

Plastic Additive Risk Trade-off Assessment Document

Summary

Development of Methodologies for Risk Trade-off Analysis toward Optimum Chemical Substance Management,

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National Institute of Advanced Industrial Science and Technology (AIST)
Research Institute of Science for Safety and Sustainability (RISS)

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Authors

Kikuo Yoshida (Project leader)	AIST
Kiyotaka Tsunemi (Assessment leader)	AIST
Hiroya Shinozaki	AIST
Yuriko Ishikawa	AIST
Joji Yamamoto	AIST
Masashi Gamo	AIST
Jun Takeshita	AIST
Wataru Naito	AIST
Masashi Kamo	AIST
Ryoji Makino	AIST

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1. Introduction

The European Parliament and the Restriction of Hazardous Substances Directive (RoHS), responsible for usage restrictions on specified toxic substances used in electrical and electronic devices, have enforced restrictions on lead, cadmium, mercury, hexavalent chromium, polybrominated biphenol (PBB), and polybrominated diphenyl ether in products since 2006. With such a directive, companies have been expected to make substitutions for these use-restricted substances. As a side note, one of the PBDEs, decabromodiphenyl ether (decaBDE), has been removed from the list of substances under the RoHS directive in 2005.

Companies are already working towards the substitution of PRTR-designated chemical substances, (along with other matters relating to being environmental conscientiousness), and there is a large movement towards the potential substitution of plastic additives such as Di(2-ethylhexyl)phthalate (DEHP) and decaBDE.

The substitution for substances which pose little hazard has been occurring, together with the gathering of information related to the exposure to such substitutions, and it appears that the risk of using such substances could be increasing. However, the verification of risk trade-offs between substituted and substituting materials faces a problem in terms of the lack of information on the hazardousness of and risk of exposure to such substituting substances. While the end products and results of the substituted and substituting substances are significantly different, it is not possible to compare the risks associated with their usage. Therefore there is no method with which to verify whether the total risk of substituting plastic additives with other substances is mitigated, and there is a call for the development of a suitable risk trade-off analysis methodology and its implementation for risk trade-off assessments.

By using such tools and models, which are being developed in parallel, the risk trade-off to human health and the ecological risk were assessed against flame retardants used in electric and electronic devices as plastic additives.

2. Scenario Setup

For a risk trade-off analysis, this assessment targeted home electronics such as TV and computers, and the chassis of electric and electronic devices as found in office machines. Fiber use was also considered as a background product, since decaBDE is used within fibers in large quantities. Substance substitution from bromine-based flame retardants to phosphoric retardants was examined, and decaBDE and condensed phosphoric acid-based bisphenol A – bis(diphenyl phosphate) (BDP) were the target substances.

Risk was assessed using the average value of emissions from 40 years between 1980 and 2020, with respect to the long-term human health risk.

Three types of scenarios were designed for analysis in order to assess the risk trade-off related to the substitution of decaBDE to BDP: 1. decaBDE substitution (baseline) scenario, 2. BDP substitution (baseline) scenario, and 3. no decaBDE substitution

scenario.

Scenario 1 assumed a case in which decaBDE data demanded from the past to present is used as is. Scenario 2 assumed a case where BDP data demanded from the past to present is used as is. Scenario 3 assumed a case where the substitution of BDP does not occur for plastic resin, and all present and future demands are for decaBDE.

For a risk trade-off assessment, changes in risk by substitution can be judged by comparing baseline scenarios 1 and 2 (where substitution takes place), with scenario 3 where decaBDE is not substituted.

As specified above, the risk trade-off was assessed using these 3 scenarios.

3. Material Flow Analysis of Flame Retardants and Estimation of Emission Towards the Environment

A material flow analysis based on the domestic demand for decaBDE and BDP was conducted, and the material flow of flame retardants used in plastics and fibers for TVs and computers from production to disposal was estimated. Because the retardants have a long life cycle, the emission factor at each stages of the cycle was configured, and emissions to the environment were estimated for each scenario from 1980 to 2020.

3.1 Material Flow Analysis

Data for domestic demand was provided by The Chemical Daily for decaBDE, and Flame Retardant Chemicals Association of Japan for BDP. Data up to 2005 are actual records, and demand from 2006 to 2020 was estimated under the assumption that the situation as of 2005 would continue. The transition in demand for each of the retardants was set by separating the use between resin and fiber. The ratio between the usages was 6:4 for decaBDE (Tokai et al., 2008), while BDP was only used for resin as it is not used in other ways. The setting by Tokai et al, (2008) was used for the domestic production of decaBDE, while BDP was assumed to have 90% of the demand produced domestically and 10% imported.

In order to maintain the retardant effect in the final product, flame retardants are already included in the final product before circulation, stocked by general consumers during the life period of the products, and later discarded. Thus, assuming the life of electric and electronic devices and textile products as 5~15 years and 5~20 years, respectively, the amount of waste and amount of stock using the cumulative Weibull distribution function was estimated. Figure 1 shows the results.

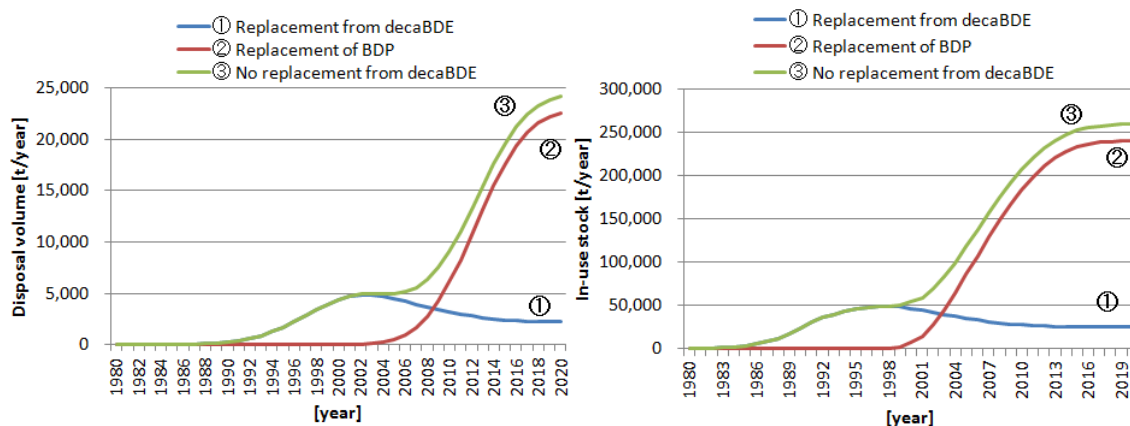


Fig. 1 Results of material flow analysis by scenario
(L: Change in waste amount over time, R: Change in municipal stock over time)

3.2 Estimation of Emissions

Emissions to the atmosphere and water are estimated for each life cycle stage, including domestic production, the forming process, consumption of final product, and disposal (general waste, industrial waste, sewage sludge). The emission factor was based on data from Tokai et al. (2008) (Table 1).

