



January 21, 2022

Hazardous Waste and Toxics Reduction Program, Washington Department of Ecology
P.O. Box 47600
Olympia, WA 98504 -7696

Re: Japan 4EE Comments on Draft report on regulatory determinations of Safer Products for Washington

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)

We, Japanese electric and electronic industrial associations (JEITA, CIAJ, JBMIA and JEMA) thank the Washington Department of Ecology (hereinafter, Ecology) very much for the opportunity to provide comments on Safer Products for Washington program starting rulemaking.

We have been vigorously committed to improving energy efficiency and to complying with chemical regulations set by other countries, including Europe, the U.S. and China, etc.

We support the basic policy of “Safer Products for Washington program” as electric and electronic equipment (hereinafter, EEE) industry, because it would be able to protect the consumers’ health and environment based on risk assessment via identifying and managing the priority chemicals and priority consumer products which may be main sources of exposure to such substances.

However, we would like to provide following comments on proposed restrictions of all the organohalogen flame retardants (HFRs) as a class in “Electric and electronic enclosures” and of bisphenols in thermal paper which is not EEE but is used with some EEE as consumables. We would be very happy if you consider the following proposals carefully.

I. About Regulations of Organohalogen Flame Retardants in “Electric and electronic enclosures”

The draft report has determined that it is appropriate to regulate organohalogen flame retardants (HFRs) as a class in electric and electronic enclosures. This determination could effectively protect the health

of consumers if the conclusions were based on appropriate assessments.

On the other hand, there is a concern that excessive regulations without an appropriate risk assessment will not only pose a burden on businesses but also cause a greater disadvantage to consumers. This is because consumers will not be able to enjoy the benefits of useful chemicals that do not pose a significant risk as a result of restricting all HFRs. Such problems can be found by appropriate benefit-cost analysis of proposed regulatory determinations.

In a similar case, in 2015, the Federal Consumer Product Safety Commission (CPSC) received a petition to ban additive HFRs by a group of non-government organizations (NGOs). In response, CPSC staff concluded to reject the petition in May 24, 2017, saying that there was "no reasonable ground to prohibit the use of HFRs as a class."¹.

Despite the above conclusions, the CPSC Committee voted to establish regulations under the Federal Consumer Product Safety Improvement Act (CPSIA).

However, at this time, rather than banning HFRs as a class, the U.S. Environmental Protection Agency (EPA) will be commissioned under the Federal Hazardous Substances Act (FHSA) to begin collecting information and conducting risk assessments for 30 HFRs under Section 8 of the Toxic Substances Control Act (TSCA)².

In view of the above situation regarding HFRs, we would like to request Ecology that the following comments be taken into consideration with sufficient caution during development process of regulations.

Issues to be solved I-1. The assessment seems insufficient for regulating organohalogen flame retardants (HFRs) in “Electric and electronic enclosures” as a class.

Our proposal I-1. HFRs to be regulated should be concretely designated according to proper risk assessment, and should not be collectively banned in class. The restricted HFRs should be clarified by indentifiers such as CAS RN.

From the view point of regulatory science, we would like to emphasize that the proper risk assessment based on science would be indispensable. We would like to ask Ecology to set appropriate thresholds based on risk assessments on the negative influence on human health. If it is difficult, we would like to recommend Ecology to regulate only intentionally-added substances.

¹ Ballot Vote: Petition HP 15-1 Requesting Rulemaking on Certain Products Containing Organohalogen Flame Retardants
https://www.cpsc.gov/s3fs-public/PetitionHP15-1RequestingRulemakingonCertainProductsContainingOrganohalogenFlameRetardants.pdf?aTsa_sSaCiSMf1Z_2CfvISjMHFEdWKZ7

² [EPA-HQ-OPPT-2020-0474; FRL-10020-38]
RIN 2070-AB11
Health and Safety Data Reporting; Addition of 20 High-Priority Substances and 30 Organohalogen Flame Retardants
<https://www.govinfo.gov/content/pkg/FR-2021-06-29/pdf/2021-13212.pdf>

This is indispensable also from the operational point-of-view. Generally speaking, if a substance in articles were regulated without setting proper thresholds, the industry cannot know the level at which the substance is managed in supply-chain. That is, the necessary level of checking impurities and by-products would be the problem to be solved. In practice, the final manufacturers of the complicated articles cannot check the presence of substances as impurities or by-products. The management of them must be specified in advance to upstream players in the supply-chain with clear conditions.

