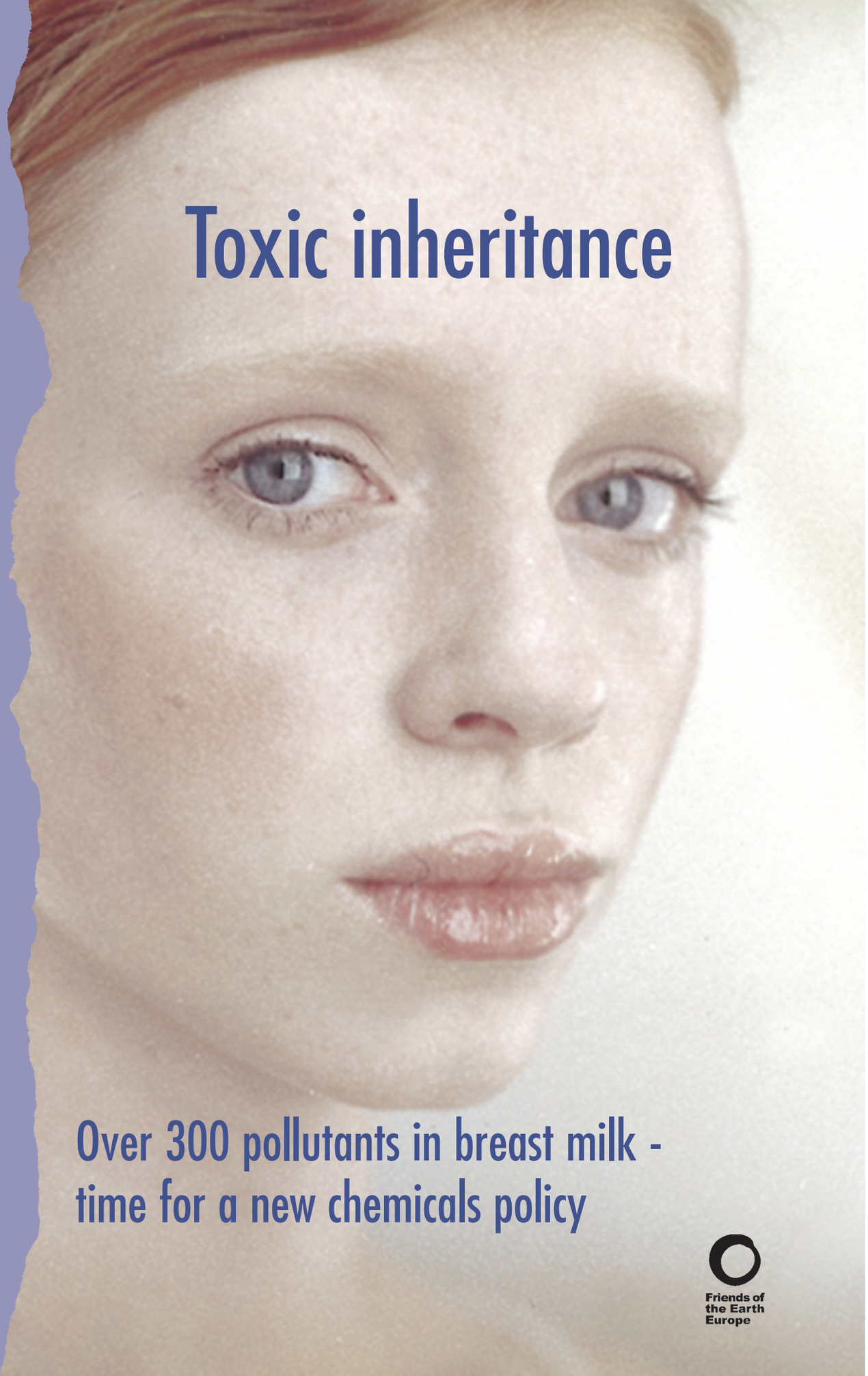

Toxic inheritance

Over 300 pollutants in breast milk - time for a new chemicals policy

Friends of the Earth Europe

IMPRINT

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Political Foreword

Dr. Martin Rocholl
Chair, Friends of the Earth Europe

The evidence is alarming - more than 300 different chemical pollutants have been found in breast milk. Enough to be a worry even without a virtually impossible assessment of the risks. And the cause? A misguided chemicals policy.

Since the beginning of mass production of synthetic chemicals in the 1940s we have been exposed to thousands of new substances. Back then nobody thought about any long-term harmful effects: chemical substances were released into the environment without official testing. Not until 1981 did chemical legislation prescribe mandatory testing for environmental and health risks before a new substance could be placed on the market. And even after this new law, around 100,000 different "existing substances" already in use still did not have to undergo any risk assessment.

In 1993, the EU attempted to ensure, belatedly, the protection of humans and the environment from risks posed by the older chemicals by introducing a new law, the Existing Substances Regulation. Under this law, substances were to be tested and then either approved for use or restricted. By 2005, the risk assessment (a necessary precursor for any legislative measures) had been completed for only 300 substances. As a result, more than 10 years after the introduction of this legislation, fundamental information concerning the risks and applications of the vast majority of substances on the market is still missing. The system is therefore not able to guarantee adequate protection from dangerous chemicals for humans and the environment.

The new EU chemicals legislation (REACH) is supposed to address this deficiency once and for all. It is the most significant reform of health and environmental protection in Europe to date. Following an opinion given by the European Parliament, it is currently being discussed by European governments, and it is expected to enter into force in early 2007. From then on, it will be the responsibility of the chemicals industry to account for the safety of its products before they are placed on the market. And thus it will no longer be the authorities' job to prove the dangers after the damage has been done.

A crucial component of this new system would be the obligation on chemical producers or importers to register details about the safety of all substances that are being produced or imported in a quantity over one tonne per year before placing them on the market. But the chemicals industry deems this approach too expensive. Through aggressive lobbying ("high costs endanger jobs") the industry has achieved significant weakening of this element. We are calling upon the European policy-makers to take the opportunity to protect children from pollutants in breast milk by ensuring that REACH will help to both identify and replace hazardous chemicals.

The cost argument, exaggerated in an unparalleled fashion by corporate and industry federations, has been refuted even by an industry-sponsored study. Nevertheless, so far, large chemical industry has managed to convince the EU's Parliamentarians to support weaker requirements for safety data on chemicals instead of championing effective health protection for the constituents. This contradicts the more positive approach of the European Parliament to the mandatory substitution of dangerous chemicals. Equally worryingly, there are indications that the interests of Europe's large chemical industry will dominate political action amongst the EU governments, leading them to

discount the potential long-term risks of irreversible damage to our health.

We are glad to say that various impact assessments have shown that REACH will not contribute to job loss. On the contrary, the policy would foster innovation and create new jobs, allowing Europe to become the largest producer of environmentally friendly and healthy products. But this can only happen if industry finally gives up its resistance and takes up this opportunity for development.

Friends of the Earth Europe urges the European Parliament and the EU's governments to establish a strong REACH legislation which protects citizens and the environment and creates business opportunities for healthy products made in Europe.

GLOSSARY

Chemicals

DDE dichloro-diphenyldichloroethylene (breakdown product of DDT)
DDT dichloro-diphenyltrichloroethane
BBP butyl benzyl phthalate
DBP dibutyl phthalate
DEHP diethyl hexyl phthalate
DIBP di-iso-butyl phthalate
DIDP di-iso-decyl phthalate
DINP di-iso-nonyl phthalate
DNOP di-n-octyl phthalate
HCB hexachlorobenzene
HCH hexachlorocyclohexane
PBDE polybrominated diphenyl ethers (polybrominated flame retardants)
Deca-BDE deca-bromodiphenyl ether
Octa-BDE octa-bromodiphenyl ether
Penta-BDE penta-bromodiphenyl ether
Tetra-BDE tetra-bromodiphenyl ether
HBCD hexabromocyclododecane
TBBA tetrabromobisphenol A
PCB polychlorinated biphenyls
PCDD/PCDF polychlorinated dibenzo p-dioxins/polychlorinated dibenzo furans
TCDD tetrachlorodibenzo-para-dioxin
POPs persistent organic pollutants

Definitions

BCF bio-concentration factor
bioaccumulating the property to accumulate in organic tissue
biocide pesticide in non-agricultural use
CMR substance with at least one of the following properties: carcinogen (cancer causing), mutagen (damaging to the genotype), reprotoxic (damaging to reproduction)
congener single substance (as part of a number of structurally similar substances)
endocrine hormonal
exposure to be exposed to pollutants
half-life time required to break down half the quantity of a substance
inherent properties properties that belong to a substance; chemical and physical properties
lipophile fat loving
metabolite break-down products
NOAEL no observed adverse effect level
persistent long-lived
pesticides chemicals toxic to pests
REACH registration, evaluation and authorisation of chemicals
TDI/TWI Tolerable Daily Intake/Tolerable Weekly Intake
TEQ/TEF toxicity equivalent/toxicity equivalent factor (i.e. normalised to the toxicity of dioxin 2,3,7,8-TCDD with a TEF of 1)

Institutions

AGLBM Ausschuss für Umwelthygiene der Arbeitsgemeinschaft der Leitenden Medizinalbeamten; German Committee for Environmental Hygiene of the Working Group of Leading Medical Civil Servants
APUG Aktionsprogramm Umwelt und Gesundheit; Environment and Health Action Program
BfR Bundesinstitut für Risikobewertung; National [German] Institute for Risk Assesment (formerly BgVV)
BgVV Bundesinstitut für gesundheitlichen Verbraucherschutz und Veterinärmedizin; [German] Institute for Consumer Health Protection and Veterinary Medicine (now BfR)
BMU Bundesministerium für Umwelt, Naturschutz und Reaktorsicherheit; [German] Ministry for the Environment, Environmental Protection and Reactor Safety
CTSEE Wissenschaftlicher Ausschuss für Toxizität, Ökotoxizitat und Umwelt der EU; EU Scientific Committee for Toxicity, Ecotoxicity and the Environment
DFG Deutsche Forschungsgemeinschaft ; German Research Foundation
HBM-Commission Human Bio-monitoring Commission
IRK Innenraumlufthygiene-Kommission; Indoor Air Hygiene Commission
SCF EU Scientific Committee on Food
UBA Umweltbundesamt; [German] Environment Ministry
US EPA US Environmental Protection Agency
WHO World Health Organisation

Summary

The production of synthetic chemicals in Europe has exploded since the 1940s. By 1980, over 100,000 substances had been placed on the market. By 1950 the insecticide DDT had been detected in breast milk. But it was not until 1981 that chemicals legislation requiring an assessment of environmental and health risks prior to the placing of chemicals on the market was introduced. Nevertheless, the substances that were already in existence at that time (the so-called "existing substances") still did not have to undergo any risk assessment. Shockingly, these amount to around 97% of substances currently on the market. This means that even today nearly all substances used in cosmetics, furniture, electronics, etc., have never been tested for the risks they may pose to humans and the environment.

Many of these chemicals are today detectable in humans. Particularly worrying are the persistent (long-lived) and lipophilic (fat-loving) substances that are not broken down and which accumulate in fatty tissue. Breast milk is a particularly well-suited indicator for contamination with these chemicals, as the accumulated substances are transported from the fatty tissues into the milk during milk production. More than 40,000 breast milk samples have been tested for chemical residues in Germany since 1980. Many toxic substances that have been banned since the 1970s – e.g. PCBs – are still being detected, even if in declining amounts. At the same time there is an ever-expanding group of substances which are giving rise to concerns and that are still in widespread use today, such as flame retardants, fragrances and plasticisers (softening agents).

Through breast feeding, mothers transfer a majority of the stored substances to their children. To date more than 350 pollutants have been detected that a baby can take up with the breast milk. And the exposure doesn't just start with breast feeding, but in the womb. Many of the chemicals the mother is exposed to can transfer from her blood into the unborn child. Unborn babies and infants are particularly vulnerable as they are in a sensitive development phase when substances can cause long-term damage. The consequences are diverse and may range from allergies, disturbances of the immune system, diminished fertility and cancer to behavioural anomalies due to impaired brain development. Hormonal pollutants may interfere with critical metabolic processes, even in minute amounts. Along with the persistent and bio-accumulative substances, this group of substances is particularly worrying.

Breast milk provides the baby with vital nutrients and strengthens its immune system. Moreover breast feeding ensures close mother-child bonding, an important prerequisite for a healthy development. The contamination of breast milk with synthetic chemicals is therefore a particularly delicate subject. Breast feeding should NOT be discouraged - information on contamination in this report is to emphasise the urgency of reform of chemicals policy.

This study is based on an extensive review of scientific literature. It compiles, analyses and presents recent scientific studies conducted by various bodies such as the German National Institute for Consumer Health Protection and Veterinary Medicine or Germany's National Breast Feeding Commission on the topic of breast milk contamination.

A NEW CHEMICALS POLICY UNFOLDS

For most of the older ("existing") substances the potential damage they may cause to humans is not known – since they have never been tested. The proposed new EU chemicals legislation, REACH (Registration, Evaluation, and Authorisation of CHemicals), is supposed to address this problem once and for all. It is the most significant reform of health and environmental protection in Europe to date. It is currently being discussed by European governments, and is expected to enter into force in early 2007.

REACH (as drafted currently) would require industry to notify the authorities with details about the safety of substances on the market, where these are produced in quantities over one tonne per year per manufacturer. Only those substances that turn out to be safe following the assessments could continue to be distributed. For the most hazardous substances applications for special permits (called authorisations) for specific uses must be submitted to and approved by the authorities. REACH offers a great opportunity to correct old mistakes and finally to lay down a legal framework for health and environment protection according to the precautionary principle.

The environmental, health and women's NGO's five key demands for reform of the EU chemicals policy

The REACH proposal as it stands today has a number of loopholes due to strong pressure from the chemicals industry. Environmental, health and women's NGOs have proposed a number of amendments to the REACH draft. The demands have been presented in five crucial points.

1. An authorisation for the use of 'chemicals of very high concern' should only be granted if no safer alternatives are available and the use is essential to society. We believe the substitution principle must be mandatory in this process.

Only when the loophole of 'adequate control' has been deleted will REACH give a clear signal on which chemicals need to be used less or removed from use. Otherwise, perfectly acceptable, safer alternatives will be sidelined and withheld from chemical users, and consumers will continue to be exposed to unacceptable risks.

2. Registration procedures must close the existing gap in safety information.

In the proposed new regulation, 20,000 chemicals have been excluded from a proper safety assessment. The three (non-animal) tests plus the Chemical Safety Report removed from the registration requirements for 1-10 tonne per annum chemicals must be reinstated in order to provide sufficient information to evaluate the hazards, exposures and safe uses of chemicals. Without sufficient information, including biodegradability tests and exposure information, chemicals cannot be classified according to their danger or prioritised for further action.

3. Industry information needs independent quality control.

REACH provides industry with a unique opportunity to take responsibility for chemicals safety. This will only work if sufficient quality auditing and regulatory quality control is supplied to guarantee the reliability of the information provided. All registration dossiers should be quality audited by an independent third or certified party, without a conflict of interest, and at least 5% of all registration dossiers must be evaluated by the national authorities.

4. Chemicals used in imported articles must have the same information requirements as those in EU-made articles.

The current proposal's weak requirements on substances in articles could allow EU companies to import articles from outside the EU containing chemicals not registered and/or maybe even banned or restricted under REACH. This loophole will not properly protect consumers from unsafe chemicals in imported products. It may also create a competitive disadvantage for certain sectors of EU manufacturing industry. Europe is the world's biggest market for consumer goods so it should provide leadership in setting new global safety standards.

