The Only Planet Guide
to the Secrets of Chemicals Policy in the EU

REACH

What Happened and Why?

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When raindrops, breast milk and human blood as a rule contain hazardous chemicals, something has gone wrong. Since 1998 the EU has been developing a chemicals policy to increase the safety of human health and the environment. However, the new policy is increasingly focusing on protection of the chemicals industry. How did this happen? Who made it happen? And most of all, *why* did it happen?

The Only Planet Guide to the Secrets of Chemicals Policy in the EU is a guide to help politicians, media and citizens navigate in this complex world.

REACH - The Only Planet Guide to the Secrets of Chemicals Policy in the EU. What Happened and Why?
Brussels, April 2004

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This book would not have been possible without the help of a few persons. First of all, Axel Singhofen, Joe DiGangi, Stefan Scheuer and Michael Warhurst who supplied endless flows of information. Miles Goldstick has been invaluable in providing technical support and linguistic guidance. The International Chemical Secretariat supplied crucial contacts, knowledge and electronics. Tor Hauksson and Jarkko Nordlund found the right pictures. Last but not least: Hanne and Filippa. Many thanks to all of you and to all the other persons who have contributed in different ways.

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This is an Internet-version of the original book. Some photos have been removed but the text is identical.

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Said about REACH:

“The potential damage to the global economy, our employees and communities in which we operate, and yes, our shareholders, is enormous.”

- Greg Lebedev, American
Chemistry Council, April 2003

“It will create a win-win situation for industry, workers and citizens and our ecosy

- Margot Wallström,
EU Commissioner, October 2003

“The proposed REACH is a shadow of the original plans”

- European Environment Bureau,
December 2003

This Book

The Only Planet

Over the past years, the EU has been shaping a new chemicals policy: Registration, Evaluation and Authorisation of CHemicals (REACH). I became the Rapporteur for the "White Paper - Strategy for a future Chemicals Policy" of the European Parliament in 2001 and I have travelled with REACH since then. It has been an exciting journey, a new world in itself to discover. I have learned a lot, not only about chemicals, but also about power, money, and tactics. I have met nice and committed people in the Commission, Parliament and industry. I have met charming lobbyists but also not so nice dinosaurs from the chemicals industry. In October 2003, the Commission presented the proposal for a new regulation. The proposal will now be debated by the newly elected Parliament and then the Parliament and Council will jointly decide on the regulation. It is an important and huge task which covers a multitude of sectors and issues.

The things I experienced in the REACH process were so interesting, but also so upsetting, that I wanted to share them with others that have an interest in politics and health and environmental issues. Thus, I decided to publish the REACH story. With the input of others the project grew and developed into this book, "The Only Planet Guide to the Secrets of Chemicals Policy in the EU."

Earth is the only planet known to be suitable for human habitation. We share this home with other living creatures and it should be the home of countless generations to come. All of us, and those not yet born, are dependent on the global ecosystem to survive. It is a closed system, and if we risk disrupting or destroying it, we threaten ourselves.

Many chemicals greatly benefit our daily lives and our health. However, many are also extremely dangerous. Some man-made chemicals do not disappear once they are released. They circulate and sooner or later show up in the atmosphere, oceans, plants and in the bodies of humans and other animals. The long-term effects are uncertain, but there is damage and there is reason to believe that the damage is more far-reaching than we understand today. A great risk is being taken.

Commissioner Margot Wallström is one of those that has been fighting hard for the creation of a comprehensive and strong EU chemicals policy and regulation. In 2003, she participated in a bio-monitoring survey conducted by WWF. Scientists took samples of her blood and looked for some chemicals that shouldn't be there. Out of the 77 man-made chemicals analysed, the laboratory found 28 of them in her body, for example PCB and certain brominated flame-retardants. I have recently gone through a similar test and am waiting for the results. I expect to have the same chemicals in my blood, a result that most people in our generation would get.

Inger Schörling has been a Member of the European Parliament since 1995. Inger was one of the founders of the Green Party in Sweden and the first Green groupleader in the Swedish Parliament 1988-91. She was also Vice President for the Greens in the European Parliament 1997-99.

In March 2004, a Greenpeace study showed that ordinary house dust, collected from the European Parliament and from my own home in Brussels, contains phthalates, alkylphenols, brominated flame retardants, organotins and short-chain chlorinated paraffins. These are hazardous chemicals that can cause cancer, damage the immune system, and affect reproductive health and/or cause disruption to the endocrine system. Unfortunately, these chemicals may be found in every home as they appear in everyday consumer products. In my everyday life, I try to buy environmentally friendly products, but there is no way of knowing everything that is in the all products we buy.

The environment, and especially chemical threats, are important, and people are worried. According to the Eurobarometer survey from 2003, 93 percent of European citizens believed that chemicals have a negative impact on their health. Some severe accidents in the chemicals industry, as in Bhopal, Seveso and Toulouse, stay in peoples minds. People worry about the exposure to chemicals in their daily environment and life. People wonder what is in the water they drink, the food they eat, the air they breath, and the milk they give to children?

This means politicians in the EU have a special responsibility. Member State governments, the European Parliament and national parliaments must take peoples' concerns seriously, and not just to create public trust. They must also take the warnings by scientists seriously. It's real.

The only reasonable goal is to make the environment free from dangerous man-made chemicals and to try to keep the levels of metals close to natural levels. When there is risk, the precautionary principle should be used. This means that the chemicals industry also has a special responsibility. They should stop producing persistent and bioaccumulating chemicals and try to find alternatives.

Finally, I want to thank a few people. Gunnar Lind, the author, made this book possible. He applied his great knowledge and enthusiasm, and handled a lot of material within a tight time frame. Special thanks also to Axel Singhofen, the excellent and passionate adviser for the Green/EFA group on chemicals and my saviour and guide. I would also like to thank everyone in the Green/European Free Alliance group in the European Parliament for their support.

Brussels and Gävle
March 2004

Inger Schörling
Member of the European Parliament

The Author

Gunnar Lind

Born in Sundsvall, a city in northern Sweden, at the time also known as the most polluted city north of Hamburg, Gunnar grew up in the USA, Mexico and Stockholm. After working with marketing for ten years, he grew sick of promoting and selling useless products and making a living on consumerism. He dropped out and joined the environmental movement in Sweden in 1993, initially working as a fundraiser. As he learned the issues, he became increasingly involved in campaigns and was soon a senior campaigner for Greenpeace. He spent the next ten years reading reports, writing press releases and background information sheets, chaining himself to suitable objects and speaking to industry, politicians and the media. He started out working with the nuclear power issue, the also worked on other issues: forests, ocean ecology, genetically manipulated organisms, climate change and toxics. After spending four months in Southeast Asia, he became addicted to Lonely Planet Guides. He is now a freelancer.

How to use this Guide

Travelling in an unfamiliar environment can be difficult. A new culture and language can turn your world upside-down. To get properly oriented in a new context, there are numerous customs, places and faces to remember, and names and words that need to be learned. Without help, an exciting new experience may turn into a nightmare. Many people who travel to new places use guidebooks. They are indispensable for navigating in a new environment. Given the time, it is possible to prepare by reading them beforehand, avoiding unnecessary confusion or mishaps. On arrival in the new surroundings, they can be kept easy at hand, making it possible to quickly find facts or hints of interest in a specific situation. A good guidebook lets you find the facts with the flick of a finger.

Over the past five years, the EU has been working on a proposal for a new chemicals regulation, called REACH. It is an important and huge task which covers a multitude of sectors and issues. The proposed new regulation was presented in October 2003 and it will be debated and developed by the European Parliament and Council over the next years.

REACH concerns all of us, but to most people it is a new world. To help those interested in navigating this fascinating place we have produced a travel guide, *The Only Planet Guide to the Secrets of Chemicals Policy in the EU*. You can either read it in the same way as you read an ordinary book, starting at the beginning and reading to the end. Or you can use it like a traveller would use a guidebook, reading here and there, finding facts and background information when you need them or when you have the time to browse.

The guide consists of three parts. The first part, *Chemicals*, covers the background, facts about the chemicals industry, the occurrence of chemicals in the environment and finally what effects these chemicals have or what concerns are being voiced about them. The second part, *Politics*, describes international chemicals policies, the current EU regulations, the political intentions behind REACH and how the initial ideas and draft regulations were watered down. The third part, *Behind the Scenes,* is an inside view that describes the aggressive lobbying campaign against REACH conducted by the chemicals industry and some governments.

An attempt has been made to cover the most important parts of the REACH process in this book. However, it is not possible to cover everything. There are always streets, buildings and alleys that are not mentioned. This is also true for this guide.

The scope of the information covered for this guide is large. Hundreds of documents containing tens of thousands of pages and a myriad of details have been examined. Prior to publishing, the text has been reviewed by experts in different sectors. Nevertheless, there may still be inaccuracies. If any are found, please send them to the publisher.

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PART TWO: POLITICS

Foreword

By Joseph DiGangi

For many of us, the words “synthetic chemicals” bring to mind far-off smokestacks or the smell of a pungent factory. They seem distant and not immediately threatening -- a nuisance or a bit of an eyesore. If synthetic chemicals seem remote, then policies that regulate them seem even more removed. Why should we be interested in either one? More to the point, why should we read a travel guide that takes us on a journey to this destination?

Actually, “The Only Planet Guide” takes us on a trip right into our homes and our bodies. Instead of far-away plumes of smoke, we can encounter synthetic chemicals when we rock our babies, relax on our sofas, watch TV, or enjoy a delicious dinner. All of us have an intimate relationship with synthetic chemicals, whether we want to or not – chemicals that invisibly surround us in our products, our air, our water, food and land – chemicals that are getting into our bodies, even if we try to avoid them.

Every day routines, even those that focus on clean living, bring the unexpected consequences of chemicals in our bodies. Some of these chemicals come from consumer products. Others linger from substances such as DDT and PCBs that seemed like great ideas decades ago. We didn’t intend to ingest them like medicine, and few of us would grant permission for them to be in our bodies, if we had the choice.

Once we acknowledge our proximity to synthetic chemicals, a common-sense assumption emerges: these things are safe, right? This question goes to the heart of policies that regulate chemicals. The “Only Planet Guide” explores this question on a European tour that draws us into a struggle with global implications.

This book tells the story of a landmark proposal to regulate synthetic chemicals, called Registration, Evaluation, and Authorization of Chemicals, or REACH for short. The story begins on a drizzly day in 1998 in Chester, UK, at a meeting of the Council of Environment Ministers. This gathering raised serious questions about the effectiveness of existing laws governing chemicals. Did the laws assure the safety of the public? How well did they work? The disappointing answers provoked an effort to improve the laws to match the expectations of the citizenry. REACH appeared on the horizon.

The ideas about reforming chemical policy were made concrete in the White Paper in 2001 and “The Only Planet Guide” offers a detailed account of its ideals and its fate. With sustainable development at its heart, REACH rested on the precautionary principle as a fundamental route to achieving its goal of responsible chemical management and control that protects public health. This placed it directly at odds with US-style regulation and incurred the wrath of the US chemical industry.

To respond to the White Paper, the US chemical industry has engaged four US government agencies to wage an aggressive campaign to weaken and defeat the proposal. Secretary of State, Colin Powell, sends cables to US embassies urging action on behalf of the industry. EPA officials fly to Europe with US chemical industry executives to lobby for US-style voluntary regulation. High-level Commerce Department officials plan outreach campaigns to sway opinion. The Office of the US Trade Representative tasks industry to develop themes to oppose REACH for use by the US government. The pressure has even extended beyond Europe to the world stage where the US government seeks to instigate opposition to the proposal from developing countries. The campaign has challenged the very notion that sovereign nations can protect their citizens by enacting better laws.

The runaway train of US government lobbying to weaken REACH has attracted repeated public condemnation from US public interest groups.

In 2002, more than 50 public interest NGOs signed a letter of protest to President Bush about the lobbying and asked the Administration to support REACH. Nearly a year later, more than 70 public interest NGOs, public health professionals, nurses, environmental and community groups wrote another letter requesting that federal funds not be used to undermine REACH and asking for Administration support in light of REACH's public health benefits. These efforts and new revelations from internal government documents attracted the attention of the US Congress. The House of Representatives Committee on Government Reform Minority Staff launched an investigation in April 2004 of the lobbying and criticized the Administration's misguided solitary reliance on the US chemical industry to determine US policy.

Ironically, while US government officials are flying off to Europe to weaken REACH, enthusiasm for it is building at home. Public interest NGOs, public health professionals, and community groups have translated the principles in the White Paper into tangible legislative proposals at the state and local levels. These policies restrict toxic chemicals, change government procurement policy, and even implement the precautionary principle as the guiding force of operation. Progressive members of the business community quietly recognize REACH as a way to reduce product liability. REACH has even drawn the attention of US Congressional Members who have begun analyzing how US laws could be updated, using the White Paper as a model.

The growing support for genuine chemical safety on both sides of the Atlantic should prompt greater international cooperation. Chemical substances easily cross borders and authentic solutions require multinational collaborative efforts. The profound economic significance of the chemical industry places it center stage on the sustainable development agenda. The serious concerns over public health and the dangerous ignorance of the chemical industry's products demand action.

The ensuing and continuing internal and external fights about REACH bring to mind unpredictable curves, deep potholes, and sudden steep hills.

In some ways the battle over REACH has divided along lines that define long- or short-term thinking. Immediate costs, the difficulties of change, and temporary uncertainties crowd the minds of the short-term thinkers. The sustainability of the chemical industry, preservation of public health, and commitment to innovation motivate the long-term thinkers.

"The Only Planet Guide" describes a serious journey toward a new European chemical policy that could pave the road toward smarter, safer chemical policy worldwide. The tug-of-war between the antiquated approaches of the past and REACH can be thought of as an upcoming fork in the road. The outmoded path is well worn and familiar. The new path is uncertain with exciting possibilities. One path rewards ignorance while the other prizes common sense. This high-stakes choice requires wisdom and thoughtfulness. "The Only Planet Guide" provides helpful hints, warnings, and knowledge to steer us in the right direction.

Joseph DiGangi, PhD
Environmental Health Fund
USA

PART ONE: CHEMICALS

Facts About the Chemicals Industry

GLOBAL INDUSTRY

Overview

The chemicals industry is the third largest industrial sector in the world. Global sales are estimated at €1,481 billion for 2002 and the industry employes some ten million people around the world. Most work in small or medium sized companies.

It is also one of the most diverse industries in the world. It covers production of innumerable substances and products, ranging from high-volume basic chemicals via pesticides, additives, sealants, coatings and pharmaceuticals to infinitely specialised products.

While almost all nations have their own chemicals industry, the bulk of chemicals are produced in OECD countries. As much as 80 percent of global production comes from only 16 countries. Europe is one of the key players in this field. With more than 30 percent of global sales, it is the largest chemicals producing region in the world.

Production

Production of chemicals has soared over the past decades. Since 1970, global sales have increased from €155 billion to €1,481 billion in 2002, representing almost a ten-fold increase. Though the chemicals industry is very diverse and is comprised of tens of thousands of companies, a large portion of production is carried out by a small number of large corporations. In 2002, the top 30 companies had aggregated sales of €378 billion and made up nearly one-third of the total global sales. The top five companies alone had sales totalling a value of €130 billion.

In more physical terms, the global production of chemicals increased from one million tonnes in 1930 to over 400 million tonnes in the year 2000. In Western Germany, the production was 25 million tonnes in 1980, which is equivalent to 400 kilograms of synthetic chemicals per person. This is roughly the same amount as the entire per capita annual production of crops, forests, flowers and other natural green organisms in Western Germany.

Global top 10 chemical companies 2002 by sales, € billion (Cefic, March 2004)

BASF (DE)	30.5
Bayer (DE)	28.0
Dow Chemical (US)	27.5
DuPont (US)	24.0
ExxonMobil (US)	20.5
Atofina (F)	18.5
Mitsubishi Chemical (J)	15.0
Akzo Nobel (NL)	13.5
BP (UK)	12.5
Shell (NL, UK)	11.5

Outlook

Based on past and current trends, it is predicted that the tremendous growth rate will continue. According to the UK Chemical Industries Association (CIA), global sales will reach €2,125 billion by 2010 and the OECD speculates there will be a staggering €4,500 billion in sales by 2020.

Most of the growth over the next decade is likely to happen in developing countries and countries in transition. Today, consumption of chemicals is far higher in OECD countries than in countries with less developed economies. A person living in Europe or the US consumes chemicals value at of over €1,500 per year, while a person living in India or Africa spends some €50 on chemicals annually. Thus, the chemicals industry sees an enormous potential in the developing world.

Globalisation

Attempting to avoid fierce price competition from developing countries, the chemicals industry in the OECD is shifting production

from basic high-volume chemicals to more sophisticated and high value-added products. The chemicals industry in richer countries will become more high-tech while industry in developing countries will account for an increasing part of the production of basic high-volume chemicals.

In the period up to 2020, there will be a shift, where non-OECD countries will increase their share of global production, from 23 percent in 1995 to 33 percent. In physical terms, the increase will be from approximately 100 million to 260 million tonnes.

The growth of the chemicals industry in the developing world, and the shift of production of basic chemicals from OECD to non-OECD countries, does not mean that European and US chemical corporations are losing ground and that competition will increase. On the contrary, they are in the fore-front, already expanding into the developing countries.

Globalisation and deregulation of trade has made it possible for them to move into these new markets. According to a survey by the Chemical Manufacturers Association (CMA) among its member companies, the US industry intends to shift its investments from Europe, Canada and the US to Asia, Eastern Europe and Latin America.

Mergers and Acquisitions

Another important trend in the chemicals industry over the past decade has been mergers and acquisitions. Large corporations merge and buy smaller companies in the quest for economies of scale and market domination.

In 1999, the value of mergers and acquisitions in the chemical industry hit a new record of €34.4 billion. An important part of this record was to advance global consolidation of the industries. In 2001, the top 50 chemical companies increased their sales by 14.3 percent in a market that grew by 2-3 percent the same year. Most of the growth was due to mergers and acquisitions of smaller businesses. Dow Chemicals increased its sales by 21 percent from 2000 to 2001, entirely through acquiring and merging with other companies such as Union Carbide.

Illustrating the frenzy for mergers and acquisitions in the business, the number of major agrochemical producers has gone from 28 to 12 since 1980. This development cuts through the entire industry and is also expected to continue, leading to fewer and larger multinational corporations dominating global production of chemicals.