The atmospheric emission factor of BDP was assumed to be proportional to the vapor pressure of the substance, while the water emission factor was assumed to be proportional to the aqueous solubility. The factors were configured and are listed in table 2. The emissions were then estimated by multiplying the material flow at each life cycle stage with an emission factor (Fig. 2).

Table 1 List of emission and transfer factors of decaBDE to the environment

Process		Atmosphere	Water	Sewer	Disposal
Domestic production		0	3.3×10^{-4}	0	1.6×10^{-2}
Formation processing	Resin	1.3×10^{-5}	4.2×10^{-6}	5.5×10^{-5}	2.7×10^{-2}
	Fiber	2.1×10^{-6}	1.7×10^{-3}	3.2×10^{-3}	9.8×10^{-2}
Consumption of final product	Resin	5.1×10^{-6}	0	0	0
	Fiber	5.1×10^{-6}	3.1×10^{-7}	6.9×10^{-7}	0
Fracturing		3.0×10^{-7}	0	0	0
Incineration		9.4×10^{-6}	0	0	0
Landfill		7.3×10^{-7}	2.3×10^{-7}	0	0

Table 2 List of emission and transfer factors of BDP to the environment

Process		Atmosphere	Water	Sewer	Disposal
Domestic production		0	3.0×10^{-5}	3.0×10^{-5}	1.8×10^{-3}
Formation processing	Resin	2.8×10^{-7}	8.8×10^{-8}	1.2×10^{-6}	5.6×10^{-4}
	Fiber	0	0	0	0
Consumption of final product	Resin	1.0×10^{-7}	0	0	0
	Fiber	0	0	0	0
Fracturing		2.4×10^{-7}	0	0	0
Incineration		2.8×10^{-7}	0	0	0
Landfill		1.1×10^{-10}	2.5×10^{-4}	0	0

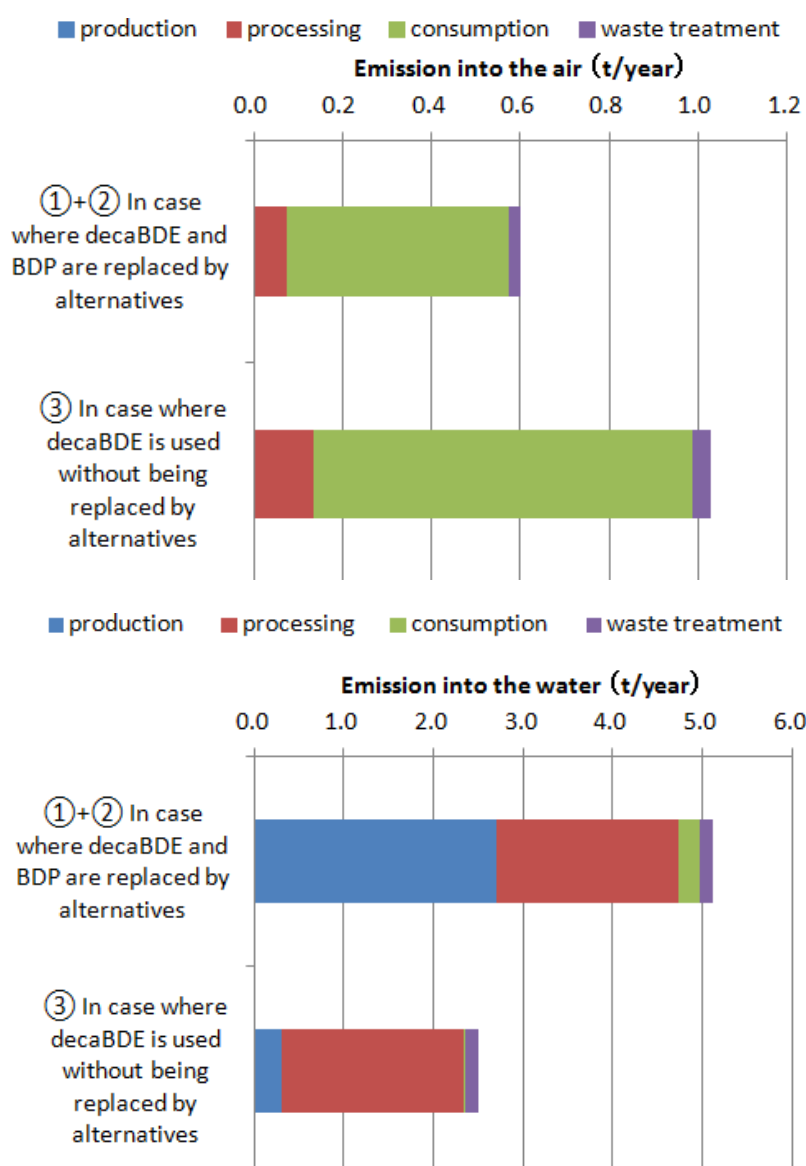


Fig. 2 Results for estimation of emissions by scenario (Upper bar: atmospheric emission, lower bar: water emission)

4. Analysis of Indoor Exposure

Using an indoor exposure assessment tool (iAIR, developed by AIST), the concentration of decaBDE, BDP, and triphenyl phosphate (TPP) in indoor air (concentration in gaseous state) and in indoor dust was estimated.

Figure 3 shows the estimation for indoor dust concentration of decaBDE and actual measurements nationwide, reported thus far. Model calculations overall matched the measured results.

