



November 10, 2022

Maine Department of Environmental Protection
PFASProducts@Maine.gov

Re: 2nd Concept Draft for the Maine PFAS in Products Program

JEITA (Japan Electronics & Information Technology Industries Association)

CIAJ (Communications and Information Network Association of Japan)

JBMIA (Japan Business Machine and Information System Industries Association)

JEMA (The Japan Electrical Manufacturers' Association)

To whom it may concern,

The Japanese electric and electronic (E&E) industrial associations - JEITA, CIAJ, JBMIA and JEMA¹ - 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 regulations as defined by the countries and regions within which we operate. 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 "2nd Concept Draft for the Maine PFAS in Products Program" issued in October 2022 and would like to share our comments and recommendations.

We hope the contents of this letter 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 Maine.

Please note that this issue may have much effect on the global supply chain. We are the industrial associations in Japan, but we will have to take measures for the Maine legislation via our U.S. companies. Therefore, we would appreciate it very much if Maine DEP kindly send us any future development, e.g., notifications about the application for postponement or about Webinar, via our secretary.

¹ The Japanese electric and electronic (E&E) industrial associations - JEITA, CIAJ, JBMIA and JEMA represent 900 member companies in total including electrical and electronic equipment, products and components manufacturers of electronics and information technology (IT) industries, info-communication network industries, business machine and information system industries, and electrical industries such as power & industrial systems, home appliances and related industries. Our members provide vast variety of products for homes and businesses across the U.S. See details of each association at the end of this letter.

Fundamental comments to the Maine PFAS in Products Program

One of the most fundamental difficulties in this issue is that the way of handling of the chemical products and that of articles, or manufactured items, are basically the same. 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 EEE are required to keep their quality and performance in their durable life. Therefore, the design engineers would usually select a material with high durability. EEE, as durable articles, are designed not to release contents into the environment during its useful life as much as possible. Generally speaking, as the risk of emission of chemicals contained in articles from finished products would be low in most cases, they are internationally managed in the different way from chemical products.

Therefore, we would like to reiterate here that, in order to make this rule feasible and to realize legitimate objectives, it is essential to exclude articles from reporting and prohibition requirements as well as limiting PFAS as is described follows.

1. Excluding PFAS-containing articles from its scope

The reasons why it is essential to exempt articles from reporting and prohibition are described in 1) to 7) below;

- 1) Generally, what article manufactures have been doing is to specify main materials and/or necessary specifications of final products to be supplied and they hardly specify each substance contained in each article excepting for substances legally restricted.
- 2) In most cases, manufacturers of final articles hardly use PFAS compounds on their own or any mixtures including PFAS above SDS-reportable level. Additionally, user of chemicals in the upstream supply chain might be not the “first tier” or “second tier” supplier but be more upstream material manufacturers, where manufacturers of final article cannot directly reach out.
- 3) In case of complex articles, it is difficult to carry out PFAS investigation throughout entire supply chain. From our experience, even if an article manufacturer obtains information that a fluorinated substance is used for a certain use, it is almost impossible to identify whether it was PFAS or not. For example, while we suppose substances used in articles as alternatives of PFOA might contain PFAS, none of our members were able to obtain specific chemical identity information for the replacement substances from upstream supply chain.
- 4) Especially for complex articles like EEE (Electrical and Electronic Equipment), their supply chain spreads globally. Many suppliers might be located in countries/regions where PFAS requirements are not applicable. Manufactures of final articles cannot obligate those suppliers (in case of not first tier suppliers, in particular) to provide detailed information on very tiny amounts of substances beyond SDS requirements in their countries. Also, since SDS is a document to list hazard information of chemicals contained in a chemical product, not all chemicals contained are listed.

Furthermore, as article is exempt from requirements for Safety Data Sheets (SDS) in many countries, it is difficult for a finished products manufacturer even to obtain SDS from upstream article suppliers. Fortunately, even if an article manufacturer obtains SDS from upstream suppliers, what is listed there is only PFAS substances which are classified as hazardous.

For your information, we show below our knowledge about the usage of PFOS and PFOA, which are the kinds of PFAS concluded to be globally restricted through the risk assessments under the Stockholm Convention. Please note that the finished products manufacturers would have only been able to get the information on the possibilities of use of some PFOS- or PFOA- related substances in these applications. For complicated articles, we had hardly been able to get any information on concrete substance identification such as CAS No., even in the investigations on these substances which are already banned by the international convention.

