

Comments on Restriction Proposal: per- and polyfluoroalkyl substances (PFAS)
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Founded in 1992, Fluoroplastics Processing Subcommittee of China Plastics Processing Industry Association (hereinafter referred to as FSCPA) now has more than 260 member units related to fluoroplastic processing, including 8 wholly-owned ventures or joint ventures of European enterprises in China.

There are many trade exchanges between FSCPA members and downstream customers and enterprises with those in various countries. And once the restriction proposal on PFAS is implemented in EU, it will have a significant impact on the industrial chain cooperation of fluoropolymer processing products between Europe and China.

FSCPA members support the EU's efforts to reduce the risk of hazardous substances and agree that reducing the use of harmful PFAS is essential. However, we believe that the restriction proposal to regulate fluoropolymers as PFAS is inappropriate because it lacks technical and legal basis, and we have the following opinions:

1. If there are many substances involved in the restriction proposal, risk assessment should be carried out separately

The restriction proposal to include around 10,000 substances under control based on their molecular structure alone is contrary to the restriction principle of the EU REACH regulation, which stipulates that substances can only be restricted if they pose an unacceptable risk to human health or the environment.

The physical, chemical and biological safety of PFAS substances of different structures is different, and all substances to be restricted should be subject to a risk assessment in accordance with Annex XV of REACH to analyze whether there is an unacceptable risk and, if not, the substance should be removed from the restriction proposal.

It is recommended to separate fluoropolymers (such as: PTFE, PVDF, FEP, PFA, ETFE, PCTFE...). Individual assessments are made to see if they pose an unacceptable risk to human health or the environment. Such substances should not be placed on restricted lists until clear conclusions have been reached.

2. The whole life cycle risk of fluoropolymer is controllable and should not be included in the scope of the proposed restriction and control

Fluoropolymers have highly stable properties, do not have bioaccumulation, long-distance migration, biotoxicity, and are difficult to pose a threat to the environment and human health. Fluoropolymers are recognized as “polymers of low concern (PLC)” by the Organization for Economic Co-operation and Development (OECD), and are not restricted substances under the REACH regulation.

From the perspective of fluoropolymer preparation process, each manufacturer implements strict control over the whole process of fluoropolymer production, and PFAS substances other than fluoropolymers can be controlled within the scope of compliance.

Fluoropolymers meet the OECD classification of "Polymers of Low Concern" and do not require

special emission control measures during normal processing and application phases. After the use of the product, the emission risk can be controlled through recycling, landfill, and standardized incineration.

Therefore, the whole life cycle risk of fluoropolymers is controllable and **fluoropolymers should not be included in the scope of the restriction control.**

3. Fluoropolymers have excellent performance and are widely used, which is difficult to be replaced

Fluoropolymer has unique chemical stability, excellent dielectric properties, high and low temperature resistance, low friction (self-lubricity), non-stick and other excellent comprehensive properties, as a functional material is widely used in the field of industrial and consumer goods. Fluoropolymer plays a role in anti-corrosion, sealing, self-lubrication, anti-sticking, insulation, filtration, isolation, heat exchange, energy conservation and environmental protection. At present, no alternative has been found with such excellent overall performance.

After more than 70 years of development, fluoropolymer processing and application has formed a complete industrial system and a huge global supply chain system. Through the integration of multiple disciplines, its application in different forms of products penetrates into all walks of life, playing a key functional role. In many application markets, fluoropolymer products have passed stringent quality system certifications and obtained corresponding compliance certifications.

For such a widely used product, it is completely unfeasible to have a transition period of only 18 months from the start of control to complete ban. As we all know, for functional materials used under harsh working conditions, the research and development, testing, demonstration and evaluation of alternatives require a long process, and the 5-year and 12-year exemption periods in the restriction proposal are far from enough, and may not even be completed in a cycle test verification under a certain working condition. Therefore, even if fluoropolymers were to be banned, sufficient time would need to be given for the research and demonstrate of alternatives.

