

General comments and answers to specific information requests

Specific information requests:

1. **Sectors and (sub-)uses:** Please specify the sectors and (sub-)uses to which your comment applies according to the sectors and (sub-)uses identified in the Annex XV restriction report (Table 9). If your comment applies to several sectors and (sub-)uses, please make sure to specify all of them.
2. **Emissions in the end-of-life phase:** The environmental impact assessment does not cover emissions resulting from the end-of-life phase. To get a better understanding of the extent of the resulting underestimation, (sub-)use-specific information is requested on emissions across the different stages of the lifecycle of products, i.e. the manufacture phase, the use phase and the end-of-life phase. Please provide justifications for the representativeness of the provided information. In particular:
 - a. Please provide, at the (sub-)use level, an indication of the share of emissions (as percentages) attributable to these three different stages. An indication of annual emission volumes in the end-of-life phase at sector or sub-sector level would also be appreciated.
 - b. If possible, please provide for each (sub-)use what share of the waste (as percentages) is treated through incineration, landfilling and recycling. Please provide information to justify the estimates as well as information on the form of recycling referred to.
3. **Emissions in the end-of-life phase:** With respect to waste management options, additional information is requested on the effectiveness of incineration under normal operational conditions (for different waste types, e.g. hazardous, municipal) with respect to the destruction of PFAS and the prevention of PFAS emissions.
4. **Impacts on the recycling industry:** To get an understanding of the impacts of the proposed restriction on the recycling industry, information is requested on:
 - a. The impacts that the concentration limits proposed in paragraph 2 of the proposed restriction entry text (see table starting on page 4 of the summary of the Annex XV restriction report) have on the technical and economic feasibility of recycling processes (together with a clear indication on the waste streams to which the described impacts relate).
 - b. The measures that recyclers would need to take to achieve the proposed concentration limits.
 - c. The costs associated with these measures.
5. **Proposed derogations - Tonnage and emissions:** Paragraphs 5 and 6 of the proposed restriction entry text (see table starting on page 4 of the summary of the Annex XV restriction report) include several proposed derogations. For these proposed derogations, information is requested on the tonnage of PFAS used per year and the resulting emissions to the environment for the relevant use. Please provide justifications for the representativeness of the provided information.
6. **Missing uses - Analysis of alternatives and socio-economic analysis:** Several PFAS uses have not been covered in detail in the Annex XV restriction report (see uses highlighted in blue and orange in Table A.1 of Annex A of the Annex XV restriction report). In addition, some relevant uses may not have been identified yet. For such uses, specific information is requested on alternatives and socio-economic impacts, covering the following elements:
 - a. The annual tonnage and emissions (at sub-sector level) and type of PFAS associated with the relevant use.

- b. The key functionalities provided by PFAS for the relevant use.
 - c. The number of companies in the sector estimated to be affected by the restriction.
 - d. The availability, technical and economic feasibility, hazards and risks of alternatives for the relevant use, including information on the extent (in terms of market shares) to which alternative-based products are already offered on the EU market and whether any shortages in the supply of relevant alternatives are expected.
 - e. For cases in which **alternatives are not yet available**, information on the status of R&D processes for finding suitable alternatives, including the extent of R&D initiatives in terms of time and/or financial investments, the likelihood of successful completion, the time expected to be required for substitution (including any relevant certification or regulatory approvals) and the major challenges encountered with alternatives which were considered but subsequently disregarded.
 - f. For cases in which **substitution is technically and economically feasible** but more time is required to substitute:
 - i. the type and magnitude of costs (at company level and, if available, at sector level) associated with substitution (e.g. costs for new equipment or changes in operating costs);
 - ii. the time required for completing the substitution process (including any relevant certification or regulatory approvals);
 - iii. information on possible differences in functionality and the consequences for downstream users and consumers (e.g. estimations of expected early replacement needs or expected additional energy consumption);
 - iv. information on the benefits for alternative providers.
 - g. For cases in which **substitution is not technically or economically feasible**, information on what the socio-economic impacts would be for companies, consumers, and other affected actors. If available, please provide the annual value of EU sales and profits of the relevant sector, and employment numbers for the sector.
7. **Potential derogations marked for reconsideration - Analysis of alternatives and socio-economic analysis:** Paragraphs 5 and 6 of the proposed restriction entry text (see table starting on page 4 of the summary of the Annex XV restriction report) include several potential derogations for reconsideration after the consultation (in [square brackets]). These are uses of PFAS where the evidence underlying the assessment of the substitution potential was weak. The substitution potential is determined on the basis of i) whether technically and economically feasible alternatives have already been identified or alternative-based products are available on the market at the assumed entry into force of the proposed restriction, ii) whether known alternatives can be implemented before the transition period ends (taking into account time requirements for substitution and certification or regulatory approval), and iii) whether known alternatives are available in sufficient quantities on the market at the assumed entry into force to allow affected companies to substitute.

A summary of the available evidence as well as the key aspects based on which a derogation is potentially warranted are presented in Table 8 in the Annex XV restriction report, with further details being provided in the respective sections in Annex E.

To strengthen the justifications for a derogation for these uses, additional specific information is requested on alternatives and socio-economic impacts covering the elements described in points a) to g) in question 6 above.

8. **Other identified uses - Analysis of alternatives and socio-economic analysis:** Table 8 in the Annex XV restriction report provides a summary of the identified sectors and (sub-)uses of PFAS, their alternatives and the costs expected from a ban of PFAS. More details on the available evidence are provided in the respective sections in Annex E.

