－Summary of the Interim Report－

Bis(2-ethylhexyl) Phthalate

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National Institute of Technology and Evaluation

Study Group for Risk Assessment & Management of Phthalates

1. Introduction

The major use of phthalates are plasticizers in polymer products mainly in polyvinyl chloride (PVC). Flexible PVC is manufactured by the addition of phthalates to PVC and used in a variety of applications. Since there have been some concerns because some phthalates are suspected to have endocrine disrupting effects, legal regulations for some phthalates are under consideration in Japan, although various kinds of voluntary actions have already been taken by the industry.

Although numerous reports on hazard assessment and risk assessment for phthalates have been published by the authors from domestic and overseas organizations, the relationships between the hazard and the exposure and those between actual status of emission volumes and the environmental concentrations have not been studied extensively in terms of domestic conditions in Japan.

Under such circumstances, the Study Group for Risk Assessment and Management of Phthalates (the Study Group) was organized in National Institute of Technology and Evaluation in July 2002, gathering experts from industry, academia, and the local government authorities.

The Study Group gathered and discussed the existing reports on the hazard and the risk assessment of bis(2-ethylhexyl) phthalate (DEHP), because its production volume is the largest among phthalates. Furthermore, the Study Group conducted a questionnaire survey and gathered information on the actions for reducing exposure taken by the industry during the production process, use, and disposal by responding to social interests as well as those taken by local governments.

This report is a summary of the interim report, discussing a realistic emission scenario based on the information of the production and use of DEHP to identify the major release sources and the environmental concentrations estimated by using various mathematical models.

2. General information

2.1 Historical and International Information

Since phthalates have been used as a plasticizer for resins, mainly for PVC, its production volume has been increased with the production of PVC. Industrial production of PVC started in 1930's in Germany and U.S.A. In Japan PVC production started in 1941 on a small scale only for military use. In 1943 the production volume of PVC in U.S.A. was 37,000 tons while in Japan in 1944 that was only 116 tons, and the production volume of phthalates was between 200 and 500 tons per year in those days.

After World War II, production of PVC in Japan has steadily grown from 1,493 tons in 1950 to 2,680,000 tons in 2000, which accounted for about 10% of the worldwide production of 25,960,000 tons.

In Japan the production volume of PVC accounted for 16% of the total production of plastics of 14,720,000 tons in 2000, which was the third largest following polyethylene and polypropylene. However, this ratio has been declining recently.

The shipping of phthalates increased together with the shipment of PVC, from 190 tons in 1948 to 360,000 tons in 2000, which was about 8% of the worldwide production 4,700,000 tons.

About 80% of plasticizers used in Japan are phthalates, about 60% of which is DEHP. DEHP makes up about 50% of the total plasticizers used in Japan.

As mentioned previously, most of DEHP is used as a plasticizer for PVC in Japan as well as worldwide. Other use such as printing ink, paints, pigments, adhesives is minor.

2.2 Information on the identification of chemical substance

Name of substance	: Bis(2-ethylhexyl) phthalate
Cabinet Order No. in Pollutant Release and Transfer Register	: 1-272
Cabinet Order No. in Chemical Substances Control Act	: 3-1307
CAS No.	: 117-81-7
Molecular formula and structure formula	: $C_{24}H_{38}O_4$

2.3 Physico-chemical properties

DEHP is a colorless liquid at ambient temperature. Melting point is -50℃ and Boiling point is 385℃. Various reports on water solubility are available ranging from 0.0006 to 1.3 mg/L.

2.4 Legal regulations in Japan

Pollutant Release and Transfer Register: Class I designated chemical substance
Fire Service Law: Hazardous substance, Category 4, Class 4 petroleum
Industrial Safety and Health Law: Hazardous substance whose name, etc. must be notified
Food Sanitation Law: Standards for apparatus, container-packages, and toys
Notification, etc.: Notification of Ministry of Health, Labour and Welfare for the Promotion of Voluntary Regulation of the Use of PVC Gloves
Plasticizer (DEHP) eluted from medical devices made of PVC

3. Hazard information and assessment

Domestic and overseas assessment reports on DEHP, published by the end of December 2002 (except for Society of Toxicology: by the end of March 2003) are reviewed.

3.1 Hazard information

3.1.1 Effects on human health

A case report on a human has shown that ingestion of 10,000mg of DEHP caused mild gastro enteric disturbances and diarrhea (Shaffer et al., 1945). In acute oral toxicity tests of DEHP, LD_{50} values for mice, rats, rabbits, and guinea pig are ranging from 26,300 to 33,900mg/kg.

No reports are available, including irritation or sensitization effects of DEHP.

Repeated administration tests showed that liver, kidney, and testis were the target organs. Poon et al. (1997) reported that the NOAEL (No Observed Adverse Effect Level) in rats 13weeks dietary administration study was 50ppm (corresponding to 3.7mg/kg/day).

Reproduction and developmental studies have shown that DEHP caused lowering of fertility rate, decrease in fetus weight, increase in malformed fetus, and death of fetus. Among these studies, 106 days dietary administration study in mice conducted by Lamb et al.(1981) showed that the NOAEL for reproductive toxicity was 14mg/kg/day.

There is a report relating carcinogenicity for rats and mice that hyperplasy of liver peroxisome brought forward the growth of liver cells that caused neoplastic transformation promoting liver cancer. However, IARC changed the classification of DEHP from Group 2B (possibly carcinogenic to human) to Group 3 (not classifiable as to its carcinogenicity to human) in February 2002, because the hyperplasy of peroxisome does not occur in Primates, and the reaction similar to the hyperplasy of peroxisome does not occur in Primates, and the reaction corresponded to the hyperplasy of peroxisome that take place in liver cells of rat does not occur in vitro culture of human liver cells.

The results of *in vitro* tests for investigating the effect of DEHP on the endocrine system shows that it is unlikely that DEHP has endocrine disrupting effect via estrogen receptor.

Schilling et al.(2001) reported that in rats reproduction study, various birth abnormalities and anomalies as the shortening of the anogenital distance of F1male(AGD), remnant papillae, and hypospadias. It seems that the mechanism is attributed to the inhibition of testosterone biosynthesis systems of provocative mechanism due to the antiandrogen effect not mediated by androgen receptors.

3.1.2 Effects on living organisms in the environment

Although numerous studies have been conducted on the effects of DEHP on aquatic organisms in the environment, only a few studies give the clear relationships between the concentration and effects because the solubility of DEHP in water is very low. The following is the summary of the reliable reports.

In the acute toxicity test in fish (Medaka, *Oryzias latipes*), the LC_{50} is 74.8mg/L (MOE, Japan, 1997). Defoe et al, (1990) obtained, exposure test of 90 days using fertilized eggs of rainbow trout, a result that the NOEC (No Observed Effect Concentration) was less than 0.502 mg/L. However, this value must be deemed as a reference value because in the view of weight of evidence the value is not appropriate for determining the NOEC for assessment.

Toxicity values for daphnia that belong to aquatic invertebrates obtained by toxicity tests show a wide variation so that it is difficult to clearly determine acute effect concentration at this moment. Of the values that have been obtained, the one obtained by Knowles et al. (1987), NOEC of 0.158 mg/L, is relatively reliable and deemed to be a reference value.

It is difficult to determine NOEC value for benthic invertebrates with high reliability, and the NOEC value of 780 mg/kg·dwt obtained by Woin and Larsson (1987) using larvae of dragonflies is deemed to be a reference value.

It is also difficult to determine NOEC values by toxicity tests with high reliability for amphibians, and the NOEC value of 25mg/kg-dry obtained by Larsson and Thuren (1987) is deemed to be a reference concentration.

It is difficult to determine the effect of DEHP on microorganisms' tests and avian tests.

3.2 Existing hazard assessment and risk assessment

Table 3.2-1 compares the results of various risk assessment reports relating to DEHP.

Table 3.2-1 Comparison of the results of various risk assessment reports

Title of the assessment report	Assessment to		Assessment performed		
	Human health	Environ ment	Hazard assessment	Exposure assessment	Risk assessment
Individual hazard assessment report (Ministry of Economy, Trade and Industry)	○	—	○	—	—
Initial risk assessment report (Chemicals Evaluation and Research Institute)	○	○	○	○	○
Environmental risk assessment of chemicals (Ministry of the Environment)	○	○	○	○	○
NTP assessment report	○	—	○	○	○
Canadian assessment report	○	○	○	○	○
EU risk assessment report	○	○	○	○	○
Environmental Health Criteria (WHO IPCS)	○	○	○	○	○

○: Object of assessment, -: Object out of assessment

3.2.1 Human health

Individual hazard assessment report of Ministry of Economy, Trade and Industry; Initial risk assessment report of Chemicals Evaluation and Research Institute (CERI); NTP assessment report; and EU risk assessment report adopt the following values as endpoints;

1) All the reports adopt the test result of Poon et al. (1997) as the endpoints for testicles.
2) The initial risk assessment report of CERI, NTP assessment report, and EU risk assessment report adopt the test result of Lamb et al. (1987) as the endpoints for genotoxicity.
3) The EU risk assessment report adopts, in addition to the above-mentioned two test results, the test result of Moore et al. (1996) as endpoints for kidney toxicity and the test result of Arcadi et al. (1998) as endpoints for developmental toxicity.

