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JBCE input/UK REACH-PFAS RMOA-Call for evidence

As a cross-sector association with member companies operating in different industries and stages in the supply chain, JBCE welcomes the contribute for stakeholders to provide information to UK initiative, the Call for Evidence regarding per- and polyfluoroalkyl substances ('PFAS').

Grouping

Fluorochemicals are being regulated by the grouping, as has been done for PFOA and PFOS. The Call for Evidence however targets a far larger group of chemicals (thousands of substances), in our view, without scientific hazard and risk assessment of each substance. We understand that the initiators of this Call for Evidence would like to prioritize efficiency of regulatory actions, rather than taking time-consuming but science-based hazard and risk assessment approach.

Precautionary principle

We note that the restrictions or complete bans solely on the basis of persistence cannot be justified under UK REACH regulation as it stands today. If the initiators of this Call for Evidence believe that their concern and action might be justified by the 'precautionary principle', we would like to remind the initiators of how the 'precautionary principle' is applied in legislation and jurisprudence.

For the action to be non-discriminatory, the action (substance of restriction) would have to be applied to all substances exhibiting the same property, namely persistence. Thus, if PFAS were to be restricted merely on the basis of persistence, then all other persistent substances, including ceramics, glass and various metals, would also need to be restricted. In the absence of restriction of other persistent substances and materials, substance restricted solely for PFAS could not possibly be consistent.

In our view, any justification for a substance restricted based on the precautionary principle – in this case persistence alone without any identified hazard – must stem from a thorough assessment of potential benefits and costs of such a restriction, as well as the scientific evidence for the risk assessment. Moreover, it must be subject to review, in light of new scientific information and strike the right balance between the risks PFAS potentially pose and the socioeconomic benefits it provides.

Applications

It should be recognized that, for substances like PFAS, the intrinsic property of persistence confers the desirable properties of high durability and unique functionality to products made and treated with this chemistry. For examples, Electrical Electric equipment is used in the variety conditions, and also required proper functional operation. To keep high reliability, components are required moisture proof, waterproof, rust proof, corrosion resistance, maintaining the performance. In order to achieve the above requirement, such functions as low dielectric constant, low dielectric loss tangent, low refractive index, and oil repellency are essential. Only PFAS substances can provide the required several functions together as one substance. In addition to these properties, high reliability and durability are required to make alternatives. There is still no alternative which covers all these properties yet (Please kindly refer the attached non-exhaustive list). Even if some substitutions are identified in the future, a careful assessment of their performance, quality, reliability, safety and durability will take time, for example around 15 years in case of semi-conductor, and potentially lead to increased costs and consumer prices.

Persistent substances and materials provide health, safety, environmental and energy savings benefits. If you look at fluoropolymers, these are critical components in numerous technologies, industrial processes and daily applications not only Electrical Electronic Equipment but also others. For instance, automotive, aerospace, chemicals & power, electronics, food & pharma, textiles & architecture, medical applications, analytical applications and renewable energy. Likewise, fluorotelomer-based products can be used for treatment of textiles, non-wovens and surfaces, which are components of personal protective garment & equipment and textile & non-woven in medical sector, and for filtration and coating in industrial applications.

On the other hands, Hydrofluorocarbons (HFC) and olefins (HFO) are not generally considered as PFAS, and most of them are not classified as ‘persistent’. Globally, these

substances are being phased down per a schedule established by the Kigali Amendment to the Montreal Protocol. Some examples of the phase down mechanisms in different countries are the EU F-Gas Regulation and the Japan Ozone Layer Protection Act. In the EU, HFCs are strictly regulated under F-Gas Regulation in light of the EU's climate goals. This Regulation is under review towards the amendment in a few years.

PFAS Emissions

The PFAS emissions during the lifecycle of a product are very limited. To ensure compliance with all applicable laws and regulations and to minimize the environmental impact, risk management measures and safety practices have been implemented. During manufacturing process, the applications of quality management systems (e.g. ISO 9001, ISO 14001, ISO 45001) reduce the emissions to a very small extend. In use phase, products must keep their quality and performance, making any PFAS emissions to the atmosphere unlikely. During the end of life of a product, the existing recycling requirements for the different types of product categories (WEEE, ELV, etc.) are ensuring that almost no emissions are released to the environment.

Measurement of PFAS

From an analytical point of view, the implementation and enforcement of PFAS restriction is not possible.

Regarding the measurement of PFAS in water, standards such as ISO 21675:2019, US EPA 537.1, US EPA 533 are available, and analytical methods have been established using LCMSMS. For the measurement of PFAS in soil, also a standard (ASTM D7968-17a) is available. However, these standards only cover a few dozen of PFASs. The methods for the analysis of many other PFASs have not yet been established.

Regarding the measurement of PFAS in articles, no established analytical method is known: The standard CEN/TS 15968:2010 for PFOS can be a reference, however, it is not known whether this method is also valid for Polymeric PFASs. In the USA, the State California will regulate PFAS in food packaging (AB-1200 Plant-based food packaging: cookware: hazardous chemicals.), however, there is no detailed description of the analytical method. The establishment of methods for the extraction of PFAS from articles is especially important for the measurement.

