Japan 4EE Comments on Annex XV restriction report on PFAS (Part 2)

22 September, 2023

Name of the associations which make this input:

The Japanese electric and electronic (E&E) industrial associations:

JEITA (Japan Electronics and Information Technology Industries Association)

CIAJ (Communications and Information Network Association of Japan)

JBMIA (Japan Business Machine and Information System Industries Association)

JEMA (Japan Electrical Manufacturers' Association)

With the endorsement of the following Medical and Monitoring & Control Equipment Industrial Associations:

JAIMA (The Japan Analytical Instruments Manufacturers' Association),

JEMIMA (Japan Electric Measuring Instruments Manufacturers' Association),

JFMDA (The Japan Federation of Medical Devices Associations),

JIMA (Japan Inspection Instruments Manufacturers' Association),

JMIF (Japan Measuring Instruments Federation),

NECA (NIPPON ELECTRIC CONTROL EQUIPMENT INDUSTRIES ASSOCIATION),

SEAJ (Semiconductor Equipment Association of Japan) and

IGMA (Industrial Gas Detectors and Monitors Manufacturers Association).

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Substance name: Per- and polyfluoroalkyl substances (PFASs)

We, Japanese four electric and electronic equipment (hereinafter JP4EE) industry, have been vigorously committed complying with chemical regulations set by many countries. We have consistently supported the ambitious attempt of EU to reduce the risk caused from the hazardous substances and sincerely and diligently taken actual measures to meet the requirements under the EU chemical regulations such as REACH. We are aware that ECHA launches a public consultation on a proposed restriction of Per- and polyfluoroalkyl substances (PFASs), its salts and related substances, 22 March 2023 and submitted our first input in 13 June 2023 (listed as No. 4543 in "rest_pfas_rcom_part21_36501_en"). This is our additional input on this matter.

The electrical and electronic equipment (EEE) are manufactured via supply-chain extending over the world, and chemical legislations in the EU, one of the big markets in the world, would have big influence over the world. Under such situation, we believe it essential that proposed requirements would not hamper the smooth international circulation of the products including EEE and would be implementable as a law reasonably.

From the point of view above, we would be very happy if you consider the following opinions carefully.

List of our comments and input:

1. **The restriction should be considered based on the risk evaluation. Especially, it would be appropriate for ECHA to reconsider the proposed restriction for fluoropolymers, if ECHA cannot provide scientific justification for such measures.**

2. **The possible risk caused from the articles should be properly considered, and convincing justification should be provided to show why the uniform restriction of PFAS in the articles is the most appropriate Union-wide measure to address the identified risks.**

3. **The regulation for the substances which are currently and widely used in the global supply-chain should be gradually introduced.**

4. **About the appropriate thresholds and denominator for the articles: The management at the level of 1,000 ppm in the article would be practical and feasible.**

5. **Necessity of sufficient time until the enforcement of the restriction. In the case of restricting substances contained in articles according to the REACH, we would like the Dossier Submitter to set sufficient time until the enforcement of the restriction. For the very small amount of PFAS in complicated EEE, it would take 48 months only to complete the investigation of containment.**

6. **Explanation of Difficulties in Obtaining Information on Chemical Substances Contained in EEE.**

7. **The period and the way of setting and maintaining a "derogation" should be further considered and established.**

8. **Necessary PFAS derogations in EEE.** (Relating to Questionnaire 6 to 8).

   Please refer to the following Annexes to our input:

   - **JP4EE Annex 3 rev List A of PFAS essential uses in EEE**: Updated Essential Application list A: Explanation starting from PFAS as chemical materials.
   - **JP4EE Annex 4 rev List B of EEE Functions needing PFAS**: Slightly-updated Essential Application list B: List of the functions and properties necessary to electrical and electronic equipment (EEE), which need PFAS materials to attain required performances.
   - **JP4EE Annex 6 Explanation on EEE Functions in Annex 4 (List B)** : Supplementary Explanation on the functions of EEE needing PFAS shown in our List B of EEE Functions needing PFAS.
   - **Annex 5. Supplementary Explanation in Relation to Japan 4EEIA Input on PFAS Dossier**. (Attached to our 1st input)

   In addition, following Annexes should be referred to, these cover also following Comment 8.

- **Annex 2. The unfeasibility of "possible substitutes" in the dossier in the actual EEE.** (Attached to our 1st input)
- **JP4EE Annex 9 Unfeasibility of other "possible substitutes" in actual EEE**

9. **Necessary PFAS derogations in manufacturing processes of EEE and its parts.** (Relating to Questionnaire 8).

   Please refer to the following Annexes to our input:

   - **JP4EE Annex 7 List C of PFAS essential uses in EEE manufacturing:** Non-Exhaustive PFAS Essential Application list C: Explanation of applications in the manufacturing process of electrical and electronic equipment and its components.
   - **JP4EE Annex 8 Explanation on PFAS essential uses in EEE manufacturing in Annex 7 (List C):** Supplementary Explanation on the manufacturing processes of EEE and its parts which need PFAS and listed in our Essential Application list C (Annex 7).

10. **A derogation for articles already placed on the market before implementing the restriction should be provided** like other restrictions covering articles under Annex XVII to REACH**.**

11. **A General exemption of spare parts without expiry date would be indispensable for complicated articles to extend their useful life, if their original products are placed on EU market before the requirement comes into force.**

12. **About the reporting requirements on each PFAS content : The articles should be excluded from the scope of reporting.**

13. **Preceding evaluations should be respected, especially for RAC/SEAC Opinion on PFHxA.**

About the following comments in our 1st input (listed as No. 4543 in "rest pfas rcom part21 36501 en"), we don't resubmit them here because they do not include any items to be updated. However, the issues are still to be solved, and please refer to them as necessary:

1-9. Possible negative impact to the occupational safety in production process from the restriction of PFAS

1-10. There are no analytical methods for complex articles at ppb order.

(Please see our 1st input to Question 10 in the questionnaire (Ref. No. 4543 in "rest pfas rcom part21 36501 en".)

List of Annexes to Japan 4EE's Input on Annex XV restriction report on PFAS:

For 2nd input from JP4EE, following annexes are submitted:

- **New! JP4EE Annex_1-2_Japan 4EE Comments on restriction dossier on PFAS Part 2** (This paper)
- **Updated: JP4EE Annex 3 rev List A of PFAS essential uses in EEE:** Updated Essential Application list A: Explanation starting from PFAS as chemical materials. (Updated cells are shown in yellow.) **EEE inevitably needs derogations for the essential applications listed in Column E of this list A from the proposed PFAS restriction.**
- **Updated: JP4EE Annex 4 rev List B of EEE Functions needing PFAS:** Slightly-updated Essential Application list B: List of the functions and properties necessary to electrical and electronic equipment (EEE), which need PFAS materials to attain required performances.
- **New! JP4EE Annex 6 Explanation on EEE Functions in Annex 4 (List B) :** Supplementary Explanation on the functions of EEE needing PFAS shown in our List B of EEE Functions needing PFAS (Annex 4)
- **New! JP4EE Annex 7 List C of PFAS essential uses in EEE manufacturing:** Non-Exhaustive PFAS Essential Application list C: Explanation of applications in the manufacturing process of electrical and electronic equipment and its components. **EEE and its parts manufacturing inevitably needs derogations for the processes listed in Column C for the Intended uses in Column D of this list C.**
- **New! JP4EE Annex 8 Explanation on PFAS essential uses in EEE manufacturing in Annex 7 (List C):** Supplementary Explanation on the manufacturing processes of EEE and its parts which need PFAS and listed in our Essential Application list C (Annex 7)
- **New! JP4EE Annex 9 Unfeasibility of other "possible substitutes" in actual EEE. :** The unfeasibility of "possible substitutes" in "A guide to PFAS in electronics" in the actual EEE.

  Note: The applications of PFAS in EEE have not been investigated in the dossier. As long as we know, the most collective available information on this matter would be *"A guide to PFAS in electronics"* by ChemSEC, and we suppose that ECHA may refer to it. However, from the point-of-view from the actual manufacturers of EEE, the listed "possible substitutes" seem to be (still) unfeasible to attain the EEE performances needed in current IT society. Therefore, we prepare this Annex for the legislators' reference.

  ChemSEC: "A guide to PFAS in electronics" :
  https://chemsec.org/reports/check-your-tech-a-guide-to-pfas-in-electronics/

Following Annexes were attached to the 1st input from Japan 4EEA (listed as No. 4543 in "rest_pfas_rcom_part21_36501_en")**.** We don't resubmit them here because they do not include any items to be updated, but the contents are still effective. Please refer to them as necessary:

- **Annex 1 Japan 4EE Comments on draft Annex XV restriction report on PFAS dated in 13 June 2023.**
- **Annex 2. The unfeasibility of "possible substitutes" in the dossier in the actual EEE.** (We attached it as 2nd sheet of Annex 9 for your convenience.)
- **Annex 5. Supplementary Explanation in Relation to Japan 4EEIA Input on PFAS Dossier.**

1. **The restriction should be considered based on the risk evaluation of the substance. Especially, it would be appropriate for ECHA to reconsider the proposed restriction for fluoropolymers, if ECHA cannot provide scientific justification for such measures.**

We have consistently supported the ambitious attempt of EU to reduce the risk caused from the hazardous substances and sincerely and diligently taken actual measures to meet the requirements. However, it is unfeasible to legislate the PFAS restrictions in this dossier as they stand, and we are deeply concerned that, if enforced, they will not only hollow out EU industry, but also make existing infrastructure unsustainable.

(1) About the risk assessment of the substances themselves.

PFAS are a huge group of substances that include many different substances with varying levels of risk. However, we believe that a blanket restriction on all PFAS may lack a risk-benefit balance and is not scientifically or socio-economically sound. As PFAS are not even SVHCs, it is impossible to provide accurate information on their use in articles within the input deadlines for dossiers, so we have to guess based on speculation. (See 6 below for Explanation of Difficulties in Obtaining Information on Chemical Substances Contained in EEE.) Risk assessments based on such guesses may lack credibility.

Despite the fact that the risks have not been identified, electronics applications are subject to restrictions with little scrutiny, and even derogation is rarely proposed. Although the socio-economic impact of implementing such restrictions will be considered by SEAC in the future, it appears that the socio-economic impact of such restrictions has not been considered in the preparation of the dossier.

