

Precautionary Risk Assessment and Risk Management of Chemicals

Part I: New Strategies for the Ecological Risk
Assessment and Risk Management of Substances

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Presented by: Jan Ahlers, Tessa Beulshausen, Thomas Bigalke, Hans-Hermann Eggers, Andreas Gies, Petra Greiner, Karl-Otto Henseling, Bernd Mehlhorn, Harald Merkel, Inge Paulini, Klaus Steinhäuser, Hans-Christian Stolzenberg, Kirsten Vormann, Suzanne Wiandt

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1. Principles

At the 1992 UN Conference on the Environment and Development in Rio de Janeiro, over 170 nations agreed upon the environmental policy ideal of sustainable – and therefore environmentally sound – development. Borrowing from the 1987 Brundtland Commission, the Enquete Commission of the 12th Bundestag, “Protecting Humans and the Environment”, described the ideal as the aim of producing development which meets the needs of the living people, without endangering the well-being of future generations.

Sustainability is intimately related to the precautionary principle. As early as 1986, six years before the Rio Conference, the German government’s “Guidelines of Precautionary Environmental Care” clearly stated the link between precaution and a sustainable future.

Herein, the precautionary principle involves three components:

- eliminating concrete environmental hazards ("danger prevention"),
- avoiding or reducing risks to the environment in advance ("risk prevention"),
- acting to shape our environment in the future, in particular to protect and improve the fundamental basis for life ("care for the future").

Risk prevention entails considering even those possibilities for harm “which cannot be ruled out, but where current information neither confirms nor denies certain causal relationships, and there is therefore no hazard, but only a suspicion or cause for concern.” *Care for the future* is best described as “developing environmentally sound production processes and products, preventing – or at least avoiding as far as possible – emissions of pollutants at their source”.

The importance of the precautionary principle is also emphasised in EU treaties, for example in Article 174 par. 2 of the Amsterdam Treaty: "Community policy on the environment shall aim at a high level of protection taking into account the diversity of situations in the various regions of the Community. It shall be based on the precautionary principle and on the principles that preventive action should be taken,

that environmental damage should as a priority be rectified at source and that the polluter should pay."

The European Commission published a communication on 2nd February 2000 on the precautionary principle (COM 2000 (1)), explaining how the principle, which applies not only to the environment but also to human, animal and plant health, is to be put into practice in risk assessment and risk management, and how it should not be used arbitrarily as a pretext for protectionist measures. However, the communication has significant deficits. In particular, the principle is only held applicable to risk assessments where scientific information on identified risks is inconclusive. The aspect of precautionary, proactive prevention of pollution (care for the future) is more or less ignored. Measures taken on the basis of the precautionary principle are generally intended to be temporary in order to be adapted according to new knowledge, and they should be subject to a cost-benefit analysis, including socio-economic considerations. During its meeting in Nice on 7. – 9. December 2000, the European Council explicitly confirmed the position of the Commission in its conclusions.

A look at legal risk assessment for chemicals confirms that it has remained almost exclusively at the level of averting concrete hazards ("danger prevention"). Van der Kolk, responsible for assessing existing substances in the Netherlands, highlighted this deficit at an EU workshop on "Industrial Chemicals: Burden of the Past, Challenge for the Future" on 24th/25th February 1999 in Brussels with the following:

- "- Rio Declaration: 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.
- EU practice: Where there is lack of scientific certainty of serious or irreversible damage, even cost-effective measures will be postponed."

This dilemma becomes especially clear in the case of existing substances. Since 1994, only 41 substances have been technically evaluated in the European Existing Substances Programme, while the EU directive on existing substances 793/93 lists c. 2600 chemicals with high production volumes, and the EINECS list, which contains

all substances produced and used before 1981, contains over 100,000 entries. The reasons that even high-priority substances require so long are twofold: firstly, the procedures themselves are complicated; secondly, a high level of scientific certainty is required to justify risk reduction measures. For this reason, a debate on reorienting chemicals policy is underway in Europe, with environmental groups and many Member States demanding greater efficiency and more weight to be given to the precautionary principle. The conclusions on chemicals policy reached by the EU Council of Ministers on 24th June 1999 point in this direction (see chapter 3).

However, regulations for specific media, e.g. the German Water Management Act or the Federal Immission Control Act, provide a predominantly emission-based framework for action on substances, more or less restricted to the medium in question. The shifting of pollutants from one medium into another is prevented, in principle and frequently also in practice. However, executive regulations do not generally achieve this consistently. For example, § 3 (2) of the Waste Water Ordinance provides that no processes be used which simply shift pollution to other media, such as to air or to soil, where there is a better technology available. However, the sector specific appendices in the ordinance do not provide quantitative requirements for air emissions caused by waste water treatment. In addition, the regulatory approach is restricted to point sources, and generally fails to consider discharges from diffuse sources. Substance specific regulations in media-based legislation are limited to a few substances especially dangerous for the media, for example heavy metals, PCB and PAH in the Federal Soil Protection Ordinance.

The principles of precautionary environmental policy and the instruments available to the state have remained more or less the same in the last 10 to 15 years. However, economic change and increasingly more detailed scientific information make it necessary to examine whether the way precautionary environmental policy is applied to chemicals is still up to date, where state action can be made more efficient or must be toned down, and which indirect instruments for modifying behaviour should be given more weight. There have been important changes in the use of chemicals which can impact on the environment, and these must be taken into account:

- State regulation has proven successful in chemicals policy. Germany has banned the manufacture or use of a number of environmentally hazardous substances, or has introduced stringent emissions limits. These substances include persistent chemicals like DDT, PCB, pentachlorophenol, lindane and dioxins, and the bans were exceptionally successful, most now having been implemented across Europe. Concentrations measured in the environmental media in Germany today

are below those measured in the 1980s, although they now remain stable at a level which is still too high.

- Direct emissions by manufacturing and processing industry have fallen, thanks in great part to regulations for waste water, waste and exhaust gas. However, attention should now shift to diffuse pollution from products, for example plasticizers, flame retardants and residues of pharmaceuticals. Frequently, too much is asked of users and consumers, or they are given no assistance in replacing hazardous pollutants with less harmful products and processes. There are virtually no recognised procedures or guidelines for proactive environmentally sound behaviour with respect to chemicals. It is significantly harder to find the original polluter in the case of pollution from products than with direct emissions.
- Problems with substances have become more global. It cannot be expected that environmental concentrations of certain persistent or bioaccumulating substances will become negligible, although they are banned in Germany, because they are highly mobile, and therefore present a threat far from the regions where they are used. Despite a fall in concentrations of these pollutants, and after fully exploiting the possibilities for domestic action, risks to public health and the environment in Germany can often not be ruled out. For example, despite a downward trend, infants' intake of dioxins is still above the tolerable level. It can be assumed that still many substances are in use which are persistent and bioaccumulating and can be transported over great distances.
- The task of assessing substances and designing subsequent regulations has become far greater, due to the large number of substances to be covered under various rules, and also far more complex, due to standardised procedures. With the additional need to harmonise regulations across several national and EU levels, this has produced delays and inefficiency, especially in respect to existing substances (see chapter 3).
- The global dimensions of environmental problems make voluntary solutions more difficult. It is frequently impossible to gain commitments from all those involved in production and processing around the world, or to monitor compliance. Legally binding international agreements for substance regulations are therefore increasingly important.
- It has proved impracticable to examine every potential negative property of substances. The extremely limited possibilities for comprehensively examining

every relevant substance have been made abundantly clear in the recent debate on endocrinally active chemicals in the environment, which can cause irreversible damage in organisms exposed to low concentrations at critical stages of development. It is therefore important to minimise the discharge of substances into the environment as a precaution, even where their harmful properties are not yet proven (see part II).

Moreover, environmental problems today are not primarily caused by specific pollutants or processes. A major problem rather lies in the quantities of material and energy resources consumed, and the form of this consumption. The substances a product contains are generally only a small fraction of the substances transported and consumed during its manufacture and processing. Integrated, cradle-to-grave substance flow analysis is therefore required, especially for mass products.

