20 June, 2023

European Chemicals Agency
P.O. Box 400, FI-00121 Helsinki, Finland

FEX Development Office
Sumitomo Electric Industries, Ltd.

Comments on Annex XV Restriction Report (PFAS Restriction Proposal)

Sumitomo Electric Industries, Ltd is a global manufacturer having extensive business operations in five industries: Automotive, Infocommunications, Electronics, Energy and Environment, and Industrial Materials. Our FEX development office develops material and coating applications for a cross-linked fluoropolymer named FEX®. We welcome this public consultation opportunity, as we fully understand your tireless effort to protect EU citizens from harmful chemical substances. While we agree with dossier submitters of the proposed regulation seeking to protect human health and environment, we have different opinions on what and how PFAS should be regulated to achieve the goal. We would like to take this opportunity to provide our comments based on scientific grounds. During the public consultation period, we plan to submit comments multiple times to complete our views. This is our initial submission.

## 1) Request for exemption

We strongly request that perfluoropolymers (e.g., PTFE, PFA, FEP) and those cross-linked by electron beams be exempt from the scope of PFAS in the proposal. The following points are given as reasons.

Perfluoropolymers and those cross-linked by electron beams are substances that are neither bioaccumulative nor biotoxic. Their unique and outstanding properties have made them indispensable to society, as it is unable to replace them with any other materials. Furthermore, perfluoropolymers are irreplaceable substances that make a large contribution to solving environmental problems.

Perfluoropolymers have totally different properties and degree of hazard from other more harmful PFAS. If they are collectively banned with those other PFAS simply because their chemical formulas are similar, without closely reviewing and classifying their properties, it is clear that this would result in significant environmental, medical science, and economic losses. These reasons are detailed in the (2) and (3) below.

## 2) Perfluoropolymers are neither bioaccumulative nor biotoxic

Because perfluoropolymers are chemically and biologically persistent and inert, they are known to elute very little ingredient (Olabisi et al., 2016). Complying with EU regulations on PFOA and PFOS, we have seen an improvement in perfluoropolymer production processes. According to a PFOA measurement analysis we had performed by a third party testing laboratory, PFOA was not detected from PTFE and PFA (see “PTFE_PFA_ analysis.pdf” as attached in Section IV). As long as there is no leached ingredient, nothing is being absorbed by animals or plants. If nothing is absorbed, then bioaccumulation and biotoxicity do not occur (Henry et al., 2009; OECD, 1993; Beyer EC.1993; Korzeniowski, S. H, et al., 2023; FCJ, 2023, see "FCJ.pdf" as attached in Section IV).

Since perfluoropolymers are chemically and biologically persistent and inert, they have been used as a material for implantable artificial organs such as pericardial patches and artificial blood vessels (Henry et al., 2009; Olabisi, 2015; Gangal & Brothers, 2000).

It is also documented in the literature that perfluoropolymers are substances with distinctly different properties from potentially toxic low molecular weight compounds such as PFOA and PFOS, which were the starting point for this proposed restriction (Henry et al., 2009; OECD 1993; Olabisi, 2019; FCJ, 2023, see "FCJ.pdf" as attached in Section IV)

### 3) Perfluoropolymers are irreplaceable materials that can contribute significantly to solving environmental concerns

Perfluoropolymers have unique and excellent properties including persistency, inertness, non-adhesiveness, sliding capability, heat resistance and a low dielectric constant. Such properties have made these substances essential to society. In addition, products that are coated with cross-linked perfluoropolymers have excellent sliding durability (several hundreds to thousands of times higher durability) while maintaining an unparalleled level of low friction coefficient (Ikeda, 2020, See "Ikeda.pdf" as attached in Section IV). This cross-linking technology has quickly accelerated practical application of perfluoropolymers. For example, cross-linked fluoropolymers are expected to be used in applications for significant contributions to carbon neutrality such as energy saving and adhesive-free processes.

We would like to present specific examples as follows, however please note that these are just a few of the many potential uses for these materials. Applications and sectors where perfluoropolymers contribute to solving environmental issues are not limited to those presented here. We are currently conducting R&D on a wide variety of applications that can contribute highly to carbon neutrality, including energy saving and low environmental load with adhesive-free/solvent-free processes.

Example 1: Reduce environmental load by solvent-free bonding with electron beam crosslinking

By forming perfluoropolymer coating on a metal surface (e.g., Al, Cu, and SUS) and crosslinking it with electron beams, the metal surface and the perfluoropolymer coating are bonded in a solvent-free condition where no adhesive or no solution with organic solvent is applied. We developed this coating technology and put it into practical use. Since a perfluoropolymer layer is formed by aqueous dispersion coating or extrusion method, this is a 100%-solvent-free process (Ikeda, 2020, See "Ikeda.pdf" as attached in Section IV).

This technology has made it possible for perfluoropolymers to not only adhere to metal in a solvent-free manner, but also bring about the benefits described in Example 2 to Example 4.

Example 2: Reduce material waste and energy consumption by coating durability with excellent sliding and non-adhesive capabilities

Using the technology to coat devices such as extrusion dies for general materials such as polyethylene, material waste and product waste are reduced. Consequently, perfluoropolymers do not cause environmental load since the technology is successful in such reductions in a solvent-free process. We will provide more details and reference(s) for this example in our subsequent public consultation submissions.

Example 3: Improve energy conversion rate by performing excellent sliding

Using the technology to coat sliding parts with perfluoropolymers, the energy conversion rate improves so that energy saving and reduction of environmental load are achieved. We will provide more details and reference(s) for this example in our subsequent public consultation submissions.

Example 4: Improve the energy conversion rate of specific electric wires by achieving a low dielectric constant and adhesive-free/solvent-free bonding

Since this coating technology does not require primer or adhesive, specific-purpose electric wires with this coating can maintain almost the same low dielectric constant of 2.1 as that of a fluoropolymer-only coating. Therefore, it improves the energy conversion rate while reducing environmental load.
We will provide more details and reference(s) for this example in our subsequent public consultation submissions.

Example 5: Unique method for producing a specific medical product

This coating technology is the only coating technology used for producing a specific medical product. We will provide more details and reference(s) for this in our subsequent public consultation submissions.

We will provide further information in separate submission(s) to complete our comments on the restriction proposal. In the meantime, please feel free to contact us if any questions arise.

Sincerely yours,

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## References


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