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Comments on Annex XV Restriction Report on Per- and polyfluoroalkyl substances (PFAS)

We JFMDA (The Japanese Federation of Medical Devices Association) was founded by medical device associations consisting of manufacturers and suppliers of medical and health-care devices, equipment, instruments and materials.

The JFMDA represents 20 medical device associations, consisting of about 4300 companies that together more than 120,000 employees.
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JFMDA would like to submit the following comments to the public consultation on a REACH restriction proposal for PFAS and to contribute to the effective and appropriate implementation of the restriction on PFAS.

General Comments

We are pleased to have the opportunity to contribute to the public consultation launched by ECHA on the proposed restriction of perfluoroalkyl and polyfluoroalkyl substances (PFAS). As a healthcare industry association, we wish to contribute to human health, the environment, society and the economy through the supply of medical devices. We are also well aware of the importance of chemical regulations such as REACH and RoHS, and we are implementing activities to reduce the risks posed by chemicals to human health and the environment.

We support the gradual strengthening of PFAS regulation within the framework of REACH. On the other hand, we have strong concerns about the legitimacy and socioeconomic impact of uniformly regulating PFAS by lumping them all together as "common hazards and risks". PFAS are lumped together on the basis of their "persistent" nature, however, the chemical structure and physical, chemical and biological properties of each sub-group of PFAS differ greatly, and their toxicity profiles are not identical. In addition, the risk to human health, the environment, and the socioeconomy varies greatly depending on the application. We request to establish appropriate grace measures for essential use, and also request to regulate on a priority basis PFAS subgroups with greater hazards or PFAS application posing higher environmental risks as well.

For example, fluoropolymers are lumped together with PFCAs and are included in the proposed restriction as posing a high risk to humans and the environment, even though they meet the criteria for a "polymer of low concern" as defined by the Organization for Economic Co-operation and Development (OECD). Fluoropolymers are the only materials that combine excellent properties such as biocompatibility, persistence (stability), chemical resistance, repellency from water and oil , low-friction, heat resistance, electric insulation, flame resistance and durability, and are known as essential materials that support social infrastructure functions such as medical devices and their progress. And more, even though disposal is controlled or manageable in medical applications, they are regulated in the same way as in consumer applications with much higher potential risk of discharge into rivers and sewers.

We believe that it is beneficial to European society to establish effective regulations for PFAS after appropriate assessment of health and environmental risks, socioeconomic impacts, risks of exposure to humans throughout the product life cycle, and feasibility of countermeasures for low concern fluoropolymers and fluoroelastmers. In other words, by prioritizing the regulation of PFAS subgroups, including Arrowheads substances, for which there is evidence or strong suspicion of hazards, and applications with severe environmental and health risks, it will be possible to effectively and efficiently reduce risks to human health and the environment with minimal socioeconomic impact.

As an organization supplying medical devices to Europe, we request the following in order to contribute to human health and safety and to socio-economic development in Europe, and to ensure that healthcare professionals and European people do not lose an opportunity to access to the best medical care.

1. Enact effective PFAS regulations in a phased manner based on appropriate risk and socioeconomic assessments
2. Exempt fluoropolymers and fluoroelastomers from the proposed PFAS regulation
3. Devices subject to Medical Device Regulation 2017/745 (MDR) and In-Vitro Diagnostic Medical Device~~s~~ Regulation 2017/746 (IVDR) shall be exempted as Essential Use
4. Exemptions shall be provided for repair parts.
5. Provide an "extension clause" that allows for an extension of the grace period.
6. Provide exemptions or maximum grace periods for medical device applications for which additional information is provided

1. PFAS regulations based on appropriate risk assessment and socioeconomic evaluation

PFAS is a generic term for fluorinated compounds with a wide variety of properties and

characteristics, and each subgroup, classified by molecular weight and chemical structure, has significantly different chemical and physical properties and risks to human health and the environment. PFAS includes "substances that are not classified as hazardous substances such as PBT, vPvB, CMR, etc." and "polymer compounds for which there is no scientific evidence that they produce such hazardous substances in the environment (polymers that are classified as substances of low concern by the OECD definition or as no Arrowhead substances)".

