

Toxic Substances and REACH

**Selected chapters of the
Environmental Report 2008
Volume 3**

This publication is a partial translation of the 2008 Environmental Report
 "Climate Protection in the Shadow of Climate Change".
 For this reason, the numbering of sections and paragraphs follows the original German
 version and hence is not fully sequential.

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Preface

In June 2008, the German Advisory Council on the Environment has published its "Environmental Report 2008: Environmental Protection in the Shadow of Climate Change". The report provides a comprehensive evaluation of national and European environmental policies in the reporting period (2004 to 2008). This period is characterized by two contrasting trends: On the one hand, environmental policy has in many areas come under pressure while, on the other hand, the alarming risks of climate change have received a high level of attention. The title of the report should be interpreted as a call for a more integrated approach which should more strongly recognize the interdependence between climate change and biodiversity. Under conditions of climate change, several other areas of environmental policy are in fact becoming more critical, either because of their potential contribution to mitigating climate change and its consequences, or because of the threat to environmental resources stemming from global warming. Special attention should be given to the importance of forests, moors and grassland, as well as to the key role played by soils as a store and sink for greenhouse gases. An inappropriate use of these resources will have negative effects for the climate.

Having perceived a considerable interest in the international community to learn more about German national environmental policy approaches, the Council has decided to translate key parts of the Environmental Report 2008, especially those which concern national policies with an international relevance. The translation is organised in three volumes, targeting different expert communities:

Volume 1: Sustainable Development, Innovation and Climate Protection:
A German Perspective

Volume 2: Land Use, Nature Conservation and Agricultural Policies in Germany

Volume 3: Toxic Substances and REACH

This third volume covers risk assessment and regulatory evaluation, focusing on selected chemical substances. The first two chapters analyse the possible adverse environmental and health effects of manufactured nanomaterials and brominated flame retardants and makes recommendations for risk reduction measures. In the third chapter, the entry into force of the European Chemicals Regulation REACH is taken as an occasion to describe the basic structures of this new regulation and to acknowledge the opportunities it provides to improve chemical safety. Nevertheless, the SRU warns that capacity problems at the European Chemicals Agency (ECHA) and in the Member States may arise and these could weaken the implementation of REACH. The final two chapters examine the existing and planned regulations for pesticides and for mercury. The Council concludes in both cases that the efficacy of the regulation with regard to environmental protection is not sufficient and recommends additional measures. The German version of the Environment Report 2008

also contains a chapter on potential releases of pharmaceuticals into the environment, but this is not included in this translation because the section essentially summarises a statement which is already available in English (see: www.umweltrat.de).

The German Advisory Council on the Environment was founded in 1971 and is one of the first academic advisory bodies in the history of German environmental policy making.

The Environmental Council is characterised by its expertise and neutrality and as well as its interdisciplinary approach. It comprises seven university professors from a range of different environment-related disciplines. The members of the Council are appointed by the German government for a four-year period of tenure. The Council's mandate provides it with the freedom to select the issues addressed in its reports and statements. The council operates autonomously and is bound neither by instruction nor order. It does not represent any economic interests and enjoys authority as the non-partisan voice of scientific expertise and provider of principles-based analyses and recommendations.

The Council's key responsibility is the periodic evaluation of the environmental situation and of environmental conditions in Germany. It fulfils several functions:

- It acts as an 'early warning' system and highlights negative trends.
- It provides new ideas for German and European environmental policy.
- It has a broad advisory mandate which includes the German government, the sixteen German *Länder*, stakeholder organisations, and the general public.
- It actively monitors the 'Europeanisation' of environmental policy.

Responsible Council members for the Environment Report 2008 were:

- Hans-Joachim Koch (Chair), Universität Hamburg,
- Christina von Haaren (Vice Chair), Leibniz Universität Hannover,
- Martin Faulstich, Technische Universität München,
- Heidi Foth, Martin Luther Universität Halle/Wittenberg,
- Martin Jänicke, Freie Universität Berlin,
- Peter Michaelis, Universität Augsburg
- Konrad Ott, Ernst-Moritz-Universität Greifswald.

Since 1 July 2008 the composition of the Council has changed (see cover page).

Martin Faulstich
(Chair)

Christian Hey
(Secretary General)

8 Substances and products

Messages

Cases are constantly occurring where environmental media are polluted with chemical substances. These need to be taken into account in assessment concepts for the protection of human health and the environment. The mere fact that substances from everyday products are even found in waters close to springs must be seen as a warning signal and an indication of potential risk situations. The assessment of environmental risks arising from chemicals is now confronted with an even broader range of problems (REACH) and the task of reviewing the effectiveness of regulatory measures (drugs, pesticides), both of which complexes will have to pay greater attention to the overall context.

- Materials and products in nanotechnology: There is a need to clarify the release of components throughout the entire production path. The established test regimes are not geared to the specific properties of free nanomaterials. The risk assessment methods prescribed in the existing substance and product safety regulations (e.g. REACH) must be adapted to the special properties of nanomaterials. Special attention should be paid to absorption and distribution processes in the organism, and also the effects at cellular level.
- Brominated flame retardants: There is need to remedy data deficits in environmental risk assessment. Assessment of the substitutes must be speeded up. The environmental risk for at least two representatives, tetrabromobisphenol A and (metabolites of) decabromodiphenyl ether, is manifestly too high, and its use – in view of existing alternatives – can no longer be justified.
- A European programme for existing pharmaceuticals should be drawn up and as soon as possible implemented, in order to remedy the unacceptable deficit regarding data on the environmental behaviour and environmental impact of approved pharmaceuticals. A project group should identify priority active substances, fill the existing information gaps, and propose measures which effectively reduce the environmental pollution detected and which can be implemented with a minimum of resources.
- The implementation of REACH calls for increases in capacity and expertise, since in view of the immense range of tasks and the tight deadlines there are capacity problems at the European Chemicals Agency (ECHA) and in the member states. Otherwise it will not be possible to guarantee the necessary depth of appraisal, quality control of the data, and the necessary entries in databases.
- Monitoring of pesticide inputs must be strengthened in qualitative and quantitative terms, and must include a critical scrutiny of special regional features. The system proposed by the European Commission, involving reciprocal recognition of approval in three zones,

requires appropriate administrative structures and high-quality monitoring. At present these conditions do not exist, and the protection of health and environment would suffer from such a pesticide approval system. For this reason, zonal approval must be rejected for the time being.

- The European mercury strategy must make a contribution to cutting mercury emissions worldwide and substantially reducing imports and exports of mercury. To this end greater efforts must be made to phase out mercury-dependent technologies, and this must be done well before the targeted deadline of 2020. Efforts must be stepped up to establish safe storage technologies for liquid mercury.

8.1 Introduction

635. A wide variety of chemical substances are used for everyday products. They may pass through a many-branched processing chain during production. Risk-conscious handling and use of chemical substances and the resulting products is possible if all users are aware not only of their potential uses, but also of their possible harmful effects and the characteristic attendant circumstances, and are able to identify these rapidly in certain use situations. Systematic assessment of risks to humans and the environment that arise from the production and distribution of chemical substances is performed in accordance with highly developed technical risk assessment concepts that also take account of the use of the products.

In view of the improved situation regarding the data on chemical substances and the resulting insights, risk assessment is increasingly being confronted with new problems. Cases are constantly being identified in which environmental media are polluted with chemical substances. These need to be taken into account in assessment concepts for the protection of human health and measures to protect the environment. Greater consideration must also be taken of the environmental context in connection with risk assessments for pharmaceuticals, because we still do not know enough about the environmental behaviour of numerous long established ones. For many pharmaceuticals, however, there is already a sufficiently dense body of data, and this shows that traditional environmental assessment merely looks at individual substances and thus fails to provide an adequate representation of the environmental situation. REACH will also result in greater attention being paid to environmental risks in the assessment of chemical substances. In other areas such as pesticides or mercury it is now recognised that the regulatory measures either take effect too late or are not rigorous enough to provide effective protection for the environment.

Unexpected pollution

636. For a certain number of chemical substances at least, pollution of environmental media is subject to regular monitoring. Nevertheless, chance findings still occasionally reveal

cases of regionally limited pollution with substances in places where they would not have been expected on the basis of known usage patterns. Many of the examples of such substances known to date have great potential in flame retardant applications, in energy saving, or in extending the useful life of goods. Some pollution situations have been traced to non-accidental point-source inputs, making prompt control possible. However, there are also pollution inputs (e.g. flame retardants) which are diffuse, i.e. they cannot be assigned to any particular point source, which means that they may indicate risk situations about which not enough is known.

Broader nature of problem

637. Some substances, such as pharmaceuticals or pesticides, are subject to a separate, differentiated risk assessment appropriate to the problem, which includes consideration of environmental risk issues by suitable methods. In view of the crucial importance of pharmaceuticals for human health, environmental inputs that result from use of these substances are tolerated in the benefit-harm balance. The knowledge-based concept and the experience gained to date are making it increasingly clear that environment-related risk assessment has separate problems of its own to cope with. This may be due to the variability of the pollution loads and to the fact that totally different substances may be involved in the same effect mechanism. There may thus be a need for a totalising balance. An assessment process keyed to the overall context would have a far-reaching creative and standard-setting influence on methods and would facilitate the implementation of new tasks in the containment of environmental risks arising from the use of chemical substances, for example under REACH.

Review of efficacy

638. The use of pesticides, which are applied in the environment and intended to act there, is of great importance for supplies of high-quality foods. Their benefit-harm balance is closely coupled to the need to observe good practice to avoid any inputs that can be prevented. Review of data on the use, distribution and effects of mercury have revealed that here too it has not been possible to contain the basic problem of excessive global releases of the substance. It is becoming obvious that regulatory decisions for some sectors ought to be evaluated with regard to their effectiveness and their benefit-harm balance. Practical application still deviates too far from the regulatory goal of environmental protection, because the overall use situations are too complex. Here there is a need to examine whether supporting measures are necessary. The product groups for which the methodological approach to risk evaluation and approval decisions on the basis of benefit-risk considerations is most highly developed are pharmaceuticals and pesticides. However, the spectrum of mutual expectations about protection from risks due to chemical substances has grown broader, requiring greater consideration of the usage context.

8.2 Synthetic nanomaterials

8.2.1 Introduction

639. Nanotechnology is the processing and manufacture of materials at atomic, molecular and macro-molecular level. It makes it possible to create new properties and functions for components and products. The size and form of the structures also play a part in determining chemical and physical properties. Thus the product properties can be influenced not only via the chemical composition, but also via the morphology of the substances. This is of great importance for the development of light and highly resistant materials, energy saving surfaces, the production of colouring agents, and also for everyday goods. Representatives of industry consider nanotechnology to be one of the most promising new technological developments, and one that will influence numerous industrial products in the future. For example, by 2014 nanotechnology is expected to be used in some form or other in 15 % of all goods produced (DAVIES 2007). One field of this technology is the use of nanoparticles, nanofibres or nanotubes. These terms are used to describe synthetic particles, fibres or tubes measuring less than 100 nm. At present only nanomaterials made from chemically inert compounds such as silicon dioxide, titanium dioxide and aluminium oxide are being produced and used in products.

640. Nanotechnology offers a wide range of options for creating new material properties. In addition to the opportunities arising from this new technology, however, there are also fears about possible adverse effects on health and the environment as a result of synthetically produced nanoscale materials. To date very little is known about the environmental behaviour and toxic properties of nanomaterials. Nevertheless, past experience indicates that ultrafine particles from combustion processes or machining processes may represent a serious health risk. Even fibres that are chemically and physically inert may have profound biological effects – one example here is the risk of lung cancer due to asbestos.

641. Thorough discussion of possible risks of this technological development is already in progress in the interests of early action to avoid repeating past errors, for example the failure to give serious consideration to first indications of the need to discuss risks. Risk management appropriate to the problems can make an invaluable contribution to safeguarding the use potential of nanotechnology. To this end it is important to seek close collaboration between all relevant actors with a view to including specialised knowledge in risk management at an early stage. The questions to be answered within this process are whether standard test methods register the exposure-effect relationships and whether nanomaterials have other adverse effects in addition to those already known for the relevant bulk material. The existing regulations rely on this basic information to ensure safety in the manufacture, processing and use of the products and safety for the environment.

8.2.2 Properties, uses and development of nanomaterials

642. The fields of application of nanotechnology that already exist or are under discussion are very varied. They range from the environmental technology sector, through materials research, to cosmetic products or new forms of drug transport in pharmaceuticals. One major feature is that, compared with larger structures of the same material, nanomaterials have a larger surface for the same weight. This means they may be chemically more reactive and may carry reactive components on their surface. In some cases, a substance may be biologically inert in coarser fractions, but display reactive behaviour as a nanostructure. Nanoparticles may have greater mechanical strength or modified optical, electrical and magnetic properties, making them particularly interesting for the development of innovative products.

643. A simplified subdivision of nanomaterials into three categories is possible on the basis of their structure. One-dimensional structure means very thin surfaces, two-dimensional structures are nanowires or nanotubes, for example, and three-dimensional structures are nanoparticles. Thus the production and use of nanoparticles, nanotubes and nanofibres comprises one – very important – field of nanotechnology. Nanoparticle is the term used exclusively for synthetically produced particles measuring less than 100 nm, to distinguish these in the nomenclature from ultrafine particles from natural sources.

644. The development and manufacture of products which make use of nanomaterials is still in its infancy. The materials already on the market include carbon particles and tubes, particles of silicon dioxide, titanium dioxide, aluminium dioxide, zinc oxide, iron oxide, gold, silver and fullerenes (macromolecules built entirely of carbon atoms). Already today, nanomaterials are considered to have a wide range of applications, and hence great market potential. Examples under development or on the market include applications in the automobile industry (tyre fillers, catalytic converters), the medical sector (drug transport systems, contrast agents), the building sector (insulating material, cement admixtures, flame retardants), the cosmetics industry (sun protection products, skin creams, toothpastes), and coatings and surface functionalisation in a variety of technical fields. One well-known example that is widespread and of great importance for consumers is the use of nanoparticles of titanium dioxide or zinc oxide for UV protection in high-performance sun creams (sun blockers) (LÖCHTEFELD 2005).

645. Today there are also moves to use nanomaterials in food production, for example silicon compounds as flow adjuvants to prevent powder products from caking. As well as being used as additives, nanoparticles made of silicon and calcium compounds are also being used directly as food supplements. However it still has to be ascertained beyond doubt whether such additives are really nanomaterials and whether they exist in free form in the product (BfR 2006).

646. Other nanoparticle applications close to the consumer are to be found in food packaging, textiles and paints. Among other things, they may serve to protect clothing against UV and water. Products which involve a risk of consumers coming into contact with free nanomaterials require special attention, since here there is a greater risk of exposure. However, there is no requirement for special labelling of products that contain nanomaterials. On the other hand, some companies are using the term “nano” for advertising purposes although the products do not in fact contain nanomaterials.

8.2.3 Possible adverse effects on health and the environment

647. A comprehensive assessment of possible risks arising from synthetic nanoparticles is hardly possible at present because of the wide variety of possible applications and the different types and compositions of the particles. Assessment suffers in particular from a lack of research data on the behaviour of synthetic nanoparticles in the environment, during intake into the organism, and regarding their effects on health and the environment. Issues of special interest include questions about transport of nanomaterials in the human body and about interactions at sub-cellular and molecular level (SCENIHR 2006). There is also a lack of information about where relevant exposure can take place and in what form. Moreover, the analytical techniques necessary for registering exposure are not yet available (KRUG and KRUG 2007). To answer this question it is first necessary to clarify the form in which the particles or fibres exist in the product, i.e. whether or not they are firmly embedded in a matrix. Risks arise primarily from free nanomaterials that may be taken in via the respiratory tract, the gastrointestinal tract or the skin.

The current view is that the greatest health risk arises from inhalable nanoparticles, nanotubes or nanofibres (BfR 2006). In principle, emissions and hence environmental risks arising from nanomaterials are conceivable at all stages in the life cycle of the products. It is assumed that the existing occupational safety measures provide adequate protection in the manufacture of nanomaterials thanks to the high level of risk management, but that this is not necessarily true of the further processing of products.

648. On the basis of an admittedly small number of studies of the effects and behaviour of synthetic nanoparticles and investigations of ultrafine particles from combustion processes (e.g. diesel soot), it is possible to arrive at a number of indications of the behaviour and effects of monodispersed particles (dispersions of particles of identical composition). Present information on the effect of particles indicates that not only their size, but also their chemical and physical properties exert a crucial influence on how they behave in the environment and in the human body or at cell level. Important factors here are the density, persistence, surface structure and reactivity of the substances (see also MAYNARD 2007). For example, nanoparticles can be expected to aggregate very quickly, but it is not clear whether and in what circumstances disaggregation takes place. In view of their light weight, particles

measuring less than 100 nm can be transported over very long distances. First indications exist that certain types of nanotubes are very persistent and display a tendency to accumulate (HELLAND et al. 2007).

In the case of aerosols (mixtures of particles and air) it may be assumed that the finest fractions are almost entirely deposited in the lungs. Very small inert particles penetrate as far as the alveoli, and in the absence of a chemotactic signal they are not phagocytised (incorporation of extracellular solid particles in cells) and hence absorbed. Ultrafine or nanoparticles trigger inflammation reactions in the lungs more strongly than coarser fractions, which is presumably connected with the greater ratio of surface area to mass. The surface area of the particles is in direct proportion to the triggering of inflammation reactions. Nanoparticles can find their way into the blood circulation and act on other organs – such as the heart and the inside of the blood vessels. Exposure to ultrafine particles (< 100 nm) in the outside air is a risk factor for cardiovascular diseases (see also SRU 2002, Item 552 f.; 2004a, Item 537). Furthermore, nanoparticles can pass through the walls of lymph and blood vessels, allowing them to penetrate into the space between tissue and organs (LIPPERT 2000).

649. Studies of the effects of nanoparticles in animal models have shown that no classic exposure-effect relationship is observed in the case of synthetic nanoparticles. Thus a number of inhalation tests showed an almost inverse dose-effect relationship, which is currently explained by a tendency to aggregation at high particle concentrations bringing about a sharp reduction in absorption capacity (DAVIES 2007; OBERDÖRSTER et al. 2005). A number of studies give cause for concern, since they have demonstrated not only a connection between particles in the blood vessel system and accelerated thrombosis formation, but also a translocation of nanoparticles to the brain. For example, an inhalation study on rats showed active intake of nanoparticles via the olfactory nerve, resulting in ultrafine carbon particles reaching the central nervous system as well (< 100 nm) (OBERDÖRSTER et al. 2004).

In an animal model, nanoscale titanium dioxide particles had a different inflammation potential in the lungs depending on the surface condition. The coating, crystalline structure and composition of the particles had an influence on the effect (WARHEIT et al. 2003; 2007). Particularly adverse effects were displayed by chloride ions on the surface of the titanium dioxide particles; these were responsible for the acid and reactive properties of the latter. This further underlines the fact that any assessment of the risks of nanoparticles must take account of the surface structure and composition of the particles and that every type of particle must therefore be treated individually with regard to structure, composition, size and surface area (KRUG 2005).

650. There is also some information available about the effects of fibres on health. This relates in particular to the use of building products such as glass, rock wool and asbestos.

Factors of importance for inhalation toxicity include the length of the fibres, the ratio of length to diameter, and their persistence in the body. One reason for the high carcinogenicity of asbestos fibres is their size ratio (length to cross-section) and their property of splitting up into very fine unit fibrils (MUHLE and WARHEIT 2004). To date there is no evidence that new synthetic nanofibres will possess properties similar to those responsible for the high inhalation toxicity of asbestos fibres.

651. With regard to the effects of nanomaterials on health, various joint research projects – Nanoderm, NanoSafe1 and NanoSafe2 – have been launched at European level and the BMBF research project NanoCare at national level. First results of these projects are now available or will be published shortly. The Nanoderm project investigated the intake of nanoparticles via the skin. One reason for the special relevance of this issue is the fact that sun creams containing nanoparticles are already on the market. The findings of this joint project suggest that no dermal absorption of titanium dioxide and zinc oxide nanoparticles takes place, regardless of shape and surface structure. This finding is supported by further studies and by an analysis of the current state of research on the effect of titanium dioxide and zinc oxide nanoparticles in sun creams which was commissioned by the Australian Government (Australian Government, Department of Health and Ageing 2006; SCHULZ et al. 2002). The report referred to points out that under the influence of sunlight these particles can form free radicals which have harmful effects on cells. However, this property would only be of relevance if the particles penetrated into living cells. The results cited relate to intact skin only. There is evidence that mechanical or chemical impacts on the skin may affect the penetration properties of particles. The European Commission's Scientific Committee on Consumer Products (SCCP) draws attention to the great gaps that still exist in the data in this field, and to the need to develop new methods for assessing the intake of nanoparticles via the skin (SCCP 2007).