Organisation

As for any major industry, keeping abreast with political and social development is essential to the chemicals industry. The International Council of Chemical Associations (ICCA) is the world-wide voice, representing 80 percent of global manufacturing operations.

ICCA is also the main channel of communication between the industry and various international organisations that are concerned with health, environment and trade-related issues, including the United Nations Environment Programme (UNEP), the World Trade Organization (WTO) and the Organisation for Economic Co-operation & Development (OECD). Furthermore, ICCA is the entity that promotes and co-ordinates voluntary industrial agreements such as Responsible Care.

Slimming the organisation, the ICCA only has a few members, typically one or a few regional associations in each continent, e.g. the European Chemical Industry Council (Cefic) and the American Chemistry Council (ACC). These member associations in turn are organised in a multitude of regional and national federations, associations, trade organisations, sector groups, institutions, councils, NGOs, think-tanks, etc.

EUROPEAN INDUSTRY

Overview

Europe is the worlds biggest producer of chemicals, having a share of approximately 35 percent of global sales. Most of this pro-

duction, 30 percent, takes place in the EU. The top European chemicals producing nations are Germany, France, Italy and Great Britain. Production in Eastern and Central Europe fell dramatically after the collapse of the Soviet Union. In 1970 these countries had a global market share of 14 percent which had fallen to a mere 3 percent by 1998.

Top chemical producing nations in the EU, percentage of total (Cefic, 2004)	
Germany	25
France	16
Italy	12
Great Britain	10

The chemicals industry is the largest industrial sector in Europe. It employs 1.7 million people directly and up to 3 million jobs are dependent on it. As well as several leading multinationals, it also comprises some 25,000 small and medium-sized companies with less than 500 employees. These represent 98 percent of the total number of enterprises but only account for 28 percent of chemical production.

In 2002, the EU chemical industry exports outside the region were worth €155 billion. Imports from outside the region amounted to some €85 billion, creating a trade surplus of €70 billion, three-quarters of the total EU manufacturing trade surplus. Most of the exports went to the USA and Asia.

Production

There are about 100,000 chemicals registered in the European Inventory of Existing Commercial Chemical Substances (EINECS) created in 1981. It is uncertain how many of these substances are actually in production. Estimates vary from 30,000 to 70,000. Additionally, there are 3,000 substances registered after 1981 in the European List of Notified Chemical Substances (ELINCS).

While some of these substances are produced in high volumes, often millions of tonnes per year, others are produced in low quantities. Approximately 10,000 of them are produced in volumes above 10 tonnes per producer and year, and a further 20,000 substances are marketed in volumes between one and ten tonnes annually per producer.

The bulk of the chemicals produced in Europe is manufactured by large corporations. Two percent of the companies produce approximately 70 percent of the volume. These companies have high-tech plants which are highly automated and can produce enormous quantities each year. Some plants are virtually self-contained cities with large numbers of workers and enormous amounts of equipment, including their own power plants, spread over huge areas. The chemical plant in Leverkusen, Germany, owned by Bayer, covers an area of 3.4 square kilometres and consists of 600 buildings.

Outlook

As markets for basic high-volume chemicals in Europe and other OECD countries are becoming mature and saturated, the EU chemicals industry is looking into other fields.

One way of expanding is to enter new markets with high growth potential, such as in non-OECD countries, either through exports or by investing in production facilities in these countries (see *Outlook* and *Globalisation* in the previous section). Investments by chemical companies in facilities in foreign countries has been growing since the 1980s and is expected to continue.

Another route of expansion is to become more specialised. European companies, like their US competitors, are becoming more innovative and specialised in areas such as biotechnology, electronics and advanced materials.

Through technological developments they have also expanded into speciality chemicals, agrochemicals, pharmaceuticals and food production, where biotechnology is creating

new commercial opportunities. Increasingly, the EU chemicals industry is becoming an industry where agriculture, biotechnology, pharmaceuticals, chemicals and food are all part of the business.

Mergers and Acquisitions

As a result of the saturated markets in the OECD and the expansion into other regions as well as into new product areas, the chemicals industry in the EU is undergoing a major restructuring. Investments in foreign countries are often done by acquiring foreign companies or merging with them. Similarly, expansion into new product areas also demands new structures.

It is anticipated that the increasing scale and growth of the global chemicals industry, together with continuing globalisation, increased openness and competitiveness, are likely to intensify recent trends of companies forming alliances.

Steadily mounting cost pressures will provide further impetus. Research and development (R&D), bringing new products to the market, managing the safe production and distribution of chemical products from cradle to grave, and meeting pressures of environmental health and safety regulations entail costs that will escalate.

The trend towards fewer and larger multinational producers is expected to continue, with companies becoming knowledge-based (speciality chemicals and life sciences) rather than asset-based (basic chemicals).

Organisation

While the International Council of Chemical Associations (ICCA) is the world-wide voice of the chemicals industry, its counterpart in Europe is Cefic, the European Chemical Industry Council. The organisation consists of 25 national federations of chemicals producers, 30 corporate members and approximately 700 business members. Acting as an umbrella organisation, Cefic has also recognised about 100 sector groups and affiliated associations

such as Eurochlor and European Brominated Flame Retardant Industry Panel (EBFRIP). Within Cefic there are eight leadership teams dealing with specific issues of high concern to the industry, e.g. trust & reputation, international trade, chlorine etc.

Cefic represents the interests of the national federations and its other members, sector groups and affiliated associations toward international organisations and treaties. The stated mission of Cefic is *"To maintain and develop a prosperous chemical industry in Europe by promoting the best possible economic, social and environmental conditions to bring benefits to society with a commitment to the continuous improvement of all its activities including the safety, health and environmental performance"*.

On the tier below Cefic, the national federations, sector groups and affiliated associations are divided into countless groups representing specific interests. For example, the European paint industry is organised in an affiliated organisation: the European Council of the Paint, Printing Ink and Artists Colours Industry (CEPE). Similar to Cefic, CEPE has 18 federations on national levels as well as 14 company members and 12 affiliated organisations and company members. As an example of a sector group within Cefic, the European Flame Retardants Association, has 15 member companies, three associate member companies and five observer organisations, among them several other sector groups and

the international Fire Retardant Chemicals Association, with further members and affiliated members.

While simple and streamlined at the top, the chemicals industry is organised in hundreds or thousands of other organisations further down. Ultimately, the organisation is virtually impossible to overlook. Many of these organisations exist mainly or exclusively to influence politics. To this end they interact and network in different constellations depending on specific needs.

An example of this is the Downstream Users of Chemicals Co-ordination group (DUCC). The organisation was founded in 2001 with the specific purpose of influencing the development of REACH. It comprises seven organisations representing some 3,700 companies that use chemicals, such as paint and ink producers, perfume producers, chemicals distributors and producers of detergents. Several of the seven member organisations, as well as many of their member companies, are also members of Cefic directly or through other sector groups.

One of the main tasks for these organisations, federations and groups is to monitor and influence policy making in an advantageous direction. However, the chemical industry also has other means of exercising a powerful lobby. Most of the major chemical companies as well as Cefic and federations, are also members of influential think-tanks such as the European Policy Centre and the European Round Table of Industrialists. The major organisations and companies also consult well known marketing and lobby organisations such as Burson-Marsteller and the European Marketing Group.

SUMMARY

The chemicals industry is one of the world's biggest and most powerful sectors, with global sales of approximately €1,500 billion. The growth rate has been high over the past decades. Within the next 20 years, sales are expected to continue growing, maybe even be tripled to €4,500 billion in todays prices. Most of the future growth is expected to take place in developing countries and countries in transition where production and consumption of chemicals has been low.

While there are tens of thousands of small companies in the industry, global production is almost entirely controlled by a few very large multinational corporations based in the OECD, primarily in the EU and US. With saturated markets in the OECD, these companies are moving into the non-OECD markets, where the future growth is expected, by investing in manufacturing facilities, mergers and acquisitions.

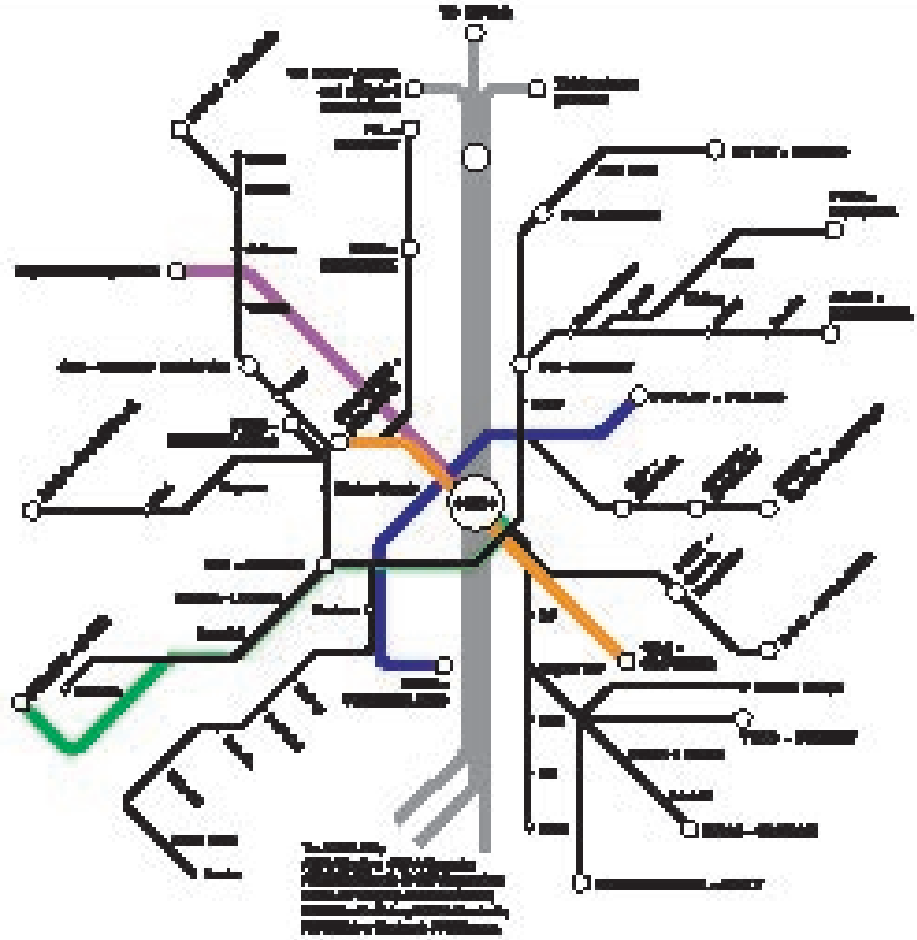
While shifting the production of basic high-volume chemicals to non-OECD countries, production of chemicals in Europe and the US is becoming more specialised. The large corporations, and the industry as a whole, are also moving into new product areas such as agriculture, pharmaceuticals and food by investing in biotechnology.

As a consequence the industry is undergoing dramatic restructuring. In the future there will be fewer but bigger companies. These are likely to also dominate the future chemicals production in non-OECD countries, and they will be active in a wider range of product areas.

Deregulation of trade barriers in non-OECD countries and globalisation of (OECD) trade is a prerequisite for the expansion of the dominating companies. In the ICCA (and Cefic in Europe) they have a powerful and efficient lobby that should be expected to protect and advance their interests. Considering the financial importance of the industry in several European countries, it is likely that governments will also protect and promote the interests of the industry in national as well as international contexts.

Map of the Chemicals Industry in Europe

Below is an illustration of the organisation of the chemicals industry in Europe. The system is more complex in reality since there are links between many of the federations, members and companies. These are also likely to have connections to other groups which are not included in the map. Most of the corporate members of Cefic are also active members in many of the federations as well as in the sector groups, which also have federations at national levels. Federations and sector groups may also have non-chemical members, such as the CIA in the UK. Among it's members are some 20 solicitors, crisis managment consultants, marketing consultants, railway companies and accountants. Additionally, there are numerous institutes, think-tanks, non-profit organisations etc. with less official connections to the industry.



Defining the Chemicals Industry

The chemicals industry covers a wide range of processes and products. However, defining the industry may be difficult and depends on who is doing it. According to Cefic, the chemicals industry consists of all the companies that use raw materials to produce chemical substances and all the companies down the line that alter or blend these substances.
Cefic defines the industry according to 11 different sectors (see below). Each sector may consist of several sector groups, of which Cefic has recognised approximately 100. Companies in these sectors are, according to Cefic, the chemicals industry and thus the basis for the figures presented by Cefic. Generally, any company which is active in at least one sector may become a member of sector groups or of a national federation and thus be a part of the chemicals industry. Some companies are only active within one sector, while others may be active in a range of sectors. Additionally, Cefic represents a number of sector groups which do not fit into the categories.
There are also other definitions of the chemicals industry. For example, the Swedish Chemical Industry Federation (Plast- och Kemiföretagen) divides the sectors differently, and also includes producers of pharmaceuticals, rubber, cement, hand-made glass, explosives as well as companies that distribute the products. This means that a national federation may have members which are not part of the industry according to Cefics definition of sectors. Nevertheless, they may be included in the statistics over the European chemicals industry if they are members of a federation or of a sector group recognised by a federation.

Cefic Sectors

Agriculture
Producers of fertilisers, biocides, food additives, insecticides, pesticides, herbicides, etc.

Biotechnology
Companies that develop or use biotechnology, primarily in medicines, vaccines, diagnostics, gene therapy and in food and agriculture to develop herbicide and pest resistant plants.

Chlorine and Other Halogens
Producers of chlorine, bromine or fluoride, used for producing a variety of chemicals, plastics, pharmaceuticals, etc.

Colorants
Producers of pigments and substances used for colouring food, textiles, plastics, dyes, etc.

Detergents
Producers of substances containing soap or other surfactants intended for washing clothes and dishes as well as hard surfaces.

Food and Feed
Producers of food additives such as emulsifiers, food contact additives, processing aids and agents, etc.

Oleochemicals
Producers of fatty acids, glycerine, alcohols and metallic soaps, fatty nitriles and their derivatives, etc. Oleochemicals are used in lubricants, soaps and detergents, cosmetics, pharmaceuticals, food additives, leather, paints and coatings, printing inks, rubber, plastics, and in metal-working and many other industries.

Paints, Coatings and Adhesives
Producers of paints, inks, dyes, glue and many other kinds of surface coatings.

Petrochemistry
Companies that produce intermediate chemicals from fossil gas and oil. These are the main suppliers of raw materials and intermediates to most of the chemicals industry.

Plastics
Producers of all kinds of plastic such as polystyrene, acrylic polymers, PVC, nylon, polyethylene, polyurethane, polyester, epoxy resins, polycarbonates, silicones, polyamides and polyacetals.

Others
Manufacturers of activated carbon, sporting ammunition, cellulose ethers, lead oxide, photographic chemicals, titanium dioxide, etc.

POLLUTION

Overview

Naturally, the environment has always consisted of chemicals and always will. Some of them are hazardous, but these are mostly deposited in the ground where they are either not readily accessible to humans and most other organisms, or have only limited impact in the immediate vicinity. Since the beginning of civilisation mankind has extracted substances for specific purposes, such as mercury or lead. This created local pollution and health problems for those exposed.

With the advent of industrialisation, the extraction and dispersal increased. But additionally, mankind started producing synthetic substances. Most of these had never existed before. Today, the bulk of chemical production consists of synthetic chemicals that are primarily based on fossil oil.

Most of the substances produced by the chemicals industry eventually end up in the environment and, via the environment, in humans. Thus, the environment today contains a greater number of chemicals than before and many of them are synthetic.

Synthetic chemicals can be found in most places: water, soil, air, plants, humans and other animals. They are also found in remote areas such as the Arctic, deep seas and mountain tops.

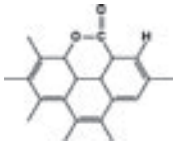
Chemicals found in such places are mostly persistent, which means that they do not degrade or break down easily. They may also be bioaccumulative, meaning that they accumulate in fatty tissue. Once released into the environment, such substances stay around for a long time.

In this section some examples are given of places where synthetic chemicals have recently been identified. In many of the studies scientists have identified more or less the same substances, often well known pollutants. This is no coincidence. When analysing something for the presence of pollutants, scientists have to know what they are looking for and they tend to look for substances which are considered hazardous. However, this does not mean that the substances identified are the only substances in the sample. On the contrary, it is very likely that the sample contains many more substances that have not been analysed.

While the findings below are disturbing in themselves, they should also be recognised as examples, indications of greater dispersal and widespread exposure which make them even more disturbing. They are warning signals of an even greater problem.

Persistence

A chemical substance consists of molecules, typically based on carbon. With time the bonds in the molecule break down and the substance decomposes. If a substance breaks down quickly, there is less time for it to cause harm, and vice versa. A substance that breaks down slowly is called persistent. Chemicals break down at different paces in different media and temperatures. A substance that breaks down in a few days in air may take months or years to decompose in water, sediment, soil or human tissue.



Rainwater

Ordinary rainwater collected in Europe has proven to contain pesticides, brominated flame retardants and other synthetic chemicals. In 2002, the Dutch institute TNO presented the results from a two-year study of rainwater in the Netherlands. The presence of many pesticides was clearly shown.

In May 2003, Greenpeace presented the results of the analysis of 50 samples of rainwater collected in the Netherlands, Germany and Belgium. The samples had been analysed by TNO for a wider range of synthetic chemi-

cals, primarily xeno-estrogens, substances that are considered to have effect on the hormone system and belong to a group known as Endocrine Disrupting Chemicals (EDCs) or Endocrine Disrupters.

The results show that these substances were present in most samples. All the samples contained phthalates, used as softeners in PVC plastic. A total of 32 percent of the samples contained bisphenol A, 28 percent contained brominated flame retardants, and almost all samples contained musk compounds, used to produce scent in perfumes, detergents, etc. Alkylphenols and ethoxylates were also present in almost all the samples. The levels varied between different compounds but also between the locations where the samples had been taken.

The Arctic

Though the Arctic region is still clean compared to many other areas in the world, for a specific group of substances - Persistent Organic Pollutants (POPs) - there is reason for concern (see separate box). The Arctic Monitoring and Assessment Programme (AMAP) has been monitoring chemicals in the Arctic for many years and have found POPs in all compartments of the Arctic.