ECHA's recently published “Assessment of regulatory needs” does not make recommendations on blanket restriction of all substances in the assessed substance groups. Typically, recommendations are made for some substances within a substance group, such as "it is appropriate to consider restrictions after CLP assessment". In light of such trends in ECHA's “Assessment of regulatory needs”, the content of the proposal in this PFAS dossier appears to lack proportionality.

Highly hazardous PFAS such as PFOS and PFOA are already restricted under REACH. If other PFAS for which a hazard classification has not yet been identified are to be restricted, a proper risk assessment should be conducted and the regulation should focus on applications with high exposure potential and well-established alternative technologies.

Specifically, the Japan Fluoropolymers Industry Association (JFIA), an upstream chemical manufacturer, states the following about the risks associated with fluoropolymers (See Ref. No.5841 in "rest_pfas_rcom_part24_36500_en".).

Fluoropolymers are thermally, chemically, photochemically, hydrolytically, oxidatively and biologically stable, barely soluble in water, immobile, insoluble (Water, Octanol, etc.) and too large

to migrate to cell membranes. Therefore, they are not incorporated into the body and are considered low concern from a human and environmental health perspective.

We also believe that this point is reasonable. We believe that there is no justification in the dossier for restricting such a substance group. If ECHA cannot provide more reasonable justification, it would be appropriate for ECHA to reconsider the proposed measures for fluoropolymers.

(2) About the assessment of the risk caused by the substances in the articles.

During the use of articles like EEE, it is presumed that an exposure amount of PFAS is generally negligibly low compared with the exposure of the PFAS as chemicals own[*1, *2]. For example, the U.S. Agency for Toxic Substances and Disease Registry (ATSDR) concluded that the route of human and environmental exposure to PFAS is mostly through ingestion of drinking water or food, and negligible exposure through consumer products. In articles, PFASs are firmly integrated into polymer matrix in most cases and are contained in very small amounts. Furthermore, due to an extremely low vapor pressure (about 10-4 Pa), PFASs are not emitted into the environment. Even if a very limited amount would be emitted or eluted from articles, it is not considered to be a level that affects humans or the environment.

It is also presumed that environment impact of PFAS from EEE (i.e. articles) is extremely low since certain EEE distributed to general consumers are properly managed in accordance with EU WEEE 2012/19/EU[1].

The blanket restriction on PFAS will affect many industries. We hope that you will consider our recommendations and information in the following sections and make a scientific and technical decision about the need for and feasibility of regulation.

References:

*1: According to the U.S. ADSTR research, PFAS exposure routes to human and environment are mainly oral ingestion from PFAS-containing foods, food packaging and/or drinking water, exposure from consumer products is low.
https://www.atsdr.cdc.gov/pfas/health-effects/exposure.html

*2: According to Duke Nicholas School of the Environment, PFAS percutaneous exposure via skin contact is negligibly low although inhalation of PFAS absorbed to house dust migrated out from PFAS-containing carpets and/or furniture might be possible.
https://sites.nicholas.duke.edu/pfas/files/2020/08/Duke-NSOE-PFAS-Background.pdf

2. The possible risk caused from the articles should be properly considered, and convincing justification should be provided to show why the uniform restriction of PFAS in the articles is the most appropriate Union-wide measure to address the identified risks.

[1] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32012L0019

In the course of risk assessment, the fact that the end-of-life stage of EEE is managed according to WEEE Directive should be well-recognised and evaluated. We would like to ask the researchers and law-makers to evaluate the industry's effort and diligence to meet the sector-specific EPR legislation properly.

For product groups such as automobiles and EEE, waste regulations and occupational safety standards have already been established. The end-of-life stage of EEE is strictly and properly managed according to WEEE Directive. No e-wastes are dumped into environment without necessary care. Other complicated products such as vehicles are also managed under their sector-specific waste legislations. Such legislations apply extended producer responsibility (EPR) to the manufacturers, and the industry has taken big effort to meet the requirement with spending huge cost and resources. We would like to ask the researchers and law-makers to evaluate such effort and diligence properly.

If there are concerns on the risk of substances and mixtures, it may be more effective to cover them by occupational safety standards or the like. We consider that the methods of management should be flexible if there are other effective options to be considered.

We believe that emissions relating to EEE are quite well managed and are quite limited as described in our comment 1 above. In the first place, at design and manufacturing stages, the use of PFAS in EEE is limited to the places where the functions of PFAS are really necessary, because PFAS materials are more expensive in exchange for high-performance than non-PFAS low-performance ones.

In addition, in use phase, EEE must keep their quality and performance in their durable life. The PFASs used in products have a very low vapour pressure and therefore do not volatilise at room temperature, and are designed to remain where they are applied to in order to provide the required function during the product life time, and to perform well under more severe conditions than the rated operating conditions. We therefore believe that it is unlikely that PFASs will be released into the atmosphere from the products during the use phase.

EEE will enter into end-of-life stage with keeping the above conditions, and the emission at EOL stage has been adequately and legally controlled because waste EEE is covered under EU recycling legislations such as WEEE Directive 2012/19/EU or Battery Directive 2006/66/EC. Therefore, we consider that PFAS contained in the products from the volume of PFAS use, 4,860t, for EEE (Electronics and semiconductor), as described in the baseline, would not be discarded to the environment. If there are any concerns on the EOL stage of EEE, requirements for separate treatment under the recycling legislation such as Article 8 of WEEE or occupational safety regulations would be more effective ways to manage them with better cost-benefit than reflecting them to the threshold of PFAS under REACH which does not cover waste in principle.

For the proportional measures for chemical substance, the Commission draft restriction of PFHxA[2], published in 13 June 2023, should be considered as a reference.

The preempts (14) and (15) of the draft Commission Regulation on PFHxA (D090483/01) are described as follows:

> *(14) Despite the existing uncertainties on the data available, the Commission concurs with RAC that releases to the environment and exposure to humans have been confirmed by a large set of environmental and human monitoring data, and that the manufacture of PFHxA, its salts and PFHxA-related substances, and the uses of those substances that result in releases to the environment that are not adequately controlled, should be minimised. Instead of a broad restriction, the Commission considers a targeted restriction as the most appropriate Union-wide measure to address the identified risks. The Commission considers that the restriction should be targeted to those uses for which RAC concluded that it is not possible to implement risk management measures to minimise emissions and SEAC concluded that restricting that specific use is likely appropriate or likely not inappropriate in terms of socio-economic benefits and costs. For those uses, the Commission considers that the risk is not adequately controlled, alternatives are available and socio-economic costs are likely to be limited in comparison to the human health and environmental benefits.*
>
> *(15) Therefore, the Commission considers it necessary to adopt a Union-wide restriction for placing on the market or use of PFHxA, its salts and PFHxA-related substances in textiles, leather, furs and hides in clothing (such as outdoor clothing like rain jackets); related accessories (such as handbags) and footwear for the general public; paper and cardboard used as food contact materials; mixtures for the general public; cosmetic products; and some firefighting foams applications.*

3. <u>The regulation for the substances which are currently and widely used in the global supply-chain should be gradually introduced.</u>

If the uniform restriction of PFAS in the articles is really planned by ECHA after the proper risk assessment, all the issues described in our following comments should be carefully considered for establishing the feasible and enforceable measures.

For complex articles such as electrical and electronic equipment (EEE), even a single substance survey will not work unless the entire global supply-chain responds appropriately to the survey. In such context, the collection of SVHC information is a well-established tool for understanding the presence of substances of concern, and through SVHC surveys, end-product manufacturers can make concrete estimates of the amount of the substance used and the potential impact if the substance is regulated.

[2] https://ec.europa.eu/transparency/comitology-register/screen/documents/090483/1/consult?lang=en

However, as the restriction of PFAS is proposed not via the route via SVHC and authorization, end-product manufacturers are unable to estimate the exact amount of use or potential impact. Forcefully requesting information on the proposed restrictions in this situation would have little chance of gathering reliable data.

In addition, even if we had been able to gather more data, we consider that the separate date of the restriction of the articles should be set as a date later than that for chemicals. For EEE, complex articles, necessary transition period would be at least 5 years or more after the feasible substitutes are available as substances or mixtures. For EEE for industrial and social infrastructures would need longer time. From this perspective, it makes practical sense to establish an "Authorisation" step before restricting a substance. Please also see our Comment 5 below.

For example, PFHxA, which is not designated as a SVHC like PFAS, is a very limited group of substances within PFAS. Nevertheless, only insufficient and unreliable data have been obtained on PFHxA.

Preempt (13) of the proposed PFHxA restriction (D090483/01) states:

> *The Commission considers that it is not demonstrated that the proposed restriction, as modified by RAC and SEAC, is the most appropriate Union-wide measure to address the identified risks, taking into account that the data presented on emissions, risk reduction and socio-economic impacts are uncertain and important data are missing. RAC clearly indicated that the reported quantitative release estimates are unreliable due to numerous inconsistencies between different sections of the Background Document to the Opinion on the Annex XV dossier, insufficient justifications for the assumptions made and significant gaps in the information presented or in the reporting of the underlying calculation methodology for the different use sectors.*

The proposed PFAS regulation, which does not take steps such as designating PFAS as SVHCs and establishing an survey system for the entire supply chain, is largely based on speculation. We believe that the situation may be similar to the PFHxA case above.

We understand the concerns about PFAS in the countries that have proposed restrictions. We also agree with the idea that hazardous PFASs (PFOS, PFOA, C9-C14PFCAs, PFHxS) have been phased out and that further regrettable substitutions should be prevented.

However, restricting PFAS other than those listed above in the proposed very short period, for which a hazard classification has not yet been identified, based on uncertain data and not on a risk basis, will result in socioeconomic losses.

In many cases, alternative is a similar substance to the original substance, but it does not necessarily have the same properties, including toxicity etc. In addition, in order to use an alternative substance

that is completely different from the original substance, it takes a lot of time not only to develop an alternative substance itself, but also to develop the peripheral technology to use it.

Ozone-depleting substances are one of the best examples of global environmental improvements. These are substances that have been regulated on a risk-based and phase-out basis, with a grace period for industrial and socio-economic applicability.

