September 25, 2023

The general comment to the Restriction report on Per- and polyfluoroalkyl substances (PFAS)

We, JAIMA (The Japan Analytical Instruments Manufacturers' Association), would like to express the gratitude of having the opportunity of stating our opinion to the general comment to the Restriction report on Per- and polyfluoroalkyl substances (PFAS).
https://echa.europa.eu/restrictions-under-consideration/-/substance-rev/72301/term
EU Commissions, ECHA and the industries not only in the EU but also outside the EU have made a great effort to reduce the hazardous substances over 15 years. We also would like to express deep respect to the efforts.

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0 Introduction

0.1 Agree with the purpose of EU REACH Regulation

The REACH Regulation has been carrying out the great role of contributing to human health by reducing the exposure risk to hazardous substances. This Regulation with foresight has been expanding globally due to the advantages and benefits to the Society. We fully understand the importance of the REACH Regulation which shall be respected and has been contributed to the REACH through our technologies. We also have highlighted the contribution to the safety, human health, and the environment through electric and electronic equipment.

0.2 Reasons for Submission of comments

If the current proposed restrictions would be applied, we will not be able to put our products on the EU market.

As described in Sections 1.1 and 1.2, our products support the social infrastructure of

the EU and have a "critical" aspect that differs from general consumer products. Numerous alternative materials have been reported for PFASs that are being restricted, but unfortunately none are applicable for our product applications. As we have shown in some cases in section 1.2.2, if our products cannot be put on the EU market at all, it could have a significant negative impact on the environment and human health in the EU.

In order to continue to achieve the protection of the environment and human health that EU REACH aims to achieve, we would like to submit this opinion in the hope that the content of this opinion will be considered.

1 Products handled by this organization

1.1 What are our organization & Examples of products manufactured by its member companies

The Japan Analytical Instruments Manufacturers' Association (JAIMA) is a sole industry association of Analytical Instruments in Japan, which established under the Japanese law. JAIMA is to contribute to the development of the Japanese economy and the cultural lives of citizens in Japan through efforts to improve and advance technologies related to analytical instruments and the analytical instruments industry for the purpose of the advancement of science & technology.

Analytical instruments are classified by application, such as for:

- laboratory (GC, LC, MS, IR, IC, Thermal, UV, XRF, XRD, SEM, TEM, NMR, PSA, pH…)
- the environment (Air and water pollution monitoring)
- process and on-site measurement
- maintenance and working environment
- medical examination devices (Clinical chemistry, immunology and hematology, In-Vitro diagnostics devices)
- automation-related devices
- information processing systems
- bio-related analytical instruments

etc.

1.2 Features of our products

1.2.1 Our products are "Specialist equipment" and their disposals are well controlled

As described in Section 1.1, our products are highly specialized equipment used in laboratories, specialized institutions, industrial sites, and medical sites. Therefore, the user must undergo special training and education in order to use it safely and correctly. In this opinion we will refer to our product as "EEE specialist equipment" to distinguish it from general consumer products.
In addition, when our products are discarded, they are basically collected by the manufacturer or by a specialized disposal company, so proper disposal is possible. Products subject to the EU WEEE Directive are collected according to the scheme of the WEEE Directive. This means our product waste is easier to control and the risk of PFAS being released into the environment is lower than in other product sectors.

1.2.2 Critical for social infrastructure

We would like to emphasize strongly that EEE specialist equipment we manufacture plays a very important role in the social infrastructure. Below are some examples. We believe that you can understand that the nature is different from the product of "nice to have".

<Case-1: Substance detectors>
Substance detectors enable the identification, measurement and analysis of chemical substances.
If the equipment disappears, it will be impossible to enforce chemical substance regulations. In addition, the monitoring and control of environmental pollution will become impossible, and the environmental pollution will progress. Furthermore, manufacturers and research institutes will not be able to conduct R&D, and innovation will come to a halt.

