Bisphenol A Risk Assessment Document

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Summary

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Chapter I. Introduction

Chapter I summarizes the background of the bisphenol A (BPA) issue. In addition, it provides general information such as identification data, physicochemical properties, and reviews of 12 risk/hazard assessment documents published in the last 7 years.

Around 1996, BPA began to attract considerable interest as a suspected endocrine-disrupting chemical. Since 1998, the issue of low-dose effects has raised considerable concern. In Japan, the Ministry of Health and Welfare (1998a), the Ministry of Health, Labour and Welfare (2001a), the Ministry of Economy, Trade and Industry (2002), the Ministry of the Environment (2004a), *etc*. convened panels of experts. Although they did not recommended prohibiting or restricting the use of BPA, some of them recommended a comprehensive assessment of the risks posed by BPA. In this risk assessment, a large amount of data regarding the exposure and hazards of BPA were reviewed and reanalyzed. The risk was characterized not only by conventional approaches, such as the hazard quotient method or the margin of exposure (MOE) method, but also by more sophisticated approaches including Monte Carlo simulations that propagate uncertainties in exposure parameters and a population-level ecological risk assessment technique.

BPA is a white solid at room temperature with a molecular weight of 228.29 and a melting point of 150°C to 155°C. It vaporizes slightly at room temperature due to its low vapor pressure of 5×10^{-6} Pa at 20°C. It is specified as a “Class I Designated Chemical Substance” according to the “Law Concerning Reporting, *etc*. of Releases to the Environment of Specific Chemical Substances and Promoting Improvements in Their Management.” Based on the Food Sanitation Law, its migration limit in food-contact polycarbonate plastics is specified as 2.5 ppm.

During the past 3 years, major risk assessments of BPA have been implemented by the (1) OECD (2002), (2) EU Scientific Committee on Food (2002), (3) Chemicals Evaluation and Research Institute, Japan (2002), (4) European Commission (2003), (5) Ministry of the Environment (2004a), and (6) the Ministry of the Environment (2004b). During the past 7 years, hazard assessments have been conducted by the (7) Ministry of Health and Welfare (1998a), (8) Ministry of Health, Labour and Welfare (2001a), (9) National Toxicology Program (2001), (10) US EPA (2002), (11) Ministry of Economy, Trade and Industry (2002), and (12) Ministry of the Environment (2004c). Each of these assessments has been summarized in this chapter.

Chapter II. Production, uses, and environmental releases

Chapter II summarizes the data on the production, uses, and environmental releases of BPA. Domestic BPA manufacturers supplied approximately 580,000 tons, and domestic consumption was approximately 430,000 tons in 2003. Approximately 72% of the domestic consumption was associated with the production of polycarbonate (PC), and approximately 16% with the production of epoxy resins (EXRs). The other applications include the manufacture of polyester resin intermediates, flame retardants, and hydrogenated bisphenol A.

Polyvinyl chloride (PVC) industries voluntarily reduced the amount of BPA used as an additive in the production of PVC; in 2003, the amount reduced to 100 tons. Thermal paper manufacturers also voluntarily substituted BPA used as a developing agent; according to available information, it appeared that the substitution was almost completed in 2003.

Chapter III. Environmental fate characteristics and monitoring data

Chapter III describes environmental fate characteristics and environmental concentrations obtained from various monitoring programs. The fate characteristics comprise degradation and distribution properties. The half-life for the reaction of BPA with hydroxyl radicals in the atmosphere is calculated as approximately 0.2 days. According to aquatic biodegradation studies, BPA appears to be readily biodegradable.

The environmental monitoring of BPA in surface water, sediment, ground water, the atmosphere, soil, aquatic and terrestrial organisms, sewage treatment facilities, rainwater, drinking water treatment plants, and tap water was conducted extensively by the Ministry of the Environment, Ministry of Land, Infrastructure and Transport, local governments, and many researchers. BPA concentrations were measured in 1,120 areas with fresh surface water. The average concentrations were 0.005 µg/L or less in approximately 30% of these areas and 1 µg/L or less in 99% of the areas. BPA concentrations were also measured in 187 areas with sea water. The average concentrations were 0.005 µg/L or less in almost half the areas and 1 µg/L or less in all the areas with the exception of one. No apparent trend was observed in the temporal change patterns of the surface water concentrations.

The highest concentrations were reported as 22 µg/L in surface water, 1,100 µg/kg-dry in sediment, 3.29 µg/L in ground water, 28 ng/m^3 in the atmosphere, 30 µg/kg in fish and shellfish, 70 µg/kg-wet in terrestrial organisms, 3.9 µg/L in influent to sewage treatment plants, 0.42 µg/L in water released from sewage treatment plants, 0.04 µg/L in rainwater, 0.06 µg/L in influent to drinking water treatment plants, 0.01 µg/L in purified water in drinking water treatment plants, and 0.007 µg/L in tap water.