3.2.2 Environment

Ecotoxicity tests and endpoints that are referred to in the assessment reports are as follows:

1) The initial risk assessment report of CERI assesses only the exposure of aquatic organisms and considers the test results of Adams et al. (1995) for algae, those of Knowles et al. (1987) for invertebrates, and those of Defoe et al. (1990) for fishes. The test results of Adams et al. (1995), which reported the minimum No Observed Effect Concentration (NOEC) (> 0.1 mg/L), are adopted for the endpoints for the assessment.
2) The environmental initial risk assessment report of Ministry of the Environment assesses only the exposure of aquatic organisms through the water path as same as in the case of the initial risk assessment report of CERI, and considers the test result of Adams et al. (1995) and Japan Environmental Agency (1997) for algae, those of Rhodes et al. (1995) and Passino and Smith (1987) for invertebrates and those of Birge et al. (1979) for fishes. NOEC, 0.077 mg/L obtained by Rhodes et al. (1995) is used in the assessment. PNEC (Predicted No-Effect Concentration) is taken as 0.77 μg/L taking the assessment factor 100 into consideration.
3) EU risk assessment report takes a stance that it is not appropriate to use the endpoints for aquatic organisms through water path to determine the NOEC value because of the poor reliability of the data. However, it attempted to establish PNEC values for other exposure paths and terrestrial organisms. Test results that were taken into consideration were: Thompson et al. (1995), Brown et al. (1996)and Solyom et al. (2001) for the exposure of benthic organisms through sediments; Woin and Laesson (1987) for amphibians; Norrgren et al. (1999) for the exposure of fishes through feed; Hüls Infracor (1999) for inhibition of respiration due to activated sludge; Diefenbach (1998) for soil plants; Wood and Bitman (1980) for birds through feed; and Poon et al. (1997) for terrestrial mammals.
4) The Canadian assessment report estimated effect threshold value of 8 μg/L using the results of the lethal effect test for *Daphnia magna* conducted by Springborn Bionomics (1984).
5) Although EHC reviews many test data, it does not establish NOEC values or threshold values.

4. Status of production and use

Since the endocrine disrupting effect became a social issue around 1997 and the government notified to reduce the exposure to humans for some applications by administrative guidance, manufacturers who use DEHP have been taking measures to meet the requirements. The Study Group conducted a questionnaire survey of related industrial associations, in the period from August 2002 to March 2003, as to the present status of the use of DEHP and measures to meet social requirements. Thirty associations responded to the questionnaire, and the lack of data was reinforced from websites of industrial associations and statistical material provided by public organizations.

4.1 Status of production, export, import, and shipment of DEHP

Phthalates account for about 80% of plasticizers used in Japan and DEHP accounts for about 60% of the phthalates, which means that DEHP accounts for about 50% of the total plasticizers (Figure 4.1-1). The domestic production of DEHP which was about 310,000 tons in 1996 has decreased to about 240,000 tons in 2001. This occurred because mass media made DEHP one of a concerned chemicals suspected having endocrine disrupting effect recently and DEHP was designated as a Class I chemical substance of PRTR Law. Consequently, replacement of DEHP with alternatives has been promoted and the share of 68% of DEHP in the phthalates in 1996 decreased to 61% in 2001. Export of DEHP has been exceeding import by 20,000 to 30,000 tons per year as shown in Table 4.1-1.

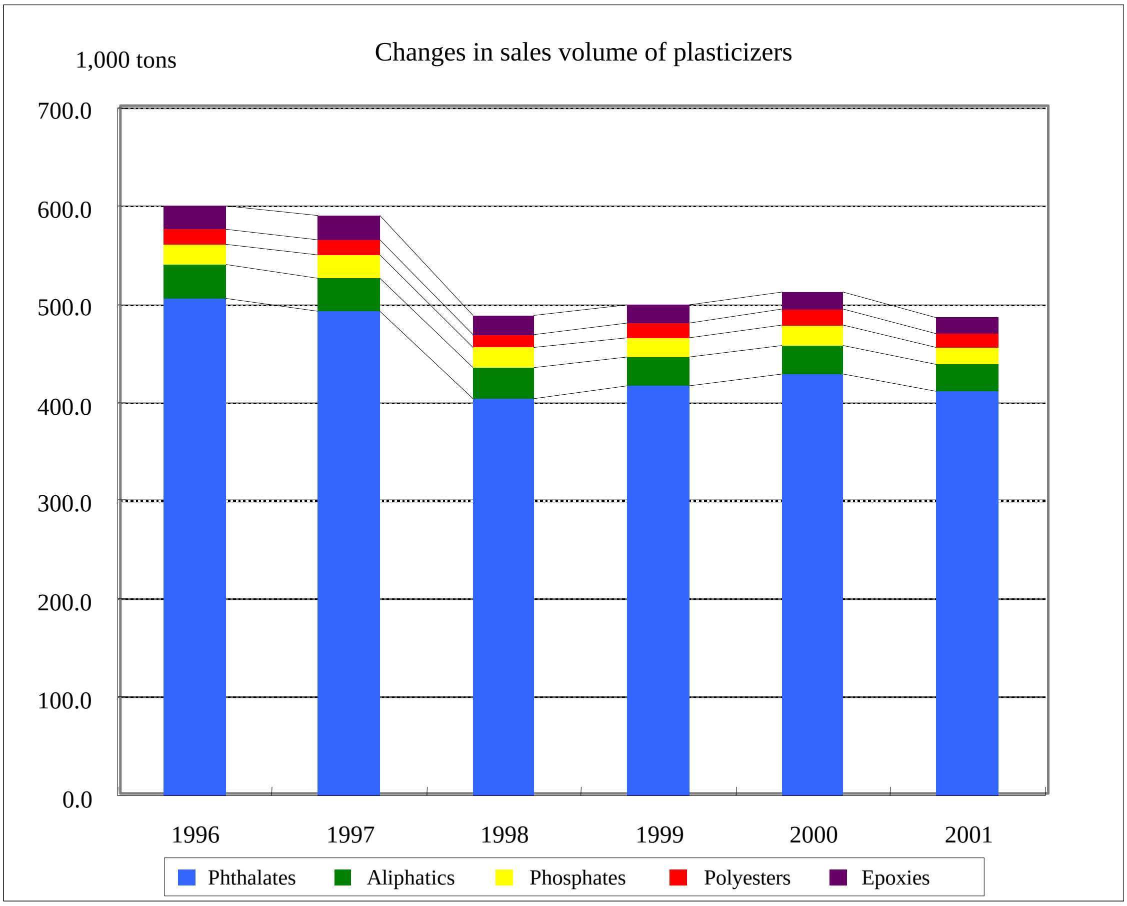

Figure 4.1-1 Changes in sales volume of plasticizers (Source: Monthly Statistics of Chemical Industry)

Table4.1-1 Changes in production, export, import, and shipment Unit: 1,000 tons

year	Domestic production		Export		Import		Domestic shipment (domestic products)	
	Total phthalates	DEHP	Total phthalates	DEHP	Total phthalates	DEHP	Total phthalates	DEHP
1996	476.1	313.1	50.9	29.8	3.7	1.2	434.1	285.3
1997	476.9	307.2	17.1	31.5	14.5	9.1	429.8	276.9
1998	402.1	260.8	12.1	30.9	8.7	6.4	367.0	227.1
1999	416.3	268.8	12.2	54.5	11.2	7.2	365.5	223.3
2000	400.1	253.7	8.1	40.7	15.1	10.9	360.3	219.3
2001	372.2	244.6	6.9	44.4	18.6	15.4	330.4	201.7

(Source: Japan Plasticizer Industry Association (July 2, 2002))

4.2 Status of the use of DEHP by applications

The DEHP volume by summing up the values of questionnaire survey of DEHP users associations was 131,000 tons. These values were considered the answered companies share in their belonging association and were taken other published information into account. The total estimated volume of 195,000 tons is 64,000 tons higher than that reported by the Associations (Table 4.2-1). The total supply of about 240,000 tons of DEHP consists of 202,000 tons supplied by the member companies of Japan Plasticizer Industry

Association, 15,000 tons of import (2001) (Table 4.2-2), and estimated amount of about 20,000 tons that is recycled from agricultural films and electrical cables. The summation of the values of questionnaire survey corresponds to about 55% of the total supply, and the corrected value corresponds to about 81%.

It is estimated that DEHP used for polymers accounts for more than 97% (PVC: more than 96%, other polymers: about 1%) and DEHP used for other applications, such as printing inks, paints, adhesives and ceramics accounts for a little less than 3%. The data on DEHP shipment provided by Japan Plasticizer Industry Association (Table4.2-2 and Figure 4.2.2) show that DEHP used for paints, pigments, and adhesives accounts for about 11.5%. However, since significant portion of this DEHP is used for polymer products such as mats, gloves, color fences, and hangers, the value is considered to reach to about 3%.

