Japan 4EE Input to **1st Stakeholder Consultation – Questionnaire for tetrabromobisphenol A – TBBP-A (CAS 79-94-7)**

15 June, 2018

Name of the associations which make this input:

The Japanese electric and electronic (E&E) industrial associations:
Japan Electronics and Information Technology Industries Association (JEITA);
Japan Electrical Manufacturers´ Association (JEMA);
Japan Business Machine and Information System Industries Association (JBMIA); and
Communications and Information network Association of Japan (CIAJ)
With cooperation of the following Medical and Monitoring & Control Equipment Industrial Associations:
JAIMA (The Japan Analytical Instruments Manufacturers' Association); and
JEMIMA (Japan Electric Measuring Instruments Manufacturers' Association)

Contact details of responsible person for this contribution

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We would like to submit our input to 1st Stakeholder Consultation – Questionnaire for tetrabromobisphenol A – TBBP-A (CAS 79-94-7)
http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_15/Questionnaire/TBBP-A_Questionnaire_1st_Cons_Pack-15.pdf
as follows:

Please note: *Following information is mostly based on Japanese industry's intelligence collected in previous studies and others. We have not gathered information on these substances from our suppliers yet, because they are currently not covered under SVHC or other legislations and we have no scheme to gather information for these substances.*

Questions and Answers:

1. Applications and quantities(ranges)in which TBBP-A is in use

Following questions seem to be for manufacturers of materials, therefore we don't have data on them. Japanese industry recognizes that this substance may be used as materials for brominated flame retardants. TBBPA may be contained in EEE when it is used as additive flame retardant, however, we don't have exact information of resulted compounds. As for the cases where it is used as reactive flame retardant, unreacted residues of TBBPA would be very low, at levels of less that the detection limits, according to the upstream industry[1].

[1] Determination of unreacted TBBPA in different production stages of printed circuit boards
October 2015

The reason of the use is because we recognise that this substance has many advantages for example, it is comparatively safe (risk assessment has been already done in the EU[2] and the Opinion from EFSA[3] is also published), and is able to give products good flame-retardancy effectively at the necessary level of safety of the users.

a. Please provide information concerning products and applications in which the substance is in use and give detail as to the annual amounts of use.

Application	**Production volume in tonnes per annum**	**Imported Tonnes in partly finished products (e.g. master batch, epoxy resins)and in finished products and components**	**Typical concentrations of TBBP-A that are applied**
Epoxy resins in printed circuit boards (reactive component)			
Epoxy resins to encapsulate certain electronic components (reactive component)			
polycarbonate and unsaturated polyester resins (reactive component)			
ABS (additive flame retardant)			
Others			

b. Please provide information as to the ranges of quantities in which you estimate that the substance is applied in general and in the EEE sector.

c. Please specify if you are aware, if aside from actual use of the substance, it may be reintroduced in to the material cycle through the use of secondary materials.

i. Please detail in this case what secondary materials may contain antimony trioxide impurities and at what concentrations as well as in the production of what

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ICL Industrial Products (IP)
http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_15/Contributions/ICL_Report_Unreacted_TBBPA_in_different_stages_of_PCBs_production_20171016__2_.pdf

[2] EU Risk assessment:Communication from the Commission on the results of the risk evaluation and the risk reduction strategies for ...tetrabromobisphenol A
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2008:152:0011:0020:EN:PDF
COMMISSION RECOMMENDATION 2008/454/EC of 30 May 2008 on risk reduction measures for ... tetrabromobisphenol A
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:158:0062:0064:EN:PDF
2,2',6,6'-TETRABROMO-4,4'-ISOPROPYLIDENEDIPHENOL (TETRABROMOBISPHENOL-A or TBBP-A) Part II – Human Health
http://echa.europa.eu/documents/10162/32b000fe-b4fe-4828-b3d3-93c24c1cdd51

[3] Scientific Opinion on Tetrabromobisphenol A (TBBPA) and its derivatives in food
http://www.efsa.europa.eu/en/efsajournal/doc/2477.pdf

components/products such materials are used.

ii. If possible please provide detail as to the changing trends of TBBP-A concentrations in such secondary materials (products) as well as the changing trend of use of the respective secondary material in EEE manufacture.

d. Please specify if TBBP-A is used as an intermediate in certain application and detail in which.