652. Little is known about the behaviour of nanoparticles in the environment, especially their tendency to aggregate and their effects on aquatic or terrestrial organisms. Initial work on the eco-toxicity of nanomaterials has shown that exposure to uncoated fullerenes can lead to oxidative stress in the brain of young largemouth bass (OBERDÖRSTER 2004). For soluble fullerenes the concentration with a lethal effect on 50 % of water fleas (*Daphnia magna*) after 48 hours (LC₅₀ value) was around 0.8 ppm (ZHU et al. 2006). Studies of the effects of titanium dioxide particles on the same species revealed an increase in toxicity with increasing concentration; the LC₅₀ value was around 5.5 ppm. On the basis of these findings, the authors believe that standardised eco-toxicity tests are suitable for assessing the risks arising from nanoparticles in aquatic systems (LOVERN and KLAPER 2006). This is a general need for further research here, with the first priority being to clarify what exposures can be expected in the environment.

8.2.4 Current initiatives

653. Various institutions have already taken up the issue of “risks of nanotechnology” at an early stage. For example, the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety (*Bundesministerium für Umwelt, Naturschutz und Reaktorsicherheit – BMU*) in cooperation with the Federal Institute for Occupational Safety and Health (*Bundesanstalt für Arbeitsschutz und Arbeitsmedizin – BAuA*) and the Federal Environment Agency (*Umweltbundesamt – UBA*) initiated a dialogue for assessing the opportunities and risks of synthetic nanoparticles in the employment and environment sectors (BMU et al. 2006). A “Nano Commission” was set up to structure this dialogue. Representatives of industry, science, non-governmental organisations and government authorities discussed the opportunities and risks associated with nanotechnology. The purpose of this initiative is a timely debate about specialised knowledge of the technical properties and potential risks of this new technology, with the aim of providing information and generating confidence. The dialogue initiated by the Environment Ministry with the participation of all groups concerned is certainly to be welcomed, because it makes a contribution to knowledge transfer and ensures an early definition of the questions to be clarified. Such a process should also be seen as an opportunity to identify possible environmental and health risks at an early stage and also to create confidence that a watchful eye will be kept on the risks of this technology. To this end there is a need for transparent presentation of existing knowledge and lack of knowledge, and of the processes initiated for future risk assessment.

This kind of risk communication is also advocated in the European Commission’s Action Plan on Nanotechnology and Nanosciences (European Commission 2005a; 2007a). In this Action Plan the European Commission undertakes to provide financial resources for research into the risks of nanotechnology, especially the manufacture of nanostructures such as nanoparticles. In the opinion of the European Commission, risks should be investigated at an early stage and at all levels, from production and further processing through to disposal of the products. Furthermore, the European Commission intends to promote the development of risk assessment standards, terminologies, models and guidelines. There are also plans to review relevant existing EU regulations with regard to the need for adapting to the special features of nanotechnology, and to make proposals for improvements if necessary.

654. The Royal Society and the Royal Academy of Engineering published a joint report on “Nanoresearch and Nanotechnology: Opportunities and Uncertainties” (Royal Society and Royal Academy of Engineering 2004). Among other things, they come to the conclusion that possible adverse effects of nanoparticles cannot be deduced on the basis of the known toxicity of macroscopically small materials bound by the laws of classical physics. For this reason they recommend treating nanoparticles or nanotubes as totally new chemicals in existing regulations – for example the new chemicals legislation (REACH).

655. A statement by the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) also comes to the conclusion that existing methods and technical guidelines for risk assessment are not sufficient to register potential dangers arising from nanomaterials, and that modifications are therefore necessary. In particular, the established methods of estimating exposure and of toxicological and eco-toxicological assessment are not sufficiently selective to identify the conceivable risks of nanomaterials (SCENIHR 2006). On the basis of this appraisal, the committee presents a number of proposals for improving existing risk identification methods (SCENIHR 2007). The central recommendation is to develop and define a framework for future identification of the environmental and health risks of nanomaterials. It proposes a four-stage approach following the principles of classic substance risk assessment. The first step is to estimate the exposure over the entire life cycle of the products. This is followed by a characterisation of the exposure. The third and fourth steps cover analysis and characterisation of the dangers arising from those nanomaterials where exposure is assumed to be likely, and finally the risk assessment.

656. In 2005 the OECD (Organisation for Economic Co-operation and Development) initiated a workshop on risks of synthetic nanomaterials (OECD 2006). One result of this event is the establishment of an OECD working group which will look into issues including nomenclature, standardisation and classification of nanomaterials. For example, there are plans to draw up a nomenclature and terminology for various nanoscale materials in conjunction with the International Organization for Standardization (ISO).

657. DuPont and the environmental protection group Environmental Defense have cooperated to issue a statement (Nano Risk Framework) on managing the risks of nanotechnology (Environmental Defense and DuPont 2007). This also proposes a multistage approach to dealing with nanomaterials, including the collation of all information about properties, inherent risks and possible exposure over the entire life cycle of the product. On this basis a decision can be taken on the further use or development of the relevant nanomaterial.

8.2.5 Regulation and labelling of nanomaterials

658. In view of the specific risks of nanotechnology, it is necessary to examine whether existing environmental legislation is equal to this new challenge. To clarify this question, the Federal Environment Agency engaged the *Öko-Institut* to prepare an expert report ascertaining whether there were gaps in the legislation at European and national level with regard to risks arising from nanotechnology, and to take this as a basis for recommending improvements or corrections (FÜHR et al. 2006). The report examined the entire life cycle of the products and the relevant legal requirements. This applied not only to research and development, manufacture and further processing of the products, but also to the use and

disposal phases. It identified numerous gaps in the regulations, many of which were due to failure to take account of the specific features of nanomaterials.

One example of this is the Seveso-II Directive (96/82/EC) on the control of major-accident hazards. This directive lays down threshold quantities commensurate with the hazardous properties of the substances; these are in the range of tens or hundreds of kilograms. This means they are far too high to cover the risks arising from nanomaterials (FÜHR et al. 2006). Similar deficits were found in the field of water legislation. The Water Framework Directive (WFD) and the Directive on pollution caused by certain dangerous substances discharged into the aquatic environment of the Community (2006/11/EC) set out limit values for classic pollutants, including certain metals. At present, however, they do not take account of nanomaterials; either there are no thresholds for such materials, or the existing quality standards and thresholds do not cover any nano-specific properties.

659. Nanomaterials fall within the registration requirements for substances and preparations under REACH – the European Union’s chemicals regulation which has been in force since 1 June 2007 – although REACH does not contain any test requirements geared to the special features of nanomaterials. Above a production volume of 1 t/a, substances and preparations must have a registration dossier listing all identified applications, i.e. including use as a (principal) component of nanomaterials. Above a production volume of 10 t/a, registration dossiers for all substances and preparations must also include a chemical safety report containing all relevant physico-chemical, toxicological and eco-toxicological information. In relation to nanomaterial this means answering questions about the particle size of the substance and all available information on adverse effects on health and the environment. Where there is justified suspicion of adverse effects on human health and the environment, REACH gives the Chemicals Agency and the national authorities the power to require risk-containing measures or test data as evidence of safety, even for substances and preparations with a volume of less than 1 t/a.

Nevertheless, one cannot expect that the obligations on manufacturers to register their substances and preparations under REACH can make any substantial contribution to addressing the risks of nanomaterials. REACH is based on established end points of toxic effects or exposure-oriented risk classifications without specific examination of the effect. This concept is not selective enough to describe potential health damage resulting from nanomaterials. The European Parliament’s Committee on Environment, Public Health and Food Safety proposed that, in view of their special properties, nanomaterials should be treated as a completely new substance group under REACH; it also saw a need to investigate whether the prescribed threshold values were appropriate for these substances (European Parliament 2006). Since REACH covers substances and preparations and also includes nanoscale applications, it is not in fact possible in REACH to introduce a group with very variable substance properties that is geared to structural properties.

8.2.6 Assessment and recommendations

660. The development and use of nanotechnology offer a large number of opportunities. However, there are also indications that this technology may involve risks. In particular, the manufacture and use of nanomaterials that are not firmly embedded in structures poses a possible risk for employees and consumers. On present knowledge, the greatest health risk is expected to arise from the handling of free nanoparticles, nanofibres and nanotubes which can enter the body via the air and the respiratory tract. It is not yet possible to say anything about potential risks to the environment, owing to lack of knowledge about relevant exposure scenarios and lack of studies on toxicity and eco-toxicity.

661. In view of the many questions still unanswered, it is important to ensure timely involvement of all relevant groups and responsible persons in the process of assessing potential risks associated with the use of synthetic nanomaterials. The existing initiatives to this end, e.g. by the Federal Environment Ministry, are very much to be welcomed and should definitely be continued.

For the reasons mentioned, the Federal Government should advocate the following measures:

- The large number of possible nanomaterials that could be used presents a special challenge for risk assessment. Adequate risk assessment is not possible owing to a lack of information about the effects of nanomaterials on health and the environment and about possible exposure scenarios that could occur during the entire lifetime of products containing such structures. Here manufacturers and users in particular are called upon to play an active part in providing information about possible exposure of humans and the environment to nanomaterials.
- It is possible that the risk of nanomaterials to humans and the environment may not be adequately represented by standard test methods. The test regime therefore needs to be geared more closely to the specific intake and distribution structures of nanoscale structures, in order to ensure better acquisition of the key parameters characteristic of the exposure-effect relationship. On the basis of this information, the technical guidelines in the existing regulations should be modified accordingly.
- An investigation should also be made of the need for further adaptation of existing regulations under substance legislation to cater for the special features of nanomaterials. For example, it is doubtful whether the highly volume-oriented approach in REACH is sufficient for early identification of potential risks.
- A first step towards risk management of nanomaterials is the creation of a risk classification for such materials based on known usage patterns and evidence of harmful effects on health and the environment. The information collected could very well be used to draw up guidelines on good practice for handling nanomaterials.

- It would be advisable to continue developing the national research concept on risks arising from the manufacture and use of nanomaterials, in cooperation with the developers, manufacturers and scientists. In particular, there is a need to develop programmes of research into the behaviour and effects of nanomaterials in the environment. To ensure a maximum of efficiency and coordination the research concept should take account of existing national and European initiatives.
- This should be supplemented by the establishment of a database of methodologically and qualitatively correct studies dealing with the behaviour and toxicokinetics of nanomaterials and their impact on humans and the environment. This database should be annotated and maintained by experts to ensure transparent presentation of the information available.
- Furthermore, a labelling requirement – if possible at European level – should be established for products containing nanomaterials. The aim is to ensure that products which contain free nanoparticles, nanofibres or nanotubes and which may therefore give rise to risks to health and the environment in the event of incorrect use are clearly recognisable as such for consumers. Another reason is to curb the improper use of the term “nano” for advertising purposes.

8.3 Brominated flame retardants

8.3.1 Introduction

662. Flame retardants are used in a wide variety of products to make them less flammable. They thus make an important contribution to preventing fires starting and spreading, and thereby help to protect human health. Brominated flame retardants (BFS) are a major group of flame retardants. These are chemicals that are produced in large quantities and used in many everyday products. The production and use of brominated flame retardants have been the subject of critical concern for many years. One particular reason is that the substances can escape from the products and are now ubiquitous in the environment. For example, brominated flame retardants have been found in Arctic organisms, and also in breast milk in various European countries. Moreover, brominated flame retardants are often highly persistent and have the property of accumulating within the food chain.

663. Although the acute toxicity of brominated flame retardants is very low, studies of long-term effects have produced evidence of effects on the endocrine and neuronal systems. Since 15 August 2004 two brominated flame retardants – pentabromodiphenyl ether (PentaBDE) and octabromodiphenyl ether (OctaBDE) – have been banned in Europe. The product decabromodiphenyl ether (DecaBDE) is still approved, however. It consists of very similar congeners (chemical compounds with a similar basic structure), but has a lower toxicity than penta- or octabromodiphenyl ether. There are however indications that

decabromodiphenyl ether in the environment is degraded to lower brominated compounds with a similar composition to the two prohibited technical products. In view of this information about the behaviour of decabromodiphenyl ether in the environment and its greater persistence, special care should be taken when assessing the substance risk and in risk management.

664. There are also indications that tetrabromobisphenol A, the most widely used brominated flame retardant, has a high hazard potential for water. For this reason it would be advisable to evaluate the present handling of this substance.

8.3.2 Use, production and substance properties

665. Flame retardants make a crucial contribution to the product safety of electrical appliances that produce heat and components having direct contact with current-carrying parts (EDER 1998). Practically all household appliances, office equipment or home entertainment systems contain flammable material and need protection against catching fire. Flame retardants also reduce the flammability of the basic material in home textiles, furnishing material or safety clothing. Various groups of chemical substances are used to provide chemical protection against flammability. Brominated flame retardants and other halogenated compounds account for about one quarter of worldwide consumption of this product group (Danish EPA 1999). In 2001, annual demand for brominated flame retardants in Europe was around 30,000 t (BSEF, no date). Among them are the three most important substance groups tetrabromobisphenol A, hexabromocyclododecane and decabromodiphenyl ether, the only polybrominated diphenyl ether still approved in Europe (PBDE).

Frequently used plastics, such as acrylonitrile butadiene styrene copolymers (ABS), polystyrene or polyethylene, contain widely varying amounts of brominated flame retardants depending on the use for which the product is intended: for example between 5 and 30 % weight percent of polybrominated diphenyl ether in the plastic material of electrical devices, or less than 3 % hexabromocyclododecane in polystyrene insulating foams (Table 8-1).

666. Brominated flame retardants are a variety of chemical substances with aromatic (tetrabromobisphenol A) and non-aromatic structures (hexabromocyclododecane), or mixtures of substances of related structure and varying degrees of bromination (polybrominated diphenyl ethers), which possess similar physico-chemical properties in spite of their structural differences. Their low flammability, high stability, low volatility, high lipophilicity and low solubility in water are the crucial requirements for the intended technical use.

In the manufacture of polymers, brominated flame retardants are used either reactively (especially tetrabromobisphenol A) or additively (especially hexabromocyclododecane, polybrominated diphenyl ethers). As reactive components the flame retardants enter into a

chemical bond with the polymerisation partners and are thus firmly incorporated in the finished product. Undesirable release into the atmosphere and hence into the environment in general can therefore occur primarily during the manufacturing process and through the release of surplus, unreacted tetrabromobisphenol A. As additive components, brominated flame retardants are added during the polymerisation process and are present in as a homogeneous dispersion in the product matrix without having formed a firm chemical compound with the polymerisation partners. Depending on their mobility, they may therefore be released from the matrix, at least in part, when the product is used.

Table 8-1

Demand for and use of brominated flame retardants in Europe (2001)

Substance group	Demand in Europe (t)	Important uses	Percentage in product
TBBPA	11600	Epoxy and phenolic resins (circuit boards, electrical components)	up to 20 %
HBCD	9500	Polystyrene foams (insulation)	0.5-3 %
DecaBDE	7600	Plastic parts for electrical and electronic devices	10-15 %
Total	28700		
TBBPA = tetrabromobisphenol A HBCD = hexabromocyclododecane DecaBDE = decabromodiphenyl ether			
SRU/UG 2008/Table 8-1; data source: BSEF, no date			

667. In Germany the manufacture and use of polybrominated diphenyl ethers was largely discontinued in 1986 as a result of a voluntary undertaking by the chemical industry and the members of the Association of the Plastics Manufacturing Industry (Verband der Kunststoffherzeugenden Industrie – VKE) (FISCHER 2004). This was due to the finding that thermal decomposition of polybrominated diphenyl ether (PBDE) resulted in the formation of polybrominated dibenzodioxins (PBDD) and dibenzofurans (PBDF), which are classified as having similar toxicity to the analogous chlorine compounds (polychlorinated dibenzo-p-dioxins/furans (PCDD/F)). This means that those products still in use throughout Germany which contain polybrominated diphenyl ethers are all imported. In 1995, under an OECD risk minimisation strategy, the most important global manufacturers of brominated flame retardants undertook to reduce the risks to humans and the environment arising from brominated flame retardants (OECD 1995). The measures include refraining from producing and selling new polybrominated diphenyl ethers, minimising emissions from pentabromodiphenyl ether production, and minimising both employee exposure in the production process and production inputs into the environment. On the product quality front,

decabromodiphenyl ether is to have a purity of 97 %, and the presence of low-brominated congeners in the technical product octabromodiphenyl ether is to be minimised to a few percent.

8.3.3 Inputs into and behaviour in the environment

668. Tetrabromobisphenol A is only released into the environment in exceptional cases during production or at production locations. Release via wastewater or in the course of waste management also tends to be of secondary importance. Estimates indicate that the greater part of inputs take place via normal product use. As a result, the main input pathway is the atmosphere, fed by diffuse, widespread sources (BUA 2003).

The data on environmental inputs of tetrabromobisphenol A is not sufficient to make quantitative statements. It has however been confirmed to be present in the air, soils, sediments and sewage sludge (see Table 8-2). Owing to its propensity to be absorbed on particles and surfaces and its low solubility in water, it is not usually found in water samples. There is currently very little data on the distribution of tetrabromobisphenol A in biota.

669. Hexabromocyclododecane escapes from products as diffuse emissions into the air, but may also be released into wastewater from textiles during washing, or into the air or wastewater from point sources such as plastics processing operations (REMBERGER et al. 2004). This class of compounds is ubiquitous and is persistent in the air and in sediments. Environmental loads are generally increasing. Hexabromocyclododecane is readily absorbed on sediments in surface waters, and in anaerobic sewage sludge it has a half-life of about five days (DAVIS et al. 2004). The data on pollution of biota of various trophic levels (position of organisms in the food chain) with hexabromocyclododecane is meagre, but indicates that the substance bioaccumulates. For example, the figures for hexabromocyclododecane in North and Baltic Sea herring and wild salmon were around 21, 58 and 51 ng/g fat, which is higher than in other environmental compartments (LAW et al. 2004; SELLSTRÖM et al. 1998a). Moreover, laboratory tests on the fathead minnow (*Pimephales promelas*) have shown an enrichment factor of 18 100 between the fishkeeping water and whole-body specimens. Different concentrations of various diastereomers are found in the technical product and in environmental samples and tissue samples, which is attributed to the fact that the diastereomers α -, β - and γ -hexabromocyclododecane are metabolised differently and it is primarily α -hexabromocyclododecane that bioaccumulates in fatty tissue.

670. Polybrominated diphenyl ethers are released into the environment via wastewater from plastics producing and processing operations and from textiles during washing. For plastics production and processing, air is probably not a relevant input pathway, though landfill of plastic polymers and textiles is more likely to be (European Commission et al. 2001; 2002; 2003). Polybrominated diphenyl ethers possess a certain volatility, but in indoor and outdoor air they primarily occur attached to particles. High substance concentrations

have been found in a Swedish electrical equipment dismantling operation. Here the concentrations measured in the air at two locations were 7.9 ng/m³ and 12 ng/m³, while the values for dust were around 24,000 µg/kg and 8,100 µg/kg (PETTERSSON et al. 2001).

671. Today polybrominated diphenyl ethers are found everywhere in the environment (see also Table 8-2). They regularly occur in river sediments in strikingly variable compositions and concentrations of various congeners. Polybrominated diphenyl ethers are practically never found in flowing water samples, but they do occur in sediments and suspended solids from river, wastewater, landfill leachate and sewage sludges, especially in the discharge flow of industrial wastewaters (maximum 210 µg/kg dry matter, see Table 8-2) (MOCHE et al. 2004).

Polybrominated diphenyl ethers have been identified, for example, in porpoises (*Phocoena phocoena*) from the North Atlantic, salmon (*Salmo salar*) from the Baltic Sea, North Sea herring (*Clupea harengus*) and beluga whales (*Delphinapterus leucas*) from the Arctic (LAW et al. 2003; SINKKONEN et al. 2004; THRON et al. 2004). It was the low and medium brominated congeners that predominated in the biota, and a number of time series studies showed a steady, almost exponential increase in the substance concentrations in the organisms. For example, the substance load in beluga whales from the St. Lawrence River doubled within three years (LEBEUF et al. 2004). There are also numerous indications that polybrominated diphenyl ethers are accumulating within the food chain, although production and use of this group of substances are now severely restricted (European Commission et al. 2006). Decabromodiphenyl ether, the only representative of this group currently approved in Europe, has so far only been found in a small number of aquatic biota and has a special role in view of its low bioavailability and low propensity to accumulate (LAW et al. 2006).

