POSITION PAPER

Japan Business Council in Europe

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JBCE'S POSITION ON REACH ANNEX XV REPORT CONSULTATION OF PER- AND POLYFLUOROALKYL SUBSTANCES (PFAS)

INTRODUCTION

Being a cross-sector association with member companies operating in different industries and stages in the supply chain (electronics, chemicals, polymer, automotive, HVACR, machinery, semiconductor, wholesale trade, precision instruments, pharmaceutical, steel, nonferrous metal, textiles, ceramics, and glass products), JBCE welcomes the opportunity to contribute to the discussion regarding REACH Annex XV report in the context of the consultation on the restriction on the manufacture, placing on the market and use of PFAS.

KEY MESSAGES

On a general note, we understand that the proposed restriction proposal on PFAS is in line with the target of having "a zero-pollution ambition for a toxic-free environment" which was proposed in the "Chemicals Strategy for Sustainability -Towards a Toxic-Free Environment- (CSS)". However, despite agreeing with and supporting its concept and purpose to protect human health and the environment, we would like to point out that **the currently proposed restriction raises various issues which need to be addressed in terms of scientific reasoning and socio-economic impact**, as highlighted by various companies across different impacted sectors represented by JBCE.

Our main points of concern are listed below, and further explanation and evidence is provided in the Annex.

1. JBCE believes that **chemical management should use a risk-based approach** and not solely a hazard-based one. In our view, any justification for a substance ban 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 ban, as well as the **scientific evidence for the risk assessment**.
2. JBCE has grave concern with the idea of basing a potential REACH restriction only on persistence. Indeed, being **"persistent" is not by itself a hazard**. It should be recognised that the intrinsic property of persistence confers **the desirable properties of high durability and unique functionality to products**.
3. JBCE believes that, if a restriction on the basis of persistence alone were to be established, this precedent would severely hamper and possibly **prevent any future innovation** in the chemical industry and its entire value chains, especially impacting industries aimed at developing innovative durable materials. In order to ensure

innovation for future research and development, a review clause shall be introduced under the PFAS Annex.

4. **Alternative for substance and/or substituent does not mean the direct alternative for products**. Products which are used as alternative substances must meet the specifications of the original product. Furthermore, even if alternative substances other than PFAS are found, it is necessary to be mindful of the hazards and risks to human health and the environment. This could potentially lead to a different form of "regrettable substitution."
5. There are numerous examples of PFAS that can provide multiple necessary functionalities as a single substance. The availability of alternative means to cover these functionalities is limited. It is crucial to assess each products group and to ensure that **necessary exemptions for specialist applications are not overlooked** to avoid negative influence on human health and environment as well as societal and supply chain disruptions especially in the field of specialist equipment such as measurement and monitoring devices and medical devices.
6. **Polymer PFAS should be reconsidered for further exemption** as fluoropolymers have documented safety profiles; are thermally, biologically, and chemically stable, negligibly soluble in water, nonmobile, nonbioavailable, nonbioaccumulative, and nontoxic.
7. **The inclusion of F-gases within the suggested REACH Universal PFAS Restriction Proposal should be avoided because of double regulation**, given that these gases are already governed by a dedicated Regulation (EU Regulation 517/2014). This existing regulation, currently under revision, already adequately addresses key concerns like containment, leakage inspections, proper handling, reporting, and end-of-life procedures.
8. **Spare parts: the "repair as produced" principle should be introduced**. 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) cannot be guaranteed. The reuse of used part/used devices should also be exempted. If not, a large amount of waste is expected to be generated. In order to ensure the repairability and continuation of the lifetime of products, a full exemption for spare parts is needed.
9. **A transition period of at least 48 to 60 months is recommended** for sufficient adaptation to the proposed PFAS restrictions. The currently suggested 18-month transition period is unrealistic for most industries given the broad impact of the restriction on many applications with complex value-chains. JBCE suggests a minimum of 48 to 60 months for compliance as manufacturers of specialist equipment will need long timeframes for the testing and validation of alternative material perform reliability tests, design changes, production management and their documentation, training, and certification to meet the new regulations and other industry and/or safety standards.
10. We strongly request to **establish the new system to be able to apply for further extension** after the termination of the exemption period. We kindly ask the authorities to take into consideration for the new submission system and process to enable to extend the transition period as for the RoHS exemptions. The proposed PFAS derogation, which permits **maintenance and refilling of existing equipment**, is important. **Extending this derogation** beyond a 12-year timeframe and considering the full product lifecycle, rather than time limits, is necessary for circularity and aligning with EU sustainability goals.

