RISK REDUCTION STRATEGY

Bis(2-etylhexyl)phtalate, DEHP

CAS No: 117 – 81 – 7

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This draft risk reduction strategy was prepared by the National Chemicals Inspectorate, acting as rapporteur according to Regulation (EEC) 793/93 on the evaluation and control of the risks of existing substances.

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1 Introduction

Bis(2-etylhexyl)phthalate (DEHP) is on the second priority list of substances (26685/95/EC) drawn up under the Existing Substances Regulation (EEC) No 793/93. Sweden is rapporteur for DEHP and the National Chemicals Inspectorate is designated as the Competent Authority for Sweden. As rapporteur Sweden is responsible for assessing the risks associated with DEHP and preparing a risk reduction strategy for areas where the risk assessment concludes that risk reduction measures are needed.

The draft risk assessment report (RAR) was delivered by the rapporteur in 1999 and has been discussed in-depth at many Technical Meetings within the Existing Substances programme. The assessment was agreed in June 2001 and the RAR was finalised in September 2001.The Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE) delivered its opinion on the risk assessment in January 2002.

In June 2002, experts in the Technical Meeting continued the discussion. The rapporteur was asked to proceed to risk reduction with the agreed RAR from September 2001 as a basis, while experts were to examine later whether in some exposure scenarios any modified health risk conclusions would be justified by recent additional studies on reproductive toxicity.

The fact remains that the risk assessment for human health has identified several exposure scenarios where there is no disagreement over the concerns for reproductive toxicity. To delay the proceeding to risk reduction measures any more would be unreasonable and therefore the rapporteur has considered it prudent to develop a risk reduction strategy, based on all the originally agreed conclusions. The readers are trusted to bear in mind that some parts of the recommended strategy may need modifications, after agreement in future discussions.

1.1 Methodology

Most of the background information in chapters 1 and 2 of this report is provided in the final report on the risk assessment of bis (2-etylhexyl)-phthalate of September 2001 (KemI, 2001a). Otherwise references are specified.

The structure of this report follows the recommendation of Technical Guidance Document on Developing Risk Reduction Strategies (October 1997) in combination with experience gained in the Community work.

Also the preparation of the risk reduction strategy has followed existing guidelines and minimum requirements of the programme. The work has been discussed within a consultative group, set up with the aim of ensuring transparency and enabling contributions from a broad range of different stakeholders. The consultative group consists of representatives from authorities, industrial associations and environmental and health organisations, both national and EU wide. For instance, producers of plasticisers as well as producers and processors of PVC have participated and also producers of medical devices, toys, cables, floorings, cars and perishables. A list of consultees that have participated in a consultative group is annexed to this report.

1.2 Production and use of DEHP

Historically, DEHP has been referred to also as DOP (Di-octyl phthalate) or DIOP (Di-iso octyl phthalate), a fact that has made a retrospective description of the consumption difficult.

In 1997 the DEHP production volume for Western Europe was 595,000 tpa. This was a significant part of the global production, estimated to be between 1 and 4 million tpa. The export from Europe was 186,000 tpa and imports were calculated as 67,000 tpa. There are 12 current production sites in Europe. Additionally, two companies import DEHP into the EU, one in the range 1,000 to 5,000 tpa and one between 10,000 and 50,000 tpa. No information is available on imports or exports of DEHP contained in finished products.

The value of DEHP is around 800 Euro per tonne, making production worth around 500 million Euro per annum, exports 150 million Euro and imports around 50 million Euro (RPA, 2000b).

DEHP is widely used as a plasticiser in polymer products, mainly PVC. Plasticisers have the function of improving the polymer material's flexibility and workability. The content of DEHP in flexible polymer materials varies, but is often around 30 % (w/w). Examples of other plasticisers are other phthalates, adipates, trimellitates, and phosphates. Important other phthalate plasticisers are Butylbenzyl-phthalate (BBP), Dibutyl-phthalate (DBP), Di-isodecyl-phthalate (DIDP) and Di-isononyl-phthalate (DINP). The group of phthalates account for 92% of the plasticiser consumption in Western Europe (RPS BKH, 2002).

In 1999 there were around 20 companies producing about 1 million tonnes of all types of plasticisers in Europe, the three biggest accounting for about 40% of overall capacity (CEC, 2000).

The European consumption of DEHP can be calculated to 476,000 tpa. DEHP represents 51% of all phthalate plasticiser use. 97% of the DEHP consumption (462,000 tpa) is used as a plasticiser in polymers, mainly soft-PVC. The remaining 3% is used in non- polymer applications such as adhesives and sealants, paints and lacquers, printing inks and capacitors. It is also used in advanced ceramic materials for electronic and structural applications.

In figure 1.1 the production and use of DEHP within the European Union is outlined. It is recognised in the risk assessment that all applications of DEHP have not been identified or quantified, which should be taken into account when studying the figure.

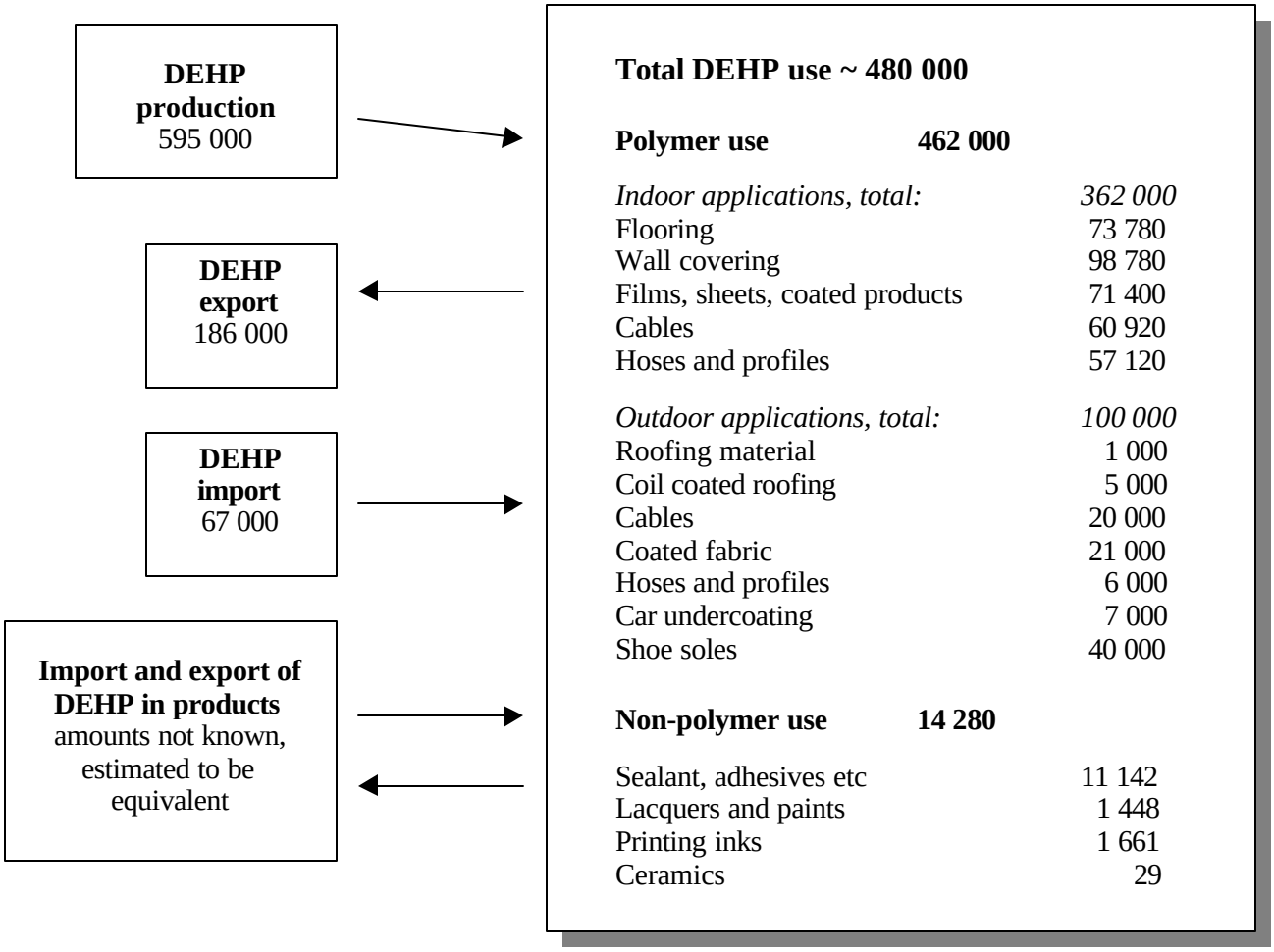


Figure 1.1 ***Production and use of DEHP in the European Union 1997 (tonnes per annum)***

1.3 Production and use of material plasticised with DEHP

Approximately 90 % of the DEHP consumed in Western Europe is used in the production of PVC. Lack of data concerning the amount and use of DEHP in imported polymers and imported finished products creates uncertainty in the identification and quantification of emission sources. Examples of imported products are shoe soles, coated fabrics for clothes and sport articles.

According to the RA, the main part (approximately 362,000 tpa, 78 %) of the total DEHP consumption is used in indoor PVC applications such as flooring. The remaining part (100,000 tpa, 22 %) is used in outdoor use that includes applications such as cables, roofing materials, coated fabrics and car undercoating.

DEHP is used to produce flexible plastics that are part of many products intended for both industrial and consumer use. These include building products (insulation of cables and wires, tubes and profiles, flooring, wallpapers, out-door wall- and roof covering, pastes for sealings and isolation mass), children's products (teething rings, squeeze toys, crib bumpers etc.), clothing (footwear, outwear and rainwear), car products (e.g. car under-coating, car seats made of imitation leather) etc. To further illustrate the widespread use and everyday DEHP encounter articles like prams, shower curtains and textile prints could also be mentioned. Several products containing DEHP may have technical lifetimes over 20 years e.g. roofing materials (20 years), cables (30 to 50 years), floors (20 years).

DEHP is not chemically bound to the PVC polymer matrix and can thus be released throughout the lifecycle of polymer products. Release of DEHP occurs not only during the production, distribution and incorporation into PVC but also when the PVC material is heated or comes into contact with certain media. Consequently, DEHP may be lost from the finished products during their use or disposal. Leaching rates may vary between products from different manufacturers or even within the same batch. Due to the long technical lifetime of some important products and the high persistency of the polymer material in the environment, emissions from products are expected to continue for a long period of time. The emissions may also be promoted as particles are produced from worn out polymer material during use of the finished products. Such particles are in some cases assumed to remain in the environment.

According to information provided by industry, formulation and processing generally occur at the same industrial site. It is estimated by industry that 15-25% of the total amount of DEHP used in Europe may be formulated into a semi-manufactured compound at one site and processed at another. Little information is provided about the size and practices of these processing sites. However, the number of sites involved in the use of DEHP for various processes is outlined in table 1.1 below.

In contrast to the number of down stream user indicated in this table, a recent Green Paper from the European Commission on Environmental Issues of PVC reported that the transformation of PVC into final products is undertaken by over 21,000 small and medium sized enterprises. Manufacture of flexible PVC products (many of which will contain DEHP) involves around 10,000 companies, producing 3.7 million tonnes of plasticised PVC (CEC, 2000). According to this information, slightly less than half of the manufactured flexible PVC products would be plasticised with DEHP and consequently quite a large part of the manufacturing companies would be affected by any risk reduction measures.

Table 1.1: ***Overview of processes, applications, used amounts and number of customers***

Process	Application	Use (tpa)	No of customers (neat DEHP)
Calendering	Films, sheets, coated products	71,400	74
	Flooring, roofing, wall covering	34,748	20
	Total, calendaring	**106,148**	**94**
Extrusion	Hoses, profiles	57,120	82
	Wires, cables	80,920	62
	Compounding	85,680	83
	Total extrusion	**223,720**	**227**
From compounding	Footwear, misc. (injection moulding and extrusion)	83,680	?
Spread coating	Flooring	39,032	21
	General (coated fabric, wall-covering, coil coating etc)	76,160	115
	Total spread coating etc	**115,192**	**136**
Other plastisols	Car undercoating	7,140	11
	Slush/rotational moulding, dip coating	9,520	27
	Total other plastisols	**16,660**	**38**
Non-polymer use	Adhesives/sealants, rubber	11,142	
	Lacquers, paints	1,448	
	Printing ink (paper and plastics)	1,661	
	Ceramics	29	
	Total non-polymer use	**14,280**	**?**
	Total all applications	**476,000**	

The many ways of processing at different stages of the manufacturing chain and the vast number of products made of plasticised PVC-polymers complicate the overview of all occupational situations and exposures. Furthermore, the lack of overview of applications and precise identification of articles, production sites, SMEs etc complicates the socio-economic assessment. Hence it has been impracticable to specify precisely the extent to which certain articles or production processes contribute to the most serious exposure (i.e. apply the proportionality principle).

1.4 Some important properties of DEHP

The **basic physico-chemical properties** of DEHP are:

At room temperature, DEHP is an oily liquid with a high boiling point (230C^{o}), a low vapour pressure (0.000034 Pa at 20°C) and a calculated saturated gas concentration of 5.3 µg/m^{3} at 20°C.

When DEHP is heated, the vapour pressure will increase with a concomitant increased volatilisation. At lowered temperatures, the volatile DEHP will form an aerosol mist, condense on airborne particles or on cooler surfaces like walls and windows..

The partitioning coefficient log K_{ow} is 7.5 for DEHP. This is a very high value, showing very lipophilic properties and indicating that the substance will adsorb strongly onto sludge and sediments. The water solubility of the substance is very low. A non-colloidal solubility of 0.003 mg/l is used in the DEHP risk assessment. Nevertheless, it should be kept in mind that the substance forms stable emulsions and that apparent water solubility can be observed up to a maximum of 0.34 mg/l. This may explain diverging results found in "older" studies on water solubility of DEHP. A colloidal solubility value of 1.3 mg/l has also been noted in the risk assessment.

Some **additional characteristic properties** relevant for the exposure assessment of DEHP are:

Degradation

Photodegradation is the main degradation pathway for DEHP in the atmosphere. The abiotic degradation in water is very slow. DEHP is inherently biodegradable in the aquatic environment and in some tests passes as readily biodegradable. The substance is, however, quite persistent in surface waters and sediments at low temperatures or restricted supply of oxygen.

Potential for migration from polymeric materials

The highly lipophilic property of DEHP is conditional for its technical use as a plasticiser in polymeric materials like PVC. Another important characteristic is the migration from the polymer matrix. The substance does leach and evaporate from manufactured products and temperature is probably a key factor in this process. In the ambient environment high peak temperatures can occur during sun light radiation. For instance, temperatures up to 70ºC have been reported in cars exposed to the sun. The vapour pressure increases considerably at such temperatures (20 to 70ºC → 320 times higher vapour pressure).

The CSTEE has collected a number of analyses of phthalates leachate from toys to saliva. The maximum emission rate for DEHP was 1600 ìg/10 cm^{2}/6hr (CSTEE, 1998).

Potential for bioaccumulation

Invertebrates bioaccumulate DEHP to a higher extent than fish (BCF 2500 in mussels, 2700 in zooplankton, between 114 and 1380 for fish). This may be due to a lower metabolic capacity

of the invertebrates. Since DEHP is readily adsorbed onto organic surfaces and particles in the water phase and in sediments, DEHP in colloidal form and DEHP adsorbed to particles might also be more easily available for these kinds of organisms.

The bioaccumulation of DEHP in fish decreases at concentrations higher than around 5 ìg/l. This could be due to a more efficient metabolism at higher exposure levels. Another possible explanation is that a significant amount of DEHP is in the colloidal form at test concentrations above the non-colloidal water solubility (around 3 ìg/l), which makes it less bioavailable for fish.

An assessment separate from the RA has concluded that DEHP is not fulfilling criteria for bioaccumulating properties in fish but that it is a borderline case in invertebrates. The criteria concerned are the proposed TGD criteria for the assessment of PBT substances.

DEHP can be measured in all environmental compartments, also in remote areas. Water concentrations are in the µg/l range, typically < 3 µg/l. In suspended solids and sediments much higher concentrations are measured (typically about 5 mg/kg dry weight, maximum 146 mg/kg dry weight). Concentrations in effluents of sewage treatment plants are generally in the same range as concentrations in surface waters. Concentrations of DEHP in sludge from municipal sewage treatment plants in Sweden, Denmark, Norway, the Netherlands and Germany vary between 0 and 661 mg DEHP/kg dry weight, with an overall mean value of approximately 100.

As a result, all organisms including man are exposed to DEHP during their entire life-time. Indirect exposure of humans via the environment may have contributed to the findings of DEHP in human breast milk.

1.5 The risk assessment conclusions

The DEHP risk assessment for human health identified several areas of concern with the following critical effects:

- **kidneys,**
- **testes,**
- **fertility** and
- **development.**

Effects on kidneys, without indication of reversibility, were observed in long–term studies (repeated dose toxicity). Effects on testes, characterised by a sequence of pathological changes resulting in atrophy (testicular tissue degeneration, decrease in testicular size) were found in young and developing individuals of several different animal species. Furthermore, DEHP was shown to reduce fertility in mice and rats and cause developmental effects on the testes of newly born rats exposed via the mother during pregnancy and lactation. The risk assessment concluded that the available data on effects in experimental animals are of concern for humans.

These data on toxic effects, both fertility and developmental toxicity, were taken into consideration in the classification[1] of DEHP as toxic to reproduction in category 2. Category 2 indicates sufficient evidence to consider the substance as detrimental to human fertility.

At the Technical Meeting in June 2002, the continued discussions related to the rapporteur's choice of No Observed Adverse Effect Level (NOAEL) for the risk characterisation of testicular toxicity. After an additional round of written comments from MS experts, no alternative NOAEL could be identified that received more support than the one chosen by the rapporteur. However, it was understood at the meeting that the rapporteur should evaluate some additional studies, due to be published later in the year, in order to see if any modifications would be justified. These studies have not been made available yet. The rapporteur was also strongly advised by the Technical Meeting to proceed to risk reduction on the basis of the agreed September 2001 RAR.

Concerns for general systemic toxicity and toxicity to reproduction have been identified in the RAR for a number of human subpopulations with direct DEHP exposure, namely workers and consumers, as patients and as children. After a contribution from the SCTEE[2] it was agreed at the Technical Meeting in June 2002 to amend the original conclusion on concern for children exposed through inhalation of indoor air. Instead, it was concluded that more information regarding exposure to DEHP through inhalation of indoor air is needed before this risk can be assessed.

In addition, all humans are indirectly exposed via the environment. Concerns for children and babies were specifically highlighted in the risk assessment. For the category "Combined" exposure, combinations have been identified and exposure described in qualitative terms, hence, the total body burden has not been estimated. So the assessment of exposure scenarios for workers, consumers, man exposed via the environment and combined exposure all resulted in a need for limiting the risks.

Exposure scenarios of concern are summarised in table 1.2. It should be noted that for two scenarios for humans indirectly exposed via the environment and for the combined exposure, the need for risk reduction measures may have to be re-examined later.

The environmental part of the risk assessment concluded that further information was needed concerning certain exposure scenarios, including secondary poisoning (exposure via the food chain). This was based on the results from a study where effects were seen on the sexual differentiation of Atlantic salmon when exposed to DEHP via food. For the remaining environmental exposure scenarios it was concluded that no further risk reduction measures are necessary.

Therefore, this Risk Reduction Strategy report will be focused on concerns for human health, including concerns relating to indirect exposure via the environment.

[1] established by Commission Directive 2001/59/EC of 6 August 2001 (OJ L 225, 21.8.2001, p.1.) adapting to technical progress for the 28th time Council Directive 67/548 on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances.

[2] Doc. C2/JCD/csteeop/DEHP/HH/09012002/D(02)

Table 1.2: ***Exposure scenarios where a need for limiting the risks to human health is identified in the risk assessment. For each identified scenario, critical effects and NOAELs (No Observed Adverse Effect Levels) are indicated.***

Exposed groups	Scenarios assessed	Critical effects and NOAEL
Consumers	**Children** - oral and dermal exposure from toys and childcare articles, - multiple pathways of exposure	*effects on kidneys; NOAEL 29 mg/kg b.w. per day* *effects on testes; NOAEL 3.7 mg/kg b.w. per day* *effects on fertility; NOAEL 20 mg/kg b.w. per day*
	Children as patients - in long term blood transfusion	
	Neonates as patients - in transfusion	*effects on testes; NOAEL 3.7 mg/kg b.w. per day* *effects on fertility; NOAEL 20 mg/kg b.w. per day*
	Adults as patients - in long term haemodialysis - in long term blood transfusion	*effects on kidneys; NOAEL 29 mg/kg b.w. per day* *effects on testes; NOAEL 3.7 mg/kg b.w. per day* *effects on fertility; NOAEL 20 mg/kg b.w. per day* *effects on development; NOAEL <3.5 mg/kg b.w. per day*
Workers	**Occupational exposure** (inhalation and dermal) - in production of DEHP, - in industrial use of DEHP, - in industrial end-use of products containing DEHP	*effects on kidneys; NOAEL 29 mg/kg b.w. per day* *effects on testes; NOAEL 3.7 mg/kg b.w. per day* *effects on fertility; NOAEL 20 mg/kg b.w. per day* *effects on development; NOAEL <3.5 mg/kg b.w. per day*
Man exposed indirectly via the environment	**Babies/Infants** - infant formulae and breast milk	*effects on testes; NOAEL 3.7 mg/kg b.w. per day*
	Children - regional exposure	*effects on testes; NOAEL 3.7 mg/kg b.w. per day*
	- local exposure	*effects on kidneys; NOAEL 29 mg/kg b.w. per day* *effects on testes; NOAEL 3.7 mg/kg b.w. per day* *effects on fertility; NOAEL 20 mg/kg b.w. per day*
	Adults - local exposure	*effects on testes; NOAEL 3.7 mg/kg b.w. per day* *effects on development; NOAEL <3.5 mg/kg b.w. per day*
Combined groups	**Combined exposure** - life time exposure from different sources and routes.	

