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Clean Baltic within Reach?

How can a new chemical policy contribute to the protection of the Baltic Sea?



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A unique and highly sensitive sea area

The Baltic Sea is the youngest sea on our planet. It is a truly unique marine ecosystem that plays an important role in the lives of the 85 million people who live in its catchment area. It is the home for marine mammals, such as seals, otters and harbour porpoise as well as cod, wild salmon and other fish. For many migratory bird species it is an important wintering, resting and feeding ground.

The Baltic Sea is also the only sea almost entirely within the European Union. If any sea is the EU's "Mare Nostrum", it's the Baltic. The EU has a special responsibility for the Health of the Baltic.

The Baltic Sea is almost entirely cut off from the Atlantic Ocean, which means that its water remains in the sea for 25 to 30 years, along with all the pollutants it contains. The hydrographical, physical, chemical and biological conditions of the Baltic Sea makes it the second largest brackish water ecosystem on the planet, especially vulnerable to persistent, bioaccumulative and toxic substances. Hazardous chemicals are released in the marine environment through wastewater, air, urban and agricultural run-off and direct emissions from ship transport, harbour operations and offshore installations.

Over the last two or three decades, the deposition of several hazardous substances (e.g. heavy metals and pesticides) has decreased and the populations of many coastal birds, such as the Baltic white-tailed sea eagle, are recovering. WWF was instrumental in the comeback of the white-tailed sea eagle through the support of research programmes and the development of a restoration strategy. Other marine species (e.g. seals) continue to be affected by persistent contaminants that accumulate in their body tissue. Many female seals have been unable to reproduce because of PCB and dioxins pollution.

Decision-makers and citizens in the Baltic region have a long tradition of environmental stewardship. For more than 30 years, the region has been the site of bold, multi-stakeholder conservation initiatives ranging from national, regional and global policy processes to market-based mechanisms, which have often set the standard for neighbouring countries and the world.

The proposed EU chemical legislation (REACH), if further improved by the European Parliament, could make an important contribution to reducing the risk to wildlife and humans from chemicals by identifying and phasing out some of the most harmful ones. REACH also offers an opportunity to promote a sustainable, innovative and forward-looking chemical industry.

REACH gives us a once-in-a-generation opportunity to have safer chemicals and a healthier future for wildlife and people. New markets for safer products, and increased trust, should make it good news for the chemical industry too. While no one would deny that some chemicals bring significant benefits to society, unfortunately certain chemicals pose a threat to wildlife and people, and the chemical industry is inadequately regulated.

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SAFER CHEMICALS
FOR A HEALTHIER FUTURE



CONTENTS

EXECUTIVE SUMMARY	6
1. INTRODUCTION	8
2. THE BALTIC SEA – A SPECIAL ECOSYSTEM OF HIGH SENSITIVITY	9
3. WHAT ARE THE CHEMICALS OF CONCERN?	10
4. BURDENS OF THE BALTIC SEA – OLD AND NEW HAZARDOUS CHEMICALS	11
5. BALTIC COCKTAIL – WHAT LESSONS CAN BE LEARNT?	21
6. HOW WILL REACH CONTRIBUTE TO REDUCE THE CHEMICAL IMPACT ON THE BALTIC SEA?	23
7. ABOVE AND BEYOND REACH	25
8. CONCLUSIONS	26
REFERENCES	27
GLOSSARY	31
APPENDIX	35



EXECUTIVE SUMMARY

The Baltic Sea is the world's second largest body of brackish water, which is characterised by a huge catchment area and limited water exchange to the North Sea. Only a limited number of species is adapted to the low salinity of the water, thus the biodiversity is low and the ecosystem structure is based on a few vulnerable key species. The Baltic Sea is a comparably shallow sea with low water exchange, therefore pollutants from point and diffuse sources are trapped there. Furthermore, low water temperatures and ice cover cause a slow biodegradation of chemicals. These conditions make the Baltic Sea a special ecosystem of high sensitivity to pollutants, which needs special attention in current and future chemical policies.

The Swedish Food Administration recommended that women of childbearing age should limit their consumption of Baltic herring and salmon because of their toxic contamination, especially dioxins and PCBs. Fish from some parts of the Baltic Sea is so contaminated that it may not be sold within the EU. A recent study estimated that the fishing industry in the Baltic removed 31kg PCB per year in the late 1980s to early 1990s, which were probably eaten by buyers of the fish. PCBs are hormone-disrupting chemicals and due to their persistent and bioaccumulative properties still a threat. On top of this, contamination by new chemicals continues. The consequences of this multiple exposure for the fish population and marine mammals and humans are still uncertain and the subject of current research.

There is strong evidence that Baltic species are thoroughly contaminated with 'new' chemicals of concern. Perfluorinated compounds, brominated flame retardants and other man-made substances have been found in harbour porpoises, seals, white-tailed sea eagles, guillemots, salmon, sea trout and flounder. Not only a large number of chemicals are found but they are also occurring in higher concentrations than elsewhere. For example, the contamination of herring with polybrominated diphenyl ethers (PBDEs) is 5 times higher in the Baltic Sea than in the Atlantic.

Current chemical legislation has failed to protect the Baltic ecosystem and its biodiversity from the toxic threat of hazardous chemicals. The need to identify and replace the worst chemicals that damage the reproduction and development of marine species is long overdue. Now, the debate about a new EU chemicals policy gives hope for a clean Baltic.

In this study, five groups of hazardous substances: perfluorochemicals (PFCs), polybrominated flame retardants (BFRs), musks, phthalates and short chained and middle chained chlorinated paraffins were selected as representatives of 'new' hazardous substances to be regulated by the forthcoming EU chemical law REACH (Registration, Evaluation and Authorisation of Chemicals). For these substances of concern, their occurrence in the Baltic Sea Region, their toxicological effects (if known) and the delays from knowledge to action were analysed.

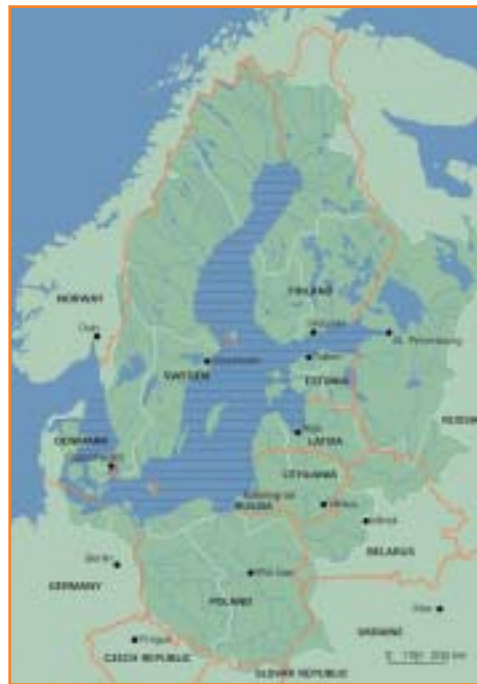
The presence of perfluorinated chemicals in Baltic harbour porpoises was at a higher level of contamination compared to species in other regions. Evidence of the risk of perfluorinated chemicals to the reproduction of animals and humans has been known by industry since the 1960s, but this knowledge was only published in 2001 after a delay of 40 years.

The potential of brominated flame retardants, especially the lower brominated diphenyl ethers (PBDEs), to bioaccumulate in fatty tissue and biomagnify up the food chain, in combination with their persistence and toxicity, make this class of chemicals of high concern to the environment and human health. The levels of polybrominated biphenyls (PBB) (banned since 2000) and PBDEs in top predators (seals, guillemots and the white-tailed sea eagle) were two to five times higher in the Baltic Sea than the North Sea and Arctic Ocean, and for herring 5 times higher.

The most common phthalate di(2-ethylhexyl) phthalate (DEHP) has been found in several freshwater and marine species, but there are no data available for wildlife of the Baltic Sea. DEHP interferes with the endocrine function and also influences sexual differentiation and accumulates especially in mussels and crustacea. Although there is concern for the occurrence and effects of those substances in Baltic Sea life, these substances are not considered in current, routine monitoring programmes. This lack of data applies to many hazardous chemicals in the Baltic.

In the Baltic Sea region high short chain (SCCPs) and medium chain (MCCPs) chlorinated paraffins levels were detected in fish (herring), ringed seal, grey seal and in birds. SCCPs and MCCPs are persistent and highly toxic to aquatic organisms. Due to their high hydrophobic character these substances strongly adsorb to sediments which can be harmful for organisms living in sediment. High levels of SCCPs and MCCPs were found in mussels, fish, marine mammals and seabird eggs in several regions.

Contamination with man-made organic chemicals in the Baltic Sea and other marine ecosystems is not only a burden of the past but an ongoing process. The cases of brominated flame retardant and the PFOS substances show that industry has failed so far to come up with its own system to ensure chemical safety. Hence, the REACH proposal is urgently needed. Once implemented, the REACH system will prevent persistent and bioaccumulative substances from further contaminating the Baltic Sea environment. By making information on substance properties and uses available, REACH provides the opportunity to derive faster and more informed predictions of the risk of substances to the marine environment. In recent times, a ban on a single compound sometimes led to increased use in another substance with equally damaging effects. With the obligation to deliver safety data in the REACH legislation there will be more information available to choose safer alternatives.





1. INTRODUCTION

The Baltic Sea's area of 366,00 km² is characterised by salt water coming in from the North East Atlantic sea and freshwater entering from rivers, rainfall and infiltration. The water exchange with the North Sea is limited, therefore the chemicals released from products and processes in a huge catchment area are "trapped" in a large brackish water ecosystem. The burden of population per m³ of water is about five times higher as, for example, in the North Sea. In addition the low water temperature and ice cover in the long winters considerably reduces the "degradation capacity" of the Baltic Sea related to hazardous substances.

In the past, the wildlife of the Baltic Sea has been severely affected by pollutants (Olsson 1994). Over the last two or three decades, the input of certain hazardous substances (e.g. heavy metals and pesticides) have decreased and the populations of many coastal birds, such as the Baltic white-tailed sea eagle, are recovering. However, other marine species continue to be affected by persistent contaminants that accumulate in their body tissue (WWF 2003a). Ringed seals and grey seals from the Baltic have been suffering from pathological impairments, including reproductive disturbances, which have resulted in a depressed reproductive capacity (Nyman et al, 2003). Also a number of fish species in the Baltic Sea have shown signs of reproductive disorder in recent decades, in particular Atlantic salmon (*Salmo salar*), sea trout (*Salmo trutta*), cod (*Gadus morhua*) and burbot (*Lota lota*) (Allsopp *et al.* 2001).

There is great uncertainty around the question of which man-made substances have contributed to these effects. Experience over the last three decades showed that generation by generation of contaminants could be detected in marine organisms, partly with an increasing concentration: brominated flame retardants, artificial fragrances like musks, plasticizers from soft plastic articles and recently the group of perfluorochemicals. The existing EU chemicals control system was obviously not able to deliver a sufficient level of protection and more of these cases could be expected in future if chemicals policy did not change.

In 2001 the EU Commission published the White Paper on the strategy for a future chemicals policy in Europe. A first legislative proposal on Registration, Evaluation, Authorisation and Restriction on Chemicals (REACH) was published in October 2003. REACH contains mechanisms aiming to prevent further accumulation of bioaccumulative and persistent substances in men and environment and subsequent toxic effects in humans and wildlife. With its REACH proposal, the EU Commission triggered a large debate between all stakeholders on the most efficient and effective way to improve chemicals safety across the supply chains in a European market. There is still no consensus between industry and governments on the basic set-up of the system.

In order to "test" the REACH mechanisms against the lessons learned from the past, five well-known groups of substances posing a threat to the Baltic Sea were selected. These cases were characterised based on available literature (chapter 4). In chapter 5 lessons learned from the past are presented. In chapter 6, the REACH system is checked against these lessons in order to establish whether the new system would be capable of preventing such cases in the future. Although REACH may be a major step towards sustainable use of chemicals it is not the solution to all problems. The need for further action beyond the current REACH proposal is illustrated in chapter 7 and chapter 8 presents some conclusions.

2. THE BALTIC SEA – A SPECIAL ECOSYSTEM OF HIGH SENSITIVITY

Due to the Baltic Sea's specific geographical, climatic and oceanographic features, it is highly sensitive to human activities, such as pollution, which takes place both at the sea and in its catchment area. The water body consists of a mixture of salt water coming in from the North East Atlantic sea and freshwater coming in from rivers, rainfall and infiltration. The Baltic Sea (including the Kattegat) shows characteristics of importance for the peculiarity of the Baltic ecosystem and its vulnerability with regard to pollution.

A) SEMI-ENCLOSED SEA WITH A LARGE CATCHMENT AREA

The Baltic Sea is a semi-enclosed sea as it is almost completely confined by the landmasses of the European continent. The exchange of saltwater with the North Sea is limited, which has several consequences for the exposure and effect of contaminants in the Baltic Sea: chemicals of a huge catchment area are “trapped” in a large brackish water ecosystem.

The Baltic Sea is characterised as relatively shallow water compared to the Atlantic Sea (average 23–50 metres, maximum depth of 459 metres). Consequently, the water volume, i.e. the dilution factor for hazardous substances, is smaller compared to other seas. Chemicals are additionally concentrated because of the limited exchange of water due to permanent and temporary stratification. Moreover, submarine elevations separate the sea floor into a series of basins (e.g. the Kattegat, Belt Sea, Baltic Proper, Bothnian Sea, Bothnian Bay and Gulf of Finland) with soft sediment seabeds (more than 200 metres thick in some areas). Each basin constitutes a distinct hydrological unit and water exchange is restricted between them. High sedimentation rates compared to that of oceans leads to an efficient input of particle-bound contaminants to sediments (HELCOM 2003).