Table 8-2

**Contamination of environmental samples with tetrabromobisphenol A,
hexabromocyclododecane and polybrominated diphenyl ethers**

Substance group	Contamination		
	In abiotic media		
	Sample location	Matrices	Concentration
TBBPA	River (Sweden), Sewage works (Sweden)	Sediment, Sewage sludge	34-270 µg/kg DW5 31 µg/kg DW5
HBCD	Baltic Sea, Southern North Sea, Sewage works (Sweden)	Sediment, Sediment Sewage sludge	0.9 µg/kg DW1 0.8-6.9 µg/kg DW9 6.9 µg/kg DW1
PBDE**	Danube	Sediment	0.32-1.06 µg/kg DW ¹⁰
PentaBDE (BDE 99)	Various rivers (Netherlands)	Sediment	0.2-5.5 µg/kg DW ¹⁶
OctaBDE (BDE 153)	Estuary ^{a)} (United Kingdom) Sewage works (Germany)	Sediment, Sewage sludge	29-1348 µg/kg DW ¹² 01.2 µg/kg DW ¹¹
DecaBDE (BDE 209)	Southern North Sea, Elbe (Germany), Sewage works (Sweden), Various European rivers	Sediment Sediment Sewage sludge, Water	132 µg/kg DW9 0.5-17.4 µg/kg DW7 140350 µg/kg DW15 < detection limit 14
	In Biota		
	Organism	Organ, tissue	Concentration
TBBPA	Humans (Germany)	Breast milk	0.29-0.94 ng/g fat ⁴
HBCD	Humans (Sweden), Falcon (Falco peregrinus) (Sweden), Herring (Clupea harengus) (Baltic Sea)	Breast milk, Eggs Muscle	0.45 ng/g fat3 220 ng/g fat6 21-180 ng/g fat1
PBDE	Humans (Germany) Herring (Clupea harengus) (Baltic Sea)	Breast milk Skin, fish-bones, muscle	2.49 ng/g fat2 0.62-1.37 ng/g WW8
PentaBDE (BDE 99)	Humans (Germany) Herring (<i>Clupea harengus</i>) (Baltic Sea)	Breast milk Muscle	0.38 ng/g fat ² 3.4-46 ng/g fat ¹³
OctaBDE (BDE 183)	Humans (Germany) Flounder (<i>Platichthys flesus</i>) (UK) Mussels (United Kingdom)	Breast milk Muscle Whole animal	0.08 ng/g fat ² < 1-7 ng/g WW ¹² 16 ng/g WW ¹²
DecaBDE (BDE 209)	Humans (Germany) Pike-perch (Sander lucioperca) (Denmark) Falcon (F. peregrinus) (Sweden)	Breast milk Muscle Eggs	0.21 ng/g fat2 2.8 ng/g fat17 110 ng/g fat6
DW = dry weight WW = wet weight a) Measured in Tees estuary * Where only individual congeners or congener groups were investigated, this is stated in brackets. ** Samples were analysed for the occurrence of various congeners.			
SRU/UG 2008/Table 8-2; data sources: ¹ REMBERGER et al. 2004, ² DÜRKOP et al. 2005, ³ AUNE et al. 2002, ⁴ KEMMLEIN 2000, ⁵ SELLSTRÖM and JANSSON 1995, ⁶ LINDBERG et al. 2004, ⁷ SAWAL et al. 2004, ⁸ ISOSAARI et al. 2006, ⁹ KLAMER et al. 2005, ¹⁰ MOCHE et al. 2004, ¹¹ HAGENMAIER et al. 1992, ¹² ALLCHIN et al. 1999, ¹³ SELLSTRÖM et al. 1993, ¹⁴ European Commission et al. 2002, ¹⁵ SELLSTRÖM et al. 1999, ¹⁶ BOER et al. 2003, ¹⁷ PAEPKE and HERRMANN 2004			

8.3.4 Health risks

672. For the general public, the most important intake path for brominated flame retardants is food, though for workers in the plastics producing and processing industries air may play a role. Polybrominated diphenyl ethers can also contribute to human exposure through inhalation and swallowing of household dust. There is a lack of human toxicological data on the intake and distribution of brominated flame retardants, which means that statements about their toxicokinetics can only be deduced from animal test data.

673. Tetrabromobisphenol A is lipophilic (soluble in fat), and in principle can therefore readily overcome cell barriers. Nevertheless, in feed tests on rats some 90 % of the dose administered was eliminated unchanged in the faeces. Thus the bioavailability of tetrabromobisphenol A is low, and the absorbed component of 10 % is primarily eliminated via the gall bladder. The substance has been detected in small quantities in almost all tissues of exposed experimental animals and was eliminated with a half-life of less than three days. The LC_{50} values were between 5 and 10 g per kg of body weight, so the substance is not toxic in acute tests (BUA 2003). Studies of the development toxicity of tetrabromobisphenol A in prenatally and postnatally exposed mice showed histological changes in liver and kidneys from a daily dose of 15.7 up to 42.1 mg/kg body weight, and also an increase in liver weight, but no effects on the reproductive organs (TADA et al. 2006). For the effects on the thyroid hormone system, see below (Item 677).

674. Hexabromocyclododecane is readily absorbed after oral administration to rats, and is primarily eliminated via the faeces with a half-life of about two hours (BUA 1996). In 2003 a Dutch study analysed hexabromocyclododecane concentrations in the blood of pregnant women and newborn babies with no occupational exposure (WEISS et al. 2004). The hexabromocyclododecane concentrations were around 1.1 and 2.4 ng per gram of blood lipids respectively. By analogy with the data from biota it must be assumed that hexabromocyclododecane can accumulate in humans as well given continuous intake. Since the LC_{50} value for rats after oral application was in excess of 5 000 mg/kg body weight, hexabromocyclododecane is not acutely toxic either (BUA 1996). Adverse effects on the liver have been observed on repeated administration in subacute and subchronic tests. The lowest dose with signs of changes in the liver (lowest observed adverse effect level – LOAEL) was 100 mg per kg body weight per day (CHENGELIS 2001). Tests on the mutagenicity of hexabromocyclododecane have not yielded any clear evidence, and there are no indications of a carcinogenic effect, though in view of the lack of data from special test systems no conclusive assessment is possible here.

675. The human toxicokinetics of polybrominated diphenyl ethers are also only partially known (European Commission et al. 2001; 2002; 2003). Intake of the low molecular congeners tri- through hexabromodiphenyl ether is almost complete, and elimination is slow. If taken repeatedly they have a marked propensity to accumulate. In rodent tests,

pentabromodiphenyl ether is readily taken up, is only metabolised slowly and has a half-life of 25 to 47 days. Its half-life in humans is actually considerably longer, and is estimated to be in the region of several months to years. Monitoring tests on humans have confirmed that pentabromodiphenyl ether accumulates in fatty tissue (European Commission et al. 2001). Orally administered polybrominated diphenyl ethers do not have a toxic effect in acute tests ($LC_{50} > 2\text{g/kg}$) and have a slight irritant effect on eyes and skin.

Data from animal tests with octabromodiphenyl ether also confirm that the substance accumulates in liver and kidneys after oral administration and inhalation (European Commission et al. 2003). Tests on humans confirm that components from the technical product octabromodiphenyl ether are absorbed and pass into fatty tissue via the blood. Animal test results permit the conclusion that repeated intake of octabromodiphenyl ether can also ultimately accumulate in human fatty tissue.

Tests for xenobiotics in breast milk have revealed that polybrominated diphenyl ether is eliminated via this pathway and thus passed on to babies through the milk of breast-feeding mothers.

676. By contrast, the bioavailability of the only representative of this substance group that still has approval, decabromodiphenyl ether, is considerably lower than that of the two other technical products (European Commission et al. 2002; HOOPER und MCDONALD 2000). The technical product contains over 97 % decabromodiphenyl ether, which is only slightly absorbed and quickly eliminated, and which has a very low bioaccumulation potential. Under certain conditions, however, it may be degraded to more bioactive congeners (SELLSTRÖM et al. 1998b). Decabromodiphenyl ether is also transformed to lower brominated congeners in the atmosphere and by micro-organisms. Here the component that is primarily bound in the soil or sediments is not accessible for photodegradation. Despite this evidence, there is still some uncertainty as to which technical product is responsible for the mostly low to medium brominated congeners of polybrominated diphenyl ether detected in the environment and in humans.

The metabolism of decabromodiphenyl ether in humans and animals is still not entirely clear. In view of test data from studies of rats and carp, one can expect decabromodiphenyl ether to be metabolised to low molecular compounds in the organism (STAPLETON et al. 2004; MÖRCK et al. 2003). This might explain why in most of the tissues investigated the proportion of low brominated polybrominated diphenyl ethers is considerably higher than one would predict on the basis of the percentages in the commercial products.

677. The contamination with brominated flame retardants found in human samples is very low, in the region of ng per g fat (see Table 8-2). This range is several magnitudes smaller than the experimental loads necessary in repeated administration to animals to produce effects on liver and kidneys. However, exposure of the general public is due to pollution of the environment and of food, so it is necessary to assess what undesirable

effects could occur given repeated lifelong intake of small quantities of these substances. In special toxicological tests, brominated flame retardants have displayed effects on the endocrine and neuronal systems. In test systems, not only tetrabromobisphenol A, but also hexabromocyclododecane and polybrominated diphenyl ethers have an influence on important control parameters in the thyroid hormone system (DARNERUD 2003; ERIKSSON et al. 2001; KITAMURA et al. 2002). The activity is probably due to the great structural similarity of tetrabromobisphenol A and metabolites of polybrominated diphenyl ethers to the thyroid hormones T4 (3,3',5,5'-tetraiodothyronine) and T3 (3,3',5-triiodothyronine). It has been shown in in vitro test systems that they bind on the receptor for thyroid hormones and also on a transport protein for thyroid hormones, namely transthyretine (TTR). Although other transport proteins, such as thyroxine-binding globulin (TBG) or albumin, and not transthyretine, are the most important T4 transport proteins in humans, it is possible that transthyretine has a key function in controlling hormone transport into the foetal circulation via the placenta. Brominated flame retardants attached to transthyretine could reach the foetus by this route (LEGLER and BROUWER 2003). At present it is not possible to assess the impact of such a process on the development of the foetus.

A functioning thyroid hormone system is of immense importance during the development of the embryo and also throughout the entire development of the child. In particular, the differentiation of the nervous system and the brain and its functions is very sensitive to disturbances of thyroid hormone homeostasis. For example, even slight decreases in T4 concentrations in the blood serum of the mothers had an influence on the intelligence and psychomotor skills of the children (MCDONALD 2002; POP et al. 1999; SALOMON 2005). It is known from experimental studies that administration of polybrominated diphenyl ethers to mice during late pregnancy and lactation has neurological effects on the behaviour of the progeny. The effect mechanisms have yet to be clarified. There are also indications that brominated flame retardants and polychlorinated biphenyls may have an additive effect in this respect.

678. The relevance for humans of the neurotoxic and endocrine effects found in cell culture tests and animal tests is still unclear, since the mechanisms that result in neurotoxic findings are not yet known. This means they cannot be either unequivocally confirmed or unequivocally refuted. To date, effects have only been achieved with very high doses in standard test systems, so there is currently no evidence that the thyroid hormone system is affected in vivo. Moreover, it is not possible to assess the sensitivity of the foetus to brominated flame retardants in the mother's blood, or of babies to their presence in the breast milk after birth. On the basis of the facts to date it is essential to pay the utmost attention to this potential developmental disturbance. For this reason one must take a critical view of the fact that brominated flame retardants, like many other lipophilic and persistent pollutants, can be detected in breast milk (AUNE et al. 2002; KEMMLEIN 2000; MEIRONYTÉ and NORÉN 2001). Unlike other substance groups, such as polychlorinated

biphenyls and polychlorinated dioxins and furans, where a steady decrease in human contamination levels has been observed in recent years, contamination with brominated flame retardants appears to be still increasing. However, long-term studies have already shown that with the phasing out of polybrominated diphenyl ethers in Sweden, human contamination levels have been declining in recent years, indicating that the regulatory measures are having an effect.

8.3.5 Environmental risks

679. Brominated flame retardants frequently display low solubility in water, a high bioaccumulation propensity, and high absorption on organic particles (Table 8-3). In the environment they are therefore found primarily in sediments and suspended solids, particularly in waters influenced by industry. It is not possible to make any statement about the desorption of brominated flame retardants from sediments (BUA 1996; 2003; European Commission et al. 2002).

Table 8-3

Environmental behaviour of tetrabromobisphenol A, hexabromocyclododecane and decabromodiphenyl ether

Substance	Solubility in water	Adsorption propensity	Log K _{ow}	Photodegradation	Active metabolites	Biodegradability
TBBPA	0.063 mg/l (at 21°C)	high	5.90	Half-life 40 hours	Bisphenol A, methylated forms of TBBPA	very low
HBCD	0.12 mg/l (at 23°C)	high	7.59	not known	not known	very low
DecaBDE	0.1 µg/l (at 25°C)	high	6.27	Half-life 100-200 hours (in sediments and soils)	Low brominated diphenyl ethers	very low
Log K _{ow} = octanol/water-distribution coefficient (for determining the lipophilicity of environmental chemicals; also gives an indication of the tendency of a compound to bioaccumulate)						
SRU/UG2008/Table 8-3; data sources: European Commission et al. 2002; 2006; BUA 1996; 2003						

680. Higher brominated polybrominated diphenyl ethers and hexabromocyclododecane have a low acute toxicity to aquatic organisms. In the few studies available either no effect was detected, or effective concentrations were close to the solubility of the tested substances. Even in the chronic test, effects were only detectable at relatively high concentrations. By contrast, pentabromodiphenyl ether and tetrabromobisphenol A have toxic effects on aquatic organisms even at relatively low concentrations. For example, fish embryos (*Fundulus heteroclitus*) displayed adverse effects in the form of behavioural changes at concentrations as low as 1 ng/l pentabromodiphenyl ether (TIMME-LARAGY et al. 2006).

Table 8-4

**Results of eco-toxicity tests on the quantitatively most important
brominated flame retardants**

Substance group	Eco-toxicity		
	Organism	Exposure via:	Effect concentration (duration of test) (specific end point)
TBBPA	Nitrifying bacteria	Soil	EC ₁₀ = 295 mg/kg soil (DW) (nitrate production) ⁵
	Water flea (<i>Daphnia magna</i>)	Water	EC ₅₀ (48h) = 980 µg/l (mobility) ⁸ LOEC = 0.98 mg/l (reproduction) ¹¹
	Earthworm (<i>Enchytraeus crypticus</i>)	Soil	EC ₁₀ = 2.7 mg/kg (reproduction) ⁵
	Bluegill (<i>Lepomis macrochirus</i>)	Water	LC ₅₀ (96h) = 510 µg/l ⁹
HBCD	Water flea (<i>Daphnia magna</i>)	Water	EC ₅₀ = 146 mg/l (mobility) ⁷
	Bluegill (<i>Lepomis macrochirus</i>)	Water	LC ₅₀ (96h) > 100 mg/l ⁷
PentaBDE (BDE -99) (BDE-71)	Water flea (<i>Daphnia magna</i>)	Water	EC ₅₀ (48h) = 14 µg/l (mobility) ¹⁰
	Fish embryos (common mummichog = <i>Fundulus heteroclitus</i>)	Water	LOEC = 1 ng/l (behaviour) ⁶
	Trout embryos (<i>Oncorhynchus mykiss</i>)	Water	NOEC (87days) = 8.9 µg/l ¹²
	African clawed frog (<i>Xenopus laevis</i>)	Food	LOEC = 1 µg/g food (metamorphosis) ⁴
OctaBDE	Blackworm (<i>Lumbriculus variegatus</i>)	Sediment	NOEC (28 days) > 1500 mg/kg (growth) ²
	Japanese medaka (<i>Oryzias latipes</i>)	Water	LC ₅₀ (48h) > 500 mg/l ³
DecaBDE (BDE 209)	Microalgae (<i>Skeletonema costatum</i>)	Seawater	EC ₅₀ > 1 mg/l (growth) ¹ NOEC = 4.5 mg/kg DW ²
	Blackworm (<i>Lumbriculus variegatus</i>)	Soil	
	Japanese medaka (<i>Oryzias latipes</i>)	Water	LC ₅₀ (48h) > 500 mg/l ³
<p>* Where only individual congeners or congener groups or specific technical products were investigated, this is stated in brackets. EC₅₀ = concentration at which an effect occurs in 50% of the test animals EC₁₀ = concentration at which an effect occurs in 10% of the test animals LC₅₀ = concentration which results in mortality of 50% of the test animals LOEC = lowest observed effect concentration LOAEC = lowest observed adverse effect concentration DW = dry weight NOEC = no observed effect concentration</p>			
<p align="right">SRU/UG2008/Table 8-4; data sources: ¹ WALSH et al. 1987, ² KRUEGER et al. 2001, ³ European Commission et al. 2003, ⁴ BALCH et al. 2006, ⁵ SVERDRUP et al. 2006, ⁶ TIMME-LARAGY et al. 2006, ⁷ BUA 1996, ⁸ MORRISSEY 1978, ⁹ CALMBACHER 1978, ¹⁰ EVANDRI et al. 2003, ¹¹ Great Lakes Chemical Corporation 1989, ¹² PAWLOWSKI et al. 2003</p>			

681. A risk assessment of the effects of tetrabromobisphenol A on humans has been completed by the European Chemicals Bureau, but an environmental risk assessment is still outstanding (European Commission et al. 2006). The Agency nevertheless proposes that

tetrabromobisphenol A be classified as highly toxic to aquatic organisms. This assessment is based on data on its acute toxicity to fish and water fleas (EC_{50} and $LC_{50} < 1 \text{ mg/l}$), its high persistence in the environment, and a bioconcentration factor (BCF) in excess of 100, which has been demonstrated in studies of fish and other aquatic organisms (see also Table 8-4). Only a methylated form of tetrabromobisphenol A was found in Japanese shellfish. It remains to be investigated whether biomethylation is widespread in the environment, since these forms could result in much greater bioaccumulation than tetrabromobisphenol A (HAKK and LETCHER 2003).

8.3.6 Substitution

682. Electrical and electronic devices in office, IT or home entertainment systems contain current-carrying parts that can give rise to fires in the event of overheating or short circuits. The basic material of circuit boards consists of a reinforcing agent (paper or fibreglass) impregnated with epoxy or phenolic resins. In view of its favourable material and processing properties, the most frequently used resin is glass fibre reinforced epoxy resin impregnated with flame retardants. Today there are bromine-free base materials for circuit boards, to which phosphor or phosphor-nitrogen compounds are added as flame retardants. Acceptance of this halogen-free base material as a suitable substitute depends on compliance with the safety standard. Moreover, new flame retardant components also alter the material and processing properties. The associated technical problems currently militate against rapid substitution of material containing tetrabromobisphenol A. In general, however, it is possible to replace tetrabromobisphenol A as a flame retardant in circuit boards.

683. In view of internal sources of fire, flame-retarded plastics are also used for the outer casings of electrical and electronic devices. Fire protection can also be achieved by increasing the distances between voltage sources and plastic parts, and by cooling. The plastics predominantly used are rubber-modified acrylonitrile-butadiene-styrene copolymers (ABS), polycarbonate-ABS blends (PC/ ABS) and HIPS (high impact polystyrene). Possible bromine-free alternatives to these plastics include various phosphate compounds (organic triaryl- and bisphosphates, bisphenol-A-diphenylphosphate) or organophosphorus compounds. The first printers and computers using only plastic parts with triaryl- und bisphosphate as flame retardants are already on the market.

A general trend can be observed towards reducing brominated flame retardants and totally dispensing with polybrominated diphenyl ethers and moving in the direction of organophosphorus flame retardant additives and designed-in fire protection. This substitution trend apparently has no adverse effects on the material and processing properties of the materials. From an environmental point of view this changeover is to be welcomed (PAKALIN et al. 2007; LEISEWITZ et al. 2001; Danish EPA 1999). However, one must not overlook the fact that these substitutes have not all been tested for their environmental risks and thus

have not all been cleared. The organophosphorus flame retardants are used as additives and have a greater volatility and probably also a greater emission propensity than tetrabromobisphenol A. Some of these substances have already been classified as hazardous to water.

684. Polystyrene-based insulating materials account for about one third of the German insulation material market in terms of volume. A flame-retardant finish is achieved for expanded polystyrene (EPS, 90 % market share) with about 1% hexabromocyclododecane (additive) and for extruded polystyrene foam (XPS, 10 % market share) with about 2 to 3 % hexabromocyclododecane. According to the manufacturers there are currently no alternatives to the use of hexabromocyclododecane for reducing the ready flammability of the basic polystyrene material (see also POSNER 2006). LEISEWITZ et al. (2001) recommend searching for substitutes to reduce the large quantities of bromine and also of dicumylperoxide, which is added to hexabromocyclododecane as an extra component and is dangerous to the environment.