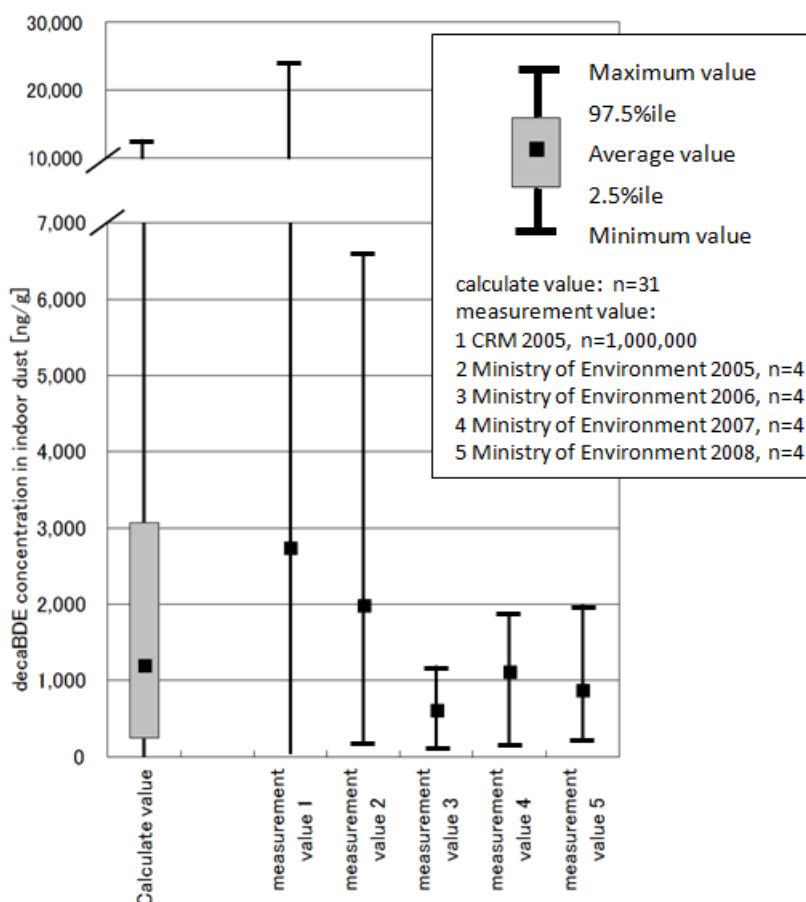


Fig. 3 Comparison of actual measurements for decaBDE concentration in indoor dust and calculated values by iAIR
(L: Calculated value, R: Measured value)

Figure 4 shows the concentration within indoor dust for each substitution scenario. When there was no substitution from decaBDE to BDP, the average value of decaBDE rose from 1,200 ng/g in the substitution scenario, to 1,400 ng/g in the no-substitution scenario. However, concentrations of BDP and TPP in indoor dust were lower by 2 orders when compared with decaBDE (Table 3).

Table 3 Estimated concentration of substance in indoor environment

Scenario	Substance	Concentration in indoor dust	Concentration in indoor air
		ng/g	pg/m ³
With Substitution	decaBDE	1,200 (240~2,500)	0.0026 (0.00052~0.0066)
	BDP	7.2 (0.0~180)	0.00033 (0.000~0.0015)
	TPP	15 (0.0~66)	5.9 (0~26)
No substitution	decaBDP	1,400(400~3,300)	0.0029(0.00085~0.0073)

Arithmetic average value (2.5 percentile ~97.5 percentile)

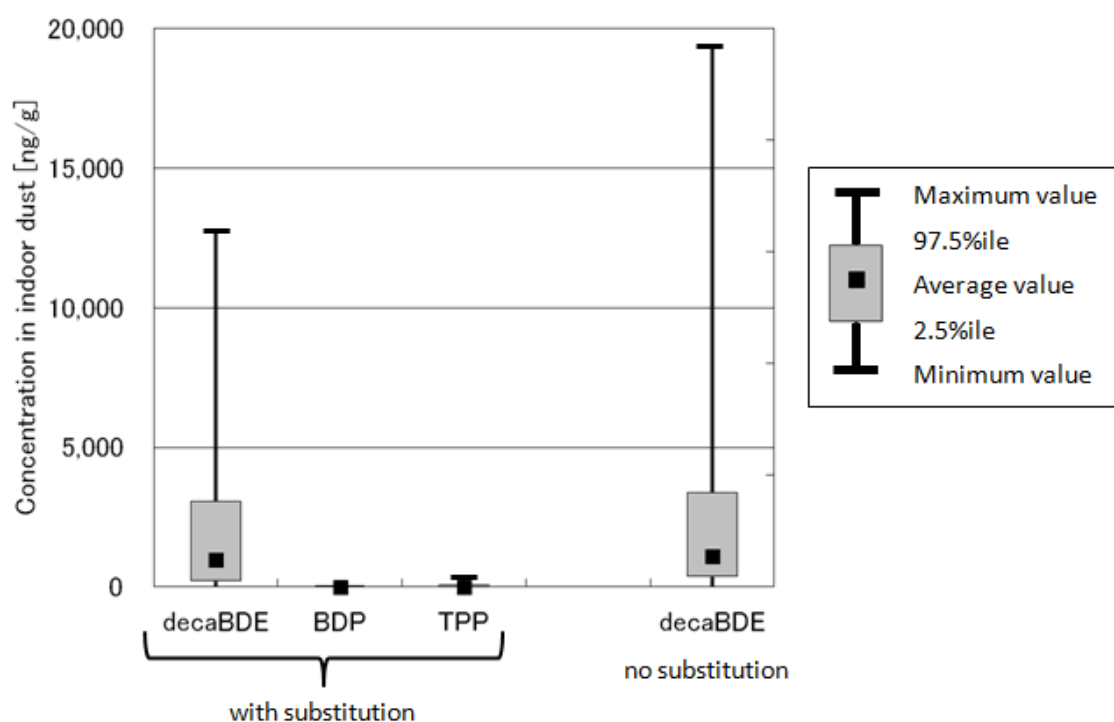


Fig. 4 Concentration in indoor dust using substitution scenario (Left: scenario①and②, right: scenario③)

5. Estimation of Environmental Concentration

Flame retardants released to the environment reach humans and other organisms in the environment through various environmental mediums. The concentrations of decaBDE and BDP in the atmosphere, rivers, and sea water were therefore estimated using a model and an estimated amount of emission.

5.1 Estimation of Atmospheric Concentration

Using the estimated emission data, the atmospheric concentration was estimated for all of Japan with AIST-ADMER. The data was organized as the distribution of the amount of emission per grid unit for each stage and use (resin, fiber), using industrial statistics shipment value, night population, information on location, etc.

Substance parameters were set as the decomposition coefficient 5.2×10^{-6} , dry deposition velocity 3.0×10^{-3} m/sec, and washout ratio 2.0×10^5 for decaBDE (Tokai et al., 2008), and 1.18×10^{-5} , 2.7×10^{-3} m/sec, and 1.8×10^5 for BDP (model estimation), respectively. Background concentration was assumed to be zero. Figure 5 shows the estimated atmospheric concentration in each scenario.