Among the plastics produced in 2000, PVC was the third in production volume following polyethylene and polypropylene. The production accounts for 16% of the total plastic products (Figure 4.2-1).

PVC is generally classified into flexible PVC and rigid PVC with flexible PVC accounting for a little less than 50%. The shipment of flexible PVC products, in which DEHP is used most, recorded the maximum in 1996 and has been decreasing since then until 2001. Reasons for this decline are: manufacture of PVC products in outside Japan, concerns that DEHP may be an endocrine disruptor and a possible candidate for the generation of dioxin by incineration of PVC products. In 2001, the production of PVC leather decreased to 43% of the peak and agricultural films decreased to 68% (Figure 4.2-3).

As to the balance between export and import of DEHP among various industrial associations in 2001, export exceeds import in Japan Plasticizer Industry Association, Japan Vinyl Goods Manufacturer's Association, and Japan Automobile Manufacturers Association, and import exceeds export in The Japan Electric Wire & Cable (Makers)' Association, The Japan Electrical Manufacturers' Association, Toy and General Merchandise Association, Footwear Association, and Japan Medical Devices Manufacturers Association. In the aggregate, export exceeds import and the yearly surplus is estimated as several tens of thousands tons.

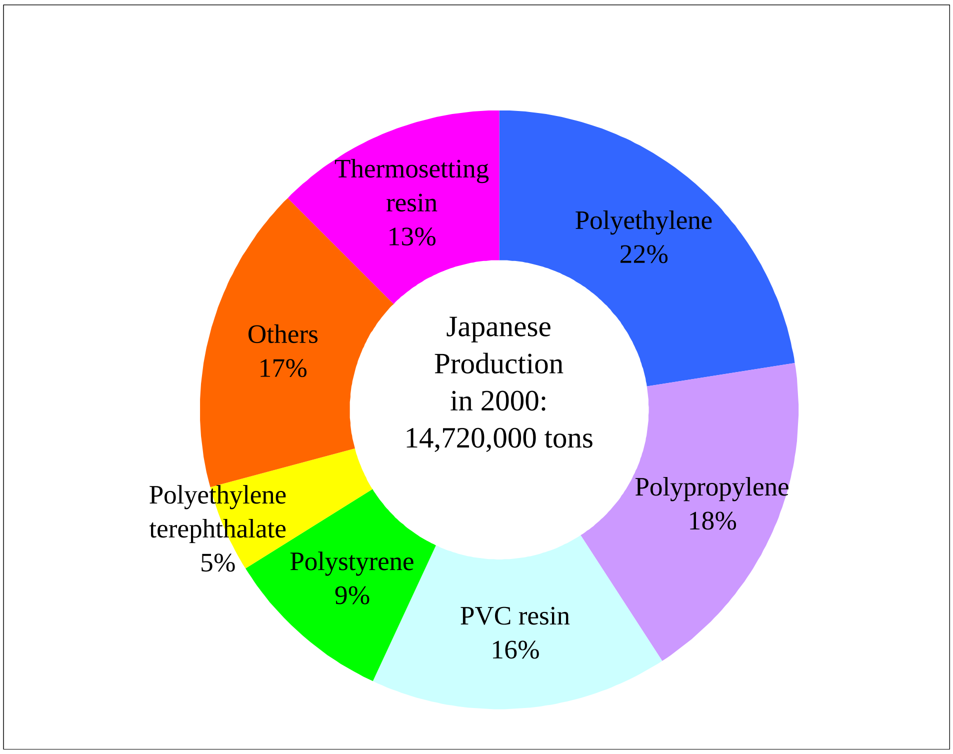

Figure 4.2-1 Ratio of production by types of plastics (Source: Vinyl Environmental Council)

Table 4.2-1 Consumption of DEHP by industries

Industrial field	Consumption in 2001[1) (tons/year)	Number of responses[2)	Estimated value for 2001[3) (tons/year)	Products using DEHP	Lifetime of products[4) (years)	Remarks
Japan Thermosetting Plastics Industry Association	565.7	19/48	1400	Film, sheet, plasticizer, curing agent, urethane resin, emulsion resin, phenol resin	1 - 10	
Japan Vinyl Goods Manufacturer's Association	79349	(34/54)	90200			
(General-purpose films)	(18300.3)			General-purpose films	1 - 15	
(Agricultural films)	(18975)			Agricultural films	2 (1 - 2)	
(Leather)	(2757.3)			Leather	5 - 20	
(Compound)	(22617.4)			Compound	5 - 20	
(Wall paper)	(6298.8)			Wall paper	5 - 20	
(Others)	(10399.7)			Others	0.3 - 25	
Japan Rubber Footwear Manufacturers' Association	3249.3	10/17	5100	PVC injection boots, PVC injection fabric shoes, sandals, shoe soles	0.5 - 5	
Japan Vinyl Hose Industry Association	6439.3	8/11	8900	Hoses (for gardening, agriculture, and industrial use), compound for packing	3 - 10	
Japan Glove Manufacturers' Association	0	3/27	0	Vinyl gloves (for medical use, food industry, and general-purpose)	1 - 3 (Disposable for medical use)	
Expandable Polystyrene Industry association	18	(5)	0	Cushioning packaging materials	5 (0.5 - 3)	
Japan PET Film Association	0	(7)	0			
Hygienic Association of Vinylidene Chloride	0	(15)	0			
Japan ABS Resin Industry Association	0	(7)	0			
Japan Urethane Raw Materials Association	1356.8	(6/8)	1800	Urethane resin for civil engineering and construction, sealing materials for civil engineering, binder, insulating materials for household electrical appliances, urethane resin for painting, urethane elastomer	10 - 20	
Japan Urethane Foam Association	0	(11)	0			
Japan Engineering Plastics Technical Committee	0	(32)	0			
Japan Polystyrene Foam Industry Association	0	(166)	0			
Japan Polypropylene Film Industry Association	0	(14)	0			
Kanto Plastic Manufacturers' Association	3	14/52	0	Plastic cover, corrugated (plate)	5	
Japan Plastics Toy Manufacturers' Association	3	26/61	0	Vinyl ball, swimming tube, small-size pool, float, doll	2 - 6	Mostly imported.
Japan (Inflatable) Vinyl Products Manufacturers' Association	0	(27)	0	Small-size pool, swimming tube, beach ball, surf float, boat, doll	2 - 6	Mostly imported.
The Japanese Electric Wire & Cable Makers' Association	2381.8	(6/143)	32000	Insulating materials for sheath of electrical cables, electrical wire and cable, sealing material	10 - 30	Estimated based on Monthly Report of Material Statistics
Japan Printing Ink Makers Association	822.5	14/42	2500	Gravure ink, ink for building materials, coating materials for electrical wire and cable, adhesive compound, ink jet sheet, printed circuit board	10 - 20	
Japan Paint Manufacturers Association	734	(116)	700	(Constructive paints) (vinyl resin, chlorinated rubber, emulsion paints (water-based))	10 (3 to 5 years for some users)	
Japan Adhesives Industry Association	0	(83)	0	Plasticizers of 15,000 tons are used by the industry but details are unknown. It is reported that DBP is used but DEHP is not used. (Standard compositions of emulsion-type adhesives (water-based) contain DEHP)		An automobile manufacturer reported in "environmental report" of 2002 that DEHP was used. (It was found during the interview that DEHP was used for adhesives.)
Japan Fine Ceramics Association	0.3	2/68	400	Fine ceramics: DEHP burns and vanishes in the burning process.		Since significant amount of use was omitted, the secretariat of the Study Group estimated the value.
Interior Floor Industrial Association	24268.2	8/8	24300	Flooring materials of PVC sheet, PVC tile, cushion floor	5 - 20 (5 years for fashionable products)	
Japan Carpet Industry Association	7046	2/54	22400	Tile carpet	5 - 10	
Plastic Resin-Coated Steel Sheets Association	1365	2/21	1400	Building materials (exterior, interior), household electric appliances, steel furniture, vehicles, general merchandise	10 - 20	Only two companies replied to the questionnaire and the total value for the industry was given by the secretariat.
Synthetic Polymeric Roofing Sheets Manufacturers' Association (KRK)	500	9/9	500	Rivet roof, waterproof sheets	15 - 20	
Japan Medical Devices Manufacturers Association	2904.8	19/221	3200	Artificial kidney, cardiopulmonary blood circuit, infusion set, tube, blood-sampling devices, blood bag, gloves	3 - 5 (Most users use only one time.)	
Japan Crop Protection Association	0	(46/55)	0	A crop protection product is registered but not produced.		
Japan Paper Association	0	(54)	0	Not used for paper and pulp production. Used for wall paper in the processing industry.		
Others	136.4	3	100	Eliminator of termites, varnish, binding agent for casting, waterproof agent, catalyst for urethane		
Total	131143.1		194900			

1) When only the amount of production was reported and DEHP content was unknown, administrative offices of relevant associations or the secretariat of the Study Group estimated the amount of DEHP used by applying DEHP content of similar products.
2) Responses of the associations in parentheses were given by administrative offices after summarizing. Numerators are the number of companies who replied and the denominators are the number of regular member companies (or regular members).
3) Where the number of responses is shown by a fractional number, portion of non-replying companies were added by proportion. However, the value for The Japanese Electric Wire & Cable Makers' Association was estimated based on the data on shipment by applications provided by Japan Plasticizer Industry Association and Monthly Report on Resources. Values for Japan Fine Ceramics Association, Japan Carpet Industry Association, Japan Medical Devices Manufacturers Association were estimated based on the shares provided in the interviews of relevant associations (All the values were rounded to the unit of 100 tons.) 4) Values similar to guaranteed period of the manufacturer.

