pipes. Even plastic bags considered as compostable on land, have half-lives of 3.1 years in marine environments (Chamas et al., 2020).

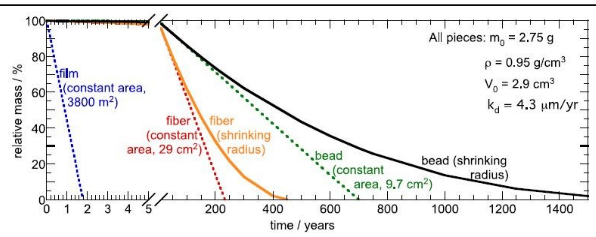

Figure 7. Comparison of predicted degradation profiles for HDPE pieces with the same mass, density, and SSDR but different shapes (thin film, fiber, and bead). The dashed lines correspond to extrapolations assuming constant surface area; the solid lines correspond to a model which assumes the radius, and therefore the surface area, decrease over time.

Fig. 2: Comparison of predicted degradation profiles for HDPE pieces
Source: Chamas et al., Degradation Rates of Plastics in the Environment; ACS Sustainable Chem. Eng, 8, 3494-3511

With regard to the main argument of persistence, serious mistakes were thus made in the preparation of the dossier, as well as in the risk assessment of the fluoropolymers.

For this reason, fluoropolymers must be exempted from regulation.

Socio-Economic Impact

In addition to the 100% loss to companies specializing in fluoropolymer products, all chemical and pharmaceutical companies that rely on these products would be affected by a ban on fluoropolymers.

The economic impact in these areas is unimaginable and unquantifiable, as is the social impact due to the loss of jobs or the discontinuation of chemical and pharmaceutical processes that would not work without the fluoropolymer materials mentioned above.

Attachments:

- SGS Fresenius FDA Test Report
- SGS Fresenius EG1935 Test Report
- Report USP VI Nelson Labs FluorTex-multiFlon GMP_full
- Intertek P2023-05807 multiFlon sheet Teflon 605XTX
- Intertek P2023-05808 multiFlon membrane Teflon 650XTX
- Intertek P2023-05809 multiFlon membrane Teflon 669NX