Pretty Nasty

– Phthalates in European Cosmetic Products

Women's Environmental Network

Swedish Society for Nature Conservation

Health Care Without Harm

Contents

Produced in Sweden.

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Executive Summary

Women's Environmental Network, Swedish Society for Nature Conservation, and Health Care Without Harm contracted a certified Swedish analytical laboratory to test 34 name-brand cosmetic products for phthalates, a large family of synthetic chemicals linked to decreased fertility and reproductive defects. The laboratory found phthalates in nearly 80% of the products. More than half of the tested cosmetics contained more than one type of phthalate. Major brands included products by Boots, Christian Dior, L'Oreal, Procter & Gamble, Lever Fabergé, and Wella. None of the products listed phthalates as an ingredient on the label.

In November 2002, the EU amended the Cosmetics Directive 76/768/EEC to order the removal of two phthalates in the very near future because of their reproductive toxicity (DEHP and DBP). The EU previously classified both phthalates as substances, *"…which should be regarded as if they impair fertility in humans"* and substances, *"…which should be regarded as if they cause developmental toxicity to humans."* The survey of cosmetics in this study shows that approximately 40% of the products contained one or both of the phthalates covered by the recent ban on their use in cosmetics.

Chemicals that cause birth defects do not belong in products marketed for personal or household use. While the levels of phthalates in some individual products were low, people are being exposed to phthalates from many different products each day. The 34 well-known perfumes, deodorants, and hair care products tested in this study represent a small fraction of the market, but the results suggest that a substantial proportion of beauty products available in retail stores contain phthalates.

Actions needed

A striking result of this study is that manufacturers have not taken notice of the dangerous properties of phthalates in their development or quality control of cosmetics. Even if manufacturers are required to evaluate the safety of their product, the environmental and health problems with phthalates are either not taken into account or underestimated.

Manufacturers should:

- Clearly label all phthalate-containing products immediately while reformulating.
- Test the ingredients in their products for phthalates or demand this information from their suppliers. This is especially important for fragrances whose contents are often not disclosed.
- Pledge to remove all phthalates from their products and perform appropriate quality control to ensure they are not present.
- Apply the precautionary principle when formulating products by avoiding ingredients when there is evidence that they may cause harm, even if their effects are not fully understood. This study shows that manufacturers are capable of making products without the use of phthalates.

What the European Union should do

The EU should pressure manufacturers to halt their current use of dangerous ingredients in cosmetic products. The amended Directive on Cosmetic Products will restrict ingredients classified as carcinogenic, mutagenic, or toxic to reproduction. However, several steps can help improve consumer protection and public health:

- Introduce an unconditional ban of all substances, including all phthalates, that cause concern for human fertility and development, and have toxic, mutagenic, and/or carcinogenic effects.
- Introduce regulations that require all ingredients in a product, including phthalates, to be

clearly listed on the label.

- Ensure that the upcoming frame legislation for chemicals ("REACH") includes cosmetic products, relating to new requirements such as testing, information, labelling, and authorization schemes.

What you can do

- Send your "Phthalate free now!" message to the manufacturers that have been found in this study to sell phthalate-containing cosmetic products. A letter can be found at http://www.nottoopretty.org At the website you can also direct messages to the European Commission Officials accountable for relevant legislation procedures.
- Contact your representatives in the national parliament and European parliament and ask them to support legislation banning phthalates in cosmetics.
- Take the list of products with you the next time you go shopping for cosmetics. Show it to the store managers and ask for their help in convincing cosmetic companies to produce phthalate-free products. Remember that just because a product is not on the list, does not mean it is free of phthalates.

Abbreviations

BBP	Butyl benzyl phthalate
CDC	US Centers for Disease Control and Prevention
CMR	Carcinogenic, mutagenic, or toxic to reproduction
DBP	Di (n-butyl) phthalate
DEHP	Di (2-ethylhexyl) phthalate
DEP	Diethyl phthalate
DHP	Di-n-hexyl phthalate
DIDP	Di-isodecyl phthalate
DINP	Di-isononyl phthalate
DMP	Di-methyliso phthalate
DNOP	Di-n-octyl phthalate
EPA	Environmental Protection Agency
EU	European Union
FDA	US Food and Drug Administration
kg	Kilogram
MBP	Mono-n-butyl phthalate
MEHP	Monoethylhexyl phthalate
mg	Milligram
MPP	Monopentyl phthalate
PVC	Polyvinyl chloride plastic
µg	Microgram

Introduction

Phthalates are a group of synthetic chemicals that have been linked to reproductive damage. They are present in flexible polyvinyl chloride plastic (PVC), cosmetics, and other consumer items. PVC represents the largest use of phthalates, occupying 90% of global plasticiser production. [1] In PVC, phthalates are added to impart flexibility. In cosmetics, phthalates are often added to provide flexibility, impart an oily "moisturizing" film, and help dissolve and fix other ingredients. [2] In addition, phthalates serve as solvents in fragrances and as denaturants in alcohols. Phthalates have contaminated the worldwide ecosystem from releases during manufacturing and in normal use of consumer products. Phthalates are so pervasive in the environment that human exposure is virtually unavoidable.

In 1999, a controversy throughout the European Union (EU) surrounding the use of soft PVC toys resulted in an emergency ban on the use of certain phthalates in toys designed for the mouth for children up to three years old. [3] The European Commission has upheld the ban despite aggressive lobbying by the European PVC industry. [4] Denmark recently proposed to expand the ban by giving notice to retailers and toy importers that they will have one year to eliminate phthalates in toys for children under six. [5]

In 2001, the EU classified two phthalates prohibited in toys (DEHP and DBP) as Category 2 substances defined as chemicals, *"…which should be regarded as if they impair fertility in humans"* and substances, *"…which should be regarded as if they cause developmental toxicity to humans."* [6] The classification implied that use of DEHP and DBP would be prohibited in chemical preparations, but their use in cosmetics was still permitted due to an exemption. In November 2002, the EU closed this loophole, banning the use of reproductive toxins in cosmetic and personal care products unless otherwise regulated in the cosmetics directive. The ban will take effect within several months.

