Risk Management Report

－Current Status and Management Goals－

Bis (2-ethylhexyl) Phthalate

April 2006

National Institute of Technology and Evaluation

Study Group for Risk Assessment & Management of Phthalates

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Glossary of Abbreviations

ABPS	:	Alkyl phenol, Bisphenol A, Phthalate , Styrene：dimers,trimers
AIST	:	National Institute of Advanced Industrial Science and Technology
CDRH	:	Center for Devices and Radiological Health
CERHR	:	Center for the Evaluation of Risk to Human Reproduction
CERI	:	Chemical Evaluation and Research Institute
Chemical Management Guidelines	:	Guidelines for the Measures that should be taken for the Manegement of Class Ⅰ and Class Ⅱ Designated Chemical Substances by Business Firms that handle Designated Chemical Substances
Chemical Substances Control Law	:	Law Concerning the Evaluation of Chemical Substances and Regulation of Their Manufacturing, etc.
CMR	:	Carcinogenic Mutagenic or Toxic to Reproduction
DBP	:	Di-n-butyl phthalate
DEHP	:	Di(2-ethylhexyl)phthalate=Bis(2-ethylhexyl)phthalate
DHP	:	Diheptyl phthalate
DIDP	:	Diisodecyl phthalate
DINP	:	Diisononyl phthalate
DOA	:	Dioctyl phthalate
EDTA	:	Endocrine Disrupters Testing & Assessment
EU	:	European Union
EVA	:	Ethylene-vinyl acetate
FDA	:	Food and Drug Administration
GHS	:	Globally Harmonized System for Classification and Labelling of Chemicals
GMP	:	Good Manufacturing Practice
HPV	:	High Production Volume
IARC	:	International Agency for Research on Cancer
IFIA	:	Interior Floor Industrial Association
IPCS	:	International Programme on Chemical Safety
ISM	:	Interior Safety Material
ISO	:	International Organization for Standardization
JAIA	:	Japan Adhesive Industry Association
JCIA	:	Japan Chemical Industry Association
JEMA	:	The Japan Electrical Manufacturers' Association
JGMA	:	Japan Glove Manufactuers Association
JHO	:	Japan Federation of Housing Organizations
JHPA	:	Japan Hygienic PVC Association
JIS	:	Japan Industrial Standard
JMED	:	Japan Medical Devices Manufacturers Association
JPEC	:	Japan PVC Environmental Affairs Council
JPIA	:	Japan Plasticizer Industry Association
JPMA	:	Japan Paint Manufacturers Association
JRFMA	:	Japan Rubber Footwear Manufacturers' Association
JSEDR	:	Japan Society of Endocrine Disrupters Research
JSIA	:	Japan Sealant Industry Association
JTA	:	The Japan Toy Association
JVGMA	:	Japan Vinyl Goods Manufacturer's Association
METI	:	Ministry of Economy,Trade and Industry
MEXT	:	Ministry of Education, Culture, Sports, Science and Technology
MHLW	:	Ministry of Health,Labour and Welfare
MLIT	:	Ministry of Land, Infrastructre and Transport
MOE	:	Ministry of the Environment

MSDS	:	Material Safety Data Sheet
NAC	:	Noubi Recycle Acceleration Council
NEDO	:	New Energy and Industrial Technology Development Organization
NEDO1 Project	:	“Development of Chemical Substance Risk Assessment and its Methods” Project
NITE	:	National Institute of Technology and Evaluation
NOAEL	:	no-observed-adverse-effect level
NOEC	:	no-observed-effect concentration
NTP	:	National Toxicology Program
OECD	:	Organization for Economic Co-operation and Development
PAE	:	Phthalic acid ester
PPAR-α	:	Peroxisome Proliferator-activated Receptor-α
PRTR	:	Pollutant Release and Transfer Register
PRTR Law	:	Law Concerning Reporting, etc. of Releases of Environment of Specific Chemical Substances and Promoting of the Improvements of in Their Management
PVC	:	Poly (vinyl chloride)
RTO	:	Regenerative Thermal Oxidizer
SPEED'98	:	Strategic Programs on Environmental Endocrine Disruptors '98
ST-Mark	:	Safety Toy Mark
SV	:	Standard Value
SVOC	:	Semivolatile Organic Compounds
TDI	:	Tolerable Daily Intake
The(the) Study Group	:	Study Group for Risk Assessment and Management of Phthalates
TOTM	:	Trioctyl trimellitate
US	:	United States
VOC	:	Volatile Organic Compounds
WACOA	:	Wall Covering Association of Japan
WHO	:	World Health Organization

1. Introduction

In Japan, industrial production of DEHP began in 1949. In recent years, over 80% of the plasticizers used in Japan were phthalates, and over 60% of the phthalate used as plasticizer was DEHP. This means that DEHP is the most popular plasticizer, with a market share of about 50% of all plasticizers.

Supplies of DEHP in 2003 amounted to about 190,000 tons, more than 90% of which was used as a plasticizer for PVC resins, with the rest used as plasticizers for resins other than PVC as well as for printing ink, paints, adhesives, and ceramics. PVC resins with DEHP are used for a wide range of applications including products for electrical insulation, plastic sheets, general-purpose films, films for agricultural applications, wallpaper, flooring materials, steel plates coated with resins, hoses, medical devices, stationery products, sundries, home electrical appliances, and automobiles.

Since the media began to cover concerns about the harmful effects of DEHP in 1973, plasticizers other than phthalates are now used for most stretch films (plastic food wrap). Report on Environmental Survey and Monitoring of chemicals sponsored by MOE began in 1974, and DEHP was listed as a target substance. DEHP concentrations in water, sediment, fish, and rain were measured, and it was found that DEHP was widespread in nature. Based on such facts and the increase in the volume of production and import, DEHP was designated as an object substance in the safety inspection of existing chemicals according to the Chemical Substances Control Law, and it has been determined that DEHP is readily biodegradable and has a low bioconcentration factor. IARC and WHO jointly carried out an evaluation of carcinogenicity in 1982, and DEHP was classified as Group 2B (possibly carcinogenic to humans). In response to these results, plasticizer industry associations of Japan, the U.S.A. and European countries have carried out a series of toxicity tests beginning around 1994 and reported the results. In 1998, the results of research on species differences in hepatic tumor susceptibility using marmosets (small monkeys) were reported in an academic journal, which led to the reclassification of DEHP by IARC in 2000 to Group 3 (not classifiable as its carcinogenic to humans).

Around 1997, it became a matter of domestic and international public concern that nonylphenol, bisphenol A, and phthalates including DEHP might disrupt the endocrine system. In 1998, MOE published “SPEED’98—Chemical Substances List”, in which DEHP was listed as one of the chemical substances that might disrupt the endocrine system. Therefore, companies that used to use DEHP as a plasticizer or PVC products containing DEHP were driven to replace DEHP with other plasticizers or PVC resins with other resins. Under the circumstances, in August 1997 JCIA established ABPS Committee in order to collect and provide information. Furthermore, with respect to DEHP, which is the most commonly used phthalate, JPIA is carrying out animal tests, and JVGMA is measuring its emission from products. Some of the results of these tests have been already published.

The government has also recognized the importance of gathering additional scientific information related to the effects of phthalates on the endocrine system and the current condition of the environment; MHLW, METI, MOE, MLIT, and other related research organizations are carrying out various tests, investigations, and analyses.

The goal now is to perform risk assessment of phthalates based on the results of hazard assessment and exposure assessment so that appropriate management of phthalates can be implemented. However, many issues have not been clarified, such as the relationship between emissions and actual environmental concentrations, and the first step is to collect the scientific facts required for the appropriate risk management of phthalates. For this reason, in July 2002 NITE established the “Study Group” consisting of experts from industry, government, and academia. The task of this Study Group is to collect information on exposure and facts on usage relating to phthalates in general, especially DEHP. The Study Group published an interim report, and started to investigate how to manage the DEHP risk based on the results of risk assessment.

At around the same time, NEDO began the “NEDO1 Project” in 2001, and the initial and detailed risks of DEHP have been assessed as a part of the integrated management of chemical substances. The initial risk assessment concluded that the risk of DEHP was not considered to be a cause for concern with respect to

the environmental effects on aquatic organisms, and that more detailed assessment was needed relating to the effects on human health. A report published by MOE stated that endocrine disruption was not clearly demonstrated at that time and more detailed information on DEHP had to be collected. Then, AIST published "Risk Assessment Report Series 1: Phthalate Ester DEHP," in January 2005, based on the above-mentioned interim report and initial risk assessment report (see p.6 for details).

Regulation via laws, administrative directives, and the promotion of control is also being implemented for DEHP. The PRTR Law that was enacted in 2001 classifies DEHP as a Class I designated chemical substance due to production quantities and import levels, carcinogenicity, oral chronic toxicity, and ecotoxicity; and requires notification of the quantities emitted and transported, and the provision of MSDSs. Furthermore, based on Article 3 of the Law, the government announced "Chemical Management Guidelines", and any business firms involved are required to implement management of chemical substances, taking the guidelines into consideration.