Ecology has determined that it is appropriate to regulate HFRs as a class to be used for EEE enclosures. However, HFRs should be evaluated more carefully since restricting all HFRs without sufficient risk assessment would pose enormous impacts on society.

In the first place, HFRs are essential flame retardants used to prevent the spread of fires and to protect human lives. Hastily regulating all HFRs based on inadequate evaluation would not only endanger the lives of Washingtonians, but would also place an enormous burden on EEE businesses, including the selection and evaluation of alternative flame retardants, which would not lead to the achievement of the policies of this program.

Ecology evaluated HFRs referring to the proposed class approach³, developed by the National Academy of Sciences, Technology, and Medicine (NASEM) at the request of the Consumer Product Safety Commission (CPSC), and concluded that all HFRs were hazardous. The NASEM's class approach proposes the scoping plan in which HFRs are classified into 14 subclasses to be assessed.

However, the evaluation of HFR conducted by Ecology has two problems.

First, the hazard assessment of HFR is inadequate.

Of the 161 HFRs listed in the NASEM scoping plan, Ecology assessed 21 substances to be hazardous using hazard assessment tools such as GreenScreen, and concluded that the other HFRs were potentially hazardous because "sufficient data was not found to conclude that they were of low hazard" despite the lack of adequate hazard data.

The NASEM class approach states in Option 3-1 of Scenario 3 that, if there is not enough data available, it is possible to make a science-based policy decision, for example, to classify the subclass as potentially hazardous on the basis of the data-rich chemicals in the subclass.

Although Ecology has made a judgment based on this statement, this judgment is not appropriate because the evaluation proposed by NASEM has not been properly conducted.

The NASEM class approach proposes to classifying HFRs into 14 subclasses and evaluating HFRs for each subclass, but when we examined the subclasses to which these 21 substances belonged, they were only 10 subclasses out of a total of 14 subclasses. For example, NASEM has presented 17 flame retardants as flame retardants belonging to the subclass "Polyhalogenated alicycles", but Ecology has not stated the

³ A Class Approach to Hazard Assessment of Organohalogen Flame Retardants

<https://www.nap.edu/read/25412/chapter/1>

evaluation results of HFRs belonging to this subclass.

Also the HFRs in each subclass were poorly evaluated by Ecology.

For example, among the 22 HFRs belonging to the subclass “Polyhalogenated Organophosphates (OPs)” as exemplified by NASEM, Ecology evaluated only 3 HFRs: tris (1, 3 dichloro -2 propyl) phosphate (TDCPP), tris (2 chloroethyl) phosphate (TCEP), and 2,2-Bis (chloromethyl) trimethylene bis (bis (2 chloroethyl) phosphate) (V6). Since TDCPP and TCEP are flame retardants that are already prohibited in components by Washington State law, and V6 is a substance that Virginia State has proposed to prohibit in children's products and in upholstered furniture, it is natural for them to be evaluated hazardous in this subclass, but it is not appropriate to conclude that an entire subclass is potentially hazardous based solely on the evaluation of these regulated or proposed regulated substances.

Second, NASEM's class approach is, in the first place, an evaluation method developed for additive-type and non-polymer-type HFRs, and it is not appropriate for Ecology to apply to all HFRs.

Since reactive HFRs are generally incorporated into the resin matrix and are not present as a single substance, they are not expected to be exposed to humans or the environment by emission or elution.

Polymer-type HFRs have higher molecular weight than non-polymer-type HFRs and are therefore less toxic and are less likely to be eluted from the resin, thus resulting in lower exposure to humans and the environment. In the absent of sufficient hazard and human exposure data for reactive or polymer-type HFRs, restrictions should be limited to additive-type and non-polymer-type HFRs.

For the reasons above, Ecology has insufficiently evaluated HFRs to conclude that it is appropriate to regulate HFRs as a class for electric and electronic enclosures.

