

# **Risk Trade-off Assessment Document**

## **- Industrial Cleaners -**

### Summary

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

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## **1. Introduction**

### **1.1 Objective of the Assessment**

As businesses make voluntary efforts to mitigate the emission of targeted substances (with concerns for their hazardousness) by substitution with non-targeted substances, it has become evident that, in undergoing such a substitution, there is no method or index with which to assess whether the risk is actually mitigated, or whether the cost entailed in taking such measures is worthwhile. This assessment aims to present methods that explain to various stakeholders the legitimacy of businesses substituting substances as a voluntary measure, and assesses the hazardousness of industrial cleaners, an area in which substitution has been widely occurring.

### **1.2 Assessment Scenario**

Analysis of tendencies in emission mitigation measures for chlorinated-type cleaners revealed that the “substitution of cleaners and solvents” was the greatest measure taken, in terms of the number of cases and amount of mitigated emissions, followed by an “improvement of operation (improvement of recovery rate, etc.)” The majority of substances substituted were hydrocarbon type and aqueous type, followed by semi-aqueous type cleaners. Therefore, the analysis scenarios for this assessment included the substitution of hydrocarbon type substances from chlorinated-type cleaners and to aqueous type from chlorinated-type. A non-substitution scenario was also used as a point of comparison in which, instead of substitution, a cleaner recovery unit was implemented as a mitigation measure.

Trichloroethylene and dichloromethane were selected for the assessment as substituted substances, as both occupy a majority in chlorinated-type cleaners used today. The assessed substances selected for substitution were n-decane (as a hydrocarbon type cleaner based on the volume of its sales and its boiling point data), and alcohol ethoxylate (AE) (as a aqueous type cleaner frequently used as a surfactant in commonly used alkaline-based cleaners).

Detailed risk assessments have already been published for trichloroethylene and dichloromethane, and it is known that both carcinogenic and non-carcinogenic risks for both substances are not at a level that would raise concerns. It should be noted, that scenarios in this report use chlorinated-type cleaners, which do not have an alarming level of risk, which is why there is a great need to scrutinize the risk trade-off and cost effectiveness of substitution of these products.

## **2. Changes in Environmental Emissions**

Changes in emissions for each targeted cleaner ingredient, after being substituted or recovered were calculated using the emission estimation formula for cleaners constructed in the “Emission Scenario Document on Industrial Cleaners”(NEDO, 2010). The

cleaning process characterization parameter values needed for the estimation were determined using data from cleaning cases. In scenarios 5 and 6, where a recovery unit was installed, the emission of the detergent was assumed to decrease by 65%.

The data in table 1 show the changes in emissions for each scenario, including products used for purposes other than as industrial cleaners. The emissions from chlorinated-type cleaners used for cleaning purposes were assumed to be zero after substitution. Both cleaner-oriented emissions of trichloroethylene and dichloromethane before substitution were calculated to be 14,244 (t/year) and 19,513 (t/year), respectively, by using values from the PRTR emission estimations (METI, 2007) for the used amount of chlorinated-type cleaners and from data reported in the Hazardous Air Pollutants Voluntary Management Report provided by each industry organization for the emissions coefficient. The emission of n-decane before substitution was calculated by multiplying the VOC emission with the composition ratio, and the emission of AE before substitution was taken from the PRTR emission data (2005 fiscal year's values).

Table 1 Estimation of changes in emissions after substitution of cleaner (national, 2005, t/year)

Scenario	Substance	Before Substitution (Before Measures)	After Substitution (After Measures)	Amount of Change
① From trichloroethylene to n-decane	Trichloroethylene	14,854	610	-14,244
	n-Decane	119,049	130,143	+11,094
② From dichloromethane to n-decane	Dichloromethane	31,909	12,396	-19,513
	n-Decane	119,049	125,260	+6,211
③ From trichloroethylene to AE	Trichloroethylene	14,854	610	-14,244
	AE	19,700	19,724	+24
④ From dichloromethane to AE	Dichloromethane	31,909	12,396	-19,513
	AE	19,700	19,713	+13
⑤ Recovery Unit Installed on trichloroethylene	Trichloroethylene	14,854	5,595	-9,259
⑥ Recovery Unit Installed on dichloromethane	Dichloromethane	31,909	19,226	-12,683