In June 2000, MHLW established a tentative TDI for DEHP and published a notice on the use of PVC gloves containing DEHP when handling foods; furthermore, another notice on the elution of DEHP from medical devices was published in October 2002. In July 2001, guidelines for indoor air concentrations of DEHP were set forth; in 2002, the use of DEHP was prohibited in some applications (such as devices, containers package in contact with foods containing fats and oils or fatty foods, and toys intended for children under six years old) based on the notice "Partial Amendment of the Standards for Foods and Food Additives." (Figure 1)

The uses of this report are as follows.

- For industry: Planning the management of DEHP in the future.
- For government: Planning political measures (i.e. Promotion of the management of chemical substances).
- For the public: Assisting the public to understand the measures taken by industry and the government.

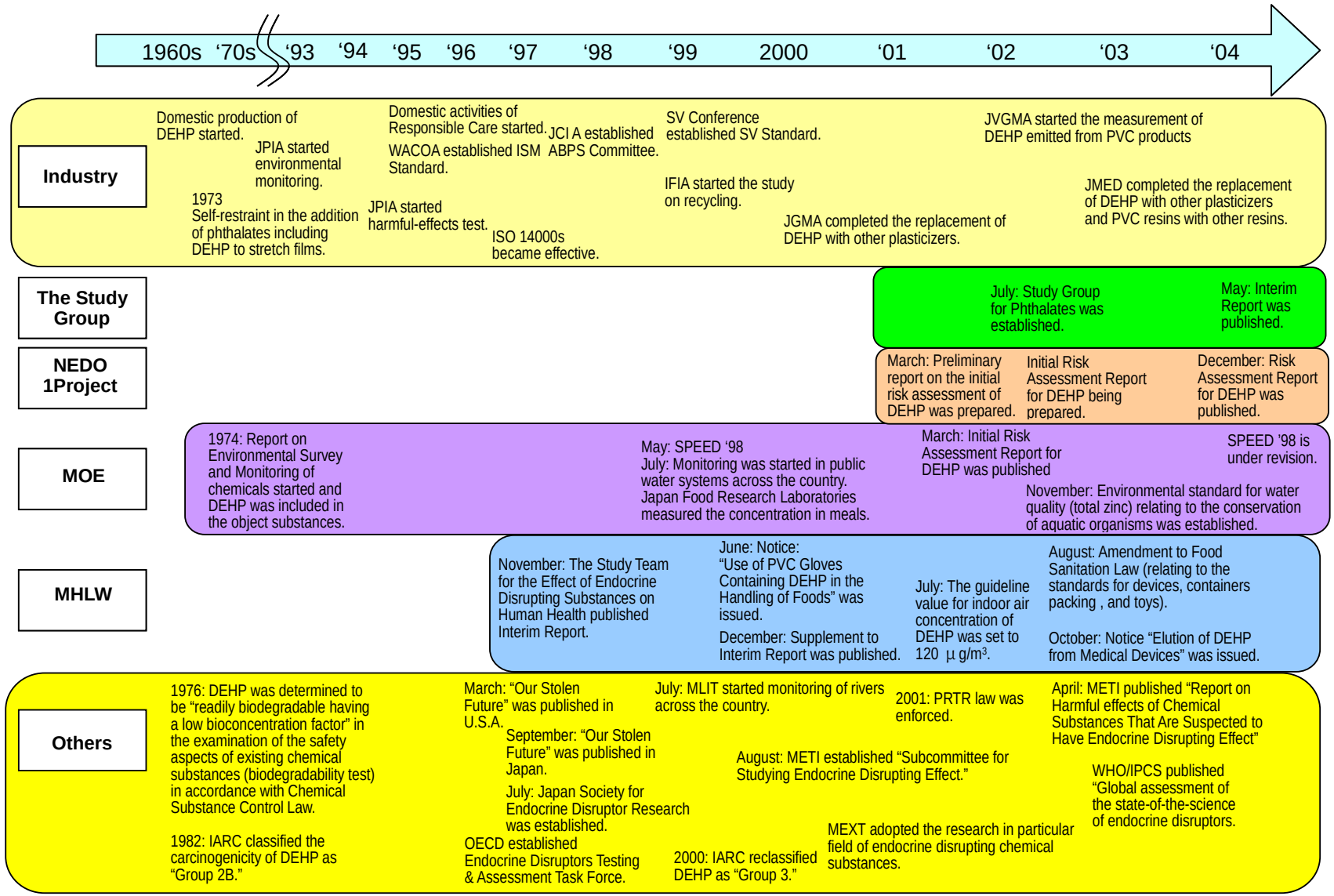

Figure 1. Time series for the completion of the best form of management

Table 1 and Table 2 show the changes in the domestic supply and market shares of phthalates, and quantities of domestic consumption of DEHP by applications, respectively.

Table 1. Changes in domestic supply and shares of phthalates

(thousand tons/year)

								Share（% of domestic supply of phthalates）		
Year	DEHP	DHP	DBP	DIDP	DINP	Others	Total	DEHP	DIDP	DINP
1992	276.4	22.1	12.0	10.6	71.8	20.6	413.5	66.8	2.5	17.4
1993	258.8	17.8	12.7	10.4	70.0	20.8	390.5	66.3	2.7	17.9
1994	284.9	9.4	13.0	10.0	77.9	23.9	419.0	68.0	2.4	18.6
1995	277.4	8.6	13.6	9.7	84.8	28.9	423.0	65.6	2.3	20.0
1996	285.3	7.4	14.0	8.1	90.0	29.3	434.1	65.7	1.9	20.7
1997	276.9	6.8	13.1	9.1	96.7	27.2	429.8	64.4	2.1	22.5
1998	227.1	6.2	10.7	7.6	94.5	20.9	367.0	61.9	2.1	25.7
1999	223.3	3.1	10.0	8.3	104.1	16.7	365.5	61.1	2.3	28.5
2000	219.3	0.0	9.1	8.7	107.0	16.2	360.3	60.9	2.4	29.7
2001	201.7	0.0	7.1	7.7	98.1	15.7	330.4	61.0	2.3	29.7
2002	194.9	0.0	5.4	6.8	94.4	15.9	317.4	61.4	2.1	29.7
2003	188.4	0.0	4.0	6.8	91.7	14.7	305.6	61.6	2.2	30.0

(Source: JPIA, 10 November, 2004.)

Table 2. Changes in the consumption of DEHP by application

(thousand tons/year)

Year	96	97	98	99	00	01	02	03	*03/96 (%)*
General-purpose films and sheets	44.7	44.4	35.4	33.7	31.5	27.9	27.6	27.6	*62*
PVC films for Agriculture	30.3	27.3	23.6	24.5	23.3	23.4	18.8	15.6	*51*
Leather	12.0	9.4	8.6	8.0	7.6	6.4	6.1	7.7	*64*
Industrial raw materials	35.5	32.1	24.6	24.0	24.4	21.9	22.3	23.3	*66*
Wire covering	50.1	45.8	39.5	40.6	36.6	32.0	33.9	31.6	*63*
Hoses and gaskets	16.4	15.6	12.7	12.6	12.5	10.6	9.7	7.8	*48*
Flooring materials	33.4	34.0	31.1	32.6	36.1	34.6	33.6	28.0	*84*
Wallpaper	25.8	27.1	19.3	17.0	18.9	18.4	18.8	25.3	*98*
Paints, pigments, and adhesives	15.4	16.8	13.6	13.2	12.3	10.8	10.9	9.1	*59*
Footwear	5.8	5.0	3.3	3.5	3.0	3.3	2.3	3.1	*53*
Others	15.9	19.3	15.7	13.5	13.1	12.5	10.9	9.9	*62*
Total	285.3	276.8	227.4	223.2	219.3	201.8	194.9	189.0	*66*

(Source: JPIA, 10 November 2004.)

Table 1 shows that the domestic supply of DEHP peaked in 1996 and decreased by about 100,000 tons (34%) in 2003. Compared with the supplies in 1998, when the replacement of DEHP started due to the endocrine disruption issue, the decrease was about 39,000 tons. On the other hand, the supply of DINP, which was the main substitute for DEHP, increased reaching a peak in 2000. Although supplies decreased somewhat after that, DINP is the only phthalate whose supplies increased compared with the annual supply in the first half of the 1990s. While the market share of DEHP decreased compared with that in 1998, the

share of DINP increased by 12% in 2003 compared with 10 years ago.

Table 2 shows, in the comparison between 1996 and 2003, declining rates of use in hoses and gaskets, PVC films for agriculture, and footwear, while the rate of decline for flooring materials is low.