A familiar example is the refrigerant used in refrigerators. Isobutane, which is completely different from Chlorofluorocarbons (CFCs), is currently mainly used. Unlike CFCs, isobutane is flammable, and it goes without saying that various technological developments and design improvements were necessary to enable its use.

The influence of ozone-depleting substances has been quantified based on scientific evidence, and based on the Vienna Convention*[3] and the Montreal Protocol *[4], they have been completely phased out after a very long period of time (e.g. HCFC*[5]). And we have achieved a very impressive result: the reduction of the ozone hole. The Protocol provides for the evaluation and review of regulatory measures on the basis of the latest scientific, environmental, technical and economic information. We believe that the restriction of PFAS can achieve effective results by introducing proper risk-based management based on scientific assessment of the hazards of the substances, stepping phase out, and their review as with this protocol.

References:

*3: "Vienna Convention for the Protection of the Ozone Layer" adopted on March 22, 1985

*4: The Montreal Protocol on Substances that Deplete the Ozone Layer, adopted on September 16, 1987. Identifying substances and regulating their production, consumption, and trade.

https://ozone.unep.org/treaties/montreal-protocol

https://ozone.unep.org/ozone-timeline

*5: The deadline for complete abolition of HCFCs is 2030. 45 years have passed since the adoption of the Vienna Convention.

4. About the appropriate thresholds and denominator for the articles: The management at the level of 1,000 ppm in the article would be practical and feasible.

We consider that the feasible denominator for the restriction of substances in the articles should be "article" and not be "homogeneous material", especially for the proposed thresholds is at ppb order. What can be surely managed by the article manufacturers are threshold value on the order of 1,000 ppm.

We are aware that the draft Regulation on PFHxA proposed the thresholds as "measured in

homogeneous material", maybe because the covered products are limited. The management of the substances based on "homogeneous material" under the EU RoHS is not requiring the analytical testing, and that it would not be generally applicable to the restriction of substances in the articles with low thresholds under REACH.

As a similar case, we are also aware that the management based on "homogeneous material" has been introduced to the CMR restriction in the textile under Entry 72 of Annex XVII to REACH. In the textile and similar products, measurement could be conducted because PFHxA used for the surface treatment would be targeted. However, please note that this is not generally applicable to other articles, because the case of the textile would be a special case in among the articles.

EEE is fortunately not covered under the regulation mentioned above, however, we have experienced that the once-defined conditions for the restriction of a certain group of the fluorinated substances have been often copied without sufficient assessment to other groups even though their hazard properties are different. We consider that the management based on "homogeneous material" would not suitable nor feasible for the articles, especially complex articles. Our proposal and justification is also aimed for future possible restrictions of the fluorinated substances in other articles.

The reasons why the PFAS in the articles should not be managed in homogeneous material are as follows:

(i) **The necessity to manage impurities by a certain threshold should be justified from the viewpoint of risk and socio-economic impact assessments.** Proposing the management in "homogeneous material" without risk assessment nor socio-economic impact assessment would lack the proportionality, transparency and justification which are required in the EU legislation.

(ii) Existing EU RoHS DIRECTIVE 2011/65/EU[3] requires the management under "homogeneous material" basis in electric and electronic equipment. However, to tell the truth, the supply chain of EEE has managed to carry out the compliance scheme, because the thresholds for RoHS are far higher (100 ppm for cadmium and 1,000 ppm for other 9 restricted substances) than those proposed in the PFAS restriction.

Likewise, the restriction of four phthalates under Entry 51 of Annex XVII to REACH, which was enacted after the publication of the regulation under EU RoHS Directive, requires the management of the substances in "homogeneous material", like RoHS. However, it has been manageable because the threshold is 1,000 ppm, similar to RoHS, though the denominator is "homogeneous material".

(iii) **In the first place, the complex articles cannot be managed on the measurement basis.** Ensuring

[3] https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32011L0065

the compliance only based on the analytical testing would not be feasible and appropriate for them. For example, tens of thousands, or in cases of complex EEE, hundreds of thousands of homogeneous materials, may exist in one EEE. In addition, various suppliers from all over the world are involved in the manufacture, from raw materials, parts and components, through to final products. In such cases, checking conformity based only on analysis testing of a huge number of homogeneous materials is unfeasible in practice. Even if we assume that it can be carried out, it can only confirm the compliance status of the tested sample at that particular time, and it cannot guarantee conformity for the whole product continuously. Given the above facts, we cannot even imagine how the compliance can be managed by testing.

(iv) **What can be managed by article manufacturers via supply-chain is at the threshold values on the order of 1,000 ppm.** For this level, it is thought that midstream manufacturers also have already an understanding on inclusion amounts from SDS information. In the first place, it is unrealistic for article manufacturers to manage substances contained in their products on the ppb order, because the manufacturers have no choice but to rely on the substance information received from the chemical manufacturers on the upstream side of the supply chain. And the management of substances on the ppb order is not an easy task for chemical manufacturers either. In the case of impurities and by-products originating in the manufacturing process, it is possible that information is not transmitted due to trade secret issues, and there are cases when the chemical manufacturer itself may not know the information unless high precision measurement is conducted. Managing substances in the complex article at ppb order is not feasible, not to speak of such management in homogeneous material.

(v) **There are no analytical methods for complex articles at ppb order.** We would not be able to manage the materials and products in this very small amount range. According with information from the chemical manufacturers, no official and reproducible analytical method for PFAS has been established yet.

There are two ways to analyse the amount of PFAS including PFAS in the materials: “liquid chromatography-mass spectrometry” and “Combustion-Ion Chromatography”. If using “liquid chromatography-mass spectrometry”, a process called extraction should be established, in which PFAS is dissolved into a fluid, such as water or organic solvent, which is suitable for the analytical method. More concretely, it is necessary to establish extraction methods by optimising the organic solvent used for extraction, extraction time, extraction temperature, etc., according to the type of polymer that constitutes the molded product and the type of PFAS to be analysed.

Even if all the complex and diverse methods of analysis are established, they must be correctly applied after distinguishing the polymer type from the PFAS type in order to perform the analysis correctly. In addition, reference materials corresponding to the type of polymer and the type of

PFAS must also be prepared. It is not feasible for downstream companies that have difficulty obtaining such information or reference materials.

On the other hand, if using “Combustion-Ion Chromatography”, we can determine total fluorine content on the order of a very small amount without its reference materials, but it is impossible to distinguish fluorine derived from PFAS from fluorine derived from other materials.

As electrical and electronic products become more functional and resource efficient, most of the components and parts used for them become smaller and more complex. It is often not feasible today to disassemble the components and parts into homogeneous materials and to obtain sufficient amount of homogeneous material sample for an analytical method. This has been pointed out in IEC 62321 Part2, for example.

5. **Necessity of sufficient time until the enforcement of the restriction.** In the case of restricting substances contained in articles according to the REACH, we would like the Dossier Submitter to set sufficient time until the enforcement of the restriction. **For the very small amount of PFAS in complicated EEE, it would take 48 months only to complete the investigation of containment.**

We are continuously investigating and reviewing the PFAS applications in EEE after the submission of our 1st input, and we consider that most of the applications found out would need applicable derogations. The reasons why are that many of substitutable applications of PFAS have already been replaced in response to the recent trend of regulating fluoro-substances and PFAS materials with high-performance are relatively expensive.

However, it takes very long time to investigate the substances which have not become even SVHCs through the whole supply-chain and to check whether there are any other unknown applications using PFAS than those currently known or not. Based on the experience of compliance with the RoHS Directive, even in the case when replacement exists, a period of at least 4 years is necessary to implement substitution in the article, even if the restricted substances are clearly identifiable and the threshold value is on the order of 1,000 ppm. PFAS is very huge group of substances, we cannot even assume the necessary transitory period, but we estimate that **at least 4 years would be needed only to complete the investigation of containment.**

Also from our experiences in the compliance with RoHS, especially for the complex articles, there are many cases where a non-substitutable application of the restricted substance is reported from an unexpected part or player in the supply-chain during transitory period between the publication of the law and the implementation of the restriction. For example, we considered that PFOA had already not

been used in EEE. However, after the publication of PFOA regulation, very small amount of PFOA as the impurity in PTFE powder was found out and additional derogation covered it.

In considering the above, the first four years had better to be set as a kind of “checking point” for the complex articles. If any application becomes known during this period and no feasible substitutions are found out at present, a mechanism to set a new derogation for such application should be established.

About the necessary steps for typical EEE when substituting a substance for which viable alternatives are established, please see our 1st comment (Annex 1(3) *“Necessity of sufficient time until the enforcement of the restriction. In the case of restricting substances contained in articles according to the REACH, we would like the Dossier Submitter to set sufficient time until the enforcement of the restriction.”* to Ref. No. 4543, in "rest pfas rcom part21 36501 en").

Please note that there are currently no concrete estimations of the timeline for replacing the PFAS applications listed as “essential” in our comment. Far from that, it has not been turned out yet whether the substitution of them is feasible or not in the first place. We would be able to research more about the possibility of substitution and, if possible, about the concrete timeline for replacement during four years of checking time after the publication, if the law gives us such time.

6. Explanation of Difficulties in Obtaining Information on Chemical Substances Contained in EEE.

We would like to explain again about the difficulties in obtaining information on chemical substances contained in EEE, as the reason why that it takes long time to investigate very small amount of substance(s) in the complex articles, as described in the comment 5 above. This is because we feel it would be difficult to have the law-makers, who have mainly covered chemicals, understand truly how the material investigation in the complex article is difficult.

(i) Framework on Investigating Chemical Substances Contained in Products in the EEE Industry.

The EEE industry has developed an international standard, IEC62474 and conducts surveys of chemical substances in supply chain based on the standard. The Declarable Substance List (DSL), which is part of this standard, lists substances of concern that are subject to restrictions under the chemical substance regulations in countries and that may be contained in EEE with the knowledge of experts in each country. Substances that have not been found to be hazardous and are not restricted by the regulations in countries are usually not added to the DSL.

Usually, even for a few substances for which CAS has been identified, it takes at least months, or more than years if number of substances is large, that a survey initiated from the EEE manufacturers, which is placed at the bottom of the supply chain, can reach the chemical manufacturers at the top of the supply chain, and then will be back to the EEE manufacturers.