5. There must be a public right to know and improved procedures on access to information throughout the supply chain.

Consumers and retailers should be able to find out about chemicals in the products they are paying for, particularly potentially harmful ones. Currently, the information flow stops once a chemical enters an article, denying users and consumers downstream the chance to choose between alternatives. Information should be handed down the entire manufacturing chain to enable retailers and consumers to know if chemicals of very high concern are present in finished articles. Articles should be labelled if authorised chemicals are present. The procedure for obtaining information from the Chemicals Agency is currently time-consuming and inefficient and we believe it is not compliant with the Aarhus Convention. Therefore, it needs to be streamlined and improved. The list of non-confidential information in REACH needs to be extended to include the names of registrants, volume categories and exposure information.

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1 Introduction

Both we humans and our environment have been exposed to thousands of synthetic chemicals that did not exist before the industrial revolution. Mostly we only realise this when extreme pollution events become scandals – e.g. PCB-contaminated school buildings or extremely high pesticide residues in strawberries or salad leaves. There are numerous indications that the increase in certain illnesses in industrialised countries is connected to the vast cocktail of synthetic substances that we are exposed to on a daily basis: allergies, certain forms of cancer and behavioural disorders in children are on the increase, sperm counts and fertility are decreasing.

In Europe, the production of synthetic chemicals has exploded since about 1940. The "European Inventory of Existing Commercial Substances" states that, in just the four decades until 1980, 100,000 chemicals were put on the European market. By 1950 the insecticide DDT was found in breast milk. But not until 1981 did chemical legislation came into force that, for the first time, demanded obligatory testing for environmental and health risks before placing a chemical on the market. The older, so-called "existing substances" – i.e. almost all substances brought into circulation before this chemical legislation – had not gone through prior risk assessment. This means that nearly all chemicals in cosmetics, furniture, electrical goods, etc., have never been examined for risks to humans and the environment. Many chemicals are today detectable in various human organs. Particularly worrying are the long-lasting (persistent) and fat-loving (lipophilic) chemicals that are not broken down in nature and which accumulate in fatty tissue. Some are known under the name of POPs (Persistent Organic Pollutants). These are distributed throughout the whole world, carried through air, water or in organisms themselves. It is not just people in industrial nations but also residents of more remote regions who are contaminated with POPs. The higher a creature is in the food chain the greater the contamination, as these pollutants are passed on through food. Piecemeal bans and regulations can decrease the production and use of some of these chemicals causes some decline in contamination by older substances – nevertheless they are still present worldwide. Even worse, many substances with similar properties continue to be produced and used. They can be found in consumer goods as well as human and animal tissue and so far most are subject to no or only minor restrictions.

A big problem is also that some chemicals can interfere with the hormonal systems of humans and animals. They represent dangers that are little known or understood and that defy traditional risk assessment. These substances cause effects at extremely low levels. Particularly insidious is the fact that they might interfere with sensitive metabolic and developmental processes in the womb and in early child development.

Breast milk is a particularly suitable bio-indicator for contamination with persistent or lipophilic chemicals as the accumulated substances are transported from the fatty tissues into the milk during milk production. Mothers transfer a considerable amount of the substances to their child: the mother is being detoxified, the child becomes contaminated. So far more than 350 pollutants have been found that the baby can ingest through breast milk (Lyons, 1999). This number is worrying even without assessment of health risks. Additionally the potential interactions of the various substances are virtually unexplored.

The "Nationale Stillkommission" (Germany's National Breast Feeding Commission) has been analysing the contamination of German women's breast milk since 1994, assessing the health risks and publishing breast feeding recommendations. Until 1995 women were recommended to have their breast milk examined for residues if they were feeding for more than four months. Because lower concentrations of pesticides, dioxin and PCBs were being detected in breast milk, the Breast Feeding Commission has recommended breast feeding without such caution since 1995. In principle it is welcome that - decades after they have been banned - such older chemicals are only present in concentrations that are deemed acceptable by this recommendation. But, as with many other decisions in environmental politics, this advice is based on a cost-benefit analysis. That means that according to the current scientific knowledge experts assess the health and emotional benefits of breast feeding for babies to be more valuable then the currently known dangers. However risks that cannot yet be tested for and those that are yet unknown are not included in the assessment. Therefore the Commission emphasises that synthetic chemicals are generally undesirable in breast milk. This is particularly important against the backdrop that recently new synthetic substances with comparable risks have been identified in breast milk. Therefore by no means should the all clear be given. The goal must be to achieve less persistent and lipophilic chemicals in the environment, in order to reduce the effects of these substances on humans and minimise these in breast milk. The favoured path of action remains to develop sensible strategies that avoid such contamination in the first place.

This study summarises up-to-date data on breast milk contamination by a number of substances that are mostly banned today, but that can still be found in humans. It describes the general conditions that enable the uptake of chemicals and their accumulation in the body and it demonstrates those factors that influence the amount of pollutants in breast milk. Using the example of PCBs, the long-term effects of substances with special attributes are addressed and the problems of current risk assessment procedures as well as the uncertainties concerning substance evaluation are presented. In the chapter on "New sins", data is presented for a number of substances that have only comparatively recently been identified as problematic. A further chapter is dedicated to the dangers to children's health.

European chemicals policy currently faces profound reform. The EU Commission has drafted a law that is supposed to reorganise the regulation of chemicals. As drafted, under the Regulation on REACH (the Registration, Evaluation, and Authorisation of CHemicals), manufacturers must register and supply data on substances produced or imported in quantities over 1 tonne per year (per registrant), including those placed on the market before 1981. Failure to comply with the deadlines may result in a marketing ban. Chemicals that turn out to be harmless following the assessment may continue to be distributed, but particularly hazardous substances will need special authorisation for specific uses only.

Therefore in future it will be the industry's job to account for the safety of its chemicals before they are placed on the market, reversing the burden of proof which used to fall onto the authorities, who had to prove the dangers only after the substances were in use. In particular, the contamination of breast milk with synthetic chemicals demonstrates the urgent need for reform. At this moment there is a great opportunity to correct the old mistakes and to lay down a legal framework for health and environment protection according to the precautionary principle.

The final part of this study discusses necessary improvements to the reforms that are vital from the point of view of environmental and consumer protection.

2 Sins of the past

Over 350 pollutants in total have already been detected in breast milk (Lyons, 1999). There are relatively few chemicals or groups of substances for which data from regular and long-term breast milk analysis are available and which would allow us to paint a relatively robust picture of the population's contamination and allow trend predictions. Particularly well examined are certain representatives of the so-called POPs (Persistent Organic Pollutants) such as the polychlorinated biphenyls (PCBs), the insecticide DDT, hexachlorobenzene (HCB) and the toxic combustion by-products dioxins and furans. These were the first chemicals that were banned worldwide by the United Nations under the POPs Convention (also known as the Stockholm Convention) in 2004 due to their persistency, potential for bio-accumulation, global distribution and high toxicity.

In Germany, breast milk, urine and blood samples have been examined by federal investigation offices for certain pesticides like DDT and PCBs as well as dioxins and furans for a long time[1]. The data has been collated since 2000 in the central (but not public) federal and national "Breast Milk and Dioxins in Humans Database" at the BgVV (Bundesinstitut für gesundheitlichen Verbraucherschutz und Veterinärmedizin, now the German National Institute for Consumer Health Protection and Veterinary Medicine (BfR)).

More than 40,000 breast milk samples have been analysed since1980. In nearly all samples many substances are still detectable in measurable concentrations despite bans on most of these substances in the 1970s. Σ DDT, HCB, β-HCH, and Σ PCBs are such chemicals. α-HCH and γ-HCH (lindane), cis-heptachloroxide (a break down product of the pesticide heptachlor) and dieldrin (another pesticide) are also still measurable in 10-50% of breast milk samples today. Many other chemicals (not listed here) are also still detectable in many samples in measurable concentration ranges.

However at the same time a continuous decrease in contamination levels of breast milk is noticeable in Germany (Table 1). Between 1980 and 1997 the contamination with organochlorine pesticides and PCBs decreased, and since the 1990s a decrease in dioxins and furans is also noticeable. The ban on PCBs for example has led to a 70% reduction of PCB content in breast milk, to a mean of 0.49 milligrams per kilogram (mg/kg) fat. However 4.3% of samples examined in 1997 still exceeded the set reference value of 1.2 mg/kg fat. This means that 4.3% of the examined women had significantly higher contamination than the upper range of background contamination (BwG, 2000; Vieth, 2002).

Table 1: Mean values and reference values of persistent organochlorine compounds in German breast milk (in mg/kg milk fat).

Residue	Mean content 1979/81	Mean content 1997	95 percentile 1997	Reference [3]
Σ DDT	1.83	0.30 [1]	0.86 [1]	0.9 [1]
HCB	1.14	0.07	0.17	0.3
β-HCH	0.33	0.04	0.11	0.1
Σ PCB	1.72	0.49 [1]	0.94 [1]	1.2 [1]
PCDD/PCDF	30.6 [2] ng I-TEQ/kg	12.9 [3] ng I-TEQ/kg	23.0 [3] ng I-TEQ/kg	no data

1) Only values from the original [German] federal states are included ; 2) Data for the time from 1986-1990; 3) Data from 1998

To distinguish whether an individual residue content lies within the typical range of background contamination for Germany, the Department for the Environment's Commission on Human Biomonitoring (HBM) sets a reference value (HGM-Kommission, 2000). It is based on the 95 percentile values determined in 1994, which mirror the upper range of breast milk contamination in the German population. However, such reference values (which also exist for residues in blood), do not in principle allow evaluations related to questions of health.

PCBs were used en masse by industry as a multi-purpose chemical in Germany and many other countries during the 1950s to 1970s. They were used for example as plasticisers (softening agents) in plastics and sealants, in buildings made out of concrete slabs, as flame retardants in paints and varnishes, as dielectric fluids in capacitors (e.g. in fluorescent lights) and transformers, in insulating, cooling and hydraulic fluids and as additives in nail varnish and textiles. Following a number of serious accidents in Asia in the 1970s, where PCB-contaminated rice oil caused serious diseases (chloracne and cancer) in many people and following the realisation that by then PCBs could be traced globally in all environmental and human samples, an initial ban on open uses was passed in 1978. Since 1989, all production, distribution and use of PCBs has finally been banned in Germany. In May 2004 the global ban on the production and use of all PCBs was agreed under the auspices of the UN.

PCBs can be separated into two groups: the dioxin-like and the non-dioxin-like PCBs. Twelve of the 209 PCBs (see footnote 1) are similar to dioxins due to their chemical structure and form. For these dioxin-like PCBs a World Health Organisation group of experts have defined Toxic Equivalency Factors (TEF) that weight the dioxin-like potency in relation to the most toxic dioxin' 2,3,7,8-TCDD (Körner, 2003). According to this, PCB 126 is on the same level of toxic potency as most dioxins and furans and it is only ten times less toxic than the most toxic dioxin, the so-called Seveso dioxin.

Dioxins have a wide spectrum of toxic and biochemical effects; some of them are known to be human carcinogens. Their hormonal (endocrine) effects are also well known. In laboratory animals a connection has been observed between dioxins and endometriosis (a proliferation on the ovaries), development disorders and neurologically determined behavioural disorders (learning disabilities), effects on development and reproduction (low sperm count, genital deformity) as well as immunotoxic effects. These effects occur at much lower levels of exposure than the carcinogenic effects (European Union, 2001).

The toxicity of dioxin-like PCBs is similar to those of the highly toxic dioxins, as they both bind to the same sub-cellular units and therefore influence the same processes in the cell. In animal experiments they are carcinogenic, neurotoxic, immunotoxic, toxic to reproduction and development and they can affect hormone systems. For example, they can disrupt thyroid function, reproduction and carbohydrate metabolism.

The effects of non-dioxin-like PCBs as a group are much less researched. They seem to affect different sub-cellular processes but the resulting effects are again very similar (Schoeters & Birnbaum, 2004; Schrenk, 2004). Apart from the effects already mentioned they can cause behavioural disorders (Schrenk, 2003). The [German] National Environment Agency (Gies et al., 2001) and the WHO (2002) offer extensive reviews and assessments of the hormonal effects of PCBs and other environmental pollutants.

Shorter terms of pregnancy have been observed in women with job-related PCB contamination (Taylor et al., 1989). But damage to human health appears at concentration levels that occur in the environment. For example, a long term study in Michigan (USA) showed that children of

1. The DDT measurements represent total-DDT content (Σ DDT) including its persistent disintegration product, DDE, which is formed from DDT in the human body through metabolic processes. The PCBs represent a mixture of substances including 209 potential single substances (congeners) that differ in the number of chlorine atoms and their position on the biphenyl ring. For the measurements of PCBs six main congeners (PCB 28, 52, 101, 138, 153, 180) are analysed using standard measurement procedures and then the results extrapolated to the overall PCB content (Σ PCB) using a multiplication factor (according to the German DIN 51527 and pollutant limits decree). The overall PCB content in the breast milk and blood samples refer only to the content of the three PCB congeners 138,153 and 180 each. The 17 dioxins and furans stored in human body fat are summed up as International Toxicity Equivalents (I-TEQ).

mothers who had eaten highly contaminated fish had reduced birth weight as well as neuropsychological abnormalities in intelligence, language and memory tests (Jacobson et al., 1985; Jacobson & Jacobson, 1996). Two epidemiological studies from Germany ("Düsseldorfer Kohorte") and Holland examined the prenatal and postnatal influences of PCB background contamination on children up to 72 months. Both studies detected mental development disorders in the infants.

Around 90% of PCB uptake takes place through food; the uptake through respiration is estimated as 10%. In 25-year olds, 12-14% of PCBs stored in the body can be traced back to uptake through breast milk (Patandin et al., 1999). PCBs are not blocked by the so-called placental barrier, therefore humans are exposed to these substances at the foetal stage even before birth.

The background contamination of the ambient air is 1-10 nanograms per cubic meter (ng/m3). In the past years and decades the consequences of the use of PCBs in buildings became apparent in the form of increased contamination of interior air, in particular in public buildings like schools and nurseries. Often the concrete walls were not plastered on the inside, which enabled PCBs to leak from the sealants into the interior air, or PCB-containing flame retardant slabs or fluorescent lights had been installed (VUA & BUB, 1999).

Largely unknown is the state of exposure in detail. However this information is much needed as PCBs can be divided into different groups that behave differently in air, soil, water and organisms. Moreover the ratios of low chlorinated (few chlorine atoms) to highly chlorinated (many chlorine atoms) PCBs differs between interior air, blood and fatty tissue and is no longer identical with the ratio in the original PCB product. The residue contents of the different dioxin-like PCBs in human, environmental and food samples are usually not analysed separately.

The Tolerable Daily Intake (TDI) is expressed in Toxic Equivalents (TEQ), calculated from the Toxic Equivalency Factors (TEF). The TDI value estimates the acceptable daily intake of a substance that a human can consume lifelong without suffering harm. The basis for the determination of this value is usually through feeding tests using rats and mice.

A report of the European Commission's Directorate General (DG) for Health and Consumer Protection has summarised all available data on residues of dioxin-like PCBs and dioxins in food (European Commission, 2000). The data suggest that dioxin-like PCBs contribute a share of TEQ that is between one and two-fold that of dioxins (Table 2). More recent studies of milk products from Germany come to the conclusion that dioxins only contribute 30% of the total TEQ; the remainder is contributed by the dioxin-like PCBs (Malsch, 2003).

Table 2: Mean contamination of food stuff in the EU with dioxins (PCDD/PCDF) and dioxin-like PCBs.