### 3. Changes in Distribution of Concentration in Environment

#### 3.1 Estimation of Distribution of Atmospheric Concentration

Changes in the atmospheric exposure concentration of substituted and substituting substances, and secondary products from the four scenarios were estimated using an atmospheric model ADMER-PRO. Figures 1 and 2 show the geographic distribution of the amount of change in the substituted substances, substituting substances, and the annual average concentration of ozone from a baseline scenario, together with a population distribution against the changes in concentration for scenarios 1 and 2, respectively.

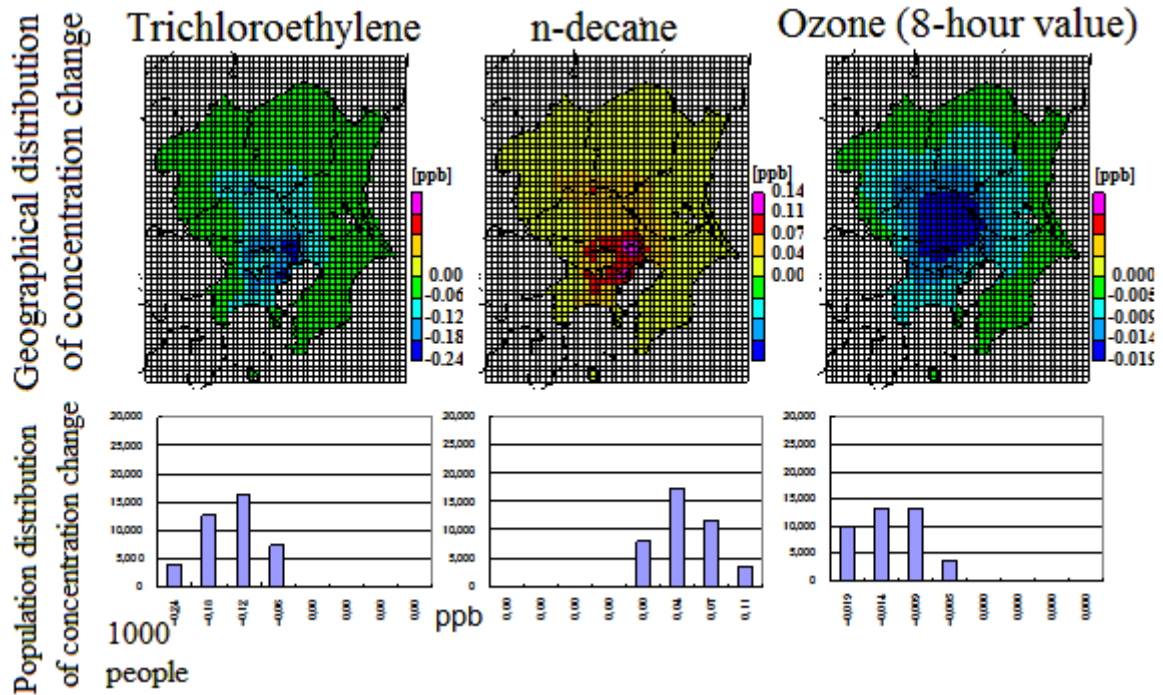


Fig. 1 Geographical and population distribution of concentration change of each substance in scenario 1 (substitution from trichloroethylene to n-decane).