2 The scope of the risk reduction strategy

The DEHP risk assessment has identified several areas of concern where risk reduction measures are needed. The critical effects of DEHP are general systemic toxicity and effects on reproduction, including atrophy of testes, reduced fertility and developmental effects on testes of newly born rats exposed via the mother during pregnancy and lactation.

Toxicity to reproduction, in general, causes very high concern. In view of the exposure patterns involved in this case, it is especially alarming that testicular effects are identified in developing individuals after perinatal exposure.

It is a community task to ensure a high level of protection of human health and the environment. To prevent accumulation of DEHP in the technosphere and a continued indirect exposure (via the environment) of future generations during their entire lifetime (as foetus, newborn, at work, in fertile ages etc) will be a challenge. Risk reduction measures will need to be taken before the effects become evident in a general population.

2.1 Applying the risk assessment conclusions

Based on the conclusions in the risk assessment **workers** and **consumers (as children and as patients)** have been identified as target groups for the risk reduction strategy. In the case of local exposure via the environment, that is giving rise to concern for both adults and children, measures that reduce the risks for children is considered sufficient since this will accordingly limit the risks also for adults. The need to widen the scope of the risk reduction strategy to include also other medical devices than those assessed in the RA is discussed in the section below.

More information is needed regarding exposure to DEHP through inhalation of indoor air. Such exposure may have a number of sources: wall covering, flooring, cables, hoses and profiles. These applications represent approximately 80% of the total amounts in indoor use. Examples of other applications are coated fabrics in clothes and sport articles, baby prams, shower curtains, gloves, car interior; textile prints to mention only a few. The additional information provided regarding this important exposure scenario will thus have to be examined later.

The **lifetime exposure** of all humans, with combined exposure over time from many different sources, including indirect exposure via the environment, was especially highlighted in the risk assessment. These aspects, where no specific guidelines for risk reduction have been developed and where new approaches will be necessary, are further discussed in section 2.5. The risk assessment has also pointed out some areas where little data is available, e.g. DEHP found in breast milk.

2.2 Children - a vulnerable group

A number of exposure scenarios put children in focus for risk reduction measures. As concluded in the RA, growing individuals, not yet fully developed, are especially vulnerable

towards the toxic effects that have been found following exposure to DEHP in experimental animals. This should imply extra awareness regarding the everyday exposure of children.

Compared to their body weight, children eat and drink more and breathe more air than adults. They also have a higher level of activity which may lead to a higher exposure to dust and chemicals and, when small, by tending to put things into their mouth. Childhood exposure may also have long-term consequences into adulthood.

The risks posed by toys and childcare articles are to some extent dealt with through the temporary provisions[3], prohibiting the placing on the market of toys and childcare articles intended to be put into the mouth by children under three years of age. Other scenarios where a need for limiting the risks to children have been concluded are:

- multiple pathways of exposure
- long term blood transfusion
- transfusions in neonates
- local exposure via the environment
- regional exposure via the environment
- feeding with infant formulae
- feeding with breast milk

It is apparent from the RA conclusions that children (and pregnant women), who also represent future generations need special attention when developing a risk reduction strategy for DEHP.

The general need for more attention to children and pregnant women will be emphasised in a forthcoming EU environment and health strategy. Speaking at Green Week's opening session, acting environment director-general Jean-François Verstrynge said it would pay "particular attention" to children and pregnant women, with a new emphasis on combined exposure to pollutants[4].

2.3 Patients

DEHP is used in plastic materials in medical devices for various treatments. Catheters intended to be used in haemodialysis and transfusions have been identified as giving rise to concern in the risk assessment. However, there are other kinds of PVC devices used in medical care that might pose similar risks. Such articles include implantation materials (e.g. artificial heart valves), different kinds of catheters, syringes, several solutions and materials in ophthalmology and dentistry.

The risk assessment stated that catheters made of plasticised PVC used for feeding premature infants and newborns might result in significant leakage of DEHP into the stomach during the feeding. As no data on the magnitude of the release was available, this use was however not an object in the risk assessment.

Other authorities and organisations have identified groups of patients at risk and types of medical devices that cause concern. The conclusions from **USFDA, USNTP, Health**

[3] European Commission (Decision 1999/815/EC) on measures within the legislative framework of the Council Directive on General Product Safety (92/59EEC) against certain phthalates in toys and childcare articles

[4] Environment Daily 1196, 15/04/02

Canada, MHLW, HCWH, Stockholm County Council, EP, RIVM and the SCMPMD are summarised below. This Risk Reduction Strategy will include the various medical devices and patient groups, which have been highlighted in the RA as well as by other authorities and organisations. The reason for these medical devices not being assessed in the RA was a lack of data quantifying the leakage of DEHP.

The US Food and Drug Administration (**USFDA)** has found that the greatest concern would be for very young male infants who are critically ill and have prolonged exposure to multiple devices containing DEHP. The USFDA actions are further described in section 3.5.1.

The United States National Toxicology Program (**USNTP**) concluded that DEHP is a reproductive and developmental toxicant in animals, that animal studies are relevant to humans, and that current exposure levels are of concern for three distinct human populations: critically ill infants, healthy infants and toddlers, and pregnant or lactating women (because they may adversely affect the development of their offspring) (USNTP 2000).

An expert group, advising **Health Canada**, stated that the subgroups most at risk were newborns, pregnant women, breastfeeding women and males before puberty. In terms of justifying restrictions on use of DEHP containing devices, the panel included the following groups and treatments:

- *Newborns receiving ECMO[5], blood exchange treatments, total parenteral nutrition[6] or and during cardiac surgery*
- *Adults undergoing heart transplant surgery or hemodialysis*
- *Patients receiving lipophilic drugs*

The Canadian actions are further described in section 3.5.2.

The Japanese Ministry of Health, Labour and Welfare (**MHLW**) has recommended healthcare professionals not to use medical devices made of PVC in which the plasticizer DEHP is used; alternative devices should be used instead. Medical devices on the domestic market have been studied. The Japanese actions are further described in section 3.5.3.

Health Care Without Harm **(HCWH)** has published a document on DEHP releases from medical devices made of PVC (Rossi and Muehlberger, 2000).

Medical devices used for the care of premature babies

Premature babies may require medical treatment resulting in exposure to DEHP from the use of various equipment. Treatment may involve blood infusions, respiratory therapy, infusion of electrolytes, sugars and medications, total parenteral (intravenous) nutrition, enteral (directly into the intestine) nutrition, blood exchange transfusions and extracorporeal membrane oxygenation (Rossi and Muehlberger, 2000). This might impose high exposure situations for individuals in a critical stage of their development.

[5] Extracorporeal Membrane Oxygenation by means of a heart-lung machine.

[6] Pre-term babies and newborns that cannot be breast or bottle feed receive their nutrition either via catheters inserted into the vein or through tubes passed into intestinal tract.

At a public hearing on PVC, organised in 2000 by the European Commission in Brussels, a feeding tube was demonstrated that had become rigid and stiff after its use, inserted into the premature infant's stomach. A hospital within the **Stockholm County Council** reported similar findings and included a chemical analysis of the used PVC tube showing that 50 percent of the DEHP content had disappeared from the tube. During a feeding period of 10 weeks and with the replacement of tubes every three days, 20-30 tubes are needed. A leakage of up to 30 mg DEHP per 24 hours was reported (Stockholm County Council, 2000).

Subsequent to the public hearing, the European Parliament **(EP)** published a resolution on the Commission Green Paper on environmental issues of PVC (European Parliament, 2000) where the Parliament:

- *calls on the Commission to examine alternatives to the uses of phthalates as plasticisers which present less risk to human health (point 18)*
- *suggests that the Commission and the PVC industry, taking also into account the current studies, should look into the possibility of setting targets for reducing the use of phthalates, particularly in medical equipment (point 19).*

A Dutch governmental policy statement has announced that the National Institute of Public Health and the Environment **(RIVM)** will draw up a review of the use of medical devices manufactured using DEHP in the Netherlands. The focus of the review will be on the link with the risk groups. The risk analysis of the manufacturers of the relevant products will then also be evaluated. The need for measures to minimise exposure to phthalates is also being studied, primarily in the risk groups consisting of neonates, babies and children. No general ban is being instituted beforehand (in anticipation of European policy) of medical devices manufactured using PVC-DEHP because this could endanger the availability of vital medical devices and a risks/benefit analysis could very well indicate that the risk associated with the use of this substance is acceptable. Further description of the Dutch policy is found in section 3.4.2.

In January 2002 the Scientific Committee on Medicinal Products and Medical Devices **(SCMPMD)** was consulted by the Health & Consumer Protection Directorate-General, European Commission and the committee adopted its opinion in September 2002: Neonates and other groups possibly at risk from DEHP toxicity, relating to medical devices containing DEHP plasticised PVC[7]. More about the questions from the Commission and the answers from the Committee can be found in section 4.2.2 of this report.

2.4 Workers

Occupational exposure of concern may occur at production and industrial uses of DEHP (formulation, processing and industrial use of finished articles containing the substance). The exposure routes considered to be relevant in these occupational situations are inhalation (gaseous DEHP, smaller or larger aerosol particles and particles with condensed DEHP on the surface) and dermal routes. The RA concluded that information on manufacture and use of DEHP in general is seen as well documented but that information is not available about formulation and processing of PVC polymers by down-stream industries (off-site; small industries) with respect to the number and size of the sites.

[7] Doc.SANCO/SCMPMD/2002/0010 Final

Transformation of PVC into final products is reportedly undertaken by over 21,000 small and medium sized enterprises, 90% of which have fewer than 100 employees. Manufacture of flexible products (DEHP may be used in half of this production) involves around 10,000 companies employing 260,000 people (CEC, 2000).

A reasonable worst-case exposure in the working environment is outlined in the table below.

Table 2.1: ***A reasonable worst-case exposure for the working environment***

Occupational exposure scenario	Inhalation TWA (mg/m^3)	Dermal exposure (skin area of 420 cm^2) (mg/day)
Industrial use of DEHP (process and maintenance personnel)	10	420
Industrial end-use of products containing DEHP	10	1,300

The model used results in a higher exposure than measured data, because the large number of sites within EU is taken into account assuming that the group is inhomogeneous with respect to size of plants, processing techniques, ventilation equipment etc.
TWA = Time Weighted Average for an eight hour period.

Information is limited on the use and effectiveness of personal protective equipment (PPE) in practical situations to reduce DEHP exposure. Therefore, the exposure has been assessed in the RA without taking into account the possible influence of PPE. Primarily, occupational health risks should be avoided by other means and PPE should be seen as the last option, mainly intended for use during operations entailing risk for increased exposure such as repair work, service and maintenance.

2.5 Indirect exposure and a lifetime exposure (combined exposure)

The indirect exposure via the environment arises from many different sources, such as flooring, clothes and shoes, cables, plastic interiors of cars, plastisols (e.g. car under coating) and printing inks. It has been impossible to obtain information on all potential exposure situations within the European Union. Therefore, it was recognised in the RA that all exposure scenarios might not have been covered.

The regional exposure scenario is an indicator of the diffuse emissions. The EUSES model used in the RA includes six pathways for indirect exposure: drinking water, fish, crops, meat, milk and air. The daily dose for humans is calculated by means of the concentrations in these media and the daily intake values.

The regional exposure scenario uses monitoring data as far as possible and, based on this information, there is concern for children. As an example, several studies show that DEHP occurs widely in dairy products. One important source identified was DEHP-plasticised tubing in the milk transferring systems. However, DEHP was also found in dairy products in countries where DEHP no longer is allowed for use in transfer tubing. This indicates that the presence of DEHP in milk is not mainly due to migration from the tubing, but originates from

environmental sources. DEHP is also found in infant formulae. Extensive studies performed by MAFF (UK) in 1998 show the maximum level 440 µg DEHP/kg dry powder. Also in Danish and German studies concentrations of DEHP (and other phthalates) have been measured in infant formulae.

Furthermore, DEHP is found in human breast milk, as monitored in German studies where the concentrations ranged between 10-160 µg/kg. Birth giving mothers are apparently exposed to DEHP and most likely, the foetuses are also exposed during pregnancy. This aspect of the indirect exposure via the environment is especially alarming, as the critical toxic effects include developmental effect on the testes of newly born animals exposed to DEHP via the mother during pregnancy and lactation.

Due to the wide use of DEHP in society and the emissions from production and products, citizens in the European Union are exposed from many different sources in their daily life. DEHP is found in various biota and media. Measurements of DEHP in women's breast milk, soil, meat, fish, dairy products, water and air support this. The total body burden is the sum of all specific exposures from all sources by all routes. For this lifetime exposure, subpopulation combinations have been identified and exposure described in qualitative terms in the RA, hence, the total body burden has not been estimated. Furthermore, there is very limited data available that could trace findings of DEHP in the environment back to its actual sources, as in the case of DEHP in food and human breast milk. The fact that information is missing regarding all sources of DEHP and the lifetime exposure adds a level of uncertainty when risks of DEHP are discussed.

2.5.1 Estimated emissions to the environment

The yearly emissions of DEHP are estimated in the RA to be about 29,000 tonnes in total. The environmental exposure analysis indicates that the main part of released DEHP originates from use and disposal of polymer products and that these emissions are dispersed widely. A rather large percentage of the total emissions originates from cables buried in the ground but, since DEHP is expected to degrade in the soil when emitted from these cables, such emissions to soil are not considered to be important. Therefore, the following relative contributions have been calculated excluding emissions from buried cables:

Table 2.2 ***Relative contributions from different life cycle stages of DEHP (excluding cables buried in the soil)***

Source of emission	Relative contribution	Uncertainty	Emission type
Production of DEHP	~5 %	low	point sources
Industrial uses	~5 %	medium	point sources
End product uses*	~89 %	high	wide disperse
Waste handling	~1 %	medium	wide disperse (+ point sources)

* particles remaining in the environment (see definition below) constitute ~65%

The estimates in table 2.2 clearly point out emissions from end products as important sources. The major part, 89%, of emissions from finished products in use can be split up into emissions of DEHP in molecular form (24%) and DEHP emissions in the form of polymer

particles produced during use, wearing and tearing of the plasticised material, thereafter remaining in the environment (65%). The normal handling of waste seemingly contributes very little to the environmental emissions.

This overall picture is described further in figure 2.2, where the estimated emissions are summarised separately for the environmental compartments air, water and soil. Also here, emissions excluding cables buried in the soil are indicated.

Figure 2.2 ***Estimated emissions to air, water and soil (tonnes per annum)***

Emissions to air **total 546**	**Emissions to water** **total 5 987**	**Emissions to soil** **excluding buried cables 8175** **(total 22 120)**
Industrial: 319	Industrial: 1074	Industrial: 74
End product use: 216	End product use: 4888	End product use: 8039
(particles: 9)	(particles: 2413)	(particles: 7240)
Waste handling: 11	Waste handling: 25	Waste handling: 62

The estimates in figure 2.2 show the relative importance of DEHP emissions to soil and water and emphasise once again the importance of DEHP emissions from the use of finished products.

Data from the RA furthermore indicate that products for outdoor use give rise to 77 % of the environmental emissions of DEHP and that, within this type of products, shoe soles, coil coated products and coated fabrics together are contributing 61% of the emissions.

Figure 2.3 ***Technical Guidance Document on Development of Risk Reduction Strategies***

3.6 When risks arise from both point and diffuse sources, it is in general easier to introduce risk reduction measures at the point source stage: such controls are for example easier to enforce, and their effect can be more closely monitored. As diffuse sources may represent a considerable contribution to overall emissions, it is necessary to investigate the possibilities to reduce diffuse emissions.	**3.7** Where risks arise from cumulative emissions, rather than from individual stages of a substance's life, rapporteurs should first consider controls on the most significant remaining source of emissions (taking into account any existing risk reduction measures). Where there are a number of significant sources, rapporteurs should aim to control emissions where this can be done most cost-effectively. Environmental quality standards may also be appropriate in such circumstances.

In conclusion, the life time exposure, the multiple sources of exposure and the very broad population, including children, considered to be at risk justify a distinct risk reduction strategy

that considerably reduces the risks identified. The measures of the strategy must aim for a continuous minimisation of emissions from a broad spectrum of applications.

Estimated possible emissions have been presented in quite detail but do not comprehensively explain why DEHP is found in foodstuffs. Available data indicate that the use of many different finished products with DEHP are diffuse sources of emissions, that contribute with a very large part of the total emissions to the environment.

Table 2.3 below gives some examples of applications giving rise to exposure and indicates the relative importance of sources of environmental emissions.

Table 2.3 ***Exposure scenarios of concern and examples of applications giving rise to exposure***

Exposed groups	Scenarios of concern	Examples of applications giving rise to exposure
Consumers	**Children** - oral and dermal exposure to toys and childcare articles	- Examples of toys and childcare articles; nursing tables, plastic coated terry, children's picture books, teething-rings.
	- multiple pathways of exposure	- Multiple pathways of exposure describes the oral + inhalation + dermal exposure from some given applications (here: indoor air + toys and childcare articles and car interiors).
	- local exposure	- Local exposure via the environment is describing exposures in the immediate vicinity of industrial plants.
	- regional exposure	- Regional exposure via the environment is derived from six pathways; daily intake of drinking water, fish, crops, meat, milk and air and the concentrations in these media. The routes for DEHP ending up in these media are not fully understood but contributions come from diffuse sources by leakage from many different products and from more direct leakage e.g. from distribution tubes or food package.
	- infant formulae	- The occurrence of DEHP in infant formulae has been assigned to milk, deriving from direct sources such as transferring tubes as well as indirect exposure of the cow via the environment.
	- breast milk	- Content of DEHP in human breast milk may arise from a great number of sources, e.g. via indoor and outdoor air, food and water, possibly medical devices and occupational exposure before giving birth.

Exposed groups	Scenarios of concern	Examples of applications giving rise to exposure
Workers	- production of DEHP, - industrial use of DEHP, - industrial end-use of products containing DEHP	- The production sites vary in size and practises, from large producers of DEHP to SMEs as down stream users of DEHP in e.g. PVC. Exposure to DEHP in production and industrial use mainly arises when the polymer material is heated e.g. during forming and workers are exposed to gaseous DEHP or as an aerosol. Also dermal exposure is of concern. Production and industrial uses are point sources, estimated to contribute to around 10 % of environmental emissions. - Occupational situations where DEHP is released in industrial use of products are e.g. spraying of plastisol containing DEHP; welding bathroom floorings or wall coverings. The use of finished products is a diffuse source of DEHP emissions, estimated to contribute with a very large part, 89%, of the total emissions to the environment (together with private end-use of products).
Combined groups	Life time exposure	All the applications above can be included in the life time exposure, but it should be stressed that the exposure does not affect special target groups, but all people. Adults, children and babies are potentially exposed from several different sources. The exposure may be equated with persistent low dose exposure. The exposure arises from e.g. building materials (indoor and outdoor), plastic materials in daily use as well as through the food chain (via the environment). Small children are exposed through breast milk and infant formulae. The use of finished products (industrial and private) is a diffuse source of environmental DEHP emissions , that is estimated to contribute with a very large part, 89%, of the total emissions. Products for use outdoors seem to be most important and, within this type of products, shoe soles, coil coated products and coated fabrics are the major contributing products.

3 Current risk reduction measures

This section provides a summary of actions that already have been taken or are on the agenda for discussion internationally, at European level and at national levels. The actions cover both existing legislative measures and industrial initiatives. They may target DEHP, phthalates as a group or plasticised PVC.

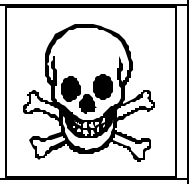
3.1 Legislative Controls in the European Union

The description of the directives below has been drafted in collaboration with the respective Swedish competent authority. The aim is to emphasise current actions and not to tire the reader with lengthy descriptions of the various legal tools. However, legislation not previously dealt with in the Existing Substances programme is described in some more detail.