Table 4.2-2 Shipment of DEHP by applications Unit: 1,000 tons

Application	1996	1997	1998	1999	2000	2001
General-purpose films, sheets	44.7	44.4	35.4	33.7	31.5	27.9
Agricultural PVC films	30.3	27.3	23.6	24.5	23.3	23.4
Leather	12.0	9.4	8.6	8.0	7.6	6.4
Industrial raw materials	35.5	32.1	24.6	24.0	24.4	21.9
Cable coating	50.1	45.8	39.5	40.6	36.6	32.0
Hoses and gaskets	16.4	15.6	12.7	12.6	12.5	10.6
Flooring materials	33.4	34.0	31.1	32.6	36.1	34.6
Wall paper	25.8	27.1	19.3	17.0	18.9	18.4
Paints, pigments, and adhesives	15.4	16.8	13.6	13.2	12.3	10.8
Footwear	5.8	5.0	3.3	3.5	3.0	3.3
Others	15.9	19.3	15.7	13.5	13.1	12.5
Total	285.3	276.8	227.4	223.2	219.3	201.8

General-purpose films, sheets: stationery, pouch, furniture, decoration, toy, umbrella, packing, vehicle, building material, sticker, various covers, laminated film, liner sheet, etc.

Agricultural PVC films: gardening, vegetables, paddy rice, tobacco

Leather: vehicle, furniture, bag, pouch, clothing material, stationery

Industrial raw materials:[compound; for cables] general purpose coated wire, harness, [compound; for general use] applications other than electrical cable, [sol] toy, undercoat (for vehicles), industrial parts

Hoses and gaskets: hose (for gardening, agriculture, and industrial use), tube (for medical applications, vehicles, etc.), gasket (for building, automobile, etc.)

Flooring materials: PVC tile, long sheet, cushion floor, tile carpet

Paints, pigments, and adhesives: PVC emulsion, sealing material, master batch

Footwear: injection molding, sandals, shoe soles

Others: mat, tape, gloves, color fence, hanger, rubber eraser, rubber, solvent, etc.

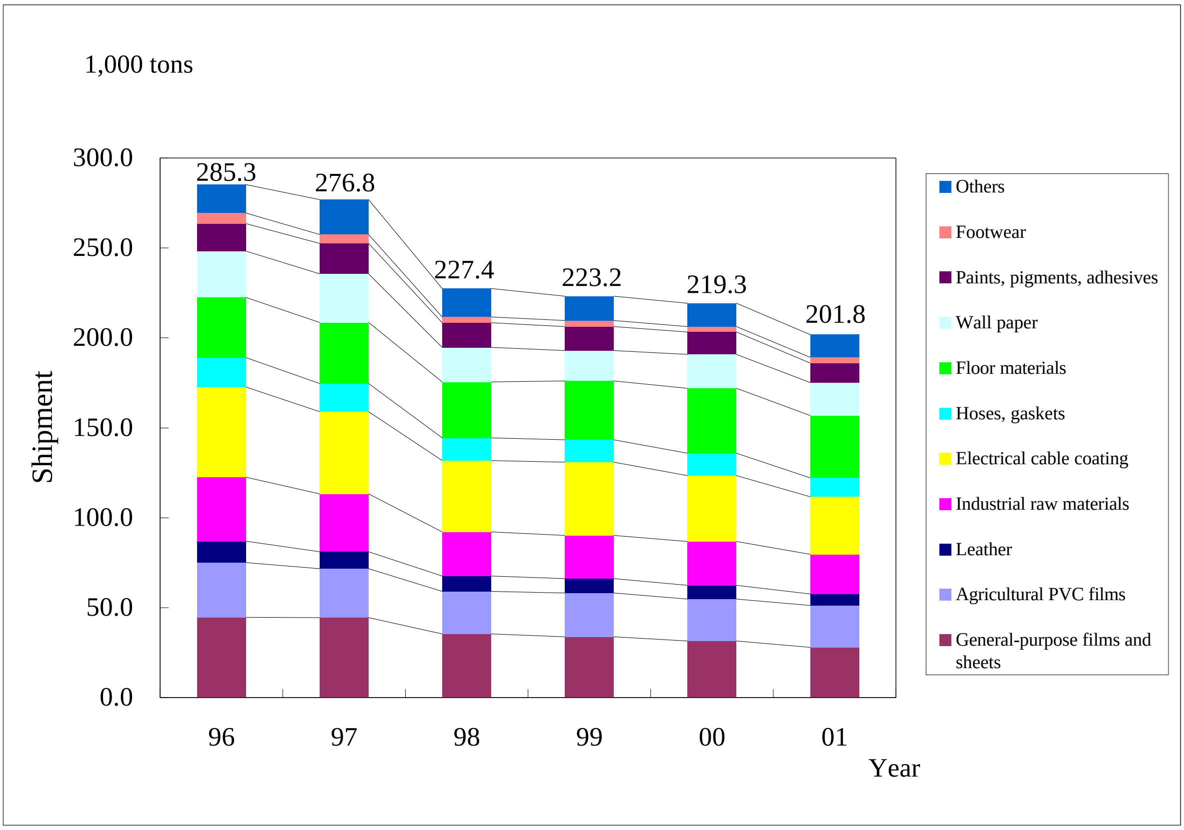

Figure 4.2-2 Shipment of DEHP by applications

(Source: Japan Plasticizer Industry Association (July 2, 2002))

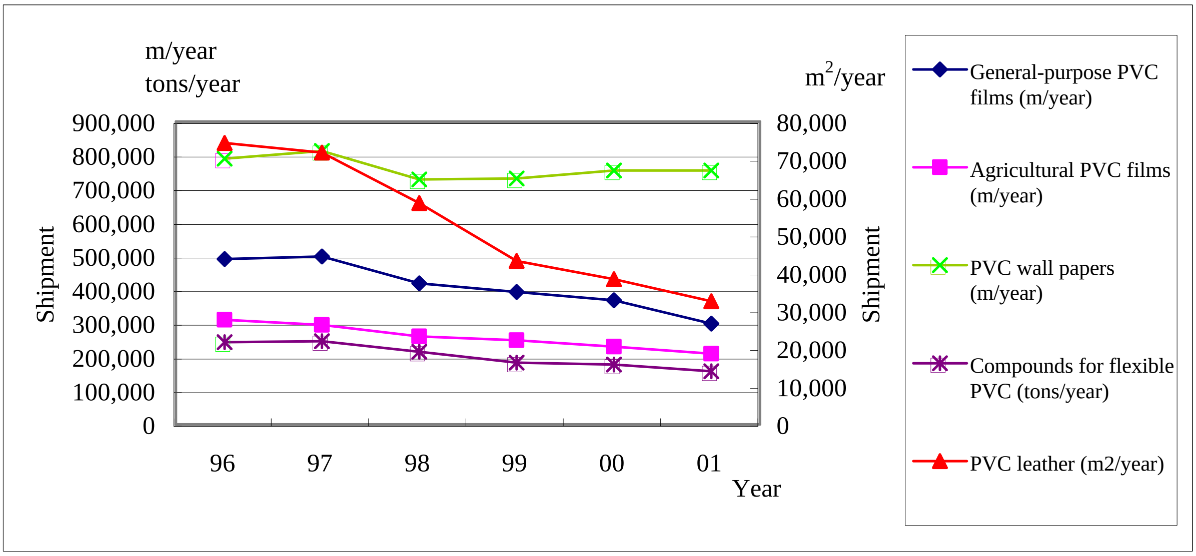

Figure 4.2-3 Shipment of flexible PVC products

(Source: Japan Plasticizer Industry Association (July 2, 2002))

4.3 Status of disposal of used products

Whereas used products containing DEHP are generally disposed of as waste, there are the industries where the recycling route for PVC products has been established and where the recycling route is now being established. The agricultural PVC industry and the electrical cable industry belong to the industry where the recycling route was established. And in 1991 about 51% of shipment was recycled in the former, and about 31% was recycled in the latter. Used packing materials are also partially recycled in the distribution industry. The flooring material industry, the carpet industry, and the building industry belong to the industry where the recycling route is being established, and it is attempted to recover PVC from buildings being constructed and demolition buildings.