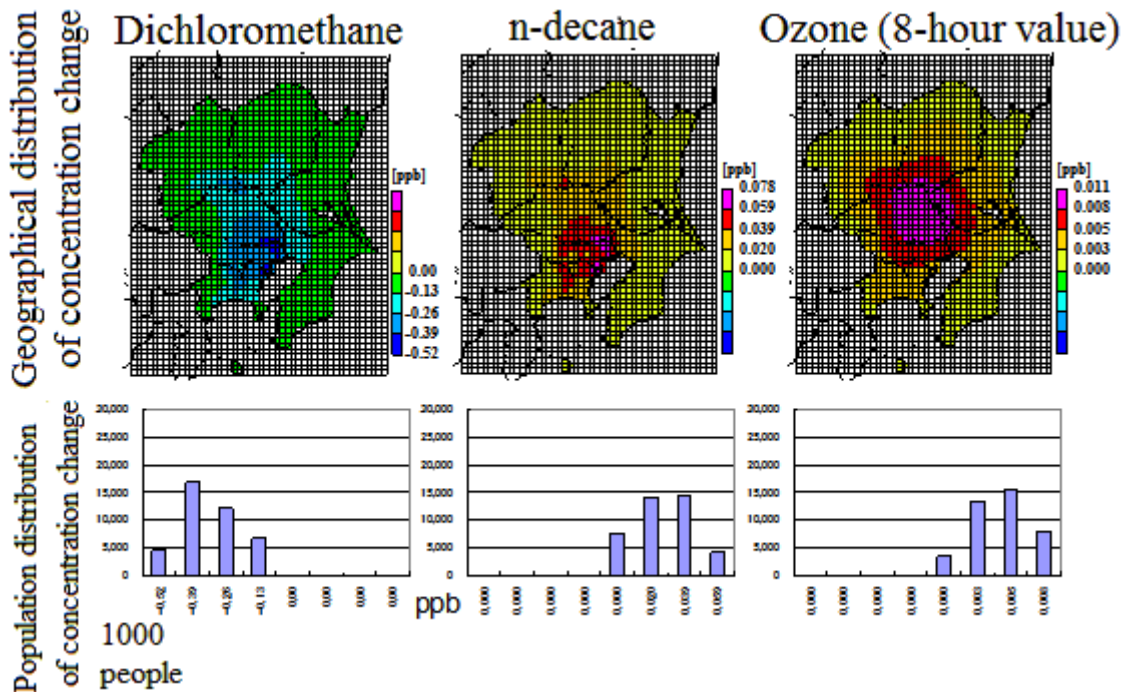


Fig. 2 Geographical and population distribution of annual average concentration change of each substance in scenario 2 (substitution from dichloromethane to n-decane).

Concentration of ozone decreases along with a decrease in the substituted substances by substitution in figure 1, but the ozone concentration increases as the substituted

substance decreases in figure 2. The ozone concentration shows different trends in scenarios 1 and 2 because scenario 1 had been substituted with a substance with lower ozone formation potential, while scenario 2 has been substituted with a substance with a higher ozone formation potential.

Table 2 gives the calculated results for the amount of change from the baseline scenario in population-weighted average concentration (annual average) for the entire Kanto region in scenarios 1 to 4. Changes in concentration in both the substituted and substituting substances are large in all scenarios, but the concentration change in ozone is at a level that cannot be ignored in all scenarios, except in scenario 4.

Table 2 Amount of change (left of dotted line) and rate of change (right of dotted line) of population weighted average concentration (annual average) for the Kanto region, estimated for each scenario.

	① Substitution from trichloroethylene to n-decane		② Substitution from dichloromethane to n-decane		③ Substitution from trichloroethylene to AE		④ Substitution from dichloromethane to AE	
Trichloroethylene	-0.1119ppb (-0.6014 $\mu\text{g}/\text{m}^3$ )	-93.5%	-		-0.1119ppb (-0.6014 $\mu\text{g}/\text{m}^3$ )	-93.5%	-	
Dichloromethane	-		-0.2514ppb (-0.8734 $\mu\text{g}/\text{m}^3$ )	-62.9%	-		-0.2514ppb (-0.8734 $\mu\text{g}/\text{m}^3$ )	-62.9%
n-decane	+0.0629ppb (+0.366 $\mu\text{g}/\text{m}^3$ )	6.76%	+0.0365ppb (+0.2124 $\mu\text{g}/\text{m}^3$ )	3.93%	-		-	
Ozone (8-hour value)	-0.0105ppb (-0.0206 $\mu\text{g}/\text{m}^3$ )	-0.0315%	+0.0060ppb (+0.012 $\mu\text{g}/\text{m}^3$ )	0.018%	-0.0210ppb (-0.0413 $\mu\text{g}/\text{m}^3$ )	-62.9%	0ppb (0 $\mu\text{g}/\text{m}^3$ )	0%

