# Risk assessment for chemical substances contained in products **Decabromodiphenyl ether**

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### Summary

In September 2000, decabromodiphenyl ether was designated as a designated chemical substance, which means it is "suspected to be a chemical substance (Class II Specified Chemical Substance) that is not highly bioconcentrative but non-readily degradable and has long-term toxicity" under the Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture etc. (Chemical Substances Control Law:CSCL). It was designated as a Type II Monitoring Chemical Substance at the time of the amendment to the CSCL in 2003. In the amendment of the CSCL in 2009, it became a general chemical substance based on the screening assessment results. At the conference of the parties in the Stockholm Convention on Persistent Organic Pollutants in May 2017, it was decided that decabromodiphenyl ether be added to the substances to be eliminated or restricted. In July 2017, it was judged to be appropriate to designate decabromodiphenyl ether as a Class I Specified Chemical Substance under the provision in Article 2, paragraph (2) of the CSCL because it is highly bioaccumulative, not readily degradable, and also has long-term toxicity.

Decabromodiphenyl ether (BDE-209)<sup>11</sup>, which is the subject substance of this risk assessment, is mainly used as flame retardant for resins and textiles, and is contained in consumer products such as electrical appliances, plastic products and car seats. The National Institute of Technology and Evaluation (NITE) conducted a risk assessment on the health effects for Japanese people who are exposed to BDE-209 via those products indoors and in a car interior.

Based on usage information in the investigation and notifications based on the CSCL, the results of an investigation of actual concentrations in Japan conducted by the Ministry of Economy, Trade and Industry (METI), and the data of risk assessments conducted in foreign countries, furniture, car fabrics, and indoor and car-interior dust, by which Japanese people might be exposed to the substance in relatively high concentrations among the products that Japanese people use in their homes or cars, were set as the exposure sources to be investigated.

Adults and children under the age of 6, living in Japan, were set as the target groups of people in this risk assessment. The reason why the assessment was conducted so as to include young children was that their intake through mouthing behaviors such as holding objects in their mouth and licking objects or through dust is different from the intake of adults.

In the hazard assessment report on polybrominated diphenyl ether issued by the

<sup>&</sup>lt;sup>1</sup> Commercial decabromodiphenyl ether (c-decaBDE) is a synthetic mixture of polybrominated diphenyl ethers, with the main component being the fully brominated congener decaBDE (BDE-209). In this report, the risk of BDE-209 is assessed.

Agency for Toxic Substances and Disease Registry (ATSDR) in March 2017, a Minimal Risk Level (MRL) of 0.2 µg/kg/day has been derived for an intermediate-duration oral MRL for BDE-209 as part of information on exposure. Use of the MRL in this risk assessment was first examined. The ATSDR, however, has only derived the MRL for intermediate-duration exposure, due to insufficient data on a chronic toxicity oral MRL. Therefore, the MRL was derived based on a LOAEL of 0.05 mg/kg/day for the intermediate-duration oral MRL in order that it could be used as a hazard assessment value for chronic toxicity exposure based on intermediate-duration oral MRL estimated by the ATSDR. The intermediate-duration oral MRL estimated by the ATSDR was derived by dividing the LOAEL value by an uncertainty factor of 300 (10 for animal-to-human extrapolation, 10 for human variability, and 3 for use of the LOAEL). In consideration of the uncertainty about the test period as well, a hazard assessment value of 0.05 µg/kg/day (50 ng/kg/day) was derived by dividing the LOAEL of 0.05 mg/kg/day by an uncertainty factor of 1000 (10 for animal-to-human extrapolation, 10 for human variability, and 10 in consideration of the use of LOAEL as well as the test period). For this risk assessment report, it was decided that this value should be used as the hazard assessment value for chronic toxicity exposure.

For the estimation of the exposure amount, eight exposure scenarios in total were set for each environment (inside houses and cars) where the products to be investigated are used or exist, and the estimation equations according to the exposure scenarios and the parameters required for the estimated equations were set. It was finally decided that the *estimated human exposure (EHE)* per day be calculated by summing the exposure amount estimated for each of the eight exposure scenarios.

The exposure scenarios and parameters were set according to the environment where the products to be investigated are used or exist or the use conditions of the products. In setting the parameters, a strict condition that the exposure amount be overestimated by a reasonable amount was adopted. Therefore, the *EHE* is calculated with this strict condition in force in most scenarios and parameters. Each parameter was set based on investigation results reported in the existing literature. For the parameters on which there was insufficient information or an insufficient check of validity of results, tests of products containing BDE-209 were conducted at the NITE Product Safety Technology Center and Hokuriku Regional Office and the results were also used.

As the results of the exposure assessment, the *EHE* was 20.4 ng/kg/day for adults and 131.9 ng/kg/day for children. In the environments inside houses and cars, the exposure amount by oral intake of BDE-209 absorbed dust released from the products was far larger for both adults and children than that by the direct intake using the products containing BDE-209, making up 97% of the *EHE*.

In the risk assessment, the Hazard Quotient (HQ) was obtained by dividing the EHE by

the *hazard assessment value*, and it was decided that if the *HQ* was 1 or larger, then the risk is at a level of concern, and if the *HQ* was less than 1, then the risk is not at a level of concern.

In the risk assessment, considering that the *hazard assessment value* is a chronic toxicity value, the respective *EHE* for adults and children were calculated in the exposure assessment, so those amounts were converted into the average exposure amount over a life-span\_from birth to 70 years old".(weighted average exposure amount in 70 years).

As a result of the risk assessment, for a chronic toxicity, the *hazard assessment value* was 50 ng/kg/day, while for the lifetime average, the exposure amount was 30 ng/kg/day, indicating an HQ of 0.6, which is below 1. Therefore, it is considered that even in the case of the results obtained applying multiple instances of the abovementioned strict condition under which the exposure amount is overestimated by a reasonable amount, the risk is not at a level of concern.

According to the exposure amount per day in childhood, the *HQ* would be 1 or higher. However, it is not appropriate to simply use the *hazard assessment value* for chronic toxicity exposure, and it is considered better to use the intermediate-toxicity oral MRL derived by the ATSDR. Also in this case, the *HQ* is 0.6, which is not at a level of concern.

BDE-209 was designated as a Class I Specified Chemical Substance under the CSCL. Therefore, import, manufacture, and sale of products containing BDE-209 are prohibited, and it is expected that the exposure amount will become smaller than the *EHE* in this risk assessment in the future. Furthermore, even if products containing BDE-209 that are currently used or placed inside houses and cars continue to be used in the future, the risk to human health due to the products is considered not to be at a level of concern.

### 1 Profile of the target substance

In September 2000, decabromodiphenyl ether was classified as a designated chemical substance, which means it is "suspected to be a chemical substance (Class II Specified Chemical Substance) that is not highly bioaccumulative but non-readily degradable and has long-term toxicity" under the Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture etc. (Chemical Substances Control Law: CSCL). It was designated as a Type II Monitoring Chemical Substance at the time of the amendment to the CSCL in 2003. In the amendment of the CSCL in 2009, it became a general chemical substance based on the screening assessment results. At the conference of the parties in the Stockholm Convention on Persistent Organic Pollutants in May 2017, it was decided that decabromodiphenyl ether be added to the substances to be eliminated or restricted. In July 2017, it was judged to be appropriate to designate decabromodiphenyl ether as a Class I Specified Chemical Substance under the provision in Article 2, paragraph (2) of the CSCL because it is highly bioaccumulative, not readily degradable, and also has long-term toxicity.

Decabromodiphenyl ether is a substance (BDE-209) with a bromine number of 10 in which all substituents of diphenylether, which is a basic skeleton, are brominated. In brominated diphenylether (BDE), a total of 209 isomers including BDE-209 exist, which are called PBDEs.

Commercial decabromodiphenyl ether (commercial mixture, c-decaBDE) consisting of the fully brominated decaBDE congener or BDE-209 (≥90-97%), with a small amount of nona- and octa-bromodiphenyl ether. (POPRC2015).

In this risk assessment report, BDE-209, which is the principal substance of c-decaBDE, is evaluated.

The profile of BDE-209 is shown in Table 1-1.

# Table 1-1 Profile of BDE-209

CSCL: Type II Monitoring Chemical Substance (before amendment) Registration No.	429 (Date of Designation in the Official Gazette 2000/9/22)
CSCL: MITI No.	3-2846
CSCL: Type II Monitoring Chemical Substance (before amendment) Chemical Substance Name	Decabromodiphenyl ether
CSCL: Type II Monitoring Chemical Substance (before amendment) CAS No.	1163-19-5
CSCL: Class I Specified Chemical Substance Cabinet Order Name (draft)	Decabromodiphenyl ether
CSCL: Class I Specified Chemical Substance CAS No.	1163-19-5
Molecular Formula	C <sub>12</sub> Br <sub>10</sub> O
Structure	$Br \xrightarrow{Br} Br \xrightarrow{Br} O \xrightarrow{Br} Br \xrightarrow{Br} Br$ $Br \xrightarrow{Br} Br \xrightarrow{Br} Br$
Synonyms	Decabromodiphenyl oxide bis(Pentabromophenyl)ether 1,1'-Oxybis[2,3,4,5,6-pentabromobenzene] 1,1'-Oxybis(pentabromobenzene) 2,2',3,3',4,4',5,5',6,6'-Decabromodiphenyl ether BDE-209 Benzene, 1,1-oxybis-, decabromo derivative Benzene, 1,1'-oxybis(2,3,4,5,6-pentabromo)- Benzene, 1,1'-oxybis[2,3,4,5,6-pentabromo-] DBBE DBBO DBDPE DBDPO Decabromo biphenyl oxide Decabromo phenoxybenzene Decabromodiphenyl ether
Existing / Newly Announced Chemical Substances	Existing Chemical Substances
Biodegradation and Bioconcentration Results	Result of Biodegradation: Non-biodegradable Result of Bioconcentration: Low bioconcentration
Act on Confirmation, etc., of Release Amounts of Specific Chemical Substances in the Environment and Promotion of Improvements to the Management Thereof (PRTR Law)	Classification: I Cabinet Order Number: 1-255
Air Pollution Control Law	Classification: Hazardous Air Pollutants Cabinet Order Number: 119 of Central Environment Council 9th Report

※ : Incorporated Administrative Agency National Institute of Technology and Evaluation Chemical Risk Information Platform (NITE-CHRIP) Date of View: 2017/8/21

# **2** Physicochemical properties

The physicochemical properties of BDE-209 are excerpted from the risk management evaluation on c-decaBDE (POPRC2015)<sup>1</sup> provided by the United Nations and are shown in Table 2-1.

, <b>,</b>										
Property	Value	Unit	Reference							
Molecular weight	959.2									
Physical state at 20 °C and 101.3 kPa	fine whitish powder	_	ECB 2002							
Melting point / freezing point	300–310	°C	Dead Sea Bromine Group 1993, cited in ECB 2002							
Boiling point	320 (decomposition)	°C	Dead Sea Bromine Group 1993, cited in ECB 2002							
Vapor pressure	4.63×10 <sup>-6</sup> (21°C) Pa Wildlife International Lto in ECB 2002		Wildlife International Ltd 1997, cited in ECB 2002							
Water solubility	< 0.1 (25 °C, column elution method)	µg/L	Stenzel and Markley 1997, cited in ECB 2002							
Partition coefficient, n-octanol / H2O (log Kow)	6.27 (generator column method: measured value) 9.97 (HPLC method: estimated value)	_	MacGregor and Nixon 1997, Watanabe and Tatsukawa 1990, respectively, cited in ECB 2002							
Partition coefficient, n-octanol / air (log Koa)	13.1	_	Kelly et al. 2007							

Table 2-1 Physicochemical properties of BDE-209

<sup>&</sup>lt;sup>1</sup> United Nations (2015), Risk management evaluation on decabromodiphenyl ether (commercial mixture, c-decaBDE), *Report of the Persistent Organic Pollutants Review Committee on the work of its eleventh meeting, Addendum, 2015* 

## 3 States of use

# 3-1 Information on notification of quantity of manufacture, etc., under the CSCL

After BDE-209 was designated as a Designated Chemical Substance in 2000, the METI had investigated the actual states of the quantity of manufacturing, import, or the like every year till FY 2009. Since FY 2010, manufacturers and importers have notified the METI about the quantity of manufacture or the like of BDE-209 as a General Chemical Substance under the CSCL every year.

# 3-1-1 Change in quantity of manufacture and quantity of import over the years

The quantity of manufacture and the quantity of import in the 15-year period from FY 2000 to FY 2014 according to investigation and notification data on the quantity of manufacture, etc., are shown in Figure 3-1.

The quantities for the period from FY 2000 to FY 2009 are the results of actual manufacture/import quantity investigations which the METI conducted on the manufacturers and importers. The quantities for FY 2010 and after are the quantities as a general chemical substance under the CSCL of which the manufacturers and importers notified the government. In these investigations and notifications, there are slight differences in how quantities are treated, and quantities of less than 100 tons cannot be regarded as the same. Therefore, for the manufacture and import quantities shown in this report, values less than 100 tons were rounded off.

The total manufacture and import quantity has been trending smaller since FY 2008 (about 3,800 tons). The total manufacture and import quantity for FY 2014 is about 1,100 tons.

#### 3-1-2 Change in quantity of shipment by usage over the years

The contents such as quantity of manufacture that require notification under the CSCL include the quantity of shipment by usage classification and the quantity of shipment by prefecture. The quantities of shipment by usage classification for the 15-year period from FY 2000 to FY 2014 are shown in Figure 3-2.

There is a difference in classification of usage data between the investigation of actual states for manufacture/import quantity conducted by the METI and the notification of manufacture/import quantity for a general chemical substance under the CSCL by manufacturers and importers. Therefore, in this report, the usage data in the investigation of actual states for manufacture/import quantities were adapted to the usage classification in the notification of the general chemical substances under the CSCL, and the resultant usage classification was used to show the change in quantity of shipment. In the same way as shown in 3-1-1, quantities less than 100 tons were rounded off.

The usage of BDE-209 is "flame retardant", which is shipped as "for resin" and "for textiles". The quantity of shipment of "flame retardant for resin" decreased from 3,200 tons in FY 2000 to 600 tons in FY 2014 (i.e., less than 20% of the quantity in FY 2000).

For "flame retardant for textiles", no clear increase or decrease in the quantity of shipment is shown, but there has been a decreasing trend since FY 2011 (500 tons).



Figure 3-1 Change in quantity of manufacture and quantity of import over 15 years



Figure 3-2 Change in quantity of shipment by usage over 15 years

#### 3-2 Information of BDE-209 containing products

As previously described, BDE-209 is used for flame retardant in Japan, 70 to 80% of which is used for resin while the remainder is used for textiles. In other countries as well, BDE-209 is mostly used for flame retardant for resin used for electronics, although the state of use varies depending on the country, and there are some cases where BDE-209 is used for flame retardant for textiles (fabrics) (POPRC2015).

#### 3-2-1 Usages of BDE-209 containing resin

For parts requiring a high flame retardancy, generally, bromic flame retardant is used.<sup>1</sup> The additive fraction of bromic flame retardant in resin is about 10 to 40%. Use of antimony trioxide as a flame-retardant aid substantially enhances the flame-retardant effect.<sup>2</sup> BDE-209 as flame retardant for resin is mainly used for enclosures and cables for electronics such as a cathode-ray tube TV made of impact-resistant polystyrene, small electrical parts, etc.<sup>2</sup>

The investigation results of the content of BDE-209 in resin products in Japan are shown in Table 3-1. BDE-209 in concentrations of 0.58 to 140,000  $\mu$ g/g was detected from electrical products such as cathode-ray tube TVs and their parts. From the toys made in China, BDE-209 in concentrations of 370 to 23,000  $\mu$ g/g was detected. In addition, the BDE-209 content was detected from two other products made in China.

According to an investigation by the METI, the concentrations of BDE-209 contained in individual pieces of the tape portion of video tape, spray insulating material, and urethane foam and in three heat-resistant coatings were less than the minimum limit value of determination (0.03 to 0.2  $\mu$ g/g, which varied by the investigation year). ((iv) METI2014, (v) METI2015, (vi) METI2016<sup>3</sup>). According to the investigation by the Ministry of the Environment (MOE), for 21 products among 33 products other than the textile products that may contain BDE-209, the concentration of BDE-209 was less than or close to the detection limit (0.01  $\mu$ g/g) ((vii) MOE2014).

<sup>&</sup>lt;sup>1</sup> Jin Nishizawa (2014), Flame Retardant Polymeric Materials (4) The Flame Retardant Materials and Flame Retardant Technology in OA Instruments, AVC Instruments and in Wire and Cable Industries, *Journal of the Society of Rubber Science and Technology, Japan, Vol. 87, No.1 pp.3-8, 2014* 

<sup>&</sup>lt;sup>2</sup> AIST (National Institute of Advanced Industrial Science and Technology) (2008), Decabromodiphenyl ether (BDE-209), *Risk Assessment Document Series on Chemical Substances 23, 2008* 

<sup>&</sup>lt;sup>3</sup> Bibliographic references are summarized as "3-4 Reference literature on the concentration in products and indoor environment"

Category	Product	Concentration (µg/g)	Reference	
Electrical	CRT-based televisions (made in	95,000	⑦MOE2014	
appliances	Malaysia)			
	Front frame of CRT-based	median: 239	12 Takigami e	
	televisions	mean: 256	al., 2008	
	n=5	minimum: 0.58		
		maximum: 140,000		
	Back frame of CRT-based	median: 7,300		
	televisions	mean: 45,460		
	n=5	minimum: 1.3		
		maximum: 120,000		
	Electric circuits in CRT-based	median: 3.6		
	televisions	mean: 9.62		
	n=5	minimum: 1.0		
		maximum: 38		
	AC adapter (made in China)	7,750	⑦MOE2014	
	Electrical switch (made in Japan)	0.8		
	Night sensor light (made in China)	82,500		
	Fan heater (made in China)	22.5		
	LED neon blade (made in China)	870		
	Loudspeaker (made in Malaysia)	3.25		
	Case of video tape (made in China)	140	⑥METI2016	
Тоу	Toy 1 (made in China)	370	⑦MOE2014	
-	Toy 2 (made in China)	9,300		
	Toy 3 (made in China)	4,750		
	Toy 4 (made in China)	6,200		
	Buddhist statue (Toy) (made in	23,000		
	China)			
Others	Rigid plastic bottle (made in China)	545		
	Ramp (made in China)	255		

 Table 3-1
 Content of BDE-209 in resin products (Japan)

Household electrical appliances manufacturers had limitedly used BDE-209 as flame retardant in some plastics covering the heating sections of cathode-ray tubes, power supply boards, etc., in order to secure the product safety against fire or the like, mainly since the latter half of the 80s. Under the RoHS Directive,<sup>1</sup> however, use of BDE-209 has been prohibited since 2008, and to comply with the Directive, the household electrical appliances manufacturers pushed forward with front-loading measures. As a result, BDE-209 has not been used in the products manufactured since 2007.<sup>2</sup> The procurement regulation prepared by major Japanese electrical and electronic equipment manufacturers stipulated that the use of PBDEs be totally abolished or its content be prohibited by April 1, 2006 at the latest, to comply with the RoHS Directive on PBDEs, and measures in advance have been pushed forward in the related industries.

In Japan, terrestrial television broadcasting was digitalized by March 2012, and along with this, CRT-based televisions were replaced with liquid crystal televisions or the like.