Article 68(1) of the REACH regulation states that new restrictions are to be introduced "when there is an unacceptable risk to human health or the environment that needs to be addressed on a Community-wide basis". The proposed restriction lumps together a variety of PFAS and concludes that they are "unacceptable risks to human health or the environment" because they are "persistent". However, there is no international consensus to conclude that all PFAS, including substances of low concern, are 'unacceptable risks' simply because they are 'persistent'. For example, there are many substances that are stable or persistent in the environment, such as artificially synthesized glass, diamonds and ceramics, but they are not restricted and are not considered to pose an unacceptable risk to human health or the environment.

The proposed restriction states that "most PFASs have insufficient data to adequately assess their effects on human health and the environment". And the proposed restriction also includes "PFASs that have not been found to be toxic or bioaccumulative" or "PFASs that have not been identified as hazardous in environmental degradation products". For the PFAS subgroups of low concern, we request that the risks to humans and the environment be assessed based on the latest scientific findings and information, and that the regulations be strengthened gradually, starting with the subgroups and applications with the greater risk, based on the precautionary principle supported by scientific evidence.

We request that the risks and benefits of PFAS be properly assessed, including their impact on the social economy. For example, automobiles claim tens of thousands of lives annually and contribute to air pollution and global warming, but they also contribute to the maintenance and development of society and the economy, so certain risk is acceptable and regulations are provided gradually and strategically. Regulations based on excessive risk assessment may impede the development of new technologies and products, which may undermine socioeconomic development. In addition, the appropriate control and use of PFAS of low concern, such as fluoropolymers, outside of Europe, such as in Asia, could reduce the EU's competitiveness and raise security concerns.

In order to effectively reduce environmental and health risks from PFAS, it is effective to identify PFAS subgroups with high toxicity and hazard and PFAS applications that discharge large

amounts into the environment, and to prioritize risk assessment, socioeconomic assessment, and regulatory enforcement for them. In Table B.60, a large amount of PFAS emissions in the medical device sector are tabulated, however, the majority (over 95%) of which are "F-gases" used as propellants for MDI (Metered Dose Inhalers). Therefore, the risk assessment and regulation for the F-gases used in MDI is significant issue. Except for F-gases, the medical device sector has very low PFAS emissions, less than a few percent of the TULAC emissions, and furthermore, significant amount of the PFAS emissions are from "substances of low concern" such as Fluoropolymers and fluoroelastomers. In other words, PFAS emissions from the medical device sector (excluding F-gases) are less than 1% of the total and have a relatively small environmental impact. Thus, the benefits and effectiveness of restricting the use of PFAS for medical devices are small and, conversely, the negative impact on the European socio-economy is likely to be significant.

As noted in B.9.10.4. summary, with the exception of F-gases from MDI, PFAS emissions from medical devices are low and their environmental and health impacts are at a minor level. Furthermore, medical devices are required by MDR and IVDR to be designed with disposal in mind and their disposal is controlled, so the potential for emissions into the environment, such as sewage and rivers, is at a much smaller level compared to daily commodities such as water repellents for clothing and food packaging materials. On the other hand, medical devices are used to maintain people's health and life, and are an essential part of the social infrastructure. In order to contribute to the health and safety of people and the maintenance and development of the social economy, and to ensure that medical professionals and the people of Europe do not lose the opportunity to access the best medical care, we request that effective PFAS regulations be enacted in stages, based on appropriate risk assessment and socioeconomic evaluation.

2. Exclusion of fluoropolymers and fluoroelastomers from PFAS regulation

“Fluoropolymers" and "Fluoroelastmers" meet the OECD's "Polymers of Low Concern", and are used as safe and stable materials in many medical devices such as catheters and guidewires, as well as in medical devices implanted in the body, such as artificial blood vessels. For example, PTFE is an excellent medical material with stability and biocompatibility, and has been used implanted in the human body for decades without showing adverse effects. Fluoropolymers are also stable in the environment, and there is limited information on their degradation products, therefore there is no international consensus to conclude that they are "hazardous materials posing an unacceptable risk to human health or the environment”.