### 3.2 Estimation of Distribution of Concentration in River Water

Changes in AE concentration in river water were estimated for scenarios 3 and 4. Based on the estimated results of the emission change, and using a river water concentration estimation model AIST-SHANEL, AE concentrations in class A rivers in Kanto were estimated monthly, per square kilometer, for the year 2005.

Figure 3 shows the difference from the baseline (current state) of AE national average concentration in scenario 3. In scenario 3, the concentration exceeds 100  $\mu\text{g}/\text{L}$  in parts of the upper tributaries of each river and the lower streams of the Ara and Tsurumi Rivers, but was mostly below 0.1  $\mu\text{g}/\text{L}$ . In scenario 4, the concentration exceeded 100  $\mu\text{g}/\text{L}$  in the upper tributaries of each river, but was below 0.1  $\mu\text{g}/\text{L}$  in other parts.

Tables 3 and 4 list the rate of change of the average AE concentration in the rivers (geometric average) against the baseline scenario in scenarios 3 and 4. The rate of concentration change was high in scenario 3, where it was 4.6% for the Tama River and 3.0% in the Sagami River, but in scenario 4 it was high at 3.1% in the Tama River but less than 1% for other rivers.

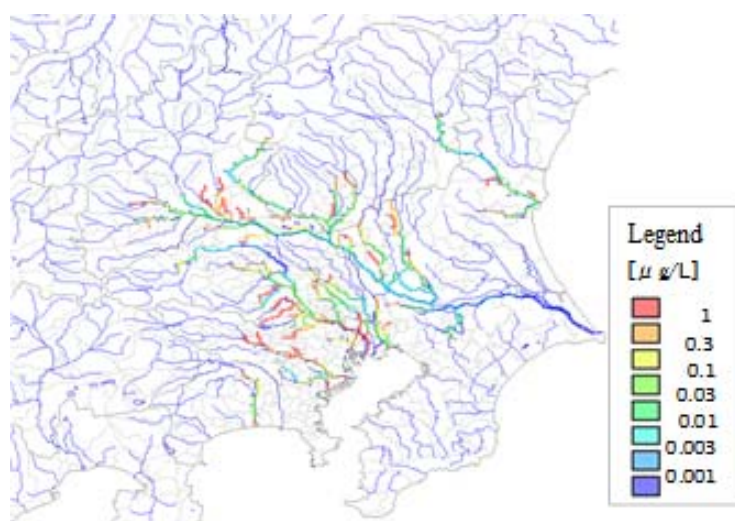


Fig. 3 Distribution of differences compared to the baseline scenario of AE concentration in rivers in scenario 3

Table 3 Geometric average concentration of AE ( $\mu\text{g/L}$ ) and rate of concentration change in scenario 3

River name	Current state of AE	Trichloroethylene substitution	Trichloroethylene substitution
	Geometric average	Geometric average	Rate of concentration change (%)
Kuji River	6.49	6.49	0.00
Tone River	8.57	8.59	0.14
Naka River	4.47	4.48	0.09
Ara River	10.96	11.02	0.55
Tama River	8.44	8.83	4.62
Tsurumi River	62.55	63.03	0.76
Sagami River	5.49	5.65	2.95

Table 4 Geometric average concentration of AE ( $\mu\text{g/L}$ ) and rate of concentration change in scenario 4

River name	Current state of AE	Dichloromethane substitution	Dichloromethane substitution
	Geometric average	Geometric average	Rate of concentration change (%)
Kuji River	6.49	6.51	0.30
Tone River	8.57	8.58	0.11
Naka River	4.47	4.48	0.12
Ara River	10.96	10.99	0.29
Tama River	8.44	8.70	3.10
Tsurumi River	62.55	62.90	0.55
Sagami River	5.49	5.50	0.30

#### 4. Changes in Risk to Human Health

A profile of the hazard of each chemical substance in relation to the effect on human health was organized, assuming inhalation exposure via atmosphere. For n-decane, the



human health risk and its increment by the inhalation of outside air was considered negligible.

