



May 18, 2023

Mr. Mark Margerum

17 State House Station

Augusta ME, 04333-0017

Department of Environmental Protection,

The State of Maine

**Re: Posting draft of Chapter 90: Products Containing Perfluoroalkyl and Polyfluoroalkyl Substances**

Dear Mr. Margerum

The Japanese electric and electronic (E&E) industrial associations - JEITA, CIAJ, JBMIA and JEMA<sup>1</sup> (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, 130th Legislature)" enacted on July 15, 2021 and the posting draft "Chapter 90: Products Containing Perfluoroalkyl and Polyfluoroalkyl Substances - Posting draft" issued in January 2023 and would like to submit our comments and recommendations.

It is worth to note that the most of our comments are those JP4EE has repeatedly submitted at the past public consultations based on our serious concerns on feasibility of the Act and the posting draft, and also requested a reference to the US TBT enquiry point from Japanese government as issues related to entire industries in Japan.

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

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<sup>1</sup> JEITA (Japan Electronics & Information Technology Industries Association), CIAJ (Communications and Information Network Association of Japan), JBMIA (Japan Business Machine and Information System Industries Association), and JEMA (The Japan Electrical Manufacturers' Association)

generation in the State of Maine.

### **General comment**

First of all, the fundamental issue is that the Act and the posting draft Rule seems to equally treat the chemical products and articles, or manufactured items. An article is the object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition. The complicated articles such as Electrical and Electronic Equipment (EEE) are required to maintain their quality and performance during their product life which is quite long. The design engineers usually select materials with high durability and EEE, as durable articles, are designed not to release contained chemicals into the environment during its life as much as possible. Since articles generally have very low risk of emission of chemicals in articles, are internationally controlled in the different way from chemical products.

Although we don't still have perfect information on PFAS contained in articles, PFASs defined in the Act and the posting draft Rule varies and we think there is a possibility that PFASs are contained in many EEE because of the useful and indispensable specifications (e.g. water repellency, oil repellency, heat resistance, chemical resistance, reflexivity, etc.). On the other hand, as stated below, we recognize that most of EEE would not be able to comply with the requirements currently proposed, and even if articles would be still in scope, not only we believe that it would not expect to reduce impact to human health and environment, which is a purpose of the Act, but also we are concerned that citizens and economy in Maine would be facing disadvantage because of not distributing EEE which would be essential for daily life but not be compliant.

#### **1. Article containing PFAS to be excluded from the scope**

In order to achieve Maine's policy objectives and make the Rule feasible, articles should be excluded from the scope by following reasons.

##### 1) Exposure from articles has a small impact to environment

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<sup>2, 3</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 negligible exposure through

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<sup>2</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>3</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>

consumer products. In articles, PFASs are firmly integrated into polymer matrix 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 recycling law in the State of Maine.

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

Generally, what article manufactures have been doing is to specify major materials and/or necessary specifications of parts or components to be supplied and they hardly specify each chemical substance contained in each article excepting for substances legally restricted.

In most cases, EEE manufacturers hardly use PFAS own or any mixtures including PFAS. Additionally, user of such chemicals might be not the "first or second tier" suppliers but more upstream material manufacturers, where manufacturers of final articles cannot directly reach out.

Especially for complex articles like EEE, their supply chain spreads globally and it is difficult to carry out the thorough investigation of PFAS usage along the entire supply chain. From our experience, even if we could obtain information that a certain fluorinated compound is used in a certain usage, it was almost impossible for article manufacturers to identify whether the compound is PFAS or not. Also, since many suppliers might be located in countries or regions outside the US where the PFAS requirements are not applicable, we cannot oblige them to provide detailed information on very tiny amounts of substances contained in articles.

In many cases, specific chemical composition of functional materials is considered as confidential business information and is never communicated to downstream users beyond the necessary level for safe use. In case of impurities and/or byproducts originated in manufacturing process, such information is not going to be transmitted to downstream users due to confidentiality. In such a case, even chemical manufacturers themselves might not be able to know the information unless high precision analysis is carried out. For example, none of our member companies could have obtained the concrete chemical name of PFOA-related substances which are covered under applicable derogations in the Stockholm Convention.

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

This posting draft requires reporting a concentration of each PFAS in a product or product component, as identified by its Chemical Abstracts Service (CAS) registration number.

Even if we would try to analyze PFAS contained in articles, as long as we know, there is no internationally-recognized analytical method which can identify the PFAS at CAS RN level and its amount excepting certain PFASs and therefore EEE manufacturers cannot obtain precise information

of PFAS contained in articles by analysis.

For example, the EPA discloses PFAS analytical methods on their website<sup>4</sup> but for PFAS subject to the Act and the Rule, no analytical method for PFAS in articles is listed.

For other detailed comments other than those stated in this letter, it would be appreciated if you could refer our comments to the 2<sup>nd</sup> concept draft.