(ii) Adding PFASs to the DSL

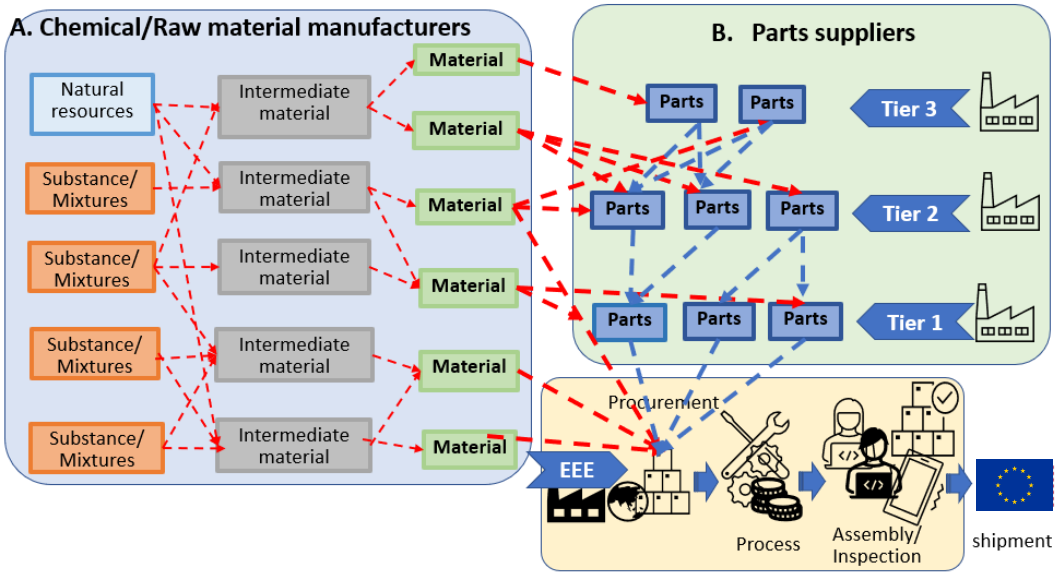
With the promulgation of the laws requiring information of PFAS in products in some American states, the EEE industry has begun to take actions as much as possible. Although most of PFAS have not been found to be hazardous, due to PFAS Law in the Maine, "PFAS" was just added to the DSL on January 17, 2023. Nevertheless, since the laws do not specify the CAS numbers of specific target substances, similar to the EU PFAS dossier, the DSL does not specify specific PFAS substances. Instead, 629 PFAS substances (indicated as “not exhaustive list”) selected based on expert knowledge were added to the Reference Substance List (RSL).

Anyway, this will enable future surveys of PFASs across the supply chain, but there are many obstacles to conducting such surveys, as described below.

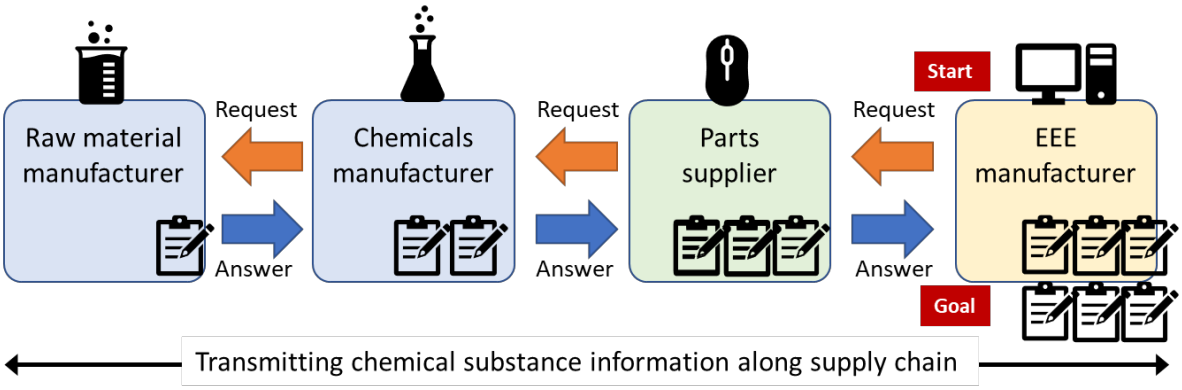
(iii) Conducting complicated Surveys

For complex articles such as EEE, the supply chain is multiply layered and complex and spread globally.

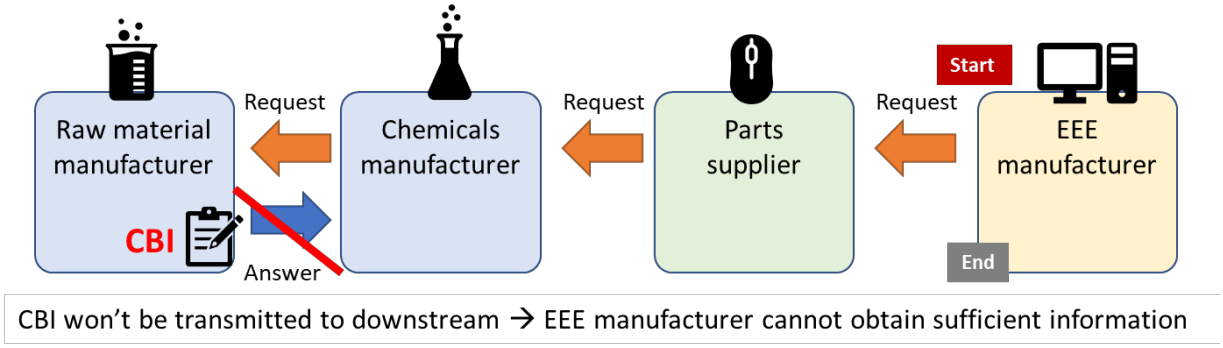
Complexity of supply chain of EEE and related sectors



In order for the final EEE manufacturer placed in downstream of the supply chain to obtain information about the chemicals contained in each part or component of the product, it is necessary to go up through the supply chain one-tier by one. On the other hand, normally, the suppliers which the final EEE manufacturer would be able to realistically reach out is two-tier upstream suppliers at the best.



The detailed chemical composition of the functional material in which the PFAS may be used is often considered a trade secret and is not communicated to the user beyond the level required for safe use. Furthermore, in the case of impurities or by-products generated during the manufacturing process, such information may not be communicated due to trade secret issues. In such cases, even the manufacturer of the chemicals may not know the information unless a highly accurate analysis is carried out. For example, as one of our members was not able to obtain specific chemical names from suppliers for PFOA-related substances covered by the PFOA exemptions prohibited under the Stockholm Convention.



The longer and more complex the supply chain and the larger the number of substances surveyed, the longer the time will be needed to obtain response (months to years or longer).

If the substances subject to survey are not uniquely identified, the supplier who is asked for the survey has no way to verify whether or not their products, purchased parts, or materials contain PFAS (and which PFAS is how much contained,), making it more difficult for the surveyor (e.g. EEE manufacturer) to get a response and taking longer.

In fact, in our experience, even when an EEE manufacturer has information that certain fluorinated compounds (not necessarily PFAS) are used in certain applications, it was almost impossible for the manufacturer to know whether or not they are PFAS.

EEE manufacturers have hundreds or thousands of suppliers in Tier1 only, and it is not even possible to estimate how much time and effort it would take to obtain information on the content of more than 10,000 PFAS from their entire supply chain.

The EEE manufacturer usually directs its suppliers to the necessary specifications of the main material or finished product, but rarely identifies each substance in each article, except for legally restricted substance. Also, in most cases, finished article manufacturers rarely use PFAS themselves or as any mixture containing PFAS. Furthermore, in the supply chain, the user of the chemical itself is not the "first or second tier" supplier, but often the material manufacturer which is further upstream.

Therefore, the manufacturer has no option but to rely on information about the substance that is transmitted incrementally from further upstream in the supply chain and ultimately delivered to the manufacturer.

For the above reasons, the addition to the DSL allows PFAS investigations, and even if PFAS content information is transmitted to EEE manufacturers several years later, there is no certainty that EEE manufacturers know the exact PFAS content in the articles, and we cannot obtain thorough information even taking longer time.

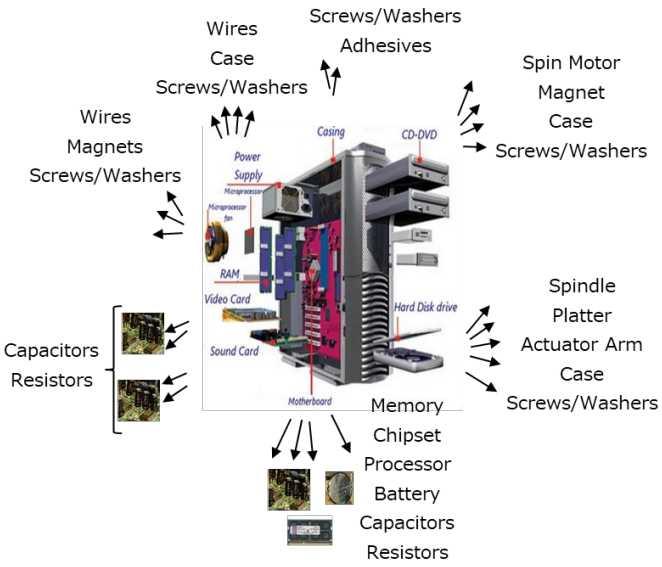
(iv) Difficulty of analysing PFAS in EEE

Internationally recognized analytical methods have been established for only some PFASs, including those already internationally regulated. The EPA provides PFAS analysis methods but it does not list methods for analysing PFAS content in articles.