For many of the (sub-)uses, the information on alternatives and socio-economic impacts was generic and mainly qualitative. In particular, evidence on alternatives was inconclusive for some applications falling under the following (sub-)uses: technical textiles, electronics, the energy sector, PTFE

thread sealing tape, non-polymeric PFAS processing aids for production of acrylic foam tape, window film manufacturing, and lubricants not used under harsh conditions.

More information is needed on alternatives and socio-economic impacts to conclude on substitution potential, proportionality, and the need for specific time-limited derogations. Therefore, specific information (if not already included in the Annex XV restriction report or covered in the questions above) is requested on alternatives and socio-economic impacts covering the elements listed in points a) to g) in question 6 above.

9. **Degradation potential of specific PFAS sub-groups:** A few specific PFAS sub-groups are excluded from the scope of the restriction proposal because of a combination of key structural elements for which it can be expected that they will ultimately mineralize in the environment. RAC would appreciate to receive any further information that may be available regarding the potential degradation pathways, kinetics or produced metabolites in relevant environmental conditions and compartments for trifluoromethoxy, trifluoromethylamino- and difluoromethanedioxy-derivatives.
10. **Analytical methods:** Annex E of the Annex XV restriction report contains an assessment of the availability of analytical methods for PFAS. Analytical methods are rapidly evolving. Please provide any new or additional information on new developments in analytics not yet considered in the Annex XV restriction report.

6399	Date: 2023/07/31 18:19 Content: Scope or restriction option analysis Hazard or exposure Environmental emissions Description of analytical methods Information on alternatives Information on benefits Other socio economic analysis (SEA) issues Transitional period Request for exemption Type: BehalfOfAnOrganisation Org. type: Company Org. name: [REDACTED] Org. country: Germany Company name confidential: Yes Attachment:  ref_6399_public.zip [REDACTED] Privacy statement: because the protection of commercial interests of our company, including intellectual	General Comments: This is an update of our confidential comment #4197 given on 2023/05/19, published in document "RCOM part 10". There are major updates in nearly all chapters. Now we also provide public information. For questions 7 and 8 we provide two versions of attachments: The confidential attachments contain the complete information. For differentiation, the confidential parts are marked with yellow background. Please find our general comment in the public attachment [01_Public_PFAS_Feedback_to_ECHA_Att_General_Comment.pdf]. Answer to specific info request 1: Referring to Table 9 of the Annex XV restriction report our comments apply to "Semiconductors" - Semiconductor manufacturing process including advanced semiconductor packaging see question 7 - Semiconductor products see question 8 Answer to specific info request 5: We give information on that in question 7 and 8. Answer to specific info request 7: Full version of our input see confidential attachment [01_Confidential_PFAS_Feedback_to_ECHA_Att_Question_7.pdf]. For a version without the confidential parts see public attachment [02_Public_PFAS_Feedback_to_ECHA_Att_Question_7.pdf]. Answer to specific info request 8: Full version of our input see confidential attachment [02_Confidential_PFAS_Feedback_to_ECHA_Att_Question_8.pdf]. For a version without the confidential parts see public attachment [03_Public_PFAS_Feedback_to_ECHA_Att_Question_8.pdf]. Answer to specific info request 10: The ECHA PFAS restriction proposal restricts the use of PFAS given defined threshold limits determined by using commercially available analytical methods. We would like to emphasize that we are not aware of any commercially available methods of analysis that might be used to reliably measure the amount of the more than 10,000 PFAS substances recommended for restriction in articles, products and product components. After reviewing the analytical
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property, would be undermined.	methods proposed by ECHA in Annex E of the restriction proposal, it is unclear whether adequate "commercially available analytic methods" approved for measuring the concentration of a substance or pollutant are available to determine the amount of PFAS with the very low proposed threshold limit of 25 ppt. It should be emphasized that no suitable test method for determining the content of PFAS in an inhomogeneous product or article has yet been established or developed. As recently as March 2023, the White House National Science and Technology Council released a study on PFAS compounds, acknowledging that only a limited number of methods for detecting PFAS have been developed, with the majority of those focusing on PFAS in various media (National Science and Technology Council, 2023)[1]. There are no methods for detecting PFAS substances in articles, products or product components. The already available analytical methods include a distinct list of PFAS target analytes with specified chemical structures for which the methods have been validated, which may differ among methods. The quantity of PFAS that can be identified by focused analysis is extremely restricted. Only approximately 1% of the proposed number of PFAS substances being restricted can accurately be determined with the commercially available targeted analysis methods, which are optimized for homogeneous materials and solutions. Because there are no approved or commercially available analytical methods for detecting and quantifying PFAS chemicals in articles, products or product components, it is unclear how ECHA expects the semiconductor industry to fully comply with the proposed restriction proposal. Semiconductor product producers are now obliged to rely on their supply chain in the little time they have to gather information and identifying the usage of PFAS chemicals in the semiconductor production process may be inaccurate at best. As a result, we suggest that ECHA endorse a derogation term of at least 13.5 years for the semiconductor sector in order to enable ample time to develop analytical test procedures that are very probably required. Furthermore to circumvent this problem we suggest an higher threshold limit in articles, products and product components aligned with the REACH directive for SVHC (Council, 2007, S. § 20) of 0.1 %. The motivation behind this is that the intentionally added concentration in homogeneous materials is above 0.01% to achieve desired technical properties (Commission, Microplastic Act - amending Annex XVII to Regulation 1907/2006, 2022). In addition, non-intentionally added impurities may have concentrations up to 20% (ECHA, 2017). Lower concentrations are typically observed when PFAS are used as an additive layer to improve surface properties, or as remaining traces of a release agent. In these cases, the substance is used in the production process, which are covered by the regulation itself if not exempted. The extremely low threshold levels proposed in the universal PFAS restriction would hinder if not completely prohibit circular economy, because circular economy builds up on the reuse of also
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		contaminated materials to upcycle these i.e. in recycled plastics. This would lead to an increase of waste (Commission, A new Circular Economy Action Plan for a cleaner and more competitive Europe, 2020) and the need of additional virgin material. The simplified detection due to the higher threshold level of 0.1 % of PFAS in articles would enable the use of the bill of materials or declared substances of a product, leading to a an effective approach and search to implement alternative materials which aim at reducing usage and emissions of PFAS efficiently, rather than being hindered by PFAS traces in products. Cited Literature: Commission, E. (2020). A new Circular Economy Action Plan for a cleaner and more competitive Europe. COM/2020/98 final. Commission, E. (2022). Microplastic Act - amending Annex XVII to Regulation 1907/2006. Official Journal of the European Union. Council, E. P. (2007). Directive 1907/2006 about REACH. Official Journal of the European Union. ECHA. (2017). Identification and naming of substances. Guidance in a Nutshell, Version 2.0, ECHA-17-G-08-EN, 6. National Science and Technology Council. (2023, March). doi: https://www.whitehouse.gov/wp-content/uploads/2023/03/OSTP-March-2023-PFAS-Report.pdf
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6400	Date: 2023/07/31 18:20 Content: Hazard or exposure Environmental emissions Information on alternatives Information on benefits Other socio economic analysis (SEA) issues Request for exemption Type: BehalfOfAnOrganisation Org. type: Company Org. name: Specialty Coating Systems, Inc. Org. country: United States of America	General Comments: -
		Answer to specific info request 1: Please refer to the attached report
		Answer to specific info request 2: Please refer to the attached report
		Answer to specific info request 3: Please refer to the attached report
		Answer to specific info request 5: Please refer to the attached report
		Answer to specific info request 6: Please refer to the attached report
		Answer to specific info request 7: Please refer to the attached report
		Answer to specific info request 8: Please refer to the attached report