Despite the justifications above, if DEP is willing to include articles into the scope of the Rule, we would like to propose following recommendations in order to make the Rule realistically feasible.

## **2. Limiting PFAS subject to the notification**

We thank DEP narrowed the scope of notification into PFAS having CAS RN.

PFAS is the generic name for fluorinated organic compounds. It is not a single chemical substance but a group of 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. Although most of PFASs are not identified as hazardous, it would be no environmental benefit to regard those as one group, presume as hazardous and impose reporting and restriction. Therefore, target PFASs should be prioritized based on sufficient risk evaluation and limit to high-priorities. In addition, the list of target PFASs should be provided in order for precise information transmission along the supply chain.

## **3. Granting extension of notification for 4 years at a minimum**

While DEP granted to extend the deadline for the submission until 6 months after the effective date of the Rule, this period of extension is simply not sufficient.

There are countless types of products in EEE and the companies have different experiences on the notification. We would like to request at least a 48-month extension even if DEP limits PFAS as requested above.

In addition, even though manufacturers show good faith efforts to comply with the rule, if further period would be needed to collect necessary information, we would like to request that the DEP creates a waiver process for companies to apply for further extension (related to comment 10).

If DEP does not limit PFAS and requires notification for more than 10,000 PFAS, it must be recognized that it is impossible to even estimate how many years it will take for manufacturers to collect that information.

Furthermore, the posting draft contains the conditions and the ways of notification clarified by the online notification system stipulated in section 3. A. (1) (c) (i) but the system has been completed yet. It is not possible to determine the necessary information for the notification in this situation and to initiate the

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<sup>4</sup> PFAS Analytical Methods Development and Sampling Research

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

investigation.

From the reasons above, we would request that;

1. Notification requirement starts after adoption of the Rules and completion of the notification system, and;
2. DEP gives a transition period of at least four years from the point of completion of the system.

#### **4. Setting the reporting threshold**

Most of our members have established and been operating extensive chemical management programs which are intended to ban or restrict the presence of chemical substances among complex global supply chain in conformity with global legislations applicable to EEE. However, the companies operating such management programs do not require their suppliers to identify the presence and amount of every chemical type for every article. Reporting thresholds are set to substances required for reporting in such programs.

It might be manageable among supply chain if a de minimis threshold for reporting is set at 0.1 % by weight and a unique identifier like CAS RN is clearly designated to substances subject to reporting, after targeting substances for reporting based on screening-level risk evaluation. By incorporating the substances into global standards like IEC62474, actors in the supply chain might be able to obtain this level of information from communication among supply chain.

Following conditions are what is desirable for feasible and operatable notification.

#### **5. Accepting "Known to or Reasonably Ascertainable by" reporting standard**

As we explained above, due to the complexity of EEE supply chain, significant time is required to determine the use/non-use of unregulated PFAS. It is not desirable to be judged as non-conformity due to the lack of a few information which is unable to collect despite collecting most of necessary information thanks to huge efforts in industries including entire supply chain.

With respect to chemicals reporting rules, EPA accepts "known to or reasonably ascertainable by" reporting standard<sup>5</sup>. This is the standard that the EPA uses for the requirements of the Quadrennial Chemical Data Reporting Rule and is also the proposed standard for the PFAS reporting rule (TSCA section 8(a)(7)). Under this standard, compliance with reporting requirements would only be justified if a company performs an appropriate level of due diligence and accurately reported what it knew or learned. The posting draft rule should also accept the "Known to or Reasonably Ascertainable by" reporting standard for articles.

#### **6. Accepting PFAS amount by data or declaration from upstream suppliers**

There is no internationally-recognized analytical method which can identify the PFAS at CAS RN level

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

and its amount excepting certain PFASs. Final product manufacturers like EEE manufactures in the downstream of the supply chain utilize a program to manage information on substances in articles along the broad supply chain and rely on the information from upstream suppliers. If “commercially available analytical methods” are required for determining the amount of PFAS, applicable analytical methods for PFAS in articles should be provided as well. Otherwise, the substances information or declaration provided by upstream suppliers via the abovementioned program should be accepted.

For reference, the European Chemical Agency (ECHA) states, in the Guidance on requirements for substance in articles, that not recommending analysis for articles and difficulties of assigning suitable analytical methods as below.

**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.*

**7. Only final products to be subject to notification**

While we requested articles to be excluded from reporting and prohibition as above, if the DEP would decide certain articles to be subject to notification, we request that only the final products delivered to the consumer to be fallen within the scope.

**8. Exempting confidential business information (CBI) from notification**

In many cases, specific chemical composition of functional materials is considered as CBI and is never communicated to downstream users beyond the necessary level for safe use. In case of impurities originated in manufacturing process, such information is not going to be transmitted to downstream users due to confidentiality. Therefore, such CBI should be exempted from notification since final product manufacturers like EEE manufactures cannot collect.