Most of the pollutants in the Arctic originate in warmer areas of the world, and are transported to the Arctic by a process known as *grasshopping* or *global distillation*. POPs travel to colder areas of the globe through a series of hops. Under warm conditions they evaporate to the air and are then deposited again to the surface, repeating the same process over and over again until they become trapped in cold areas. There are also sources of POPs in the Arctic, e.g. military installations and rivers depositing water in the Arctic.

Through bioaccumulation (see box on page 24), persistent chemicals may stay in the fatty tissues of humans and other animals. Over time the concentrations add up to high levels, even when the levels in the environment are low. A human or other animal living

Persistent Organic Pollutants (POPs)

Persistent organic pollutants (POPs) include a wide range of substances: industrial chemicals (such as PCBs) and by-products of industrial processes (e.g. HCB, and dioxins) whose toxic characteristics are unintentional, and others, such as pesticides (e.g., DDT) and herbicides (e.g., lindane – HCH), that are designed to have toxic properties.
Interest in the presence of POPs in the Arctic environment arises in particular because of the concern that Indigenous people and other northern residents depending on traditional food for all or part of their diet may be adversely affected by chronic exposure to these pollutants.
POPs are of special concern because:
1) They persist in the environment for long periods of time, which allows them to be transported large distances from their sources, are often toxic, and have a tendency to bioaccumulate; many POPs biomagnify in food chains;
2) Many Indigenous people in the Arctic depend on traditional diets that are both an important part of their cultural identity and a vital source of nourishment; alternative sources of food often do not exist; however, traditional diets are often high in fat and POPs tend to accumulate in fatty tissue of the animals that are eaten;
3) Most northern residents have not used nor directly benefited from the activities associated with the production and use of these chemicals; however, certain Indigenous populations in the Arctic have some of the highest known exposures to these chemicals.

AMAP POPs fact sheet #1

at the top of the food chain may have concentrations that are hundreds of thousands of times greater than in the surroundings.

AMAP studies have found POPs in Arctic air, water, snow, plankton, amphipods, cod, whales, seals and polar bears.

Mountains

The same phenomena that brings POPs to such remote places as the Arctic, also disperse POPs in other remote places, for example the crystal clear lakes in the Alps. In 2001, studies on fish from lake Schwarzsee ob Soelden, which is located 2,800 metres high up in the Oeztal Alps in Austria, showed substantial pollution with industrial chemicals such as DDT and PCB.

Lake Schwarzsee is far away from local sources of pollutants and draws its water solely from the neighbouring mountain tops. The pollutants found in the water enter almost entirely from the atmosphere.

In the study, done by the Mountain Lake Research Project (MOLAR) in the EU, fish and sediments from a total of 19 mountain lakes in Europe were analysed. This research established an important connection: the concentrations of the persistent pollutants in the lakes clearly increased with height and as the temperature fell.

The following year, Greenpeace analysed fish from the same lake, but looked for six other substances. This time, analyses showed that the lake was also contaminated by brominated flame retardants, HBCDs, chloroparaffins, phthalates, toxaphenes, and chlorinated dioxins and furans. By analyses of snow, the presence of POPs has also been proven in the North American Rocky Mountains, another high remote area.

Fish

Fish is one of the places where synthetic chemicals are most often analysed and found. As a rule, fish contain pollutants from industrial and civil discharges to water.

There are many studies showing synthetic chemicals in wild fish. However the variation in substances and levels is large and depends on where the fish lives and the fat content of the fish. A fatty fish, such as a salmon or herring, will accumulate more chemicals than a leaner fish, since many industrial chemicals accumulate in fatty tissue.

Today it is difficult to find fish which does not contain man-made chemicals. Among the most frequent pollutants found in fish are dioxins, PCBs, brominated flame retardants, plasticisers and organotins.

In some areas of the world, like the Baltic Sea and several rivers and lakes, fish are often so contaminated that they are not considered to be fit for human consumption. However, most of the fish being sold in supermarkets

Dioxin in Fish

Dioxins are a group of extremely toxic POPs that are primarily unintentional by-products of industrial processes. The EU has adopted limits for permissible levels of dioxins in food for human consumption. The levels are set above safe levels to accommodate the food industry, but the aim is to lower them over time. As can be seen in the table below, fish is the only commodity regulated on picogram per gram of *freshweight* (the whole fish) while other foodstuffs are regulated on a *lipid* (fat) base. Since fat content is often only ten percent of the freshweight, a regulation permitting similar levels of toxins in freshweight will mean much higher permissible levels. Most of the fish sold in Europe contains levels of dioxins that are above the permissible levels for meat, eggs, milk, etc.

Maximum allowed levels for dioxins, EU

Bovine and sheep meat	3 pg/g lipid base
Poultry and farmed game	2 pg/g lipid base
Pig meat	1 pg/g lipid base
Liver and derived products	6 pg/g lipid base
Fish and fishery products	4 pg/g fresh weight
Milk and milk products	3 pg/g lipid base
Hen eggs and egg products	3 pg/g lipid base
Oils and fats (various)	0.75-3 pg/g lipid

across Europe would be banned from sale if fish had the same limits for dioxin as meat, eggs, milk or other regulated food. Nevertheless, eating fish is still recommended.

Vegetables, Fruit and Oil

A total of 1,770 samples of fresh and frozen fruit and vegetables were examined for residues of pesticides by the National Food Administration in Sweden in 2002. The samples came from nations all over the world, though primarily from the EU, and had been collected from supermarkets and restaurants.

A total of 44 percent of the fruit and vegetables contained residues of at least one pesticide. At the same time, 19 samples of olive oil were analysed, of which 17 contained the pesticide endosufan. Out of 43 samples of fried potato products, such as chips, 15 contained the pesticide klorprofam.

House Dust

In another study, in May 2003, Greenpeace presented the results of analysis of ordinary house dust taken from 100 volunteer homes across the UK.

The analyses focused on finding industrial chemicals from five different groups: phthalates, used as plasticisers in PVC plastic; alkylphenols, mostly used in cosmetics; organotins, used as stabilisers in PVC; brominated flame retardants from furniture and electronic equipment; and finally chlorinated parafins used in plastics, rubber and paint.

All the samples from the UK contained phthalates, brominated flame retardants and organotin compounds. More than 75 percent of the samples also contained chlorinated parafins and alkylphenols. With just one exception, all the samples contained a range of other industrial chemicals such as pesticides, solvents and plastic additives.

Human Blood and Tissue

Considering the presence of industrial chemicals in water, air and food, it comes as no surprise that the human body also contains quite a few industrial chemicals.

Bioaccumulation

Many persistent chemicals are deposited in the fatty tissue of organisms. Since they do not break down quickly, the amount accumulated in the body increases even if the intake is low. Thus, a human or other predator accumulates chemicals from its prey and stores them in its own fat reserve. The only way the body can get rid of them is by disposing of the fat or through breast milk.

In a study from 2002 led by Mount Sinai School of Medicine in New York, USA, researchers found an average of 91 industrial chemicals and pollutants in the blood and urine of nine volunteers, with a total of 167 chemicals found in the group. Like most of us, the people tested do not work with chemicals nor live near industrial facilities. The substances found included PCBs, dioxins, DDT, insecticides, plasticisers, musk and volatile compounds. The scientists refer to this contamination as a person`s body burden.

In 2003, Greenpeace reviewed what studies had been made of certain industrial chemicals in human tissue with relevance to children before and slightly after birth. The review found that a number of man-made chemicals such as alkylphenols, bisphenol A, brominated flame retardants and plasticisers had been identified in umbilical cords, ovaries, placenta and blood.

In a study of blood samples from 155 volunteers from 13 locations in England, Northern Ireland, Scotland and Wales, WWF analysed the content of 78 different chemicals. All of the chemicals belonged to one of three groups: chlorinated pesticides, brominated flame retardants or PCBs.

The results showed that all the volunteers carried at least one substance from each chemical group. The highest number of chemicals found in a single person was 49. One volunteer carried 90 percent of the 78 substances.

Human Breast Milk

Since persistent industrial chemicals tend to deposit in fat, the pollutants found in human tissue (see above) are likely to also be present in human breast milk.

The 1999 report "Toxic Legacy" from WWF shows that more than 350 synthetic contaminants have been found in the breast milk of mothers, including dioxin, PCBs, DDT, flame retardants, plasticisers, musk compounds and pesticides. Moreover, even more contaminants are likely to be present according to WWF since the number of substances that these studies looked for was limited.

In another WWF study from 2003, the content of certain chemicals in the blood of 155 volunteers in the UK was analysed (see *Human Blood and Tissue* on previous page). One of the conclusions from this study was that women have significantly lower levels of PCBs in their blood than men. The levels also seem to fall with the number of children that the mother has given birth to. This implies that women may off-load PCBs to their babies, thereby reducing their own bodyburden.

Summary

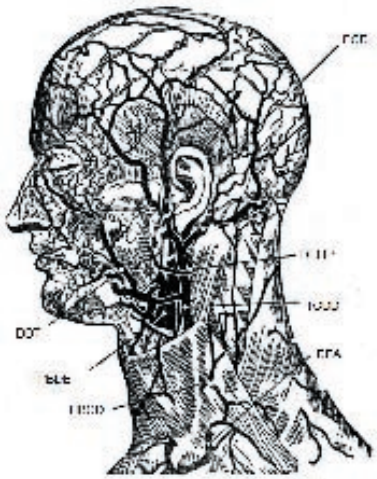
Annually, some 400 million tonnes of chemicals are produced in tens of thousands of varieties by mankind. Most of it is produced from natural resources such as fossil oil, salt, lime, minerals, etc. Most of it, if not all, re-enters the environment in its new form, interacting with humans, other animals, plants and other organisms.

Some of these substances may decompose quickly but little is known about the actual rate or the effects of the breakdown products. There are examples showing that the breakdown product from an industrial chemical can be very hazardous. DDT is one of the most familiar cases.

However, some of the chemicals break down slowly, stay in the environment for a long time and build up in soil and sediment, even in organisms through bioaccumulation. Other chemicals are so abundant that they are present everywhere all the time, even though they are not persistent.

Industrial chemicals therefore seem to be present in most places. Over the years, scientists have identified them in all of the environmental compartments they have looked in. Perhaps the most upsetting fact is that they seem to be present in all humans, flowing in our blood.

However, there is still a huge gap in knowledge. Since scientists always look for a limited number of specific chemicals, those are the only ones they find. What other substances are present in humans and the environment is largely unknown.



Body burden:
All 155 volunteers in a WWF study had chlorinated pesticides, brominated flame retardants and PCB in their blood. A study on nine volunteers from the USA found an average of 91 industrial chemicals in their blood. Some 350 synthetic substances have been found in breast milk.

EFFECTS

Overview

Humans and other organisms have always been exposed to chemicals that flow around on Earth. Over millions of years they have adapted and become more resistant in order to survive and multiply. However, the increased exposure to natural toxins such as metals, has caused problems. Organisms are not adapted to today's higher levels of lead, mercury and copper and have in many cases been damaged.

Another problem is the dispersal of new chemicals produced by mankind - synthetic chemicals - with the advent of industrialism and development of the chemicals industry. Organisms are now continuously exposed to low doses of chemicals that they have never been exposed to before and are not adapted to handle.

A third problem is that the releases of natural and synthetic chemicals to air, water and soil alters the chemical composition of the recipient. Such changes may have dramatic effects for life on Earth. The depletion of the stratospheric ozone-layer is one example. Global climate change is another.

Finally, chemicals may play an indirect but crucial role in other issues. For example, the increasing amounts of waste and the problems associated with the treatment of waste, would be less troublesome if the waste did not contain high levels of hazardous chemicals.

Exposure Types

Chemical exposure to humans and other organisms can be characterised as being either acute or chronic. Acute exposure is by definition limited in time and duration but may cause severe effects for those exposed depending on the toxicity and exposure level in question. Chronic exposure is a prolonged - even life-long - exposure to low doses of one or many hazardous substances to individuals or a large population.

Characteristics of Exposure Types

	Acute	Chronic
Exposure level	High	Low
Duration of exposure	Short	Long term
Size of exposed group	Limited	Unlimited
Size of exposure area	Local	Global
Composition	Simple	Complex
Effect development	Dramatic	Subtle
Effect assessment	Easier	Complex

Acute Exposure

Since acute exposure to hazardous substances may cause dramatic and visible damage in the short term, it is often easier to identify and monitor. The chemical and source in question may be simple to establish and its effects are often either well known or possible to assess. Exposure can also be prevented, minimised and controlled to a certain extent through technical measures. Today, acute exposure is predominantly caused by industrial accidents and spills that injure and kill large numbers of people.

Chronic Exposure

Chronic exposure is more complex. It is caused by a number of sources and by pollution in the general environment, water, air, food, etc. It consists of an unknown - but large - number of identified and unidentified substances and their breakdown products. The effects are not as immediate as those caused by acute exposure. Instead the effects may take years or decades to develop. The damage may even turn up in the offspring of the exposed individual, making connections very difficult to prove.

Causality

Since the number of substances that humans and the eco-system are continuously exposed

to is so large (see the previous section), it is virtually impossible to positively connect an observed effect with any particular substance. The effect may even be caused by the breakdown substances or by synergistic effects, where two or more substances interact causing damage which none of the substances causes alone.

Consequently, the full range of damage caused by chronic exposure to synthetic chemicals are presently not possible to quantify. However, according to many scientists there is an increasing amount of data and observations indicating that chronic exposure to synthetic chemicals has severe consequences for human health as well as for the environment.

As in the previous section, *Chemicals in the Environment*, examples which are causing concern among scientists and politicians around the world are presented. Again - however troubling these examples may be in themselves, they are mere examples and indicators of a larger problem. The greatest problem with chronic exposure is the time-frame and scope. Once damage has been identified, it is very difficult to reverse the situation. Persistent and bioaccumulative chemicals stay around for a long time, and when they are dispersed into every corner of the environment, there is no way to clean them up.

Causality and Association

It is sometimes fairly easy to show that a measure of ill-health (e.g. the number of admissions to hospital per day) is associated with a possible cause, such as the day-to-day variation in levels of air pollutants. However, to show that a causal relationship exists is more difficult. A number of guidelines or tests have been developed to help assess this. These include identifying whether there is a "dose-response relationship" between the proposed causal factor and the effect, whether the sequence of events makes sense (i.e. the cause always precedes the effect), checking the consistency of results between different studies, and the way in which the results of different studies fit together (coherence). Proof of causality is often very difficult but, by the application of these and other criteria, an expert judgement as to whether an association is likely to be causal can often be made. Where effects are likely to be serious and/or irreversible, then a low level of proof, as in the "precautionary principle", may be sufficient to justify actions to remove or reduce the probable causes.

WHO & EEA, 1997

ENVIRONMENT AND WILDLIFE

Overview

Chemicals play an important role in many environmental issues. It is a problem that cuts through many others, which normally are not conceived as associated with chemicals.

In its 1998 assessment of major environmental concerns in Europe, the European Environment Agency (EEA), identified 12 areas which need urgent attention and further measures. Although synthetic chemicals play a role in all of them, either directly or indirectly, defining the extent to which they contribute to the problems is difficult and can only be estimated. Any such estimation is bound to be debated, but is nevertheless presented for the sake of visualisation (see separate box on the next page). In nine of the areas of concern identified by the EEA, the role of synthetic chemicals may be considered significant or major.

Climate Change

Emissions of CO_2 from fossil fuels are undoubtedly the main cause of climate change, representing some 80-90 percent of the effect. Industry is the second largest consumer of oil, at approximately 25 percent of the total. About one-fourth of industrial oil is consumed as chemical feedstocks, slightly over five percent of global fossil oil consumption. The oil is used to produce chemical substances, plas-

tics, etc., and is eventually released as CO_2 to the atmosphere. Fossil oil in chemicals makes a minor contribution to global CO_2 releases.

There are also other chemical substances that contribute to global warming. Three of the six greenhouse gases covered under the Kyoto protocol are synthetic substances that have powerful effects: HFC, PFC and SF_6. Releases of such substances are small, representing a few percent of the total effect.

Ozone Depletion

Depletion of the stratospheric ozone-layer is caused entirely by synthetic substances known as chloro- and bromofluorocarbons used as refrigerants, industrial cleaners, foaming agents and fire extinguishers. International agreements have been reached to phase out ozone-depleting substances, but even if they are fully implemented, it will take 70 years before ozone depletion stops.

Concentrations of ozone at mid-latitudes over Europe have declined by 6-7 percent over the past decade and Europe contributes about one-third of global annual emissions of ozone-deleting substances.

Consequences of ozone depletion are possible changes in atmospheric circulation and increased UV-radiation. Skin cancer deaths in Europe due to increased radiation are expected to reach two per million by the year 2030. Effects on wildlife and the environment may also be severe.

Loss of Biodiversity

The populations of more than one-third of the bird species in Europe are in decline, most severely in North-Western and Central Europe. This is mainly caused by damage to their habitats by land-use changes and logging.

However, synthetic chemicals are an additional burden making it even more difficult for species to survive. In numerous cases, severe damage to the reproduction of fish, birds, shellfish and mammals have been connected to exposure to persistent synthetic chemicals.

Major Accidents

The chemicals industry produces and handles a great number of hazardous substances. These are often transported widely across the European continent and globally.

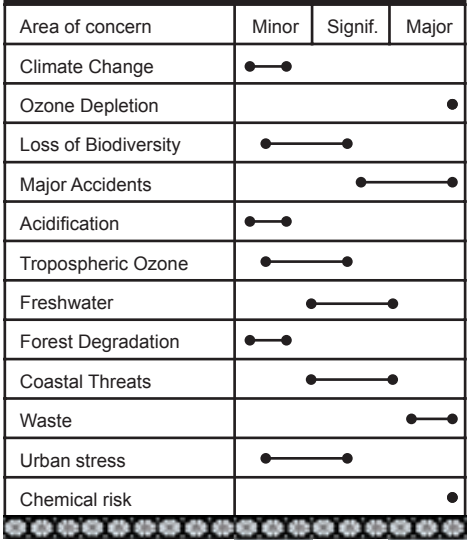
There have been many serious accidents in chemical plants and involving transports of hazardous substances globally and in Europe. The tragedies in Bhopal, Seveso and recently in Toulouse are the most known examples where chemical facilities have caused great havoc. The potential for major accidents with severe consequences for humans and the environment is large.

Tropospheric Ozone

Levels of oxidants such as ozone are increasing in the lower atmosphere. WHO Air Quality Guidelines for ozone are frequently exceeded in most parts of Europe. The oxidants arise from the main precursors nitrogen oxides, volatile organic compounds, methane and carbon monoxide.