Classification and labelling of dangerous substances (67/548/EEC)

While the risk assessment of DEHP was undertaken, the substance was not yet classified at Community level (the classification previously applied by the manufacturers was category 3). The effect data were taken into account in the harmonised classification[1] of DEHP as toxic to reproduction, both fertility and developmental toxicity, in category 2. Category 2 indicates sufficient evidence to consider the substance as detrimental to human fertility. Member States shall implement the community classification by 30 July 2002. Accordingly, DEHP as such and chemical preparations containing > 0,5 % shall be labelled with the skull and crossbones symbol. The classification and the scull and crossbones symbol will initiate an increased level of protection in the working environment, also in preventing the dermal exposure to DEHP.

Table 3.1: ***Classification and Labelling of DEHP***

Indication of danger	R-phrases	Symbol
T – Toxic	R60 – May impair fertility R61 – May cause harm to the unborn child	
		Toxic

According to a written contribution, the European Council of Plasticisers and Intermediates (ECPI) has launched a number of risk communication efforts in order to ensure that down stream users of DEHP are aware of their responsibilities according to the classification as a category 2 reproductive toxicant. The actions taken include a "Guide to Classification and Labelling" and a "Classification road show" (ECPI, 2001). A website[8] on DEHP in nine languages will also be available.

3.1.1 Protection of Consumers (children and adults)

The Directive on the Safety of Toys ((88/378/EEC)

Although DEHP is not specially addressed, the general requirements of the directive states that toys must not contain dangerous substances or preparations, according to the dangerous substances directive[9] and the preparations directive[10], in amounts that may harm the health of the children using them.

It is further stated that toys placed on the market should not jeopardise the safety and/or health of the users. Toys are defined as any product or material designed or clearly intended for use in play by children of less than 14 years old.

The directive is focused on acute health effects due to ingestion, inhalation or contact with the skin, mucous tissues or eyes. Long term effects or effects on the environment are not taken into account.

As there was an urgent need for restrictions on the use of DEHP in toys and child care articles, the Directive on General Product Safety was used for the interimistic ban on phthalates within this use.

The Directive on General Product Safety (92/59/EEC)

On 7 December 1999 the European Commission **(Decision 1999/815/EC)** decided to adopt measures within the legislative framework of the Council Directive on General Product Safety (92/59EEC) against certain phthalates in toys and childcare articles. Thereby, the placing on the market is interimistically prohibited for toys and childcare articles that are intended to be put into the mouth by children under three years age and made of soft PVC containing DEHP or five other phthalates; DIDP, DINP, DBP, BBP and DNOP. The duration of the decision is limited to three months, with the possibility to be prolonged for another three months each time. For the moment the Decision is applicable until 20 February 2003.

The decision was taken while awaiting an amendment to the Directive on Restrictions on marketing and use. Denmark, Austria, Greece, Finland, Sweden, Italy, France and Germany have notified national restrictions on these articles with slightly different scope.

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[8] http://www.dehp-facts.com

[9] Directive 67/548/EEC on the approximation of laws, regulations and administrative provisions relating to classification, packaging and labelling of dangerous substances.

[10] Council Directive 88/379/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous preparations

The General Product Safety directive has two complimentary objectives, namely to ensure:

- a high and consistent level of protection for consumer health and safety throughout Europe
- the proper functioning of the Internal Market.

The directive was based on Article 100 a, presently article 95 of the Treaty. It covers articles which are not subject to sectorial legislation and situations when existing sectorial legislation does not address risk and safety aspects.

The directive places a general obligation on the importers and manufacturers of articles intended for consumer use, to ensure that articles do not present unacceptable risks under normal and reasonably foreseeable conditions of use. The directive is under the responsibility of the Commission DG for Health and Consumers (DG SANCO).

The directive states that the manufacturer shall provide consumers with relevant information to enable them to assess the risk throughout the normal or reasonably foreseeable period of use, and to take precautions against those risks.

Member States can raise an issue either by notifying to the Commission a new piece of national legislation or by a decision taken at a national court of law, which may restrict of the free movement of goods within the EU market.

The directive has recently been revised in order to improve its effectiveness in ensuring that only safe products are put on the market. The new directive shall be implemented by the member states before 15 January 2004.

The Directive on Restrictions on the Marketing and Use of Certain Substances and Preparations (76/769/EEC)

The marketing and use of DEHP and preparations containing DEHP intended for consumer use is in the process of being prohibited. DEHP is proposed to be included in the list in the appendix to Annex 1 to the Directive[11].

A proposed restriction regarding the use of phthalates in toys etc. is under discussion within the framework of the directive. The discussion includes both a ban and migration limit values on phthalate-containing toys and child care articles capable of being mouthed by children under the age of three.

The Directive on Cosmetic Products (76/768/EEC)

In November 2002, the European Parliament and the Council agreed on an amendment to the Cosmetics Directive. Through this amendment, restrictions on the use of CMR substances of category 1 and 2 (listed in the appendix to Annex I to the Restrictions Directive 76/769/EEC) will be incorporated into the Cosmetics Directive.

[11] Proposal for amending the twenty-fifth time of the Council Directive 76/769/EEC – Final proposal from the Commission 28.05.2002 O.J. C 126E/398

The directive was originally adopted in 1976, under article 100 of the Treaty of Rome. Several amendments have been subsequently adopted. The directive regulates the marketing of cosmetic products, aiming to harmonise any national provisions and to protect human health.

General requirements concerning safety, labelling and information duties for manufacturers and importers are established in the directive. The main requirement is that cosmetic products may not be hazardous to human health under normal and foreseeable use. Annexed to the directive are lists of substances that are banned or restricted and lists of substances that may be used as colouring agents, preservatives, UV-filters etc. (positive lists).

The Directive on Plastic Materials and Articles Intended to Come in Contact with Foodstuffs (90/128/EEC)

The Scientific Committee for Food has evaluated DEHP[12]. A Tolerable Daily Intake (TDI) was set at 50 ìg/kg body weight, which corresponds to a Specific Migration Limit (SML) of 3 mg/kg foodstuff, based on the daily consumption of 1 kg packed foodstuff and a body weight of 60 kg). Presently an 8th amendment of the directive is under discussion within the Working Group for Packaging Materials of DG SANCO. It is proposed in this amendment that DEHP should not be used in polymers coming into contact with fatty foodstuff. However, DEHP was not included in the recent, fully harmonised incomplete list of additives[13].

The directive relates to plastic materials and articles intended to come into contact with foodstuffs. Restrictions on the use of additives are mostly introduced into this directive due to their impact on human health. From 1 January 1993, only those monomers and other starting substances that are listed in Annex II, Section A, shall be used for the manufacture of plastic materials and articles, subject to the restrictions specified therein.

3.1.2 Protection of Patients

The Directive on Medical Devices (93/42/EEC)

In January 2002 the European Commission consulted the Scientific Committee on Medicinal Products and Medical Devices regarding medical devices containing DEHP. Their opinion was delivered in September 2002. In general, the outcome of the consultation with the Scientific Committee was that no specific recommendation could be made to limit the use of DEHP in any particular patient group and that no Tolerable Intake value for DEHP in medical devices could be recommended. See section 4.2.2 for further discussion on the questions raised and the answers given by the Committee.

The Directive on Medical Devices (93/42/EEC) harmonises regulations relating to medical devices and provides security and performance characteristics of medical devices. The directive is under the responsibility of DG Enterprise. According to principles set out in connection with the new approach to technical harmonization and standardisation (Council

[12] Reports of the Scientific Committee for Foods (series 36 1997) “Opinions on Di-2-etylhexl phtalate” European Commission; Directorat General Industry

[13] Commission Directive 2002/72/EEC of 6 August 2002

Resolution, May 1985), rules regarding the design and manufacture of medical devices must be confined to meet essential requirements.

The demands on medical devices are described in general terms in the directive. Among the demands are considerations on risk and benefits, safety of materials and biocompatibility.

Annex I to the directive describes the essential requirements. The first requirement states that the risk associated with a medical device must be acceptable when weighted against the benefits to the patients and that the device must be compatible with a high level of protection of health and safety. Another requirement states that the devices must be designed and manufactured to minimize the risks posed by substances leaking out from the device.

In order to demonstrate and verify conformity with the essential requirements, harmonized European standards may be used. The standards are not compulsory and compliance with the essential requirements can be verified in other ways.

Medical devices should as a general rule, be labelled with the CE mark to indicate their conformity with the provisions of this directive and to enable them to move freely within the community. The manufacturer is responsible for labelling the product with the CE mark.

Medical devices are classified in four product classes, based on the vulnerability of the human body and taking into account the potential risks associated with the technical design and manufacture of the device. These classes are denoted Class I (low risk) IIa, IIb and III (high risk). Class II and III require verification by a notified body.

The legislation on medical devices is based on the principle that the producers to a great extent take the responsibility to make sure that the requirements are met. A notified body, however, verifies the compliance by regular inspections of facilities and documentation. The manufacturer is thus responsible for classifying medical devices and for verifying their compliance with the directive. In case of products in Class IIa, or higher, a notified body must certify the compliance with the requirements. Feeding tubes for premature infants and catheters used in hemodialysis and blood transfusion belong to Class IIa or IIb.

In the case of pharmaceutical preparations like nutrients, whole blood or blood components, the biological fluid may be stored in bags made of DEHP-containing plastic material. As the bags are seen as a part of the medicinal product, the approval includes both the pharmaceutical preparation and the package. Changes in the construction of the package or in the material of the package have to be approved by a Competent Authority for medicinal products[14] before being placed on the market. In the European Pharmacopoeia a number of plastic package materials are described, among others PVC plasticized with DEHP, which thereby are accepted to fulfil the pharmaceutical demands on storage. The only pharmaceutical devices mentioned are aqueous infusion solutions and blood.

The Member States shall notify the Commission of the notified bodies that they have designated for medical devices. The Commission shall compile and publish a list of the notified bodies in the Official Journal of the European Communities. Except for the manufacturer of the medical device, only the actual notified body will know of the content of chemical substances and the outcome of the manufacturer's risk-benefit analysis. Up to date

[14] Regulation 2309/93 for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products

there are approximately 65 notified bodies within the Community, where almost 50 % of them are situated in Germany. There is however no Central body with the competence to survey the risk assessments behind the classification of the different medical devices or to take actions at Community level against the risks posed by certain chemical substances.

A safeguard clause is included in the directive on Medical Devices. When urgently needed, Member States shall take interim measures to withdraw devices that compromise health or safety, from the market or prohibit or restrict them from being placed on the market. The Member State shall immediately inform the Commission of any such measures and the reason for the measures taken.

In addition to the provisions in the safeguard clause, the directive calls for an information exchange between the Competent Authorities on incidents related to the use of medical devices. The information system is based on the Member States reporting of malfunction and deterioration in the characteristics and/or performance of a device. The Competent Authority makes an assessment and evaluates the reason for the incident along with the measures taken to prevent further incidents. The investigation is made in cooperation with the manufacturer of the device. Depending on the nature and severity of the incident, the outcome of the evaluation could result in different measures, e.g. changes in design or manufacturing, more distinct recommendations on use and voluntary withdrawal of the device from the market. The investigation is compiled in a "Competent Authority Report" and forwarded to the Commission and the other Member States.

The directive does however not provide any mechanism for a general withdrawal of the medical device from the entire European market. In case a national Competent Authority considers that a medical device might be hazardous to the patients or users, the authority can limit or ban the marketing of the product or may demand that it is withdrawn from the national market. If Community wide restrictions need to be achieved, each individual competent authority in all Member States would have to take such a decision.

Three committees assist the Commission in issues relating to medical devices. The Committee on Standards and Technical Regulations is set up by Article 5 Directive 98/34/EC[15] (formerly 83/189/EEC). The representatives in the committee contribute with technical knowledge in the elaboration of technical standards and the evaluation of which standards that could be used in order to demonstrate and verify conformity with the essential requirements.

The Committee on Medical devices is set up by Article 6 of Directive 90/385/EEC[16]. Its main task is to supervise issues regarding the legislation on medical devices and propose amendments if necessary. The committee delivers opinions on drafts from the Commission and thereby is able to influence the decision-making process.

Finally, the Commission can seek for advice and assistance from a Scientific Committee on Medicinal Products and Medical devices. This is presently being done concerning DEHP leaking from among others medical devices used by neonates (See the first paragraph in this section.) The Committee is informal in so far as the representatives only represent themselves as scientists with expert knowledge within different fields connected to medical devices.

[15] Directive 98/34/EC laying down a procedure for the provision of information in the field of technical standards and regulations

[16] Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices

3.1.3 Protection of Workers

The Directive on the Protection of the Health and Safety of Workers from Risks Related to Chemical Agents at Work (98/24/EEC)

No occupational exposure limit values have been established for DEHP at Community level, but several Member States have national limit values. These national limit values for an eight-hour working period range from 3 to 10 mg/m3. Although such national measures are thought to have an impact on occupational exposure in these Member States, it may be questionable if the levels are protective enough according to the worst case exposure scenarios described in the Risk Assessment Report on DEHP.

Table 3.2 ***National Occupational Exposure Limits for DEHP in some Member States***
TWA = Time Weighted Average (eight-hour working period)
STEL = Short Time Exposure Limit

Member State	8 h TWA (mg/m3)	STEL (mg/m3)	Notes
Austria	5		
Belgium	5	10	
Denmark	3		
France	5		
Germany	10		Pregnancy
Great Britain	5	10 (30 min)[1]	
Sweden	3	5 (15 min)	
The Netherlands	5		

[1)] Once per day

The directive on chemical agents at work (98/24/EC) is a framework directive, stating general provisions for safety and health at work. The legal basis for the directive was article 118a in the Treaty of Rome, presently article 138 (which concerns consultations between parties on the labour market). Member States should implement the Directive no later than 5 May 2001 and report to the Commission every five years on its practical implementation.

The directive lays down minimum requirements for the protection of workers from risks to their safety and health arising from the effects of chemical agents in the workplace. The scope of the directive includes any chemical substance or preparation that may pose a risk to safety and health of workers due to physicochemical, chemical or toxicological properties. However, chemical substances and preparations that are “hazardous to the environment” only are not covered.

To ensure that the risks from hazardous chemical agents are eliminated or reduced to a minimum, the employers are requested to conduct a risk assessment. The risk assessment must be documented. If it is not possible to substitute the chemical agent or process that may pose a risk, the next steps to be taken are engineering controls, use of adequate equipment or

general protection measures such as ventilation. The last option is to use individual personal protective equipment.

The chemical agents directive also establishes the procedure for setting binding or indicative occupational exposure limit values at Community levels. After consultation with an Advisory Committee on Safety, Hygiene and Health protection, the Commission submits a proposal on establishing either a binding or an indicative exposure limit value. After adoption of this limit value, the Member States are obliged to establish a corresponding occupational limit value. In the case of an indicative occupational exposure limit, Member States may establish limit values also at a higher or a lower level.

The Directive on Pregnant Workers and Workers who have Recently Given Birth or are Breastfeeding (92/85/EEC)

DEHP is included in Annex II, Section A in this directive, as the substance has been classified as toxic to reproduction in category 2. However, the risk phrases stating these inherent properties have not been updated in the directive. Pregnant workers may under no circumstances be obliged to perform duties connected with exposure to chemical agents that are listed in the Annex II and that could jeopardize safety or health.

The purpose of the directive is to encourage improvements in the safety and heath at work of pregnant workers and workers who have recently given birth or are breastfeeding. Among other things, the directive places a duty on the employer to temporarily introduce measures to avoid exposure through adjustment of working conditions, granting leave or moving the employee to another job.

3.1.4 Legislation applicable to the lifetime exposure

The Directive on Waste (91/689/EEC)

Chemical preparations containing more than 0,5 % of a teratogenic substance are classified as teratogenic according to the criteria laid down in the preparations directive. Most of the waste categories included in the list of “hazardous substances,” referred to in the directive on waste and decided by the Commission, are materials, articles or mixtures of different remainders. As the definition of hazardous waste in the directive is based on identified properties of the waste, it is possible to consider all categories of wastes, i.e. also disposed products containing more than 0,5 % DEHP as hazardous waste.

Council Directive 91/689/EEC on waste lays down general requirements for the management of hazardous waste. Domestic waste is exempted from the provisions in the directive. The legal basis for the directive is article 130 s of the Treaty of Rome corresponding to the article 175 in the present treaty.

The scope of the directive is to improve the effectiveness of the management of hazardous waste and to ensure that disposal and recovery of hazardous waste is monitored in the fullest manner possible. Member States are required to take necessary measures to record and identify sites where tipping (discharge) of hazardous waste takes place and to avoid mixing of

different categories of hazardous waste. Furthermore, Member States are obliged to ensure that, in the course of collection, transport and temporary storage, hazardous waste is properly packed and labelled in accordance with the international and Community standards.

Among other provisions, installations handling hazardous waste on the behalf of third parties must obtain a permit from the competent authority. More detailed demands on hazardous waste, e.g. concerning permits, applications, identification forms, fees etc, are laid down in national regulations.

According to the directive, a harmonised list of "hazardous waste" should be drawn up. Such a list is established in the Council Decision 94/904/EC and updated in the Commission Decision 2000/532/EC. The list will be periodically reviewed. The list includes e.g. remainders from different industrial processes, packagings, construction and demolition materials as wood, glass, metals and plastics, discarded equipments and components.

Waste classified as hazardous is considered to display one or more of the properties listed in Annex III. Among others, the property teratogenic[17] (corresponding to the risk phrases R 60 – May impair fertility and R 61 – May cause harm to the unborn child) in category 1 and 2 is included in the list. This is based on the criteria laid down in the preparations directive. If the total concentration of one or more substances toxic for reproduction is >= 0,5 %, the waste is considered to be classified as hazardous. According to an amendment, Commission Decision 2001/118/EEC, the wording one or more substances has been replaced by one substance.

The Directive on Integrated Pollution Prevention and Control (96/61/EC)

The production of DEHP is covered by the requirements in the IPPC directive, as this substance is an "oxygen-containing hydrocarbon" produced in relatively large amounts.

Since DEHP may affect reproduction if exposure occurs via air or water, the substance is also considered to belong to Annex III, an indicative list of main polluting substances needing emission limit values.

DEHP could also be highlighted in forthcoming work on a BREF Document on the best available techniques (BAT) for polymerisation processes, planned to be finalised in 2004. According to recent information, plasticisers may however not be covered by the BREF.

The scope of the IPPC-directive, is to lay down measures designed to control emissions in order to achieve a high level of protection to the environment as a whole. It integrates provisions and measures dealing with emissions to air, water and land, including measures concerning wastes as well as the efficient use of resources like energy. The legal basis for the directive is article 175 of the Treaty.

One basic requirement of the directive is the use of best available techniques. Another is that no significant pollution is caused. The replacement of hazardous substances with less hazardous substances is also emphasised.

[17] A teratogenic substance may pose a risk by impairing fertility and/or cause harm to the unborn child.

The directive covers mainly medium-sized and large scale industrial installations but also waste management installations. The activities affected by the directive are listed in Annex I to the directive. Chemical installations for the production of basic organic chemicals are included in this Annex. Among others, manufacturers of polymers are explicitly mentioned. Industries producing finished articles containing DEHP, like floorings etc., are however not covered.

New installations listed in Annex I require a permit from the competent authority before being put into operation. Existing installations (in operation before October 2000) will have to operate in accordance with the directive by 30th October 2007 at the latest.

The permit shall include emission limit values for pollutants likely to be emitted from the installations in significant quantities. Emission limit values shall be based on best available techniques (BAT).

In order to facilitate the exchange of information between Member States and industry, BAT Reference Documents (BREFs) are published. They are an important source of information e.g. on the possibility to reduce emissions in the sectors. Such measures include both substitution of a chemical and technical measures to prevent or reduce the emissions. Until now, 15 BREFs have been published and at least 17 further brefs are set to emerge over the coming years. They are to be taken into account by national authorities when granting a permit. The work on a BREF regarding polymers is planned to start in 2002 and be finalised in 2004 (personal communication, Nyström, 2001).

The Water Framework Directive (2000/60/EC)

The European Parliament and the Council adopted a revised Commission proposal of the list of priority substances on 20 November 2001[18]. The list comprises 33 substances. DEHP is included in the category “priority substances under review”. These are substances that show properties similar to those substances identified as priority hazardous but need further scrutiny. The Commission was to make a proposal for the final classification of these substances no later than December 2002. A community wide Environmental Quality Standard is to be discussed for DEHP, as the substance is included in the list of priority substances.

The Water Framework Directive (WFD) directive establishes a framework for Community action in the field of water policy. The aims of the directive are maintaining and improving the aquatic environment. The legal basis for the directive is article 175 of the Treaty. The directive covers inland surface waters, transitional waters, coastal waters and groundwater. The aquatic environment of surface waters includes water column, sediment and biota.