Food stuff	PCDD/PCDF (pg TEQ/g fat)	Dioxin-like PCBs (pg TEQ/g fat)
Fish	10	30
Meat	0.4–0.7	0.3–1.5
Milk/dairy products	0.6–1.0	0.6–1.3
Vegetable food stuff, eggs	Insufficient data	

In the various Member States of the EU the mean content of dioxins and furans in breast milk amounts to 8-16 picograms international toxic equivalents per gram fat (pg I-TEQ/g) according to DG Health and Consumer Protection. The contamination of breast milk is therefore of the same order as that of fish, the most highly contaminated food. Where dioxins and dioxin-like PCBs have been analysed in parallel the mean PCB-TEQ content varies between being of the same order and up to three times higher. In comparison with a number of other countries, Germany has the fourth and fifth highest levels for dioxins/furans and dioxin-like PCBs respectively with regards to breast milk contamination (Malisch, 2003) (Figures 1 and 2).

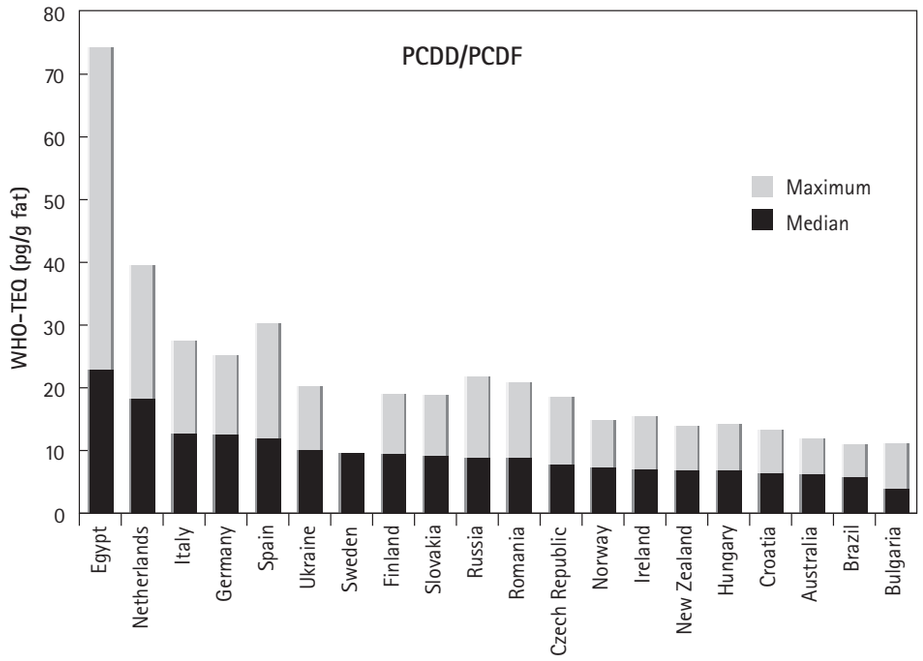

Figure 1: Content of dioxins and Furans in breast milk.

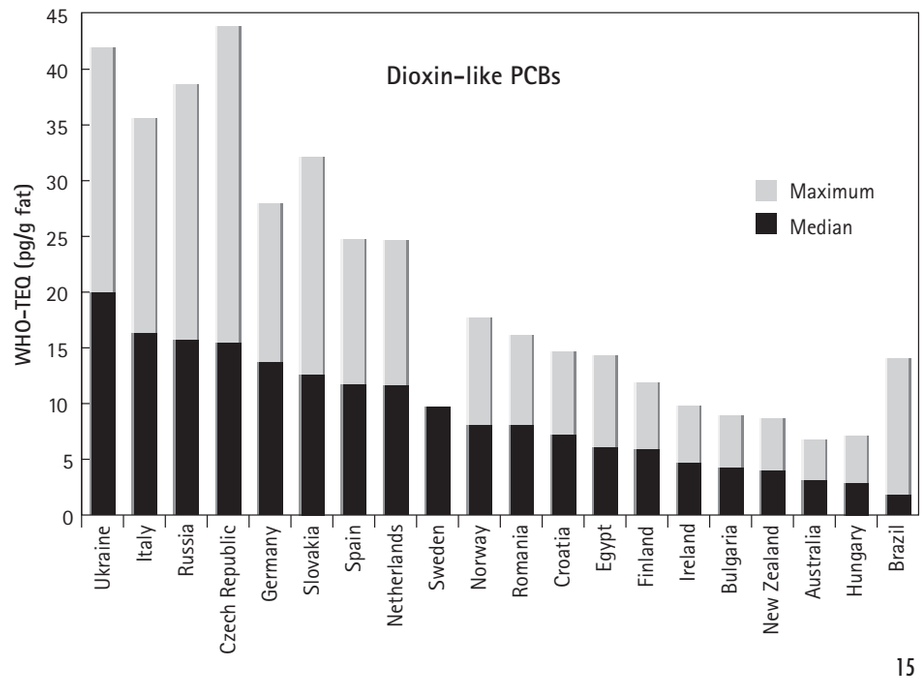

Figure 2: Content of dioxin-like PCBs in breast milk.

During the period of breast feeding a baby takes up two to four times more total PCBs than the provisional limit for the tolerable daily intake (TDI) of PCBs and the contamination with dioxins and dioxin-like PCBs is approximately one order greater than in adults. Officially this is considered not to be worrying as a six-month long breast feeding period represents less than 1% of the mean life expectancy and the TDI-limit is based on life-long pollutant intake (Vieth & Przyrembel, 2003). But this view disregards the highly sensitive phases of development in children and thus completely different and grave consequences of contamination (see Chapter 5).

A German study has examined for the first time both the blood and breast milk of 169 pregnant women about two weeks after giving birth (Wittsiepe et al., 2004). The scientists found levels of contaminants comparable to other studies and found good correlations between blood and milk concentrations for both the dioxins as well as for the dioxin-like PCBs (Table 3). The main congeners (structural variants of the molecules) found in blood and milk are PCB 126 (the most toxic PCB congener) and 156. In relation to the toxic equivalent the share of PCBs is 40% in blood and 48% in breast milk.

Breast fed babies have an average blood content of DDE and PCBs that is 0.25 and 0.4 micrograms per litre (µg/l) respectively, higher than that of babies that are not breast fed (0.17 and 0.27 µg/l). Statistical analyses prove a significant positive relationship between the values for residues in the babies' blood and the length of the breast feeding period, particularly for PCBs, DDE and HCB; i.e. the longer the breast feeding period, the higher the contamination. The reference values for blood in relation to age can be seen in Figure 3. All substances and substance groups show a distinct increase with rising age between 9 and 69 years, a clear indication for the persistence and the potential for bio-accumulation of these substances.

The comparatively high DDE reference values in the blood of residents of the new German federal states (two to four times higher than in the original federal states) can presumably be attributed to the extended use of DDT in the GDR up until 1989. Even though a ban on DDT was passed there in the 1970s, as in West Germany (1972), the substance continued to be used because of a number of exemptions. The PCB and HCB reference values dropped up to 30% compared to the assessment in 1999 for the age group under 49 (HBM-Kommission, 2003).

Studies from Germany and other countries also prove the occurrence of a number of other "old generation" pesticides and biocides in breast milk and other human samples. These too are listed as global environmental pollutants in the UN POPs convention, have been banned in Germany for a long time or had no importance here as a pesticide agent. They are classified as toxic or very toxic and hormonal effects have been demonstrated for most of them.

The DDT content in German breast milk is illustrated in Table 1. The values have decreased significantly between 1979 and 1997. In addition to the numerous other toxic properties that ultimately led to the ban of DDT, its hormonal effects have now been shown.

In a study of blood samples of Members of the European Parliament, DDE could be found in all 47 volunteers. It exhibited the highest average concentration in blood serum (as opposed to whole blood) of all the 76 substances found (WWF, 2004).

Table 3: Concentration of dioxins and furans as well as PCBs in blood and milk of German mothers between September 2000 and January 2003.

WHO-TEQ (pg/g fat)	Blood			Milk		
	Median	Min.	Max.	Median	Min.	Max.
PCDD/PCDF	15.32	2.73	55.07	13.30	1.80	34.70
PCBs	10.81	1.40	42.23	13.00	1.21	50.10
PCDD/PCDF+PCBs	26.13	4.13	97.30	26.30	3.01	84.80

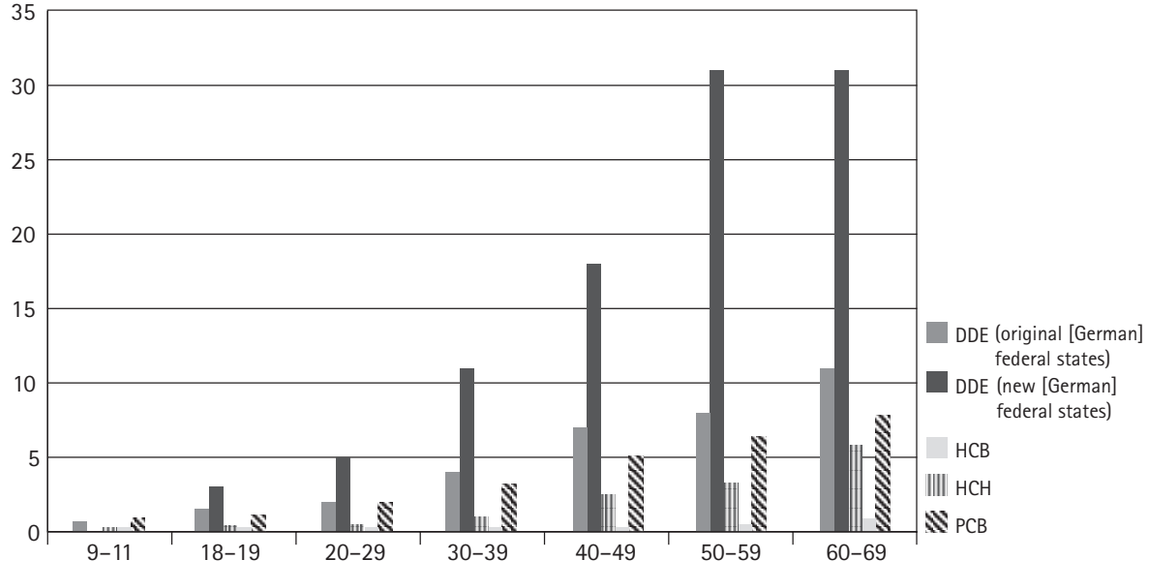

Figure 3: Reference values (µg/l) for various organochlorine compounds in blood in relation to age.

Technical grade hexachlorocyclohexane (HCH) consists of approximately 65-70% α-HCH, 7-10% β-HCH, 10-15% γ-HCH and 10% of other isomers. The pesticide lindane consists of more than 99% γ-HCH and is extracted from HCH through a purification process. Lindane can be contaminated with traces of β-HCH. In animal tests lindane has been shown to cause cancer (a carcinogen), to damage genes (a mutagen) and to be toxic to reproduction (a reprotoxic substance). Studies on β-HCH point to development of breast cancer. According to the European Commission, lindane has been proven to be hormonally active and it is therefore to be made a high priority within the scope of the assessment of hormonal pollutants (Gies et al., 2001; WWF, 2002). Since 1998 lindane has not been approved as a pesticide for the German market. According to EU pesticide law (Directive 91/414), lindane may not be authorised as a plant protection agent in the EU since June 2002. In the 1980s lindane was still used in wood preservatives. But it is still found world-wide today, including in Germany, as a biocide agent in anti-lice remedies for humans (mostly used as a shampoo for children) and in insecticides for pets, e.g. in "Jacutin" products. HCH residues are found in numerous animal food products (see food monitoring report of the German Institute for Health and Consumer Protection and Veterinary Medicine and Institute for Risk Assessment (BgVV and BfR, 1998). Lindane residues could also be found in vegetable food of German origin until 1998 (PAN, 2001). The Committee for the Environment, Public Health and Consumer Protection of the EU Parliament has pushed for an immediate ban on HCH including lindane in their statement on the implementation of the UN POPs Convention in EU legislation.

In breast milk and blood β-HCH dominates, as it is the isomer with the highest persistence and the strongest bio-accumulation. The values for Germany can be seen in Table 1. In the German human monitoring study α-HCH was found in the blood of 1.7% of adults, γ-HCH (lindane) was found in 5.2% and β-HCH was found in 34%. β-HCH was found in nearly all blood samples of children (92.3%) (HBM-Kommission, 2003). In

the study on MEPs, more than 90% of the 47 people examined showed β-HCH in the blood serum samples (WWF, 2004).

Hexachlorobenzene (HCB) was used directly as a pesticide (fungicide), but it is also found as a contaminant in other pesticides. It was also used as an industrial chemical, e.g. in rubber production, and it is still being used today in the production of solvents. In the UK, releases into the atmosphere of at least 0.9 tons were reported in 1998 (WWF, 2004). As a pesticide it has been banned in Germany and in the EU since 1988. The substance is classified as very toxic and a probable carcinogen. Studies point to hormonal effects (WHO, 2002) and - in this context - to an increased risk of breast cancer (Glas et al., 2001).

The consumption of HCB-dressed wheat seeds caused cases of severe poisoning and deaths in Turkey in the 1950s. Very high HCB concentrations of 15-20 micrograms per gram (mg/g) were found in the breast milk of affected mothers (Jensen & Slorach, 1991).

A dramatic reduction of residues in breast milk and blood has been achieved in Germany through the pesticide ban and technical improvements in industrial production processes (Table1). Nevertheless, even with the current residue contents in breast milk, the daily HCB intake of a baby can exceed the Tolerable Daily Intake (Vieth & Przyrembel, 2003). In the recent study with MEPs, HCB was found in the blood serum of all individuals (WWF, 2004).

3. Risk assessment of pollutants

When chemicals are detected in humans and animals they must first have entered the body and been taken up by certain tissues. This process of "coming into contact" is called exposure. The concentration of pollutants found in the tissue is not just dependent on the amount taken up through contact, but is also dependent on the chemical and physical properties, the so-called inherent properties. If a substance can be excreted and/or if it can be degraded through metabolic processes (biodegradable) it will be found in smaller amounts or not at all. If these processes cannot happen, or happen to a lesser extent (it is persistent), its continued uptake will lead to ever higher concentrations in the tissue: i.e. the substance is "bio-accumulative". The combination of (potential) exposure together with certain properties of the substance therefore results in the chemical's potential for danger or risk. Thus an openly deployed substance with bio-accumulative properties will certainly be found in tissues it comes into contact with – one only has to look for it (assuming the analytical methods exist).