Used automobiles, household electric appliances, personal computers, and copying machines (ratio of PVC products containing phthalates is low) are crushed after recovering usable parts, and the metals are recovered from the scrap. However, since the technology to separate plastics from the scrap has not been established, most of plastic products are disposed of by landfill or incineration.

Most of used medical devices are incinerated according to the manuals for infectious waste.

Household waste is mainly disposed of by local governments by means of landfill or incineration.

5. Environmental monitoring data

In the “Strategic Programs on Environmental Endocrine Disruptors (SPEED) ’98” , that was published in 1998 and revised in 2000 by Ministry of the Environment Japan, DEHP was listed as one of the 65 chemical substances that might have the endocrine disrupting effects. Since 1999, environmental monitoring of DEHP has been carried out by various organizations.

The Study Group gathered monitoring data from web sites of Ministry of Land, Infrastructure and Transport, Ministry of the Environment, local governments of 40 prefectures, universities, and research institutes.

Table 5-1 shows the summary of the DEHP concentrations in the atmosphere, surface water, sediments, soil, drinking water, sewage treatment plants, landfill sites, aquatic organisms and wild life.

Table 5-1 Summary of DEHP concentrations

Environmental media, etc.		Concentrations	Detection Limits
Air	Outdoor Air	Not Detected (ND) at most measured sites Max. 1,100 ng/m^3	4.2-510 ng/m^3
	Indoor Air	Detected at all measured sites. Max. 3,400 ng/m^3	
Surface water	River	ND at most measured sites Max. 42 μ g/L	0.2-1 μ g/L
	Lake	ND at most measured sites Max. 4.1 μ g/L	0.05-0.5 μ g/L
	Sea	ND at most measured sites Max. 9.2 μ g/L	0.05-1 μ g/L
Underground Water		ND at most measured sites Max. 36 μ g/L	0.05-1 μ g/L
Sediment	River	Detected at most measured sites. Max. 210mg/kg [1)]	25 μ g/kg
	Lake	Detected except one site. Max. 5,200 μ g/kg	100 μ g/kg
	Sea	Detected at most measured sites. Max. 6,600 μ g/kg	25 μ g/kg
Soil		ND at most measured sites Max. 1,100 μ g/kg	10 μ g/kg
Drinking water	Raw water, Purified water, Tap water	ND at most measured sites	0.2-5 μ g/L
Sewage treatment plant	Influent	Detected at all measured sites Max 68 μ g/L	0.5 μ g/L
	Effluent	Detected except 2 sites. Concentrations are lower than in influent.	0.2-0.5 μ g/L
Landfill site	Effluent, Leachate, Wastewater, Regulating reservoir	Detected at approximately half of the sites. Max. 11.9 μ g/L	0.5-7.7 μ g/L
Aquatic organism	River	ND in most samples. Max. 410 μ g/kg in crucian carp (*Carassius carassius*) and carp (*Cyprinus carpio*)	25 μ g/kg
	Lake	ND in most samples. Max. 350 μ g/kg in Japanese barbel (*Hemibarbus barbus*) and rainbow trout (*Oncohynchus mykiss*)	25 μ g/kg
	Sea	ND in most samples. 180 μ g/kg in striped mullet (*Mugil cephalus*), 180 μ g/kg in Japanese corbicula (*Corbicula japonica*) and 210 μ g/kg in blue mussel (*Septfer virgatus*)	25 μ g/kg
Wild Life		ND in most samples. Max. 363 mg/kg in racoon dog (*Nyctereutes procynoides*)	0.3-340 μ g/kg

6. PRTR Data

In 2001, 651 facilities of 46 prefectures excluding Miyazaki Prefecture reported the release and transfer of DEHP in accordance with Pollutant Release and Transfer Register. The aggregate amount of releases and transfers reported was about 5,400 tons and the releases that were not reported are estimated as about 1,180 tons, the total amounting to 6,580 tons. The amount reported accounts for 82% of the total volume. It was reported that 5,010 tons, which corresponded to 76% of the grand total, was transferred off-site from facilities as waste (Figure 6-1). The volume of release reported was 392 tons, most of which was released into the atmosphere. Since the estimated releases of outside notification were made mainly by listed industries, it is likely that most of the estimated releases were also made into the atmosphere. Since the releases which were from outside notification were estimated based on the plasticizers of paints, most of the DEHP is considered to have been released into the atmosphere.

Among the prefectures, Osaka Prefecture released the most, and then come Saitama Prefecture, Tokyo Metropolis, Tochigi Prefecture, Ibaraki Prefecture, and Fukui Prefecture in this order. The total of the top 10 prefectures accounts for 65%.

The plastics industry accounts for 65% of the reported release, then come the textile industry, chemical industry, pulp industry, rubber product industry, publishing, printing, and related industries; the sum of the top nine industrial fields amounts to 99% of the total.

In 28 prefectures out of the 46 prefectures that reported the release to the atmosphere, more than 60% of the total release was made by only one facility. Furthermore, releases from relevant industrial fields were dominantly made by only one or two facilities. Since the reporting was made for the first time in accordance with PRTR Law, it seems that facilities that reported did not have enough experience. This can be also said to other substances, and it is necessary to confirm the appropriateness of the data by interview.

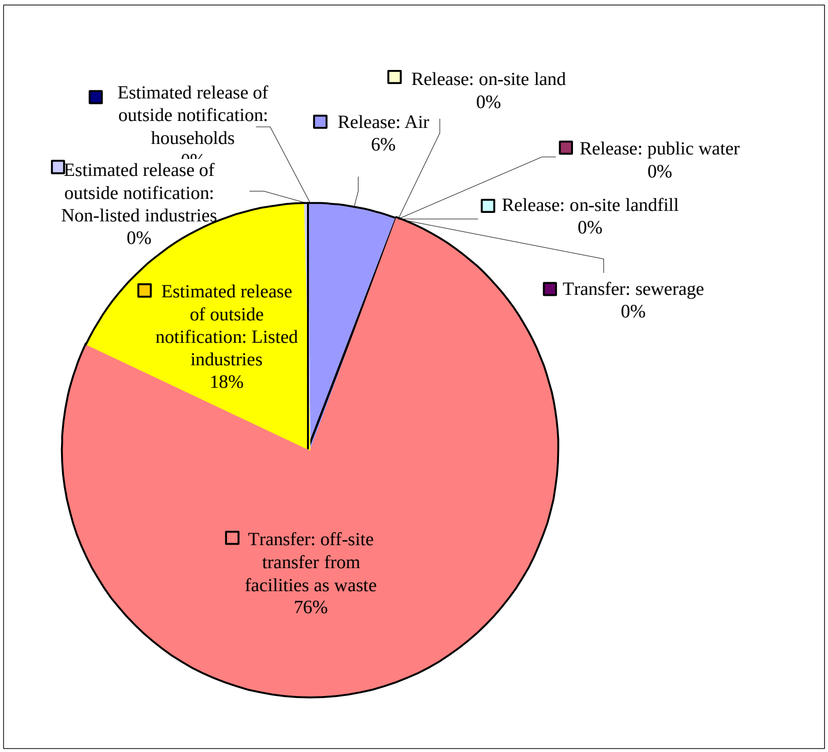

Figure 6-1 Ratio of release and transfer of DEHP

7. Product related human exposure

Following plastic products are mainly made of PVC and DEHP may cause human exposure via these products. Regulatory measures related to these products have been taken.

1) PVC gloves

   High-concentration DEHP was detected in commercial packed lunches and hospital feeding prepared using PVC gloves. In the migration test, elution of DEHP from PVC gloves to the food was confirmed. Therefore, notification requesting replacement of PVC gloves containing DEHP was issued by Ministry of Health, Labour and Welfare on June 4, 2000.

2) Child Toys

The studies on mouthing time and oral elution tests of infants using toys containing DEHP and DINP revealed that the exposure exceeding tentative TDI (tolerable daily intake) may occur. Therefore the Standards for apparatus, container-package and toys in the Food Sanitation Law were amended on August 2, 2002 in order to prohibit toys containing DEHP and DINP

3) Medical Devices

Based on the test results as to DEHP eluted from PVC medical devices, Ministry of Health, Labour and Welfare issued a notification to medical device manufacturers on October 17, 2002. This notification requests to state clearly that DEHP might migrate from PVC medical devices into human body and to promote development of alternative materials other than PVC with DEHP

Ahead of these notifications, industries have been taking voluntary actions, such as substituting DEHP plasticizer or replacing PVC with other materials.

8. Emission Scenario

8.1 About Emission Scenario

The life cycle of DEHP is comprised of several life stages such as production, formulation, primary and secondary processing, use, sewage treatment and disposal (Figure 8.1-1). In the emission scenario, the release and the transfer of DEHP at each life stage were estimated scientifically in order to identify the major release sources. And the results were used to calculate the environmental concentration of DEHP using models in chapter 9.