<Case-2: Gas detectors>
Gas detectors enable the detection and alerting of gas leaks.
If the equipment disappears, the safety in all facilities such as homes and factories will be reduced.

<Case-3: In-vitro diagnostic devices>
In-vitro diagnostic devices enable disease diagnosis and prognostic observation after treatment.
If the equipment disappears, the quality of medical care that can be provided will

be significantly decreased.

1.2.3 Low volume of production, long-life, long supply chain

The EEE specialist equipment is made in small numbers, is produced for long periods without modification or changes, and is a long-life product. The equipment would have been replaced typically after 7-10 years or more from the release of the products.[1] The supply chains are very long and take time to eliminate restricted substances from the supply chain.

Characteristic	Test equipment	Mobile phone
Typical numbers sold	350	5.5 million
% of pre- 2003 products on market in 2006	>80%	<1%
Number of current distinct models per manufacturer	1600	300
Number of engineers available for each product	1.9	61.6
Time between launch of one product and its replacement	7 years on average	~ 6 months
Custom made parts	~25%	<5%
Time required for reliability testing (average per model)	4.3	0.7
Authorisations	Up to 2 years	< 6 months

Data from the Test and Measurement Coalition.

Table 1 Table comparison of industrial test equipment with mobile phones[2]

Table 5-4 Amount of EEE (tons) put on the EU market, per year and product category, "Support for the Evaluation of Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment Final Report" shows the percentage of category 8 and 9 products is only 3.5 of all amounts of electric and electronic equipment (EEE) (tons) put on the EU market (see the below).[3]

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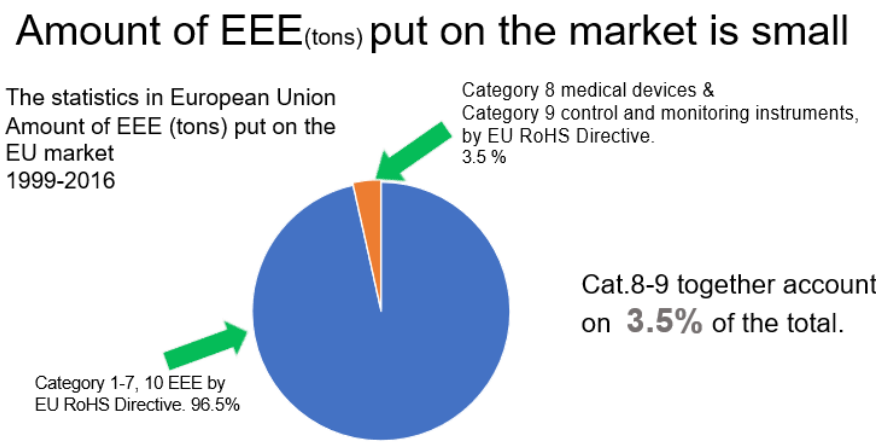
[1] Dr Paul Goodman, Review of Directive 2002/95/EC (RoHS) Categories 8 and 9 – Final Report, ERA Technology, 2006 Page 27-34

https://ec.europa.eu/environment/pdf/waste/weee/era_study_final_report.pdf

[2] Dr Paul Goodman, Review of Directive 2002/95/EC (RoHS) Categories 8 and 9 – Final Report, ERA Technology, 2006 Page 34 Table 2
https://ec.europa.eu/environment/pdf/waste/weee/era_study_final_report.pdf

[3] Table 5-4 Amount of EEE (tons) put on the EU market, per year and product category, Support for the Evaluation of Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment Final Report, p.147
https://op.europa.eu/en/publication-detail/-/publication/5b807311-9d93-11eb-b85c-01aa75ed71a1/language-en



The picture is produced from Table 5-4 Amount of EEE (tons) put on the EU market, per year and product category, Support for the Evaluation of Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment Final Report, p.147 https://op.europa.eu/en/publication-detail/-/publication/5b807311-9d93-11eb-b85c-01aa75ed71a1/language-en

1.2.4 Spare (Repair) parts are necessary

Spare parts are necessary to guarantee the expected lifetime (more than 20 years in the longest case) of EEE specialist equipment. Especially since EEE specialist equipment requires high performance and high reliability, we would like to emphasize that the same spare parts are required throughout the life of the product as when it was first evaluated. Without spare parts, waste minimization according to the principles of "Right to repair" and "Repair as produced" cannot be achieved.