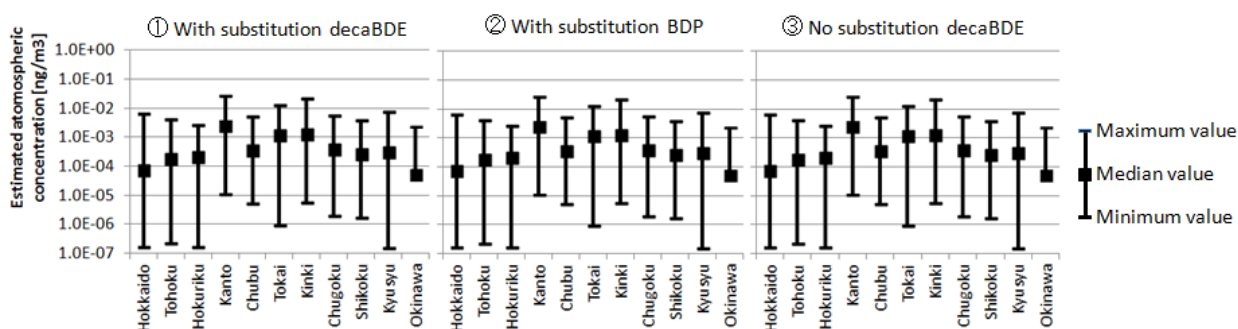


Fig. 5 Results for estimated atmospheric concentration in each scenario (Left: scenario①, center: scenario②, right: scenario③)

5.2 Estimation of Concentration in Rivers

The monthly concentration in river water, per 1-km mesh, in class A water systems in the Kanto region was estimated for each scenario using a river model (still in development), based on the estimated emission results. Table 4 lists the model input parameters.

The model does not take input from soil erosion into consideration, and therefore the atmospheric deposition of decaBDE and BDP was plugged directly into the river water using the mesh and the river water concentration was estimated.

Table 4 Physicochemical parameters of decaBDE and BDP

	decaBDE	BDP
Molecular weight (g/mol)	959.2	693
Vapor pressure (Pa)	4.63×10^{-6}	2.75×10^{-6}
Water solubility (mg/L)	1.00×10^{-4}	7.3×10^{-11}
Koc (L/kg)	5.16×10^9	2.3×10^8
River water half-life (day)	693	693
Half-life in solid-phase river sediment (day)	693	693
Half-life in solid-phase soil (day)	693	693

Figure 6 shows the minimum, maximum, and median values of estimated results of the monthly average concentration in rivers for each scenario. In scenario 1 there was a favorable comparison for the decaBDE substitution.

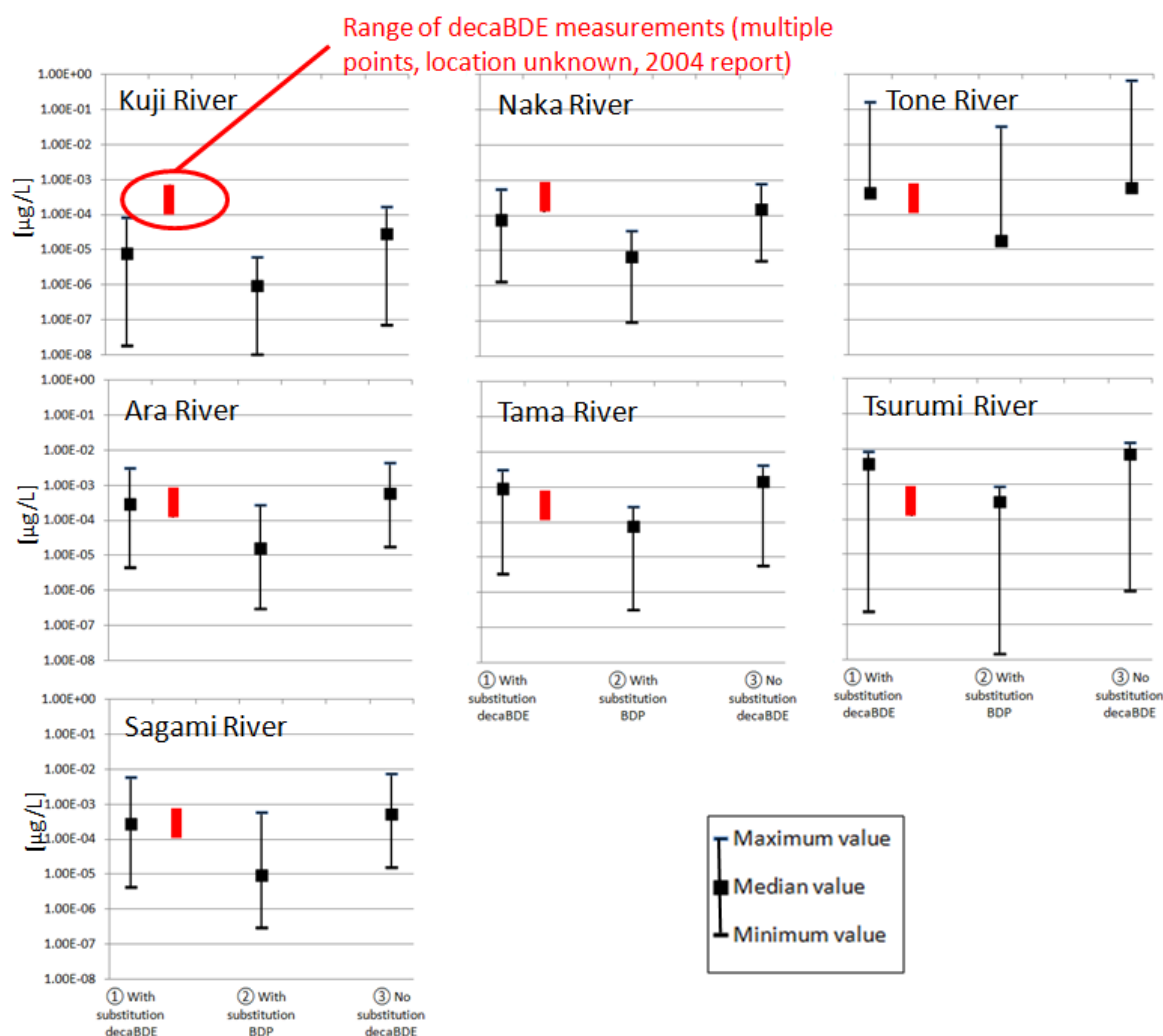


Fig. 6 Estimated concentration in class A rivers in the Kanto region for each scenario

5.3 Estimated Concentration in Seawater

Based on the results of the emission estimation and the load of decaBDE and BDP that flows into the sea from rivers, concentrations in seawater and sediments in Tokyo Bay were estimated using AIST-RAMTB. Table 5 lists the parameters used by AIST-RAMTB.

