Dealing with Risk Factors

Modern society has become dependent on a wide range of chemicals; however, it was not until the second half of the 20th century that we acknowledged that many of these compounds cause severe environmental and health problems. An early response was to assess the environmental risk associated with selected chemicals; depending on the results, various countries subsequently introduced regulations governing their use. Today, there is a consensus that, at least in principle, all chemicals that are in use must be evaluated. Unfortunately, the number of chemicals to be tested is enormous. Therefore, appropriate prioritization procedures are employed that identify particularly dangerous substances, which may then be subjected to more extensive risk assessment. In recent years, an increasing effort has been made to solve chemical pollution problems on an international level.

In 1775, the English physician Sir Percival Pott documented in his book "Surgical Observations" an increased incidence of skin cancer among London's chimney sweeps. He identified the problem as a professional disease, probably caused by frequent exposure to soot. The responsible substance in soot, benz(a)pyrene, was only identified another 150 years later. Benz(a)pyrene belongs to the so-called polycyclic aromatic hydrocarbons (PAH).

In the early 1970s, the chemists Crutzen, Molina and Rowland warned against the use of chlorofluorocarbons, more commonly known as "freons" and mostly used as propellants and coolants. They predicted that these chemicals might damage the ozone layer in the stratosphere. In 1985, the so-called "ozone hole" over the Antarctic was observed for the first time. Only two years later, a worldwide ban on freons was established by the Montreal Protocol. Since then, a number of other ozone-depleting chemicals have been added to the international agreement. In 1995, Crutzen, Molina and Rowland received the Nobel Prize in chemistry for their pioneering work in environmental risk assessment.

Benz(a)pyrene and freons are examples of chemicals occuring as environmental risk factors that were recognized early on (Tab. 1). The goal of this article is to summarize the policies that currently deal with chemical contaminants. It will be described how the environmental risk of an individual chemical is assessed, how prioritization procedures are used to screen large numbers of chemicals in order to identify substances that warrant immediate ban or use restrictions, and how environmental protection policies tackle the problem of chemical pollutants.

Industrially produced chemicals

- 18 million substances are listed and described in the "Chemical Abstracts".
- 400 million tons of chemicals were produced worldwide in 2000. For comparison, the total production in 1930 was 1 million tons.
- 100,000 chemicals were listed with the EU in 1981 (old chemicals).
- 2,700 chemicals have been reported to the EU since 1981 (new chemicals).
- 30,000 chemicals are on the market in quantities over 1 ton.
- 5,000 chemicals are being produced in quantities over 100 tons.
- 720 chemicals were newly listed under the Swiss Ordinance on Environmental Pollutants between 1988 and 2000.
- 8,700 different food additives are known.
- 3,300 substances are being used as drugs or in human medicine.

Categories of Risk Factors

Our modern civilization produces approximately 100,000 chemicals in various quantities (see box). During manufacturing, use and/or disposal, a portion of these substances are released into the environment. In addition to these artificial risks, there are natural risks, such as arsenic in drinking water or the presence of various pathogenic microorganisms.

Table 1 tries to differentiate the environmental risk factors that are known to date into 15 categories; some factors may be assigned to more than one category. How and where a particular chemical is used determines the path by which it is introduced into the environment. Obviously, the contanminants' chemical and physical properties are important determinants for their behaviour and fate in the environment. Effects of acute releases into the environment, due to catastrophes or accidents, are often the most devastating and also the most obvious. More difficult to recognize are environmental impacts caused by chronic inputs.

Assessment of Environmental Risks and Establishment of Limite Values

In order to assess the environmental risk of a particular substance, we need to know both how it enters the environment and how it behaves after its release. In addition, we need to assess its effects on a range of different organisms. The primary tools are exposure analysis and effect assessment (Fig. 1).

Exposure analysis identifies potential pathways for a chemical to reach the environment, estimates quantities that could be released, and predicts the behavior of the chemical in the environment based on its chemical and physical properties. Important parameters in exposure analysis are PEC