The semi-enclosed sea has to carry a high density of human population. The demands of the 85 million people in the Baltic catchment area and a relative low water body of 25,000 km³ results in intensive burdens per unit of marine water about five times higher than, for example, in the North Sea.

B) YOUNG AND LARGE BRACKISH WATER ECOSYSTEM

During the last glaciation the Baltic Sea was sometimes a huge marine bay and sometimes a large, freshwater lake. Several ecosystems developed and were successively replaced (Plinski 1994). The current brackish water ecosystem, with a salinity varying between 0 to 20‰ (Kautsky and Andersson 1997), is at 3,000 years old relatively young. The brackish water conditions influence the composition of species in the Baltic Sea, and mainly freshwater and marine organisms with a wide salinity tolerance have been able to survive. The biodiversity is low, thus the Baltic Sea has only a few key species, i.e. species that have an important ecological role in the ecosystem. If these species decline, there are no other species taking over their functions. The key species for the Baltic Sea are, for example, the white-tailed sea eagle (*Haliaeetus albicilla*), bladderwrack (*Fucus vesiculosus*) and the blue mussel (*Mytilus edulis*) (HELCOM).

The Baltic Sea coastal habitats range from the extensive archipelagos of the central and northern Baltic to the sandy beaches and lagoons of the south and east. A survey undertaken by HELCOM (1998) identified 146 biotopes and biotope complexes, 83% of which were rated either “heavily endangered” (15%) or “endangered” (68%). The Baltic Sea is highly productive and is an important wintering, resting and feeding ground for many migratory bird species (WWF 2003a).

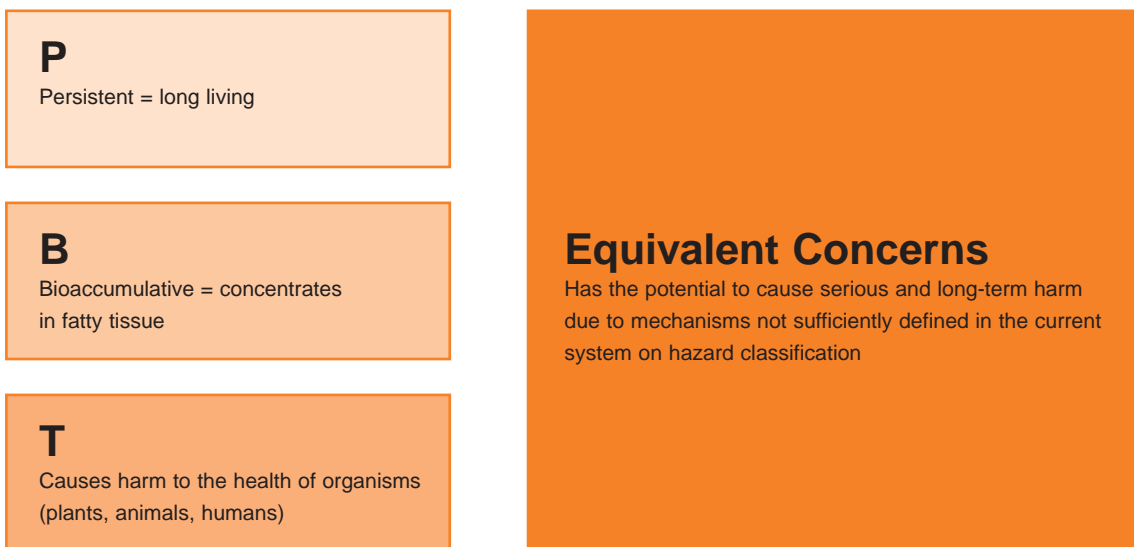
The hydrographical, physical, chemical and biological conditions of the Baltic Sea make it especially vulnerable to persistent, bioaccumulative and toxic substances. In the past, the wildlife of the Baltic Sea has been severely affected by pollutants (Olsson 1994) and other pressures. Over the last two or three decades, the deposition of several hazardous substances (e.g. heavy metals and pesticides) has decreased and the populations of many coastal birds, such as the Baltic white-tailed sea eagle, are recovering. Still, other marine species (e.g. seals) continue to be affected by persistent contaminants that accumulate in their body tissue (see chapter 4).



3. WHAT ARE THE CHEMICALS OF CONCERN?

Some chemicals are regarded as environmentally hazardous and are regulated under various (international) frameworks, e.g. within the Helsinki Convention for the protection of the Baltic Sea (HELCOM). Because of the high number of man-made chemicals entering the environment a “PBT” concept is applied to them to prioritise which chemicals need the most urgent action. **PBT** stands for **P**ersistent, **B**ioaccumulative and **T**oxic. The physical or biological degradation of some chemicals in the environment is very slow. This means that they **persist** in the environment and over time their concentration in the environment rises. A substance **bioaccumulates** if it has a tendency to build up in animal (fatty) tissue (lipophilic) and is not metabolised in the organism. Concentrations of these substances in living organisms increase during exposure. A substance is regarded as **toxic** under the PBT concept when it has the potential to cause harm to the health of organisms or humans due to the following types of hazards: very toxic to aquatic organism, toxic to human health at long-term exposure or potential to cause cancer, genetic defects, fertility loss or harm to offspring, or disrupt the endocrine system.

Figure 1: Definition of PBT-criteria



PBT substances can be transported over very long distances from the original emission source, biomagnify in wildlife via the food chain and may be additionally transferred from adults to offspring. The toxic effects of these substances in wildlife and the ecosystem often become visible after a long time and are usually irreversible. Substances which are very persistent and very bioaccumulative are classified as “**vPvB**” substances and regarded as hazardous even when adverse effects have not (yet) been demonstrated. The EU threshold values for the classification as PBT or vPvB substance are summarised in Table A1 in the Appendix.

4. BURDENS OF THE BALTIC SEA – OLD AND NEW HAZARDOUS CHEMICALS

Studies of the chemical burden of ‘new’ hazardous substances¹ in different geographical regions showed that the wildlife in the Baltic Sea belongs to the highest contaminated areas. For example the contamination of herring with PBDEs is 5 times higher in the Baltic Sea than in the Atlantic (see Table 1).

Table 1: Comparison of burdens of PBDEs in Herring in Baltic and Atlantic

Herring (*Clupea harengus*)

PBDEs	0.0-19.91 ppb fat	Baltic	Burreau <i>et al.</i> 2000
PBDEs	0.0-4.1 ppb fat	Atlantic	Burreau <i>et al.</i> 2000

Most of the scientific literature investigating hazardous substances in the Baltic Sea deals with the occurrence of chemicals belonging to past industrial practice: namely the ‘dirty dozen’, priority pollutants, which fall under the global ban of the Stockholm Convention because of their properties as persistent organic pollutants (POPs). A very detailed literature review is presented in the report *POPs in the Baltic* (Allsopp *et al.* 2001). An overview of the existing monitoring activities in the Baltic Sea states can be found in the baseline report on “Integrated monitoring of dioxins & PCBs in the Baltic Region” which was produced in the framework of the European Environment and Health Strategy (SCALE, 2004).

In contrast, the monitoring data of new chemicals is limited (HELCOM 2003). However, in the following chapters of this study a small selection of chemicals of the second and third generation which cause concern in the marine environment, with special focus on the Baltic Sea, and which will be covered by the upcoming REACH regulation, will be introduced. These chemicals are chosen as representatives also for other pollutants in the Baltic Sea. It will be demonstrated that our knowledge about the ecological importance and sensitivity of the Baltic Sea on the one hand, and the hazardous potential due to PBT properties of the substances on the other hand, raise evidence of concern for their impact in the Baltic Sea. Biocides, like tributyltin (TBT), pesticides and oil will not be considered in this study as they are regulated in other EU directives.

4.1. MULTIPLE BODY BURDEN IN BALTIC SPECIES

At the end of the 1960s the detrimental effects of metals and organochlorines on Baltic biota were observed and the increased concentrations of anthropogenic substances in biota were correlated to decreasing populations of many fish-feeding species (Olsson 1994). The eco-toxicological implications of organochlorines and some heavy metals required some effort from the various Baltic Sea states to ban or reduce the use of pesticides such as DDT, dieldrin and aldrin, to reduce or ban the use of mercury both in industrial processes and as a pesticide, and to ban the use of PCBs (Olsson 1994).

Consequently, several concentrations of hazardous substances, e.g. HCH-isomers (lindane), dioxin and PCBs, have declined in water and biota in the Baltic Sea since the 1980s, but this decrease partly levelled off in the 1990s (HELCOM 2003).

The improvement of the breeding success of marine birds (white-tailed sea eagle and guillemot) and the recovery of populations of the three seal species are thought to be related to the diminishing levels of organic contaminants. However, there are still serious concerns with regard to the level of contamination and evidence of toxic effects in biota. At the same time that levels of organochlorines, including PCBs, DDTs, PCDDs and PCDFs, were going down in wildlife from the 1970s until today, concentrations of chemicals like PBDEs have been increasing (Tanabe 2004).

Ringed seals and grey seals from the Baltic have been suffering from pathological impairments, including reproductive disturbances, which have resulted in a depressed reproductive capacity (Nyman *et al.*, 2003). Many female seals have been unable to produce pups due to uterine occlusion related to PCBs and dioxins in the environment (Reijnders, 2003). Also the immune system function is affected by the complex mixture of environmental contaminants including PCBs as was shown for Harbor seals from the Baltic (Van Loveren *et al.* 2000, De Zwart *et al.*, 1996). This is linked with increased diseases among seal populations (Olsson *et al.*, 1994). The chromosome survey of seals in the Baltic Sea in 1998-1992 revealed possible mutagenic effects caused by chemical pollutants (Hongell, 1996).

¹ The term “new” means recently discovered in the environment and not a new substance only recently placed on the market.

Also the contamination of Baltic fish is alarming. The Swedish Food Administration recommended that women of childbearing age should limit their consumption of Baltic herring and salmon due to dioxins, furans and PCB contamination. Some of the Baltic fatty fish do not comply with the maximum level requirement of the EU and would therefore be excluded from the diet, a measure which could have a negative health impact. Consequently, for a transitional period ending on the 31 December 2006, Sweden and Finland have been authorised, to place on the domestic market fish from the Baltic region with higher dioxin levels. This allowance has been granted provided that a system is put in place to ensure that consumers are fully informed about the situation, and particularly about the risks associated with dioxin for identified vulnerable groups of the population (HELCOM 2004). Recently a study showed that the standing stock of the most abundant fish species in the Baltic Sea was a sink for 260 kg of PCBs in the late 1980s to early 1990s, and that the fisheries removed 31kg PCB per year (Mackenzie *et al.* 2004) which ends up in the consumers. Taking into consideration the endocrine, neurotoxicological and reproductive effects of these chemicals, the EU developed a strategy with the aim to reduce the human consumption of furans, dioxins and PCBs lower than 14 pg WHO-TEQ per kg bodyweight per week (EU 2001).

A number of fish species in the Baltic Sea have shown signs of reproductive disorder in recent decades, in particular Atlantic salmon (*Salmo salar*), sea trout (*Salmo trutta*), cod (*Gadus morhua*) and burbot (*Lota lota*) (Allsopp *et al.* 2001).

The chemical burden of important Baltic fish species in Table 2 demonstrates that Baltic Sea wildlife has been threatened by a mixture of “old” and “new” hazardous chemicals in the last ten years. It also demonstrates the persistent and bioaccumulative potential. The knowledge of the effects and the critical body burden for substance mixtures is limited. However, e.g. the “new” chemical polybrominated diphenyl ethers (PBDEs) are structurally similar to PCBs, chlorinated compounds with similar physical and chemical properties (Tanabe 2004). Therefore, it can be assumed that contamination with these long-living compounds that keep on accumulating over time may lead to serious impacts on reproduction, and threatens the biodiversity of the Baltic fish species.

Table 2: Overview of the multiple chemical body burden of “old” and “new” chemicals in selected fish species of the Baltic Sea, Kattegat and Skagerrak.