At ground level, photochemical oxidants including ozone, can cause premature ageing of the lungs, eye, nose and throat irritation,

Indication of Role of Synthetic Chemicals in Areas of Concern



chest discomfort, coughs and headaches. They can also affect crop and possibly forests.

In the northern hemisphere ozone concentrations are expected to keep rising at one percent per year. No goals for limits have yet been set and in Europe the actions already undertaken are not thought to be sufficient.

Management of Freshwater

Consumption of water in Europe has increased from 100 to 650 km^3 per year from 1950 to 2000. In some countries, up to 30 percent of the water is lost in the distribution system. Agriculture is the dominant consumer of water, mainly for irrigation. Of all the manufacturing industries in Europe, the chemicals industry is the largest consumer of water, using approximately 45 percent of the total industrial consumption.

It should be noted that the impacts of using water is not limited to the amounts used. The quality in which it is returned to the environment is also crucial. In this respect, chemicals also play an important role. Waste water from agriculture, treatment plants, industries and other sectors are, as a rule, contaminated by synthetic chemicals.

Despite the introduction of water quality regulations in the EU and the attention to water quality in the Environmental Action Programme for Central and Eastern Europe, there has been no overall improvement of river quality since 1989/90.

Groundwater quality is affected by increasing concentrations of nitrate and pesticides from agriculture. Groundwater concentrations of certain pesticides frequently exceed EU maximum admissible concentrations. Significant pollution from heavy metals, hydrocarbons and chlorinated hydrocarbons has also been reported in many countries.

Forest Degradation

A 1992 survey of 113 tree species in 34 European countries showed that in 24 percent of the trees, defoliation exceeded 25 percent and ten percent were suffering from discoloration. In certain areas as much as 54 percent of the forests may have suffered irreversible damage.

Although acidification is considered to be a major cause, the processes leading to this damage are not fully understood. There are several hypothesis including factors such as climate change, nutrification, insects and fungus. It seems likely that the damage is not due to a single problem. Instead, the damage may be caused by a wide range of interacting factors where air pollution plays an important role.

Some countries, such as former Czechoslovakia, Germany and Poland, where several thousands of hectares of forests have been severely degraded, consider air pollution with its associated atmospheric deposition of nutrient, growth-altering, or toxic substances, to be a factor leading to the weakening of forest ecosystems. The extent to which synthetic chemicals contribute to this problem is unknown.

Coastal Threats

The European coastline, which is at least 148,000 km long, has great importance for biodiversity and as a buffer between land and sea. Human activities creating physical modifications of the coastline and emissions of contaminants have led to the deterioration of habitats and water quality.

Though only limited data is available, mainly covering Western and North-Western Europe, chemical pollution of the coastal zone is a serious problem in all of Europe's seas. Contamination of sediments, animals and plants by anthropogenic chemicals seems to be common in almost all European seas.

Elevated concentrations (above natural background) of heavy metals and PCBs have been found in fish and sediment, with high levels near point sources of emission. Bio-accumulation of these substances pose a threat to ecosystems and human health.

Waste

Europe produces more than 250 million tonnes of municipal waste and more than 850 million

tonnes of industrial waste annually. In the OECD countries of Europe there are 10,000 annual transfrontier movements of hazardous waste, totalling two million tonnes.

More than 55,000 contaminated sites have been registered in just six European countries, and the total contaminated area in Europe is estimated to be between 47,000 and 95,000 km^2 including 1,000-3,000 km^2 of contamination from landfills.

A determining factor in the waste problem is the chemical content of the waste. Typically all kinds of waste contain a multitude of synthetic chemicals of which many may cause negative effects if released to the environment. If waste was free from hazardous substances, re-use, recycling and deposition would be a minor problem.

Urban Stress

Urbanisation is continuing, despite the fact that around three-quarters of the population of Western Europe and the newly independent states (NIS), and slightly less than two-thirds of that in Central and Eastern Europe (CEE), already live in cities. The rapid increase in private transport and resource-intensive consumption are major threats to the urban environment and, consequently, to human health and welfare. Extensive car transports, noise levels, air pollution, waste generation and water consumption are all parts of urban stress. No doubt synthetic chemicals play a part in the increasing consumption and transports.

Chemical Risk

As mentioned initially, most environmental problems in Europe and in the world can be traced back to some form of excessive chemical loading. Many of these problems have been covered in the above. The specific and direct influence of chemicals on human health is covered below.

A general indication of the the potential extent of the problem is given above. However, there are many other ways of categorising effects of chemicals that are not addressed here.

HUMAN HEALTH

Overview

Calculating damage to human health caused by exposure to synthetic chemicals involves many problems. Thus, any such calculation may only serve as a preliminary indication in the absence of better data and scientific knowledge.

First of all there is a great lack of data concerning health effects from synthetic chemicals. Some 85 percent of all the high production volume chemicals (HPVs) lack basic toxicity data (see separate box, page 52).

Second, there is the time problem: certain effects, such as damage to the reproductive function, appears after a very long time or even in the next generation.

Third, some effects are very subtle and difficult to assess, such as minor brain damage and developmental dysfunctions. Finally, there may be contributing and confounding factors: a specific effect may have multiple causes making it impossible to attribute it to a single source.

When attempting to assess whether a chemical may cause damage, the substance is tested on animals. If the substance in question has already been released to the environment, it is also possible to collect samples of exposed organisms from wildlife. When assessing possible effects on humans, scientists either have to rely on the observed effects on animals, or when possible, on observations and experiences from accidents, spills and work-places where humans have been exposed unintentionally.

The above uncertainties make it extremely difficult to prove causal connections between the exposure to a certain chemical and an observed effect (see page 27). Nevertheless, many scientists are convinced that there is a connection between a number of illnesses and disorders and long-term exposure to a large number of synthetic chemicals.

Some Numbers

There is no doubt that man-made chemicals are having a large scale effect on human

Human Health Effects from Certain Chemicals

The below table summarises the main health effects of certain chemicals. The link with chemicals varies from wellknown causal relationships such as benzene and leukaemia, to suggestive associations, such as chemical sensitivity and pesticides. Most harmful effects are the result of many causes acting together, such as genetics, lifestyle, radiation, diet, pharmaceuticals, chemicals (manufactured and natural), smoking and air pollution, including indoor and outdoor exposures. It is also important to consider sensitive groups, such as the elderly, children, the embryo, the sick, and pregnant women, who may be affected at much lower doses than others.

UNEP/EEA 1997

Health effect	Sensitive group	Some associated chemicals, examples
Cancer	All	Asbestos, Polycyclic aromatic hydrocarbons (PAHs), benzene, some metals, some pesticides, several hundred animal carcinogens, some solvents, natural toxins
Cardiovascular diseases	Especially elderly	Carbon monoxide, arsenic, lead, cadmium, cobalt, calcium, magnesium
Respiratory diseases	Children, especially asthmatics	Inhalable particles, sulphur dioxide, nitrogen dioxide, ozone, hydrocarbons, some solvents, terpenes
Allergies and hypersensitiv.	All, especially children	Particles, ozone, nickel, chromium
Reproduction	Adults of reproductive age	PCBs, DDT, phthalates
Developmental	Foetuses, children	Lead, mercury, other endocrine disruptors
Nervous system disorders	Foetuses, children	PCBs, methyl mercury, lead, manganese, aluminium, organic solvents

health. According to the latest estimates from the International Labour Organization (ILO), a staggering 439,000 workers were killed by chemicals and other hazardous substances in 2003. Some 35 million persons are currently suffering from work-related diseases caused by hazardous substances.

But these figures give an incomplete and misleading picture. They refer to people damaged at work and exclude the persons who are subject to long-term exposure outside industrial facilities through their day-to-day life.

In an attempt to assess the human impact from long-term exposure to chemicals in Sweden, the National Chemicals Inspectorate (KemI) has estimated that five percent of the total burden of illnesses in the industrialised world, including cancers, may be attributed to chemical pollution, including air pollution and occupational exposure to chemicals. This would mean, for example, that chemical pollution in all its forms causes some 130,000 cases of cancer in Europe annually.

Cancer

Cancer has been the predominant issue of concern for discussions about health effects from synthetic chemicals for decades. The reason is that cancer was one of the first potential health problems identified with chemicals. Although cancer is undoubtedly an issue of concern, the spectra of effects studied by scientists and authorities has grown and includes several other issues of similar concern.

Some chemicals clearly cause cancer within some exposed groups, but the overall causation is unclear. Any increased cancer incidence is likely to be limited to a certain group of people, and may not be clearly visible in the general statistics.

Particularly troubling is the dramatic increase in testicular cancer among young men in the last decades. Since the 1950s, the incidence has increased some 400 percent. Of similar concern, there is an increase in the incidence of breast cancer in women. Long-term exposure to synthetic chemicals are considered to play an important role through hormonal influence (see *Reproduction* below).

Annually there are approximately 10 million new cancer patients in the world. Europe has a disproportionately high share of the incidence: in 1995 the number of new cases was 2.6 million, more than one-quarter of the global burden. Out of these, 1.6 million were fatal.

Tobacco and diet are by far the major known causes of cancer in Europe, representing 65 percent of the cases. Long-term exposure to chemicals, including air pollution and workplace exposure, is considered to cause five percent of the cases, some 130,000 cases and 80,000 fatalities per year in Europe.

Reproduction

It is a known fact that some chemicals have negative effects on the reproductive systems of wildlife. Human reproduction has become a main area of concern.

Many of the effects observed in wildlife are considered to be caused by oestrogenic and anti-oestrogenic influence from chemicals. Malfunctioning or suppression of other natural hormones is another observed effect in wildlife. Chemicals which are considered to cause any of these effects are called *Endocrine Disrupters* or *Endocrine Disrupting Chemicals (EDCs)*.

Over the past decade, there has been an increasing concern that humans are also affected by EDCs. However, since tests can not be performed on humans, scientists have to rely on experiences from real life.

Clinical experience involving human exposure to a specific EDCs is very limited. The most important experience is the administration of the pharmaceutical DES in the 1940s to 1960s. DES, which has an oestrogenic effect, was given to women to prevent miscarriage. Eventually it has been proven that the daughters to these women have a significantly increased incidence of vaginal cancer and that sons and daughters have a higher rate of birth defects.

Three important lessons may be learned from this tragedy. The first is that the effects of DES on humans was very similar to those observed on animals in clinical studies. The second is that even minute amounts of a substance may cause serious effects on an offspring, especially if it occurs during a sensitive time during the development of the foetus. The third, and perhaps most troubling lesson, is the time it took for the effects to become apparent.

Another human experience of EDC concerns the production of the pesticide Kepone. A study on the male workers producing Kepone shows that their sperm production had been affected and some were even sterile.

There are a number of clinical effects that have been observed and documented in humans which could be caused by influence from such substances. The dramatic increases of testicular cancer in young men and breast cancer among women is one such area. Others are prostate cancer, kryptorkidism (when a testicle stays in the abdomen), defects on male genitalia and miscarriage.

One of the most hotly debated areas where EDCs may play an important role is declining sperm counts. It is a known fact that EDCs, such as Kepone, may impair sperm production in humans. According to several studies, the number of sperms in human semen, and their quality, has decreased dramatically over the past 50 years. This has given rise to the concern that human reproduction as such may be threatened by synthetic chemicals.

Allergies and Asthma

The immunological system is also highly dependent on hormonal balance and may be disturbed by EDCs, especially in the foetus

stage or in the early years of life. It is well known that the immunological systems of wildlife have been damaged by EDCs and there are concerns that they may have similar effects on humans.

This concern is fuelled by the fact that illnesses with an immunological background are increasing worldwide. For example, the incidence of asthma among school children in some European countries has increased from one percent in the 1950s to almost ten percent today. The fact that some 20 percent of the population in industrialised countries have some form of allergy is also troubling.

It is likely that there are several factors involved in this development. Outdoor air pollution, the quality of indoor air and sterile surroundings are considered to be major causes. However, the influence of EDCs may also be involved.

Economic Costs

Assessing the economic costs incured on the global society by hazardous chemicals is impossible. Such an assessment would need to cover a multitude of issues. These would include, but not be limited to, the global costs from depletion of the stratospheric ozone layer and other environmental effects, loss of income for fishermen, farmers and forestry, costs for water treatment, health-care costs, clean-up costs for hundreds of thousands of acres of polluted soil and liability for the loss of tens of thousands of human lives.

However, it is possible to give some indications of the costs involved in some of these issues. For example, it has been estimated that chemical pollution causes some five percent of the health problems in the industrialised world and five percent of the health-care costs. The socio-economic costs for allergies alone in the EU have been estimated at €29 billion per year. Thus the costs for allergies induced by chemical pollution may be estimated at €1.4 billion annually in the EU.

In the US, the annual costs for morbidity, mortality. lead posioning, asthma, cancer and developmental disabilities caused by environmental pollution have been estimated to be €50-60 billion. The annual overall health costs caused by toxic substances in the US and Canada, have been estimated to be up to €320 billion. While these figures are huge, they are only fractions of the total costs created by chemical pollution.

SUMMARY

The extensive production, use and dispersal into the environment of man-made chemicals, creates or contributes to a number of problems. While the direct effects of such chemicals on wildlife and humans is difficult to quantify, there is little or no doubt that the effects are vast and an issue of great concern. Hundreds of thousands of people die and millions are injured by hazardous chemicals every year.

Man-made chemicals are also responsible for other severe problems such as depletion of the stratospheric ozone layer and a major contributor to current problems with waste. Additionally, the chemicals industry and its products play a significant role in many other areas of concern, such as loss of biodiversity, water consumption and degradation of coastal areas. The total annual cost to society is immense.

Summary of Part One

Chemicals Industry

The chemicals industry is the third largest industrial sector in the world. It employs some ten million persons and the global sales in 1998 were approximately €1,500 billion. Eighty percent of the production takes place in 16 countries, primarily in the OECD.

While the majority of workers are employed in small and medium-sized enterprises, sales are completely dominated by a few large multinational corporations. In Europe, the worlds largest chemicals producing region with some 35 percent of world production, two percent of the companies produce 72 percent of the volume.

The consumption of chemicals is also unevenly distributed around the world. Most of it takes place in OECD countries. A person living in Europe, USA or Japan consumes chemicals worth €1,500 per year, while an Indian or African only spends €50.

Markets in the OECD region are becoming mature and saturated with basic high-volume chemicals. Thus, the industry is looking at new market strategies. On the one hand, they are moving production and sales of basic chemicals to non-OECD countries, predicting that consumption will increase dramatically in these areas. On the other hand, they are using biotechnology and increased know-how to move into agriculture, food, pharmaceuticals and production of more specialised chemicals in Europe. This requires a dramatic restructuring of the industry.

Sales of chemicals are predicted to continue to grow. By 2020 the global sales, counted in today's prices, may have tripled. Most of this growth is likely to take place in non-OECD countries.

Chemicals in the Environment

Although most chemicals have not been assessed, sales are permitted until they have been proven hazardous or unacceptable. Such chemicals are widely used and dispersed, mainly through products, into the environment and eventually to humans. Low levels of synthetic chemicals have been found by scientists in every corner and environmental compartment of the world, from the high alpine lakes to ocean sediments. They are found around the globe in food, water, dust, human blood and human milk.

Effects of Chemicals

The full impact on the environment and human health cannot be assessed. But there are few environmental problems that cannot be traced back to chemical over-loading. There is no doubt that even low levels of certain - mostly still unidentified - synthetic chemicals are responsible or contributing to a multitude of serious effects on the environment and also on human health. While the full socio-economic costs of chemical pollution can not be assessed, they cover a wide range of issues and amount to enormous sums.

PART TWO: POLITICS

International Chemicals Policy

BRIEF HISTORY

Prehistoric

Since the beginning of civilisation, mankind has extracted, manufactured and used chemicals from the environment. Insects have been used as pigments, metals and minerals have been mined and wood has been fragmented and boiled to produce paper.

Many of the processes turned out to have certain disadvantages to human health and the environment. However, production was limited to small-scale operations causing effects that were mostly local and personal and there was little understanding of long-term effects.

Early Industrialism (1700-)

With the advent of industrialism and large-scale operations, problems increased and authorities started to intervene on - as far as they could see - the most devastating operations.

The primary concern was the health of people living close to operations, and if an operation moved to another, less populated area, the problem of pollution was considered to be solved. Still, there was little understanding of long-term effects or the mobility of pollutants, and the practices continued as production increased.

1800-

With the increasing large-scale production, concern rose regarding the health of workers. Industrial facilities began to pop up in every small town of the industrialised parts of the world, creating discomforts to the neighbours and citizens. At this time, industrial smoke stacks were considered a sign of prosperity and wealth and a favourite motif of artists. Another issue of concern was the increasing use of chemicals in war.

Although the progress made possible through industrialisation was widely hailed, there were protests against the increased pollution and mass-production. The Arts & Crafts movement, which had a somewhat romantic ideal, was very active against industrialism in the United Kingdom and USA between the 1890s and 1920s.

The First Conventions

The very first international convention considering chemicals was signed in 1868, the Saint Petersburgh Declaration. This convention covered the use of certain flammable chemicals in war.

In 1906, an international workers organisation organised a conference in Bern, Switzerland, to negotiate a convention regarding the use of phospor in the production of matches. After the first world war, in 1919, the International Labour Organisation was created and two of its first conventions concerned the use of chemicals: lead and phosphor.

The Petro-Chemistry Boom

From the early 1900s, the arrival of petrochemistry dramatically changed society. For the first time, humans could produce new substances in a large scale. One of the end products was, of course, gasoline, or petrol. Other substances derived from the same process were benzene, toluene, xylene, ethylene and propylene. All of them could be processed into a number of new substances and were the building blocks for the emerging chemicals industry.

These building blocks were used to develop products that found great markets and

the industry started developing thousands of new substances for every possible use. Paints. plastics, pesticides, textiles, fuels and cosmetics are some examples where the new substances had created a revolution. Of course these substances were welcome by society and when the real boom came in the 1940s and 1950s, few persons voiced any concern, much less any ambition to regulate production and use.

Now we know that some of the new substances were not entirely positive. It was at this time that substances and products such as PCB, DDT, PVC, phthalates, chlordane and other notorious toxins were developed and put into large scale production and use. Simultaneously, there was a huge increase in the extraction and use of many toxic metals, such as lead, mercury and cadmium.