<sup>&</sup>lt;sup>1</sup> Restriction of Hazardous Substances (RoHS) Directive : Directive 2002/95/EC of the European Parliament and of the Council of 27 January 2003 on the restriction of the use of certain hazardous substances in electrical and electronic equipment

<sup>&</sup>lt;sup>2</sup> "Document 1-2: Association for Electric Home Appliances" at " 3rd POPs Review Committee on Promotion of Waste Disposal Proper Disposal" that was held on December 7 in 2016, by MOE

Therefore, it is considered that, at present, there are few houses that have CRT-based televisions containing BDE-209.

#### 3-2-2 Usages of BDE-209 containing textiles

BDE-209 as flame retardant for textiles is used in backings of textile products for cars (car fabric: textiles for fabric seat, fabric floor mats, etc.), banners, advertisement screens, heavy fabrics, blinds, cloth-covered furniture, low partitions, carpets, and special clothes.<sup>1</sup> BDE-209 is not used for general clothes (EU2001<sup>2</sup>). It is reported that, in Japan, vehicle seats account for 60% of the c-decaBDE use, while an additional 15% is reportedly used for other textile applications (POPRC2015).

The investigation results of the content of BDE-209 in textile products in Japan are summarized in Table 3-2. BDE-209 was detected at concentrations of 12  $\mu$ g/g in flameproof carpet made in Japan. In the outer cloth and filling material of the safety hood, BDE-209 was detected at concentrations of 5,000 to 25,000  $\mu$ g/g, and in fire-prevention and flame-retardant sheet, BDE-209 was detected at concentrations of 0.6 to 19,000  $\mu$ g/g. BDE-209 was detected at concentrations of 1,850 to 19,000  $\mu$ g/g in car seats and 0.75  $\mu$ g/g in child seats. In addition, BDE-209 content was observed in one kind of disaster-prevention goods and one kind of motorbike goods.

According to the results of the investigation by the METI, the concentrations of BDE-209 in two flame-proof carpets, two cushions (one of which is for infants), two safety hoods, seven flame-proof and flame-retardant seats (including covers), a child seat for a car, a cover for a car interior mat, a portable pillow for use in a car, an apron, and a bike cover were less than the minimum determination limit value (0.03 to 0.2  $\mu$ g/g, which varied by the investigation year) ((iv) METI2014, (v) METI2015, (vi) METI2016). According to the results of the investigation by MOE, the concentrations of BDE-209 in 7 textile products among 12 textile products that might contain BDE-209 were less than or close to the detection limit (0.01  $\mu$ g/g) ((vii) MOE2014).

<sup>&</sup>lt;sup>1</sup> "Document 2-2-2: submitted document from Flame Retardant Chemicals Association of Japan" at "Study meeting on Measures to Prevent Workers' Health Damage by 3rd Chemical Substance in FY2015" that was held on 7th October in 2015 by MHLW

<sup>&</sup>lt;sup>2</sup> European Chemicals Bureau (2001), European Union, bis(pentabromophenyl) ether, *Risk* Assessment Report, CAS No: 1163-19-5, EINECS No: 214-604-9, 2001

Category	Product	Concentration	Reference
outogory	1100000	(µg/g)	Reference
Carpet	Flameproof carpet (made in Japan)	12	④METI2014
Safety hood	outer cloth of the safety hood	25	
	(made in Japan)		
	filling material of the safety hood	5	
	(made in Japan)		
	outer cloth of the safety hood	3.2	⑤METI2015
	(made in China)		
Fire prevention	fire prevention and flame retardant	0.4	④METI2014
and flame	sheet 1		
retardant sheet	(made in Japan)		
	fire prevention and flame retardant	29,000	⑤METI2015
	sheet 2		
	(made in Japan)		
	fire prevention and flame retardant	0.6	
	sheet 3		
	(made in Japan)		
	fire prevention sheet	15	⑥METI2016
	(made in China)		
Car seat	car seat 1 (unknown country of	12,000	⑦MOE2014
	manufacture)		
	car seat 2 (unknown country of	19,000	
	manufacture)		
	car seat 3 (unknown country of	1,850	
	manufacture)		
	child seat (unknown country of	0.75	
	manufacture)		
Others	simple emergency set (including 7	55,500	
	goods) (unknown country of		
	manufacture)		
	bike cover (made in China)	39,000	

 Table 3-2
 Content of BDE-209 in textile products (Japan)

In FY 2016, the METI conducted interviews for the Japan Automobile Manufacturers' Association (JAMA) and the industrial associations dealing with curtains, blinds, or the like, which were assumed to be those using flame retardant for products present in human living environments. The results showed that BDE-209 was used for car fabrics and indoor blinds among the end products at the time of the survey.

In the project commissioned by MOE,<sup>1</sup> an interview on bromic flame retardants was conducted for JAMA in February 2011. According to the interview, the use of BDE-209 started in the mid-1990s, and at the time of the interview, it was still used mainly in back coatings of car seat upholstery and electronic parts (engine compartment) ,which varies depending on the vehicles, grades and specifications. The usage amount across all the member companies in and around 2010 was several tens of tons, but it is estimated that the amount will decrease following the same trend as in North America, etc.

A document from MOE dated December 7, 2016, "3rd Study Committee on Promotion of Proper Waste Treatment of POPs", describes that, in the automobile industry, BDE-209

<sup>&</sup>lt;sup>1</sup> FY2011 brominated flame retardant countermeasure investigation business report on end-of-life vehicle recycling, *FY2011 Subcontracting work report for MOE, March 2012* 

has been used for textile materials for seats or the like and for resin materials mainly for electronic parts (light electric parts) so far, but its use in new-model cars and continuously produced cars is supposed to be abolished, targeted for around 2017.<sup>1</sup>

It is said that the average service life of a car is 12.76 years (passenger car).<sup>2</sup> Therefore, although there has been replacement with new products, it is considered that cars and their replacement parts using fabrics containing BDE-209 are still used or kept in stock even at the present time.

<sup>&</sup>lt;sup>1</sup> "Document 1-3" at "3rd POPs Review Committee on Promotion of Waste Disposal Proper Disposal" that was held on December 7 in 2016, by MOE

<sup>&</sup>lt;sup>2</sup> Automobile Inspection & Registration Information Association (2016), Car ownership trend in Japan: Average number of years of use by type of vehicle, *March 2016* 

#### 3-3 Report about the concentration of BDE-209 in indoor environments

Since BDE-209 is still used as described above, there is concern about exposure in the environments inside houses and cars.

In this section, the results of the investigation of actual concentrations from exposure in Japan are described mainly based on the reports of projects conducted by Japanese ministries and agencies, as well as reports on other investigations conducted in Japan, but the situations abroad are also examined as needed.<sup>1</sup>

#### 3-3-1 Concentration of BDE-209 inside houses

A survey was conducted on the situations in Japan concerning the concentration in indoor air, the concentration in dust,<sup>2</sup> and the concentration of BDE-209 eluted from products in houses.

#### (1) Concentration in the indoor air of houses

For the concentration in the indoor air of houses, the investigation results obtained domestically and internationally are shown in Table 3-3 and Table 3-4.<sup>3</sup>

Within the range of the investigated documents, the concentrations of BDE-209 in the indoor air of houses in Japan was N.D. to  $0.95 \text{ ng/m}^3$ . The range of the maximum values for the concentrations of BDE-209 in the indoor air of houses overseas was 268.6 × 10<sup>-3</sup> to 4.46 ng/m<sup>3</sup>, which was almost the same level as the median value of the maximum values obtained from each document, compared to the concentration in the indoor air of houses in Japan.

Category	Site	n	Concentration (ng/m <sup>3</sup> )	Reference
Housing	Housing in Japan	21 houses	median: 0.20 or les	①MHLW2015
			maximum: s	
			0.95	
	Housing in Japan	50 houses	All N.D.	
	Housing in Sapporo	6 houses	All N.D.	10 Takeuchi et al., 2014
	Apartment in Tokyo	1 apartment	N.D.	①Saito et al., 2007
		unit		
	Housing in	2 houses	mean: 0.019	<ol> <li>Takigami et al.,</li> </ol>
	Hokkaido	2 rooms	minimum: 0.0081	2009a
			maximum: 0.027	
Hotel	Hotel in Osaka	1 building	N.D.	1) Takigami et al.,
				2009b

Table 3-3 Concentration of BDE-209 in the indoor air of houses (Japan)

<sup>&</sup>lt;sup>1</sup> Citations with circled numerals indicate domestic (Japanese) documents. References given as only a number (not circled) from 1 to 14 are from the foreign literature. The literature list is summarized as "3-4 Reference literature on the concentration in products and indoor environment".

<sup>&</sup>lt;sup>2</sup> Dust refers to textile dust and other small particles; it does not include solid matter such as hair, skin pieces, food waste, etc.

<sup>&</sup>lt;sup>3</sup> The red and blue cells in the tables show the reports of the largest concentrations in Japan (red) and overseas (blue), respectively.

Country	Year	n	Median (ng	/m³)	Maximum (I	ng/m³)	Reference
USA*	2007	20	-		268.6×10 <sup>-3</sup>		4
USA*	2007	20	-		651.2×10 <sup>-3</sup>		4
UK	2016	15	0.170		3.8		5
Norway	2014	38	0.00376		4.15		6
Germany	2009	34	0.0095		0.438		3
Taiwan	2015	3	-		0.1		15
			maximum:	0.17	maximum:	4.15	
Overall			mean:	0.06	mean:	1.57	
			median:	0.01	median:	0.54	

 Table 3-4
 Concentration of BDE-209 in the indoor air of houses (overseas)

X: For a given house, the top row is the value measured in the living room and the bottom row is the value measured in the bedroom

A comparison of the above-described concentrations (maximum values) of BDE-209 in the indoor air of houses domestically and abroad is shown in Figure 3-3.





%: Excludes references with N.D. and maximum values not listed

In addition, the investigation results for the emission rates<sup>1</sup> from various products are shown in Table 3-5. The emission rates for the products in which BDE-209 content was detected by an investigation of BDE-209 content for the products distributed on the Japanese market are shown. ((vii) MOE2014)

<sup>&</sup>lt;sup>1</sup> These can be converted into indoor concentrations by assuming the BDE-209 emission rates for the products and the indoor environmental conditions (indoor volume and ventilation frequency) in which the products are installed.

# Table 3-5 Emission rate from the BDE-209 containing products inside houses (Japan)

Category	Product	Emission rate (ng/cm <sup>2</sup> /hr)	Reference
Electrical appliances	Night sensor light	0.0019*	⑦MOE2014
Others	Bike cover (made in China)	0.0016 <sup>*</sup>	⑦MOE2014

%:Including absorbed BDE-209 on the wall at the experiment of emission rate.

#### (2) Concentration in indoor dust

The investigation results for the concentration in indoor dust of houses, etc., obtained domestically and internationally are shown in Table 3-6 and Table 3-7.

Within the range of the investigated documents, the concentrations of BDE-209 in the indoor dust of houses in Japan were 88 to 6,500 ng/g.

In addition, in order to obtain concentrations in indoor dust from other sources than monitoring data, migration and absorption from products to dust was estimated based on the vapor pressure using functions of the National Institute of Advanced Industrial Science and Technology - Indoor Consumer Exposure Assessment Tool (AIST-ICET)<sup>1</sup>. As a result, the estimated value was 1,019 ng/g.

<sup>&</sup>lt;sup>1</sup> According to AIST-ICET, using the following equation, which is an empirical formula obtained by a transfer test of BDE-209, bisphenol A, bis diphenyl phosphate (BDP), triphenyl phosphate (TPP) from a plastic element to a dust in the simulator. Transfer amount from product to dust ( $\mu$ g/g) = 75 × Vapor pressure (Pa)<sup>0.35</sup>

Category	Product	n	Concentration (ng/g)		Reference
Housing	Housing in	19 sites	median:	364	① MHLW2015
	Japan		maximum:	3,300	
	Housing in	44 sites	median:	225	
	Japan		maximum:	4,300	
	Housing in Kanto region	5 houses	maximum:	6,500 <sup>**</sup> 1	② MOE2012
	Housing in	19 houses	median:	550	⑧Suzuki et al.,
	Japan		mean:	820	2006
			minimum:	100	
			maximum:	2,600	
	Housing in	9 houses	around TV	88, 90,	⑨ Kono et al.,
	Tama area,	13 sites	(n = 3):	3,200	2007
	Tokyo		around washing machine (n = 1):	2,800	
			on floor (n = 1):	540	
			others <sup>*2</sup> :	160 or le ss	
	Housing in	2 houses	mean:	390	① Takigami et
	Hokkaido		minimum:	160	al., 2009a
			maximum:	620	,
Office and	Office in	3 facilities	median:	1,100	⑧Suzuki et al.,
the like	Japan	14 rooms	mean:	2,400	2006
			minimum:	150	
			maximum:	17,000	
	Office in Osaka	1 building	median:	1,100 *2	(I) Takigami et al., 2009b
Others	Dust inside	5 units	median:	239,000	12 Takigami
	the flame of		mean:	256,000	et.al, 2008
	CRT-based		minimum:	56,000	
	televisions		maximum:	490,000	
	estimate	—		1,019	AIST-ICET

 Table 3-6
 Concentration of BDE-209 in indoor dust of houses, etc. (Japan)

%1: Estimated from report content

2: Fluorescent lamp cover (n = 4), air conditioner filter (n = 2), dust bag of vacuum cleaner (n = 1), fan heater filter (n = 1)

Concerning the concentration of BDE-209 in the indoor dust of houses overseas, there are many previously reported investigation results reviewed in the treatise by Todd Whitehead et al. published in 2011 (Reference 1) and many other reports. According to these reports, the concentration of BDE-209 in the indoor dust of houses in other countries differs greatly by country (region). In particular, the concentration in the United Kingdom is high, with the maximum value of 2,200,000 ng/g. Among overseas countries excluding the United Kingdom, Belgium has the highest value, which is 303,000 ng/g.

					(
Country	Year	n	Median (ng/g)	Maximum (ng/g)	Reference
Australia	2008	10	730	13,000	1
	2009	10	291	-	1
	2009	5	151	587	1
Philippines	2010	25	118	524	1
Singapore	2007	31	1,000	13,000	1
Korea	2012	46	1,200	11,000	
China	2010	76	1,792	9,602	1
	2010	27	4,039	40,500	1
Kuwait	2006	17	83	338	1
Saudi Arabia	2016	15	275	1,670	11
Canada	2005	68	630	10,000	1
	2008	10	560	1,100	1
U.S.A.	2005	9	665	65,777	1
	2005	17	1,350	8,750	1
	2007	11	<500	9,600	1
	2008	20	4,502	184,600	1
	2008	20	1,300	3,300	1
	2008	10	2,000	21,000	1
	2008	1	40	40	1
	2009	20	190	66,000	1
	2009	38	1,398	-	1
	2009	12	903	9,210	1
	2009	4	1,038	4,156	1
	2010	50	1,482	32,366	1
	2010	30	1,534	-	1
	2010	27	2,476	72,133	1
	2014	39	1,443	16,792	2
	2012	16 <sup>%a</sup>	1,400	15,000	14
	2012	16 <sup>%b</sup>	1,200	8,500	14
Nigeria	2016	12	390	940	8
Belgium	2004	23	<100	303,677	1
	2008	8	144	292	1
	2009	19	106	588	1
	2010	43	313	> 1,513	1
France	2003	8	420	3,400	1
Spain	2003	4	425	1,700	1
	2007	6	184	1,615	1
	2008	1	138	138	1
Portugal	2010	9	953	1,832	1
Finland	2003	1	100	100	1
Italy	2003	1	1,600	1,600	1
Romania	2008	1	27	27	1
UK	2003	10	7,100	19,900	1
	2006	9	3,796	54,795	1
	2008	30	8,100	2,200,000	1, 9
	2008	28	2,800	520,000	1
	2008	10	10,000	54,000	1
	2016	45	4,500	370,000	5
Denmark	2003	1	260	260	1
	2011	42	332	58,064	1
Sweden	2007	5	158	1,560	1
Norway	2014	38	303	204,000	6
Germany	2003	40	265	19,100	1

 Table 3-7
 Concentration of BDE-209 in the indoor dust of houses, etc. (overseas)

	2003	1	2,800		2,800		1
	2008	10	63		410		1
	2009	34	312		1,460		1,3
Overall			maximum: mean: median:	10,000 1,408 595	maximum: mean: median:	2,200, 000 83,528 8,500	

 $\%\colon$  In the same house, measured in 2006 (a) and 2011 (b).

A comparison of the concentration of BDE-209 in the indoor dust of domestic and foreign houses is shown in Figure 3-4.



#### Figure 3-4 Comparison of the concentration of BDE-209 from the domestic and foreign references

(maximum value in the indoor dust of houses)

**%:** Excludes references with N.D. and maximum values not listed

Fang Tao et al. (Reference 5) collected indoor dust of houses and offices in the UK and compared the concentrations in the collected indoor dust with those reported in the past. They found that the concentrations of BDE-209 in the collected indoor dust of houses were lower in some places than those in the past, but there were no significant differences (p > 0.05). On the other hand, in offices, indoor dust concentrations had been significantly reduced (p < 0.05). They attributed this to the replacement cycle of products being faster in offices than in houses. Therefore, it is considered that BDE-209 in the indoor dust of houses will also decrease along with replacement of products in the future.

#### (3) Elution from products

The data on elution from the BDE-209 containing products inside houses to water in Japan are shown in Table 3-8.

Within the range of the investigated references, the elution concentrations from the BDE-209 containing products to water in Japan were N.D. to 170 ng/g (7.2 ng/cm<sup>2</sup>). The elution to water was examined based on MOE Notification No. 13 "Method for determining metals, etc., contained in industrial wastes"<sup>1</sup>.

In addition, it has been reported that in the sampling test of seven products, BDE-209 was detected in a vinyl leather sofa and the concentration was 100 ng/cm<sup>2</sup>. However, the sampling test was conducted for the purpose of investigating the source of indoor dust and the obtained data were not data on elution.

Category	Product	Concentration (ng/g)	Reference
Resin	Night sensor light (made in China)	1200	①MOE2014
products		(0.6 ng/cm <sup>2</sup> )	
	Night sensor light (made in China)	0.0042	
		(0.024 ng/cm <sup>2</sup> )	
	Buddhist statue (toy) (made in China)	170	
		(7.2 ng/cm <sup>2</sup> )	
	Case of video tape (made in China)	0.93	⑥METI2016
Textile	Flameproof carpet	N.D.	④METI2014
products	Outer cloth of safety hood (made in Japan)	0.05	
	Filler of safety hood (made in Japan)	0.37	
	Fire prevention and flame retardant sheet, 2 (made	N.D.	⑤METI2015
	in Japan)	N.D.	
	Fire prevention and flame retardant sheet, 4 (made	99	⑥METI2016
	in China)	0.00074	
	Simple emergency set (including 7 goods)	0.00074	⑦MOE2014
	(unknown country of manufacture)	(0.055 ng/cm <sup>2</sup> )	
	Bike cover (made in China)	0.0049	
		(0.27 ng/cm <sup>2</sup> )	
Others	Wipe of surface of product <sup><math>*</math></sup> n = 7	Vinyl leather sofa: 100	①HLW2015
		ng/cm <sup>2</sup>	
		6 other products: N.D.	

 Table 3-8
 Elution from the BDE-209 containing products inside houses to water (Japan)

※: Measurements were taken on a quartz filter to which methanol had been added and wiped five times vertically and horizontally, after removal of dust on the surface of the product.