We don't have any information either, because final products manufacturers do not use the substance by themselves. However, even if there is any cases where TBBPA is used as an intermediate, such TBBPA would not be contained in final products as it is an intermediate. We cannot understand the intention of this question.

e. In which countries (worldwide) is TBBP-A currently being applied in EEE manufacture (respectively in components supplied by the supply chain) and win what quantities?

2. Production and regulation of TBBP-A

a. TBBP-A is not produced in the EU. Globally TBBP-A is produced in China, USA, Japan, Jordan and Israel. Please estimate current amounts and the expected trend over the coming years.

b. Please specify if you are aware of voluntary initiatives to phase out TBBP-A, for example of certain OEMs or in certain EEE sectors.

Some criteria mainly for office equipment in voluntary environmental labels such as Blue Angel require not to use any brominated flame retardants in external plastic parts. Some green public procurement criteria also have similar requirements.

3. Potential emissions in the lifetime (use phase) of products and waste stream

a. For specific products and components in which TBBP-A is present, please detail potentials for emissions in the use phase.

Following documents would be useful for discussing this issue. These document do not cover only TBBPA but flame retardants in general:

Plastic Additive Risk Trade-off Assessment Document
Summary
Development of Methodologies for Risk Trade-off Analysis toward Optimum Chemical Substance Management
March 10, 2014
Funding provided by New Energy and Industrial Technology Development Organization (NEDO) and Japan Ministry of Economy, Trade and Industry (METI)
https://en.aist-riss.jp/wp-content/uploads/sites/11/2014/11/RiskTradeoffAssessment_summary_FlameRetardant.pdf

CPSC Staff Statement on the Toxicology Excellence for Risk Assessment Report,
"Flame Retardant Exposure Assessment"

September 28, 2016
https://www.cpsc.gov/s3fs-public/FR-exposure-assessment-contractor-report-18-09282016-with-cover.pdf?miFGGrplONrzWVCDOIQSOY1lTeGzQvWi
About the TBBPA, please see from p.74:

"3.8.1 Discussion of TBBPA Results
Given the available data, none of the environments presents an exposure greater than 0.01 ng/kg/day to any population group. There were no data available to represent air concentrations of TBBPA in the child care environment, and measurements of air from the home showed only non-detectable levels.
This assessment may underestimate exposure from the child care environment because there are no available data for air concentrations of TBBPA, although the available data indicate very low concentrations of TBBPA in dust and air in all environments where measured. There were no data to represent air or dust concentrations in cars, yielding a possible underestimate for the exposure from all environments combined."

TBBPA: Quantitation of the potential emissions (blooming) from the surface of ABS (Acrylonitrile-Butadiene-Styrene)
27 July 2017
Based on ICL internal reports: JR 2685 (2012) and JR 4204 (2017)
Yakov Rachmilevich, Yaniv Hirschsohn
http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_15/Contributions/ICL_Report_on_Blooming__TBBPA__from_ABS_Prop65_20170727__2_.pdf
The conclusion is as follows:

"After ageing at 70 C for 35 days, TBBPA blooming levels from the surface of ABS were found to be below LOQ 0.5µg/cm2, indicating a low potential of emission."

b. Please provide information on how EEE applications containing TBBP-A are managed in the waste phase (with which waste is such EEE collected and what treatment routes are applied).

We don't have information on it, however, "Evidence of waste relevance" seems to be still too poor. In the priority list made by the Austrian Umweltbundesamt, there are many substances which are judged to be "red" (there is evidence), though even an "evidence of waste relevance" for each substance concerned is not shown. Only four references were listed, and for one of them, concrete referenced document is not identified. From the purpose of RoHS Directive, and according to the "Methodology", waste relevance issues become the turning point of the judgment on whether a substance should be regulated under the RoHS. We consider that the Methodology itself is basically reasonable for screening and prioritizing substances under RoHS. Therefore so much we believe that the prioritization should not dare to be done based only on the poor data, but should be considered after having collected the necessary data about each substance and inspected such data.