The core objective laid down in the WFD is to prevent deterioration of the status of surface and groundwater. In addition, for surface waters the aim is to achieve good surface water status within 15 years. For groundwater, in addition to the requirements of good status, any significant and sustained upward trend in the concentration of any pollutant should be identified and reversed.

[18] Decision No 2455/2001/EC) (O.J. 15.12.2001 L331/4).

The WFD recognises that individual substances or groups of substances may present a significant risk to or via the aquatic environment and requires action against pollution caused by these substances. Substances that present a significant risk to, or via the aquatic environment, will be prioritised for action on the basis of risk ("priority substances"). Article 16(2) of the directive introduces a scientifically based methodology for selecting priority substances on the basis of their significant risk to or via the aquatic environment. Risk may be identified e.g., by risk assessment carried out under the Existing Substances Regulation. "Priority hazardous substances" will be identified among the priority substances.

The Commission shall submit proposals for:

- *the environmental quality standards (EQS) applicable to the concentrations of the priority substances in surface water, sediments or biota,*
- *product and process controls for point and diffuse sources.*

For priority substances, the proposed controls shall aim at progressive reduction of discharges, emissions and losses and for priority hazardous substances cessation or phasing out of discharges, emissions and losses within 20 years.

The Commission is to submit such proposals for EQSs and control measures within two years of the inclusion of the substance on the list of priority substances. The proposed product and process controls are to be established under the relevant Community or national legislation. In the absence of agreement on EQSs and control measures at Community level six years after the date of entry into force of the WFD, the Member States are to establish EQSs and controls for principal sources.

3.2 The OSPAR Convention

OSPAR is the Convention for the Protection of the Marine Environment of the North-East Atlantic. In 1998 the first OSPAR List of Substances for Priority Action was established. The objective is to prevent pollution of the maritime area by continuing to reduce discharges, emissions and losses of hazardous substances with the ultimate aim of achieving concentrations in the marine environment near background values for naturally occurring substances and close to zero for man-made synthetic substances. Every endeavour will be made to move towards the target of cessation of discharges, emissions and losses of hazardous substances by the year 2020. DEHP is listed amongst the 30 priority substances /groups of substances in this list (OSPAR, 2000).

In the field of the Water Framework Directive, DEHP is identified as a "priority substance" under review. If DEHP is identified as a "priority hazardous substance" the intentions in the OSPAR Convention could be considered as implemented by European legislation.

3.3 Taxes and fees

Economic instruments can provide incentives for innovation and development of alternatives that are not affected by taxes or fees. A tax or fee can act as a separate measure or in conjunction with other measures. There is little practical experience from taxes or fees designed to affect certain products, as most of the charges today are emission charges.

See also below in section 3.5.1 National Actions – Denmark.

3.4 National Actions

3.4.1 Denmark

In agreement with the Danish environment minister, Danish toy importers and retailers are since November 2002 drafting a plan for identifying and phasing out phthalates in toys for children aged three-to-six.

The Danish Environmental Protection Agency has initiated a range of projects on issues related to substitution of phthalates (Danish Environment Ministry, 1999). One of the projects focuses on alternatives to phthalates. In consultation with the industry, eleven substances or groups of substances were selected as possible alternative plasticisers. The substances have been assessed with respect to inherent properties and potential risk to humans and the environment.

In December 1999 a law on taxes on PVC and phthalates in certain products was adopted in Denmark (Danish Parliament, 1999). The law has been in force since 1 July 2000. The tax is differentiated depending on the content of phthalates. One objective of the law was to increase recycling of PVC products and to prevent incineration of PVC Another goal was to reduce the use of phthalates in products listed in an Annex. The groups of articles covered by the law provide about 85 per cent of the Danish consumption of PVC and 65 per cent of the Danish consumption of phthalates in soft plastics. The tax is expected to provide further incentive to choose other plasticers than phthalates or other materials than PVC

The Danish EPA has also produced information sheets on alternatives to PVC and phthalates related to specific product groups. The information sheets can be downloaded from their website www.mst.dk.

3.4.2 The Netherlands

A Dutch governmental policy statement on plasticisers has been elaborated jointly by the Ministries of Economic Affairs, Social Affairs and Employment, Public Health, Welfare and Sport and Transport, Public Works and Water Management, coordinated by the Ministry of Housing, Spatial Planning and the Environment (DGM SAS, 2002). The policy statement gives an overview of the plasticisers used, their areas of applications, the possible hazards and risks and the policy and measures designed to reduce those hazards and risks for man and the environment. The statement has been based mainly on the risk assessments undertaken within the Existing Substances Regulation together with some new studies: Inventory of plasticisers (TNO, 2002b); Alternatives for phthalates (TNO, 2002a); Hazard assessment of plasticisers (RPS BKH, 2002).

In a recent status report from the Ministry of Housing, Spatial Planning and the Environment, a number of “policy spearheads” are included that regards plasticisers with sufficient data, a.o. DEHP:

Baby toys and childcare articles. Within the EU, a temporary ban now applies to DEHP, DBP, BBP, DINP, DIDP and DNOP in these products. The Ministry of Health, Welfare and Sport is preparing a general administrative order providing for a systematic ban on the use of these plasticisers in the Netherlands for baby toys and childcare articles (which can reasonably be expected to be put in the mouth).

Working environment. Because the EU risk assessment indicates that the current MAC values for DEHP and DBP do not provide adequate safeguards for the protection of workers, the Ministry of Social Affairs and Employment wishes to adapt these Dutch MAC values as quickly as possible (and possibly temporarily) at the national level in the light of these new insights.

DEHP. In the case of this specific plasticiser, the Netherlands will urge the EU, after the adoption of the EU risk assessment, to take fast and effective action to eliminate the observed risks. To reduce diffuse emissions to the environment and the subsequent indirect exposure of humans, products associated with large emissions of DEHP, such as coatings under cars, construction sheeting and tarpaulins, should be covered by the risk reduction measures.

In addition to the "policy spearheads", the Dutch government announces that the following steps will be taken in a supplementary national policy:

Medical devices. According to the draft DEHP risk assessment, a number of applications of medical devices involve risks for certain risk groups (neonates, babies and children) which are considered to be important enough to merit further study. In anticipation of European policy, the National Institute of Public Health and the Environment (RIVM) will draw up a review of the use of medical devices manufactured using DEHP in the Netherlands. The focus of the review will be on the link with the risk groups. The risk analysis of the manufacturers of the relevant products will then also be evaluated. The need for measures to minimise exposure to phthalates is also being studied, primarily in the risk groups consisting of neonates, babies and children. No general ban is being instituted beforehand of medical devices manufactured using PVC-DEHP because this could endanger the availability of vital medical devices and a risks/benefit analysis could very well indicate that the risk associated with the use of this substance is acceptable.

Environmental emissions. The current Dutch Emission Guideline (NeR) will be revised. For substances in the category that includes DEHP, a minimisation duty is proposed, meaning that companies must make continuous efforts to achieve zero emissions to air.

3.4.3 Sweden

In the Bill 1997/98:145 – "Swedish Environmental Quality Objectives" the Swedish Government proposed 15 environmental objectives in order to achieve a non-toxic environment within a generation, i.e. 2020. The Swedish Parliament approved these objectives in April 1999. One section in the Bill focused on a national chemical policy for the 21st century. In this section reduction objectives were set up targeting some hazardous plasticisers, among others DEHP. The objectives were to be met through substitution by voluntary initiatives.

In a progress report to the Government it was concluded that the rapid substitution of DEHP to be completed by 2001 in outdoor articles, aimed for in the Government Bill, could not be fully achieved. In other groups of articles, the substitution rate would depend on the acceptance by the suppliers of the replacement of DEHP by 2005 (KemI, 2001b). The need for a rapid phase out of DEHP and other phthalates toxic to reproduction in feeding tubes for premature babies was stressed.

3.5 Actions taken by authorities outside the European Union

3.5.1 United States

The US Food and Drug Administration (FDA), Center for Devices and Radiological Health, has examined the potential risks posed by patient exposure to DEHP by comparing the doses of this compound that patients may receive to a Tolerable Intake (TI)[19] value for DEHP. The FDA found that the greatest concern would be for very young male infants who are critically ill and have prolonged exposure to multiple devices containing DEHP. The National Toxicology Program under the National Institutes of Health recently reached a similar conclusion (USNTP, 2000). In contrast, little concern was found for adults receiving intravenous solutions or undergoing peritoneal dialysis.

FDA has communicated to health care providers across the US that it recommends using medical devices that do not contain DEHP for high risk procedures to be performed on male neonates, pregnant women who are carrying male foetuses, and peripubertal males. FDA is also evaluating ways to address the potential risks that may be associated with use of DEHP-containing devices in certain procedures. For example, FDA is investigating the availability of medical devices made from alternative materials, particularly for procedures performed on newborn boys. FDA will continue to make new information available on their website (www.fda.gov).

According to a recent article, FDA has concluded that manufacturers should consider eliminating the use of DEHP in devices that can result in high exposure in sensitive patients and that certain products should be labelled with their DEHP content (Williams, 2002).

3.5.2 Canada

Health Canada has consulted an Expert Advisory Panel on DEHP in Medical Devices on the use of DEHP in medical treatments. The aim of the consultation was to get input in form of clear advices and recommendations on the use of DEHP. The panel was specifically asked for their standpoint on restricting the use of DEHP containing devices in certain medical procedures or certain patients. The panel stated that the subgroups most at risk were:

- *Newborns*
- *Pregnant women*
- *Breastfeeding women*
- *Males before puberty*

[19] A TI value is the dose of a compound that is not expected to produce adverse effects in exposed patients.

In terms of justifying restrictions on use of DEHP containing devices, the panel included the following groups and treatments:

- *Newborns receiving ECMO[20], blood exchange treatments, total parenteral nutrition (TPN)[21] and during cardiac surgery*
- *Adults undergoing heart transplant surgery or hemodialysis*
- *Patients receiving lipophilic drugs*

Nevertheless, the panel indicated a need for more studies on storage times on blood before making recommendations for use of DEHP free bags for blood storage. (www.hc-sc.gc.ca) Health Canada has given instructions for the use of nonDEHP-PVC in a variety of devices, with the explicit indication that alternative measures are immediately justified to protect those patients at risk (Health Canada, 2002)

3.5.3 Japan

The content of DEHP in toys is regulated under the Food Sanitation Law in Japan. From August 2003, the following will apply for toys intended for children under the age of 6:

- Any synthetic resin toys (such as pacifiers) which come into direct contact with the mouth of infants and young children may not be made of polyvinyl chloride including di(2-ethylhexyl) phthalate (DEHP) or diisononyl phthalate (DINP).
- Any other synthetic resin toys for infants and young children may not be made of polyvinyl chloride including di(2-ethylhexyl) phthalate (DEHP).

(Japan WTO, 2002)

According to other recent information, the use of DEHP will be banned from August 2003 also in plastic wrapping made from polyvinyl chloride. The reason for this restriction is that DEHP can be found in 80 percent or more of foods of various forms consumed in Japan, according to findings by the Environment Ministry presented at a ministry investigative panel. The findings also indicated that the concentrations of DEHP was higher than before in the umbilical cord of newborn infants and in indoor air. The average amount of DEHP in home-cooked meals was about the same as in restaurant or ready-to-eat meals ministry officials said. While the amounts are not enough to immediately harm human health, the study noted that polluting foods that people consume on a daily basis is a danger in itself (Japan Times, October 2002).

The Japanese Ministry of Health, Labour and Welfare (MHLW) has recommended healthcare professionals not to use medical devices made of PVC in which the plasticizer DEHP is used; alternative devices should be used instead.

MHLW has studied devices available in the domestic market, in which DEHP is used. The results of these safety tests have been reported in "Pharmaceuticals and Medical Devices Safety, etc. Information No.182" dated October 31. DEHP is designated as a general toxic

[20] In Extracorporeal Membrane Oxygenation (ECMO) a heart-lung machine is used that performs most of the work for the child's heart and lungs.

[21] Pre-term babies and newborns that cannot be breast or bottle fed receive their nutrition either via catheters inserted into the vein or through tubes passed into intestinal tract.

chemical substance having toxic effects on the testis; its TDI is specified as 40-140 micrograms/kg/day.

The safety tests were carried out for six PVC medical devices using DEHP: a blood bag, blood lines for an artificial kidney, blood lines for an artificial heart-lung machine, an infusion set, an extension tube, and a feeding tube. In these tests, the blood bag and the artificial heart-lung machine gave results that surpassed the TDI limit.

As a result, MHLW has issued a recommendation that alternatives to tubes and blood lines using DEHP should be used as far as possible in view of the possible adverse effects on newborn babies and infants in particular. *(Japan Chemical Week, 2002)*

3.6 Voluntary actions

Industrial actions on a voluntary basis are important and necessary in order to implement an "Integrated Product Policy" (IPP) at Community level. The driving idea of IPP is to integrate environmental impacts at each stage of a products life cycle, which calls for a strong and extensive stakeholder co-operation.

The European PVC industry (PVC manufacturers, PVC additive producers and PVC converters as represented by their European Associations ECVM, ECPI, ESPA and EuPC) has adopted a "Voluntary Commitment on the PVC Industry" in 2000 (ECVM et al, 2000). The commitment builds on the principles of Responsible Care. Concerning plasticisers, the commitment implies that:

- *The plasticisers industry will continue to conduct research in order to provide scientific studies.*
- *If warranted by the results from the Risk assessments on, among others, DEHP, the sector will take appropriate risk reduction measures.*
- *The sector will work towards completion of a database on various plasticisers for PVC by the end of 2000.*

An annual report on the progress against the Voluntary Commitment is planned every year until 2005.

PVC Forum, a division of the Swedish Plastics and Chemicals Federation, has set up an environmental programme with the aim to clarify and intensify the PVC trade's environmental work (PVC Forum, 1999). The companies that endorse the programme undertake to work towards bringing about visions and objectives set. The programme is conducted in consultation with authorities, researchers and trade customers and will be revised gradually in order to meet new requirements.

This environmental programme covers all kinds of plasticisers. Producers of raw material and manufacturers of soft PVC are thus obliged to:

- *Develop and design plasticised products in such a way that as little as possible of the plasticiser is emitted during the use or as a post-used product.*

The requirement is associated with the setting of limit values for emissions. The manufacturers and distributors of platicisers also contribute with knowledge about the plasticiser and measurements of concentrations in the environment approximately every fifth

year. Finally it is stated that the programme must be reviewed when the EU risk assessments of the most common phthalates are finalised.

Medical devices
After the findings of DEHP leakage from feeding tubes for neonates (see chapter 2), one Danish supplier of medical devices has introduced the labelling of feeding tubes containing DEHP "to be used 24 hours at maximum". The company recommends polyurethane tubes if it is necessary to use the tube more than 24 hours (pers. comm. Hastrup, May 2001).
At a national seminar organised by the Chemical Inspectorate on 12 September 2002 it was concluded that feeding tubes for neonates nowadays substantially are made of polyurethane.

Floorings
A Swedish manufacturer of floorings has taken a policy decision not to use chemicals classified as toxic and labelled with a skull and crossbones. DEHP has thus been substituted by another phthalate plasticiser; DINP. The company's share of the market at Community level is estimated to approximately 25 – 30 % corresponding to 30 000 tpa in terms of PVC floorings (Friberg, pers.comm. May 2001). After testing different alternatives a more general substitution to DINP is carried out by Swedish producers of floorings according to information provided at the seminar on 12 September 2002.

Cables
According to information from the European Confederation of National Associations of Cable Manufacturers (ECBL), DEHP has already been substituted in some applications.

Food packaging
Normpack - The Swedish Code for Food Packaging Materials- establishes Swedish material norms to obtain product reliability for materials and products in contact with food and develops routine systems for the self-imposed control regarding product reliability. Normpack is a part of The Swedish Institute for Packaging and Logistics. According to a temporary standard, established by Normpack, DEHP is not permitted as an additive in food packaging films intended for fatty foods such as cheese. All the major producers are affiliated to Normpack and a number of supermarket chains request that the packaging complies with the Normpack standards.

3.7 Summary of current risk reduction measures

The classification of DEHP as toxic to reproduction in category 2 and labelling with a skull and crossbones leads to restrictions in consumer accessibility to DEHP as a chemical substance. For articles such as floorings, cables and medical devices etc., the classification has no direct impact, as the system for classification and labelling does not cover these kinds of articles.

The Directive on General Product Safety is used for the temporary ban on phthalates in toys and child care articles. For the time being, this is the only kind of article containing DEHP that is affected by restrictions on marketing.

DEHP is under discussion to be included in an Annex of the 8th amendment of the Directive on Plastic Materials in Contact with Foodstuffs. In this amendment the use of DEHP is proposed to be limited to polymers not coming into contact with fatty foodstuff. Neither

DEHP nor restrictions in its use were however included in the incomplete list of additives in the Commission Directive 2002/72/EEC.

The Directive on Medical devices relies on essential requirements, among others, a risk-benefit analysis. There are no specific demands concerning hazardous chemical substances. There is therefore uncertainty if the risks to human health, identified in the Risk Assessment, will be taken into account in the risk-benefit analysis carried out by the producers.

In the Chemical Agents directive for the working environment there are no special provisions for substances that are toxic to reproduction.

The risk phrases stating the inherent properties of toxicity to reproduction have not been updated in the Directive on Pregnant Workers and Workers who have Recently Given Birth or are Breastfeeding.

The Directive on Integrated Pollution Prevention and Control affects large installations producing the PVC polymer and the substance DEHP, but not the manufacturing of articles such as floorings etc. Presently no other legal measures are aimed to minimize emissions from installations producing articles containing DEHP at Community level. The present requirements laid down in the IPPC directive could only to a limited extent reduce the DEHP emissions, as practically no down stream users of DEHP are affected. Regarding existing installations, the requirements will not come into force until 2007.

Within the Water Framework Directive a list of “priority substances” has been established. DEHP is included in the list and is also under discussion for classification as a priority hazardous substance. The aim is to continuously reduce discharges, emissions and losses from such substances. If DEHP were to be classified as a “priority hazardous substance”, the pressure would increase on measures in other relevant legislation to reach the goal of emission cessation within 20 years. Furthermore, such a classification would implement the intentions in the OSPAR Convention in European legislation.

One interpretation of the intentions in the directive on waste could be to consider all categories of waste containing 0,5 % or more DEHP, i.e. also disposed articles, as hazardous waste.

Industrial initiatives leading to DEHP risk reduction at Community level are sparse, based on information available to the rapporteur. A shift to other plasticisers has to some extent been carried through which provides good examples on successful substitutions A few manufacturers of articles containing DEHP have taken a policy decision not to use DEHP or have implemented national standards substituting DEHP as an additive. Most measures taken by industry mainly focus on the downstream users´ responsibility, due to the classification as a substance toxic to reproduction in category 2, when handling DEHP.

The experience of taxes and fees as risk reduction measures is very limited so far. The Danish law on taxes on PVC and phthalates has been in force too short a time to be evaluated with respect to its impact on the reduced emissions of DEHP.

In summary looking at exposed groups at risk, the direct exposure has been reduced at Community level only for children. Toys and childcare articles, however, represent only very few of the various types articles giving rise to DEHP exposure.

As DEHP is widely used in the society, people are exposed to DEHP throughout their entire lifetime via food, via emissions from products containing DEHP to the indoor air etc. As discussed in section 2, no sources can be said to be unimportant concerning contribution to the diffuse emissions. Furthermore, all sources cannot be quantified nor can they always be identified. The exposure of vulnerable groups, such as children and patients in certain kinds of medical treatment, needs special attention.

The description in this section provides the baseline for the discussion and evaluation of further risk redaction measures although a quantification of the current risk reduction as well as the point of time for their entire impact is hard to estimate.

The following instruments will be further discussed in chapter 4, as possible ingredients in a risk reduction strategy on DEHP:

- The Directive on the Safety of Toys
- The Directive on General Product Safety
- The Directive on Restrictions on Marketing and Use
- The Directive on Plastic Materials and Articles Intended to Come into Contact with Foodstuffs
- The Directive on Medical Devices
- The Directive on Chemical Agents at Work
- The Directive on Pregnant Workers and Workers Who Have Recently Given Birth or are Breastfeeding
- The Directive on the Protection of Workers from the Risks Related to Exposure to Carcinogens at Work
- The Directive on Waste
- The Directive on Integrated Pollution Prevention and Control
- The Water Frame Work Directive
- Taxes and fees at Community level
- Voluntary actions at Community level

4 Possible risk reduction measures

In the following section possible further risk reduction measures for controlling risks associated with DEHP will be discussed. Before this, a brief summary of the EU strategy for a Future Chemicals Policy is given. The reason for including the strategy in this context is that DEHP as a substance toxic to reproduction would be very likely to be affected of the new chemicals policy. The new policy should therefore be kept in mind in the following discussion.