<sup>&</sup>lt;sup>1</sup> Environment Agency Notification No. 13, "Method for testing metals, etc., included in industrial waste": Elution amount into water when the sample was pulverized into fragments 5 mm in diameter or less, then mixed so that the weight-volume ratio with pure water was 10%, and agitated continuously for 6 hours at 200 rpm at room temperature and atmospheric pressure

#### 3-3-2 Concentration of BDE-209 inside cars

#### (1) Concentration in the air

The investigation results for BDE-209 on the concentration in the air and the emission rate from BDE-209 containing products inside cars domestically and abroad are shown in Table 3-9 and Table 3-10.

In Japan, monitoring data on concentrations in the air inside cars were not available.

Concerning the emission rate, there are investigation results on the surface material of the car seat (Appendix material 1: National Institute of Technology and Evaluation (NITE)) which contains BDE-209 in the highest concentration at present among the car seats whose content have been confirmed by the trial purchase investigation for car seats by the Department of the Environment ((vii) MOE2014) and by the industrial association.

 Table 3-9
 Emission rate from BDE-209 containing products inside cars (Japan)

Product	Concentration (ng/cm <sup>2</sup> /hr)	Reference
Car sheet	9.3×10 <sup>-5※1</sup>	⑦MOE2014
	N.D. <sup>**2</sup>	NITE (Appendix 1)

%1: including absorbed BDE-209 on the wall surface of products

%2: Gaseous BDE was not collected, but absorbed BDE on the wall surface was detected.

The data on other countries were only available from one report from the UK.<sup>1</sup> The maximum value of concentration in the air inside cars in the UK (4.0 ng/m<sup>3</sup>) was almost the same as the maximum value in the investigation of concentration in the air inside houses (Norway: 4.15 ng/m<sup>3</sup>, UK: 3.8 ng/m<sup>3</sup>).

Country	Year	n	Median (ng/m <sup>3</sup> )	Maximum (ng/m <sup>3</sup> )	Reference
UK	2010	20*	1.3	4.0	13
	2010	19*	0.9	3.7	13

Table 3-10 Concentration of BDE-209 in the air inside cars (overseas)

: In the same car, n = 20 is measured around the driver's seat, n = 19 is measured in the trunk compartment.

#### (2) Concentration in dust

The investigation results for concentration of BDE-209 in the dust inside cars obtained domestically and abroad are shown in Table 3-11 and Table 3-12.

Within the range of the survey, the monitoring data of concentration in the dust inside cars in Japan was only obtained from one report ((iii) MOE2015). According to the report, the maximum values were 352,000 ng/g for the floor surface and 136,000 ng/g for the seating surface.

In the NITE test (Appendix material 1), it was examined whether BDE-209 in products was transferred and absorbed to simulated dust. The result was that the amount of BDE-209 transferred and adsorbed from the car fabrics to the simulated dust in 28 days was 0.04  $\mu$ g/cm<sup>2</sup> per unit area in the environment having a temperature of 60°C, where this high temperature was based on summer conditions. The amount of simulated dust used for the test was about 0.5 g per 1 cm<sup>2</sup> of the car seat, and the simply calculated adsorption amount per dust weight was 78.4 ng/g.

However, according to the results of the emission test by the passive flux sampler reported in the

<sup>&</sup>lt;sup>1</sup> Considering the physicochemical properties of BDE-209, these data may be a result of BDE-209 being classified as a semi-volatile organic compound (SVOC, boiling range >400 °C) or particulate organic matter (POM, boiling range <380 °C) and deviating from the measurement target.

same NITE report, it cannot be considered that BDE-209 emitted from the car seat was uniformly adsorbed to the 0.5 g/cm<sup>2</sup> per 1 cm<sup>2</sup> of dust on the seat, and it is assumed that the transfer and adsorption occur in the extreme vicinity in contact with the car fabric. Therefore, assuming that 0.04  $\mu$ g of BDE-209 is adsorbed to the 0.005 g/cm<sup>2</sup> of simulated dust (one-hundredth of the dust) in the immediate vicinity of the car fabric, the concentration of BDE-209 in the dust after 28 days (dust age = 28 days) is 8,000 ng/g. Assuming that the inside of the car is cleaned once a year (average dust age = 183 days), the concentration of BDE-209 in the dust is 52,140 ng/g.

		. /	
Product	Concentration (ng/g)	Reference	
41 Japanese domestic cars (36 scrapped	maximum(floor): 352,000 <sup>×1</sup>	③MOE2015	
cars from domestic end-of-life vehicle	maximum(seat): 136,000 <sup>%1</sup>		
dismantling factories, and 5 active cars)			
car seat	52,140 <sup>%2</sup>	NITE (Appendix	
		1)	
estimate	1,019 <sup>%3</sup>	AIST-ICET	

 Table 3-11
 Concentration of BDE-209 in the dust inside cars (Japan)

%1: Estimated data from the report content

%2: Estimated data from the results of the migration test using simulated dust

%3: Estimated data from physicochemical properties by AIST-ICET (repetition from 3-3-1 (2))

The concentration of BDE-209 in the dust inside cars overseas differs greatly by country. In particular, in the UK, the concentration is high even inside cars, the maximum being 2,600,000 ng/g. The maximum value observed overseas except in the UK is 52,000 ng/g (Nigeria).

Comparing the average maximum value overseas including the UK with that in Japan, the (average) maximum value overseas is about lower than one-third that in Japan.

Table 5-12 Concentration of BDE-205 in the dust inside cars (overseas)							
Country	Year	n	Median (ng/g)		Maximum (	Maximum (ng/g)	
USA	2009	12	3,100		-		8
Egypt	2015	5	1,540		-		8
Nigeria	2016	16	780		52,000		8
Nigeria	2015	12	122		347		8, 11
UK	2008	20	100,000		2,600,000		9
UK <sup>*</sup>	2011	14	190,000		-		7
UK <sup>*</sup>	2011	14	2,700		-		7
Kuwait	2016	19	391		16,100		10
Saudi Arabia	2016	15	200		35,500		11
			maximum:	190,000	maximum:	2,600,000	
Overall			mean:	33,204	mean:	540,789	
			median:	1,540	median:	35,500	

 Table 3-12
 Concentration of BDE-209 in the dust inside cars (overseas)

: In the same car, n = 20 is measured around the driver's seat and n = 19 is measured in the trunk compartment.

A comparison of the concentration of BDE-209 in the dust inside cars domestically and abroad described above is shown in Figure 3-5.



Figure 3-5 Comparison of the concentration of BDE-209 based on the domestic and foreign references (maximum values in the dust inside cars)

\*: Excludes references with N.D. and maximum values not listed

It is said that the concentration value for BDE-209 in the dust inside cars is larger than that in the indoor dust of ordinary houses by 1 to 2 digits ((iii) MOE2015). Within the range of the investigated references, comparing the indoor dust amount of ordinary houses to the dust amount on floor surfaces inside cars, the dust amount of inside cars is over 50-fold larger than that of ordinary houses.

#### (3) Elution from products

The data on elution from the BDE-209 containing products inside cars in Japan are shown in Table 3-13. These data were obtained from the results of an elution test conducted using artificial saliva (Appendix material 2: NITE) on the surface material of the car seat that contains BDE-209 in the highest concentration, among the products whose content of BDE-209 has been confirmed ((vii) MOE2014) and the products whose content has been confirmed by the industrial organizations, in an investigation of the content amount in products that might contain BDE-209 and have been distributed on the domestic market.

	Product	Concentration	Reference
Elution test	Car seat (unknown country of	0.03 ng/cm <sup>2%1</sup>	⑦MOE2014
	manufacture)	(2 × 10 <sup>4</sup> ng/g)	
	Car seat (made in Japan)	56 ng/cm²/day <sup>%2</sup>	NITE (Appendix
		(concentration in artificial	2)
		saliva: 4 ng/mL)	

%1: Result of the elution test according to Notification No. 13 from the Environment Agency

 $\ensuremath{\ensuremath{\mathbb{X}}}\xspace{2}$  : Result of 24-hour elution test using artificial saliva

# 3-4 Reference literature on the concentration in products and indoor environment

#### [Domestic information]

(i) MHLW, 2015

Chemical substances risk research project under the Health Labour Sciences Research Grant in March 2015, Research on multi-route exposure assessment for semi-volatile organic compounds in indoor environment, FY 2012 to FY 2014 Comprehensive Research Report, Representative researcher: Hideto Jinno

#### <Outline>

In this report, in order to grasp the actual concentrations of indoor environmental pollution by bromic flame retardants containing BDE-209, an investigation was conducted at houses located throughout Japan, from Hokkaido to Okinawa, in FY2013 and FY2014. In FY2013, investigation was conducted at 21 houses (19 houses for house dust). As a result, BDE-209 was detected in the house dust of all the houses, giving a detection rate of 100%, with the median value of the concentrations being 364 ng/g and the maximum value being 3,300 ng/g. The detection rate of BDE-209 in the indoor air was 15.8%, with the median value being 0.20 ng/m<sup>3</sup> or lower, which was the minimum determination limit value, and the maximum value being 0.95 ng/m<sup>3</sup>. In FY2014, investigations were conducted at 50 houses (44 houses for house dust). As a result, BDE-209 was detected in the house dust of all the houses (i.e., a detection rate of 100%), with the median value of the concentrations being 225 ng/g and the maximum value being 4,300 ng/g. The detection rate of BDE-209 in the indoor air was 0%; that is, in all the houses, the concentration was less than or equal to 0.20 ng/m<sup>3</sup>, which was the minimum determination limit value.

In addition, an investigation of emission sources was conducted for the houses which had a high concentration of BDE-209 in house dust. The surfaces of the household electrical appliances (refrigerator, TV, massage chair) and the textile products (2 kinds of sofa, seating surface of chair, curtain) in the houses were wiped for dust and the concentrations of BDE-209 in the dust were measured. As a result, 100 ng/cm<sup>2</sup> of BDE-209 was detected from one kind of vinyl leather sofa, and this product was regarded as the major BDE-209 emission source.

#### (ii) MOE, 2012

FY 2009 to FY 2011 Research projects under the grant for comprehensive promotion of environmental research in March 2012, Research on BFR risk control in product life cycle including cyclic process, Comprehensive Research Report, Representative researcher: Hidetaka Takigami

#### <Outline>

In this report, in order to grasp the particle size distribution of house dust and the accumulation characteristics of organic bromine compounds, house dust was collected at 5 ordinary houses in the Kanto district in 2009 and the concentrations of PBDEs were measured. In this measurement, the house dust was fractionated not only by particulate or fibrous form but by particle size and the weight of BDE-209 per fractionated dust was measured. As a result, in the particulate dust having particle sizes of 106 to 250  $\mu$ m, 7,500 ng/g of PBDEs at maximum was detected. In the fibrous dust having the same sizes as those of the particulate dust, 7,900 ng/g of PBDEs at maximum was detected. Both the particulate dust and the fibrous dust were collected in the same house. The particulate dust made up 41 to 68% of the overall weight of dust.

BDE-209 was detected in all the houses, and the detected BDE-209 made up 63 to 94% of PBDEs. (There is no description about the concentration of BDE-209 alone, and according to the estimation from the graphs or the like, it is about 6,200 ng/g in the particulate dust and about 6,900 ng/g in the fibrous dust. Considering the rate of the particulate dust to the overall weight, the concentration in the house dust is about 6,500 ng/g.)

#### (iii) MOE, 2015

FY 2012 to FY 2014 Research projects under the grant for comprehensive promotion of environmental research in March 2015, System analysis on the resource potential and the environmental load of end-of-life vehicles (ELV), Comprehensive Research Report, Representative researcher: Shinichi Sakai

#### <Outline>

In this report, in order to determine whether the circulative resources obtained by recycling of end-of-life vehicles (ELV) can become exposure sources of hazardous substances, interior components of a total of 45 cars, including 36 domestically produced ELVs, 4 foreign-made ELVs, and 5 currently used cars, were examined for content of bromine and in addition, dust was collected from the floor surfaces, the seating surfaces, and the dashboard surfaces (of a total of 41 cars, all except the foreign-made cars) and analyzed for bromic flame retardants, at an ELV disassembling factory in Japan. The results showed that some bromine in the components derived from PBDE formulations, but the relationship between the detected PBDEs and the manufacture year of the cars was not identified. It was suggested that in 12 samples among the detected PBDEs, c-DecaBDE whose primary substance is BDE-209 might be used. The concentration range of PBDEs in the dust on the floor surface was 530 to 440,000 ng/g, with the median value being 4,500 ng/g, with the maximum value being 352,000 ng/g. The concentration range of PBDEs in the dust on the seating surface was 960 to 170,000 ng/g. (Assuming that the same ratio can be applied to the dust on the seating surface, the maximum value of BDE-209 is 136,000 ng/g.)

#### (iv) METI, 2014

Project commissioned by the METI in March 2014, FY 2013 Chemical Substance Safety Measures, Safety investigation report on products containing Class I Specified Chemical Substances, Contract organization: Chemicals Evaluation and Research Institute, Japan

#### <Outline>

In order to prevent Class I Specified Chemical Substances under the CSCL from adversely affecting people, animals, and plants via the environment and to implement an appropriate control of them, the actual concentrations on the content of the substances in products were investigated by trial purchase inspections. Therefore, the investigation results shown in this report are not the concentrations in indoor environments but the content amounts in products used in indoor environments.

For 3 kinds of heat-resistant paints (all made in Japan), a safety hood (made in Japan), a portable pillow for use in a car (made in China), 3 kinds of flame-proof/flame-retardant seats (all made in Japan), and 3 kinds of flame-proof carpets (all made in Japan) that might contain PBDEs, the content amount in each product and the elution amount from each product to water were analyzed.

The results showed that BDE-209 was contained in the surface material of the safety hood (25  $\mu$ g/g), the filling material of the safety hood (5.0  $\mu$ g/g), one kind of flame-proof/flame-retardant seat (0.4  $\mu$ g/g), and one kind of flame-proof carpet (12  $\mu$ g/g). The *elution rates* of PBDEs from the products to water were 0.00018% for the surface material of the safety hood (the elution amount of BDE-209 was 0.05 ng/g), 0.0074% for the filling material in the safety hood (the elution amount of BDE-209 was 0.37 ng/g), and 0.00008% or less for one kind of flame-proof carpet (no elution of BDE-209 was detected).

#### (v) METI2015

Project commissioned by the METI in March 2015, FY 2014 Chemical Substance Safety Measures, Safety investigation report on products containing Class I Specified Chemical Substances, Contract organization: Chemicals Evaluation and Research Institute, Japan

#### <Outline>

In order to prevent Class I Specified Chemical Substances under the CSCL from adversely affecting people, animals, and plants via the environment and to implement an appropriate control of them, the actual concentrations on the content of the substances in products were investigated by trial purchase inspections. Therefore, the investigation results shown in this report are not the concentrations in indoor environments but the content amounts in products used in indoor environments.

For 2 kinds of safety hoods (made in China), 3 kinds of flame-proof/flame-retardant seats (all made in Japan), a cushion for infants (made in China), 2 kinds of flame-retardant covers (made in Japan, made in China), urethane foam (made in the Netherlands), and an apron (made in Japan) that might contain PBDEs, the content amount in each product and the elution amount from each product to water were analyzed.

The results showed that BDE-209 was contained in the surface material of the safety hood made in China (3.2  $\mu$ g/g) and in 2 kinds of flame-proof/flame-retardant seats (0.6 and 29,000  $\mu$ g/g). In the elution test for one kind of flame-proof/flame-retardant seat in which BDE-209 was contained in high concentration, no elution to water was detected.

#### (vi) METI, 2016

Project commissioned by the METI in March 2016, FY 2015 Chemical Substance Safety Measures, Safety investigation report on products containing Class I Specified Chemical Substances, Contract organization: Chemicals Evaluation and Research Institute, Japan

#### <Outline>

In order to prevent Class I Specified Chemical Substances under the CSCL from adversely affecting people, animals, and plants via the environment and to implement an appropriate control of them, the actual concentrations on the content of the substances in products were investigated by trial purchase inspections. Therefore, the investigation results shown in this report are not the concentration in indoor environment but the content amounts in products used in indoor environment.

For 3 kinds of flame-proof/flame-retardant seats (all made in China), a motorbike cover (made in China), a cover for mat used in a car (made in China), 2 kinds of safety hoods (all made in China), a cushion (made in the U.S.), a video tape (made in China), a child seat for a car (made in China), and an spray insulation material (made in Korea) that might contain BDE-209, the content amount in each product and the elution amount from each product to water were analyzed.

The results showed that BDE-209 was contained in one kind of flame-proof/flame-retardant seat (15  $\mu$ g/g) and the casing part of a video tape (140  $\mu$ g/g). In addition, the *elution rates* of BDE-209 to water from the two products in which BDE-209 was contained were 0.66% for one kind of flame-proof/flame-retardant seat (the elution amount of BDE-209 being 99 ng/g) and 0.00066% for the casing part of the video tape (the elution amount of BDE-209 being 0.93 ng/g).

#### (vii) MOE, 2014

Project commissioned by Department of the Environment in March 2014, FY 2013 monitoring survey report on hazardous chemical substances in products, Contract organization: Mizuho Information & Research Institute, Inc.

#### <Outline>

There is concern that hazardous chemical substances in products affect people, animals, and plants depending on the content state and possibility of elution. In order to grasp their forms distributed in the market and the actual concentrations, the products that might contain BDE-209 were obtained and analyses of contents, elution tests, and emission tests were conducted.

For 45 products (13 electric and electronic products, one transportation-related product, 8 building/construction-related products, 4 cables, 7 recycled products, and 12 textile products) that might contain BDE-209, the contents of BDE-209 were analyzed. The results showed that 7 products (one electric and electronic product, one transportation-related product, one recycled product, and 4 textile products) contained BDE-209 at 1% or higher, 5 products contained at 0.1 to 1%, 5 products contained 0.1% or lower, and N.D. was determined for 28 products. Among the 7 products, 6 products

(a car seat made in an unknown country, a toy of Buddha image made in China, a night sensor light made in China, a set of 7 simple disaster supplies made in an unknown country, a cover for a motor bike made in China, and a CRT-based television made in Malaysia) were selected in consideration of the kind of product and elution tests were conducted. The results showed that the elution amount per unit area was 550 ng/cm<sup>2</sup> at maximum for the set of 7 simple disaster supplies. For 3 products (a car seat made in an unknown country, a night sensor light made in China, and a cover for a motor bike made in China), emission tests were conducted. The results showed that the night sensor light exhibited the maximum emission rate of  $1.9 \times 10^{-3}$  ng/cm<sup>2</sup>/hr.

#### (viii) Suzuki et al., 2006

Suzuki G et al., PBDEs and PBDD/Fs in house and office dust from Japan, Organohalogen Compounds 68, 2006, pp.1843-1846

#### <Outline>

In the period from May to December in 2005, dust was collected at 19 houses (n=19) and 3 organization offices (n=14) in Japan and the contents of PBDEs in the dust were measured. At the time of collection, a questionnaire survey was also conducted about the cleaning frequency, area, house age, kind of floor, ventilation state, and number of TVs and PCs in the house and their states of use.

The results showed that the concentration of BDE-209 in the dust inside the 19 houses was in the range of 100,000 to 2,600,000 pg/g, with the median value being 550,000 pg/g and the mean\_value being 820,000 pg/g, and that the concentration of BDE-209 in the dust in 14 offices was in the range of 150,000 to 17,000,000 pg/g, with the median value being 1,100,000 pg/g and the mean value being 2,400,000 pg/g. Also, a correlation between the information on the indoor environment based on the questionnaire survey and the highly brominated BDE that contains BDE-209 in the dust was not observed.