Category	Example: chemical, source
I. Early recognized chemicals	Polycyclic aromatic hydrocarbons (PAH), chlorofluorocarbons (CFC, freons)
II. Acutely released chemicals	Dioxins (Seveso, 1978), radioactivity (Tschernobyl, 1986), agrochemicals (Schweizerhalle/Rhine, 1986), oil tanker accidents (e.g., Torrey Canyon, Amoco Cadiz)
III. Chemicals with detectable chronic effects	Branched alkylbenzenesulfonates, anionic surfactants in detergents (foam formation), phosphates in detergents (eutrophication of surface waters)
IV. Chemicals that are accumulated in biological systems	DDT, polychlorinated biphenyls (PCB), persistent organic pollutants (POP), heavy metals (lead, cadmium, mercury)
V. Chemicals for specific applications	Detergents, pesticides, herbicides, concrete admixtures, anti-fouling agents (organotin compounds)
VI. Substitute chemicals	Linear alkylbenzenesulfonates (LAS), nitrilotriacetate (NTA), Zeolite A, organophosphorus insecticides
VII. Intermediates of biological transformation (metabolites)	Methylmercury, nitrosamines, nonylphenol
VIII. Analytical side results (ghost peaks)	PCB, perchloroethylene, clofibric acid
IX. Product impurities	Polychlorinated dibenzodioxins and dibenzofurans
X. Side products in water technology	Chlorophenols, trihalomethanes, haloacetic acid, nitrosodimethylamine (NDMA), bromate
XI. Late recognized chemicals	Arsenic (see articles by M. Berg, p. 12; and H.-R. Pfeifer and J. Zobrist, p. 15)
XII. Erroneously assessed chemicals	Methyl-tert-butylether (MTBE, see article by T. Schmidt, p. 18)
XIII. Chemicals that are difficult to assess	Hormonally active compounds (bisphenol A, β-estradiol, see article by M. Suter, p. 24), drugs
XIV. Emerging contaminants	Antibiotics (see article by C. McArdell, p. 21), brominated flame retardants, fluorinated sulfonate surfactants
XV. Recurrent risk factors	Sewage sludge (see article by P. Stadelmann, p. 9), pathogens in drinking water (see article by W. Köster, p. 26)

Tab. 1: Classification of environmental risk factors in 15 categories.

values (predicted environmental concentration) and MEC values (measured environmental concentration). MEC values are often difficult or expensive to obtain and are only available for a relatively small number of chemicals.

The purpose of effect assessment is to determine the potential harmful effects of a chemical as a function of its concentration, i.e., to determine the dose-response curve. This information is used to determine a PNEC value (predicted no effect concentration), a threshold value representing the smallest concentration at which an effect can be observed. In the subsequent risk assessment, PEC and MEC are compared to the PNEC. If environmental concentrations are higher than the PNEC, mitigation measures need to be considered.

Policies on Priority Pollutants

In principle, the environmental risk should be determined for each chemical compound that is in use. But because of the enormous number of contaminants, this is impossible. The strategy, therefore, is to identify the important chemicals out of the multitude and to thoroughly examine those that are selected. One such prioritization scheme was developed as part of the OSPAR convention on the protection of marine ecosystems (see article by H.-J. Poremski and S. Wiandt, p. 6).

The American National Academy of Sciences [1] has proposed another prioritization procedure. This method focuses on identifying the most important chemical and biological contaminants in drinking water. In the USA, the Environmental Protection Agency is required by law to publish an updated candidate contaminant list every five years (Fig. 2). In a first step, potential pollutants are classified as belonging to one of four compound categories (Fig. 3). Chemicals that fall into areas I–IV go on a list of provisional candidate contaminants. In a second step, the hazard level for each of these compounds is assessed, leading to the identification of the final list of candidate contaminants. The hazard potential is determined by a mathematical model as well as by "expert judgement".

Concerted Actions on the International Level

In the past, individual countries mostly performed their own risk assessment and issued their own regulations on the use of chemicals. Examples include the Swiss Ordinance on Chemicals Hazardous to the Environment and the list of priority pollutants in drinking water in the USA.

However, since our knowledge of risk factors is far from complete, and sources and effects of chemicals can be separated temporally and spatially, international cooperation is essential. The OECD has been engaged in risk assessment and risk management of chemicals for more than 40 years. Their central task is the development of internationally accepted testing methods. Countries bordering on the North Atlantic joined together in the OSPAR Com-

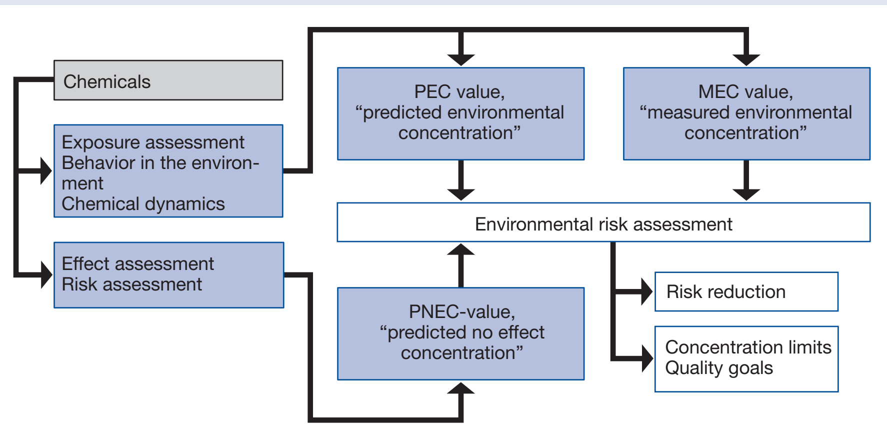

Fig. 1: Environmental risk assessment of chemicals.

mission in order to work jointly towards the protection of the oceans. With the Convention of Sintra (1997), OSPAR set the important goal of stopping the discharge of hazardous substances into the North Sea and the Baltic Sea within one generation.
Since the 1990s, the European Union (EU) has also become increasingly active. The European Office on Chemicals, for example, located in Ispra, Italy, is under the auspices of the EU and is maintaining a database on chemicals and coordinating risk assessments. At the beginning of the new millennium, the EU has also produced two key documents: the Water Framework Directive [2] and the White Paper on the Strategy for a Future Chemicals Policy [3]. The Water Framework Directive aims at protecting inland waters without stopping at national borders. In January 2001, the EU presented as a supplement to the Water Framework Directive, a list of 32 priority pollutants which are gradually to be taken out of circulation and of which 11 substances are particularly hazardous.