Some side-chain fluorinated polymers have bonds in the molecule that are easily degraded in the environment, and the degraded products can become arrowhead substances that can be toxic. Therefore, they need to be carefully assessed on the basis of the precautionary principle. On the other hand, fluoropolymers and fluoroelastomers are persistent in the environment, and no evidence has been obtained to show that their degradation products cause environmental pollution. “Fluoropolymers and Fluoroelastomers” and “side-chain fluorinated polymers” which release toxic substances through hydrolysis, etc., should be risk assessed as a separate subgroup.

Fluoropolymers in medical devices used in medical institutions can be managed at the time of their disposal, therefore they are not discharged into the ocean through sewage or rivers, as is unlike the case with fluorinated polymers used in food wrapping paper and water repellents for clothing. The reason for regulating fluoropolymers is listed as "generation of microplastics" (Annex B.7.6), but the fluoropolymers used in medical devices are disposed of at waste disposal sites, and are therefore not released into the ocean and are not considered to be a major source of microplastics. In addition, although the persistence of fluoropolymers is described as a cause of microplastic pollution, research reports investigating the materials of microplastics show that the chemical composition are mainly polyethylene, polypropylene, polyethylene terephthalate, and polystyrene, and that fluoropolymers are not commonly found in microplastics. (Nature Reviews Materials volume 7, p138-152, 2022: Risk assessment of microplastic particles)

Fluoropolymers and Fluoroelastmers are of concern in the proposed restriction because of the environmental impact of the final degradation products. However, in the case of medical devices, environmental risks can be greatly reduced by proper disposal as industrial waste. For example, a report by K Aleksandrov et al. (Chemosphere, Vol 226, July 2019, P898) shows that PFAS are not formed when PTFE waste is incinerated and that fluorine can be recovered from PTFE. With the development of recovery, reuse, and chemical recycling technologies, it is considered that the coexistence of fluoropolymers and fluoroelastmers with humankind will be possible in the future.

The restriction proposal points out the issue of low molecular weight PFAS contained in fluoropolymers as a by-product or additive, which are released into the environment during the polymer production process and use. Strict regulation of additives and these low molecular weight PFAS will reduce the release of PFAS into the environment and promote their recovery and reuse. In addition, by regulating the amount of additives and other low molecular weight PFAS remaining in polymers, poor quality polymers can be removed from the market, eliminating the need to remove the fluoropolymers themselves. As a result, fluoropolymers will become more expensive, and their use in non-essential-use consumer applications will be

limited.

As described above, "Fluoropolymers" and "Fluoroelastmers" are substances of low concern with little evidence of hazardousness and do not meet the requirements for "unacceptable risk to human health or the environment" as restricted substances under Article 63. 'Fluoropolymers' combine biocompatibility, persistence (stability), chemical resistance, repellency from water and oil , low-friction, heat resistance, electric insulation, flame resistance, durability, etc., while 'fluoroelastomers' also combine high stability, chemical resistance and flexibility. Since these properties derive from the C-F bond, there are currently no equivalent alternative materials. These materials are therefore required as components and coating materials for a wide range of medical devices, such as endovascular treatment devices and radiological diagnostic equipment. We request that fluoropolymers and fluoroelastomers be excluded from the scope of the restriction proposal, at least for medical devices, because their disposal can be controlled and their risk to the environment is very low.

3. Exemptions for MDR 2017/745 and IVDR 2017/746 covered devices

3.1 Characteristics of medical devices

Like pharmaceuticals, medical devices are invariably used in the treatment and diagnosis of diseases and other medical procedures, supporting our lives. Medical devices are constantly evolving, incorporating the latest technologies and combining various techniques. This evolution has made it possible to diagnose previously undetectable diseases at an early stage and to cure diseases and injuries that could not be cured in the past. It has also contributed to improving people's quality of life by reducing the burden on patients.