Chapter IV. Human health risk assessment

1. Hazard identification and dose-response assessment

This section presents an overview of the toxicological profile of BPA, reviews of published hazard assessment documents, and no observed adverse effect levels (NOAELs) and a benchmark dose lower confidence limit (BMDL) that are used for characterizing human health risk. The key toxicological endpoints for BPA include photosensitization, reduction in body weight gain, effects on the liver, and reproductive toxicity.

For photosensitization, no established method is available for extrapolating animal toxicological data to effects on humans. However, the photosensitization will be insignificant in ambient exposure, although careful control of occupational exposure, which is beyond the scope of this assessment, may be required.

The NOAEL for the reduction in body weight gain by oral administration was identified as 5 mg/kg/day based on the results of a three-generation study in rats. During the evaluation of the MOEs based on this NOAEL, it was concluded that there was no unacceptable risk when the MOEs exceeded 100, which represented uncertainties in species differences (10) and individual differences (10).

The BMDL for the observed liver effect (multinucleated giant hepatocytes) was identified as 23 mg/kg/day based on a reanalysis of the results of a continuous breeding study in mice. During the evaluation of the MOEs based on this BMDL, it was concluded that there was no unacceptable risk when the MOEs exceeded 500, which represented uncertainties in species differences (10), individual differences (10), and extrapolation from short-term to long-term exposure durations (5).

In relation to the reproductive toxicity, the NOAEL for effects on fertility was identified as 50 mg/kg/day based on the three-generation study in rats. During the evaluation of the MOEs based on this NOAEL, it was concluded that there was no unacceptable risk when the MOEs exceeded 100, which represented uncertainties in species differences (10) and individual differences (10).

An additional uncertainty due to the low-dose effects was not incorporated because the findings in the low-dose studies were not robust, while those in negative studies were consistent.

2. Exposure assessment

Daily BPA intakes were estimated by employing two different approaches. In the first approach, exposure levels from possible sources (atmosphere, water, food, tableware, toys, *etc*.) were estimated and aggregated. Since the parameters required in this approach, such as the amount of food consumption, breathing volume, and frequency of PC tableware use, depended on age, the daily BPA intakes were separately estimated for 6 age groups: infants aged 0–5 months, infants aged 6–11 months, children aged 1–6 years, students aged 7–14 years, young persons aged 15–19 years, and adults aged >19 years. In the second approach, the daily BPA intakes were determined from urinary excretion by backward calculations. In both approaches, the parameters required for the calculation of the BPA intakes were characterized as distributions, and Monte Carlo simulations were performed to propagate uncertainty and variability in the parameters. Furthermore, it was possible to analyze uncertainty in the functional relationship between sources and exposure by comparing the results of the two approaches.

The first approach estimated that children aged 1–6 years had the highest level of exposure; in 1998, their average daily intake was 1.2 μg/kg/day. This was due to relatively high dietary consumption per body weight and the use of PC tableware for this age class. However, in recent years, the BPA exposure from PC tableware reduced because in 1998, social concern about endocrine-disrupting chemicals increased in Japan and certain proportions of PC tableware as well as PC feeding bottles were substituted with non-PC articles thereafter. In students aged 7–14 years, the level of exposure was the second highest with an average daily intake of 0.55 μg/kg/day. The average daily intakes for infants aged 0–5 months, infants aged 6–11 months, young persons aged 15–19 years, and adults aged >19 years were estimated as 0.028–0.055, 0.16–0.18, 0.36, and 0.43 μg/kg/day, respectively (the daily intake indicates the average for males in 1998).

For individuals aged 6 months and above, food was the most significant BPA source. For individuals aged 1–14 years, the intake levels of BPA from canned food and drinks were almost equivalent to those from non-canned food and drinks. On the other hand, for individuals aged 15 years and above, the intake levels from canned food and drinks were approximately twice those from non-canned food and drinks. This would reflect a difference in the consumption of canned beverages that contained a relatively large amount of BPA.

In the second approach, the 95% confidence intervals of the daily intake for high-exposure populations (*i.e.*, 95th percentiles) were estimated as 0.037–0.064 µg/kg/day for adult males and 0.043–0.075 µg/kg/day for adult females. Further, the values for average-exposure populations were 0.028–0.049 µg/kg/day for adult males and 0.034–0.059 µg/kg/day for adult females.

The average and 95th percentile intakes estimated by the first approach were 4–7 and 7–13 times those estimated by the second approach, respectively. These differences resulted from the assumption of the first approach that BPA concentrations in food items, which were in fact highly skewed toward 0, were characterized by uniform distributions. Therefore, the values estimated by the second approach appeared to be more realistic than those of the first approach.