There are three important aspects to the controversies associated with the bans on phthalates in cosmetics and PVC toys. First, the EU joins other government regulatory agencies that view certain phthalates as a potential hazard for human reproduction. Second, a variety of phthalates have been found in the human body indicating widespread exposure. Finally, phthalates found in humans are also present in cosmetics as demonstrated in recent testing conducted in Germany and the US. [7] [8]

Given the potential impact of phthalates on public, environmental, and occupational health, Women's Environmental Network, Swedish Society for Nature Conservation, and Health Care Without Harm asked whether phthalates might be present in well-known cosmetics sold in Europe.

Materials and Methods

Thirty-four cosmetic products including perfumes*, deodorants, hair gels, hair mousses, and hair sprays were purchased at prominent national retail stores in Sweden and the UK by members of the Women's Environmental Network, Swedish Society for Nature Conservation, and Health Care Without Harm. The list of products is shown in Tables 3 and 4. The primary criterion for sample selection was market position. Swedish retailers supplied sales data to identify market leaders. In addition, cosmetic industry estimates of market share were derived from industry trade publications. [9]

* Note that "perfume" will be used in this report to loosely describe perfume, cologne, and scented body sprays.

Analycen (Lidkoping, Sweden) performed sample preparation and phthalate analysis. Analycen is a certified laboratory with the following accreditations: SWEDAC accreditation number 1125 (EN45001); ISO 14001:1996; and ISO 9001:2000 for environmental management and quality. Samples were prepared according to internal method A209:15, Thurén A, 1988. Phthalate content was determined using GC/MS in SIM mode. Products containing less than 1 mg/kg were considered to have trace levels of phthalates.

Results

Phthalates are present in EU cosmetics

An investigation of 34 name-brand cosmetics purchased in prominent EU retail stores showed that most of them contained phthalates. Products were separated into two groups: a group lacking or containing only trace levels of phthalates, and a group containing phthalates equal to or greater than 1 mg/kg. Using this criterion, nearly 80% of the products contained phthalates and more than half of them contained multiple phthalates in the same consumer item (Table 1). Product categories included deodorants, perfumes, hair mousse, hair gel, and hair spray. Phthalate concentrations ranged from 1 mg/kg to nearly 2 percent of the product formulation. These levels suggest both contamination and deliberate addition of phthalates (see below).

Table 1. Summary of phthalate occurrence and amounts in cosmetic products

Phthalate	Percent of products (number)	Types of products	Average concentration (mg/kg)	Maximum concentration (mg/kg)
All	79% (27)	Deodorant, perfume, hair mousse, hair gel, and hair spray		
Multiple	53% (18)	Deodorant, perfume, hair mousse, hair spray		
DEHP	29% (10)	Deodorant, perfume, hair mousse, hair spray	9.3	24
DBP	24% (8)	Deodorant, perfume, hair mousse, hair spray	22	150
BBP	6% (2)	Hairspray	5.4	6.6
DEP	68% (23)	Deodorant, perfume, hair mousse, hair gel, and hair spray	2,200	19,000
DMP	3% (1)	Perfume	2.2	2.2
DNOP	21% (7)	Deodorant	1.4	1.6

Abbreviations: DEHP, Di(2-ethylhexyl) phthalate; DBP, dibutyl phthalate; BBP, butyl benzyl phthalate; DNOP, di-n-octyl phthalate; DEP, diethyl phthalate; DMP, dimethyl phthalate; mg, milligram or one-thousandth of a gram; kg, kilogram or 1000 g. Products purchased at retail stores in Sweden and the UK. Note that the average concentration represents the mean of positive tests.

A significant number of cosmetic products contain phthalates banned by the EU

Cosmetics containing newly banned phthalates are readily available in retail stores. Approximately 40% of the products surveyed in this study contained DEHP or DBP. Table 2 shows that approximately one-third of these products contained both phthalates. Prominent products on the list include deodorants by The Body Shop and Nivea; popular perfumes such as Eternity and Poison; hair mousses by Wella and Studio Line; and hair sprays by Wella and Vidal Sassoon. Manufacturers producing products with banned phthalates include prominent companies such as Beiersdorf, Boots, Christian Dior, L'Oreal, Procter & Gamble, The Body Shop, Lever Fabergé, and Wella.

The phthalates in Table 2 form part of a group of "Category 2" substances determined by the EU to be risks for human fertility and development. Other well-known members of the group include cadmium chloride, ethylene glycol, vinclozolin, cycloheximide, and formamide. [10] Consumers might question the use cosmetics containing cadmium (highly toxic metal) or ethylene glycol (used in anti-freeze), but unknowingly apply phthalates to their skin and hair in many cosmetic products every day.

Table 2. Products containing reproductive toxicants as defined by the European Union

Manufacturer	Product	Reproductive toxicant
Beiersdorf	Nivea “deo compact” deodorant	DBP
Boots	Essentials Natural Hold hair spray	DEHP
Chanel	Chanel no 5 eau de parfum	DEHP
Christian Dior	Poison eau de toilette vaporizer	DEHP, DBP
L’Oreal	Tresor eau de parfum spray	DEHP, DBP
L’Oreal	Studio Line Styling Mousse	DBP
L’Oreal	Elnett Satin hair spray	DEHP, DBP
Lever Faberge	Impulse Oxygen Air Body Spray deodorant	DBP
Procter & Gamble	Vidal Sassoon hair spray	DBP
The Body Shop	The Body Shop Aloe Vera deodorant	DEHP
Unilever	Eternity eau de parfum spray	DEHP
Wella AG	Wella Volume Mousse	DEHP
Wella AG	Shockwaves Strong Bid Body Mousse	DEHP
Wella AG	Wella Super Strong hair spray	DEHP, DBP

Abbreviations: DEHP, Di(2-ethylhexyl) phthalate; DBP, dibutyl phthalate. Total number of products containing Category 2 reproductive toxicants = 14 (41% of products tested; 52% of products containing phthalates). Four products contained more than one Category 2 reproductive toxicant. See Table 3 for concentrations.