(ix) Kono et al., 2007

Kono Y et al., Polybrominated dioxins (PBDDs/DFs) and polybrominated diphenyl ethers (PBDEs) in house dust in ordinary homes, *Organohalogen Compounds 69, 2007, pp.2781-2784* 

#### <Outline>

At 9 houses in the Tama area, Tokyo, a total of 13 dust samples were collected from around a TV (n=3), the surface of a fluorescent lamp cover (n=4), the filter of an air conditioner (n=2), the dust bag of a vacuum cleaner (n=1), around a washing machine (n=1), the filter of a fan heater (n=1), and a floor surface (n=1), and the concentrations of BDE-209 or the like in the dust were measured.

The results showed that one sample from around a TV had the highest concentration of BDE-209, 3,200 ng/g (the other two samples contained 88 and 90 ng/g, respectively) and the second highest concentration was 2,800 ng/g in the dust from around a washing machine. The BDE-209 concentration in the dust from a floor surface was 540 ng/g, and the concentrations in the dust from all the others were 160 ng/g or less (14 to 160 ng/g).

#### (x) Takeuchi et al., 2014

Takeuchi S et al., Detection of 34 plasticizers and 25 flame retardants in indoor air from houses in Sapporo, *Japan, Science of The Total Environment 491-492, 2014, pp.*28-33

#### <Outline>

In summer (July, August) in 2012, indoor air was collected from the living rooms and the bedrooms of a total of 6 two-story houses, including one newly built house in Sapporo City, and the concentrations of BDE-209 or the like were measured. As a result, no BDE-209 was detected.

#### (xi) Saito et al., 2007

Saito I et al., Indoor organophosphate and polybrominated flame retardants in Tokyo, Indoor Air

#### 17, 2007, pp.28-36

#### <Outline>

At a newly built apartment house in Tokyo, the concentrations of organophosphate and polybrominated flame retardants in the indoor air were measured, and in order to check whether migration of substances had occurred, the sampler was placed in contact with the TV/PC monitor in the room and the migration amount of substances was measured. As a result, BDE-209 was not detected from the indoor air. In the measurement of substance migration as well, no BDE-209 was detected.

#### (xii) Takigami et al., 2008

Hidetaka Takigami et al., Transfer of brominated flame retardants from components into dust inside television cabinets, *Chemosphere 73, 2008, pp.161-169* 

#### <Outline>

Five CRT-based television sets (disposed) produced by Japanese manufacturers, which had been used until 2005, were obtained, and the dust accumulated inside the TV sets and on the front and rear faces of the cabinets and the circuit boards was collected, and the contents of BDE-209 or the like were measured. The results showed that the concentrations of BDE-209 inside the dust were in the range of 56,000 to 490,000 ng/g, with the mean value being 256,000 ng/g and the median value being 239,000 ng/g. The concentrations of BDE-209 contained on the circuit boards were in the range of 1,000 to 38,000 ng/g, the mean value being 9,620 ng/g and the median value being 3,600 ng/g. The concentrations of BDE-209 contained on the front faces of the cabinets were in the range of  $5.8 \times 10^2$  to  $1.4 \times 10^8$ , with the mean value being 28,014,952 ng/g and the median value being 8,500 ng/g, while those on the rear faces of the cabinets were in the range of  $1.3 \times 10^3$  to  $1.2 \times 10^8$ , with the mean value being 45,460,520 ng/g and the median value being 7.30  $\times 10^6$  ng/g. Concerning PBDEs in the dust, BDE-209 was predominant. It is considered that these PBDEs derived from the cabinets.

#### (xiii) Takigami et al., 2009a

Hidetaka Takigami et al., Brominated flame retardants and other polyhalogenated compounds in indoor air and dust from two houses in Japan, *Chemosphere 76, 2009, pp.*270-277

#### <Outline>

At two houses in Hokkaido (House A and House B), the concentrations of BDE-209 or the like in the outside air, indoor air (1st floor, 2nd floor), house dust, and ventilation air were measured. The results showed that at House A, the concentration of BDE-209 was 19 pg/m<sup>3</sup> in the outside air, 35 pg/m<sup>3</sup> in the ventilation gas, 8.1 pg/m<sup>3</sup> in the1st-floor indoor air, and 27 pg/m<sup>3</sup> in the 2nd-floor indoor air, and the concentration of BDE-209 in the dust was 620 ng/g. At House B, the concentration of BDE-209 was 9.9 pg/m<sup>3</sup> in the outside air, 9.7 pg/m<sup>3</sup> in the ventilation gas, 18 pg/m<sup>3</sup> in the 1st-floor indoor air, and 21 pg/m<sup>3</sup> in the 2nd-floor indoor air, and the concentration of BDE-209 was 9.9 pg/m<sup>3</sup> in the 2nd-floor indoor air, and the concentration of BDE-209 was 10 pg/m<sup>3</sup> in the 2nd-floor indoor air, and 21 pg/m<sup>3</sup> in the 2nd-floor indoor air, and the concentration of BDE-209 was 10 pg/m<sup>3</sup> in the 2nd-floor indoor air, and 21 pg/m<sup>3</sup> in the 2nd-floor indoor air, an

#### (xiv) Takigami et al., 2009b

Hidetaka Takigami et al., Flame retardants in indoor dust and air of a hotel in Japan, *Environment International 35, 2009, pp.688-693* 

#### <Outline>

At a hotel in Osaka (constructed in 1987, 10 stories, 57 rooms, remodeled in 2003, includes a restaurant and a facility for wedding parties, etc.), dust was collected inside rooms, the restaurant, around the front desk, etc., and the indoor air of the rooms and facilities was also collected. The results showed that BDE-209 made up 82 to 94% of PBDEs in the dust, and the median value for PBDEs was 1,200 ng/g (assuming a BDE-209 fraction of 94%, its concentration was about 1,100 ng/g). No BDE was detected in the indoor air, but BDE-209 on the order of 1 nanograms was detected from the filter installed at the intake port of an air cleaner. The detected BDE-209 is

considered to derive from the dust produced or existing in the indoor air.

#### [Overseas information]

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### 4 Hazard assessment

BDE-209 was a Type II Monitoring Chemical Substance under the CSCL before the amendment of the Law in 2009 and also a substance that should be reported under the Law Concerning Pollutant Release and Transfer Register (PRTR Law). For Type II Monitoring Chemical Substances, the screening assessment was conducted at the time of the amendment of the CSCL in 2009. As a result, BDE-209 was regarded as a general chemical substance.

The *hazard assessment value* used in the screening assessment at that time was based on the designation grounds under the PRTR Law. The designation ground for BDE-209 under the PRTR Law was a NOEL value of 1 mg/kg/day obtained from a positive mutagenesis result and 30-day test data on rats. Uncertainty factor (UF) set for the NOEL value according to the assessment guidance<sup>1</sup> of the CSCL is 600 (10 for animal to human extrapolation, 10 for human variability, and 6 for test period). Therefore, the *hazard assessment value* set with the NOEL of 1 mg/kg/day and UF of 600 is 0.0017 mg/kg/day, and the screening assessment is conducted using this value.

Over the last 10 years, the European Food Safety Authority (EFSA)<sup>2</sup>, the United States Environmental Protection Agency (U.S. EPA)<sup>3</sup> and the Agency for Toxic Substances and Disease Registry (ATSDR)<sup>4</sup> have separately conducted assessments of BDE-209 and set *hazard assessment values*.

The EFSA set the benchmark Dose Lower Confidence Limit (BMDL<sub>10</sub>) for neurobehavioral toxicity at 1.7 mg/kg/day based on the comprehensive effects on the physical activities of rats in 2011. In addition, since there is no difference in the in-vivo half-life of BDE-209 between human beings and other animals, the value is used without correction by the weight. The BMDL<sub>10</sub> was set based on a detailed review of many research reports, and it is considered that this value has a high reliability.

In 2014, the U.S. EPA set the oral reference dose (RfD) of chronic toxicity oral exposure at 7 ×  $10^{-3}$  mg/kg/day using the NOEAL value of 2.22 mg/kg/day obtained by an investigation of neurobehavioral effects. In addition, the cancer oral slope factor was set at 7 ×  $10^{-4}$  (mg/kg/day)<sup>-1</sup> and the unit risk of drinking water was set at 2.0 ×  $10^{-8}$  (µg/L)<sup>-1</sup>. Therefore, when the permissible risk level is  $10^{-5}$ , the values are 0.014 mg/kg/day and 0.5 mg/L (=0.02 mg/kg/day). These values were derived based on a detailed review of many research reports, and it is considered that the values

<sup>&</sup>lt;sup>1</sup> MHLW, METI, and MOE (2014), Technical guidance document of the Risk Assessment on Priority Assessment Chemical Substance(s) (PACSs) in the Chemical Substances Control Law; CSCL, 2014

http://www.meti.go.jp/policy/chemical\_management/kasinhou/information/ra\_1406\_tech\_guidance. html

 <sup>&</sup>lt;sup>2</sup> EFSA (European Food Safety Authority) (2011), Panel on Contaminants in the Food Chain (CONTAM), Scientific Opinion on Polybrominated Diphenyl Ethers (PBDEs) in Food, *EFSA Journal*, 9 (5):2156, 2011

<sup>&</sup>lt;sup>3</sup> U.S. EPA (2014), Technical Fact Sheet - Polybrominated Diphenyl Ethers (PBDEs) and Polybrominated Biphenyls (PBBs), U.S. Environmental Protection Agency, Washington, DC, EPA 505-F-14-006, 2014

<sup>&</sup>lt;sup>4</sup> ATSDR (Agency for Toxic Substances and Disease Registry) (2017), Toxicological Profile for Polybrominated Diphenyl Ethers (PBDEs), *2017* 

have a high reliability.

In 2017, the ATSDR derived and made public the Minimal Risk Level (MRL) on BDE-209 based on a review of the latest several research reports. An MRL of 0.01 mg/kg/day has been derived by the ATSDR for Acute (acute-duration oral) exposure to BDE-209 and 0.0002 mg/kg/day for Intermediate (intermediate-duration oral) exposure to BDE-209. No MRL was derived for Chronic (chronic toxicity oral) exposure to BDE-209 because of insufficient data.

The intermediate-duration oral MRL estimated by the ATSDR was derived based on a minimal LOAEL of 0.05 mg/kg/day for a 12% increase in serum glucose in rats exposed to BDE-209 for 8 weeks via gavage (Zhang et al., 2013). The MRL of 0.0002 mg/kg/day for intermediate-duration oral exposure was estimated by dividing the 0.05 mg/kg/day LOAEL by "a UF" of 300 (3 for use of a minimal LOAEL, 10 for animal to human extrapolation, and 10 for human variability). The MRL for intermediate-duration oral exposure was derived based on a detailed review of many research reports, and therefore this value is considered to be highly reliable. However, note that no target organ has been identified and that the endpoints used for MRL derivation were the 12% increase in serum glucose levels and 1,257 liver gene transcript changes induced by BDE-209 as observed from microarray analysis, etc.

As described above, in addition to the *hazard assessment values* used in the screening assessment under the CSCL, the *hazard assessment values* estimated by the EFSA, the U.S. EPA, and the ATSDR are available. Among them, the MRL for intermediate-duration oral exposure estimated by the ATSDR is the smallest and latest *hazard assessment value*. Therefore, in this risk assessment, the *hazard assessment value* is derived according to the literature on which the ATSDR derived the intermediate-duration oral MRL is based.

The purpose of the hazard assessment is to derive the *hazard assessment value* for chronic toxicity exposure caused by use of products containing BDE-209 throughout a lifetime. The *hazard assessment value* under the CSCL should be determined in reference to a chronic toxicity oral MRL estimated by the ATSDR. However, the ATSDR has reported that no MRL was derived for chronic toxicity oral exposure to BDE-209, because of insufficient data. Therefore, the *hazard assessment value* for chronic toxicity oral exposure used in this risk assessment shall be derived by extrapolating the value used as the intermediate-duration oral MRL.

The intermediate-duration oral MRL estimated by the ATSDR was derived by dividing the 0.05 mg/kg/day LOAEL by "a UF" of 300, since the toxicity with a minimal LOAEL of 0.05 mg/kg/day was observed in the report by Zhang et al. as described above. Considering the uncertainty factor of 3 for use of LOAEL and the test period of 8 weeks, an uncertainty factor of 10 for these aspects was derived. The uncertainty factor of 1,000 was estimated based on three uncertainty factors (10 for animal to human extrapolation and 10 for human variability as well as 10 for these aspects).

Accordingly, the *hazard assessment value* is determined to be 0.00005 mg/kg/day (50 ng/kg/day) from Equation 4-1.

### LOAEL 0.05 mg/kg/day

# $\overline{UFs \ 1000 \ (Test \ period + LOAEL \ 10 \times Species \ difference \ 10 \times Individual \ difference \ 10)} = 0.000050 \ mg/kg/day$

### Equation 4-1

The test data and the hazard assessment value are summarized in Table 4-1.

Route	of	Repeated oral administration		
administration				
Species		Adult male Sprague-Dawley (SD); 10 rats in each group		
Test period		8 weeks		
Doses	- 1	3 treatment groups (0.05, 1, 20 mg/kg) and control		
concentrations				
References       Public Health Service, Agency for Toxic Substances and E         Registry, Toxicological Profile for Polybrominated Diphenyl (PBDEs), March 2017         Zhan et al., Mechanism of BDE209-induced impaired g         homeostasis based on gene microarray analysis of adult r		<ul> <li>U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, Public Health Service, Agency for Toxic Substances and Disease Registry, Toxicological Profile for Polybrominated Diphenyl Ethers (PBDEs), March 2017</li> <li>Zhan et al., Mechanism of BDE209-induced impaired glucose homeostasis based on gene microarray analysis of adult rat liver, <i>Archives of Toxicology, 87, 2013, pp.1557–1567</i></li> </ul>		
Chronic toxicity				
NOEL et al. LOAEL 0.05 mg/kg/day		LOAEL 0.05 mg/kg/day		
EndpointThe effect of BDE-209 on mechanisms such as was investigated. In the group of 0.05 mg/kg/ serum glucose of 12% was confirmed. In this s control, genome gene expression microarray, ge and pathway analysis revealed that BDE-209 1,257 liver gene transcripts and was significant		The effect of BDE-209 on mechanisms such as glucose homeostasis was investigated. In the group of 0.05 mg/kg/ day, an increase in serum glucose of 12% was confirmed. In this sample group and the control, genome gene expression microarray, gene ontology analysis, and pathway analysis revealed that BDE-209 induced a change in 1,257 liver gene transcripts and was significantly concentrated in 18 standard pathways.		
		1000 = Species difference (10) × Individual difference (10) × (LOAEL		
factors (UFs)				
Hazard				
assessment value				

Table 4-1	Test data and hazard assessment value
# 5 Exposure assessment

In the exposure assessment, the exposure to people is estimated according to the exposure scenario setting.

A large difference may be caused by differences of individuals and use environments. Therefore, in this exposure assessment, the worst-case scenario that products are used or installed under the most severe conditions conceivable in Japan is used to estimate the exposure amount in expectation of thorough "safety".

In setting of the conditions (parameters), however, in the case where multiple data are available, the data under the severest condition are not simply selected but rather the data are checked in detail first.

Usage out of common sense or other than normal usages<sup>1</sup>, which may cause trouble or accidents, shall be excluded.

#### 5-1 Exposure scenario

#### 5-1-1 Target groups of people in the assessment

In this exposure assessment/risk assessment, the target groups of people are adults and children living in ordinary houses. The reason why children are included in the target groups is that mouthing behaviors such as holding objects in the mouth and licking objects are observed in their early childhood and their intake amount of dust or the like is estimated to be larger than that of adults.

In this risk assessment, as in another exposure/risk assessment<sup>2</sup>, a human lifetime of 70 years is adopted, among which 6 years are childhood under 6 years old. Therefore, the exposure factor for children is set in consideration of the distribution of children under 6 years old.

The common factors used in the exposure assessments on adults and children and the grounds for their settings are described below.

#### (1) Weight

<u>The weight of adults</u> used in this risk assessment is <u>50 kg</u>. This value is used in the risk assessment on priority assessment chemical substances under the CSCL.<sup>3</sup>

<u>The weight of children</u> used for this assessment is <u>15.2 kg</u>, which is the simple average of the weights of children ages 1 to 6 by sex based on the results of the "National Health and Nutrition Survey"<sup>4</sup> conducted by the Ministry of Health, Labour and Welfare (MHLW) in 2015. This value is the same as the average weight (15.2 kg) of children ages 3 to 4 in the same survey. In the "Guideline for the method of risk assessment on indoor use of insecticides which are over-the-counter drugs and quasi-drugs (proposal)"<sup>5</sup> by the MHLW, 15 kg (3-year-old child) is also

<sup>&</sup>lt;sup>1</sup> The normal usages include a foreseeable misusage.

<sup>&</sup>lt;sup>2</sup> In the study of the emission target of PFOS containing residue in "Ministry of the Environment Minister's Secretariat, Waste / Recycling Division (2011) Technical remarks concerning treatment of PFOS-containing waste", and taking into account the lifetime average daily soil food intake, childhood is considered to be 6 years and adulthood is considered to be 64 years, giving a lifetime of 70 years.

<sup>&</sup>lt;sup>3</sup> MHLW, METI, and MOE2014), Technical guidance document of the Risk Assessment on Priority Assessment Chemical Substance(s) (PACSs) in the Chemical Substances Control Law; CSCL, 2014 <u>http://www.meti.go.jp/policy/chemical\_management/kasinhou/information/ra\_1406\_tech\_guidance.html</u>

<sup>&</sup>lt;sup>4</sup> MHLW, The National Health and Nutrition Survey in Japan http://www.mhlw.go.jp/bunya/kenkou/kenkou eiyou chousa.html

<sup>&</sup>lt;sup>5</sup> MHLW (2007), Opinion solicitation case; Risk assessment method guidelines for indoor use of insecticides as general-purpose medicines and quasi-drugs (draft), Pharmaceutical Foods Division

used as the default value for the weight of a child.

#### (2) Respiration rate

<u>The respiration rate of adults</u> used for this risk assessment is <u>20 m<sup>3</sup>/day</u>. This value has been used for the risk assessment on priority assessment chemical substances under the CSCL.

The respiration rates of children are 5.16 m<sup>3</sup>/day for a one-year-old child and 8.72 m<sup>3</sup>/day for a five-year-old child, according to the data of the International Commission on Radiological Protection (Publication 71), in the calculation example for the radiation dose received from radioactive substances in the air by the National Institute of Radiological Sciences<sup>1</sup>. In addition, according to the data on Japanese children reported by Kawahara et al.<sup>2</sup>, who measured the average daily inhalation rate of 10 children ages 5 to 6, the respiration rate is estimated to be 8.3 ± 1.4 m<sup>3</sup>/day. This value is almost the same as that of the International Commission on Radiological Protection (Publication 71).

Therefore, for <u>the respiration rate of children</u> used in this assessment, <u>8.72 m<sup>3</sup>/day</u> is adopted, which is the value for a 5-year-old child by the International Commission on Radiological Protection (Publication 71).

The target children in this risk assessment are not older than 6 years old. The average weight of children ages 1 to 6 (corresponding to the average value of 3-year-old children) is adopted. It is considered that the adoption of the value of a 5-year-old child, which is larger than the average for the respiration rate, is for the assumption on the side of safety.

#### (3) Dust intake amount

Since intake of dust greatly contributes to exposure, determination of the intake amounts of dust per day for adults and children is required for estimation of the BDE-209 exposure amount.