8.3.7 Situation regarding legal regulations

685. To protect human health and the environment from exposure to certain brominated flame retardants, the European Parliament and the Council have passed three directives. The 24th revision (2003/11/EG) of Directive 76/769/EC of 6 February 2003 prohibited the use of and trading with pentabromodiphenyl ether and octabromodiphenyl ether and products containing these substances. The limit value for these two congener groups was set at 0.1 weight percent of the product. The directive was transposed into German law by the Seventh Ordinance amending Chemicals Prohibition Ordinance (*Chemikalien-Verbotsverordnung (ChemVerbotsV)*, new version of 13 June 2003, BGBl. I p. 867).

686. Directive 2002/96/EC, the Waste Electrical and Electronic Equipment Directive (WEEE Directive), lays down that the end-of-life electrical and electronic devices listed must be separately collected and recycled. Accordingly, plastic parts containing brominated flame retardants of any kind must be removed from the old devices and sent for recycling or disposal in accordance with Article 4 of the Waste Framework Directive.

687. Directive 2002/95/EC on the Restriction of Hazardous Substances (RoHS Directive) originally prohibited electrical and electronic devices placed on the market on or after 15 August 2004 from containing any polybrominated diphenyl ethers. Despite the resistance of a number of member states, the European Commission made an exception to this directive for the use of decabromodiphenyl ether (European Commission decision of 13 October 2005; 2005/717/EC). The European Court of Justice has since declared the Commission's decision to be null and void (ECJ judgement of 1 April 2008, Ref. C-14/06). As a result of this judgement, the marketing of electrical and electronic products containing decabromodiphenyl ether is prohibited as from 1 July 2008.

The RoHS Directive and the WEEE Directive have been transposed into German law by the Act governing the Sale, Return and Environmentally Sound Disposal of Electrical and Electronic Equipment (Electrical and Electronic Equipment Act - ElektroG) of 16 March 2005. The aim of this legislation is to prevent waste from electrical and electronic devices, reduce waste quantities, and reduce the pollutant content of such devices.

688. Under Decision 2455/2001/EC of the European Parliament and of the Council of 20 November 2001 on the introduction of a list of priority substances in the context of water policy, polybrominated diphenyl ethers were included in the list of priority substances of the Water Framework Directive. Only pentabromodiphenyl ether was additionally classified as a particularly dangerous substance.

8.3.8 Conclusions and recommendations

689. Brominated flame retardants enter the environment primarily via normal use of the products, and are now ubiquitous. Most representatives of this group of substances have a high persistence and a high bioaccumulation propensity. Human exposure probably takes place largely via the food chain, though several other exposure paths have not yet been investigated sufficiently. Whereas the acute toxicity of the substances is very low, the risk discussion centres round questions of a possible chronic effect in the low dose range. It has been shown that brominated flame retardants have the potential to modulate the neuronal system and the thyroid hormone system. In general, any effects on the thyroid hormone system are of great relevance, especially to the development of infants. The evidence of brominated flame retardants in breast milk must therefore be taken as a serious matter.

690. With regard to the question of a possible environmental risk due to brominated flame retardants, an eco-toxic potential has been shown to exist primarily for tetrabromobisphenol A and pentabromodiphenyl ether. In addition, tetrabromobisphenol A shows great persistence and a tendency to bioaccumulation. As a whole, not enough is known about the behaviour of brominated flame retardants in the environment.

In particular, there is currently a need for research to obtain further clarification of the chronic effects of decabromodiphenyl ether and its transformation into low brominated compounds in the environment.

691. Substitutes that on present knowledge pose a lower environmental risk now exist for both decabromodiphenyl ether and tetrabromobisphenol A. It is therefore justifiable to prohibit the use of decabromodiphenyl ether – as originally planned. The phasing out or substitution of tetrabromobisphenol A should be targeted insofar as a water hazard potential is confirmed.

692. For the reasons mentioned, the Federal Government should advocate the following measures:

- For definitive regulation of the handling of decabromodiphenyl ether, it is necessary to answer the outstanding questions about the environmental behaviour of decabromodiphenyl ether. Until any degradation of this brominated flame retardant to more toxic compounds has been ruled out, it would be advisable to prohibit its use, as in the RoHS Directive. At the same time there is a need to push ahead with the environmental risk assessment of available substitutes.
- If the water hazard potential of tetrabromobisphenol A is confirmed on completion of risk assessment by the European Chemicals Bureau (ECB), phase-out or substitution of this flame retardant – preferably at European level – should be sought. In this case there is also a need for more detailed environmental risk assessments for the existing alternatives.
- Little is known at present about the behaviour of hexabromocyclododecane in the environment and its toxic or eco-toxic potential. In view of the ubiquitous presence of hexabromocyclododecane in the environment, there is an urgent need to fill the existing knowledge gaps and perform a risk assessment on this basis.
- As a basic principle, substitution by less environmentally dangerous substances should be sought, as now provided under REACH, for all chemical products that have been shown to have persistent, bioaccumulative and toxic properties.

8.5 REACH

8.5.1 Introduction

721. The European Regulation concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) entered into force on 1 July 2007. The first registrations can be submitted from 1 June 2008 onwards. First the European Chemicals Agency (ECHA) must be fully established and must provide concrete details of a number of procedures, e.g. use of alternative test strategies or exposure-based waiver of the requirement to collect test data.

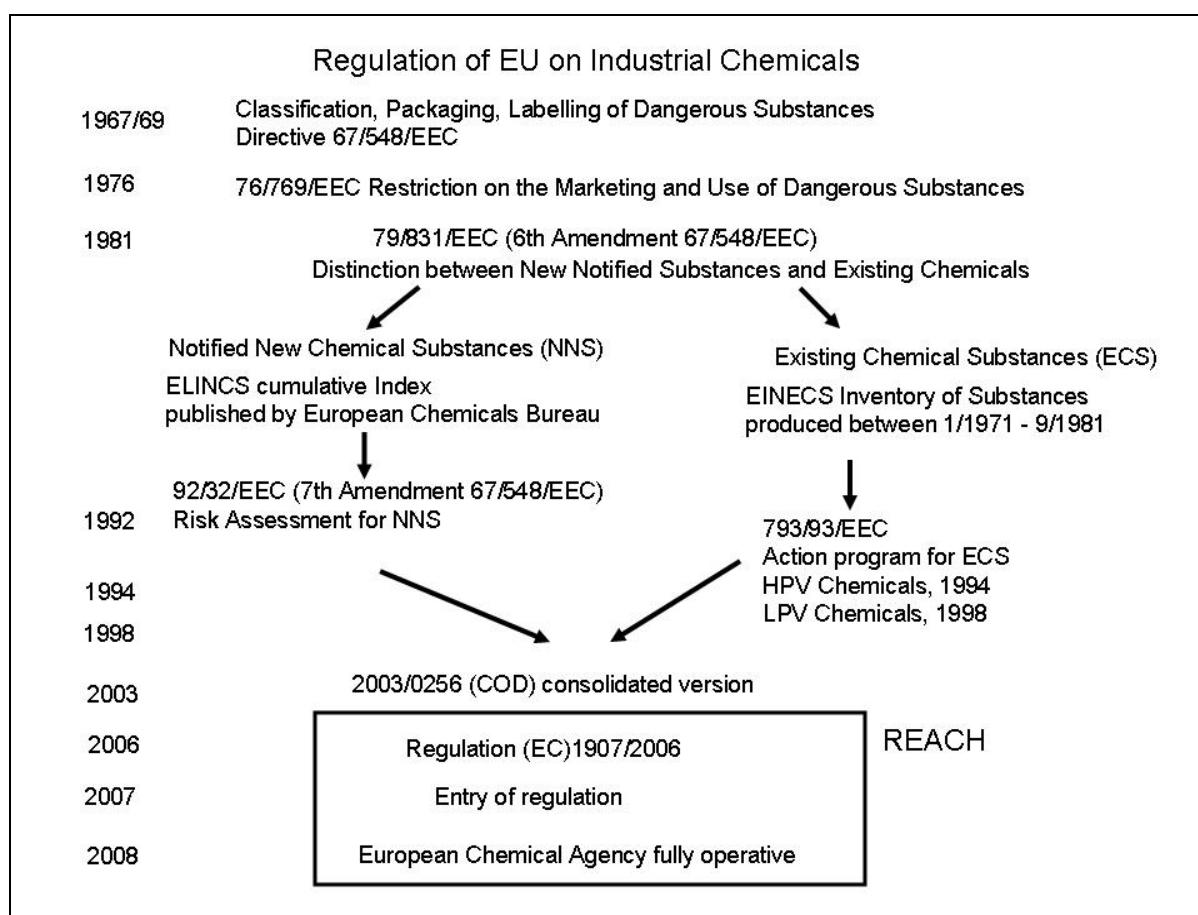
REACH puts into practice an important revision of chemicals legislation. It abolishes for all European member states the distinction between new notified substances (NNS) and existing chemical substances (ECS). The aim of REACH is to organise the handling of chemical substances in a way that ensures future sustainability and is more responsible for humans and the environment. The concept behind REACH pools experience regarding the strengths and weaknesses of previous regulations and can reduce or even eliminate the existing knowledge deficits (FOTH and HAYES 2008a).

722. The basic concept of REACH has been in place for several decades in various regulations on chemical substances, and is thus tried and tested, for example since 1967 in the Dangerous Substances Directive 67/548/EEC on the Classification, Packaging and

Labelling of Dangerous Substances, since 1981 in the Sixth amendment to the Directive (notification and testing requirements for new substances), and since 1993 in the Seventh amendment (risk assessment procedures) (FOTH and HAYES 2008b). These rules have now been integrated in a comprehensive regulation which is to be implemented as standard in the EU (Fig. 8-1). This requires a reorganisation of responsibilities, information provision and assessment, and archiving and pooling at aggregated levels.

Figure 8-1

Further development of the European regulation on chemical substances



Source: FOTH and HAYES 2008

To overcome the identified capacity shortages, REACH has to take new approaches and use new control instruments to bring about broad application of substance assessment and regulation. As a result, the implementation of REACH is work-intensive and by no means easy. It is however a major step in the right direction, and will also have a decisive influence on international responsibilities relating to appropriate handling of chemical substances.

8.5.2 REACH: A rigorous step towards more chemical safety

723. The purpose of REACH is to generate information on the properties of chemical substances that is needed for other sets of rules, e.g. occupational safety and production safety. In the past, substances for certain fields of application such as pharmaceuticals or pesticides, and also new substances, have been subject to data generation, authorisation and notification requirements. REACH is intended to streamline workflows in substance evaluation, supplement the test regime for substance assessment by alternative methods of describing effects, and establish a new knowledge base on the distribution of substances in supply chains. The importance of these goals is undisputed, but it would not be possible to achieve them on the broad front envisaged using the existing rules. These rules are nevertheless the basis of REACH, and their concepts, methods and goals are integrated in it (see Table 8-5). As a result, the weaknesses inherent in these rules – especially the large amount of time and effort necessary to achieve appropriate depth of examination and appraisal – will continue to exist.

- Chemical substances, which have both desirable and undesirable effects, can in principle be controlled by means of authorisation procedures which define the nature and circumstances of trouble-free handling. Examples of successful rules with an authorisation procedure and restrictions on use are pharmaceuticals, biocides, pesticides and cosmetics. Under REACH, an authorisation procedure is to be introduced for the use of certain substances that give cause for concern.
- Safe handling of chemical substances by users is possible if the dangers are known and the measures to contain them are effective. The measures necessary to describe the dangers were taken forty years ago in the form of the labelling requirement (Directive 67/548 EEC) and its supplements. This introduced the classification of dangerous properties, and the necessary database has been continuously developed. These measures will be continued under REACH, and the data acquisition requirements will be extended.
- There must be speedy access to clear information about dangerous properties of chemical substances which have immediate and long-term effects on humans and the environment, in order to permit competent protection measures in the case of sudden events (e.g. accidents involving dangerous substances). The instrument of safety data sheets developed for this purpose will continue to exist under REACH (safety data sheets – SDS) and will be supplemented by a condensed description of the final exposure scenarios. Substances will be or become safer a priori within the supply chain, since downstream users and final users will also be included.
- Under REACH additional documents such as the chemical safety report (CSR) will be produced to serve the authorities and, at least in excerpts, the interested public as a source of information. In the chemical safety assessment system (CSA – Item 730) the

aggregated information from the CSR is to be supplemented by further findings and information on existing knowledge deficits which put manufacturers in a position to provide immediate information on the occurrence of sudden events such as accidents. The CSA is thus an internal document and contains a substantive evaluation of the data (FOTH and HAYES 2008a).

- Many chemical substances have useful technical properties and are in widespread use. As a result, some of them find their way into final products and the environment, where they can pose risks to humans and the environment that are difficult to control. REACH will remedy data and evaluation deficits with regard to the behaviour and presence of chemical substances in the environment and their persistence, bioaccumulation and toxicity.
- Directive 76/769/EEC states that the placing on the market of chemical substances with dangerous properties, e.g. carcinogenic, mutagenic and reprotoxic effects, will be subject to restrictions. Despite the effectiveness of this restrictive directive, the means available for curbing the use of dangerous chemical substances are generally not strong enough. REACH introduces a risk assessment by manufacturers/importers, down stream users and final users for chemical substances in the EINECS list as well (European Inventory of Existing Chemical Substances). The authorisation procedure which may be necessary depending on the risks identified has a restrictive effect on the use of certain chemical substances. This removes the burden of evaluation work from the national supervisory authorities, leaving them free to focus on their controlling function (FOTH and HAYES 2008b).

Table 8-5

Innovations in regulation of chemicals under REACH

	Before REACH	Since REACH
Registration of chemical substances with test data		
	New substances, substances for certain fields of application	All substances >1t/a
Evaluation of dangerous properties		
	Classification: chemical-physical, toxicity, CMR	Classification plus risk assessment
Approval of chemicals		
	pharmaceuticals, pesticides, biocides, cosmetics	All chemical substances with very dangerous properties*, systematic examination of EINECS substances as well
CMR = properties which are carcinogenic, mutagenic or toxic to reproduction EINECS = European Inventory of Existing Chemical Substances (Directive 67/548/EEC) *All substances with very dangerous properties (CMR, PBT, vPvB and comparable substances of very high concern) are to require approval regardless of whether they have been registered. Thus registration is not a precondition for the possibility of requiring an approval procedure for the substance.		
SRU/UG2008/Table 8-5		

8.5.3 Basic structure of registration

724. Under REACH all substances with a production or import volume exceeding 1 t/a are to be registered and characterised, with the aim of identifying those substances which in view of their special dangerous properties need to undergo a detailed risk assessment as a basis for decisions on restrictive measures. Thus REACH can extend the instrument of approval to certain industrial chemicals. A core element here is the registration requirement for all chemical substances with a produced or imported quantity of more than 1 t/a for every manufacturer, importer, down stream user or end user. This could concern up to 30 000 chemical substances, possibly involving several times that number of registrations. To these must be added the approximately 6 000 notified new substances which count as registered for the purposes of REACH and which must therefore be entered in the databases as REACH-compatible records. Responsibilities within the procedure are structured and depend on trust-based cooperation supporting the aims of REACH (see Tables 8-6 and 8-7). The workload for all concerned is nevertheless expected to be massive.

Table 8-6

Tasks of Manufacturers/Importers and Down stream users

	Pre-registration	Registration	Completion
	6-12/2008	by 12/2010 1st group by 6/2013 2nd group by 6/2018 3rd group	≈ 2013 or later ≈ 2016 or later ≈ 2022 or later
Manufacturers/ Importers	Notify registrant's CAS number Then or later, decision on - Product portfolio - Use patterns - Existing data - Registration consortia	Among other things: safety data sheets (SDS) substance safety report (CSR) chemical safety assessment (CSA) including - Classification of risks to humans and environment - Information on effect thresholds (DNEL, PNEC) - Exposure information - Gaps in data - Proposals for eliminating gaps in data including animal tests	
Down stream users/ End users	With effect from 2/2009: Ongoing checks on whether raw materials are pre- registered and whether use patterns are covered	Supplement to - SDS - CSR - Proposals for supplementary tests	
SRU/UG2008/Table 8-6; data source: REACH Regulation			

Table 8-7

Tasks of the European Chemicals Agency

Before pre-registration	After pre-registration (from 12/2008)	Within registration of existing and new substances (registration phase: by 12/2010 1 st group by 6/2013 2 nd group by 6/2018 3 rd group
By 6/2008 definition of the justification criteria (reasons for not conducting a standard test procedure) Start-up of databases for supplying the public with data on substances	In 1/2009 listing of pre-registered substances with CAS number; registrant From 2/2009 to 6/2018 fostering of the Substance Information Exchange Forum (SIEF)	From 6/2008 work on notified new substances (NNS) Work on dossiers for newly registered substances (180-day window) from 6/2008 to 12/2012 1 st group to 6/2016 2 nd group to 6/2022 3 rd group Dossier evaluation – Technical evaluation (5 % of dossiers) – Evaluation of test proposals (100 % of all dossiers in 1 st and 2 nd groups) – Demands for missing tests From 6/2009 publication of first working list of candidate substances for listing in Annex XIV to the approval procedure In 1/2011 preliminary selection and publication of registrations for which substance evaluation is planned
SRU/UG2008/Table 8-8; data source: REACH Regulation		

Tasks of the registrant

725. The registration of chemical substances produced before 1981 presents the biggest challenge in terms of workload, but also offers great potential benefits. Manufacturers and importers must comply with the registration requirements in three groups in 2010, 2013 and 2018. By then, all existing data on the substances must be collected and, where necessary, supplemented. In the case of planned animal tests, proposals for eliminating gaps in the data must be submitted. The tests for substances in Group 1 (Annex X to REACH) and Group 2 (Annex IX to REACH) may not be carried out until after evaluation of the test proposals by the ECHA. Even for substances in the first group, the registration documents will not be fully complete until between 2013 and 2016 (see Table 8-6).

726. REACH assigns manufacturers and importers a key function in the classification of dangerous properties and the assessment of effective protective measures. This concept is

of crucial importance for the effectiveness of REACH. It will nevertheless be essential to have the classifications and their justifications checked independently.

REACH relaxes the requirement, which has applied to the notification of new substances since 1981 that classifications of dangerous properties may only be made on the basis of data obtained in standard test procedures. Other, non-standardised information sources will also be accepted, which could mean considerable limitations on the quality and comparability of data relevant to assessment (HENGSTLER et al. 2006; FOTH and HAYES 2008a).

Under REACH, down stream users and end users of chemical substances are also involved in the assessment of the risks their products present to consumers and the environment. This approach is innovative and target-oriented, especially for environmental aspects, because the enforcement authorities can insist on their discharging their duties, at least in the event of suspected problems. However, lack of expertise can be expected to result in distortions and discrepancies in the assessment process which will have to be brought under control.

Tasks of the European Chemicals Agency

727. The concept of REACH has created a new institution, the European Chemicals Agency (ECHA), based in Helsinki. The ECHA is the central registration authority and is to provide the European Commission and the member states with scientific and technical support in the implementation of REACH. The ECHA will not be fully established until June 2008, but until then it already has complex preparatory tasks to perform, such as defining criteria for accepting justifications where registrants deviate from the standard test regime, or for waiving the requirement to perform tests. This is an extremely demanding balancing act of great decisive importance, because it can result in the perpetuation of data deficits in the registration dossiers. It also reduces the prospect of being able to use the data subsequently in new strategies like categorisation or of being able to assess candidate substances for which only experience/evidence from handling to date is available and for which useful information might have been derived from a comparison with standard data on closely related substances. In the pre-registration phase the ECHA, in addition to listing and supplying information on pre-registrations, has the new task of helping to establish the Substance Information and Exchange Forum (SIEF). This is intended to foster the formation of consortia with a view to reducing subsequent workloads and costs, especially for substance tests for registration purposes.

728. The registration of the first group is scheduled for June 2008 to December 2010. This group comprises some 2,700 chemical substances with a production or import volume of 1,000 t/a or more, plus about 750 chemical substances with known dangerous properties (substances that are carcinogenic, mutagenic or toxic to reproduction (CMR), category 1 or 2; persistent, bioaccumulating and toxic (PBT) substances; and very persistent and very

bioaccumulative (vPvB) substances). The ECHA must subject these dossiers to a check for completeness, a technical evaluation in at least 5 % of all registrations, and an evaluation of the necessity for and completeness of the proposed animal tests for all registration dossiers. This work phase must be completed by December 2012. It also includes 60 days public exhibition of the test proposals submitted, with a period of 45 days for interested organisations to enter objections. The registration phase for the second group runs in parallel. This group of substances with a production or import volume of more than 100 t/a comprises around 4,200 substances, and may involve several times as many registrations unless registrants form consortia for registration purposes. The registration period ends in June 2013, and the ECHA has to complete the technical evaluation process in the same way as for Group 1 by June 2016 (FOTH and HAYES 2008a).