The 12th Enquete Commission of the German Bundestag "Protecting of man and the environment" formulated four basic rules for a sustainable precautionary management of chemicals and substances, and the corresponding Commission of the 13th Bundestag added a fifth rule, relating to public health.

To build a management of chemicals and substances oriented around the principles of sustainability and precaution, environmental quality and action targets must be set to provide actors with guidance and security. Environmental quality targets which describe the desired state of the environment can only partially be described in a general form, e.g. with respect to "hazardous" substances. For example, the Swedish parliament passed an act on "Environmental Quality Objectives" in April 1999, including a target for chemicals. "The environment must be free of anthropogenic substances and metals which represent a threat to health and biodiversity. This means that environmental concentrations of naturally occurring substances must be close to their background levels, while concentrations of substances produced by humans should be near zero." (Swedish environment ministry, June 1999).

This target reflects similar formulations in marine protection agreements (HELCOM and OSPAR), although the Swedish formulation does not specify which properties render substances dangerous to health and the environment. In its report on "Action Areas and Criteria for a Precautionary, Sustainable Substance Policy, Using the example of PVC" (in English: February 2001), the German Federal Environmental Agency (UBA) described five substance related environmental action targets as steps towards relieving the environment. These targets are presented below in a slightly changed version:

- *The irreversible discharge of persistent and bioaccumulating, or persistent and highly mobile, xenobiotics into the environment is to be avoided completely, irrespective of their toxicity. This also applies to substances whose metabolites exhibit these properties.*

Where xenobiotics remain in the environment for a long period, harmful effects can never be ruled out, even if they are as yet unknown or not fully researched. Where the substances accumulate in organisms or are highly mobile, this presents an especially high risk.

- *The irreversible discharge of xenobiotics with carcinogenic, mutagenic or reproduction toxic effects (CMR substances) into the environment is to be avoided completely. This also applies to substances whose metabolites exhibit these properties.*

These properties affect key functions in organisms and ecosystems, which thereby could be affected irreversibly.

- *The anthropogenic release of persistent and bioaccumulating, persistent and highly mobile, carcinogenic, mutagenic or reproduction toxic natural substances into the environment must not lead to an increase in geogenic or biogenic background concentration.*

This requirement corresponds to the first two, but it is impossible to reach zero pollution for naturally occurring substances.

- *The anthropogenic release of other (eco-)toxic substances (including naturally occurring substances) which do not fall into the above categories into the environment is to be reduced to the technically unavoidable level. This also applies to substances whose metabolites exhibit these properties.*

This requirement means precautionary prevention of pollution and health risks from toxic substances.

- *An increase of chemical discharges into environmental media is to be avoided, regardless of the effects known so far and other intrinsic properties, where high distribution and/or low exchangeability makes recovery practically impossible.*

This final target is a “requirement to minimise” substances not covered by the first four, and aims to reduce pollution in general, especially of the atmosphere, seas and ground water, where lower emissions do not at all or only in the long run lead to lower substance concentrations.

Persistence and bioaccumulation is a combination of properties which is increasingly being recognised as problematic in the European debate on chemicals. Regardless of the results of quantitative risk analysis (comparison of exposure and effect), such substances pose a risk, as their discharge into the environment is irreversible, they remain there for long periods and they can additionally accumulate to potentially harmful concentrations in organisms. Knowledge on harmful effects in principle can never be complete, and a biological effect frequently emerges only from long-term multigeneration studies, which are complex, and therefore seldomly conducted. When new discoveries are made, the persistence of such substances means that harmful effects cannot be eliminated for long periods. This is especially true for environmental sinks, such as the seas.

Persistence and mobility in combination also represent a particular hazard. Highly mobile substances which are persistent can spread over long distances through the atmosphere, and either affect atmospheric chemistry (e.g. CFC) or be precipitated in areas far from the source of emission (e.g. POP). High mobility in the soil or ground water is also particularly critical: if persistent substances enter aquifers, they will remain in the ground water for long periods. Contaminated ground water cannot be completely cleaned up, and this is a special problem if the source is used for drinking water, as contaminated drinking water does not meet hygienic standards irrespective of toxicologically based limit values. Two examples are methyl-t-butylether (MTBE, fuel additive) or n-phenylsulphonylsarcosin (metabolite of an anti-corrosion agent).

However, the combination of the properties high mobility and persistence, unlike persistence and bioaccumulation, has received very little attention in the European debate as yet. Apart from licensing for crop protection agents, ground water has also received little attention at all in legally based assessment of chemicals. However, in the frame of the EU risk assessment of existing substances, recently risk reduction measures for MTBE are recommended solely based on its relevance for ground and drinking water.

It should be noted that, in its most recent special report "Environment and Health – assessing the risks correctly", the German Council of Environmental Advisors (SRU) does not agree that persistence is especially important: "The council cannot accept risk assessments based solely on the nature of exposure or substance properties" (Tz. 137). This is a relatively traditional understanding of risk. More recent approaches to risk assessment, such as those of the German Scientific Council for Global Environmental Change (WBGU, annual report for 1998), which covers

properties like ubiquity, persistence and reversibility as well as the extent and likelihood of harm, are referred to, but not accepted. The SRU favours assessments which take account of the precautionary principle where little secure information is available. It obliges the state to systematically extend the knowledge on the risks and to justify precautionary measures transparently in the political process.

As in the aforementioned report of the Federal Environmental Agency (UBA) on "Action Areas and Criteria for a Precautionary Sustainable Substance Policy Using the Example of PVC", these environmental quality and action targets and the need to conserve resources mean that the following areas require action:

- *Reducing the material used for products and services*: functions in demand should be fulfilled with as little material intensity as possible.
- *Reducing consumption of natural material resources*: this should be understood as an incentive for technical progress towards conserving resources.
- *Reducing energy utilisation during product life-cycles*, in particular to minimise releases of mass pollutants such as climate gases (e.g. CO₂) and acidifiers.
- *Increasing products' long-term fitness for use*: this is also a measure to minimise material flows. It concerns a product's durability and suitability for repair.
- *Improving environmentally compatible recovery options*: this concerns both a product's recyclability and the environmental compatibility of recycling methods.
- *Minimising emissions to the technically unavoidable level*: the levels and harmfulness of emissions should be minimised, and anthropogenic material flows should be separated from natural substance cycles.
- *Reducing the complexity of material flows*: this applies to the number of levels and the interdependence of technical processes, as well as risks for accidents, for example due to risk potential of intermediate products.
- *Reducing risks to prevent an overburdening of the environment with ecotoxic and toxic substances*: this applies to (eco-) toxic substances where a comparison of exposure and effect, including effects in combination, reveals a risk.

- *Developing and implementing substances with environmentally and health compatible properties:* the concept of sustainability requires the prevention of the discharge of persistent and bioaccumulating/highly mobile substances. Developing substances which are “green by design” should help in future to replace substances with a hazardous profile which are currently indispensable.

The relative importance of the abovementioned action areas will vary for different substances and substance flows, and may compete with one another. For example, for substances applied to the environment directly, such as crop protection agents, their properties and application techniques (to reduce consumption) are most important. In contrast, for substances used in closed systems, such as phosgene, the controllability of substance flows is most important.

In principle, a vertical approach which considers only single substance flows is not sufficient. What is needed is a horizontal comparison of the alternatives (including avoiding the use of the substance). Hereby the considerable gaps in our knowledge about the environmental and health effects of most chemicals in commercial use pose a serious problem. Alternatives must be sufficiently tested before their introduction, and comparative product assessments lack the necessary transparency. Our knowledge about the chemical composition of products is generally inadequate, as is the information about their areas of application.

2. Substance-based targets for certain environmental media: the necessity and options for their implementation

The discharge of substances can affect different media within very different time frames. Unless they accumulate in sediment, organic substances in flowing water generally decrease relatively quickly or are transferred to other media. By halting or reducing the discharge, negative effects can be relatively rapidly and completely eliminated. In other media, particularly the marine environment and ground water, negative changes are more difficult to correct and often completely irreversible for long periods. Once a substance reaches these compartments, their poor potential for degradation means that a substance may be predictably persistent, even if tests have shown it to be principally degradable. There are also (almost) no technological methods for recovering substances from these media, once they have spread.

