



September 20, 2023

**JP4EE comments and questions to An Act To Stop Perfluoroalkyl and Polyfluoroalkyl Substances Pollution (LD 1503, 130<sup>th</sup> Legislature) and Public Law 2023, c. 138, An Act to Support Manufacturers Whose Products Contain Perfluoroalkyl and Polyfluoroalkyl Substances (LD 217, 131<sup>st</sup> Legislature)**

The Japanese electric and electronic (E&E) industrial associations – JEITA, CIAJ, JBMIA and JEMA (JP4EE) – hereby express gratitude to the Maine Department of Environmental Protection’s for years of efforts to preserve, improve and prevent diminution of the natural environment of the State. We conduct our businesses in the US and all over the world and are firmly committed to protecting human health and the environment and to complying with chemical substance legislations as defined by the countries and regions where we operate. Also, we support active prevention or minimizing chemical pollution by PFAS. In this spirit, we have carefully and conscientiously reviewed “An Act To Stop Perfluoroalkyl and Polyfluoroalkyl Substances Pollution (LD 1503, 130<sup>th</sup> Legislature)” and the Public Law 2023, c. 138, An Act to Support Manufacturers Whose Products Contain Perfluoroalkyl and Polyfluoroalkyl Substances (LD 217, 131<sup>st</sup> Legislature), and would like to submit our comments and recommendations.

It is worth to note that most of our comments are those that JP4EE has previously submitted during the past public consultations, and are based on our serious concerns regarding the feasibility of satisfying the requirements under the Act. This has also resulted in our request to refer to the US TBT enquiry point from the Japanese government as these issues impact the entire industries in Japan.

First, we believe the fundamental issue is that the Act seems to treat chemical products and articles (or manufactured items) the same. Examples of articles include devices that utilize the physical properties of chemical substances and set equipment that function by combining different devices. PFASs, as defined in the Act, consist of a broad scope of substances, and PFASs may be contained in many electric and electronic equipment (EEE) because of their functional and indispensable qualities (e.g. water repellency, oil repellency, heat resistance, chemical resistance, reflexivity, etc.). In contrast, as stated below, the current requirements under the Act exceed the EEE industry’s current best practices, thereby increasing our concerns about the feasibility of complying with the requirements. Even if articles were in the scope, we do not believe that regulating articles would contribute to fulfilling the objectives of the Act of reducing the negative impact to human health and the environment. Additionally, we are concerned that the citizens, as well as the economy, of Maine would be negatively impacted due to the restriction of the sale and distribution of essential EEE that are found to be noncompliant to this PFAS law.

Therefore, we, JP4EE would like to propose following items in order for feasible legislation considering the balance between DEP’s policy objectives and industry’s best effort.

## **1. EEE and parts used in EEE to be excluded from the scope (for reporting and prohibition of sales requirements)**

EEE and parts used in EEE should be excluded from the scope of the Act from following reasons.

### 1) Exposure from articles results in minimal impact to environment

During the use of articles like EEE, it is presumed that PFAS exposure is generally negligibly low compared to PFAS exposure from PFAS substances/mixtures themselves<sup>1,2</sup>. The 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 exposure through consumer products is negligible. In articles, fluoropolymers are firmly integrated into the polymer matrix and are contained in very small amounts. Furthermore, due to their extremely low vapor pressures (approximately  $10^{-4}$  Pa), PFASs are not emitted into the environment. Even if very limited amounts were emitted or eluted from articles, it would not at a level that affects human health or the environment.

It is also presumed that the environmental impact of PFAS from EEE (i.e. articles) is extremely low since certain types of EEE distributed to general consumers are properly managed in accordance with the State of Maine's recycling law.

### 2) Sufficient information cannot be obtained even with the industry's best efforts

EEE manufacturers specify, to their suppliers, the primary materials and/or necessary specifications of parts or components to be supplied, but besides from the substances that are legally restricted, they rarely specify the chemical substances contained in each article. In most cases, EEE (finished goods) manufacturers themselves rarely use PFAS substances or PFAS-containing mixtures. Users of such chemicals/mixtures may not be the "first or second direct tier" suppliers for the EEE manufacturers, but may be material manufacturers located further upstream in the supply chain. EEE manufacturers may be unable to directly communicate with such upstream suppliers. Therefore, EEE manufacturers have no choice but to rely on substance information communicated through their direct channels. The information that the EEE manufacturers ultimately receive from these direct channels may consist of information from suppliers further upstream. For complex articles like EEE, the supply chain spreads globally and it is difficult to conduct investigations of the use of PFAS throughout the entire supply chain.