3. Risk characterization

Human health risk was characterized by using the MOEs that were calculated by dividing the NOAEL or BMDL by the daily BPA intakes. For children aged 1–6 years who had the highest exposure level, the MOEs calculated by using the average daily intake were 4,200 for the reduction in body weight gain, 19,000 for multinucleated giant hepatocytes in the liver, and 42,000 for the reproductive toxicity. The

Table 1 MOEs for each endpoint (reduction in body weight gain, multinucleated giant hepatocytes in the liver, and reproductive toxicity)

Exposure estimation	Age class (sex)	Period	Reduction in body weight gain NOAEL = 5 mg/kg/day		Multinucleated giant hepatocytes in the liver BMDL = 23 mg/kg/day		Reproductive toxicity NOAEL = 50 mg/kg/day	
			Average	95th percentile	Average	95th percentile	Average	95th percentile
1st approach	0–5 months (m)	1998	91,000	45,000	420,000	210,000	910,000	450,000
	0–5 months (f)	1998	81,000	31,000	370,000	140,000	810,000	310,000
	6–11 months (m)	1998	28,000	15,000	130,000	68,000	280,000	150,000
	6–11 months (f)	1998	25,000	13,000	120,000	59,000	250,000	130,000
	1–6 years (m)	1998	4,200	1,300	19,000	5,900	42,000	13,000
	1–6 years (f)	1998	4,200	1,200	19,000	5,600	42,000	12,000
	7–14 years (m)	1995–2000	8,600–10,000	3,600–4,200	40,000–46,000	16,000–19,000	86,000–100,000	36,000–42,000
	7–14 years (m)	2001–2002	14,000–15,000	6,300–6,500	64,000–68,000	29,000–30,000	140,000–150,000	63,000–65,000
	7–14 years (f)	1995–2000	9,400–12,000	3,800–5,000	43,000–53,000	18,000–23,000	94,000–120,000	38,000–50,000
	7–14 years (f)	2001–2002	15,000	6,500–6,700	68,000–70,000	30,000–31,000	150,000	65,000–67,000
	15–19 years (m)	1995–2000	13,000–17,000	4,500–6,500	58,000–77,000	21,000–30,000	130,000–170,000	45,000–65,000
	15–19 years (m)	2001–2002	25,000	11,000	120,000	50,000–52,000	250,000	110,000
	15–19 years (f)	1995–2000	15,000–17,000	5,900–7,400	68,000–79,000	27,000–34,000	150,000–170,000	59,000–74,000
	15–19 years (f)	2001–2002	24,000–25,000	10,000	110,000–120,000	47,000	240,000–250,000	100,000
	>19 years (m)	1995–2000	11,000–13,000	4,200–5,000	51,000–61,000	19,000–23,000	110,000–130,000	42,000–50,000
	>19 years (m)	2001–2002	26,000	11,000	120,000	52,000	260,000	110,000
	>19 years (f)	1995–2000	14,000–16,000	5,400–6,200	64,000–72,000	25,000–28,000	140,000–160,000	54,000–62,000
	>19 years (f)	2001–2002	22,000	8,900–9,100	100,000	41,000–42,000	220,000	89,000–91,000
2nd approach	Adult (m)	Recent years	100,000–180,000	78,000–140,000	470,000–820,000	360,000–620,000	1,000,000–1,800,000	780,000–1,400,000
	Adult (f)	Recent years	85,000–150,000	67,000–120,000	390,000–680,000	310,000–530,000	850,000–1,500,000	670,000–1,200,000

The conclusion of the risk assessment by the European Commission is “there is need for further information and/or testing in relation to developmental toxicity” and “there is at present no need for further information and/or testing and for risk reduction measures beyond those which are being applied already in relation to all other endpoints.” The other human health risk assessments summarized in Chapter I conclude that the risks are below the levels of concern. Our conclusion is the same as that of most existing risk assessments. They assume worst-case scenarios and calculate the point estimates of exposure, while we consider more realistic scenarios and the distribution of exposure with two different approaches.

With regard to the nature of uncertainty in risk assessment, it is possible to distinguish between stochastic variability and “lack of knowledge” uncertainty (NCRP 1996). This assessment incorporated the stochastic variabilities of most exposure parameters; however, we could not characterize the individual differences in canned-food consumption and those in the elimination half-life of BPA in the body, whose nature is categorized as stochastic variability. The major influential components of the “lack of knowledge” uncertainty in this assessment includes uncertainties that originated from the assumptions of the shapes of the concentration distribution in exposure media, such as food items, and the frequency of the use of EXR-coated chopsticks. Most of these concentration distributions were characterized by uniform distributions that would result in the overestimation of the frequency of higher concentrations. As a worst-case scenario, the frequency of the use of EXR-coated chopsticks was assumed to be 100%. Detailed information on these parameters will improve the estimation of the daily BPA intake; however, it will not change the current conclusion of this risk assessment.