There are therefore especially strict precautionary requirements for these compartments in regulations and international agreements. For example, § 34

Wasserhaushaltsgesetz (Water Management Act) requires categorically that there must be "no need for concern about harmful pollution of the groundwater or any other negative change of its properties" caused by substances. This ambitious target is also expressed in the lines of the Convention for the Protection of the Marine Environment of the Northeast Atlantic (OSPAR) which call for reducing concentrations of anthropogenic substances to almost zero within one generation.

However, legislators did not directly define instruments to attain these targets. The following illustrates this "instrument gap" with the aid of the example of the implementation of the marine protection agreements.

The Commissions for the Helsinki Convention on the Protection of the Marine Environment of the Baltic Sea (HELCOM) and the Oslo and Paris Convention for the Protection of the Marine Environment of the Northeast Atlantic (OSPAR), at their meetings on 23rd–27th March 1998 in Helsinki and 20th–24th July 1998 in Sintra, decided on strategies to eliminate by the year 2020 (i.e. within one generation) discharges of substances which are hazardous, i.e. whose persistence, bioaccumulation, toxicity or ecotoxicity makes them especially problematic, or which give cause for concern for other reasons. This was also the target set by the ministerial declaration of the 4th North Sea Conference in 1995. In order to achieve these targets, substances are to be identified according to their inherent chemical properties and their incidence and discharge levels into marine waters. A still unspecified programme of action is then to reduce marine discharges, eventually eliminating them altogether, and thereby to finally reduce concentrations of naturally occurring substances to their background levels and the concentrations of industrially synthesised substances to almost zero.

A decision taken at Barcelona in 1976 calls for reducing discharges of (eco-)toxic and persistent or bioaccumulating substances which could reach the marine environment of the Mediterranean to a level which is neither harmful to humans nor the environment by 2005, with the eventual goal of eliminating them altogether.

National regulations are inadequate for implementing the marine protection agreements; EU-wide approaches are significantly more effective. However, a problem often arises in that the EU is a signatory to various marine protection agreements, including OSPAR, but is still not prepared to implement its decisions fully. An example is the foreseen regulation by the EU Commission for short-chained chlorinated paraffins within the existing substances programme. While PARCOM decision 95/1 considers it necessary to cease using this substance group in four

areas, the draft EU guideline continues to permit numerous environmentally open applications mentioned in the decision – paints, lamination, sealants, rubber, plastics and textiles. The regulation restricts itself more or less to fields of application (including some which were not mentioned by PARCOM, such as leather) where a PEC/PNEC ratio > 1 has been found. The proposed measures affect the sources of more than 95 % of current total pollution. However, future shifts in the pattern of application or new applications have not been ruled out. The Environmental Committee of the European parliament on 8th January 2001 heavily criticized that the PARCOM decisions were implemented only incompletely.

The debate on reorganising EU chemicals policy brought a recognition by the Council of Ministers in Luxembourg (24th June 1998, No. 5-7) that community chemicals policy should make a major contribution to enabling the community and its Member States to comply with such international commitments, although no concrete proposals were made as to instruments or procedures for implementation.

Existing EU regulations for chemical risk assessment in the Technical Guidance Documents (TGD) currently do not contain final assessment methods for the seas. There is now a broad consensus that the PEC/PNEC model, which generally produces meaningful results for local and regional assessments in limnic and terrestrial areas, does not apply to the particular hazard situation in the seas. Above all the potential hazard from bioaccumulating and persistent substances, which accumulate in the food chain, is thereby underestimated. Therefore, the following additional aspects should be taken into consideration:

- Accumulation of hazardous substances in certain areas (sinks) of the marine environment can have unpredictable long-term effects, and would be practically irreversible.
- Remote stretches of ocean should remain untouched by anthropogenic hazardous substances, as their intrinsic value must be protected from the effects of human activity.
- The open seas cannot meaningfully be divided into separate areas within which PEC values can be calculated.

The current marine EU assessment strategy must therefore be extended, in terms of both time frame and scope. This applies especially to PBT substances (**p**ersistent, **b**ioaccumulating, **t**oxic), which remain in the environment for long periods and can accumulate in living organisms, because they can cause harmful effects long after and far away from the actual emissions. This hazard actually exists for any

environmental compartment, but is especially significant for the seas for the following reasons:

- Once such a substance has reached the open seas, emission reductions do not necessarily lead to a fall in concentrations.
- Owing to the slow reproductive cycles of many important marine species, the possible effects of chronic exposure will not be recognised until it is too late.

OSPAR and the EU Commission are currently working on a joint assessment model to take these aspects into account (Draft Summary Record DYNAMEC (2), 99/10/1, Annex 6). The proposed strategy contains three levels:

- local assessment
- regional assessment
- assessment of the open seas

At first, discharges by point sources are assessed locally, as the highest concentrations, and therefore an increased risk, is to be expected in the immediate vicinity of the source or in the nearest sink. The methodology described in the TGDs is essentially appropriate for local assessments, and may be used with few modifications: a quantitative approach (PEC/PNEC ratio) is generally practicable.

A regional assessment may become necessary where the discharges from several point sources are combined, or significant discharges are transported (atmosphere, dredged material), for example. The key step in this case is to circumscribe the marine area to be assessed. The protected region may be an especially sensitive stretch of sea, such as the tidal shallows or other coastal regions. The PNEC should then be determined on the basis of long-term test results on organisms relevant for this subcompartment. It is planned to generally apply higher safety factors when calculating PNEC values in order to account for the higher diversity of the marine fauna.

A third assessment phase will be required for PBT substances because, as explained above, a quantitative approach using the PEC/PNEC ratio would underestimate the risks. The substances' intrinsic properties create an immediate need for action where there are significant emissions into the seas: any emission sources identified (even diffuse sources) must be closed.

If this strategy can be embodied in the Technical Guidance Documents, Europe-wide implementation of the substance based goals in the marine protection agreements in the frame of the existing substance programme would become easier in the future.

The OSPAR DYNAMEC process is currently ranking substances which are potentially hazardous to marine environments according to their inherent properties and their possible discharge into the seas, in order to identify the most hazardous. Substances characterised as high-priority indicate a need for speedy action to halt further discharges into the marine environment.

Experience to date with regulating toxic and persistent substances shows that no time is to be lost, if we are to come close to the marine protection agreements' targets for 2020. It already seems too late for those especially persistent chemicals which are also highly mobile. For example, data from the German Environmental Specimen Bank show that concentrations of PCB, DDT and its metabolites in wild organisms in Germany have remained constant for many years, despite an earlier downward trend, although these substances have been banned in Europe for ten or twenty years (however, the still widespread incidence of PCB in products with a long useful life, e.g. sealants and small condensers, must be taken into account here).

To speed up measures aimed at meeting the targets in marine protection agreements, there are generally two options:

- A Council initiative could ask the EU Commission to propose a feasible EU-wide regulation (political activity).
- National legal regulations, taking into account the legislation relating to the internal market, could put the Commission under pressure to implement the decisions completely and throughout the EU (legal activity).

Since there is currently no adequate legal framework for protecting the marine environment in the EU, Member States have some room for manoeuvre in making domestic regulations, but the final and preferable goal is an Europe-wide implementation.

Discharges of hazardous substances can be reduced by bans and restrictions on their manufacture or use, as well as reducing emissions from industrial plants. The following EU legislation could function as possible instruments here:

- the EU Integrated Pollution Prevention and Control (IPPC) Directive, 96/61/EEC (sector specific recommendations for reducing emissions from plants with best available techniques, BREFs, as in the Seville process),
- EU directives on substances and products (67/548/EEC, 76/769/EEC) and the EU Existing Substances Regulation 793/93.

These instruments are not mutually exclusive, but complement one another. It should be emphasised that the IPPC Directive regulates only emissions from point sources, and not from diffuse sources like products. However, blacklists of substances whose application is not BAT within a certain sector can produce significant emission reductions, e.g. the ban on substances like mercury, chromium or organic tin compounds in cooling waters.