3.1 How does a chemical get into the body?

The basic requirement for uptake of a pollutant into the body is contact with it – i.e. the exposure to the chemical substance. Synthetic substances arrive in the environment in different ways and for different reasons. These include production as a by-product, as a degradation product or waste product of chemical manufacture, through accidental release (e.g. during transport) or through improper storage or disposal. Furthermore they are often released during the daily use of products and objects that contain synthetic substances or through their deliberate release into the environment - as in the use of herbicides and insecticides in agriculture or in the use of biocides (pest control agents in non-agricultural areas). Use of pesticides and biocides is subject to legal controls (although they still enter the environment), but the unwanted and often unplanned release of synthetic chemicals from everyday products is very little understood. On the whole such releases are not regulated by law because of this ignorance and because they are regarded as negligible or non-existent. But it is a fact that many chemicals are not firmly bound in an article, but disengage from it through a number of different mechanisms (outgassing, exuding, washing out, etc.) and then can be taken up by humans via

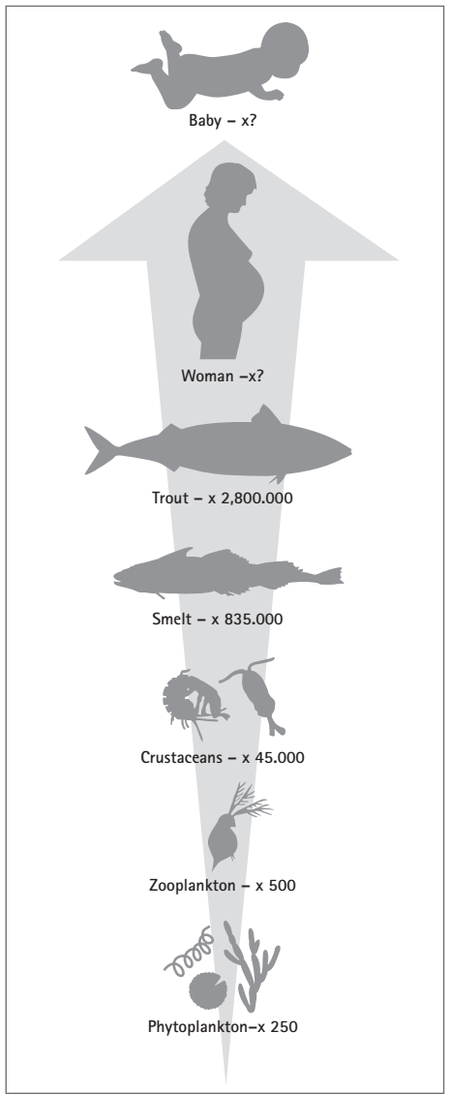

Figure 4: Accumulation of pollutants along the food chain.

respiration (inhalative), through the skin (dermally) and/or via food (orally).

Although the longevity of a chemical (its persistence) is a desirable property in many applications, this property also becomes a great problem under these circumstances of release into the environment. Persistent substances are only very slowly transformed and degraded chemically or biologically (e.g. through the action of microorganisms or through metabolic processes or chemical reactions) in water bodies, in the soil or in tissues. The measure of this process is the "half-life period", the time that is needed to reduce the amount of a substance by half. There is also the problem that products of metabolic or degradation processes (metabolites) may be even more persistent than the original substance and even possess different, possibly even more toxic, properties. A half-life of 40-60 days is currently considered the EU criterion for undesirable persistence.

Another chemical property that is often manipulated beneficially in products is the ability of some chemicals to dissolve more easily in organic solvents than in water. Substances with this property are called lipophilic (literally "fat loving") or hydrophobic ("water hating"). This property can easily be determined in the laboratory. The substance is put in a test tube filled in equal parts with water and the organic solvent octanol (which does not mix with the water). After shaking and waiting until equilibrium is reached the concentration of the substance can be measured in each of the solvents. The more lipophilic the substance the higher is the concentration in octanol compared to the concentration in water. This standard measurement is known as the octanol-water partition coefficient (or KOW). A KOW of 1000 means that the substance ends up in the octanol phase at a 1000 times higher than in the water phase.

This phenomenon regarding the distribution of substances can also be observed in nature. For example, in water, the organic phase can be organic components in sediments or in suspended solids but also organisms themselves – such as algae, fish, crustaceans and all other aquatic life. The terms "bio-concentration" and "bio-concentration factor" (BCF) refer to the tendency of a chemical to stay in the water phase or to accumulate in an organism. The bio-concentration potential can either be theoretically estimated (e.g. with the help of the KOW) or it can be practically determined through experiments with test organisms. For convenience sake, the BCF, which is strictly speaking only applicable to aquatic organisms, can also be used as a measurement for bio-accumulability, i.e. the tendency of a chemical substance to accumulate in an organism.

At a bio-concentration factor of more than 2000 it is assumed that the substance has an ability for bio-accumulation that could lead to the accumulation of potentially dangerous substances through the food chain (European Commission, 2001). For example, pollutants contained in a crustacean build up further in a fish according to the amount of crustaceans it has eaten, and similarly the seal and the polar bear will further accumulate such pollutants as the bear eats the seal that ate the fish that ate the crustaceans. The higher an organism is in the food chain, the higher is its contamination (Figure 4).

The distribution mechanism described above and the accumulation through the food chain are responsible for persistent, lipophilic substances ending up on the plates of the population in fatty food such as dairy products, meat and fish and therefore inside the human body. This distribution mechanism is also responsible for different concentrations inside the human body according to the fat content of the organs. The liver and brain have a high fat content, as does breast milk. Milk fat, which constitutes about 3.5% of breast milk, is produced from the body's fat tissue during pregnancy and in this way lipophilic substances stored in the mother's fat deposits are transported into her milk.

3.2 Factors influencing the residue content

Dietary habits play a significant role as a majority of synthetic substances relevant for breast milk are taken up through food. In particular the regular and continuous consumption of fatty food leads to increased contamination. The contamination of fruit and vegetables with pesticides adds to this. Pollutants also get into foodstuffs through packaging materials. And synthetic chemicals can also be taken up through breathing or through the skin. For example, brominated flame retardants (see Chapter 4.1) released from electronic devices such as TVs or computers or synthetic musk compounds (see Chapter 4.2) contained in body lotions and cleaning fluids can come into direct contact with the skin. The significance of these paths for contamination is insufficiently known for most substances. Therefore they are often ignored by the official substance classifications, e.g. in the determination of the acceptable daily intake (ADI) by the World Health Organisation.

Time also plays a significant role. Environmental chemicals are usually found in higher concentrations in the body fat and blood of elderly people than in younger people. Mothers over 39 years of age statistically exhibit a three times higher contamination with pollutants than mothers under 25 years, because they have accumulated the toxins during the course of their life (Niedersächsisches Landesgesundheitsamt, 2003). A further cause of these values could be the higher levels of general contamination in the past.

Chemicals are transferred from mother to child during pregnancy as well as at breast feeding. The highest amounts of substances are fed to the child in the first weeks of breast feeding – 10-20% of all stored organochlorine compounds during the first three months of breast feeding according to one study (Mersch-Sundermann et al., 2000). The contaminant levels in the baby rise with longer breast feeding periods. The amount of extrinsic substances in the breast milk decreases with the length of breast feeding and the number of breast-fed children. Therefore the first born children of older mothers are particularly affected. The mother detoxifies herself through her child.

Mean values from official publications are often taken as a basis for assessment of the German population's contamination with extrinsic substances. But the mean values hide contamination peaks such as those found around some waste sites or former production sites like Bitterfeld (in Germany) (Benkwitz et al., 2002). Similarly, individuals from rural areas with low agricultural usage are usually less contaminated then individuals from industrialised areas. Thus the contamination values can vary considerably between individuals from different areas (Schmid et al., 1997). Moreover distinct differences could be observed in the 1990s between those living in the new and old federal states of Germany. The citizens of the old German Democratic Republic (GDR) for example were spared from high PCB contamination as no PCBs were used there. On the other hand the insecticide DDT was still in use in forestry areas in the GDR until the end of the1980s, while in West Germany it had already been banned in 1972. An individual's level of contamination will be affected by their origin and travel history.

3.3 The handling of uncertainty

Problematic properties of chemicals include persistence (P), bio-accumulability (B) and toxicity (T), as well as the potential for movement around the world (global transport) and therefore for the contamination of distant, non-industrialised regions. Acute or short-term toxicity is usually stated with the help of a threshold value such as the "no observed effect concentration" (NOEC) or the "no observed adverse effect level" (NOAEL). Thus the higher the NOEC or NOAEL the less toxic the chemical – at least for the particular effect or "end-point" being observed. Besides acute toxic effects, chronic longer-term effects of chemicals are mainly assessed as cancer inducing (carcinogenic), damaging the genotype

(mutagenic) or toxic for reproduction (reprotoxic). Such substances are collectively referred to as the CMR substances.

It is particularly problematic if substances combine a number of adverse properties. From the combination of these properties arise the various substance groups that are often referred to such as the POPs (persistent organic pollutants), PBTs (persistent, bio-accumulating, and toxic substances) as well as the vPvBs (very persistent, very bio-accumulating substances).

The POPs currently comprise twelve pollutants (the list may be extended at a later date) for which a worldwide ban was agreed under the 2001 Stockholm Convention (POPs Convention). One of the best known is pentachlorophenol, PCP. The POPs, which belong to different chemical groups, are extremely long-lived and are spreading worldwide through the atmosphere, inland water and oceans. Their accumulation in organisms and their toxic properties can lead to damage in organisms and their offspring or can be manifested in the disturbance of whole ecosystems. Some of the POPs were banned long before the Stockholm Convention, at least in Western industrialised regions. But the accumulation of POPs demonstrates that, even if their production is stopped or strongly reduced, they can still be found for decades after in animals and humans.

PBTs and vPvBs have been defined in the EU's technical guidance on the risk assessment of chemicals. They differ in persistence and bio-accumulability; the PBTs are additionally known to be toxic. A number of newer chemicals can be counted here, e.g. the brominated flame retardants (see Chapter 4.1). But also extremely long-lived and bio-accumulative substances, known as vPvBs (very persistent, very bio-accumulative) harbour significant potential dangers for man and the environment as their risk consists in the possible but unknown toxic effects. In line with the precautionary principle these substances should not be allowed to escape into the environment as – once released – they stay in the environment for decades, if not centuries. And they cannot be removed from the environment at some later date should high toxicity be detected in the future.

There are also cases in which the three criteria are not fulfilled or not explicitly fulfilled but which nevertheless give cause for concern. This includes for example substances that do not absolutely fulfil the persistence and bio-accumulation criteria according to the above definitions, but which are released in such high quantities that critical concentrations can be reached in organisms. The plasticiser DEHP is a case in point (chapter 4.3).

Hormonally active substances are a good example of how quickly the state of knowledge on the toxicology of chemicals can change. This particular incidental property of some substances was virtually unknown up until a decade ago and toxicological science attached no importance to it. These are substances that may affect the hormonal system of humans and animals in very small quantities. These substances imitate naturally occurring hormones, blocking them or interfering with the hormone synthesis. A change in the hormonal system may cause lasting damage, particular during sensitive stages of life. Contamination during the embryonic development or in early childhood is particularly dangerous as during these stages important physiological and morphological development processes are taking place with the help of the hormonal system. Reproductive organs, parts of the brain and a working immune system are being formed, so that deformities, infertility, immunodeficiency or modification of behaviour can be the result (WWF, 2002). A list published by the European Commission names 564 chemical compounds that are suspected to be hormonally active (European Commission, 2000a).
Synthetic musk compounds are a further example. Until recently these were still regarded as relatively safe for human health as compared to some other chemical groups due to a lack of scientific insight. In recent times new test results have been published showing the whole group in a very different light (Luckenbach & Epel, 2005). According to this work nitromusks and polycyclic musk compounds are allegedly able to inhibit the transport of dangerous substances out of the cell, enabling these to unleash their harmful effects (chapter 4.2).

As an example of how extremely difficult can be the risk assessment of a dangerous chemical (particularly with regard to the inadequacy of scientific knowledge) we will take a more intensive look at polychlorinated biphenyls (PCBs). The PCBs are divided into two groups, the dioxin-like PCBs and the non-dioxin-like PCBs. Whether separate principles for their assessment are necessary and which group is ultimately more dangerous for humans and the environment is not yet established. Even though the PCBs have been relatively well studied the assessment is not yet fully completed due to constant new insights into their mode of action. A toxicological re-assessment of PCBs is currently taking place on part of the EU and the WHO (BgVV, 2001; Bayrisches Landesamt für Umweltschutz, 2003; Vieth & Przyrembel, 2003).

Currently recommended limits for dioxins and dioxin-like compounds are set on the basis of toxicity equivalents (TEQs). After consulting with experts, the WHO proposed a tolerable daily intake of 1-4 picograms TEQ per kilogram body weight per day (pg TEQ/kg bw/day) in 1998 (WHO, 2000). The EU Scientific Committee on Food (SCF) recommended a similar provisional value, which refers though to a tolerable weekly intake (TWI) of 7 pg TEQ/kg bw (SCF, 2000). Only six months later the value was doubled and relaxed to 14 pg TEQ/kg per week (SCF, 2001) due to the inclusion of further studies. The WHO too changed their value and arrived at a recommendation of 70 pg TEQ/kg per month (JECFA, 2001).

The German Federal Environmental Agency (Umweltbundesamt, UBA) criticised the raising of the TDI by the SCF as they thought the uncertainties were insufficiently regarded (UBA, 2002; Gies et al., 2004). They made a number of points. The uptake of substances into the body was set at 50%, even though studies show significantly higher rates (up to 89%) and it is known that children take up substances in their body particularly efficiently and quickly. Data from tests on (male) rat reproduction effects form the assessment basis for the limit. Other studies on the hormonal and immunological effects, behavioural studies, epidemiological studies and the carcinogenic properties of the substances were disregarded. Sensitive sub-populations were not considered, neither was the high contamination of children through breast milk and the danger that a reservoir is formed in the body that could contribute to the later daily uptake. Moreover calculations are based on a half-life of fifteen years. New German studies show that breast-fed children are still 20% more contaminated at the age of 9-11 years than non-breast-fed children of the same age (BMU, 2002). Moreover the TEQ currently only takes into account dioxins, furans and dioxin-like PCBs, so underestimating the true TEQ uptake as there are more dioxin-like compounds, e.g. hexachlorobenzene (HCB), polychlorinated naphthalenes and polybrominated diphenylethers. These underestimates should be considered in the assessment process by allowing for further safety margins.

For the above reasons the UBA and the BfR favour the lower TDI proposed by the WHO of 1 pg TEQ/kg bw/day. Moreover this would be in line with the WHO's own goal to reduce the population's de facto daily intake of dioxins and dioxin-like substances to under 1 pg TEQ/kg bw/day (Gies at al., 2004; Mathar, 2003; UBA, 2001).

According to more recent data (post-1995) the average dietary intake of total TEQ in the EU is 1.2 - 3 pg TEQ/kg bw/day (European Commission, 2001). Therefore, the current EU limit can be

regarded as relatively high (Mathar, 2003) and is only cutting cases of unacceptable peak risk. The residue limits for dioxins and furans in food were reconsidered by the SCF, taking into account the dioxin-like PCBs as well, by the end of 2004. Unfortunately the stronger German position and the WHO's goal were not followed. The permitted residues in food remain on the basis of the TDI at 2 pg TEQ/kg bw/day.

A review and necessary amendment are also imminent for the recommendations regarding PCB contamination of indoor air. Currently a precautionary value of 300 ng/m3 and a danger value of 3000 ng/m3 apply for total PCBs (according to DIN, the German industry norm). In a study by Körner & Kerst (2003), dioxin-like PCBs only were measured separately in indoor air. Based on the TDI of 1 pg TEQ/kg bw/day proposed by the UBA it was calculated that the danger value for dioxin-like PCBs was already exceeded when the level of total PCBs was only 40% of their danger value. To what extent the consideration of dioxin-like PCBs will influence the new recommendations on these reference points is so far uncertain (Schwenk, 2003; Körner & Kerst, 2003). But the recommendations are under close scrutiny since the understanding of the risks of the non-dioxin-like PCBs is still limited. This group is not yet included in the assessment concept and it is not known whether the health risks posed by total PCBs are being underestimated. For example there is so far no TDI value for non-dioxin-like PCBs. At the moment the German authorities as well as experts of the EU and the WHO are working on the question of whether and which separate assessment standards are necessary here.

As a certified toxicological assessment of PCBs is still unavailable there is also no adequate risk management in place that would be capable of protecting humans and the environment from potential dangers. Warning or intervention threshold values (at which measures to minimise contamination would need to be implemented) are still missing for concentrations relevant to environmental medicine. These values are called HBM (Human Biomonitoring) values and they are set by the Human Biomonitoring Commission of the Federal Environmental Agency (UBA). In the case of PCBs the Commission currently does not feel it is in a position to set HBM values that would be sufficiently scientifically justifiable because this would need verified insights into the relationship between dose and effect. In the Commission's view the available studies show that the difference between current reference values (in blood) and the beginning of the range of effects is probably small (HBM Commission, 2003). It must be stressed here that this worrying statement refers to the current state of contamination of the population even after 25 years of a ban on PCBs and significantly declining contamination levels.