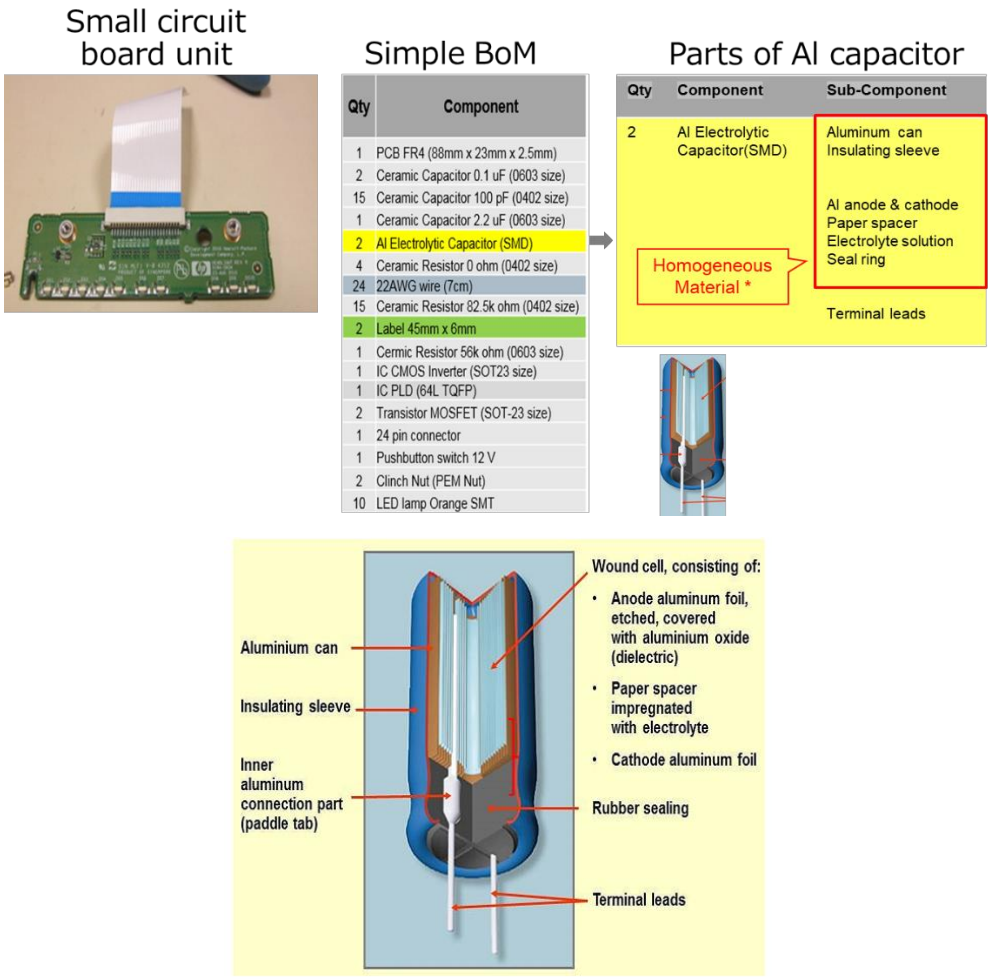
In addition, the Act allows the report as the total organic fluorine when individual PFASs cannot be identified. However, Combustion-Ion Chromatography (CIC), the commonly known analysis of fluorine, detects not limited to organic fluorine but also inorganic fluorine. Therefore, it is not possible to detect only total organic fluorine.

Even if an EEE manufacturer were to conduct an analysis, it would be impractical because the EEE consists of tens of thousands of parts, and it would take a tremendous amount of time and effort to analyse each of these parts to determine the PFAS content.

Here is an example. A computer consists of many parts as shown in the figure.



Each part consists of many tiny parts (a board unit is shown as an example).



In order to analyse, it is necessary to prepare the samples to be tested by decomposing to the material (homogeneous material) level constituting the tiny parts. However, no methods have not been established to prepare such a sample for which can be carried measurement at the level set in the dossier in a reproducible manner.

Even a very tiny part consists of multiple materials, it is hard to imagine how much time, effort and cost it would take to conduct analysis for each component of every EEE.

Based on the above, it is not practical for an EEE manufacturer as downstream of the supply chain to analyse and identify the type and content of PFAS contained.

The above is what the manufacturers of the complex articles have to do when the management of the huge number of substances is required with very low threshold and without the preparatory period in managing them as SVHC. This is also the reason why we need at least four years for investigation, as stated in our Comment 5 above. From the same reason, we consider that it would

not be feasible that the reporting requirements on each PFAS contents is obligated for the articles, as we stated in our Comment 12 below.

7. The period and the way of setting and maintaining a "derogation" should be further considered and established. The criteria for setting a derogation for the essential use for the complex articles should be similar to those of RoHS, and the date set for a derogation should not be an expiry date of the derogation but be a date for reviewing it.

Under current REACH, the criteria to set a derogation for the essential use for the complex articles have not been specified yet, and the procedures to apply a derogation or the ways of maintenance have not been clarified either.

(1) About the criteria for setting a derogation for the essential use for the complex articles.

As PFAS is the huge group of the industrial chemicals taking indispensable uses on complex articles at present, the conditions set in the Article 5(1)(a) of RoHS DIRECTIVE 2011/65/EU should be considered in determining appropriate derogations for the PFAS in the complex articles as follows:

(a) inclusion of materials and components of EEE for specific applications in the lists in Annexes III and IV (note: exempted applications from the restriction under RoHS), … where any of the following conditions is fulfilled:

- *their elimination or substitution via design changes or materials and components which do not require any of the materials or substances listed in Annex II (note: restricted substances) is scientifically or technically impracticable,*
- *the reliability of substitutes is not ensured,*
- *the total negative environmental, health and consumer safety impacts caused by substitution are likely to outweigh the total environmental, health and consumer safety benefits thereof.*

If a derogation is not adequately set for an application fulfilling any of the above three conditions, the article product groups needing it would not be able to be produced anymore, and such situation may give big socio-economic impact.

(2) About the procedures relating to applying, setting and reviewing a derogation.

Current PFAS dossier proposes three types of the duration, that is, five years, twelve years, and without limitation, for the listed derogations.

However, we feel uncertain whether the duration of five years plus transitory period would be feasible for the substitution. Such duration would be feasible when there are practical substitutes which can be used in the actual products with a certain reliability, but we have experienced many cases where some non-substitutable applications are inevitably found out in pushing forward the actual substitution. We would like to ask ECHA to provide a guidance to show the industry the way of submitting an application for setting an additional derogation or for extending the duration of an existing derogation.

In addition, we also feel concern about the duration of twelve years plus transitory period, because there is no guarantee that some alternative technology is developed and that the substitution becomes practically feasible within such duration for PFAS applications relating to semi-conductors, for example.

The big technical innovation such as the substitution of all the PFAS cannot be planned and readily made. In addition to the first innovation, other technical innovations are needed to apply it into practice before the innovative technology becomes available for actual uses. The LED would be useful as an example of such innovations. Though the red LED was invented in 1965 and the blue LED was developed in 1989, it was since 2010s that the LED was put into use in many products and became popular than existing lighting technologies. About a half century had passed since the first innovation.

No matter how speeding up the recent technical development, it would not be a realistic timeline to complete the whole processes from the innovation to practice in twelve years. For example, the technical innovation is carried out to make PFAS needless at first, then, this technology is put into actual uses and replaced with existing technology within twelve years in the semiconductor industry and in all other industries making use of semiconductors. Is it really feasible? Please also see our comments 3 and 5 above, for the timeline.

Accordingly, the complex article manufacturers consider that **the date set for a derogation should not be an expiry date of the derogation but be a date for reviewing it**.

For your reference, under current RoHS Directive, all the exemptions (derogations) are checked by the industry every five years. Then, for the applications which have not become substitutable yet, the Commission technically reviews them in response to the requests for renewal of the exemption from the industry. However, the review and renewal of many exemptions at five years' interval would not be practical, because the burden for such actions is so heavy not only for the industry but also for the authority. We consider twelve years' interval would be practical and feasible to review the derogations, in considering the broad coverage of PFAS group, the time for the chemical industry to develop the new materials and wide-variety of the final applications in EEE.

8. Necessary PFAS derogations in EEE. (Relating to the Questionnaire 6 to 8).

There are currently no feasible substitutes for PFAS which can attain the performance needed for EEE for the applications listed in Column E of our revised JP4EE Annex 3. We would like to request ECHA to set the derogations for them, as the feasibility in EEE becomes assessable only after the viable substitute materials are established.

Please see our previous Annex 2 “The unfeasibility of “possible substitutes” in the dossier in the actual EEE” and new JP4EE Annex 9 “Unfeasibility of other “possible substitutes” in actual EEE”, for the explanation of reasons why the candidate substitutions are not feasible in the actual EEE. Please see the JP4EE Annexes 3 to 6 for the applications needing derogations and reasons.

We consider the following applications would need derogations for EEE (Please see the column E of JP4EE Annex 3.):

< Fluoropolymers and Perfluoropolyethers >

1) Sliding elements in mechanical section
2) Optical elements
3) Piezoelectric elements
4) Insulating material requiring flame-retardancy and/or heat-resistant, where the use is needed for safe functioning and safety of equipment
5) Optical elements for LCD panels
6) Electronic circuit boards for high-frequency applications
7) Anti-dripping agent used for safety and to enhance flame retardancy
8) High performance materials for mold release and protection purposes used in the article molding process
9) Batteries
   *Please refer to the input from the battery industries, such as those from RECHARGE (Ref. No. 3925 in RCOM Part.2) or from Battery Association of Japan (BAJ) (Ref.No.4331 in RCOM part 14), for the concrete details.
10) Film, sheet or membrane requiring surface performance which ensures multiple functions such as electrical insulation property, chemical resistance, heat resistance, flame resistance, flex resistance and excellent elongation followability at the same time
11) Hermetic sealant requiring low percentage of the compression set as well as simultaneously other functions such as excellent elongation followability, durability, flame resistance, heat and hot water resistance, low water absorption, low moisture permeability, chemical resistance and/or low outgassing.
12) Fluid tubes and containers requiring chemical resistance, high cleanliness
13) PFAS used for semiconductor manufacturing process, semiconductor manufacturing equipment, and semiconductor
14) PFAS used for thin-film device (Micro Electro Mechanical System/MEMS, SAW device, Capacitor, etc) manufacturing process, thin-film device manufacturing equipment, and thin-film device

15) Functional material used in printing process
    *Please refer to the input from the related industries, such as Japan Business Machine and Information System Industries Association (JBMIA), for the concrete details.

< Fluoroalkyl compounds with functional groups (such as -OH, -COOH, N-R, etc.) and Side-chain fluorinated polymers >

16) High performance materials for mold release and protection purposes, which ensures multiple functions such as electrical insulation, heat resistance, chemical resistance or flame resistance, etc. at the same time.
17) Semiconductor manufacturing process
18) Thin-film device (Micro Electro Mechanical Systems/MEMS, SAW, Capacitor, etc) manufacturing process
19) Functional material used in printing process
    *Please refer to the input from the related industries, such as Japan Business Machine and Information System Industries Association (JBMIA), for the concrete details.