11. JBCE would also like to emphasise the importance and the necessity of availability of analytical methods allowing for the proper enforcement of the restriction. Because of the difficulty in identifying which parts of complex articles are to be analysed, and **the general lack of analytical 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 without proper validated analytical methods.
12. Finally, JBCE would like to ask the European Chemicals Agency and the European Commission to take the above comments into consideration, and to have discussions with stakeholders in the context of a clearly defined process.

ABOUT JBCE

Founded in 1999, Japan Business Council in Europe (JBCE) is a leading European organization representing the interests of about 100 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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ANNEX

2. DETAILS

2-1: Definition / Hazard

(i) Chemical structure

In this restriction proposal, PFAS is defined as follows:

Any substance that contains at least one fully fluorinated methyl (CF_3-) or methylene (-CF_2-) carbon atom (without any H/Cl/Br/I attached to it). A substance that only contains the following structural elements is excluded from the scope of the proposed restriction: CF_3-X or X-CF_2-X', where X = -OR or -NRR' and X' = methyl (-CH_3), methylene (-CH_2-), an aromatic group, a carbonyl group (-C(O)-), -OR", -SR" or –NR"R"', and where R/R'/R"/R"' is a hydrogen (-H), methyl (-CH_3), methylene (-CH_2-), an aromatic group or a carbonyl group (-C(O)-).

- The Annex XV report and annex B explain that fully degradable subgroups, which can be described by their key structural elements, do not fulfil the underlying concern of high persistence, and are therefore excluded from the scope of the restriction proposal. According to this explanation, Trifluoro methanol (CF_3OH -> CO_2 + HF) is excluded, but Trifluoro acetic acid (CF_3CO_2H) and trifluoro methane sulfonic acid (CF_3SO_3H) are within the scope of this restriction based on the logic of the degree of persistency.
- The following table 1 shows the GHS classification of the smallest units of certain fluorochemicals. JBCE believes that chemical management should use a **risk-based** approach and not solely hazard-based. It is common sense for industrial stakeholders to handle hazardous substances very carefully. Even when handling large quantities of non-hazardous chemicals inappropriately, and thereby increasing the exposure to operators, the risk would drastically increase. It is a premise that chemicals should be handled with sufficient care.
- Is it logical that HF is safer than CF_3CO_2H and CF_3SO_3H, even from a hazard-based perspective? Chemical substances containing sub-structure of CF_3O-R should rather be treated with caution because there is a concern that hydrofluoric acid HF might be generated in the decomposed product. In general, the degradability of this sub-structure means an unstable, short lifetime, and makes it necessary to handle it very carefully.[1]
- It has been reported that there is an inverse proportionality relationship between carbon chain length and toxicity. The fluoro chemical which has a shorter carbon chain is less harmful than a longer one. Although trifluoroacetic acid has been mainly detected in the environment, information on its toxicity seems insufficient. For trifluoromethanesulfonic acid, additional studies are needed. We would like to state that it should be scientifically clarified what a hazard is and what is acceptable for a fluoro chemical structure. In addition, even though some assumptions of hazards could be made, C1 chemistry should be excluded and

[1] Org. Chem. Front., 2017,4, 214-223

C>2 or C4 could be considered.[2345]

- Table 1. Comaprison of the GHS classification among HF, CF_3CO_2H, and CF_3SO_3H

Name	Hydrogen fluoride	Trifluoroacetic acid	Trifluoromethanesulfonic acid
Formula	HF	CF_3CO_2H	CF_3SO_3H
CAS	7664-39-3	200-929-3	1493-13-6
GHS Classification by EU-CLP			-