Chapter V. Ecological risk assessment

1. Problem formulation

An assessment endpoint of ecological risk assessment is an explicit expression of the actual environmental value that is to be protected, operationally defined by an ecological entity and its attributes. The following three assessment endpoints were selected to assess the impact of BPA on the sustainability of local populations of aquatic life, particularly fish: (1) survival, reproduction, growth, and development of susceptible aquatic species; (2) the growth rates of local fish populations including white-spotted char (*Salvelinus leucomaenis*), pale chub (*Zacco platypus*), Japanese dace (*Tribolodon hakonensis*), barbel steed (*Hemibarbus barbus*), and nekogigi (*Pseudobagrus ichikawai*); and (3) the presence and conditions of fish species confirmed by field observations in highly contaminated areas in Japan (Fig.1).

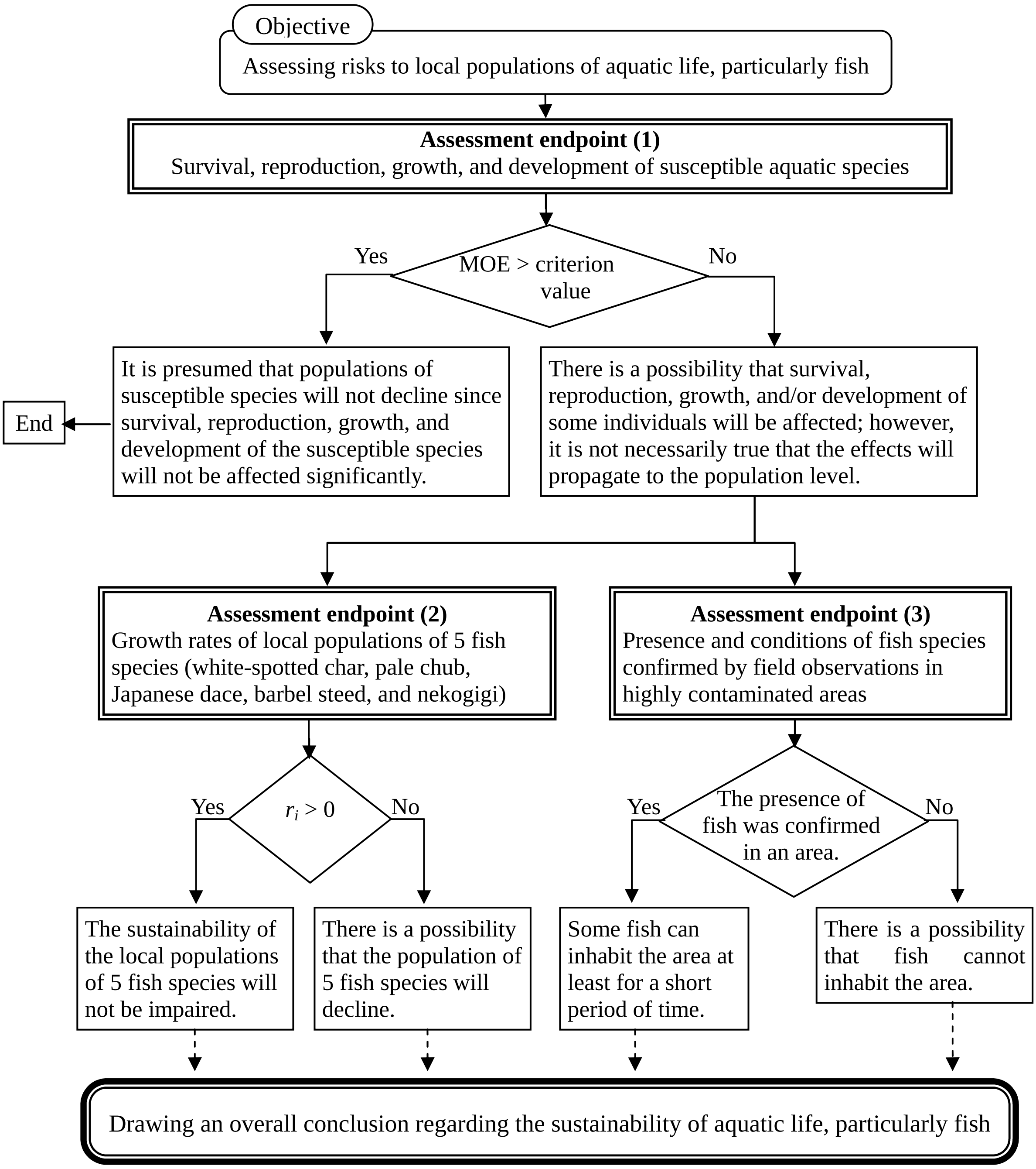

Fig.1 Framework of ecological risk assessment for BPA

In ecological risk assessment, one of the inherent difficulties is how to deal with uncertainties due to our incomplete knowledge about an ecosystem of concern. In order to assess the risks of a chemical substance to an ecosystem from various viewpoints that consider such uncertainties, it is preferable to establish a series of assessment endpoints that reflect multifaceted ecological values instead of selecting a single assessment endpoint. The overall conclusion was drawn based on the outcomes of the evaluation of all three assessment endpoints.

2. Effects assessment

With regard to acute toxicity for freshwater algae, a single species of green alga *Pseudokirchneriella subcapitata* was tested by two groups (Ministry of the Environment 2004d, Alexander *et al*. 1988). Their results indicated that EC_{50} values ranged from 2,730 to 4,900 µg/L.

The acute toxicity for freshwater invertebrates was tested based on the immobilization of *Daphnia magna*. The values of 48 h EC_{50} ranged from 10,200 to 13,000 µg/L (Ministry of the Environment 2004d, Alexander *et al.* 1988). LC_{50}s for shrimp *Gammarus pulex* were reported as 12,800 µg/L in 24 h, 5,600 µg/L in 48 h, and 1,500 µg/L in 5–10 days (Watts *et al*. 2001).

The acute toxicity was also determined for rainbow trout (*Oncorhynchus mykiss*), Japanese medaka (*Oryzias latipes*), swordtail fish (*Xiphophorus helleri*), and fathead minnow (*Pimephales promelas*), which are freshwater fish. The toxicity values of 96 h LC_{50} for these fish species ranged from 3,000 to 17,930 µg/L (Reiff 1979, Kwak *et al*. 2001). The differences in the sensitivity of the fish were relatively small; they were up to approximately 6-fold.