< Fluoroalkanes and fluoroalkenes, and Fluoroethers and fluoro-ketones >

20) Refrigerant used in various appliances such as those for Refrigeration, Air Conditioning and Heat Pump (RACHP) products
    *Please also see the input from the related industries, such as Japan Refrigeration and Air Conditioning Industry Association (JRAIA) (the first input is Ref. No.4292 in RCOM part 13 and the 2nd will be submitted soon.), About the details of the essentiality of the PFAS refrigerants.
21) Refrigerant, coolant, cleaning agent and solvent used for semiconductor process
22) Refrigerant, coolant, cleaning agent and solvent used for thin-film device (Micro Electro Mechanical Systems/MEMS, SAW etc) process
23) Chemicals for ultra-fine processing applications, as typified by semiconductor and MEMS manufacturing processes
24) Fluids for immersion processes (testing, measuring or adding function) in production processes and laboratories.

< Others (PFAS other than ones mentioned above) >

25) Transparent electronic circuit board and circuit
26) Liquid crystal display (LCD) elements
27) Optical elements
28) Functional materials used in printing process
    *Please refer to the input from the related industries, such as Japan Business Machine and Information System Industries Association (JBMIA), for the concrete details.

< All the PFAS (fluoropolymers and others) >

29) Functional coatings*

(* "Functional coating" is a coating applied to an article in order to give it the required functions, such as low dielectric properties, low dielectric loss tangent, electrical insulation, heat resistance, UV resistance, chemical resistance, corrosion resistance, weather resistance, water repellency, oil repellency, slipperiness, low refractive index and so on. "Functional coating" includes, but not limited to, "conformal coating" used to protect electronic materials. In our input, we use the term "functional coating" because the required functions are not only to protect the objects.)

30) Lubricants where the use takes place under harsh conditions or the use is needed for safe and intended functioning and/or safety of equipment.

The essential applications listed above (and in our JP4EE Annex 3) are indispensable for the following functions of EEE, which need PFAS materials to attain required performances. Please also see our JP4EE Annexes 4 and 6 for details.

The Co-relation between the EEE functions/properties required and necessary PFAS applications

Functions and properties required for EEE (Column C,D of JP4EE Annex 4)	**Necessary applications of PFAS to attain the functions and properties** (Column E of JP4EE Annex 3)
1. Optical function and required properties	2) Optical elements. 5) Optical elements for LCD panels. 25) Transparent electronic circuit board and circuit. 27) Optical elements. 29) Functional coatings.
2. High-speed communication/ transmission function and required properties	6) Electronic circuit boards for high-frequency applications. 29) Functional coatings.
3. Piezoelectric function and required properties	3) Piezoelectric elements
4. Sliding function in mechanical section and required properties	1) Sliding elements in mechanical section. 8) High performance materials for mold release and protection purposes used in the article molding process. 11) Hermetic sealant requiring low percentage of the compression set as well as simultaneously other functions such as excellent elongation followability, durability, flame resistance, heat and hot water resistance, low water absorption, low moisture permeability, chemical resistance and/or low outgassing. 29) Functional coatings.

Functions and properties required for EEE (Column C,D of JP4EE Annex 4)	**Necessary applications of PFAS to attain the functions and properties** (Column E of JP4EE Annex 3)
	30) Lubricants where the use takes place under harsh conditions or the use is needed for safe and intended functioning and/or safety of equipment.
5. Display function (Liquid crystal) and required properties	26) Liquid crystal display (LCD) elements.
6. Safety and safety functions and Required properties	4) Insulating material requiring flame-retardancy and/or heat-resistant, where the use is needed for safe functioning and safety of equipment. 7) Anti-dripping agent used for safety and to enhance flame retardancy. 8) High performance materials for mold release and protection purposes used in the article molding process. 10) Film, sheet or membrane requiring surface performance which ensures multiple functions such as electrical insulation property, chemical resistance, heat resistance, flame resistance, flex resistance and excellent elongation followability at the same time. 12) Fluid tubes and containers requiring chemical resistance, high cleanliness. 16) High performance materials for mold release and protection purposes, which ensures multiple functions such as electrical insulation, heat resistance, chemical resistance or flame resistance, etc. at the same time. 29) Functional coatings. 30) Lubricants where the use takes place under harsh conditions or the use is needed for safe and intended functioning and/or safety of equipment.
7. Functional surface and required Properties	8) High performance materials for mold release and protection purposes used in the article molding process. 10) Film, sheet or membrane requiring surface performance which ensures multiple functions such as electrical insulation property, chemical resistance, heat resistance, flame resistance, flex resistance and excellent elongation followability at the same time.

Functions and properties required for EEE (Column C,D of JP4EE Annex 4)	**Necessary applications of PFAS to attain the functions and properties** (Column E of JP4EE Annex 3)
	16) High performance materials for mold release and protection purposes, which ensures multiple functions such as electrical insulation, heat resistance, chemical resistance or flame resistance, etc. at the same time. 29) Functional coatings.
8. Semiconductor and required Properties	13) PFAS used for semiconductor manufacturing process, semiconductor manufacturing equipment, and semiconductor. 17) Semiconductor manufacturing process. 21) Refrigerant, coolant, cleaning agent and solvent used for semiconductor process. 23) Chemicals for ultra-fine processing applications, as typified by semiconductor and MEMS manufacturing processes.
9. Thin film device production process and required Properties	14) PFAS used for thin-film device (Micro Electro Mechanical System/MEMS, SAW device, Capacitor, etc) manufacturing process, thin-film device manufacturing equipment, and thin-film device. 18) Thin-film device (Micro Electro Mechanical Systems/MEMS, SAW, Capacitor, etc) manufacturing process. 22) Refrigerant, coolant, cleaning agent and solvent used for thin-film device (Micro Electro Mechanical Systems/MEMS, SAW etc.) process. 23) Chemicals for ultra-fine processing applications, as typified by semiconductor and MEMS manufacturing processes.
10. Energy supply (Battery) and required Properties	9) Batteries.
11. Refrigerant function (Refrigerant gas) and required Properties	20) Refrigerant used in various appliances such as those for Refrigeration, Air Conditioning and Heat Pump (RACHP) products.

Note: “Functional material used in printing process” (No.15, 19, 28 in JP4EE Annex 3) is separately covered by the input from the related industries, such as Japan Business Machine and Information System Industries Association (JBMIA), for the concrete details, and is not included in the above table.

Note 2: The function needing “Fluids for immersion processes (testing, measuring or adding function) in production processes and laboratories (No.24 in JP4EE Annex 3)" is not listed in Column C of JP4EE Annex 4 but in Column C of JP4EE Annex 7, under "1. Immersion process".

Please also see our previous input (Annex 1(5) Ref.No.4543, in "rest pfas rcom part21 36501 en"), for the reasons of needing PFAS in EEE and points to be cared of in considering derogations for EEE.

9. **Necessary PFAS derogations in manufacturing processes of EEE and its parts.** (Relating to Questionnaire 8).

There are currently no feasible substitutes for PFAS which can attain the performance needed to produce the parts needed for EEE for the applications listed in JP4EE Annex 7. We would like to request ECHA to set the derogations for them, as the feasibility in EEE becomes assessable only after the viable substitute materials are established.

Please see our previous Annex 2 “The unfeasibility of “possible substitutes” in the dossier in the actual EEE” and new JP4EE Annex 9 “Unfeasibility of other “possible substitutes” in actual EEE”, for the explanation of reasons why the candidate substitutions are not feasible in the actual EEE. Please see the JP4EE Annexes 7 and 8 for the applications needing derogations and reasons.

The items considered necessary for derogation in the manufacturing process of EEE and its components are as follows (Column C of JP4EE Annex 7):

1. Immersion process.
2. Electrode formation process with safety function for film capacitors.
3. Electrode formation process of Electric Double Layer Capacitor (EDLC).
4. Coating process of optical film for electronic displays.

The essential applications listed above (and in our Annex 7) are indispensable for the following functions of the manufacturing process of EEE and its components, which need PFAS materials to attain required performances.

	Classification (Column C of JP4EE Annex 7)	**Intended use in manufacturing process of EEE and its component** (Column D of JP4EE Annex 7)	**Products used by EU citizens** (Column E of JP4EE Annex 7)
1-1	Immersion process	Measurement and inspection of temperature characteristics for temperature measuring components	Medical equipment, automobiles and transportation equipment. Other products in the RoHS Category 1-11 require this process to produce electronic

			components which controls the operating temperature of EEE with high accuracy and secure its operation.
1-2		Gross-leak and fine-leak test	Medical equipment, automobiles and transportation equipment. Other products in RoHS categories 1- 11 would need this process to produce hollow structural electronic components for reliable applications.
1-3		Piezoelectric polarizing	Medical equipment, automobiles and transportation equipment. Other products in RoHS categories 1- 11 would need this process to produce resonators, oscillators, and transmitters and ceramic piezoelectric sensors.
1-4		Measurement and inspection of voltage proof and/or breakdown voltage of electronic components	Home appliances, mobile equipment, EV chargers, factory automation equipment and solar power generation facilities. Other products in RoHS categories 1-11 would need this process to produce or develop electronic components to be incorporated into a high voltage applied power supply unit.
2	Electrode formation process with safety function for film capacitors	Addition of fuse function and insulation function	Film capacitors are widely used in automobiles, transportation equipment, medical equipment, industrial/ infrastructure equipment, home appliances, mobile phones, solar power generation, other renewable energies and energy distribution. Other RoHS Category 1-11 products require this process to produce the device film capacitor.
3	Electrode formation process of Electric Double	Electrode formation for mass storage of electric charge and fast charge/discharge (activated	Automobiles, industrial equipment, etc. Other RoHS Category 1-11 products require this process to produce the

	Layer Capacitor (EDLC)	carbon is bound to the electrode foil with binder (PTFE))	device Electric Double Layer Capacitor (EDLC).
4	Coating process of optical film for electronic displays	Prevents localization of electric charges and fires when coating a functional coating layer (insulator) on a base material (insulator) during the production of optical films for electronic displays.	Consumer displays (e.g. TV, PC monitors, car monitors, etc.) Industrial displays (e.g. medical equipment monitors, etc.)

