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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 our organization

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

Japan Electric Measuring Instruments Manufacturers' Association (JEMIMA) is Japanese industries' association for □electric measuring instruments and control instruments□ which are the fundamental tools for research, development, design and manufacturing in lots of area of industry. JEMIMA handles 8 categories of products in Table 1-1.

Table 1-1 Product categories of JEMIMA's member companies

Indicating Instruments	Instruments to indicate or record electrical quantities including electricity, voltage, electric power, power factors, and frequency, and other related apparatus
Electricity Meters	Instruments to measure the demand and supply of electric power and other related equipments
Electric Test and Measuring Equipment	Equipment to measure, observe, or record electrical and magnetic quantities by electronic means, and Equipment and Apparatus to generate electric and magnetic signals
Test and Measuring Instruments using Electronic Technology	Equipment and apparatus to detect, measure, indicate, or record physical, chemical, sensory, and other quantities other than electric and magnetic quantities: Excluded are equipments and apparatus for measurement and control in factory automation and process automation, environmental measurement, and radiation measurement. Also excluded are equipments and apparatus that measure mainly by mechanical means, even when their indicators or displays are electronic.
Measuring and Control Instruments for Factory Automation - FA-	Equipment and systems to identify and measure the status of objects in industrial processes such as machining & assembly industries, mainly handling solids and powder / granular materials, and other equipments and apparatus related to them, including general-purpose equipments converted into measurement and control equipments for factory automation application.
Process Measuring and Control Instruments	Equipment and systems to continuously measure and control variables of industrial processes that mainly handle fluids, gases, and vapor and related components & parts
Instruments for Environmental Monitoring	Measuring instruments to measure pollution of the natural environment and changes in natural phenomena, and other related equipments & apparatus
Radiation Measuring Instruments	Measuring instruments to measure quality and quantity of radiation [x, γ , β , α rays, neutrons and others], measuring instruments that utilize radiation, and other related equipment apparatus

The products of JEMIMA's member companies are instruments which measure, for example, temperature, pressure, voltage, electric current, weight, flow rate and so on, and display them, record them. Automatic control instruments and devices for the factory or the chemical plant using these measured values are also in the product

category. Furthermore, measuring instruments of environmental pollution and radiation and radiation related equipment are included.

Without products in JEMIMA's member companies, almost all the factories and plants cannot continue their operation. Although it is more familiar, both water supply and electricity supply to the citizen would be impossible. Innovation of the technologies would be impossible without measuring instruments which are JEMIMA's products. Without instruments for environmental monitoring, we cannot measure the environmental conditions and it is impossible to maintain and improve it. Radiation measurement is utilized for non-destructive testing, food inspection and medical care and it is very important for safety of the plant / factory, many products and food and citizen's healthcare. Our products also play a role in preventing and detecting leakages of chemical substances, and protect human health and the environment from chemical dangers. Because these products have high reliability and long life, long-term stable environmental protection has been realized. However, there is a concern that the long-term and stable environmental protection system that has been realized will collapse due to the deterioration of reliability and product life. As described above, the products of JEMIMA's member companies are essential for supporting society and environment and healthcare and different from the product of "nice to have" completely in the importance.

1.2. Features of our products

1.2.1 Our products are □Specialist equipment□

As described in Section 1.1, our products are highly specialized instruments used in laboratories, specialized institutions, and industrial 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.

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: Measuring and Control Instruments for Factory and Process Automation
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Measuring and Control Instruments for Factory and Process Automation are a

product group for automating the operation of facilities and equipment in factories and infrastructure.

These products are indispensable for the production of all kinds of products that support people's lives and the economy, from raw materials industries such as petroleum and petrochemical products, iron and steel, and paper, to processing and assembling industries such as automobiles, electrical and electronic equipment, to food manufacturing industries such as beverages, and to pharmaceutical and medical equipment manufacturing industries.

It is also widely used as an important facility for the safe and uninterrupted supply of infrastructure such as electricity, gas, water and sewage.

In today's factories and infrastructure, these devices enable efficient and environmentally friendly facility operations and risk management measures, and provide safe and stable living environments for people.

However, parts containing PFAS are used in many Measuring and Control Instruments for Factory and Process Automation.

With the exception of electronic components, these devices have many parts that come into contact with products such as gas, water, and petroleum products and materials necessary for their production (including harmful chemical substances). They are used in a variety of environments, and therefore require high performance, such as, heat resistance, weatherability, chemical resistance, repellency from water and oils, electric insulation, and low friction.

PFAS is the only chemical substance that satisfies all of these requirements, and it is an indispensable material for long-term stable operation of factories and infrastructure.

If the use of PFAS is prohibited, Measuring and Control Instruments for Factory and Process Automation cannot be used within the EU, and infrastructure and economically important products will not be supplied.

