PFAS PUBLIC CONSULTATION: BRIEF PLASTIC SHAPES FOR MACHINING

Brussels, 25 September 2023

***EuPC** is the leading EU-level Trade Association, based in Brussels, representing European Plastics Converters. EuPC now totals about 51 European Plastics Converting national and European industry associations, it represents close to 50,000 companies, producing over 50 million tonnes of plastic products every year. The European plastics industry makes a significant contribution to the welfare in Europe by enabling innovation, creating quality of life to citizens and facilitating resource efficiency and climate protection. More than 1.6 million people are working in about 50,000 companies (mainly small and medium-sized companies in the converting sector) to create a turnover in excess of 280 billion € per year*

***EPSM** is a sector group of EuPC representing and promoting the interests of the European manufacturers of Engineering Polymer Shapes for Machining in Europe. The development of a sustainable trading environment for the sector is one of the main objectives of the association. EPSM's members are global players, active in Europe as well as in third countries, offering engineers the widest range of General Engineering Plastics (PA, POM, PET, PC, etc.) and Advanced Engineering Plastics (PBI, PAI, PTFE, etc.) across many industries, including packaging, medical, material handling and chemical.*

Introduction

Following our initial submission, EuPC intends to comment on specific applications. Since those are very diverse, each application will be covered in a separate submission. This brief addresses **Engineering Polymer Shapes for Machining (EPSM**), a sector group of European Plastics Converters (EuPC), a plastics sector group with diverse final applications.

This submission is built upon a survey conducted across the members of Engineering Polymer Shapes for Machining.

This sector involves 15,000 employees, 1.4 billion €/year in sales, and 58 million €/year in R&D investment.

Use of fluoroelastomers in polymer shapes

Due to their unique chemical and physical properties, per- and polyfluoroalkyl substances (PFAS) have been widely used in various industrial and commercial applications. Within the machinery sector, we have registered the use of the following fluoropolymers:

- PTFE (EC number: 618-337-2; CAS number: 9002-84-0);
- PVDF (EC number: 607-458-6; CAS number: 24937-79-9); and
- PFA (EC number: 682-550-7; CAS number: 26655-00-5).

Toxicity

Fluoropolymers are very stable because of their intrinsic physicochemical properties. If lost in the environment, they are therefore currently considered as persistent.

However, they do not display any hazardous property/property of concern referred to by the dossier submitter; i.e., bioaccumulation, mobility, long-range transport potential (LRTP), accumulation in plants, ecotoxicity, endocrine activity/endocrine disruption, effects on human health and concerns triggered by a combination of these properties.

Moreover, **PTFE** and **PFA**, as fluoropolymers, meet the OECD criteria for polymers of low concern [1,2].

Regarding residual monomers in articles made from fluoropolymers, it is theoretically possible that small quantities of residual monomers can migrate from finished products.

[1] 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. Integr. Environ. Assess. Manag., 14 ; 316-334.*https://doi.org/10.1002/ieam.4035*

[2] Korzeniowski, S. H. et al. A critical review of the application of polymer of low concern regulatory criteria to fluoropolymers II: Fluoroplastics and fluoroelastomers. 2022.*https://setac.onlinelibrary.wiley.com/doi/full/10.1002/ieam.4646*

Fluoropolymers should be excluded from the scope of the restriction

Based on the non-toxic properties described above, fluoropolymers (including fluoroelastomers) should in our view be excluded from the scope of this restriction. We however provide additional information showing both its negligible emission and the disproportionate socio-economic impact that would be linked to its substitution.

Derogation for uses solely in industrial settings

Substances used solely in industrial settings should be derogated with appropriate risk management measures at manufacturing plant level if appropriate.

Needed transition period and inclusion in the proposed derogation combined with a review clause

In case the industrial use in machinery would not be derogated, we recommend **a long transition period of 13,5 years** to be applied based on the feedback of our survey and time needed to place the alternatives on the market at industrial level.

There is currently considerable uncertainty whether or not suitable alternative can be Implemented at industrial level within the proposed transition periods. The restriction should therefore include a **review clause** and process whereby it may be evaluated whether or not the alternatives could be successfully placed on the market potentially allowing if needed extension of those transition periods.

Note: the following sections numbers correspond to the sections numbers from ECHA's Comments for Annex XV restriction report for Per- and polyfluoroalkyl substances (PFAS).

1. Sector and sub-use

This comment is related to the following use: Plastic components containing PFAS used in the Engineering Polymer Shapes for Machining Association industry.

The following fluoropolymers have been reported as used in engineering polymer shapes for machining:

- PTFE (EC number: 618-337-2; CAS number: 9002-84-0)
- PFA (EC number: 682-550-7; CAS number: 26655-00-5)

The applications where these substances are used include:

- Wide range of applications (automotive/chemical industries/food contact/medical/parts in machines);
- PTFE as lubricant for semi-finished products. The technical application of the products;
- PTFE based coatings needed in a wide range of tooling systems.

Main functions: lubrication and/or chemical resistance; polymer; as part of complex products.

Use/application: industrial applications (chemical industry); food contact materials & packaging; and electronics and semiconductors. **Derogation is therefore partially considered for equipment for food and feed production, but many other machinery applications are impacted. We suggest to provide a derogation for industrial applications/machinery.**

2. Emissions during the end of life

Fluoropolymers being very stable an in the polymeric form, migration is assumed to be negligible. One reference that could be taken is the OECD exposure scenario document for plastics, whereby fluoropolymers would very much behave as polymeric impact modifiers. Releases during landfilling are assumed as 0% [3].