Figure 7 shows the results for the dissolved concentration (surface layer, water depth 0~2m) estimated in each scenario. In a comparison between scenarios 1 and 3, both the dissolved concentration and the sedimentary concentration tended to be slightly higher in scenario 3. This is because of an increase in the inflow load from the atmosphere and rivers. The dissolved concentration near the rivers was high in scenario 2 and the distribution coefficient was smaller in comparison with that of decaBDE, suggesting that it is more likely to exist in a dissolved state than to be adsorbed as suspended solids, and thus decreasing the deposited amount.

Table 5 Setting data for AIST-RAMTB

Item	Set Value
Target area	Entire Tokyo Bay
Spatial resolution	1km mesh
Initial condition	Dissolved and sediment concentration set at 0
Bay mouth boundary condition	Dissolved and adsorbed suspended solid set at 0
Sedimentation rate of suspended solids (cm/sec)	Plant plankton: 2.0×10^{-4} Detritus: 5.8×10^{-4} Inorganic suspended solids: 5.8×10^{-4}
Degradation rate constant (1/sec), temperature coefficient (1/°C)	Under water 1.16×10^{-8} Sediments 4.11×10^{-9} , temperature coefficient 0.0693
Adsorption rate constant (1/sec)	Plant plankton: 2.0×10^{-5} Detritus: 2.0×10^{-5} Inorganic suspended solids: 0.0
K_{oc} (L/kg)	Plant plankton: 5.16×10^9 (decaBDE), 1.15×10^6 (BDP) Detritus: 5.16×10^9 (decaBDE), 1.15×10^6 (BDP)

Comparing the actual measurements of deposited concentrations of decaBDE in Tokyo Bay (PBDE concentration, in which over 90% was BDE 209, a major constituent of decaBDE products) to the calculated results (scenario 1), the calculated value showed a higher value than the observed data, but the order of concentration by area was the same.

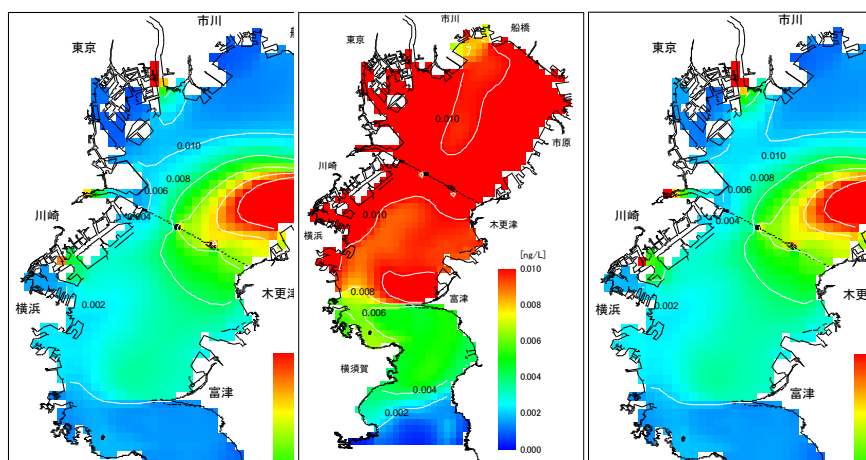


Fig. 7 Results for annual calculation of dissolved concentration in Tokyo Bay (Left: scenario①, center: scenario②, right: scenario③)

6. Estimated Human Intake

The amount of intake via food (agricultural produce, livestock, and fish) as a result of a substitution from decaBDE to BDP was estimated for the 3 scenarios, based on the distribution of atmospheric and Tokyo Bay seawater concentrations of decaBDE and BDP, estimated by AIST-ADMER and AIST-RAMTB, respectively. While taking the concentration of indoor dust into account, the total ingested and inhaled intake was also estimated for each scenario.

To estimate the ingested intake via agricultural and livestock products, an environmental media migration model was used to consider the circulation route to the

product consumed. The concentration in fish products was estimated using a model for the biological accumulation of toxic chemical substances, in order to estimate the intake via fish products caught in the Tokyo Bay.

6.1 Estimated Oral Intake via Agricultural and Livestock Products

Intake via agricultural and livestock products was estimated under the following assumptions.

- Concentration distribution in vegetables is equal to the average concentration distribution of 12 species of agricultural product.
- Concentration distribution in domestic pork and chicken is equal to that of beef.
- Concentration distribution of imported agricultural and livestock products are equal to estimated average concentration distribution of domestic products.

For the 2-dimensional Monte Carlo simulation using Crystal Ball 2000 (Kozo Keikaku Engineering Inc.), a Latin Hypercube Sampling was employed for 50 external simulations (uncertainty) and 1,000 internal simulations (variability). Table 6 lists the average daily intake via domestic agricultural and livestock products in the Keihin district, after the values were corrected with a distribution of the actual/estimated concentration ratio.

Table 6 Distribution of decaBDE intake via domestic agricultural and livestock products in each scenario (unit: $\mu\text{g}/\text{kg}/\text{day}$)

Scenario	① With Substitution decaBDE	② With Substitution BDP	③ No substitution decaBDE
Human intake (average, male)	3.76×10^{-5}	2.77×10^{-6}	1.47×10^{-4}
Human intake amount (95th percentile, male)	1.22×10^{-4}	8.99×10^{-6}	4.76×10^{-4}
Human intake amount (average, female)	4.19×10^{-5}	3.08×10^{-6}	1.64×10^{-4}
Human intake amount (95th percentile, female)	1.27×10^{-4}	9.36×10^{-6}	4.96×10^{-4}

6.2 Estimated Oral Intake via Fish from Tokyo Bay

Concentrations in Japanese conger from Tokyo Bay were estimated using a model for biological accumulation of toxic chemical substances, based on the estimated seawater and suspended solid adsorption concentration of decaBDE and BDP (fig. 9). Based on the probability density function of estimated amounts of decaBDE and BDP, the intake via fish products from Tokyo Bay was estimated.

6.3 Estimated Total Intake via Food and Indoor Dust

Total intake was calculated (as below) from the estimated intake via food (agricultural, livestock, and fish products) and the intake based on indoor dust concentration. Figure 9 shows the ratio of intake from different routes.

① Scenario where a substitution for decaBDE exists (showing current state of substitution).