2. Key points in planning the management of chemical substances

2.1 Importance of voluntary management

The role of industry in chemical substance management is very important. Society expects that business firms that manufacture or use chemical substances take a positive attitude towards managing their impacts so that environmental burdens are reduced and human health is protected. This is because the general public does not know how harmful each chemical substance is. Some chemical substances accumulate in the human body and the harmful effect appears later, while the harm from some substances appears immediately after contact or intake. In addition, the way chemical substances are used differs from firm to firm, so only the firm involved is considered to know the appropriate management method and is thus the most suitable party to be responsible for the management of the substance. In order to cope with problems caused by worsening global environment and developing technologies, it has become impossible to regulate based only on uniform rules. Therefore, it has become a global concept that business firms should act responsibly.

Under such a concept, it is essential for business firms handling chemical substances not only to comply with laws and regulations but also to voluntarily take appropriate measures that are considered to be necessary for preventing environmental effects and human health effects even when such measures are not required by laws and regulations.

The PRTR law aims to promote such voluntary management, requiring that business firms that handle designated chemical substances manage production and use of those chemical substances taking into consideration the Chemical Management Guidelines based on the law. This spirit of voluntary management should be also applied when handling chemical substances that are not designated by the law, as well as by business firms that do not have an obligation to give notification in accordance with the PRTR System established by law. In the chemical industry in Japan, “Responsible Care®” activities have already begun, and other industries have also initiated similar activities. Many companies have introduced environmental management systems like the ISO14000s, and the results achieved through these activities are published in annual reports.

2.2 Necessity of risk management over the life cycle of the substances

Business firms that handle and require chemical substances have managed them so as to keep a good balance between risks and the social and economic benefits to the public. In particular, manufactures are fulfilling the important role of implementing appropriate management by providing information (i.e. MSDSs) along the supply chain.

In many cases, in addition to the producers of chemical substances, downstream business firms play an important role in assessing the effects on humans and other living organisms.

However, because of external events the full expected benefits of voluntary measures cannot be obtained even with the best efforts of individual business firms to implement internal management of these chemicals. Therefore, when business firms plan risk-reduction programs, it is necessary to review the entire life cycle of the substance, assess the risk in a comprehensive manner, and focus on the applications and/or areas in which risks arise. Since such a risk management effort often expands beyond the territory each business firm can control, cooperation between business firms is required and public organizations also have to enter into the picture.

3. Results of risk assessment

In the NEDO1 Project, AIST carried out a scientific assessment on the risk for environment and human health caused by DEHP, and a Risk Assessment Report was published in January 2005, reffering to the Initial Risk Assessment Report prepared by the CERI and NITE, and using other available data, and used method developed by AIST. The Report was prepared on the assumption that the results of the assessment will be widely used by government organizations, business firms, and the general public. It was also intended that the data help business firms to recognize the risks associated with chemical substances and to manage them appropriately.

The Risk Assessment Report includes environmental risk assessment and human health risk assessment.

[Environmental risk]

In the environmental risk assessment, the end points were the effects (on vegetation, lethality, reproduction, growth, development, etc.) at the individual level (such as algae, crustacea (daphnia), fish, and amphibians). Aquatic environmental media were divided into two classes—water and sediment. Crustacea were considered to be affected by water quality and amphibians by sediment.

Measured DEHP concentrations in the environment were used for the exposure assessment. These data were taken from those published by the national government, local governments, universities, and research institutes during the period between 1998 and 2002.

In the risk assessment, the margin of exposure was calculated by dividing the NOEC obtained from toxicity tests on crustacea and amphibians by recurrentative values (such as the geometric average, 95th percentile, or maximum value) of the measured concentration in the environment (such as rivers, lakes, and sea water) for each year. Then the margins of exposure were compared with the factor-of-ten uncertainty that had been determined from the quantity and type of toxicity data. This showed that the margins of exposure for all years, calculated from geometric averages and 95th percentiles of the measured concentrations in water, were larger than the factor-of-ten uncertainty, which indicates that the risk is not significant (the same conclusion was also obtained for sediment).

For the spots of high concentration where the margins of exposure calculated using the maximum values were smaller than the uncertainty factor, the Risk Assessment Report reviews the possible causes and effects. The Report considers that there is little likelihood that DEHP produces harmful effects on aquatic organisms in these areas, but that it is necessary to continue investigation and periodic monitoring of these high-concentration areas in order to discover the source of the contamination.

[Human health risk]

Human health risk was assessed from animal test data. Two effects, on testicles and reproduction, were taken as the end points for assessing human health risk although the relationship between these two effects and the effect on the endocrine system is not clear. The possibility that DEHP is carcinogenic in human beings is deemed to be very low, judging from a comprehensive review of carcinogenicity tests using animals. Endocrine disrupting effects are not clearly seen in the tests performed by MOE.

In the exposure assessment, the effect on the testicles was examined in human males in the general population from 1 year old to 60's and infants of less than 12 months. The effect on reproduction was assessd in the general population (males and females) from 16 year old to 60's. Patients exposed to DEHP due to medical treatment were excluded from the assessment.

To determine DEHP intake (excluding infants), the values used for the assessment were obtained by multiplying the DEHP concentrations in meals analyzed by Japan Food Research Laboratories in 1998 and 2001 as commissioned by MOE, and the indoor air concentrations measured by Tokyo Metropolitan Government in 2000, by the food and respiratory intake of each age group. The results show that DEHP is taken in mostly through foods and that the DEHP intake in 2001 decreased to one-third that of 1998. As for

the DEHP intake of infants, for each age in days or months the values used for the assessment were obtained by multiplying the estimated DEHP concentrations in mothers' milk, commercially available dried milk, and baby foods by their consumption of each food. Using the results of these calculations, the distribution of DEHP intake for each age group is shown in the exposure assessment.

In the risk assessment, reference values for the assessment of effects on the testicles and reproduction were calculated by dividing the "NOAEL" obtained from animal tests, levels at which no effect on the testicles or reproduction is observed, by a margin value determined by taking the species difference between animals and humans and individual differences of humans into consideration. The risk was assessed by comparing the reference values with the distribution of DEHP intake of each age group. The assessment indicates that the human health risk is not significant in terms of effects on the testicles and reproduction, for all the DEHP intake distributions for all age groups.

The report concludes from a cost-effectiveness analysis of the measures to reduce DEHP emissions that the substitution of non-PVC resins after 1997 will contribute in the future to the reduction of DEHP emissions from products, that replacement of DEHP with other plasticizers such as DINP reduces the risk from DEHP, and that the installation of exhaust gas treatment facilities may place a heavy financial burden on medium and small business firms.

Based on this assessment of environmental risk and human health risk, the report concludes that the environmental risk and human health risk are not so high as to be of concern and that there is no need to take immediate action to reduce DEHP.

The Risk Assessment Report contains a great deal of information that can be referred to when companies in the industry draw up plans for DEHP management from now on. The report is not only based on precautionary approach, but also on the results of risk assessment derived from scientific information and analysis.

4. Current status of chemical management

With respect to legal regulation, DEHP is designated as a Class I chemical substances according to the PRTR law, and the use of DEHP is restricted in devices, containers package in contact with foods containing fats and oils or fatty foods, and toys intended for infants less than under the age of 6.

Under the circumstances, business enterprises that handle DEHP, DEHP producers and users (processing industries), are taking voluntary actions to prevent DEHP release into the environment. In addition, producers of DEHP are carrying out various animal tests and environmental monitoring in order to verify the safety of DEHP, and they are also promoting public information activities.

With respect to the implementation of legal regulations on DEHP used for the specific applications described above, the businesses concerned voluntarily complied with the legal regulations ahead of schedule by replacing DEHP with other plasticizers and substituting non-PVC resin products, so that countermeasures had almost been completed when those regulations went into effect.

Businesses whose applications are not subject to legal regulations are also replacing DEHP with alternative materials to meet the requirements of downstream users.

Actual examples of voluntary activities to meet legal regulations, prevent DEHP emissions into the environment, collect safety information, and promote public relations that are being implemented by business enterprises handling DEHP are described below.

A questionnaire survey and interviews were conducted on case examples of DEHP management and the results are summarized in Table 3.