8.2 Estimation of release in each life stage

To estimate the release at stages from the production to the secondary processing, release data provided by Japan Vinyl Goods Manufacturers' Association and emission factor described in the manuals of Release Estimation Techniques prepared by various industrial associations were used.

At the use stage, the results of elution tests on products containing DEHP in Japan and the emission factors of the EU risk assessment report for DEHP were used. The release from sewage treatment plants where wastewaters from whole life stages except disposal stage are treated was estimated.

The total volume disposed in landfills of used products containing DEHP was estimated based on the data of shipment from 1976 to 2001 provided by related industrial associations. The release was obtained by multiplying the estimated values by using the emission factors adopted for the use stage and other stages.

The values of release for each life stage are summarized in Table 8.2-1.

Since emission factors are unknown for the release of uninvestigated columns in Table 8.2-1, the volumes were expected to be negligible when compare the data for shipment of DEHP in 4.2 by uses.

Table 8.2-1 Release and transfer from each life stage in 2001 (tons/ year)

Life stage/ media		Air	Water	Waste (transfer)
Production		0.004	0.02	0.8
Formulation & Primary Processing	PVC resin	180	0.001	1,000
	resins other than PVC	—	—	—
	products other than plastic products	—	—	—
Secondary processing		※	※	※
Use of end products[1)]		900	Outdoor: 20 - 170 Indoor: to sewage treatment plant	460,000
Sewage treatment plant		—	3.3 - 3.7	19
Waste disposal site		—	2	—

"—": Not investigated.　"※": Include use stage

1) Sorts of application of PVC resin (8 applications of PVC resin products produced in the period from1976 to 2001)

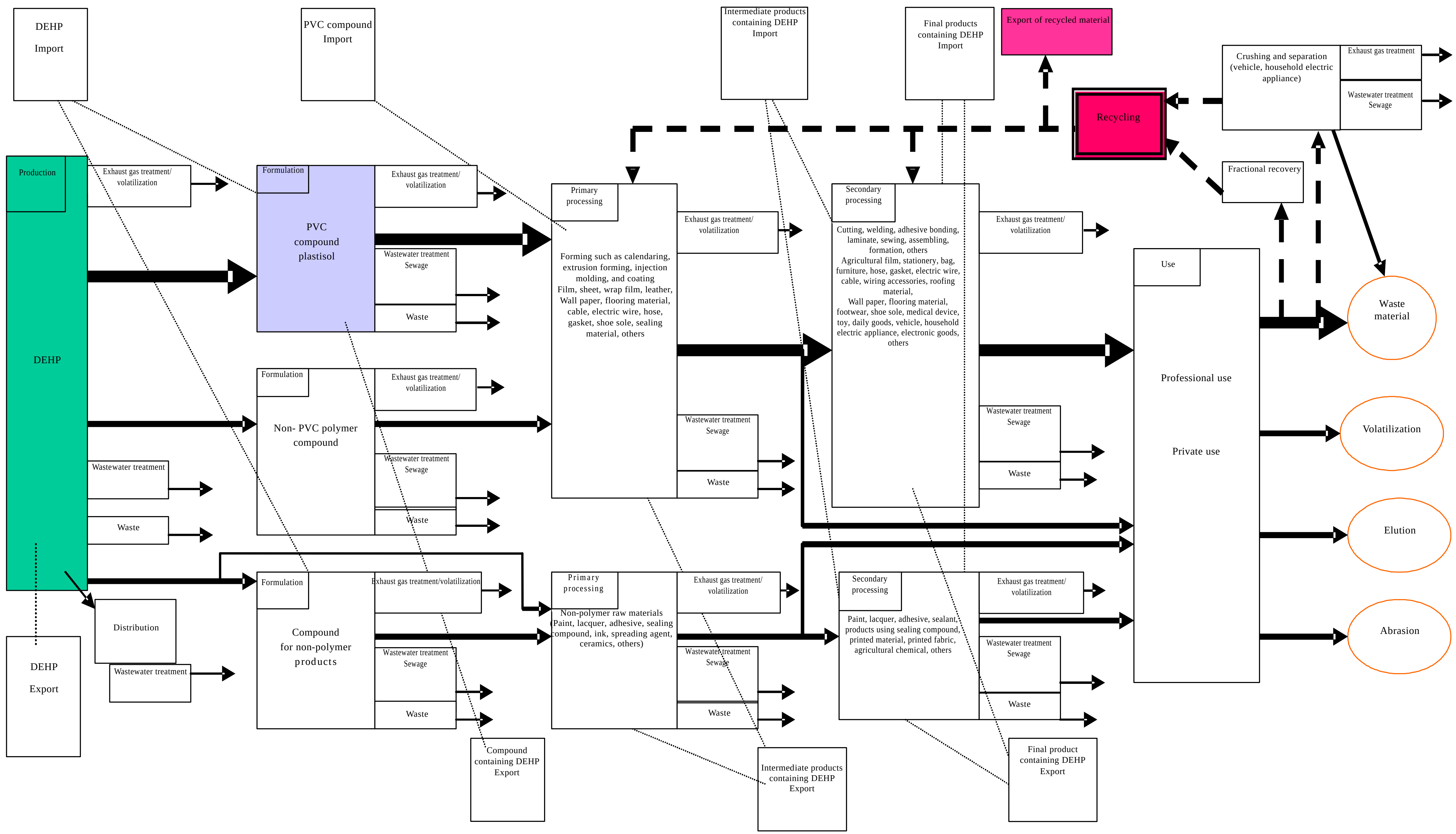

Figure 8.1-1 Life cycle of DEHP

9. Concentration calculation using models

9.1 Concentration calculation of DEHP using simplified models

Major behavior of DEHP in the environment and main transfer paths to exposure media were elucidated adopting simplified models using average values for meteorological and environmental parameters. The results are as follows:

- DEHP concentrations in the atmosphere and soil were calculated for the period from 1970's to 2006 using the data provided by industries and the estimated values of release and transfer of DEHP (assuming that the structure of production and use of DEHP in the period from 2002 to 2006 is similar to those of 2001), which were described in 8.2. The curve showing the changes in DEHP concentrations by year has the same trend as the curve showing the changes in the stock of used and disposed products containing DEHP (mainly flexible PVC). This indicates that the DEHP concentration depends on the amount of stock in the environment (Figure 9.1-1).

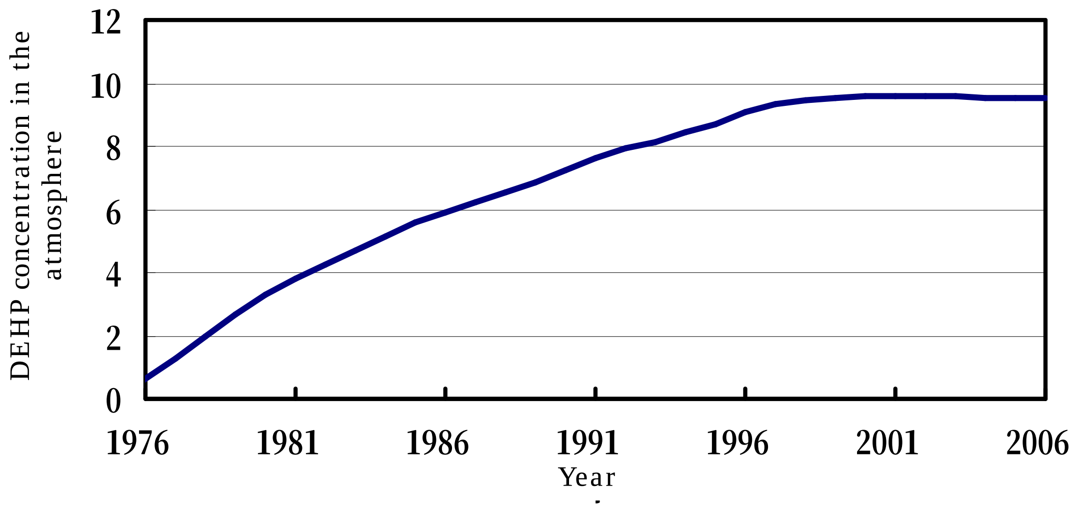

Figure 9.1-1 Changes in DEHP concentration in the atmosphere by year (Tokyo Metropolis)

- To estimate the average daily intake of DEHP by humans, it is necessary to elucidate the release from DEHP producing firms, and manufacturing and processing firms of flexible PVC resins as well as the release from products made of flexible PVC resins in use and the release from landfills. In particular, DEHP released into the atmosphere determines the DEHP concentration in the atmosphere and soil. Furthermore, the DEHP in the atmosphere migrates into plants and then to firm animals. Thus, DEHP emission into the atmosphere is important exposure source for humans.
- When estimating the DEHP concentration in the soil, it is important to assume a non-steady state in consideration of the fact that the decay rate in the soil is low. Although it is not possible to assess the importance of the transfer of DEHP, which deposited from atmosphere to soil, to the water environment at this moment because the amount of release from facilities and landfills is unknown, it cannot be neglected in the determination of the DEHP concentration in water environment, particularly in rivers.
- DEHP flows into rivers from diversified sources including business firms and disposal sites as well as the inflow from soil, and accumulates in the sediments in high concentrations.