A variety of products contain phthalates

Table 3 shows that all of the deodorants, perfumes, and hair sprays that were tested contained phthalates. This includes prominent name-brand deodorants such as The Body Shop, Sure, Rexona, and Dove. Famous perfumes such as Eternity, Chanel No. 5, Poison, and Tommy Girl all contained phthalates. Heavily used hairsprays such as Vidal Sassoon, Essentials, and Wella also contained phthalates. These products were purchased in Sweden or the UK, but most of them are available throughout Europe.

Thirteen cosmetics listed in Table 3 contain phthalates that are not covered under the new amendment to the EU directive on cosmetics that effectively bans DEHP and DBP. These products include: ACO, Bats, Degree, Dove, Herbina, Rexona, and Sure deodorants, Tommy Girl cologne, Essentials, Finesse, and Fructis hair mousse, Finesse hair gel, and Pantene Pro V hair spray. These cosmetics expose consumers to phthalates that give cause for concern, but are legal under current EU regulations (see Reproductive Toxicity of Phthalates).

Table 3 also demonstrates that many products contain more than one type of phthalate. In fact, approximately two-thirds of the products that tested positive contained multiple phthalates in the same consumer item. When cosmetics containing phthalates are used in combination with each other aggregate phthalate exposure results. For example, application of Impulse Body Spray, Tresor perfume, and Essentials hair spray exposes a consumer to products containing, DEHP, DBP, BBP, DEP, and DMP. Aggregate phthalate exposures increase even more when these cosmetics are combined with phthalate exposures from PVC consumer and medical products. Despite daily exposures from multiple sources, EU regulations only recognize single exposures to a single phthalate from a single product.

Table 3. Phthalates in 27 cosmetic products (mg/kg)

Product	Purchased	DEHP	DBP	BBP	DNOP	DEP	DMP
Deodorant							
ACO snabbtorkande roll on	Sweden				1.5	1.0	
Bats, extra effektiv	Sweden				1.4		
Degree Fresh	Sweden				1.4	320	
Dove Original	Sweden				1.4	40	1.0
Herbina antiperspirant Linum	Sweden					670	
Impulse Oxygen Body Spray	UK		150			392	
Nivea “deo compact”	UK		2.3		1.0	560	
Rexona 24 hr intensive	Sweden				1.5	1,600	
Sure Ultra Cotton Fresh	UK				1.6	260	
The Body Shop Aloe Vera	Sweden	8.6			1.6		
Perfumes							
Chanel no 5 eau de parfum	UK	1.0				210	
Eternity eau de parfum spray	UK	3.8				17,000	
Poison eau de toilette	UK	4.2	1.1			4,000	
Tommy Girl cologne spray	UK					370	
Tresor eau de parfum spray	UK	6.8	1.0	1.0		19,000	2.2
Hair mousse							
Essentials Styling Mousse	UK					3.3	
Finesse Volume Mousse	UK					58	
Fructis Style Volume Mousse	Sweden					1,700	
Shockwaves Strong Big Body	UK	1.1					
Studio Line Styling Mousse	Sweden		8.4			265	
Wella Volume Mousse	Sweden	1.2				8.0	
Hair gel							
Finesse Gel Super Strong	Sweden					32	
Hair spray							
Elnett Satin	UK	1.6	1.0	6.6		5,700	
Essentials Natural Hold	UK	41				1.3	
Pantene Pro-V Extra Hold	UK					1.0	
Vidal Sassoon	UK		8.6	4.2		92	
Wella Super Strong	Sweden	24	1.1			510	

Abbreviations: DEHP, Di(2-ethylhexyl) phthalate; DBP, dibutyl phthalate; BBP, butyl benzyl phthalate; DNOP, di-n-octyl phthalate; DEP, diethyl phthalate; DMP, dimethyl phthalate. Total number of products = 27. Number of products containing more than one phthalate = 18 (66% of products containing phthalates).

The phthalate levels observed in cosmetics suggest both contamination and deliberate addition. The high levels of DEP suggest that it is deliberately added to cosmetics. The levels of DEHP, DBP, BBP, DMP, and DNOP probably reflect poor quality control in product formulation and/or contamination of DEP. All the phthalates shown in Table 3 contribute to an aggregate exposure. Each small amount present in a single product used a single time adds to a growing aggregate exposure when products are combined and used over time.

Inadequate labelling

To add to the consumer confusion, none of the 34 products tested for phthalates listed them as an ingredient on the label. This was even true for products containing more than 10,000 mg/kg DEP. Labels may indicate the presence of denatured alcohol or fragrances but do not reveal their components. Current EU law does not require full disclosure of cosmetic ingredients. This compromises consumer protection since buyers who wish to avoid phthalate exposure cannot identify which products contain them. No warning is present for consumers who wish to avoid using products containing chemicals linked to reproductive damage in offspring.

A significant proportion of products do not contain phthalates

Phthalates are often added to cosmetics to provide flexibility, impart an oily "moisturizing" film, and help dissolve and fix other ingredients. [11] In addition, phthalates serve as solvents in fragrances and as denaturants in alcohols. However, Table 4 indicates that a significant proportion of the leading products that were tested did not contain phthalates.