Species	Substance measured	Concentration	Reference
Flounder (<i>Platyichthis flesus</i>)	Dioxins (PCDDs) and Furans (PCDFs)	8.4 ppt iTEQ fat	Falandysz <i>et al.</i> 1997d
	PCBs	4800 – 9400 ppt fat	Falandysz <i>et al.</i> 1998 a
	PCBs	910 – 9400 ppb fat	Falandysz <i>et al.</i> 1997c
	DDT	1500 – 1700 ppb fat	Falandysz <i>et al.</i> 1998
	DDT	1600 ppb fat	Falandysz <i>et al.</i> 1999b
	PCNs	36 – 83 ppb fat	Falandysz <i>et al.</i> 1997g
Cod (<i>Gadus morhua</i>)	Dioxins (PCDDs) and Furans (PCDFs)	7.8 ppt iTEQ fat	Falandysz <i>et al.</i> 1997d
	PCB	1400 ppb fat	Falandysz <i>et al.</i> 1997c
	DDT	1200 ppb fat	Falandysz <i>et al.</i> 1999b
	HCB	60 ppb wwt in liver	Falandysz 2000
Atlantic salmon (<i>Salmo salar</i>)	Dioxins (PCDDs) and Furans (PCDFs)	16.7 – 84.9 ppt iTEQ fat	Becher <i>et al.</i> 1998
	PBDE	0.4-45.8 ppb fat	Burreau <i>et al.</i> 2000
	PBDE	0.4-7.6 ppb fat	Burreau <i>et al.</i> 2000
	Sum PCBs	1462 – 3090 ppb fat	Atuma <i>et al.</i> 1998a
	p,p'DDE	25 – 56 ppb kg wwt	Fromberg <i>et al.</i> 2000
	HCB	1.4 ppb wwt	Falandysz 2000
Perch (<i>Perca fluviatilis</i>)	2,2',4,4'-tetrabromodiphenylether	6.4-10 ppb fat	Olsson <i>et al.</i> 1999
	PCBs	570 – 6400 ppb fat	Olsson <i>et al.</i> 1999; Falandysz <i>et al.</i> 1998a
	DDT	180 – 1500 ppb fat	Olsson <i>et al.</i> 1999; Falandysz <i>et al.</i> 1999b
	αHCH	4.7 – 126 ppb fat	Olsson <i>et al.</i> 1999
	βHCH	5.4 – 63 ppb fat	Olsson <i>et al.</i> 1999

HCB	0.85 ppb wwt	Falandysz 2000
HCB	3.8 – 15 ppb fat	Olsson <i>et al.</i> 1999
Dieldrin	4.3 – 17 ppb fat	Olsson <i>et al.</i> 1999
PCNs	19 – 69 ppb	Falandysz <i>et al.</i> 1997g
Herring (<i>Clupea harengus</i>)		
Dioxins (PCDDs) and Furans (PCDFs)	250 ppb fat, in oil	Korhonen & Vartiainen 1997
Dioxins (PCDDs) and Furans (PCDFs)	81 ppt iTEQ fat	Falandysz <i>et al.</i> 1997d
Dioxins (PCDDs) and Furans (PCDFs)	<1 – 3.6 ppt iTEQ fwt	Korhonen & Vartiainen 1997
PCBs	<1-3 ppt iTEQ fwt	Korhonen Vartiainen 1997
PCBs	1 ppm fat	Korhonen <i>et al.</i> 1995
DDT	280 – 1300 ppb fat	Roots 1995 ; Falandysz <i>et al.</i> 1999b
HCB	3.7 ppb wwt	Falandysz <i>et al.</i> 2000
SCCP*	1,400 µg/kg lipid, in muscle (5.4% fat)	Jansson <i>et al.</i> 1993
SCCP*	1,500 µg/kg lipid, in muscle (4.4% fat)	Jansson <i>et al.</i> 1993
SCCP*	1,600 µg/kg lipid, in muscle (3.2% fat)	Jansson <i>et al.</i> 1993
PBDEs	0.0-19.91 ppb fat	Burreau <i>et al.</i> 2000
Pike (<i>Esox lucius</i>)		
Dioxins (PCDDs) and Furans (PCDFs)	0.5 ppt iTEQ fwt	Korhonen & Vartiainen 1997
Dioxins (PCDDs) and Furans (PCDFs)	1 ppt iTEQ fwt	Korhonen & Vartiainen 1997

*Refers to chlorinated paraffins with 6-16 chlorine atoms and so may contain chlorinated paraffins other than C10-13

4.2. PERFLUOROCTANE SULFONATE (PFOS) AND PERFLUOROCTANOIC ACID (PFOA)

Perfluorochemicals (PFCs) in wildlife and the environment

The occurrence of PFCs in the environment was first recognised in the 1970s and has continuously increased since then (BMU 2004). Studies suggest that PFCs, in particular PFOS, are spread worldwide in wildlife and humans (Giesy and Kannan 2001; Kannan *et al.* 2001a, 2002b; Olsen *et al.* 1999). Even in remote arctic areas such as the Arctic Ocean, a detectable amount of fluorinated organochemicals could be quantified in the blood or organs, such as liver and kidney, of wildlife (e.g. fish, birds and marine mammals) (Giesy and Kannan 2001). PFOA and PFOS do not accumulate in the fatty tissue as most of the POPs, but in liver, kidney and bladder which consequently leads to the biomagnification in the food-chain (BMU 2004). This assumption was confirmed by field studies, where top predators showed the highest contamination of PFOS and PFOA (BMU 2004). Further, accumulation patterns seem to be different from those observed for other organohalogen compounds, like PCBs and DDTs, since no clear relationship with age and/or sex could be determined (Van de Vijver *et al.* 2004). Also, freshwater sources are affected by the contamination of perfluorinated compounds: Perfluorinated compounds were recently detected for the first time in the Great Lakes, one-fifth of the Earth's fresh water and the source of drinking water for more than 7 million people in Illinois and 33 million others in the United States and Canada (Hawthorne 2004).

PFCs in the wildlife of the Baltic Sea

The threat due to bioaccumulation of PFCs in marine mammals of the Baltic Sea was detected in several comparative studies. In one study, 247 tissue samples from 15 species of marine mammals collected from North American coastal waters, the Arctic and the northern Baltic Sea were analysed for PFOS. PFOS was detected in liver and blood of marine mammals from most locations including those from Arctic waters. The highest concentrations of PFOS were found in the liver and blood of a bottlenose dolphin from Sarasota Bay, Florida, and in a ringed seal from the Northern Baltic Sea (Bothnian Sea) (Kannan *et al.* 2001). PFOS and related fluorinated hydrocarbons were also analysed in the livers of ringed seals (*Phoca hispida*), gray seals (*Halichoerus grypus*), white-tailed sea eagles (*Haliaeetus albicilla*), and Atlantic salmon (*Salmo salar*) from coastal areas of the Baltic Sea and other marine mammals (see Table 3), fish and birds of the Mediterranean Sea (Kannan *et al.* 2002). PFOS was detected in all of the wildlife species analyzed. Concentrations of PFOS in livers of seals were 5.5 times greater than those in corresponding blood samples. Trend analysis of PFOS concentrations in the livers of white-tailed sea eagles collected from eastern Germany and Poland since 1979 indicated an increase in concentrations during the 1990s.

PFOS is a widespread contaminant in wildlife from the Baltic and the Mediterranean Seas, while PFOA was detected only in certain locations, indicating their sporadic spatial distribution (Kannan *et al.* 2002). The perfluorochemical burden of the marine mammals of the Baltic Sea was confirmed in a baseline study of one of the smallest of all whale species, harbour porpoises (*Phocoena phocoena*) from northern Europe. The concentration range of PFOS in the German Baltic Sea was significantly higher compared to Iceland and Norway, corresponding to previous reports on increased pollution levels in this area (Van de Vijver *et al.* 2004) (see Table 3). Although there is evidence for concern, PFOS and PFOA are not considered in current monitoring programmes in the Baltic Sea (Monitoring Base, June 2004).

Table 3: Overview of the chemical burden of mammals in the Baltic Sea with the substances selected in this report

Species	Substance measured	Concentration	Reference
Harbour porpoise	PFOS	534 ng/g	Van de Vijer <i>et al.</i> 2004
	PFOA	< 62 ng/g wet weight in liver (detection limit)	Van de Vijer <i>et al.</i> 2004
Ringed seal (<i>Phoca hispida</i>)	PFOS	92 – 242 ng/ml in blood, 130 – 1100	Kannan <i>et al.</i> 2001; Kannan <i>et al.</i> 2002
	PFOS	16 – 230 ng/ml in plasma	Giesy and Kannan 2001
	PBDEs	0.32 – 0.38 ppm fat in blubber	Andersson & Wartanian 1992, Haglund <i>et al.</i> 1997
Grey seal (<i>Halichoerus grypus</i>)	PFOS	14-76 ng/ml in plasma	Giesy & Kannan 2001
	PFOS	25.5 – 43.9 ng/ ml blood; 148 – 1140 ng/g wet weight in liver	Kannan <i>et al.</i> 2001; Kannan <i>et al.</i> 2002
	PBDEs	0.28 ppm fat in blubber of juvenils	Andersson & Wartanian 1992
	PBDEs	0.468 ppm fat in blubber	Haglund <i>et al.</i> 1997
	SCCP*	280 µg/kg lipid, in blubber (74% fat)	Jansson <i>et al.</i> 1993

Investigations about substance specific effects with regard to marine or Baltic organisms are not available in the scientific literature. Thus the prediction of effects to the Baltic wildlife are still uncertain.

Toxicological effects of PFCs

PFOS was found to accumulate in the brain tissue of rats, particularly the hypothalamus, suggesting that PFOS crosses the blood-brain barrier and may interfere with reproductive hormones through the pituitary-hypothalamus process that stimulates their production (Austin *et al.* 2003). Recent laboratory studies with PFOA involving rats show low birth weight, small pituitary gland, altered maternal care behaviour, high pup mortality, and significant changes in the brain, liver, spleen, thymus, adrenal gland, kidney, prostate, testes and epididymides (Thayer *et al.* 2004). Several studies indicate that PFOA increases oestrogen and leads to testosterone dysfunction in males. There is even more evidence that PFOA, as well as chemicals that metabolise to PFOS and PFOA, leads to underactive thyroid activity. Thyroid dysfunction during pregnancy can lead to many developmental problems, including faulty brain development and neurological and behavioural problems that affect not only infants and young animals (or humans), but continue into adulthood. The US EPA considers both PFOS and PFOA to be a carcinogen in animals, with testicular, pancreatic, mammary, thyroid and liver tumours most frequently seen in exposed rats (BMU 2004). All studies to date indicate perfluorinated compounds damage the immune system (WWF 2003b). PFCs were first identified in human blood in the end of the 1960s due to better analytical methods. A study conducted in 2003 on PFOS and PFOA in the US Red Cross blood banks estimated average concentrations in humans to be 30-40 parts per billion (ppb), with males having higher levels (Olsen *et al.* 2003). PFOS has also been identified in the sera of non-industrially exposed humans (Kannan 2001a). Studies on affected workers showed a significant correlation between exposition of PFOS and bladder cancer and PFOA and prostate cancer (BMU 2004).

SUBSTANCE PROPERTIES AND USE

There are several types of perfluorinated compounds. But many of them appear to break down in the environment or the body to one of two chemicals, perfluorooctane sulfonate (PFOS) or perfluorooctanoic acid (PFOA). Neither PFOS nor PFOA appears to break down further (BMU 2004). Because of these properties, PFOS and PFOA have emerged over the past four years as an important class of persistent global pollutants referred to as perfluorochemicals (PFCs). PFCs are chains of fully fluorinated carbon atoms of varying lengths, yielding chemicals that are extremely resistant to heat, UV-radiation, chemical stress, and repel both water and oil.

Because of these properties PFCs have been widely used since the 1950s by industry as surfactants and emulsifiers and in commercial products, including stain or water protectors for carpet, textiles, auto interiors, camping gear and leather; food packaging; floor polishes; photographic film; shampoos; dental cleaners; inert pesticide ingredients and lubricants for bicycles.

PFOA manufacturing aid is used to produce polytetrafluoroethylene, a compound more commonly recognized as Teflon and Gore-Tex. Teflon and Scotchgard have been promoted as modern marvels for their ability to keep food from sticking to pots and fast-food packaging, repel stains on carpets and furniture and make water roll off coats and clothing (Hawthorne 2004).

Studies on animals showed that PFOS and PFOA bioaccumulate and are not metabolised. They have a long half-life time: PFOS between 7.5 days up to 21 years in vertebrates and PFOA from 1.5 – 13 years in humans (BMU 2004).

For more details about properties and use of PFOS and PFOA see Appendix (Table A2).

Delays from knowledge and action

Industry records show that manufacturers have been concerned about the safety of chemicals since the early 1960s (Hawthorne 2004). But with a time delay of more than 40 years, the data on the evidence of PFOS, PFOA and other PFCs in human blood were published in 2001 (BMU 2004). In July 2004 the US Environmental Protection Agency accused DuPont Co. of withholding for more than 20 years of evidence that a perfluorinated compound used to make Teflon endangered its workers and the public. Company memos show that the compound was passed in 1981 from a pregnant employee to her fetus, but DuPont allegedly failed to report the information to the EPA as required under federal law. The company has denied the allegations (Hawthorne 2004).

4.3. POLYBROMINATED FLAME RETARDANTS

BFRs in wildlife and the environment

PBDEs and related compounds entered the focus of environmental interest because of their detection at significant levels in air, water, fish, marine and terrestrial mammals as well as in human breast milk and blood (Tanabe 2004). PBBs and PBDEs have been found to contaminate the blubber of sperm whales (*Physeter macrocephalus*), which normally stay and feed in deep water, indicating that these compounds have reached the deep waters of the Atlantic (de Boer *et al.* 1998). This indicates the stability and long-range transportation of the substance (OSPAR 2001).

BFRs in the wildlife of the Baltic Sea

PBB and PBDE were analysed in samples of top predators, seals, guillemots and the white-tailed sea eagle, collected in the Baltic Sea, the North Sea and the Arctic Ocean. The levels of PBB and PBDE were two to five times higher in samples from the Baltic than in samples from other places, possibly indicating local sources (Jansson & Asplund 1987). A study of the contamination of PBDEs in seal blubber showed that the levels in grey seal and ringed seal collected from the Swedish Baltic coast (see Table 3) were slightly higher than levels reported in juvenile harbour seals from the Swedish west coast (Andersson & Wartanian 1992). In addition, this study reported the presence of methoxy-PBDEs in seal blubber. The source of methoxy-PBDEs is currently unknown but multiple sources are possible, including breakdown products (metabolites) of PBDEs, microbial degradation of PBDEs and a variety of industrial sources (Allsopp *et al.* 2001). BFR have also been found in birds in the Baltic catchment: DecaBDE in eggs of peregrine falcons breeding in Sweden (Sellström 2001) and PBDE in guillemot (see Table 4) (Sellström *et al.* 2003). Higher concentrations of specific PBDE congeners were also found in salmon (*Salmo salar*) and herring (*Clupea harengus*) from the Baltic Sea in comparison to those caught in the Atlantic (see Table 1) (Burreau *et al.* 2000). PBDEs were also detected in all samples of perch (*Perca fluviatilis*) caught in the Gulf of Riga, on the eastern coast of the Baltic Sea (Olsson *et al.* 1990). BFRs are considered in the Cooperative Monitoring Programme of the Baltic Sea (HELCOM COMBINE) since 1992 (Monitoring Base, June 2004).