Another example from the younger generation of substances are the phthalates (plasticisers used in plastics) and DEHP (diethyl hexyl phthalate) in particular (chapter 4.3). Even though there are few new substances that have been so well studied experts have argued for a long time (and still do) about the indications for human health of the diverse scientific studies. This has led to completely insufficient regulation to this day despite massive problems for human health and the environment. The TDI values calculated from animal experiments vary by a 1000-fold depending on which species has been used and which type of paramenter was under study. How effective health protection is supposed to be carried out based on such a risk assessment remains more than dubious. The precautionary principle should be employed, and measures should already be adopted if the science has not clarified beyond doubt to what extent detrimental effects can occur.

3.4 Conclusion

PCBs are some of the most studied environmental pollutants of all. But they are not just an example to show how long persistent and lipophilic substances can contaminate humans and the environment. They represent an impressive example of how much time science needs to work out a certified assessment regarding the health effects of this contamination. This process will not end for a long time yet and it must be assumed that certain limitations to scientific understanding may never be overcome. PCBs are also an example showing how political decision makers shy away from measures which would make an explicit commitment to the precautionary principle due to the potential economic consequences. For example, stricter limits would have economic consequences for the fishing industry or a drastic reduction of indoor air reference values would have to lead to extensive refurbishment measures in public buildings. The declining contamination in Germany is a positive sign, as can be seen in breast milk (chapter 2), but this is not a total success story and by no means the end of the story.

4. New sins

While levels of PCBs and other "old" substances continue to decline due to bans on their production and usage, new groups of substances (such as the brominated flame retardants (Figure 5)) are being detected with increasing values and now these are coming into the focus of scientific and public concern. One reason for this is that some chemicals serve as replacements for the dangerous older substances. The new substances often have the same or similar properties as the older existing substances, i.e. they are persistent, lipophilic or bio-accumulative. Many have already turned out to be toxic and/or hormonally active. In contrast to the older chemicals though they are still currently used in numerous products and consumer goods. Even though such substances are seen to be contaminating humans today and have been detected in breast milk and other human samples, so far no comprehensive bans or regulations have been passed. It is therefore apparent that the current chemical policy is not yet capable of protecting consumers and the environment from hazardous chemicals.

4.1 Flame retardants

For the purpose of fire prevention polybrominated diphenylethers (PBDEs) are added to plastics as "additive flame retardants". They are found mainly in electronic products, e.g. in computers, TVs and cables, but they can also be present in other consumer articles, like textiles or fabric toys. The PBDE substance group is made up of compounds of the same structure but with a variable number of bromine atoms. Of commercial significance are the compounds with 5,8 and 10 bromine atoms (penta-, octa- and deca-BDE). Like PCB products they each consist of a mixture of several congeners: penta-BDE with the main congeners 47, 99, 100, 153, 154, octa-BDE with the main congeners 183 and 153 and deca-BDE with the main congener 209. In Europe 75% of the yearly consumption of PBDEs is attributed to deca-BDE; this corresponds to 8,200 tons. The remaining share is in about equal parts penta-BDE (10%) and octa-BDE (15%). Also significant in Europe are the brominated flame retardants tetrabromobisphenol A (TBBA) and hexabromocyclododecane (HBCD).

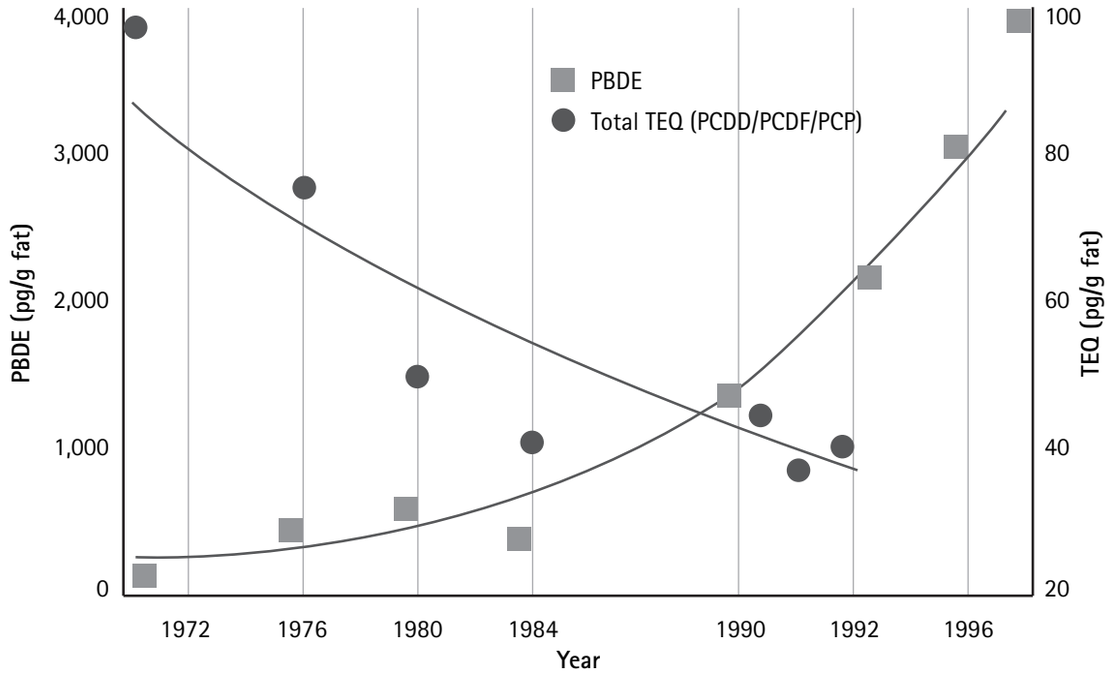

Figure 5: Comparison of brominated flame retardants (PBDE) and toxicity equivalents (TEQ) for PCBs, dioxins and furans in breast milk, 1972-1996.

These substances were only detected in breast milk in 1999 - to much surprise - as a new class of lipophilic environmental chemicals. But this was despite the fact that there had already been indications at the beginning of the 1980s that polybrominated flame retardants are persistent and bio-accumulative substances. At that time they had been detected in the Arctic, including in seals and whales, far away from their production and usage (de Wit et al., 2004). Despite these results no systematic studies on the contamination of the natural world and humans took place. But by now, PBDEs are counted amongst the most omnipresent of environmental pollutants. They are found everywhere - in the air, in house dust, in soil samples, in water, in sediments, in organisms and in food such as fish, meat, milk and eggs – and increasingly so. That these chemicals can now also be detected in breast milk does not come as quite such a surprise now. PBDEs have the ability to accumulate in fatty tissue. Once released into the environment they accumulate because of this intrinsic property in organic, fat-rich tissue – therefore also in breast milk.

The main route of intake for humans is through food. Brominated flame retardants have been found in fish and other sea food, but also in cow's milk (3.6 micrograms per kilogram (µg/kg fat)) (IPCS, 1994). As flame retardants can be washed out from artificial textiles during washing processes they are also found in sewage sludge and through agricultural fertilisation can also end up in our food. The estimated daily intake of penta-BDE through food, drinking water and respiration adds up to a daily intake of 0.8 µg/kg body weight. Besides other brominated flame retardants penta-BDE has been detected with concentrations up to 100 µg/kg in human fat tissue.

Tetra-BDE – a component of the commercial product penta-BDE – is taken up through the intestines and, by passing through the blood-brain barrier (the brain's natural protective barrier) it is transported into the brain and the spinal marrow (Burreau & Broman, 1998). Tests with mice suggest that brominated flame retardants can deeply disrupt the development of the brain. Mice that were given a single dose at the age of ten days showed learning difficulties and behavioural disorders like hyperactivity and difficulties in adapting to new environments. The disorders increased with progressing age (Erikson et al., 1998). In liver cells of male rats a chemical change of the female hormone estradiol has been observed – a trigger for the start of cancer (Segura-Aguilar et al., 1997). For octa-BDE a disruption of the reproduction processes has been observed in animal tests. It resulted in for example reduced birth weight, deformities and death of the offspring.

Deca-BDE was not considered dangerous as it was assumed that it would not easily pass through biological cell membranes of the lung, the intestines and the skin due to the large size of the molecule and, unlike penta-BDE and octa-BDE, so far it has not been regulated by law. But this is despite experiments that show that deca-BDE can disintegrate into lesser brominated compounds (i.e. with a lower number of bromine atoms) under the influence of sun light (Sellström et al., 1998). These smaller molecules can then accumulate more easily in organisms. Breakdown of deca-DBE can also take place in

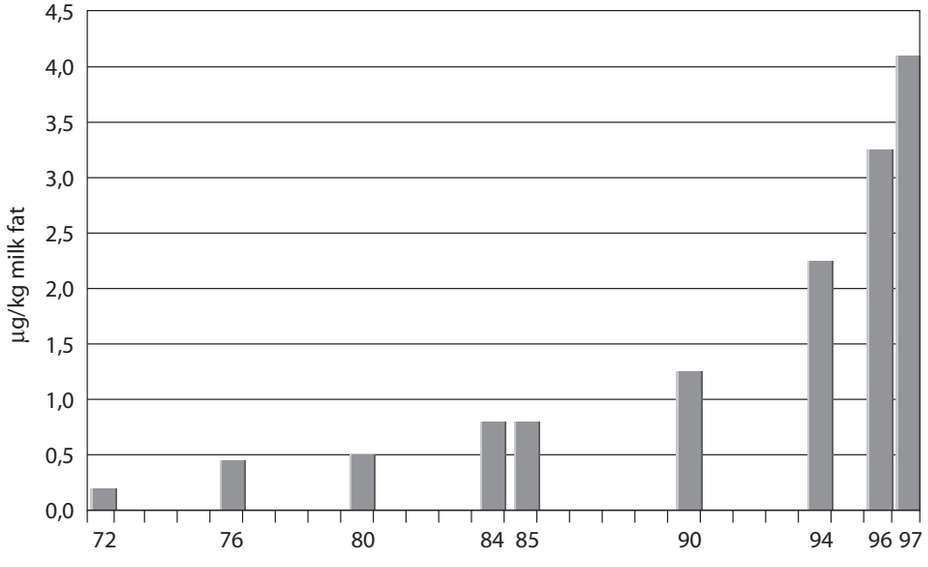

Figure 6: Concentration of polybrominated flame retardants in Swedish breast milk between 1972 and 1997.

organisms through the metabolic processes (Kierkegaard et al., 1997). As it is quantitatively the most widely used brominated flame retardant, the industry's resistance against potential legal restrictions on this substances is particularly strong.

Breast milk was first analysed by a Swedish group of scientists when they examined stored samples from the years 1972-1997 with respect to this group of substances. The results were alarming - the contamination doubled every five years. The total concentration rose from 0.07 to 4 µg/kg fat (Norén & Meironyté, 1998; Meironyté et al., 1998, 1999; Figure 6). Darnerud et al. (1998) detected a mean concentration of 3.4 µg/kg fat in 39 breast milk samples from Swedish women. A peak concentration of 28.17 µg/kg was measured.

Particularly alarming were the results from the USA where very strict regulations on fire prevention are in place. Numerous products in daily use - such as mattresses, curtains and even bedding - are treated with flame retardants. The consequence is a PBDE concentration in the breast milk of USA women some 10 to 70 times higher than in European women (She et al., 2004).
Tests on blood serum show a very wide range of PBDE levels. The cause of this cannot yet be correlated with different factors such as diet, age or employment situation. More recent studies on house dust also have not shown a straightforward connection between dust contamination and the type of house, its furnishings or the number of TVs or computers. But in smaller flats with younger residents who used their computers regularly (more than five hours per week), deca-BDE had a higher share of the total contamination. A general principle is that the domestic environment and/or house dust can play a significant role in the contamination of the population (Stapleton et al., 2004). In a US-wide analysis of dust on computers in universities and offices, PBDEs were found in all samples. Of these, deca-BDE was in the highest concentrations, up to 213 picograms per cubic metre (pg/m3) (McPherson & Blake, 2004).

In 2003 the blood serum of 155 volunteers were tested for PBDEs and other organohalogens in a number of British towns (WWF UK, 2004). In contrast to other studies, significant regional differences were found in penta-BDE levels, although in line with the known wide spectrum of concentrations. There seems to be one group of lesser contaminated and one group of higher contaminated individuals, although the reasons for this are still unknown. Mothers with several children exhibited a slightly lower contamination level compared to women in the same age group without children. The concentrations of penta-BDE and octa-BDE were comparable to those found in other European countries and substantiated widespread contamination. In a small group of eleven individuals, but from five different towns, residues of deca-BDE were also detected. Here the peak value of 240 nanograms per gram fat lay within the range of the Swedish tests, but with the difference that these were not individuals who had come into contact with the substance through their jobs. This result is alarming in as far as it indicates - independently of regional differences - an unspecific deca-BDE contamination of the general public at significant levels (Figure 4). This finding was confirmed by a European-wide examination of blood samples for 101 substances: deca-BDE was found in 34% of the volunteers and furthermore exhibited the highest concentrations of all substances. It is particularly alarming that the levels found were 10 times higher than in individuals who are exposed to BDEs through their jobs. (The same result was incidentally also found for TBBA; and HBCD was detected for the first time in a human blood sample in this study (WWF, 2004)).

A further study of blood samples used three generations of each family volunteering for the study. It was found that chemicals that have only recently been found in our environment (like PBDEs) were present in higher concentrations in the children than in the adult members of the family. 75% of individuals in whom deca-BDEs were found were children (WWF UK, 2004a).

In Germany only little data is available so far on the contamination of the population with PBDEs. However the measurements that do exist for German blood samples also show an increase in levels between 1985 (3.1 ng/g) and 1999 (3.9 ng/g) (Schröter-Kermani et al., 2000) (Figure 4). According to the German National Agency for Consumer Health Protection and Veterinary Medicine (Bundesinstitut für gesundheitlichen Verbraucherschutz und Veterinärmedizin, BgVV), the mean content in 1999 was 5.5 µg/kg fat and therefore higher than in the Swedish blood samples (BgVV, 2002).

In 2001, the BgVV initiated a study to investigate the PBDE content in breast milk in the Berlin area. One aim was to gain insights into possible influences (e.g. profession) and the relevant routes of exposure (e.g. food). The study also aimed to pursue the question of whether breast feeding reduces the overall contamination of women, i.e. whether significant amounts of the stored pollutants are transferred from mother to child. So far 93 samples from the years 2001 to 2003 from both vegetarians/vegans and non-vegetarians have been examined for 9 BDE congeners (Figure 5). An average PBDE value of 2.2 ng/g fat (in a range of 0.6 - 7.25 ng/g fat) can be assessed as the background contamination of German women. This lies within the range of other European studies (Table 4) and below the US American finding by a factor of 10-100 (Vieth et al., 2004). The averages are comparable to one other German study (2.4 ng/g fat), while a third study found a higher average (7.2 ng/g fat) (Fürst, 2001; Weber & Heseker, 2004).

From Table 5 it is evident that dietary habits influence the PBDE levels in humans. Vegetarians/vegans exhibit a 30% lower mean PBDE contamination. However a significant reduction of the levels during the 10 weeks of breast feeding could not be observed. Yet the findings indicate that women exhibit a significantly lower PBDE concentration in their breast milk while feeding their second or third child.