The chronic toxicity for green alga *Pseudokirchneriella subcapitata* was reported in terms of NOECs of 320–1,800 µg/L by the Ministry of the Environment (2004d). Alexander *et al*. (1988) reported a 96 h NOEC of 1,200 µg/L for the same species based on cell count and total cell volume.

The chronic toxicity for invertebrates was reported by Caspers (1998) and the Ministry of the Environment (2004d) based on 21-day *Daphnia magna* reproduction tests. NOECs ranged from 3,160 to 4,600 µg/L.

In order to determine the chronic toxicity for fish, tests were conducted on fathead minnow, Japanese medaka, and zebrafish (*Danio rerio*). The smallest NOEC was reported as 16 µg/L; it was identified in a three-generation study on fathead minnow based on the hatchability of the F2 generation (European Commission 2003).

In addition to the conventional endpoints of ecotoxicological studies, the suspected endocrine-disrupting effects were reviewed in this section. Furthermore, the relationship between such effects and the assessment endpoints was discussed.

3. Exposure assessment

We obtained a total of 3,956 observations of the BPA concentration in fresh surface water covering 1,120 areas in 752 rivers in Japan. Each area was observed once or up to several tens times. The average concentrations were 1 µg/L or less in approximately 99% of the areas (Fig.2). However, in approximately 30% of the areas, the average concentrations were below the quantification limit. Relatively high concentrations of BPA (1.5 µg/L or higher) were detected in the Suikawa River (Iwate Prefecture), Edogawa River (Chiba Prefecture), Lake Teganuma (Chiba Prefecture), Ayase River (Tokyo), Tsurumi River (Kanagawa Prefecture), Numakawa River (Shizuoka Prefecture), Itonuki River (Gifu Prefecture), Yagou River (Mie Prefecture), Mitaki River (Mie Prefecture), Tenpaku River (Mie Prefecture), Amaike River (Mie Prefecture), Kasama River (Nara Prefecture), and Hirokawa River (Fukuoka Prefecture). Leachate from landfills and effluents from paper mills were suspected to be primary sources of BPA in some of these rivers. Specific BPA sources were not identified for urban rivers such as the Edogawa River and the Ayase River whose basin had insufficient wastewater treatment systems due to rapid population growth and urbanization. However, in the urban rivers, high concentrations were detected only when some specific conditions were satisfied since they were observed infrequently.