Table 4: PBDE and SCCP contamination in birds of the Baltic catchment area

Species	Substance measured	Concentration	Location	Reference
Osprey	SCCP	530 µg/kg lipid in muscle	Pooled sample in and around Sweden, 1982-198	Jansson <i>et al.</i> , 1993
Guillemot	PBDEs	1.0 - 2700 ng/ g lipid in eggs	Baltic Sea	Sellström <i>et al.</i> 2003

Investigations about substance specific effects with regard to marine or Baltic organisms are not available in the scientific literature. Thus the prediction of effects to the Baltic wildlife are still uncertain.

BFRs in humans worldwide and in the Baltic Sea region

PBDEs were detected in human breast milk in the US, Japan and Europe. Exposure routes were assumed to be uptake via food, especially



fish and shellfish, through nursing and by exposure to electronic devices containing PBDEs. Researchers recently reported levels of PBDEs in the breast milk of forty-seven women from US / Texas who had an average level of 73.9 ng/g lipid. Such levels are sharply higher than those found in European studies (Schechter *et al.* 2003). A study on the human exposure to PBDE through the diet (fish, vegetables and meat) and the levels in human milk of nursing woman in Japan showed a strong positive relationship between PBDE concentrations in human milk and dietary intake of fish and shellfish. The results of this study of food products commonly consumed in Japan and the levels found in nursing women raise concerns about low-level PBDE contamination of fish and other foods intended for human consumption (Ohta *et al.* 2002).

PBDEs have also been found to contaminate human breast milk in Sweden (Darnerud *et al.*, 1998). The concentration of PBDEs in human milk from the Stockholm region has increased exponentially over the period 1972 to 1997, showing a doubling of levels every five years (Norén & Meironyté, 2000). Levels in 1972 were 0.07 ng/g lipid or ppb (sum PCDEs) and increased to 4.01 ng/g lipid (ppb) in 1997. The amount of PBDEs accounted for about 1% of the total of organohalogen contaminants present in breast milk. PBDEs are not produced in Sweden but are imported for flame retardant applications and in goods containing flame retardants (Allsopp *et al.* 2001).

PBDEs were also present in the blood of Swedish office workers who use computers, and also in hospital cleaners and workers at an electronics-dismantling plant. The highest levels were in the latter, demonstrating the role of electrical goods in the contamination (Sjordin *et al.*, 1999). Increasing concentrations of PBDEs were also detected in samples of whole blood from Germany between 1985 and 1999. Levels increased from a median of 3.075 to 4.687 ng/g lipid (ppb). The study noted that levels were generally higher than levels previously determined in Sweden (Schröter-Kermani *et al.*, 2000).

Toxicological effects of BFRs

In laboratory studies with mammals (rats and / or mice) some BFRs were associated with developmental neurotoxicity (Eriksson *et al.*, 1998), disruption of the thyroid system (Darnerud & Thuvander, 1998; Hallgren & Darnerud, 1998), effects on pubertal development (Birnbaum & Staskal 2004), behavioural effects, memory and learning (Eriksson *et al.*, 1998). Certain BFRs were highly toxic to aquatic animals (crustaceans) (Birnbaum & Staskal 2004). Besides their potential to cause thyroid disruptions, PBDEs (Darnerud & Thuvander, 1998; Hallgren & Darnerud, 1998), (PentaDBE [OSPAR 2001], PBB [OSPAR 2001]) can also cause liver cancer in rats and mice (Tanabe 2004).

SUBSTANCE PROPERTIES AND USE

Brominated flame retardants (BFRs) are a diverse group of chemicals. They all contain bromine and are all used to prevent consumer items from catching fire. They are added to many products, including computers, TVs and household textiles.

Two substances – decabromodiphenyl ether (DecaDBE) and Tetrabromobisphenol A (TBBP-A) account for about 50% of world use of brominated flame retardants. Most concern has been expressed over polybrominated biphenyls (PBB), which have been used, but due to its PCB-like properties, production was stopped in September 2000. Two other polybrominated diphenyl ethers (PBDEs) – octabromodiphenyl ether (OctaDBE) and pentabromodiphenyl ether (PentaDBE) – have been banned in the EU since August 2004 (EU Directive 2003/ 11/ EC).

The capacity of BFRs, especially PBDEs, to bioaccumulate in fatty tissue and biomagnify up the food chain, in combination with their persistence and toxicity, make this class of chemicals of high concern to the environment and human health (OSPAR 2001). Because of the chemical similarity of PBDEs to PCBs (and some other POPs), it has been suggested by several authors that all these compounds may be toxic, having teratogenic, mutagenic and carcinogenic effects on wildlife (Tanabe 2004).

The annual world production and usage of PBDEs in 2001 was 67,440 tons. The worldwide demand was mainly distributed between North America (47%), Asia (37%) and Europe (12%).

For more details about the properties and use of Deca-DBE see Table A3 in Appendix.

4.4. MUSK FRAGRANCES

Musks in wildlife and the environment

Due to their dispersive use and the relatively low rate of degradation, many musk ingredients have been detected in environmental samples and human milk and tissue (OSPAR 2000). In samples of fish and crustaceans taken from various freshwater and marine waters throughout Europe, musk xylene and musk ketone were detectable in nearly all the samples analysed. The highest reported concentrations were for fish from the river Stör in Schleswig Holstein, Germany. Musk xylene concentrations were consistently higher than musk ketone concentrations,

except in some river fish (Allsopp *et al.* 2001). The polycyclic musks HHCB and AHTN are recognised as ubiquitous in the aquatic environment at levels exceeding those of musk xylene (OSPAR 2000).

Mussels and shrimp from the North Sea and the Baltic Sea contained low concentrations of musk xylene and musk ketone (10-50 ppb fat). The results suggested that the primary sources for these compounds were communal wastewater treatment plants rather than industrial sources (Rimkus & Wolf 1995). The assumption was confirmed by a recent investigation (Kallenborn *et al.*, 2001) of synthetic musk levels, including musk xylene and musk ketone, in marine fish samples collected in the vicinity of densely populated areas in Norway. Sampling sites around Trondheim and Tromsø were selected, close to municipal sewage treatment plants, assuming that high levels would be found close to sewage treatment outlets. Possible primary industrial sources were covered by samples from the Oslofjord and Grenland fjord areas. The highest concentration of musk ketone was found in Atlantic cod liver samples from the densely populated Oslo area (42 µg/kg lipid in liver). The highest musk xylene level (178 µg/kg lipid) was found in haddock from the inner harbour of Trondheim. Compared with conventional organochlorine contaminants, synthetic musks were found in about the same concentration ranges as polychlorinated biphenyls and pesticides. The relatively high concentrations found demonstrate impressively the still underestimated environmental potential of this contaminant class (Kallenborn *et al.* 2001).

Musks in the wildlife of the Baltic Sea

The data of musk xylene and musk ketone in the biota of the Baltic Sea are limited. Musk xylene and musk ketone are not covered in continuous monitoring programmes in the Baltic Sea (Monitoring Base, June 2004). A study of the impact of musk ketone on reproduction in zebrafish (*Danio rerio*) clearly shows that musk ketone negatively affects reproduction and early life-stage survival in zebrafish (Carlsson 2000). Musk ketone showed high toxicity in tests with marine crustacea (see Table A5 in Appendix).

Investigations about substance specific effects with regard to marine or Baltic organisms are not available in the scientific literature. Thus the prediction of effects to the Baltic wildlife are still uncertain.

Musks in humans

The nitro musks, musk xylene and musk ketone, and the polycyclic musks have been detected in human milk and fat since the early 1990s. The concentrations found in human milk are similar to wildlife rates for musk xylene (0.01 – 1.220 mg/kg fat), higher than for musk ketone (0.01 – 0.29 mg/kg fat) (OSPAR 2001), which have a similar concentration than polycyclic musks (0.1 – 0.36 mg/kg fat) (Eschke *et al.* 1995b; Kypke-Hutter 1995). No essential differences were observed between synthetic musk concentrations in human milk and human fat. According to more recent European data, a decline in concentrations of musk xylene and musk ketone seems to be likely (Waizenegger *et al.* 1998), presumably as a consequence of restrictions in the use of these compounds in laundry detergents and cosmetics and a decline in production. For musk xylene, oral intake by eating fish was considered to be negligible compared to direct exposure through the use of cosmetic products (Kokot-Helbling *et al.* 1995 cited in OSPAR 2000). Reviews of previously published experiments and estimates confirmed dermal uptake from cosmetics and fabrics to be the main exposure route for human beings (Rimkus 1997; Kevekordes *et al.* 1999).

SUBSTANCE PROPERTIES AND USE

Musk ingredients are substances with a typical musky odour, which are widely used in cosmetics, detergents, fabric softeners and other household products. Two groups of substances with similar substantive properties but otherwise completely different chemical structure are used: nitro musks (musk xylene, musk ketone, moskene and musk tibetene) and polycyclic musks (such as HHCB and AHTN). Musk xylene, musk ketone, AHTN and HHCB represent about 95% of the market (OSPAR 2000). The nitro-musks are highly persistent and bioaccumulative for which the toxic effects in the environment are still unknown.

The use of musk xylene and musk ketone has decreased from 298 t/a in 1992 (OSPAR 2000) to 67 t/a in year 2000 in the EU (ECB 2003). On the one hand this can be regarded as a success, on the other hand, the increased use of polycyclic musks as substitutes is not a success at all, as the polycyclic musks also have bioaccumulative and persistent properties (OSPAR 2000).

For more details about the properties and use of musk xylene, musk ketone and HHCB, see Tables A4-A6 in Appendix.

4.5. PHTHALATES

Phthalates in wildlife and the environment

Phthalates are lipophilic and have a slow degradation which leads to a bioaccumulation in sediments and biota. They were detected in plants, freshwater and marine invertebrates, fish and mammals. Contamination of DEHP were found in several fish, freshwater and marine



species, like flounder, sticklebacks, roach, and pike in the North Sea and in Finland (Draft RAR ECB 2001). High DEHP concentration has been cited in unspecified shark samples (7100 µg/kg) and in salmon in Canada (up to 16,400 µg/kg [lipid weight]) and in the blubber from a common seal pup (*Phoca vitulina*) (10,600 µg/kg [lipid weight]). No collection site was stated for the seal (Draft RAR ECB 2001).

Phthalates in the wildlife of the Baltic Sea

In the scientific literature the number of estimated or analysed concentrations for DEHP in the marine environment is limited (OSPAR 2002). Although the high bioaccumulative potential of DEHP is recognised, especially for mussels and crustaceans and the knowledge of the reprotoxic metabolite MEHP, there seem to be no data on DEHP or MEHP in Baltic species available. Phthalates are not considered in continuous monitoring programmes in the Baltic Sea (Monitoring Base, June 2004). Thus, the burden of the Baltic Sea species to phthalates is uncertain. There is a strong need to integrate phthalates in monitoring programmes.

Investigations about substance specific effects with regard to marine or Baltic organisms are not available in the scientific literature. Thus the prediction of effects to the Baltic wildlife are still uncertain.

Phthalates in humans

Both humans and wildlife can be exposed to various phthalates. Because flexible vinyl products made with DEHP are so pervasive that the plasticiser is a regular contaminant in food products, ambient air, and drinking water, which are all potential exposure sources for humans. Fatty foods such as oils, milk, cheese, meat, and fish typically contain considerably higher DEHP residues than other foods because DEHP readily dissolves in fat (Růžičková *et al.* 2004). High concern is raised about the exposure of pregnant women and children to contaminated medical devices and milk. Brock *et al.* (2002) measured the level of several phthalate metabolites in the urine of 19 children living in the Imperial Valley, California. They found phthalates in all children examined. Children absorb chemicals more efficiently, process them more slowly and eliminate them less efficiently than adults (Růžičková *et al.* 2004). Blood samples from members of the European Parliament found DEHP to be among the most common contaminants in the human body.

The EU has banned DEHP from cosmetics, personal care products and certain toys. But the EU continues to allow the use of DEHP in medical devices, which are used on sick infants and other vulnerable populations, and which can result in far higher levels of exposure. The EU has drafted a DEHP Risk Assessment and Risk Reduction Strategy recommending that pregnant women and infants are immediately protected from DEHP-containing medical de-vices, and a directive concerning medical products that would restrict phthalate exposure from medical devices when alternatives are available. But chemical industry pressure has prevented the finalisation of these protective measures so far (Růžičková *et al.* 2004).

Toxicological effects of phthalates

Some phthalates appear to exert endocrine-disrupting effects, and can act against the male hormone, androgen, through pathways other than binding to androgen or oestrogen receptors. Numerous laboratory studies underpin the concern. For example, a study has shown that DEHP BBP, and DINP administered to pregnant rats induced feminized breasts in the male offspring, as well as other reproductive malformations, including small testes in the case of the DEHP and BBP (Gray *et al.* 2000). US researchers recently reported the effects of DEHP on Leydig cells (testosterone-producing cells in the testes) in rats (Akingbemi *et al.* 2003).

While there is little research on the effects of phthalates on wildlife per se, some studies suggest that there may be serious consequences for both wildlife and humans. Of particular concern is phthalate exposure in pregnant females: some researchers have proposed that the anti-androgenic properties of phthalates *might* be linked to testicular dysgenesis syndrome, the manifestations of which range from birth defects in males, including undescended testes, to low sperm counts and testicular cancer (Sharpe 2003).