If certain HFRs are to be regulated on the basis of the results of the Ecology assessment, the regulated HFRs should be determined from those specified in “Table 3: Organohalogen flame retardants (HFRs) with existing hazard assessments” of the report identified as hazardous based on hazard assessment tools. In fact, not only evaluation using tools, but also proper evaluation based on scientific viewpoint should be conducted. In this sense, it is reasonable to limit the regulated HFRs to following 3 HFRs, which have been recognized as harmful and regulated in other countries.

- Short chain chlorinated paraffins (SCCP) 85535-84-8
- Tris(2-chloroethyl) phosphate (TCEP) 115-96-8
- Tris(1,3-dichloro-2-propyl) phosphate (TDCPP) 13674-87-8

It should be noted that a minimum grace period of four years, as described in “Our proposal I-4”, is essential for substitution of any HFR that is regulated.

It should be noted that it is essential to specify the CAS RN of the target substance when limiting HFRs subject to the regulations. Without CAS RN designation, chemical substances in complex and long supply chains such as EEE would not be able to be managed. Therefore, we request at least an exhaustive list with CAS RN be provided.

In the management in the whole supply-chain, from upstream to downstream, it would be appropriate to set thresholds as 1000ppm, at the same level of which EU RoHS Directive has prohibited brominated

flame retardants, PBB and PBDE, in EEE. These two groups have higher hazard among the halogenated flame retardants, but EU RoHS has attained great reduction of the risk with this threshold without spoiling the advantage of consumers.

In addition, identifiers such as CAS RN should be clearly specified to each of substances to be regulated. EEE is manufactured via global supply chain, and there are few cases where the finished products manufacturers at the end of the chain can directly exchange information with the first materials manufacturers. Therefore, the setting of substances to be managed and the conditions of management is needed to be simple and intelligible necessary for a component material and the designation of the management condition to be simple, intelligible and clear so that any world local manufacturers can understand. If the designation of substances and thresholds are clear, the industry can incorporate them into the substance management scheme based on the global standards such as IEC 62474, and will become able to gather necessary information from the communication within supply-chain.

Issues to be solved I-2. The assessment seems insufficient for selecting alternatives for organohalogen flame retardants (HFRs).

Our proposal I-2. In selecting alternatives, their feasibility should be carefully judged with considering practical issues, such as the quality ensuring in actual products and the possible effect on global supply-chain.

The presentation of the possible alternatives by the governmental agency is the important premises of this legislative process, and some possible alternatives for HFRs or bisphenols are suggested in this report. In determining the alternatives, the authorities should judge the feasibility and actual availability in the market of the candidate alternatives by setting sufficient periods for investigation and obtaining information from the stakeholders widely. Based on the gathered information, the appropriate grace period or necessary exemptions should be adequately set.

Especially, in selecting the alternatives for HFRs in the enclosure of wide variety of EEE, the detailed investigation would be sufficiently needed about whether they are really “feasible and available” in the actual products and their manufacturing processes. If possible, such review should be performed by using real product models. If the “possible alternatives” are not “feasible and available” in practice, the safety and quality of the products may be negatively and seriously affected. In addition, if the suppliers are not able to purchase such alternative materials from general market, they might have to face the problems in the supply-contract. Thus, unfeasible alternatives may cause big confusion in the global supply-chain.

In addition, it is necessary for Ecology to take the fact that many finished products manufacturers of EEE produce products outside of the U.S. into consideration, when reviewing candidates. The global supply-chain is very complicated, and Ecology also should pay attention to this complexity to judge whether the candidates are "feasible and available" in the actual world. (If Ecology examined only the situation of the U.S. market in relation to the candidates, it would not cover the actual EEE manufacturing.)

Furthermore, the evaluation process for the "feasible and available" alternatives should be transparent and the background numerical data on which the conclusion is based should be disclosed to the stakeholders such as citizens or the industry. The examples of such data include the number of chemical substances identified as alternatives, number of the company showing that the alternatives would be feasible in their products among the total number of consumer brands supplying products to Washington State.)

We believe that the Article 6 (1) of EU RoHS Directive (DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment ⁴) would serve as a good reference on regulating a substance in complicated manufactured products such as EEE. Among them, the following condition is to keep supplying the safe and reliable products and not to spoil the benefit of consumers.