Medical devices require not only clinical efficacy but also high safety and quality. To achieve them, PFAS is widely used in medical devices because of its biocompatibility, persistence (stability), chemical resistance, repellency from water and oil, low-friction, heat resistance, electric insulation, flame resistance, durability, flexibility and other characteristics. (Details of PFAS applications in medical devices are described later in Chapter 6.)

In addition, medical devices have the following characteristics

1) Clinical efficacy and safety
   - Third-party certification is required.
   - Sevier requirements for safety than consumer products are required and it takes long period to evaluate biocompatibility and long-term reliability.
   - It also needs to assess whether the design change will have any impact on clinical efficacy.

2) Long supply chain

   Time-consuming to identify PFAS-containing parts

3) High-mix low-volume production

Evaluation by substitution is necessary for each product type, and reliability evaluation is time-consuming. In addition, the low volume of parts purchased makes it difficult for parts suppliers to recover their investment, resulting in a low priority for alternative technology development and time-consuming development of alternative technologies.

4) Long product development cycle

Many products are used for long period while undergoing repairs

If the inclusion of PFAS is regulated for medical devices, it is easy to imagine the socioeconomic impact on the stable supply of existing medical devices and the development of medical devices using new technology, and the socioeconomic impact of European citizens being unable to receive the latest technology in medical care.

3.2 Term required for PFAS free

Based on the characteristics of medical devices described above, we will discuss the time period required to become PFAS-free for medical devices.

<Identification of parts containing PFAS>

Due to the extremely long supply chain of medical devices and the large number of parts, it is expected to take several years to identify parts containing PFAS. Since the proposed regulation would apply not only to the medical device sector but also to products in all sectors, it is easy to imagine that a very large number of survey requests would be concentrated on component suppliers and that it would take a very long time to obtain survey responses.

<Substitution of parts>

For example, in the case of medical electrical equipment, design engineers rarely specify PFAS as a material for parts. In most cases, they present the required specifications such as repellency from water, chemical resistance, flame resistance, and low-friction, etc., to the parts manufacturer, who then selects a material that meets the required specifications. Even if there are a variety of alternative candidates at the material level, each has different physical properties, so the parts manufacturer must develop an alternative technology that satisfies the part's required specifications. Reliability evaluation at the component level is also necessary.

Since the supply of parts for medical equipment is small, parts suppliers tend to give low priority to responding, and it takes time for parts suppliers to develop their own parts.

<Evaluation of alternative components in medical devices>

PFAS-free alternatives developed by parts manufacturers shall be evaluated for adoption in medical devices.

Parts in direct contact with the human body and wetted parts (*) are required to be evaluated

for biocompatibility and shall be evaluated based on the EN ISO 10993-1 series standard.
In the case of devices that invade the human body, material changes may require a clinical trial, which requires a study protocol, contract with physicians, approval by the ethics committee of the medical institution, informed consent from the person undergoing the trial, protection of personal information, implementation of the trial, analysis of data, etc., and evaluation over several years.
In the case of medical electrical equipment, if the changed component is an electrical safety critical component, the safety test must be redone.
Even for medical devices for which such evaluations are not required, it is necessary to verify that design changes to alternative components do not affect performance and safety, which requires a much longer evaluation period than for consumer products.

*Wetted parts:
Parts that (re)administered medicines, body fluids or other substances, including gases, to/from the body, or that transport or store such medicines, body fluids or other substances, including gases, to be (re)administered to the body

Using endoscopes as an example, the time required to become PFAS-free would be as follows, and we believe that the maximum grace period of 13.5 years in the proposed regulation would make the switch impossible.