The detection of deca-BDE (BDE 209) is again significant. In 40% of the 62 samples examined

Table 4: PBDE concentration in breast milk, blood and serum of the population of several European countries (ng/g)

Region	Year	Sample	Median (range)		
			Σ BDE	Octa-BDE 183	Deca-BDE 209
Great Britain	2003	Serum	4.6 (0.52-420)	0.59 (0.19-1.8)[a]	83 (35-240)[b]
London & Lancaster	2001-2003	Milk	6.6 (0.3-69) **		
Sweden	2001/2002	Blood	4.9* [c]		
Finland	1994-1998	Milk	2.1*		
Germany [d]	1985	Blood	3.1*		
	1990		3.6*		
	1995		3.7*		
	1999		3.9*		
Sweden	1972	Milk	0.07*		
	1980		0.45*		
	1990		1.2*		
	2000		2.6*		
Norway	1977	Serum	0.44*		
	1986		1.1*		
	1995		3.1*		
	1999		3.1*		
Sweden	1997	Serum		11 (3.0-25) E	4,8 (<0.29-9.5) E
	1999			1.2 (0γ23-6.1) C	1,5 (<0.96-6.8) C
	2000			< 1.9 G	34 (6.7-280) G

*Σ BDE = BDE 47, 99, 100, 153, 154; a = only samples with a positive result for BDE (n=85); b = only samples with a positive result for BDE (n=11); c = Σ BDE 47, 99, 153; d = BDE 47; * = arithmetic mean; ** = 95 as percentile; volunteers: E = electronic scrap disassembly workers, C = computer technician, G = rubber cable production workers.*

the values exceeded the detection limit. This is the first proof of background contamination with deca-BDE, as previously this congener had only been detected in isolated human samples of occupationally contaminated individuals or in isolated breast milk samples in the USA. This again brings home the message about the potential folly of substitution from within the same group of substances.

So far the EU has banned the use of the technical products penta- and octa-BDEs as of August 15th 2004. Regulations concerning deca-BDE are still missing. This is being justified by a lack of data and by contradictory or unfinished final evaluations as part of the EU risk assessment. The latest studies from Germany on the amount of measurable residues in breast milk (Vieth et al., 2004), on the occurrence in house dusts (Stapleton et al., 2004) and computer dusts (McPherson & Blake, 2004), as well as their presence in the sediments of Arctic lakes (de Wit et al., 2004) and in the blood of polar bears (WWF, 2005), are explicit indications for their persistence, bio-accumulability and their distribution and transport over long distances – the characteristic properties of the persistent organic pollutants (POPs). Blood tests on European volunteers also showed higher concentrations for deca-BDE than for penta- and octa-BDE (WWF, 2004). The legislature should urgently prohibit further releases with the help of bans on production and use of these flame retardants. Penta-BDE is already being treated as a candidate for an extended UN POPs Convention, but in our opinion other representatives of the brominated flame retardants should also be included.

4.2 Fragrances

A further group of products that can be detected in breast milk and other human samples are synthetic musks. Natural musk has become an increasingly expensive fragrance of the perfume and cosmetic industry and since the musk deer, whose glands are used to produce the musk, was nearly eradicated in Asia, the chemical industry developed synthetic musk compounds as a substitution. Today there are about 1000 substitute substances with musk-like scent, but of these only about 30 are economically significant. The two economically most important substance groups among the synthetic musk compounds are nitromusk compounds (musk xylol and musk ketone) and the polycyclic musk compounds galaxolide (HHCB) and tonalide (AHTN). The musk compounds are used in cosmetics, washing agents, fabric softeners, domestic and industrial cleaners and many other fragrant products. They enter the body mainly through the skin.

Nitromusk compounds have been detected in indoor air and in dust particles in nurseries and flats in Berlin (Fromme et al., 2004). In 1993 musk xylol and musk ketone were detected for the first time in breast milk samples. The concentrations lay between 5 - 190 µg/kg milk fat (Rimkus et al., 1993, 1994). In 1995 Eschke et al. succeeded in identifying the second class of synthetic fragrances, the polycyclic musk compounds.

The data on mean levels of synthetic musk compounds in German breast milk in Table 6 originate from the surveys of BgVV's database on breast milk and dioxin in humans (Vieth, 2002). The levels of nitromusk compounds, decreasing between 1993 and 199 as compared to the increasing polycyclic musk compounds, clearly reflect the shift in market share. On the basis of these residue levels Table 7 shows the amounts a baby takes up on average during breast feeding. The data assumes an age of 4 months for the baby, an average feeding amount of 821 ml (fully breast feeding), a body weight of 6.5 kg and a 3.5% fat content of the breast milk (Vieth & Przyrembel, 2003).

Table 5: Mean PBDE concentration in German breast milk (ng/g fat) differentiated according to dietary habits, November 2001 to December 2003

Dietary habits of women	Meat eaters and Vegetarians/Vegans	Meat eaters	Vegetarians/Vegans
Number of samples	62	37	25
BDE-28	0.04	0.05	0.04
BDE-47	0.82	0.99	0.58
BDE-66	0.01	0.02	0.01
BDE-99	0.25	0.30	0.16
BDE-100	0.21	0.23	0.18
BDE-153	0.63	0.66	0.57
BDE-154	0.02	0.03	0.02
BDE-183	0.09	0.10	0.07
BDE-209	0.17	0.17	0.17
Σ BDE	2.23	2.54	1.78

Studies on 105 breast milk samples from women from Bitterfeld-Wolfen in Saxony-Anhalt in 1999/2000 came up with data comparable to the results from 1997 and confirmed the decreasing trend of residue amounts of nitromusk compounds. The means were 12 µg/kg milk fat for musk xylol and 6 µg/kg fat for musk ketone (Benkewitz et al., 2002). In the study by Ott et al. (1999) breast milk samples from central Hesse were tested for nitromusk compounds. Musk xylol was detected in 100% of the 55 tested samples from the year 1995. The mean content was 41 µg/kg fat. The samples are therefore about 58% above the national average of 26 µg/kg fat. In 87% of samples musk ketone was also found with a mean content of 10 µg/kg fat.

These findings reflect widespread contamination of the population with nitromusk compounds. In the scientific literature several reasons are given as to why musk ketone is not found in all sam-

Table 6: Mean content of synthetic musk compounds in German breast milk (µg/kg fat)

Year	Nitromusk compounds		Polycyclic musk compounds	
	Musk xylol	Musk ketone	Galaxolide (HHCB)	Tonalide (AHTN)
1993	56	18		
1995	26	12	03	78
1997	18	10	39	36

ples or only in small concentrations. On the one hand a quick bio-transformation as well as excretion seems to take place, on the other hand musk ketone is six times less lipophilic than musk xylol, which leads to a smaller accumulation. Moreover xylol compounds represent a share of 1-20% of synthetic scents, ketone compounds only a share of 0.5 - 10%, so that the released amounts differ in quantity.

The authors calculated the amount of musk xylol that a breast fed baby takes up from milk during its first few weeks. With 0.742 µg/kg fat per day the reference value for an "acceptable risk" of 0.003 µg/kg body weight per day is exceeded by a factor of 250. But as the acceptable risk figure refers to a lifelong uptake for which one person in a million would suffer damages to their health, the authors deem this excess of little relevance, as the breast feeding period represents only 1% of a human life. Unfortunately in this purely mathematical calculation they disregard other and later exposures to the chemical, they do not consider the possibility of combined effects with other substances and they totally ignore the special sensitivity of children (see Chapter 5).

The clear decrease in the content of musk xylol in breast milk is credited to the voluntary withdrawal of its use by the members of the German industry federation for cosmetics and detergents since 1994. The withdrawal was a result of the detection of musk xylol and musk ketone in the food chain, in drinking water and in breast milk samples in the early 1990s.

In 1998 the Senate Commission of the German Science Community (Deutsche Forschungsgemeinschaft, DFG) pointed out that potentially toxic substances that accumulate in the body are generally undesirable. Therefore the contamination of humans with synthetic musk compounds should be avoided or reduced as far as possible for the purpose of preventive environmental protection.

By now musk xylol and musk ketone are no longer produced and used in the EU. This is due to indications that after take up through the skin they probably have a damaging effect on reproduction and development (EU Risk Assessment Reports for musk xylene and musk ketone, 2001). Additionally they are persistent and bio-accumulative.

Table 7: Daily uptake of synthetic musk compounds in a four months old fully breast fed baby (µg/kg body weight)

Calculated daily uptake	Nitromusk compound residues		Polycyclic musk compound residues	
	Musk xylol	Musk ketone	Galaxolide (HHCB)	Tonalide (AHTN)
Mean	0.08	0.04	0.17	0.16
95 percentile	0.18	0.14	0.40	0.26

A further indication for detrimental health effects is provided by a study that analysed five different musk compounds in the blood of 152 women who were being treated for gynaecological problems in the university clinic of Heidelberg in 1994-1996 (Eisenhardt et al., 2001). Here too 95% of all samples were contaminated with musk xylol (mean: 65.5 nanograms per litre (ng/l), maximum: 1183 ng/l) and 85% with musk ketone (mean: 55.5 ng/l, maximum: 518 ng/l). This finding is important as a significant correlation between the concentrations of these substances and various diseases of the hormonal system could be established. The compounds seem to disrupt the relation between the hormonal regulatory systems of the diencephalon (interbrain) and the ovaries and therefore lead to their malfunctioning. Also reported are effects in animal experiments at low concentrations. For example, sperm maturation is disrupted in male animals that have been treated with musk ambrette, a further nitromusk compound. Musk ambrette also acts as a neurotoxin and musk xylol and musk ketone can cause skin allergies.

According to the authorities no indications can be taken from these animal observations to say that the amounts detected in breast milk could be dangerous for the breast-fed baby (Vieth & Przyrembel, 2003). Also no TDI value was set as the musk compounds are taken up through the skin (dermally) and not through food (orally). However the state of knowledge concerning their dangers is still very limited in all synthetic musk compounds and a final assessment is not yet possible. A recent discovery is very worrying though: both groups of synthetic musk compounds (nitro- and polycyclic) are said to have the ability to inhibit the transport mechanisms which remove other dangerous substances on a long term basis, so that these can enter the cell unhindered to unleash their harmful effects (Luckenbach & Epel, 2005). But such combination effects are not taken into consideration given the single substance testing during the risk assessment process for individual chemical substances.

Reliable statements on the trend of the general contamination by polycyclic compounds are not yet possible in Germany due to the low number of samples and the short time period of observation. But higher concentrations of these compounds detected in breast milk reflect their increased market share. As they are increasingly used as substitutes for nitromusk compounds, contamination could rise in future. Additionally the potential for consumers to come into contact with musk xylol and musk ketone continues despite the end of EU production as they continue to come onto the European market without control through imports from China (the main current producer) as admixtures with other products (EU Risk Assessment Report for musk ketone, 2001). In general, studies to monitor the contamination situation should be conducted on synthetic musk compounds continuously and these should also consider a wider spectrum of substances.

4.3 Plasticisers

90% of the plasticisers used in the EU are used in PVC products to make them softer and more flexible. Among the plasticisers DEHP (diethyl hexyl phthalate) is the most common compound, responsible for about 45% of consumption (about 475,000 tons per year). Further phthalates often used as plasticiser are DBP (dibutyl phthalate) and DINP (diisononyl phthalate) as well as DIDP (diisodecyl phthalate). But phthalates are also used in many other areas. They are used as a carrier for fragrances, deodorants and other cosmetics. They are components in nail varnish and hairsprays and they are used in formulation agents in pesticides, as industrial solvents, as lubricants and as additives in the textile industry.

As softening agents the substances are found in rain coats, toys, flooring, medical products, food wrappings, paints and glues and other products. Flooring, toys and medical products can contain up to 50% plasticisers. As they are not bound to other compounds in the plastic they leach out of the objects and find their way into domestic dust particles for example. It is estimated that out of the total of DEHPs escaping into the environ-

ment in the EU only 1.5% originate from releases during production and 2% from industrial usage. More than 90% of the yearly environmental contamination of 30,000 tonnes is caused by outgassing, abrasion, washing out and other diffuse losses from consumer goods (EU RAR for DEHP (2000)). This leads to an omnipresent distribution in the environment and continuous exposure of the general public with phthalates. They can be detected in a number of environmental and human samples. Even in Arctic ice one can find concentrations of up to 0.53 micrograms per litre (µg/l) (Desideri et al., 1994).

Humans can take up phthalates from the air, through the skin and with food. Measurements of indoor air in offices, schools and nurseries in Denmark resulted in values of 0.86 µg/m3 DEHP on average. In a room with new PVC flooring the values were 200-300 µg/m3; and in a car heated up by the sun DEHP concentrations of up to 1,000 µg/m3 could be measured. Even in ambient air DEHP can be detected in concentrations of 0.0003 - 0.3 µg/m3 in some European regions (EU RAR for DEHP (draft), 2000).

The Bavarian Federal Authority for Health and Food Safety examined the presence of phthalates in 59 flats and in 74 play schools in 2000/2001 (Fromme et al., 2004). DBP caused the highest residues in the indoor air of flats and play schools (1.083 µg/m3 and 1.188 µg/m3). DEHP was identified in house dust with a mean content of 703 mg/kg (with a range of 231-1,763 mg/kg). Thus it makes up 80% of the phthalates.

Textiles in clothes and the application of cosmetics as well as direct contact with soft plastics can be sources of phthalate uptake through the skin. In an analysis of clothing textiles it was established that the phthalate content depends on the material used. While textiles made from pure cotton had a total phthalate content of 4,100-8,900 µg/kg, in mixed fabrics concentrations of 10,200-16,300 µg/kg were detected. The total phthalate content varied between 3,200-7,100 µg/kg in carpets and 3,100-5,400 µg/kg were measured in cushioning fabrics (Bruns-Weller & Pfordt, 1999).

Apart from uptake through the skin and by respiration, internal uptake of phthalates is also caused by contaminated food. In particular, fatty food packaged in wrapping that contains phthalates shows high residues. (See Bruns-Weller & Pfordt (1999) for a literature review.) The front-runner for total phthalate content is cheese; a (wrapped) soft cheese sample was measured at 114,000 µg/kg, followed by peanuts with 38,000 µg/kg and poultry with 8,800 µg/kg. Tests on cow milk showed different contamination levels in various EU states, which may be dependent on different methods of packaging. Cow milk from Germany was contaminated with 20-150 µg DEHP/kg, Norwegian milk with 60-380 µg DEHP/kg and English with <10-90 µg DEHP/kg. Baby food in the form of formula milk (powder) in Germany contained <50-200 µg DEHP/kg, values for soft food in jars were between 50-210 µg/kg (Gruber et al., 1998).

Many toys for babies and toddlers are made from soft PVC. Babies and toddlers suck and chew on these products, and saliva acts as a solvent supporting the release of phthalates. This is a significant source of phthalate uptake via the mouth.

Even though phthalates only disintegrate slowly in the environment, a relatively quick breakdown is assumed in the human body with a half-life of eight to ten hours (Bruns-Weller & Pfordt, 1999). While phthalates exhibit lipophilic behaviour, bio-accumulation in fat tissue or breast milk is rather unlikely according to the current state of knowledge. The big problem of phthalates is the continuous and high exposure that humans, particularly children, are confronted with on a daily basis.

Analyses of German breast milk samples have shown residue contents of 70-160 micrograms per kilogram (µg/kg) for DEHP (Gruber, 1998), 10-110 µg DEHP/kg, 50 µg DBP/kg as well as evidence for DIBP in traces (Bruns-Weller & Pfordt, 1999). From this data and on the basis of a maximum DEHP value of 160 µg/kg, the BgVV calculated an exposure of 21 µg/kg bw/day at age up to 3 months and 8 µg/kg bw/day at age 3 to 12 months. In the younger age group these values exceed the lowest TDI value of 4 µg/kg bw/day quoted in the literature five-fold and two-fold in the older group (Table 8).