(d) (whether a substance or a group of similar substances) could be replaced by substitutes or alternative technologies which have less negative impacts.

Issues to be solved I-3. The regulation of all the “electric and electronic enclosures” uniformly would not be appropriate because the expected risk would be different.

Our proposal I-3. Only the “electric and electronic enclosures” which might have greater effects on human health or the environment should be prioritized instead of uniform regulations.

According to the Hazard Assessment Scoping Plan for class approach of NASEM, HFRs are classified into 14 sub-classes, and assessment of hazard is proposed to be conducted on each sub-class. However, its BOX 1-1, “Statement of Task”, recommends as follows (underlines added) :

The National Academies will develop the plan, taking into account that the plan, when executed, will provide a hazard assessment of OFRs as a class that will be used by a CHAP, along with data on exposure and human health effects, to complete a quantitative risk assessment.

Generally speaking, EEE is required to keep their quality and performance in their durable life. Therefore, the design engineers would usually select a material with high durability. Furthermore, the applications of consumer EEE have wide variety and there are many EEE which the users do not touch on a daily basis.

However, Ecology decided that all the EEE enclosures be subjected to the restriction of HFRs, only based on the study finding that HFRs are emitted from EEE and human may inhale it via house dust. However, the quantitative evaluation on its exposure to human has not been conducted.

HFRs are firmly integrated into polymers used as the enclosures, and in many cases, HFRs have reacted with base polymer and become a different compound together. It basically is not emitted to the air because vapor pressure is too low to cause such emission. Even if HFRs are emitted in very small volume, it would not reach the possible level posing any negative health impact to human. We sincerely would like to ask Ecology to designate the kinds of EEE enclosures specifically to be regulated, after carrying out the

⁴ <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32011L0065>

quantitative evaluation of possible exposure to human based on the appropriate use scenarios.

In limiting the EEE enclosure to be regulated, aligning with the New York State Law (Section 4630 B/A 5418 B⁵) promulgated in January 2022, it would be considered appropriate to adopt the following electronic displays for consumers:

4. "ELECTRONIC DISPLAY" MEANS A CONSUMER PRODUCT WITH A DISPLAY SCREEN AND ASSOCIATED ELECTRONICS THAT, AS ITS PRIMARY FUNCTION, DISPLAYS VISUAL INFORMATION FROM WIRED OR WIRELESS SOURCES AND IS AVAILABLE FOR PURCHASE BY INDIVIDUALS OR HOUSEHOLDS FOR PERSONAL USE IN A RESIDENTIAL SPACE. ELECTRONIC DISPLAY SHALL NOT INCLUDE: (A) ANY ELECTRONIC DISPLAY WITH A SCREEN AREA SMALLER THAN OR EQUAL TO ONE HUNDRED SQUARE CENTIMETERS OR FIFTEEN AND ONE-HALF SQUARE INCHES; (B) PROJECTORS; (C) VIRTUAL REALITY HEADSETS; (D) ALL-IN-ONE VIDEO CONFERENCE SYSTEMS; OR (E) DISPLAYS THAT ARE INTEGRATED WITH APPLIANCES AND ARE NOT AVAILABLE FOR PURCHASE AS SEPARATE PRODUCTS BY END-USERS.

This New York State Law was formulated with reference to the Revised eco-design regulation for TV/Display (EU 2019/2021⁶) in which the reasons to select consumer electronic display were stated as follows;

" have a significant environmental impact and presenting significant potential for improvement through design in terms of their environmental impact, without entailing excessive costs ", It suggests that consumer electronic display has been selected since it benefits society as a whole based on risk trade-off assessments.

⁵ <https://www.governor.ny.gov/news/governor-hochul-signs-legislation-protect-new-yorkers-harmful-flame-retardant-chemicals>

⁶ <https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32019R2021&from=EN>

Issues to be solved I-4. The draft report does not seem to consider the possible impact on the operation in the complicated global supply-chain.

Our proposal I-4. The appropriate grace period should be given. Four years would be necessary for the consumer EEE in general to substitute substances in products.