Based on the estimated concentration distribution of the substituted and substituting substances, secondary products in the atmosphere, and changes in human health risk were estimated as an increase and decrease in cases of carcinogenesis and number of deaths by ozone. The following equations were used to estimate the number of carcinogenesis cases by inhalation exposure to trichloroethylene and dichloromethane, and the number of cases that shortened life expectancy due to inhalation exposure to ozone.

**• Number of carcinogenic cases by exposure to trichloroethylene and dichloromethane (/yr) = unit risk of each of the substances × population during nighttime × population weighted average of annual average concentration of each substance ÷ 70 (yr)**

**• Number of cases that shortened life expectancy by exposure to ozone (/yr) = rise in death rate per unit concentration × number of annual baseline deaths (/yr) × weighted average of number of baseline deaths for annual average ozone 8 hour concentration**

Table 5 gives the estimated results. The number of deaths by ozone increases in scenario 2, implying the possibility that a risk trade-off is occurring.

Table 5 Change in estimated human health risk for each substitution scenario (Kanto Region)

Scenario	Fluctuation in Carcinogenic cases (Case/Year)	Fluctuation in number of deaths due to Ozone (Case/year)
①	-0.014	-0.40
②	-0.00075	+0.36
③	-0.014	-1.05
④	-0.00075	0.00000
⑤	-0.0090	-0.68
⑥	-0.00048	0.00000

A change in Quality Adjusted Life Year (QALY) for the effect on the liver and kidneys by the substitution of trichloroethylene and dichloromethane with n-decane was calculated using a developed hazardousness inference algorithm. Vinyl chloride and cadmium were used as reference substances for their effect on the liver and kidneys, respectively. Tables 6 and 7 list the change in atmospheric concentration of trichloroethylene in scenario 1 and the estimated risk (QALY) against the change in atmospheric concentration of dichloromethane in scenario 2, respectively. Regardless of

substitution, it was shown that the absolute value of risk against the effect on the liver and kidneys expressed by QALY was quite small, less than 0.001 years of life per person. Therefore, in a probabilistic risk trade-off analysis from here on, only QALY based on cancer deaths related to chlorinated-type cleaners and deaths related to ozone exposure, were considered.

Table 6 Risk level of estimated effect on the liver and kidneys against an atmospheric concentration of trichloroethylene in scenario 1 (estimated average value, population weighted average value)

QALY、 Weighted average value of population (year)	Before Substitution	After Substitution
Effect on Liver	<< 0.001 ( $3.4 \times 10^{-15}$ )	<< 0.001 ( $6.7 \times 10^{-23}$ )
Effect on Kidney	<< 0.001 ( $3.9 \times 10^{-45}$ )	<< 0.001 ( $8.4 \times 10^{-86}$ )

Table 7 Risk level of estimated effect on the liver and kidneys against atmospheric concentration of dichloromethanes in scenario 2 (estimated average value, population weighted average value)

QALY、 Weighted average of value population (year)	Before Substitution	After Substitution
Effect on Liver	<< 0.001 ( $3.4 \times 10^{-17}$ )	<< 0.001 ( $5.5 \times 10^{-20}$ )
Effect on Kidney	<< 0.001 ( $2.5 \times 10^{-37}$ )	<< 0.001 ( $2.3 \times 10^{-49}$ )

## 5. Changes in Ecological Risks

A change in the ecological risks posed by the use of AE ( $\Delta Risk$ ), before and after substitution, was estimated using the following equation.