A complete strategy therefore contains the following options:

- Rapidly completing a marine environment assessment module to be integrated into the EU's technical guidance (the TGD), without using PEC/PNEC for the open seas, but rather basing assessment on inherent substance properties.
- Producing an assessment module for ground water, which should also aim for complete prevention of anthropogenic discharges ("near-zero concentrations"). The key substance properties are persistence and mobility.
- Making EU chemicals policy – especially on existing substances – more efficient, to implement the substance based goals in marine protection agreements quickly (see chapter 3).
- Examining the feasibility of passing national legislation to further restrict short-chained chlorinated paraffins, as proposed EU restrictions under the Existing Substance Regulation do not fully implement the PARCOM decision 95/1.
- Improved co-ordination between the departments involved in marine protection and chemicals policy implementation within the EU and within Member States.
- International monitoring programmes within the marine protection agreements can identify sources and causes of pollution, and help to justify measures and monitor their efficiency, although the difficulty in gaining representative data means the instrument must be restricted to substances with at least a potential need for regulation. Monitoring of effects (i.e. observing biological effects in sensitive marine areas, e.g. tidal shallows) may indicate further need for action.

3. Options for more efficient risk assessment and risk reduction of chemicals

3.1 Description and criticisms of current procedures

The need for clear principles in chemicals assessment for existing regulations has been met at EU level by Technical Guidance Documents (TGD), which provide binding principles for assessments of *existing* and *new substances* in Member States. The basic principle for determining environmental risk for single substances is a comparison of the measured or calculated concentration of a substance in each environmental compartment (PEC) with the concentration at which no negative effects on the ecosystem are expected (PNEC). There is nonetheless a fundamental problem in that our knowledge about harmful effects will always be incomplete. Available studies, mostly acute to subchronic, do not indicate all possible effects, e.g. effects on the endocrine system (see part II). At present, the precautionary principle is only satisfied in that gaps in the data on effects are filled by high assessment factors, while missing information about exposure is compensated by assuming “realistic worst case” scenarios.

The procedure has generally proven adequate. The question remains, however, whether this procedure produces appropriate results for substances with certain problematic properties (persistence/bioaccumulation, persistence/mobility and CMR). Also, the procedure is not applicable to certain compartments, in particular the open seas or ground water (see chapter 2). In these cases, the goal should be to design regulations without a quantitative comparison of exposure and effect.

An additional problem is that the European Existing Substances Programme has, despite great efforts, succeeded in technically completing the risk assessment for only 41 substances. The key reasons for this unsatisfactory result up to now are:

- complex, contradictory, and above all incomplete data,
- the considerable efforts associated with a *comprehensive* risk assessment,
- before the assessment is concluded, the options for refining the results with additional, more precise data are fully exploited,
- the structure and complexity of the administrative procedure.

The greater difficulty in assessing existing compared to new substances is to some extent unavoidable for a number of reasons:

- Data for new substances are collected before they are marketed, depending on the production volumes. Exposure can be modelled on the basis of the substances' properties and intended use, which can generally be described unambiguously. In contrast, existing substances are produced or marketed in

quantities of well over 1000 t/a. They have been in use for many years and have numerous, frequently unknown applications. It is therefore very difficult to determine the exposure in all the relevant environmental compartments and subcompartments. Any available data from monitoring must also be included.

It is also time-consuming and irritating that industry fails to provide sufficient data, especially on exposure, and that too little is generally known about emissions during down-stream use of chemicals. Detailed knowledge about such data is required in most cases, in order to identify the most significant sources of emissions and take appropriate measures to reduce them.

- In contrast to new substances, for which well-defined data on their effects are presented according to internationally agreed guidelines, the data for existing substances, from which an overall view of the threats to each environmental area has to be deducted, are generally copious, heterogeneous, frequently non-standardised and contradictory. Crucial basic data are often missing.
- While the main goal of examining new substances is to determine whether there are objections to their marketing, existing substances must be examined to determine existing risks and, where necessary, minimise them. Such reduction measures mean intervening in markets, and must therefore be well-founded.

These framework conditions require more flexible and efficient examinations for existing substances, in order to accelerate the process and introduce measures to minimise risks at an early stage.

Another serious delay is in the administrative procedure, both on national and at EU level. Within the EU Commission, the Directorate-General Environment (formerly DG XI) is responsible for the Existing Substances Regulation, but the DG Enterprise (formerly DG III) is charged with implementing risk reduction measures relevant for the internal market. In future, the DG for Consumer Policy and Protection (formerly DG XXIV) will also be involved. Collaboration is anything but smooth: in Germany, three agencies are concerned with assessments – the UBA (environment), BgVV (consumer protection and veterinary medicine) and the BAuA (occupational health and safety) – not counting the additional unit for registration at the BAuA. Furthermore, the German Administrative Ordinance on Existing Substances provides for participation by the Advisory Committee on Existing Substances (BUA). At EU level, the risk assessments are frequently discussed at Technical Meetings at the European Chemicals Bureau (ECB), and the OECD is also involved. At all levels, industry has opportunities to exert an influence or provide additional data. Any

change in the data stock necessitates a comprehensive redraft of the assessment report in most cases.

These problems have caused Germany and other EU Member States to consider urgently how the assessment process can be speeded up. The following points on EU's chemicals policy were taken up by the Council of Environmental Ministers in their conclusions on 24th June 1999, but need some refinement and concrete specification.

3.2 Options for precautionary and efficient management of existing substances

The conclusions of the Council of Ministers are aimed at making assessment of existing substances more efficient. Point 18 of the conclusions affirms that the precautionary principle, the goals of sustainable development and a smooth functioning of the internal market should provide the basis for a new chemicals policy. The Environmental Ministers asked the Commission to develop a White Paper where the strategy for a future chemicals policy of the EU should be presented basing on the Council conclusions [Remark: The Commission published this White Paper at 13th February 2001].

The following points in the Ministerial Declaration are especially relevant to this discussion:

Shifting the burden of proof: more responsibility for industry (point 20)

The demand that industry assume more responsibility for collecting and evaluating data should be welcomed. This responsibility can be met by laying all the relevant data on the table from the outset, and not waiting until a need for regulation appears likely under the TGD. On the other hand, assessment by industry itself is counterproductive. In the experience of the UBA, it takes considerable time to uncover and eliminate the causes of implausible assessment results – namely faulty, sometimes even biased, initial parameters. The full responsibility of state authorities should nonetheless, as the Council describes, focus on the substances which a suitable priority-setting has identified as potentially seriously problematic (see point 23).

A voluntary commitment by the ICCA (the International Association of the Chemicals Industry) declares its willingness to provide basic ecotoxicological and toxicological data, including a preliminary hazard assessment, for c. 1000 high-volume

substances until 2004. German chemicals industry is participating on c. 160 substances. This OECD-co-ordinated initiative is a welcome step towards identifying substances which have an especially high potential need for regulation. However, up to now industry has not selected a single environmentally relevant substance.

In the draft German book of environmental law (UGB) drafted by an independent expert commission, § 600 UGB-KomE renews the current division of roles between authorities and producers, but it takes up the problem on p. 1450, calling for a change in the burden of proof at EU level: "It would better reflect both the precautionary principle and the polluter-pays principle if the burden of doubts as to a substance's impact on the environment or public health should fall on the creator of a potential source of hazard, rather than – even if only for a short time – on the general public."

Assessing and managing risks (point 21)

The goal of comprehensive scientific risk assessment is to determine whether action is required to reduce risks from substances. The EU Existing Substances Regulation 793/93, Articles 10.3 and 11, requires the rapporteurs of risk assessments for high-priority existing substances to present a risk reduction strategy. If this strategy proposes restrictions on the marketing or use of a substance, an analysis of its advantages and drawbacks and the availability of substitutes is also required.

The strategy is developed according to the EU '*Technical Guidance Document on Development of Risk Reduction Strategies*' of October 1997. The rapporteur presents the risk assessment and risk reduction reports to the EU Commission, where they form a basis for the necessary political decisions and legislative or other measures. The goal is also to structure the decision-making process better and more transparently.