(ii) "Persistence alone" and Article 68 of REACH Regulation

- JBCE has grave concern with the idea of basing a potential REACH restriction only on the persistence criteria. JBCE understands that this 'persistence alone' approach has been proposed by some Member States as well as some academics (1: Cousins, Ian T., et al. "Why is high persistence alone a major cause of concern?" Environmental Science: Processes & Impacts 21.5 (2019): 781-792.), but notes that this argument does not consider the full picture of risk assessment which is required by the REACH Regulation.
- In the previous Call for Evidence, five EEA countries argue that *the consequences of this persistence include that the presence of these substances in the environment is practically irreversible, and pose an unacceptable risk to the environment and humans*. But persistence alone does not pose a hazard *per se*. Persistent substances can only be a concern if they also entail some hazard. If they entail a hazard, their potentially increasing presence in the environment from use and/or emissions could be a reason for concern, but only then, not in the absence of a hazard. As we understand the REACH Regulation, **'persistence' itself is not considered as a hazard**. Instead, it is a factor to be considered in the risk assessment of a chemical substance together with bioaccumulation and/or toxicity. This is evident from the Preamble, paragraph 76 of REACH Regulation. Thus, persistence alone cannot be an intrinsic property that has an adverse effect on human health or the environment in the absence of any other property that constitutes a hazard.
- This logic leads us to question the legality and proportionality of a REACH restriction based on persistence alone. According to Chapter 2 of the REACH Regulation, for a restriction to be adopted, not only must a hazard be identified, but the resulting risk must be assessed and found to be 'unacceptable' to human health or the environment and the proposed restriction found to be the most appropriate measure to manage the identified risk.
- It should be recognised that, for substances like PFAS, the intrinsic property of persistence

[2] Toxicol Sci. 2008 Nov;106(1):162-71.
[3] Toxicol Sci. 2009 Sep;111(1):89-99
[4] J Hazard Mater. 2021 Feb 5;403:123618.
[5] Int J Hyg Environ Health. 2021 Aug;237:113830.

confers the desirable properties of high durability and unique functionality to products made and treated with this chemistry. 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, 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. This property results in significant maintenance and durability of materials, contributing to waste reduction in line with the EU's objectives for a circular economy, and in protection of human health, for example. In our view, less durability would lead to frequent maintenance and/or replacement of materials, as well as to a potential increase of waste. Prohibiting substances on the basis of persistence alone runs completely counter to the goal of a sustainable Circular Economy.

It is worth noting that the increased focus on persistence is likely to lead to restrictions of potential alternatives as they would require similar properties in order to fulfil the abovementioned critical functions in industrial applications. In addition, we are concerned that this kind of restriction would discourage researchers and companies from developing materials and business for sustainable future, and, as a result, limit future innovation for betterment of the society in the EU.

- JBCE believes that, if a restriction on the basis on persistence alone were to be established, this precedent would severely hamper and possibly prevent any future innovation in chemical industry, in particular innovation aimed at durable materials. We therefore would like to encourage the relevant authorities in the EU to reconsider the future direction of the EU's chemicals' strategy. Do we really want products that inevitably break and fail after a short time and are impossible to recycle because they chemically degrade?

(iii) Precautionary principle

We note that restrictions or bans solely on the basis of persistence cannot be justified under the REACH regulation as it stands today. If the submitters of this restriction proposal believe that their concern and action might be justified by the 'precautionary principle', we would like to point out that the 'precautionary principle' is indeed a basis of the EU legal framework, as a preventive function to protect the environment. The European Commission has issued a Communication on the precautionary principle (2.2.2000 COM(2000)[6]):

Where action is deemed necessary, measures based on the precautionary principle should be, inter alia:

- ***proportional*** *to the chosen level of protection,*

- ***non-discriminatory*** *in their application,*

- ***consistent*** *with similar measures already taken,*

- ***based on an examination of the potential benefits and costs*** *of action or lack of action*

[6] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:52000DC0001

(including, where appropriate and feasible, an economic cost/benefit analysis),

*- **subject to review**, in the light of new scientific data, and*

*- **capable of assigning responsibility for producing the scientific evidence necessary** for a more comprehensive risk assessment.*

- JBCE believes that the aforementioned conditions are not met in the PFAS restriction proposal. In order for any action such as the substance bans under consideration to be proportional to the chosen level of protection, a negative effect must first be identified. Case law (for example 174/82, T13/99, C-192/01, C-236/01, C-333/08) makes it abundantly clear that it is not sufficient to merely suggest a hypothetical risk. For such a broad range of substances and extremely diverse properties under consideration for PFAS ban, the risk postulated by the Dossier Submitters proposing their ban can only be purely hypothetical.
- For the action to be non-discriminatory, the action (substance ban) would have to be applied to all substances exhibiting the same property, namely persistence. Thus, if PFAS were to be banned merely on the basis of persistence, then all other persistent substances, including ceramics, glass and various metals, would also need to be banned. In the absence of bans of other persistent substances and materials, a substance ban limited to PFAS would therefore not be consistent.
- In our view, any justification for a substance ban 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 ban, as well as the scientific evidence for the risk assessment. Moreover, it must be subject to review, in light of new scientific information. Precautionary principle itself does not exempt regulators from looking into available scientific information; this is clear by certain Court Judgements and Regulatory Decisions. It is doubtful that an approach based on persistence alone in the absence of any common hazards and which addresses such a huge and varied group of substances with completely diverse properties, without reviewing available scientific evidence, could possibly be justified under precautionary principle as implemented in EU Law.