As a result of an investigation of the intake amount of dust and soil, the following data were obtained:

- a) Only house dust: 60 mg/day (child), 30 mg/day (adults)
   Soil (clouds of dust) + house dust: 100 mg/day (child), 50 mg/day (adults)
   Recommended values for soil and dust ingestion rates in the U.S. EPA Exposure Factors Handbook (EPA-EFH)<sup>3</sup>
- b) 100 mg/day (child), 50 mg/day (adults)
   Conservative recommended values for the house dust ingestion rate in the Dutch RIVM report<sup>4</sup>
- c) 200 mg/day (child), 100 mg/day (adults)

Review & Administration Division, November 28th, 2007

<sup>&</sup>lt;sup>1</sup> National Institute of Radiological Sciences, Basic knowledge on radiation exposure, 6th report, 2011 <u>http://www.nirs.qst.go.jp/data/pdf/i14\_j6.pdf</u>

<sup>&</sup>lt;sup>2</sup> Junko Kawahara et al. (2011), Estimation of daily inhalation rate in preschool children using a tri-axial accelerometer: A pilot study, *Science of The Total Environment, 409, pp.*3073-3077, 2011

<sup>&</sup>lt;sup>3</sup> U.S. EPA (2011), Exposure Factors Handbook 2011 Edition (Final Report), U.S. Environmental Protection Agency, Washington, DC, *EPA/600/R-09/052F, 2011* 

<sup>&</sup>lt;sup>4</sup> RIVM (2008), Exposure to chemicals via house dust, The Dutch National Institute for Public Health and the Environment (RIVM), *RIVM Report 609021064, 2008* 

Soil ingestion rate in the FY2000 Soil Ingestion Rate Survey<sup>1</sup> by the Department of the Environment

- d) 100 mg/day (child), 50 mg/day (adults)
   House dust intake amount adopted in a Scientific Research Report for the MHLW<sup>2</sup>
- e) 50 mg/day (adults)
   House dust intake amount adopted in the AIST-ICET<sup>3</sup>

a) In the EPA-EFH, as the representative values for the intake amounts of only indoor dust, it is recommended to use 30 mg/day for children of 6 weeks old to 1 year old, 60 mg/day for children of 1 year old to 6 years old and 6 years old to 21 years old, and 30 mg/day for adults. The maximum value among all ages is 100 mg/day, which is for children of 3 years old to 6 years old. As the representative values for the total amount of soil (clouds of dust) and house dust, it is recommended to use 60 mg/day for children of 6 weeks old to 1 year old, 100 mg/day for children of 1 year old to 6 years old to 21 years old, and 50 mg/day for adults.

b) In the RIVM report, the intake amounts of house dust used in various countries are reviewed and a study of the intake amount is conducted based on the below-mentioned literature of c). As a result, the conservative and realistic estimated intake amounts are 100 mg/day for children and 50 mg/day for adults.

c) In the investigation of soil ingestion rate by the Department of the Environment, by dividing the difference between the total amount of elements in feces and the total amount of elements in foods by the average concentration of elements in soil, the soil ingestion rate is estimated. In this estimation method, the value is determined irrespective of oral or inhalation intake route or location (regardless of whether ingestion/inhalation occurred indoors or outdoors). Therefore, the resultant intake amount is approximately the total amount taken into the human body from objects other than foods.

In the report of d) and the tool of e), the values are determined in order to assess Japanese exposure and risk, and in both the report and the tool, the RIVM report of b) has been referenced.

Accordingly, in b), d), and e), the intake amounts are estimated to be 100 mg/day for children (except e)) and 50 mg/day for adults, and the amount for soil + dust is a similar value in a) as well. For c), the soil ingestion rate is estimated, but considering the estimation method, it corresponds to the amount ingested from something other than foods. Therefore, if the value is used as a dust ingestion rate, overestimation may occur.

These values basically indicate the dust ingestion amounts under the assumption that suspension of dust in the air is caused by children's moving around or adults' activities inside houses.

Inside cars, children are on baby seats or child seats and adults are also seated. Therefore, free behaviors are limited, and as a result, suspension of dust is also limited. It is considered that the frequency of contact with dust is lower than inside houses.

<sup>&</sup>lt;sup>1</sup> MOE (2011), FY2000 Soil feeding intake survey, 2001

<sup>&</sup>lt;sup>2</sup> MHLW (2015), Grant-in-Aid for Scientific Research Grant Subsidies Chemical Risk Research Project, Study on multi-path exposure assessment of semi-volatile organic compounds in indoor environment, FY2012-2014 Comprehensive research report, March 2015

<sup>&</sup>lt;sup>3</sup> AIST-ICET (2016), House / Household / Person Database Description Document, 2016 (※Explanatory document is included in the tool)

However, it is difficult to set the intake amount of dust inside cars because insufficient data are available, and in this risk assessment, assuming that the intake of dust inside cars is the same as that inside houses, <u>100 mg/day for children and 50 mg/day for adults</u> are adopted.

# (4) Time of mouthing behaviors

The following data on the time of child's mouthing behaviors were obtained:

a) 23 min/day

Value adopted in the risk assessment report on the HBCD by Canada (Canada-HBCD)<sup>1</sup>

- b) 10 min/day
   Value adopted in the risk assessment report on the HBCD by EU (EU-RAR-HBCD)<sup>2</sup>
- c) 20 min/day (the reading error of 6 to 15 min/day is taken into account)
   Reading from the graph in the article by Sugita et al.<sup>3</sup> cited in the risk assessment<sup>4</sup> for phthalate acid ester by the MHLW

a) The *mouthing time* in the Canada-HBCD is set based on the data in the Child-Specific Exposure Factors Handbook (CSEFH)<sup>5</sup> by the U.S. EPA. In this handbook, the investigation results on the *mouthing time* from two kinds of information sources are described, and the respective average *mouthing time* for the items "pacifiers", "fingers", "toys", and "other objects" are listed. In the Canada-HBCD, in consideration of the products to be assessed, the *mouthing time* for "other objects" was adopted, and the *mouthing time* of 23 min/day is adopted from the report of 22 min/day for infants of 0 to 18 months old (n=46), 24 min/day for infants of 6 to 9 months old (n=15), and 23 min/day for infants of 15 to 18 months old (n=14). The recommended value is set in the CSEFH as well, but the objects for mouthing are wide-ranging, and as with the Canada-HBCD, it is necessary to start by considering what settings were used for the described data Therefore, in this report, the recommended value in the CSEFH is not adopted as data.

b) In the EU-RAR-HBCD, the 95% ile *mouthing time* from investigation results by the U.S. Consumer Product Safety Commission is adopted, and assuming that the frequency of mouthing for the target product is once every three days, the *mouthing time* is set at 10 min/day.

c) In the article by Sugita et al., the investigation results on the actual concentrations of Japanese

<sup>4</sup> MHLW (2010), Equipment Container Packaging Section of Food Hygiene Subcommittee of Pharmaceutical Affairs / Food Sanitation Council (Held on February 22, 2010) <u>http://www.mhlw.go.jp/shingi/2010/02/s0222-6.html</u>

Document 1-1 Partial revision of standards for phthalate ester related to toys (draft) (Equipment Container Packaging Section of Food Hygiene Subcommittee of Pharmaceutical Affairs / Food Sanitation Council (Held on February 22, 2010)) Appendix 2 Exposure of phthalate esters by toys mouthing

http://www.mhlw.go.jp/shingi/2010/02/dl/s0222-6d.pdf

<sup>&</sup>lt;sup>1</sup> Environment Canada (2011), Health Canada, Screening Assessment Report on Hexabromocyclododecane, *2011* 

<sup>&</sup>lt;sup>2</sup> European Chemicals Bureau (2008), European Union, Hexabromocyclododecane, *Risk Assessment Report, CAS No: 25637-99-4, EINECS No: 247-148-4, 2008* 

<sup>&</sup>lt;sup>3</sup> Sugita Takiko et al. (2003), Estimation of Daily Oral Exposure to Phthalates Derived from Soft Polyvinyl Chloride Baby Toys, *Journal of the Food Hygienic Society of Japan, Vol. 44, No. 2, pp.96-102, 2003* 

Appendix 3 Risk calculation <u>http://www.mhlw.go.jp/shingi/2010/02/dl/s0222-6e.pdf</u>
 <sup>5</sup> U.S. EPA (2008), Child-Specific Exposure Factors Handbook, U.S. Environmental Protection Agency, Washington, DC, *EPA/600/R-06/096F, 2008*

infants' mouthing behaviors are described. In the investigation, the behaviors of 25 infants of 6 to 10 months old in various regions of Japan were recorded for a total of 150 minutes on two days with a video camera by their parents. According to the past observation records of infants of 3 to 12 months old, the *mouthing time* of infants of 6 to 10 months old is especially long. The *mouthing time* by age in months was measured in seconds individually for "pacifiers", "fingers/body", "toys", "synthetic resin other than toys", and "others (textiles, papers, etc.)" and the results are shown in <u>a</u> bar graph form.

The data of c) are for infants of ages in months whose *mouthing time* is especially long. In consideration of the content and elution state of BDE-209, the *mouthing time* of textile products such as car fabrics, which will be adopted as a representative object for mouthing in the assessment described later, corresponds to that of "others (cloth, paper, etc.)". Therefore, in this assessment, a *mouthing time* of <u>20 min/day</u> is adopted.

If the mouthing frequency is not taken into account in the EU-RAR-HBCD of b), the *mouthing time* is 30 min. Within the investigation range, no large difference in the *mouthing time* of infants by country was observed.

#### (5) Mouthing area

The following data about the area of mouthing per day in children's mouthing behaviors were obtained:

a) 50 cm<sup>2</sup>
Value adopted in the Canada-HBCD
b) 50 cm<sup>2</sup>

Value adopted in the EU-RAR-HBCD

For the area of mouthing, in the Canada-HBCD of a), 50 cm<sup>2</sup> is adopted on the grounds that the value is adopted in the HBCD risk assessment by the U.S. National Research Council (NRC). As a result of investigating the basis of NRC's value, it was found that the value was determined assuming that a 7.75 in<sup>2</sup> fabric was sucked and that the subcommittee for the risk assessment by the NRC estimated the value as an appropriate value.

In the EU-RAR-HBCD of b), the total value per day is estimated to be 50 cm<sup>2</sup>, although the grounds for this are unclear.

In these investigations about *mouthing time*, there is no large difference by country, and in two or more risk assessment reports, similar values are adopted. Therefore, in this assessment, 50 cm<sup>2</sup> is adopted.

### 5-1-2 Exposure environment and emission source

Based on the information of BDE-209 containing products described in Chapter 3, there is a possibility that Japanese people are exposed to BDE-209 from dust or the like associated with or resulting from use of BDE-209 containing products inside houses and cars. Therefore, in this risk assessment report, the exposures in two environments, inside houses and cars, are described. Diagrams illustrating\_emission of BDE-209 from the BDE-209 containing products and exposure to

BDE-209 in each environment are shown as Figure 5-1.

Inside houses, the content of BDE-209 was observed in some of the resin and textile products distributed in Japan, but the contents and concentrations in the products varied. In this risk assessment, the assessment about inhalation exposure and oral exposure to dust inside houses is conducted referring to monitoring information, and the assessment about oral exposure and dermal exposure by mouthing is conducted mainly on\_the sofas, with which people may contact at the highest frequency and in the largest area, among the products for which BDE-209 content (and exposure) data are available, as described in Chapter 3.

For the inside of cars, the investigation results showed that BDE-209 was not contained in all car fabrics. However, there are various conditions related to ownership and use of a car. Therefore, the exposure assessment is conducted assuming the worst case where a car having BDE-209 containing fabrics is owned and adults and children are in the car for a certain period of time every day.



Figure 5-1 Diagrams of emission of BDE-209 from the BDE-209 containing products and exposure to BDE-209 in each environment

The factors on the times spent inside cars and inside houses and the grounds for settings are as follows:

# (1) Time spent in a car

Concerning the time spent in a car per day, the following data were obtained:

a) 4 hours (adults), 2 hours (children)
 Value adopted in the EU-RAR Risk Assessment Report (EU-RAR-DEHP)<sup>1</sup>

#### b) 1 hour

Value adopted in the NICNAS Risk Assessment Report (NICNAS-HBCD)<sup>2</sup>

c) Weighted average value of times on weekdays and on holidays: 50 minutes

<sup>&</sup>lt;sup>1</sup> European Chemicals Bureau (2008), European Union, Bis(2-Ethylhexyl)-Phtalate (DEHP), *Risk* Assessment Report, CAS No: 117-81-7 EINECS No: 204-211-0, 2008

<sup>&</sup>lt;sup>2</sup> NICNAS (National Industrial Chemicals Notification and Assessment Scheme) (2012), Hexabromocyclododecane, *Assessment Report No.34*, 2012

(Value calculated using each maximum value of the number of trips and the trip length throughout the country (average value by city region))

Results of the Investigation<sup>1</sup> by City Bureau, Ministry of Land, Infrastructure, Transport and Tourism

d) Weighted average value of times on weekdays and on holidays: 2.4 hours (90%ile)
 NITE, Information about life/behavior patterns related to indoor exposure<sup>2</sup>

a) The values adopted by the EU-RAR-DEHP are 4 hours for adults and 2 hours for children, which are the largest values among four data. The conditions under which the values were set are unknown.

b) The NICNAS-HBCD adopted a value assuming that both adults and children ride in a car for one hour per day based on the investigation results in Australia, etc. Another grounds for the adoption of the value is that the research results in the U.S. showed that children under 11 years old spend 1.1 to 1.6 hours per day in a car.

c) The investigation results by the City Bureau, Ministry of Land, Infrastructure, Transport and Tourism shows the number of trips of one Japanese in one day, the time required for one trip, and the total required time for\_central and local cities in Japan. All the values obtained for the city areas indicate the average values. According to the investigation results, the average numbers of trips in one day by one person using a car are 1.40 on weekdays and 1.51 on holidays at most in the local city areas among all cities. The average time required for one trip by car is 33.9 minutes on weekdays and 37.6 minutes on holidays at most in the central cities among all cities.

d) NITE investigated the average driving time of an adult who routinely uses a car on weekdays and holidays, not riding times. The driving time of the respondents who said that they drive a car on weekdays (n=1,411) and the respondents who said that they drive a car holidays (n=1,387) were averages over 5 days for weekdays and 2 days for holidays, respectively. 90% ile of the weighted average of driving time of all respondents of the questionnaire (n=1,707) was 2.4 hours per day.

As described above, the numbers of hours spent riding in a car domestically and abroad were obtained. However, it is considered that the usage of cars differs by country, and in this risk assessment, from the data of c) and d), which are Japanese data, the 2.4 hr/day of d), which enables us to overestimate the exposure amount by a reasonable amount, was adopted as the time spent in a car.

However, the value of d) is over double the value of c), and especially for children, the setting of not only riding in a car every day but riding 2.4 hr/day may result in a significant degree of overestimation.

# (2) Time spent in a house

Concerning the time spent in a house per day, the following data were obtained:

<sup>&</sup>lt;sup>1</sup> MLIT City Station City Planning Section Urban Planning Research Office (2012), People movement in the city–From the results of the survey of nationwide urban traffic characteristics in 2010–, *Survey on urban traffic characteristics nationwide, August 2012* 

http://www.mlit.go.jp/toshi/city\_plan/toshi\_city\_plan\_tk\_000007.html <sup>2</sup> NITE (2017), 4.1. Car driving time, *Life / Behavior Pattern Information on Indoor Exposure, 2017* <u>http://www.nite.go.jp/chem/risk/exp\_4\_1.pdf</u>

- a) Time spent in a house: Time-weighted average of 20 hours (90%ile)
   Data of life/behavior patterns related to indoor exposure by NITE<sup>1</sup>
- b) 21.6 hours
   Assuming that all time except the 2.4 hours spent riding in a car is time spent in a house

a) The investigation results by NITE shows the weighted average of the time spent in a house for 5 weekdays and 2 holidays for 3,536 males and females aged 20 to 79 years in Japan.

b) All time other than the previously described time riding in a car is regarded as time spent in a house.

Judging from the above, since a) and b) are almost the same values, and considering the consistency with the time riding in a car, the value of b) is considered as appropriate.

In this risk assessment, <u>21.6 hr/day</u> is adopted in view of consistency with the value used for time riding in a car.

#### 5-1-3 Exposure route/scenario setting

It is considered that there is a low possibility that BDE-209 in the form of gas exists in the air. In the monitoring data, there are few reports on concentrations in the air and the emission rates inside houses and cars, and in most of the reports, the emission rates are less than the minimum limit value of detection and the concentrations are low in Japan. However, though the number of reports about concentrations in the air is small, it is not zero domestically and abroad. In this assessment, it is assumed that exposure to BDE-209 in the form of gas via inhalation also occurs.

On the other hand, BDE-209 in dust was detected in all the reported investigations inside houses and cars domestically and abroad. In this assessment, the exposure amount is estimated assuming that BDE-209 adsorbs to dust or becomes particulate inside houses and cars, suspends in the air, or adheres to hands or bodies, and then is ingested unintentionally.

In some dust assessments, the inhalation exposure and the oral exposure are differentiated by the different states of delivery to pulmonary alveoli due to particle sizes. Since it is difficult to assume the composition or particle size distribution of dust, dust in the air is comprehensively assessed as unintentionally ingestion in this risk assessment.

The exposure via oral route by mouthing is estimated, assuming that BDE-209 migrated into saliva by mouthing is ingested.

Concerning the exposure via dermal route, it is assumed in this assessment that exposure to BDE-209 eluted in the aqueous phase (sweat) on the skin surface is via dermal route, and the absorption rate into the body is also taken into consideration. Several other estimation methods are available. For example, the amount (or rate) of migration from a product to a skin surface and the absorption rate into the body are taken into account, the rate of absorption from a skin surface into the body is estimate the exposure amount via dermal route.

The exposure route scenarios conceivable inside houses and cars are described below.

<sup>&</sup>lt;sup>1</sup> NITE (2012), 1.1. Housing (2) residence time, *Life / Behavior Pattern Information on Indoor Exposure,* 2012

http://www.nite.go.jp/chem/risk/exp\_1\_1\_2.pdf

#### (1) Inside houses

As described in Chapter 3, BDE-209 is reported to be contained in many products inside houses. Some of the BDE-209 containing products are around consumers and the consumers may be directly exposed to BDE-209 with a high frequency. Under the present circumstances, however, the diffusion rate of the BDE-209 containing products and the states of their installation are unknown. Therefore, using the monitoring data, etc., described in Chapter 3 as parameters for estimating the exposure amount, exposure scenarios with the representative behaviors that may cause the largest indoor exposure amounts are set for assessment.

In the exposure assessment for the inside of houses, the following 4 exposure scenarios are set based on the data on the BDE-209 containing products obtained in Chapter 3 and the behaviors in houses:

- i. Exposure to BDE-209 via inhalation route in the indoor air of houses
- ii. Exposure to BDE-209 via oral route by unintentional ingestion of the indoor dust of houses
- iii. Exposure to BDE-209 via oral route by mouthing the BDE-209 containing sofa in houses
- iv. Exposure to BDE-209 via transdermal route by skin contact with the BDE-209 containing sofa in houses

# (2) Inside cars

Fabrics used inside cars contain BDE-209. Car fabrics are textiles for cloth seats, cloth floor mats, etc. BDE-209 is contained in the back coating agent (backing) used for flame retarding those products. In some reports, BDE-209 is contained in electronic components, but they are used in engine compartments and are excluded from the products to be assessed for exposure inside cars.