Table 4. Products containing undetectable or trace levels of phthalates

Product	Purchased
Blavitt Hargel Strong hair gel	Sweden
Pantene Pro-V Classic Care hair gel	UK
Pantene Pro-V controlling smooth and sleek hair mousse	UK
Shockwaves Ultra Strong Max Hold hair gel	Sweden
Studio Line Creating Gel Super Strong hair gel	Sweden
Stuff Rok Hold hair gel	UK
Wella Styling Gel Super Strong hair gel	Sweden

Twenty percent of the products in this study either contained phthalates at trace levels or phthalates could not be detected (7 products). Note that all the products without phthalates were hair gels and hair mousses. All the deodorants, hair sprays, and perfumes tested in this study contained phthalates. Phthalate-free products can be produced by attention to quality control or reformulation. The data in Table 3 suggests that careful quality control could quickly provide phthalate-free deodorants and hair sprays. A previous study of phthalates in cosmetics sold in Germany indicates that many phthalate-free perfumes are also available. [12] Taken together, the data suggests that the cosmetics industry is capable of eliminating phthalates from commercially viable products.

Companies can produce products without phthalates

Table 5 demonstrates that companies can make hair gel and hair mousse with and without phthalates.

Table 5. Manufacturers make products with and without phthalates

Manufacturer or distributor	Products with phthalates	Products with trace levels or no detected phthalates
ACO Hud AB	Deodorant: ACO snabbtorkande	
Beiersdorf	Deodorant: Nivea “deo compact”	
Boots	Hair spray: Essentials Natural Hold	Hair gel: Stuff Rok
Boots	Hair mousse: Essentials	
Cederroth AB	Deodorant: Bats, extra effektiv	
Chanel	Perfume: Chanel no 5	
Christian Dior	Perfume: Poison	
Coop		Hair gel: Blavitt Hargel
L’Oreal	Perfume: Lancome Tresor	Hair gel: Studio Line
L’Oreal	Hair mousse: Studio Line	
L’Oreal	Hair spray: Elnett Satin	
Lever Fabergé	Hair mousse: Fructis	
Lever Fabergé	Deodorant: Degree Fresh	
Lever Fabergé	Deodorant: Rexona 24 hr intensive	
Lever Fabergé	Deodorant: Dove Original	
Lever Fabergé	Deodorant: Impulse Oxygen	
Lever Fabergé	Hair mousse: Finesse	
Lever Fabergé	Hair gel: Finesse Gel	
Lever Fabergé	Deodorant: Sure Ultra Cotton Fresh	
NOIRO	Deodorant: Herbina antiperspirant	
Procter & Gamble	Hair spray: Pantene Pro-V Extra Hold	Hair gel: Pantene Pro-V Classic
Procter & Gamble	Hair spray: Vidal Sassoon	Hair mousse: Pantene Pro-V
The Body Shop	Deodorant: Aloe Vera	
Tommy Hilfiger	Perfume: Tommy Girl	
Unilever	Perfume: Calvin Klein Eternity	
Wella AG	Hair mousse: Wella Volume	Hair gel: Shockwaves
Wella AG	Hair mousse: Shockwaves	Hair gel: Wella Styling Gel
Wella AG	Hair spray: Wella Super Strong	

Boots sells Stuff Rok hair gel without phthalates, but 41 mg/kg DEHP is present in their Essentials hairspray. L’Oreal’s Studio Line mousse contains DBP and DEP but Studio Line hair gel does not contain phthalates. The Table also illustrates that the same type of product can be made with and without phthalates. For example, Fructis hair mousse by Lever Fabergé contains phthalates while Procter & Gamble’s Pantene Pro V hair mousse does not. Sometimes, even products made by the same company with similar names differ in phthalate content. Procter & Gamble makes Pantene Pro-V hair gel and mousse without phthalates, but low levels of DEP are found in Pantene Pro-V hair spray. In a similar manner, DEHP is found in Shockwaves hair mousse but not in the company’s Shockwaves hair gel.

All the deodorants, perfumes, and hair sprays tested in this study contained phthalates including products by Lever Fabergé and L’Oreal. However, a similar study of cosmetics in the US found deodorants and hair sprays from Lever Fabergé and L’Oreal that did not contain phthalates. [13] This indicates that these prominent companies can formulate and sell products without phthalates.

Table 5 and other studies of phthalates in cosmetics suggest that phthalate exposures from cosmetics are unnecessary. The presence of products without phthalates implies that cost-effective formulations for phthalate-free cosmetics already exist in the retail market.

Confirming earlier studies

The results in this study confirm and extend earlier studies of phthalates conducted in Germany and the US. In Germany, DEP was found in a variety of cosmetics including hair dye, shampoo, tanning lotion, deodorant, perfume, foundation, and lotions. [14] In each product category, the investigation found products with, and without phthalates at a detection level of 10 mg/kg. For example, in 2002, DEP was found in 15 deodorants, but 20 deodorants did not contain phthalates. The results indicate that commercially viable cosmetics without phthalates are readily available in Germany. In the US, 72% of the products that were tested contained phthalates such as DEHP, DBP, BBP, DEP, or DMP. [15] Cosmetics containing phthalates included deodorant, perfume, hair gel, hair mousse, hair spray, and lotions. Phthalate levels were generally higher than those observed in European products and products from the same manufacturer often contained different levels and sometimes a different spectrum of phthalates. Like the German study, the investigation found that products were readily available on the US market that did not contain phthalates.

Nail polish

Nail polish products were not tested in this study, but an earlier analysis in the US indicates that they also represent a significant source of phthalates. [16] A survey of US pharmacies found DBP in 37 leading nail polishes, top-coats, and hardeners including Avon, Cover Girl, Maybelline, Oil of Olay, and MaxFactor products. An examination of patent records found that 38 companies hold 105 cosmetics-related patents that include DBP as an ingredient. According to these legal records, DBP levels in nail polishes average about 50,000 mg/kg. Interestingly, the study also found a significant number of nail polishes that did not contain phthalates including prominent brands by L'Oreal, Maybelline, and Revlon.