Because PFAS used in the manufacturing processes of electrical and electronic equipment and their components are strictly controlled in the existing framework and have a very low risk of being released or exposed as such, the environmental impact of restriction derogation is assumed to be limited and negligible, significantly unbalanced against the socio-economic impacts of restriction. Essential industrial chemicals should be restricted only if their environmental impact cannot be controlled by the existing regulatory regime in view of their socio-economic impact.

Specifically, substances and mixtures used in the manufacturing processes of electrical and electronic equipment and their components are under strict controlled, so the risk of their release or exposure would be significantly lower. In addition, even if the content of hazardous substances is low below the reference value (mostly around 0.1% or so), it is recommended to communicate information by SDS if it is judged to be hazardous. By controlling substances and mixtures based on the GHS, substances and mixtures used in the manufacturing process can be controlled on the same basis globally and in consideration of hazards.

We also consider that emissions for the manufacturing processes of EEE and their components are very well controlled and limited to very small quantities. In the first place, PFAS-containing materials are more expensive than low-functional materials without PFAS in exchange for their high performance. Therefore, the use of PFAS in the manufacturing process of electrical and electronic equipment and their components is limited to where it is really needed, and the amount of PFAS-containing materials used is very small. Furthermore, the Industrial Emissions (Integrated Pollution Prevention and Control) Directive 2010/75/EU (IED) exists as a waste regulation for industrial processes including the manufacturing process of electrical and electronic equipment and their components. PFAS emissions from processes should be considered in the IED framework. For example, for an EEE manufacturing process using PFAS, a BAT reference document under Article 13 (BAT Reference Documents and Information Exchange) of the IED may be established.

Based on the above, we believe that the issue of PFASs used in the manufacturing process of electrical and electronic equipment and their components should be addressed by the existing control regulations and not by the REACH regulations.

The currently timeline for the restriction on PFAS used in the manufacturing process of electrical and electronic equipment and their components is not feasible. Therefore, even if ECHA concludes that some PFAS for these processes should be restricted, the current proposed effective date is inappropriate.

It is generally known that basic research on chemical substances and their industrial mass production require a period of at least 5 years, and at most 10 years. Moreover, even if alternative substances can be developed, a transition period of at least 4 years would be needed for the replacement of the chemicals. Without a scientific assessment of the hazards of individual substances, attempts to comprehensively eliminate PFASs because of the presence of a single hazard, persistence (P), are clearly unbalanced and excessive in terms of possible risks and benefits. With respect to PFAS restrictions, we believe that risk-appropriate benefits can be derived from careful scientific assessment of individual substances and their applications to establish risk-based regulatory measures, and from assessment and review of regulatory measures based on the latest scientific, environmental, technological and economic information.

10. A derogation for articles already placed on the market before implementing the restriction should be provided like other restriction covering articles under Annex XVII to REACH.

Proposed derogation:
Paragraph 2 shall not apply to articles already placed on the EU market before the date referred to in paragraph 3.

Please note that the draft Regulation on PFHxA, published in 13 June 2023, includes this derogation as follows:

> *6. By way of derogation from paragraph 1, that paragraph shall not apply to articles placed on the market before [PO: please insert the date = 24 months from the date of entry into force of this Regulation].*
>
> *7. By way of derogation from paragraph 2, that paragraph shall not apply to articles placed on the market before [PO: please insert the date = 36 months from the date of entry into force of this Regulation].*

We consider that a similar derogation should be set also for the PFAS restriction.

Justification:

Under current REACH, used or refurbished products must comply with the same requirements as new products. However, other technical legislations under the New Legislative Framework exclude products which were already placed on the EU market before the legislative requirements are applied. Though REACH is a chemical law, it is also technical requirements as the complicated articles concerned, and similar consideration as NLF would be needed for such products. In fact, such a derogation is also common for other existing REACH restrictions of substances in articles.

After its service life some Electrical and Electronic Equipment is refurbished and sold again. In the light of the ambition for a circular economy, the re-use of products is one of the most effective measures. The current wording of the proposed restriction prohibits the refurbishment and sales of older product. A general restriction on articles with PFAS would make it impossible to be certain about compliance for refurbished products. We will not be able to refurbish products in the future and will be forced to dispose of them.

This will result into huge adverse impact on the environment and economy in the EU. Also, if the product to be reused or refurbished has been manufactured before enforcement of the restriction or before its listing as SVHC, it is simply impossible to check the compliance of the product since the product was not managed to comply with the restriction.

We therefore ask for a derogation for articles already placed on the market before entry into force of the restriction.

11. A General exemption of spare parts without expiry date would be indispensable for complicated articles to extend their useful life, if their original products are placed on EU market before the requirement comes into force.

After submitting our previous input, DIGITAL EUROPE, the leading trade association representing digitally transforming industries in Europe, inputted their comments about this issue (Please see Ref. No.5927 listed in “rest_pfas_rcom_part25_36502_en”. We, Japan 4EE industrial associations endorsed the comments along with other stakeholders in Japan. Please recognise and understand that this is the common and important issue for the industry relating to the complex articles.

In relation to this matter, a study for the possible policies in future RoHS covering EEE has been published recently, and many measures are proposed for EEE to contribute further to the circular economy.

Study to support the assessment of impacts associated with the general review of Directive 2011/65/EU (RoHS Directive) Final report

https://op.europa.eu/en/publication-detail/-/publication/b9188764-f465-11ed-a05c-01aa75ed71a1/language-en/format-PDF/source-286516984

The report includes following recommendation:

"Ensuring that RoHS contributes to increased use of recovered spare parts

Reuse of products or parts of products is an important part of circular economy as it can contribute to reduce the material footprint and increase resource efficiency. The current wording of Article 4(5) of the RoHS Directive only allows the reuse of spare parts from EEE which have been placed on the EU market within certain temporal conditions. This wording therefore restricts the recovery of spare parts which limits the potential of the Directive to strengthen circular economy objectives.

The objective is that RoHS should not disproportionally hinder the use of recovered spare parts, while simultaneously alleviating administrative burden on economic operators and regulatory bodies. For this, one possibility could be opening the temporal and geographical scope of Article 4(5). Stakeholders would have legal certainty that the reuse of recovered spare parts from any device is possible. Alternatively, only the geographical scope could be opened, but the temporal limitations kept. This would mean that certain time-limited exemptions for the medical industry are not necessary anymore, however some legal complexity would still remain due to the remaining temporal limitations."

However, current dossier would hamper the circular economy relating to EEE without exclusions this exclusion.

We believe that the procedures to make it possible to use the spare parts and recycled materials should be established from the view-point of circular economy. Availability of spare part must be secured to establish circular economy. Complicated products such as EEE need spare parts same as those used in the first production of each product, because changing a part is not simple procedures as shown below. Especially when the sale of a product model is ceased, only old spare parts before the restriction would be available for such model. If EEE cannot have spare parts as produced, the EEE will not be able to be repaired and then it might shorten its lifetime and abandoned earlier than its intended lifetime.

As we mentioned above, RoHS Directive 2011/65/EU set uniform exclusions for cables or spare parts for the repair, the reuse, the updating of functionalities or upgrading of capacity of the products placed on the market before the date when the restriction started to apply to them. We believe that similar exclusion of spare parts would be indispensable in the future restriction also under REACH for realising the circular economy.

The change of important parts (including the change of their materials) is never simple task. Even if some alternatives are proposed by chemical manufacturers in future, there is no guarantee that the same performance as before can be obtained. The device manufacturers such as semiconductor

industry must assess their performance, reliability, safety or any other features of such alternatives. Furthermore, the change of the very important parts often needs redesign of the finished products as a whole. Such redesign is beyond "repair" process.

Especially in the cases of long life and large products such as those used as parts of social infrastructure or production plant, their useful life would be very long (often longer than 20 years). The manufacturers can repair such products "as produced" by replacing same parts as before, but cannot redesign parts, components or the whole system to use similar but different parts. In such cases, it would be almost impossible to assure the same or similar performance, safety and reliability as before.

About making use of recycled material, there are similar problems as spare parts. Recycled materials or parts may come from products before some restriction. If substance of concern can be removed from recycled parts or materials by cost-effective and relatively easy procedures, or if there is some legal arrangement for them, the manufacturers can choose them. However, if not, nobody can make use of them.

Therefore, we sincerely consider that the exclusion of spare parts for products which have already been placed on the market before a restriction is in effect, as well as some arrangement on recycled materials, would contribute to establish sustainable society and circular economy.

12. **About the reporting requirements on each PFAS contents : The articles should be excluded from the scope of reporting.**

We consider that it is impractical for article manufacturers to carry out thorough investigation, record and report on thousands of PFAS compounds that would be covered by the proposed rule. Information that article manufacturers at the downstream in a supply chain can obtain depends on the information received from component suppliers at upstream in the same supply chain. Since PFAS compounds as a class have not been restricted in any other jurisdictions, it would not be able to obtain accurate information such as the identity of each substance and each volume used in a part or product via broad, long and complex supply chain. As the result, the information ECHA would receive would be incomplete and of uncertain reliability, and it likely would not be of much value to ECHA in achieving its regulatory objectives.

Taking into account the above, **we would like to propose excluding PFAS-containing articles from the scope of reporting.** At least, **we consider it unfeasible and excessive to require manufacturers, importers of PFASs and PFAS containing articles to provide information on "the identity and quantity of the substances placed on the market in the previous year."**

(1) Problems in the Dossier: "ANNEX XV RESTRICTION REPORT PROPOSAL FOR A RESTRICTION":

The Dossier requests the following from manufacturers and importers of PFAS containing articles that take advantage of the exclusion of the currently listed derogations that are due 12 years + a derogation period and those that are indefinite:

i. the derogation that the intended use belongs to;

ii. the identity and quantity of the substances placed on the market in the previous year.