Important aspects of a goal oriented linking of risk assessment and management regarding the contents as well as the organization were discussed at a conference in Bielefeld 1999: "Reforming the European Regulation of Dangerous Chemicals". (Proceedings "Risk Assessment and Risk Management of Toxic Chemicals in the European Community" (Nomos Verlagsgesellschaft Baden-Baden 1999)).

The following points are particularly important for rapidly and efficiently developing and implementing risk reduction strategies:

- Effective risk reduction strategies can only be elaborated with a thorough knowledge of the risk assessments behind them. The exposure analysis within the risk assessment must always have reduction strategies in mind, just as the development of a reduction strategy must continually refer back to the risk assessment. Both the content and authors of risk assessment and risk reduction strategy must therefore be closely interconnected.
- A comprehensive cost-benefit analysis should not generally be required. Instead, a cost-efficiency estimate should find the cheapest way to eliminate the risks determined by the risk assessment. Owing to the lack of certainty in estimating long-term environmental harm, which hardly is to monetarize, quantitative cost-benefit analyses frequently dominate the short-term economic advantages of continued use of the substance.
- In order to implement the risk reduction strategies smoothly in actual regulations, this task should fall within the competence of the Environment DG of the EU-Commission.
- If the assessment cannot be concluded within a specific timeframe, due to lack of data, a secondary assessment conclusion should come into play, to prevent the process from freezing up. It could be formulated like this: 'There is cause for concern, although the information is insufficient to determine this with certainty; preliminary risk reduction measures will be introduced; producers and importers have the opportunity to remove this cause for concern.'
- Applications of especially problematic substances (PBT and/or CMR) should be banned completely or only permitted if it can be demonstrated that the application is safe (e.g. substances handled in closed systems). Where certain applications cannot be substituted at short notice, these should be authorized explicitly and transition periods should be laid down. After the transition periods expire, the total ban will come into force. This has been put into practice in the EU directive 86/94/EEC on the degradability of detergents: certain non-ionic detergents (EO/PO detergents in the beverage industry and in metal processing) were initially excluded from the ban of use, despite being insufficiently biodegradable, until the transition period had expired. A similar procedure was used in the ordinance banning CFC and halons (FCKW-Halon-VV), which requires regular reports on substitution options.

- In cases where no complete ban is proposed, it must be assured that new areas of application or an expansion of permitted uses do not counteract the benefits of the original strategy. This could be achieved by requiring explicit permission for any such changes – a *de facto* permission or notification procedure.
- Involving industry more in the responsibility for risk reduction and substituting hazardous chemicals is worth considering. One practice has become established in the UK, linking voluntary commitments or binding contracts with civil law. After identifying an unacceptable risk, and therefore a need for action, a dialogue with the affected industry requires it to develop a proposal for technical solutions or substitution within a certain time. The proposed solutions are agreed between the affected manufacturers and users or their associations for a given trial period. With the support of participating industry, a regulation then comes into force, to ensure full implementation in the entire sector. This prevents free-riding by companies who counteract the voluntary agreement and seek short term financial benefits, and rewards those volunteers who develop marketable alternatives at an early stage.

Removing existing deficits in collecting exposure data (point 22)

Experience to date in assessing substances under the EU Existing Substances Regulation shows that deficits in determining exposure data are one of the key reasons for the EU's slowness in assessing the risk of existing substances.

The EU regulation only requires producers and importers to provide the data listed in Appendix III of 67/548/EEC, which contains little information on exposure. Only when a substance appears on a priority list the data must meet the requirements in Appendix VII A (basic requirements for new substances). However, the data provided by industry often fail even to satisfy these requirements. To identify and assess high-priority substances in future, Appendix III must be revised to require exposure data to be provided together with the IUCLID data.

A questionnaire covering the necessary exposure data for existing substances has been developed by the OECD and further developed by the EU; it is a specification and extension of Appendix VII A. Unfortunately, it is not used by all Member States. Legally requiring industry to provide complete exposure data according to the questionnaire would considerably speed up risk assessment of existing substances (see also point 23). At present, numerous time-consuming interviews with

representatives from each production location are needed to clarify which data are required, and the data must then actually be submitted.

Exposure data is particularly poor for down stream uses. The data needed for an assessment are not available to manufacturers or importers and are often extremely difficult to trace, if this is at all possible. The EU legislation must include the down stream users in future.

A product register might be a suitable aid in gathering more precise information on human exposure, the release of chemicals into the environment and substance flows than it is available today. A research project commissioned by the UBA is currently examining whether and under what circumstances to develop an European product register can be developed. In several European states, especially Scandinavian states and Switzerland, such registers already provide valuable information.

The aforementioned ICCA initiative should also provide sufficient exposure information to help speed up and improve selection of high-priority existing substances.

Making risk assessment flexible - targeted risk assessment (point 23)

Making risk assessment flexible must be considered together with the issues of point 22 (deficits in collecting exposure data), point 24 (measures based on inherent substance properties) and point 25 (substance grouping). A minimum of data, including meaningful exposure data, is generally needed, at least for production volumes > 1000 t/a. Only then can priorities be set reasonably and systematically. During this priority-setting, more attention should be paid to the results of other prioritising procedures, such as the OSPAR DYNAMEC list and the COMMPS list under the EU water framework directive. A series of steps, involving a basic assessment beyond priority-setting, such as generic exposure calculations or estimates based on structure-activity relationships, can reveal whether a substance requires a comprehensive risk assessment or merely a targeted risk assessment or an assessment based primarily on its inherent properties (point 24). The priority-setting could also identify the substances which pose a potential environmental threat, but where the single-substance approach of the EU existing substances regulations does not provide appropriate instruments, for example substances which consist mainly of mixtures (petroleum-derived hydrocarbons), or are discharged into the environment as unintentional by-products (polychlorinated dibenzodioxins and dibenzofuranes, or octachlorostyrene). Such chemical pollution is better controlled

with other legal instruments, such as the IPPC or the solvents directives, or with instruments still to be developed. The final selection should then contain mainly the substances for which risk reduction measures according to the Existing Chemicals Regulation are very likely to be required. It must be emphasized that at least simple regulations (e.g. labelling, workplace safety) can be introduced on the basis of basic data, without waiting for the entire assessment.

A targeted, or “tailor-made”, risk assessment is a reasonable substitute for a comprehensive risk assessment in cases where the risk is only suspected in certain areas (e.g. the workplace) or environmental media (e.g. water or soil), or where there are already sufficient risk reduction measures in place for some areas. A limited assessment could also be adequate for substances that are only intermediates, or where exposure is only expected in specific applications or sectors. Current law under § 9 par. 3 of the EU regulation does not permit to ignore aspects of an assessment simply because they are considered unimportant in a specific case. Until the regulation is suitably amended, such aspects should be mentioned briefly in reports, for formal completeness’ sake.

As shown in point 21, risk assessment and risk management interact closely with one another. An extended priority-setting and an initial assessment must first identify the key information requirements and determine where emission reduction measures will probably be necessary. The detailed assessment will then only be required for these aspects, in order to sufficiently justify the necessary measures.

Where feasible and meaningful, the extended priority-setting should also group substances with similar structures into substance groups, or those with similar applications to use clusters, and later assess them jointly (see point 25).

Effective risk management measures for substances with certain inherent properties (point 24)

As shown in chapter 1, substances which are both persistent and bioaccumulating/*or* persistent and highly mobile *or* which exhibit CMR properties, must be considered particularly hazardous. The action target is to avoid irreversible discharges into the environment as completely as possible. Therefore an authorization procedure for unavoidable applications would be the preferable measure to prevent exposure of humans or the environment (see point 21 and chapter 3.3). These substances should in future be subject to a simplified assessment procedure, not involving the PEC/PNEC ratio. Nevertheless, qualitative exposure data on the type of application

and quantities used, and on the emissions arising, are also required in order to take the appropriate risk reduction measures (see chapter 2). If the assessment shows that the substances meet the criteria of the UNEP POP convention, efforts should be made to have them included in this global prohibition and restriction instrument. The criteria for classifying substances as persistent, bioaccumulating and highly mobile still are to be specified in detail. If a substance is found in human or environmental samples, especially from remote areas far from the sources, there is already reason for concern. In these cases, emission reduction measures should be aimed for without requiring further tests on adverse effects.