729. To date there has been no comparable procedure for the regulation of chemical substances that has to cope with such a massive workload in such a short time from an organisational and substantive point of view with the new instrument of an integrated opportunity for all stakeholders to lodge objections. Even in this early phase of its work, the ECHA will be faced with the task of making binding decisions on the acceptance of the test proposals submitted, with regard to necessity and, above all, completeness. At this early stage it will not be possible to take adequate account of the alternative methods designed to minimise animal tests, the scientific validation check and the more time-consuming formal validation check (LILIENBLUM et al. 2008). The burden of testing work could be relieved in the field of exposure-based arguments (see Item 733). Here too there is still a great discrepancy between the requirements of scientifically sound exposure determination and assessment, which for procedural and data reasons will not be possible under REACH for registrations in the first and second groups.

8.5.4 Forthcoming definition of concrete details for registration

REACH implementation projects

730. A core element of the REACH procedure for registering substances is the Chemical Safety Report (CSR) and the Chemical Safety Assessment (CSA) that forms part of it. By this means, manufacturers and importers are to document the fact that they produce, import or use the relevant substances in a way that does not endanger either human health or the environment. The framework and basic requirements for this report are set out in Annex I to the REACH Regulation ("General provisions for assessing substances and preparing chemical safety reports"). The basis for the substance safety assessment is a comparison of the potentially harmful effects of a substance with the known or realistically foreseeable exposure of humans and/or the environment to this substance. A CSR only has to be

prepared and forwarded to the ECHA for substances with an import or marketing volume of 10 t/a or more.

Details of the procedural steps in the preparation of a CSR are currently being worked out in the "REACH Implementation Process" (RIP) by a European Commission working group. In the RIP all stakeholders (industry, environmental associations, authorities) work together on the technical background documents for the REACH Regulation. RIP 3.2 is to draw up a Technical Guidance Document (TGD) on the preparation of a CSR. Of major importance for the revision of the contents of Annex I (which is scheduled to take place by 1 June 2008) are the working group on exposure determination (Task I) and the working group on hazard assessment and PBT assessment, Task II) (ECB, no date a).

RIP 3.3 is the core document with details of the information required from manufacturers and importers on registration. As can be seen from the final report on the TGD for RIP 3.3, as an example of other RIPs, this is a detailed but unwieldy version that sets out open issues. To answer these it will be necessary to call for a wealth of substance information that cannot be supplied at all for many substances, as this information is not asked for REACH.

Exposure determination

731. In view of the variety of substances and their individual exposure potential, many companies would be hard put to it to develop their own exposure scenarios. The REACH Regulation therefore provides that broad exposure scenarios can be developed which can be employed for several substances or uses. The difficulty lies in finding a balance between simplicity and precision. After all, the exposures estimated on the basis of the exposure scenarios form part of the risk assessment and hence of the decision as to whether or not a substance is adequately controlled. There is a need for technical guidance and the development of suitable computerised aids. The above mentioned EU working group has created an initial basis for this (see also ECB, no date a).

A working group of the International Programme on Chemical Safety (IPCS) has made a close scrutiny of the scientific background to exposure estimates, and especially the uncertainties and how to overcome them. Its report, presented in December 2006 as a draft Guidance Document (WHO 2006), provides impressive confirmation that while exposure estimates can be an important instrument in risk assessment, they make considerable demands with regard to underlying data and their quality. By contrast, the concept of exposure estimation used in REACH is a rough classification of the exposure potential on the basis of the substance use pattern, and can only be understood and used in conjunction with appropriately coordinated testing of the effects of a substance. This is the purpose of substance evaluation, in which decisions may be taken to request further data. The authorities would have to furnish justification for such demands. Similarly, the

manufacturers/importers would have to provide justification if the data they intend to generate falls short of what is required in the Annexes.

Defining a no-effect threshold for dangerous substances

732. The DNEL (Derived No Effect Level) denotes a threshold below which, on present knowledge, exposure does not present any threat to human health. The DNEL is used to determine whether a specific substance exposure can be regarded as adequately controlled. Sound determination of actual safety thresholds (No Observed Adverse Effect Level – NOAEL) is crucial, because the relevant substance can be handled safely, given adequate control of potential exposure, and may be approved under REACH (Art. 60 of the REACH Regulation). Depending on the effect mechanism, it is in principle not possible to derive a DNEL for certain substances, e.g. those having a carcinogenic effect, or in certain cases, e.g. a non-mutagenic mechanism, it is only possible on the basis of data exceeding the scope of testing under REACH. Cases with receptor-mediated complex effects, e.g. hormonally active substances, are extremely demanding with regard to their evaluation and can be critical in cases of misjudgement. Numerous examples from substance regulation experience to date show that no-effect thresholds can only ever be laid down on a temporary basis and may have to be corrected upward or downward in the light of scientific findings. When all is said and done, there are many substances for which insufficient testing data and big knowledge deficits make it impossible to define no-effect thresholds with the necessary certainty (SANTILLO and JOHNSTON 2006).

Means of data acquisition under REACH

733. The basic concept for the data needed to describe substances is taken over from existing provisions and is based on graded requirements for performing standardised tests in animal experiments under good laboratory practice (GLP) conditions. High production volumes and known particularly worrying effects of substances are given priority attention. It is basically possible to depart from compliance with a standard testing regime. Under Annex XI to the REACH Regulation, there are general options (“General Adaptation”) for waiving animal tests if

- it is possible to use test data from non GLP compliant tests, existing experience/evidence, computerised forecasts of structure-activity relationships or alternative test methods, or if
- testing in animal experiments is technically not possible.

For substances with a volume in excess of 100 t/a there is also the general possibility of exposure-based waiver of testing in animal experiments. The minimum data requirements for all registration groups will result in classification on the basis of physico-chemical hazards (flammability, explosive and oxidising properties), acute toxicity class and evidence of hazardousness to water. Comprehensive classification with regard to properties that are

carcinogenic, (terato-)mutagenic or toxic to reproduction will only be undertaken for high-volume substances. On other areas, cuts will be compared with the hitherto existing requirements for new notified substances (NNS). The general possibility of deviating from the standard test regime by making substance-specific exposure-based tests for Groups 1 and 2 will, at least in some cases, present serious obstacles to the goal of a systematic broadening of the knowledge base on chemical substances under REACH.

Volume-based data requirements

734. Under REACH, substances with dangerous properties are to be identified at an early stage and grouped in lists of candidate substances for approval that offer potential users rapid guidance and simplify the search for alternatives. However, the volume based data requirements implemented in REACH means, for example, that PBT substances below a volume range of 100 t/a cannot be identified as critical using the REACH criteria. This procedural limitation must be opened up by means of suitable screening or quantitative structure-activity relationships (QSAR) (see also SRU 2004a, Item 1002 f.), generating information about suspicions as a basis for demanding clarification of PBT properties regardless of the production volume of the substance in question. The data requirements for the registration of substances in the 2nd Group (100 t/a and over) are substantially higher than those for the next lower group (10 t/a and over). Since the production or import volume always relates to one registrant, the situation could arise, if there are many suppliers and full advantage is taken of the tolerated volume range, that the total production or import volume actually lies well within the next higher volume range. In the light of experience gained during the implementation of REACH for the first two registration groups, and especially during pre-registration, opportunities must be created, in line with the basic concept of REACH, for closer scrutiny of substances whose cumulative individual registrations are well above the tolerance threshold for the next higher volume range.

8.5.5 Basic structure of evaluation and approval

Tasks of the European Chemicals Agency

735. Another core element of REACH is that information submitted with the registration documents serves the purpose of deeper evaluation and risk assessment. To this end it will be necessary to pre-select candidates for substance evaluation from around 2,800 substances in the first group and around 4,200 in the second group. With regard to this substance evaluation the Agency is to prepare, starting on 1 December 2011, an ongoing action plan for priority substances which it will update annually (draft Community rolling action plan, see Art. 44 (2) of the REACH Regulation). Risk assessment of these selected substances is to be undertaken by the national authorities of the member states.

736. From the existing information on dangerous properties and the newly generated information for registration purposes, authorisation working lists in preparation for selection of candidates for admission to the authorisation procedure will be generated in a phased process (Art. 59 (1) of the REACH Regulation). The first preliminary selection of substances is to be presented on 1 June 2009, and the complete series of seven working lists is to be prepared by June 2021 (see Table 8-8). From these working lists it will be possible to identify those substances for which a decision will have to be taken on inclusion in lists of substances requiring approval (Annex XIV to REACH), and these will then have to pass through the approval process.

Table 8-8

Timetable and tasks of the European Chemicals Agency

Timing	Agency task
From 1 June 2008	New substances can be registered, "phase-in" substances pre-registered (until Dec. 2008)
1 June 2009	Publication of first working list on substances requiring authorisation
1 December 2010	End of registration for CMR substances $\geq 1\text{t/a}$, aquatotoxic substances $\geq 100\text{t/a}$ and all substances $\geq 1000\text{t/a}$
1 June 2011	Publication of second working list of substances requiring authorisation, report by Agency on implementation of REACH
1 June 2013	End of registration for all substances $\geq 100\text{t/a}$, publication of third working list of substances requiring approval
1 June 2014	Status report by Agency on certain implementation processes
1 June 2015	Publication of fourth working list of substances requiring approval
1 June 2016	Status report by Agency on certain implementation processes
1 June 2017	Publication of fifth working list of substances requiring authorisation, status report by Agency on certain implementation processes
1 June 2018	End of registration for substances reaching 1t/a or more
1 June 2019	Publication of sixth working list of substances requiring authorisation
1 June 2020	Status report by Agency on certain implementation processes
1 June 2021	Publication of seventh working list of substances requiring authorisation
1 June 2022	Status report by Agency on certain implementation processes
The tasks of ECHA under the registration process are shown in <i>italics</i>	
SRU/UG2008/Table 8-8; data source: REACH Regulation	

737. The actual assessment task on the regulatory side will relate to the selection of substances which must be regarded as candidates for detailed evaluation in view of suspicions about serious dangers to human health and the environment (substances of very high concern). These procedures are extremely work-intensive because of the immense importance of a possible wrong decision in risk assessment, which means that the phased pre-selection of substances for inclusion in working lists will have to be performed with due care and expertise, and will require resources. As far as the approval decision is concerned, the procedures for derivation of no-effect thresholds (PNEC or DNEL) and their acceptance

and justification requirements still have to be clarified. This concretisation is also very complex and will require considerable expertise and resources.

Tasks of the member states

738. The federal authorities are essentially responsible for carrying out the substance assessment processes, for receiving and passing on information at EU level, and for taking part in EU decision processes. REACH results in the following tasks for the federal authorities (Federal Institute for Occupational Safety and Health (*Bundesanstalt für Arbeitsschutz und Arbeitsmedizin – BAuA*), Federal Institute for Risk Assessment (*Bundesinstitut für Risikobewertung – BfR*), Federal Institute for Materials Research and Testing (*Bundesanstalt für Materialforschung und -prüfung – BAM*), Federal Environment Agency (*Umweltbundesamt – UBA*)) (the articles cited relate to the REACH Regulation):

Tasks in connection with dossier evaluation:

The competent authorities must take note of the list of dossiers to be examined by the Agency (Art. 41 (2)) and its dossier evaluation (Art. 42 (2)) including the conclusions contained therein, and must investigate the need for any further orders.

Tasks in connection with substance evaluation:

The competent authorities must carry out the selection and evaluation of substances and must draw up proposals for decision documents if further information is needed (Art. 45 (1, 2 and 5), Art. 46). In the case of intermediates where there is a suspicion of risk (CMR, PBT, Art. 49), information must be demanded and, where appropriate, recommendations made regarding suitable risk mitigation measures, and comments must be provided during all relevant stages in the substance and dossier evaluation processes. In parallel with this, the parties concerned are to be consulted.

Where necessary, or as a result of substance evaluation, the competent authorities must accompany the inclusion of a substance in Annex XIV (Art. 59 (3)) and make proposals for restrictive measures (Art. 69 (4)) and for harmonised classification and labelling (Art. 115 (1)).

Miscellaneous tasks

Tasks devolve upon the authorities in connection with research and development projects and when submitting comments on decision drafts prepared by the Agency (Art. 9 (8)). In the case of on-site isolated intermediates (Art. 49) they must demand information, where appropriate in consultation with the *Länder* authorities, and must take part in the decision processes of the Agency and the European Commission. This requires sending representatives to Agency bodies (Art. 76). The authorities are also responsible for technical

preparation of votes by the Federal Government in the Regulatory Committee and for cooperation with the competent authorities of other member states (Art. 122).

They also have a duty to inform the public about substance risks (Art. 123) and to inform the Agency about findings relating to substances, including those resulting from monitoring activities (Art. 124 (1)). They must take part in the system of official controls (Art. 125) and must establish and maintain a national centre for information about REACH ("Helpdesk", Art. 124 (2)).

8.5.6 Conclusions and recommendations

739. REACH will establish a new form of division of labour between the manufacturers, importers and downstream users of substances and the Chemicals Agency and the authorities in the member states. This interaction is subject to tight deadlines. Thus lack of clarity about procedures and content is counter-productive, as are foreseeable bottlenecks in the workflows.

740. Especially in the first four years, the Chemicals Agency will be under great pressure to prove itself. The spectrum of tasks for all actors is immense. After the end of the pre-registration phase, the Agency will probably have to list 30 000 to 40 000 pre-registrations and publish them by January 2009. It will have an interest in promoting the dialogue in SIEF about possible cooperation on registration. Although the concept of joint registration (one substance, one registration – OSOR) is implemented in principle, its execution, e.g. as regards the data to be compared, is very limited. In spite of incentives there is no reason to expect that it will save a substantial amount of work.

741. The hopes of being able to use (quantitative) structure-activity relationships ((Q)SAR) (Item 734) in order to dispense with certain tests required by the REACH Regulation are exaggerated. Moreover, the possibility of using in vitro test methods as an alternative to standard animal tests will initially not go beyond present levels, because the outstanding validation processes will still take years and will come too late for most registration deadlines.

742. As early as 1 June 2009 the Agency, after a one-year processing period, will have to publish the first working list of candidate substances for inclusion in the evaluation procedure. Here it will be necessary to make preliminary checks on the newly registered substances (several hundred) and the known CMR substances (about 750 in Class 1 and 2).

After a further 18 months the Agency will be faced with the task of screening the technical dossiers for some 2 800 HPV substances (HPV – high production volume substances $\geq 1\,000$ t/a), which have to be evaluated within two years with regard to the need for animal tests and completeness of the test plan. This presupposes screening of the entire registration dossier including a critical assessment of the data presented. For a 45-day period, the

Agency must present all decision options in connection with animal experiments to the public and process objections.

Potential for standardisation is virtually non-existent, at least in the first eight years following the entry into force of REACH.

Recommendations

743. The quality of the assessment depends on the data being free from errors and inconsistencies. Past experience with the testing of substances indicates that this cannot be expected. Quality control of the data and the entries in databases is not guaranteed and should therefore be introduced. This point can ruin the success of REACH if no satisfactory solution is found.

The information about chemical substances which is to be generated under REACH for registration purposes, e.g. classification with regard to dangerous properties including justification of the classification and effective protective measures for safe handling, should be bundled in databases and made available to interested parties. New databases need to be established for this purpose. The entries must be subject to ongoing scrutiny to ensure that their quality and freedom from inconsistencies is maintained.

744. In view of the considerable work that the implementation of REACH means for the relevant ministries and the downstream authorities at federal and Länder level and also at European level, this will only succeed if human resources and research capacity at all these levels are stepped up. More chemicals safety through REACH cannot be achieved without additional investment in these areas. Moreover, the necessary work should be coordinated at national level and responsibilities bundled as far as possible to prevent unnecessary duplication of work or frictional losses in multi-level cross-sectoral coordination.

8.6 Plant protection products (pesticides)

8.6.1 Introduction

745. Pesticides are needed in the crop-growing sector to inhibit the growth of undesirable accompanying plants (herbicides), kill off insects (insecticides) and fungi (fungicides), and control bacteria (bactericides) and viruses (viricides). They therefore have useful effects on the growing, development and storage of crops. However, they also have harmful effects on non-target organisms and pollute the environment, especially if the active substances are persistent and bioaccumulative. In the authorisation of pesticides, data from impact tests and estimates of exposure due to the use of pesticides are subjected to a risk-based decision on whether the undesirable effects can be tolerated. Since the introduction of authorisation requirements the spectrum of pesticides has shifted in the direction of less risk-prone active

substances, but further incentives are needed to develop active substances with even more favourable risk profiles.

Furthermore, the actual pollution of surface waters in many regions is higher than one would expect on the basis of use in conformity with the authorisation. This environmental pollution appears to be due in particular to excessive and thoughtless application of pesticides. The incentives to appreciate the real pollution potential of pesticides and achieve a reduction in the quantities applied are insufficient. The draft currently under discussion for a revision of the European Pesticides Directive provides for a large-scale zonal authorisation of pesticides which would endanger the standard of protection for man and the environment achieved to date. Regulation of pesticides has reached a high environmental standard as far as risk-based authorisation is concerned, but this is diminished by insufficient user awareness of the problems.

8.6.2 State of pollution

Quantities applied

746. In 2006 some 262 active substances were authorised in Germany in 678 pesticides (BVL 2007a). The largest quantity is used for weed control, followed by control of fungi, bacteria and viruses (cf. Table 8-9). In terms of individual crops in the EU, the largest quantities of pesticides are used for vines, grain, vegetables and potatoes (European Commission 2002a).

747. Following a slight drop of 1.6 % per year on average (SCHMIDT 2003) in the quantity of pesticide active substances sold in Germany between 1995 and 2001, domestic sales of active substances rose again by 14 % from 2001 to 2006 to reach around 32 kt (BVL 2007a). Since then the area of farmland in Germany has decreased slightly (0.8 % between 2001 and 2006; Statistical Yearbook 2003; 2006) and the share of farmland due to organic farming has increased from 3.7 % (2001) to 4.7 % (2005) (UBA 2007). Within the EU-15, sales of pesticide active substances showed no reduction from 1992 to 2003 and currently stand at just under 300 kt/a (European Commission 2006a).

Table 8-9

**Fields of application and sales quantities of pesticides in Germany
(domestic deliveries) 2006**

Field of application	Domestic deliveries (t)
Herbicides (weed control agents)	49597
Fungicides, bactericides, viricides (for control of fungi, bacteria and viruses)	24353
Insecticides and acaricides (for control of insects and spiders), pheromones (attractants) - without inert gases	4505
Growth regulators and germination inhibitors	7602
Soil decontamination agents	27
Molluscicides (for control of snails)	5378
Rodenticides (for control of rodents)	1880
Game deterrents	210
Improving and wound sealing agents	991
Additives	13
Total	94556
SRU/UG2008/Table 8-9; data source: BVL 2007a	

The fact that the quantities sold have remained more or less constant for ten years shows that new pesticides with much lower application rates per hectare have so far not much effect on the total quantity, despite the considerable differences in application rates. For example, the required quantity of a herbicide on changing from an older active substance to a new one falls from 1 500 g/ha (dichlorprop) to 7 g/ha (thifensulfuron), or in the case of an insecticide from 363 g/ha (methamidophos) to 10 g/ha (cypermethrin) (PAN 2003). As far as quantities applied are concerned, the climate, shifts towards more pesticide-intensive crops (e.g. rape), the disappearance of set-asides and the increasing trend to ploughless cultivation (which requires greater use of pesticides) all play a much greater role than new products with reduced application rates (SCHMIDT 2003).

Residues in foodstuffs

748. Authorised pesticides are allowed to be used for treating crop plants and may therefore be detectable as residues in the crops themselves. The authorisation decision is based on assumptions about correct use. The resulting contamination levels to be expected in foods are laid down as maximum residues. The annual food monitoring report by the Federal Office of Food Safety and Consumer Protection (*Bundesamt für Verbraucherschutz und Lebensmittelsicherheit – BVL*) showed that in 2004 residues were detected in 60 % of the foods investigated, including imports; in 7.4 % of these cases the maximum levels were exceeded (BVL press release dated 14 March 2006). In 2005 the share of foods in which residues were detected was 62 %, and the maximum levels were exceeded in 5.8 % of these

cases (BVL 2007b). In Europe some 5 % (2003) and 4.7 % (2004) of the foods investigated were found to exceed the maximum residue levels (European Commission 2006c).