9.2 Exposure assessment of DEHP

In 9.1, DEHP concentrations were calculated under various assumptions. Since the results of the calculation of concentration and the values obtained by environmental monitoring are a value near in order, in-depth assessment of DEHP exposure will be carried out based on the following procedure:

1) Release to the environment
   In addition to the release from production plants of DEHP and production and processing plants of flexible PVC resins identified by both of the interview survey of industrial associations and the PRTR data, the release from end products made of flexible PVC and landfills will be clarified.
2) Concentration in the atmosphere
   As the DEHP into the atmosphere determines the concentrations in agricultural products and stock farm products that humans take in, it will be estimated using AIST-ADMER (Atmospheric Dispersion Model for Exposure and Risk assessment) that enables the estimation of regional distribution of the DEHP concentration in the atmosphere. Furthermore, concentrations in the areas around business firms will be estimated, as the need arises, using an atmospheric diffusion model.
3) Concentration in the soil
   Since the properties of soil vary with the location and a treatment in non-steady conditions is required for the estimation of DEHP concentration in the soil, soil models that enable monthly dynamic prediction will be used.
4) Concentration in the water
   Since the release sources to the water environment are diversified, behavior of DEHP in the sediments must be taken into account, and the behavior under non-steady conditions has to be assessed, models that enable the estimation of DEHP under non-steady conditions will be used for the estimation of concentrations in water. Furthermore, models that enable the estimation of elution from disposal sites will be used as the need arises. In addition, since the DEHP concentrations in sea areas are important for the estimation of DEHP intake via fishes and shellfishes, the estimation of DEHP concentration in the sea will be also studied, if there are any available models.
5) Average daily intake
   The DEHP concentrations in agricultural products, stock farm products, and fishery products will be estimated using the plant models, living organism migration models for farm animals, and living organism accumulation models for fishes. Since regional distribution of DEHP concentration and changes by years can be obtained making use of the estimation of DEHP concentration in the environmental media obtained by using ADMER, realistic average daily intake will be estimated taking the shipment of agricultural products and stock farm products by prefectures and distribution channels, if possible, into consideration.

10. Voluntary actions taken by the industry

Voluntary actions taken by the industry against the release of DEHP into the environment were also investigated in the questionnaire survey and interviews described in Section 4.

10.1 Actions against DEHP being taken

Table 10.1-1 summarizes the total 194 responses to the questionnaire relating to the actions being taken against release into the environment.

Replacement of DEHP (including the shifting to non-PVC products) is dominant accounting for about 50%.

Table 10.1-1 Actions taken against DEHP

Action	Number of cases	%	Remarks
Replacement of DEHP	91	46.9	Replacement with other plasticizers and non-PVC products.
Recycling of waste material	47	24.2	Including selling to recycling firms.
Recovery and treatment of volatile components, mist, and fume	31	16.0	Installation of electrostatic dust collectors, pipe filters, etc.
Change of production process and facilities	12	6.2	Changing to the closed production process and improving the yield.
Incineration	10	5.3	Including the subcontract to industrial waste disposal firms.
Wastewater treatment	3	1.5	Including oil separation

10.2 Reasons for taking actions

There were 102 responses in total relating to the background of these actions, which are summarized in Table 10.2-1. “Request of users (*1),” which ranks the first, derives from the sense of aversion of users due to the fact that DEHP became an issue of concern on the mass media as an endocrine disrupter (*2) and that it was designated as a designated chemical substance of Class I in accordance with PRTR Law. The total of the first-ranked reason, ”requests of users”, the second-ranked reason, “recognition of endocrine disrupter issue by the manufacturers,” and the sixth-ranked reason, “designation as a designated chemical substance of Class I in accordance with PRTR Law” accounts for about 70%.

Table 10.2-1 Reasons for the actions

Background	Number of cases	%	Remarks
Request of users (*1)	35	35	Replacing with other plasticizers and non-PVC products.
Endocrine disrupters issue (*2)	25	25	Including dioxin issue
Changes of product standards	11	11	Placing new products on the market and improving performance.
Response to regulations	11	11	Voluntary regulations by the industry including those in anticipation of regulation by the government.
Consideration of environment	9	9	Measures taken for ISO14000 and the environmental report.
Class I designated chemical substance in accordance with PRTR Law	8	8	Troubles with reporting and negative image.
Tight supply of DEHP	3	3	

(*1) Refers not to general consumer public but to the manufacturers of the intermediate products and the end products containing DEHP

(*2) Most of the responses to the questionnaire survey phrased this issue as “environmental hormone issue.”

10.3 Status of implementation of replacement

The total 133 responses to the question on the substitutes for DEHP plasticizer and PVC products containing DEHP are summarized in Table 10.3-1 and Table 10.3-2.

The number of cases in which DEHP is replaced with other plasticizers is 90 cases (67.7%). The substitutes include phthalates (DINP is dominant accounting for 38 cases and DIDP comes next), adipates, and tris(2-ethylhexyl) trimellitate.

The number of cases in which PVC resins is replaced with other resins is 43 (32.3%), and there is no predominant substitute material.

Table 10.3-1 Substitute plasticizers for DEHP

Substance name	Number of cases	%	Remarks
Other phthalates	42	46.7	DINP;38, DIDP;4
Adipates	9	10.0	DOA;3, DINA;2
Tris (2-ethylhexyl) trimellitate	8	8.9	
Citrate	5	4.4	
Other acid esters	7	7.8	Fatty acid glycerine ester;2, maleic acid esters, sebacic acid esters, etc.
Epoxidated soybean oil	3	3.3	
Others	16	17.8	Plasticizers other than phthalates, etc.

Table 10.3-2 Substitute materials for PVC

Substance name	Number of cases	%	Remarks
Polyester	10	23.2	
Polyurethane	7	16.3	
Polyethylene	5	11.7	
Polypropylene	5	11.7	
Polybutadiene	4	9.3	
Others	12	27.9	Non-PVC:10, Polyolefin:2

10.4 Measures scheduled in the future

Relating to the measures scheduled in the future, there were 82 responses, 59 (72%) of which described that certain actions were scheduled. There are 66 types of actions in total including replacement of DEHP and PVC products, improvement of recycling ratio, and recovery and treatment of fume and volatile components as preferred ones. There were 44 responses in total that considered replacement, 32 cases (68.2%) of which were for replacing the plasticizer function of DEHP and 12 cases (31.8%) were for replacing the function of PVC material. The substitute materials are the same as shown in Table 10.3-1 and Table 10.3-2.

10.5 Reasons for the actions to be taken in the future

There were 59 reasons in total for the measures to be taken in the future, of which “request of users” was the most with 18 (30.5%) responses. The number of “consideration of social problem (including endocrine disrupters issue)” was 15 cases (25.4%), that of “measures for environmental issue” was 8 cases, that of “measures for PRTR Law” was 7 cases, that of “measures for regulations by the government” was 6 cases, and that of “concerns about hazardous effect of DEHP” (mainly in the medical device industry) was 5 cases.

There were 23 responses that indicated no measures were scheduled. Reasons were as follows. Since the performance and costs of DEHP and PVC products using DEHP are excellent and there are no appropriate substitutes: 13 cases (59%); DEHP is deemed to be harmless: 5 cases (22.7%); there are no plasticizers whose safety has been proved: 2 cases; and users requires the use of products containing DEHP due to its excellent performance and costs: 2 cases.

10.6 Conclusion

Voluntary actions, such as installation of facilities to suppress and prevent release of DEHP into the environment have been taken by the industry, and it seems that the major purposes of these measures are to cope with the endocrine disrupters issue and to prepare for anticipated regulations by the government.

It is also seen that the replacement of DEHP and PVC has been implemented only because the substitutes are not listed as the Class I or Class II designated chemical substances according to PRTR Law or not designated as the designated substances according to Chemical Substances Control Law. The substitution is not based on a scientific comparison of hazardous effects because data on hazardous effects for such alternatives are not available as in the case of DEHP and PVC.

Some responses are based on the understanding that the government has certified the hazardous effect of DEHP. Therefore, it is necessary to give persuasive explanation based on scientific facts when giving administrative directives.

11. Case examples of Actions taken by local governments

In the "Strategic Programs on Environmental Endocrine Disruptors '98 (SPEED '98) project, Ministry of the Environment listed up 65 substance groups in May 1998 (67 substance groups were listed up originally but 2 substance groups were eliminated in 2000), and 20 substances were selected in 2000 and 2001 as those whose risk assessment should be implemented preferentially. The following are the case examples of measures taken by local governments in response to this.