	Attachment:  ref_6400_public.pdf 	
6401	Date: 2023/07/31 19:45 Content: Scope or restriction option analysis Hazard or exposure Information on benefits Other socio economic analysis (SEA) issues Transitional period Request for exemption Type: BehalfOfAnOrganisation Org. type: Industry or trade association Org. name: Org. country: United States of America Company name confidential: Yes Attachment:  ref_6401_public.pdf	General Comments: -
		Answer to specific info request 1: Manufacture; Metal Plating and manufacture of metal products; Transport; Energy Sector; Construction products; Lubricants; and, Petroleum and mining.
		Answer to specific info request 6: See attached letter and analysis.
		Answer to specific info request 7: See attached letter and analysis.
		Answer to specific info request 8: See attached letter and analysis.

6402	Date: 2023/08/01 03:21 Content: Scope or restriction option analysis Other socio economic analysis (SEA) issues Type: BehalfOfAnOrganisation Org. type: Company Org. name: [REDACTED] Org. country: Japan Company name confidential: Yes Attachment:  ref_6402_public.pdf	General Comments: Hirata Valve Industry Co.,Ltd. supports the statement made by JVMA on the issues of proposed restriction, as per attached in Section IV.
6403	Date: 2023/08/01 03:28 Content: Scope or restriction option analysis Other socio economic analysis (SEA) issues Type: BehalfOfAnOrganisation Org. type:	General Comments: KOMEI MFG Co., LTD. supports the statement made by JVMA on the issues of proposed restriction, as per attached in Section IV.

	Company Org. name:  Org. country: Japan Company name confidential: Yes Attachment:  ref_6403_public.pdf	
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6404	Date: 2023/08/01 03:29 Content: Request for exemption Type: BehalfOfAnOrganisation Org. type: Company Org. name:  Org. country: Japan Company name confidential: Yes	General Comments: Fluorinated Ethylene Propylene (FEP), a fluoropolymer, is used as a Backplate (Electret board) for Electret condenser microphones. The function that FEP provides for this application is Quasi-permanent electric charge phenomenon (Electrostatic/Electret phenomenon). FEP is the only material capable of long-term charging and meeting product performance specifications. Currently, no alternative materials have been found that meet performance specifications in both the basic research and commercial sectors. We ship approximately 170,000 units per year. If FEP is prohibited by this regulation, the economic impact on the industries that use it (Recording, Conferencing, Lectures, Broadcasting, etc.) will be immeasurable, as they will no longer be able to supply such products to the market. For these reasons, we request that this matter be waived for an unlimited time derogation.
		Answer to specific info request 1: PFAS main applications and sub-uses in Annex XV report are as follows: Main applications: Electronics and semiconductors (Annex E.2.11.); and, Sub-uses: Electronic components
		Answer to specific info request 2: The percentages of emissions are as follows: The use phase 0%; and, The end-of-life phase 100%
		Answer to specific info request 5:

		This use is not included in the uses and evaluation results considered by the proponent countries and no exemptions are proposed.
		Answer to specific info request 6: b. Quasi-permanent electric charge phenomenon (Electrostatic/Electret phenomenon): The use of FEP material in Electret condenser microphones has been in the market for a long time since it was first reported in the 1960s by Gerhard M. Sessler and James E.M. West of Bell Laboratories in the United States. Since then, its use in Electret condenser microphones has had a long history in the market. c. Since Backplates (Electret boards) are always used in Electret condenser microphones, all stakeholders who manufacture and sell them, as well as related companies in the same industry and users of Electret condenser microphones, are affected. There are approximately 160 companies involved in the production (Processing, Parts purchasing, and Assembly) of our products. d. There is no availability of alternatives for related uses. In addition, there are no technically and economically feasible alternatives. e. We have considered possible alternatives, but at this time there are no alternatives that satisfy the quality and durability requirements and would require more than 12 years to complete, taking into account the duration of the alternative study. f. iii. Materials other than FEP significantly reduce long-term chargeability, resulting in poor product quality and supply shortages, and poor performance for all parties using Electret condenser microphones. g. If FEP is prohibited by this regulation, the economic impact on the industries that use it (Recording, Conferencing, Lectures, Broadcasting, etc.) will be immeasurable, as they will no longer be able to supply such products to the market.
		Answer to specific info request 7: This use is not included in the uses and evaluation results considered by the proponent countries and no exemptions are proposed. Fluoropolymers such as FEP have been reported to meet the Organisation for Economic Co-operation and Development's (OECD) Polymer of Low Concern (PLC), which determines that these resins are chemically stable, non-toxic, bioavailable, non-water soluble and non-mobile substances with no significant environmental and human health impacts. https://setac.onlinelibrary.wiley.com/doi/full/10.1002/ieam.4035
		Answer to specific info request 8: This use is not included in the uses and evaluation results considered by the proponent countries and no exemptions are proposed.
6405	Date:	General Comments:

	2023/08/01 03:33 Content: Other socio economic analysis (SEA) issues Type: BehalfOfAnOrganisation Org. type: Company Org. name: FUKUI SEISAKUSHO CO.,LTD. Org. country: Japan Attachment:  ref_6405_public.pdf	We, FUKUI SEISAKUSHO CO.,LTD. support the statement made by JVMA on the issues of proposed restriction, as per attached in Section IV.
6406	Date: 2023/08/01 03:39 Content: Scope or restriction option analysis Other socio economic analysis (SEA) issues Type: BehalfOfAnOrganisation Org. type: Company Org. name: [REDACTED] Org. country:	General Comments: HISAKA WORKS,LTD supports the statement made by JVMA on the issues of proposed restriction, as per attached in Section IV.

	Japan Company name confidential: Yes Attachment:  ref_6406_public.pdf	
6407	Date: 2023/08/01 03:52 Content: Scope or restriction option analysis Transitional period Type: BehalfOfAnOrganisation Org. type: Company Org. name: ADVANCE ELECTRIC COMPANY INC. Org. country: Japan	General Comments: ADVANCE ELECTRIC COMPANY INC. designs valves and processes in consideration of the environment. We are also working on GHG reduction in the Environmental Committee of the Japan Valve Manufacturers Association. We appreciate that we can make public comments. We produce valves that are installed in medical devices and medical analyzers. During the three years of the COVID-19 pandemic, maintenance of valves for medical devices and medical analyzers was not possible. Fluoropolymers have a high molecular weight and are more reliable than other polymers. Fluoropolymers may be of over-quality for some applications. However, they may have saved the device from failure. We memorized the lifetime of the device. It is very dangerous to betray that expectation by changing materials. If valves in the medical device sector fall under the restrictions, socio-economic benefits will suffer. There are potential risks arising from some alternatives. Those risks are expected to be greater than the risks of PFAS persistence. We demand conditions of restriction” until 13.5years after EiF”for valves in the medical device sector. The PFAS substances applying for exemption are PTFE, PVDF, CTFE, PFA, ETFE, FKM, FFM and fluorine grease. Medical devices include multi-use dialysis machines, multi-person dialysate supply machines, dialysis monitoring machines, O157 treatment machines, and ventilators. Medical devices also include medical analyzers. Medical analysis equipment includes

		automatic weighing equipment, automatic blood transfusion equipment, blood component separation equipment, microplate cleaning equipment, endoscope cleaning equipment, fully automatic electrophoresis equipment, sterilization evaluation equipment, automatic blood analysis equipment, fecal latent blood measurement equipment, biological This includes chemical analyzers, electrolyte analyzers, reagent supply for these medical devices, and sample supply equipment. We are waiting for some feedback from RAC.
6408	Date: 2023/08/01 03:55 Content: Other socio economic analysis (SEA) issues Type: BehalfOfAnOrganisation Org. type: Company Org. name: NAKAKITA SEISAKUSHO CO.,LTD. Org. country: Japan Attachment:  ref_6408_public.pdf	General Comments: We (NAKAKITA SEISAKUSHO CO., LTD.) supports the statement made by JVMA on the issues of proposed restriction, as per attached in Section IV.
6409	Date: 2023/08/01 04:06 Content: Request for exemption	General Comments: □ Poly(tetrafluoroethylene) (PTFE), a fluoropolymer, is used in food processing equipment. □ The function that PTFE provides for this application is detachability of food in food processing. □ PTFE has excellent detachable properties in food processing and is the only material that meets the performance specifications of the product. It is also more hygienic than other