In Europe, 23.4 % of the samples in 2004 tested positive for two or more active substances in or on the food (European Commission 2006c). In Germany 41.4 % of the samples in 2005 were found to contain quantifiable amounts of more than one active substance (BVL 2007b), while the figure for 2004 had been 36.5 % of the samples (BVL press release dated 14 March 2006). The Federal Institute for Risk Assessment (BfR) is currently working on a concept for assessing multiple residues. Many experts assume that combination effects only occur in the case of substances with similar action profiles (BfR 2005).

Pesticide finds in groundwater and surface water

749. For decades now, pesticides have been input into the environment as a result of their use in the agricultural sector and for weed control on public spaces (parks, railway sidings etc.). Measurements regularly reveal elevated pesticide active substance concentrations in the groundwater and infringements of the limits for drinking water (Measurements by the *Länder* 2004 and 2005, UBA 2006b). For the period 1996 to 2000, active substances were detected at one in every four groundwater measuring stations, and at one in every ten measuring stations the limit laid down by the Drinking Water Ordinance was exceeded (0.1 µg/l) (LAWA 2004). Between 2000 and 2002 the target levels laid down by the Federal States Working Group on Water (LAWA) for protection of surface waters for 38 pesticide active substances of relevance to the water sector were exceeded frequently for 5 substances and in isolated instances for 25 substances (BMU 2004).

A survey of water supply companies revealed that in water quality tests 38.2 % of the cases tested positive (STURM et al. 2006). Some 43 % of these finds related to authorised pesticides, while the rest concerned pesticide active substances that were no longer authorised. In view of the nature of the survey it is not possible to distinguish whether the latter finds were due to residues of old applications of previously authorised pesticides or illegal uses of pesticides already banned. Of the responses, 65 % related to groundwater, 31 % to surface water and 4 % to bank-filtered water.

The pesticide active substances most frequently found in bodies of water are all herbicides (e.g. Diuron, Isoproturon, Bentazon; STURM et al. 2006). This is due to the large quantities applied, the specific properties of the active substances and the direct application to the soil. Many active substances based on chlorinated hydrocarbons which are known to accumulate in the food chain (e.g. DDT, Alachlor, Aldrin, Endrin, Lindan, Endosulfan) are either no longer approved in the EU or their approvals are due to expire. The approval of a number of neurotoxic organophosphates (e.g. Parathion, Diazinon, Malathion) has also been withdrawn. Some of these active substances are still found in the environment. Four pesticide active

substances which are now prohibited are therefore included in the list of priority substances of the Water Framework Directive (WFD) (Table 8-10).

Table 8-10

List of priority substances under the WFD

Active substance	Approval status
Chlorfenvinphos, Atrazin, Simazin, Alachlor	No longer approved
Endosulfan	Pesticides containing Endosulfan had to be taken off the market by December 2007
Hexachlorocyclohexane (technical)	Prohibited (γ -HCH = Lindan was allowed to be used as an insecticide until the end of 2007)
Trifluralin	Still approved, but pesticides containing Trifluralin must be taken off the market by December 2008
Isoproturon, Diuron, Chlorpyrifos	Approved
SRU/UG2008/Table 8-10; data source: WFD	

Indicators

750. With the aid of a model for synoptic assessment of the environmental risk of pesticide active substances (SYNOPS), the Federal Biological Centre for Agriculture and Forestry (*Biologische Bundesanstalt – BBA*) has investigated how the risk potential of the pesticides authorised in Germany has changed since 1987 (BBA 2006). In SYNOPS the risk potential is expressed as the quotient of the estimated environmental concentration (exposure) and the toxicity of the active substance, and is thus a quantitative measure representing the hazardousness of a pesticide active substance. SYNOPS has so far focussed exclusively on the compartments soil, fringe biotopes and surface waters, and regards earthworms, algae, *Daphnia* (water fleas), fish and bees as indicator organisms. The exposure is calculated from the estimated application quantities of an active substance (calculated from the national sales data and the estimated crop-specific and pest-specific applications of the active substances) and stipulated application conditions (including loamy sandy soil with 1.5 % organic carbon content, slope 3 %, water ditch at a distance of 1 m, intense rainfall after application; instructions for use are not taken into account). According to the Federal Biological Centre, the calculated risk indicators characterise the risk potential of the active substances under “worst-case” conditions (BBA 2006).

The results show that with the exception of the acute risk to algae from fungicides there was a considerable reduction in the risk potential between 1987 and 2004 (Table 8-11). However, the assessment lacks criteria for assessing the distribution of the active substance in the environment (e.g. mobility, persistence or bioaccumulation). Furthermore, the application conditions represent fairly moderate rather than extreme “worst case” conditions.

751. Indicators are also being developed in a similar way at EU level with a view to permitting assessment of the risk potential of pesticides for terrestrial and aquatic ecosystems. In conjunction with geographical information systems containing soil, climate and environmental data and information on land use and farming practices, they make it possible to calculate risk potentials at regional level (area of 10 km²) (European Commission, no date b). The development of these indicators is of great importance for goal setting and monitoring of a sustainable pesticides strategy (e.g. for risk-based quantity reductions or risk-based levies). To this end, however, it has to be possible to make a proper, unequivocal and at the same time simple assignment of active substances to a risk group. In this respect the indicator systems described above are not yet fully developed and require further refinement.

Table 8-11

**Comparison of risk potentials of active substances during the base period (2000, 2002, 2004)
with the relevant active substances in 1987 (1987 figures = 100 %)**

1987=100%	Acute risk potential (figures in %)					Chronic risk potential (figures in %)			
Function	Earth worm	Daphnia	Fish	Algae	Bees	Earth-worm	Daphnia	Fish	Algae
Herbicides	37	44	45	36	46	31	47	51	35
Fungicides	60	33	66	131	55	81	22	52	76
Insecticides	11	8	36	7	14	20	24	93	6
Source: BBA 2006, modified									

8.6.3 Legal regulations on pesticides

Authorisation of pesticides

752. Since 1993 only assayed pesticide active substances which are listed in Annex I to Directive 91/414/EEC of 15 July 1991 concerning the placing of plant protection products on the market (Pesticides Directive, transposed into German Law by the Crop Protection Act (*Pflanzenschutzgesetz – PflSchG*)) may be used in the EU. Decisions on the inclusion of the active substances in Annex I (“approval”) are taken by the European Commission and the member states in a Community procedure involving a multi-stage, standardised approval process with detailed comments on the active substance data by notifiers and member states, followed by consultation and evaluation by expert committees of the European Commission. The “authorisation” of the plant protection product, by contrast, takes place in the individual member states. The approval conditions for the inclusion of active substances in Annex I to the Pesticides Directive are set out in Article 5 of the directive. This states, among other things, that use of the active substances in pesticides must not have any harmful effects on human or animal health or on the groundwater, nor any unacceptable impacts on the environment. Data requirements and assessment criteria for these approval

conditions are laid down in the “Technical Guidance Documents” (TGD) of the European Commission (ECB, no date b). The authorisation of an active substance is basically valid for ten years only, after which a fresh application for authorisation must be made. This means that a new assessment is then made in accordance with the latest state of scientific knowledge and technology.

Since 1993, all active substances which were on the market before the entry into force of the Pesticides Directive have to be examined to see whether or not they can be included in Annex I (“existing substances programme”). Of the 917 existing pesticide active substances, 93 have so far been included in Annex I to the Pesticides Directive, 601 active substances have not been included, and more than 200 active substances are to be reviewed by 2008 (European Commission 2007b).

753. As long ago as 2002 the European Commission criticised the existing pesticides regulations for the fact that they did not take account of multiple exposure to pesticides and that there were no powers at Community level for reviewing the implementation of the directive in the member states. There was also no comparative assessment of active substances, and the substitution principle was missing (European Commission 2002a). Furthermore, in the opinion of the Germany Advisory Council on the Environment (SRU), there is a lack of unambiguous criteria for the inclusion of active substances in Annex I or clear exclusion criteria for critical properties (for further details see Item 757; cf. also SRU 2004a, Item 373). With regard to regulation of the use of pesticides it is a deficit that good professional practice, although a binding requirement, is not defined in sufficient detail.

Authorisation in Germany

754. When authorising pesticides, the competent authorities in the member states investigate the efficacy, effects on plants, practical use and benefits of the pesticide, and also its effects on the natural ecosystem functioning and on human and animal health. In Germany the Federal Office of Food Safety and Consumer Protection (BVL) is the central authorisation body. In its authorisation the authority stipulates the crops the agent can be used for, the safety information that must be printed on the pack, and the waiting periods to be observed between last application and harvest. It may also impose conditions and rules for use. Pesticides, like active substances, are only authorised for a limited period not exceeding ten years, after which a fresh application for authorisation is necessary. The Federal Environment Agency (*UBA*) is a consulting authority and is responsible for examining, assessing and managing the environmental risk arising from pesticides.

One special feature is the exceptional authorisation pursuant to Section 18b) of the Crop Protection Act. Under this provision the BVL may in individual cases and on request permit the use of an authorised pesticide in a field of application other than that stipulated in the authorisation, if it is to be used either on plants that are only grown on a small scale, or

against harmful organisms that cause considerable damage in specific areas only. Such permits pursuant to Section 18b) of the Crop Protection Act are currently not notifiable and do not require the consent of the consulting or contact authorities. Considering the environmental damage that such exceptional authorisations can cause, this practice is difficult to understand. However, no overview is available of the exceptional authorisations issued nationwide which would permit an estimate of the scale of such environmental harm. To create greater transparency, it would make sense to have a nationwide notification procedure for authorisations pursuant to Section 18b), as is planned in the revision of the Crop Protection Act (Deutscher Bundestag 2007). The exceptional authorisation should in any case remain restricted to important exceptions and should take greater account of nature and species conservation concerns. The same applies to authorisations pursuant to Section 11 (2) of the Crop Protection Act. Under this provision, the BVL may, in the event of risks arising from delay in controlling specific harmful organisms, permit the placing on the market of a non-authorised pesticide or an extended authorisation for a period not exceeding 120 days. Use was made of this clause in 2007, for example, when a number of Länder permitted the open use of mouse poison on fields to prevent harvest damage by excessively large mouse populations, although the official authorisation only allowed its use in baited traps. After a short time some Länder withdrew these permits because of suspicions that hares might have been poisoned as well.

755. In view of the great diversity of pesticide mechanisms and application techniques, assessing their risks is a complex and expensive process. The more closely an assessment focuses on a specific pesticide, the better can one derive effective and appropriate mitigation measures. Furthermore, both the assessment concepts and the risk mitigation measures must be subject to ongoing development to reflect the latest state of science and technology. For example, the increasing finds of multiple residues in foods (Item 748) show that greater attention must be paid to the problem of combined effects. With regard to the exposure estimation performed as part of the environmental assessment of pesticides, the finds of authorised pesticides in bodies of water in excess of the precautionary values indicate that for some active substances the retention capacity of bank filtering has been overestimated in the environmental assessment (Item 749; STURM et al. 2006). With this in mind, the work of the body responsible for environmental assessment, the Federal Environment Agency (UBA), must be supported and strengthened. The provision in the Crop Protection Act that the UBA is the consulting authority for pesticide authorisation makes a major contribution to ensuring that environmental protection is taken into account. Amending this consulting provision to a contact provision, as in a recent proposal by the Länder (Bundesrat 2007), would considerably weaken the protection of the environment.

8.6.4 Revision of pesticide authorisation

756. In July 2006 the European Commission published its Thematic Strategy on the sustainable use of pesticides (European Commission 2006a). As part of this strategy, the European Commission proposes, among other things, a revision of the existing Pesticides Directive (European Commission 2006b). This proposal envisages that, as in the past, the decision on the inclusion of an active substance in Annex I (active substance approval) should be taken by the European Commission and the member states, whereas the authorisation of pesticides should take place at the level of the member states. In addition, however, the Commission's proposal contains a number of significant changes with regard to authorisation criteria, authorisation periods and authorisation procedures, comparative assessment and the substitution principle, and also mutual recognition (zonal authorisation).

Approval criteria for active substances

757. There are to be precisely defined approval criteria for the approval of active substances or safener or synergists (Art. 4 and Annex II to the above mentioned Commission proposal). In the interests of health, substances with carcinogenic, mutagenic, reprotoxic or endocrine properties must not be approved unless their "exposure is negligible on the basis of realistic assumptions" (Annex II No. 3.6 to 3.9). In view of their environmental behaviour, persistent, bioaccumulating and toxic substance, and also very persistent and very bioaccumulating substances (PBT and vPvB substances) are to be excluded, but the criteria laid down for this are very difficult to satisfy (see below). Furthermore, inclusion in Annex I is to be denied to all active substances that have to be classified as persistent organic pollutants (POP) because they satisfy the criteria for persistence, bioaccumulation and long-distance transport (mobility in environmental media) that are laid down in the international agreements on persistent organic pollutants (cf. the POP Protocol of the UNECE (United Nations Economic Commission for Europe) and the Stockholm Convention of the UNEP (United Nations Environment Programme) on persistent organic pollutants).

The introduction of these criteria is necessary and sensible. However, the criteria proposed by the Commission are not very precaution oriented to. For example, under the Commission's proposal the bioaccumulation criterion is not satisfied until a bioconcentration factor (i.e. the experimental measure of the concentration of the active substance in the investigated tissue) of at least 2 000 is reached. Under the Convention on the Protection of the Marine Environment of the Northeast Atlantic (OSPAR Convention) a substance is regarded as bioaccumulating as soon as the factor reaches 500 (POREMSKI and WIANDT 2002). Under the OSPAR Convention it is also possible, instead of a complicated concentration study with animal experiments, to use the n-octanol-water distribution coefficient (k_{ow} , a measure of fat solubility) as an alternative parameter. The open use of pesticides in the environment justifies the introduction of precaution-oriented criteria, in other

words lower thresholds for the exclusion of active substances from Annex I (see also SRU 2004a, Item 351). With regard to the k_{ow} coefficient, it must however be borne in mind that this does not have the same information value as a bioaccumulation factor determined in line with the state of the art. Thus the k_{ow} coefficient can only provide a guide.

Furthermore, the criterion “effects on biodiversity” has been added to the approval requirements (Art. 4 (3) e): “The use of the plant protection products [...] shall have no unacceptable effects on the environment, having particular regard to the following considerations [...] iii) its impact on biodiversity.”). However, the inclusion of the protection for biodiversity remains ineffective as long as there are no specific approval conditions that lay down (among other things) what effects would have to be investigated to ensure the conservation of biodiversity.

Comparative assessment, substitution and period of approval

758. According to the revision proposal, “normal” pesticide active substances and basic substances are to be joined by active substances with lower risk potential (“low risk substances”) and “candidates for substitution” (Art. 22 to 24). The criteria for low risk substances have not yet been defined. It is merely stated that pesticides with these active substances are to “pose only a low risk to human and animal health and the environment”. Active substances are to be regarded as candidates for substitution if they present a greater risk to man and the environment than the majority of other active substances already approved. Here it is necessary to consider whether the ADI (Acceptable Daily Intake), ARfD (Acute Reference Dose) or AOEL (Acceptable Operator Exposure Level) is significantly lower than those of the majority of the approved active substances, whether two of the three PBT criteria are met, and whether the active substance contains a significant proportion of non-active isomers (Annex II, 4.).

First approval for low risk active substances is for up to fifteen years, for “normal active substances” up to ten years, and for candidates for substitution up to seven years. For basic substances, approval may be granted for an unlimited period of time. For all active substances, however, successful renewal is to be for an unlimited period (Art. 14 (2)). In the past, approval has had to be renewed every ten years (Item 752). The period of authorisation of a pesticide should correspond to the period of approval of the active substance contained in the pesticide.

In the case of pesticides containing a “low-risk” active substance, the procedure is to be simplified by reducing the examination period for authorisation to 120 days (or 90 days in the proposal of the Presidency (Council of the European Union 2007)) compared with the present period of one year (Art. 46 (3)). Pesticides containing candidates for substitution, by contrast, must in the course of authorisation undergo a comparative assessment with other pesticides containing alternative active substances. Pesticides must not be authorised if

certain requirements are met (e.g. the alternative active substance is significantly safer for man and the environment, the pesticide with the alternative active substance does not present any significant economic or practical disadvantages, and the development of resistance is not fostered, Art. 48). The member states are to repeat this comparative assessment at least every four years for authorised pesticides containing candidates for substitution.

759. The idea of introducing active substances with low risk potential and making authorisation of pesticides containing these substances easier is basically to be welcomed, because it can provide an additional incentive for industry to develop such low risk active substances. Manufacturers of active substances would thus receive recognition for exceeding the requirements for approval of active substances. However, it is not certain whether the incentive of a shorter examination period is sufficient. In any case the criteria for low risk active substances must be ambitious and unambiguous, especially if the examination of the relevant pesticide is to be shortened. A proposal by the German Presidency mentions the following criteria: no carcinogenic, mutagenic or reprotoxic (CMR) properties, neither persistent nor bioaccumulative, and readily degradable (Council of the European Union 2007). Over and above these, one could use more ambitious PBT criteria (see Item 757).

The introduction of the substitution principle could also stimulate a trend towards use of less dangerous substances. It would however be necessary to define precise and unambiguous criteria for pesticide authorisation to ensure more or less consistent assessment at member state level. However, the proposal itself speaks of a "case-by-case" assessment. Many criteria, such as the consideration of whether there are significant economic or practical disadvantages, leave scope for interpretation. Many experts are of the opinion that there will in any case be only a small number of active substances that can be identified as candidates for substitution. Moreover, it may prove difficult in many cases to demand substitution if registrants argue that it is not possible to manage without a certain range of variation of the active substances because of the danger of resistance development.

The classification of active substances and pesticides into agents that are dangerous or not dangerous to man and the environment must be reviewed regularly. New findings relating to effects or new results from pesticide monitoring must constantly be fed back into the assessment process. The unlimited approval period for active substances and pesticides after successful renewal must therefore be strictly rejected. The possibility of an ad hoc review on the basis of new findings (Art. 21) is too weak. It is more effective to prescribe a review at regular intervals that takes adequate account of advances in scientific knowledge.

Zonal authorisation

760. As in the past, pesticides are to be authorised at the level of the member states, but there is to be mutual recognition of the authorisations of member states in a common authorisation zone. The authorisation zones are selected such that the agricultural and ecological conditions (including climate) and the conditions for plant health are similar. This is intended to avoid duplication of work in the authorisation procedures for registrants and assessors, and to reduce the administrative input both for industry and for the member states. It is also intended to ensure “harmonised availability” of pesticides, so that a situation cannot arise where a preparation is prohibited in one member state, but on sale in a neighbouring country. The authorisation zones are: Zone A (North): Denmark, Estonia, Finland, Latvia, Lithuania and Sweden; Zone B (Central): Austria, Belgium, Czech Republic, Germany, Hungary, Ireland, Luxembourg, Netherlands, Poland, Slovakia, Slovenia and United Kingdom; and Zone C (South): Cyprus, France, Greece, Italy, Malta, Portugal and Spain.

Basically a step in the direction of Europe-wide authorisation of pesticides should be welcomed, because this offers the prospect of establishing a consistently high level of pesticide authorisation in the EU in the long term. However, the preconditions for the functioning of such a system do not exist either for the three zones or for the EU. The member states do not have a uniform level with regard to either the quality of risk assessment or the monitoring of pesticides. Under the Commission’s proposal, individual member states cannot refuse to recognise a pesticide if it has been authorized by another member state in the same zone. This could result in member states having to recognise pesticides hitherto prohibited in their own country or less stringent environmental requirements for the use of a pesticide. There is a risk that health and environmental protection in countries with stricter requirements for environmental and consumer protection might be watered down. Also, pesticide management measures (e.g. the rules for use associated with the authorisation) generally relate to smaller regions than the zones proposed by the Commission, since the differences in climate and soil are on a much smaller scale. Germany alone can be divided into 42 different soil-climate zones (ROßBERG 2003).

The three-zone system of mutual recognition of authorisation proposed by the European Commission should therefore be rejected, because the conditions under which such an authorisation system could promote a uniform level of environmental and health protection do not yet exist. Authorisation in large zones would also have to take account of the fact that the rules for use associated with the authorisation (authorisation conditions) and any monitoring of the use of pesticides would have to be geared to regional needs. It must remain the responsibility of the member states to decide the authorisation conditions and to prescribe adequate monitoring. It should continue to be possible for a member state to refuse recognition of an authorisation in its own country in special cases.