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<sup>1</sup> According to 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>

<sup>2</sup> 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>

### 3) Identifying PFAS and its concentration by scientific analysis are impossible

This Act requires reporting the concentration of each PFAS in a product or product component, as identified by its Chemical Abstracts Service (CAS) registration number, or as the amount of total organic fluorine if the amount of each PFAS compound is not known.

Even if we were to try to analyze the amount of PFAS contained in articles, to the best of our knowledge, there is no internationally-recognized analytical method that can quantify the amount and identify PFAS at a CAS RN level (except for certain types of PFASs). Therefore, EEE manufacturers are unable to obtain precise information of PFAS contained in articles through scientific analysis. The EPA discloses PFAS analytical methods on their website<sup>3</sup>, but for the PFAS subject to the Act and the Rule, no analytical methods for PFAS in articles are listed.

In addition, although the report on total organic fluorine is accepted, Combustion-Ion Chromatography (CIC) detects both organic and inorganic fluorine, and is unable to detect only total organic fluorine.

Even if total organic fluorine were capable of being detected through testing, it would not be realistic for EEE manufacturers to analyze the total organic fluorine of all of the products that are or will be distributed in the State of Maine. EEE consists of hundreds or thousands of components, thereby making it impractical for manufacturers to test for each and every one of these components.

As referenced below, the European Chemical Agency (ECHA) recommends in their Guidance (on requirements for substance in articles) that analysis not be conducted for articles, and also mentions the difficulties associated with assigning suitable analytical methods for unidentified substances.

***Guidance on requirements for substances in articles (version 4.0)***

[https://echa.europa.eu/documents/10162/2324906/articles\\_en.pdf](https://echa.europa.eu/documents/10162/2324906/articles_en.pdf)

*5.2 Chemical analysis of substances in articles*

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*It is to be noted that chemical analyses may yield ambiguous results and/or be very costly and are thus not recommended as the preferred instrument for obtaining information.*

*5.2.1 Challenges of chemical analyses*

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*If the identity of the substances of potential concern is not known, it may be difficult to assign suitable analytical methods.*

Based on the abovementioned reasons, we propose that EEE and parts used in EEE be excluded from the scope of the Act.

If EEE and their parts are ultimately kept within the scope of the Act, we would like to propose the following to allow

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<sup>3</sup> PFAS Analytical Methods Development and Sampling Research

<https://www.epa.gov/water-research/pfas-analytical-methods-development-and-sampling-research>

the industry to satisfy the requirements to the best extent possible.

## **2. Limiting PFAS subject to the notification and subsequent prohibition**

PFAS is the generic name for fluorinated organic compounds. It is not a single chemical substance but consists of multiple substances. EPA's PFAS master list includes fluoropolymers such as Polytetrafluoroethylene (PTFE) and Polyvinylidene fluoride (PVDF), which are widely used for water and oil repellency purposes. Fluoropolymers are large, stable, insoluble molecules that are neither bioaccumulative nor bioavailable and that have been demonstrated to satisfy internationally-accepted criteria for polymers of low concern<sup>4</sup>. Despite the fact that most of PFASs are not identified as hazardous, we are concerned that presuming them hazardous as simply "PFAS" and imposing notification and prohibition requirements would unnecessarily restrict trade.

Targeted substances (subject to the notification and prohibition requirements) should be prioritized based on their risk assessments and limited only to high priority substances. Specifically, we propose that PFASs that have been internationally-recognized to be harmful to be targeted first, and then those that have been determined to be harmful be subsequently added as regulated substances. In addition, the list of target substances should be specifically identified to allow for accurate transmission of information throughout the supply chain.

## **3. Setting the reporting threshold (for reporting requirements)**

Most of our members have established and are implementing extensive chemical management programs. These chemical management programs are designed to ban or restrict the presence of chemical substances throughout the complex global supply chain in conformance with global laws and regulations applicable to EEE. However, the companies operating such management programs do not require their suppliers to identify the presence and amount of each and every chemical substance contained in every article.

It might be manageable throughout the supply chain if a de minimis threshold for reporting is set at 0.1 % by weight, and unique identifiers (CAS RNs) are provided for substances subject to reporting and subsequent prohibition, provided that the targeted substances for reporting and prohibition be based on the results of their risk evaluation.