The average total decaBDE intake was estimated as 2.04×10^{-4} $\mu\text{g}/\text{kg}/\text{day}$ for males, and 2.07×10^{-4} $\mu\text{g}/\text{kg}/\text{day}$ for females. The 95th percentile was estimated as 7.27×10^{-4} $\mu\text{g}/\text{kg}/\text{day}$ for males, and 6.91×10^{-4} $\mu\text{g}/\text{kg}/\text{day}$ for females.

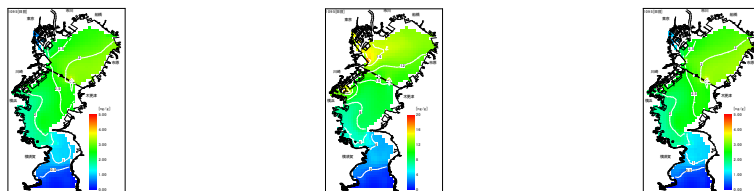


Fig. 8 Estimated concentrations in Japanese conger in Tokyo Bay (water depth 8~10m)
(Left: scenario①, center: scenario②, right: scenario③)

② Scenario with BDP Substitution (showing current state of substitution)

The average total BDP intake was estimated as 7.17×10^{-4} $\mu\text{g}/\text{kg}/\text{day}$ for males, and 7.19×10^{-4} $\mu\text{g}/\text{kg}/\text{day}$ for females. The 95th percentile was estimated as 2.59×10^{-3} $\mu\text{g}/\text{kg}/\text{day}$ for males, and 2.46×10^{-3} $\mu\text{g}/\text{kg}/\text{day}$ for females.

The average total TPP intake was estimated as 2.17×10^{-7} $\mu\text{g}/\text{kg}/\text{day}$ for males, and 2.45×10^{-7} $\mu\text{g}/\text{kg}/\text{day}$ for females. The 95th percentile was estimated as 2.34×10^{-7} $\mu\text{g}/\text{kg}/\text{day}$ for males, and 2.61×10^{-7} $\mu\text{g}/\text{kg}/\text{day}$ for females.

③ Scenario with no decaBDE substitution (decaBDE is not substituted; fictitious situation).

The average total decaBDE intake was estimated as 3.19×10^{-4} $\mu\text{g}/\text{kg}/\text{day}$ for males, and 3.31×10^{-4} $\mu\text{g}/\text{kg}/\text{day}$ for females. The 95th percentile was estimated as 1.07×10^{-3} $\mu\text{g}/\text{kg}/\text{day}$ for both males and females.

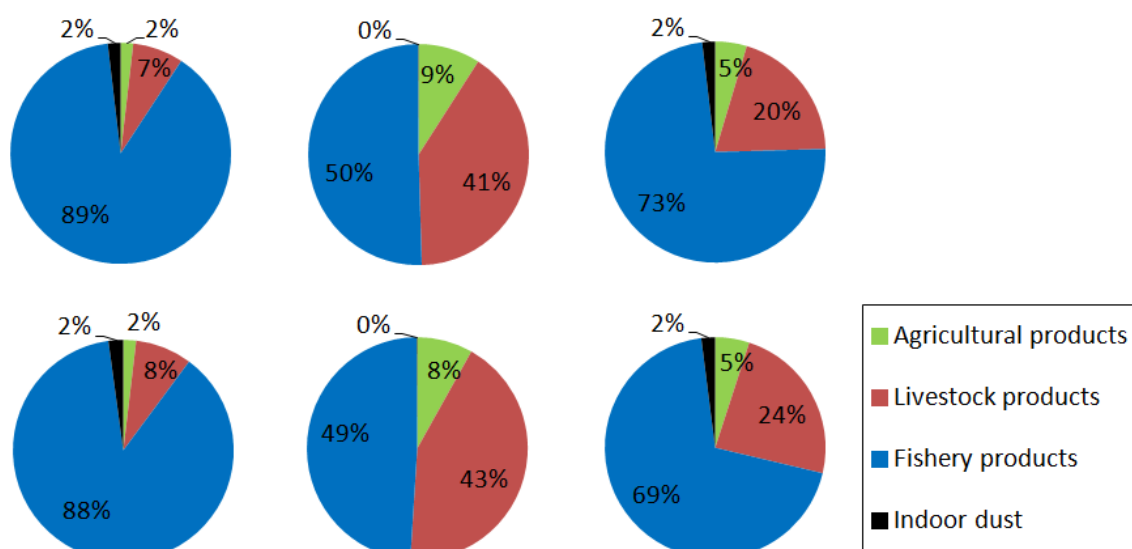


Fig. 9 Intake ratio from food and indoor dust for residents in the Keihin district by route (Left: scenario①, center: scenario②, right: scenario③ top: male average, bottom: female average)

7. Human Health Effect and Risk Trade-off Assessment

Based on intake estimates for decaBDE and BDP, substance risks in substitution scenarios were estimated using quality adjustment life years (QALY).

7.1 Estimated Toxicity Equivalence Factor per Affected Organ

The toxic equivalence factor of decaBDE, BDP, and TPP against a reference substance was calculated using an inference algorithm (under development), where vinyl chloride monomer and cadmium were chosen as the reference substances that impact the liver and kidneys, from the availability of human epidemiological information. Test results from oral administration were used for the calculation. For rats and mice, true values for no observed effect level (NOEL) for each of the organs were determined (if the literature value was available). Otherwise, the estimated value from the inference algorithm was used for the calculation. The dose-response relationship (oral exposure), as seen in figure 10, was derived from the relationship of the liver and kidney with the reference substances.

If the chemicals are substituted, the increase of an intake of flame retardants is a simple weight addition where relative toxicity is not considered, but the intake (and the risk) of using a decaBDE equivalent is thought to decrease in relation to the impact on both liver and kidneys by consideration of relative toxicity. As shown in a 95th percentile worst-case scenario, however, there is also a possibility of an increased intake (and risk) by use of a substitution.