8.6.5 Monitoring of pesticide use

Application conditions for authorised pesticides

761. When authorising pesticides, the competent authorities assume, in the user's favour, that the user will comply with the provisions of crop protection legislation. The forecasts of environmental pollution arising from pesticides are therefore based on this assumption. However, checks by the authorities reveal that in many cases proper use in the intended manner evidently does not take place. In a field study, 50 % of the cases observed failed to comply with the application conditions, for example the prescribed minimum distances from water (UBA 2006a; see also BVL 2007c). The general trusting assumption of compliance with the requirements regarding distance from water which are laid down in the authorisation evidently does not reflect the situation in practice. On this basis, refusal of the declaration of consent in the authorisation procedure ought to be considered more frequently in the case of pesticides with eco-toxic effects (UBA 2006a).

These infringements of the authorisation conditions cannot be tolerated. Moreover, this failure to observe good professional practice is a problem. For example, in some regions of Germany the discharge of tailings and cleaning fluids into farmyard drains or sewers – an infringement of the principles of good professional practice set out by the Federal Ministry of Food, Agriculture and Consumer Protection (*Bundesministerium für Ernährung, Landwirtschaft und Verbraucherschutz – BMELV*) (BMELV 2006, p. 54) – results in relevant inputs of pesticides into surface waters (UBA press release dated 8 September 2004). There is evidently a need for greater success with efforts to make users see that responsible handling of pesticides and effective environmental protection are in their own interests and to include them on a sustainable basis in their practical decisions. The debate about sustainable use of pesticides must therefore seek to achieve closer integration of the users.

762. Compliance with authorisation conditions and good professional practice must be supervised through increased monitoring and by means of suitably frequent and stringent checks. Moreover, application conditions, e.g. in the form of a permanent non-farmed green strip alongside waters, would come closer to the protection target. It remains to be seen how far the new Environmental Damage Act (*Umweltschadensgesetz – USchadG*), which assigns the user strict liability for damage due to pesticides, will help here.

Infringements of the authorisation conditions and of good professional practice cannot be included in the forecasting of environmental pollution. However, usage habits that are common in practice should be taken into account in authorisation and risk assessment, and should among other things be reflected in the conditions for the application of pesticides.

763. At present, static exposure scenarios are used as a basis for assessing the environmental risks of pesticides and for the resulting application conditions. As a result, it is possible to require as application condition certain distances of up to 20 m from water.

Instead of these static exposure scenarios, the Länder are urging the use of a probabilistic, geo-referenced method that yields a more differentiated picture of reality. The aim is to reduce the number of categories of distances and the distances from water itself which are to be complied with. This development can only lead to an improvement compared with present distance rules if the standard of protection is maintained and compliance with the application conditions is monitored by a suitable system.

Pollution monitoring

764. Pesticides are input into the environment during use. The resulting potential pollution of water and soils and the potential exposure of humans to residues in crops must be kept under surveillance. The environmental pollution is monitored by the *Länder* in water quality monitoring programmes. There is still no systematic investigation of residues in the soil. Good professional practice provides instructions on how to use pesticides as intended. The degree of compliance with these rules is reflected by the residues found in foods.

765. As part of their groundwater monitoring, the Länder monitor pollution with pesticide active substances in order to detect active substances and measuring stations with levels in excess of 0.1 µg/l, for which clarification would be required under the Crop Protection Act (see below). Unfortunately the monitoring network, the parameters measured and the information generated from them are too heterogeneous and fragmentary to generate a supra-regional (inter-Land) overview of the actual pollution situation. What is more, the variations in monitoring network intensity create a misleading situation, because Länder with relatively thorough monitoring tend to be noticed because they detect more exceedances. In the interest of saving costs, fragmentary and very heterogeneous data are generated. By focusing on active substances that are approved and of relevance to decisions on subsequent approval, such data prevents an overall picture of the actual pollution situation. As a result it is not possible to exonerate approved active substances and generate positive evidence of environmentally sound application practice.

A concentration exceeding 0.1 µg/l in the groundwater may in certain circumstances require authorisation holders to provide clarification, because authorisation is subject to the condition that groundwater protection is guaranteed given proper application as intended. 94 % of positive finds (Item 749) are attributed by industry to sampling problems, such as mixing with surface water or wastewater, other contamination sources and poor measuring station quality (SCHMIDT et al. 2005). By contrast, the UBA estimates that two thirds of the positive finds are due to causes of relevance to authorisation (personal communication of 26 October 2006).

766. Ongoing further development of pesticide analysis is urgently needed. In addition to the lowest possible detection limits, it must at least cover the main substances used locally (the range of pesticides used varies considerably from one region to another) so that

pollutant inputs into the groundwater can be identified and countermeasures taken at an early stage. To ensure meaningful use of the limited resources, a regional monitoring would be good. This would measure different pesticide active substances in each region depending on the main pesticides used within the region. However, to draw up such priority lists it would be necessary to have field indexes, or at least information from dealers and intermediaries on the quantities they have sold in a particular region.

8.6.6 Conclusions and recommendations

767. The authorisation of pesticides, and hence the implementation of the criteria of the Pesticides Directive, is an important pillar of sustainable, environmentally sound use of pesticides. The assessment of the long-term effects of pesticides on man and the environment creates incentives to develop active substances with a more favourable risk profile.

The SRU therefore welcomes the provisions in the European Commission's proposal for a revised Pesticides Directive under which especially dangerous substances would be excluded simply on the grounds of inherent properties at the level of the approval of pesticide active substances. The procedural simplifications for low risk substances and the substitution rule support this concern. However, the substitution rule should not result in any watering down of the approval criteria for active substances. The revised Pesticides Directive must therefore contain clear criteria for the subdivision of approved active substances into the three risk classes. A basis for this would be substance properties such as carcinogenicity, mutagenicity or reprotoxicity (CMR properties), persistence, bioaccumulation and toxicity (PBT properties) or endocrine disrupting properties.

The approval criteria relating to persistence, bioaccumulation and mobility of active substances should nevertheless be more strongly precaution-oriented, in other words brought into line with the stricter figures of the OSPAR Convention.

The three-zone system of mutual recognition of authorisation proposed by the European Commission should be rejected, because the conditions do not yet exist under which such an authorisation system could yield benefits for environmental and health protection. The SRU also rejects the idea that, following successful renewal, approval of active substances and authorisation of pesticides would be for an unlimited period. The assessment of active substances and pesticides must be reviewed at regular intervals, as this is the only way of catering adequately for advances in scientific knowledge.

768. The assessment of pesticides during authorisation must take greater account of the practice of using multiple pesticides and of their residues in foods. The application rules must be made precaution oriented and abuse-proof (e.g. establishment of fixed buffer zones beside waters). Compliance with them must be monitored by official inspections and a suitable monitoring programme, the results of which should be published regularly. The

exceptional authorisations pursuant to Section 18b) of the Crop Protection Act, under which the authorisation requirements can be suspended, should be notifiable and should be published.

Monitoring of pesticide inputs must be strengthened in qualitative and quantitative terms, and must include a critical scrutiny of special regional features. With regard to substance selection for monitoring purposes, it is necessary to set priorities, harmonise measuring systems and include the environmental medium “soil” in the monitoring system. A field index of the nature and quantities of the products used in a region would be helpful.

8.7 Mercury

8.7.1 Introduction

769. Mercury (Hg) is a heavy metal with high toxic potential which is very problematical for man and the environment. Especially since industrialisation, the quantity of mercury released into the environment has increased significantly, with the result that regional environmental pollution with mercury has in some cases been found to be as much as twenty times the natural background level. Mercury oxidises in the environment, after which it is converted in the aquatic system in particular to methyl mercury, which displays marked persistence and bioconcentration in the food chain. Everyone is exposed to mercury to a certain extent through food, though the variations due to the living environment may be substantial and must be borne in mind (SRU 2004a, Item 559).

770. Inorganic mercury is primarily produced by mining, and occurs as a secondary raw material in natural gas production and ore dressing. Many states have recognised the global character of the mercury problem and have taken steps to reduce inputs and gradually reduce the use of mercury. The EU with its strategy on mercury is playing a leading role in solving this problem. Mention must also be made of the voluntary UNEP Mercury Programme (UNEP Chemicals 2005) and the resolutions of the 24th session of the UNEP Governing Council (February 2007, Nairobi), which also come to the conclusion that serious joint efforts must be made worldwide and without delay to reduce pollution of the environment with mercury and, for example, to protect fish as a particularly valuable source of protein and food. The 24th session of the UNEP Governing Council initiated a process under which a report on mercury with proposals for further international action, including legally binding measures, was to be presented by the 25th session of the UNEP Governing Council in February 2009.

8.7.2 State of pollution

Air

771. The global cycle begins with the release of zero-valent Hg gas from flue gases (combustion of coal and gas and industrial emissions), volcanic activity or evaporation from land and ocean surfaces. In the atmosphere, zero-valent Hg is oxidised within several years and is returned to the land or sea by wet deposition (CLARKSON 2002). In Germany, the background concentration of mercury in outside air is around 2 to 4 ng/m³. In city air the figures may reach up to 10 ng/m³. In the past, levels at workplaces in the mercury processing industry have been found to exceed the maximum workplace concentration of 0.1 mg/m³.

Water

772. The wastewater system is polluted as a result of the worldwide use of mercury and its compounds in industry, trade, forestry and agriculture or in the medical sector. Here mercury is found in various forms attached to particles and sediments. In screenings of river sediments in the Elbe, Weser and Rhine in 1990, figures of between 0.2 and 2 mg mercury per kg fine material (diameter < 20 µm) were found; since then there has been a downward trend. Locally up to 120 mg of elemental mercury per kg and 130 µg/kg methyl mercury was found in the sediments of the Elbe, which was due to regional inputs from industrial sources. Comparatively high pollution levels are still observed in lakes in several North European countries. These are largely explained by the former practice of using organomercury compounds as fungicides for winter-felled timber before rafting in the spring/summer. Mercury concentrations of < 0.02 µg/l have been measured in uncontaminated waters in Germany.

Direct and indirect inputs of mercury into the North Atlantic fell by more than 50 % between 1990 and 1999 (NIXON et al. 2003). Mercury pollution levels in the Baltic Sea have not altered significantly since 1990. For many heavy metals, pollution is higher than in the North Atlantic (HELCOM 2006), which is also reflected by the more or less constant pollution levels in herring and other fish species in the Baltic (HELCOM 2003; SRU 2004b, Item 161). Time series of mercury levels in biota in the North Sea also display a mixed trend, though here the concentrations are much lower than in the Baltic (SRU 2004b, Item 56; BSH 2005).

Soils

773. Because of their fungicidal effect, alkyl mercury compounds used to be employed in forestry and agriculture to treat and prevent root rot, and also to preserve seed corn for winter storage (CLARKSON 1997; WHO 1990). In forest humus layers, a tenfold increase in mercury levels above normal background levels has been reported for the Czech Republic, a fourfold increase in southern Sweden and a doubling in the Arctic (BARREGARD 2005). It is assumed that the existing mercury pollution is already having a serious effect on degrading

organisms in forest soils. The critical figure of 0.5 mg/kg (MEILI et al. 2003) which is to be complied with as far as possible is apparently exceeded by most countries in Central Europe (UBA 2004).

8.7.3 Health risks

Exposure

774. The average daily intake of mercury from the air is 0.2 mg for a respiratory volume of 20 m³ per day, assuming physical work and a mean mercury level of 0.01 mg/m³ in urban air. The average daily intake through drinking water is below 0.05 mg; if the permitted limits for drinking water are used to the full it may be between 1 and 2 mg per day. In quantitative terms, the presence of amalgam fillings is the most significant intake path for inorganic mercury in the general public. With an average number of amalgam fillings, an individual may take in 14 mg per day. The intake rates are derived from provocative tests with analysis of the exhaled air, and are therefore a conservative estimate in favour of safety assumptions, since chewing mainly releases particles, which are not readily absorbed (TORKY and FOTH 2007).

775. Intake from food is mainly in the form of methyl mercury, daily intakes of which may show a thousand-fold variation between best and worst value depending on dietary preferences. The average range is between 1.3 and 97.3 mg per week (NRC 2000); fish, crustaceans and shellfish are the principal sources. Contamination levels are influenced by location-specific factors, diet, position of species in the food chain, lifespan of the species, and fat content. Most mercury contamination levels in fish were between 0.05 and 1.4 mg/kg, the mercury content being detected primarily or almost entirely as methyl mercury (UNEP 2002).

Intake and effects on man

776. Metallic mercury is taken up very readily (80 %) via the respiratory tract, whereas swallowed mercury is hardly taken into the body. Uptake of mercuric oxides is only about 10 to 15 %. Methyl mercury and other organomercury compounds, such as ethyl mercury, are readily absorbed from the biological matrix and almost entirely pass into the body. Skin contact is also a toxicologically relevant gateway for such compounds because of their good fat solubility.

Metallic mercury is sufficiently lipophilic, and within the organism it reaches, among other things, the central nervous system. In the blood, however, metallic mercury is enzymatically oxidised to divalent ionic mercury, which has only a limited capacity to overcome biological membranes and therefore mainly remains outside the central nervous system. Mercury(I) ion

spontaneously dismutates to divalent ionic mercury and elemental mercury, both of which are responsible for further distribution and toxic effects.

Methyl mercury is widely distributed in the organism and also reaches the central nervous system in particular. Mercury compounds pass into the foetus via the placenta. Foetal levels therefore correlate with the overall level in the mother. The overall mercury concentration in umbilical blood is associated with that of the mother's circulation, and mother's milk is also a transfer path for mercury between mother and child.

777. For the population without occupational exposure, methyl mercury is of greatest relevance for the risk of adverse effects on health. It also has a long effect latency period and may lead to irreversible damage. Methyl mercury is classified as "H" – penetrates via the skin (so classified since 1966), "Sh" – sensitises human skin (since 1969) and carcinogenic – Category 3B. However, the organ system which is chronically and primarily affected at low methyl mercury intake rates is the central nervous system.

Fortunately, methyl mercury contamination in food leading to proven toxic effects on humans is a rare occurrence. Between exposure and clinical effect there may be a long latency period of between several weeks and months, or even, in certain circumstances, years. Mercury levels in the hair have proved to be a sensitive biomonitoring parameter for forecasting. Methyl mercury has neurotoxic and developmentally toxic effects on man (TORKY and FOTH 2007).

778. Two major dietary studies on 800 and 1,000 mother-child couples on the Faroe Islands and the Seychelles have created the basis of data for deriving a No Observed Effect Level (NOEL, 5 mg/g hair) for child development. In 2003 the European Food Safety Authority (EFSA) reduced the tolerable weekly intake rates for mercury and methyl mercury from 3.3 to 1.6 mg/kg body weight. This implemented suggestions by the Joint FAO/WHO Expert Committee on Food Additives (JEFCA). Making full use of the reference dose (RfD) would result in mercury levels in the hair of between 1 and 2 mg/g, umbilical blood levels of 5 to 6 mg/l and blood levels of 4 to 5 mg/l (EPA 2001). It has been estimated that 1 to 5 % of the adult population of Europe have diet which takes them over the RfD. Probabilistic studies in France on contamination in children aged three to six have shown that about 11 % are above the RfD recommended by JEFCA. Attention is however drawn to a systematic overestimation of the intake rates, since children in this age group prefer certain types of fish which usually display very low contamination with methyl mercury.

8.7.4 Legal provisions to reduce mercury inputs

779. Mercury is released into exhaust air during the combustion of coal, natural gas, household waste, industrial waste and sewage sludge. The mercury content of European coal may range up to 1 mg/kg. Thus on an international comparison, European coal is highly contaminated. Some areas of industry use mercury and are thus regional sources of

emissions. They include the chlorine industry, cellulose and timber processing, or the manufacture of batteries, electrical equipment and lights.

For more than three decades, mercury limits in the exhaust air from industrial plants, large combustion plants, crematoria or waste incineration plants have been the subject of different legal regulations in Germany and Europe. As a result, total emissions of mercury in Europe were reduced by 60 % between 1990 and 2000 (UNEP 2002). Since then the annual reduction rates have dropped considerably. Variable trends in mercury emissions are forecast for the individual countries in Europe, i.e. both increases and decreases are forecast. Inputs have also been reduced by means of Directive 98/101/EC for the adaptation to technical progress of Council Directive 91/157/EC on batteries and accumulators containing certain dangerous substances, the Directive on mercury levels in electrical and electronic equipment (RoHS), and the ban on fungicides containing mercury. The binding requirement since 1989 to introduce amalgam separators in dental practices (Annex 50 Dental Treatment to the Wastewater Ordinance (*Abwasserverordnung – AbwV*)) has resulted in a marked reduction in mercury contamination of sewage sludge.

780. Numerous measures aimed at reducing transboundary and overall mercury emissions at EU and international level are making their effect felt. These include the Heavy Metals Protocol under the UNECE Convention on Long-Range Transboundary Air Pollution – CLRTAP), the PIC-Rotterdam Convention, the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal, or the OSPAR and Helsinki Conventions for the protection of the North Atlantic and the Baltic Sea from dangerous substances, and the Directive on integrated pollution prevention and control (IPPC Directive). The so called „Artikelgesetz“ (Articles Act) of 27 July 2001 transposed the requirements of the IPPC Directive into German law.

8.7.5 Measures by the chlorine industry

781. One industrial sector that receives special attention in the discussion about effective measures because of its use of pure mercury is the chlorine industry. The emission limiting regulations (Item 782) were accompanied at an early stage by voluntary activities in a spirit of responsible care by the European Chlorine Industry Federation (Euro Chlor). In addition to an undertaking to phase out the amalgam process, these include various technical measures to reduce mercury emissions (ROTHERT 2005; VCI 2006).

In Western Europe some 55 % of the chlorine, caustic soda and hydrogen produced in 2005 was obtained by the amalgam process, which uses liquid mercury as cathode material. The chlorine gas and caustic soda produced in this way are of high quality and can therefore be used as raw materials for further chemical synthesis processes. Mercury-free production alternatives are the diaphragm process, which is not preferred owing to its use of asbestos, and the membrane process, which is state of the art for new plants. The amalgam process

remains indispensable, however, for the production of specialities such as alkali alcoholates, sodium dithionite, high-purity potassium hydroxide and sodium (VCI 2003).

782. In Germany, chlorine production capacity at the end of 2005 was about 4.4 million t per annum, of which 1.2 million t (approx. 26 %) used the amalgam process, 1.1 million t (approx. 26 %) the diaphragm process and about 2.1 million t (approx. 48 %) the membrane process. Since 1998 conversion to the membrane process has taken place at nine locations, mainly in the course of expansion projects. In existing German amalgam plants, mercury emissions into products, wastewater and exhaust air were reduced by nearly 99 % between 1972 (108.8 t Hg/a) and 2003 (1.2 t Hg/a) (VCI 2006). In Western Europe too, extensive investments succeeded in reducing mercury emissions by 97 % between 1977 (221 t Hg/a) and 2003 (5.8 t Hg/a). Worldwide mercury emissions from the amalgam process were estimated at 87 t Hg/a in the year 2000 (VCI 2006). The worldwide demand for mercury for chlor-alkali plants is expected to be reduced to less than 300 t/a by 2020 as a result of changes in technology (MAXSON 2004). At present the mercury cells used in the EU for chlor-alkali electrolysis contain about 12,000 to 15,000 t mercury (Euro Chlor 2006).

Under Section 67 (5) Federal Immission Control Act (*Bundes-Immissionsschutzgesetz – BImSchG*), existing chlor-alkali plants have also been required to use the Best Available Technology since 30 October 2007.

The Reference Document on Best Available Techniques (BAT Reference Document) in the Chlor-Alkali Manufacturing Industry regards the membrane process as the best available technology for the production of chlorine and caustic soda (UBA 2001).

The European Parliament has requested the European Commission to take immediate action to ensure strict compliance with the IPPC Directive. The European Parliament bases this request on the recommendation by the Paris Commission (PARCOM decision 90/3 of 14 June 1990 on reducing atmospheric emissions from existing chlor-alkali plants) that all amalgam plants be closed down by the year 2010 for environmental protection reasons. The Chlorine Industry Federation is seeking to continue operating the existing plants until 2020. It bases this on the argument that the plants existing today are in any case very low emitters, and on the fact that the PARCOM recommendations do not have any legally binding effect.

8.7.6 Production, demand and trade

Mercury production

783. Mercury is still mined in ten countries, especially in Kyrgyzstan, China and Algeria. In the only European mine, the largest mercury-only mine worldwide, operated by MAYASA not far from the Spanish town of Almadén, some 745 t were extracted in 2003. Production stopped in 2004, but MAYASA collects mercury from former plants in the West European chlor-alkali industry and other sources, and sells it to international customers (mainly in

developing countries) (MAXSON 2006). Primary mercury extraction in China was 612 t (2003) and > 700 t (2005), and in Kyrgyzstan 397 t (2003) and 600 t (2005). Mercury is also produced as an accompanying component of non-ferrous metals (mainly Cu, Zn, Pb) and in natural gas production, and is therefore obtained as a secondary raw material during processing. For example, it is known that one Finnish zinc production plant alone produces 50 to 70 t mercury per year as a by-product. Natural gas from the North Sea has a comparatively high mercury concentration, and the treatment of North Sea gas in the Netherlands thus results in some 10 t mercury (European Commission 2002b). The highest concentrations of 4,400 µg/m³ have been measured in German natural gas.