SUBSTANCE PROPERTIES AND USE

Phthalates are a group of chemicals used as softeners in a variety of plastic products, including the ubiquitous polyvinyl chloride (PVC). Products containing phthalates include medical devices (e.g. blood bags), building products (e.g. insulation of cables and wires), car products (e.g. seats) and children's products (e.g. teething rings, squeeze toys, clothing and rainwear). Concern about children's exposure to phthalates prompted the EU to ban six types of phthalate softeners in PVC toys designed to be mouthed by children under three years of age. Europe is a significant producer and exporter of plasticisers. In 1993 manufacturers in Europe produced 46% of the world demand of plasticisers and consumed 37%.

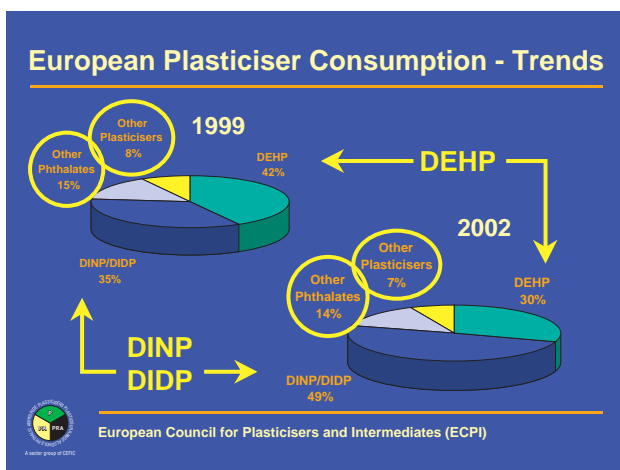
The most common phthalate is di-(2-ethylhexyl)phthalate (DEHP), which comprises half of all phthalates produced in western Europe (WWF 2003b), with a production volume of 595,000 tons per year (in western Europe 1997) (Draft RAR ECB 2001). 90% of DEHP consumed in Europe is used as a plasticiser in polymers, mainly PVC. DEHP is persistent, bioaccumulates and can interfere with the endocrine function and also influence sexual differentiation (e.g. Gray *et al.*, 1999; Jones *et al.*, 1993). Its persistency is characterised by a very slow photo-oxidation of DEHP in aquatic environments and when DEHP is degraded in the environment mono (2-ethylhexyl) phthalate (MEHP) is the major metabolite. This gives cause for concern, as MEHP has proven to be reprotoxic in studies with mammals and the substance could be responsible for many of the effects seen in toxicity studies with DEHP (Draft RAR ECB 2001).

For more details about properties and use see Table A7 in Appendix.

Delays from knowledge to action

The first indications that DEHP may affect reproduction were published in the late 1970s and early 1980s by Gray *et al.* Environmental studies on the widespread occurrence of DEHP in river ecosystems (Rhine and Elbe) became available in the second half of the 1980s and the beginning of the 1990s (Jacobs 1988, Furtmann 1993). However it was not before 2002, when the decision of the European Commission and the Member States to classify DEHP “toxic to reproduction” triggered a rapid decline in DEHP market shares (see Figure 2).

Figure 2: DEHP - delay from knowledge to action



When did phthalates become an issue and why?

- 1980:** Testicular effects of DEHP observed by GRAY *et al.*
- 1982:** DEHP identified as carcinogenic in rodents by NTP/IARC
- 1983:** Release of DEHP from toys investigated by CPSC
- Mid 1990s:** "Phthalates shock the food industry"
- from mid 70s:** DEHP was found in various environmental media
- from mid 80s:** Developmental and fertility effects in rodents
- 1997:** The release of phthalates from toys was investigated by the Danish authorities and by Greenpeace
- 2001:** DEHP classified reproductive toxicant category II in EU
- 2002:** Ongoing discussion on level of risk

4.6. SHORT CHAINED AND MIDDLE CHAINED CHLORINATED PARAFFINS (SCCPs AND MCCPS)

SCCPs and MCCPs in wildlife and the environment

High levels of SCCP and MCCP have been measured in mussels, fish, marine mammals and seabird eggs in several regions: in seals from Iceland and walrus from Western Greenland, in beluga from the St Lawrence River in Canada, beluga collected in different Arctic places, in fish and mussels in the Wyre estuary close to a paraffin production site, in grey seal in the United Kingdom (HELCOM 2002). High concentrations of chlorinated paraffins (C10 to C20) were detected in seabird eggs, in heron and guillemot, and in herring-gull. The contamination of the biota in the Arctic and its formula group profiles, with a higher proportions of the lower chlorinated congeners (C15-C17), indicates the long-range atmospheric transport of SCCPs and MCCPs, far away from the emission source (HELCOM 2002).

SCCPs and MCCPs in the wildlife of the Baltic Sea

SCCP and MCCP levels were detected in fish (herring), ringed seal, grey seal and in birds [heron, herring-gull (UK) and osprey (Sweden)] (see Table 6 and Table 8). Several studies about the contamination of wildlife with chlorinated paraffins (C6-C16) were conducted in Sweden in 1986 and 1987. High concentrations were analysed in rabbit and moose, but also in reindeer suet, in osprey, and in freshwater whitefish. In Arctic char muscle chlorinated paraffins were found (HELCOM 2002).

Although the chemical properties of SCCPs and MCCs are very worrying from the environmental point of view, the amount of data on the body burden of Baltic species is limited. SCCPs and MCCPs are not subject to current monitoring programmes in the Baltic Sea (Monitoring Base, June 2004), thus the threat of the Baltic Sea due to SCCPs and MCCPs is uncertain and needs further observation.



Investigations about substance specific effects with regard to marine or Baltic organisms are not available in the scientific literature. Thus the prediction of effects to the Baltic wildlife are still uncertain.

Toxicological effects of SCCPs and MCCPs

In laboratory studies SCCPs and MCCPs indicated a high toxicity to aquatic organisms. Due to its high hydrophobic character the substances strongly adsorb to sediments which can be harmful for in sediment-living organisms (ECB 2002). Tests with mammals showed tumours of the liver, thyroid and kidney (male rats only) in a lifetime carcinogenic study (HELCOM 2002). Further, short chain length chlorinated paraffin produced developmental effects in rats at a dose which also caused maternal toxicity (ECB 2002). The human health risk assessment has raised concerns over the presence of MCCPs in human breast milk (CSF 2001). In human breast milk from Inuit women living in communities on Hudson Strait in Northern Quebec, mean levels of 13 µg/kg of SCCP were measured on a lipid basis (HELCOM 2002). Further studies on the contamination of human breast milk with MCCPs detected 7 µg/kg in mothers' milk (Greenpeace 1995).

SUBSTANCE PROPERTIES AND USE

Short chain (C10-13) (SCCPs) and medium chain (C14-17) (MCCPs) chlorinated paraffins are a mixture of different carbon chain lengths and different degrees of chlorination. Short chain chlorinated paraffins (SCCPs) are present in preparations of MCCPs and consequently any assessment of MCCPs needs to consider SCCPs. SCCPs and MCCPs are viscous liquids of very low volatility which are not hydrolysed in water and are not readily or inherently biodegradable. They have a high log Kow value (4.39 to 8.69 and 5.47 to 8.21), indicating a high potential for bioaccumulation. High bioconcentration factors for SCCPs, ranging from 1,000 to 50,000 for whole body, with high values for individual tissues, have been reported with a variety of freshwater and marine organisms. High toxicity to the aquatic environment was measured in toxicity tests with SCCPs and MCCPs (see Tables A8 and A9 in Appendix). These PBT characteristics, including the estimated atmospheric half-life of 1.9-7.2 days for SCCP, raises concerns with regard to long-range transport. High levels of SCCP in biological samples from the Arctic could indicate that these chemicals are effectively transported over long distances (HELCOM 2002).

For more details about properties and use of SCCPs/MCCPs see Tables A8 and A9 in Appendix.

Delays from knowledge to action

Occurrences of chlorinated paraffins in the environment were first reported in the early 1980s. The properties of SCCPs were more or less known at the same time (e.g. Madley *et al.* 1983). It took about 20 years before regulatory action at EU level was taken. However a large German car manufacturer, VW, had already begun to develop alternative solutions for SCCPs in cutting fluids in the beginning of the 90s. The German producer of SCCPs, Hoechst AG, ceased its production in 1995, and also in 1995 the OSPAR states adopted a recommendation to phase out all applications of SCCPs. But the EU regulatory process (including risk assessment) was slow enough to delay action for years further.



5. BALTIC COCKTAIL – WHAT LESSONS CAN BE LEARNT?

The case studies of harmful substances in the Baltic Sea in chapter 4 indicate the environmental consequences resulting from an ineffective chemicals' management in Europe. The high levels of contaminants in the Baltic show that the ecosystem is seriously exposed to pollutants, but also that we do not know enough about their effects. The 'old' chemicals are still harmful, especially for the marine organisms higher up the food chain and for the 'new' chemicals increasing evidence of reproductive or immunotoxic damage is found. In the following chapter, some conclusions are presented which then lead to the arguments in Chapter 6 why the REACH regulation is urgently needed for the health of the Baltic ecosystem.

5.1. ENVIRONMENTAL OBSERVATION HAS NOT PREVENTED DAMAGE IN THE BALTIC SEA

Observation and monitoring of the Baltic ecosystem up to now has been very important to detect the occurrence of man-made substances in the marine environment and to identify their adverse effects. It has raised awareness of the problem among policy-makers, the public and industry. However, analytical measurements of chemicals and effect monitoring are insufficient to prevent adverse effects since in general these effects only become visible after a long time and it is difficult to link effects in the environment to single substances and their sources. Today we know, for example, that young grey seals in the Baltic suffer from chronic intestinal ulcers. However, there is still great uncertainty on the factors causing these effects.

5.2. WE KNOW ENOUGH TO PREVENT FURTHER DAMAGE

All substances comparable to the five examples presented here (in terms of chemical-physical properties, degradability, potential to bioaccumulate, market volume and use patterns) can very likely be identified in the environment, when someone starts looking. The mechanisms related to the environmental fate of substances are well understood. Prevention is a question of systematic assessment of substance properties and their use patterns, management and political will. Organic industrial chemicals that do not readily mineralise in the environment tend to accumulate in sediments and biota if the rate of losses from products and processes exceeds the degradation and dilution capacity in the environment. In the Baltic Sea especially, with its low water exchange rate and low temperatures, researchers can detect the fingerprints of the past as well as the current stock of substances existing in the European market.

5.3. EFFECTIVE CHEMICALS' MANAGEMENT LONG OVERDUE

Substances used in articles will continue to find their way into the Baltic Sea environment from diffuse losses in small quantities. In case that the market volume is sufficiently high and degradability in the environment is low, a long-term stocking-up process takes place. In particular, losses from products with a long life-time will continue to contaminate the environment for decades after use in manufacturing has ceased. This will add up to the already very high load of pollutants in the Baltic Sea through emissions from the past decades.

5.4. SUBSTANCES OF EQUIVALENT CONCERN

There are not only those substances meeting the EU criteria for PBT or vPvB that are found in water, sediments and organisms higher up in the food chain. Also prevalent are substances for which the amount entering into the environment is higher than the degradation rate. The increasing concentrations of hormone-disrupting phthalates in the environment is a good example for this phenomenon (see chapter 4.5). A European market volume of about 1 million tons per year to be used in various kinds of soft plastic products results in considerable diffuse losses to the environment (leaching and volatilisation). Due to their poor water solubility phthalates adsorb to sediments and tend to be trapped in environmental compartments with poor oxygen supply. Hence they persist in the environment, although they are readily biodegradable in a screening test and hence do not meet the PBT criteria.

This indicates the general problem, that degradability under laboratory standard conditions does not necessarily ensure that a substance will sufficiently quickly degrade in the environment. This is in particular true for poorly water-soluble substances released into the marine environment in high amounts (e.g. DEHP), or substances which are released into waters at a temperature far below 20°C, the standard temperature of laboratory tests. In such cases a simulation test would be needed to reflect real conditions.

5.5. ENVIRONMENTAL MONITORING ROUTINES DID NOT LEAD TO ACTION

When xenobiotic chemicals have been identified in organisms, in many cases it took a long time before the major sources could be identified. The occurrence of penta and hexabrominated diphenylether in salmon and marine mammals was, for example, difficult to explain through European production and use figures presented by industry in the EU risk assessment process. Thus risk management may fail even if a problem is acknowledged, even by industry itself, but when relevant information on uses is missing. In other cases, environmental observation under public responsibility completely failed to identify one of the most recent issues. In the PFOS case, it was the producer announcing a withdrawal before measurement in the European environment had begun. The first public indication that PFOS and PFOA were problematic



came in May 2000 when 3M, the primary global manufacturer of many perfluoroalkanesulfonates and PFOA, announced plans to phase out by the end of 2001 the production of perfluorooctanyl chemistry that underpinned their extremely successful Scotchgard™ and Scotchban™ product lines (3M 2000). 3M took this course of action, under pressure from the US Environmental Protection Agency (EPA) (Barboza 2000) after learning that PFOS, PFOA and other perfluorooctanysulfonate degradation products of chemicals used in Scotchgard™ and Scotchban™ could readily be found in blood samples from the general population in the United States and / or wildlife specimens from across the globe (WWF 2003b).

5.6. POTENTIAL TO BIOACCUMULATE AND CHRONIC TOXICITY OF SUBSTANCES OFTEN UNDERESTIMATED

Substances with poor water solubility (< 1 mg/l) are difficult to test, since the potential to bioaccumulate and chronic aquatic toxicity can be easily underestimated under laboratory test conditions. Only if the real concentration in water under test conditions (which may be much lower than the amount of substance put into the testing vessel) is measured, the effects and bioconcentration can be properly determined. Much time has been spent, for example, to determine correct bioconcentration factors during the risk assessment of medium chain chlorinated paraffins or DEHP.

