－Summary of the Interim Report－
Bisphenol A

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National Institute of Technology and Evaluation
Study Group for Risk Assessment & Management of Bisphenol A

1. Introduction

Bisphenol A (BPA) is one of the chemical substances suspected to have endocrine disrupting effects, and has therefore been the subject of considerable public concern. While industries have independently implemented an initiative to control its release, further scientific information is required to prove the relationship between current release and environmental concentrations and also to institute appropriate management based on risk assessment.

In July 2002, the National Institute of Technology and Evaluation (NITE) established the Study Group for Risk Assessment and Management of Bisphenol A with the aim to gather and discuss the exiting reports on the hazard and the risk assessment of BPA and to establish a BPA emission scenario based on the current manufacture, use and disposal of BPA in Japan. The group consists of experts from industry, academia and local government authorities. Six meetings of the Study Group have been held since July 2002, and invaluable data were presented by the group members. It seems to contribute to risk assessment by collecting the necessary information for the in-depth risk assessment. The results of its study were prepared as an interim report, which is composed of eleven chapters and documents with nomenclature and abbreviations at the end.

This report summarizes the interim report prepared by the Study Group.

2. General Information

BPA was first synthesized in 1891 and its production as a raw material for Polycarbonate and epoxy resin (EX resin) has expanded since their development in the 1950's.

BPA is a white solid with a melting point of 152-155℃ and a poor solubility in water of 120 ppm (25℃). Its vapor pressure is low and it hardly vaporizes.

3. Results of Existing Hazard and Risk Assessments

3.1 Existing reports on hazard assessment

3.1.1 Effect on living organisms in the environment, and human health

The interim report includes the following information

1) Ministry of Economy, Trade and Industry, Chemical Substance Management Section, Committee for the Study of Endocrine Disruption (2002), "Hazard Assessment of Bisphenol A".
2) Chemicals Evaluation and Research Institute of Japan (CERI) (2003), "Initial Risk Assessment Report for Chemical substances (A Preliminary version) No.4, 4,4'-Isopropylidendiphenol (Bisphenol A) as the main sources and
3) EU (2002), Risk Assessment Report (RAR) (Draft) as a reference.

3.1.2 Discussion on the low dose issue

In addition to the above two reports of 1) and 2), following two reports were used for the preparation of the interim report.

1) Ministry of Health, Labour and Welfare (2001), "Supplement to Interim Report, Investigation Commission on Health Effects of Endocrine Disruption Chemicals".
2) U.S. National Toxicology Program (2001), Report on Low-Dose Endocrine Disruptors, Peer Review.

3.1.3 No-Observed-Effect Concentration (NOEC), No-Observed-Adverse-Effect Level (NOAEL)and Uncertainty Factor(UF) used for risk assessment

The NOEC, the NOAEL and the UF used for the risk assessment for environment and human health are summarized from both Initial Risk Assessment Report and EU RAR (Draft) as mentioned above. In addition, the rationale for tolerable daily intake (TDI) of BPA acceptable domestically and internationally (including the EU Scientific Committee on Food (SCF)) is summarized.

3.2 Existing reports on risk assessment

Reports 1) to 4) were used for the interim report.

1) EU (2002), Risk Assessment Report (RAR) (Draft).
2) OECD (2002), SIDS Initial Assessment Report (SIAR) for SIAM 14, March 26-28.
3) CERI Japan, (2003), "Initial Risk Assessment Report for Chemical substances (A Preliminary version), No.4, 4,4'-Isopropylidendiphenol (Bisphenol A).
4) EU Scientific Committee on Food (SCF) (2002), "Opinion of the Scientific Committee on Food on Bisphenol A, SCF/CS/PN 3939 Final.

Reports 1) to 3) above assess both the human health risk and the ecological risk, while report 4) above considers only the human health risk.

Results for both main hazard and risk assessments are given below.

3.2.1 Environment

1) Both the EU RAR (Draft) and OECD SIAR used a full life cycle test of the fathead minnow to determine the Predicted No-Effect Concentration (PNEC) of 1.6 μg/L, assuming a NOEC (on the hatching rate) of 16 μg/L and UF of 10. The EU RAR used this value to assess the risk for every uses in EU and concluded that BPA used as an additive to thermochromic paper and polyvinyl chloride resin had to be reduced to lower its risk.
   In a preliminary study, the conservative PNEC was estimated at 0.1 μg/L using an UF of 10 for a Lowest-Effect Concentration (LOEC) of 1 μg/L for inhibition of sperm formation in the fathead minnow. However, expert opinion is still divided on acceptance of this value.
2) Initial Risk Assessment Report for Chemical substances (A Preliminary version) used a NOEC of 160 μg/L in a growth and hatching rate test of the fathead minnow for 164 days as well an UF of 50. The PEC was 0.12 μg/L for 95percentile of the monitored data in Japan. The margin of exposure was 1,333 so they concluded that a hazardous effect is less likely.