When the same parameters that are set in the exposure assessment for the insides of houses are also set in that for the insides of cars, the same values are adopted.

In the exposure assessment for the insides of cars, based on the states of use of car fabrics and contact with them, the following four exposure scenarios are set:

- i. Exposure to BDE-209 via inhalation route in the air inside cars
- ii. Exposure to BDE-209 via oral route by unintentional ingestion of the dust inside cars
- iii. Exposure to BDE-209 via oral route by mouthing the BDE containing car fabrics inside cars
- iv. Exposure to BDE-209 via dermal route by skin contact with the BDE-209 containing car fabrics inside cars

# 5-2 Estimation of exposure amount

In the exposure assessment of this substance, using the estimated equation along with the setting exposure scenario, the exposure amount is calculated by substituting the data value into each parameter.

After the *EHE* for each exposure environment and each intake route is obtained, the *EHE* are summed separately for adults and children to obtain the respective total *EHE* (Section5-3) for use in the risk assessment (Chapter 6).

# 5-2-1 Inside houses

# i: Exposure to BDE-209 via inhalation route in the indoor air of houses

# (1) Estimation method and exposure amount

The exposure amount is estimated assuming that BDE-209 existing in the indoor air is inhaled during the time spent in houses.

The EHE is calculated using the following Equation 5-1:

#### EHE via inhalation

 $=\frac{Exposure \ concentration \ in \ the \ indoor \ air \ of \ houses \ (ng/m^3) \times Dwell \ time \ ratio \times Respiration \ volume \ (m^3/day)}{R_{\rm exp}}$ 

Body weight (kg)

Equation 5-1

The parameters substituted into Equation 5-1 are shown in Table 5-1.

# Table 5-1 Parameters used for the estimation of the exposure amount of BDE-209 in the indoor air of houses via inhalation route

Parameter	Adults	Children	Reference for setting/background
Exposure concentration of BDE-209 in the indoor air of houses (ng/m <sup>3</sup> )	0.95		5-2-1i (2)
Dwell time ratio (dimensionless)	0.9		21.6 (hr/day) / 24 (hr/day)
Time spent in houses (hr/day)	21.6		5-1-2 (2)
Respiration volume (m³/day)	20	8.72	5-1-1 (2)
Body weight (kg)	50	15.2	5-1-1 (1)

Judging from the above, the values of *EHE of BDE-209 in the indoor air of houses* via inhalation route are 0.34 ng/kg/day for adults and 0.49 ng/kg/day for children.

#### (2) Grounds for setting the parameter

The grounds for setting the *exposure concentration in the indoor air of houses* shown in Table 5-1 are described below.

#### Concentration in the indoor air of houses

In Japan, the number of consumer products whose emission rates are known is limited, and the states of installation of the consumer products are unknown. Therefore, in this assessment, the monitoring data for the concentration in the indoor air of houses in Japan are used for estimation of the exposure amount via inhalation route.

Concerning the concentration of BDE-209 in the indoor air of houses, the following data were obtained:

Category	Site	n	Concentrat	tion (ng/m <sup>3</sup> )	Reference
Housing	Housing in Japan	21 houses	median:	0.20 or less	①MHLW2015
			maximum:	0.95	
	Housing in Japan	50 houses	All N.D.		
	Housing in Sapporo	6 houses	All N.D.		10 Takeuchi et al., 2014
	Apartment in Tokyo	1 apartment unit	N.D.		①Saito et al., 2007
	Housing in Hokkaido	2 houses	mean:	0.019	③Takigami et al., 2009a
		2 rooms	minimum:	0.0081	
			maximum:	0.027	
Hotel	Hotel in Osaka	1 building	N.D.		<sup>(]]</sup> Takigami et al., 2009b

#### [Repetition]

 Table 3-2
 Concentration of BDE-209 in the indoor air of houses (Japan)

<u>The concentration in the indoor air of houses</u> used in this risk assessment is  $0.95 \text{ ng/m}^3$  ((i) MHLW2015), which is the maximum value of the concentrations shown in the four reports in the above table.

In this assessment, 0.95 ng/m<sup>3</sup> ((i) MHLW2015), which is the maximum value obtained in the investigation range, is adopted, while the median value of the resultants for the 21 houses investigated in the report is the minimum limit value of determination (0.20 ng/m<sup>3</sup>) or lower. The resultant values of the same investigation in the following year were all N.D. Two other reports (n=6 and n=1) also showed N.D. In one report indicating the detection of BDE-209 (n=2 houses × 2 rooms), the maximum value was 0.027 ng/m<sup>3</sup> ((xiii) Takigami et al., 2009a).

Judging from the above, it is considered that adoption of 0.95 ng/m<sup>3</sup> for the concentration in the indoor air in Japan may result in an overestimation by about 100-fold at maximum.

In overseas monitoring, the maximum value is reported to be 4.15 ng/m<sup>3</sup> (Reference 6: Norway). However, several data are available in Japan, and it is considered that their environment in houses and living activities are different from those of Japanese people. Therefore, the value is not adopted in this assessment.

# ii: Exposure to BDE-209 via oral route by unintentional ingestion of the indoor dust of houses

# (1) Estimation method and EHE

In this risk assessment, the exposure amount is estimated assuming that the whole quantity of dust to which BDE-209 emitted from products inside houses adsorbed or in which BDE-209 became particulate due to exfoliation from products is ingested via oral route.

The EHE is calculated by the following Equation 5-2:

EHE via oral

 $= \frac{Exposure \ concentration \ in \ the \ indoor \ dust \ of \ houses \ (ng/g) \times Dust \ intake \ per \ day(g/day) \times Dwell \ time \ ratio}{Body \ weight \ (kg)}$ 

Equation 5-2

The parameters substituted into Equation 5-2 are shown in Table 5-2.

# Table 5-2 Parameters used for the estimation of the exposure amount of BDE-209 in the indoor dust of houses via oral route by unintentional ingestion

Parameter	Adults	Children	Reference of setting/background
Exposure concentration of BDE-209 in the indoor dust of houses (ng/g)	6,500		5-2-1 ii (2)
Dwell time ratio (dimensionless)	0.9		21.6 (hr/day) / 24 (hr/day)
Time spent in houses (hr/day)	21.6		5-1-2 (2)
Ddust intake per day (g/day)	0.05	0.10	5-1-1 (2)
Body weight (kg)	50	15.2	5-1-1 (1)

Judging from the above, the values of *EHE* of BDE-209 in the indoor dust of houses via oral route by unintentional ingestion are 5.9 ng/kg/day for adults and 38.5 ng/kg/day for children.

# (2) Grounds for setting the parameter

The grounds for setting the *exposure concentration of BDE-209 in the indoor dust of houses* shown in Table 5-2 are described below.

# Exposure Concentration of BDE-209 in the indoor dust of houses

In order to estimate the exposure amount of BDE-209 by unintentional ingestion of the indoor dust, the concentration in the indoor dust collected from indoor air of houses in Japan was examined and the following data were obtained:

#### [Repetition]

Category	Product		n	Concentration (ng/g)		Reference
Housing	Housing in 19 sites Japan			median: maximum:	364 3,300	③ MHLW201 5
	Housing Japan	in	44 sites	median: maximum:	225 4,300	
	Housing Kanto region	in	5 houses	maximum:	6,500 <sup>×1</sup>	④ MOE2012
	Housing Japan	in	19 houses	median: mean: minimum: maximum:	550 820 100 2,600	⑧Suzuki et al., 2006
	Housing Tama are Tokyo	in ea,	9 houses 13 sites	around TV (n = 3): around washing machine (n = 1): on floor (n = 1): others <sup><math>\times</math>2</sup> :	88, 90, 3,200 2,800 540 160 or les s	⑨Kono et al., 2007
	Housing Hokkaido	in	2 houses	mean: minimum: maximum:	390 160 620	(1) Takigami et al., 2009a

Table 3-3 Concentration of BDE-209 in indoor dust of houses (Japan)

%1: Estimated from report content

\*2: Fluorescent lamp cover (n = 4), air conditioner filter (n = 2), dust bag of vacuum cleaner (n = 1), fan heater filter (n = 1)

The concentration of BDE-209 in the indoor dust used in this risk assessment is <u>6,500 ng/g</u> ((ii) MOE2012), which is the maximum value of the concentrations indicated in the 6 reports on houses shown in the above table.

In this assessment, 6,500 ng/g ((ii)MOE2012), which is the maximum value of the concentrations obtained within the investigation range, was adopted. Five reports indicate the following maximum values: 6,500 ng/g (n=5), 3,300 ng/g (n=19), 4,300 ng/g (n=44), 2,600 ng/g (n=19), and 620 ng/g (n=2).

Judging from the above, it is considered that adoption of 6,500 ng/g for the value of the concentration of BDE-209 in the indoor dust in Japan results in an overestimation of the exposure amount by about two-fold at maximum in the worst case in the living environment and under the behavioral conditions of Japanese people.

In overseas monitoring, the maximum value is reported to be 2,200,000 ng/g (Reference 9: UK). However, several data are available in Japan, and it is considered that their housing environment and living activities are different from those of Japanese people. Therefore, the value is not adopted in this assessment.

# iii: Exposure to BDE-209 via oral route by mouthing the BDE-209 containing sofa inside houses

# (1) Estimation method and EHE

As described in 5-1-2, the assessment about oral exposure and dermal exposure by mouthing inside houses is conducted on the sofa as a representative product, with which people may come in contact at the highest frequency and in the largest area, among the products about which the BDE-209 content or exposure data are available.

Since mouthing behaviors are specific to children, adults are not under assessment. In this assessment, the oral exposure amount when a child conducts mouthing is estimated.

The EHE is calculated using the following Equation 5-3:

### EHE via oral by mouthing

*Elution rate*  $(ng/cm^2/min) \times Mouthing area (cm^2) \times Mouthing time (min/day) \times Dwell time ratio$ Body weight (kg)

**Equation 5-3** 

The parameters that are substituted into Equation 5-3 are shown in Table 5-3.

Table 5-3	Parameters used for the estimation of the exposure amount of BDE-209 via oral
	route by mouthing the BDE-209 containing sofa

Parameter	Children	Reference of setting/background
Elution rate (ng/cm <sup>2</sup> /min)	0.039	5-2-1 iii (2)
((ng/cm²/day))	(56)	5-2-1 III (2)
Dwell time ratio (dimensionless)	0.9	21.6 (hr/day) / 24 (hr/day)
Time spent at houses (hr/day)	21.6	5-1-2 (2)
Mouthing area (cm <sup>2</sup> )	50	5-1-1 (4)
Mouthing time (min/day)	7	5-1-1 (5)
Body weight (kg)	15.2	5-1-1 (1)

Judging from the above, the value of EHE of BDE-209 for children via oral route by mouthing the BDE-209 containing sofa is 0.81 ng/kg/day.

# (2) Grounds for setting the parameter

The grounds for setting the elution rate from the BDE-209 containing sofa inside houses shown in Table 5-3 are described below.

#### Elution amount/elution rate

As a result of the investigation on elution of BDE-209 from the BDE-209 containing products, which are distributed in Japan, to water or the like, the following data were obtained:

# [Repetition]

Category	Product	Concentration (ng/g)	Reference	
Resin	Night sensor light (made in China)	1200	①MOE2014	
products		(0.6 ng/cm <sup>2</sup> )		
	Night sensor light (made in China)	0.0042		
		(0.024 ng/cm <sup>2</sup> )		
	Buddhist statue (toy) (made in China)	170		
		(7.2 ng/cm <sup>2</sup> )		
	Case of video tape (made in China)	0.93	6METI2016	
Textile	Flameproof carpet	N.D.	④METI2014	
products	Outer cloth of safety hood (made in Japan)	0.05		
	Filler of safety hood (made in Japan)	0.37		
	Fire prevention and flame retardant sheet, 2 (made in Japan)	N.D.	⑤METI2015	
	Fire prevention and flame retardant sheet, 4 (made in China)	99	⑥METI2016	
	Simple emergency set (including 7 goods)	0.00074	⑦MOE2014	
	(unknown country of manufacture)	(0.055 ng/cm <sup>2</sup> )		
	Bike cover (made in China)	0.0049		
		(0.27 ng/cm <sup>2</sup> )		
Others	Wipe of surface of product <sup><math>\times</math></sup> n = 7	Vinyl leather sofa: 100	①HLW2015	
		ng/cm <sup>2</sup>		
		6 other products: N.D.		

#### Table 3-4 Elution from the BDE-209 containing products inside houses to water (Japan)

: Measurements were taken on a quartz filter to which methanol had been added and wiped five times vertically and horizontally, after removal of dust on the surface of the product.

In addition, the test results for elution from a car seat, which is not a product placed inside houses, to water and artificial saliva were obtained.

#### [Repetition]

#### Table 3-5 Elution from the BDE-209 containing products inside cars (Japan)

	Product	Concentration	Reference
Elution test	Car seat (unknown country of	0.03 ng/cm <sup>2%1</sup>	⑦MOE2014
	manufacture)	(2 × 10 <sup>4</sup> ng/g)	
	Car seat (made in Japan)	56 ng/cm²/day <sup>%2</sup>	NITE (Appendix
		(concentration in artificial	2)
		saliva: 4 ng/mL)	

%1: Result of the elution test according to Notification No. 13 from the Environment Agency%2: Result of 24-hour elution test using artificial saliva

The <u>elution amount/elution rate</u> used in this risk assessment is <u>56 ng/cm<sup>2</sup>/day (NITE) (= 0.039 ng/cm<sup>2</sup>/min)</u>, which was obtained by a test about the elution to artificial saliva, which is considered to be representative of the most common exposure state.

In the previously mentioned references, the maximum value for the concentration of BDE-209 elution from the BDE-209 containing products inside houses to water was 170 ng/g (7.2 ng/cm<sup>2</sup>) from the image of Buddha (toy) made in China. However, the possibility that this product is placed in an ordinary house is very limited, and the test method does not contain the assumption about mouthing. Therefore, it is considered that adoption of the value for the elution amount at the time of mouthing is not appropriate.

In this risk assessment, a sofa is selected as the target product because the results of the wiping test of the vinyl leather sofa showed that BDE-209 was contained and it is considered that people contact sofas at high frequency and in a large area inside houses. The purpose of the wiping test itself, however, is to search for the BDE-209 containing products, and the test was conducted by wiping the surface of the sofa lengthwise and crosswise, each 5 times, with a quartz filter to which methanol had been added. Therefore, it is not appropriate that the results obtained by this test be adopted as the elution amount at the time of mouthing.

On the other hand, in the elution test by NITE, based on the premise that BDE-209 is ingested by mouthing, a car fabric of 72 cm<sup>2</sup> (area of one side) was put in 1 L of artificial saliva with consideration of the physicochemical property (water solubility) of BDE-209, and after a lapse of 24 hours, the concentration of BDE-209 was measured. This test method is considered to be that whose exposure scenario and exposure conditions are closest to those in this risk assessment. The usage pattern of the target product is also similar, and the typical content of BDE-209 in the resin which is a material of the sofa is the same level as the content in the surface material of the car seat which is a specimen of the NITE test (11.3 wt% in the whole surface material, 48.1 wt% in the backing). Therefore, it is assumed that the degree of elution is also similar.

Judging from the above, as the rate of elution of BDE-209 from a BDE-209 containing product, 56 ng/cm<sup>2</sup>/day (NITE) (=0.039 ng/cm<sup>2</sup>/min) is adopted.

In this test results, however, the *elution rate* per unit area is determined by dividing by the area of one side the *elution rate* of BDE-209 from both sides including the elution from the backing, for which there is no possibility of being subject to direct mouthing.

Therefore, there is a possibility that the obtained value has been overestimated by about 2-fold compared to values generally estimated for the scenario where BDE-209 is eluted by mouthing of the sofa.

# iv: Exposure to BDE-209 via dermal route by skin contact with the BDE-209 containing sofa in houses

#### (1) Estimation method and exposure amount

The exposure amount via dermal route is estimated assuming that the skin which is not covered with clothes contacts the BDE-209 containing sofa via sweat during time spent indoors.

The EHE is calculated using the following equation 5-4:

EHE via dermal

 $=\frac{A_{surface} \text{ (cm}^2/\text{day}) \times T_{aq} \text{ (cm)} \times C_{BDE-209} (\mu g/\text{cm}^3) \times R_{dwell \, time} \times R_{adsorption} (\%)}{Body \, weight \, (\text{kg})}$ 

**Equation 5-4** 

The parameters substituted into Equation 5-4 are shown in Table 5-4.

# Table 5-4 Parameters used for the estimation of the exposure amount of BDE-209 via dermal route by skin contact with the BDE-209 containing sofa

Parameter	Adults	Children	Reference of setting/background
<i>A<sub>surface</sub>: Surface area of skin contact with the sofa per day</i> (cm <sup>2</sup> /day)	3,065	1,345	5-2-1 iv (2)
<i>T<sub>aq</sub>: Thickness of the aqueous phase (sweat)</i> (cm)	0.01		5-2-1 iv (2)
<i>C</i> <sub>BDE-209</sub> : Concentration of BDE-209 in aqueous phase (sweat) (ng/mL)	4.0		5-2-1 iv (2)
<i>R<sub>dwell time</sub>: Dwell time ratio</i> (dimensionless)	0.9		21.6 (hr/day) / 24 (hr/day)
<i>Time spent at houses</i> (hr/day)	21.6		5-1-2 (1)
<i>R<sub>adsorption</sub>: Rate of absorption of BDE-209</i> <i>into the body</i> (%)	3		5-2-1 iv (2)
Body weight (kg)	50	15.2	5-1-1 (1)

Judging from the above, the values of *EHE* of BDE-209 via dermal route by skin contact with the BDE-209 containing sofa are 0.07 ng/kg/day for adults and 0.10 ng/kg/day for children.

# (2) Grounds for setting the parameters

The grounds for setting the parameters used for *EHE* via dermal route by skin contact with the BDE-209 containing sofa in houses shown in Table 5-4 are described below. Specifically, the parameters are the *surface area of skin contact with the sofa per day, concentration of BDE-209 in aqueous phase (sweat)* on the skin surface, *thickness of the aqueous phase (sweat)*, and *rate of absorption into a body*.

# Surface area of skin involved in exposure per day

Concerning the skin surface area that contacts the seat during riding in a car, the following data were obtained:

- Adult: 1,918 cm<sup>2</sup> (weight: 60 kg)
   Baby: 333 cm<sup>2</sup> (weight: 5.8 kg)
   Infant: 606 cm<sup>2</sup> (weight: 12.9 kg)
   Values adopted by the NICNAS-HBCD
- b) Adult: 3,065 cm<sup>2</sup> (weight: 50 kg, height: 160 cm)
   Child: 1,345 cm<sup>2</sup> (weight: 15.2 kg, height: 100 cm)
   Estimated values obtained by multiplying the contact ratio and the skin surface area obtained from the estimated equation by Kurazumi et al.<sup>1</sup>

a) In the NICNAS-HBCD, assuming that 25% of the total surface of thighs and torso of Australian adults (weight: 60 kg) are in contact with the car fabrics, the skin surface area involved in exposure per day is set at 1,918 cm<sup>2</sup>. The skin surface area of a child is obtained by multiplying the skin surface area of an adult and the 3/4th power of the weight ratio of adults and children. As a result, the skin surface area of babies (weight: 5.8 kg) is set at 333 cm<sup>2</sup>, and that of infants (weight: 12.6 kg) is set at 606 cm<sup>2</sup>.