4.1 EU Strategy for a Future Chemicals Policy

In February 2001 the Commission presented a White Paper with proposals for a strategy on future chemicals policy in the Community. The Council agreed on conclusions regarding the strategy in Luxembourg 7 June 2001.

The Council supports the development of the REACH system for the management of chemicals (**R**egistration, **E**valuation and **A**uthorization of **Ch**emicals). Authorization means that for substances of very high concern, authorities will have to give specific permission before such a substance can be used for a particular purpose. The authorization process will cover, among others, substances that are carcinogenic, mutagenic or toxic to reproduction (CMR substances) in categories 1 and 2. As a substance classified as toxic to reproduction in category 2, DEHP would be subject to the future authorization procedure, according to the REACH system.

Although it will take some time before the Chemicals Policy is in force, the political decision to create an authorisation procedure affecting CMR substances has already been agreed on by the Council and the Parliament.

4.2 Legislative Controls in the European Union

4.2.1 Protection of Consumers (children and adults)

The Directive on the Approximation of the Laws of the Member States concerning the Safety on Toys ((88/378/EEC)

A systematic approach could be to introduce general restrictions on the use of all substances classified as carcinogenic, mutagenic or toxic to reproduction category 1 and 2 in all toys.

The Directive on General Product Safety (92/59/EEC)

The directive has so far only been used for the temporary ban on phthalates in toys and childcare articles (see section 3.2.2).

When regulating specific categories of articles, the general rule has been to use sectorial legislation if such directives are in force. If the handling of an article is not included in such a directive, or if the procedure for measures to be taken is time consuming or vague in addressing risks to human health or to the environment, the directive on product safety might be an alternative when restrictions are urgently needed.

One possible urgently needed measure could be to restrict within this directive the use of DEHP in medical devices for neonates, e.g. feeding tubes.

The Directive on Restrictions on Marketing and Use of Certain Substances and Preparations (76/769/EEC)

Restrictions on DEHP and five other named phthalates in toys and childcare articles are under discussion within this directive. Until such restrictions are adopted, there is a temporary ban covering the same products under a Commission decision (See section 3.1.1).

Restrictions on marketing and use could be used within a broad area, including medical devices. The restriction can cover a total ban in all kind of uses or just address limited areas of use or certain articles. It is also possible to impose time-limited exemptions for specific uses, allowing for the development of alternatives. Another alternative is to place restrictions upon the migration from products.

It is thus possible to apply restrictions on marketing and use of DEHP to a broader area of products than childcare articles in order to tackle the scenario with diffuse sources and life time exposure. A broadening of the scope for toys and childcare articles by emitting the qualification ”intended to be put in the mouth” and “under the age of 3” is one measure which needs to be considered. Another possible measure is a broader restriction on DEHP in medical devices others than those intended for neonates.

The Directive on Plastic Materials and Articles Intended to Come in Contact with Foodstuffs (90/128/EEC)

A step towards a reduced exposure from food packages has been taken, in that the use of DEHP is proposed to be restricted to polymers not coming into contact with fatty foodstuffs. Although leakage of DEHP to acid or water-soluble foodstuffs seems to be low, restrictions covering all kind of foodstuffs need to be considered. Excluding DEHP from the positive list would eliminate plastic food-packages as a source, which by direct exposure, contributes to the life time exposure of DEHP.

Relation to the Authorisation procedure

The authorization procedure, as envisaged in the future chemicals policy, will entail a ban to use DEHP, unless permits are granted for specific uses. The starting point is that restrictions on use already in force will remain. In addition to that, all other uses not being subject to an authorisation, will be restricted.

Granting an authorisation, raises issues on whether there are uses where an authorisation should be denied irrespectively of socio-economic benefits. Such a situation could be widespread use in articles intended for consumer uses, as the exposure from such uses would be very hard, if not impossible, to control.

4.2.2 Protection of Patients

The Directive on Medical Devices (93/42/EEC)

The Scientific Committee on Medical Products and Medical Devices was asked by the Health & Consumer Protection DG within the European Commission to answer the following questions:

- *Are there particular medical devices containing DEHP used for neonates which give cause for concern?*
- *Are there any other patients groups, which also would give cause for concern?*
- *What Tolerable Intake Value of DEHP leaking from soft PVC should be used as a basis for risk assessment for neonates, taking into account gender and route of exposure?*

The Committee concluded that:

- At this moment no specific recommendation can be made to limit the use of DEHP in any particular patient group.
- No Tolerable Intake Value for DEHP in medical devices can be recommended.
- So far there are no indications that neonates of high DEHP exposure have any altered long-term fertility patterns.
- Nevertheless, the levels of DEHP that induce toxic effects in rodents are of the same order as the exposure experienced by some neonates in clinical practice.
- A lack of data does not lead to a conclusion that DEHP is without adverse effects. Specifically it is agreed that in critically ill neonates, who constitute an inherently high-risk group patients, the lack of evidence of causation between DEHP-PVC and any disease or adverse effect does not mean that there is no risks.
- Patients who experience prolonged periods of DEHP exposure e.g. haemodialysis or in receipt of repeated blood product transfusions, risks and benefits should be considered carefully.
- It is always necessary to evaluate and balance the risks and the benefits of the alternatives.

The general outcome from consultation of the Scientific Committee on Medical Devices, was that no specific recommendation could be made to limit the use of DEHP in any particular patient group and that no Tolerable Intake value for DEHP in medical devices could be recommended.

Nevertheless, the Committee drew attention to that the levels of DEHP inducing toxic effects in rodents are of the same order as the exposure experienced by some neonates in clinical practice and that a lack of data does not lead to a conclusion that DEHP is without adverse effects. Specifically it was agreed that in critically ill neonates, who constitute an inherently high-risk group, the lack of evidence of causation between DEHP-PVC and any disease or adverse effect does not mean that there are no risks. Furthermore, concerning patients who experience prolonged periods of elevated DEHP exposure e.g. haemodialysis or in receipt of

repeated blood product transfusions, the Committee stated that risks and benefits should be considered carefully.

The groups of patients, where the Scientific Committee on Medical Devices could not exclude concern, are thus the same as identified in the risk assessment made by the rapporteur.

These circumstances underline the need to find alternatives to DEHP and to introduce restrictions in uses described above. Such Community wide restrictions could either be addressed directly in this directive or through the Restriction Directive or through the General Product Safety Directive.

4.2.3 Protection of Workers

The Directive on the Protection of the Health and Safety of Workers from Risks Related to Chemical Agents at Work (98/24/EEC)

As stated in the section "Current risk reduction measures" the directive provides general provisions for safety and health at work. The provisions for risk evaluation could however be difficult to implement, especially concerning small and medium-sized enterprises.

The directive also establishes the procedure for setting Community level occupational exposure limit values. For the time being, there is no binding or indicative exposure limit value for DEHP.

The substitution principle is included in the directive in the sense that substitution is the first measure outlined to reduce a risk according to the use of a hazardous substance or process.

Possible measures within the directive could be to put more emphasise on substitution when the compulsory risk assessment, carried out by the employer, indicates a risk to the human health, and furthermore to establish a exposure limit value at Community level. The worst-case exposure scenarios presented in the RA, indicates that the levels of existing national exposure limits might not be protective enough.

The Council Directive on pregnant workers and workers who have recently given birth or are breastfeeding (92/85/EEC)

The employer is required to assess any risks to the safety or health and any possible effect on pregnancy or breastfeeding. Annex 1 includes, among others, chemical agents that should be paid special attention to; chemical substances labelled with risk phrases R 40, R 45 (carcinogens) and R 46 (mutagens). Risk phrase R 47 (might cause damage to the foetus) is also mentioned, but this particular risk phrase is no longer included in the directive on classification and labelling. The present risk phrases for damage to fertility and the foetus are R 60 and R 61. Thus, the directive needs to be updated so that R 60 and R 61 replace R 47 in Annex 1 of the directive. A high level of protection of pregnant and breastfeeding women would also reduce the risks to the unborn child as well as the infant.

The Directive on the Protection of Workers from the Risks Related to Exposure to Carcinogens at Work (90/394/EEC)

The directive provides a step-by-step approach for the control of workplace risks associated with chemical substances and preparations that meet the criteria for carcinogens and mutagens (category 1 and 2) according to the dangerous substances directive and the preparations directive. Substances that meet the criteria for toxic to reproduction are not included in the directive.

To improve the level of protection, it should also be considered whether the directive could be amended to include in its scope also risks posed by substances toxic to the reproduction. As an alternative, the framework legislation for worker protection could be extended with measures equivalent to the Carcinogen Directive for substances classified as toxic to reproduction, category 1 and 2.

Relation to the Authorisation procedure

The need for further actions related to the working environment would depend on the final extent and shape of the envisaged authorization procedure concerning substances of very high concern. Demands on a higher level of protection in the working environment could for some uses e.g. be time limits and conditions for authorisations.

4.2.4 Legislation applicable to the lifetime exposure

The Directive on Waste (91/689/EEC)

The continuous emissions during the production and use of articles seem to be the most important sources of exposure. This emphasises the need for measures affecting the production and use, as there is a time-lag between PVC consumption and presence in the waste stream. Although waste management only affects the very last stage in the lifecycle of products, the anticipated increased volumes of PVC waste within the coming decades could be of importance. In a Green Paper on Environmental Issues of PVC, the volume of PVC waste is thought to have increased by 30 % in 2010 and by 80 % in 2020, in particular due to the increase of non-plasticised waste from long span products, like PVC-materials (CEC, 2000). The data is however lacking on the increase of plasticised PVC waste.

The Commission considers in the Green Paper that recycling of PVC should be increased. Such a consideration is an example on a conflict of interests in society and raises issues on special conditions concerning the content of hazardous substances such as DEHP in PVC.

Classification and treatment of DEHP-containing waste as hazardous waste would reduce the risk of diffuse emissions from landfills etc. to the environment. One interpretation of the intentions in the Waste directive is that all categories of waste containing 0,5 % or more DEHP, i.e. also articles as floorings, could be considered as hazardous waste.

The Directive on Integrated Pollution Prevention and Control (96/61/EC)

The requirements in the directive will from 2007 affect existing large and medium-sized installations producing the PVC polymer and the substance DEHP. The manufacturing of PVC articles such as floorings etc will not be affected.

According to Article 18 of the directive, community emission limit values could be set acting on a proposal from the Commission. Currently there are no community values, neither for DEHP nor for any other substances. In general, the time schedule for setting such values is thus uncertain. At least, plant permits for the production of DEHP and PVC should include limit values for DEHP emissions.

Furthermore the BREF for polymerisation processes, planned to be finalised in 2004, could also include considerations on DEHP. In a longer run a general approach on CMR substances needs to be considered in the work on BREFs.

The Water Framework Directive (2000/60/EC)

Within the framework of the directive, a list of 33 priority substances has been established. DEHP is included in the category "priority substances under review". As a consequence of being included in the list of priority substances, a continuous reduction of emissions is demanded. Additionally, community wide Environmental Quality Standards (EQS) are under preparation. The importance of an EQS as a tool for risk reduction depends, among other things, on the level of the standard, on the establishment of monitoring programmes, on the possibility to locate sources if the standard is exceeded and on the actions that will be taken. To be effective in establishing an EQS, it is important to take the physical properties of the substance into account and set standards for compartments where the substance would be found. Concerning DEHP, the adequate compartments are i.e. sediments or biota as DEHP is a highly lipophilic substance.

At the Technical Meeting in July 2002 experts agreed, when assessing PBT properties, that DEHP should not be considered as fulfilling the criteria, although for some of the criteria it is a borderline case. However, the experts also agreed that additional factors such as widespread diffusion into the environment and measurements in remote areas, suggesting lifetime exposure, should be highlighted but that it should be left to the **EAF** (Expert Advisory Fora; a working group within the Water Framework Directive) whether these are factors of importance for deciding that the substance should be a priority hazardous substance. A classification as a "priority hazardous substance" would mean increased demands on a cessation of discharges, emissions and losses of DEHP within 20 years. Should DEHP be classified, the intentions in the OSPAR Convention could be considered as implemented in European legislation.

Relation to the Authorisation procedure

The need for further actions relating to the environment depends on the final extent and shape of the envisaged authorization procedure concerning substances of very high concern. Demands on risk reduction measures in the environment could for some uses e.g. be conditional for granting an authorisation.

4.3 Voluntary actions at Community level

Voluntary actions might be suitable in situations with a limited number of uses of a substance and a small number of parties, as the performance is dependent of co-operation within industry. A commitment can be made at national or Community level. As the commitments are not legally binding, the impact of them may vary. A commitment should preferably be combined with the assumption that regulatory measures will be taken if they are not fulfilled.

In view of the concerns for the most vulnerable groups, children and patients, voluntary actions might not be suitable to ensure rapid and safe actions. In general it may be uncertain to rely on agreements with a limited numbers of stakeholders in cases of serious concerns with implication on future generations. An example of unsuitable inequalities could be that some health care institutions are able to pay for more expensive and less hazardous alternatives, while others with less purchasing power and less knowledge about the risks posed by DEHP, might continue to use devices with DEHP.

In addition, voluntary commitments call for a limited number of organisations, which can verify that members fulfil the commitments and also ensure monitoring and verifying the impact of the commitments.

The voluntary actions taken so far at Community level are, however, very few and of general character and affect individual types of manufactured articles to a less extent. For the time being, voluntary actions covering a broad area of articles and uses, do not seem to be an effective tool in a risk reduction strategy on DEHP. The measure will thus not be considered in a further evaluation of possible risk reduction tools.

Relation to the Authorisation procedure

The EU strategy for a Future Chemicals Policy does not give a scope for voluntary actions for substances of very high concern. Voluntary actions may however support the envisaged authorisation procedure.

4.4 Taxes and fees at Community level

The difference between a tax and a fee is that a fee corresponds to a specific service in return, while taxes are not earmarked for specific purposes. In this way, there would be no assurance that the income from a tax will be used for development within the environmental area.

The level of taxes in general differs between the Member States. The approach has so far been, that the kind of taxes and the level of the tax is a decision to be taken by the Member State. In case of value added taxes and excise duties, these taxes are set on a minimum level and left to the Member State to decide on the level of the tax. A low tax rate and generous exemption clauses could be obstacles in the impact of the tax, in the sense that the tax will not be an effective tool.

Experience gained from the Swedish work to reduce cadmium contents in phosphate fertilisers, however, shows that a tax has been an important part of the national policy.

Introducing a tax or fee thus might be one step to reach an objective, but it often needs to be complemented by other measures, voluntary or legal.

Due to lack of experience and the foreseen difficulties to reach agreements at Community level on the nature and level of a tax or fee, economic instruments will not be taken into further consideration.

Relation to the Authorisation procedure

The intentions in the authorisation procedure, in the EU strategy for a Future Chemicals Policy do not give a scope for taxes or fees. They may, however, in the same way as voluntary actions, support and speed up the substitution of DEHP in case of permitted use areas.

4.5 Summary of possible further measures

A number of possible risk reduction options have been identified. It has also been discussed how the measures would apply to the populations at risk. Most of the measures only partly cover the populations at risk. Moreover, they do not cover all stages of the DEHP lifecycle. No single measure affects all risk scenarios concluded in the RA. More emphasis is needed on the lifetime exposure, due to releases of DEHP from a great number of various articles, in the evaluation of possible risk reduction tools.

The EU Strategy for a Future Chemicals Policy has been discussed in order to picture the anticipated coming regulations for substances as DEHP, classified as toxic to reproduction in category 2. Such substances will be subject to an authorisation procedure and must not be put on the market unless they are given a specific permit. The authorisation procedure will play an important role in the coming EU-regulation and should therefore be taken into consideration in the risk reduction strategy.

In the end of 2001 the Scientific Committee on Cosmetic Products and Non-Food Products Intended for Consumers (SCCNFP) on request by the Commission, announced the opinion that the presence of carcinogens, mutagens and substances toxic to reproduction in cosmetic products is of concern to the health of the consumer. Such substances must therefore not be added intentionally to cosmetic products. This opinion could be the beginning of a more general approach in order to harmonise chemical regulations and regulations addressing different kind of articles. Concerning DEHP, such a general approach on restrictions on the use of CMR substances should be considered when amending the directives addressing safety of toys, medical devices and food packaging materials.

There are a number of existing directives covering specified types of manufactured articles and addressed to protect consumer health. Risks connected with the use of such articles should on the first hand be regulated by these directives. In cases when restrictions on marketing and use are urgently needed, the Directive on General Product Safety could offer a temporary settlement. The possibility to urgently activate this directive, concerning medical devices intended for use by neonates, should be further evaluated.

Restrictions on marketing and use could be used within a broad area covering all kind of articles including medical devices. The restrictions may cover a total ban of DEHP in all

kinds of uses or just address limited areas of use or certain manufactured articles. It is also possible to impose time-limited exemptions for specific uses, allowing for the development of alternatives. To what extent restrictions on marketing and use are preferable, needs a further evaluation.

In general, restrictions on marketing and use will also reduce the occupational exposure to DEHP as well as emissions to the environment from the production and processing of DEHP and plasticised PVC articles. In this way there will be less need for controls of direct exposure to workers or to the environment.

Restrictions covering the use of DEHP in packaging material for all kinds of foodstuff need to be considered. This could be done by excluding DEHP from the positive list and thereby food-packages would be eliminated as a source of exposure.

The groups of patients, where concern could not be excluded by the Scientific Committee on Medical Devices, are the same as identified in the risk assessment made by the rapporteur. The need to find alternatives to DEHP, consider their risks and benefits and introduce restrictions in the use of DEHP is underlined. Such Community wide restrictions could either be addressed directly in this directive or through the Restriction Directive or through the General Product Safety Directive.

For the time being there is no occupational exposure limit value at Community level for DEHP. An occupational exposure limit value would contribute to safety at work irrespectively of other measures taken. More emphasis on substitution in interpreting the intentions in the directive would also contribute to a higher level of protection.

A minor adjustment in the Annex 1 of the directive on pregnant and breastfeeding woman, so that the risk phrases R 60 and R 61 replace R 47, would ensure these groups to be covered by the demands in the directive.

Substances that meet the criteria for toxicity to reproduction are not included in the Carcinogens Directive. It should be considered whether the carcinogens directive could be completed to include in its scope also risks posed by substances toxic to the reproduction. An alternative measure is to extend the framework legislation on worker protection with measures equivalent to the Carcinogen Directive for substances classified as toxic to reproduction.

In the light of the anticipated increased volumes of PVC waste within the coming decades, an effective management of DEHP-containing waste might prevent leakage from e.g. landfills.

As the Directive on Integrated Pollution Prevention and Control is framed, the production of DEHP and PVC-polymers is covered. A BREF for polymerisation processes is to be finalised in 2004, and could include considerations on DEHP. In a longer run, general considerations on CMR substances should be included in the work on BREFs. The downstream users that manufacture finished articles containing DEHP are not affected by the provisions in the IPPC directive. Another limitation are that the directive mainly covers the control of emissions from medium-sized and large-scale industrial installations and that existing installations are affected only from 2007.

A classification as a "priority hazardous substance" within the Water Framework directive would increase the pressure on a cessation of discharges, emissions and losses within 20 years. This is important in the perspective of life time exposure and the protection of future generations. Furthermore such a classification would implement the intentions in the OSPAR Convention into European legislation.

DEHP is used in a vast number of articles and by thousands of down stream industrial users. To realise any voluntary commitments, covering all these uses, would be time consuming and raises issues on efficiency, monitoring etc. For these reasons, voluntary actions will not be considered further as a tool in the risk reduction strategy on DEHP although they can provide good examples.

Due to lack of experience and the foreseen difficulty to reach an agreement at Community level on the nature and level of a tax or fee, economic instruments will not be taken into further consideration.

In chapter 6, the following tools will be evaluated regarding their effectiveness, practicality, economic impact and monitorability:

- The Directive on Safety of Toys
- The Directive on General product safety
- The Directive on Restrictions on Marketing and Use
- The Directive on Plastic Materials and Articles Intended to Come in Contact with Foodstuffs
- The Directive on Medical Devices
- The Directive on Chemical Agents at Work
- The Directive on Pregnant Workers and Workers Who Have Recently Given Birth or are Breastfeeding
- The Directive on Carcinogens
- The Directive on Waste
- The Directive on Integrated Pollution Prevention and Control
- The Water Framework Directive

5 Alternatives

This chapter provides summaries of information provided at a seminar at the National Chemical Inspectorate in September 2002 and of experience gained in the work with a progress report to the Swedish Government on reduced environmental load from PVC. Although most of this information has been submitted by national suppliers and users, the examples could prove to be more or less applicable for the European market, as many of the articles are marketed also in other Member States within the European Union.

Also some studies on alternatives that have been performed in Denmark, the Netherlands and by the organisation Health Care Without Harm are summarised. Reference is likewise made to the Scientific Committee on Toxicity, Ecotoxicity and the Environment opinion on certain citrates and adipates used as a substitute for phthalates as plasticisers in certain PVC products as well as the risk assessment conclusions from the Existing Substances Programme for the alternative phthalates DIDP and DINP.