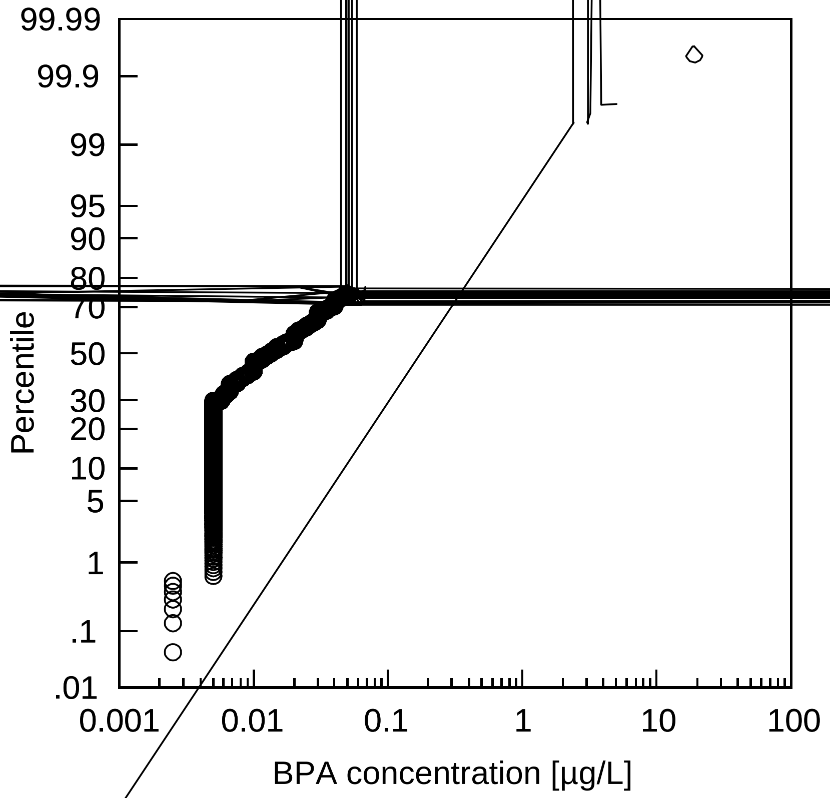

Fig.2 Cumulative distribution of average BPA concentration in 1,120 areas with fresh surface water

4. Risk characterization

4.1 Assessment endpoint (1): Survival, reproduction, growth, and development of susceptible aquatic species

A hazard quotient (HQ) is defined as

$$\mathrm{HQ} = \frac{C}{TV\ /\ AF},$$

where C is the BPA concentration in water [µg/L], TV is the smallest toxicity value of LC_{50} or NOAEL [µg/L], and AF is the assessment factor. The value of AF is 10 when chronic NOEC values of at least three species representing three trophic levels as well as one acute $\mathrm{L(E)C}_{50}$ value from each of the three trophic levels of fish, zooplankton, and algae are available.

On the other hand, an MOE is defined by the following equation:

$$\mathrm{MOE} = \frac{TV}{C}.$$

In this assessment, a *TV* of 16 µg/L was considered adequate according to the results of the three-generation study on fathead minnow. When the *HQ* is less than one, *i.e.*, the MOE is greater than the

AF, it is presumed that even the populations of susceptible species will not decline because it is expected that their mortality, growth, reproduction, and development, which govern the population dynamics, are not affected significantly.

Based on the maximum BPA concentrations, MOEs in 19 areas of 12 rivers and a lake were smaller than the *AF* of 10. Based on the average BPA concentrations, MOEs in 7 areas of 6 rivers were less than 10. The areas in which the MOEs were less than 10 were identified as targets for further assessments from the viewpoint of assessment endpoints (2) and (3). In the other areas of more than 1,100, it was presumed that BPA did not decrease the populations of susceptible species.

4.2 Assessment endpoint (2): Growth rates of local populations of 5 fish species

The sustainability of the local populations of the 5 fish species—white-spotted char (*Salvelinus leucomaenis*), pale chub (*Zacco platypus*), Japanese dace (*Tribolodon hakonensis*), barbel steed (*Hemibarbus barbus*), and nekogigi (*Pseudobagrus ichikawai*)—was assessed by using their instantaneous population growth rate (r_i) values. These values were calculated as the natural logarithms of finite population growth rates (λ). λ can be expressed as the dominant eigenvalue of a population projection matrix (also known as a Leslie matrix), which has positive entries only in the first row (fertilities) and the subdiagonal (survival probabilities). An instantaneous population growth rate (r_i) can also be expressed as

$$r_i = \ln (N_{t+1}/N_t), \qquad (1)$$

where N_t is the number of individuals at time t and N_{t+1} is the number of individuals at time $t + 1$. Therefore, if r_i is greater than 0, the population will increase during the period from t to $t + 1$. If r_i is less than 0, the population will decrease, and if r_i is exactly 0, it will remain unchanged during that period. The parameters required for calculating the values of r_i were obtained from literature or estimated by a newly developed method. In general, an instantaneous population growth rate (r_i) often decrease with an increase in the population density except when Allee effects occur. The maximum r_i is referred to as the intrinsic rate of population growth (r_m).