<sup>&</sup>lt;sup>1</sup> Kurazumi et al. (1994), The body surface area of Japanese, *Jpn. J. Biometeor., Vol.31, No.1, pp.5-29, 1994* 

b) The estimated equation by Kurazumi et al. is an empirical equation (estimated equation) based on the measurement results for 45 Japanese adults, and it allows estimation of the whole surface area by the height, the weight, and the sex, and the skin surface area for each body part. The values of b) are estimated by multiplying the respective skin surface area obtained based on the sex and the height assumed from adults' and children's weights in 5-1-1 (1) and (2) by the contact ratio with the sofa (1/4 (head, neck, upper arms, thighs, legs, feet) and 1/2 (ears, forearms, hands)).

In this risk assessment, the <u>3,065 cm<sup>2</sup> (adults) and 1,345 cm<sup>2</sup> (children)</u> values described in b) are adopted, which are the estimated values for the Japanese skin surface area that is in contact with a sofa in a given day and are overestimated by 1.5- to 2-fold compared to a).

#### [Calculation of the Japanese skin surface area that is in contact with the sofa]

Using the estimated equation by Kurazumi et al., the skin surface area for whole body and each body part can be estimated by the height, the weight, and the sex. In this risk assessment, the adult weight is set at 50 kg, but the height and the sex are not set. Therefore, using the results of the 2015 National Nutrition Survey<sup>1</sup> by the MHLW, the average heights for males and females when the average weight is 50 kg were checked. As a result, it was found that the weights of males 13 to 14 years old are 47.6 to 51.2 kg, which are around the average weight of 50 kg, and their heights are in the range of 159.3 to 164.3 cm. The weights of females 15 to 19 years old are 48.1 to 53.4 kg, which are around the average weight of 50 kg, the height is around 160 cm. Therefore, for both males and females, when the weight is 50 kg, the height is 50 kg, their height is 160 cm.

In the estimation of the skin surface area using the equation by Kurazumi et al., the factors are different between males and females. In this estimation, the individual skin surface area are estimated by sex, and then the values are averaged.

Assuming that the equation by Kurazumi et al. can be applied to children in the same way, the same check was conducted. As a result, it was found that when both males and females are 3 to 4 years old (14.1 to 16.6 kg), the average weight is around 15.2 kg, and their heights are 96.7 to 103.2 cm. Given this, as with adults, assuming the height of both male and female children is 100 cm, the individual skin surface area were calculated by sex using the equation by Kurazumi et al., and then the average value was obtained.

The skin surface area values of adults and children for the whole body and each body part are shown in Table 5-5.

<sup>&</sup>lt;sup>1</sup> MHLW (2017), The National Health and Nutrition Survey in Japan, 2015, *March 2017* 

	Adult	Adult	Adults	Child male	Child	Children
	male	female	Aduits	Child male	female	Children
Skin surface area	15,027	15,188	15,108	6,659	6,602	6,630
(whole body)						
Head	1,067	1,109	1,088	486	469	477
Ears	90	76	83	33	40	36
Neck	556	456	506	200	244	222
Chest	932	972	952	426	409	418
Abdomen	947	790	868	346	416	381
Back	1,082	1,124	1,103	493	475	484
Waist	466	349	408	153	205	179
Upper arms	1,503	1,519	1,512	666	660	663
Forearms	887	866	876	380	389	385
Hands	751	729	740	320	330	325
Buttocks	1,202	1,245	1,224	546	528	537
Thighs	2,570	2,962	2,766	1,298	1,129	1,214
Legs	1,909	1,944	1,926	852	838	845
Feet	1,067	1,063	1,065	466	469	467

 Table 5-5
 Skin surface area for whole body and each body part (cm<sup>2</sup>)

From the results of the skin surface area for the whole body and each body part shown in Table 5-5, it is assumed that the body parts that may not be covered with clothes all day are head, ears, neck, upper arms, forearms, hands, thighs, legs, and feet. Assuming that the ratios of the skin surface area that are always in contact with the sofa with the skin surface area for each body part are 1/4 (head, neck, upper arms, thighs, legs, feet) and 1/2 (ears, forearms, hands), the skin surface area per day that may be in contact with the sofa are shown in Table 5-6.

Table 5-6	Skin surface area for each body part per day that may be in contact with the sofa
	(cm²/day)

	Head	Ears	Neck	Forearms	Upper arms	Hands	Thighs	Legs	Feet	Total
Contact ratio	1/4	1/2	1/4	1/4	1/2	1/2	1/4	1/4	1/4	—
Adults	272	42	127	378	438	370	692	482	266	3,065
Children	119	18	56	166	193	163	304	211	117	1,345

The skin surface area that may be in contact with the sofa corresponds to 20% of the whole skin surface area (for both adults and children).

The above-mentioned values indicate the skin surface area used in the estimation assuming that adults and children are in contact with the sofa every day while they are in houses. In this assessment, the time spent in houses is set at 21.6 hours per day, and it is impossible to keep sitting on a sofa for 21.6 hours every day in real life. On the other hand, in this assessment, a sofa is adopted as a representative product considering the contact with the other BDE-209 containing products inside houses.

Judging from the above, the value obtained on the assumption of remaining seated on the sofa, as a representative product, for 21.6 hours every day is an overestimated value for the sofa. However, the presence of other BDE-209 containing products and the frequency of being in contact with them are unknown, and the uncertainty for indoor dermal contact is not known.

#### Thickness of the aqueous phase (sweat)

Concerning the *thickness of the aqueous phase* on the skin surface, the following data were obtained:

- a) Thickness of an aqueous phase on the skin surface: 0.01 cm NICNAS-HBCD
- b) Thickness of aqueous layer (phase) on the skin surface: 0.01 cm Default setting value for the AIST-ICET

a) It is assumed that the *thickness of the aqueous phase (sweat)* on the skin surface is 0.01 cm.

b) The *thickness of the aqueous phase* (sweat for a molded object, mixture itself for a mixture) on the skin surface is defined as "Thickness of the aqueous layer on the skin surface", and assuming that it is the same as the default value (0.01 cm) for the thickness of a mixture on the skin surface in the EU Technical Guidance Document on Risk Assessment<sup>1</sup>, the value is applied.

Therefore, in this risk assessment, the *thickness of the aqueous phase (sweat)* is set at the 0.01 cm which is adopted in a) and b).

For the *thickness of the aqueous phase (sweat)*, the value generally adopted in various risk assessments is used. However, the data are not sufficient, and the degree of uncertainty is unknown.

#### Concentration of BDE-209 in the aqueous phase (sweat) on the skin surface

Concerning the concentration of BDE-209 in the aqueous phase (sweat) on the skin surface, no report with consideration given to elution to sweat was obtained within the investigation range.

The composition of artificial saliva and that of artificial sweat are not identical, but similar substances are contained in artificial saliva and artificial sweat, and the conditions such as size of specimen and kinds of products are closer to those of the exposure scenario than those of other tests. Therefore, in this risk assessment, as with mouthing in iii, the NITE test using a car seat (Appendix material 2) is adopted and the concentration in the aqueous phase (sweat) is set at 4 ng/mL.

The adopted test uses artificial saliva assuming mouthing, and the test results may be different from the state of elution to artificial sweat. Also, although the specimen is larger than that of other tests (0.5 to 5 mm), it is cut into a 2 cm square and the elution concentration per unit area is determined by dividing the concentration of elution from both sides, i.e., including the back side, for which there is no possibility of being subject to contact, by the area of one side. Therefore, it is

<sup>&</sup>lt;sup>1</sup> European Chemicals Bureau (2003), European Union, Technical Guidance Document on Risk Assessment, *2003* 

considered that the obtained value is a substantially overestimated value relative to the value obtained in the scenario where people are in contact with BDE-209 via sweat while sitting on a sofa, although the degree of overestimation is unknown.

#### Absorption into body (skin)

Concerning the rate of absorption of BDE-209 into a body (skin) through skin, the value of 3%, which is adopted as the rate of dermal absorption into a body (skin) in the PBDE exposure assessment by the U.S. EPA<sup>1</sup>, is used for this assessment.

This value is probably set because it is adopted in the reassessment on dioxin by the U.S. EPA (2003). Since PBDEs have structures similar to those of dioxin and PCB, use of the absorption rate of dioxin into a body (skin) is regarded as appropriate to some extent. In the reassessment, the value is used as the absorption rate into a body (skin) of PBDEs (BDE-28, 47, 99, 100, 138, 153, 154, 183, 209) including multiple isomers, but compared to a low-bromine isomer, BDE-209 is difficult to absorb into the body (skin) when its molecular structure is taken into consideration.

Therefore, although the data are limited, the exposure amount is considered to be a reasonably overestimated value among the obtained data.

#### Summary and consideration of the exposure amount inside houses

The *EHE* in the exposure scenarios inside houses described in 5-1-3 are summarized in Table 5-7.

Exposure route		Exposure scenario	Adults		Children		
	Inhalation		0.34		0.49		
Oral	Oral	ingestion of dust	5.9	5.9	38.5	39.3	
	Urai	mouthing	—		0.81		
Dermal			0.07		0.10		
EHE incide houses			Adults		Children		
ЕПС	EHE inside houses			6.3		39.9	

#### Table 5-7 EHE of BDE-209 inside houses (ng/kg/day)

These results show that, <u>both for adults and children</u>, the exposure via oral route by unintentional ingestion of dust contributes greatly to the exposure amount of BDE-209 inside houses and it makes up over 90% of the total amount via all routes (93.7% for adults, 98.5% for children).

Note that the exposure amount by unintentional ingestion of dust may be overestimated by at least about 2-fold as previously described.

<sup>&</sup>lt;sup>1</sup> U.S. Environmental Protection Agency (2010), An Exposure Assessment of Polybrominated Diphenyl Ethers, *EPA/600/R-08/086F, May 2010* 

### 5-2-2 Inside cars

### i: Exposure to BDE-209 via inhalation route for air inside cars

#### (1) Estimation method and exposure amount

The exposure amount is estimated assuming that BDE-209 contained in the air inside cars is inhaled during riding in cars.

The EHE is calculated using the following Equation 5-5:

### EHE via inhalation

 $= \frac{Exposure \ concentration \ in \ the \ air \ inside \ cars \ (ng/m^3) \times Dwell \ time \ ratio \times Respiration \ volume \ (m^3/day)}{}$ 

```
Body weight (kg)
```

**Equation 5-5** 

The parameters substituted into Equation 5-5 are shown in Table 5-8.

# Table 5-8 Parameters used for the estimation of the exposure amount of BDE-209 in the air inside cars via inhalation route

Parameter	Adults	Children	Reference of setting background
Exposure concentration of BDE-209 in the air inside cars (ng/m <sup>3</sup> )	4.0		5-2-2 i (1)
	0.1		
Dwell time ratio (dimensionless)	0.1		2.4 (hr/day) / 24 (hr/day)
<i>Time spent in cars</i> (hr/day)	2.4		5-1-2 (1)
<i>Respiration volume</i> (m <sup>3</sup> /day)	20	8.72	5-1-1 (2)
Body weight (kg)	50	15.2	5-1-1 (1)

<u>Accordingly, the EHE of BDE-209 in the air inside cars via inhalation route are 0.16 ng/kg/day for</u> adults and 0.23 ng/kg/day for children.

# (2) Grounds for setting the parameter

The grounds for setting the *exposure concentration in the air inside cars* shown in Table 5-8 are described below.

#### Exposure concentration in the air inside cars

In order to estimate the exposure amount via inhalation route, it is necessary to estimate the concentration in the air inside cars from the monitoring results of the concentration in the air inside cars/the emission rate test results and then to calculate the exposure amount.

Concerning the *exposure concentration of BDE-209 in the air inside cars*, the following data were obtained:

# [Repetition] Table 3-6 Emission rate from BDE-209 containing products inside cars (Japan)

Product	Concentration (ng/cm <sup>2</sup> /hr)	Reference
Car sheet	9.3×10 <sup>-5※1</sup>	⑦MOE2014
	N.D. <sup>**2</sup>	NITE (Appendix 1)

%1: including absorbed BDE-209 on the wall surface of products

%2: Gaseous BDE was not collected, but absorbed BDE on the wall surface was detected.

#### [Repetition]

	Country	Year	n	Median (ng/m <sup>3</sup> )	Maximum (ng/m <sup>3</sup> )	Reference
ſ	UK	2010	20*	1.3	4.0	13
		2010	19*	0.9	3.7	13

: In the same car, n = 20 is measured around the driver's seat, n = 19 is measured in the trunk compartment.

The concentrations obtained within the investigation range in Japan were only the values including BDE-209 adsorbed on wall surfaces or the values of the detection lower limit or under. Therefore, for the *exposure concentration in the air inside cars* used in this risk assessment, <u>4.0</u> ng/m<sup>3</sup> (Reference 13) is adopted, which was obtained from only one report on the concentration in air, although it is a value obtained outside Japan.

According to the report by Harrad et al. (Reference 13) adopted in this assessment, the concentration in the air inside 20 cars (driver's seats) in the UK was measured, and the resultant median value was 1.3 ng/m<sup>3</sup> with the maximum value being 4.0 ng/m<sup>3</sup>.

The saturated vapor pressure concentration calculated<sup>1</sup> from the saturated vapor pressure and the molecular weight of BDE-209 is 1,790 ng/m<sup>3</sup>, while the saturated vapor pressure concentration calculated from the vapor pressure ( $6.23 \times 10^{-10}$  Pa) according to the EPI Suite prepared by the U.S. EPA is 0.24 ng/m<sup>3</sup>. Compared to the latter saturated vapor pressure, the reported value in the UK, 4.0 ng/m<sup>3</sup>, is an abnormal value.

Concerning use of overseas data, the values in the UK in the monitoring data shown in Chapter 3 indicate very high concentrations compared to the values in Japan (the maximum value for indoor air of the overseas data is 4.0 times as large as that of the domestic data, that for indoor dust is 130 times, and that for dust inside cars is 7.4 times) and the other values used overseas.

Given the above, the adopted value of 4.0 ng/m<sup>3</sup> may be an overestimated value, or if any data other than the data in this report are obtained, whether the value in that data\_may be adopted should be examined.

# ii: Exposure to BDE-209 via oral route by unintentional ingestion of dust inside cars

#### (1) Estimation method and EHE

In this risk assessment, the exposure amount is estimated assuming that the whole quantity of dust to which BDE-209 emitted from car fabrics adsorbed or in which BDE-209 became particulate due to exfoliation from fabrics is ingested.

The estimated exposure amount is calculated using the following Equation 5-6.

<sup>&</sup>lt;sup>1</sup> Calculated from the calculation 4.63×10<sup>-6</sup> Pa × 959.16 g/mol × 0.4037 mg mol/g/Pa/m<sup>3</sup>

EHE via oral

Exposure concentration in the dust inside cars  $(ng/g) \times Dust$  intake per day  $(g/day) \times Dwell$  time ratio

Body weight (kg)

# Equation 5-6

The parameters substituted into Equation 5-6 are shown in Table 5-9.

# Table 5-9Parameters used for the estimation of the exposure amount of BDE-209 in the<br/>dust inside cars via oral route by unintentional ingestion

Parameter	Adults	Children	Reference of setting background
Exposure concentration of BDE-209 in the dust inside cars (ng/g)	136,000	)	5-2-2 ii (2)
Dwell time ratio (dimensionless)	0.1		2.4 (hr/day) / 24 (hr/day)
<i>Time spent in cars</i> (hr/day)	2.4		5-1-2 (1)
Dust intake per day (g/day)	0.05	0.10	5-1-1 (3)
Body weight (kg)	50	15.2	5-1-1 (1)

Judging from the above, <u>the values of EHE of BDE-209 in the dust inside cars via oral route by</u> <u>unintentional ingestion are 13.6 ng/kg/day for adults and 89.5 ng/kg/day for children.</u>

# (2) Grounds for setting the parameter

The grounds for setting the *exposure concentration of BDE-209 in the dust inside cars* shown in Table 5-9 are described below.

# Exposure concentration of BDE-209 in the dust inside cars

In order to estimate the amount of BDE-209 exposure by unintentional ingestion of dust, the concentration in the dust collected inside cars was investigated and the data below were obtained.

The *exposure concentration of BDE-209 in the dust inside cars* used for this risk assessment is set at <u>136,000 ng/g ((iii) MOE2015)</u>, which is the maximum dust concentration value for the seating surface, on which people stay in contact with for the longest time inside cars, among the values detected in high concentration in the table shown above.

# [Repetition]

# Table 3-8 Concentration of BDE-209 in the dust inside cars (Japan)

Product	Concentration (ng/g)	Reference	
41 Japanese domestic cars (36 scrapped	maximum(floor): 352,000 <sup>%1</sup>	③MOE2015	
cars from domestic end-of-life vehicle	maximum(seat): 136,000 <sup>%1</sup>		
dismantling factories, and 5 active cars)			
car seat	52,140 <sup>%2</sup>	NITE (Appendix	
		1)	

%1: Estimated data from the report content

%2: Estimated data from the results of the migration test using simulated dust

In this assessment, among the values obtained within the investigation range, 136,000 ng/g ((iii) MOE2015), which is the maximum value for the dust concentration of seating surface, was adopted. This is only one data value obtained for the concentration of BDE-209 in the dust inside cars in Japan.

The concentration of BDE-209 in the dust on the floor surface is higher than that on the seating surface, but ingestion of dust on the floor surface is not a realistic behavior in a car. Therefore, in this assessment, the concentration for the seating surface was adopted. Considering the concentration of BDE-209 in the dust of PBDEs on the seating surface (960 to 170,000 ng/g, median value of 11,000 ng/g) described in the report and the ratio of BDE-209 (about 80%) to PBDEs in the specimen having the maximum concentration, the maximum concentration of BDE-209 in the dust on the seating surface is estimated to be 136,000 ng/g. Assuming that the same ratio may be applied to the median value, it is estimated to be 8,800 ng/g, which is about 1/15 of the maximum value. For the dust on the floor surface, the maximum value can be estimated to be 352,000 ng/g and the median value to be 3,600 ng/g. The median value is about 1/100 of the maximum value, and the gap between the values is large.

In this investigation, 41 domestically produced cars are assessed, which is a small number. They were collected from a disassembling factory of end-of-life vehicles (ELVs), and it cannot be denied that some loads have been applied under the storage conditions of the ELVs before disassembly.

The longer the time during which dust stays in the car (dust age) is, the larger the amount of adsorbed substances becomes. Therefore, the concentration of BDE-209 in the dust inside cars differs by the frequency of cleaning inside the cars. According to the NITE investigation<sup>1</sup>, over 60% of people clean the inside of their cars by themselves, and over 60% of the respondents (n=1,180) clean the inside of their cars one or more times every three months. In the latter result, however, people who clean the inside of their cars at gas stations or car dealers are not included, and the actual average cleaning frequency may be different from the above values.

Given the above, there is a possibility that adoption of the maximum value of 136,000 ng/g for the concentration of BDE-209 in the dust on the seating surface of the cars collected from the ELV disassembling factory may result in overestimation of the exposure amount. The estimated value based on the test results for the adsorption from the BDE-209 containing car seats to the dust conducted by NITE is 52,140 ng/g. Thus, 136,000 ng/g is over twice the estimated value of the NITE.