11.1 Actions taken by Tokyo Metropolitan

11.1.1 Background

The actions to be taken by the Tokyo Metropolitan was defined, in July 1998, in "Measures for the endocrine disruptors to be taken by the Tokyo Metropolitan—Policy of Tokyo Metropolitan to Cope with Environmental Hormones." And "understanding of current status," "promotion of survey and research," and "collection and provision of information" have been implemented according to this policy.

Object substances and numbers of substances have been decided for each year for each environmental medium based on the 67 substance groups listed up in SPEED '98 (revised to 65 groups in 2000) according to the status of detection.

11.1.2 Results of survey

Table 11.1.2-1 shows the results of DEHP detection in each environmental medium.

11.1.3 Actions to be taken in the future

Although environmental monitoring of DEHP in the public water and atmosphere was not implemented in 2002, survey on tap water, sewage water, fishes and shellfishes, and indoor air is being continued. The plan for environmental monitoring will be established based on the results of risk assessment conducted by Ministry of the Environment and other organizations.

11.2 Actions taken by Osaka Prefecture

11.2.1 Background

In 2001, Osaka prefectural government selected 11 substances, whose concentrations in the Osaka area were higher than the average values in Japan in the survey conducted by Ministry of the Environment and Ministry of Land, Infrastructure and Transport in the period from 1998 to 1999, from the 20 substances that had been designated as preferential substances.

11.2.2 Results of survey

General survey on the environmental hormones was carried out by Osaka Prefecture in 2001, and in the interium report the results of surveys on phthalates conducted by various organizations in the period between 1998 and 2001 were also summarized. Table 11.2.2-1 shows the results of this survey.

11.2.3 Measures that have been taken and actions to be taken in the future

(1) Measures that have been taken

From the viewpoint of the prevention of air pollution, Osaka prefectural government established “Guidelines for appropriate management of chemical substances in Osaka Prefecture” based on Article 40 of Ordinance on the preservation of living environment in Osaka Prefecture, and put it into force in May 1995.

The purpose of Article 40 is to classify hazardous chemical substances for the human health (carcinogenicity, general toxicity) into regulated substances and controlled substances, and to restrict the release regulated substances (mandatory approach) and oblige the business firms to implement appropriate voluntary control to suppress the release of controlled substances (voluntary approach). The purpose of the obligation of appropriate control is to promote the voluntary control of low-harm substances by business firms so that penalties are not included.

(2) Future actions and measures

As to substances that are not regulated at present such as phthalates, information on measurement results of surveys conducted by the national government and other organizations, results of risk assessment and hazardous assessment will be collected and the reduction of release by voluntary actions of business firms will be promoted.

Table 11.1.2-1 Detection of Bis(2-ethylhexyl)phthalate (Tokyo Metropolitan)

Year		Water of river and sea (μg/L)	sediments of river and sea (μg/g)	Atmosphere (ng/Nm^3)	Indoor air (ng/Nm^3)	Fish & Shellfish (μg/g)				Tap water (μg/L)	Sewage outflow (μg/L)	Sewage inflow (μg/L)
						Common sea bass	Mullet	Gizzard shad	Blue mussel			
1998	Detection ratio	10/34	15/17	0/20	-	-	-	-	-	0/5	23/48	19/19
	Range	ND to 17	ND to 7.8	ND	-	-	-	-	-	ND	ND to 4.9	7.2 to 40
1999	Detection ratio	9/34	17/17	41/60	69/69	0/10	0/10	0/10	0/10	5/24	29/49	47/47
	Range	ND to 0.15	ND to 7	ND to 130	51.8 to 592	-	-	-	-	ND to 0.5	ND to 1.9	5.3 to 31
2000	Detection ratio	5/34	16/17	59/60	135/135	0/10	0/10	0/10	0/10	5/24	16/21	21/21
	Range	ND to 0.8	ND to 4.4	7.6 to 300	15 to 2370	-	-	-	-	ND to 0.4	ND to 1.2	5.6 to 22
2001	Detection ratio	9/34	16/17	46/60	134/135	-	-	-	-	6/14	8/8	8/8
	Range	ND to 5	ND to 5	1.8 to 29	ND to 1350	-	-	-	-	ND to 0.4	tr to 0.9	6.3 to 15

Table11.2.2-1 General survey on environmental hormones in Osaka Prefecture in 2001(Excerpt for phthalates)

Name of water area	Name of river	Sampling sopt	Water: Phthalates (μ g/L)					Sediments: Phthalates (μ g/kg·dry)				
			Bis (2-ethylhexyl) phthalate	Benzyl butyl phthalate	Di-n-butyl phthalate	Dicyclohexyl phthalate	Diethyl phthalate	Bis (2-ethylhexyl) phthalate	Butyl benzyl phthalate	Di-n-butyl phthalate	Dicyclohexyl phthalate	Diethyl phthalate
Water area of Kanzaki-gawa	Kanzaki-gawa	Tatsumi-bashi	N.D.	N.D.	N.D.	N.D.	N.D.	3200	N.D.	130	19	N.D.
Water area of rivers in Osaka City	Aji-gawa	Aji-gawa-ohashi	N.D.	N.D.	N.D.	N.D.	N.D.	8300	N.D.	330	37	N.D.
	Kizu-gawa	Senbonmatsu-watashi	N.D.	N.D.	N.D.	N.D.	N.D.	7200	N.D.	230	93	N.D.
Water area of Senshu rivers	Otsu-gawa	Otsu-gawa-bashi	N.D.	N.D.	N.D.	N.D.	N.D.	850	N.D.	55	N.D.	N.D.
	Haruki-gawa	Haruki-bashi	N.D.	N.D.	N.D.	N.D.	N.D.	1700	N.D.	220	N.D.	N.D.
	Chikagi-gawa	Chikagi-gawa-bashi	N.D.	N.D.	N.D.	N.D.	N.D.	1700	N.D.	49	N.D.	N.D.
	Miide-gawa	Miide- bashi	N.D.	N.D.	N.D.	N.D.	N.D.	1200	N.D.	48	N.D.	N.D.
	Kashii-gawa	Kashii-gawa-bashi	N.D.	N.D.	N.D.	N.D.	N.D.	1500	N.D.	51	N.D.	N.D.
	Ozato-gawa	Ozato-gawa-bashi	N.D.	N.D.	N.D.	N.D.	N.D.	820	N.D.	52	N.D.	N.D.
	Oh-kawa	Shonan-bashi	N.D.	N.D.	N.D.	N.D.	N.D.	1500	N.D.	41	N.D.	N.D.
Detection limit			0.3	0.02	0.2	0.01	0.01	25	10	25	10	10

12. Conclusion

The interim report consists of the survey of existing hazard and risk assessments, production and use of DEHP, emission scenarios and estimation of environmental concentration.

However, quantitative assessment of exposure to DEHP for humans and aquatic organisms was not implemented. For the future, it is scheduled to quantitatively assess the exposure of humans and environment to DEHP and its risk and further study the cost effectiveness of management measures. It is also necessary to determine endpoints in the risk assessment of DEHP for human health and environment based on the hazard information summarized in the interim report so that appropriate dose-response relationship can be selected.

Issues that must be studied in the future are as follows:

1) Refinement of emission scenario

   The uncertain estimation of release of DEHP to the environment from each life stage affects not only the results of exposure assessment but also the results of risk assessment and analysis of cost-effectiveness. The present estimation is significantly inaccurate and so it is necessary to refine the data on the changes in shipment of DEHP for uses by years, life-time of various end products made of flexible PVC resins, and emission factors for DEHP released from various end products in use and disposal waste.

2) Quantitative assessment of exposure

   It is clear that DEHP is released mainly into the atmosphere from the results of the study of emission scenario and published PRTR data. Therefore, it is necessary to estimate the concentrations in the atmosphere on a regional scale as well as to estimate the concentrations in the high-concentration areas around the facilities. The release to public water also cannot be neglected. For the exposure assessment with consideration to cost-effectiveness of measures taken for DEHP management, contribution of various exposure pathways from the source to humans and aquatic organisms must be quantitatively assessed. Therefore, it is required to estimate the concentrations of DEHP in the environment, exposure concentrations, and daily intake of DEHP using the models for estimation the concentration not only in atmosphere but also in soil and in water, as well as to validate the results of estimation obtained by these.

3) End points for risk assessment

   For the human health risk, the endpoints for the assessment and standard values such as TDI (tolerable daily intake) have been determined in Japan and overseas based on the results of toxicity studies of DEHP using rodents. However, since the study using Primates (marmosets) has been also reported, it is necessary to investigate the endpoints for risk assessment taking the species difference into consideration.

   As for ecological risk, it is necessary to study the physical influence on the interpretation of the results of ecotoxicity tests and water solubility. It is further necessary to investigate the effects on the benthonic organisms.

4) Cost effectiveness analysis of measures taken for DEHP management

   It is necessary to judge if the current management is adequate or not and propose the appropriate measure which have high cost-effectiveness based on the cost effective analysis for risk reduction measure.

—Summary of the interim report—
Bis(2-ethylhexyl)phthalate

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