Figure 3 shows the effect of the BPA concentration in water on the conservatively estimated r_i of the 5 fish species. The maximum BPA concentrations of the areas in which the MOEs < 10 were less than 1/8 of the concentrations at which the conservatively estimated r_i became 0. The average BPA concentrations of the areas in which the MOEs < 10 were less than 1/23 of the concentrations at which the conservatively estimated r_i became 0. Therefore, it is unlikely that the 5 fish species are at unacceptable risks in terms of population sustainability due to the current levels of BPA in ambient water.

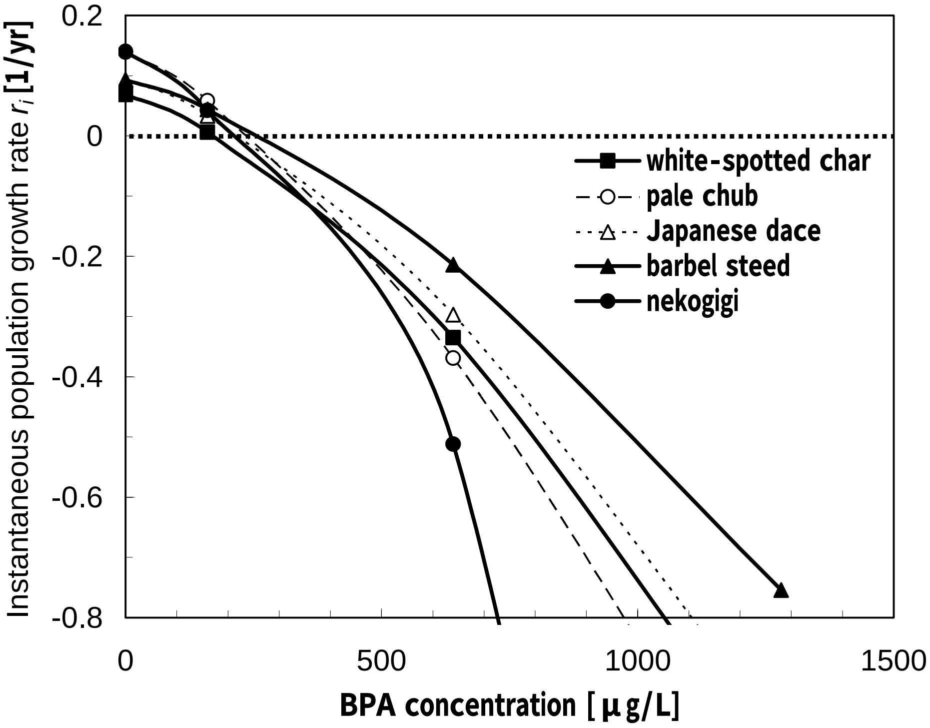

Fig.3 Effect of BPA concentration in water on the conservatively estimated r_i of 5 fish species

4.3 Assessment endpoint (3): Presence and conditions of fish species confirmed by field observations in highly contaminated areas

Literature and our sighting survey confirmed that various fish species inhabited the areas in which the average and/or maximum BPA concentrations were several µg/L or less. Information on the presence of fish was not obtained for the areas in which the maximum BPA concentrations exceeded 10 µg/L; however, in the Yago River, 12 fish species including carp and Japanese dace were observed approximately 5 km downstream in the area with average and maximum BPA concentrations of 4–7 µg/L and 15–20 µg/L , respectively. Therefore, it was indicated that fish populations in rivers contaminated with up to 20 µg/L of BPA did not become extinct readily.

4.4 Overall conclusion regarding the sustainability of aquatic life, particularly fish

In summary, the analysis under assessment endpoint (1) indicated that ecological risks posed by BPA were below the level of concern in most areas. The analysis under assessment endpoint (2) confirmed that the 5 surrogate fish species were unlikely to face unacceptable risks in terms of population sustainability due to the current levels of BPA in ambient water. The analysis under assessment endpoint (3) proved that fish populations in rivers contaminated with up to 20 µg/L of BPA do not become extinct readily. The results of assessment endpoints (2) and (3) were consistent with each other. From these considerations, the current exposure levels of BPA will not pose unacceptable risks to the local populations of aquatic life, particularly fish.

Chapter VI. Economic impact analysis of risk reduction activities

In this chapter, costs and reduced BPA intakes were assessed for two risk reduction activities conducted in Japan: the substitution of PC tableware used for school lunches and the voluntary alternation of the method for inactivating the inner surface of drink cans. It was expected that this assessment would present a viewpoint for considering the problem of endocrine-disrupting chemicals rather than supporting future BPA control.