Reproductive Toxicity of Phthalates

The recent regulatory action of the EU focuses on potential reproductive harm from DEHP and DBP. However, many other members of the phthalate chemical family display reproductive toxicity in animal studies. The effects of human exposures to these phthalates have not been well studied, but the reproductive toxicity of phthalates has generated concern in the medical community as well as government regulatory agencies.

Reproductive damage in animals

The reproductive effects of phthalates in animals include decreased fertility in females, foetal defects, reduced survival of offspring, birth defects, altered hormone levels, and uterine damage. Phthalates that display one or more of these effects include BBP, DBP, DEP, DHP, DIDP, DINP, MBP, MDP, and MEHP. [17] [18] [19] [20] [21] [22] [23] [24] [25] Many of these phthalates were found in cosmetics shown in Table 3.

Phthalates such as DEHP, DBP, and DEP are readily transferred to the placenta and the growing embryo and foetus. [26] [27] [28] In the 1970s, DEHP was found in human placenta. [29] Phthalates are also passed to offspring during lactation. For example, animals efficiently transfer DEHP to breast milk causing a reduction in the quality and quantity of the milk and

exposing the offspring. [30] Phthalates have also been found in human breast milk in two German studies. One study found DEHP at levels ranging from 71 – 160 µg/kg. [31] Another found levels that varied from 10 – 110 µg/kg. [32]

In males, phthalates cause prostate damage, female-like areolas/nipples, and reproductive malformations in infants, including altered hormone levels, testicular atrophy, reduced sperm production and mobility, undescended testes, hypospadias (defect of the penis), Sertoli cell damage (required to support sperm development), and Leydig cell tumours (hormone-producing cells of the testes). Phthalates that display one or more of these effects include BBP, DBP, DEHP, DEP, DHP, DINP, DPP, MEHP, MBP, and MPP. [33] [34] [35] [36] [37] [38] [39] [40] [41] [42] [43] [44] [45] [46] Many of these phthalates were also found in cosmetics listed in Table 3.

Animal studies are relevant to humans

Several regulatory agencies have recently concluded that animal studies showing reproductive and developmental damage due to phthalates are relevant to humans.

- In 1998, the EU Scientific Committee on Toxicity, Ecotoxicity and the Environment stated in its review of DEHP in soft PVC toys that the testicular effects of DEHP were relevant to humans and that the small margin of safety, *"…for DEHP raises clear concern."* [47]
- In 2000, the Center for the Evaluation of Risks to Human Reproduction of the National Toxicology Program in the US concluded in its review of DEHP toxicity that the *"…rodent data are assumed relevant to predicting that DEHP has the potential to produce adverse reproductive system effects in humans."* [48]
- In 2001, the Swedish National Chemicals Inspectorate concluded in its review of DEHP for the EU that, *"The effects on testis, fertility, and development, observed in different animal species and at relatively low levels, are considered to be relevant to humans."* [49]
- In 2002, Health Canada's Expert Advisory Panel on DEHP in Medical Devices concluded that, *"…the mechanism by which developmental and testicular toxicity in particular occur in rodents appears relevant to humans."* [50] The agency identified sub-populations, *"…who may be at increased risk for the adverse effects of DEHP…"* These included pregnant women *("…adversely affect the development of their offspring")*, breast feeding women *("possible risk of excretion of DEHP in breast milk")*, and pre-pubescent males *("…potential risk to reproductive organs.")*
- In 2002, the National Toxicology Program (NTP) concluded in its review on the potential human impact of DBP exposure that, *"Based upon recent estimated DBP exposures among women of reproductive age, the NTP has some concern for DBP causing adverse effects to human development, particularly development of the reproductive system."* [51]

Human correlates

Very little human data is available concerning the reproductive toxicity of phthalates. However, several limited studies suggest adverse reproductive effects in humans associated with phthalates.

In women, higher urinary levels of phthalates and complications in pregnancy such as anaemia, toxaemia, and preeclampsia were correlated with residence near a PVC plastics manufacturer. [52] In another study, occupational exposures to phthalates at high levels were correlated with decreased pregnancy and higher rates of miscarriage. [53] Finally, a study of Puerto Rican girls with premature breast development found elevated levels of phthalates in the blood causing the authors to ask whether an association exists between phthalate exposure and this type of abnormal reproductive development. [54]

Several investigations suggest that phthalates may affect human sperm quality. One study found DMP, DBP, and DEHP in semen from college students. [55] The levels of DBP were compared to the sperm densities. The results revealed that the higher the DBP concentration, the lower the sperm density. Another study examined the effect of phthalates on human sperm mobility. [56] Sperm from healthy men was incubated with DEHP, DBP, DEP, or DMP for various times and the effect on velocity and motion was measured. All of the phthalates reduced mobi-

lity in a dose-dependent manner with DEHP and DBP being especially potent. Finally, a recent study associates general levels of phthalates in the US population with altered semen quality. [57] High levels of the metabolite of DBP (mono-butyl phthalate) correlated with poor sperm mobility and lowered sperm concentration. The results also suggested an association between the metabolite of BBP (mono-benzyl phthalate) and lowered sperm concentration and the metabolite of DMP (mono-methyl phthalate) and poor sperm morphology. Metabolites of DBP, BBP, and DMP were all associated with diminished semen quality.