In a study of blood samples of EU Members of Parliament, DEHP was detected in all 45 tested individuals. The median concentration was the highest of all 76 residues detected. The maximum value was 1,152 µg/kg; the mean was 155 µg/kg blood. DIBP was present in 84% of all samples and DINP in 38% of samples (Figure 7; WWF, 2004).

New test methods and results from the University of Erlangen attracted world wide attention as they indicated that all other previous studies had underestimated the contamination of humans considerably. In the study by Koch et al. (2003), urine samples from 85 individuals from Erlangen and the surrounding area were examined. The method did not measure the DEHP itself but analysed three of its breakdown products (metabolites), making a new and more reliable method. From the data the individual daily uptake of DEHP was calculated. The values for daily DEHP uptake were 2.6 – 166 µg/kg bw/day with a mean of 13.8 and a 95% percentile of 52.1 µg/kg bw/day. These results for contamination of the German public with DEHP exceeded hitherto published values by at least a factor of ten. The Erlangen scientists also examined children in play schools and their teachers and parents (Koch et al., 2003a). From urine samples the children's DEHP contamination was found to be twice as high as that of the adults. This gives cause for concern since pollutants – particularly the ones that are hormone-like – can cause far more serious damage to children's health than to that of adults (see Chapter 5).

A study by Binder & Obenland (2004) also shows that toddlers are exposed to DEHP to a far higher degree than adults. This insight is all the more worrying given that babies already take up a considerable amount per day through breast feeding. Their daily DEHP absorption of 12 µg/kg bw/day exceeds that of adults by a factor of 6.

Other authors also confirm this result. Meek & Chan (1994) estimated the daily uptake in 0.5 – 4 year olds as 19 µg/kg bw/day. According to their calculations this age group (and most sensitive sub-population) is the most highly contaminated at 3.3-fold the contamination level of adults. With a base level contamination of 12 µg/kg bw/day the TDI of the Dutch National Institute for Public Health and the Environment is exceeded by a factor of 2 (Table 8). Not included in this estimate is contamination caused by sucking or chewing on toys that contain DEHP or by wearing clothes made from PVC like raincoats, wellington boots or sandals. The DEHP released and taken up through this route exceeds the base level of contamination several-fold even in normal use: up to 200 µg/kg bw/day can be taken up by sucking and chewing on toys (CSTEE 1998) and up to 79 (rain coats) and 340 (sandals) µg/kg bw/day per day respectively can be taken up via the skin. And note that these figures are not calculated in the way that Koch and his colleagues did so may still be an underestimate (see above).

The level of contamination of the population is very alarming in respect to the hormone-like (endocrine) effects of phthalates and the toxic effects on reproduction and development. This substance group is suspected to be linked to - among other things - increasing infertility in men. Animal tests have shown a reduction in the number and weight of offspring, slowed bone development and deformities particularly in male

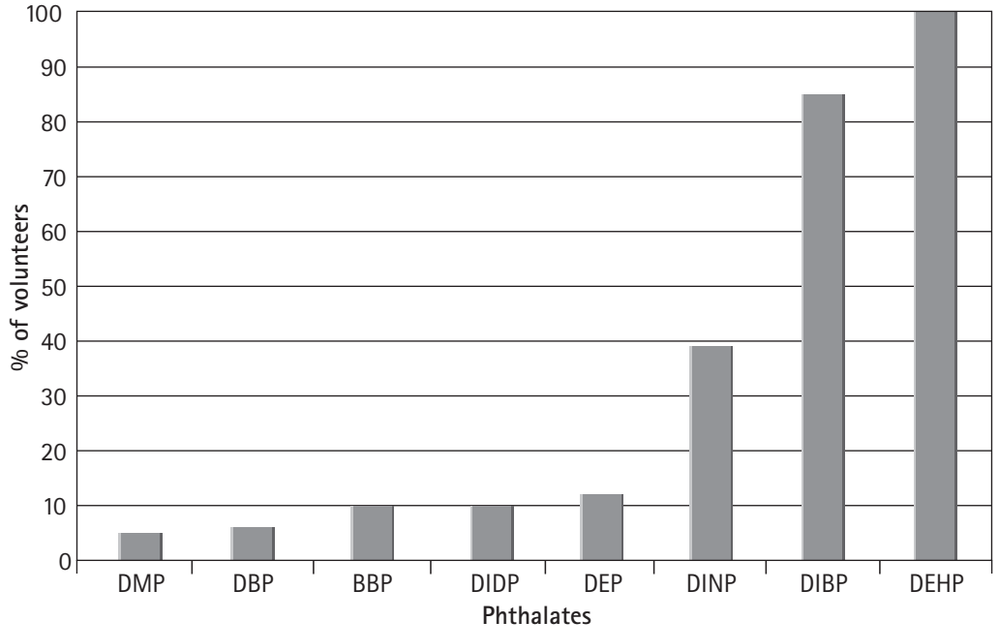

Figure 7: Occurrence of various phthalates in blood samples of European volunteers

reproductive organs as well as in kidneys and eyes (Bruns-Weller & Pfordt, 1998; WWF, 2000; WHO, 2002). The EU classifies them as priority substances in respect of their hormonal effects and their potential for exposure (Gies et al., 2001).

A risk assessment for DEHP is taking place at present within the scope of the European "existing chemicals" programme (under the Existing Chemicals Regulation 793/93). So far advanced measures to minimise risks have only been deemed necessary for children, and not for adult consumers - despite the detrimental effects that DEHP may have. Based on the new results of the University of Erlangen, the German Institue for Risk Assessment (BfR) has deemed necessary a review of the current DEHP risk assessment at European level (BfR, 2003). The BfR sees indications that the general public's exposure to DEHP (and potentially other phthalates with similar toxic effects) is higher than assumed so far, although it notes the difficulties in assessing the multitude of toxicological data which can be interpreted differently among experts. The BfR concludes that clarification of the potentially relevant sources of exposure should be of the highest priority, and special emphasis should be placed on the examination of food (and its packaging) and consumer goods. This would also help clarify the sources of high dust contamination indoors (BfR, 2003). Further regulation measures are not spelled out.

On the basis of studies on animals various institutions have calculated amounts of DEHP that they consider still tolerable in humans. But the results differ by more than a factor of ten (Table 8). The BfR names further studies that result in TDI values that vary by a factor of as much as 1000 (BfR, 2003). The lowest TDI of 4 µg/kg bw/day is quoted by the Dutch National Institute for Public Health and the Environment (RIVM). It is based on a study by Poon et al. (1997) that had determined a NOAEL (no observed adverse effect level) of 3.7 µg/kg bw/day in tests with rats. (The NOAEL states the concentration below which negative effects are not observed in the animal tests.) Damage to testicular cells was examined as an end point in this study. As this result was deemed relevant by the RIVM to both young and adult male animals a safety factor of 10 was used to extrapolate to lifelong exposure. A safety factor of 100 was used to allow for the variation between species and within a species. Using these factors they arrived at the TDI value of 4 µg/kg bw/day (Baars et al., 2001). Binder & Obenland (2004) consider this approach legitimate as DEHP is so far the only plasticiser which has been subject to proper observations with respect to uptake by humans. Therefore for the time being it is not an isolated figure but also has the function of being representative for a multitude of industrially used phthalates. Koch et al. (2003) have shown that other phthalates can often be found in high concentrations alongside DEHP in urine. Koch et al. assume additive toxic effects of these compounds when they act in the same way. A potentially overestimated safety margin in DEHP could compensate for a potentially underestimated total phthalate uptake.

Country – Institution	Reference value (µg/kg bw/day)	Label	End point	Author
Netherlands - Rijksinstituut voor Volksgezondheid en en Millieu (RIVM)	4	TDI (MPR)	Reproduction toxicity	Baars et al 2001
USA - Environmental Protection Agency (EPA)	20	RfD	Increased liver weight	IRIS 2004
World Health Organisation (WHO)	25	TDI	Peroxisome proliferation in the liver	WHO 1996, cited according to Baars et al. 2001
EU: Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE)	48	TDI	Development toxicity and testicular toxicity	CSTEE 2004

Table 8: Reference values of various institutions regarding tolerable DEHP uptake

TDI: Tolerabele Daily Intake; MPR: Maximum Permissible Risk Level; RfD: Reference Dose (for chronic oral exposure);

Despite the numerous scientific findings on the detrimental effects of some phthalates they are still being used widely in a large number of consumer goods, although there are now some legal regulations. According to Directive 67/548/EEC on the classification and labelling of dangerous substances, DEHP has been classified as detrimental to reproduction (reprotoxic) since 2002. To indicate the danger risk phrases have been assigned: R60 – "May impair fertility" and R61 – "May cause harm to the unborn child". DEHP as such and chemical preparations containing more than 0.5% DEHP must be labelled with the skull symbol and the warning "toxic" (Table 9). But this does not apply to consumer goods, some of which contain DEHP in considerably higher concentrations (e.g. toys and flooring with up to 50%).

As CMR (carcinogenic, mutagenic or reprotoxic) substances in cosmetic products pose a serious risk to consumer health, DEHP was banned due to its classification as reprotoxic by the cosmetics Directive 2003/15/EEC. At EU level certain phthalate plasticisers have been banned in toys intended for children up to three years of age as well as in teething rings since 1999 due to the suspected hormonal effects (EU Commission's preliminary decision). Since March 2000 a corresponding regulation has been in force in Germany. In September 2004 the European Council spoke out in favour of a ban on DBP, BBP (butyl benzyl phthalate) and DEHP in toys for all age groups; for another three phthalates DINP, DIDP and DNOP (di-n-octyl phthalate) the ban is supposed to remain in place only for the age group up to three years as well as for toys that are being mouthed. The EU Parliament's resolution for an environment and health action plan in February 2005 calls for a restriction on the marketing and use of six phthalates (DEHP, DINP, DBP, DIDP, DNOP, BBP) in domestic products for

Table 9: Classification and labelling of DEHP.

Danger label	Risk phrases	Symbol
T toxic	R60 - May impair fertility R61 - May cause harm to the unborn child	Toxio

indoor use and in medical devices to which newborns, children, pregnant women, elderly individuals and workers are particularly exposed. A precondition is that safe alternatives should be available and that the restriction would have no negative impact on medical treatment. In Austria phthalates are banned – with exceptions – in food packaging (EU 2003). The BfR plastics Commission advises an end to the use of cling-film containing soft PVC which could come into contact with foodstuffs (BfR 2003).

According to guidance on the use of environmentally safe substances the German Federal Environmental Agency regards the substitution of DEHP in plastics as necessary (UBA, 2003). Various alternatives are already available on the market: e.g. adipates, citrates, phosphoric acid ester, alkyl sulphonic acid ester and cyclohexene dicarbonic acid ester.

From the point of view of a precautionary protection of the environment and human health the use of phthalates must be banned in all products when exposure to humans and the environment can be expected. This would particularly include baby and children's goods, food packaging, medical products, textiles and furnishings as well as goods used in outdoor applications and exposed to the weather.

5. The danger to children's health

Children are affected by pollutants in particular ways. The contamination does not start with breast feeding after birth, but already occurs in the womb. Many of the chemicals that contaminate the mother can penetrate the placental barrier, i.e. they can travel from the mother's blood into the unborn child. For the growing and developing foetus this can lead to detrimental and irreversible harm. Particular mention must be made of the recently discovered so-called endocrine or hormone disruptors that - even in small quantities – may interfere with crucial metabolic processes by imitating or blocking natural hormones that serve to control vital functions in the body. This can lead to impairment of growth, of the immune system, of the future ability to reproduce as well as of the brain's development and therefore of future mental abilities and behaviour. After the breast feeding period the contamination continues through the consumption of food contaminated with pesticides, through the contamination of indoor and ambient air or through the exposure to chemicals that are "hidden" in everyday goods, some of which children come into contact with intensively (and more so than adults), e.g. by chewing or mouthing their toys.

On the one hand children in Western industrial nations are mostly better off as compared to children in historic times and to those in developing countries. The incidence of dangerous infectious diseases is much lower, nutrition has been improved and access to clean drinking water is ensured. The life expectancy of a baby born today is more than twenty years higher than that of a baby born at the beginning of the 20th century. On the other hand children today live with the risk of being exposed to maybe 30,000 synthetic chemicals that were all placed on the market within the last 50 years without prior testing of their potential toxicity. The increase in certain chronic diseases and new forms of illnesses needs to be mentioned here because it is thought that a quarter of them can be traced back to environmental causes, including, amongst others, to the effects of dangerous chemicals. The rise in allergies in children, the increase in asthma, leukaemia and brain tumours as well as neurological developmental disorders must count among these illnesses (Landrigan et al., 1999).

Children are not "small adults": many aspects of their contact with chemicals differ from the situation with adults. In Germany particular attention is being paid to this issue within the scope of the Environment and Health Action Programme (Aktionsprogramm Umwelt und Gesundheit, APUG). The programme was presented in 1999 by the Federal Environment Ministry and the Federal Health Ministry. Within its scope a study was produced on "the consideration of the high-risk group children in the derivation of environmental standards concerning health issues" (Schneider et al., 2002). The following aspects are to be considered:

- children are more exposed to environmental pollutants than adults;
- at an age of one to five years children eat three to four times more food and drink five times more than adults in relation to their body weight;
- the consumption of milk in relation to their body weight is nine times that of an adult;
- children have a more unbalanced diet than adults, e.g. the consumption of apples can be up to 20 times higher than in adults.

These nutritional habits can - in children - lead to an uptake of pesticides exceeding the TDI value (BgVV, 1999).

The intensity of respiration is also higher in babies and children. Based on the respiratory volume and body weight a baby takes up an air volume 1.5 times greater than that of an adult. The relatively larger body surface and the fact that substances are taken up more easily and quickly though chil-

dren's skin needs to be considered when considering dermal uptake. By now it is certain that mouthing (putting objects into their mouths) as well as the swallowing of dust and other ground particles leads to a higher uptake of substances.

The rates of metabolism and excretion differ with age. Therefore during the first year of life substances stay in the body for much longer than in adults due to the immature kidneys. Moreover children up to year five have - as a general rule - a higher rate of metabolism than adults. Children grow and develop very quickly. From birth to puberty they pass through a succession of different developmental phases. With respect to the toxic effects of environmental chemicals, the maturation phases of organs (e.g. kidneys, central nervous system or sexual organs) are always critical phases. Important developmental processes can be interrupted, delayed or altered. During these sensitive phases vital systems are being formed in the body. If cells of the developing brain, of the immune system or the reproductive organs are being destroyed by toxic substances or if their development is disrupted - for example by hormone disrupting substances - the risk of a permanent malfunction looms. Depending on the affected organ a loss of intelligence, a malfunction of the immune system or problems in reproduction can occur.

Children have in general more years of their life still in front of them and therefore more time to develop chronic illnesses years later triggered by exposure early on in their lives. A contamination with pesticides for example in babyhood is more likely to lead to an illness than a comparable contamination during adulthood.

Because of this nature of children it is obvious that the risk assessment of chemicals should include special assessment standards for children and babies. Currently only the Indoor Air Hygiene Commission (Innenraumluft-Hygenie-Kommission, IRK) of the German Federal Environmental Agency, Environment Ministry and the Committee for Environmental Hygiene of the Working Group of Leading Medical Civil Servants (AGLMB) pay attention to the special situation of children. The Commission ruled that for the purpose of deriving reference values for indoor air quality, in addition to using a factor of ten to take into account the variance within one species an additional factor of two should be employed to take into account the higher respiration rate in relation to the body weight of children (IRK, 1996).