Type: BehalfOfAnOrganisation Org. type: Company Org. name: [REDACTED] Org. country: Japan Company name confidential: Yes	materials because its processed surface is smoother and easier to clean. ☐The safety of this application has been approved and standardized in major countries. ☐Currently, no alternative materials have been found that meet performance specifications in both the basic research and commercial sectors. ☐We ship approximately 4,000 units per year. ☐If PTFE is prohibited by this regulation, the product cannot be supplied to the market, and the economic impact on the user industries (Hotels, Food service industry, Supermarket retailers, etc.) will be immeasurable. ☐For these reasons, we request that this matter be waived for an unlimited time derogation. Answer to specific info request 1: PFAS main applications and sub-uses in Annex XV report are as follows: ☐Main applications: Food contact materials and packaging (Annex E.2.3.); and, ☐Sub-uses: Industrial food and feed production Answer to specific info request 2: The percentages of emissions are as follows: ☐The use phase 0%; and, ☐The end-of-life phase 100% Answer to specific info request 5: The proposed regulation is greatly lacking in rationale. Safety standards for this use are clearly defined for food processing applications. Although the Annex XV report proposes for a 5-year derogation, an unlimited time derogation is considered appropriate. Answer to specific info request 6: b. Detachability of food in food processing c. PTFE is used in most of the food processing equipment on the market today and has a long history of market success. If PTFE were to be regulated, all stakeholders who manufacture and sell food processing equipment, as well as related companies in the same industry and users would be affected. There are approximately 2,000 companies involved in the production (Processing, Purchasing parts and Assembly) and use of our products. d. There is no availability of alternatives for related uses. In addition, there are no technically and economically feasible alternatives. e. We have considered possible alternatives, but at this time there are no alternatives that can satisfy the quality, and we will certainly need more than 12 years to take into account the duration of the alternative study. f. iii. Materials other than PTFE significantly reduce detachability of food in food processing, resulting in poor product quality and supply shortages and reduced performance for all parties using food processing equipment. g. If PTFE is prohibited by this regulation, the product cannot be supplied to the market, and the economic impact on the user industries (Hotels, Food service industry, Supermarket
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		retailers, etc.) will be immeasurable.
		Answer to specific info request 7: Fluoropolymers such as PTFE have been reported to meet the Organisation for Economic Co-operation and Development's (OECD) Polymer of Low Concern (PLC), which determines that these resins are chemically stable, non-toxic, bioavailable, non-water soluble and non-mobile substances with no significant environmental and human health impacts. https://setac.onlinelibrary.wiley.com/doi/full/10.1002/ieam.4035 Standards for this application have been established in major countries, and its safety for food processing applications has been recognized. Standards for this application are as follows: EU: Plastic Implementation Measure (PIM) Regulation (EC) No.1935/2004 and (EU) No 10/2011; U.S.A.: National Sanitation Foundation (NSF) Certification; and, Japan: Food Sanitation Act
		Answer to specific info request 8: The proposed regulation is greatly lacking in rationale. Safety standards for this use are clearly defined for food processing applications. Although the Annex XV report proposes for a 5-year derogation, an unlimited time derogation is considered appropriate.

6410	Date: 2023/08/01 04:32 Content: Scope or restriction option analysis Transitional period Request for exemption Type: BehalfOfAnOrganisation Org. type: Company Org. name: [REDACTED] Org. country: Japan Company name confidential: Yes	General Comments: PFASs are used in optical filters in electronic devices. Since no alternative technology has been found at this time, a regulatory option with a grace period of 7 years is appropriate. We support the statement made by FCJ on the issues of proposed restriction, as per attached in Section IV.
		Answer to specific info request 1: Optical filters in electronic devices
		Answer to specific info request 5: Attached as confidential material in Section V.
		Answer to specific info request 6: Attached as confidential material in Section V.

	Attachment:  ref_6410_public.pdf  Privacy statement: Please treat this as confidential material because it contains our product technical information, PFAS alternative study data, and confidential information regarding our market share.	
6411	Date: 2023/08/01 04:47 Content: Scope or restriction option analysis Hazard or exposure Transitional period Type: BehalfOfAnOrganisation Org. type: Company Org. name: ADVANCE ELECTRIC COMPANY INC. Org. country: Japan	General Comments: We appreciate that we can submit comments from the EU beyond. We manufacture valves installed in semiconductor manufacturing, medical devices, analytical equipment, liquid crystal flat panels, fuel cell manufacturing, LiB manufacturing, and synthetic fuel manufacturing equipment made from Co2. Those valves are not available for purchase by the general consumer. Many of them are restricted for export by governments because fluoropolymer valves are needed for chemical and biological warfare and uranium enrichment. During Valve's life it is not exposed to the general public. End-of-life valves should be properly disposed of by specialized companies in the EU. We think there are regulations for disposal, because the valves are contaminated with acidic liquid chemicals, alkaline liquids, blood, etc. The spread of PFAS substances could be prevented with additional regulations and incentives. Valves in the sectors of semiconductor manufacturing, medical devices, analytical equipment, liquid crystal flat panels, fuel cell manufacturing, LiB manufacturing, and equipment for manufacturing synthetic fuels made from Co2 pose a very small residual risk of PFAS substances. We demand conditions of restriction "until 13.5years after EiF"" for valves for semiconductor manufacturing, liquid crystal panel manufacturing, and solar panel manufacturing. These sectors and their valves have a very important mission for a sustainable society.