Substance grouping (point 25)

Grouping of substances instead of assessing single substances separately can mean a considerable efficiency gain, during the extended priority-setting or risk assessment, or when carrying out risk reduction measures (see point 23).

Approaches can be distinguished as follows:

- Grouping substances based on structural similarity (e.g. homologous substances), QSAR techniques may be used for the extension of the data. If substances being assessed together exhibit the same type of effect, the PEC should usually relate to the total concentration of all members of the substance group.
- Use clusters of substances used for the same applications make comparative assessments possible. Much of the necessary examination of substitution issues has then already been completed when introducing risk reduction measures.

Substituting hazardous with less hazardous substances (point 26)

The substitution principle should be included in the discussion on risk reduction measures, and the use cluster approach also makes such a procedure possible. A strong incentive for substitution would be created if the substitution requirements under § 16 par. 2 of the Hazardous Substances Ordinance were extended to cover not only substances which are harmful for human health but also environmentally hazardous substances.

Stricter time frames for risk assessment and appropriate responses to failure to meet deadlines (point 27)

The chemicals industry's response to public pressure, in stating its willingness to provide basic data by 2004 for c. 1,000 high-volume substances to enable a preliminary assessment of potential hazard, is to be welcomed. If this deadline is not met or the data are so incomplete that the target cannot be achieved, the EU should set strictly binding deadlines, after which any substance will automatically be considered a new substance. A second stage should extend the procedure to cover existing substances with a production or sales volume > 10 t/a. If existing substances exceed the given tonnage limits in future, this is to be communicated, and the necessary data provided speedily.

More information from manufacturers for substance users (point 30)

The polluter-pays principle and especially the responsibility of the producer for its products requires that manufacturers and importers provide their clients with the necessary information. Therefore, manufacturers and importers should be required to provide the users with all the information about substances' inherent properties needed (improved safety data sheets). A note (e.g. "incompletely tested substance") should explicitly indicate whether essential basic data are unknown. Classification or labelling, in particular, must make clear whether a substance cannot be classified on the basis of performed tests or due to lack of data. This would give the user or consumer the option of selecting the least hazardous of a number of substances, when a choice exists.

Under the new Administrative Ordinance on the Classification of Water-Hazardous Substances (VwVwS), this precautionary kind of system is already in use. If basic data are not available, the official classification automatically results in the worst case possible according to whatever data is available.

Information for users and consumers about risks could be improved by lists of substances for which insufficient data has been made available or which have dangerous properties ("undesirable substances"). These lists could be regularly published, either by or in co-operation with the authorities, as has been done in Denmark and Sweden. When managing substance flows (see chapter 4), substance lists based on industrial sectors would be useful, creating a considerable incentive to use less hazardous substances (see point 26, and chapter 3.4 for "whitelists").

Scrutinising existing structures and instruments (point 33)

As described in chapter 3.1, existing structures are too complicated, time consuming and bureaucratic, involving EU committees, the OECD and a Scientific Committee. Even if assessment standards are uniform across Europe, their application differs from state to state. The role of the central European Chemicals Bureau (ECB) in Ispra therefore needs significant enhancement. As commissioner M. Wallström explained at a CEFIC Workshop in Brussels on 6th December 1999, the EU Commission considers a central authority for risk assessment and chemicals management, possibly by expanding the ECB. Transferring competence to European institutions should be welcomed in principle. Such an agency should nevertheless genuinely save resources and improve efficiency. It should be ensured that the expertise of national authorities is exploited, as is the case when new pharmaceuticals are licensed by the central EMEA in London, for example, making use of rapporteurs from Member States and their expertise. Maintaining expertise in Member States is also necessary in order to formulate and implement ambitious national environmental targets. Up to now, it has not been clarified how the Commission wants to implement these plans.

Further measures not addressed in the Council of Ministers' conclusions

- The Technical Guidance Document (TGD) for assessing existing and new substances is currently under revision. New scientific results need to be considered, knowledge gaps (e.g. on risks to the marine environment, see chapter 2) must be filled, and biocides included. The revision should also further develop procedures for assessing risks to ground water and the atmosphere, possibly based on the approaches already developed for crop protection agents. This would represent a significant step towards harmonising assessments, and in the medium term, procedures for industrial chemicals should be fully harmonised with assessments of crop protection agents. Moreover, integrating pharmaceuticals (and cosmetics) is especially important, as they have not as yet been subject to (adequate) environmental risk assessments.
- Classification and labelling rules should be developed further. In particular, rules for classifying terrestrial environmental hazard must be determined. The initiative to develop criteria for substances which accumulate in the food chain is to be welcomed. Harmonising classification systems and labelling, especially with the rules on transporting hazardous goods, should also be pursued further.

- It would be illusory and is not intended to wish a comprehensive risk assessment for all existing substances. This is not even realistic for the c. 3,000 high-volume chemicals. As explained above, a valid priority-setting procedure is therefore needed to identify potentially hazardous existing substances. In the long term, however, the majority of the c. 100,000 entries in the EINECS list cannot continue to enjoy a permanent production and distribution license, and it is an open secret that the majority of the substances in the list are not, or no longer on sale. The Danish environment ministry has made an interesting proposal for giving the list a "spring clean" ("A strategy for intensified efforts in the field of chemicals", January 1999): levying a charge for every substance which is still in regular use.

Since there is no legal framework for levying such a charge, levying a special charge for a further sales license in every member state would probably be the most suitable instrument. If the charge, possibly calculated according to market volume, is not paid, the substance would eventually be removed from the list and would need to be registered as a new substance in order to receive a new license.

3.3 Options for an efficient precautionary policy on new substances

In contrast to existing substances, the notification procedure for new substances, with its legally required tests certainly is a "filter" for marketing new substances. The graded obligation to provide data for assessment is a relatively well-functioning system which is uniform across the EU.

The recent discussion in the EU on streamlining the procedure for new substances, by some Member States frequently justified as a way of freeing resources for assessment of existing substances, should not be allowed to lead to the provision of less information, as this could prevent possible environmental risks to be recognised in time. The resources expended on assessing new substances are so small in comparison with activities on existing substances that even a reduction would hardly lead to a significant increase in the assessment of existing substances.

The discussion on streamlining the new substances procedure was initiated primarily by SLIM, an activity under the EU Commission's Directorate-General for the Internal Market (formerly DG XV), which examined directive 67/548/EEC, on which the procedure is based, for ways of increasing efficiency. The SLIM group eventually concluded that the directive essentially fulfills its purpose in its present form. The group's proposed improvements address various areas of the directive. Some welcome proposals were, for example, to structure the directive more clearly and

reorganise Appendix 1 more effectively, and to improve data sharing. This means that, when two manufacturers from different EU Member States notify the same substance, data on the substance should be mutually transferable (as provided at a national level in Germany by the Chemicals Act), also avoiding the need for unnecessary animal experiments. However, the proposal to shift responsibility for producing risk assessments from authorities to industry itself is critical. It is not helpful, as past experience has shown that risk assessments produced by industry must be scrutinised carefully, which generally occupies authorities for just as long as a risk assessment itself. The proposal to soften data requirements for intermediate products must also be criticised, as the past has also shown how, especially in case of accidents involving intermediate products, a lack of necessary data causes problems.

As for chemicals with particularly hazardous properties (persistent/ bioaccumulating, persistent/mobile or CMR, see chapter 1), introducing a separate procedure instead of the currently used notification procedure should be considered. If a registered substance which could, if used improperly, enter the environment, exceeds certain yet to be determined thresholds, it would be necessary to immediately determine by extensive testing whether the substance has a combination of hazardous properties. A licence would then have to be granted within a predetermined period. The independent commission of experts working on the German book of environmental law (UGB) also suggested to "consider the community-wide introduction of an authorization procedure for certain hazardous substance groups" (UGB-KomE, p. 1450). It should be emphasised that research by the BAuA (Anmeldestelle) and by the UBA has shown that the existing data for several new substances are inadequate for a safe judgement as to whether they are persistent organic pollutants (POPs). The existing system for presenting substance tests should therefore be revised to make it possible to identify new POPs with confidence in cases where a suspicion exists. The UNEP POP convention passed on 10th December 2000 provides that new substances with POP characteristics shall be regulated with the aim of prevention by signatory parties (Articles D2 bis).