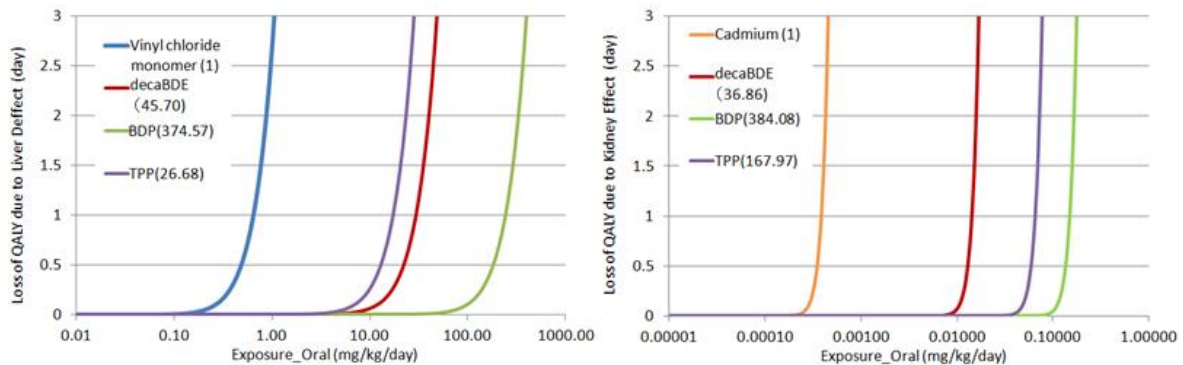


Fig. 10 Relationship between dose-response on liver (L) and kidney (R)
 Relationship between exposure ($\mu\text{g}/\text{kg}/\text{day}$) and loss of QALY (day: lifelong value per person)
 (The number in parentheses behind substance names is the toxic equivalence factor)

7.2 Changes in Risks by Substance Substitution

The estimated human decaBDE, BDP, and TPP intake values (average for males and females) in each scenario were compared after being weighted with the toxicity equivalence factor. Figure 11 shows the weighted intake comparison (μg decaBDE equivalent/kg/day) between scenarios.

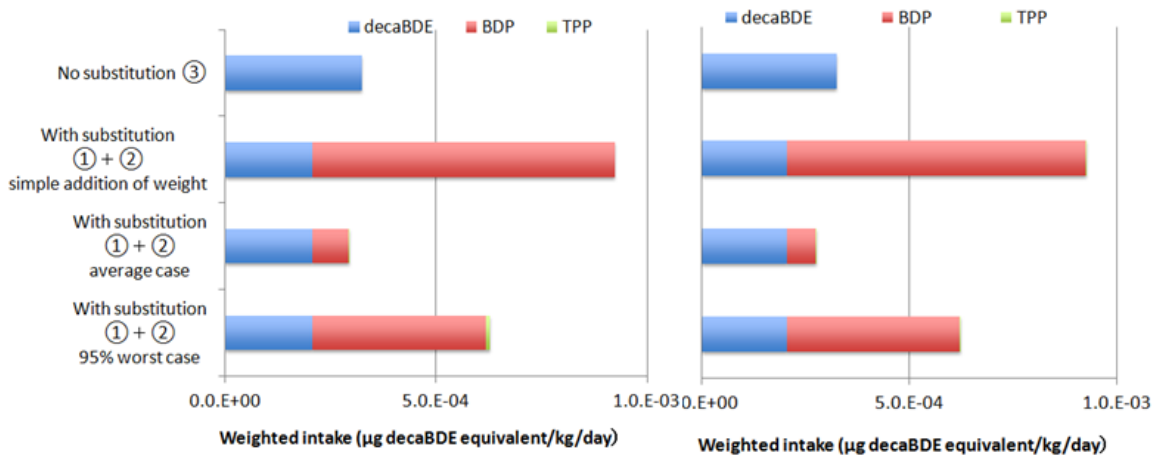


Fig. 11 Changes in weighted intake by substance substitution
 (L: Effect on liver, R: Effect on kidney)

A decrease in the QALY was also estimated from the dose-response relationship with the amount of intake (Table 7). It was shown that the absolute value of risk from QALY loss was quite small (less than 0.01 days worth of life), regardless of the substitution or lack thereof. Substitution thus cannot be justified by a change in the risk itself. The same conclusion is also drawn if a lower limit of the 95% estimate of relative toxicity is used (95% worst-case scenario in table 7).

Table 7 Risk (=QALY loss) by substance for substitution scenario (day: lifelong value per person)

	With substitution (Substitution in current state)		No substitution (Imaginary situation)
	①decaBDE、②BDP、TPP		③decaBDE
	average case	95%ile worst case	
Effect on Liver	<< 0.001 (2.8×10^{-57})	<< 0.001 (2.0×10^{-53})	<< 0.001 (9.5×10^{-57})
Effect on Kidney	<< 0.001 (1.4×10^{-140})	<< 0.001 (1.0×10^{-122})	<< 0.001 (8.8×10^{-137})
Total	<< 0.001 (2.8×10^{-57})	<< 0.001 (2.0×10^{-53})	<< 0.001 (9.5×10^{-57})

average case: Case in which geometric average of estimation is used as relative toxicity
 95%ile worst-case: Case in which lower confidence limit of 95%ile estimation is used as relative toxicity

8. Ecological Impact and Risk Trade-off Assessment

Limited information on ecological toxicity from decaBDE and BDP exists, and it is difficult to estimate a species sensitivity distribution (SSD) from the known toxicity values. Because of this, a method for estimating the SSD, which has insufficient chemical substance and toxicity information, was developed, and changes in the risk were estimated using the results from the method.

8.1 Estimating the Species Sensitivity Distribution

SSDs were developed using chemicals with abundant data, and the average and variances of decaBDE and BDP SSDs were estimated using the developed SSDs.

Existing toxicity values were collected from the Screening Risk Assessment Report (NITE/CERI, 2005). The explanatory variables were the molecular weight, boiling point, freezing point, log Kow, and Henry coefficient. The average and variance were calculated for 91 substances, assuming a lognormal distribution.

In order to use meaningful explanatory variables in a linear multiple regression, a model selection using Akaike's Information Criterion was performed. From this, the boiling and freezing points, together with log Kow, were selected. Table 8 gives the regression coefficients with statistics, while figure 12 shows the estimated values of the model and its actual measurements. Regression coefficients of boiling and freezing points are significant, but their absolute values are small. However, log Kow greatly contributes to the estimation of the average value. Using the model, the predicted average values for decaBDE and BDP were 0.018 and 0.12 (mg/L), respectively.