5.7. PHASE OUT OF PERSISTENT AND BIOACCUMULATIVE SUBSTANCES NEEDED

The only way to prevent further adverse impacts is to cease any releases of persistent and bioaccumulating substances into the marine environment. Organisms in the Baltic Sea, especially those reaching an age of many years to decades old, are exposed to bioaccumulative substance for their whole life. It is impossible to predict the effects on organisms exposed to the substances during their whole lifetime. This applies in particular to modes of action not well understood, for example interference with the endocrine system. Hence, there is no toxic threshold for persistent and bioaccumulating substances to determine a safe level of exposure or a sustainable emission rate into the Baltic Sea.

5.8. SAFE MOLECULAR SIZE OR MOLECULAR WEIGHT CANNOT BE DETERMINED

In theory, large organic moleculars (> 15 Angström or MW > 800) should not be able to enter into the food chain. However, the detection of decabromodiphenylether in birds' eggs indicates that such substances enter into the food chain even though they are not expected to do so. Therefore, any strategy to prevent persistent substances from entering the food chain by simply increasing molecular size or weight should be considered with extreme caution.

5.9. SUBSTITUTION NEEDS PROPER ASSESSMENT OF THE ALTERNATIVES

Brominated flame retardants are a good example for the failure of substitution strategies not based on a systematic and comparative assessment of substances. Although PCBs were already identified as a problem in the early 1970s, the production of polybrominated biphenyls (PBBs) for flame retardant use was begun in the beginning of the 1970s and continued until the second half of the 1990s. These types of flame retardant were later substituted with brominated diphenylethers which again did not turn out to be an environmentally sound solution. A similar example was the substitution of musk xylene and musk keton with polycyclic musks which still tend to persist and bioaccumulate in the environment.



6. HOW WILL REACH CONTRIBUTE TO REDUCE THE CHEMICAL IMPACT ON THE BALTIC SEA?

The proposed REACH system with the areas of registration, evaluation and authorisation (and restrictions) is crucial for the improvement of the current EU system on chemical control. The REACH legislation will provide - if strengthened - a suitable framework to prevent persistent and bioaccumulative substances from being used and released into the environment, including the Baltic Sea. This applies in particular to the following REACH mechanisms.

NEW CHEMICAL POLICY IN THE EU

In 2001 the EU Commission published the White Paper on the strategy for the future chemicals policy in Europe. A first legislative proposal on Registration, Evaluation, Authorisation and Restriction on Chemicals (REACH) was published in October 2003. It consolidates the seven main European chemicals directives (and regulations) with all their amendments over the last 35 years into one consistent framework for all chemicals. This includes a registration of all substances produced and marketed in the EU in amounts > 1 t per year. At the same time, REACH introduces a shift of paradigm to chemicals management in the EU. In the future, the producers and importers of substances will be responsible for carrying out a safety assessment for all uses of their products as a pre-requisite to maintain marketing. The authorities will concentrate on assisting industry to make this system work, including spot checks on compliance. For very hazardous substances (e.g persistent, bioaccumulative and toxic substances) the Commission and the Member States can set up an authorisation requirement. This means that all uses will be forbidden from a certain point in time unless the producer or user can demonstrate that the substance is adequately controlled or that no alternative is available. For other substances, the authorities will carry out their own assessments only in cases when the market volume is so high and the use patterns are so broad that, even though the single producers carry out proper safety assessments, the combined emissions from all sources may pose a risk.

With its REACH proposal, the EU Commission triggered a large debate among all stakeholders on the most efficient and effective way to improve chemical safety across supply chains in a European market. Still there is no consensus between industry and governments on the basic set-up of the system.

Parallel to the new chemicals policy, the EU Commission works on a strategy to protect and conserve the marine environment. Also, harmonised environmental quality criteria and control strategies for priority substances in freshwater and coastal waters are currently under development in the context of the EU Water Framework Directive.

6.1. INFORMATION ON USES OF HAZARDOUS CHEMICALS WILL BE AVAILABLE

Under REACH, the importer or producer of a substance is obliged to consider the uses of his product further down the supply chain and to define the conditions of safe use. The formulators of preparations and the industrial or professional users of preparations are obliged to I) comply with the generic use and to implement the conditions of use as communicated by their suppliers or II) to take responsibility for their own safety assessment if they act differently. In such cases, the formulator or industrial user must send a notification to the Agency. Thereby, in theory, uses not registered by the manufacturer will nevertheless become known to the authorities. This will be an important mechanism to identify, for example, open uses of persistent and bioaccumulative substances not supported by the producer which may trigger an immediate authorisation requirement for this particular substance.

6.2. COMPANIES PLACING HAZARDOUS SUBSTANCES ON THE MARKET WILL BECOME IDENTIFIABLE

All substances currently existing in the marketing at a volume of > 1 t/y will be registered and can be traced back to their manufacturer and importer (except for substances imported in articles). Also the uses existing in the market will be identified based on the manufacturer or importer registration mechanism or the downstream user notification mechanism. This makes information available to the national authorities and the new Chemicals Agency.

However, in the current REACH proposal there is still room for improvement. Up to now the obligation to publish the substance name, the producer's or importer's name and the corresponding hazard information together on the internet is not included in the draft text. This is a particular obstacle to gaining a more transparent chemicals market.

6.3. SAFETY ASSESSMENTS

Producers or importers placing substances with a volume of more than 10 t/a on the market will have to assess the degradability of a substance, the potential for bioaccumulation and the (eco)toxicity. Thus, persistent substances liable to bioaccumulate will be identified during the chemicals



safety assessment and can be handled accordingly. Very persistent and very bioaccumulative substances will be regarded as of very high concern even if their toxicity has not been established yet.

However, in the current REACH proposal there is still room for improvement: all releases of hazardous substances from imported articles will be covered by the system only after 2017, much too late to meet the generation goal of the marine conventions. This is, for example, most relevant to flame retardants, plasticisers, dyestuffs or textile finishing chemicals (like Scotchgard™ for example) in imported goods. Apart from that, for substances below < 10 t, REACH information on biodegradability and a systematic assessment on liability to bioaccumulate is not required. Recent experience shows for example, that there are several single substances within the PFOS/PFOA family which are placed on the market in volumes <10 t but all together nevertheless pose a long-term environmental risk.

6.4. MANUFACTURER IS OBLIGED TO DEFINE TYPE AND CONDITIONS OF SAFE USE

If a manufacturer or user intends to maintain marketing and use of a substance despite its dangerous properties, it is up to him to demonstrate that safe use throughout the substance's whole life cycle is possible. Modelling of exposure to predict risks is used here rather than measurement in the environment after decades of further use.

However, in the current REACH proposal there is still room for improvement. The instruments and procedures for exposure assessment under REACH need to be developed during the next few years and it is important to meet a sufficient level of precaution when designing these instruments. It is important that the current risk assessment methodology for the marine environment as agreed among EU Member States is maintained in the chemicals safety assessment under REACH, and carried out under the responsibility of industry. This includes for example the use of an extra safety factor for the effects assessment of substances addressing the uncertainty with regard to the sensitivity of organisms specialised to live under marine conditions, e.g. in the Baltic.

6.5. AUTHORISATION FOR SUBSTANCES PBT AND vPvB SUBSTANCES

For substances of very high concern like PBTs and vPvB which are included in annex XIII of REACH, the manufacturer or user has to apply for the allowance to maintain the use of the substance. Otherwise it is automatically forbidden to further produce or use the substance. This will make the mechanisms to restrict the marketing and use of very hazardous substances much more effective.

However, in the current REACH proposal there is still room for improvement. The current REACH proposal permits even substances of very high concern to be further used if "adequate control" is ensured. The draft regulation translates this in annex 1 to the phrase "minimising exposure" which is as unclear as "adequate control". To be in line with the Marine Conventions, the Draft Marine Strategy of the EU and the Water Framework Directive, "adequate control" under REACH can only mean no releases at all to the environment from the substance's entire life cycle. If REACH sets stringent requirements here, in most cases manufacturers and users would not take the effort to meet such a demanding requirement or to apply for authorisation based on socio-economic justifications. They will rather seek to develop less hazardous substitutes. The substitution mechanism will only work if the requirements for the "adequate control" are sufficiently demanding.

6.6. COMMUNICATE THE CONDITIONS OF SAFE USE TO CUSTOMERS

The knowledge needed to comply with the REACH requirements is distributed over different levels of the supply chain - substance producers, formulators and industrial / professional user of preparations (UBA, 2004). The producer or importer of a substance is obliged to define the safe condition of use and communicate these to his customer. In order to use the existing knowledge in the most beneficial way for all three stakeholder groups, new ways to organise the vertical flow of information up and down the supply chain and the horizontal data sharing needs to be organised. When industry successfully manages this challenge information existing in the chains will be linked, and the development of a common language on risks between substance manufacturers, formulators and professional users can be expected.

Since every manufacturer of substances and preparations will be obliged to define the safe conditions of use further down the supply chain he will be forced to consider which substances would best suit best his customers' conditions of use. Since the substances registered in the REACH system will have standard information on their environmental fate available, alternatives with similar technical performance can be compared to each other. This can be regarded as the second substitution mechanism in REACH.



7. ABOVE AND BEYOND REACH

Some of the drivers for contamination of the Baltic Sea cannot be influenced through REACH. There are still a number of issues to be addressed by other means and instruments. This concerns three different areas:

Firstly, REACH only addresses risks from defined, single substances. Metabolites, reaction products or other mixtures of undefined substances (e.g. dioxins, furans, PAH) occurring in many production processes, are outside the scope of REACH. Prevention and control of hazardous compounds in such emissions remains an important task of the national permit systems for production sites.

Secondly, Russia will not fall under the REACH regime, which means that about 20% of the market around the Baltic will continue to work outside REACH. Nevertheless, all chemicals traded between Russia and the EU countries (including new Member States) will be covered by the REACH registration requirement.

Thirdly, four of the states bordering the Baltic Sea have only recently joined the EU and still need to work hard to implement all the new requirements and structures. This applies to authorities as well as to companies, who have however already become well aware of the importance of chemical control and their roles in it. In the three Baltic States for example, intensive information and training programmes for companies and authorities have been carried out during the last eight years (Baltic Environmental Forum 2004a). In a way, small countries like Estonia, Latvia and Lithuania are going to develop an institutional setup that may be more efficient in the end than the bureaucratic systems developed over decades in some of the large EU 15 states.

7.1. FURTHER RESEARCH NEEDED

Safety assessment under REACH is based on a set of pre-defined standard information requirements, including standard tests. These standard requirements reflect what has been learnt about chemicals during the last 40 years. However, new modes of action or new types of effects will not all be discovered through the information requirements in annexes V to VIII of REACH. Surprises about (eco)toxic effects will be still possible. Thus, further research is needed to better understand to which extent marine organisms are more sensitive to chemicals or show other effects compared to freshwater organisms. However the regular assessment of degradability and liability to bioaccumulate form a safety net, in that substances will not accumulate in the environment for many years before they are discovered to cause new types of serious effects.

7.2. IMPROVEMENTS ON SUBSTANCES IN IMPORTED ARTICLES NEEDED IN REACH TEXT

Losses from imported articles will start to be quantified by the importer only after 2017. This is a major drawback for meeting the 2020 Deadline of the Marine Conventions. No vPvB assessment is anticipated even then, since the notification requirement refers to substances classified as dangerous in the traditional sense of Directive 67/548 [(eco)toxicity is established]. Since, for example, electronic goods and textiles are mainly imported to the EU, REACH will fail to control a relevant mass flow of chemicals released from such articles during use. Therefore the REACH proposal should be modified in a way that after the first registration period the Agency already starts to identify those substances which may be present in articles in high amounts.

7.3. ENOUGH CAPACITY IN NATIONAL AUTHORITIES CRUCIAL

Under REACH every manufacturer will carry out a safety assessment for their own market. Assessment of the cumulative EU market volume and its potential impact remains a task for the authorities. It is therefore important that there will be still enough capacity available in the national authorities of the individual Member States. The same applies to the other important tasks of the REACH system (e.g. evaluation).

7.4. INTERACTION OF DIFFERENT SUBSTANCES OR FORMING OF METABOLITES

The REACH system has been designed to assess the safety of single substances. Neither cumulative effects of different substances nor metabolites and degradation products are included in the assessments under REACH. This is a problem for the evaluation of substances forming more toxic metabolites than the parent compound. Moreover, humans and the environment are always exposed to many compounds, and additive or other combination effects are rarely considered so far.



7.5. ENVIRONMENTAL LIABILITY STILL WEAK

Liability will continue to be unrelated to environmental risks. In particular, the occurrence of man-made substances in the marine environment (sediment, biota or water) will not trigger any serious liability claims. Hence, a strong regulatory system and appropriate enforcement strategies are needed to increase the motivation of companies to replace hazardous substances by safer alternatives.

7.6. MOTIVATION OF ACTORS CRUCIAL

Implementation will continue to depend on the motivation of the actors. This includes robust and sufficiently simple standard routines under REACH, clever inspection strategies by the authorities, a demand for safer products expressed by consumers and a sufficient frequency of “contamination cases” discussed in the public.

8. CONCLUSIONS

More knowledge on substance properties is as important as knowledge on how to prevent losses of substances into the environment. Both redesign of substances and better management in the supply chains will contribute to a cleaner Baltic Sea. Contamination with man-made organic chemicals in the Baltic Sea and other marine ecosystems is not only a burden of the past but an ongoing process. The cases of brominated flame retardant and the PFOS substances show that industry has failed so far to come up with its own system to ensure chemical safety. Hence, the REACH proposal is urgently needed. Once implemented, the REACH system will prevent persistent and bioaccumulative substances from further contaminating the Baltic Sea environment. The same applies to substances likely to accumulate due to the high amounts released into the Baltic Sea without being persistent (e.g. DEHP) or bioaccumulative (e.g. Decabromodiphenylether) in a strict sense.