5.1 Seminar for Swedish down stream users

In September 2002 the Swedish Chemicals Inspectorate organised a seminar on the issue "How does the EU Strategy for a Future Chemicals Policy imply on companies using DEHP as a plasticiser?" The target group was down stream users of DEHP. One aim of the seminar was to inform on the new strategy by discussing DEHP as a concrete example on a possible application of the policy. Another aim was to discuss practical experiences on substitution of DEHP in terms of economic and technical consequences. The time frame for risk reduction activities was also on the agenda. The discussions were focused on articles used in buildings and constructions (mainly floorings, roofing and paintings), cables and medical devices.

In short, the following information was provided:

- In general downstream users, e.g. building companies, are important actors as their demands on less hazardous products and information on the content of chemicals in articles have a direct impact on the manufacturers.

- The participating manufacturers of feeding tubes for neonates concluded that these nowadays substantially are made of polyurethane.

- Citrates and benzoates were discussed as alternatives to use in blood bags although DEHP is more effective in preventing haemolysis of red blood cells.

- Latex as an alternative material to PVC in medical gloves has induced skin sensitization.

- After testing different alternatives a more general substitution to DINP has been made by the Swedish producers of floorings. The substitution was not difficult to carry through as the same equipment can be used but DINP is more expensive than DEHP.

DINP is not yet produced in similar amounts and the availability on the market is thus not as good as for DEHP. The initial cost was however paid back when the production and the demand increased.

- There are alternatives to DEHP in cables. In general a decision on substitution depends on costs, time frames, how efficient such actions are considered to be and the incentives to make alterations.

5.2 Swedish progress report on reduced environmental load from PVC

In December 2000, the National Chemicals Inspectorate reported to the Swedish government on the ongoing work to reduce the environmental load from PVC (KemI, 2001b). In the report, the substitution of harmful or suspected harmful phthalates was described for each application.

According to the findings of the report, mostly DEHP is replaced with DIDP or DINP on the Swedish market. Other alternatives in use to a lesser extent are adipates and trimellitates. In table 5.1 alternatives for different applications are summarised.

Table 5.1 ***Alternatives in use in different applications***

Application	Alternatives in use
Coil coated roofing	DIDP, polyurethane, polyester
Fabric coating	DIDP, DINP
Floor and wall coating	DINP, polyolefines
Cable	DIDP or other phthalates
Foil	DIDP
Profiles	DINP

5.3 Danish assessment of Alternatives

In a recent report from the Danish EPA, a range of alternatives to phthalates and to flexible PVC are assessed with respect to their inherent properties and potential risk for humans and the environment (Miljöstyrelsen, 2001)[22]. The Danish EPA five substances and in concert with industry another six substances were selected as examples for the remaining groups of alternative plasticisers. Also two polymeric materials, as alternatives to flexible PVC, have been selected and assessed.

One criteria for plasticisers identified as possible substitutes for phthalates was that most of the information should be available for both health and environment. Other criteria for the selected plasticisers were that their use pattern should involve high PVC volume and/or expected high exposure of humans and/or the environment.

[22] Miljostyrelsen (2001) Environmental and Health Assesment of Alternatives to Phtalates and to flexible PVC. Environmental project No. 590.

In table 5.2 identified alternative substances and materials for different applications are summarised.

Table 5.2 ***Identified alternative substances and materials in different applications***

Application	Alternative substance/material
Cables	Di(2-ethylhexyl)phosphate Tri(2-ethylhexyl) phosphate Tri-2ethylhexyltrimellitate Akylsulfonic acid esters
Floor and wall covering	Butane ester Di(ethylhexyl) adipate Trimethyl 1,3-pentanediol diisobutyrate
Toys	Polyethylene
Printing inks	O-acetyl tributyl citrate Dioctyl sebacate
Fillers	Polyester Dipropylene glycol dibenzoate

5.4 Dutch study on alternatives for phthalates

The Dutch Ministry has commissioned a report designed to quickly analyse to what extent phthalates used in PVC can be replaced by alternative substances or by alternative materials (TNO, 2002a)[23]. The study concentrates on an assessment of technical possibilities and an environmental comparison.

Ten priority product groups were selected on the basis of earlier studies and interviews with phthalate producers and importers on emission factors and exposure. Alternatives to phthalates were listed by making use of information gathered in interviews and literature studies.

The report concludes that in general there is a broad range of alternatives to most of the product groups with the exception of medical devices where legal quality rules apply. It also appears that PVC has been the material of choice for medical devices for historical reasons.

In terms of risk reduction the report cautiously states that the use of benzoates and possibly citrates, instead of phthalates might have some benefits for human health and the environment. Another conclusion is that it is likely that the use of plasticisers that are known not to give rise to emissions will result in a significant reduction of risks.

In table 5.3 alternative substances and materials are listed. Apart from the alternatives mentioned in the table, sorbitol-based plasticisers could become available in the near future.

[23] TNO Strategy, Technology and Policy (2002). Alternatives for phthalates. TNO-report STB-01-55

Table 5.3 ***Alternatives substances and materials***

Application	Substance alternatives	Material alternatives
Flooring	Benzoates. Phosphates, trimellitates and mesamoll[24] are suggested but not tested.	Linoleum, rubber, polyolefins, wood and textile (sometimes different functionalities)
Cables	Trimellitates and polymeric plasticisers	Polyethylene
Roofing	Mesamoll and polymeric plasticisers (inconclusive suggestions)	Tar/bitumen, chlorinated polyethylene and EPDM[25]
Building plate	Polymeric plasticisers	Polyester
Car undercoating	Benzoates and mesamoll; part can be replaced by rape oil fatty acid methyl ester	Bitumen/rubber mix and polyurethane
Tarpulins	Benzoates and mesamoll	Polyurethane, EPDM, rubber coated cotton, polyethylene and polypropylene
Coated fabrics	Poly ester plasticisers, benzoates, phosphates and other polymers	Polyurethane for artificial leather. Paper for wall paper. Polyethylene for foils and acrylates
Toys	Citrates(?) and adipates	Polyethylene, Polypropylene and rubber
Medical devices	Trimellitates and citrates(?)	Some applications: polyethylene, glass and latex (gloves)

5.5 HCWH report on neonatal exposure to DEHP

Health Care Without Harm (HCWH) is a campaign for environmentally responsible health care. It consists of 319 organisations, healthcare institutions and associations in 29 countries. Members of the campaign are hospitals, nurses, environmental organisations, religious organisations, trade unions and patient groups.

Their report on neonatal exposure discusses two alternative ways to substitute DEHP in medical devices; by replacing PVC-products with PVC-free products or replacing DEHP with an alternative plasticiser (Rossi and Muehlberger, 2000)[26]. According to HCWH either PVC-free or DEHP-free products are available on the market for most of the medical applications of concern, among others many applications in intensive care units for neonates.

The products that have been studied in the report are body fluid collection products, dialysis products, enteral feeding products, gloves, intravenous products and respiratory therapy products.

The primarily identified alternative plasticizers for medical products are citrates and trimellitates. Potential alternative plasticizers are also phosphates, benzoates and aliphatic

[24] alkyl sulphate derivate
[25] ethylene propylene rubber
[26] Rossi, Mark, Muehlberger, Manfred (October 2000). Neonatal Exposure to DEHP and Opportunities for Prevention in Europe, *Health Care Without Harm*.

dibasic esters. Alternative polymeric materials are ethylene vinyl acetate, polyethylene, polypropylene, polyurethane and silicone.

HCWH has however identified three product areas where there seem to be no PVC-free plastic alternatives on the market. These areas are:

1. extra corporeal membrane oxygenation (ECMO)
2. red blood cell bags
3. whole blood bags

However, there is at least one red blood cell bag that is DEHP-free on the market. DEHP has in this case been substituted with citrates.

5.6 Alternative technology

Substitution of DEHP with other substances and materials are not the only alternatives. By inventing or using new technology the need for plasticising by using phthalates might decrease. Alternative technique on its own or combined with another substitution action might thus be a possible solution.

One technology under development is grafting in order to incorporate subgroups into the polymer structure. In this way copolymers are created that are flexible in themselves and thus without the need for added plasticisers. This technique is already applied for plyolefins like polyethylene. The grafting technology takes place in the production stage of the polymer, which means that one of the advantages with PVC would be lost, namely the possibility of a standard PVC resin to be mixed with different additives.

Moreover, grafting is a technique that implies large bulk parties to be produced in order to avoid excessive costs. This technique can thus only be a possible option for large bulk producers of PVC, who do not need the kind of flexibility in properties/formulations that can be obtained by mixing a standard PVC resin with different plasticisers and other additives.

Another technique is the formulation of PVC with other polymers like ethylvinylacetate (EVA) and polyurethane (PU). By this technique mixtures of PVC can be obtained with different flexibility without plasticisers. This technology is still under development; one example of problems identified is the mixing of different polymers.

Research about the possibilities to use phthalates fixed within the polymer and not as an additive that can migrate is also taking place.

5.7 Scientific Committee on Toxicity, Ecotoxicity and the Environment

The Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE) has published their opinion on the toxicological characteristics and risks of certain citrates and adipates used as a substitute for phthalates as plasticisers in certain soft PVC products (CSTEE, 1999).

The committee evaluated the toxicological characteristics and risks of certain citrates and adipates in order to examine whether such substances may be used as substitutes for phthalate

plasticisers in PVC toys (that may be mouthed by children). Due to the many data gaps the CSTEE concluded that citrates and adipates are not suitable alternatives to phthalates in children's toys.

5.8 Risk assessments on DIDP and DINP in Existing Substances Programme

As can be seen from the information above in some applications other phthalates has been chosen to substitute DEHP. The most common alternative phthalates are DIDP and DINP. These two phthalates are also assessed within the EU program on Existing substances (Ministère, 2001 and 2001a).

The risk assessments came to the conclusion that with present-day use there is an adequate margin of safety. In the case of DIDP, however, concern is identified regarding effects on infants and children up to the age of 3 if all other phthalates in toys were to be replaced with DIDP. For DINP the margin of safety is adequate even with alternative scenarios like these.

For the environmental scenarios the conclusion was no concern for neither DIDP nor DINP.

Neither DIDP nor DINP are for the time being classified as harmful to health or to the environment.

5.9 Examples of alternatives in some specific groups of articles

A short survey of possible alternatives to DEHP in certain applications according to the information above is given below. Medical devices, floorings and cables are used as examples of how DEHP can be substituted.

In general there is no single alternative suitable for all applications of DEHP. More likely there are a number of possible alternatives; other phthalates, other plasticisers or other materials than PVC. By developing new techniques the need for using additives in order to produce flexible polymers might decrease.

5.9.1 Medical devices

At the seminar at The National Chemical Inspectorate in September 2002 the participating manufacturers of feeding tubes for neonates concluded that these nowadays substantially are made of polyurethane.

In general there are a lot of activities going on to find equivalent alternatives to PVC softened with DEHP, in Europe as well as in the United. States. Many of the manufacturers of medical devices are big international companies that often have representatives in Europe. Continuous research is going on in order to find new materials and additives to existing materials. The suppliers of raw material have an important role in this, in cooperation with research institutes with e.g. experts in polymer technology.

Replacing DEHP-softened PVC with one single material or plasticiser is not likely to occur. More likely there is a need for several alternatives in order to achieve the benefits of PVC

softened with DEHP. Other materials as ethylene vinyl acetate, polyethylene, polypropylene, polyurethane and silicon are under discussion or are already in use as substitutes. Concerning other plasticisers, citrates and trimellitates seem to be the main alternative. Other possible alternatives are phosphates, benzoates and adipates. DEHP in blood bags is however in favour compared to citrates and benzoates because of a better potential for preventing haemodialysis of red blood cells. Citrates and benzoates have also been reported to have an unpleasant smell. The materials and plasticisers mentioned above are discussed among others in the report from Health Care Without Harm as alternatives in body fluid collection products, dialysis products, enteral feeding products, gloves, intravenous products and respiratory therapy products.

The Grenaa Hospital in Aarhus County, the Danish Energy Minister and the Danish EPA has published a handbook, where the following non-PVC products are listed: medical products, medical product packaging, office products, kitchen products, kitchen product packaging, cleaning products, cleaning product packaging and empty packaging. Each product list includes the name of manufacturer and distributor, primary plastic material and packaging material. A list of all manufacturers and distributors and their contact information is included. This handbook is updated and can be found on the Aarhus County website: www.aaa.dk/pvc.

5.9.2 Floorings

After testing different alternatives a substitution to DINP has been made by the Swedish producers of floorings according to information provided at the seminar at the National Chemicals Inspectorate in September 2002. The switch was not difficult to carry through as the same equipment can be used, but DINP is more expensive than DEHP. DINP is not yet produced in the same large amounts as DEHP and the access on the market is thus not as good as for DEHP. The initial cost was however paid back when the production and the demand increased.

Downstream users, as e.g. building companies, are important actors as their demands on less hazardous products and information on the content of chemicals in the articles have a direct impact on the manufacturers.

Other possible plasticisers, according to information from the reports described above, are benzoates, adipates and phosphates. One Swedish manufacturer of floorings however informed that when benzoates were tested, the staff complained about an unpleasant smell. A slight trend towards other materials as wood, linoleum and laminates can also be seen.

5.9.3 Cables

At the seminar at The National Chemical Inspectorate in September 2002 it was concluded that there are alternatives to DEHP. In general a decision on substitution depends on costs, time frames and incentives to make alterations. Production capacity and access to enough volumes of an alternative substance are also important factors for the time frame to carry through a substitution

According to information from SELCABLE[27] the predominant plasticiser in PVC cables manufactured in Sweden is DIDP. Almost all applications of DEHP have been substituted by DIDP. However imported cables for installations to a great extent still contain DEHP.

According to information from the other reports also trimellitates and phosphates are possible alternatives to DEHP.

[27] Swedish Manufacturers of Cables and Wires Service AB (A member of The European Confederation of Associations of Manufacturers of Insulated Wires and Cables)

6 Evaluation of possible risk reduction measures

An evaluation of possible measures for risk reduction is carried out in order to recommend the most appropriate line of action, e.g. resulting in a recommendation focusing on the most proportionate measures. The image and opinion concerning risks and benefits may vary depending on the concerned actor. The aim is therefore to present a broad evaluation in relation to each possible measure. How well this aim can be fulfilled depends a.o. on the information provided by the consultees. For the time being this evaluation can only be seen as an indication of the likely magnitude of the consequences, including costs.

In focus for interest lies the tools for reduction of risks that impose the minimum burden on the society and that at the same time reduce the exposure of DEHP to a high degree. This also emphasises the question of exposure - the indirect and the direct as well as the cumulative exposure through the technosphere. As some of the products in which DEHP is used are long-lived, another factor of importance to this evaluation is the time aspect. The time period considered in the evaluation should adequately reflect future benefits as well as risks. Other factors of importance given in the risk assessment are summarised in chapter 2 of this report. The sources of exposure to DEHP are multiple and of concern to a broad population. The main exposed groups raised in the risk assessment are consumers, workers, man exposed indirectly via the environment and combined groups.

The rapporteur has made some simplifying packages of measures in order to be technically able to carry out the evaluation. Instead of evaluating measures individually we have grouped the measures in packages focusing the exposed groups identified in chapter 2. The RA indicates that measures have to be implemented to reduce the exposure of concerned groups. To what extent and how to carry out such restrictions is differentiated in the packages and evaluated against the evaluation criteria.

6.1 Evaluation Criteria

The current and possible measures described in chapter 3 and 4 of this report are evaluated on the basis of the criteria recommended in the TGD: effectiveness, practicality, economic impact, and monitorability.

Effectiveness

"*The measure (or measures) must be targeted at those significant hazardous effects and routes of exposure where risks that need to be limited have been identified by the risk assessment; and must be capable of reducing the risks that need to be limited within and over a reasonable period of time."* (The Technical Guidance Document on Development of Risk Reduction Strategies, October 1997)

The rapporteur's reflection on this criterion is that "within a reasonable period of time" would in this case mean within one generation. DEHP is used in long-lived applications and will therefore be of importance for exposure of users over a longer period of time.

Practicality

"The measure (or measures) should be implementable, enforceable and as simple as possible to manage [such that smaller enterprises are able to comply]. Priority should therefore be given to consideration of commonly used measures that could be properly carried out within existing infrastructure (though not to the exclusion of novel measures)." (The Technical Guidance Document on Development of Risk Reduction Strategies, October 1997)

In this case the perspective of small and medium sized enterprises as well as the practical implications for authorities will be of major importance in the evaluation.

Economic impact

"The rapporteur can make a rough qualitative estimate of the impact of the measure on producers, processors, users and other parties on the basis of his experience and judgement. However, regarding restrictions on marketing and use the rapporteur should provide a more detailed analysis of the advantages and drawbacks of the measures." (The Technical Guidance Document on Development of Risk Reduction Strategies, October 1997)

The rapporteur will at this stage only briefly estimate the economic impacts. The analysis may be both quantitative and qualitative considering the impact of the measure on producers, processors, users and other parties. The time perspective indicated under the criterion for effectiveness will be of importance also for the evaluation of impacts on society and future generations.

Monitorability

"*Monitoring possibilities should be available to allow the success of the risk reduction to be assessed."* (The Technical Guidance Document on Development of Risk Reduction Strategies, October 1997)

The monitorability criterion is established to give the basis for considerations on whether further measures are necessary or not. Such evaluations will provide experience on measurability, enforceability and follow up that may be useful in developing future strategies on other substances as well. Therefore monitorability should not be seen as a criterion that is restricted to the monitoring of pollutant concentrations in the environment.

6.2 Evaluation of the baseline

According to the TGD the rapporteur should assess the effectiveness of existing measures and any relevant practical experiences and also consider if the implementation of existing controls could be more efficient. This is why a baseline assessment is performed in this strategy. The baseline describes the situation in 2002, with activities already taken at this time and the anticipated outcome. The baseline measures were described in chapter 3 but are briefly summarised in the box below.

Baseline measures

Classification and Labelling (67/548/EEC): DEHP classified as toxic to reproduction in category 2 with risk phrases R60 and R61 (for impaired fertility and harm to the unborn child).
Marketing & Use (76/769/EEC): restrictions on consumer use of DEHP (as a substance or in preparations).
General Product Safety (92/59EEC): an intermistic ban on phthalates in toys and childcare articles (intended to be put into mouth; under 3 years of age).
Plastic Materials in contact with Food (90/128/EEC): working group discussions on restricted use of DEHP in packaging material for fatty foods.
Medical Devices (93/42/EEC): discussions in Scientific Committee on restricted use of DEHP in medical devices for neonates and other exposed patient groups of concern: no specific recommendation could be made.
Water Framework Directive (2000/60/EC): DEHP is listed as a "priority substance" under review: the Commission is to propose an Environmental Quality Standard and product and process controls, aiming for progressive reduction of DEHP emissions from point sources and diffuse sources.
Initiatives taken by Industry: substitution of DEHP in some applications e.g. medical devices, food packaging, flooring, cables.

Effectiveness

The classification of DEHP as toxic to reproduction involves labelling with a skull and cross bone symbol. This means that DEHP and preparations containing DEHP are to be labelled, but not the finished articles containing DEHP. The classification is clearly not enough as a single risk reduction measure but it may affect the usage of DEHP since industrial users can be expected to ask for alternatives to DEHP to a greater extent than before. The exposure of worker will be reduced when less DEHP is used in the production chains. In addition the new labelling symbol is understood to enhance safety in work place handling. For instance dermal exposure may be reduced. Consumers will now be less exposed, at least in theory, as the consumer use of DEHP as a chemical is restricted.

The direct exposure of children under the age of 3 is reduced already by means of the intermistic ban on phthalates in toys and childcare articles indented to be put in the mouth. This measure may also to some extent limit the exposure of these children's family members when less DEHP is released to the indoor air. However, it is not effective for all children in all age groups, as most toys are used over longer time periods and by children in age groups other than the intended one.

The outcome of the working group discussions on restrictions on the use of DEHP in packaging materials for food should be awaited before evaluating the efficiency of this measure.

The Scientific Committee on Medical Devices could not make any specific recommendation on limitations on the use of DEHP in any particular patient group. Neither could they recommend a Tolerable Intake Value for DEHP in medical devices. The groups of patients, for which the committee could not exclude concern, are the same as those identified in the risk assessment made by the rapporteur. To introduce restrictions for the use of DEHP in medical devices for these patient groups would efficiently reduce the exposure.

In the field of water policy DEHP has been included among the "priority substances", subject to review for a possible identification as "priority hazardous substance". If DEHP remains on the list of priority substances, a proposal for emission controls and an environmental quality standard (EQS) and emission controls should be proposed by the Commission within 2 years after the inclusion on the list of priority substances and the measures shall aim at the progressive reduction of DEHP discharges, emissions and losses.