Some of the effects caused by DEHP in male rodents include altered zinc concentrations, testicular atrophy and infertility. [58] The US Food and Drug Administration notes that these same symptoms are seen in male haemodialysis patients who are exposed to DEHP from PVC dialysis tubing. In fact, the Agency called the similarity between the testicular damage observed in animals and male haemodialysis patients *"strikingly similar"* and concluded that the effects seen in rodents *"…may have a clinical correlate in humans."*

Trends in reproductive health

The growing concern about the reproductive toxicity of phthalates in males is occurring against a backdrop of disturbing trends in reproductive health. Germany, France, Italy, and England are now the leading countries for incidence of testicular cancer and the rate of the disease has risen by 84% in the UK since the 1970s. [59] The occurrence of hypospadias, a defect of the penis, doubled in Norway and Denmark during the 1970s and 1980s. [60] Finally, an analysis of approximately 100 studies of sperm counts between 1934 and 1996 demonstrates significant declines in Europe. [61]

Other toxic effects

The reproductive effects of phthalates represent part of a spectrum of toxic effects observed in animal studies including adverse effects on the liver, kidneys, heart, lungs, and blood. Phthalates increase liver weight, affect liver function, and alter liver enzymes in rodents. These effects have been observed after exposure to four of the phthalates tested for in this study: DBP, DEHP, DMP, and DEP; plus two others: DINP and DIDP. [62] [63] [64] [65] [66] Human patients undergoing haemodialysis are exposed to large doses of DEHP from PVC tubing. Changes in liver enzymes similar to those observed in animal studies are also seen in these patients. [67] Phthalates, including common ones such as DEHP and DINP, cause liver carcinoma and adenomas in rodents. [68] [69] [70] The chemical industry has aggressively pushed a hypothesis that the carcinogenic effects of phthalates occur only in rodents and are not relevant to humans. However, the hypothesis contains data gaps and incorrect assumptions and has never been adequately tested. [71] The lack of liver tumours in mice that do not contain a receptor that interacts with phthalates (PPARalpha) is often used as proof by the industry that the receptor is required for tumour formation. [72] However, toxic lesions were seen in both the kidney and testis in that study and there is some question whether tumours would have appeared in the liver if the study had continued for a longer, more standard time period. [73] Phthalates can also adversely impact the heart and blood pressure. One study observed a slowing of the heart rate in response to MEHP, the metabolite of DEHP, at levels encountered by coronary bypass patients. [74] [75] The effects of phthalates on the lung are not well known but DIDP increases the width of alveolar septa (partitions between lung sacs) and causes inflammatory reactions in animal studies. [76] In humans, lung disorders similar to hyaline membrane disease occurred in several pre-term infants ventilated with PVC tubing containing DEHP. [77] The symptoms diminished when the PVC tubing was replaced with ethylene vinyl acetate tubing that does not contain plasticisers. A 1999 study found that phthalates such as DEHP and BBP migrate from PVC flooring to house dust. [78] The authors reported a higher frequency of children with bronchial obstruction, characteristic of asthma attacks, in homes with PVC flooring. [79] They proposed that the structural similarity between phthalates and prostaglandins might provide a mechanistic explanation for the observed association. The US FDA cites numerous studies that indicate that DEHP stimulates com-

plement activation and platelet aggregation and that these effects are significantly reduced when non-PVC/non-DEHP alternatives are used. [80] Platelet aggregation can lead to the formation of small blood clots that are thought to cause neurological complications in cardiopulmonary bypass patients (whose blood is mechanically oxygenated since the heart and lungs are stopped) and infarcts (areas of tissue death) of the brain, lung, and kidney in patients that receive extracorporeal membrane oxygenation. [81]

Major Pollutants and Aggregate Exposure

Major environmental pollutants

The manufacture, use, and disposal of cosmetics, PVC, and other phthalate-containing products have resulted in extensive environmental releases of phthalates. Phthalates are now one of the most abundant industrial pollutants in the environment, and are widely present in air, water, soils, and sediments. [82] [83] Phthalates such as DEHP have been measured in virtually all fresh water and marine environments and in lake sediments, storm water runoff, sewage treatment plants, and sewage sludge. DEHP has been found in the Antarctic pack ice, the Antarctic sub-surface snow at depths up to three metres, and in deep-sea jellyfish from more than 1,000 metres below the surface of the Atlantic Ocean. [84] [85]

Manufacturing and disposal

More than eight billion kilograms of phthalates are manufactured annually, most for use in flexible PVC. [86] Cosmetics represent a small portion of this manufacturing capacity since over 90% of global plasticiser production is used in PVC. [87] Available data underestimate the release of phthalates from manufacturing facilities since companies are not required to report releases of all commonly produced chemicals. However, the small amount of data that exists indicates the magnitude of environmental pollution. For example in Germany, total DEHP emissions during processing were estimated at over 680,000 kg per year in 1998 and the overall annual environmental release of DEHP in Germany is estimated to be considerably in excess of 1.5 million kg. [88] When buried in landfills, PVC products release phthalates into liquid leachates. [89] This has been observed in landfills located in Sweden, Italy, Germany and the UK. Concentrations in leachates for phthalic acid, DEP, and DMP have been measured at 18,900 µg/kg, 540 µg/kg, and 300 µg/kg respectively. [90]

Consumer products, food, and medical products

Phthalates are a principal component of flexible PVC products such as toys, clothing, flooring, wallpaper, and medical products. Product testing reveals significant phthalate concentrations in these products. For example, a recent study by the Danish EPA tested PVC shower curtains, flooring, gloves, carpet tiles, wallpaper, and bags and found at least one type of phthalate in all products at levels that varied from 24 - 630 g/kg. [91] PVC medical products are another source of exposure since they contain DEHP at levels ranging from 200-800 g/kg (20-80%). [92] [93] Food is also contaminated by phthalates during its processing and packaging. A Danish study found DBP, DEHP, and BBP in baby food and infant formula at levels ranging from 0.11 – 0.49 mg/kg. [94] In addition, DEHP contaminates a variety of European dairy products including milk, butter, and margarine. [95] In Japan, a recent investigation by the Environment Ministry found DEHP in more than 80% of the foods consumed in the country. [96] These widespread uses of phthalates in consumer and medical products are largely invisible to the public because most products do not require labels to identify their presence.