Table 8 Statistical quantity (degree of freedom adjusted $R^2=0.24$)

Explanatory variable	Regression coefficient	p -value
Boiling point	0.0029	0.011
Freezing point	-0.0080	0.015
log Kow	-0.59	<0.001
Intercept	3.17	<0.001

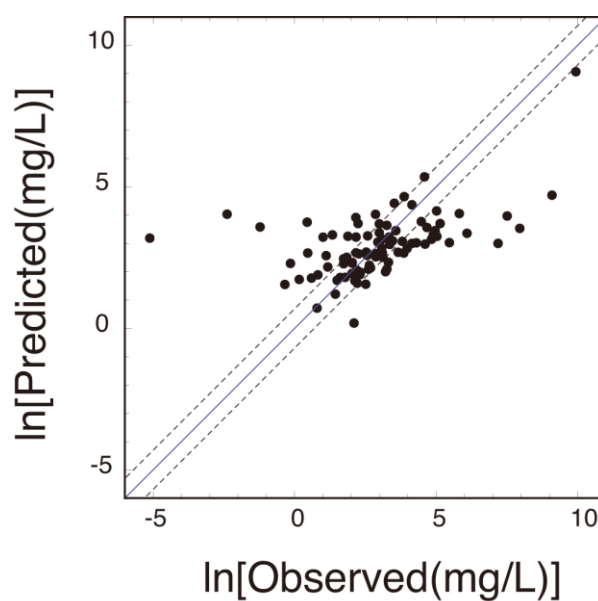


Fig. 12 Comparison of actual measurements of species and predicted values for sensitivity distribution average

The dotted line is double the observed values. 39 out of 91 substances are within the double boundary

A median (2.58) for the known sensitivity distribution was used, since estimation of variance is relatively difficult. Sensitivity distribution is expressed as:

$$\text{decaBDE: } f_{\text{decaBDE}}(\ln[x]) = \int_{-\infty}^{\ln[x]} \frac{1}{\sqrt{2.58 \times 2\pi}} \exp\left\{-\frac{(y - \ln[0.018])^2}{2 \times 2.58}\right\} dy$$

$$\text{BDP: } f_{\text{BDP}}(\ln[x]) = \int_{-\infty}^{\ln[x]} \frac{1}{\sqrt{2.58 \times 2\pi}} \exp\left\{-\frac{(y - \ln[0.12])^2}{2 \times 2.58}\right\} dy$$

Risk was assessed by combining the results from the sensitivity distribution and exposure assessment.

8.2 Changes in Ecological Risks from Flame Retardants

Using river water concentration and species sensitivity distribution, the risk was calculated from the above equation (table 9).

Table 9 Estimated results of ecological risks

River name*	With substitution		No substitution
	decaBDE	BDP	decaBDE
Kuji River system	4.04×10^{-17}	0	1.65×10^{-15}
Naka River system	3.12×10^{-13}	0	1.59×10^{-12}
Tone River system	1.34×10^{-10}	0	2.85×10^{-10}
Ara River system	1.27×10^{-9}	0	5.67×10^{-9}
Tama River system	1.97×10^{-9}	0	8.35×10^{-9}
Tsurumi River system	1.26×10^{-7}	1.56×10^{-18}	5.11×10^{-7}
Sagami River system	8.13×10^{-9}	0	1.73×10^{-8}

*All targets are the main river

The risk of BDP is far smaller than that of decaBDE in scenarios with substitutions, and most of the risk comes from decaBDE. Assuming no substitution, the risk of decaBDE is expected to increase (about 2~40 times), but the total amount is estimated to be very small in both cases.

9. Economic Analysis of Flame Retardant Risk Trade-off

The cost effectiveness of risk reduction measures for a flame retardant substitution was assessed by estimating the cost of substitution from decaBDE to BDP, and calculating the effective unit reduction cost of a substitution, then comparing the results with existing unit risk reduction costs with other chemical substances. The data in table 10 show changes in cost of substitution from decaBDE to BDP, and increments in human health risk that accompany the process.

Table 10 Cost and effect increment for substitution of BDP for decaBDE

	Cost (hundred million yen/year)	Effect (Reduction of QALY loss)
No substitution scenario ①+②	$C_{Y3} = 72.5$	$R_3 = 1.1 \times 10^{-51}$ (year/person/life)
With Substitution scenario ③	$C_{Y1+2} = 138.3$	$R_{1+2} = 5.0 \times 10^{-53}$ (year/person/life)
Difference	$\Delta C = 65.7$	$\Delta R = 5.8 \times 10^{-48}$ (year/population/year)

From ΔC and ΔR , an annual QALY acquisition cost (the cost per year to acquire 1 QALY for the life of all population) was calculated as follows.

$$\Delta C / \Delta R = 65.7 \text{ [hundred million yen/year]} / 5.8 \times 10^{-48} \text{ [year/population/year]} = 1.1 \times 10^{49} \text{ [hundred million yen} \cdot \text{ population/year]}$$

The annual QALY acquisition cost, taking measures against other chemical substances is 2.2 hundred million yen/year for a reduction of 1,3-butadiene in a self-managed process, 1.5 hundred million yen/year for permanent measures against dioxin in waste treatment facilities, 0.4 hundred million yen/year for banning chlordane used to control

termites, and 2.2 hundred million yen/year for restricting benzene content rate in gasoline. Therefore the annual QALY acquisition cost for substituting decaBDE with BDP is very large compared to the QALY data for other substances, suggesting that cost-effectiveness is quite poor.

10. Conclusion

This scenario selected three scenarios for substance substitution from bromine-based flame retardant decaBDE to the phosphorus-based flame retardant BDP: 1. decaBDE (baseline) scenario with substitution; 2. BDP (baseline) scenario with substitution; 3. decaBDE scenario with no substitution. The trade-off between human health risk and ecological risk was then analyzed before and after substitution, as well as the socioeconomic impact.

By assessing the human health risk trade-off for residents in the Keihin district (where the amount of intake is large), it was revealed that the intake (and risk) of a decaBDE equivalent is mitigated in terms of the effects on both liver and kidneys by considering relative toxicity, but that the possibility of an increased risk by substitution cannot be ruled out due to uncertainty from the toxic equivalence factor. It was also shown that, regardless of substitution or not, the absolute value of risk expressed by QALY loss is quite small.

The results of an ecological risk trade-off assessment performed in the Kanto region (where emissions are relatively large), revealed that while risk mitigation takes place by substitution, the risk in each scenario (ratio of affected species) is quite small.

A socioeconomic analysis revealed that the cost-effectiveness of substituting decaBDE with BDP is quite poor.

As seen above, a risk trade-off assessment for substance substitution from decaBDE to BDP was conducted. A risk trade-off assessment is necessary to analyze the usefulness of substituting substances by businesses on as a voluntary basis, or for the substitution as a result of regulatory compliance, though its specificity may vary from case to case. It is hoped that businesses present advance information to local residents, employees and customers, concerning the validity of substance substitution (from the point of using a risk mitigation feasibility study and from the perspective of cost effectiveness), and that the government will do the same for the population through a regulation impact analysis.

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