By making information on substance properties and uses available, REACH provides the opportunity to derive faster and more informed prediction of the risk of substances to the marine environment. In recent times, a ban on a single compound sometimes led to increased use in another substance with equally damaging effects. With the obligation to deliver safety data in the REACH legislation there will be more information available to choose safer alternatives.

In particular, substitution will be facilitated since the different options among substances to provide a certain functionality will become comparable with regard to their risks. However, assessing the risk of a chemical to cause adverse effects in the marine environment is still connected with high uncertainty. Further research on marine ecosystems is therefore necessary in order to reduce uncertainty in the extrapolation from freshwater data to marine data.

The current monitoring programmes in the Baltic Sea mainly focus on well-known hazardous substances. For four of the five groups of hazardous substances addressed in the current report, analytical data are not available although these substances are of high concern. Also, screening surveys are needed as a kind of safety net for gaps in the current risk assessment methods. However, monitoring programmes should always be combined with less expensive strategies to obtain information. For example, based on information on market volume, use patterns and intrinsic properties of a substance, environmental concentrations can be easily predicted.

In order to make REACH a success, both elements are needed: I) information on biodegradability and liability to bioaccumulate and II) exposure assessment for all substances. Hence, the REACH proposal for substances with market volumes below 10 t/a needs to be amended accordingly. In addition, it is absolutely crucial that the requirements related to articles will not be removed from the REACH proposal. Without the inclusion of imported articles one major source of losses of substances into the water environment (e.g. textiles, building materials) will be missed out in the system. REACH will only address risks due to defined single substances. Hence, the efforts to improve integrated pollution prevention and control at production sites, transport vehicles and any kind of combustion techniques cannot be replaced through a REACH system.



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GLOSSARY

Acute toxicity: Damage (fatal or not fatal), resulting from (continuous or interrupted) exposure to a substance or a mixture of different substances over a time period which is shorter than a generation of the affected organisms (from minutes to several days). Normally the duration of environment-related acute test systems remains under 96h.

Anaerobic degradability: Degradation of a substance taking place with very low oxygen concentrations (lack). Anaerobic degradability provides for conclusions on the behaviour of substances in sewage plants (sludge) or sediments.

BAT (Best Available Technique): BAT describes the environment related “state of the art., at European level. Techniques which are already realised in industry are described.

BCF (Bio-concentration factor): The relation between the substance concentration in an organism and surrounding waters which is determined via experiments (OECD 305 A-E).

Bioaccumulation: Accumulation of a substance in an organism resulting in concentrations in the organisms exceeding those in the medium in which it lives. Bioaccumulation covers the taking up of the substance from the surrounding medium (bioconcentration) and via food (biomagnification).

Carcinogeny: Carcinogenic effect of substances and preparations via inhalation, swallowing or skin contact, as well as the increase of cancer cases.

Classification of substances: Assessment of a substance according to the dangerous properties on the basis of Europe-wide harmonised criteria and standardised test methods. Depending on the dangerous properties the substance is assigned, one or more risk phrases (R-phrases). The classification must not automatically lead to a corresponding labelling as “dangerous substance”.

Chronic toxicity: Non-fatal damage, resulting from a continuous exposure to a substance or a mixture of different substances over a time period which is not shorter than a generation cycle of the affected organisms.

Combined effects: additive (sum of single effects), synergies (enhancement of single effects) and antagonistic effects (single effects either cancel out or attenuate each other).

Compounds: Polymer granulate containing additives which are used in plastic processing. The content of additives is in accordance with the use concentration.

Dangerous chemicals: According to §19 of the ChemG (*German Law on Dangerous Chemicals*), dangerous chemicals are: dangerous chemicals and preparations in the sense of the EU directive 67/548; substances and preparations with other chronic toxic properties; substances, preparations and articles from which dangerous substances and preparations may be formed or released during production and use.

Diffuse losses: Emission of mobile substances from finished products and preparations outside installations and other closed uses or disposal systems. The entry of the substance into the environment is not determined by point sources, meaning that production or processing is not the predominant source of emissions.

EC₅₀ (Effective concentration): Concentration of a substance at which 50% of the test organisms exhibit the examined effect.

EINECS (European Inventory of Existing Chemical Substances): List of substances which were available on the European market before 18th September 1981 (approx. 100 000 entries).

ELINCS (European List of Notified Chemical Substances): EU register of substances registered after 18th September 1981 (approx. 3000 entries).

Endocrine disrupting substances: Substances foreign to the body which cause changes in the body’s hormone system and thereby adverse effects for the organisms or their offspring. There is a general definition for marine systems: substances which directly or indirectly interfere with the hormone system of organisms, by showing hormone-like effects, or enzyme systems which steer the hormonal balance.

Existing substances: Substances which have been produced and/or marketed in the European Union before September 1981.

Finished product: Product manufactured from one or more different materials (fibres, polymer matrix, metal grids, glass), whose properties are mainly determined by the material construction and surface structure. Chemical substances and preparations can be contained in the form of additives or contamination.

Exposure: Exposure of an organism to substances or to the chemical composition of environmental media.

Formulator: Industrial or commercial company which manufactures preparations by mixing individual substances.

Half-life: Time period in which half of a quantity of a substance is biologically degraded or physically or chemically destroyed.

HELCOM: Helsinki Commission on Marine Protection in the Baltic Sea, foundation of the co-operation between the nine countries bordering on the Baltic Sea.

Inherent degradability [= potential (bio)degradability]: Classification of a substance meeting the pass level in standardised degradation tests (OECD 302 A-C). It is assumed that these substances may be primarily or totally degraded under aerobic conditions in the aquatic environment.

Labelling of substances: Labelling of substances or preparations as dangerous with respective symbols and R-phrases and S-phrases. Not all dangerous properties of a substance automatically lead to labelling.

LC₅₀ (Lethal concentration): Concentration of a substance which is lethal for 50% of the test organisms.

Lifecycle of a product: Covers the generation of raw materials, manufacture, marketing, use and disposal of a product.

log Pow: Logarithm of the octanol-water partitioning coefficients; substances which have a log $P_{ow} > 3$ have a tendency to accumulate in organisms.

Mineralization: Total degradation of an organic substance to carbon dioxide, water and inorganic salts.

Mutagenicity: Effect of a substance causing heritable genetic damage resulting in phenotypic characteristics of an organism. This means any permanent change in the amount or the structure of genetic material in an organism which has an observable influence on the function or appearance of the organism.

Natural background values: Natural concentrations of non-synthetic substances in the environment.

NOEC (No observed effect concentration): Highest concentration of a substance which does not cause an observable effect in long-term tests.

Notified new substances: Substances which have been placed onto the European market after September 1981. These chemicals must be registered in accordance with the Chemical legislation.

OSPARCOM: Oslo and Paris Commission which coordinates the co-operation of the contracting parties in the frame of the OSPAR Convention for the "Protection of the north-east Atlantic from pollution" (by ships, aeroplanes and from land). Until 1996 the Paris-Commission (PARCOM) and the Oslo Commission (OSCOM) were the precedent organisations.

PEC (Predicted Environmental Concentration): Environmental concentrations for certain areas of the environment are calculated on the basis of production and market volumes, use patterns and physical-chemical properties of substances. This is done with the aid of mathematical models which simulate the substance transport and emissions.

Persistence: Durability of a substance in the environment. For a specific environmental medium, persistence is the property of a substance which determines the length of its stay in this medium before it is physically removed, chemically altered or biologically degraded.

PNEC (Predicted No-Effect Concentration): On the basis of acute or chronic effect concentrations established in laboratory tests, concentrations are calculated using safety margins, for which no effects are expected to occur in the environment.

Preparation: Mixtures, combinations and solutions consisting of two or more substances including polymer-containing preparations such as "masterbatches" or "compounds".

Primary degradation: Changes in the chemical structure of a substance which can be traced back to biodegradation. Occasionally the primary degradation simply leads to the formation of biologically stable metabolites. The percentage of total degradation achieved would be correspondingly small.

Product: Substances, preparations, semi-finished or finished products, complexly constituted consumer products or other goods, which are industrially manufactured with the purpose of being marketed.

POP (Persistent Organic Pollutant): Organic substances which are persistent in the environment, which can accumulate, have toxic properties and which can be transported over long distances.

PTBs: Substances which are persistent, toxic and bioaccumulative at the same time.

Ready degradability: Classification of substances which meet the pass level (70% degradation of organic hydrocarbon DOC, 60% formation of CO_2/O_2) in standard degradation tests (OECD 301 A-D, OECD 306). It is assumed that these substances are subject to a quick total degradation (mineralization) in an aquatic environment with sufficient oxygen supply.

Reproductive toxicity: Harmful effects on reproductive functions or capacity as well as non-inheritable effects on progeny caused by substances. The effects are categorised under the two main headings "effects on male or female fertility" and "developmental toxicity".

R-Phrase (Risk Phrase): Characterisation of dangerous properties (e.g. "toxic for aquatic organisms" = R51) of substances according to EU Directive 67/548/EEC

Simulation test on degradability: Test method with which degradation under environmental conditions is simulated (water-sediment system, temperature, bacterial society and concentrations typical for a specific habitat).

Sub-acute toxicity: A not immediately fatal damage, resulting from a continuous or interrupted exposure to a substance or mixture of different substances over a time period which is shorter than a generation of the affected organisms.

Substance: Chemical elements and their compounds in natural form or manufactured in a production process, including the necessary additives for guaranteeing product stability and contamination which cannot be avoided during manufacture, with the exception of solvents, which can be extracted from the substance without impairing its stability or changing its composition.

Teratogenicity: substance property causing structural defects to unborn life. Apart from the dose of a teratogenic substance the time when the embryo is exposed to it plays a role (see also reproductive toxicity).

TGD (Technical Guidance Document): Technical rules for the implementation of the EU Directive on the risk assessment for New Substances (notified after September 1981), the Regulation 1488/94 on the risk assessment of Existing Substances and for risk assessments for biocides under the EU Directive 98/8.

Toxicity: The potential of a substance to cause harmful effects on an organism and its offspring. Toxic effects are, for example, decrease of survival rates, growth or reproduction as well as carcinogenicity, mutagenicity, teratogenicity or other adverse effects modulated through the endocrine system.



Vapour pressure: Inherent pressure under which a substance evaporates from a solid or a liquid phase. The vapour pressure increases with increasing temperature and characterises the volatility of a substance.

Volatility: Transition of a substance from a solid or liquid state into the atmosphere via evaporation.

ANNEX

AHTN	a polycyclic musk compound
BBP	Benzbutylphthalat
BCF	Bioconcentration Factor
BFR	Brominated flame retardant
CPSC	US Consumer Product Safety Commission
DDT	Dichlordiphenyltrichlorethan
DeBDPE	Decabromodiphenylether
DEHP	Di(2-ethyl-hexyl)phthalate
DIDP	Diisodecylphthalat
DINP	Diisononylphthalat
DOC	Dissolved organic carbon
DT₅₀	Time necessary for a 50% degradation of a substance (half-life)
EC₅₀	Concentration of a substance in testing at which 50% of the test organisms show the adverse effects
ECB	European Chemicals Bureau
GDP	Gross Domestic Product
GHS	Globally Harmonised System (on hazard classification and labelling)
HCB	Hexachlorobenzene
HCH	Hexachlorocyclohexane
HELCOM	Helsinki Commission
HHCB	a polycyclic musk compound
IARC	International Agency for Research on Cancer
LC₅₀	Concentration of a substance in testing at which 50% of the test organisms die (lethal concentration)
Log K_{ow}	Logarithm of the octanol-water partitioning coefficient of a substance
MCCP	Medium chain chlorinated paraffins
MEHP	Mono (2-ethylhexyl) Phthalate
MW	Molecular weight
NOEC	No Observed Effect Concentration = highest concentration in testing at which no effect could be observed
NTP	US National Toxicology Program
OctaDBE	Octabromodiphenyl Ether
OSPAR	Oslo and Paris Commission
PAH	Polyaromatic hydrocarbons
PBBs	Polybrominated Biphenylethers
PBDEs	Polybrominated Diphenyl Ethers
PBT	Substances, which are persistent, bioaccumulative and toxic
PCBs	Polychlorinated Biphenyls
PCDD, PCDF	Polychlorinated Dibenzo-dioxin, Polychlorinated dibenzofuran
PCN	Polychlorinated naphthalene
PCP	Pentachlorophenol
PentaBDE	Pentabromodiphenylether
PFCAs	Perfluorocarbon acids
PFCs	Perfluoro chemicals
PFOA	Perfluorooctanoic acid
PFOS	Perfluorooctane sulfonate
PNEC	Predicted No Effect Concentration
POPs	Persistent Organic Pollutants
Ppb	Parts per billion
PVC	Polyvinylchloride



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R45	Risk phrase: May cause cancer
R46	Risk phrase: May cause heritable genetic damage
R48	Risk phrase: Danger of serious damage to health by prolonged exposure
R60	Risk phrase: May impair fertility
R61	Risk phrase: May cause harm to the unborn child
R62	Risk phrase: Possible risk of impaired fertility
R63	Risk phrase: Possible risk of harm to the unborn child
R64	Risk phrase: May cause harm to breastfed babies
REACH	Registration, Evaluation, Authorisation of Chemicals
SCCP	Short chain chlorinated paraffins
TBBA	Tetrabrombisphenol A
TBT	Tributyl tin
TGD	Technical Guidance Document
US EPA	U.S. Environmental Protection Agency
vPvB	Substances which are very persistent and very bioaccumulative
WHO-TEQ	World Health Organisation-Toxicity equivalent

APPENDIX

Table A1: EU classification criteria for PBTs and vPvBs

		PBT	vPvB
Persistence	t _{1/2} marine	> 60 d <i>or</i>	> 60 d
	t _{1/2} freshwater	> 40 d <i>or</i>	> 60 d
	t _{1/2} marine sediment	> 180 d <i>or</i>	> 180 d
	t _{1/2} freshwater sediment	> 120 d <i>or</i>	> 180 d
Bioaccumulation	BCF	> 2000 <i>or</i>	> 5000
	Log K _{ow}	> 4.5	> 5
Human Toxicity	Certain types of long-term toxic effects	R45, R46, R48, R60, R61, R62, R63, R64 or equivalent concern	
Aquatic Toxicity	long-term NOEC	< 0.01 mg/l	
	short-term L(E)C ₅₀	< 0.1 mg/l	

- The Persistence of a substance is expressed in the number of days (d) it takes in a simulation test that half of the substances degrade into metabolites. This time is called half-life (t_{1/2}).
- The liability to bioaccumulate is expressed by a bioconcentration factor (BCF) (concentration of the substance in water in comparison to the concentration of the substance in the tissue of the exposed organism) or its distribution in octanol against water (log K_{ow}).
- Aquatic toxicity is measured in short term or long-term bioassays. The concentration where 50% of tested organism show an effect in short-term bioassays are expressed as EC₅₀ or LC₅₀ (mortality). According to the EU risk assessment procedure long-term tests are used to derive NOEC, which is the highest tested concentration at which no effect can be observed. In a chronic toxicity test the effect of the substance on the reproduction (life-cycle) of the organism is assessed.