After the studies in 2014, Fraunhofer ITEM and IPA carried out an independent evaluation of TBBPA according to the RoHS methodology by the Austrian Umweltbundesamt, upon the request of BSEF. Assessment of TBBPA (tetrabromobisphenol-A) according to the "Methodology for Identifi-cation and Assessment of Substances for In-clusion in the List of Restricted Substances (Annex III) under

the RoHS2 Directive"
Part II and Part III assessment
http://rohs.exemptions.oeko.info/fileadmin/user_upload/RoHS_Pack_15/Contributions/TBBPA_under_RoHS_13102015_clean__2_.pdf

The new study filled much of data gaps in "Evidence of waste relevance", and its Chapter 5 "WASTE MANAGEMENT OF ELECTRICAL AND ELECTRONIC EQUIPMENT" (from P.39 to P.61) covers the questions. We consider that it would be useful for discussing this issue.

i. Please refer in your answer to the treatment of specific products and components in which TBBP-A is present, for example, how does the presence of TBBP-A in printed circuit boards affects the recyclability of resources contained in these components?

ii. Please detail potentials for emissions in the relevant treatment and disposal processes.

4. Substitution

We don't have any information, because final products manufacturers do not use substance by themselves, but only require suppliers to supply parts/materials having necessary specifications. However, in general, to substitute parts/materials completely, each of material suppliers, parts manufacturers and manufacturers of finished products must have technical processes for reviewing and developing substitution, testing its quality and reliability, and acquiring certification on applicable standards such as on flame retardancy or on safety as necessary. Therefore, the feasibility study for possible substitution (if any) should be done all the stages of the production of EEE.

a. For which applications is substitution underway? Please specify in this respect which alternatives are available on the substance level (substitution) and which are available on the technological level (elimination). For example, what other flame retardants can be used instead of TBBP-A in epoxy resins used in printed circuit board applications and what other resins could be applied to eliminate the need for TBBP-A?

i. For which applications is substitution scientifically or technically not practicable or reliable and why.

ii. What constraints exist to the implementation of the named substitutes in a specific application area (provide details on costs, reliability, availability, roadmap for substitution, etc.).

iii. If substitution has begun or is expected to begin shortly, please estimate how the trend of use is expected to change over the coming years.

iv. Which chemical (e.g. DOPO) or technological alternatives may be relevant for this purpose? Please give an overview of the present market shares of alternatives in relation to the respective applications.

5. Socio economic impact of a possible restriction

We don't have data, however, especially when policy options would be considered for widely-used substances, advantages of such substance should be properly reviewed. For example, in considering advantages of flame retardants, product safety assessment report of power code would be useful as a reference.

In the socio-economic impact assessment, benefit and risk of presumed scenarios must be quantified, then compared and evaluated. Especially, following aspects would be important:

- benefit and risk of the use of the substance under review,
- detailed risk assessments of substitute substances in themselves,
- assessments of whether applications of the substance under review can really be replaced,
- reliability of parts/products using substitutes,
- necessary period to evaluate them, and
- influence on product safety.

We believe that such aspects having big socio-economic impact should be taken into consideration properly. Furthermore, we believe that the inspection of cost for substitution should be performed at each stage of supply chain. Even in the cases where some parts/materials could be technically substituted, for substituting such parts/materials completely, each of material suppliers, parts manufacturers (in general, there are far more parts manufacturers than manufacturers of finished products, and each supply-chain usually extends to the secondary, tertiary or more) and manufacturers of finished products must have technical processes for reviewing and developing substitution, testing its quality and reliability, and acquiring certification on applicable standards such as on flame retardancy or on safety as necessary. To manage these technical processes, managing processes and costs also occur. Such processes need not only the related costs but also considerable time for each of the related suppliers and manufacturers.

Please provide information as to the socio-economic impacts if TBBP-A is restricted under RoHS. Please specify your answers in relation to specific applications in which the substances are used and/or in relation to the phase-in of specific alternatives in related application areas. Please refer in your answer to possible costs and benefits of various sectors, users, the environment, etc. where possible; please support statements with quantified estimations.

6. Further information and comments

The information compiled on this substance for the stakeholder consultation has been prepared as a summary of the publicly available information reviewed so far. If relevant, please provide further information in this regard, that you believe to have additional relevance for this review, as well as references where relevant to support your statements.

(1) Existing risk assessment reports and resulting regulatory options for TBBPA under other EU legislation and in other countries should be taken into consideration.

For example, following reports would be useful to consider this issue.