Aggregate Exposure

The EU chemicals regulation regime considers the exposure to one phthalate at a time from one type of product. However, actual human exposures to chemicals do not occur singly, but in aggregate, complex mixtures. Humans are exposed to phthalates through food, water, air, and the use of phthalate-containing consumer products that may be eaten, inhaled, or applied directly to the skin and absorbed. Evidence for this in humans has been gathered by the US Centers for Disease Control (CDC).

In 2000, the CDC published a study that demonstrated, *"…that phthalate exposure is both higher and more common than previously suspected."* [97] The study revealed that 75% of the human participants had been exposed to DEHP, DEP, BBP, and DBP. The authors described the levels of DEP in women as a *"…substantial internal dose."* This is consistent with the high DEP concentrations observed in products shown in Table 3. Most disturbing was the finding that the highest levels of DBP exposure appeared in women between the ages of 20 and 40. In Europe, there are approximately 150 million women in this age-group compared to about 50 million in the US. [98] The potential number of exposed women is significant even if only occupational exposures are considered. For example, in the UK alone there are 170,000 female hairdressers and 88% are under the age of 30. [99]

The chemical industry described the results of the CDC study showing multiple exposures to phthalates in humans as *"…good news…"* [100] The industry argued that exposure to each individual phthalate from each individual product was below government-established "tolerable intakes". [101] For example, the US Phthalate Esters Panel of the American Chemistry Council emphasizes that the DBP exposures found by the CDC are below the US EPA's "tolerable intake" of 100 µg/kg/day. The industry does not reveal that this value was based on a study conducted in 1953, before evidence about the reproductive and developmental toxicity of DBP existed. This means that the "tolerable intake" value for a common ingredient in cosmetics does not take into account its reproductive and developmental toxicity or any knowledge that has accumulated in the last fifty years. Finally, the EPA describes its own "tolerable intake" values for DBP and DEP as numbers in which it has "low confidence."

Using the CDC data to estimate aggregate phthalate exposures suggests that significant numbers of people are close to or even exceeding "tolerable intakes" when multiple sources are considered. This approach is supported by the general consensus that at least several common phthalates act, at least in part, through a common anti-androgenic mechanism when they independently cause harmful effects on the developing male reproductive system, which appears to be their most sensitive endpoint. A preliminary estimate using this method found that approximately two million US women between 20 and 40 are contaminated with levels of DBP at levels near a "tolerable intake". [102] When any of these women requires medical care, even more phthalates are added from DEHP exposure that comes from PVC medical devices.

The tendency to use multiple cosmetics illustrates the potential for aggregate exposure to phthalates. A survey of cosmetic use among women in the UK that indicates up to 26 products may be used in a single day. [103] The range of products contained many items known to contain phthalates including shampoo, nail polish, perfume, body lotion, deodorant, hair gel, hair mousse, hair spray, and foundation.

The multitude of cosmetic, soft PVC, and other phthalate-containing products produces a consistent aggregate human exposure that is largely unnecessary. This study demonstrates the availability of phthalate-free cosmetics. Other reviews list materials that can replace PVC and eliminate phthalate exposures from this predominant source. [104]

Regulation of Phthalates in the EU

General regulation of cosmetics

Cosmetics in the EU are regulated by directive 76/768/EEC. This directive essentially places the responsibility for regulating cosmetics in the hands of the powerful European cosmetics industry that produced sales topping 54 billion Euros in 2001. [105] The core responsibility of cosmetics manufacturers is to perform safety assessments. These assessments do not account for aggregate exposures from other products and most of them do not require an assessment of the whole product; only the individual toxicity of the ingredients. Two exceptions are when skin penetration is more likely or if interactions between ingredients might form new potentially toxic substances. Despite the governmental requirement for safety assessments, consumers do not have access to them. To make matters worse, the safety assessments do not affect the appearance of a cosmetic on the market since they are usually not even reviewed by regulatory authorities. Like the US, essentially no pre-market authorization exists for cosmetics in the EU. The industry "regulates" itself.

Classifying hazardous chemicals

The EU classifies substances that may cause cancer, mutations, or harmful reproductive effects (CMR) into three categories of severity. For reproductive toxicants these categories are:

- Category 1 Substances known to impair fertility in humans.
- Category 2 Substances that should be regarded as if they impair fertility in humans and/or regarded as if they cause developmental toxicity to humans.
- Category 3 Substances that cause concern for human fertility and/or possible developmental toxicity.

Classifying DEHP and DBP

In 2001, the EU classified DEHP and DBP as substances toxic to reproduction by Directive 67/548EEC; the directive on classification and labelling of dangerous substances. The two phthalates were assigned to Category 2 that defines them as chemicals, *"…which should be regarded as if they impair fertility in humans"* and substances, *"…which should be regarded as if they cause developmental toxicity to humans."* [106] The classification did not prohibit specific uses but instead identified the two phthalates as reproductive toxicants. This classification places DEHP and DBP in a group of chemicals that includes: cadmium chloride, benzo[a]pyrene, ethylene glycol, vinclozolin, dinoseb, and cycloheximide.