Table 3. Measures taken by the industry

	Interviewed companies and industrial organizations	Measures taken	Commencing time
Producer	JPIA	Toxicity testing in animals Environmental monitoring Collecting, compiling, using, and providing information	From 1994 From 1993 —
Users			
PVC resins: General-purpose films and sheets Industrial raw materials Leather Wallpaper	JPEC JVGMA Companies A to H (WACOA) (SV Conference)	Replacing plasticizer (use in wallpaper: by company) Measurement of emission from products Collecting, compiling, using, and providing information Installation of facilities for exhaust gas treatment Waste management Promotion of recycling and reuse	From 1995 From 2002 — From 1960s — From 1970s
PVC films for Agriculture	Company D (NAC)	Installation of facilities for exhaust gas treatment Promotion of recycling PVC films for Agriculture Collecting, compiling, using, and providing information	From 1980 to 2002 From 1960s —
Hoses and gaskets	Japan Vinyl Hose Industry Association Company I and Company J	Plasticizers are being replaced for limited products. (by company) Promotion of recycling and reuse	— From 1972
Flooring materials	IFIA Company K	Promotion of recycling and reuse Installation of facilities for exhaust gas treatment	From 1999 From 2001
	Japan Carpet Industry Association Company L	Promotion of recycling and reuse (by company)	— From 2001
Paints, pigments, and adhesives	JPMA	Plasticizers are being replaced for limited products. (by company)	—
	JAIA	Plasticizers are being replaced for limited products. (by company)	—
	JSIA	Replacement of plasticizers is being studied.(by the industrial association) Plasticizers are being replaced for limited products. (by company)	— —
Footwear	JRFMA Company M Company N	Plasticizers are being replaced for limited products. (by company) Promotion of recycling and reuse	— From 1999 From the middle of 1980s
Others	JEMA	Plasticizers and PVC resins are being replaced. (by company)	From 1998
	JGMA	Response to legal regulations: Plasticizers have been replaced. (by the industrial association) (Gloves are not manufactured in Japan.)	From 1996 to 2000
	JTA	Response to legal regulations: Plasticizers have been replaced. (by the association) Replacement of PVC resins for limited applications (by company)	From 1999 to 2002 From 1999
	Company O (Baby goods manufacture)	PVC resins have been replaced.	From 1998 to 2002
	JMED	Response to notice Replacing Plasticizers and PVC resins. (infusion set and catheter) Collecting, compiling, using, and providing information	From January 2002 to March 2003

(Source: Study Group for Risk Assessment and Management of Phthalates)

As shown in Figure 2, there are four primary factors influencing the replacement of DEHP by the manufactures of products containing DEHP in Japan:

1) Response to regulations and administrative judgement

2) Prevention of harmful rumors

3) Response to consumers' needs

4) Self-restraint by the industry

The replacement measures taken so far have tended to be reactive, taking factors 1) and 2) into consideration, and active measures based on local initiative have not been taken. However, it should be appreciated that the measures have been fully enacted even though the motives may have been passive ones.

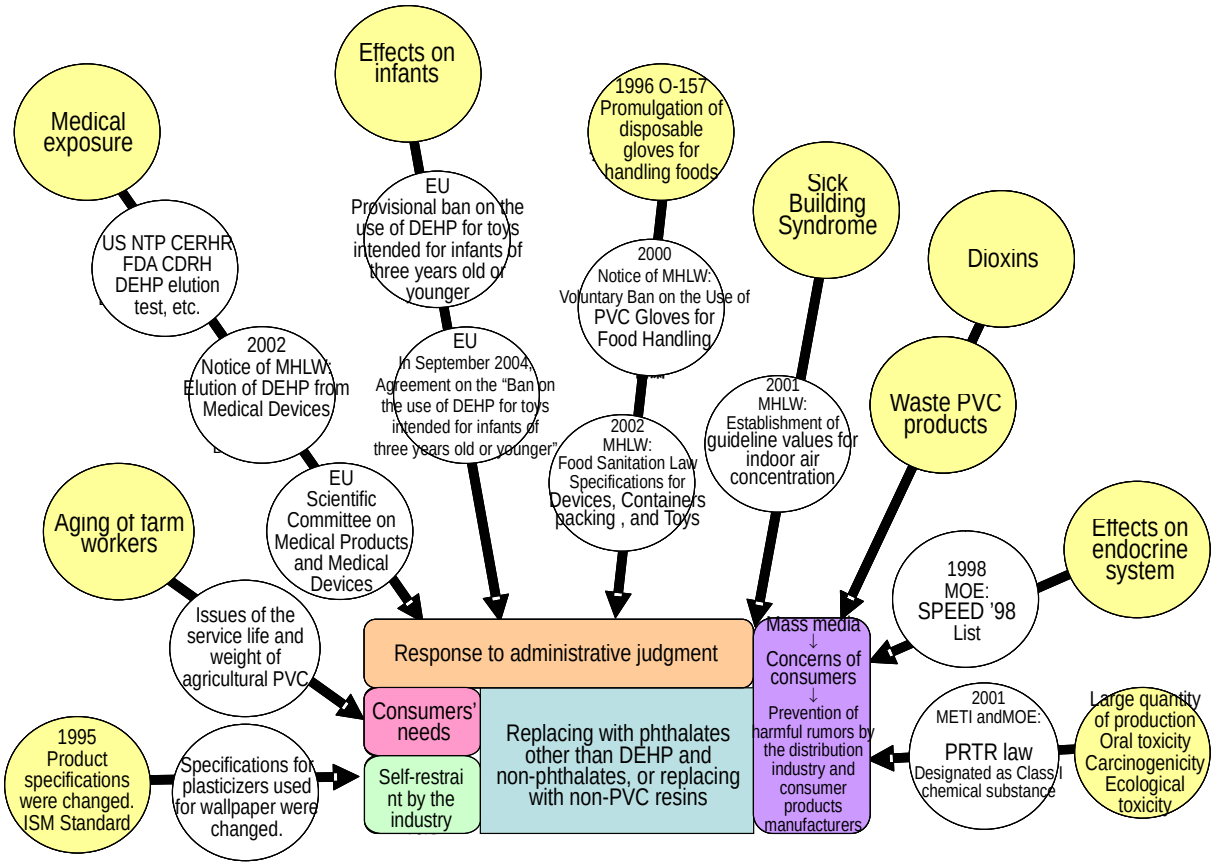

Figure 2. Background of the replacement of DEHP

4.1 Voluntary actions by the industry

In this section, details of voluntary actions in the supply chain are introduced based on a questionnaire survey and interviews.

(1) Manufactures (DEHP producers)

The number of domestic DEHP producers as of 2004 was three, and the JPIA is leading the DEHP management activities of the group.

The JPIA collects data on the quantities of production, export, and import of DEHP, and has provided the Study Group for Risk Assessment and Management of Phthalates with data for the 28 years from 1976 to 2003.

The JPIA has established an Environment Committee and a Technical Committee. The Environment Committee has a PAE (phthalic acid ester) Environmental Safety Committee, consisting of all members of the association, under which four working groups—Safety, Environment, Public Informations, and Investigation Working Groups—have been established. The Technical Committee, on the other hand, handles international issues and measures from a technical perspective in response to legal regulations such as MSDS, HPV, Fire Service Law, and GHS.

The JPIA emphasizes public informations activities, and publishes the informational magazine "Plasticizer Information" (twice a year) as well as brochures that explain the details of endocrine disruption. A website was also created in 2001 to provide safety information and MSDSs for seven plasticizers including DEHP.

The JPIA holds informational meetings for user companies and associations relating to the safety of plasticizers, toy issues, and material regulations based on the EU's CMR, etc. These meetings are usually co-hosted with the industries involved with PVC resins. The meetings have been held for various industries including the auto and electrical machinery industries as well as for government offices such as the Tokyo Metropolitan Government and the MLIT. In 2002, meetings were held in consumer centers across the country.

The JPIA has carried out 17 toxicity tests since 1994 as part of safety assessment. The results of these tests have been retained as internal information although some of the data have been published in brochures by the Association. However, the Association is now taking a positive attitude towards disclosing the data to the public, for example, by submitting papers to academic journals. A paper submitted to the academic journal "Toxicological Sciences" in 1998 contributed to the IARC's reclassification of DEHP from Group 2B to Group 3. The paper reported the results of 13-week repeated-dose toxicity tests using marmosets to determine the species difference for hepatic tumor.

In addition to those 17 tests, the following three tests are being carried out: 1) repeated-dose toxicity tests using juvenile marmosets for a detailed comparison of pharmacokinetics between rats and marmosets, 2) preliminary reproductive and developmental toxicity tests using pregnant rats and marmosets, and 3) tests using PPAR-α knockout mice. In addition, 4) a bio-monitoring test in which exposure is estimated by the analysis of human urine, and 5) reproductive and developmental toxicity tests using marmosets are being scheduled. Recently, these toxicity tests have been carried out with co-funding from plasticizer associations in Japan, the U.S.A., and Europe, and are focusing on the differences in toxicity between primates and rodents. The JPIA is playing a positive role in these programs by exchanging information with foreign countries and contributing to detailed risk assessment.

Furthermore, in 1993, the JPIA started environmental monitoring at 22 locations in Kanto and Kansai (8 streams that feed lakes and rivers, 6 groundwater sources, 4 running city water sources, and 4 sea water sites) twice a year in spring and fall. This monitoring was outsourced. In this environmental monitoring, three compounds, DEHP, DBP, and DINP are measured. The results of the monitoring are found on the website, and were also currented in the brochure "Plasticizers in Daily Life" published in April 2003.

(2) Users (DEHP users, and users of DEHP-containing products)

Most DEHP users are industries and companies that handle PVC resins. The following are measures taken by PVC-related industries and companies.

- JPEC:

JPEC is an organization consisting mainly of associations of processing industries of PVC products and PVC producer associations. In May 1997 the name was changed from the "PVC Recycling Promotion Council," which had been established in October 1991. The number of supporting companies is 113, and the main activities include technical research and development and surveys to solve the environmental problems caused by PVC resin and its products, technical research and development and surveys to

promote the recycling of PVC resin and its products, and the provision and promulgation of correct information on PVC resin and its products.