P.12 in the Dossier, the Dossier submitter concluded as follows:

> *"The Dossier Submitters are aware that the formulator is, in contrast to the downstream user, not defined in the REACH Regulation. However, reporting by all downstream users is not considered practical by the Dossier Submitters. Manufacturers and importers often lack detailed knowledge on the whole supply chain, in particular if these are complex. Limiting the reporting obligation only to these actors might not provide sufficient use information to enable reviewing of the derogations. Formulators are usually the first downstream users of a substance and already have a good knowledge of the remaining supply chain and the (end) uses of substance. Therefore, it is proposed to include formulators, but not further downstream users in the reporting obligation."*

In other words, **the manufacturer or importer of the product does not have knowledge, so if the first formulators of the substance are made subject to the notification obligation, the necessary knowledge can be obtained without making the downstream user of the substance subject to the notification obligation.** It is true that a manufacturer whose supply chain is completed in the EU and who purchases the substance in the EU and makes the article is not subject to the reporting obligation as a "further downstream user."

However, **a manufacturer who imports a complex article or purchases it in the EU and makes the article is not a "further downstream user" of the substance.** As for the lack of knowledge about the PFAS contained in it, they know that it is the same as "further downstream users," but there is no consideration for the manufacturer or importer of the article.

For the difficulty of collecting information on complex articles, see 6 above. Formulators are often located far upstream in the supply chain, often outside the EU. Communication of such trace amounts of PFAS has never been required in any country, and even within the chemicals supply chain is kept confidential and details are not communicated. Furthermore, it is impossible for final article manufacturers far down the supply chain to obtain information on the substances contained in the ppb order. Such regulations are likely to disrupt the supply chain, thereby impeding the supply of products/materials and adversely affecting them.

To satisfy the proposed requirements to identify and report on every PFAS compound as well as their volume is impossible for article manufacturers to carry out. Not only it will take much more time and cost, but also it is unfeasible to obtain the information which the dossier submitter intends.

(2) There are more important factors than (inaccurately estimated) volume of the substance in determining whether a derogation should continue for the articles.

In addition, we believe that the amount used is not the most important factor in determining whether a derogation should continue for the articles. Please refer to our comment 7 regarding the derogation criteria required for the articles. In complex articles, the derogation should be reviewed based on the development and practical use of truly technologically and socioeconomically replaceable technologies, rather than on the increase or decrease in substance use (often based on estimates). See practices in the EU RoHS Directive and the ELV Directive.

In the first place, the release of PFAS from articles is limited, and the end of life of many products such as EEE is already covered by individual EU legislation. In such a situation, it is not very meaningful to request information from articles, at least the current 7 (ii), in order to determine the existence of derogation related to articles, and it seems to be an excessive request. Although derogations exist not only in the operation of the EU RoHS exemptions, but also in the REACH Annex XVII restrictions for many substances with more definite hazards than PFAS, such an excessive request for notification is not set up.

We would like you to consider a reasonable request that is balanced with the benefits.

13. **Preceding evaluations should be respected, especially for RAC/SEAC Opinion on PFHxA.**

If proposed PFAS restriction covers also PFHxA, all the derogations proposed in the final "RAC and SEAC Opinion on an Annex XV dossier proposing restrictions on undecafluorohexanoic acid (PFHxA), its salts and related substances"[4], published in May 2022, should be incorporated, because they are resulted from the full socio-economic impact assessment. Especially, following conditions and derogations are indispensable for the EEE industry.

- 5. Paragraphs 1 and 2 shall not apply until XX XX XXXX [five years after the entry into force] to:
  (a) hard chrome plating;
  (b) photographic coatings applied to films and in printing plates;

[4] Committee for Risk Assessment (RAC) / Committee for Socio-economic Analysis (SEAC) Opinion on an Annex XV dossier proposing restrictions on undecafluorohexanoic acid (PFHxA), its salts and related substances
ECHA/RAC/RES-O-0000006976-57-01/F
ECHA/SEAC/RES-O-0000007039-72-01/F
https://echa.europa.eu/documents/10162/97eb5263-90be-ede5-0dd9-7d8c50865c7e

- 7. Paragraphs 1 and 2 shall not apply until XX XX XXXX [12 years after the entry into force] to:
  (b) semiconductors and semiconductor related equipment.

- 8. Paragraphs 1 and 2 shall not apply to any of the following:
  (h) medical devices as specified in Regulation (EU) 2017/745 of the European Parliament and of the Council; woven, knitted and nonwoven medical textiles as specified in Regulation (EU) 2017/745 of the European Parliament and of the Council with a minimum performance requirement of >20 cm hydrostatic head according to EN 13795; in vitro diagnostic medical devices as specified in Regulation (EU) 2017/746 of the European Parliament and of the Council as well as parts thereof;
  (i) filtration and separation media used in high performance air and liquid applications that require a combination of water- and oil-repellency for filters used in industrial settings or by professionals.

- 10. The concentration limits referred to in paragraph 2 shall be:
  (a) XXX [information on concentration limits requested in SEAC consultation] for the sum of PFHxA and its salts in fluoropolymers;
  (b) XXX [information on concentration limits requested in SEAC consultation] for PFHxA related low molecular substances in fluoropolymers.

- 12. Paragraphs 1 and 2 shall not apply to flat panel displays used in electrical and electronic equipment until XX XX XXXX [7 years after entry into force].

- 13. Paragraphs 1 and 2 shall not apply to functional coating used in electrical and electronic equipment until XX XX XXXX [7 years after entry into force].

The above are our second comments updated and added. We would like to ask ECHA to consider our first and second input along with our all other attachments carefully. We expect that ECHA would examine the dossier in a balanced way in considering the risk/benefit of the proposed measures.

Chemical regulations of EU have been a model of the global legislations in this area for many years. In such situation, we sincerely hope that ECHA and the European Commission would be able to contribute to the effective protection of human health and environment via reasonable and appropriate management of chemical substances based on regulatory science and accountability, by considering our comments above.

About Japanese electric and electronic (E&E) industrial associations:

About JEITA

The objective of the Japan Electronics and Information Technology Industries Association (JEITA) is to promote the healthy manufacturing, international trade and consumption of electronics products and components in order to contribute to the overall development of the electronics and information technology (IT) industries, and thereby further Japan's economic development and cultural prosperity.

About CIAJ

Mission of Communications and Information network Association of Japan (CIAJ). With the cooperation of member companies, CIAJ is committed to the healthy development of info-communication network industries through the promotion of info-communication technologies (ICT), and contributes to the realization of more enriched lives in Japan as well as the global community by supporting widespread and advanced uses of information in socio-economic and cultural activities.

About JBMIA

Japan Business Machine and Information System Industries Association (JBMIA) is the industry organization which aims to contribute the development of the Japanese economy and the improvement of the office environment through the comprehensive development of the Japanese business machine and information system industries and rationalization thereof.

About JEMA

The Japan Electrical Manufacturers' Association (JEMA) consists of major Japanese companies in the electrical industry including: power & industrial systems, home appliances and related industries. The products handled by JEMA cover a wide spectrum; from boilers and turbines for power generation to home electrical appliances. Membership of 291 companies, http://www.jema-net.or.jp/English/

About electric equipment manufacturers' coalition of medical devices, and analysis, measurement, test, control and monitoring instruments that have endorsed this paper:

About JAIMA

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.

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.

About JFMDA

The Japan Federation of Medical Devices Associations (JFMDA) was founded in February 1984 by medical device associations consisting of manufacturers and suppliers of medical and health-care devices, equipment, instruments and materials. Since then, JFMDA has been addressing various national and international issues related to all its member associations. By taking appropriate actions on these issues, and through the support of innovation and sustainable supply of medical devices and technologies to the world, JFMDA has contributed to the growth of the industries it represents and to the improvement of welfare and health care in Japan. JFMDA became a legal entity as of January 6th, 2014.

About JIMA

Japan Inspection Instruments Manufacturers' Association (JIMA) is a corporation aggregate of manufactures and sellers for non-destructive inspection instruments and systems. JIMA is the only industry group in Japan for non-destructive inspection instruments. JIMA would eventually contribute to the safety of social capital and facilities, and quality assurance in various productions through non-destructive inspection technology, and supports the safety and reassurance of people's lives.

About JMIF

Japan Measuring Instruments Federation (JMIF) is an industrial association for measuring instruments manufacturers and related organizations/companies in Japan. JMIF was established in 1952 to develop the whole measuring instruments industry through improvement of measuring instruments, aiming to contribute to the eventual development of the Japanese economy and society.
The main activities by JMIF include supporting new technology development, conducting demand trends survey, developing domestic and overseas markets, and enhancing global cooperation.

About NECA

NIPPON ELECTRIC CONTROL EQUIPMENT INDUSTRIES ASSOCIATION (NECA) was established in 1964 and promoting the growth of the electric control equipment fields such as Relays, Switches, Sensors, PLC/FA System Equipment and others, Safety Control Equipment. NECA has 30 companies as regular members and 35 companies as support members, and shipping amount of relevant products were 812.3billion Yen in FY2022. Our website provides further information on our recent news and activities:
https://www.neca.or.jp/en/

About SEAJ

Semiconductor Equipment Association of Japan (SEAJ), founded in March 1985, promoted by the major semiconductor equipment manufacturers, is a nationwide organization of semiconductor manufacturing equipment, flat panel display (FPD) manufacturing equipment and equipment manufacturers that applied their technology and related equipment manufacturers.
SEAJ had existed as an incorporated association from July in 1995. From April 1st in 2012, SEAJ has been authorized by Cabinet Office as a General Incorporated Association that related to the reform of the public-interest corporations system.
The Japanese semiconductor manufacturing equipment, FPD manufacturing equipment and equipment industries that applied their technology is playing great role in supporting the world's semiconductor industry due to the manufacture of semiconductors, FPDs that lay the foundation of the advanced information oriented industries by supplying manufacturing equipment and the indispensable producer goods to the semiconductor industry to Japan and abroad.
In order to promote the development of the semiconductor manufacturing equipment industry and other related industries and to contribute to the further development such as investigative research on production and distribution, proposing and indicating the direction of semiconductor equipment technologies, investigating and studying the area of Emerging Technology, the activities of popularization and enlightenment by conducting of various seminars and lectures, planning of project and promotion of standardization.

About IGMA

The Industrial Gas Detectors and Monitor Manufacturers Association (IGMA) is the organization that promotes the further spread of safety equipment used in various industries such as oil refining, petrochemicals, chemical plants, and civil construction. It contributes to the prevention of workplace accidents such as explosions involving high-pressure gases, flammable gases, toxic gases, harmful gases, as well as poisonings and oxygen deficiency incidents.