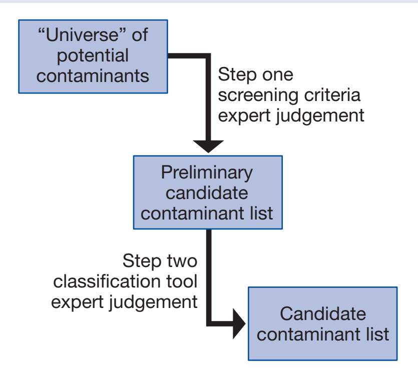

Fig. 2: Prioritization concept for drinking water contaminants in the USA [1].

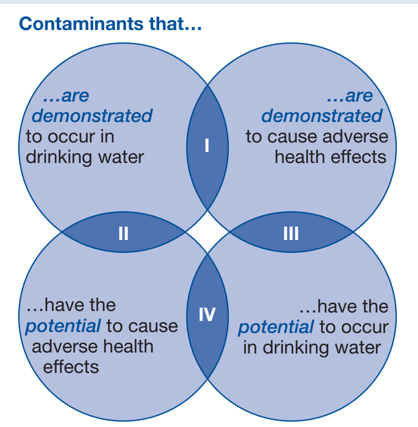

Fig. 3: Step one of the prioritization scheme for drinking water contaminants in the USA [1].

Future EU Chemicals Policies

The primary goal of the EU White Paper on the Strategy for a Future Chemicals Policy in February 2001 is to protect human health and the environment [3]. The basic concept is to identify the most dangerous chemicals – carcinogens, chemicals that accumulate in the environment, and chemicals that interfere with reproduction – and to withdraw them from the market, replacing them with safer compounds. The guiding rule is the precautionary principle: Action should be taken as soon as a certain level of risk has been exceeded, even if the exact cause-effect relationship has not been documented in detail. A key element in the EU policy on chemicals is to develop a transparent evaluation system. The so-called REACH system has three major components: **R**egistration, **E**valuation and **A**uthorization of **CH**emicals:

- *Registration* of basic information on approximately 30,000 old and new chemicals that are produced in quantities larger than 1 ton;
- *Evaluation* of the potential risk for all substances produced in quantities larger than 100 tons, or for chemicals produced in smaller quantities if there is an increased level of concern;
- *Authorization* of substances with certain hazardous properties, i.e., CMR substances (carcinogenic, mutagenic or reprotoxic substances) and POP (persistent organic pollutants).

Another important element of the EU policy is a reversal of the burden-of-proof. In the future, it will be up to industry – not the government – to provide information on the environmental risks associated with chemicals that are to be imported or produced. It will be the task of government agencies to evaluate the data provided by industry, to ensure that adequate test protocols were used and to decide on further steps to be taken.
Switzerland has recently adopted a new Law on Chemicals, which is planned to be in force starting in 2005. The goal is to achieve better coordination with laws in the European Union [4].

Holistic Concept

An integrated approach to assessing and mitigating environmental pollution problems is a major challenge for science, government agencies, the chemical industry as well as non-governmental environmental protection groups and consumer organizations. In addition to the scientific and technical aspects, we also have to give some consideration to socio-economic aspects, such as consumer acceptance or economic acceptability of substitute chemicals. From an environmental protection perspective, however, the risk-based assessment must have priority over socio-economic aspects. The guiding principle of chemicals policy has to be sustainable development, where the negative impacts of chemicals are kept at an acceptable level such that future generations can live in an intact environment and have healthy water resources. Good efforts are already under way, but we have to make improvements in a number of areas; early recognition of problem chemicals being a particularly important one. For optimal protection, we have to apply the precautionary principle; unfortunately, this principle was not adhered to in the case of freons. Humans will eventually have to accept the fact that it is ultimately impossible to reliably and conclusively determine the risk associated with any particular chemical.

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[1] National Research Council (2001): Classifying drinking water contaminants. National Academy Press, 113 pp. Order address: www.nap.edu
[2] Commission of the European Communities (2000): Water Framework Directive. Document available under: http://europa.eu.int/comm/environment/water/water-framework/index_en.html
[3] Commission of the European Communities (2001): White Paper. Strategy for a future chemicals policy. Document available under: www.europa.eu.int/comm/environment/chemicals/0188_en.pdf
[4] Future Swiss Law on Chemicals (2001). Document available in german under: http://www.bag.admin.ch/chemikal/gesetz/d/index.htm