At current, the main method to determine the small quantity of plasticizers emitted from PVC products is a gravimetric method whose measurement accuracy is ±2%, and it is desired that a more accurate and sensitive method is developed. The analytical method for VOCs specified in a JIS Standard that was established in January 2004 cannot give accurate analytical values for plasticizers such as DEHP because they are decomposed in the sampling stage.

For this reason, JPEC developed an analytical method with high accuracy and sensitivity in cooperation with a private analysis center and in a two-year plan beginning in 2001 standardized the “Analytical method for measuring DEHP emissions from PVC resin construction materials”. This method is one the major candidates for the standard testing method for SVOCs in the standardization project, which the Japan Testing Center for Construction Materials is promoting under a three-year plan beginning in 2003.

- JVGMA:

JVGMA consists of 51 PVC resin processing companies (as of 2004), and has six working groups, according to the type of application such as the Compound Working Group and the Architectural Decoration Working Group. The Technical and Environmental Committee is made up of the technical chairperson of each working group and other members, and collects and reviews technical and environmental information on PVC resins and delivers the information to member companies. Information on the activities of these working groups and committees is available on the website. In particular, since December 2000, the Stretch Film Working Group has been disclosing information on chemical constituents of stretch films so that consumers can ascertain the safety of stretch films used for food packing .Furthermore, MSDSs for plasticizers were prepared and published in March 2002, for stabilizers in July of the same year, and for anti-fogging agents in March 2003. All the chemical materials whose data have been published are approved by JHPA as permissible additives to PVC products used for food packing .None of these chemical substances are included in the SPEED’98 list announced by MOE.

In response to enforcement of the PRTR law in 2001, JVGMA started to measure the amount of DEHP emissions per year from PVC products in 2002, ahead of public organizations. These data are expected to be used as the basic data for the non-point source estimation performed by MOE and METI in accordance with the PRTR law. The data obtained in these two years indicate that DEHP emissions are within the range of analytical error.

MOE is also carrying out similar tests, and similar results have been obtained. Both parities intend to continue additional tests for two more years in order to increase the accuracy of analysis.

According to the questionnaire survey conducted by NITE in 2002 (34 respondants/54 member companies), 32 of the 34 companies responding to the questionnaire are taking various measures to prevent DEHP emission into the environment. Five companies have installed exhaust gas treatment facilities and 15 companies are collecting volatile components using wet-type electrical precipitators or other equipment. Three companies are further planning an increase the number of precipitators, the introduction of deodorization equipment, or gelation of the paste. In addition, 15 companies are developing recycling technologies for waste materials.

Company A:

Company A is a manufacturer of stretch films (wrap) made of PVC resins. When the concern about the harmful effect of DEHP was covered by mass media, although DEHP was listed in the positive list (PL Standard) established under the leadership of the MHLW, Company A replaced DEHP with safer adipate plasticizers. The controversy surrounding harmful effects has cooled down, but the use of adipates continues.

Company B:

Company B is a producer of compounds for electric cables, automobiles, construction materials, and general merchandise. Company B assumes that DEHP is safe for human beings because of the IARC assessment that DEHP is not carcinogenic in humans and the assessment of MOE that no endocrine disrupting effect of DEHP in humans has been demonstrated. However, the company fulfills the requirements of downstream users for replacement of DEHP and legal regulations for devices, containers package of oil-based foods and toys..

Since phthalates are not suitable for devices, containers package for oil-based foods, they have not been used from the beginning. In toys, DEHP plasticizer and PVC resins were replaced with other plasticizers and non-PVC resins when concerns about the harmful effect of phthalates in toys were expressed in Europe in the late 1990s, so that the replacement had been completed when the legal regulations began to be enforced.

In addition, the company started to prepare product lists of devices, containers package for general foods that contain DEHP since the summer of 2003 in order to enhance quality control, and the list is reviewed periodically.

The requests for replacement by downstream users began as early as 1970, and the requests intensified every time the mass media took up the issue, such as when carcinogenicity became a concern and phthalates were listed in SPEED'98. When the measure is only to replace plasticizers, information to ensure safety is obtained from plasticizer producers.

When the measure is only to replace the plasticizer, the period required for replacement is from one to two weeks; however, it takes about one to six months to check quality and safety. However, this period is not sufficient to meet the requirement of the specification for automobiles "M-313-:88 PVC Leather for Automobiles" relating to haze (a phenomenon in which windows fog up due to the volatilization of plasticizers contained in interior materials at the ambient testing temperature). In order to meet this requirement, it is necessary to use plasticizers whose boiling point is higher than that of DEHP, and it requires six months or more to develop such plasticizers.

As to manufacturing facilities, electrical precipitators were installed in all the production lines for environmental pollution control so that the white fume from the stacks was eliminated in the latter half of the 1960s.

To reduce the volume of waste, production yield has been improved and the separation of scraps generated in the production line is completely separated so that the volume of waste disposed by landfills has been decreased by 30% in these three years.

Company C:

Company C manufactures a wide range of PVC products including foamed materials and calendered films. Giving special consideration to environmental pollution, electrical precipitators for exhaust gas control to reduce DEHP emissions was initially introduced in 1984, and then 20 sets of exhaust gas control equipment, such as fume eliminators using glass fiber felt rolls (HEAF), combustion deodorization equipment, and pipe filters, were installed in the order of estimated volume of emission by 2002. DEHP emissions in 2002 were significantly reduced (by 75%) compared with emissions in 2001. Introduction of two sets of exhaust gas control equipment of the pipe filter type that were installed from 2001 through 2002 contributed to this significant improvement.

Since the 1950s, Company C has been recycling the waste materials of single-layer PVC products such as films generated in the plant, and composite products consisting of different materials, such as leather and wallpaper, are disposed by landfill. The composite materials were recycled in the 1970s, but this was halted because of low cost-effectiveness. From the viewpoint of effective utilization of resources, however, in 2001 a process was initiated to crush composite materials to separate PVC resins from other materials so that only PVC resins are recycled. As a result, the amount of DEHP in waste was reduced by half from

2001 to 2002.

Company D:

Company D, a producer of agriculture vinyl films, installed electrical precipitators in the rolling plant of the production line in the latter half of the 1980s. Since DEHP was listed in SPEED'98 and designated as a Class I chemical substance of PRTR Law in the latter half of the 1990s, a policy to enhance voluntary management was adopted, and the capacity and number of electrical precipitators increased in April 2002. This resulted in a 30% reduction in DEHP emissions into the atmosphere in 2002 compared with 2001. These results have been published as environmental reports.

A five-year plan to reduce waste materials started in 1999 by separating waste plastics and recycling waste product, which has resulted in the reduction of DEHP in waste by one-thirds. Furthermore, part of the DEHP collected by the electrical precipitators is reused.

Although Company D is considering replacing DEHP with other plasticizers as well as producing polyolefin films for agricultural, users favor agriculture vinyl films containing DEHP because they have been using them for a long period and they like the performance of vinyl films. Therefore, DEHP continues to be used while information is exchanged with the JPIA to ensure safety.

To enhance the recycling system for waste agriculture vinyl films, Company D established the NAC in cooperation with companies in the same trade and related associations in 1999. The objective of the NAC is to realize a completely recycling society in the future. The actual extent of recycling in 2001 was 48.1%.

Company E:

Company E uses DEHP as a plasticizer for PVC resins used for agriculture vinyl films, leather, and wallpaper. Due to the dioxin issue in the first half of the 1990s and endcrine disrupting issue in the latter half of the 1990s, soft polymers that did not contain chlorine and plasticizers were required for wallpaper, and the technology that met this requirement was developed in the period from 1998 through 1999.

From 2001 through 2002, production of agriculture vinyl films and leather was shifted to overseas countries and the company withdrew from domestic production. In the period from 2000 through 2001 there was a changeover to epoxy plasticizers and olefin resins for wallpaper.

The major reason why DEHP emission into the atmosphere in 2002 was reduced to one-fourth that of 2001 is considered to be the reduced volume of DEHP handled in the production process.

The company installed electrical precipitators in the first half of the 1970s in order to treat exhaust gas, and has been trying to increase the treatment capacity by increasing the number of washing and enhancing facilities.

<Wallpaper>

- WACOA

WACOA established an ISM standard called "Guidelines for interior materials with consideration for the safety of the living environment" in June 1995, and it came into effect in February 1999. Article 5 of the standard requires that plasticizers used in the production line and for the products must have a boiling point of 400°C (760 mmHg) or higher so that the global environmental burden is reduced. At the time when the standard was established in 1995, the ISM Organization of the WACOA specified the boiling point as 400°C or higher with the intention to exclude DEHP from usable materials because the harmful effects of DEHP became irrefutable. The ISM Organization is reviewing the standard with the purpose of revising it in 2004, and it is intended to change the expression relating to plasticizers to "When using phthalate plasticizers, the boiling point shall be 400°C (760 mmHg) or higher." In addition to wallpaper, this standard specifies requirements for curtains, carpets, water-based paints for interior decoration, and adhesives for wallpaper.