- 5) Specific chemical composition of functional materials, in many cases, is considered as trade secret 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 trade secret considerations. In some instances, it might be possible that even chemical manufacturers themselves do not know the information unless high precision measurement is carried out. For example, none of our members has been able to obtain the concrete chemical name of PFOA-related substances which are covered under applicable derogations in the Stockholm Convention.
- 6) An exposure amount of PFAS during article usage is generally presumed as negligibly low compared with the exposure of the PFAS as chemicals^{*1,*2}. 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, with negligible exposure through consumer products. PFAS is firmly integrated into polymer matrix in articles and is contained in very small amounts. PFAS have also an extremely low vapor pressure (about 10^{-4} Pa), therefore they are not emitted into the environment. In addition, they do not dissolve into the environment even when exposed to acid rain because PFAS are insoluble in water. Even if a very limited amount is emitted or eluted from articles, it is not considered to be a level that affects humans or the environment. In addition, it is also presumed that environment impact from EEE (i.e. articles) is extremely low since certain EEE distributed to general consumers are properly managed in accordance with recycling law in Maine. Based on such scientific proofs, there are no PFAS regulations for articles including EEE in the United States and globally, and even if articles are subject to regulation in the first place, it is unlikely that the objective of this regulation, which is to protect people and the environment in Maine, will be achieved.

References;

*1: 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>

*2: According to Duke Nicholas School of the Environment, PFAS percutaneous exposure via skin contact is negligibly low although inhalation of PFAS absorbed to house dust migrated out from PFAS-containing carpets and/or furniture might be possible.

<https://sites.nicholas.duke.edu/pfas/files/2020/08/Duke-NSOE-PFAS-Background.pdf>

7) Articles would fail to meet the reporting requirements required by this concept draft.

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

Furthermore, several sections require the “amount as determined by a commercially available analytical method” for each PFAS.

However, as long as we know, there is no analytical method which can identify the PFAS at CAS number level even in the chemical products. Moreover, the analytical measures for articles are much more complicated and difficult than those for chemical products. Generally speaking, chemicals in articles cannot be analyzed as they are. The preparation of test samples from the complicated articles to the form which can be tested is indispensable to analyze the contents, however, there are no internationally-recognized standards for such preparation.

In the first place, tens of thousands of many different kinds of parts may be incorporated in a complicated product, and the possibility of content of PFAS and kind of PFAS contained would be different depending on the part. As the result, it would not be feasible to detect the exact identification of each contained PFAS out of 12,000 kinds of similar substances either by analytical method or via investigation through supply chain, much less about the amount of each PFAS.

From these facts, we believe that it would be unfeasible for complicated articles to report the concentration of each PFAS with CAS number.

For these reasons above, it is not appropriate to require reporting of PFAS concentrations for articles because there is no environmental benefit while only impose a significant burden on the business.

2. Limiting PFAS subject to this program

Next, we would like to describe the reasons why it is necessary to limit PFAS subject to this program as follows;

PFAS is the generic name for fluorinated organic compounds. It is not a single chemical substance but a group of substances containing more than 12,000 chemical substances according to EPA’s PFAS master list. This includes fluoropolymers such as Polytetrafluoroethylene (PTFE) and Polyvinylidene fluoride (PVDF), which are widely used for water and oil repellency. There is no environmental benefit to presume all PFASs as hazardous, though most of them are not identified as hazardous, and impose reporting requirements and restriction. Therefore, target PFASs for reporting should be prioritized based on risk evaluation and limit to high-priorities with a chemical-specific identifier such as a CAS Registry Number.

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 (e.g. at de minimis level) among complex global supply chain in conformity with global legislations applicable to EEE.

The only substances that should be reported under these programs are those classified as hazardous chemicals under the GHS and are already globally regulated or under consideration for regulation, such as PFOS and PFOA, their salts and their related substances regulated under the EU REACH or POPs Regulations, as well as perfluorohexane sulfonate (PFHxS), its salts and related compounds that were adopted for inclusion in Annex A under the Stockholm Convention.