(iv) PFAS contribute to the safety of products

- Based on the information provided by a stakeholder, PFAS contribute to safety at manufacturing sites to prevent fire accidents caused by static electricity. It is well known that PFAS have been preferably used as a surfactant or lubricant. Thanks to their electron-withdrawing substituents, PFAS surfactants are used at manufacturing sites because they suppress static electricity due to their charge- neutralizing effect.

  Static electricity should be treated with extreme caution at manufacturing sites, and all measures must be taken to ensure stable and safe production. Figures 1 and 2 below show the potential consequences of fire accidents caused by static electricity. It should be noted that in the examples below, information is lacking whether PFAS-based surfactants were actually used. However, these examples show the dramatic consequences of such accidents, and the importance of implementing all possible measures such as the use of PFAS surfactants to prevent them.

Fig. 1. Fire accident caused by static electricity(i) Fig 2. Fire accident caused by static electricity(ii)

(v) Condition of use and previous opinion by the Court of Justice of the European Union

- The Court of Justice of the European Union (CJEU) has consistently defined risk assessment as consisting of three elements: hazard, exposure, and risk based on the hazards manifesting themselves in the exposure in the specific case. For example, Advocate General Bot's opinion delivered on 24th March 2011 in Etimine, C-15/10, EU:C:2011:179: "*Risk assessment is concerned with the likelihood that one of the hazards associated with a substance will occur as a result of human or environmental exposure to that substance*".
- We should also take into account that the CJEU has annulled the Commission Delegated Regulation of 2019 in so far as it concerns the harmonised classification and labelling of titanium dioxide as a carcinogenic substance by inhalation in certain powder forms in November 2022.

In JBCE's opinion, the Dossier Submitters have not adequately conducted an appropriate risk assessment for such a large group of diverse chemical compounds and JBCE would question its legal legitimacy.

(vi) The concern on TFA

The proposal includes degradation products of PFAS substances. Specifically, some F-gases (HFCs and H(C)FOs) break down into persistent trifluoroacetic acid (TFA), justifying their inclusion based on REACH Annex XIII criteria. TFA differ from other longer chain PFAS substances. The latest EEAP Assessment Report [7] regarding Environmental Effects of Stratospheric Ozone Depletion, UV Radiation, and Interactions with Climate Change published in May 2023 underlines that *"it is very unlikely to have adverse toxicological consequences for humans and ecosystems".*

The Report concludes that *"Trifluoroacetic acid has biological properties that differ significantly from the longer chain polyfluoroalkyl substances (PFAS) and inclusion of TFA in this larger group*

[7] https://ozone.unep.org/system/files/documents/EEAP-2022-Assessment-Report-May2023.pdf

of chemicals for regulation would be inconsistent with the risk assessment of TFA" (page 25).