1.2.5 Long development cycle

Our products are required to be highly reliable because they are manufactured for a long period of time without modification. Along with this, long-term reliability tests are required. If there is a certification request, a longer period is required to obtain it.

As a result, development cycles are longer compared to other consumer products.

An example of development process is below:

- Searching of parts and materials: 1-2 years
- Reliability test: performance test of the product: 1-2 years
- Device design: 0.5-1 year

- Develop the production line /buy new production equipment: 1-2 years
- Create Technical Documentation: 0.5 year
- 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 or customer approvals

1.3 Current status of PFAS applications and alternative technologies

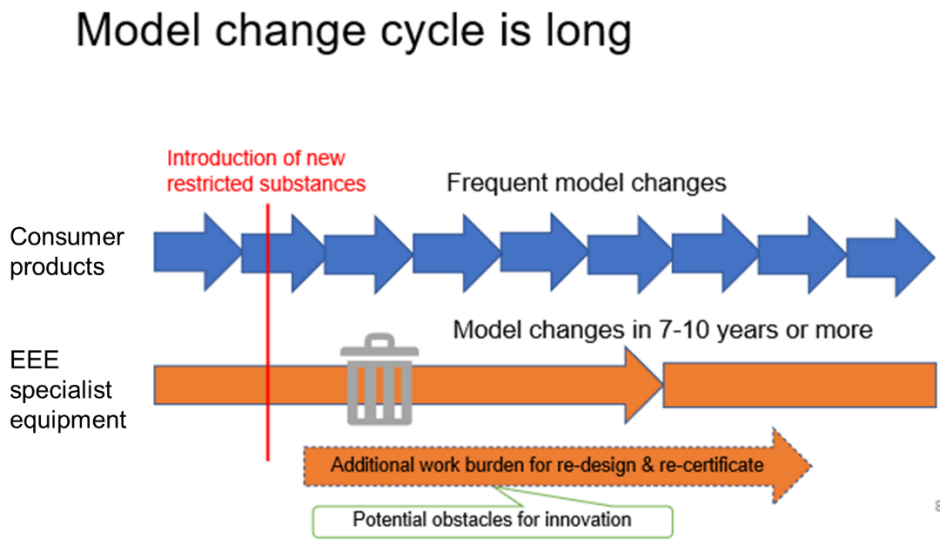
Please see the Appendix 1 & 2.

2 Suggestions and requests from us

2.1 The long grace period and extension are required

If the alternatives are become available in the future, a long grace period is required until PFAS become restricted

As described in 1.2.4 and 1.2.5, the equipment is made in small numbers, is produced for long periods without modification or changes, has to be reliable and need long term test for reliability.



The equipment would have been replaced typically after 7-10 years or more from the release of the products.[4] The supply chains are very long and take time to eliminated restricted substances from the supply chain.

[4] Dr Paul Goodman, *Review of Directive 2002/95/EC (RoHS) Categories 8 and 9 – Final Report*, ERA Technology, 2006 Page 27-34
https://ec.europa.eu/environment/pdf/waste/weee/era_study_final_report.pdf

If the electric and electronic equipment mentioned above cannot use PFAS anymore and PFASs are to be substituted, the long grace period is required in order to test the product to comply with the safety requirements defined with IEC and other safety standards, and obtain the re-certificates according to the requirements.