One EU directive regulates the legal limit of pesticide residues in baby food and it sets a limit of 0.01 mg/kg. But not taken into account here is the fact that after a few months toddlers are often fed supplementary freshly blended fruit and vegetables for which "adult values" apply. By contrast USA food law from 1996 sets an additional safety margin of a factor of ten for residue limits for pesticides in food for children (Olin, 1998).

Further studies on exposure and potential health risks in children are necessary. On the grounds of precaution, children should be assessed as a high-risk group until the questions are resolved due to the life span still in front of them. Limits and reference values for the purpose of protecting human health should be aimed at the most sensitive groups of the population and those most in need of protection.

6. The reform of EU chemicals policy – a solution?

There should be socio-political consensus that humans and the environment must be protected from dangerous, toxic substances. It should also be agreed that synthetic chemicals should not enter the environment and/or the human body if they possess the property to accumulate there for years, decades or even forever. This principle should apply independently of toxicological insights about the substances, particularly considering that scientific insights into the effects on humans and the environment are only a snapshot of the current state of knowledge. The traditional risk assessment system therefore needs to be reviewed and an adequate handling of uncertainty needs to be developed. The new research into the properties of endocrine pollutants as well as the latest insights into the health risks of synthetic musk compounds (chapter 4.2) must be taken into account, not just in individual cases but in the general handling of the problem. The still prevailing disagreement concerning the assessment of PCBs (which have been in circulation for decades and have been banned globally) as well as the numerous contradictory scientific findings concerning the plasticiser DEHP (chapter 4.3) underpin this demand.

The old sins of the PCBs (chapter 2) are a particularly good example that shows the importance of comprehensive testing on risks for human health and the environment ahead of commercial marketing. Furthermore the case provides evidence that persistent and lipophilic substances should not be authorised for open uses in the first place. But so far there are no legal instruments for this purpose. It should also not be forgotten that by now a large number of further industrial chemicals have been detected in human samples. And not all of them have received as much attention in continuous monitoring as the polychlorinated naphthalenes, which have been used since the beginning of the last century as a substitute for PCBs. They too can already be found in breast milk and they behave in their effects like dioxins (Lundé & Norén, 1998). Furthermore there are numerous chemicals that are not yet the focus of research, i.e. which have not been looked for yet and where little information is available to the authorities. Yet any persistent, lipophilic and bioaccumulating substance in open use will be detectable in breast milk sooner or later once the progress in scientific analysis enables this and where the financial resources of research programmes permits it.

6.1 Prehistory

When mass production of chemicals began nobody thought of the potentially dangerous long-term effects of chemical substances: chemicals were released into the environment without any testing by the authorities. In the 1960s and 1970s the first surprising findings of residues were made in environmental and human samples. With respect to pesticides the need for an approval system based on safety tests was recognised relatively early since these compounds are explicitly designed to kill unwanted weeds and pests. For biocides other than those used in in agriculture an EU directive has also been issued. Following its implementation into German law in 2002, now biocides also have to be specifically authorised for use.

For all other chemicals – the so-called "industrial chemicals" – regulations have only been issued in certain individual cases. For example, there are restrictions on the use of various dangerous substances in electrical and electronic

goods (2002/95/EC), regulations concerning cosmetics (76/768/EEC and amendments) as well as concerning the safety of toys (88/378/EEC and amendments).

Usually regulations to reduce certain dangers are only issued when problems which have occurred in the environment or to human health require action to restrict usage of the culprit chemical. In such cases the burden of proof rests with the aggrieved party or with the authorities who are expected to deliver a complete line of evidence for the causal connection between the substance and the harm before the industry side agrees to restriction.

The first fundamental shift in tackling this problem took place in the context of the negotiations on the protection of the marine environment, particularly the Convention for the Protection of the Marine Environment of the North-East Atlantic (OSPAR Convention). In 1998 the environment ministers of the adjacent states of the North-East Atlantic (including a representative of the European Commission) issued the so-called "one generation target", namely an end to emissions and accidental releases of dangerous substances into the marine environment by the year 2020. For the first time the persistent, bioaccumulating and hormone disrupting substances in particular were identified as dangerous substances. This agreement was very ambitious due to the number of potential candidate substances, but eventually led to the precautionary approach on which the current draft of the EU chemicals policy reform is based.

In 1981 chemical legislation came into force that for the first time prescribed mandatory testing for chemicals for environmental and health risks before they could be placed on the market. All 100,195 chemicals that had been marketed in Europe prior to this date (the "existing substances") had not undergone such risk assessment but could continue to be marketed. Not until 1993 was the EU's Existing Substances Regulation passed which was supposed to ensure the (belated) protection of humans and the environment from risks posed by these chemical substances. Under this Regulation, prioritised substances are now being assessed in a time-consuming process and either approved for free use or subjected to certain restrictions. But by 2005 only 300 substances had completed the risk assessment process even though this is a necessary precursor for any legislative measures. The system is therefore not able to guarantee humans and the environment adequate protection from dangerous chemicals, as more than 10 years after the introduction of the system fundamental information about the risks and applications of most substances on the market is still not available.

On May 17th 2004 a milestone in the regulation of dangerous chemicals was reached with the coming into force of the United Nations' Stockholm Convention (or POPs Convention). As mentioned before, this international agreement bans or restricts twelve globally occurring long-lived toxic substances known as Persistent Organic Pollutants or POPs. The politics needed nearly half a century to respond adequately to the global threat, and without the tough endeavours of numerous environmental organisations this important agreement would probably not have materialised in this form. NGOs are also striving to extend the number of substances in the Convention, e.g. to include hexachlorocyclohexane (HCH) and pentabromodiphenyl ether (PBDE).

In parallel to the Convention negotiations, in April 1998, environment ministers of several Member States came together in Europe to express their concern about EU chemicals policy. Following the demand of the Environment Council for a new approach to improve regulation of the numerous substances on the EU market, the EU Commission presented the chemicals White Paper ("Strategy for a Future Chemicals Policy"). In the same year this found the support of the Council of Ministers and the Parliament, with some supplementary proposals. The text revised by the Commission was then posted on the internet for all stakeholders to comment on (May to July 2003). But the policy, which in principle was a good approach, was significantly weakened due to unparalleled aggressive lobbying by the chemical industry – who used totally exaggerated arguments on the cost of the reforms. Now the first draft for REACH in its current form (presented in October 2003) no longer guarantees sufficient protection for the environment and human health, and needs improving in many vital areas.

The twelve chemicals of the UN POPs Convention

Pesticides	aldrin, chlordane, dieldrin, DDT, endrin, heptachlor, hexachlorobenzene (HCB), mirex, toxaphene
Chemicals	polychlorinated biphenyls (PCBs) and hexachlorobenzene (HCB)
Undesirable byproducts	dioxins and furans

6.2 REACH – the new EU chemicals legislation

The new EU chemicals legislation on the registration, evaluation and authorisation of chemicals, REACH, is to date the most far-reaching and significant reform of environmental and health protection law in Europe. As the current draft stands, a central component of the new system is the duty for all companies to harm neither human health nor the environment during production, import and use of chemicals. As noted above, the authorities have had the responsibility of proving the dangers of a chemical in order to restrict use. In the new regulation it will be up to the companies to demonstrate the safety of a chemical before it is marketed. The manufacturer will be obliged to assess the potential risks along the entire chain of use (including waste production and disposal). Moreover REACH includes a new mechanism to limit the uses of the most dangerous substances. In future, approval (an authorisation) will be needed for the use of a substance with a very high danger potential, otherwise uses are automatically banned. Until now such bans could only be introduced on a case-by-case basis and only if the authorities could prove a relevant risk.

A brief description of the draft legislation as it stands at present follows.

Registration: Manufacturers and importers of chemicals will be obliged to collect the most important information about a substance in a registration dossier which is then sent to a central Chemicals Agency. The extent of the data that needs to be included depends on the quantity of the substance manufactured or imported and on its hazardous properties. Besides the substances' inherent properties and data on toxicity tests, the dossier also includes information about the use of the substance and its entire life cycle. This information is passed on through the supply chain. REACH will only apply to an estimated 30,000 substances that are produced or imported in amounts of more than one tonne per year. The new system will be introduced step by step. Substances have highest priority if they are manufactured in very large quantities (over 1,000 tonnes per year per manufacturer) and if their carcinogenic, mutagenic and/or reprotoxic potential is already established. Eleven years after coming into force at the latest all substances should be registered. Non-compliance with the given deadlines leads to a marketing ban.

Evaluation: The registration dossiers are checked for completeness and a conclusion is drawn from the submitted data. This inquiry may lead to either a ban or restrictions to minimise the risks or it may not result in any measures, depending on the risk assessment.

Authorisation: Chemicals that meet the criteria of "very high concern" have to undergo an authorisation procedure if the manufacturer

wishes to market the chemical despite the potential dangers. CMR chemicals are of very high concern as are very persistent and very bio-accumulative substances or substances that are persistent, bio-accumulative and toxic. A further clause in the draft legislation paves the way for inclusion of endocrine disrupting substances and substances that are identified as being of equivalent concern.

Currently the draft law is being discussed in the EU Parliament, which has just voted at first reading in November 2005. The Council of Ministers - composed of the Member State governments – is also working on proposals for amendments, which will be included in a revised text by the EU Commission. Then follows the second reading when both Parliament and Council have to adopt it jointly – presumably at the end of 2006 or early 2007, although if necessary, a conciliation procedure between Parliament and Council could delay this further.

6.3 The NGOs' essential proposals for amendments

The current REACH draft has unacceptable omissions caused in particular by the massive intervention of industry interests during the 2003 internet consultation. For example:

- For chemicals of less than a tonne per year (per manufacturer) no information at all will be available. This is unacceptable, particularly from the point of view of industrial safety.
- The data to be provided for chemicals that are produced in amounts between 1 - 10 t/year will not be sufficient to derive appropriate safety measures.
- Chemicals in consumer goods are excluded from effective controls. Substances which need authorisation may continue to be sold if the risk is "adequately controlled" – even if safer alternatives are available at a comparable price. This is exactly the approach that has not worked in the past.
- The chemical industry's excessive demands for secrecy prevent appropriate public access to information about the safety of products.

In consequence, a number of proposals for amendments have been drawn up by BUND (Friends of the Earth Germany) and its European representative Friends of the Earth Europe, together with the European Environmental Bureau, Greenpeace International and WWF as well as European NGOs for health (EPHA Environment Network) and women (Women in Europe for a Common Future). The five main demands of the NGOs can be found on page $.

It must be noted that REACH does not apply to some 70,000 chemicals that are produced or imported in amounts of less than one tonne per year. To close this loophole a legally binding obligation for duty of care is needed for all manufacturers and users of chemicals, which would bind them by law to be responsible for the safety of their products. Under REACH it is up to manufacturers, importers and users of chemicals to make sure that the products they produce, import or use do not harm human health or the environment. The regulation is reinforced by the precautionary principle: in the choice of chemicals for production or use the manufacturer and succeeding users should choose the safest available alternative.

The REACH draft proposes that the registration of substances be prioritised according to manufactured or imported tonnage and also including CMR substances as first priority. This is a realistic and legally certain measure and is the best proposal for phasing-in the registration of the huge number of chemicals. (In our view, all substances of very high concern should have priority here, i.e. including the PBT and vPvB substances - not just the CMR substances as proposed by the Commission.) The proposal of some industry representatives to carry out "risk-based" prioritisation is unworkable - without sufficient safety information the risk cannot in fact be assessed and this information is only generated during the registration process.

The information requested for chemicals at a yearly production volume of 1 - 10 tonnes is not sufficient to identify particularly hazardous substances of very high concern. REACH must not downgrade the current level of information required in the system for evaluation and labelling of dangerous chemicals. Three (non-animal) safety tests must be reintroduced: the in vitro toxicity cell test on mammalian cells (to detect carcinogenic and mutagenic properties), the test on inhibition of algal growth (to detect chronic toxicity in aquatic organisms) as well as a test on bio-degradability. A chemical safety report should be mandatory so that customers can become aware of the hazards and exposures and so that they can pass on conditions for safe use to successive downstream users.

With respect to the registration of substances in consumer goods, the current REACH proposal does not ensure sufficient protection of consumers and the environment. The threshold for mandatory registration of chemicals in imported products should be regarded as per importer rather than per product. Registration also depends on importers knowing if the release of a substance from a product is likely and knowing its estimated toxicity. This clause should be removed - the importer should urge its subcontractors to only use chemicals registered within the scope of REACH.

At the moment REACH does not sufficiently take into consideration the particular sensitivity of children and does not account for exposure at various stages of development. Appropriate protection of children must be ensured to rule out detrimental effects on behaviour, learning, motor capabilities, the immune system and future fertility. Even though chemicals may cause the same effects in adults and children this can happen at different levels of contamination. Moreover substances can lead to effects that only occur in children and that are connected to the development of organs and organ systems. In particular, changes that originate in exposure during development and that are only manifested in later life can easily remain undiscovered.

The data submitted for evaluation should be spot-checked to ensure a generally high quality. The Member States themselves should also evaluate a sample of the registration dossiers and safety data submitted by industry.

The authorisation procedure must be designed in a way that encourages innovation and the search for alternatives. Chemicals of very high concern must only receive an authorisation if no safer alternatives are available, if the social benefit outweighs the dangers to the environment and human health and if emissions as well as accidental spillages into the environment are kept at a minimum. Currently however an authorisation can be granted if the industry can prove that it "adequately controls" the substance, that the social benefit outweighs the risk or that no safe alternatives are available. Where an authorisation is granted it should always be temporary and it should include a review clause. The possibility of including chemicals of "equivalent" concern in the authorisation process must also be made easier - in the current REACH proposal serious and irreversible damage to humans or the environment must first be identified. This could of course take a very long time (if it is at all ever possible beyond doubt) and contradicts the precautionary principle.

It should be guaranteed that everyone has access to information concerning chemicals that they are handling or buying. Information about substances in consumer goods should be available to all commercial users, retailers and consumers. Products that incorporate chemicals of very high concern that need authorisation should be labelled in order to inform all downstream users including retailers and consumers and to enable them to seek alternatives.

The procedure for obtaining information held by the authorities is extremely cumbersome and

slow and provides industry with significant rights to veto the release of information. The public interest in access to information must receive more consideration. The list of permanently accessible information must be extended to include the entire registration dossier, the substance safety report, information on amounts of production and import and the name of the registering person. All data on toxicity, life cycle, exposure, categories of use and risk assessment must be publicly accessible. The list of confidential information should not contain any data significant for protection of human health or the environment. Any decision to withhold such information should be preceded by an evaluation of public interest in this data.

Deca-BDE as a case study for the need for the chemicals reform

Concerns about deca-BDE (deca-bromodiphenyl ether) have resulted in it being a priority substance in the current "existing chemicals" programme and it has been under scrutiny for many years by experts of the Member States. Within this system the authorities of the Member States have to investigate all the data about this substance before regulatory decisions can be made. And if the uses are to be restricted, the authorities have to know if safe alternatives are available for all applications - not necessarily an easy task for regulators. So far it has been concluded that the accumulation in animals and humans and the current knowledge of its toxicity does not warrant the imposition of controls (Chapter 4.1).

Even though deca-BDE contaminates animals and humans in regions far away from civilisation it does not fully fulfil the current criteria for very persistent, very bio-accumulating (vPvB) substances. Therefore within the scope of REACH it could only be included in the authorisation process through being declared as a substance of "equivalent concern". But it is doubtful whether at this stage the current criterion of "serious and irreversible effects" could be demonstrated. Thus to ensure an effective mechanism through the authorisation process, this condition needs to be removed from the REACH text. Under the current system industry could try to obtain an authorisation by arguing that the risk posed by the chemical was "adequately controlled" and the authorities would have to grant an authorisation even if alternatives exist.

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