Post WW II

After the second World War, the United Nations World Health Organisation (WHO) and Food and Agriculture Organisation (FAO) were formed. Both of them were engaged in chemicals, predominantly pesticides, from the start. Ironically, their main ambition was to increase the use of pesticides such as DDT.

It took until the early 1960s before authorities started to react. By that time, concerned reports from scientists and protests from individuals and organisations were mounting and it was obvious that something needed to be done. DDT and mercury became the early focus after the publication of Rachel Carson's book "Silent Spring" in 1962. In 1966 the Danish scientist Sören Jensen presented evidence that PCB, a substance used in industrial oils, could be found in birds eggs.

Among the first to react were the authorities in the USA and in the Nordic countries (Denmark, Sweden, Norway and Finland) where environmental and health effects had become apparent. The production and use of certain substances was banned or regulated in some countries, starting in the early 1970s. DDT, mercury and PCB were among the first to be regulated. They were followed by lead, chlordane, dieldrin and others.

Time for Treaties

A political breakthrough was reached in 1972 at the United Nations Conference on the Human Environment in Stockholm, the first UN conference to focus on environmental issues. A declaration was adopted and it was agreed to establish a separate UN programme for the protection of the environment - the United Nations Environment Programme (UNEP).

After this point, numerous treaties, agreements, conventions, declarations and protocols for the protection of the environment - including measures against chemical pollution - were negotiated globally. Some of them are truly global, encompassing over one hundred nations, while others are regional.

Though the USA and the Nordic countries were the most active, authorities in some other countries started to react. From the late 1970s through the 1990s, several other nations, primarily in Europe, took an active role. However, the majority nations in the world still play a passive role, following the developments and implementing regulations when demanded.

Loss of Leadership

Since the 1970s it has become apparent that the problems are not limited to a small number of substances. Scientists and authorities eventually realised that it was impossible to protect the environment and human health by picking one substance at a time. New problems were identified continuously and the number of potentially problematic substances was too great. Additionally, new substances were being developed and marketed every day. A different approach was necessary.

Lately, the USA seems to have abandoned its ambition to be one of the global leaders in this area. Similarly, the Nordic countries have taken a more passive approach, possibly in order to adapt to the general policies of the EU. While working for stronger regulation

inside the EU, they are reluctant to implement stronger national regulations. Hopefully, the EU as a whole will now take on the task of being a global leader in the regulation of chemicals and protection of human health and the environment.

GLOBAL INSTRUMENTS

Some Definitions

Global instruments to protect the environment are negotiated in many different fora and have different status depending on which instrument has been chosen for the agreement. Most of the important instruments have been negotiated under the United Nations.

Over the past centuries, state practice has developed a variety of terms to refer to international instruments by which states establish rights and obligations among themselves. In spite of the diversity of terminology, no precise nomenclature exists. In fact, the meaning of the terms used is variable, changing from state to state, from region to region and instrument to instrument. Some of the terms can easily be interchanged: for example, an instrument that is designated "agreement" might also be called "treaty."

The title assigned to such international instruments thus has normally no overriding legal effects. The title may follow habitual uses or may relate to the particular character or importance sought to be attributed to the instrument by its parties. The degree of formality chosen will depend upon the gravity of the problems dealt with and upon the political implications and intent of the parties.

Although these instruments differ from each other by title, they all have common features and international law has applied basically the same rules to all of them. These rules are the result of long practice among the states, which have accepted them as binding norms in their mutual relations.

As a general rule, the title of an instrument serves as an indicator of its legal status, but there are many exceptions. Thus the status must be defined case by case.

Declaration

Although "declarations" are generally not legally binding, they are very important as indicators of the ambitions and directions of the global community. The term is often deliberately chosen to indicate that the parties do not intend to create binding obligations but merely want to declare certain aspirations which will later be laid out in other, legally binding, instruments. An example is the 1992 Rio Declaration. Declarations can however also be treaties in the generic sense intended to be binding by international law. It is therefore necessary to establish in each individual case whether the parties intended to create binding obligations.

Treaty

There are no consistent rules when state practice employs the terms "treaty" as a title for an international instrument. Usually the term is reserved for matters of some gravity that require more solemn agreements. The signatures of the parties are usually sealed and they normally require ratification.

Agreement

"Agreements" are usually less formal than treaties and deal with a narrower range of subject-matter. There is a general tendency to apply the term "agreement" to bilateral or restricted multilateral treaties. It is employed especially for instruments of a technical or administrative character, which are signed by the representatives of government departments, but are not subject to ratification.

Convention

The term "convention" is usually used for formal multilateral treaties with a broad number of parties. Conventions are normally open for participation by the international community as a whole, or by a large number of states. Usually the instruments negotiated under the auspices of an international organisation are

entitled conventions. Conventions are also considered binding, for example the Statute of the International Court of Justice refers to "international conventions, whether general or particular" as a source of law, apart from international customary rules and general principles of international law.

Protocol

The term "protocol" is used for a variety of instruments. Typically, they are less formal than conventions and treaties or they may be subsidiary to framework conventions, defining what measures to implement, targets to reach or other technical matters. An example is the 1987 Montreal Protocol on Substances that Deplete the Ozone Layer adopted on the basis of the 1985 Vienna Convention for the Protection of the Ozone Layer.

Ratification

"Ratification" is when an international instrument is adopted on a national regulatory level, usually by parliaments of the contracting parties. Some instruments, especially treaties and conventions, require ratification of a certain number of governments before they enter into force internationally.

UN Instruments Concerning Chemicals

The problems associated with chemicals are of concern to the global population. Thus the management of chemicals is addressed in a number of UN organisations, treaties, programmes and declarations. The main UN body dealing directly with chemicals is the United Nations Environment Programme (UNEP).

However, control of chemicals concerns many other UN bodies. Therefore,in 1995, the UN created the Interorganisation Programme for the Sound Management of Chemicals (IOMC). The programme consists of a cooperative agreement among UNEP, the International Labour Organisation (ILO), the Food and Agriculture Organisation (FAO), United Nations Industrial Development Organization (UNIDO), United Nations Institute for Training and Research (UNITAR) and the Organisation for Economic Co-operation and Development (OECD).

The Stockholm Declaration

The first time long-term chemical pollution was officially addressed at a high level was during the 1972 United Nations Conference on the Human Environment (UNCHE) in Stockholm, where chemical pollution was recognised as an issue of global concern. At the conference, a number of guiding principles for the protection of the environment were adopted. These have been important in the successive development of other instruments.

Another important outcome of this conference was the agreement to create a new programme for global environmental protection under the United Nations: UNEP.

The MARPOL Convention

The International Convention for the Prevention of Pollution from Ships (MARPOL) was first adopted in 1973, but was later modified in 1978. The aim of the convention is to minimise releases of oil, noxious liquids, harmful substances, sewage and garbage from ships. The convention stipulates certain criteria for ships travelling the seas and also designates some marine areas to be especially sensitive, thus requiring a higher level of protection and stricter rules. The convention had 118 contracting parties in 2001.

The Vienna Convention

The evolving insight that certain man-made chemicals were destroying the stratospheric ozone layer finally triggered action. In 1985, the Vienna Convention was agreed upon. This is a framework convention which needs the development of measures in separate protocols (see also *the Montreal Protocol*). The convention had 176 parties in 2001.

The Montreal Protocol

As a protocol under the framework of the Vienna Convention (see above), the Montreal

protocol was first adopted in 1985 and has been adjusted five times. It aims to reduce and eventually eliminate the emissions of man-made ozone depleting substances by ceasing its production and consumption. The protocol had 175 contracting parties in 2001.

The Rio Declaration and Agenda 21

The second time chemicals were addressed broadly in a global effort was at the United Nations Conference on Environment and Development (UNCED) in Rio de Janeiro, Brazil, in 1992. At the conference, the signatories once again laid out important principles. The principles of greatest relevance to chemicals are number 8, which declares that states should reduce and eliminate unsustainable consumptions patterns, and principle 15 which declares the importance of using the precautionary principle.

Additionally, the states agreed on an action plan, that was named "Agenda 21," based on these principles. The agenda consists of 40 chapters which are intended to create a sustainable development for the 21st century.

Chemicals are widely covered in the agenda. The entire Chapter 19 concerns safe use of chemicals and chemicals are also covered in Chapter 6 (protection of human health), Chapter 9 (protection of the atmosphere), Chapter 14 (sustainable agriculture), Chapter 17 (protection of the seas), Chapter 18 (protection of fresh water) and Chapter 20 (treatment of hazardous waste).

The Stockholm Convention

In the mid-1990s, negotiations to eliminate releases of persistent organic pollutants (POPs, see also box in *Chemicals in the Environment* in Part One) were initiated. The negotiations focused on the 12 most hazardous substances - the Dirty Dozen - and were finalised in 2001 in Stockholm, Sweden.

In a historic agreement in May 2001, the nations of the world for the first time agreed to eliminate all releases of certain chemical substances. The treaty is also known as the POPs Treaty. Eventually other POPs are likely to be added to the list and be banned globally.

The Basel Convention

In order to control the transboundary movements of hazardous wastes, the Basel Convention was adopted in 1989. The convention lays out principles for avoiding damage to the environment from such transports. In 1995, an amendment to the convention was also adopted, banning the export of hazardous waste for final disposal, recovery or recycling from OECD countries to non-OECD countries. The convention had 148 contracting parties 2001.

The London Convention

First adopted in 1972, the Convention on the Prevention of Marine Pollution by Dumping of Wastes and Other Matter, concerns dumping of wastes which contain hazardous chemicals or radioactivity as well as incineration of hazardous wastes at sea.

The convention was amended several times and was finally replaced in 1996 by a framework convention and protocols. While the original convention was permissive in the sense that it allowed dumping in general except for matters defined in the convention, the 1996 convention reverses the logic. It bans dumping in general, except for certain matters that are defined in the protocols, such as organic waste.

One of the most important innovations was the introduction of the "precautionary approach." This states that preventive measures should be taken when there is reason to believe that wastes or other matter introduced into the marine environment are likely to cause harm even when there is no conclusive evidence to prove a causal relation between inputs and their effects. The protocol also states that "the polluter should, in principle, bear the cost of pollution" and it emphasizes that contracting parties should ensure that the protocol should not simply result in pollution being transferred from one part of the environment to another.

The Rotterdam Convention

Aiming to control trade of hazardous substances to countries with insufficient knowledge about chemicals and lax border control, an agreement to inform authorities in the receiving countries in advance was negotiated. Chemicals covered by this convention are pesticides and industrial chemicals that have been banned or severely restricted for health or environmental reasons by parties of the convention, and which have been notified by parties for inclusion in the Prior Informed Consent (PIC) procedure.

The agreement, called the Rotterdam Convention on Prior Informed Consent, was adopted in 1998 and also stipulates that the receiving country must give consent to the import before it may take place. In 2001, the convention had 14 parties.

The Convention Concerning Safety in the Use of Chemicals at Work

The objective of the Convention is the enhancement of the existing legal framework for occupational safety, by regulating the management of chemicals in the workplace. It has the broad purpose of protecting the environment and the public, and the specific objective of protecting workers from harmful effects of chemicals. It applies to all branches of economic activity in which chemicals are used, and it covers all chemicals with particular measures concerning hazardous chemicals.

The preamble of the Convention notes that the protection of workers from harmful effects enhances the protection of the general public and the environment. In addition, workers have a need for, and a right to, information about the chemicals they use at work.

UNFCCC

The United Nations Framework Convention on Climate Change (UNFCCC), which was adopted in 1992, aims to stabilise the releases of greenhouse gases. It establishes certain principles and provides a process for agreeing on action. The technical measures to be taken were defined in the Kyoto Protocol in 1997. The convention had 186 parties 2001.

The Kyoto Protocol

Under the Framework Convention on Climate Change (see above) the Conference of the Parties in 1997 adopted the Kyoto Protocol containing stronger reduction commitments for developed countries in the post-2000 period. The convention covers six specific greenhouse gases, of which three are man-made chemicals, HFCs, PFCs and SF_6.

The Convention on the Control of Harmful Anti-fouling Systems on Ships

Regulation of the use of tributyltin (TBT) and other hazardous substances as paint on ships (anti-fouling) was first addressed in Chapter 17 of Agenda 21 and has been negotiated in the IMO since 1999. In 2001 a convention was adopted.

Under the terms of the convention, parties to the Convention are required to prohibit and/or restrict the use of harmful anti-fouling systems on ships flying their flag, as well as ships not entitled to fly their flag but which operate under their authority and all ships that enter a port, shipyard or offshore terminal of a party.

Anti-fouling systems to be prohibited or controlled will be listed in an annex to the convention, which will be updated as and when necessary.

World Summit on Sustainable Development (WSSD)

In September 2002, the World Summit on Sustainable Development (WSSD) in Johannesburg, South Africa, adopted a historic objective much similar to the generation goal set in the Esbjerg Declaration from 1995 and in the OSPAR convention from 1998 (see *Regional Instruments* below).

The WSSD goal is that, by the year 2020, chemicals will be used and produced in ways that *"lead to the minimization of significant adverse effects on human health and the environment, using transparent science-based risk*

assessment procedures and risk management procedures, taking into account the precautionary approach, as set out in principle 15 of the Rio Declaration on Environment and Development".

The Summit also endorsed the further development of a strategic approach to international chemicals management (SAICM), based on the IFCS Bahia documents, by 2005 and urged UNEP, IFCS, other international organizations dealing with chemical management and other relevant international organisations and actors to cooperate closely in that regard, as appropriate. The Plan of Implementation of the Johannesburg Summit also identified the need to increase efforts to achieve sustainable consumption and production, cleaner production processes and methods and prevention and/or minimisation of the generation of wastes

Strategic Approach to International Chemicals Management (SAICM)

In February 2002, the United Nations General Assembly adopted a decision to develop a global strategy for chemical management. This was confirmed by the participating states at the World Summit of Sustainable Development (WSSD) in Johannesberg, South Africa, in September the same year. The first negotiations for a Strategic Approach to International Chemicals Management took place in Bangkok in November 2003. The intention is that negotiations will be finalised by 2005, resulting in a Ministerial declaration and global convention.

Other UN Activities

UNEP is also a driving force in other areas concerning chemicals, such as the promotion of cleaner production, the phase-out of lead in petrol, global assessment of mercury pollution and enabling information sharing.

Beside the agreements made under UNEP, other UN bodies also address chemical control in specific sectors or indirectly. Such activities are conducted through a variety of programmes and have resulted in a large number of global instruments. Examples of such bodies are the United Nations Economic Commission for Europe (UNECE) which created the first international agreement on air pollution in 1979 and the Convention on Long-range Transboundary Air Pollution (CLRTAP), also known as the Geneva Convention.

The United Nations Food and Agriculture Organisation (FAO) covers some aspects of the use of pesticides, primarily through the Code of Conduct. The World Health Organisation (WHO) also addresses specific aspects of chemicals, such as establishing tolerable daily intakes (TDIs) of pesticides and other pollutants. The International Maritime Organisation (IMO) covers some aspects of chemical pollution at sea and operational regulations for ships. The International Labour Organization (ILO) covers work-related issues of chemical safety.

The International Programme on Chemical Safety (IPCS), a cooperative programme of the UNEP, WHO and ILO, was formed in 1980 to assist states in the evaluation of risks associated with chemicals and strengthening their capacity in preventing damage to human health and the environment.

IFCS

At UNCED in Rio de Janeiro in 1992, some 100 nations and organisations formed the Intergovernmental Forum for Chemical Safety (IFCS). The forum is an independent organisation which is administered by WHO but funded by IFCS members.

The objective of IFCS is to help nations to implement the agreements concerning chemicals made in Rio de Janeiro. However, at the Forum III meeting in Salvador da Bahia, Brazil, in October 2000, the organisation adopted a new declaration, reviewed its objectives and adopted new priorities for global control of chemicals beyond the year 2000, thus making a commitment to achieving a number of key goals within a defined time frame and drawing the attention of governments and the

The OECD High Production Volume (HPV) Programme and SIDS

In 1990 the OECD established a programme on the co-operative investigation of existing chemicals. This programme focuses on chemicals produced in high volumes (i.e. produced in greater than 1000 tonnes in one OECD country or the European Union) of which there are about 5,000. Little is known about the toxicity for some 75-85 percent of these chemicals. A minimum set of data - the Screening Information Data Sets (SIDS) - upon which an initial hazard assessment can be based for HPV chemicals will be provided by OECD countries in co-operation with industry.
To this end, the OECD countries have identified a number of data elements needed for screening chemicals to determine whether further work is necessary. The SIDS is comprised of a limited number of data elements which can give information on certain characteristics - such as persistence and bioaccumulation - and effects of chemicals. Similar to the Minimum Pre-marketing Set of Data (MPD) for new chemicals, SIDS is used in the HPV Chemicals Programme by many countries and in voluntary industry programmes.

public to the need for action on chemicals issues. IFCS has also played an important role in the negotiations of many of the more recent agreements. In particular, it has been active in promoting the need for a global strategy (SAICM, see previous page).

OECD

The Organisation for Economic Cooperation and Development (OECD) is an intergovernmental organisation with 30 member states. Its primary purpose is to achieve the highest possible sustainable economic growth, improve the economic and social well-being of its population and to contribute to global development in general.

The OECD has an extensive programme concerning chemicals. The focuses of the activities are to assist member states in risk management, promoting the public right to know, preventing disturbances in the trade of chemicals and to promote new technologies.

The Chemicals Programme

Specifically, the OECD Chemicals Programme provides guidelines for the testing of chemicals, principles for good laboratory practices, a system for the mutual acceptance of data, harmonised methods of risk assessment, cooperative testing and assessment of high volume production chemicals, support for national activities regarding risk management and proposals for a harmonised classification system for chemical hazards. The Chemicals Programme is also developing a project to coordinate national and regional activities concerning endocrine disrupting chemicals (EDCs).

The Chemical Accidents Programme

The OECD Chemicals Accidents Programme, which began in 1988, addresses prevention, preparedness and response related to accidents involving hazardous substances. Its activities focus on the development of common principles and policy guidance for public authorities, industry, labour, communities and others as well as the sharing of information and experience among OECD and non-member countries.

The PRTR Programme

The OECD Work on Pollutant Release and Transfer Registers (PRTRs) was initiated in 1993, as a follow-up to UNCED in Rio de Janeiro 1992, with a project to prepare guidance for, and promote the development of, PRTRs. This work was undertaken in close cooperation with IPCS, WHO, UNEP, UNITAR and UNIDO. A 1996 OECD Council Recommendation calls on member countries to establish PRTR systems.