		We are waiting for some feedback from you. ADVANCE ELECTRIC COMPANY INC. designs valves and processes in consideration of the environment. We are working group leader for valve standards of SEMI, an international semiconductor industry association. We are also working on GHG reduction in the Environmental Committee of the Japan Valve Manufacturers Association.
6412	Date: 2023/08/01 04:54 Content: Scope or restriction option analysis Other socio economic analysis (SEA) issues Type: BehalfOfAnOrganisation Org. type: Company Org. name: MIYAWAKI INC. Org. country: Japan Attachment:  ref_6412_public.pdf	General Comments: MIYAWAKI INC. supports the statement made by JVMA on the issues of proposed restriction, as per attached in Section IV.
6413	Date: 2023/08/01 05:08 Content: Scope or restriction option analysis Transitional period	General Comments: We appreciate that we can submit comments. We produce valves that are installed in environmental analyzers and medical analyzers. Under the PFAS restriction proposal, the standard reference for PFAS analysis is a derogation without a time limit. By the same logic, environmental analyzers and medical analyzers should be derogation

	Request for exemption Type: BehalfOfAnOrganisation Org. type: Company Org. name: ADVANCE ELECTRIC COMPANY INC. Org. country: Japan	without a time limit. Environmental analysis includes ozone gas concentration measurement equipment, automatic acid rain measurement equipment, automatic ammonia measurement equipment, automatic COD measurement equipment, automatic total phosphorus and total nitrogen measurement equipment, exhaust gas analysis equipment, alkalinity meter, residual chlorine meter, multi-item water quality meter, hydrochloric acid □Automatic nitric acid analyzer, sample and reagent channel switching for environmental analyzer, channel switching for formulation sampling device, total phosphorus and total nitrogen automatic measuring device, refractometer, selenium monitor by chemical form, fluoride ion monitor, It includes a sulfur dioxide measuring device, an automatic compound sorting device, an airborne particle melting analyzer, and an ammonium fluoride monitor. Medical analysis equipment includes automatic weighing equipment, automatic blood transfusion equipment, blood component separation equipment, microplate cleaning equipment, endoscope cleaning equipment, fully automatic electrophoresis equipment, sterilization evaluation equipment, automatic blood analysis equipment, fecal latent blood measurement equipment, biological This includes chemical analyzers, electrolyte analyzers, reagent supply for these medical devices, and sample supply equipment. We would like your feedback on our opinion. Please tell me which sector of the PFAS restriction proposal the environmental analyzer falls under.
6414	Date: 2023/08/01 05:11 Content: Request for exemption Type: BehalfOfAnOrganisation Org. type: Company Org. name: [REDACTED]	General Comments: □Fluoroelastomers, a type of fluoropolymer, are used in the industrial cleaning rollers and sheets we sell. □Our products have a large market share among semiconductor manufacturers that produce semiconductor wafers. We ship approximately 1,200 units per year. □The main function that Fluoroelastomers provide for the product application is adhesion. Fluoroelastomers are more durable (heat resistance, weather resistance, abrasion resistance and chemical resistance) and less polluting than other materials, and have a longer product life. Fluoroelastomers are the only materials that meet the performance specifications of the product. □Currently, no alternative materials have been found that meet performance specifications in both the basic research and commercial sectors.

	Org. country: Japan Company name confidential: Yes	☐ If Fluoroelastomers are prohibited by this regulation, the products cannot be supplied to the market, and the economic impact on the industries that use them will be immeasurable. ☐ For these reasons, we request that this matter be waived for an unlimited time derogation. Answer to specific info request 1: PFAS main applications and sub-uses in Annex XV report are as follows: Main applications: Electronics and semiconductors (Annex E.2.11.); and, Sub-uses: Electronic components Answer to specific info request 2: The percentages of emissions are as follows: ☐ The manufacture phase 0%; ☐ The use phase 0%; and, ☐ The end-of-life phase 100% Answer to specific info request 5: This use is not included in the uses and evaluation results considered by the proponent countries and no exemptions are proposed. Answer to specific info request 6: b. Adhesion: Fluoroelastomers are more durable and less contaminating than other materials, making it possible to meet the challenging needs of user industries (e.g., Semiconductor manufacturers producing semiconductor wafers). c. Our Fluoro-elastomer-based products have a large market share in the application industry and have been on the market for a long period of time. If Fluoroelastomers are prohibited by this regulation, all of our stakeholders who manufacture and sell them, as well as related companies and users in the same industry, will be affected. d. There is no availability of alternatives for related uses. In addition, there are no technically and economically feasible alternatives. e. We have considered possible alternatives, but at this time there are no alternatives that satisfy the quality and durability requirements and would require more than 12 years to complete, taking into account the duration of the alternative study. f. iii. Materials other than fluoroelastomers not only significantly reduce adhesion, but also have a high risk of contaminating clean objects due to bleeding. This is expected to result in lower product quality and supply shortages, and lower performance for all parties using the product. g. If Fluoroelastomers are prohibited by this regulation, the products will no longer be supplied to the market, and the social and economic impact on the industries that use them will be immeasurable. Answer to specific info request 7: ☐ This use is not included in the uses and evaluation results considered by the proponent countries and no exemptions are proposed. ☐ Fluoropolymers such as Fluoroelastomers have been reported to meet the Organisation for Economic Co-operation and Development's
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		(OECD) Polymer of Low Concern (PLC), which determines that these resins are chemically stable, non-toxic, bioavailable, non-water soluble and non-mobile substances with no significant environmental and human health impacts. https://setac.onlinelibrary.wiley.com/doi/full/10.1002/ieam.4035 Answer to specific info request 8: This use is not included in the uses and evaluation results considered by the proponent countries and no exemptions are proposed.
6415	Date: 2023/08/01 05:15 Content: Scope or restriction option analysis Other socio economic analysis (SEA) issues Type: BehalfOfAnOrganisation Org. type: Company Org. name: [REDACTED] Org. country: Japan Company name confidential: Yes Attachment: [REDACTED]	General Comments: Fushiman Co. supports the statement made by JVMA on the issues of proposed restriction, as per attached in Section IV.
6416	Date: 2023/08/01 05:22 Content: Scope or restriction option analysis	General Comments: NBV supports the statement made by JVMA on the issues of proposed restriction, as per attached in Section IV.