- SV Conference

The SV Conference, which was organized in January 1999, established a SV standard with the purpose of providing wallpaper products suitable for generating safer, healthier, and more pleasant environments for human living. To prepare the standard, German quality control standards for wallpaper and Japanese JIS A 6921 “Wallpaper and wall coverings for decorative finishing” were taken into consideration and an original concept was added so that higher safety is achieved. According to the SV standard, “plasticizers shall be refractory substances having a boiling point of 300°C or higher. DBP shall not be used.” DEHP meets this requirement.

- JVGMA (Interior Decoration Working Group)

According to the questionnaire survey conducted by NITE in 2002 (34 respondents out of 54 member companies), the quantity of DEHP used for wallpaper by the member companies of JVGMA in 2001 was about 6,300 tons.

DEHP used to be used as a plasticizer for wallpaper, but it was found by the survey conducted by JVGMA in 2004 that about 35% of the member companies of the Association had replaced DEHP with DINP whose boiling point is higher than that of DEHP.

Company F:

Company F has been using DINP rather than DEHP as a plasticizer since before endcrine disrupting issue arose and caused concern about PVC resin wallpaper. Although it is intended to replace all the DEHP used, it is difficult to replace completely with DINP because DINP is expensive and the cost cannot be passed on to the product price, the total amount of domestic production and import of DINP is not sufficient to replace all DEHP used for wallpaper, and the installation of exhaust gas treatment equipment, although it was once considered, is difficult due to its high cost and the level of carbon dioxide emissions. Since DEHP is also easier to handle in the production line, DEHP is still used, in spite of endcrine disrupting issue, with a continuing exchange of information with the JPIA to ensure safety.

Company G:

Company G mainly produces long-life products such as wallpaper and leather, and currently uses DEHP as a plasticizer. Although users requested that DEHP be replaced when endcrine disrupting became an issue around 1998, Company G was concerned about the increase in cost and change in product quality. The company discussed safety issues and the possibility of replacement with the JPIA, carried out the volatility test specified by the JIS Standard, and confirmed that the indoor air concentration was lower than the guideline value. Consequently, Company G is still using DEHP.

Although some companies use DINP as a substitute for the wallpaper plasticizer, Company G does not use it because the domestic supply of DINP is insufficient and the price is high. When users request the use of plasticizers other than DEHP regardless of higher cost, the company uses plasticizers such as adipates. Regarding the reduction of DEHP emissions, the company installed two electrical precipitators in the embossing process and foaming process when the plant was built. These facilities are continually renewed to prevent deterioration due to aging. In 1996, a wet-type electrical precipitators was added at a cost of 80 million yen. The waste oil collected by the electrical precipitators is passed over to an external contractor and used as a fuel. In 2002, there was a complaint about unpleasant odors from neighboring residents and the town office. Therefore, RTO was installed in order to conform to the prefectural ordinance. Although the initial investment was about 100 million yen and the yearly running cost is about 10 million yen, odor concentration has been reduced by about 90% and complaints from neighboring residents have disappeared. Since waste oil is not generated as a result of the RTO installation, the volume of waste has also been reduced. In addition, RTO is expected to be introduced as an effective measure in the VOC regulation under the Air Pollution Control Law that is currently under study.

Although waste materials are properly treated, it is difficult to recycle waste product of wallpaper and leather products because their surfaces are printed with patterns and using them as raw material degrades product quality. Although there are machines to finely pulverize wallpaper and leather, and collection traders are operating, these approaches are not cost effective. Since waste materials are also generated from the demolition of buildings, it is thought to be necessary to establish an integrated recycling system that enables recovering of all these materials including flooring materials.

Company H:

Company H produces various types of wallpaper, for many of which DINP is used as a plasticizer, and DEHP is used only in a limited number of products. The company started to study the replacement of DEHP with DINP as early as 1994 – 1996 before endcrine disrupting became an issue, and the replacement has been implemented gradually. The replacement is a slow process because DINP is more expensive than DEHP and DEHP is easier to handle in the foaming process. Furthermore, the extent of unpleasant odor emissions initially differed from manufacturer to manufacturer and it was necessary to select manufacturers with caution to avoid complaints from neighboring residents relating to these odors. The reason that DEHP emissions into the atmosphere in 2002 were reduced by more than 90% was the replacement of DEHP with DINP.

In the wallpaper being produced using DEHP, the company does not intend to replace DEHP because this does not appear to be a safety issue, since the concentration of DEHP in indoor air is lower than the guideline value, and the alternative materials are expensive.

Since many users ask what kinds of chemical substances are contained in wallpaper products, the company has prepared MSDSs as explanatory material for users.

When the plant was built, cooling filters were used for exhaust gas treatment. However, an electrical precipitator was installed in 1993, and its performance was further improved in 1999. When the facility was upgraded, about 100 million yen was spent so that the exhaust gas from all three production lines is treated together. Measurements of odor concentration showed that the removal rate achieved by the electrical precipitators was higher than 90%. Taking into consideration the VOC regulation that is currently under study due to the Air Pollution Control Law, RTO installation is being investigated.

Although reduction in waste materials is being studied, actual measures have not yet been taken. Since wallpaper is thin and contains a paper component, unlike the case with flooring materials, recycling is difficult. The company is now investigating pelletizing after finely shredding the paper, and how best to make use of the pellets.

<Hoses and gaskets>

- Japan Vinyl Hose Industry Association

Company I:

Company I uses DEHP for gardening hoses, industrial tubes, pressure hoses (for household use, agricultural and gardening use, transportation of industrial water, transportation of mineral oil, etc.), compounds (for electrical cables, automobiles, construction materials, and packing), and has been recycling the waste materials in-house by pulverizing since 1972. In addition, the waste materials have also been used outside the company from 1999 as internal fillers for construction materials and resins.

Further, when the foods and toy standards of the MHLW were amended, DEHP was replaced with DINP, polyester plasticizers, and trimellitate plasticizers. The future replacement of PVC resins with polyolefin materials is also under consideration when required by legal regulations or the customer.

Company J:

Company J, which uses DEHP for PVC products (hoses) started to reduce and reuse waste materials around 1990.

Since DEHP is listed in SPEED'98, the company is considering the replacement of DEHP with TOTM and adipate polyesters.

<Flooring materials>

- IFIA:

The IFIA, consisting of eight manufacturers of PVC flooring materials, initiated studies of the recovery and reuse of discarded materials generated in new construction of buildings, and was designated a "wide-range area recycling industrial waste disposal firm" by MOE in March 2003, a first for an industrial association, and it started recycling "from flooring material to flooring material." Research on the separation of PVC flooring materials from their concrete bed has been conducted since 2002 because PVC flooring materials are directly glued down to concrete in most buildings, and it is difficult to separate the PVC flooring materials from the concrete.

According to the questionnaire survey conducted by NITE in 2002 (8 respondents/8 member companies), the amount of DEHP used by the member companies of the IFIA in 2001 was about 24,000 tons.

Company K:

Company K revamped its electrical precipitators, which had been installed in the flooring material production line in 2001, to collect DEHP and other chemical substances in the exhaust gas and to improve collection efficiency as measures to reduce DEHP emissions into the environment.

In addition, waste product generated in the production line are recovered and pulverized for reuse as raw material, which reduces the amount of DEHP used.

- Japan Carpet Industry Association:

Company L:

Company L is a manufacturer of carpet tiles for flooring. The company started to recycle waste materials generated in the plant to reduce the raw material cost, a move not aimed solely at DEHP. After that, the use of waste materials generated outside the company was studied and this has been in full operation since 2003.

While believing that DEHP is the best plasticizer for PVC resins at current, the company is trying to reduce the amount of DEHP it uses.

<Footwear>

- JRFMA:

Company M:

Company M, which uses DEHP for general-purpose footwear, has been recycling sole materials since 1999.

The company is also investigating the replacement of DEHP with adipate plasticizers when legal regulations are enforced or customers make this a requirement.

Company N:

Company N, which uses DEHP for general-purpose footwear, has been reusing the sprue (material block solidified in the runner) generated in the molding process of thermoplastic resins since the middle of 1980.

The company is also investigating ways to reduce the quantity of industrial waste in the future. When dioxin became a serious social issue, PVC resins were replaced with non-PVC resins. Further replacement for the sake of reducing environmental burdens is also being studied.

<Other applications (electrical machinery)>

- JEMA:

JEMA is an industrial association consisting of companies that manufacture electrical machinery and apparatus, motors for power generation, and nuclear plant components, and components for related businesses; it has 187 regular members and 94 supporting members. The member companies use products containing DEHP, such as adhesives and paints, and PVC products, such as electrical cables and various parts.