The Pesticides Programme

The Pesticide and Biocides Programme was formally launched in 1994, after recognition by member countries of the pressing need to initiate new international work on pesticides and biocides. The goals of the project are to harmonise pesticide and biocide review procedures for registration and use, to share the work of evaluation of pesticides and biocides and to find new approaches to risk reduction.

Other OECD Programmes

Beside the activities undertaken in the different programmes directly associated with chemicals, the OECD has many other activities that are indirectly connected. Examples are activities regarding climate change and an extensive programme on waste issues.

The World Bank

In its own words, the UN World Bank assists countries in order to alleviate poverty and improve living standards. The Bank has been extensively criticised for investing into unsustainable and destructive technology and projects. Today the World Bank recognises that that its goals can only be achieved if they address local, regional and global environmental issues and sustainability.

The World Bank claims to take into account issues of sustainable development and protection of the environment in the development and review of lending projects. Guidance has been developed for use in Bank-funded projects to raise attention to pollution prevention, including issues related to chemical safety.

The World Bank is involved in a number of activities relating to global environmental agreements, including climate change, persistent organic pollutants (POPs), ozone depletion and the Global Environment Facility (GEF). The International Finance Corporation (IFC), the private sector part of the World Bank Group, helps the private sector develop projects that promote the objectives of the climate change and biodiversity conventions.

World Trade Organisation (WTO)

The WTO is an international organisation overseeing the rules of international trade. Its purpose is to help trade flow smoothly, in a system based on rules, to settle trade disputes between governments, and to organise trade negotiations.

There is wide concern that the liberalisation of trade is allowed to over-ride measures to protect the environment and human health through multilateral environmental agreements (MEAs). This has two dimensions: firstly, multilateral and global agreements that have already been agreed may be difficult to implement, and secondly it may become more difficult to develop new instruments.

The WTO claims that a range of provisions in the WTO can accommodate the use of trade-related measures needed for environmental purposes, including measures taken pursuant to MEAs. Of key importance are the WTO provisions relating to non-discrimination and to transparency as well as the exceptions clauses allowing a WTO Member to legitimately place its public health and safety and national environmental goals ahead of its general obligation not to raise trade restrictions or apply discriminatory trade measures.

REGIONAL INSTRUMENTS

United Nations

In addition to the global instruments, the United Nations also negotiate regional and multilateral agreements for protection of the environment. Some of them are connected to global instruments, such as the Barcelona Convention, others are independent agreements. There are also a few conventions which have not been negotiated under the United Nations, such as the Helsinki and OSPAR conventions.

CLRTAP

The Convention on Long Range Transboundary Air Pollution (CLRTAP), adopted in 1979, is a European instrument developed under

UNECE. The objective of this Convention is to protect man and the environment against air pollution and to endeavour to limit and gradually reduce and prevent air pollution including long-range transboundary air pollution.

The Convention sets up an institutional framework, bringing together policy and research components. It establishes a number of co-operative programmes for assessing and monitoring the effects of air pollution.

Since its entry into force, the convention has been extended by eight protocols regulating releases and transboundary movement of air pollution, among them sulphur, nitrogen oxide, volatile organic compounds (VOCs), some heavy metals and 16 POPs. The convention had 48 contracting parties in 2001.

Regional Seas Programme

One of the first attempts at global instruments made by UNEP was the Regional Seas Programme, established in 1974. The programme aims to tie nations together in regional maritime fora in order to protect the marine and coastal environment. While the approach is regional, it has global reach.

In this programme, the world's seas are divided into 14 regions where each region has a specific programme to address the specific issues of concern. These regions remain the central UNEP initiative to implement Chapter 17 of Agenda 21 (see *Rio Declaration*). Thirteen of the regions have adopted individual action plans and nine have adopted regional conventions, such as the Barcelona Convention (see below).

The United Nations Regional Seas Programme does not include certain marine areas that are covered by other conventions, such as the North-East Atlantic and the Baltic Sea.

The Barcelona Convention

The Mediterranean Sea is one of the regions that has adopted a convention under the UNEP Regional Seas Programme (see above). The Convention, which is called The Barcelona Convention (Barcon), was adopted already in 1976. In recent years the convention has been increasingly focusing on releases of hazardous substances to the marine environment from land-based sources.

In 1995, Barcon adopted the precautionary principle and also set the objective to eliminate all releases of hazardous substances to the Mediterranean, making its objective very similar to those of OSPAR and HELCOM.

Other Instruments

The Esbjerg Declaration

At the Ministerial Conference of the North Sea Ministers in Esbjerg, Denmark, in 1995, the Ministers adopted a declaration voicing concern regarding the state of the North Sea and - for the first time - defined an operational objective. The declaration concludes that the only acceptable level of hazardous substances - man-made and natural - are background levels. To achieve this, all releases of hazardous substances to the marine environment must cease within one generation, i.e. before the year 2020. This objective has later been called "the generation goal" (see separate box).

This declaration and the generation goal have come to set the agenda for several regional conventions, such as the OSPAR, Barcelona and Helsinki Conventions, and is now finding its way into global instruments as well. Similar wordings were adopted in June 2001 by the Council concerning the objectives of the new EU chemicals strategy (see *REACH*) and at the WSSD in 2002 (see above).

The Esbjerg Declaration is probably the first international political declaration explicitly seeking to eliminate the threats from chemicals at their source.

The OSPAR Convention

The OSPAR Convention, or The Convention for the Protection of the Marine Environment of the North-East Atlantic, which is the full name, was adopted in 1992, replacing the previous Oslo-Paris Convention. The OSPAR convention seeks to protect the marine environment in a large area, from Gibraltar to northern Norway and Russia, by taking

OSPAR and The Esbjerg Declaration

At the North Sea Ministerial meeting in Esbjerg, Denmark in 1995, the Ministers adopted the following declaration. It has become the new standard for other regional instruments and is increasingly finding its way also into global policies.

"The Ministers AGREE that the objective is to ensure a sustainable, sound and healthy North Sea ecosystem. The guiding principle for achieving this objective is the precautionary principle.

This implies the prevention of the pollution of the North Sea by continuously reducing discharges, emissions and losses of hazardous substances thereby moving towards the target of their cessation within one generation (25 years) with the ultimate aim of concentrations in the environment near background values for naturally occurring substances and close to zero concentrations for man-made synthetic substances."

Map of the OSPAR Convention area with 16 contracting parties.

all possible steps to prevent and eliminate pollution and take the necessary measures to protect the sea area against the adverse effects of human activities. It also aims to safeguard human health and to conserve marine ecosystems and to restore marine areas which have been affected.

To this end, the Ministers in the contracting parties adopted the Esbjerg Declaration in 1998 in Sintra, Portugal (see above). The convention has 16 contracting parties. OSPAR now has an extensive programme to identify hazardous substances which will be phased out by the contracting parties in order to achieve the generation goal as defined in the Esbjerg Declaration.

The Helsinki Convention

For the first time ever, all the sources of pollution around an entire sea were made subject to a single convention, signed in 1974 by all Baltic coastal states. The 1974 Convention entered into force on 3 May 1980.

In the light of political changes, and developments in international environmental and maritime law, a new convention was signed in 1992 by all the states bordering on the Baltic Sea, and the European Community. After ratification the Convention entered into force on 17 January 2000.

The Convention has ten contracting parties and covers the whole of the Baltic Sea area, including inland waters as well as the water of the sea itself and the sea bed. Measures are also taken in the whole catchment area of the Baltic Sea to reduce land-based pollution. In 1996 the Helsinki Commission adopted an objective similar to the Esbjerg Declaration and generation goal of OSPAR.

The Rhine Convention

In what was to become possibly the first convention intended to protect the environment, the five states living along the Rhine River in Europe started discussing chemical pollution of the river in the 1950s. The negotiations led to the adoption of the Convention on the Protection of the Rhine Against Pollution (the Bern Convention) in 1963. The Convention was amended many times over the years and was finally replaced by the Rhine Convention in 1999.

The convention aims to protect the Rhine river, its catchment area, groundwater and ecosystem against chemical pollution. The convention largely focuses on restoration of the badly polluted river area, using the precautionary principle as well as the polluter pays principle. Five nations and the European Community are contracting parties.

CORPORATE INITIATIVES

To address its own environmental and safety performance, improve public relations and/or avoid increased regulations (take your pick), the chemicals industry has launched numerous voluntary programmes and measures. Most of them are specific to certain sectors, but there are also more general initiatives of global character.

Responsible Care

One of the largest such programmes is called Responsible Care and was established in 1985 by the chemicals industry. Today some 47 chemical industry associations around the world are partners of the programme. The industry associations in each country or region are responsible for the implementation in their countries.

Individual Responsible Care programmes are at different stages of development and have different emphasis. The programme, which is managed by the International Council of Chemical Associations (ICCA), consists of a set of rules and principles, information sharing schemes, checklists and verification procedures.

Responsible Care is the largest of many voluntary initiatives launched by the chemicals industry. Another example is Coatings Care, a similar initiative launched by the printing ink industry association CEPE and SunCare, a programme developed by the dominant company in the ink and coatings manufacturing industry, Sun Chemicals.

However, Responsible Care has very little relevance to risk management of chemicals and long-term exposure to low doses (see *Effects of Chemicals* in *Part One*).

Furthermore, it is uncertain to which extent such programmes have improved safety and health within the industry or has helped to avoid accidental releases of chemicals. While industry often presents figures pointing to the success of the programme, others have reported figures showing that Responsible Care has little or no positive effect.

In 1997, the International Federation of Chemical, Energy, Mine and General Workers' Union (ICEM) presented a survey showing that Responsible Care "had no impact on most of the world`s chemical workers" and ICEM concluded that "the voluntary nature of the RC programme may mean that it is more of a public relations exercise."

The HPV Initiative

In October 1998, ICCA announced a global industrial initiative to speed up the process of data collection and hazard assessment of existing chemicals (see boxes on pages 52 and 55). According to the plans, the initiative will establish a priority list of 1,000 High Production Volume (HPV) chemicals.

These substances will then be screened for potential effects on human health or the environment according to the same procedure that is already used by the OECD in the Screening Information Datasets (SIDS).

The screening is intended as a first indicator of potential effects and should not be mistaken for a risk assessment. The screening of the 1,000 HPVs is intended to provide an improved basis for risk assessment in existing programmes, and is to be completed by the end of 2004.

The HPV Initiative is financed through industry who also state that the results of the screenings are made available to authorities and the general public. According to other sources, the industry only publishes summaries of what it wants to release.

The Long-range Research Initiative

In October 1998, ICCA also launched the Long-range Research Initiative (LRI), financed by chemicals industries in the USA, EU and Japan. It provides support for research to focus on scientific understanding of the mechanisms via which chemicals have impact on human health and the environment. Subjects targeted are endocrine disrupters, exposure assessment, carcinogenesis, respiratory toxicity, immunotoxicity and allergies.

HERA

Human and Environmental Risk Assessment on Ingredients of Household Cleaning Products is the full name of a joint project between Cefic and the International Association for Soaps, Detergents and Maintenance Products (AISE). The aim is to provide a common risk assessment framework for the household cleaning products industry and show that this process will deliver evaluated safety information on the ingredients used in these products in a speedy, effective and transparent way. This process is intended to support a risk-based approach to chemicals legislation in the European Union, and may serve as a pilot for the application of the same process in other sectors and/or geographical areas.

SUMMARY

Chemical pollution has a long history, beginning when mankind started extracting minerals. However, large-scale adverse effects did not arise until the advent of industrialisation in Western society. With the boom of the petro-chemical industry in the first half of the 1900s, production and dispersal of man-made substances was introduced and created a new dimension to the problem. Today, the long-term exposure to man and the environment by low levels of synthetic chemicals has become a pressing concern of global dimensions.

Regulation was all but non-existent until the late 1960s when some states and the United Nations started to act. From the 1980s, international and global cooperation also picked up speed and many multilateral instruments were negotiated.

However, political activities have been characterised by their inability to address the problems in a pre-emptive manner. Authorities and intergovernmental organisations have been chasing substance after substance, trying to catch up but lagging further behind every day.

There are numerous global and regional instruments as well as corporate initiatives addressing chemicals in different ways. Some of them focus on protecting a certain environmental compartment, while others focus on specific uses of chemicals. Some are legally binding and far-reaching, while others tend to have the character of management systems or window-dressing.

However, they are far from sufficient. Most of them are very general in their approach and unclear in the objectives. Others have limited scope, focus on end-of-pipe solutions and aim to control releases and effects of a limited number of substances. Others are of technical character, improving cooperation but having little progressive implication. Very few of the instruments come close to addressing the problem at the source, i.e. regulating the production and use of certain chemicals.

There are some exceptions. The adoption of the Esbjerg Declaration into the OSPAR Convention, and similar declarations in the Helsinki and Barcelona Conventions are positive examples, setting clear objectives that have the ability to protect human health and the environment when reached. Notably, the Stockholm Convention is the only global instrument taking a similar approach. SAICM, which is being negotiated currently, may also be pro-active in this sense.

Some of the nations that have been the global leaders regarding chemical safety seem to be abandoning their ambitions and roles. It is crucial for world development that they revitalise their efforts and that others now join in.

RISK MANAGEMENT

Overview

Chemicals have the ability to cause damage on the environment and human health. Thus, society needs to have a mechanism to minimise the risk of harm by establishing whether a chemical substance poses a threat and, if necessary, define what measures should be taken against it.

Developing such a mechanism - or regulation - is an extremely difficult task. Chemicals are very diverse to their nature and have different properties that may pose risks in a myriad of different ways. There are a multitude of different factors to consider and the amount of information and data needed is extensive. In most cases there are serious data gaps regarding effects on humans or the ecosystem.

The predominant way to deal with the problem hass been to use an approach based on Risk Assessment. Typically, the procedure consists of two different processes: an assessment of what risk the substance in question poses, based on scientific research, and in a second phase, a risk reduction strategy on regulatory action that needs to be taken, if any. The latter is based not only on the outcome of the risk assessment, but also weighs in social and economic factors and the consequences of a possible regulation.

Existing and New Substances

The current situation in Europe is characterised by the fact that there are two groups of chemicals. By far the largest group are the 100,106 substances that were registered in the EU before 1981 - also known as *existing substances* and listed in the European Inventory of Existing Commercial Substances (EINECS). The second group only contains some 3,000 substances registered after 1981 - known as *new substances* - listed in the European List of Notified Chemical Substances (ELINCS).

While all the new substances have undergone a certain degree of testing, hardly any of the existing substances have been evaluated for possible effects on humans or the environment. When EINECS and ELINCS were established, the intention was that also the existing substances would be tested, but this has not happened. Only some 140 of the existing substances have been identified as priority substances and are subject to comprehensive assessments. To date, only 17 assessments have been published and only four of them have been implemented into community legislation.

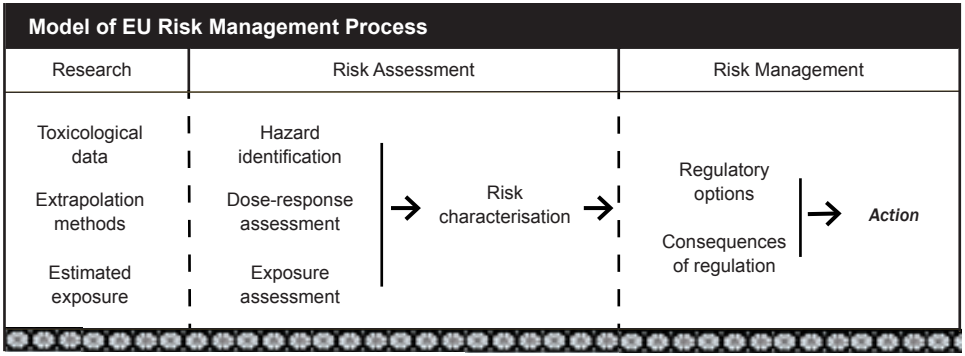
The reasons are debated: the enormous amount of information needed for a single risk assessment, delayed reporting by the industry, lack of resources by Member States, bureaucracy, etc. Some also point out that producers have little interest in speeding up the process as sales are permitted until risk reduction measures are adopted. Such measures can only be taken after a full-fledged risk assessment and an extensive regulatory process.

The EU Model

Current regulation in the EU is based on ideas developed jointly by authorities in Europe and the USA in the late 1970s, almost 30 years ago (see the simplified model in the box on the next page). One of the main features of the EU model is that it prescribes that the risk assessment should be complete before any regulatory action is considered.

This model is considered to have certain advantages. Theoretically it enables a fully scientific approach to assessing the risk associated with a substance. The result of this scientific risk assessment can then be used to decide on any regulatory action. In theory, this should prevent political decisions based on assumptions and ignorance.

But it also has some serious disadvantages. In particular, it prescribes that a complete risk assessment should be made before any regu-



latory action may be taken. This requires obtaining a reasonably complete set of data, an extensive and extremely resource demanding process. Until the completion of such an assessment, any regulatory action is blocked.

A fundamental problem with this model - and risk assessments in general - is that it disregards that there are always data gaps in the scientific part of an assessment. It is simply impossible to determine all the relevant aspects that need to be covered. Instead, assumptions have to be made all the time. Decisions are taken on incomplete, sometimes even rudimentary, information. Yet, risk assessments are presented as a scientific and fully neutral process.

Such assumptions, also called *defaults*, are of different character depending on what purpose or use the substance is intended to have on the market and what kind of data are lacking. If the substance in question is a food additive lacking data about toxicity, the data gap will be considered serious. The following assumption will be that the substance should be regulated as being toxic. If, on the other hand, the substance in question is a basic industrial chemical it may be assumed to be non-toxic.

Introducing Precaution

Since the current risk assessment model was developed and introduced in the late 1970s, there have been important discoveries resulting in a different way of looking at risk. Such discoveries are the effects of substances like PCB, DDT and CFCs. These substances had been risk assessed in much the same way as in the model above, and considered safe on scientific grounds. As is well known, this was proven wrong.

These discoveries led to the development of the precautionary principle, perhaps one of the most important policies for the protection of humans and the environment to date. But

The Four Elements of Risk Assessment

Hazard identification: The identification of the inherent capacity of a chemical to cause adverse effects, without regard to the likelihood or severity of such effects.
Hazard characterisation (dose-response assessment): Following exposure to the chemical, the quantitative evaluation of the nature of adverse effects, including assessment of toxic potency and, where possible, a dose-response assessment.
Exposure assessment: The quantitative evaluation of the likely exposure of the environment and, via the environment, humans to a chemical.
Risk characterisation: The quantitative estimation of the probability that an adverse effect will occur, and of its severity and duration in a given population under defined exposure conditions, based on the three previous elements.