	Other socio economic analysis (SEA) issues Type: BehalfOfAnOrganisation Org. type: Company Org. name: Nippon Ball Valve Org. country: Japan Attachment:  ref_6416_public.pdf	
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6417	Date: 2023/08/01 07:21 Content: Scope or restriction option analysis Other socio economic analysis (SEA) issues Type: BehalfOfAnOrganisation Org. type: Company Org. name: [REDACTED] Org. country: Japan Company name confidential:	General Comments: Our company supports the statement made by JVMA on the issues of proposed restriction, as per attached in Section IV.
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	Yes Attachment:  ref_6417_public.pdf	
6418	Date: 2023/08/01 07:31 Content: Scope or restriction option analysis Transitional period Type: BehalfOfAnOrganisation Org. type: Industry or trade association Org. name: Japan Valve Manufacturers' Association Org. country: Japan	General Comments: Japan Valve Manufacturers' Association (JVMA) appreciates the opportunity to provide comments to the PFAS restriction proposal. 1. Introduction JVMA was established in 1954 and has been a representative association of Japanese valve industry for nearly seventy years. As of today, we are comprised of 115 major domestic valve manufacturers including several Japanese subsidiaries of European valve makers and additional 68 associate companies. Since our establishment, we have implemented various effective programs to contribute to society, occasionally cooperating with some of Central Government Ministries and Agencies. Especially we are pouring the biggest effort to resolve environmental problems, so the Environmental Committee and four working groups in our organization are working on the following issues: - Greenhouse gas reduction. - Design for the environment of valves. - Life cycle assessment of valves. - Gathering information on restricted substances. - Environmental education. To response to the PFAS restriction proposal, we have prepared a technical and socioeconomic statement which is attached document. 2. Comment We conducted a survey on industrial fields that use valves made of fluor resin and fluor rubber. We provide Sector and Use information. These valves are used in chemical plants, water supply and drainage, water treatment, gas supply, laundry, boilers, pharmaceutical manufacturing, regenerative medicine, paper manufacturing, iron manufacturing, textiles, electrical equipment, ceramics, polishing, sawing, rare earths, environmental analysis, leisure equipment, and safety. Used in training equipment, cosmetics manufacturing, air conditioning (HVAC), food manufacturing, medical devices, precision instrument