The Association has an "Environment Policy Committee," and a meeting of the "Chemical Substance Integrated Management Expert Committee" of the Environment Policy Committee is held every month to exchange information. Unscheduled meetings are also held as required, and working groups are organized as required.

When the SPEED'98 list was published, industry marketing people requested that these materials be avoided, and there was a tendency for many companies to follow the crowd. Each company ranked chemical substances based on independent criteria, and now to some extent they self-regulate their use of products containing DEHP and those made of PVC. This resulted in regulations being imposed on upstream manufactures who produce raw materials or components. Some companies describe the measures taken for these materials in advertising media or environmental reports.

4.2 Activities of the industry in response to legal regulations

(1) Notices (medical devices, gloves)

1)"On the Use of PVC Gloves for Foods" (Notice of MHLW: June 14, 2000)

When DEHP was detected in foods cooked at a feeding center in Nishinomiya in 2000, investigation by MHLW traced the contamination to elution from gloves made of PVC. In the deliberations of the joint meeting of the Toxicity Working Group and the Devices, Containers and Packing Working Group of the Food Sanitation Investigation Council, it was concluded that DEHP had testicular and reproductive toxicity, and the tentative TDI of DEHP was determined to be 40 to 140 μg/kg/day, and this notice was given to related parties.

- JGMA:

The JGMA is an industrial association consisting of 20 companies that manufacture gloves made of natural rubber, PVC, synthetic rubber, polyethylene, etc. The name of the Association was changed from the earlier "Japan Rubber and Vinyl Glove Industrial Association" in March 2002. There are three working groups according to the particular application— the Professional Glove Working Group, Household Glove Working Group, and Medical Glove Working Group, and the issue of gloves made of PVC was studied by the Household Glove Working Group (8 member companies).

Problematic gloves were disposable gloves called "Disposals." These gloves were not manufactured in Japan but imported mainly from Malaysia. Although disposable gloves were used for medical use, their use in the food industry and households increased drastically after the Ministry of Education issued "Guidance for the Use of Gloves When Cooking School Catering, etc." as a measure against "food contamination due to O-157" that occurred in Osaka prefecture in 1996.

Recurrentatives of the association visited the overseas companies that produced the gloves shipped to Japan, and explained the contents of the notice. Consequently, alternatives to DEHP are now used. As to importers who are not members of the association, it is not clear whether they have conformed to the notice.

Most professional gloves other than Disposals are also imported from Malaysia and Taiwan, and it is understood that in Taiwan also DEHP was replaced with non-phthalate plasticizers after the notice was

issued.

Gloves for household use are mostly manufactured by overseas plants owned by Japanese manufactures or outsourced to overseas companies. Japanese manufactures reported to the MHLW that the replacement of DEHP with other plasticizers had been completed before the notice was issued.

2)"On the Plasticizer (DEHP) Eluted from PVC Medical Devices" (Notice of MHLW: October 17, 2002)

MHLW tested the elution of DEHP from medical devices in 2001, and issued this notice based on the test results. In the United States, a draft recommendation to replace medical devices made of PVC containing DEHP with those made of other materials as required was issued in July 2002, three months before the notice. This recommendation was based on the results of tests on elution of DEHP from medical devices carried out by the CDRH of the FDA.

- JMED:

JMED consists of companies that manufacture or sell artificial heart-lung machines, artificial kidneys, catheters, infusion solution bags, tubes, etc., with 240 regular member companies and 30 associate member companies. The association has 13 working groups according to product type and 11 committees including Public Relations, GMP, Medicine Act, and Safety Information. The notice was discussed in the Environmental Issues Committee.

According to the questionnaire survey conducted by NITE in 2002 (19 respondents), the amount of DEHP used by the members of the JMED in 2001 was about 2,900 tons.

Some of the requirements of the notice had been already implemented because the administrative board of the association established voluntary standards, "Precautions for the Use of Products Containing DEHP," on January 15, 2002. This took into account the information from the safety assessments conducted by various overseas organizations into DEHP eluted from medical devices made of PVC resins and the information that the MHLW was carrying out similar tests, and the association informed related business firms of these precautions.

Member companies were sufficiently informed of the notice, and the status of implementation was checked by a questionnaire survey.The results of the survey which is the list of replacements with plasticizers other than DEHP and non-PVC resins for medical devices subject (infusion set and catheter) to the regulation were released on the website of the association on March 17, 2003. The results are summarized in Table 4 and Table 5.

Table 4. Products in which DEHP has been replacing with other plasticizers

Product	Substitute material Number of cases is shown in（ ）.	Remarks
Infusion set	TOTM(90)、DOA(2)	Tube section
Extension tube for catheter	TOTM(12)	
Manifold set	TOTM(4)	Tube section
Implantable catheter set	TOTM(5)	Tube section
Syringe set	TOTM(4)	Tube section
Feeding tube	TOTM(34)	
Dialysis circuit for artificial kidney	TOTM(1)	Tube section

Table 5. Products in which PVC resins have been replacing with other materials

Product	Substitute material Number of cases is shown in ( ).	Remarks
I/A tube for ACS	Silicone (1)	Tube section of ultrasonic surgical instrument
Infusion set	Polybutadiene (223), thermoplastic elastomer (12)、silicone (12), polyethylene(3)	Tube section
Extension tube for catheter	Polybutadiene（66）, polyethylene (42), teflon (11), polyethylene-EVA double-layer (10), polyurethane (3), polypropylene (1)	Polyethylene is used for the wetted part of the double-layer tube
Feeding tube	Polyurethane (84), silicone rubber (33), polybutadiene (17), natural rubber (6), polyolefin (1)	

(Website of the JMED: Medical devices such as infusion sets and catheters that do not contain DEHP)

(2) Amendments to standards for devices, containers package, and toys

The health science research of 2000 made it clear that when PVC products containing DEHP contacted foods containing oil, DEHP easily migrated into the foods. As to toys, health science and other research on the oral behavior of infants has demonstrated that infants often continue to suck on a pacifier for extended periods, and DINP elution tests showed that it was possible that a large quantity of DINP was eluted into saliva when adults chewed test specimens made of PVC containing DINP, although quantity of migration in the mouth varies widely. Based on these facts, standards for phthalates have been amended.

1) Amendment to the standards for devices, containers package (notified August 2, 2002 and enforced August 1, 2003 by MHLW.)

Synthetic resins whose principal component is PVC containing DEHP shall not be used for devices, containers package for foods containing oils and fats. This provision does not apply if there is no possibility that DEHP is eluted or seeps out so that it is blended into the foods.

- JGMA

The JGMA carries out the test specified by the standard (measurements of content and elution for DEHP) once a year in spring before new products are put on the market by outsourcing sampling tests to independent organizations.

Company O:

Company O, which is one of the major manufacturers of baby-related products such as baby tableware, nursing bottles, and toys, replaced PVC with polypropylene as much as possible before the notice was issued since distributors refused to accept products made of PVC around 1998. This was because it had become difficult to sell such products due to the endocrine disrupting effect and dioxin generation that were caused by PVC. Therefore, it was not necessary for the company to take additional measures when the notice was issued.

In-house standards for chemical substances are being established as part of the requirements for the acquisition of ISO14000 qualification. It is determined by the assessment of degradability of raw materials at the design stage whether particular materials are usable.

2) Amendment to the Standard for Toys (MHLW: notified August 2, 2002 and enforced August 1, 2003)

Synthetic resins whose major component is PVC containing DEHP or DINP shall not be used for toys that babies essentially hold in the mouth. Synthetic resins the major component of which is PVC containing DEHP shall not be used for toys other than those described above.

- JTA:

JTA consists of 212 regular member companies, which manufacture, sell, or distribute toys, one supporting member company, and 14 members who are wholesalers, warehouse dealers and industrial associations. Their main business is to familiarize and propagate the Safety Toy Standard System under which the ST-Mark is attached to toys that conform to the safety standard. The Safety and Environment Working Committee, one of the seven Working Committees, takes care of the safety standard for toys.

A self-imposed restriction that PVC shall not be used for toys that babies essentially hold in the mouth (Safety Toy Standard: ST-Mark) was established and implemented at the end of 1999. After the notice was issued, a revised Safety Toy Standard was announced on September 1, 2002 and the new standard was applied to the toys marked with ST from April 1, 2003. Conforming to this standard, member companies now use PVC resins that do not contain DEHP or DINP.

(3) Guideline values for indoor air

MHLW set the guideline value for indoor concentration of DEHP to 120 μg/m^3 (7.6 ppb) in "Guideline Values for Indoor Concentrations for Individual Substances, etc." adopted by the 7th Investigative Commission on Sick House (indoor air concentration) held on July 5, 2001. MHLW added the following explanation.

