

July 15, 2022

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Re: 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 "Concept Draft for the Maine PFAS in Products Program" issued in June, 2022 and would like to share our comments and recommendations on the Concept Draft. 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.

First of all, we respect the Manie DEP's advanced actions against environmental issues. On the other hand, we consider that it is impractical for article manufacturers to carry out thorough investigation, record and report on thousands of PFAS compounds that would be covered by the proposed rule. Information that article

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.

manufacturers in the downstream supply chain can obtain is dependent on information being received from component suppliers in the upstream supply chain. Since PFAS compounds as a class have not been restricted in any other jurisdictions, it is difficult to obtain the information that the Maine DEP is seeking from broad, long and complex supply chains. Therefore, the information the Maine DEP would receive would be incomplete and of uncertain reliability, and it likely would not be of much value to the DEP in achieving its regulatory objectives. We therefore respectfully share our concerns and suggestions as follows.

1. Excluding PFAS-containing articles from its scope

To identify and report on every PFAS compound as well as their volume is impossible for article manufacturers to carry out. Not only it will take much time and cost, but also it is very difficult to obtain the information which the Maine DEP intends. The reasons are as follows:

- 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, not all chemicals contained are listed. Hence, even if an article manufacturer obtains SDS from upstream suppliers, what is listed there is only PFAS substances which are classified as hazardous. PFOS and PFOA are the most major examples of such hazardous PFAS and have already been restricted globally. Though they are not contained in current products, we would like to provide the Maine DEP with our knowledge on PFOS and PFOA, which we obtained in the course of complying with the restriction.

- 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.

Therefore, we propose that (1) articles should be excluded from the scope of reporting and prohibition and (2) the Maine DEP would examine the future steps by conducting sufficient study taking into account the point 2 and 3 below. In accordance with scientific based approach, the better balance should be assessed between the actual or reasonably predictable risk and the excessive burden for searching huge numbers of non-hazardous PFAS especially in articles. This would be the key action in order to minimize impact from hazardous substances in practice without fail.

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

Also, realistically, following conditions should be introduced to targeted PFAS in order to obtain significant data in line with its legitimate objectives.

2. Further clarification and prioritization of scope

PFAS is the generic name for all compounds containing fluorine. It is not a single chemical substance but a group of substances containing approximately 5,000 chemical substances. This includes fluoropolymers such as Polytetrafluoroethylene (PTFE) and Polyvinylidene fluoride (PVDF), which are widely used for water and oil repellency. Even though most PFAS have not been identified as hazardous, there is no environmental benefit to presume them as hazardous and impose reporting requirements or restrictions. Therefore, target substances for reporting should be prioritized based on risk evaluation and confined to those with a chemical-specific identifier such as a CAS Registry Number. For example, only perfluorooctane sulfonic acid (PFOS), perfluorooctanoic acid (PFOA) and their related substances could be regulated in this regulations because they are designated as hazardous substances under the GHS and are already restricted worldwide by the Stockholm Convention.

Extremely tiny volume of impurities and byproducts which could be present as unintendedly contaminants should be exempted from reporting and prohibition requirements. While it would be a huge challenge to measure and grasp such impurities and byproducts from technical and cost point of view, such information would likely have little if any practical utility to the Maine DEP.

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.

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.

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 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. Clarify and prioritize its scope
 - Focusing on prioritized substances with identifiers such as CAS number. It is desirable to regulate only PFAS that have been determined to be harmful internationally (See 2 above).
 - Excluding byproducts and impurities
 - > Exempting substances used for research and development
- 3. Include a de minimis threshold for reporting

In order to develop feasible and effective regulations, we propose that a longer review period, at least one year, and preferably three years, be set first, and that sufficient hearings be conducted from industry and appropriate risk and socioeconomic impact assessments be conducted.

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,

Jukasa Dimuna

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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/