In overseas monitoring, it is reported that in the UK, the maximum value for the concentration of BDE-209 in the dust inside cars is 2,600,000 ng/g (median value 100,000 ng/g) (Reference 9). The same source also reports the concentration of BDE-209 in the indoor dust of houses in the UK, which is considered a very high concentration, being about 340 times higher than the maximum value of the concentrations of BDE-209 in the indoor dust of Japanese houses. The concentration of BDE-209 detected in the indoor dust of houses in the UK is also a remarkably high compared to the concentrations reported in other overseas countries, and there is a possibility that the environment and the behavior pattern are specific to the UK. Therefore, the UK value is not adopted in this assessment. The concentration of BDE-209 in the dust inside cars differs as a result of multiple

<sup>&</sup>lt;sup>1</sup> NITE (2017), 4.3. Cleaning the car, *Life / Behavior Pattern Information on Indoor Exposure, 2017* <u>http://www.nite.go.jp/chem/risk/exp\_4\_3.pdf</u>

factors such as lifestyle, habit of cleaning the inside of the car, the BDE-209 containing products carried in the car, and the kinds of the dust coming or carried into the car from the outside, and so the concentration is considered to be a result reflecting the conditions of the country.

# iii: Exposure to BDE-209 via oral route by mouthing the BDE-209 containing car fabrics inside cars

# (1) Estimation method and EHE

The target objects of children's mouthing behaviors are "objects (toys, etc.)" which can be held in the hands, in principle, "clothes" the child wears, and the "hands" themselves of the children. While in a car, a child is normally fastened to a baby seat or child seat. Therefore, it is considered that the behavior of direct mouthing of car fabrics is limited.

However, many of children's behaviors and habits are uncertain, and the exposure amount by ingestion is estimated assuming the worst scenario that a child conducts mouthing while riding in a car. Since mouthing behaviors are considered to be specific to children, the exposure amount for adults is not estimated.

The EHE is calculated using the following Equation 5-7:

### EHE via oral by mouthing

 $= \frac{Elution \, rate \, (ng/cm^2/min) \times Mouthing \, area \, (cm^2) \times Mouthing \, time \, (min/day) \times Dwell \, time \, ratio}{Body \, weight \, (kg)}$ 

# Equation 5-7

The parameters to be substituted into Equation 5-7 are shown in Table 5-10.

# Table 5-10 Parameters used for the estimation of the exposure amount of BDE-209 via oral route by mouthing the BDE-209 containing car fabrics

Parameter	Children	Reference of background	setting				
Elution rate (ng/cm <sup>2</sup> /min)	0.039	5-2-2 iii (2)					
Dwell time ratio (dimensionless)	0.1	2.4 (hr/day) / 24 (hr/day)					
<i>Time spent in cars</i> (hr/day)	2.4	5-1-2 (1)					
Mouthing area (cm <sup>2</sup> )	50	5-1-1 (4)					
Mouthing time (min/day)	7	5-1-1 (5)					
Body weight (kg)	15.2	5-1-1 (1)					

<u>As a result of the estimation using the above Equation 5-7 and the parameters, the EHE of</u> <u>BDE-209 for children via oral route by mouthing the BDE-containing car fabrics is 0.09 ng/kg/day</u>.

# (2) Grounds for setting the parameter

The grounds for setting the *elution rate* from car fabrics shown in Table 5-10 are described below.

# Elution amount/elution rate

As a result of the investigation of the elution amount/*elution rate* from car fabrics, the following data were obtained:

DIE	ie 3-9 Elution from the BDE-209 containing products inside cars (Japan)										
		Product	Concentration	Reference							
	Elution test	Car seat (unknown country of	0.03 ng/cm <sup>2%1</sup>	⑦MOE2014							
		manufacture)	(2 × 10 <sup>4</sup> ng/g)								
		Car seat (made in Japan)	56 ng/cm²/day <sup>%2</sup>	NITE (Appendix							
			(concentration in artificial	2)							
			saliva: 4 ng/mL)								

# [Repetition] Table 3-9 Elution from the BDE-209 containing products inside cars (Japan)

%1: Result of the elution test according to Notification No. 13 from the Environment Agency

&2: Result of 24-hour elution test using artificial saliva

<u>The elution amount/elution rate</u> used for this risk assessment is set at <u>56 ng/cm<sup>2</sup>/day (NITE)</u> (=0.039 ng/cm<sup>2</sup>/min), which was obtained by a test of elution to artificial saliva, which is considered to be the best representation of the actual exposure state among the data on elution inside cars obtained within the investigation range.

In the NITE elution test, assuming that ingestion is caused by mouthing and in consideration of the physicochemical property (water solubility) of BDE-209, a 72 cm<sup>2</sup> (area of one side) car fabric is put in 1 L of artificial saliva, and after a lapse of 24 hours, the concentration of BDE-209 was measured. It is considered that this test is conducted under the conditions closest to the exposure scenario and the exposure conditions in this risk assessment.

In this test, however, the *elution rate* per unit area is determined by dividing the *elution rate* from both sides, i.e., including elution from the back side, for which there is no possibility of being subject to direct mouthing, by the area of one side.

Therefore, in the scenario for elution by mouthing of a car seat, the value may be about twice the normally estimated value. As previously described, the area and time of mouthing in the state of being fastened to a seat by a belt or the like may be smaller than they would be otherwise.

# iv: Exposure to BDE-209 via dermal route by skin contact with the BDE-containing car fabrics inside cars

# (1) Estimation method and EHE

The exposure via dermal route is estimated assuming that the skin which is not covered with clothes is exposed via sweat to BDE-209 contained in the car seat while riding in a car.

The EHE is calculated using the following Equation 5-8:

EHE via dermal

 $=\frac{A_{surface} (\text{cm}^2/\text{day}) \times T_{aq} (\text{cm}) \times C_{BDE-209} (\mu g/\text{cm}^3) \times R_{dwell \, time} \times R_{adsorption} \, (\%)}{Body \, weight \, (\text{kg})}$ 

**Equation 5-8** 

The parameters substituted into Equation 5-8 are shown in Table 5-11.

# Table 5-11 Parameters used for the estimation of the exposure amount of BDE-209 via dermal route by skin contact with the BDE-209 containing car fabrics

Parameter	Adults	Children	Reference of setting background	
$A_{surface}$ : Surface area of skin contact with the sofa (cm <sup>2</sup> /day)	3,065	1,345	5-2-1 iv (2)	
<i>T<sub>aq</sub>: Thickness of the aqueous phase</i> ( <i>sweat</i> ) (cm)	0.01		5-2-1 iv (2)	
<i>C</i> <sub>BDE-209</sub> : Concentration of BDE-209 in aqueous phase (sweat) (ng/mL)	4		5-2-1 iv (2)	
R <sub>dwell time</sub> : Dwell time ratio (dimensionless)	0.1		2.4 (hr/day) / 24 (hr/day)	
<i>Time spent in cars</i> (hr/day	2.4		5-1-2 (1)	
<i>R<sub>adsorption</sub>: Rate of absorption of BDE-209</i> <i>into the body</i> (%)	3		5-2-1 iv (2)	
body weight (kg)	50	15.2	5-1-1 (1)	

As a result of estimating using the above Equation 5-8 and parameters, the values of *EHE* of BDE-209 via dermal route by skin contact with car fabrics are  $7.4 \times 10^{-3}$  ng/kg/day for adults and 0.011 ng/kg/day for children.

# (2) Grounds for setting the parameters

The parameters used in the estimation of the exposure amount via dermal route by skin contact with the BDE-209 containing car seats are the same as the parameters used for scenario iv for the exposure inside houses, and therefore, here, the same parameter values are used.

# Summary and consideration for the exposure inside cars

The values of *EHE* in the exposure scenarios inside cars described in 5-1-3 are summarized in Table 5-12.

Exposure route Exposure scenario		Adults		Children		
	Inhalation		0.16		0.23	
Oral		Ingestion of dust	13.6	13.6	89.5	89.6
	Orai	Mouthing	—	13.0	0.09	09.0
	Dermal		7.4×10 <sup>-3</sup>		0.011	
EHE inside cars			Adults		Children	
			13.8		89.8	

Table 5-12 EHE of BDE-209 inside cars (ng/kg/day)

These results show that for both adults and children, the exposure via oral route by unintentional ingestion of dust greatly contributes to the BDE-209 exposure amount inside cars, as with the exposure inside houses, and makes up most of the total exposure amount via all routes (98.6% for adults, 99.8% for children).

As previously described, note that the exposure amount by unintentional ingestion of dust may be an overestimated value.

### 5-3 Estimated exposure amount (EHE) over a lifetime (average/total)

In the previous section, Section 5-2, the exposure amount was estimated by environment, group (adults, children), and exposure route (inhalation, oral, dermal). Here, to set the *EHE* to be compared with the risk assessment, that is, the *hazard assessment value*, the total *EHE* corresponding to the hazardous degree is determined.

The *hazard assessment value* shown in Chapter 4 is a value for chronic toxicity exposure via oral route. The chronic *hazard assessment value* does not indicate the hazard only for a certain period (Acute or Intermediate) but indicates the possibility that hazardous effects may be expressed when a long-term exposure occurs. Therefore, a risk assessment cannot be conducted in a certain period using the *EHE* only for the period and the chronic *hazard assessment value*.

In order to perform a risk assessment on effects when continuous ingestion is conducted over a lifetime, it is necessary to consider the *human lifetime* and averaging over time to determine the *EHE*.<sup>1</sup> In this risk assessment, *EHE* values are estimated for the two cases of childhood (6 years old) and adulthood.

Accordingly, in *EHE averaged over a lifetime*, assuming that the *human lifetime* is 70 years, the *daily intake for children* is kept for 6 years without change, and the *daily intake for adults* is kept for the following 64 years, the *EHE averaged over a lifetime* can be estimated<sup>2</sup> using the following Equation 5-9.

EHE averaged over a lifetime

 $= \frac{\text{Daily intake for children} \times 6 \text{ years} + \text{Daily intake for adults} \times 64 \text{ years}}{\text{Human lifetime (70 years)}}$ 

#### **Equation 5-9**

In this risk assessment, the exposure amount is estimated so that it is overestimated in the environment where BDE-209 containing products are used, and assuming that the exposure is continued over a lifetime in the same environment, the total *EHE* is determined.

The total *EHE* is shown in Table 5-13.

е	xposure route	<i>EHE</i> averaged over a lifetime			
	inhalation	0.52			
	oral	28.9			
	dermal	0.08			
to	otal <i>EHE</i>	29.5			

#### Table 5-13 Total EHE of BDE-209 (ng/kg/day)

<sup>&</sup>lt;sup>1</sup> U.S. EPA (1992) Guidelines for Exposure Assessment. 2. GENERAL CONCEPTS IN EXPOSURE ASSESSMENT. *EPA/600/Z-92/001,1992* 

<sup>&</sup>lt;sup>2</sup> In the study of the emission target of PFOS containing residue in "Ministry of the Environment Minister's Secretariat, Waste/Recycling Division (2011). Technical remarks concerning treatment of PFOS-containing waste" taking into account the lifetime average daily soil food intake, six years for children and 64 years for adults, a lifetime consists of 70 years.

[Repetit	tion]					
Table 5-7 EHE of BDE-209 inside houses (ng/kg/day)						
	Exp	oosure route	Exposure scenario	Adults	Ch	
					-	

Exposure route		Exposure scenario	Adults		Children	
	Inhalation		0.34		0.49	
	Oral	ingestion of dust	5.9	5.9	38.5	39.3
		mouthing	—		0.81	
	Dermal		0.07		0.10	
EHE inside houses		Adults		Children		
		6.3		39.9		

# [Repetition]

### Table 5-12 EHE of BDE-209 inside cars (ng/kg/day)

Exposure route		Exposure scenario	Adults		Children	
	Inhalation		0.16		0.23	
	Oral	Ingestion of dust	13.6	13.6	89.5	89.6
		Mouthing	-		0.09	
	Dermal		7.4×10 <sup>-3</sup>		0.011	
EHE inside cars		Adults		Children		
		13.8		89.8		

From the above results, with the BDE-209 containing products and in the product use environment, the *EHE averaged over a lifetime* is 29.5 ng/kg/day. Using this value, the risk assessment is conducted.

# 6 Risk assessment

When the *HQ* obtained by dividing by the *hazard assessment value*, which is the total *EHE* in Chapter 5, is 1 or more, it is evaluated as "the risk is at the level of concern," and when the *HQ* is less than 1, it is evaluated as "the risk is not at the level of concern."

In the calculation of the HQ on chronic toxicity exposure via oral route, the EHE averaged over a *lifetime* is used.

EHE averaged over a lifetime (ng/kg/day)	$=\frac{29.5 \text{ ng/kg/day}}{50 \text{ ng/kg/day}}=0.6$		
$HQ = \frac{1}{Hazard assessment value (ng/kg/day)}$	= 50 ng/kg/day $=$ 0.0		
EHE averaged over a lifetime:	29.5 ng/kg/day		
Hazard assessment value:	50 ng/kg/day		
HQ:	0.6		

As a result of the risk assessment, the HQ is 1 or less, and it is considered that the risk of chronic toxicity oral exposure is not at the level of concern when the existing consumer BDE-209 containing products continue to be used.

<Reference>

The EHE over a childhood was estimated to be 129.7 ng/kg/day because the EHE over a childhood is relatively large due to behaviors specific to children. When the hazard assessment value for chronic toxicity oral exposure is applied to this EHE, the HQ becomes 1 or larger, and the risk seems to be at the level of concern. The hazard assessment value for chronic toxicity oral exposure, however, is an index for the exposure dose over a lifetime, and it is considered inappropriate to use this value for exposure for a limited period. Therefore, for childhood, it is considered appropriate to use the minimal risk level (MRL=200 ng/kg/day) for intermediate toxicity oral exposure estimated by the ATSDR as a hazard assessment value. Accordingly, this MRL for intermediate toxicity oral exposure was used as the hazard assessment value to conduct the risk assessment only during childhood for reference.

$HQ = \frac{EHE \text{ over a childhood (ng/kg/day)}}{Hazard \text{ assessment value (ng/kg/day)}} =$	$\frac{129.7 \text{ ng/kg/day}}{200 \text{ ng/kg/day}} = 0.6$	
EHE over a childhood:	129.7 ng/kg/day	
Hazard assessment value:	200 ng/kg/day	
HQ:	0.6	

Accordingly, the *HQ* is 1 or less, and it is considered that the risk is not at the level of concern in childhood as well.

# 7 Summary and considerations

In this chapter, the results in the previous chapters are summarized and this summary of the risk assessment is discussed.

#### 7-1 Summary and considerations

As a result of the risk assessment, the HQ is 1 or less, so it is considered that the risk is not at the level of concern under the current use state, and no special measure is required for the existing BDE-209 containing products in individual houses.

In this risk assessment, not every exposure assessment is conducted setting only the worst conditions; rather the parameter values are set so that the exposure amount is as large as possible while remaining reasonable. Concerning the exposure scenarios, all predictable wrong uses are included in consideration of multiple scenarios, and the exposure amount via all conceivable domestic exposure routes are estimated and summed. Therefore, the exposure amount is estimated by multiplying the parameters that are set so that the *EHE* is as large as possible. The resultant total *EHE* is a value overestimated manyfold, and it can be considered that a person who is always exposed to such a large amount may not exist.

The MRL was derived based on the *hazard assessment value* estimated by the ATSDR, which is the lowest concentration among the *hazard assessment values* currently published by the public authorities. The endpoints used for derivation of intermediate toxicity oral MRL by the ATSDR are based on the fact that an increase in serum glucose levels by 12% was observed in the 0.05 mg/kg/day exposure group, compared with a control group, and that BDE-209 induced 1,257 liver gene transcript changes and that 18 canonical pathways were significantly enriched after whole genome gene expression microarray, gene ontogeny category and pathway analyses were conducted in this group and the control group. However, no target organ has been identified, and there is a possibility that the *hazard assessment value* of 50 ng/kg/day is an overestimated derivation, considering the fact that the endpoints used for MRL derivation were liver gene transcript changes induced by BDE-209 as observed from microarray analysis, etc., as well as the increase in serum glucose levels.

Accordingly, since the total *EHE* is a sufficiently overestimated value, it cannot be said that the exposure margin is not sufficiently set just because the *HQ* is close to 1, since the *hazard* assessment value may also be overestimated, although the *EHE* contains some degree of margin.

From the results of this risk assessment, it is considered that the existing products inside houses or cars are not at the level of concern even if they are continuously used until the end of their product lifetimes.

#### 7-2 Other considerations

Concerning BDE-209 containing products, some products no longer exist in most houses (CRT-based televisions, case of video tapes, etc.) and use of BDE-209 containing products has already been reduced in the related industries. Therefore, it is unlikely that the number of the BDE-209 containing products for use inside houses will increase in the future. Therefore, the *EHE* of

BDE-209 is expected to decrease in the future.

The major exposure source is ingestion of dust. By cleaning the insides of houses and cars as appropriate and by removing the BDE-209 containing dust, the *EHE* and risk can be reduced. It is said that children's intake amount of chemical substances via the dust is larger than that of adults, and it is important to reduce the generation of the dust and the intake amount, irrespective of whether BDE-209 is contained or not, by cleaning or the like.

C-decaBDE consists predominantly of the congener BDE-209 ( $\geq$ 97%), with low levels of other PBDE congeners such as nonabromodiphenyl ether (0.3-3%) and octabromodiphenyl ether (0-0.04%). (POPRC2015). In some reports, it is pointed out that bromine of BDE-209, which is a deca-brominated body, desorbs under high-temperature conditions to form another brominated body. However, there are a lot of uncertainties about to what degree BDE-209 turns into other brominated bodies in the period from the purchase to the end of product life in the actual environments inside houses and cars.

In this risk assessment, only BDE-209 is assessed and no brominated substances other than deca-brominated substances are assessed. BDE-209 containing products have already been decreasing, and it is considered that the other substances will decrease in indoor environments.

Concerning the substances other than BDE-209, it is desirable to conduct monitoring as appropriate and to grasp the actual concentrations.

BDE-209 has been used as flame retardants in resin and textile products since the latter half of the 1980s. Use of flame retardants in various products prevents the products from catching fire when any accident occurs, and even if the product catches fire, any spread of the fire is prevented by flame-retardancy and time for saving human lives can be secured. Since BDE-209 is designated as a Class I Specified Chemical Substance under the CSCL, it is considered that replacement of other flame retardants or change of specifications will be conducted in the future, but in such a case, without a thorough verification of the effects of replacement or change of specifications and a proper transmission of information among the concerned parties, replacement or change of specifications may cause new risks. This is called an antinomy issue or risk trade-off.

There was a case in the past where the bromic flame retardant in the resin materials used for household electric appliances was replaced with red phosphorus to comply with the RoHS Directive or the like. At that time, the information about the change of substance/material specifications was not correctly transmitted from the chemical substances manufacturer to the end product manufacturers or the end product manufacturers were not informed at all (silent change). As a result, a number of cases were reported in which the adverse effects due to the use of red phosphorus (red phosphorus and moisture in the air chemically react, phosphoric acid, which is a conductive material, is formed, and electric current flows in the insulating resin, resulting in shorts, etc.) caused product accidents such as operation failures, high-temperature heat generation, deformation, and ignition, and in the cases of some products, recalls occurred.<sup>1</sup>

<sup>&</sup>lt;sup>1</sup> NITE (2014), (3) On flame retardancy method of plastics and case examples of trouble due to flame retardant, FY2014 Product Safety Business Reporting Meeting, Oral presentation document, 2014 <u>http://www.nite.go.jp/data/000055670.pdf</u>

It is considered that, in order to prevent such product accidents associated with chemical substance control, it is necessary to properly transmit the information on replacement of BDE-209 with other substances or changes of specifications among the manufacturers, and to conduct thorough verification and assessment not only of the risk of the chemical substances but of the risk of product accidents and to pay attention to the risk trade-offs.