		manufacturing, semiconductor manufacturing, electronic component manufacturing, transportation, aerospace, energy and petrochemical industries. It is difficult for us to understand Annex XV and to write comments because the sectors described in the proposed regulation are not exhaustive. We request that the valves used in those industrial fields be fully listed in the Use column of the ANNEX XV. Chemical plants include chemical industry, chemical plant facilities, plastic manufacturing, elastomer manufacturing, printing inks, photosensitive materials and fine chemical manufacturing. Water supply and drainage includes water supply facilities, building and residential applications. Water treatment categories include potable water treatment, water treatment, ultrapure water production, medical RO water production, hydrogen functional water production, ozonated water production, carbonated water production, wastewater treatment, and chemical dilution and neutralization. Gas supply areas include fuel gases, nitrogen for analysis, factory hydrogen facilities, high-purity gases for semiconductor manufacturing, etching gases for glass manufacturing, and material gases for pesticide manufacturing. Boiler includes a piping system for steam-related supply, venting, distribution, etc. Steam may be mixed with other gases. Pharmaceutical manufacturing also includes vaccine manufacturing, the manufacturing of physiological saline solutions, nutritional supplements, and functional beverages. Pharmaceutical manufacturing involves transportation of gases, liquids, and powders. Pharmaceutical manufacturing also includes the manufacturing of physiological saline solutions, nutritional supplements, and functional beverages. Pharmaceutical manufacturing involves transportation of gases, liquids, and powders. Valves for regenerative medicine are used to control cell culture fluids, fluids containing original cells, supernatants, blood and body fluids. In addition, gas such as H₂O₂ is also flowed through the valve for sterilization. Paper plants have pipelines for bleach, pH control, whitening chemicals and steam. In the ceramics industry, valves are used to supply glazes. In the field of polishing and grinding, abrasives may contain chemicals. Strong chemicals are also used for slurry removal and surface modification after polishing. The rare earth industry uses chemicals to extract certain substances from rocks. The rare earth industry also includes chemical recycling. Environmental analysis includes ozone gas concentration measurement equipment, automatic acid rain measurement equipment, automatic ammonia measurement equipment, automatic COD measurement equipment, automatic total phosphorus and total nitrogen measurement equipment, exhaust gas analysis equipment, alkalinity meter, residual chlorine meter, multi-item water quality meter, hydrochloric acid, Automatic nitric acid analyzer, sample and reagent channel switching for environmental analyzer, channel switching for formulation sampling device,
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		total phosphorus and total nitrogen automatic measuring device, refractometer, selenium monitor by chemical form, fluoride ion monitor. It includes a sulfur dioxide measuring device, an automatic compound sorting device, an airborne particle melting analyzer, and an ammonium fluoride monitor. Precision equipment manufacturing includes ozone gas generator, plating solution manufacturing and analysis equipment, concentration equipment, fully automatic viscosity measurement equipment, and high refractive liquid supply equipment. Leisure equipment uses valves to control hydraulic and pneumatic equipment and entertainment water. In the energy field, there are also fields that contribute to GHG reduction, such as the production of synthetic fuels using CO₂ as a material, the production of fuel cells, hydrogen supply facility, the production of solar panels, and the production of lithium-ion batteries. Medical devices include multi-use dialysis machines, multi-person dialysate supply machines, dialysis monitoring machines, O157 treatment machines, and ventilators. Medical devices also include medical analyzers. Medical analysis equipment includes automatic weighing equipment, automatic blood transfusion equipment, blood component separation equipment, microplate cleaning equipment, endoscope cleaning equipment, fully automatic electrophoresis equipment, sterilization evaluation equipment, automatic blood analysis equipment, fecal latent blood measurement equipment, biological this includes chemical analyzers, electrolyte analyzers, reagent supply for these medical devices, and sample supply equipment. In the semiconductor manufacturing field, valves are divided into those for chemical liquids and those for gases. Liquid chemical valves are used in cleaning process equipment, polishing equipment, wet etching equipment, immersion exposure equipment, jig cleaning equipment, liquid quality analysis equipment, and coater equipment. Gas valves are used in etching equipment, diffusion process equipment, and wafer inspection equipment. Valves are also used as flow controllers. These valves use not only fluor resins and fluor elastomers, but also fluor grease, depending on necessity. As our information indicates, the used section and Use of fluor elastomer valves is broad. Their uses are essential and critical. At a later date, the Japan Valve Manufacturers' Association and valve manufacturers will submit comments on the uses and sub-uses, as well as the technical functions required of the substances. We have not obtained other materials that can replace the multi-functionality of fluoroplastics and fluor rubbers. We may be able to develop alternatives, but we cannot prepare everything in a short period of time. For that reason, we require valves to comply with the conditions of restriction “until 13.5 years after EiF”. It is desirable that the conditions of restriction corresponding to the multiple Uses described in this comment be
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		clarified in the opinion of RAC and SEAC. We would like your feedback on our opinion and consideration of the conditions of restriction criteria. Best regards,
6419	Date: 2023/08/01 08:00 Content: Scope or restriction option analysis Transitional period Type: BehalfOfAnOrganisation Org. type: Industry or trade association Org. name: Japan Valve Manufacturers' Association Org. country: Japan	General Comments: Japan Valve Manufacturers Association (JVMA) appreciates the opportunity to provide comments to the PFAS restriction proposal. 1. Introduction JVMA was established in 1954 and has been a representative association of Japanese valve industry for nearly seventy years. As of today, we are comprised of 115 major domestic valve manufacturers including several Japanese subsidiaries of European valve makers and additional 68 associate companies. Since our establishment, we have implemented various effective programs to contribute to society, occasionally cooperating with some of Central Government Ministries and Agencies. Especially we are pouring the biggest effort to resolve environmental problems, so the Environmental Committee and four working groups in our organization are working on the following issues: - Greenhouse gas reduction. - Design for the environment of valves. - Life cycle assessment of valves. - Gathering information on restricted substances. - Environmental education. To response to the PFAS restriction proposal, we have prepared a technical and socioeconomic statement which is attached document. 2. Comment The origin of valves is thought to be wooden cocks excavated from ancient Egyptian ruins around 1000 years ago. In ancient Roman times, aqueducts were installed and bronze faucets were used. Humans have evolved civilization. The uses of valves, which started with drinking water and beer, have diversified. Valves are required to have sealing performance. Until the invention of polymers, seals were made from plant-based materials such as rope and various fibers. Rubber was the best material for the seal.

		However, along with the deepening of sealing materials, liquids and gases that decompose them have also come to be used in industry. In response, fluoropolymers and fluor elastomers have been used only where necessary. There may be no evidence left behind why the fluor resin material was selected. Factory owners and consumers will not tolerate excessive quality. Fluoropolymers and fluor elastomers have been properly adopted in various sectors over the years. Technically and economically feasible alternatives are not generally available. Loss of functionality of valve sealing could have substantial economic implications, including shorter operational lifetime of infrastructures, increased frequency and costs of maintenance, and increased operational downtimes. Valve seal parts include gaskets, packing, valve seats, linings, bearings, and press-fit seal members. We require valves to comply with the conditions of restriction “until 13.5 years after EiF”. We would like your feedback on our opinion. Best regards,
6420	Date: 2023/08/01 08:14 Content: Scope or restriction option analysis Other socio economic analysis (SEA) issues Type: BehalfOfAnOrganisation Org. type: Company Org. name: [REDACTED] Org. country: Japan Company name confidential: Yes Attachment:	General Comments: Nippon Ball Valve is supports the statement made by JVMA on the issues of proposed restriction,as per attached in SectionIV

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