A possible alternative would be introducing the system that upstream suppliers who have the CBI directly provide DEP with the CBI like joint submission which is accepted under TSCA inventory notification<sup>6</sup>.

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<sup>6</sup> <https://www.epa.gov/chemical-data-reporting/asserting-confidential-business-information-cbi-claims-and-certification#part2joint>

#### **9. Accepting notification of PFAS as an amount**

While 38 M.R.S. §1614 requires notification of PFAS as an amount, the posting draft requires as “a concentration”. For complex articles like EEE which consist of hundreds or thousands of parts/components, it is quite burdensome and not feasible to calculate PFAS concentration per product for each PFAS because same or different PFAS could be contained in multiple parts and/or components by different concentrations. As originally required in the Act, PFAS notification as an amount should be accepted. Furthermore, for improving efficiency, following reporting method would be desirable; DEP to show a range of PFAS amount as options so that applicants can simply tick the either of the options instead of inputting individual amount.

#### **10. Adding a condition of waiver**

DEP should add a new waiver condition like “other reasons” as a reason to apply waiver request.

In following case for example, waiver should be allowed.

- Upstream supplier is reluctant to submit CAS RN due to confidential reason
- No reasonable and practical substitution exist for certain PFAS

#### **11. Relaxing the range of the reporting unit**

We thank that DEP have allowed to use HTS number for the reporting unit. Moreover, in order to reduce EEE manufacturers’ burden without hampering DEP’s purpose, we would like to ask for relaxing the requirements for the products for which one time notification specified in 3. Notification C. as follows and accepting reporting with total amount of respective PFAS in products in the same product group.

##### 1) Allowing higher level of category hierarchy

We would request to amend “a single GPC brick code or a HTS number” specified in 3.Notification C.(1) as the reporting unit to the higher level of the category hierarchy.

We understand that DEP aims, in the reporting requirements, to understand uses of PFAS and identify currently irreplaceable uses of PFAS.

On the other hand, even if GPC or HTS number is changed to the higher level, information on PFAS contained in the products would not be changed and DEP will still be able to sufficiently understand uses of PFAS in products since PFASs are used as irreplaceable use for common parts of EEE.

In addition, we believe if DEP accepts reporting as GPC or HTS numbers in the higher level, it will be able to reduce the excessive administrative and financial burden for EEE manufacturers, who are required to report for all products which are thought to have very little potential PFAS exposure to human health and the environment because not completely equal but very similar products can be reported at once.

Concretely, GPC and HTS number should be changed to the higher level as follows.

-HTS number: using the first 4-digits number that is an internationally standardized number and deleting last 2-digits number that is an extended code set out uniquely in the US from the total 6-digits number originally required.

-GPC: although GPC is internationally standardized code, grouping by Class that is in one higher level than Brick code in the bottom of the category hierarchy.

## 2) Deleting requirements on PFAS containment

We would request deleting following conditions,

- C (2): The same PFAS are present in every product, and

- C (3): Each PFAS is present in every product, either (a) In a substantially similar amount as determined by a commercially available analytical method, or (b) If reporting by range of concentration is available, within the same concentration range.

As stated in 1), we believe even if higher level of GPC or HTS number would be used in reporting, information on PFAS contained in the products would not be changed.

However, importers of articles in downstream supply chain are not able to collect complete information to satisfy the conditions stated in C.(2) and (3).

Firstly, for use of PFAS that has not been internationally regulated, information on the detailed composition of chemical products may be subject to confidential information. As there is no country where all PFAS are regulated, suppliers outside the U.S. do not always provide information beyond legal requirements in their own country with final product manufacturers.

Secondly, it is impossible for recipients of articles (i.e. final product manufacturers) to analyze the articles and identify each PFAS contained. Analytical methods, which are internationally recognized and enable to identify types and amount of most PFAS in articles except some PFAS, have not been established.

As described above, we believe the conditions stated in C. (2) and (3) do not achieve the purposes of understanding uses of PFAS and identifying currently irreplaceable use of PFAS. Also, although it will not contribute to providing additional information, the requirements will simply owe huge administrative and financial burden to EEE manufacturers. Therefore, such conditions should be deleted.

## **Conclusion**

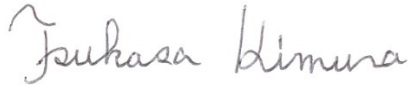
We support active prevention or minimizing chemical pollution by PFAS and submitted comments and recommendation based on serious concerns on the feasibility of the Act and the posting draft Rule. We hope our comments would provide substantive information on smooth and practical implementation of PFAS management to realize a healthy environment and a sustainable economy for present and future



generation in the State of Maine.

We would welcome to work together with DEP to make the Act and the Rule feasible. Please contact JEITA secretariat whenever necessary.

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/>