$$\Delta Risk = \left( \int_0^{\infty} E'(c)SSD(c)dc \right) - \left( \int_0^{\infty} E(c)SSD(c)dc \right)$$

Here,  $E'(c)$  is the concentration distribution of AE in river water after substitution,  $E(c)$  is the concentration distribution of AE in river water before substitution, and  $SSD(c)$  is the species sensitivity distribution. Based on SSD developed using chronic toxicity estimated by the neural network model (Fig. 4) and river water concentration distribution data of AE before and after substitution, the risk before and after substitution and the  $\Delta Risk$  in 7 water systems in Kanto was calculated (table 8).

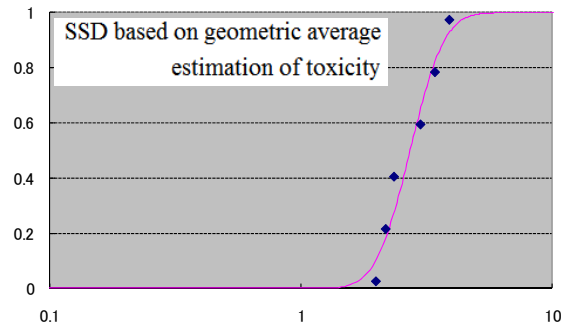


Fig. 4 Species sensitivity distribution developed from estimated chronic toxicity

Table 8 Calculated results of the ecological risk before and after substitution in 7 Kanto rivers

River	Scenario	Risk (The Expected value of the ratio of species that will be affected)			Incremental risk after substitution
		2.5%ile	Geometric Average	97.5%ile	Incremental Range
Kuji River	Present Condition	$8.63 \times 10^{-4}$	$1.55 \times 10^{-5}$	$1.39 \times 10^{-7}$	—
	Scenario③	$8.63 \times 10^{-4}$	$1.55 \times 10^{-5}$	$1.39 \times 10^{-7}$	No increase
	Scenario④	$8.72 \times 10^{-4}$	$1.57 \times 10^{-5}$	$1.41 \times 10^{-7}$	$2.34 \times 10^{-9} \sim 8.57 \times 10^{-6}$
Naka River	Present Condition	$1.33 \times 10^{-2}$	$1.27 \times 10^{-3}$	$4.94 \times 10^{-5}$	—
	Scenario③	$1.34 \times 10^{-2}$	$1.27 \times 10^{-3}$	$4.96 \times 10^{-5}$	$1.09 \times 10^{-7} \sim 2.03 \times 10^{-5}$
	Scenario④	$1.34 \times 10^{-2}$	$1.27 \times 10^{-3}$	$4.96 \times 10^{-5}$	$1.27 \times 10^{-7} \sim 2.04 \times 10^{-5}$
Tone River	Present Condition	$6.82 \times 10^{-5}$	$3.76 \times 10^{-7}$	$1.79 \times 10^{-9}$	—
	Scenario③	$6.85 \times 10^{-5}$	$3.78 \times 10^{-7}$	$1.81 \times 10^{-9}$	$1.26 \times 10^{-11} \sim 3.07 \times 10^{-7}$
	Scenario④	$6.86 \times 10^{-5}$	$3.79 \times 10^{-7}$	$1.80 \times 10^{-9}$	$1.66 \times 10^{-11} \sim 4.01 \times 10^{-7}$
Ara River	Present Condition	$9.58 \times 10^{-5}$	$1.78 \times 10^{-7}$	$5.75 \times 10^{-10}$	—
	Scenario③	$1.02 \times 10^{-4}$	$1.97 \times 10^{-7}$	$6.44 \times 10^{-10}$	$6.89 \times 10^{-11} \sim 6.52 \times 10^{-6}$
	Scenario④	$9.81 \times 10^{-5}$	$1.84 \times 10^{-7}$	$5.98 \times 10^{-10}$	$2.32 \times 10^{-11} \sim 2.32 \times 10^{-6}$
Tama River	Present Condition	$7.58 \times 10^{-2}$	$5.11 \times 10^{-3}$	$3.99 \times 10^{-4}$	—
	Scenario③	$8.08 \times 10^{-2}$	$5.23 \times 10^{-3}$	$4.07 \times 10^{-4}$	$7.43 \times 10^{-6} \sim 5.05 \times 10^{-3}$
	Scenario④	$7.91 \times 10^{-2}$	$5.16 \times 10^{-3}$	$4.00 \times 10^{-4}$	$6.61 \times 10^{-7} \sim 3.36 \times 10^{-3}$
Tsurumi River	Present Condition	$5.93 \times 10^{-3}$	$8.74 \times 10^{-6}$	$2.47 \times 10^{-8}$	—
	Scenario③	$5.68 \times 10^{-3}$	$7.65 \times 10^{-6}$	$2.16 \times 10^{-8}$	No Increase
	Scenario④	$5.75 \times 10^{-3}$	$7.94 \times 10^{-6}$	$2.24 \times 10^{-8}$	No Increase