2-2: Grouping / Essential Use / Risk Based Approach product by product

- The PFAS restriction proposes to regulate chemicals compounds by a grouping procedure which has already been adopted for other fluorochemicals such as PFOA and PFOS. This restriction proposal, however, targets a much larger group of chemicals (thousands of substances), and in our view, without proper scientific hazard and risk assessment of each substance or group of substances.
- We understand that this Dossier Submitters would like to prioritise efficiency of regulatory actions, rather than taking a time-consuming but science-based hazard and risk assessment approach. We agree that efficiency is important in general, especially when a large trade and political union is governed. However, it must be pointed out that this 'mega' grouping, which includes hydrofluorocarbons (HFC), olefins (HFO), small molecules (surfactants) and polymers with high molecular weight is over-simplified. This broad approach shortcuts proper science-based assessment and treats substances with very different chemical, physical and biological characteristics as if they were a single substance.
- Further, in view of the enormous breadth of substances for which a restriction is contemplated, beyond the chemical persistence of the parts of the molecule that contain CF2- or –CF3, these substances have almost no unifying shared properties. Some are toxic, others are not toxic at all. Some are gases, others are liquids and still others are solids. Some are water solvable, others are fat soluble and still others are completely insoluble. Some are chemically reactive, others are chemically inert. Some are volatile, others are not. How can such diverse properties possibly be adequately covered by a single risk assessment?
- **PFAS grouping restriction may cause conflict with existing EU environmental standards**
  - For example, multi-functional printers and printers by using toner in market create text and images as follows; Charging -> Exposure -> Development -> Transfer -> Fusing. In this process, the materials related to charging must display excellent wear and stain resistance in order to reliably maintain stable toner image formation. PFAS materials are being used in almost all processes. Especially, for the Fusing process, the toner must be melted at a high temperature from 150 to 200 ^{o}C and fixed to the paper by heating and pressure so that the images do not drop off. In the fixing process which uses heating and pressure for fusing, and colouring the powdered toner onto the paper, it is necessary to maintain the heat resistance to bear 150 to 200 ^{o}C with having the releasability and abrasion resistance. A specific material which satisfies these functions is required. Availability of polymers which have sufficient heat resistance are extremely limited.
  - For office equipment, it is a standard to fit the eco-labels such as the German Eco-label (Blue Angel)[8]. Products must be designed for deep consideration on energy saving, resource saving, and resource recycling. Furthermore, in terms of quality, stable operation which can satisfy printing of approximately 3 million papers is generally required.
  - A stakeholder conducted a simulated experiment with/without PFAS conditions for

[8] https://www.blauer-engel.de/en

printing by toner. Even though it was only a one time process trial, the toner could not properly transfer toner to the paper (Figure 1 and 2) and a paper jam occurred (Figure 3 and 4). If this had happened on an actual machine in real life conditions, an enormous amount of paper would have been wasted. This is in complete contradiction with the goals of both the circular economy and development of sustainable products as aimed for by the EU.

- We would like to strongly emphasize that the PFAS restriction would negatively affect and impact to the environment friendly and sustainable product design objectives the EU is striving for.

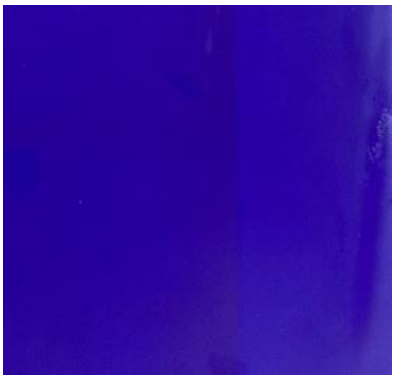

Figure 1. Printed paper with PFAS treated fusing belt

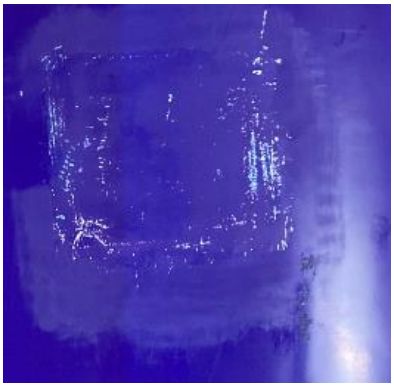

Figure 2. Printed paper without PFAS treated fusing belt

Figure 3. Paper jamming at the fusing belt

Figure 4. After printing and waste paper

2-3: Avoid Double Regulations

The validity between the previous restriction proposal of certain fluorochemicals and this restriction proposal for PFAS

- Bisphenol AF (BPAF, CAS: 1478-61-1) is also under consideration by the restriction proposal of bisphenols with endocrine disrupting properties for the environment and their

salts[9]. Although we recognize that the authority is aiming to finalize and enforce the PFAS Restriction in 2026/2027, JBCE is really concerned that the transition periods for some specific applications like BPAF could be reversed. This kind of duplicate regulations and/or contradiction should be avoided and a clear understanding of how these overlapping restrictions will be enforced should be provided.