No detailed information is available on extraction from by-products or on recovery or recycling of the mercury quantities produced in Europe.

Demand

784. Mercury still plays an outstanding role in the chlor-alkali industry in the production of chlorine and caustic soda using the amalgam process. In medical technology and measurement engineering, devices containing mercury have largely been replaced by other technologies. Mercury and mercury chloride are used in the manufacture of electrodes and electrical equipment, relays, switches and fuses, and mercury arc lamps and mercury vapour tubes, though since 2006 these have largely had to be substituted. Under the Batteries Ordinance (*Batterieverordnung – BattV*) batteries containing mercury, which have a low propensity to leak or explode, have not been allowed to be placed on the market since 2001. Only slight admixtures are tolerated in small batteries or button cells.

785. In the dental filling material amalgam, the mixture ready for use consists of between 44 % and 51 % (w/v) elemental mercury plus the metals silver, copper and tin. As a rule, so-called g₂-free amalgams are used (here the copper component in the alloy powder is higher, the silver component lower). These liberate less mercury from the crystal structure than older mixtures. Depending on the size of the cavity, about 0.4 to 1.0 g mercury is used. Of this, an average of about 0.35 g remains in the cavity, the remainder being left over as waste from finishing the filling or as unused residue.

786. Amalgamation basically means the property of liquid mercury that enables it to form alloys with a wide variety of metals. This property is put to technical use in gold production (“artisanal goldmining”). Heating completely drives all the mercury out of the alloy, thereby endangering the workers. The mercury escapes completely into the atmosphere and rivers. In spite of national bans, this method has increasingly been used again since 1970 because of the rise in the price of gold and the continuing difficult socio-economic conditions in the regions concerned, e.g. China or Brazil (Amazon Basin) (VEIGA 1997).

787. The total demand for mercury in the EU is around 440 t/a (2005) including the amounts imported with products. The biggest consumer of metallic mercury in the EU is the

chlor-alkali industry, with about 190 t in 2005. In second place in the EU comes its use in dental amalgam, accounting for 90 t per annum. Other important uses are in the medical measurement and monitoring fields, including thermometers and blood pressure manometers (see Table 8-12).

Table 8-12

EU-25 and worldwide mercury consumption by sectors (2005)

Applications	Global demand (t)	EU-25 market demand (t)
Gold production	1000	5
Chlor-alkali	619	190
Batteries	400	20
Dental amalgam	270	90
Measuring equipment and monitoring devices	150	35
Lighting industry	120	35
Electrical and electronic equipment	140	35
VCM (vinyl chloride monomer)	700	probably zero
Other uses	40	30
Total	3439	440
Source: Euro Chlor 2006; MAXSON 2006		

Trade

788. Europe is the biggest exporter of mercury worldwide. Total mercury exports in the EU-25 fell by about 50 % from 2000 to 2004 (see Table 8-13). This fall within the EU-25 is primarily due to the significant reduction or substitution of the mercury content in regulated products (paint, batteries, pesticides) and processes (for chlor-alkali production etc.), and to a general shift in the manufacture of products containing mercury (thermometers, batteries etc.) from the EU-25 countries to third countries. The export customers are the developing countries in particular (MAXSON 2006).

Table 8-13

**Mercury exports of the main European exporting countries (EU-25)
during the years 2000 to 2004**

Country	2000	2001	2002	2003	2004
	Mercury (t)				
Germany	128	162	125	93	69
Netherlands	272	312	292	145	228
Spain	850	648	730	678	444
United Kingdom	255	259	47	70	24
Others	111	89	455	123	59
Total	1616	1470	1648	1110	824
Source: MAXSON 2006					

8.7.7 Mercury strategy of the European Commission

789. As long ago as 2002 the European Commission published a report on what to do about the mercury released in the chlor-alkali industry (European Commission 2002b). On the basis of this the Directorate General Environment drew up a proposal for a strategy to protect human health and the environment from releases of mercury (European Commission 2005b). This was to consider the life cycle and to address issues in connection with production, use, waste management and emissions. The conclusions in the European Commission's communication "Community Strategy Concerning Mercury" (European Commission 2005b) were accepted by the European Council and the European Parliament. In some respects they even called for more stringent measures than those proposed. They envisaged a more stringent timetable for implementing the ban on the use of mercury in certain technical sectors or for putting into practice the safe storage of metallic mercury, and a ban on EU exports of mercury capable of being used in gold mining.

Goals of the strategy on mercury

790. The central goal of the strategy is to reduce mercury levels in man and the environment. In particular, the exposure of humans to the methyl mercury present in fish, shellfish and crustaceans is to be reduced. In view of the great persistence of mercury and its compounds in the marine ecosystems it will take decades to achieve this goal. The EU has already taken numerous measures to reduce the use and release of mercury, and these are definitely making their effects felt. Full implementation of existing measures by the member states is becoming more and more urgent, as is progress at global level. Protection of man and the environment should be ensured by reducing both supply and demand, and by means of regulations for long-term solutions to the problem of mercury surpluses and their long-term storage. Finally, the aim is to make it easier to address the full complexity of the mercury problem and its possible solutions. With its strategy, the EU is seeking to play a pioneering role in international measures.

Measures within the strategy

791. The European Commission's proposal for a strategy on mercury addresses several factors that are regarded as particularly important for an effective reduction in environmental levels. One potential area for emission reductions is seen in the field of large combustion plants with a capacity of over 50 MW, and in coal firing. Free trade in mercury on the world market is to be influenced by restricting the supply. The EU contributes net annual exports of around 1 000 t to the worldwide supply of 3 600 t per annum. This contribution is gradually to be reduced to zero. Technical demand for mercury, for example in the chemical industry, gold production, electronics or for dental fillings, is to be reduced by checking uses to identify opportunities for discontinuation, technical optimisation or restrictions. Mercury surpluses arising from changes in process technology are to be stored safely, and this measure is also

to contribute to reducing the amount of mercury circulating in the trade. Consumer exposure due to food should be evaluated with regard to possible loopholes in protection and information deficits for sensitive individuals, with a view to remedying such gaps and deficits. The EU's efforts to improve the global pollution situation are to be supported by promoting international measures with the aim of reducing emissions. The focus here is on the combustion of coal, the use of pesticides containing mercury, the use of batteries containing mercury, and in particular the use of mercury in gold production. The table below describes the measures proposed by the European Commission for each of these goals (see Table 8-14).

Table 8-14

**Measures stated in the European Commission's proposal
for a strategy on mercury**

Goal	Measure
Reducing emissions	<ul style="list-style-type: none"> – Use “best available technology” in plants – Analyse the effects of the IPPC Directive on emissions – Provide information on the release of mercury – Reduce mercury emissions from the combustion of coal – Management of waste dental amalgam
Reducing supply	<ul style="list-style-type: none"> – Discontinue primary production in the EU – Prohibit market re-entry of mercury surpluses, gradually prohibit mercury exports from the EU by 2011
Reducing demand	<ul style="list-style-type: none"> – Evaluate environmental and health risks due to amalgam – Stricter restrictions on placing on the market of electronic measuring and monitoring instruments containing mercury – Examine remaining products containing mercury to see if they are necessary
Surpluses and reservoirs	<ul style="list-style-type: none"> – Storage of mercury in connection with the ban on exports from 2011 – Short and medium-term clarification of measures for products containing mercury that are already in use
Protecting from exposure	<ul style="list-style-type: none"> – Investigate the effects of mercury intake resulting from eating seafood – Provide information on mercury in food
Improve knowledge	<ul style="list-style-type: none"> – Continue mercury research in the 7th Framework Programme for Research and Technological Development
Promote international measures	<ul style="list-style-type: none"> – Promote EU projects with third countries to reduce the mercury problem – Draw up an EU funding plan for reducing mercury emissions from combustion of coal in China, India and Russia – PIC procedures for mercury (PIC = prior informed consent procedure for certain hazardous chemicals and pesticides in international trade) – Support for UNECE Convention on Long-Range Transboundary Air Pollution with regard to heavy metals – EU support for the UNEP mercury programme – Global reduction in mercury in gold mining (UNDP/GEF/UNIDO* project) – Efforts to bring about global phasing out of primary production
*UNDP = United Nations Development Programme, GEF = Global Environment Facility, UNIDO = United Nations Industrial Development Organization	
SRU/UG2008/Table 8-14; data source: European Commission 2005b	

792. Some of the measures mentioned in the strategy proposal have been or are being implemented in legislation. For example, the use of measuring instruments containing mercury has been restricted by Directive 2007/51/EC of 25 September 2007 amending Directive 76/769/EEC relating to restrictions on the marketing of certain measuring devices containing mercury. In future measuring instruments such as clinical thermometers, barometers or blood pressure manometers which are intended for sale to the general public must not contain mercury and such instruments must not be placed on the market. The ban does not apply to measuring devices which are more than fifty years old and which therefore have to be classified as antiques or cultural assets. Under the directive, measuring devices currently in use are “to be phased out” and replaced by other devices.

Furthermore, mention must be made of the proposed regulation prohibiting exports of mercury (with effect from 1 July 2011) and requiring the safe storage of metallic mercury from the chlor-alkali industry, natural gas purification and the extraction of non-ferrous metals (European Commission 2006d). In the first reading, the European Parliament advocated stricter rules for exports of mercury. Questions relating to extension of scope, earlier imposition of the export and import ban, safe storage or a tracking system for trade in mercury were discussed in the Council as a result of member states’ proposed amendments to the Commission’s proposal for a regulation. On 20 December 2007 the Council adopted a Common Position on the proposal for the above mentioned regulation.

8.7.8 Conclusions and recommendations

Conclusion

793. The special nature of mercury pollution of the environment lies in its physico-chemical basic properties, its behaviour and continued existence in the environment, and its widespread use going far back into history. In the long term, mercury from regional sources has a global impact, because mercury can evaporate and is therefore inevitably distributed in the atmosphere. The natural non-volatile mineral forms of mercury are released into the atmosphere by combustion and fumes. The global pool of mobile mercury in existence at present therefore reflects its present and also its historical use and is a special case of a pollutant cycle. Every new input from direct or indirect production, combustion of fossil fuels or diffuse emission of products containing mercury via the waste path makes an additional contribution to the global pollutant cycle.

794. The health relevance of the circulating mercury pool is largely determined by the fraction that enters bodies of water, where it undergoes biomethylation in aquatic systems and reaches the food chain. Biomethylated mercury is taken up via fish, crustaceans and shellfish used for human nutrition or for feeding (e.g. aquacultures). It has been shown to have harmful effects on health and developmental toxicity. The level of mercury

contamination via seafood that is considered to be safe after evaluation of all human toxicological data known to date is already exceeded by between 1 and 5 % of the European population. Since the time between the input of mercury and its oxides into the water and the contamination of organisms, especially those at the end of the food chain in cold seas, is some 10 to 15 years, future contamination of the seas is already present in the globally circulating pool.

795. The European strategy on mercury sets out to make a substantial contribution to reducing worldwide mercury pollution. The approach taken, namely that of arriving at a prioritised list of measures through life-cycle analyses and integrative assessment of the entire chain of production, trade, technical use and waste management, is target-oriented and commensurate with the basic problem. Other aspects which are very much to be welcomed are the inclusion of a better information policy and the aim of contributing to international emission reduction activity and thereby playing a leading role.

The measures already under way can bring about considerable progress in cutting emissions and pollution due to waste, and reducing products containing mercury (see Item 779). However, a number of legislative measures are still outstanding, such as the introduction of emission reduction technologies in crematoria or monitoring of the management of dental amalgam waste, and further reductions in mercury emissions from large combustion plants. New inputs of mercury into the global cycle can only be reduced by determined action to reduce trade in mercury and limit its release from the combustion of gas and coal. Genuine reductions in the global pool, by contrast, are only conceivable in the waste path. Many of the measures mentioned in the proposed strategy are worded in general terms. Giving them concrete shape is the responsibility of the member states, which need to be aware of this responsibility. An overall review of progress made on the mercury strategy is to be undertaken by the end of 2010.

Recommendations

796. The priority activities must be geared to further emission reductions, targeted intervention in the quantities available for trading, discontinuation of mercury-dependent technologies for which safe alternatives exist, and intensification of efforts to reduce exposure. Pollution of the environment with mercury is a global problem: national initiatives cannot have the necessary impact.

In Germany the potential for reducing mercury emissions by cleaning up industrial exhaust gases is largely exhausted. By contrast, emissions from combustion of coal and natural gas in small combustion plants are too high. The amount of mercury present in industrial chlor-alkali plants in the EU, namely around 12,000 to 15,000 t, can be substantially reduced by largely discontinuing use of the amalgam process. This phasing out should therefore be speeded up and should be achieved well before the date of 2020 sought by the chlor-alkali

industry. Its should be based on the PARCOM recommendation of 1990, which in view of the mercury problem advocates discontinuing the amalgam process by 2010. The real emission risk lies not so much in the operation of technically up-to-date plants as in the dismantling of old plants. The remaining service life of amalgam plants should be laid down when the BAT Reference Document on Best Available Techniques in the Chlor-Alkali Manufacturing Industry is revised in 2008. During these remaining operating periods, further measures should be taken to reduce mercury emissions in the handling, transport, storage, treatment and disposal of waste containing mercury.

- The reduction in the supply of mercury by means of safe storage of metallic mercury and the proposed European ban on exports should be applied as early as possible (i.e. earlier than 2011). The companies concerned should be encouraged to do everything in their power to minimise exports until the final ban comes into force. The ban on exports should also apply to mineral mercury compounds that can be transformed relatively easily into elemental mercury, and to products which contain mercury and are not allowed to be sold within the EU. The ban on imports of metallic mercury and mercury compounds is very welcome, since the EU is in any case faced with the problem of the surplus mercury pool. There is a need for a tracking system for trade in mercury within the EU and with third countries with a view to identifying developments that run counter to the prohibition.
- Moves to reduce demand for mercury by means of use restrictions and product substitution in Europe and Germany have already been successfully initiated. However, measures within the EU alone are not sufficient to make an effective reduction in global emissions. For this reason, legally binding measures are needed to reduce technical uses of mercury in gold mining, battery manufacture and the chlor-alkali industry to the absolutely essential minimum. In objective terms, progress at global level is indispensable. Here the EU is bound by political constraints. In 2002 and 2005 it noted in political conclusions by the Council that there was a need for a legally binding international instrument on mercury.
- Liquid mercury must be stored in suitable facilities which in particular ensure guaranteed protection from evaporation. Marketable methods for sequestering liquid mercury in rock are currently being developed. For the moment, therefore, temporary storage is to be preferred. The 12,000 to 15,000 t of surplus mercury from the chlor-alkali industry in the EU have a volume of around 900 to 1,100 m³.
- Protection from exposure to mercury during “artisanal goldmining” in small-scale gold mining operations is a priority international task, also with the aim of preventing the release of some 1,000 t/a at the present time. Alternative production technologies must be initiated, and financial assistance must be provided for phasing out this process with its high environmental and health risks.

- By promoting international activities, including legally binding measures, the EU should play a leading role in the worldwide phasing-out of primary production of mercury, and should vigorously discharge its obligations in the implementation of other relevant international agreements and projects (e.g. PIC Convention, UNEP Mercury Process and Programme, UNIDO-GEF (United Nations Industrial Development Organisation, Global Environment Facility)).

8.8 Summary

Extending the field of environmental protection tasks

797. Adverse effects on human health and the environment can arise from the production, transport and use of chemical substances. The relevant action thresholds and attendant circumstances, particularly for the employment sector and for accident scenarios, are largely known from systematic investigations. However, the substances remain in the processor, user and waste chain, and may therefore have consequential effects on the health of product consumers and on ecosystems. These may be different from experience gained in the employment sector and in dealing with adverse effects after accidents.

798. The overall situation regarding use of chemical substances is very complex. Differences in the risk awareness of actors within the user chain or their readiness to take action have a decisive impact on the long-term prospects of achieving sustainable control of the pollution of environmental media. This raises the question of the methods, criteria and concepts that could and should be used in precautionary assessment of environmental risks.

Responsibility for appropriateness of methods

799. Substance risk assessment defines safe handling of the substance and the resulting products on the basis of possible effects determined using scientifically based methods and evaluation methods. As a whole, the systematic assessment of risks to human health and the environment follows a well developed concept which combines various working levels of effect and exposure forecasting. This concept includes investigating whether experience offers evidence of specific effects and whether the data situation is sufficient for an assessment. However, to perform this special assessment task it is necessary to set timely priorities in the selection of substances on the basis of experience, the information be supplied and the effect to be evaluated. In many cases the data available for assessing use profiles are incomplete or not sufficiently representative. Missing information is bridged by means of estimates and models, also making use of correction factors derived from assumptions based on consensus decisions in expert committees. Exposure levels are estimated on the basis of various use situations and their planned and unplanned consequences given compliance with the rules, including incorrect uses that experience shows are bound to occur.

Transparency of procedure and implementation

800. The spectrum of tasks involved in assessing environmental risks due to substances and products has become broader and more difficult. This is because, although knowledge about the overall context of substance dispersal and its possible effects has improved, the facts to be evaluated for this purpose are to some extent contradictory and hence not sufficiently reliable, or the data are (still) too fragmentary. Laboratory studies are used to generate extensive data records on the substances to provide a wide-ranging catalogue of detailed aspects. While this has resulted in an abundance of data, it has not necessarily resulted in a wealth of information on environmental risks (see Flame Retardants, Pesticides, Pharmaceuticals). Especially when dealing with environmental risks, the relationship between efforts and benefits can only be successful if monitoring, effect description, user interests and environmental protection are brought together on a cross-sectoral basis (see Mercury, Pharmaceuticals, REACH). This has hardly been achieved to date because different requirements exist with regard to standards and intensity of regulation, and it has not so far been possible to bring about harmonisation.

801. The interpretation of scientific data involves implicit value judgements which are brought together by expert bodies at various technical levels, in EU bodies and subsequently by the national authorities. It is on this basis that the national authorities have to decide what measures to take to protect human health and the environment. This is appropriate for addressing knowledge deficits that indicate a need for further research, and for dealing with the complexity of the scenarios involved. It is however essential for success that the procedures and reasons for decisions are transparent and understandable across sector boundaries. The actors must have the knowledge and capacity to communicate risks.

Development of a risk discussion

802. In the final analysis, it is necessary to make value judgements for the purpose of risk management, since without value judgements it is not possible to say what protection from risks is “appropriate”. The example of pesticides shows clearly that a reduction in environmental inputs is only possible through greater involvement of the groups concerned – users and consumers. There has evidently been a lack of success with efforts to make users see that responsible handling of pesticides and effective environmental protection are in their own interests and to get them to implement this on a sustainable basis in their practical decisions. Decisions in the course of risk management, which are taken too early or too late, too hesitantly or too strictly, or which are attributed to the wrong causes and are therefore incorrect, may sometimes have substantial repercussions. They may result in irreversible action and strategic decisions, and thus involve considerable risks of their own.

803. Many of the individual questions that need to be addressed in the risk discussion are too complex to be discussed and managed with the participation of all actors. It is only by

throwing the discussion open at an early stage with the involvement of actor levels in the fields of development, use and evaluation, and by ensuring a transparent context, that the critical areas for a responsible approach to the problem can be identified sooner and the actors can arrive at mutually acceptable solutions. The condition for success is that the data used for a decision are generated by standard methods, and that the principles to be used in risk identification follow a standard procedure accepted by all the parties involved. Inclusion of the perspective of affected parties may be regarded as expertise in its own right and can ultimately result in better decisions in the weighing-up process.

Recommendations

804. In the light of the above, a suitable approach to regulating environmental risks should take account of the following:

- The basis of scientific data should be more closely geared to understanding the mechanisms responsible for effects in the environment, in order to gain action-oriented insight into problems and ensure suitably targeted measures.
- Environmental risk assessment must be more strongly keyed to an approach that identifies overarching considerations in the evaluation of environmental risks, and which at the same time points out the limitations of environmental risk assessments based on substance assessments using hazard classification and occupational and consumer risks.
- Within expert-based decision procedures, the normative criteria for assessment must be made transparent. In practical implementation, the reasons for assessments of environmental risks must be communicated and made clear in the debate with users and affected parties. First and foremost, this calls for interdisciplinary discussion capacity. In the participants it requires practice, experience and communication skills on the lines of a “competence label for risk communication”, especially for experts from scientific disciplines, risk assessment and administration.

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