The HELCOM criteria for identification of hazardous substances are a bit more protective. The trigger for liability to bioaccumulate is log Pow 4 and aquatic toxicity is 1 mg/l.

Table A2: Short profile of PFCs substances (based on BMU 2004)

	PFOA and PFOS
Abiotic degradation	- No photolysis, hydrolysis degradation; nor oxidative or reductive transformation.
Biodegradation	- Neither aerobic nor anaerobic biodegradation.
Log K_{ow}	- Due to the amphiphilic (hydrobic and lipophobic) character, the n-octanol-water partitioning coefficient is not appropriate for the prediction of its bioaccumulative potential.
Bioaccumulation / BCF	- Up to 2800 (PFOS); - 4 – 40000 in rainbow trout for PFCA with different perfluorinated chain length.
Toxicity / PNEC	- The toxicity profile of PFOS and PFOA in a set of bioassays indicates a risk of unwanted chronic effects in aquatic and terrestrial ecosystems.
Main use	- Surfactants and emulsifiers in carpets, textiles, leather furniture, paper, food packaging (fast food), paints, cleaning agents, cosmetics, pesticides, fire extinguisher; in photographic-industry, semi-conductor industry and medical technique.
Quantity used [t/y]	- ca. 500 in EU; ca. 3665 worldwide (3M).
Short extract of risk assessment	- The body-burden of PFOS and PFOA in wildlife and the measured ecotoxicological effects in laboratory studies differ only about a factor between 1 - 10 which is insufficient. PFOS and PFOA are classified as PBT substance. Due to the worldwide evidence in biota and human blood in conjunction with its reproductive toxicity and cancerogenity a risk is identified. Risk assessment procedures have to consider further PFCs which break down to PFOA and PFOS.

Table A3: Short profile on Deca-DBE based on the EU Risk Assessment Report (ECB 2004).

Deca-DBE	
CAS – number	- 1163-19-5
Abiotic degradation	- Seems to be hydrolytically stable in the environment. - The half-life for atmospheric degradation by reaction with hydroxyl radicals was estimated to be 94 days. - Photodegrades under a range of conditions.
Biodegradation	- Not readily biodegradable, - Is considered to meet the very persistent (vP) criterion.
Log K_{ow}	- 6.27
Bioaccumulation / BCF	- Uptake by organisms in the environment occurs if the organisms are exposed to Deca-DBE in a suitable form (e.g. via food).
Toxicity / PNEC	- For the marine environment it is not possible to derive a meaningful PNEC _{marine} , water (as no effects being seen up to the substances water solubility limit). - PNEC for marine sediment is ≥ 29.6 mg/kg wet weight and 833 mg/kg for food.
Main use	- 70% of total being used in plastic/polymer applications. - 30% of total being used in textile applications.
Quantity used [t/y]	- Current total EU usage is around 8300.
Short extract of risk assessment	- Decabromodiphenyl ether is likely to be very persistent (vP), but neither bioaccumulative nor toxic in the marine environment based on the criteria provided in the EU TGD. - However, the PBT assessment is complicated by data available on the: <ul style="list-style-type: none"> - widespread occurrence of the substance in top predators (e.g. birds and mammals, including terrestrial species) and the Arctic; - neurotoxic effects and uptake of the substance by mammals in laboratory studies; and - possible formation of more toxic and accumulative products such as lower brominated diphenyl ether congeners and brominated dibenzofurans in the environment.

Table A4: Short profile of Musk Xylene based on the EU Risk Assessment Report (ECB 2003 musk xylene)

Musk Xylene	
CAS – number	- 81-15-2
Abiotic degradation	- It is assumed that hydrolysis of does not take place, but photolysis occurs.
Biodegradation	- Assumption: it is not readily biodegradable.
Log K_{ow}	- 4.9
Bioaccumulation / BCF	- BCF fish 4400 l/kg
Toxicity / PNEC	- PNEC water: 1.1 µg/l; - PNEC sediment: 18.3 mg/kg dw; - PNEC STP of >10.7 mg/l. It is realized that this value is much higher than the water solubility of musk xylene of 0.15 mg/l.
Main use	- Ingredient in fragrance compositions. - In cosmetic products, in detergents, fabric softeners, household cleaning products and other fragranced products.
Quantity used [t/y]	- 67 tonnes (including export to non-EU countries; not including import into EU) (year 2000).
Extract of risk assessment	- Musk xylene is considered to be a PBT candidate substance. - The persistence criterion seems to be fulfilled. - The bioaccumulation criterion is fulfilled as the experimental BCF is above 2000. - The toxicity-criterion would not be fulfilled for ecotoxicity with no ecologically relevant NOECs less than 10 µg/l. However based on human health toxicity, musk xylene does fulfill the T-criterion (Carc. Cat. 3; R40).

Table A5: Short profile of musk ketone based on the final draft of the EU Risk Assessment Report (ECB 2003 musk ketone)

Musk Ketone	
CAS – number	- 81-14-1
Abiotic degradation	- It is assumed that hydrolysis does not take place. - It can be concluded that photolysis of musk ketone occurs. Therefore, in the environmental risk assessment no photodegradation will be assumed.
Biodegradation	- Assumption: not inherently biodegradable.
Log K _{ow}	- 4.3
Bioaccumulation / BCF	- BCF fish (experimental): 1380 l/kg
Toxicity / PNEC	- PNEC water: 6.3 µg/l; - PNEC sed: 0.5 mg/kg dw; - PNEC STP of > 3.9 mg/l. This PNEC is higher than the water solubility of musk ketone of 0.46 mg/l.
Main use	- Ingredient in fragrance compositions. - In cosmetic products, in detergents, fabric softeners, household cleaning products and other fragranced products.
Quantity used [t/y]	- There is no production of musk ketone in the EU. Several European companies have terminated their productions in the last decade. - Producers in China are now the most important source for the European imports.
Extract of risk assessment	- Musk ketone is considered not to be a PBT candidate substance. - Although the Persistence criterion seems to be fulfilled, the Bioaccumulation criterion is not met as the experimental BCF is below 2000. - The Toxicity-criterion would be a borderline case for ecotoxicity with the tentative NOECs of 10 µg/l for (PNEC1 µg/l) <i>Acartia</i> and <i>Nitocra</i> . - For human health toxicity, the situation around musk ketone fulfilling the T-criterion is not clear yet.

Table A6: Short profile of HHCB (based on OSPAR 2000)

HHCB	
CAS – number	- 1222-05-5
Abiotic degradation	
Biodegradation	- Not readily biodegradable.
Log K _{ow}	- 5.9 – 6.3
Bioaccumulation / BCF	- Fish: 1584 – 1624
Toxicity/ PNEC	- Aquatic organisms: 6.8 µg/l
Main use	- Ingredient in fragrance compositions. - In cosmetic products, in detergents, fabric softeners, household cleaning products and other fragranced products.
Quantity used [t/y]	- 1473 (in 1998 in EU)
Extract of risk assessment	- The hazard profile is similar to that of the nitro-musks



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Table A7: Short profile of DEHP based on the Draft EU Risk Assessment Report bis(2-ethylhexyl) phthalate (ECB 2001 DEHP)

	DEHP
CAS – number	- 117-81-7
Abiotic degradation	<ul style="list-style-type: none"> - Atmospheric degradation: A half-life of one day. - Very slow abiotic hydrolysis of DEHP to mono(2-ethylhexyl)phthalate (MEHP) and 2-ethylhexanol, estimated half-life of ca. 2000 years. - Photooxidation of DEHP in aquatic systems is very slow.
Biodegradation	<ul style="list-style-type: none"> - Ready-, Inherent-, Anaerobic degradation: <ul style="list-style-type: none"> - The results from available studies on ready biodegradability vary from 4-5% mineralisation to 60-86% mineralisation after 28 days. - Mono (2-ethylhexyl) phthalate (MEHP) is the major metabolite when DEHP is degraded in the environment, which is toxic to mammals.
Log K _{ow}	- 7.5
Bioaccumulation / BCF	<ul style="list-style-type: none"> - BCF values (default values): <ul style="list-style-type: none"> - BCF-fish 840 - BCF-mussels 2500 wwt - BCF-amphipods 2700 wwt
Toxicity / PNEC	<ul style="list-style-type: none"> - PNEC Water: <ul style="list-style-type: none"> - There are no reliable long-term studies below the apparent water solubility of DEHP indicating effects on organisms exposed to DEHP in water. Hence a PNEC value for water cannot be specified. - PNEC Sediment: <ul style="list-style-type: none"> - Since no PNEC water could be determined, the equilibrium partitioning method cannot be used to estimate PNEC sediment.
Main use	<ul style="list-style-type: none"> - Widely used as a plasticiser in polymer products, mainly PVC. - The content of DEHP in flexible polymer materials varies but is often around 30 % (w/w). Flexible PVC is used in many different articles e.g. toys, building material such as flooring, cables, profiles and roofs, as well as medical products like blood bags, dialysis equipment etc. - DEHP is used also in other polymer products and in other non-polymer formulations and products.
Quantity used [t/y]	- The production volume of DEHP in Western Europe for 1997 is 595000 t/y.
Additional information of the risk assessment	<ul style="list-style-type: none"> - Both in vivo and in vitro study results indicate that DEHP can interfere with the endocrine function and also influence the sexual differentiation (e.g. Gray <i>et al.</i>, 1999 & Jones <i>et al.</i> 1993). - MEHP Mono (2-ethylhexyl) phthalate (MEHP) is the major metabolite when DEHP is degraded in the environment as well as in biota. MEHP has proven to be toxic in studies with mammals and the substance could be responsible for many of the effects seen in toxicity studies with DEHP. It is therefore reasonable to believe that MEHP will be toxic also to other species like birds, fish, frogs etc.

Table A8: Short profile of SCCP based on EU Risk Assessment Report (ECB 2000 alkanes, C 10-13 , chloro)

SCCP (C10-C13)	
CAS – number	- 85535-84-8
Abiotic degradation	- Atmospheric half-lives of 1.9-7.2 days.
Biodegradation	- Not readily biodegradable; - SCCP with low chlorine contents (e.g. <50% wt Cl) may biodegrade slowly in the environment, particularly in the presence of adapted microorganisms.
Log K_{ow}	- Ranging from 4.39 to 8.69* indicate a high potential for bioaccumulation.
Bioaccumulation / BCF	- Short chain length chlorinated paraffins were shown to bioconcentrate to a large extent in fish and molluscs. - High bioconcentration factors (ranging from 1000 to 50000 for whole body, with high values for individual tissues) have been reported with a variety of freshwater and marine organisms. - Chlorinated paraffins were taken up rapidly; uptake may be slower at the higher end of the chlorination range.
Toxicity / PNEC	- PNEC of 0.5 µg/l for the aquatic compartment - PNEC for the marine/estuarine subcompartment of 0.7 µg/l - There are no studies available on sediment-dwelling organisms exposed via sediment.
Main use	- Metal working fluids, sealants, as flame retardants in rubbers and textiles, in leather processing and in paints and coatings.
Production volume [t/y]	≤ 15000

* depends on the chlorine content

Table A9: Short profile of MCCP based on the Draft on Risk Assessment of alkanes (ECB 2002 alkanes, C14-17, chloro)

MCCP (C14-C17)	
CAS – number	- 85535-85-9
Abiotic degradation	- Atmospheric half-lives of 1-2 days; - In aqueous systems, MCCP are not expected to degrade significantly by abiotic processes such as hydrolysis.
Biodegradation	- No standard ready or inherent biodegradation tests are available. - MCCP can be considered to be not biodegradable.
Log K_{ow}	- 5.47 – 8.21*
Bioaccumulation / BCF	- BCF fish: 1087 l/kg
Toxicity/ PNEC	- PNEC _{water} : 0.2 µg/l - PNEC _{sediment} : 1mg/kg;
Quantity used [t/y]	- 65256 in 1997 - MCCP are used as substitutes of SCCP, a decrease of SCCP due to reduction measures could lead to an increase of MCCP.
Main use	- The main area of use is as secondary plasticiser in PVC (polyvinyl chloride), as extreme pressure additives in metal working fluid, as plasticisers in paints, as additives to adhesives and sealants, in fat liquors used in leather processing and as flame retardant plasticisers in rubbers and other polymeric materials.

* depends on the chlorine content



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