With respect to the action area to developing substances with better environmental and health properties (see chapter 1), the possibilities for promoting "green chemistry" within the legal procedures for new substances should also be examined. As a first step, the substances which prove safe during the notification procedure (e.g. unclassified according to hazardous properties) should be grouped by application areas and published, along with their names and manufacturers' addresses. The BAuA has already done so for paints with respect to occupational safety. These

"whitelists" could also contain sufficiently tested existing substances which are non-hazardous. A further incentive to market new substances less hazardous for human health and the environment would be to reduce the test requirements in stages 1 and 2 of the notification procedure if favourable properties can be proven during the base stage.

3.4 International activities beyond the EU

The frequent transboundary pollution by chemicals and increasing global trade require international action beyond the EU.

The OECD is an important forum for achieving consensus on chemicals management between industrialized countries. Various committees exchange information and find agreement on important issues in international chemicals management, for example globally harmonising substance classification systems or risk assessment and risk management methods. Synopses of key issues in chemicals safety form an essential basis for a consensual further development of national and European approaches. Hereby, the test guidelines programme is especially important, developing internationally agreed, valid testing procedures as a sound basis for mutual international recognition of substance data and therefore also for risk assessments. International standardisation avoids unnecessary (and in the case of animal experiments, unjustifiable) duplication of tests regarding the same hazardous property. An especially important focus of the programme is on developing procedures for testing effects on the endocrine system (see part II).

Globally, the UNEP, the WHO and the FAO are developing a series of international, legally binding agreements on chemical safety. For example, greenhouse gases like CFC and sulphur hexafluoride are regulated by the Climate Convention, and CFC and other ozone depleters in the Montreal Protocol.

The PIC Convention (prior informed consent) signed in Rotterdam in September 1998 contains a binding procedure which strictly regulates trade with particularly hazardous substances, and places obligations on states which export chemicals that are banned or heavily restricted domestically. Germany should ratify the convention as soon as possible, to enable it to come into force quickly.

On 10th December 2000, the text of a global POP convention was agreed. Hereafter, a global ban - or at least strong restrictions - is planned on 12 POPs which can cause problems at great distances from their points of emission. Moreover, a

procedure is included that new substances with POP characteristics shall be regulated with the aim of prevention by the parties. In May 2001, this convention is to be signed in Stockholm.

Under the UN ECE convention on long-range transport of air pollutants (LRTAP), a POP protocol was agreed in June 1998 in Århus (Denmark), covering 16 substances. For Europe (including Eastern Europe and Central Asia) and North America, the protocol contains provisions which in parts exceed the provisions required from the POP Convention. Because of the standards already achieved in Germany, only minor adjustment is still needed for legal and formal reasons: Therefore, ratification should soon be performed to enable implementation and entry into force.

As a major industrial chemicals producer, Germany has a special responsibility in international negotiations on chemical safety. In agreement with the other EU Member States, efforts should be made to ensure that the EU continues to take a lead internationally in environmental and health safety. This is also important to guarantee Europe's competitiveness as a location for chemicals production. In particular, the precautionary principle should be anchored bindingly in international agreements (not in preambles only), and environmental conventions must not be subordinated to global trade agreements (WTO/GATT).

Promoting transfer of knowledge and technology is essential for the implementation of international chemical safety agreements, both in Central and Eastern European countries (some of whom are candidates for EU membership) and in the developing world. Some developing countries and countries with economies in transition have no management of chemicals at all, and targeted projects to support them are indispensable. One example for such a project is the GTZ project for producing a PCDD/F emissions inventory in Thailand. The new POP Convention contains provisions for financial and technical support. Therefore, it could be a suitable basis for international management of chemicals.

3.5 Final note

Legal regulation of chemicals cannot be the only instrument used to ensure that chemicals are used safely and without harm to the environment. The high level of proof required for statutory regulation means that only especially hazardous substances can be regulated. In order to effectively substitute harmful substances, soft instruments to modify behaviour indirectly and informational instruments must be used. It is essential that manufacturers and users have sufficient information to be

able to choose the most environmentally sound available alternative (see the following chapter 4).

4. Assessment of and acting on substance flows

Global pollution is increasingly caused by diffuse inputs, in which products (during use and disposal) play a significant role. A wide-reaching reduction in the environmental burdens associated with products is therefore necessary, and life-cycle analysis of substance and energy flows is a crucial instrument for conserving resources and reducing pollution.

Assessing of and acting on substance flows is therefore intimately connected with environmental policy on products. A fundamental principle of integrated product policy (IPP), as formulated in the background document on product-related environmental policy for the EU meeting of environmental ministers in Weimar in 1999 (Umwelt 6/1999, Sonderteil), is "to monitor substance flows from cradle to grave". Meanwhile, the EU Commission has published a greenpaper on integrated product policy which will be a fundamental basis for further discussions.

In view of the variety and rapid change in the cradle-to-grave substance flows caused by production and products, from substance extraction until disposal, monitoring them can be a function of the state only to a very limited extent. The state must directly regulate hazardous substances using chemicals legislation, but problems with overexploitation of resources, for example, or creeping accumulation of hazardous substances in the environment, can only be solved to with non-legal instruments. Most appropriate are instruments for indirectly modifying behaviour and instruments for self-regulation.

The necessary information about chemicals and less polluting alternative chemicals or technical solutions is often available (only) to private actors, who should, mostly on their own initiative, use the information in environmental management of companies, substance flow management across companies, and voluntarily pass it on to consumers and other users, in quality control, product labelling or eco-labelling, for example.

The key to a precautionary, sustainable development lies in innovation which systematically includes the environment in planning, developing and designing products. This kind of innovation requires transparent transfer of information and the

participation of customers and users. The UBA wants to encourage innovation with the handbook ("Was ist Ecodesign?").

Innovation alliances between actors are required to realise potential for environmental innovation throughout a product's life-cycle and to manage substance flows between companies. Depending on the task in hand, these actors may include research institutes, user groups, consumer associations, environmental groups and trades unions, as well as companies in the substance chain (see the UBA publication "Sustainable Germany", 1997).

A decisive factor in the success of environmental innovation in products and services is knowledge about the environmental importance of the materials and auxiliary substances involved in their production. Based on a description of the desired function, the most resource efficient and low pollution variant can be identified, a process assisted significantly by life-cycle and product line assessments.

There is frequently a wide range of substances to choose from for a specific purpose (e.g. auxiliary agents for textiles), but users are frequently inadequately informed about their impact on the environment or human health. Classification schemes are an appropriate instrument for producing and communicating information for users about the relevant properties of substances or preparations. The UBA has taken up the suggestions by the Enquete Commission on protecting the environment and human health for a classification system for textile auxiliary agents, and commissioned a study to devise a procedure for studying and classifying them ("Konzipierung eines Verfahrens zur Erfassung und Klassifizierung von Textilhilfsmitteln", FKZ 109 01 210). As a result of this work and the pressure it exerted, the chemicals industry, represented by the association for textile and leather auxiliary agents, tanning agents and detergents' raw materials producers (TEGEWA), undertook a voluntary commitment on classifying auxiliary textile agents by their significance for water quality "Selbstverpflichtung zur Klassifizierung von Textilhilfsmitteln (THM) nach ihrer Gewässerrelevanz" in November 1997. They describe a model for classifying the agents which corresponds only in part to the ideas of the UBA. In March 1999, the association presented its first report, grouping the number and quantity of agents in use in Germany in three waste water classes.

The user's guide to requirements for the input of chemicals into water ("Anforderungen an Stoffeinträge in Gewässer - Hinweise für Anwender", UBA-Texte 60/99) had a similar aim, providing the users of chemicals with notes towards a

comparative risk assessment, enabling them to find an environmentally sound process or product.