- The core legislation overseeing the usage of fluorinated gases is the F-gas Regulation. In 2016, signatories of the 1987 Montreal Protocol on Substances that Deplete the Ozone Layer (referred to as 'the Protocol') made a decision through the Kigali Amendment to execute a gradual reduction in the production and consumption of HFCs (hydrofluorocarbons) by more than 80% over the next three decades, considering their greenhouse impact. Impressively, the EU Regulations are already surpassing the targets set by the Montreal Protocol.
- The EU F-Gas Regulation was driven by two primary objectives:
  - Mitigating the release of F-gases from existing equipment by enforcing inspections, proper servicing, and the recovery of gases at the equipment's end of life.
  - Enhancing leak prevention from equipment containing F-gases through measures such as:
    - Ensuring gas containment during the operational lifespan of refrigeration, air conditioning, heat pump (RACHP) systems.
    - Facilitating the retrieval of F-gases during maintenance and at the equipment's end-of-life stage.
    - Establishing training and certification standards for personnel and companies involved in handling these gases.
    - Mandating equipment containing F-gases to be appropriately labeled.
    - Requiring reporting on F-gas imports, exports, and production.
- Additionally, there are prohibitions on the usage of F-gases in specific applications where environmentally friendlier alternatives are readily available. These bans are determined by considering the Global Warming Potential (GWP) and stipulated dates, applying to both new equipment and maintenance activities. The inclusion of F-gases within the suggested REACH Universal PFAS Restriction Proposal is thus unnecessary, given that these gases are already governed under a separate one. This existing regulation adequately addresses key concerns like containment, leakage inspections, proper handling, reporting, and end-of-life procedures.

2-4: Applications of PFAS

It should be recognized that, for a group of 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 chemical. For example, PFAS is used in Electrical Electric Equipment and is needed to be fully functional under a variety of harsh conditions. To keep this high reliability and performance level, components are required to be moisture, water, and rust proof as well as resistant to corrosion and extreme temperatures. In order to achieve the above requirement, such functions as low dielectric constant, low dielectric loss tangent, low refractive

[9] https://echa.europa.eu/registry-of-restriction-intentions/-/dislist/details/0b0236e1853413ea

index, and oil repellency are essential. Only PFAS substances can provide all the required functions and performance. As of today, no alternatives display the combination of all the properties listed above. (Please kindly refer to the attached non-exhaustive list of uses of PFAS substances. This would be useful for identifying applications that may have been overlooked.)

It is important to assess each product category separately – especially for specialist equipment - since each product category make use of unique properties of PFAS as mentioned above. For example, analytical devices mostly use chemicals and are often operated in special conditions, such as high/low temperatures and high pressure. Very fine differences in properties have a significant impact on the performance of the devices. Failure to provide accurate measurement results has critical negative impacts on our society. For example, deteriorating the quality of medicines and food, inability to accurately monitor water and air pollution, hindering innovation, and failing to ensure the safety of social infrastructure. It is therefore necessary to be able to guarantee the same performance of devices when using alternatives to PFAS in components.

2-5: Alternatives of PFAS

(i) Alternative for substance and/or substituent does not mean the direct alternative for products

- For example, in the Annex XV report, alternatives for the category in Electronics states "*Weak evidence that technically feasible alternatives exist, i.e. cyano group instead of CF_3, for liquid crystal displays*.". This only looks at one aspect of the electron-withdrawing group of the trifluoromethyl group, and there is no evidence provided suggesting alternatives to PFAS are available for this application. Furthermore, the degree of electron-withdrawing group in Hammett equation indicates as follows; Cyano group: para-factor:+0.66, meta-factor: +0.56, Trifluoromethyl group: para-factor:+0.54, meta-factor: +0.43. The electronic effects of these substituents are not comparable with each other, and it is necessary to distinguish and confirm very carefully whether alternatives can be used as a substituent, as a chemical substance, or as a product.
- Refrigeration, air conditioning, and heat pump (RACHP) equipment exhibit a high degree of complexity, encompassing intricate systems and advanced technologies. Shifting towards substitute solutions, encompassing new refrigerants and alternative fluoropolymers utilized in materials, necessitates thorough developmental phases and rigorous testing. These protocols are in place to guarantee that the replacement options not only adhere to safety, performance, and efficiency benchmarks but also seamlessly integrate with the pre-existing infrastructure and equipment.

(ii) C-F bond and function of PFAS

- The function provided by PFAS is based on the fundamental of the strong carbon-fluorine bond. The diversity of PFAS applications related to the strength of this carbon-fluorine bond is quite variable. For example, releasing sheets made by a fluoropolymer such as PTFE is used for its specific characteristics such as slipperiness, low dielectric constant, peel ability, stability, water and oil repellency, and heat-resistance. PFAS have these multiple characteristics at the same time. As for many other applications, the fluoropolymer is used for many different properties and finding or developing an alternative displaying all these properties may in many cases be impossible.