The concept draft shows the federal EPA's list of PFASs as a reference for PFAS and its CAS, which includes more than 12,000 of the full range of PFAS currently available to EPA researchers, with no priority given to hazardous PFAS, and the vast majority of PFASs are not recognized as hazardous at all, such as the aforementioned fluoropolymers.

For your information: Our knowledge on the use of PFOS and PFOA, kinds of PFAS known as hazardous

For the reasons above, it is difficult to carry out the investigation for concrete use of PFAS in EEE. On the other hand, as mentioned in 2 of our comments, the following table provides content information on PFOS and PFOA and their related substances to the best of our knowledge for EEE manufacturers.

Please receive this table in lieu of reporting PFAS content information for articles.

It should be noted that these substances are already banned in the EU and other countries, so they are almost never included in EEE.

Table. Results of investigation on PFOS and PFOA contained in articles

Note: these substances have already been prohibited and now they are not contained in EEE.

Category	Role	Where used
EEE	Fluorosurfactant	conductive paste, adhesive film for rust prevention, release agent, lubricant, grease, photoresist, coating agent, liquid crystal, photocurable composition for imprint, phase difference film and organic issue display element, soldering flux, leveling agent of epoxy resin
	Fluoropolymer (PTFE, PFA, FEP, ETFE, FKM, FEPM, FFKM, PVDF)	gasket, batteries, cable cover, insulating layer of printed circuit board, coating, eutectoid plating, antirust agent, antistatic agent, sealant/encapsulant of semiconductor, sealing tape, color filter, recording head, antifouling surface treatment of touch panel, heat fixing roll of printing machine, cloth iron, water boiler, rice cooker, flame retardant for plastic case, organic piezoelectric film for keyboard, photoresist/pellicle/mold releasefilm of semiconductor lithography, clat material of optical fiber, backseat of solar cell, polar material binder/gasket/separator of lithium batteries, film capacitor
EEE package	Fluororubber	general packaging materials, label
	Fluoropolymer	ink, pigments, dyes, lining materials, water/grease proof paper, sea, chemical bottle
	Fluoropowder paint	lining materials for container
	Fluorinated oil	fluorine-based lubricant

Additional comments on the second concept draft

In addition, we request the following amendments to the requirements in the concept draft.

1. We would like to request that DEP allows the content to be reported is based on "information that can be reasonably confirmed."

Due to the complexity of the supply chains in the electronics sector, significant time is required to determine the use/non-use of unregulated PFAS chemicals. Therefore, notification requirements should be based on "reasonably confirmable" information. With respect to chemical reporting rules, EPA typically requires "known or reasonably confirmable" reporting information. This is the standard that the federal EPA uses for the requirements of the Quadrennial Chemical Data Reporting Rule and is also the proposed standard for the PFAS reporting rule. Under this standard, compliance with reporting requirements would only be achieved if a company performed an appropriate level of due diligence and accurately reported what it knew or learned.

2. At least 4-year extension is requested.

Without changing the enforcement from January 1, 2023 as stated in the law, although DEP gives 6-month extension of the reporting deadline from January 1, 2023 for businesses upon application, this period of extension is simply not sufficient to comply.

First, there are countless types of products in EEE and the companies have different experiences on the notification.

We, the members of the 4 Electrical and Electronics Associations, would like to request at least a 48-month extension even if DEP limits PFAS as described above.

Nevertheless, though manufacturers show good faith efforts to comply with the law, we presume that 48-month extension is practically not sufficient. Therefore, we would like to require that the DEP creates a waiver process for companies to apply for additional exemptions in the case that businesses need additional time to secure the necessary information.

If DEP does not limit PFAS and requires notification for all PFAS with more than 12,000 substances, it must be aware that it is impossible to even estimate how many years it will take manufacturers to collect that information.

Second, the current Concept Draft still has uncertainty in the notification requirements and the methods, such as the concentration range approved by DEP. And even the system to be used for notification has not been established yet. In this situation, if an enforcement starts from the legal deadline of January 1, 2023, businesses may be required multiple reporting at before and after the completion of the notification system and it is not reasonable.

We therefore request that;

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

3. De minimis threshold for reporting

It might be manageable from upstream to downstream of supply chain if a de minimis threshold for reporting is set at 0.1 % by weight and an 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, midstream manufacturers might be able to obtain this level of information from communication among supply chain.