From EU:

- Scientific Opinion on Tetrabromobisphenol A (TBBPA) and its derivatives in food
  Published in 2013
  European Food Safety Authority (EFSA), Parma, Italy
  http://www.efsa.europa.eu/en/efsajournal/doc/2477.pdf
  Main points:
  - *…current dietary exposure to TBBPA in the European Union does not raise a health concern.*
  - *Also exposure of infants via human milk does not raise a health concern.*
  - *Additional exposure, particularly of young children, to TBBPA from house dust is unlikely to raise a health concern.*

- Communication from the Commission on the results of the risk evaluation and the risk reduction strategies for the substances: sodium chromate, sodium dichromate and 2,2',6,6'-tetrabromo-4,4'-isopropylidenediphenol (tetrabromobisphenol A)
  http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2008:152:0011:0020:EN:PDF

- COMMISSION RECOMMENDATION 2008/454/EC of 30 May 2008on risk reduction measures for the substances sodium chromate, sodium dichromate and 2,2′,6,6′- tetrabromo-4,4′-isopropylidenediphenol (tetrabromobisphenol A)
  http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:158:0062:0064:EN:PDF
  Main recommendation:
  "For TBBPA, although some uncertainties are identified concerning the possible impact of breakdown products, no further risk reduction measures beyond those already applied are advised."

- Risk assessment Report: 2,2',6,6'-TETRABROMO-4,4'-ISOPROPYLIDENEDIPHENOL (TETRABROMOBISPHENOL-A or TBBP-A) Part II – Human Health
  http://echa.europa.eu/documents/10162/32b000fe-b4fe-4828-b3d3-93c24c1cdd51
  Summary:
http://echa.europa.eu/documents/10162/6434698/orats_summary_2_2_6_6-tetrabromo-4_4-isoprop_en.pdf

From U.S.:

- CPSC Staff Statement on the Toxicology Excellence for Risk Assessment Report,
  "Flame Retardant Exposure Assessment"
  September 28, 2016
  https://www.cpsc.gov/s3fs-public/FR-exposure-assessment-contractor-report-18-09282016-with-cover.pdf?miFGGrplONrzWVCDOIQSOY1ITeGzQvWi
  (Please also see 5.a above.)

From Canada:

- CEPA Screening Assessment Report
  http://www.ec.gc.ca/ese-ees/BEE093E4-8387-4790-A9CD-C753B3E5BFAD/FSAR_TBBPA_EN.pdf
  Canada published CEPA Screening Assessment Report on TBBPA in 30 Nov. 2013, and concluded that Canada doesn't need to restrict TBBPA.

(2) Consultation period is too short to prepare concrete comments.

Only in 60 days as the period for contribution, all we can do is to reply to the consultation solely based on the materials at our hand and our knowledge.
We industry would like to request to set at least 180 days (same as the period set for the consultation of draft dossiers by RAC/SEAC under REACH) as the period for comments on draft dossiers in the future consultation so that we may give more useful input to the consultation after more-detailed review. We believe full consideration among all the stakeholders would make the RoHS Directive contribute to European sustained development.

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.jemanet.or.jp/English/

About Medical and Monitoring & Control Equipment industrial associations:

About JAIMA

The Japan Analytical Instruments Manufacturers' Association (JAIMA) is a sole industry association of Analytical Instruments in Japan, which established under the Japanese law. Member of JAIMA are more than 200 leading companies in Japan. JAIMA is to contribute to the development of the Japanese economy and the cultural lives of citizens in Japan through efforts to improve and advance technologies related to analytical instruments and the analytical instruments industry for the purpose of the advancement of science & technology.

About JEMIMA

Japan Electric Measuring Instruments Manufacturers' Association (JEMIMA) has been an active forum for measuring instruments manufacturers since its establishment in 1948. It has 85 companies as regular members and 29 companies & 7 organizations as supporting members. JEMIMA members contribute to a wide variety of industries by supplying products as "Mother Tools of the industry" for R&D design, and manufacturing. JEMIMA activities are becoming more and more global, since most of the issues our industry is facing are also global. By actively working on these issues, we help our members to meet the challenge and promote the development of the industry worldwide. To achieve these goals, JEMIMA take "Globalization & promotion of International activities" to be one of the focal activities.