Because of the fundamental importance of information on the composition and properties of chemical products to environmentally compatible innovation, the question should be examined whether classifying them for other areas of use is also meaningful. As well as classification schemes, "whitelists" are also a way of providing a rapid overview of green alternatives in certain areas of application.

A variety of requirements on products is deduced from the topic indoor air quality, an important area of public health. The German government's 1992 plan for improving indoor air quality contains a detailed examination of possible sources of indoor air pollution, as well as concrete proposals to reduce them. The main goal of the plan is to eliminate, or to permanently reduce, the sources of pollution, which can only be achieved with precautionary measures. Product requirements are especially important, in particular for building materials used indoors, such as paints and varnishes, adhesives, plaster, sealants, putty, grout, preservatives for buildings and furnishing.

In designing and awarding eco-labels, systematic knowledge of the environmental properties of products is also essential, and there are certainly ways of guaranteeing confidentiality for data which are important for competition. The procedure for examining applications for the eco-label for low-pollutant paints demonstrates that this is possible and practical. The LAMBDA database, developed for the UBA, collects, processes and maintains all the data on raw materials, chemical ingredients and addresses needed for the assessment and for processing the application itself. The database guarantees a high level of security.

Assessment of and action on substance flows do not focus primarily on the relative environmental soundness of specific chemicals used in a product. Instead they examine its function, and how this function can be fulfilled with a minimum impact on the environment. The following illustrates the procedure with the example of flame retardants.

Fire damage is among the most serious and far-reaching, and humans has long been trying to reduce the risk of fire. One possibility is to modify flammable materials by adding flame retardants, making them less flammable. Three lines of development in the second half of the twentieth century made this measure for fire safety increasingly important. Firstly, the advent of plastics brought more and more

flammable articles onto the market. Secondly, the spread of electrical and electronic equipment meant that these materials were increasingly used in equipment where a malfunction brought a high fire risk (short circuits, etc.) with it. Thirdly, the chemicals industry greatly extended the range of flame retardants, in particular with the development of organohalogen compounds. The insurance companies and the emergence of technical regulations, e.g. CEN or CENELEC, also encouraged the use of flame retardants in products.

Today, flame retardants based on various kinds of chemicals are manufactured and used:

- *Inorganic flame retardants*: boron, aluminium, antimony, molybdenum or magnesium compounds; inorganic phosphates, elemental (red) phosphorus
- *Organic flame retardants*:
 - a. *Organohalogen flame retardants*: brominated compounds (e.g. polybrominated diphenylethers and biphenyls), chlorinated phosphorous compounds (e.g. tris-(2-chlorethyl)phosphate) or phosphor free chlorinated compounds (e.g. chloroparaffins)
 - b. *Halogen free organic flame retardants*: phosphor (e. g. triaryl phosphates), or nitrogen compounds (e. g. melamine and its derivatives)

These groups of substances cover a large number of individual chemicals - global turnover in the flame retardant market in 1992 was c. 610,000 t/a, about 90,000 t/a in Germany alone, even ignoring substance flows in import/export. In general, organohalogen flame retardants have a greater potential health and environmental hazard than the majority of inorganic products and products free of halogens.

Polybrominated diphenylethers (PBDE) are an important group of substances which is currently heavily and intensely discussed. Persistency is a characteristic of PBDE and, as lipophiles, they have a great potential for geoaccumulation. The question of whether highly brominated members of the group can be debrominated to produce more toxic and bioaccumulating compounds cannot as yet be answered with certainty. The overall goal should be to achieve a ban of the production and use of these persistent xenobiotic substances in the EU in the medium term. It is to be expected that, regardless of the agreed short-term goal of rapidly substituting pentabromodiphenylether, an EU-wide ban on the use of the entire substance group will be hard to achieve. Another approach might be the planned ban on using all polybrominated biphenyls and diphenylethers in the envisaged EU directive on electronic scrap. However, it seems very likely that this directive will be linked to the

results of the risk assessments for existing substances according to the Existing Chemicals Regulation.

The type and extent of flame retardant use is crucially influenced by the basic fire safety philosophy, society's acceptance and weighting of safety risks and the inherent properties of the materials. The legitimate desire to reduce the risk of fire as far as possible has long obscured the concurrent increased risks for public health and the environment. The majority of organohalogen flame retardants in particular, is a group with a high potential of toxicity for humans and the environment, persistence and bioaccumulation. The use of flame retardants on computer keyboards is an example of excessive and unnecessary fire safety: devoid of a high voltage power supply, keyboards present as little fire risk in themselves as the papers and other office materials lying next to them.

A strategy to reduce the health and environmental risks caused by hazardous flame retardants should therefore approach less the substitution of the individual chemicals rather than the basic issue of fire safety measures which are neutral to the environment and human health. In an R&D project on product chain controlling ("Stoffflüsse ausgewählter umweltrelevanter chemischer Stoffe: Produktlinien-Controlling", UBA-Texte 80/96), these broader issues were taken up in an examination of alternatives to flame retardants in personal computers and automobiles, which fell into the following basic types:

- *Using non-flammable materials:* merely substituting flammable with non-flammable materials, e.g. plastic with ceramic circuit boards, can render the use of flame retardants irrelevant.
- *Preventing fire risk by improving design:* Increasing the distances between possible flashpoints and flammable materials may be sufficient.
- *Scrutinising fire safety regulations:* Are existing fire safety regulations genuinely justified, when the risk of fire is weighed against the risks associated with flame retardant chemicals (e.g. keyboards)?
- *Substituting hazardous flame retardants* with products that have less impact on the environment and human health.

In the aforementioned report, these alternative fire safety measures were discussed with important actors in computer and car seat producing industry, to give an impetus to innovations in these directions. It emerged clearly that decisions on environmental innovation require a more or less safe estimate of the future directions in the requirements for handling products and chemicals.

The UBA has commissioned a further R&D project, which is currently working on principles for assessing the merits of substituting flame retardants. The goal is to provide robust information on the major areas of flame retardant use, assess the (eco-)toxicity of selected chemicals and examine options for replacing critical substances.

Similar procedures could be applied to every other environmentally significant substance group, application or technique. Providing information and assessment principles is essential, both for drafting chemicals policy action and to support substance flow management by economic actors. A flexible mixture of instruments, adapted to suit each specific situation is generally required.

In order to take more account of the precautionary principle and sustainability in chemicals and product management measures based on substance flows, the UBA considers the following measures urgently necessary:

- Improving the provision - by industry, associations and authorities - of public and consumer information on the risks of chemicals.
- Optimising the transfer of knowledge with legally based duties for manufacturers and importers.
- Extending the substitution requirement under § 16 par. 2 of the Hazardous Substances Ordinance to cover environmental risks as well as health risks (at present only health risks are covered) to provide an incentive to use substitutes which pose less risk to the environment.
- Extending labelling requirements to include declaring certain product ingredients, e.g. additives in plastics.
- Substance flow analyses of important economic sectors, in order to provide users and consumers with the essential information they need in order to develop less polluting and more resource efficient products and processes.
- Updating the criteria for eco-labelling with a comprehensive, uniform treatment of the issues related with the risks of ingredients, to provide better consumer information.

- Further methodological development of the LCA impact categories for human health and ecotoxicity, to assist product optimisation and comparative advertising.

- Developing comparative risk assessment schemes for users of chemicals:
 - Sector specific classification systems for critical product groups
 - Voluntary commitments by industrial sectors to develop comparative risk assessment procedures (as in the textiles industry)
 - Promoting environmental management systems to reinforce environmentally responsible company practice
 - Financial aid for users of products and processes which pose less risk for human health and the environment.

- Subsidies and research funding for the development of chemicals and processes which pose less risk on the environment and human health ("green chemistry").

- Greater integration of environmental requirements - including those on chemicals - in product standards, e.g. for building products (in standards of CEN/CENELEC). Conversely, scrutinising product standards which encourage the use of hazardous chemicals (e.g. brominated fire retardants).

- Consistent consideration of criteria based on environmental and human health issues by the public sector when purchasing and awarding contracts.