## **4. Accepting "Known to or Reasonably Ascertainable by" reporting standard (for reporting requirements)**

As we explained above, due to the complexity of the EEE supply chain, significant time is required to determine the use/non-use of unregulated PFAS. While the industry is committed to conducting its due diligence in good faith to compile as much information as possible throughout the supply chain, there may be instances where information cannot be collected from upstream suppliers despite the industry's best efforts. Companies do not wish to be held as being inadvertently noncompliant in such instances.

With respect to chemical reporting rules, EPA accepts a "known to or reasonably ascertainable by" reporting standard<sup>5</sup>. This is the standard that the EPA utilizes for the Quadrennial Chemical Data Reporting Rule (TSCA (Toxic

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<sup>4</sup> Korzeniowski, S.H., et al. 2022. A critical review of the application of polymer of low concern regulatory criteria to fluoropolymers II: Fluoroplastics and fluoroelastomers. *Integr Environ Assess Manag*, 19: 326-354. <https://doi.org/10.1002/ieam.4646> ; Henry, B.J., et al. 2018. A critical review of the application of polymer of low concern and regulatory criteria to fluoropolymers. *Integr Environ Assess Manag*, 14: 316-334. <https://doi.org/10.1002/ieam.4035> .

<sup>5</sup> <https://www.epa.gov/chemical-data-reporting/completing-form-u#report>

Substance Control Act), Title 40, Chapter I, Subchapter R, Part 711 Chemical Data Reporting Requirements). Under this standard, a company will be compliant with the reporting requirements as long as the company conducts its due diligence and accurately reported the information that the company could reasonably obtain. The Act should accept a similar “Known to or Reasonably Ascertainable by” reporting standard for articles.

For example, in many cases, specific chemical composition of functional materials is considered as CBI (Confidential Business Information) and is not communicated to downstream users beyond the information necessary for its safe use. For impurities originated during the manufacturing process, such information is not going to be transmitted to downstream entities due to confidentiality. Therefore, such CBI should be exempted from notification since finished goods manufacturers (i.e. EEE manufacturers) are unable to obtain such information.

#### **5. Only final products (finished goods) should be subject to notification and prohibition**

While we requested EEE and parts used in EEE to be excluded from the reporting and prohibition requirement (as mentioned above), if the DEP ultimately includes articles within the scope of such requirements, we request that only finished goods delivered to end-users to be within the scope, and that spare (repair/replacement) parts for existing products manufactured prior to the sales prohibition date be excluded from the reporting and prohibition requirements. Products (that contain intentionally-added PFAS) that were manufactured prior to the prohibition of sales may require the use of PFAS-containing parts for their proper use and repair, and the exclusion of spare parts allows such products to be repaired and used for a longer period of time, thereby reducing unnecessary waste.

#### **6. Industry’s Comments and Concerns Should be Taken into Consideration to Determine “Currently Unavoidable Use”**

The Act exempts companies from the notification and prohibition of sale requirements if the PFAS contained in the product is for a “currently unavoidable use.” When determining the criteria for “currently unavoidable use,” we ask that the department take industry’s concerns and comments into consideration.

#### **Questions to the Maine DEP**

##### 1. Future Rulemaking

With the enactment of LD217, will the [posting draft](#) of the rule be further amended? If so, we request to know the schedule for the new rulemaking.

##### 2. Extension of the reporting deadline

We understand that the department granted extensions to the reporting deadline for companies that applied for such extensions. We believe this extension was granted under Public Law 2021, c. 477, and we assume that the extension will remain in effect even though LD217 was enacted. Is this assumption correct?

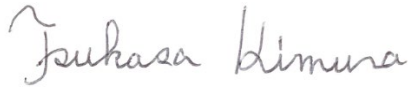
#### **Conclusion**

We hope our comments provide substantive information to ensure the smooth and practical implementation of PFAS management to realize a healthy environment and a sustainable economy for the present and future

generation in the State of Maine. We are looking forward to hearing your feedback at the meeting.

We wish to work together with the DEP to make the Act and the Rule feasible for implementation. Should you have any questions, please do not hesitate to contact the JEITA secretariat.

Sincerely yours,

A handwritten signature in cursive script that reads "Tsukasa Kimura".

Tsukasa Kimura

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## About Japanese electric and electronic (E&E) industrial associations (JP4EE):

### 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) 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/>