Saga mi River	Present Condition	$2.80 \times 10^{-12}$	$1.71 \times 10^{-18}$	$5.54 \times 10^{-19}$	—
	Scenario③	$4.93 \times 10^{-12}$	$3.60 \times 10^{-18}$	$9.18 \times 10^{-19}$	$3.64 \times 10^{-19} \sim$ $2.13 \times 10^{-12}$
	Scenario④	$3.03 \times 10^{-12}$	$1.91 \times 10^{-18}$	$5.94 \times 10^{-19}$	$4.01 \times 10^{-20} \sim$ $2.32 \times 10^{-13}$

From the geometric average values of risk given in table 8, the increment of AE risk before and after substitution in 2 scenarios was determined to be negligible for all rivers. Based on the geometric average, the ecological risk to each river was, in order: the Tama River > Naka River > Kuji River > Tsurumi River > Tone River > Ara River > Sagami River.

## 6. Risk Trade-off Analysis

The number of carcinogenic cases, (as a human health risk via inhalation from the atmosphere), and the number of deaths due to ozone need to be converted to “lost life expectancy,” in order to express such values on a unified scale and assess the risk of trade-off. However, there is a great uncertainty as to the lost life expectancy from deaths related to an increased concentration of ozone, and the risk is therefore estimated as a distribution. The weight of evidence was considered for major parameters related to exposure and hazardousness and uncertainty was estimated as listed in table 9. This gave a distribution deemed appropriate for the parameters where uncertainty was judged to be medium or large. The distribution of saved life expectancy was calculated for each scenario afterwards.

Table 10 gives the calculated results. The 5th percentile of saved life expectancy distribution, (the median), was negative in scenario 2 (substitution from dichloromethane to n-decane), suggesting a high possibility that a risk trade-off may occur. Scenario 4 did not have parameters with a configured distribution, so the estimated saved life expectancy was also a distribution-less, single value.

Table 9 Parameters used in risk assessment and Weight of Evidence of the model

Risk Assessments	Uncertainty	Probability Density Function (PDF)
Amount of n-decane emissions after substituting the cleaner	Medium	Estimated at section 2
Atmospheric concentration estimate model	Low	None
Unit risk of carcinogenesis due to chlorinated-type cleaners	Low	None
Rate of increase in deaths as concentrations of ozone increase	Medium	Estimated normal distribution of the below statistics Average : 0.00020(ppb <sup>-1</sup> ) Standard Deviation : 0.00005(ppb <sup>-1</sup> )
Lost life expectancy per case from carcinogenesis due to chlorinated-type cleaners	Low	None (Set at approximately 1 case every 10 years)
Lost life expectancy per case of death due to an increased concentration of ozone	High	Estimated log uniform distribution the statistics listed below Least value : 0.00822 years (Equivalent to 3 days) Maximum value : 1 year

Table 10 Distribution of saved life expectancy (years) in each scenario (Kanto, 2005)