EEE consists of a large number of components whose materials and components are manufactured in a complicated global supply-chain throughout the world. Therefore the management of substances in a product would be impossible only by the efforts of finished EEE. The methods are internationally standardized and the list of substances to be managed are unified throughout the industries. For EEE industry, IEC 62474 “Material Declaration for products of and for the electrotechnical industry” is available.

Substitution of a substance currently having some functions in EEE generally takes at least about 4 years, in cases where the substances to be regulated are clearly identified, the thresholds are set at 1000ppm, and appropriate alternatives are already available. Therefore, EU chemical substances regulations such as EU RoHS Directive provide a preparatory period of about 4 years when a substance to be restricted is newly specified. Based on the success of smoothly implementing legal compliance for articles in EU, we would like to request a grace period of at least 4 years for consumer EEE.

The following is an ideal timeframe that outlines the process to phase out chemicals from consumer EEE. Each step shows the fastest timeline in cases where the substance to be regulated and the appropriate thresholds are clearly and properly specified. However, there are hardly any cases that all the steps are finished in shortest timeline without fail, therefore the 4-year grace period is necessary. Please note that each step and timeframe may vary depending on each product and company.

- Procurement and Assessment of Substitute Parts with Suppliers: 6 months at the shortest, usually longer. If there are no suitable alternatives, this measures would reach a dead end at this steps.
- Internal quality assessment: 3 months at the shortest, but it would need more time in many cases.
- Quality and Safety Certification: 6 months at the shortest, but it would need more time in many cases.
- Supplier Coordination and Manufacturing Changes: 6 months at the shortest, but it would need more time in many cases.
- Shipment, Import and Distribution in US: 3 months at the shortest.

II. About Regulations of Bisphenols in Thermal Paper

Our proposal II-1. Establishment of appropriate thresholds and identification of restricted substances

While there are no existing regulations on bisphenols as a class in thermal paper in other countries, there are many regulations on thermal paper (or receipt paper) containing bisphenol A (or BPA). The European Union (EU) limits the concentration of BPA in thermal paper products to 0.02% by weight, and Switzerland limits its alternative, bisphenol S (or BPS), to similar concentrations.

Efficient management of substances in articles manufactured through the supply chain requires simplicity and clarity that can be understood by manufacturers in any part of the world. Since the types of bisphenols used in the thermal paper are limited, it is desirable to clearly indicate the restricted substances with an identifier such as CAS RN.

In addition, it is necessary to prohibit "intentional addition of restricted substances" or to set a threshold appropriate for risk management. If a threshold is to be set, it is reasonable to set a minimum threshold at 0.02% by weight, the same level as that set by the EU REACH regulation limiting BPA in thermal paper and Swiss ChemRRV limiting BPA and BPS in thermal paper. At this threshold, the exposure risk from the substances has been significantly reduced without compromising consumer benefits. These are substances and threshold that can be realized as BPA-free thermal paper. At present, there are no appropriate methods to analyze the content of 0.02% or less and to evaluate the risk, and it would be extremely costly to do so.

Our proposal II-2. Establish 36 Months Grace Period

A grace period of 36 months after the entry into force of the EU REACH Regulation was established for the restriction of BPA. In view of the fact that we have been able to smoothly implement the compliance of goods in the EU, we would like to request a grace period of at least 36 months.

Conclusion

In light of the above issues and proposals, we would like to request Ecology to develop regulations that benefit society as a whole based on risk trade-off assessments. We hope our comments will contribute to better regulation.

As for HFRs, the Federal CPSC is conducting a detailed evaluation of 30 flame retardants based on NASEM's scoping plan. I would like you to evaluate HFRs in cooperation with CPSC.

For the details of risk trade-off assessments, we strongly recommend Ecology to refer to "Plastic Additive Risk Trade-off Assessment Document"⁷, prepared by Japanese National Institute of Advanced Industrial Science and Technology (AIST), as an excellent example of risk-risk trade-off assessment of chemical substance.

⁷ National Institute of Advanced Industrial Science and Technology (AIST), Plastic Additive Risk Trade-off Assessment Document Summary
http://en.aist-riss.jp/wp-content/uploads/sites/11/2014/11/RiskTradeoffAssessment_summary_FlameRetardant.pdf

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 the very future Japan's economic development and cultural productivity.

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 contributions 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 theory.

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/>