(iii) Risk for another "regrettable substituent"

- A trifluoromethyl group (CF_3-), which is the smallest unit of perfluoro substituents, is known to improve fat solubility and solubility of poorly soluble functional materials (pharmaceuticals, and polymers). For example, in the past, insoluble polymers could only be dissolved by using huge amounts of hazardous solvents such as N,N'-dimethylformamide (DMF) and N-Methyl-pyrrolidone (NMP). Polymer containing fluorine substituents can be handled with safer organic solvents. Therefore, if al PFAS were banned, industries would need to revert to the use of large amount of organic solvent. As a consequence, the hazards and risks for humans during operation and the environment would increase. Even if industries can find alternatives that are not within the definition of PFAS used in the restriction proposal, these might be another "regrettable substitution".

(iv) Possible disadvantages of alternatives

- PFAS restriction can damage human health and the environment because specialist equipment such as analytical devices cannot deliver the accurate measurement and result.
- Components without PFAS are more susceptible to deteriorate, requiring frequent replacement and increasing waste. It may damage the environment and therefore goes against the objective of having a sustainable society.
- PFAS restriction cannot be enforced if analytical devices are not available on the EU market because of the PFAS restriction.
- The change to alternatives would increase the costs and consequently the price of the devices would also increase.

2-6: Derogation for specific application

(i) Polymer PFAS should be reconsidered for further exemption.

- A recent review states that "*16 unique families of commercially popular fluoropolymers meet the OECD Polymer of Low Concern criteria*". Abstract says below: Fluoropolymers possess a unique combination of properties and unmatched functional performance critical to the products and manufacturing processes they enable and are irreplaceable in many uses. Fluoropolymers have documented safety profiles; are thermally, biologically, and chemically stable, negligibly soluble in water, nonmobile, nonbioavailable, nonbioaccumulative, and nontoxic. Although fluoropolymers fit the PFAS structural definition, they have very different physical, chemical, environmental, and toxicological properties when compared with other PFAS. Even if the polymer is persistent, large molecule such as polymer cannot permeate to cell membrane. Polymer PFAS should be reconsidered as further exemption.
- Considering that fluoropolymers are not hazardous and, consequently, cannot be associated with any risks, JBCE believes that they should be exempted from the restriction proposal. Furthermore, these products are required in many applications linked to several major EU projects (Green Deal, Decarbonization, Chips Act, etc…), and a complete ban of fluoropolymers would have a tremendous negative impact for EU's innovation projects and its overall economy.

- Reference) https://setac.onlinelibrary.wiley.com/doi/epdf/10.1002/ieam.4646
- Reference) https://www.oecd.org/env/ehs/risk-assessment/42081261.pdf

(ii) Special condition necessary for devices in scope of MDR and IVDR

- A PFAS-free component should be tested in accordance with the ISO 10993-1 series to assess its safety in vivo. Regarding the devices that are implanted in the human body or that come into contact with bodily fluids and return those fluids to the body, they may in some cases require clinical trials in order to confirm their clinical efficacy and the safety of the materials. This task is huge and comparable to the work of developing a new product. Medical device manufacturers have a wide variety of devices, however, they have limited engineers - one engineer is responsible for several models. Consequently, evaluation of PFAS-free products will reduce the speed of development of new innovative medical devices. Therefore, we strongly recommend a "legacy approach" for the devices with a long design cycle such as medical devices: the devices – which Declaration of Conformity is issued before the introduction of PFAS restriction – should be exempted from the scope of new restriction.

2-7: Spare parts and maintenance/refilling

(i) A "repair as produced" principle should be introduced

- We strongly believe that spare parts for EEE placed on the market before the implementation of the restriction should be exempted from the restriction without expiry date. If spare parts are not exempted, the lifetime of many products and articles used and sold in the EU will be shortened, and the volume of waste will rapidly increase. Again, this goes against the EU's objective of having a more sustainable and circular economy. Therefore, a "repair as produced" principle should be introduced and taken into account in the PFAS restriction proposal.
- Products placed on the market need to be repaired with the same spare parts as the ones originally used in the original product. A re-design of spare parts with alternative material often requires a re-design of the entire product, because otherwise the original performance (i.e. safety and durability) cannot be guaranteed. Considering the supply chain and production processes of many manufacturers, such a re-design is not a realistic solution.
- We also believe that the reuse of used parts/used equipment should be exempted from the restriction without expiry date. Without this exemption, the volume of waste will rapidly increase and it is not sustainable.