Royal Commission on Environmental Pollution, Chemicals in Products, 2003

the risk assessment model used by the EU has no specific mechanism for precaution. Even if there is scientifically relevant suspicion of a substance causing harm, no action will be taken until completion of the risk assessment, which normally takes several years. Thus, harm may be done before the knowledge or suspicion reaches the eyes of the persons who should use the precautionary principle: the regulators.

Liability

As a general principle in society, those who cause damage should pay compensation for the damage. But the current liability regimes in the EU are insufficient to uphold this principle regarding chemicals. For someone to be held liable, it is necessary to prove a causal connection between the damage and the source of the damage.

It is virtually impossible for victims of chemical pollution to prove such a causal connection. There is insufficient knowledge about the pathways and effects of most chemicals and there are many confounding factors.

Responsibility

Performing a risk assessment is a lengthy and resource-demanding process where a multitude of testing and examinations need to be undertaken. The process takes many years and the costs are substantial. Under the current EU legislation, the responsibility for performing the assessment lies with the authorities, not with the companies that produce, import or use the substances.

Furthermore, while producers and importers are required to provide information for the assessment, there is no such requirement on the companies that buy the chemicals, the down-stream users. As a consequence, it is difficult to estimate the final destiny of the substances and exposure to the environment and humans, which is a vital part of a risk assessment (see previous page).

If authorities should want to perform further testing of substances, a decision to do so can only be taken via a lengthy committee procedure. During this procedure it is not only necessary to further examine the risks posed by the substance, but the authorities are also obliged to carry out an analysis of the benefits and costs prior to any proposal or adoption of a regulatory measure which effects the chemicals industry.

Here is the catch: initiating such a procedure can only be done if the authority can prove that the substance may present a serious risk. However, proving serious risk is impossible without test results.

Summary

There is an urgent need to assess the approximately 30,000 existing substances in production that have not been assessed regarding their potential to cause damage to the environment and humans. However, the risk assessment process is limited to only a fraction of the total of existing substances, it is slow and resource demanding. Its current application, which assumes that all chemicals are "innocent" until harm is proven, also disregards the precautionary principle. Thus, only very few decisions to restrict the use of hazardous chemicals have been adopted on the basis of precaution.

Most of the responsibility for performing risk assessment lie with the authorities. However, the authorities lack the power that needs to go with such responsibility.

CURRENT REGULATION

Overview

"There is no elaborated overall policy for chemicals with short and long-term goals". These are the elucidating words used in March 1998 to describe the current EU chemicals policy in a paper from Austria, Denmark, Finland, The Netherlands and Sweden to the Council of Environment.

While the above statement would be equally valid for almost any nation in the world, it points at the basic problem: regulation of

Data Gaps Regarding High Production Volume Chemicals (HPVs) in the EU

Prior to the introduction of pre-market regulation in 1979, industrial chemicals could be put on the market with very little or no information concerning their potential risks to human health and the environment. The exact number of such "existing" substances still on the EU market is unknown. 100,106 were registered before the deadline 1981 but all of them are not in production. The current estimates for those actually on the market vary widely from 30,000 to 70,000 (EEA/UNEP, 1998). Given the large number it is considered unfeasible to conduct extensive testing on all of them within a reasonable timeframe.

The starting point for setting priorities for information gathering, testing and assessment among this large number of chemicals has generally been production volume, which is considered to reflect potential exposure. Thus, substances being produced in volumes above 1,000 tonnes per year, also called High Production Volume (HPV) chemicals, are prioritised for assessment. But also the number of HPVs is considered too great for immediate risk assessment. There are 2,465 HPVs in the EU and only a few of them have a “full” data set, including long-term eco-toxicity results, degradation behaviour in various environmental compartments and a complete mammalian toxicity profile. Thus another tier of prioritisation is used to identify which of the HPVs should be prioritised. To this end, the EU has identified a minimum package of information - known as a base set - needed to make an initial assessment. The data required to fulfil a base-set are similar to those required in the OECD SIDS (see separate box in the section *International Chemicals Policy*, page 43, and box on page 55).

But even data for prioritising is scarce:

- 3 percent of the HPVs in the EU have a full data set
- 14 percent have data at the level of the base-set (including the above)
- 86 percent have less than the base-set level (including the below), and
- 15 percent have no data at all.

chemicals in the EU is based on the objectives of free trade policies, not on protection of human health and the environment.

Protection of workers has been an issue in chemicals regulation for over 100 years. Initially the focus was on crude and dramatic risks such as explosions, fire and corrosion, but eventually other risks have also been addressed. Risks to the environment and human health in the general population was not introduced as an issue until 1979.

With time environmental and human health issues have however managed to influence the regulation. Complementary instruments have been adopted and amendments had been made when necessary to accommodate the most pressing needs. Unfortunately, these adjustments create confusion and cannot change the structure and underlying problems. For example, the precautionary principle has not been implemented into the regulations.

Today there are many different pieces of regulation concerning many different classes of chemicals in the EU, but concerning industrial chemicals the basis is laid out in a few key provisions (see below). These have all been amended and adapted numerous times, making the legislation difficult to understand and sometimes even incomprehensible.

1967: The Directive on Classification and Labelling of Chemicals

The first EU regulation on industrial chemicals was adopted in 1967 (Dir 67/548/EEC). At the time, the regulation of chemicals in the six Member States differed widely and were an obstacle for Community trade.

The Member States agreed to harmonise regulation and adopted a Directive with provisions on the classification and labelling of dangerous chemical substances in order to protect public health, in particular the health

of workers, against acute exposure. Protection of the environment and long-term chronic exposure were not addressed.

Notably, producers and importers were not required to do any testing, supply any data regarding their substances or classify them. The Directive only stipulated the requirement to classify and label a substance if the producer or importer knew or suspected that the substance may be dangerous.

Initially there were eight different classifications of dangerous substances. Examples are Flammable, Explosive, Toxic and Carcinogenic. Eventually the number of classifications grew and have come to include more than 15. Although amended numerous times since its adoption, and although other Directives have been adopted to complement it, this Directive is still the basis for EU regulation of industrial chemicals.

1976: The Directive on Restrictions of Certain Substances

The 1967 Directive was generally successful in enabling Community trade with chemicals. However, some problems remained. In the 1970s some Member States had started banning or otherwise restricting the production and use of certain chemicals or products while other chemicals were being restricted in other Member States. Again an obstacle against trade had been identified and again there was a decision to harmonise. In 1976 a complementary Directive was adopted, laying out how regulation should be implemented in the community and which substances to restrict (Dir 76/769/EEC).

Under this Directive the Commission has also committed itself to carry out risk assessments and adequate analyses of the costs and the benefits prior to any proposal or adoption of a regulatory measure affecting the chemical industry. Thus, the responsibility for identifying a dangerous substance and proving its guilt lies with the authorities. They must also prove that the benefits of restricting it outweigh the costs.

1979: Amendment Concerning Existing Substances

By the mid-1970s chemicals were flowing freely and in large numbers and quantities in the Community. Essentially there was very little, if any, control of what substances were being produced, in what quantities they were being released or what effects they could have on humans or the environment. But concerns were being voiced from different directions and in 1979 an amendment of the first directive from 1967 was adopted. This was the first time that concerns for the effects of chemicals on the environment were introduced into the regulatory system.

The amendment states that all substances being produced in, or imported to, the community must be registered before 18 September 1981. Future trade in these "existing" substances could continue, making this a business-as-usual situation. However, any introduction of a "new" substance after this date would only be accepted if the producer or importer could supply certain data about the substance.

This created a situation of reversed substitution. Tens of thousands of "existing" substances, many produced in huge volumes and almost all of them without even basic data or tests, were traded freely while "new" substances needed to be tested and risk assessed. Of course, industry continued producing and selling the existing substances and the development of new substances was made more difficult.

1988: Directive on Classification and Labelling of Preparations

Even though classification of substances had been harmonised since 1967, there was still friction in trade since Member States had different regulations concerning the classification and labelling of preparations (mixtures of substances). Most of the chemicals being sold on the common market were in the form of preparations, e.g. solvents, fuels, lubricants, pesticides, consumer products, etc.

Already in 1969 the Community addressed this in a programme dealing with the elimination of technical barriers against trade. By 1988 the Council had adopted another three Directives dealing with the classification of certain preparations such as solvents, prints, varnishes, glues, inks and pesticides.

In June 1988 they were all replaced by a Directive concerning the classification and labelling of all dangerous preparations, albeit there are exemptions such as pesticides (Dir 88/379/EEC). The Directive prescribes the same classification and labelling system irrespective of how the preparations were intended to be used. The objective was to eliminate trade barriers and to increase protection of human health and the environment.

1993: The Council Regulation on Evaluation of Existing Substances

Eventually it was widely acknowledged that the structure of the regulation was unacceptable. The existing substances posed a substantial threat to human health and the environment until they had been tested, risk assessed and approved.

In 1989 - some 25 years after the alarming discovery of the effects of DDT and PCB and four years after the adoption of the United Nations Vienna Convention to phase out ozone-depleting CFCs - the EU Council "recognises" that the control of chemical substances should be based on the evaluation of their risks to man and the environment.

Luckily, a general overview of the community situation at the same time showed that considerable disparities in the national legislations of the Member States concerning chemicals were (again) creating trade obstacles. It was time to re-establish uniformity for the purpose of trade while also increasing the level of protection for humans and the environment.

Another four years passed before a regulation was adopted in 1993 (Reg EEC 793/93). According to the Regulation, existing data about certain properties and uses of substances produced in more than 1,000 tonnes per year and manufacturer should be provided. For substances produced in volumes between 10 and 1,000 tonnes, only the name, the quantity produced, the classification and foreseeable uses were required.

On the basis of the information submitted by manufacturers and importers for all of these substances, the Commission, in consultation with Member States, should regularly draw up lists of priority substances or groups of substances requiring immediate attention because of their potential effects on man or the environment.

So far, out of the 100,106 existing chemicals registered in the EU, of which some ten percent are produced in volumes above ten tonnes per year, only 141 priority substances have been risk assessed.

As described in a previous section, (see *Risk Assessment*), risk assessment is a cumbersome and resource demanding process. A report from the Commission in 1998 showed that only four substances had been assessed so far. Progress was excruciatingly slow. But for the chemicals industry it was still business as usual; sales of an existing substance is - according to the 1979 amendment (see above) - permitted while a risk assessment is ongoing.

In the meantime, the authorities have limited possibilities of restricting or banning the use of an existing substance. Such restrictions can only be adopted if the authority can show strong evidence that the substance is in some way having adverse effects. Normally this requires testing, but without test results it is almost impossible to provide such evidence.

INITIATIVES FOR INCREASED SAFETY

Overview

By the mid-1990s it was apparent that the system was not working well. While most trade barriers had been eliminated or significantly reduced, the regulations were not able to protect human health and the environment.

Existing and New Substances

Before the late 1970s, regulation of chemicals was all but non-existent throughout the world. Chemicals were developed, produced and used with little or no consideration to long-term effects on the environment and human health. Producers in Europe and other Western countries were only required to classify a substance according to a crude system if they suspected or knew that a substance was dangerous. But there was no requirement to test the substance to find out.
When authorities became aware of the effects that chemicals could have on human health and the environment, there were so many substances being produced and used in large volumes that testing them all seemed impossible. Instead they decided that any new substance would need to be tested and risk assessed before being marketed, while the existing substances could stay in production without any testing. Thus, there was a line drawn regarding the safety requirements between old and new substances in most OECD countries in the late 1970s and early 1980s. In the EU, substances registered before September 1981 are called "existing" substances, while substances registered thereafter are called "new" substances.
There are 100,106 "existing" substances registered in the EU. However, all of them are not produced. It is estimated that between 30,000 and 70,000 are currently in production. More than 2,000 of them are produced in volumes above 1,000 tonnes per year and per producer. Existing substances represent some 95 percent of the chemicals produced in the EU.
By comparison, there are few "new" substances, i.e. substances registered after September 1981, in the EU. To date, some 3,700 substances have been registered.

Since the establishment of the existing regulation, there have been major developments, scientifically as well as politically, concerning chemicals and protection of human health and the environment. Increased knowledge about endocrine disrupters and political declarations to create a toxic-free environment, as in the Esbjerg declaration, are examples of developments that require a different approach.

Of special concern are the thousands of existing substances still being produced in vast quantities without even basic data or testing. The higher requirements for new substances were also stifling development of potentially safer substances.

Voices were raised for a complete review of the system. Many stakeholders were proposing a new regulation where the safety of existing substances was addressed. They made the claim that all substances need to be equally tested and assessed irrespective of when they were first produced. Thus existing substances should be assessed in the same way as new substances were already being treated and industry should pay for it.

The chemicals industry could see that the days of the existing substances loophole were being counted and they did not like what was being proposed. Nevertheless they held a low profile initially, promoting voluntary measures, such as the HPV-programme, as a solution and highlighting the need for industrial initiatives in general.

March 1998: Proposal for a Policy

At an informal discussion meeting, representatives from Austria, Denmark, Finland, The Netherlands and Sweden met experts to discuss the situation and what should be done. The discussion resulted in a joint position by these Member States and a document laying out some ideas intended for discussion at an informal Council meeting in April.

The document identified several operational problems with the present regulation, but concluded that the main problem was the lack of an overall chemicals policy (as described in the beginning of this section). The five Member States therefore proposed that a chemicals policy be introduced in the EU and also iden-

tified some key components:
• Operative goals should be adopted, such as the ones set up in the Esbjerg Declaration (see pages 45-46).
• The responsibility of different stakeholders needed to be clarified. The burden of proof that a substance is harmless must lie with the producer or importer. The producer or supplier of a product must inform the consumers of the possible impact of the chemicals in products on man and the environment.
• General guidelines on precaution, substitution, minimisation and the safe management of chemicals need to be introduced.
• Substances that have irreversible toxic effects or are persistent and bioaccumulative should not be used in products.
• The precautionary principle should be applied
• Costs for risk assessment and similar work should be carried by industry - not as today by the Community.

April 1998: Council Requests Review

The lack of progress regarding risk assessments on the 110 priority substances (and the remaining 30,000 or so existing substances in production) and an increasing concern for endocrine disruption from substances that had been risk assessed already, forced the Council to act.

To this end, the Environment Ministers met at an informal meeting in Chester, UK, to discuss the Community approach to the safe management of chemicals. A number of factors and guiding principles were identified. These included:
• Protecting the environment and human health as an integral part of sustainable development.
• The principles established by the Rio Declaration and the treaties of the EU.
• The economic and social benefits that the use of chemicals bring to society and to the quality of life.
• The importance of maintaining an effective single market.
• The wide range of legal instruments associated with chemicals management.
• The need for international cooperation on the testing and assessment of chemicals.

Following discussions on existing substances, it was suggested that a wide review of the system as a whole was necessary. In this context, the paper tabled by Austria, Denmark, Finland, the Netherlands and Sweden (see above) was welcomed and it was proposed that the concept of a framework directive should be considered.

Concerning the assessment and management of risk in general there was a shared view that the principles of sustainable development should be included in chemicals management.

The meeting concluded in suggesting a number of ways in which the present Community framework could be improved. The Ministers welcomed the idea of the European Commission to take stock of existing legislative instruments dealing with chemicals, in particular the regulation of existing substances. This stocktaking exercise was expected to include a brain-storming exercise and should enable the Commission to identify the weaknesses of the instruments. The meeting welcomed the Commission´s proposal to report back on its findings by the end of 1998.

October 1998: Call by Parliament for Action on Endocrine Disrupters

See separate box on the next page.

October 1998: Launches of Global Initiatives by Industry

At their Board of Directors Meeting in Prague of early October, the ICCA established a framework for a series of global programmes to improve its cooperation with international authorities.

The first of the three programmes launched on 12 October, was an effort to speed up data collection and hazard assessment of existing substances globally. This programme, called the HPV Initiative, is based on the OECD

Regulating Endocrine Disrupters

Although observed already in the 1960s, the effects of long-term exposure to certain chemicals on the reproductory and hormonal system popped up as an issue of increasing concern during the 1990s. It had become known that a large number of substances had such effects but it was not being addressed in the risk assessments of any chemicals. Strangely it had become a forgotten issue in the wake of the increasing focus on the risk of cancer. Substances with such effects are called endocrine disrupters, and it is not known which substances affect the reproductory and hormonal systems or how to assess the risk they pose. They are simply not caught in the risk assessment procedures and authorities have initiated programmes to assess this "new" problem.

In October 1998, the European Parliament adopted a Resolution calling upon the Commission to take action in this area to improve the legislative framework, reinforce research efforts and to make information available to the public.

In March 1999, the Scientific Committee for Toxicity, Ecotoxicity and the Environment (SCTEE) issued a report, "Human and Wildlife Health Effects of Endocrine Disrupting Chemicals, with emphasis on Wildlife and on Ecotoxicology test methods." The report identified a "potential global problem" for wildlife. It also stated that "impaired reproduction and development causally linked to endocrine disrupting substances are well-documented in a number of wildlife species and have caused local and population changes."

Against this background, the Commission Communication, presented in June 2001, identified four key requirements to address the phenomenon of endocrine disruption: further research; international cooperation; communication to the public, and appropriate policy action. Short, medium and long term action was proposed to cover these requirements. According to the Commission Communication, it was clear that the strategy on endocrine disrupters would, in the longer-term, form an integral part of the overall strategy on chemicals being developed.

SIDS programme for High Production Volume chemicals and aimed to establish a priority list of 1,000 substances to be screened for hazardous properties before the end of the year 2004.

The second new programme, called the Long-range Research Initiative (LRI), aims to provide financial support for research on the mechanisms via which chemicals impact on the environment and human health. Special attention would be given to endocrine disrupters. The third initiative was to send representatives to the Sectoral ILO meeting in February 1999 where the ICCA would concentrate on its commitment to the Responsible Care programmes.

At the conclusion of the meeting, the Chairman of the Board of the Chemical Manufacturers Association concluded that the ICCA in the future would contribute better to the deliberations of various UN bodies since it had been accorded a formal NGO status there. (See also *Corporate Initiatives* on page 47 in the previous section.)