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 (e.g. at de minimis level) among complex global supply chain in conformity with global legislations applicable to EEE. 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. As such, especially in the case that reporting threshold is very low or not specified, it would be complex and time-consuming endeavor for companies to undertake a thorough evaluation to identify whether PFAS is found in their articles at trace levels that are tolerable under legislative requirements in other jurisdictions.

4. Clarify the definition of PFAS as a concentration

Although 38 M.R.S. §1614 2. (3) requires the amount of PFAS, the second concept draft 3. A. 1. (c) requires the amount of PFAS “as a concentration”. For complex articles like EEE which consist of thousands of parts and/or components, it is not practical to report PFAS amount as a concentration. For example, it is difficult to calculate the concentration of PFAS in case of the same PFAS contained in multiple parts or components for one product.

EEE manufacturers cannot report the amount of PFAS in accordance with the concept draft unless the calculation method on the concentration is clarified.

5. We request that only the final products be reported.

While we requested articles to be excluded from reporting and prohibition as above, if the DEP has determined certain articles to be regulated based on a thorough risk assessment and scientific evidence which shows a significant impact on people and the environment, we request that components incorporated into the product to be excluded, and only the final product delivered to the consumer to be covered.

6. Clarification for the definition of packaging

38 M.R.S. §1614 4. stipulates a product subject to Title 32, chapter 26 A or 26 B (Reduction of Toxics in Packaging, Toxic Chemicals in Food Packaging) is exempted. On the other hand, the concept draft 2. S. indicates packaging is included in product component. Also, Q&A of the Maine DEP website explains “A product can include components, such as packaging.”. We would like to request the Maine DEP to clarify the scope of product subject to the regulation. If 38 M.R.S. §1614 exempts packaging, the concept draft and Q&A should also exempt packaging from the scope.

7. Fee amount

Regarding the fee amount it is mentioned in 6 A. of 2nd Concept Paper as "a fee of \$250 for the first three notifications submitted under Section 3(A) and an additional \$50 for each additional notification."

During the stakeholder meeting held on Oct. 27th,'22, DEP confirmed that the fee is paid for a notification for a product or a category that consists of several products, but not for each product that form a category. DEP should put that explanation as clear language in the rule.

8. Exemption of products for research and development use

Substances, mixtures and articles used for only the Research and Development (R&D) purpose should be exempted from the reporting requirements. Under control by professionals, small amounts used for only the purpose of R&D causes little exposure risk to human and environment. It would be important to apply this R&D exemption for developing and introducing cutting-edge technologies and/or products in Maine.

Conclusion

Japan 4EE members are in support of the Maine DEP's intention to further protect the environment and the health of consumers.

However, for above reasons, we still have significant concerns about second Concept Draft and even the program itself, and believe that reporting and prohibition of PFAS in general for an article is not beneficial and not feasible.

As such, we would like to suggest a realistic approach as follows to accommodate the chemical management that are implemented amongst the various industries:

1. Exclude PFAS-containing articles from its scope
2. Limiting PFAS subject to this program

Also, in order to develop feasible and effective regulations, we would like to propose the following items.

1. We would like to request that DEP allows the content to be reported is based on "information that can be reasonably confirmed."
2. At least 4-year extension is requested.
3. De minimis threshold for reporting
4. Clarify the definition of PFAS as a concentration
5. We request that only the final products be reported.
6. Clarification for the definition of packaging.
7. Fee amount
8. Exemption of products for research and development use

We sincerely hope to collaborate with the Main DEP to ensure that the management of PFAS is implemented in a manner that is effective and sustainable for both the present and future generations of the State of Maine.

Sincerely yours,



Tsukasa Kimura
Senior Manager for Environmental
Business Development Department
Business Strategy Division
Japan Electronics and Information Technology Industries Association (JEITA)

Ote Center Bldg.,1-1-3, Otemachi, Chiyoda-ku, Tokyo 100-0004, Japan

TEL +81-70-3297-8700

t-kimura@jeita.or.jp

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

About JEITA

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

About CIAJ

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

About JBMIA

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

About JEMA

The Japan Electrical Manufacturers' Association (JEMA) 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/>