3.2.2 Human health

1) Both the EU RAR (Draft) and the OECD SIAR used a LOAEL of 120 mg/kg/day for oral toxicity from a chronic toxicity test in mice to establish hepatotoxicity in general toxicity, and a tentative NOAEL of 50 mg/kg/day for reproduction toxicity from a reproductive and developmental toxicity test conducted on three generation rats. The EU RAR (Draft) evaluated a margin of safety in each use situation in the risk assessment. They concluded that there was no need for further information, testing, or action other than the risk reduction measures already practiced with regard to any effect on hepatotoxicity and birth rate, while further information was required on developmental effects.
2) Initial Risk Assessment Report for Chemical substances (A Preliminary version) used a NOAEL of 5 mg/kg/day for general toxicity obtained from the reproductive and developmental toxicity test on the three generation rats mentioned above and assumed an UF of 500. They estimated a human daily intake of 2.0 μg/kg/day. This resulted in a margin of exposure of 2,500, exceeding the UF.
3) The EU SCF, in a consensus opinion, uses a NOAEL of 5 mg/kg/day for oral administration from the reproductive and developmental toxicity test on three generation rats and obtained a Tolerable Daily

Intake (TDI) of 0.01 mg/kg/day provided that the UF was 500.

4) The US Environment Protection Agency (U.S. EPA) used a Reference Dose (RfD) of 0.05 mg/kg/day from a two year rat carcinogenic test (chronic toxicity test).

5) In Japan, Food Sanitation Law established an elution criterion for Polycarbonate tableware of less than 2.5 ppm. While a reason for this estimate was not published, it is suggested that the data on the two-year rats carcinogenic test (chronic toxicity test) used by U.S.EPA to estimate RfD was used. It appears that a TDI of 0.05 mg/kg/day estimated from a LOAEL of 50 mg/kg/day and an UF of 1,000 were used to establish the above elution criterion.

4. Status of Production and Uses

BPA production volume (supply volume) increased every year to reach 490, 000 tons in 2001. The BPA producers' domestic shipping volume was 396,900 tons in 2000. By application, 71.7% was used for Polycarbonate and 20.5% for EX resin production, totaling 92.2% for these two resins. Following polyester resin intermediate (3.2%), a fire retardant intermediate (1.4%), and other applications (less than 1%). Because, on these resins, BPA becomes part of polymer by chemical reaction, traces of BPA remain as unreacted monomer in resins. When considering the possibility of BPA release into the environment, it is necessary to discuss the release of BPA which remains as unreacted BPA and are produced by decomposition of the polymer in products.

In addition, BPA is used as a developer in thermochromic paper and as an additive to polyvinyl chloride resin and other resins. The supply volume for these applications is small, but details of release to the environment have to be thoroughly understood because BPA is used as additives in final products.
Investigation of the current status for each application led to the following conclusions.

The development and use of an alternative developer for thermochromic paper has been completed with shipment of BPA for use in thermochromic paper ceasing in 2001. Replacement of BPA as a stabilizer in polyvinyl chloride resin is also underway and its shipment for this use decreased from 300 tons in 1997 to less than 100 tons in 2001. There is little information on its use in other applications such as other resins, an additive to ink resin, paint, and as an adhesive and a binder additive for ceramic molds. Another application is as an additive to brake fluid. Two hundred tons of BPA were used as a stabilizer for brake fluid until 1997, but an alternative material was then developed which will end this application in the near future.

Polycarbonate, which is one of main uses of BPA, is used in electrics/electronics, office equipment/optical media, sheets/films, cars/machines, medical/safety products, other sundry goods and alloy etc. Products to which humans are possibly directly exposed include medical equipment, artificial teeth, baby bottles, tableware, and health food mixers.

EX resin, which is the other main use of BPA, has various applications in paints, electrics, civil engineering and adhesives. The details of these applications are not well understood. Humans could possibly be directly exposed to BPA eluted from the inner linings of food and beverage cans. Similarly, the possible elution of BPA from the inner coating of water pipes is also mentioned.

Release from other applications is less likely.

5. Environmental Monitoring

Analysis of available data for BPA environmental monitoring shows that the national institutions (Ministry of the Environment and Ministry of Land Infrastructure and Transport), local governments, citizen groups, and researchers have monitored the concentrations in environmental media including surface water, sediment, underground water, tap water, atmosphere, soil, and living organisms.

Surface water: In freshwater, surface water in about 30% and 99.5% of the sampling sites contains an average concentration of BPA lower than 0.005 μg /L and 1 μg/L, respectively. In the sea, surface water in more than a half and all sampling sites but one had an average concentration of BPA lower than 0.005 μg /L and 1 μg/L, respectively.

Sediment: In freshwater, the highest concentration of BPA was 1,100 μg/kg-dry, found in the Ajio water channel in Osaka Prefecture in November 2001. Type classification of this site has not been specified yet. In the sea, the highest concentration of BPA was 120 μg/kg-dry in Hiuchinada, Ehime Prefecture.

Underground water: The concentration of BPA in underground water was measured at 94 sites to generate a total of 153 specimens. BPA was detected in 21 out of 153 specimens (detection limit 0.01 μg/L.)

Soil: The concentration of BPA in soil was measured at 29 sites from 1999 to 2002 and was lower than 5 μg/kg (detection limit) at every site.

