



September 14, 2023

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

We, Japan Inspection Instruments Manufacturers' Association (JIMA) 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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1 Introduction

1.1 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.

1.2 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 2.1 and 2.2, 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 2.2.2, if our products cannot be put on the EU market at all, it could have a significant negative impact on the environment, safety and people's life 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.

2 Summary

Our suggestions and requests are the following three items.

- 1) We would like to have a transition period of about 10 years for "EEE Specialist equipment".
- 2) 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.
- 3) It is recommended that existing mechanisms be used to respond to exemption reporting requests.

3 Products handled by this organization

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

Japan Inspection Instruments Manufacturers' Association (JIMA) is a corporation aggregate of manufactures and sellers for non-destructive inspection instruments and systems. Our inspection Instruments are used in two fields: (1) quality testing in the field of manufacturing, and (2) safety testing in the field of maintenance. We categorize our products in the table below.

1	Eddy current Testing Instruments (ET)
2	Magnetic Particle Testing Instruments (MT/PT)
3	Radiographic Testing Instruments (RT)
4	Ultrasonic Testing Instruments (UT)

3.2 Features of our products

3.2.1 Our products are "Specialist equipment"

As described in Section 2.1, our products are highly specialized instruments used in specialized institutions, chemical plants, factories, and transportation. 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.

3.2.2 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: Eddy current Testing Instruments >

Eddy current testing instruments use electromagnetic field such as an eddy current and a leakage magnetic flux to enable non-contact high-speed inspection. And they can test conductive materials, and are used for flaw detection of wires, bars, tubes and plates in the manufacturing process, and identification tests of different materials. Concerning maintenance test, they are used for testing nuclear power facilities, aircraft, plants and etc. Metal detectors used at airports and unexploded bomb/mine detectors used for post-war security also fall under this category. If these instruments disappear, there will be an increase in accidents due to deterioration in the quality of products and facilities, or a direct negative impact on human safety, such as security and handling of hazardous materials.

<Case-2: Radiographic Testing Instruments >

Radiographic testing equipment are testing equipment that use various characteristics of X-ray or γ-ray. They include X-ray film photographic equipment using the photographic effect, analyzers using the diffraction phenomenon and fluorescent X-ray, radiographic thickness measuring equipment using the transmitting/absorbing effect, and TV fluoroscopic equipment and CT equipment combining a radiation detector and an image processor using the fluorescent effect and the ionization effect. These equipment are used for measuring the thickness of steel in the rolling process, testing internal structures of parts or testing their defects, testing internal structures of semiconductors, testing

soldered regions of printed boards, testing foreign material contained in foods, etc. If these instruments disappear, failures and accidents in industrial products and health hazards due to food foreign matter are assumed.

3.2.3 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 instruments 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 phones²

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 amount of electric and electronic equipment (EEE) (tons) put on the EU market (see the below).³

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

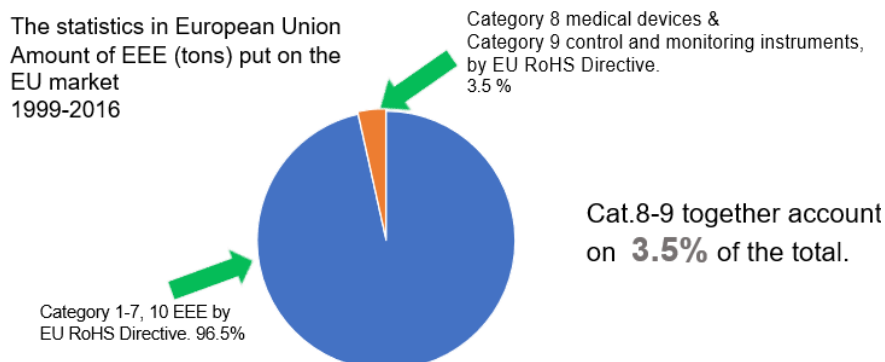
² Dr Paul Goodman, *Review of Directive 2002/95/EC (RoHS) Categories 8 and 9 – Final Report*, ERA Technology, 2006 Page 34 Table 2

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>

Amount of EEE_(tons) put on the market is small



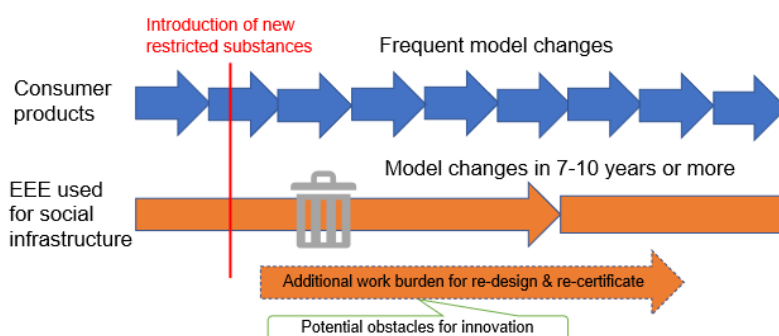
The picture is produced from Table 5-4 Amount of EEE (tons) put on the EU market, per year and product category, Support for the Evaluation of Directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment Final Report, p.147 <https://op.europa.eu/en/publication-detail/-/publication/5b807311-9d93-11eb-b8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

3.2.4 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.

Model change cycle is long



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 typical example would be a 10-year process.

3.2.5 Spare (Repair) parts are necessary

Spare parts are necessary to guarantee the expected lifetime (more than 20 years) 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.

3.3 Current status of PFAS applications and alternative technologies See "Appendix Uses and substitutions of Specialist Equipment"

4 Suggestions and requests from us

4.1 The long grace period and extension are required

Even if the alternatives are become available in the future, a long grace period is required until PFAS become restricted as described in 2.2.3, 2.2.4.

If the electric and electronic equipment mentioned above cannot use PFAS anymore and PFASs are to be substituted, we request that a transition period of about 10 years be established based on the typical development process described in 2.2.4.

We will explain in the supplement. 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 COM Part 21, No. 4543, and comments to be submitted). 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

4.2 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.

4.3 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. SVHCs in articles are collected in order to meet the obligation of Article 33 of REACH regulation, and registration in the SCIP database according to the Waste Framework Directive. 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.

4.4 Reference Materials should be excluded from the scope

As proposed in this consultation, reference materials should be excluded from the scope.

Foreign objects standards for food inspection equipment contain fluororesin. If the use of fluororesin for foreign objects standards is prohibited, it will interfere with the inspection of fluororesin contamination in food. Therefore, reference materials for its inspection should be excluded from the scope.

The general comment to the Restriction report on PFAS as of September 14, 2023
Japan Inspection Instruments Manufacturers' Association (JIMA)