Restricting or even banning fluoropolymers will have an immeasurable serious impact on the entire industrial system. Industrial corrosion, fluid leakage, substandard emissions, shortened product service life, and a significant increase in the frequency of maintenance and renewal will cause a serious burden on the economy and the environment. Chemical, semiconductor, new energy, electronic communications, medical, environmental protection, transportation and other fields will face comprehensive retrogression or stagnation of technological development due to the loss of key supporting materials.

Many of the areas currently in the restriction proposal are not covered, and the six-month public consultation period is not enough for all users to know that the products they use are at risk of restrictions.

Some alternatives are listed in Table 8 of the Proposal for Restrictions, but the information on alternatives is unclear and alternatives are not sufficiently demonstrated and evaluated, such as:

Example 1: Annex E.2.1. declares use of PFASs as polymerisation aids in manufacture of fluoropolymers: Sufficiently strong evidence that technically and economically feasible alternatives exist for non-polymeric PFASs as polymerisation aids in the production of PTFE, PVDF and FKM. When the fluorine polymerization additives are exempted in Table 9, PTFE, PVDF, and FKM are excluded.

It is understood that in addition to one company, the rest of the world's PTFE resin manufacturers,

has not launched the use of non-fluorinated polymerization additives produced PTFE resin, and the only exception of the company's product processing and use performance has not been fully evaluated by the market. PTFE and PVDF have a variety of synthetic categories, different application performance of the product, the 18-month transition period stipulated in the proposal is not even enough time to evaluate experiments, let alone complete economic and technical analysis and toxicological research. In the absence of qualified alternatives, limiting the use of fluoropolymerization additives in the synthesis of PTFE and PVDF will make the fluoroplastics processing industry lose about 40% of raw materials, the key is that the other 60% of raw materials can't be replaced at the application end, and downstream filtration, sealing, fluid transportation, batteries, coatings, cables, medical and other industries will face a disaster of losing important support materials.

Example 2: Annex E.2.13. shows weak evidence of the existence of technically and economically feasible alternatives to PTFE thread sealing tapes.

PTFE thread sealing tape has the properties: corrosion resistance, good sealing performance, no aging, not easy to damage, non-toxic, and easy to disassemble. It is widely used in oil, natural gas, high temperature gas, fluid pipelines and civil gas and water supply and drainage pipeline sealing. It is the whole society generally recognized sealing products, and is used as maintenance materials at home reserve. The restriction proposal is in the absence of clear alternatives, no strict alternative evaluation experiments and consumer application experience, but proposed the restriction use of thread sealing tape, and no exemption period. This will bring huge resource loss, and environmental and safety risks to society due to leakage.

In view of the fact that there is so much more, we believe that:

- 1) For the listed alternatives, the risks and advantages of the substitutes need to be compared with the substances proposed to be restricted, and the technical and economic feasibility needs to be fully assessed;
- 2) In the absence of proven alternatives, it is recommended that the risks of continued use of the proposed restricted substance be compared with the socio-economic impact of non-use.

On the basis of comparison and evaluation, it suggests to determine whether to limit or exempt to ensure that restrictions do not affect the achievement of the EU's socio-economic objectives.

4. The implementation of the EU proposal will create trade barriers

Article 2.2 of the World Trade Organization's Agreement on Technical Barriers to Trade (TBT) states: "Technical regulations shall not be more trade-restrictive than necessary to fulfil a legitimate objective, taking into account of the risks that non-fulfilment would create."

Fluoropolymers do not pose a significant risk to human health or the environment, but are irreplaceable in many important areas due to their excellent and unique properties and increasing applications. The restriction proposal would include fluoropolymers in the regulation without sufficient and reasonable scientific evidence, and the corresponding trade restrictions exceed those necessary to achieve legitimate objectives. The EU should allow reasonable intervals in accordance with Article 2.12 of the TBT when introducing the proposed restrictions. It needs to give time to give stakeholders, in particular producers in developing country Members, to adapt their products and production methods to EU requirements.

In summary, fluoropolymers are substances of low concern, and having excellent performance,

wide applications, and controllable life cycle risks. But there is currently no effective alternative. It is by the use of fluoropolymer products, so that we can achieve the goal of green environmental protection and sustainable development. Therefore, it is recommended to distinguish fluoropolymers from other PFAS, remove them from the proposed restricted substances, and give a permanent exemption to fluoropolymers.