1. Substitution of PC tableware used for school lunches

According to surveys conducted by the Ministry of Education (1998b, 1999b), PC tableware was used in 1,686 municipalities in May 1998; however, more than 300 of these municipalities substituted it with tableware of different materials within a year. Furthermore, as of May 1999, approximately 500 municipalities planned to change their PC tableware. In order to obtain detailed information on the substitution including time, scale, costs, *etc*., we distributed questionnaires to 10 municipalities randomly sampled from those that had already substituted their PC tableware as of May 1999 and 90 municipalities randomly sampled from those that planned to change their PC tableware as of May 1999. Sixty municipalities responded to the questionnaires (60% recovery rate).

Among 54 municipalities that were able to confirm the past use of PC tableware, 48 substituted it with tableware of different materials and 6 did not. Polypropylene was the most popular material for the substitution; it was selected by 38.3% of the municipalities that substituted their PC tableware. Ceramic (including reinforced porcelain) was the second most popular material used by 18.3% of the municipalities. Other materials included melamine, ABS resin, polyethylene naphthalate, and stainless steel.

The reason(s) for the substitution (multiple answers allowed) were stated in the questionnaire: 96% of the municipalities substituted PC tableware because of concerns about endocrine-disrupting effects of BPA and 16% substituted it because of respect for the food culture in Japan that traditionally used ceramic tableware. In fact, all the municipalities that substituted their PC tableware because of respect for the food culture selected ceramic tableware.

Collateral investments in facilities were made only when PC tableware was substituted with ceramic tableware. Three of the 11 municipalities that introduced ceramic tableware replaced their dishwashers. However, this was not only because they were unsuitable for fragile ceramic tableware, but also because they were decrepit. Six of the above 11 municipalities replaced and added sterilization cabinets and/or movable sinks. Three of the 6 replaced and added them because ceramic tableware required more space than PC tableware and the existing ones were aging. The other 3 municipalities added them only because of the increased handling space required for new tableware. Since sterilization cabinets and movable sinks were less expensive than dishwashers, they were introduced additionally even before their replacement time.

The net cost for the reduction in the BPA intake by the substitution of PC tableware is the difference between the total expenses incurred only for reducing the BPA exposure and the expenses expected if PC tableware were not substituted. The total expenses include those incurred for the first replacement of the tableware and related facilities, their additional introduction at the time of substitution, and subsequent replacements at the end of their lifetime. By assuming the discount rate as 3%, the incremental national costs over 30 years from 1996 to 2025 were estimated to be 11 billion yen, which is equivalent to 370 million yen per year or 127 yen per year per student who uses the substituted tableware. The reduction in the daily BPA intake by this substitution was estimated to be 0.2–0.3 μg/kg/day.

2. Alternation of the method for inactivating the inner surface of drink cans

In 1998, 0.6–10 μg/L of BPA was detected from 12 out of 20 canned drinks during product testing at the Hokkaido Consumer Affairs Center. The center then instructed the related industries to prevent the migration of BPA (Hokkaido Consumer Affairs Center 2003). This would become a part of consumer demands to manufacturers. Can manufacturers were asked to reduce the migration level to almost 0 by canned-drink manufacturers. Since the detection limit of BPA at that time was 5 μg/L, reduction below 5 μg/L was voluntarily set as a control standard.

Two approaches were employed to reduce the migration of BPA. One was to change the inner surface inactivation of cans from the EXR coating to the PET film lamination and the other was to use EXR paint from which a small amount of BPA migrates. Since industrial equipment for manufacturing film-laminated cans had already been developed and such cans were economically preferred, no facility investment was made only for reducing the migration of BPA.

Due to the alternation of the method for inactivating the inner surface of drink cans, 0.1–0.2 μg/kg/day of the BPA intake was reduced for average-exposure individuals and 0.2–0.6 μg/kg/day was reduced for high-exposure individuals (*i.e.*, 95th percentiles).

Chapter VII. Conclusion

This chapter summarizes Chapters I–VI and discusses future issues.

Since both the human health risk assessment (Chapter IV) and ecological risk assessment (Chapter V) concluded that the risks posed by BPA were below the levels of concern, it will be unnecessary to prohibit or restrict the use of BPA at this time.

The following points were identified as topics for future research and recommendations against the current risk levels of BPA.

(1) A wide range of stakeholders including consumers, industry, and public sector regulators should continue to share information on the risks posed by BPA in order to achieve a broad consensus on the management of these risks. It would be necessary to create an environment that encourages the disclosure of the voluntary management activities of industries without suffering unfair disadvantages from the disclosure, particularly in industries that manufacture food articles and products for infants and children.

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