(ii) Extending proposed derogation of maintenance and refilling for circularity

- The proposed derogation in the PFAS proposal, which allows for the maintenance and refilling of existing HVACR equipment, is a crucial provision. However, it is important to consider extending this derogation beyond the specific time frame of 12 years and basing it on the entire lifecycle of the product rather than limiting it in time.
- To ensure circularity and align with the sustainability goals of the EU, it is necessary to take into account the lifetimes of RACHP equipment, which can extend well beyond 12 years and up to 30 years for certain applications. By limiting the derogation in time, there is a risk of premature replacement of HVACR units that could otherwise be repaired and maintained.
- The repair and maintenance of existing equipment is an essential aspect of a circular economy. It reduces waste, conserves resources, and minimizes environmental impact. In conclusion, extending the derogation beyond a specific time frame and basing it on the entire lifecycle of the product is a logical and necessary step to ensure circularity and align with the

sustainability goals of the EU.

2-8: Sufficient transitional period

(i) Default transition period should be at least more than 60 months.

- Currently, 18 months is proposed as a general transition period after entry into force. According to the information shared during a webinar by ECHA on 7th February 2023 on the proposal to restrict PFAS chemicals in the EU, "*18 months can be applied in the consumer market*". However, this is not realistic when considering the impact of the current restriction proposal on the complex and numerous industry value-chains.
- As a reference, ECHA proposed a transition period of 36 months within the restriction proposal for PFHxA and its salts[10]. Given the much broader scope of the PFAS restriction proposal, JBCE believes that a 48-month transition time – and up to 60 months depending on the type of sector - would be the strict minimum required by the industry to adapt its products and ensure compliance with the restriction.

(ii) Sufficient transitional period for some product groups

- The manufacturers of specialist equipment need sufficient time to ensure that the new devices without PFAS have at least the same performance as before. For example, for measurement and monitoring devices as well as medical devices, the following process are necessary after the potential alternative is found:
  - Testing of alternative material: 1-2 years (if negative, repeat until alternative is found)
  - Reliability test: performance test of the product: 1-2.5 years (if negative, repeat until alternative is found).
  - Device design change: 0.5-2 year
  - Change the production line/ buy new production equipment: 1-2.5 years
  - Create Technical Documentation: 0.5 years
  - Training at the production site: a few months
  - Production management (information to customers): 0.5-1 year
  - Third-party certification: 1 year without clinical trial/ a few years or more with clinical trial

2-9: Exemption renewal and re-evaluation

Request to establish the new system to be able to apply for further extension after the termination of the exemption period.

- The industry would like to make maximum efforts to find alternatives and/or develop alternative technologies to replace substances for which an unacceptable risk has been demonstrated. However, fluorine-free alternatives are not always available or even safer. It is not always possible to develop the appropriate alternative product before the end of the extended transition period proposed for specific derogations. We therefore kindly ask the authorities to take into consideration the adoption of a review system similar to what is currently implemented for the RoHS exemptions.

[10] https://echa.europa.eu/registry-of-restriction-intentions/-/dislist/details/0b0236e18323a25d

2-10: Measurement of PFAS: the implementation and enforcement of PFAS restriction is not possible.

- JBCE would also like to emphasise the importance of the availability of analytical methods. Generally, analytical methods are inevitable for the enforcement of chemical substance legislation. As of now, there are no validated and certified analytical methods for the entire range of PFAS which includes several thousands of compounds. First of all, the structure of all PFAS has not been identified for analysis. Secondly, neither analytical methods nor the certified references for all kinds of known PFAS are currently available. Therefore, the restriction is currently unenforceable.
- There are standards for the measurement of PFAS, however, these are very limited: 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 PFAS. 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 of 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. It is therefore not possible to reliably implement and monitor the enforcement of the PFAS restriction as only a very limited number of PFAS analysis methods have been established so far.
- Practical methods for evaluating fluorinated impurities at the recommended thresholds (25 ppb for individual compounds and 250 ppb in total) are not readily accessible to all downstream users and manufacturers. To verify these proposed levels, Gas or Liquid Chromatography coupled with Mass Spectroscopy (GC-MS/LC-MS) a technique primarily utilized in research laboratories, becomes necessary.
- It is difficult to identify which parts of complex articles contain PFAS: Small amounts of PFAS are frequently used in the manufacture of components of complex equipment. It would be an enormous challenge to identify which components of the equipment contain PFAS. Under the current situation, it is not possible to identify the type of PFAS contained even if we could detect PFAS.
- For the reasons stated above, the enforcement of such a broad PFAS restriction is not feasible. Restrictions must be enforceable in the interest of both sustainability and compliance related level-playing field.