- The guideline values are set based on the best scientific information on toxicity that can be obtained at the current time so that human health does not suffer harm even if air with the specified concentration were to be inhaled by humans for a lifetime.
- For many substances for which guideline values have been set, the relationship between the substances and impaired physical condition has not been proved.
- It is expected that many people can avoid experiencing poor health by using construction materials that provide dwellings and buildings that conform to the guideline values based on the best information on toxicity that can be obtained at the current time, and by promoting these measures and ensuring that the parties concerned are familiar with them.
- The guideline values are subject to change, when necessary, as new information becomes available and is taken into account by international assessments.

MHLW asks related industries, relevant personnel such as managers of buildings, and the general consumer to fully appreciate the fact that the setting of guideline values does not necessarily mean that those substances exert harmful effects on humans under any circumstances.

- JHO:

JHO issued a press release on the revision of "Guideline for the Quality of Indoor Air Relating to Chemical Substances in Dwelling Houses" on May 2, 2003. The revision contains the provision that "to the greatest extent possible, building and construction materials that contain DEHP shall not be used for interior finishing."

- JPIA:

In response to the press release issued by JHO in May 2, 2003, the JPIA announced that there is no problem at current usage of DEHP on July 18, 2003, based on the following issues.

(1) The indoor concentrations of DEHP in Japan were about 1 μg/m$^{3.}$ (guideline value is 120 μg/m^3)
(2) The purpose of JHO, "early achievement of the guideline values for indoor concentrations" had already been reached.
(3) JHO revised the guideline not based on the present risk of DEHP.

- JAIA:

The Association has not taken any particular measures. Each company is taking measures based on its autonomous judgment (as of November 2004).

- JPMA

The Association has not taken any particular measures. Each company is taking measures based on its autonomous judgment (as of November 2004).

- JSIA:

Measures are under discussion at the Association. At current, each company is taking measures based on its autonomous judgment (as of November 2004).

4.3 Effects of current chemical management

Considering the facts that the DEHP concentration in the outdoor atmosphere remains unchanged and the concentration in water and sediment is tending to decrease, and the status of management described in this section, the voluntary actions taken by the industry contribute to reduce the emissions of DEHP into the environment and suppress the exposure of humans and aquatic organisms to DEHP.

Thus, it can be said that the voluntary actions taken by industry have brought about positive results even though some of the measures are passive ones implemented in response to external pressure such as SPEED'98 and guideline values for indoor air concentration.

As to legal regulations, a notice was issued and legal amendments were made to prevent exposure to DEHP emitted from products by limiting the applications of DEHP. Since relevant industrial associations had taken, generally speaking, voluntary actions in advance, it seems that necessary measures were taken before the assigned time limit.

As an actual example of achievement, investigations conducted in August 2000, two months after the notice "On the Use of PVC Gloves in the Handling of Foods" was given, showed that the average DEHP content in school-provided lunches and box lunches in the marketplace was 1/22 that of the previous year, 1999.

5. How should risk management be handled?

In this section, risk management that integrates both voluntary actions and legal regulations is described based on the results of risk assessment for DEHP and the current status of chemical management.

In the Risk Assessment report of NEDO1 Project, as described above, the effect at the individual level was taken as the assessment end point for the environmental risk caused by DEHP, and it was concluded based on the results of ecological assessment at screening level that the risk of DEHP to aquatic organisms is considered not to be at the level of concern in the marine system (water and sediment) in Japan. Therefore, it is concluded that the risk at the population level is also is not at the level of concern.

As for the risk to human health due to DEHP, assessment was made based on the testicular and reproductive effects observed in animal tests and the current exposure to DEHP (mainly through foods), and it was concluded that the risk to human health was not a cause for concern in either infants or adults.

Considering the results of risk assessment and the current status of chemical management described in Chapter 4, it can be concluded that the risk reduction measures that have been taken by industries and governments are effective to a certain extent because the supply of DEHP in Japan has decreased due to the decrease in the amount of use and promotion of recycling. Technologies to reduce DEHP emissions have

been introduced, and the exposure through foods has been decreased due to the restriction of applications.

Therefore, the Study Group proposes that it is not necessary to intensify the risk management of DEHP, or to add legal regulations, although the current level of management must be maintained.

Under the current legal regulations, relevant national and local governments took care to avoid creating prejudice against DEHP with alarmist comments. But, as a matter of fact, the regulations brought about a great impact beyond their original purpose. Governmental agencies should recognize the potential for this and take appropriate actions. However, the purpose of the Risk Assessment Report is not to verify whether such regulations are necessary or not. In addition, other detrimental effects caused by these regulations are not recognized at the current moment. It is recommended, therefore, that relevant parties review the necessity of these regulations by extending the current study, and that risk communication, including the risk assessment of alternatives initiated as a result of the implementation of regulations, is carried out adequately among stakeholders including governments in charge so that appropriate measures are taken.

The following are the opinions of the Study Group about risk management for DEHP. It is recommended that business firms that handle DEHP set voluntary management targets taking these points into consideration in order to continue the current management.

(i) Measures for risk reduction

When a business firm that handles DEHP plans to introduce new exhaust gas treatment equipment or recycling technology for the purpose of reducing the risk, it is recommended that the cost effectiveness be reviewed based on conventional criteria.

(ii) Replacing with alternative materials

Although it is the basis of business to accept a customer's request to replace DEHP, it is necessary to verify whether such replacement actually contributes to the reduction of risk. In the risk management, it is necessary to collect, compile, and utilize related information in addition to remaining in compliance with legal regulations. Manufacturers of alternatives for DEHP and the firms that have decided to use such alternative materials have a responsibility to collect information on harmful effects and exposure (especially of the concentration in foods) at the same level as that of DEHP and prepare correct and scientific analyses.

In the same way, when government promotes the replacement of chemical substances or when industry organizations such as industrial associations promote such replacement by self-imposed regulation, it is necessary to move ahead so that the replacement is effectively carried out without increasing the risk by collecting information on the alternative materials and giving the information to the related business firms.

(iii) Collecting information

1) Hazard

The results of risk assessment were obtained by covering all the data of animal tests available at the time and assessing the data, and then extrapolating it to humans. It is desired that industrial associations continue necessary tests in cooperation with overseas associations in the same business field as well as collect information on animal tests relating to species differences and their mechanisms, and submit them at international conferences.

2) Exposure

From the viewpoint of risk to aquatic organisms, there are some high-concentration spots, although the number is very small, where it is difficult to conclude that there is no need for concern because the MOE calculated, based on the data of the current risk assessment, from the maximum values of monitoring data is smaller than the analytical uncertainty factor. Therefore, it is desirable for the industry and monitoring at such high-concentration spots in order to discover their causes rather than proceeding to

countrywide monitoring of water and sediment.

JVGMA and MOE are now measuring DEHP emissions from PVC products containing DEHP. It is desired that the test data that have been taken are sufficiently reviewed so that useful data are obtained from now on so the results contribute to elucidating the amount of exposure from products.

From the viewpoint of risk to humans, risk assessment shows that most of the DEHP intake of Japanese people can be attributed to foods. It has not been sufficiently elucidated at current, however, how the DEHP emitted in the environment is carried to humans. Therefore, it is desired that industry and related public organizations continue to perform surveys, collecting information on intake, not from the viewpoint of the risk assessment results but from the viewpoint of risk management corresponding to the public concern.

(iv) Compiling and utilizing information

Manufacturers must continue to collect information on the quantities of production and import, quantities consumed by applications, the status and effects of the above-mentioned voluntary measures, and the results of risk assessment, and systematically compile the data in relation to regulations. In addition, it is necessary to construct a system that allows the supply chain to share information in case new information is obtained relevant to the future tasks described in the Risk Assessment Report and additional measures are required. Such information should be shared not only within the industry but also with the downstream consumer goods manufacturing industry, the distribution industry, consumer organizations, and the general public so that such information is used effectively in risk communication.

Information and risk communication should be continuously provided by the industry in a timely way, and multilaterally in cooperation with downstream industries and related local governments as much as possible.

(v) Role of public agencies

The role of governments is to make the public familiar with the correct meaning of legal regulations, and to promote the enrichment and utilization of this intellectual foundation.

6. Issues to be studied relating to phthalates

Phthalates, including DEHP, are used as plasticizers. There is a problem with their management as chemical substances in that they are emitted not only from plants where they are handled, but also from products (although this volume is not so large). This emission occurs through volatilization and elution, and the substances then enter the environment (the atmosphere, water, and sediment) as well as foods.

In the management of other phthalates, since their chemical properties are similar to those of DEHP, a system can be established by collecting information on harmful effects and exposure, keeping track of actual conditions of use, and carrying out autonomous risk assessment, making use of the results of the survey conducted by the Study Group. Furthermore, since these phthalates are used not only in Japan but also all over the world, research and development of new technologies and standards for the prevention of elution and volatilization, recycling, and methods of waste disposal must be conducted internationally, including in Asian countries.

- Dates of Study Group meetings

July 14, 2002
September 10, 2002
October 31, 2002
December 12, 2002
March 13, 2003
May 22, 2003
December 24, 2003
May 11, 2004
December 6, 2004

- Members of the Study Group

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1) URLs are as of January 31, 2005.

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