Process	**Required term (approximately)**
Testing of alternative of materials / components	7 years If alternative technology does not be developed, the required term will be longer.
Reliability testing / Durability testing	2.5 years
Redesign of product for alternative solution	3 years
Product specific requirements: biocompatibility testing and evaluation including toxicological assessment and clinical trials	1 year
Product specific requirements such as clinical trials or notified body approval / Global approvals	1 year
Total	Over 14.5 years + α (more required depending on number of models)

3.3 Quantities of PFAS in Medical devices

The majority (more than 95%) of PFAS emissions in the medical device sector are "fluorinated gases emitted when MDI (Metered Dose Inhalers) are used". The impact of PFAS emissions from

medical devices, excluding fluorinated gases, is low, and their impact on the environment and human health is negligible.

Since the number of medical devices sold in the European market is small and the amount of PFAS used in medical devices is also small, except for fluorine gas, the absolute amount of PFAS released into the natural world is considered to be very small compared to devices in other sectors.

We believe that fluorinated gases should be regulated separately, such as in the F-gas regulations.

3.4 Waste Management

The MDR and IVDR, which are medical device regulations, contain provisions on disposal. Article 14.7 of MDR Annex I and Article 13.6 of IVDR Annex I require the safe disposal of medical devices. In addition, medical devices are required to be traceable under Article 25 of the MDR and Article 22 of the IVDR, so the risk of illegal dumping is extremely low.

Therefore, the impact of PFAS contained in medical devices on the natural environment is expected to be very small.

3.5 Our proposal

We ask that you consider excluding medical devices from the scope of this proposed regulation and adding them to the scope again at an appropriate time when other sectors have made some progress in becoming PFAS-free.

As mentioned above, simply changing the design of an existing product to a PFAS-free component would require a considerable number of years of evaluation, and if a sufficient grace period were not set, there would be a shortage of medical devices in the European region.

In addition, medical device manufacturers will be forced to concentrate human, financial, and other resources on design changes, which will affect the technological development of medical devices. The launch of medical devices with the latest technology in Europe will be delayed, resulting in lost opportunities for European citizens to receive the latest technological medical care.

Since the amount of PFAS used in medical equipment, excluding fluorinated gases, is small and disposal is properly managed, the need to regulate PFAS content in medical equipment in the same manner as in other sectors is extremely low.

As a result of such considerations at the time of the RoHS directive ~~regulation~~, the regulation for medical devices was applied eight years later than for general electrical and electronic products. Since the number of substances covered by this PFAS is an order of magnitude greater than the initial six substances of RoHS, a grace period of 13.5 years or more is considered

necessary.
Since regulating other sectors first will lead to a switch to PFAS-free in medical devices for general-purpose components even without regulating medical devices, it would be more socio-economically beneficial for medical devices to focus resources on new development and prioritize the introduction of medical devices with the latest technology. We believe that it is more beneficial from a social and economic perspective to focus resources on new development and prioritize the introduction of the latest technology in medical equipment.

The proposed regulation asks to weigh the clinical benefits and the environmental risks. Please listen to the opinion of healthcare professionals about that as well.

4. Spare parts exclusion request

Spare parts shall be excluded from the PFAS restrictions.

As the concept of "repair as produced" is widely recognized in the RoHS Directive, this concept should be applied to REACH as well**.** And the right to repair in the EU Green Deal is also an important environmental protection measure, the proposal regulation should not prevent this environmental protection measure.

5. Addition of "extension clauses

We propose that a provision shall be established to review grace periods after the regulations come into effect, and that these shall be appropriately reviewed in accordance with market trends.

If the proposed restrictions were to become law as is, it would cause significant disruption to supply chains around the world. Even for products for which alternative materials currently exist, the entire supply chain will need to be evaluated, and it is expected to take a considerable amount of time before this is realized. In addition, in areas where alternative materials have not yet been found, the development of such alternatives will have to proceed, and even a 12-year grace period may not be sufficient to complete the substitution process.
We believe that the provision for review of grace periods, which is also allowed under the RoHS directive, is necessary.

6. Request of exemptions or maximum grace periods for medical device applications for which additional information is provided

We will provide in September a second submission with data on identified uses of PFAS.