Atmosphere: The concentration of BPA in air was measured at 42 sites from 1997 to 2002 and detected at only 8 sites (detection limit, 1-7 ng/m^3). The highest concentration was 28 ng/m^3.

Indoor Air: There are few measurements of BPA concentration taken in interior rooms. However, in 2003, the Health Department of the Tokyo Prefecture measured the BPA concentration at a total of 34 sites, including a residential house and a building, and reported a detection frequency of 57 out of 68 in summer and 38 out of 67 in winter and an average concentration of 1.5 ng/m^3 in summer and 0.81 ng/ m^3 in winter.

Aquatic organisms: BPA was detected in 11 out of 485 specimens of fish and shellfish (quantification detection limit, 5 μg/kg). The highest concentration was 30 μg/kg in a carp (in a Samukawa water intake dam, Kanagawa Prefecture). BPA concentrations of 4.5 μg/kg and 2.8 μg/kg were found in two tangled algae specimens.

Land living organisms: From 1998 to 2000, 120 specimens from birds and mammals were analyzed for BPA. The detection frequency was 31 out of 120 (quantification detection limit, 0.06-320 μg/kg-wet). And the quantification concentration ranged from 0.15 to 70 μg/kg-wet.

Pre-treated Sewage Water: BPA was detected in all 98 specimens from the influent water to the sewage treatment plants. The concentration detected ranged from 0.09 to 3.9 μg/L.

Rainwater: BPA concentration in rainwater was measured twelve times over six months from July 1997 to January 1998 in Iwagami-cho, Maebashi, Gunma Prefecture. Three cases were higher than the detection limit of 0.02 μg/L and the highest concentration was 0.04 μg/L.

6. PRTR data

The total release and transfer volume of BPA based on the Pollutant Release and Transfer Register (PRTR) in 2001 was 449 tons, reported by 138 businesses in 33 prefectures. Approximately 99% of this volume was reported as a transfer volume into sewage lines outside of the businesses and approximately 3.5 tons as a total release volume. The main channel for this release is via the atmosphere, although establishing an release estimation technique is problematic and the real magnitude is probably much smaller. There is no estimated volume other than those reported by businesses.

7. Use with Possible Human Exposure via Products

Cases where humans are possibly exposed to products are chosen from those in Chapter 4. They are tableware, baby bottles, medical equipment made of Polycarbonate, inner linings of food and beverage cans,

water pipes with an EX resin lining, and a dental material using BPA as a raw material. References for elution of BPA in these applications are listed in the interim report.

8. Emission Scenario

An emission scenario for BPA can be summarized as follows.

1. This scenario is based mainly on the aquatic environment as the main channel for BPA release.
2. After evaluation, contribution from five point sources and one non-point source in 2000 can be given as follows.
   1) Manufacturer：1.8 kg/year
   2) Primary user：Polycarbonate 120 kg/year
      EX resin 7 kg/year
   3) Further downstream user such as recycled paper plant：120-50,000 kg/year
   4) Final product user：51 kg/year
   5) Sewage treatment plant：200 kg/year
   6) Waste treatment plant：30 kg/year.
3. The current study could not identify a release source for BPA present in trace quantities into the environment. At present, it seems that there is little release of BPA into the atmosphere except by processes not yet investigated. Release into the aquatic environment which comes from recycled paper plants rather than BPA production and resin fabrication plants, is responsible for the BPA detected in river water.

Use of final products and sewage and waste treatment plants contribute to BPA release as much as point sources like the plants handling BPA based product.

Information that has not yet been investigated needs to be analyzed in conjunction with the supplemental PRTR data. This is very difficult to do because the target volume of unreacted BPA not listed in Material Safety Data Sheet (MSDS) is very low (The content is less than 1% in products).

4. Future tasks include:

1) An investigation on the effect of BPA stock on waste treatment plants,
2) Gathering information on an elution test in products and their outdoor use,
3) Selection of products including BPA with consideration of its environmental effect and understanding of its elution mechanism and
4) Comparison of the concentration calculated by a mathematical model based on the emission scenario using BPA's environmental fate and geographic information with the environmental monitoring data listed in Chapter 5.

9. Voluntary actions taken by the Industry

Industry initiatives are summarized in this chapter. Industries have voluntarily initiated work on reduction of the volume used, and conversion to alternate materials when concern over possible endocrine disruption by BPA was raised, even though the risk posed by BPA had not been fully understood.

10. Case examples of actions taken by local governments

Cases examples by Okayama and Tokyo Prefectures are presented. These local governments actively monitor the BPA concentration in rivers and keep a watch on the trends.

11. Conclusion

As far as possible, the interim report gathers and organizes the information on the current status of BPA hazard and risk assessment and discusses a scenario for BPA release in Japan. These results suggest the desirability of carrying out the following tasks:

1. In-depth risk assessment considering exposure in the sites where high BPA concentrations are locally observed.
2. Improvement of accuracy with a certain issue in the development of the emission scenario.
3. Further follow-up on the development of a study on reproductive and developmental toxicity, particularly low dose effects and consumer exposure to BPA.

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