November 1998: Commission Review

As desired by the Ministers of Environment, the Commission initiated a review of the regulation concerning chemicals, in particular existing substances. In November the review was presented to the Council. The Commission evaluated the operation of four regulatory instruments: Council Directive 67/548/EEC, Directive 88/379/EEC, Council Regulation (EEC) 793/93 and Directive 76/769/EEC on restriction regarding certain substances.

The review identified a large number of weaknesses in all of the instruments but particularly in the two pieces of legislation that were meant to control and/or restrict the uses of existing chemicals, Council Directive 76/769 and Regulation 793/93. The review identifies 22 issues to be considered in the development of a new regulation (see summary in separate box on page 59).

Throughout the current regulation, the Commission identified the need to use the

regulation more effectively and to implement and enforce it rigorously and consistently, to develop the instruments further and the need to give full consideration to the precautionary principle. More specifically, the findings highlight the importance of:

• Using hazard identification as the initial key step in protecting human health and the environment from hazardous chemicals. A policy that makes it possible to regulate substances on the basis of their inherent properties, such as persistence, bioaccumulation and toxicity, would increase protection while reducing the need for completing risk assessments. In this context, the possibility to evaluate substances as groups, based on their properties, is also suggested.

• Reversing the burden of proof. Producers should be made responsible for collecting and submitting data on the substances they produce enabling risk assessments and evaluation of the need for regulatory measures.

• Creating a clear strategy for assessing the harmful effects of existing substances.

December 1998: Council Feedback

On 20 December, the Environment Council welcomed the review and adopted the following statement: "The Council welcomed the Commission document which revealed shortcomings in the application and efficiency of the Community instruments dealing with risk assessment and risk management for chemicals. It underlined the necessity to adopt a more coherent approach to the legislation on chemical products, notably on control procedures, in order to ensure a higher level of protection for public health and the environment and welcomed the Commission's intention to work on such an approach, in consultation with the Member States."

February 1999: Stakeholder Brainstorm

As requested by the Council, the Commission held a brain-storming meeting where all stakeholders were invited to attend. At the meeting, held on 24-25 February, it was agreed that process was too slow. The fundamental issue of relying on risk assessment was debated. Cefic reiterated the voluntary commitment made in October 1998 by the ICCA to provide toxicological and ecotoxicological data for 1,000 High Volume Production chemicals by the end of 2004 and investments in the LRI programme where the European industry contributed some €4.5 million in 1999.

April 1999: Council asks for Precaution

On 13 April the Council adopted a resolution urging the Commission inter alia "to be in the future even more determined to be guided by the precautionary principle in preparing proposals for legislation and in its other consumer-related activities and develop as priority clear and effective guidelines for the application of this principle."

June 1999: Industry Increases Efforts to Create Confidence

At the Cefic general assembly in Madrid on 11 June, president Bryan Sanderson said that as calls for restrictions and bans were becoming louder, industry has a responsibility to bring answers to the concerns being raised about chemicals. To this end Cefic would enhance "significantly and visibly its commitment to the responsible risk management of chemicals."

Among other things, this meant engaging in dialogue with green groups, governments, the Commission, consumer groups, academics and the scientific community. Cefic also pointed out that "a number of major industry initiatives at the European and international level have been launched with the ultimate aim of achieving a higher level of public confidence in chemicals".

A few days later, at the 3rd WHO Ministerial Conference on 16 June, Cefic announced that the European chemicals industry would increase its contribution to the LRI programme from some €4.5 million to €20 million a year.

June 1999: Council Adopts Conclusions for a Future Strategy

At its meeting 24-25 June, the Council adopted a document outlining the background, components and objectives of a new chemicals strategy. The Council concluded that the EU needed a new integrated and coherent chemicals strategy to increase protection of humans and the environment. Such a strategy should make a major contribution towards enabling the Community and Member States to fulfil its international obligations, such as the generation goals of OSPAR and HELCOM.

While welcoming the initiatives of the industry to make initial assessments of 1,000 HPV chemicals by the end of 2004, the Council called on the Commission to base the new strategy on the principles of sustainability and precaution. Further, the Council inter alia concluded that the strategy should shift the burden of proof, giving industry the responsibility for risk assessments; require that industry provides adequate information and data to users and the public and encourage substitution of dangerous substances by less dangerous ones.

A proposal from the Commission was requested for the end of 2000.

December 1999: Commission Presents Fundamental Elements

The Commission presented the progress in formulating a new chemicals policy to the Internal Market Council on 7 December and to the Environment Council on 13-14 December. The focus of the work was on existing substances, problematic chemicals such as persistent, bioaccumulative and toxic (PBT) substances, preparations and products and what resources and structures were needed to build a more successful system.

Redefinition of the responsibility of the industry and the public regulator, the burden of proof, risk assessment, the precautionary principle and endocrine disrupters were all described as aspects and principles which needed to be addressed.

Commission Review

On the request of the Council in April 1998, the Commission performed a review of the current chemicals regulation to identify what was causing the delay in assessing existing chemicals and to suggest a strategy for a future policy better equipped to protect humans and the environment. Below are some specific issues for consideration identified by the Commission review.

Directive 67/548/EEC and Reg. 793/93:

- Address operational weaknesses, specifically the risk assessment and risk reduction strategy procedures.
- Restructure, clarify and increase transparency.
- Clarify the roles of member states for completing work on existing substances.
- Review data on hazardous properties of existing substances and develop guidelines and criteria.
- Address the burden of proof issue.
- Ensure that member states consider liability as well as withdrawal of substances as a means to improve compliance.
- Ensure that instruments keep up with scientific development, such as the potential threat from endocrine disrupters.

Directive 88/379/EEC:

- Assess whether target groups understand the labelling of dangerous substances.
- Identify the causes of delays and non-compliance from member states, take appropriate measures and consider withdrawal of preparations as a means of increasing compliance.

Directive 76/769/EEC:

- Accelerate the adoption of new restrictions by giving preference to the Committee Procedure.
- Accelerate the adoption of restrictions characterised by scientific uncertainty or high economic costs by improving risk assessment procedures.
- Address the delays in the practical implementation of new restrictions.
- Ensure that the precautionary principle is given full consideration in the introduction of marketing and use restrictions of dangerous substances and preparations.

The Precautionary Principle

The development of a new chemicals strategy in the EU uses the precautionary principle as a basis for future regulation. The weight thus given to precaution has been one of the major issues of disagreement over REACH between the EU and the USA, where the precautionary principle does not have the same standing. The precautionary principle has been cited in 14 multilateral agreements over the past 15 years and was adopted by the EU in 2000. The most widely used definition of the precautionary principle is the one adopted at the UNCED in Rio de Janeiro 1992. It states:
"In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation."

The Commission's work was described as aiming at laying down the basis for an efficient, integrated and coherent EU system taking into account the interest of the environment and public health but also taking on board the industry. The Commission intended to present its White Paper on the issue by summer 2000.

December 1999: Cefic Launch Stakeholder Dialogue Meetings

Following its strategy to improve public perception of the chemicals industry by avoiding conflict and being seen as a partner in dialogue, Cefic invited stakeholders to discussions in a Stakeholders Dialogue Meeting. The intention was that such meetings would become routine over the coming years. The first meeting, in December 1999, showed very little result. In December 2000 the second meeting, with similar result, was organised. There have been no more meetings.

February 2000: Communication on the Precautionary Principle

Following the request from the Council in April 1999, the Commission presented its communication regarding the precautionary principle on 2 February. The communication proposed when, where and how the principle should be used.

April 2000: Industry Calls for Partnership

The academic and industrial communities concerned with chemicals issued a joint statement on 14 April under the banner of the AllChemE Alliance. In the statement, Europe´s chemical community was adamant that it could deliver the quality of life which is expected by the European citizens, but only if governments help by creating the necessary organisational and financial structures. It was stated that Europe needs a partnership for prosperity, bringing together the chemical industry, academics and governments.

June 2000: Commission Presents Progress

The Environment Council was informed by Commissioner Wallström of DG Environment on 22 June regarding the progress made with the future strategy. Commissioner Wallström described the strategy as "being based on the principle of sustainable development, the fundamental objective being to ensure a high level of protection of human health and the environment. At the same time, the efficient functioning of the internal market and the competitiveness of the industry will have to be preserved."

Other important principles pursued by the Commission in the development of its new strategy were the precautionary and the substitution principles as well as producer responsibility and the polluter pays principle.

The Commission intended to adopt a White Paper before the end of 2000 so that it could be presented to the Environment Council in December.

October 2000: Industry and Commissioner Stress Growth and Innovation

At a joint conference attended by chemicals industry, trade unions, representatives of member states and the Commission, Commissioner of Enterprise Erkki Liikanen and the Director General of Enterprise, Fabio Colasanti, discussed and reviewed the possible consequences of a new chemicals strategy. Commissioner Liikanen pointed out that a new strategy, besides looking at protection of human health and the environment, also needs to consider the importance of a favourable regulatory climate for the competitiveness of the European chemicals industry.

Eggert Voscherau, member of the Cefic board, pointed out that research and technical progress were indispensable drivers and thus a regulatory framework that promotes innovation rather than hindering it was needed.

The participants shared the view that the present review of the regulation was a good opportunity to improve the framework, that dialogue was needed, that the decision-making process must be based on science, that the single market be safeguarded to maintain free circulation of goods and that the situation of the candidate countries be considered.

Highlights

1992: Contracting parties at UNCED agree to address the threat from chemicals.

1995: OSPAR countries agree to phase out releases of hazardous substances to the marine environment within one generation (25 years.)

1998: Council asks Commission to review EU chemicals regulation.

1999: Council asks Commission to develop guidelines for using the precautionary principle.

1999: Council defines components and objectives of a new chemicals strategy for the EU in order to increase protection of human health and the environment.

1999: Commission presents fundamental elements of the Strategy for a Future Chemicals Policy in the EU.

SUMMARY

The current EU regulation regarding industrial chemicals is mainly based on instruments that were drafted in the 1960s and 1970s to enable trade in the common market. Since the early and mid-1980s environmental and health issues have caused increasing concern, resulting in alterations and amendments of the instruments. However, these amendments had not given sufficient protection of human health nor the environment. They have also made the instruments unfocused and confusing.

Following UNCED in Rio in 1992 and the adoption of the generation goal in the OSPAR and HELCOM conventions, it became increasingly clear that the instruments needed to be reviewed. The Council and Commission had repeatedly during the later part of the 1990s declared that an integrated policy with the main objective to protect human health and the environment was needed. Such a policy needed to implement the precautionary and sustainability principles and make a major contribution to achieve the objectives defined in the Rio Declaration, OSPAR and HELCOM.

While the Council and Commission drafted elements and principles for such a regulation from summer 1998 to January 2001, other stakeholders were invited to participate. Initially industry reacted by highlighting the voluntary programmes being launched. Toward the end of 2000 it seemed industry would oppose the new regulation on grounds of competitiveness and trade.

THE WHITE PAPER

Overview

The Commission finally adopted the "White Paper on a Strategy for a Future Chemicals Policy" on 13 February 2001. The overriding goal of the strategy was sustainable development as described in the Rio Declaration. Additionally the strategy aimed to ensure a high level of protection of human health and the environment as enshrined in the Treaty, both for the present generation and future generations, while also ensuring the efficient functioning of the internal market and competitiveness of the chemicals industry.

The precautionary principle was considered fundamental to achieving the objective. Whenever reliable scientific evidence is available that a substance may have an adverse impact on human health and the environment, but there is still scientific uncertainty about the precise nature or the magnitude of the potential damage, decision making must be based on precaution. The reason for this was to prevent damage to human health and the environment. Another important objective was to encourage the substitution of dangerous by less dangerous substances where suitable alternatives were available.

The strategy also considered it essential to ensure the efficient functioning of the internal market and the competitiveness of the chemicals industry. The EU policy for chemicals should provide incentives for technical innovation and development of safer chemicals. According to the White Paper, recent experience has shown that innovation (e.g. in developing new and often safer chemicals) has been hindered by the burdens of the present notification system. Ecological, economic and social aspects of development had to be taken into account in an integrated and balanced manner in order to reach the goal of sustainability.

To protect human health and promote a non-toxic environment, the Commission proposed that existing and new substances should in the future be subject to the same procedure under a single system. The current new substances system should be revised to become more effective and efficient and the revised obligations be extended to also cover existing substances by 2012.

The proposed system was called REACH, an acronym for **R**egistration, **E**valuation and **A**uthorisation of **CH**emicals. The requirements, including the testing requirements, of the system depend on the proven or suspected hazardous properties, uses, exposure and volumes of chemicals produced or imported. According to the system, all chemicals produced in volumes over one tonne should be registered in a central database. At higher production volumes, special attention would be given to the long-term and chronic effects.

Political Objectives

In order to achieve the overriding goal of sustainable development, the Commission identified a number of objectives that must be met within the framework of the Single Market. These were defined as:

- protection of human health and the environment,
- maintenance and enhancement of the competitiveness of the EU chemicals industry,
- prevention of fragmentation of the internal market,
- increased transparency,
- integration with international efforts,
- promotion of non-animal testing, and
- conformity with EU international obligations under the WTO.

Elements

As indicated by the acronym, the proposed system consisted of three elements which stand at the heart of the regulation: registration, evaluation and authorisation. The elements represent three different tiers of safety requirements.

Registration

All substances produced or imported in volumes above one tonne per year must be registered. Registration would require a manufacturer or importer to notify an authority of the intention to produce or import a substance and to submit a dossier containing the information required by the legislation. The authority puts this information into an electronic database, assigns a registration number and performs spot-checks and computerised screening of the registered substances for properties raising particular concern. The registration dossier should include the following information:

- data/information on the identity and properties of the substance including data on toxicological and ecotoxicological properties,
- intended uses, estimated human and environmental exposure,
- production quantity envisaged,
- proposal for the classification and labelling of the substance,
- a "Safety Data Sheet,"
- preliminary risk assessment covering the intended uses, and
- proposed risk management measures.

Evaluation

This element would require authorities to carefully examine the data provided by industry. It also requires them to decide on substance-tailored testing programmes, following industry proposals.

- Substances above 100 tonnes per producer or importer: When the quantity produced or imported reaches the level of 100 tonnes, the manufacturer or importer would be required to submit to an authority all available information and to propose a strategy for further testing based on the general information requirements defined in the legislation, and additional information would be required if the quantity reached 1,000 tonnes. The authority would evaluate the information and the testing strategy submitted by industry and decide on the appropriate course of action. In essence, the current approach for new substances would be maintained for substances above 100 tonnes. The availability of a risk assessment drawn up by the manufacturer or importer would reduce the workload of the authorities. Testing programmes at Level 1 (100 tonnes) and Level 2 (1,000 tonnes) would be substance-tailored.
- Substances below 100 tonnes per manufacturer or importer: Substances which are suspected to be persistent and liable to bioaccumulation, substances with certain hazardous properties such as mutagenicity or high toxicity, or substances with molecular structures giving rise to concern would require an evaluation by the authorities at volume levels below 100 tonnes. Based on this evaluation, immediate safety measures and/or further testing may be needed. Thus, the authorities' right to request additional information for low volume substances on a case by case basis, as possible under the current notification system, would be retained. Furthermore, authorities should be empowered to require additional testing, when the aggregate volume produced

REACH Presentations

The Strategy for a new chemicals policy in response to the request by the Council to increase protection of human health and the environment, has been developed and presented by the Commission in three steps:
1. The White Paper (February 2001), laying out principals and main elements.
2. The Draft Regulation (May 2003), presenting the regulatory details of the strategy to the public and stakeholders for comments.
3. The Proposal (October 2003), the final regulatory proposal on REACH from the Commission.
During 2004 and 2005 the proposal will be debated and commented in a co-decision procedure by the European Parliament and Council. The role of the Commission in the continued process is to amend the Proposal according to the findings of Parliament and Council until there is agreement.

and/or imported by all manufacturers and/or importers exceeded to a considerable degree the next higher tonnage threshold for a single producer or importer.

Authorisation

For the production and import of substances of very high concern, authorities would have to give specific permission before such a substance could be used for a particular purpose, marketed as such or as a component of a product. The scope would be clearly defined and strict deadlines be set for both industry and authorities.

New and existing substances, including those produced in volumes below 100 tonnes, which have hazardous properties giving rise to very high concern would be progressively subjected to an authorisation regime. These include substances that are carcinogenic, mutagenic or toxic to reproduction (CMR substances categories 1 and 2) and substances with POPs characteristics. However, uses that do not give rise to concern would generally be exempted.

PBT, vPvB and Endocrine Disrupters

The White Paper was indecisive regarding substances that are persistent, bio-accumulative and toxic (PBT) and substances that are very persistent and very bio-accumulative (vPvB) other than those that fulfil POPs criteria. It was stated that further research is needed to develop criteria for the identification of such substances and the Commission would decide at a later stage how substances with these properties should be treated.

The majority of the endocrine disrupting chemicals would have to undergo authorisation in the REACH system. Serious human health effects which have so far been associated with endocrine disrupting chemicals are testicular cancer, breast cancer, prostate cancer, decrease in sperm concentration and semen volume, cryptorchidism, hypospadia and impaired development of the immune system and the nervous system. All these effects would qualify a substance either to be classified as carcinogenic or as toxic for reproduction and so would trigger its submission to authorisation. Furthermore, adverse effects on the endocrine system of wildlife species have been causally linked to certain POPs, which would be subject to authorisation.

Scope

All existing and new chemicals produced or imported in volumes larger than one tonne per year and producer/importer would be covered by REACH. The Commission estimated that there are 30,000 such substances.

Most of these - about 80 percent - are produced or imported in volumes below 100 tonnes per year and are expected to be of little concern. Thus, they would only be required to undergo the first step of the system, registration.

The number of substances produced or imported in volumes above 100 tonnes, or being of concern and thus requiring evaluation in the second step of the system, was estimated to be 5,000.

Finally, about five percent, or 1,400 substances, are expected to have properties which would require authorisation in the third step or be taken off the market. However, uses which do not give rise to concern - such as well controlled industrial uses or uses in research laboratories - may be subject to general exemptions from the authorisation procedure.

Accelerated Risk Assessment

Specific uses of substances which do not have one of the properties listed under the authorisation system but for which restrictions are needed, should be addressed in an improved and accelerated procedure. The following four elements are prescribed in REACH to bring about the necessary acceleration of risk assessments:

(1) Due to the registration requirement of all chemicals above one tonne there would be extensive data available on the health and safety properties of all substances marketed.