This will have a major impact on society and the economy.

<Case-2: Environmental Measuring Instruments>

Maintaining the environment, including the air, water and soil, is very important for our survival and must be sustained for the future of EU.

Environmental measuring instruments can be used to measure air, water and soil quality and check the status of various types of pollution. Vibration and noise are also measured. They are important tools for maintaining the environment.

Like measuring and control instruments for factory and process automation, many

of these products, as well as many other environmental measuring instruments, use parts and other components containing PFAS. High performance is required in terms of heat resistance, weatherability, chemical resistance, repellency from water and oil, electrical insulation and low friction.

PFASs are the only chemical that has the performance to satisfy all of these requirements, and are essential materials for proper environmental measurements. If the uses of PFASs are banned, environmental measuring instruments will no longer be available. If environmental measurement instruments, which play an important role in maintaining a safe, healthy and comfortable environment, are no longer available, EU citizens will lose the tools to maintain the environment. This could be against goals of sustainable development.

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 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

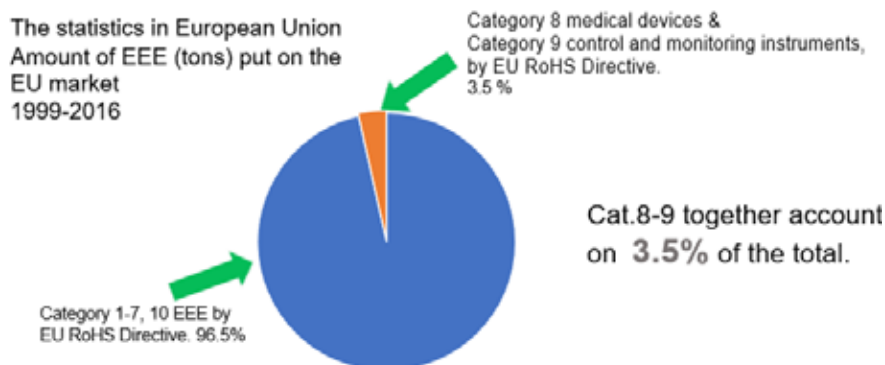
¹ Dr Paul Goodman, *Review of Directive 2002/95/EC (RoHS) Categories 8 and 9 – Final Report*, ERA Technology, 2006 Page 27-34

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

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

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>

1.2.4 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.

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

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>

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 Appendix 1 “Uses and substitutions of Specialist Equipment (Appendix 1-1/2 Functions of PFAS, the uses and substitutions_JEMIMA.pdf)” for explanation on functions of PFASs, uses of specialist equipment, and alternative materials. Please see Appendix 2 “List of JEMIMA products and uses of PFASs (Appendix 2 The list of JEMIMA products which contain PFAS.pdf)”

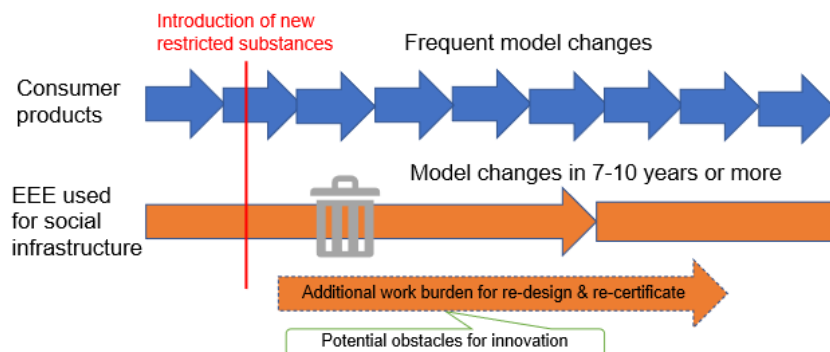
2 Suggestions and requests from us

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

The instruments are made in small numbers, are produced for long periods without modification or changes, and have to be reliable and need long term test for reliability.

Model change cycle is long



The instruments 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 eliminate restricted substances from the supply chain.

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, 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

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

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. 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.

About JEMIMA

Japan Electric Measuring Instruments Manufacturers' Association (JEMIMA) is the only one association representing this industry in Japan. Electric measuring instruments support all kinds of manufacturing industries as so-called "Mother tools" that support innovative activities for research, development, design and

manufacturing.

JEMIMA has active committees that collect technical and market information of electric measuring instruments, and provide member companies with useful information for their businesses. Regarding regulations such as environmental, safety and EMC (Electro-Magnetic Compatibility) issues, JEMIMA has been investigating details and providing proposals to legislative organizations summarizing requirements from the industry in cooperation with international related organizations.

Through these activities, JEMIMA will continue to contribute to the steady growth of electric measuring instruments and related industries in Japan.