In addition, small amounts of PFAS are frequently used in the manufacture of components of complex equipment. For enforcement, even identifying which components of the

equipment to try to measure would present an enormous challenge.
As a consequence of the difficulty in identifying which parts of complex articles to try to measure coupled with the general lack of analysis methods applicable to the broad range of substances and matrices in which PFAS are used, enforcement of a broad PFAS restriction will not be feasible. In the interest of both sustainability and compliance related level-playing field restrictions must be enforceable.

Ensure availability of spare parts

Products need the same spare parts as those used in the first production of each product. A re-design of spare parts often also requires a re-design of the products, because otherwise the original performance (i.e. safety and durability) can't be guaranteed. Considering the supply chain and production processes of many manufacturers, such a re-design will be impossible in most cases. Thus, a PFAS restriction for spare parts would lead to a non-availability of such parts, resulting in a shortened lifecycle of products and unnecessary waste
As a result, JBCE asks for an exemption for spare parts in accordance with the "the repair as produced" principle.

Sufficient transitional period

To find alternatives and to avoid confusion in the market and in the long and complex global supply chains, it is essential that a sufficient transition period is set before a possible implementation of a PFAS restriction.

ABOUT JBCE

Founded in 1999, the Japan Business Council in Europe (JBCE) is a leading European organization representing the interests of over 90 multinational companies of Japanese parentage active in Europe.
Our members operate across a wide range of sectors, including information and communication technology, electronics, chemicals, automotive, machinery, wholesale trade, precision instruments, pharmaceutical, textiles and glass products.
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Non-exhaustive list of uses of PFAS substances

		Use	Reasons of using PFAS substances
Electric Equipment	Electric components	Printed circuit boards and electric components Photodiodes and laser diodes	Electric equipment is used in the variety conditions, and also required proper functional operation. To keep high reliability, components are required moisture proof, waterproof, rust proof, corrosion resistance, maintaining the performance. In order to achieve the above requirement, such functions as low dielectric constant, low dielectric loss tangent, low refractive index, and oil repellency are essential. Only PFAS substances can provide the required several functions together as one substance.
	Mechanical components	Mechanical components (O-ring, valve material, and sliding portion)	PFAS-related substances contribute the functionality such as sealing, non-adhesive and abrasion resistance.
		Parts to be contacted to reagents, gases, analytical samples	These parts require functions such as high chemical resistance, rust proof, water proof, and cleanliness. In order to achieve the above requirement, such functions as chemical resistance, and water repellency are essential. Only PFAS substances can provide the required several functions together as one substance.
		Parts of optical components, detectors, and optical fibres	These parts require functions such as high chemical resistance, corrosion resistance adhesion prevention, and water proof. In order to achieve the above requirement, such functions as chemical resistance, corrosion resistance, water repellency and non-adhesive function are essential. Only PFAS substances can provide the required several functions together as one substance.
		Parts to be contacted to foods and beverages	These parts require functions such as preventing the foods and beverage adhesion, reducing abrasion, preventing oil adhesion to the foods, and resistance to boiled water, hot water, and chemical resistance. In order to achieve the above requirement, such functions as chemical resistance, corrosion resistance, water repellency and non-adhesive function are essential. Only PFAS substances can provide the required several functions together as one substance.
	lubricants and grease		If the lubricant coated on the sliding portion of the precision parts is spread, the durability and performance of the products will be significantly reduced. In order to prevent from the above

			failure, PFAS related substances are added in the lubricants and grease, because PFAS related substances have function such as high dispersible, and high repellency. Fluorochemicals have smaller attraction forces between molecules (the cohesive energy between the molecules) because of the stable C-F bonds, so PFAs related substances can provide high oil repellency. Recently the parts getting smaller and smaller, it is difficult to take mechanical measures to prevent the lubricants from spreading. It is same purpose and function as “epilames used in watches” which SEAC Draft opinion proposed to exempted from the PFHxA restriction under REACH. The amount of PFAS use in this application is also very low.
	Photoresist		As the previous report stated, the Photoresist is being used for producing semiconductor devices with a photolithography process. The detailed application on Photoresist is "Positive Tone Photoresist", "Negative Tone Photoresist" and "Negative Tone Color Imaging-resist". The function of PFAS in the photoresist is; 1) The PAG (Photo Acid Generator) to use at the photolithography process, 2) Surfactant to control surface tensions and surface property. 3) Polymer to control surface distribution, 4) Initiator of polymerization, 5) Specific Pigment
	Display materials		PFAS are being used for controlling molecular orientation, surfactant, smoothing, and leveling reagent.
Reference material	Reference material for the analysis		Reference material is essential for the reliable comparable, traceable accurate analysis, such as NMIJ CRM 4056-a, and NMIJ CRM 4220-a.
Analytical equipment	Oil Content Analyzer	Extraction solvent	Oil is often poorly biodegradable and must be disposed of properly. Otherwise, it will cause the negative impact to the environment. NDIR analysis (infrared spectroscopy) is used for this analysis. Oil is extracted from the sample with an extraction solvent that does not have a C-H bond, and the bond of C-H, which is an oil component, is analyzed by NDIR. PFAS substance is required as a solvent with no C-H bond, low volatility and high oil-dissolving power.