Residual monomer content is below 1 ppm and oligomer content considered to be negligible [4,5].

[3] OECD Environment Health and Safety Publications (2009), Series on Emission Scenario Documents No. 3, Emission Scenario Document Plastics additves, https://www.oecd-ilibrary.org/docserver/9789264221291-en.pdf?expires=1694011368&id=id&accname=guest&checksum=511DD8B4F91DB362643FB439D0FFFC79]

[4] 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. Integr. Environ. Assess. Manag., 14 ; 316-334. *https://doi.org/10.1002/ieam.4035*

[5] Korzeniowski, S. H. et al. A critical review of the application of polymer of low concern regulatory criteria to fluoropolymers II: Fluoroplastics and fluoroelastomers. 2022. *https://setac.onlinelibrary.wiley.com/doi/full/10.1002/ieam.4646*

5. Proposed derogation tonnage and emissions

5.1. Volumes of fluoroelastomers used in engineering polymers

According to the study conducted by Conversio on behalf of ProK [6], the total amount of fluoropolymer materials sold to European product manufactures is estimated to be 40 Kt/year in 2020, whereof 9% are used in a category including additives, compounding, **engineering polymers**, and other minor applications.

[6] Fluoropolymer Waste in Europe 2020 – End-of-life (EOL) Analysis of Fluoropolymer Applications, Products and Associated Waste Streams." Final Report Made on Behalf of pro-K, Conversio. July 2022. URL: *https://www.ft.dk/samling/20222/almdel/euu/spm/49/svar/1951975/2698345.pdf*

5.2. Related emissions during converting and service life

Concerning the fluoropolymer **manufacturing stage**, the Fluoropolymers Product Group (FPG) of Plastics Europe established a program focusing on the emission reduction of non-polymeric PFAS chemicals from European fluoropolymer manufacturing, including average emission targets, promoting state-of-the-art technologies to minimize emissions and a commitment to inform downstream users of fluoropolymers on their safe handling of fluoropolymer resins [7].

During the **masterbatching, compounding and converting stage**, the spillage of pellets is negligeable. There is only presence of dustiness; although air filters reduce the risk of emitting dust, as well as the presence of filters in water drains prevents the emission into water.

Various converting processes are involved, including extrusion, injection molding, and direct forming, that are essential for shaping materials. These methods operate within specific temperature ranges, with extrusion typically occurring at 200°C or below, depending on the application. Standard extrusion processes adhere to temperature guidelines provided by resin suppliers, with maximum operation temperatures varying between 100-160°C or even up to 300°C for specific materials.

These processes are critical in the manufacturing industry, facilitating the production of a wide range of products with precision and efficiency.

During **service life**, the potential emissions are considered to be negligible given the low migration rate from the polymeric matrix. Moreover, the risk of emissions during the end-of-life is low if properly handled. The materials under consideration exhibit remarkable stability and environmentally friendly attributes, as they are chemically inert and non-degradable, placing them in the category of low concern for environmental impact.

Given also the glassy nature of fluoropolymers, leaching of residuals from those would be greatly slowed down. Fluoropolymers being firmly bound in the polymer matrix, they are not expected to leach.

[7] The Fluoropolymers Product Group (FPG), Plastics Europe (2023), *FPG Manufacturing Programme for European Manufacturing sites, https://fluoropolymers.eu/wp-content/uploads/2023/09/FPG-Manufacturing-Programme-for-European-Manufacturing-sites-Final-September-2023.pdf*

7. Derogation for reconsideration: information on socio-economic impact and analysis of alternatives

We herewith provide an overall view of the alternatives. It is not limited to derogated application, use in machinery (industrial application) should be derogated in a generic manner.

7.1. Analysis of Alternatives

PTFE is used in plastic compounds due to their low friction, chemical resistance, high temperature, resistance, electrical insulation, flame retardancy, chemical inertness, etc; which makes them hard to be substituted in many cases.

For the aforementioned applications, using alternatives would lead to different products, changing the characteristics of these.

Some properties of fluoropolymers make them difficult to be replaced:

- Chemical Resistance: PFAS is essential in food contact material and packaging due to its outstanding chemical resistance, which ensures the safety and integrity of food products.
- Unique Lubricating Properties: The lubricating properties of PFAS are only partially replaceable with non-PFAS substances, making it a key component for effective food contact applications.

Some PFAS applications are reported to be partially replaceable with other tribological combinations. In some cases, PFAS can be partially replaced with alternative tribological combinations. PTFE, used to reduce friction, has possible alternatives depending on specific requirements and applications. However, those have not been fully tested yet.

In other cases, PFAS are considered irreplaceable due to outstanding chemical resistance, PFAS cannot be substituted for applications requiring exceptional chemical resistance.

7.2. Time needed for substitution/potential socio-economic effects

Depending on the application, the substitution could take between 5-12 years for the replacement to be deployed at industrial level. More particularly use of PTFE in engineering polymers such as PEEK, POM but also for PET and coating was estimated to take up to 12 years for substituting.

7.3. Socio-economic impact

The socio-economic impact depends on the potential transition period foreseen. R&D cost is estimated at 500 k€ per company per fluoropolymer. It would therefore amount to around 15 million € for the whole sector. In case the transition would be too fast, then we should consider the whole turnover associated to PFAs to be at stake.

In the scope of our study, a calculation of the turnover related to PFAS-related articles in this sector as a proportion of the total turnover, later scaled by the overall market size, yielded a figure of €107 million – or 7% of the total turnover of this industry.

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