The voluntary actions taken by industry so far at community level are few and the extent of them is sparse. A few manufacturers have reported that DEHP has been or is being replaced with other plasticisers in some articles. One example is national replacement of feeding tubes within neonatal care. These actions have not substantially reduced the DEHP emissions.

Practicality

The measures in the baseline scenario have been or are in the process of being implemented and are therefore seen as enforceable and possible to carry out within existing infrastructure. This includes the classification and labelling as well as the intermistic ban through the General Product Safety directive and restrictions on consumer use.

The Commission will consider the practicalities of any actions for DEHP, recommended by the Working Group for food packaging materials or by the Working Group for medical devices.

The practicalities of measures to be developed within the Water Framework Directive are less well known at the moment. The WFD gives the possibility to set environmental quality standards (EQS) for water, sediment or biota. Establishing EQSs will be complicated in cases with highly lipophilic substances like DEHP. Considering the environmental distribution of this substance, it seems reasonable to establish DEHP limits in for example sediments, biota or sewage sludge.

The flow of information along the supply chain about the risks connected to the use of DEHP and about available substitutes to DEHP is not a commonly used measure today. Such flow of information is needed in order to make voluntary actions practicable, especially in cases where the supply chain is extended or complicated.

Economic impact

The classification of DEHP as toxic to reproduction will in itself have an effect on the use of DEHP. A reduced production of DEHP can be expected but the sizes of these consequences are not known. This decrease is likely to be compensated by an increase in the sale of alternatives and thereby an economic benefit for producers of such alternatives.

Changes of classification and labelling involve some initial costs for producers and suppliers when changing the information and the labelling of chemicals. The cost of the amended labelling should however be very modest since the requirements of classification and labelling are well known.

The cost relating to restrictions on consumer use of DEHP should be minimal since DEHP in practice is not a consumer used chemical. The intermistic ban on phthalates in toys and childcare articles has been in place for a few years. Therefore the economic impacts cannot be considered to be any different from the present situation.

If restrictions on the use of DEHP in food packaging material or medical devices are introduced, some economic impacts will follow.

The economic impact cannot be estimated at this time concerning measures taken within the Water Framework Directive but according to article 16(6) and 16(8) of the directive, a comprehensive assessment of the impacts will be carried out ‘to identify the appropriate cost-effective and proportionate level and combination of product and process controls for both point and diffuse sources. Naturally, monitoring obligations will involve some costs to Industry and authorities.

Monitorability

The MS authorities may monitor the compliance with the provisions for DEHP. The intermistic ban on phthalates in toys and childcare articles will continue to be an important instrument for monitoring compliance. Findings in Denmark, Norway, Austria and Sweden show the importance of follow up and control of such an instrument. In Denmark, testing has shown that phthalates still appear in toys designed for children under the age of three despite the national ban in force since 1999. Similar results have been shown in Norway, Austria and Sweden. In Sweden, phthalates have been found in seven out of ten children’s plastic swimming toys in contravention to the national ban (articles that children under the age of three might chew or suck on).

The Commission will consider the monitorability of any actions for food packaging materials and medical devices.

Monitoring of DEHP concentrations in water, sediment and biota will be carried out through the Water Framework Directive. However such monitoring will not give the full picture since DEHP occurs in all environmental compartments and not just in the water environment.

Industry may report on voluntary actions and the effects on down stream users, as an important contribution to monitoring of the outcome of the baseline actions.

A summary of the evaluation of baseline measures (the present actions)

The measures in the baseline scenario will undoubtedly have an effect on the usage of DEHP. However, these measures do neither cover all aspects of risk, nor all significant exposure relating to the use of DEHP. Further measures will therefore be necessary in order to limit the exposure for all concerned groups. The present actions do not for instance sufficiently reduce the exposure of children over the age of 3 and will only reduce the exposure of workers to a minor extent. Possibly, the most significant aspect not covered by the baseline measure is the longer time perspective relating to exposure.

The measures in the baseline scenario can be carried out within existing infrastructure and are therefore considered to be practical. However, it should be noted that the flow of risk related information through the supply chain needs to be improved.

The measures can be monitored within the structure of classification and labelling and restrictions as well as through the General Product Safety directive. In addition to this, industry's report on voluntary actions will be of importance. The importance and the further need for monitoring instruments such as inspections was clarified by the findings on shelves in Denmark, Norway, Austria and Sweden. These findings underline the need for more permanent provisions.

6.3 Evaluation of immediate measures to carry out within present systems

The baseline actions are not enough and further measures will be needed fairly soon in order to deal with all significant routes of exposure for the exposed groups and the time aspect of exposure. Some measures identified as possible to implement soon and within the present structure are presented in the box below. These measures will now be evaluated according to the four TGD parameters.

Immediate measures

In addition to the baseline measures

Marketing & Use (76/769/EEC): broadened restrictions on the use of DEHP in toys and childcare articles, to cover all such items that could be put in the mouth of a child and that are intended also for children above 3.
Plastic Materials in contact with Food (90/128/EEC): restrictions on the use of DEHP in packaging material for fatty foods.
Medical Devices (93/42/EEC): restrictions on the use of DEHP in medical devices giving rise to exposure of groups of concern.
Marketing & Use (76/769/EEC): restrictions on the use of DEHP in medical devices giving rise to exposure of groups of concern (if not achieved in the medical devices directive).
General Product Safety (92/59EEC): interimistic ban on DEHP in medical devices for uses giving rise to exposure of neonates (if not quickly achieved in other ways).
Pregnant Workers (92/85/EEC): replacement of the outdated risk phrase R47 by R60 and R61 (for impaired fertility and harm to the unborn child).

Effectiveness

A broadening of the ban on DEHP in toys and childcare articles will reduce the direct exposure and bring a higher level of protection to a wider age group of children in a more permanent legal provision. For example, exposure of siblings and day-care groups would also be reduced. In the risk assessment the exposure from toys and childcare articles was estimated to represent approximately 90 % of children's direct exposure to DEHP.

Although the direct exposure from toys and child-care articles is reduced, concerns for indirect exposure of all children may still remain. The reduced DEHP emissions resulting from the interimistic ban is very minor compared to the dimensions of use in the production in other kinds of articles. At a very rough estimate, DEHP in toys and child-care articles represent less than one percent of the total amounts of DEHP in articles/materials used in the indoor environment. As a consequence, restricting the use of DEHP in toys and child-care articles is not seen as effective enough to limit the risk to children, as the indirect exposure of children would still remain.

A restriction on the use of DEHP in packaging material for fatty foods will bring a higher level of consumer protection, as less direct exposure will occur through food. This will also reduce the lifetime exposure of DEHP. It is expected that the DEHP leakage from packaging material to fatty foodstuffs will be significantly reduced. To exclude DEHP from the positive list altogether cannot be considered efficient, since the additional reduction of direct exposure to DEHP would only be minor. Due to its lipohilic characteristics, the substance would not tend to migrate from the plastic packaging material to non-fatty foods.

In special focus for additional measures to be taken fairly soon are patients in certain types of treatment, and even more so, neonates. The exposure of these groups can be significantly reduced by any of the alternative measures in the box above, but there are however technical factors, e.g. how permanent the restrictions will be, that separate the different measures. Restrictions concerning DEHP in medical equipment should primarily be carried out through the Medical Devices directive because of its characteristics as a product directive. If this cannot be achieved, measures in the Marketing and Use directive could be equally effective. As a last resort, an intermistic ban through the General Product Safety legislation could be considered for the immediate protection of neonates. This measure for urgent matters can be effective but is interimistic and must be continuously updated. In any case, it was agreed in the Medical Devices Scientific Committee that for critically ill neonates, being an inherently high-risk group, the lack of evidence of causation between DEHP-PVC and any disease or adverse effect would not mean that there are no risks. The risks and benefits should, however, be considered in order for such actions to be efficient.

The efficiency of restrictions on the use of DEHP in medical equipment for patients of concern should also be seen in the light of actions taken in other parts of the world. Recommendations and instructions have been given by Ministries of Health and related authorities in the US, Canada and Japan not to use medical devices made of PVC with DEHP, sometimes in combination with labelling requirements for products with DEHP. Such recommendations may rapidly initiate development of alternative technology.

Prevention of the direct DEHP exposure of pregnant workers can be somewhat improved by an adjustment in the Annex I of the directive on pregnant and breastfeeding women. This action would to some very small extent reduce risks to the unborn child and to breast-feeding infants.

The immediate measures, added to the baseline, are not seen as effective enough to achieve the intentions of the Water Framework Directive since the measures do not broadly address a progressive reduction of DEHP discharges, emissions and losses from both point and diffuse sources.

Practicality

Since the measures are already in the process of being established or on the agenda for discussion, they can be implemented and carried out within existing infrastructure and are therefore practical.

Restrictions on the use of DEHP in medical devices in general may not be fully practicable. For instance, some uses DEHP are known to be significant for treatment and lifesaving of patients. An evaluation of the risks and benefits of DEHP and available alternatives must therefore be carried out first. Depending on the outcome of this evaluation, restrictions in medical devices for patients of concern should be considered. Studies have shown that substitution is possible in some applications. Furthermore, national reviews of DEHP uses in medical devices are presently performed in Japan and the Netherlands, focusing risk groups. Such reviews will add more data relating to practicality.

Economic impact

Some economic impacts will follow a broadened restriction on DEHP use in toys and childcare articles. One alternative to DEHP that has been identified and used in toys is benzoates. Benzoates may have benefits for human health and the environment (because of less extractability and less migration capacity) and still be less expensive.

Some economic impacts will follow restrictions on DEHP in packaging material for fatty foods, but as some changes are already made additional economic impacts would only be modest.

Some economic impacts will follow restrictions on DEHP in medical devices. Replacing DEHP with alternatives could initially involve some economic impacts on producers and users, like research costs and increased purchase costs for substitutes. The cost of a product depends however on several other factors such as supply and demand, contracts, subventions and the turnover of products.

The economic impacts of updating the directive on pregnant workers will be insignificant.

Monitorability

Since the immediate measures are to be carried out within the existing infrastructure, established systems for monitoring already exist. The directive for General Product Safety is under revision and will introduce new obligations on producers and distributors to inform and collaborate with authorities when consumer products are found to be dangerous.

Workplace controls can to some extent be simplified by an update of risk phrases in the directive on pregnant workers, in so far as the directive will correspond better to the information provided in the labelling and in the safety data sheets for workplace chemicals.

A summary of the evaluation of immediate measures

The measures added to the baseline actions will further limit the direct exposure of the concerned groups. The implementation of these measures can be fairly straightforward within existing infrastructure. Without further risk reduction measures, the indirect exposure of humans via the environment and lifetime exposure will still be considerable.

The fact that information is missing in the risk assessment concerning the lifetime exposure indicates a need for further risk reduction. Another factor that underlines the need for reducing the exposure is the consideration for future generations. The longer it takes to considerably reduce the exposure of DEHP, the longer the present and future generations will be exposed to DEHP during their most vulnerable period of growth and development and throughout their lifetime.

In conclusion, the immediate risk reduction measures at Community level are not seen as sufficiently effective in limiting the risks. They are not sufficient, as they do not cover all groups identified for concern. Nor do the immediate measures cover all stages in the DEHP lifecycle. Measures are needed to address releases from a magnitude of diffuse sources, in particular emissions from various articles. A continuous minimisation of these emissions is necessary.

6.4 Evaluation of further possible measures

The remaining measures that were identified as possible in chapter 4 will now be evaluated. Due to the broad usage of DEHP, the complex pattern of exposure and the number of ongoing activities, the rapporteur has chosen to evaluate packages of further possible measures The content of the packages has been chosen according to exposed groups and possible increased level of protection. The packages are used to facilitate the evaluation of measures but the content of these four packages may anyhow need to be revised later in the process.

6.4.1 Focusing consumer exposure

All measures presented in the box below are, like the baseline and the immediate measures, focusing consumers as a target group and the reduction of exposure and risk of this group.

A) Measures focusing consumer exposure

In addition to baseline + immediate measures:

Safety of Toys (88/378/EEC): restrictions on the use of all substances classified as CMR, category 1 and 2, in toys.
Plastic Materials in contact with Food (90/128/EEC): restrictions on the use of all CMR substances, category 1 and 2, in packaging material for food.
Medical Devices (93/42/EEC): restrictions on the use of all CMR substances, category 1 and 2, in medical devices.

Effectiveness

Restrictions for DEHP use in toys, food packaging material and medical devices would eliminate these sources of direct exposure and therefore also lower the contributions to the life time exposure. With a broad restriction covering all confirmed carcinogenic, mutagenic and reprotoxic (CMR) substances in toys and food packaging material no prior assessment of exposure - related risks would be needed and no extra evaluation concerning any positive lists would be needed. The measure could therefore be considered effective.

Such restrictions on CMR substances are already under discussion for cosmetics, following recommendations given by the Scientific Committee for cosmetics. The committee concluded that CMR substances pose a significant threat to the health of consumers when used in cosmetic products. Although the exposure routes are not the same, toys, food packaging materials and medical devices may be seen as parallel cases giving rise to direct exposure of the consumers. A systematic approach restricting the use of all confirmed CMR substances in these applications would be efficient in improving the level of protection of consumers and future generations.

Practicality

Restrictions that utilise a systematic approach, referring to the classification of substances, for toys, food packages and medical devices would give certain advantages as the legislation would not need updating for every new decision on classification of CMR susbtances.

These measures would be practical since studies show that alternative materials are available. For toys such a measure may not be conceived as practical as the directive in its present form covers only acute health aspects. If a measure is considered practical or not depends on political and ethical views as well as on user acceptance. As similar measures are discussed presently within the field of cosmetics, the thought of such a generic measure could be acceptable also for toys, food packaging materials and medical devices, although these applications are covered by several different pieces of legislation.

If the use of CMR substances of category 1 and 2 would be restricted, this measure may not be fully carried out for all applications in medical devices, as evaluations of risks and benefits must be carried out.

To further evaluate the benefits and risks with alternative substances and materials are of great importance. As long as there is no regulation on the use of CMRs in medical devices, there is no incentive for research in order to find safe alternatives. Any measures taken that motivate research contribute to an increased practicality.

Economic impact

The economic impacts following generic restrictions on the use of CMR substances in toys, food packaging materials and in medical devices may be substantial but this could be moderated if a long term phase out period initiated a development of alternative substances and technologies.

Monitorability

The measures evaluated in this box are to be carried out within the existing infrastructure why established systems for monitoring already exist.

Reports on voluntary actions and information about alternatives will be of importance. Monitoring instruments like analysis and inspections will be needed.

Less monitoring measures may be needed to control the direct exposure of workers and the environment to CMR substances.

6.4.2 Focusing occupational exposure

One target group identified in the risk assessment are workers. In the box below further measures are outlined, focusing reduction of the occupational exposure (in addition to the baseline measures and the immediate measures).

B) <u>Measures focusing occupational exposure</u>

In addition to baseline + immediate measures:

Chemical Agents at Work (98/24/EC): emphasis on substitution and establishment of a sufficiently protective community Occupational Exposure Limit value for DEHP.
Carcinogens Directive (90/394/EEC): extension to also cover substances classified as toxic to reproduction, category 1 or 2.

Effectiveness

An effective measure within the intentions of the directive for Chemical Agents at Work would be to emphasise substitution of DEHP. This would contribute to a higher level of protection for workers but also further reduce the exposure of pregnant workers and future parents. The worst-case exposure scenarios presented in the RA indicate that the existing national exposure limit levels may not be protective enough. An occupational exposure limit that is sufficiently protective would contribute to an improved safety, irrespective of other measures taken. In order for these measures to be effective, considerable efforts for workplace controls will be needed.

Practicality

The measures evaluated in this box are considered to be possible to carry through within the existing infrastructure and practical.

Economic impact

Users of DEHP may experience some costs related to a stricter occupational regime but in the long run this could also mean an improved working environment. As shown in chapter 1 formulators and users include many SME:s.

A substitution procedure always includes some initial costs but may eventually bring benefits in comparison to competitors. A reduction of some costs could also be the consequence of a substitution. An example of this is appearing in the flooring industry where some producers have removed DEHP in favour of other phthalates.

Monitorability

Monitoring could be integrated with existing and functioning workplace controls.

6.4.3 Focusing man exposed indirectly via the environment

Another target group identified in the risk assessment is man exposed indirectly via the environment. In the box below further measures focusing that target group are mentioned.

C) Measures focusing indirect exposure via the environment

In addition to baseline + immediate measures

Marketing and Use (76/769/EEC): restrictions on the use of DEHP in products with high production volume and giving rise to outdoor exposure, i.e. roofing, coil coating, cables, coated fabric, hoses, profiles, car undercoating, shoe soles.
Integrated Pollution Prevention and Control (96/61/EC): inclusion of DEHP emission limit values in permits for production plant; considerations on DEHP in the BAT Reference Document for polymer production.

Effectiveness

Through restrictions on the use of DEHP in high production volume products for outdoor applications, diffuse emissions from e.g. roofing, coil coating, cables, coated fabric, hoses and profiles, car undercoating and shoe soles would be reduced. The total usage of DEHP in outdoor applications within the European Union was 100 000 tonnes per annum in 1997. Restrictions on this use would be an efficient measure as the outdoor applications contribute with the main part of environmental emissions although it is a smaller use area. Restrictions on the marketing and use in products for outdoor use will furthermore reduce emissions from point sources like production sites and the number of occupationally exposed workers.

DEHP emission limit values set in permits for production plants may contribute to reduced emissions, however, production and industrial uses of DEHP are estimated to contribute with only 10% of the environmental emissions. A BREF covering polymer production plants could be put on the agenda of work for the IPPC directive. In a longer perspective the directive would need to be enlarged to cover the downstream users of DEHP as well in order to be effective. If the directive were to be extended issues on timeframe are important.

Practicality

Restrictions on the use of DEHP in outdoor applications is possible to carry out in the longer time perspective, depending on the availability of substitutes. According to information given to the rapporteur alternatives are available for many of these applications, something that supports that the measure should be undertaken. It cannot, however be considered practical to carry out the restrictions immediately, as there are problems relating to the identification of existing articles that contain DEHP.

The production of DEHP and PVC-polymers are covered by the IPPC directive but not the down stream users, manufacturing articles containing DEHP. In addition, the practicality of this measure is limited since the directive mainly affects emissions from medium-sized and large-scale industrial installations, and for existing installations it will do so only after 2007.

In order to cover also down stream users of DEHP, the directive would have to be enlarged and issues on timeframes for such enlargement need to be discussed and evaluated.

Economic impact

Applications for outdoor use represents around 20% of the total consumption of DEHP. To prevent environmental emissions through marketing and use restrictions for such applications would involve considerable impacts to industry.

A markedly reduced EU market will bring costs for producers of DEHP but this could to some extent be compensated by an increase in the sale of alternatives, i.e. economic benefits for producers of alternatives. There are currently 12 production sites for DEHP in Europe that are mainly but not all large international chemical companies and the economic impacts could be great for these companies. Additionally, formulators and users of DEHP could initially have serious economic impacts through increased research costs and purchase costs for alternatives. In cases where alternative materials cannot be processed with existing equipment, manufacturers might need to invest in new product lines or develop new processing technologies.

However, in cases where available substitutes could be incorporated relatively easy within a required timeframe and for which no shift in economic activity to outside the EU would occur (e.g. when the company that produces DEHP also produce the most suitable substitute) the socio-economic impacts would be only minor.

Monitorability

Through marketing and use restrictions on outdoor applications controls can be carried out. With limit values for DEHP the monitorability of emissions from productions plants is secured. The question on how to ensure an effective control of the great number of small and medium size installations remains to be solved.

6.4.4 Focusing exposure of combined groups with lifetime exposure

In the box below further measures focusing exposure of combined groups with lifetime exposure are outlined (in addition to the baseline measures and the immediate measures).

D) Measures focusing combined groups - lifetime exposure

In addition to baseline + immediate measures

Marketing and Use (76/769/EEC): restrictions on the use of DEHP in all PVC products: no more DEHP added to the technosphere.
Directive on Waste (91/689/EEC): collection and treatment of disposed material containing DEHP as hazardous waste.
Water Framework (2000/60/EC): classification of DEHP as a "priority hazardous substance"; adoption of measures that aim for the cessation or phasing out of discharges, emissions and losses within 20 years.

Effectiveness

As said before in this strategy, no sources can be seen as unimportant in contribution to the diffuse emissions of DEHP. The emission sources cannot be quantified nor always identified. But certainly the exposure of all concerned groups would be highly limited when no more DEHP is added to the technosphere. The efficacy can probably be met for many of the applications through substitution. The effectiveness of such a ban would mostly be seen from the following actions taken by industry. Many smaller users of DEHP are however already reported to be leaving the products or being bought by larger companies.

If DEHP-containing waste were to be treated as hazardous waste the environmental emissions from landfills etc would be reduced by only 1%.