Recommending against use in cosmetics

As a response to the classification of substances as carcinogenic, mutagenic, and toxic to reproduction, the Scientific Committee on Cosmetic Products and Non-Food Products Intended for Consumers (SCCNFP) was asked to comment on the uses of these chemicals in cosmetic products. [107] The Committee expressed clear concerns over incorporating toxic chemicals into cosmetics. *"SCCNFP considers that the presence of carcinogenic, mutagenic, or substances toxic to reproduction in cosmetic products is of concern to the health of the consumer."*

Market restrictions

Substances classified by the EU in Categories 1 or 2 are to be banned in preparations available to consumers by Directive 76/769/EEC; the directive on market restrictions. The ban takes effect when the substance is added to the annex of Directive 76/769. Normally several months pass between classification and the introduction of the ban. This process is still ongoing for DEHP and DBP.

Closing the loophole

In November 2002, the EU amended Directive 76/768/EEC that covers cosmetics. The seventh amendment incorporates chemicals on the list of market restrictions from Directive 76/769/EEC on the annex of the cosmetics directive. This will effectively prohibit the use of DEHP and DBP in cosmetics due to their classification as reproductive toxicants unless otherwise regulated in the cosmetics directive. The amendment does not affect the use of other phthalates or labelling.

The current way of thinking

Despite the recent advances in regulating phthalates, the EU approach to regulation has not protected consumers, workers and hospital patients from aggregate phthalate exposures. The recent amendment prohibits DEHP and DBP in cosmetics, but permits exposure to BBP, DNOP, DEP, and all the other members of the phthalate family. The emergency ban on phthalates in PVC toys permits exposure to a whole host of phthalates in toys that are designed for older children or present in toys that are not designed for the mouth, but are still placed in the mouth. The presence of phthalates in a wide variety of products results in multiple exposures. Even if the exposure from a single product is less than the "tolerable" limit, that product can actually contribute to an unsafe aggregate exposure. The reality of aggregate phthalate exposures calls for fundamental changes in chemical manufacture, use, and regulatory policies.

Inadequate industry responses

The chemical industry usually deals with regulatory pressures on phthalates as a lobbying and public relations problem. The PVC and chemical industries ignore aggregate exposures and create huge delays by demanding full individual risk assessments for each substance prior to any regulatory action and suggesting the use of voluntary agreements as a solution. [108] While some companies may quietly reformulate to avoid phthalates, many will continue to publicly defend them. Many more will ignore the possibility of substituting at the material level. Material substitution uses naturally flexible plastics in place of PVC and alternative cosmetic formulations that do not contain phthalates.

A new way to regulate

Regulatory agencies charged with protecting consumers, medical patients, public health, workers and the environment must substantially revise procedures and protocols to consider the potential impacts of cumulative phthalate exposures, rather than as single chemical exposures. Consumers must insist on the right to know about what chemicals are in commercial products and must have unhindered access to toxicity and exposure data. Finally, manufacturers can and must shift to cleaner production practices that produce cleaner, sustainable products more suited to the contemporary world and the one that we will leave to future generations.

Summary of regulatory actions surrounding phthalates in the EU

1998: The Oslo and Paris Commission (OSPAR) lists DBP and DEHP among substances for priority action. The 13 countries named as Contracting Parties agreed to make, *"…every endeavour to move towards the target of cessation of discharges, emissions and losses of hazardous substances by the year 2020. We emphasize the importance of the precautionary principle in this work."* [109] [110]

1998: Sweden passes an Environmental Bill that states, *"…all uses of phthalates and other plasticisers with harmful or potentially harmful effects should be phased out on a voluntary basis."* [111] The phase-out of DEHP is prioritised and further measures including prohibition are to be introduced if the voluntary phase-out fails.

1999: The EU passes an emergency ban that prohibits the use of DEHP, DBP, BBP, DINP, DNOP, and DIDP in PVC toys designed for the mouth. [112]

1999: The German Environmental Protection Agency recommends a phase-out of soft PVC. [113]

1999: The Danish government formulates a PVC Strategy that includes an Action Plan for reducing and phasing out phthalates in soft plastics. [114] The Plan prioritises large uses and emissions of phthalates and includes bans, taxes, levies, subsidies, public sector green purchasing, and eco-labelling.

2001: The Swedish National Chemicals Inspectorate (KEMI) recommends to the Swedish Government that, *"The Swedish PVC industry should continue its work to phase out DEHP and should broaden that work so as also to include DBP and BBP, insofar as these phthalates are used."* [115] KEMI also recommends the *"…rapid phase-out of DEHP and other fertility-impairing phthalates in feed tubes for premature babies".*

2001: The Swedish National Chemicals Inspectorate concludes in its review of DEHP for the EU that, *"The effects on testis, fertility, and development, observed in different animal species and at relatively low levels, are considered to be relevant to humans."* [116]

2001: The EU Directive 67/548/EEC classifies DEHP and DBP as Category 2 substances defined as chemicals, *"…which should be regarded as if they impair fertility in humans"* and substances, *"…which should be regarded as if they cause developmental toxicity to humans."*

2001: The Scientific Committee on Cosmetic Products and Non-Food Products Intended for Consumers (SCCNFP) is asked to comment on the uses of Category 1 and 2 chemicals in cosmetic products. *"SCCNFP considers that the presence of carcinogenic, mutagenic, or substances toxic to reproduction in cosmetic products is of concern to the health of the consumer."*

2001: The EU amends the water framework directive 2000/60/EC to add DEHP to the Annex as a, *"…priority hazardous substance under review…"* [117]

2002: The EU amends Directive 76/768/EEC thereby banning the presence of DEHP and DBP in cosmetics unless a risk assessment proves them safe as used.

2002: In 2002, the US National Toxicology Program (NTP) concluded in its review on the potential human impact of DBP exposure that, *"Based upon recent estimated DBP exposures among women of reproductive age, the NTP has some concern for DBP causing adverse effects to human development, particularly development of the reproductive system."* [118]

2002: Danish Environment Minister, Hans Christian Schmidt, gives retailers and toy importers one year to eliminate phthalates in toys for children under six. [119]

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