Scenario	5th percentile	Median	95th percentile
① From trichloroethylene to n-decane	0.13	0.17	0.55
② From dichloromethane to n-decane	-0.28	-0.021	0.005
③ From trichloroethylene to AE	0.15	0.23	0.98
④ From dichloromethane to AE	$7.46 \times 10^{-3}$	$7.46 \times 10^{-3}$	$7.46 \times 10^{-3}$
⑤ Recovery Unit Installed on trichloroethylene	0.092	0.15	0.64
⑥ Recovery Unit Installed on dichloromethane	$4.1 \times 10^{-3}$	$4.9 \times 10^{-3}$	$5.6 \times 10^{-3}$

(Sampling: Latin hypercube, sample size=500, number of tests = 5000, precision control (reliability): 99%)

Sensitivity (rate of contribution to variance) of each of the estimated parameters for saved life expectancy was analyzed. “Saved life expectancy per case of increased number of deaths by increased ozone concentration” was highly sensitive for all scenarios, exceeding 90%. However, contributions were small from parameters related to the amount of emissions in the cleaning process, such as cooling temperature and wind speed.

Table 11 lists the estimated values for cost increment for implemented measures in each scenario. A negative value for the cost means that the cleaner purchase cost has decreased (amount used or unit cost decreases) by using the implemented measure. The distribution of cost needed to save 1 year of life expectancy was estimated by the Monte Carlo method. Cost was assumed to be a triangular distribution where the arithmetic average value of the minimum and maximum range of annual costs was the maximum value. Table 12 gives the results.

Table 11 Estimated cost of mitigation measures for each scenario

Scenario	Initial Cost [100 million yen]	Running Cost (Including cleaner costs) [100 million yen/year]	Annual Cost [100 million yen/year]
①	60~105	-4~3	1~12
②	82~144	-1~9	6~21
③	38~150	49~81	52~94
④	51~206	27~72	32~89
⑤	120~188	-9~-8	1~8
⑥	165~257	-10~-8	4~14

Table 12 Cost of saving a year of estimated life expectancy in each scenario (hundred million yen/year)

Scenario	5th percentile	Median	95th percentile
①	8.4	33	67
②	—*1	—*1	—*1
③	74	310	530
④	5,500	8,100	11,000
⑤	6.0	26	61
⑥	1,100	1,900	2,700

\*1) Not shown since the distribution included negative values  
(Sampling: Latin hypercube, sample size = 500, number of tests = 5000,  
precision control (reliability): 99%)

The cost of saving a year of life expectancy varied greatly between scenarios. The cost effectiveness was higher for the trichloroethylene scenarios (1, 3, and 5) than for the dichloromethane scenarios (2, 4, and 6). A comparison of the cost-effectiveness of the substitution and recovery unit implementation scenarios for trichloroethylene (1, 3, and 5), showed it was more cost-effective to substitute n-decane (1) and to implement a recovery unit (5). However, it was less cost-effective to substitute with AE (3).

A comparison of the dichloromethane scenarios (2, 4, and 6) showed that the implementation of a recovery unit (6) was the most highly cost-effective solution, while

substituting with AE (4) was the least cost-effective. When substituting with n-decane (2), part of the distribution of cost for saving a year of life expectancy is negative, since the saved life expectancy itself has the possibility of being negative, implying that the risk may be increased by paying the costs.

The results presented in this risk trade-off assessment are with the assumption that all businesses in the Kanto region substitute simultaneously. The report is not intended to provide an ex-post evaluation of an actually implemented substitution case. It is intended to illustrate the overall perspective of a risk trade-off analysis, and to show element technologies and the combination of element technologies necessary for analyzing a risk trade-off.

Because the level of the risk to human health from chlorinated-type cleaners is very low to begin with, a rise in the risk to human health through the contribution of ozone (a secondary product) concentration from the use of substituted hydrocarbon type cleaners is a concern. An analysis of the risk trade-off in substituting dichloromethane shows the need to carefully assess in advance whether it actually mitigates the risk to human health. It is noted that the ecological risk related to an AE increment would not be very large.

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