If DEHP were to be identified as a "priority hazardous substance" in the Water Framework Directive, the relatively tight timeframe will necessitate stringent and effective measures in order to achieve the aim within 20 years.

Practicality

Marketing and use restrictions on DEHP used in all PVC products would be possible to carry out in the long run but cannot be considered as practical in a shorter time perspective, as there are problems relating to the identification of existing articles containing DEHP. Something that would justify such measures in a longer time perspective is that alternatives to DEHP are available in several applications.

However, to completely replace DEHP would involve both technical and economical difficulties and consequences. Other phthalates, materials and techniques may be suitable for some applications but one single alternative cannot replace DEHP in all usage. For many of the alternatives there are limited toxicity data and information on technical suitability. Therefore, this measure cannot be carried out directly within existing infrastructure and is not considered as practical. Further information, voluntary actions, more research on alternatives and new thinking are needed.

With increasing amounts of waste containing DEHP, measures to secure the treatment of this kind of waste as hazardous waste must be considered impractical.

The practicalities of the control measures for DEHP within the Water Framwork Directive cannot be evaluated at this time.

Economic impact

The cost of a phase out of DEHP would vary according to the specific use of the phthalate. Something that can be seen as an argument for restrictions to be considered in terms of uses rather than the substance itself. There are of course also cases where cost implications would be greatly increased if unintentional uses and sources of DEHP were targeted. Other difficulties are caused by lack of information on the possible substitutes in different applications, their availability and the costs of substitute chemicals. The costs of a phase out could however be significantly reduced for industries that already have taken actions to reduce the use of DEHP. When used in very minor applications a phase out of DEHP would tend to introduce relatively few costs upon the EU industries. However DEHP is considered to be critical in terms of safety, health and environmental benefits in certain areas of use.

The value of DEHP was around €800 per tonne in 1999/2000. The production was worth about €500 million per annum, the export €150 million and imports around €50 million. Referring to these figures, a total ban can be expected to result in extensive costs for industry and the society. With an estimated value of products for manufacturers within the EU of about 0.5 billion Euro effects on the turnover can be expected to be big even for larger companies.

In some cases a phase out of DEHP could lead to impacts upon income distribution or upon particular groups in society. Some smaller companies are already reported to be leaving the products and or being bought by larger companies. The consequences of marketing and use restrictions for all PVC products plasticised with DEHP could therefore be greater for the bigger producers and professional users. This could in the longer run lead to a shift in employment and production activity to outside EU, e.g. business as usual but at an other geographical area. However DEHP or products containing it would not be allowed to the EU market.

If a phasing out of DEHP in the long term initiated a development of substitutes this could offset at least some of the short-term costs. However many of the alternatives are said to be more expensive. The fact that these price figures are based on the situation of today, where DEHP is a main plasticiser, naturally has an impact also on prices and costs. One company has at least 80% of the world market share of the alternative phthalates DIDP and DINP. (pers. comm. Wisén, August 2001).

The measures concerning waste would cause very high costs for the collection and treatment of all waste containing DEHP as hazardous waste.

There can be very significant socio-economic impacts associated with an immediate cessation or phasing out of discharges, emissions and losses of DEHP. Or the situation could occur where substitutes can be developed within normal reformulation activities of products and thereby DEHP could cease to be essential for particular uses within the 20-year timetable, thus the costs would be reduced.

Monitorability

It is not possible at the time of writing this report to meaningfully evaluate the monitorability of measures implemented for priority hazardous substances within the Water Framework Directive. But if no more DEHP where to be added in production and use, the success of the measure could be monitored in the production stage, various industrial users and the waste treatment stage. These monitoring actions could be carried out by either authority inspections,

companies' own internal processes or within the system of Environmental Management systems.

A summary of the evaluation of further possible measures

The measures concerning consumer exposure in box Aare considered to be effective as the use of DEHP, a reprotoxic substance, would be reduced in toys, food packaging materials and medical devices. The CMR approach is also considered to be effective as these measures can be implemented for all CMR substances at the same time. The measures are also found to be practical as alternative materials are available for applications that contribute to the direct exposure of consumers. The economic impacts that might follow are some costs e.g initial investment costs for manufacturers. Monitoring systems are already available and will be of importance.

The measures in box B will be effective if workplace controls are implemented and workplaces emphasise on substitution. Occupational exposure limits would improve the protection of workers and contribute to a better safety. The measures are considered practical, as they are possible to carry out within the existing infrastructure. Some economic costs will follow for users of DEHP as occupational regimes become stricter and as substitution is carried out. Monitoring systems and instruments are available and should be applied.

A restriction covering the use of DEHP in products for outdoor applications would be effective as the outdoor applications contribute with the main part of environmental emissions although representing a smaller use area. The measures in box C are considered to be practical to carry out in a longer time perspective, e.g. when substitutes are available for all DEHP applications and identification of existing articles containing DEHP has been carried out. The economic impacts would however be considerable especially if suitable alternatives are not available. Controls on outdoor applications can be carried out if marketing and use restrictions are implemented. Limit values for DEHP emissions from production plants will have limited importance.

The effectiveness of the measures in box D depends on the following industry actions. The measures would be effective when less DEHP is added to the technosphere. The measures evaluated in box D are (except for waste management) considered somewhat more practical and justifiable to implement in a longer time perspective but not within a shorter time perspective. The economic impact of such measures would be extensive for industry and the society if implemented today. Monitoring actions would be possible to carry out within different management or control systems.

In summary, further measures are necessary in order to reduce the exposure of the concerned groups identified in the risk assessment and achieve a proportionate risk reduction strategy. The recommended measures are presented in chapter 7.

7 Proposed risk reduction strategy

The possible further measures for risk reduction have been evaluated against the TGD criteria. On the basis of this evaluation, a number of measures are proposed in this chapter for protection at Community level of all the groups at risk identified in the RA.

The critical effects identified in the DEHP risk assessment are general systemic toxicity and effects on reproduction, including atrophy of testes, reduced fertility and developmental effects on testes of newly born rats exposed via the mother during pregnancy and lactation. Some expert discussions are unfinished relating to the No Observed Adverse Effect Level (NOAEL) for the risk characterisation of DEHP testicular toxicity, and it is to be examined later whether in some health risk scenarios any modified conclusions would be justified. Readers of this report are trusted to bear in mind that some parts of the recommended strategy may need modifications after agreement in future discussions.

Human subpopulations with direct DEHP exposure that gives rise to concern are workers and consumers, as patients and as children. In addition, the releases of DEHP from production and products lead to exposure of all citizens in the European Union in their daily life. DEHP is found in women's breast milk, soil, meat, fish, dairy products, water and air. For exposure of all humans indirectly via the environment, combinations including exposure from different sources and routes and lifetime exposure have been identified and described in qualitative terms and especially highlighted as giving rise to concern.

The fact that expert agreement is still pending in a few cases and that information is missing regarding all sources of emissions and lifetime exposure, adds a level of uncertainty to discussions on risks relating to DEHP and, more specifically, to the assessment of the proportionality of measures in a risk reduction strategy. But uncertainty should not prolong the proceeding to risk reduction actions.

7.1 Overview of proposed measures

Due to the complex nature of the exposure profile for DEHP and the relatively large number of actions already taken to reduce exposure, the measures are presented in table 7.1 for better overview. In this table, all measures aiming for reduced exposure are listed for each exposed group at risk, i.e. baseline actions that are already taken as well as recommended actions.

The baseline actions, describing the situation in 2002, provide a necessary foundation for the proposed measures. The evaluation of the expected outcome has shown that the baseline actions do not to sufficiently reduce the exposure for all concerned groups.

As seen in table 7.1, the risk reduction strategy recommended by the rapporteur is split into two types of proposed measures: Immediate actions and Further actions to undertake. This split relates to the stepwise evaluation performed in chapter 6 but it may anyhow need some more explanation.

In the risk reduction part of the Existing Substances programme, the rapporteur's task concerns proposing proportionate measures to reduce the risks associated with a substance. The recommended "Immediate actions" in table 7.1 represent such a proposal. In the case of DEHP, however, it is seen necessary to ensure that actions taken do not lead to a replacement with substitutes that have similar severe properties. Therefore, this strategy also recommends "Further actions to undertake" measures of a more generic nature e.g. taking a systematic approach towards the use of all substances that are classified as CMR, category 1 and 2.

It is expected that such generic measures will increase the level of protection but, it might be that the increase in safety will not immediately be balanced against the time and resources needed for introducing them into several pieces of legislation. Nevertheless, it is the responsibility of the rapporteur to point out this need and indicate the necessary time frame.

Moreover, this risk reduction strategy has been elaborated during a period when a new legislation for chemicals is being developed. Although the specific requirements are still uncertain, Council and Parliament have taken the political decisions to create an authorisation procedure for the use of CMR substances, in category 1 or 2, seeing that this will be a key element in the new chemicals policy. It is natural to introduce thoughts on a generic approach also in this risk reduction strategy, since DEHP is a substance classified as toxic to reproduction, category 2.

Table 7.1 ***Overview of exposed groups, base line measures and recommended actions***

Exposed group	Baseline measures	Immediate actions	Further actions to undertake
Consumers	**General Product Safety (92/59EEC)**: intermistic ban on phthalates in toys and childcare articles (intended to be put into mouth; under 3 years of age). **Marketing & Use (76/769/EEC):** restriction on consumer use of DEHP (as a substance or in preparations). **Plastic Materials in contact with Food (90/128/EEC):** working group discussions on restricted use of DEHP in packaging material for fatty foods. **Medical Devices (93/42/EEC):** discussions in Scientific Committee on restricted use of DEHP in medical devices for neonates and other exposed patient groups of concern; no specific recommendation could be made. **Initiatives taken by Industry:** substitution of DEHP in some applications e.g. medical devices, food packaging, flooring, cables.	**Marketing & Use (76/769/EEC):** the interimistic ban on the use of DEHP in toys and childcare articles should be secured and broadened to cover all such items that could be put into the mouth of a child and that are intended also for children above 3. **Plastic Materials in contact with Food (90/128/EEC):** the use of DEHP should be restricted in packaging materials for fatty foods. **Medical Devices (93/42/EEC):** the use of DEHP should be restricted in medical devices giving rise to exposure of neonates and groups identified in the RA to be of concern. **General Product Safety (92/59EEC):** DEHP should be interimistically banned in medical devices for uses giving rise to exposure of neonates (if equivalent measure cannot be quickly achieved in other ways).	**Safety of Toys (88/378/EEC):** The use of all substances classified as CMR, category 1 and 2, should be restricted in toys. **Plastic Materials in contact with Fo (90/128/EEC):** The use of all substanc classified as CMR, category 1 and 2, should be restricted in packaging mate for food. **Medical Devices (93/42/EEC):** The use of all substances classified as CMR, category 1 and 2, should be restricted in medical devices.

Exposed group	Baseline measures	Immediate actions	Further actions to undertake
Workers	**Classification and Labelling (67/548/EEC):** DEHP is classified as toxic to reproduction in category 2 with risk phrases R60 and R61 (for impaired fertility and harm to the unborn child). **Initiatives taken by Industry:** substitution of DEHP in some applications e.g. medical devices, food packaging, flooring, cables.	The number of workers exposed to DEHP will be reduced through other immediate actions in this strategy, at industrial sites producing or using DEHP as well as in workplace use of PVC-articles with DEHP. **Pregnant Workers (92/85/EEC):** The outdated risk phrase R47 should be replaced by R60 and R61 (for impaired fertility and harm to the unborn child). **Chemical Agents at Work (98/24):** Substitution of DEHP should be emphasised and a sufficiently protective Occupational Exposure Limit value should be established on community level. Such a limit value should be used in work-place monitoring and the general degree of reduction should be estimated in a community follow up.	**The Framework legislation for worl protection** should be extended to inclu also substances classified as toxic to reproduction, category 1 or 2, in meası equivalent to the measures for carcinogens. The future **REACH** system should set time limits for authorised uses of CMR substances, category 1 and 2, in order to increase efforts of substitution.

Exposed group	Baseline measures	Immediate actions	Further actions to undertake
Man exposed indirectly via the environ-ment	**Water Framework Directive (2000/60/EC)** DEHP is listed as a "priority substance" under review: the Commission is to propose an Environmental Quality Standard and product and process controls, aiming for progressive reduction of DEHP emissions from point sources and diffuse sources.	The indirect exposure via the environment will be reduced through other immediate actions recommended in this strategy, but probably only to a smaller extent. **Water Framework (2000/60/EC)**: The actions relating to exposure via the environment recommended in this strategy should be the basis for the controls to be proposed by the Commission. The Environmental Quality Standard for DEHP should be established for non-aqueous compartments of the aquatic ecosystem (i.e. sediment or biota). The protection of human health should be taken account of when the standard is established. Such a standard should be used in periodic monitoring, to enable the control of local emission sources and follow up of the progressive reduction of emissions on community level.	**Marketing and Use (76/769/EEC)**: The use of DEHP should be restricted in products with high production volume and giving rise to outdoor exposure, i.e. roofing, coil coating, cables, coated fabric, hoses, profiles, car undercoating, shoe soles. **Integrated Pollution Prevention and Control (96/61/EC)**: the permits for DEHP production plants should include emission limit values; the BAT Reference Document for polymer production should include considerations on DEHP; work on BAT Reference Documents in general should consider CMR substances.

Exposed group	Baseline measures	Immediate actions	Further actions to undertake
Combined groups with life time exposure		The exposure of children, patients and workers is expected to be reduced through other actions recommended in this strategy. It is understood, however, that this may not contribute sufficiently to reductions of the continuous life-time exposure of all humans. Concentrations of DEHP in sewage sludge, in cow's milk and in human breast milk should be periodically followed on community level as additional important markers for environmental emissions and continuous exposure to DEHP.	A comprehensive community follow up of the outcome of actions taken should be initiated. It should include work place exposure, environmental emissions and concentrations in sewage sludge, in cow's milk as well as in human breast milk. If by 2010 this community follow up indicates an insufficient reduction of direct and indirect exposure of humans, a ban on all remaining uses o DEHP should be activated through **Marketing and Use (76/769/EEC)**. Such a measure should also be activated if DEHP were to be classified as a "priority hazardous substance" under **Water Framework Directive (2000/60/EC)**.

7.2 Analysis of advantages and drawbacks

The evaluation in chapter 6 has shown that the **measures proposed for Consumers** are efficient and practical for reducing the direct exposure of vulnerable groups and the general population. However, the proposed actions are expected to reduce the indirect exposure of all humans via environmental emissions only to a smaller extent. The socio-economic impact relating to the proposed actions is expected to be of minor significance, since in many cases there are alternatives available that are not classified as CMR.

The number of exposed workers at industrial sites producing or using DEHP as well as in workplace use of PVC-articles will be reduced through measures proposed for other exposed groups. In addition, the **measures proposed for Workers** are considered to be practical and efficient for reducing the direct exposure of workers. Possibly these measures will not contribute much to a reduced indirect exposure of all humans via the environment, since the industrial sites producing or using DEHP contribute with only 10% of the environmental emissions. The socio-economic impact relating to the proposed workplace actions is unclear.

The reduction of the indirect DEHP exposure of all humans through measures proposed for other groups is likely to be minor. The **measures proposed for Man exposed indirectly via the environment** are efficient for reducing the indirect exposure of all humans via environmental emissions. The outdoor uses, i.e. roofing, coil coating, cables, coated fabric, hoses, profiles, car undercoating, shoe soles represent a smaller part, 22%, of the DEHP used but are estimated to contribute to 77% of the environmental emissions.

The complex nature of the DEHP use profile makes restrictions on marketing and use the most practical means to reduce emissions, as only such restrictions can ensure that alternative substances, materials or processes are used. The down stream users of DEHP are mostly SMEs, where engineering controls may prove to be difficult and where industry organisations have little possibility to provide sufficient practical guidance. Thus, the proposed restrictions on the marketing and use of DEHP in outdoor applications are practical in several aspects, but it is recognised that such restrictions will raise certain problems relating to the identification of articles containing DEHP.

The socio-economic impacts relating to the proposed restrictions on marketing and use may be significant but, the fact that alternatives to DEHP are available and in some cases are used already, would justify the measure in a somewhat longer time frame. Alternatives (both substitute chemicals, alternative materials and processes) are available and already used in practice in many applications. However, there may be cost implications associated with the use of alternatives.

The exposure of children, patients and workers will be reduced through the measures proposed for these groups. It is understood, however, that such reductions may not contribute sufficiently to a reduction of the continuous lifetime exposure of all humans. If needed, the **measures proposed for Combined exposure over time from many different sources** would be efficient in preventing all direct and indirect exposure of humans. The socio-economic impacts would be extensive but could be significantly moderated during the phase-out timeframe, as alternatives to DEHP are available in many cases already.

7.3 Monitoring arrangements

For various reasons, very little information has been available for the evaluation against the four criteria. In addition, there are obvious difficulties in assessing when results can be expected from a multitude of proposed provisions in many different areas of legislation. It could take a long time before the actions taken will reduce emissions, but this should be followed closely. The measures proposed should therefore be matched with a Community follow up of the results of actions taken.

A comprehensive follow up is included among the proposals in table 7.1, to monitor reductions in workplace exposure, environmental emissions and concentrations in sewage sludge, in cow's milk as well as in human breast milk. It is proposed to evaluate the outcome of actions taken by 2010, at the latest, to see whether the direct and indirect exposure of humans are sufficiently reduced or not and if further measures are necessary.

ANNEX

List of consultees, participating in at least one meeting of the Consultative group

Industrial Associations

Romain Ferrari
Syndicat Francais des Enducteurs Calandreurs (SFEC), PARIS

Adam Jones
Smiths Medical, London
(EUCOMED)

Maxime Ouanounou
Atofina SA, Paris

Tonny Sandell
BASF AB, Göteborg

Jörgen Bäckström / Anita Ringström / Michael Reineskog
Kemikontoret, STOCKHOLM
The Association of Swedish Chemical Industries

Jean-Pierre De Grève
European Council of Vinyl Manufacturers (ECVM), Brussels
Division of The Association of Plastics Manufacturers in Europe (APME)

Karin Kvist
Bil Sweden, Stockholm
The Association of Swedish Automobile Manufacturers and Wholesalers

Ami Lindkvist
Kooperativa Förbundet (KF)
The Swedish Cooperative Union and Wholesale Society, STOCKHOLM

Jerker Olsson
Perstorp AB, Stenungssund

Philippe Verdonck
Baxters
(EUCOMED)

David Cadogan
European Council for Plasticisers and Intermediates (ECPI), Brussels

Barry Lynham
Government Policy Consultants International, BRUSSELS

Fredrik Hellman
Astra Tech AB, MÖLNDAL
Sjukvårdens Leverantörsförening
The Swedish Association of Suppliers of Medical Devices

Gunnel Wisén-Persson
ABB AB, STOCKHOLM
The European Confederation of Associations of Manufacturers of Insulated Wires and Cables (Europacable)

Peter Okmark
Tarkett Sommer Commercial, Ronneby
European Resilient Flooring Manufacturers´ Institute (ERFMI)

Lena Lundberg
PVC Forum, STOCKHOLM
Division of The Plastics and Chemicals Federation (Sweden)

Annette Kunde
BASF AG, LUDWIGSHAFEN

Ole Grøndahl Hansen
PVC-Rådet, KÖPENHAMN
PVC Information Council

Svante Burge
Gislaved Folie AB, GISLAVED
European Automotive Trim Supplier (EATS)

Klas Elm / Johan Leffler
The Swedish Federation of Trade (Toys and Hobby Articles), Stockholm

Other organisations

Helena Nyberg / Hanna Eriksson / Mikael Karlsson
SNF, STOCKHOLM
Swedish Society for Nature Conservation (member of EEB)

Pierre-Emmanuel Neurohr
Centre national d´information indépendante sur les déchets (CNIID), PARIS
Health Care Without Harm Europe

Per Rosander
Apoteket AB, STOCKHOLM
The National Corporation of Swedish Pharmacies

Marita Severin
Södersjukhuset, STOCKHOLM
Neonatal Hospital Ward

Åke Wennmalm
Landstingskontoret, STOCKHOLM
Stockholm County Council

Roy Holland
NIOM, Haslum
Scandinavian Institute of Dental Materials

Sven Nyberg
Landsorganisationen i Sverige (LO), STOCKHOLM
The Swedish Trade Union Confederation

Sture Bengtsson
Industrifacket, STOCKHOLM
Industrial Workers Union

Authorities

Ingrid Roland
Statens Forurensningstilsyn (SFT), OSLO
Norwegian Pollution Control Authority

Shima Dobel / Lea Friman Hansen
Miljöstyrelsen, KÖPENHAMN
The Danish Environmental Protection Agency

Kerstin Wahlberg
Arbetsmiljöverket, SOLNA
The Swedish Occupational Health and Safety Authority

Kettil Svensson
Livsmedelsverket, UPPSALA
The National Food Administration

Åsa Lindquist
Konsumentverket, STOCKHOLM
The Swedish Consumer Agency

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