An example of substitution process is below:

- Testing of alternative materials: 1-2 years
- Reliability test: performance test of the product: 1-2 years
- Device design change: 0.5-1 year
- Change the production line /buy new production equipment: 1-2 years
- Create Technical Documentation: 0.5 year
- 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 or customer approvals

As mentioned above ("An example of substitution process"), even if an alternative is found, the replacement takes a long time. EEE specialist equipment therefore needs a longer transition period.
If " Testing of alternative materials: 1-2 years " and " Reliability test: performance test of the product: 1-2 years " prove unusable to EEE specialist equipment, the process starts over. Then, it is not possible to predict when the replacement will be completed. It is necessary to check the status of alternative materials at regular intervals and extend the transition period if no alternative materials have been found.
Our equipment also uses general electronic circuit components (see application information in Japan 4EE Opinion RCOM 21, No. 4543). In other words, it may use common parts with general consumer EEE. In this case, even if a replacement part for general consumer EEE is found, it may not be applicable as a replacement part for EEE specialist equipment. As mentioned above, performance and reliability requirements are high for EEE specialist equipment, so even if you try to apply replacement parts for general consumer EEE to EEE specialist equipment, there is a possibility that they will not pass various tests. In that case, too, the extension of the transition period is necessary.

2.2 The derogation of spare (repair) parts are required

The exclusion of the spare (repair) parts which are used for EEE Specialist Equipment

placing on the EU market before the entry into force is required.
As explained in the 1.2.4, EEE specialist equipment requires the same spare parts for the life of the product as when first evaluated. If spare parts were not derogated and its equipment had already been in EU market, to repair that equipment after entry into force, only spare parts will become to be design changed. These changes to spare parts can affect to some conformance of related directives and regulations for its EEE. It means the re-evaluation is necessary. The evaluation process is equivalent with that of new products.
It would be against the EU green objectives, as expressed in the EU Circular Economy Action Plan, to prematurely end the service life. It is not feasible and is not efficient. Therefore, the derogation for spare(repair) parts are allowed with EU RoHS Directive. It is also related to "Right to repair" and "Repair as produced" principles. We hope the derogation for spare(repair) parts in REACH Regulation would be set.

2.3 Reasonable implementation of Reporting Requirement for EEE Specialist Equipment in case of exempted

Although reporting requirements have been proposed for PFASs used in exempt applications, it is recommended that existing mechanisms be used as several similar reporting requirements have already been implemented in other regulations. It also reduces the administrative burden.

For example, gases within the PFAS group are subject to the F-gas Regulation, which already has reporting requirements.
(https://climate.ec.europa.eu/eu-action/fluorinated-greenhouse-gases/f-gas-portal-hfc-licensing-system-quota-allocation-authorisation-and-reporting_en)

PFASs are widely used in EEE Specialist equipment. Information on SVHCs in articles are collected in order to meet the obligation of Article 33 of REACH regulation. Information on the uses of chemical substances which are classified with CLP regulation is also collected for chemical products and products which are subject to MDR, in order to meet the obligation of communication on hazardous substances.

The following describes the current status of information transmission through the supply chain regarding PFASs.
Not all PFASs are designated as SVHC or classified under the CLP regulations. Therefore, we have not obtained the information on use of PFASs. The minimum

threshold specified in the Regulations is 0.1%. We cannot obtain the information on uses as the units of ppb as proposed. Our supply chains are very long and take time to obtain the information on the uses from the supply chain.

As mentioned above, it is very difficult to obtain information on all PFASs.
However, regarding SVHC and CLP classified substances that have been recognized as hazardous or toxic, the information can be collected through the existing communication flow, so this is the most feasible method.

PFASs that are found to be harmful or toxic will automatically follow the above information transfer flow and will be transferred to the EU regulatory authorities.

2.4 Reference Materials should be excluded from the scope

As proposed in this consultation, reference materials should be excluded from the scope.
Reference materials and substances used in scientific research and development are necessary for the analysis of PFAS. Without these, precise analysis is not possible. Therefore, reference materials for its analysis should be excluded from the scope.