

Chemical safety



Chemical Safety—An International Challenge**

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Today, when we talk of chemistry, we usually mean more than just the science in its purest sense. The term chemistry is often associated with products, industry, jobs, trade, progress, and risks. In the last 15 years in particular, improved levels of knowledge, and the experience of certain incidents, have raised awareness of possible risks in the chemicals sector, both amongst scientists and the public at large. Germany's response has been to create an appropriate statutory framework. However, particularly in an industry which relies on global trade, guarding against these risks is an international task. The export and import of chemicals has created flour-

ishing global trade flows; the natural transportation of chemicals through the atmosphere, water, or the food chain, resulting in their presence in environmental compartments or geographical regions where they are undesirable or even potentially harmful, is also a significant factor as chemicals become more widespread. There is also the economic aspect to consider, whereby one-sided restrictions may lead to distortions of competition in this fiercely contested market. Above and beyond this, it is a question of combining the economic interests of the industrialized nations with their moral obligations towards developing countries. Faced with these conflicts of

interests, numerous bodies and organizations, at both the national and international level, have taken up the issue with the aim of harmonizing the approach to chemical safety as far as possible. This review aims to provide an overview of the principal bodies and organizations involved in this field, and give an insight into the closely interwoven structures of cooperation taking place at both a political and a technical level.

Keywords: chemical safety • ecology • environmental protection • toxicology

1. Introduction

The chemical industry employs a large number of people and, hence, represents a key social and economic factor. The Organization for Economic Cooperation and Development (OECD) has estimated that some 12 million jobs around the world are dependent on the chemical industry. However, the production and use of certain chemicals also entails potential hazards for humans and the environment. Environmental awareness and particularly an awareness of the risks to human health have risen sharply in recent years. What is more, international commitments have been formed to create global conditions for sustainable development. These commitments were undertaken partly out of a sense of moral responsibility towards developing countries, who are themselves rarely producers but often customers or consumers of goods from

industrialized nations. This role distribution means that developing countries are often less knowledgeable about the risks associated with these products than the industrialized countries which produce them. There have been policy responses to address this issue. One key aspect is improving the level of knowledge vis-à-vis individual chemicals and expanding the exchange and dissemination of such knowledge.

2. National Regulations and the European Community

The formulation and introduction of statutory regulations and technical measures to reduce the adverse effects of chemicals is an on-going process in the Federal Republic of Germany. At the heart of these statutory regulations is the *Act on Protection against Dangerous Substances* (Chemicals Act).^[1] The essential character of the Chemicals Act is the manner in which it transcends individual products, media, and protection objectives.

- The substances themselves, as well as their presence in various products or usage forms, are evaluated with regard to their potential risks.

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[**] A list of the abbreviations used is presented in the Appendix. Further information concerning the flags and symbols in the frontispiece on the left are available from the authors.

- The effects on all compartments of the environment are significant.
- Equal weighting is given to the three protection objectives: environmental protection, occupational safety, and health protection.

The Chemicals Act has been concretized in numerous subsidiary regulations such as the Ordinance on Dangerous Substances, the Chemicals Prohibitions Ordinance, the Ordinance on Test Certifications and Other Documents under the Chemicals Act, the Ordinance on Costs of Official Acts under the Chemicals Act, the Poisons Information Ordinance, and the Ordinance on the Execution of Regulations of the European Communities on Substances and Preparations, as well as administrative regulations governing existing and new substances and good laboratory practice.

A large number of employees in industry, science, and government agencies are involved in implementing the Chemicals Act. At government level, there is a central chemicals registration office at the Federal Institute for Occupational Safety and Health (Bundesanstalt für Arbeitsschutz und Arbeitsmedizin, BAuA) and three evaluation offices: BAuA, the Federal Environmental Agency (Umweltbundesamt, UBA), and the Federal Institute for Health Protection of Consumers and Veterinary Medicine (Bundesinstitut für gesundheitlichen Verbraucherschutz und Veterinärmedizin, BgVV). The aim is to ascertain the potential hazards of a substance in its *entirety*. This approach serves as a basis in all EC states within the context of complete harmonization of chemical legislation within the EC through directives and regulations. The principal statutory instruments are the following directives: The directive on dangerous substances, the directive on the application of the principles of good laboratory practice, directives on risk evaluation for new and existing substances, directives relating to restrictions on

marketing and use, and preparation directives. These are supplemented by regulations on existing substances, the import/export of dangerous substances (prior informed consent procedure, PIC), and on substances which deplete the ozone layer. Substance legislation is characterized by the following three aspects:

- Obtaining scientifically validated data on the substance in question.
- Identifying the hazardous properties of substances through classification and labeling.
- Creating the necessary legal measures under administrative law to minimize the risks for humans and the environment.

Figure 1 contains an overview of the principle EC regulations. Regulations relating to the protection of the ozone layer are not included here.

Before a new chemical is launched on the market, all such “new substances” must be subjected to testing within the context of registration; the extent of testing is based on the planned substance volume. On the basis of the results, scientifically valid statements can be made concerning the dangers of a substance with regard to the protection objectives cited, and appropriate measures can be introduced to minimize the potential risks.

To achieve equally high protection objectives for existing substances (i.e., substances which were brought into circulation prior to September 18, 1981) the *Council Regulation (EEC) No. 793/93 of March 23, 1993 on the Evaluation and Control of the Risks of Existing Substances* was passed at the EC level. This introduced a procedure for uniform control and risk evaluation which also covered existing substances. Initially, existing data is accumulated on the most significant substances in terms of volume; these substances will then be subjected to comprehensive analysis within the context of risk

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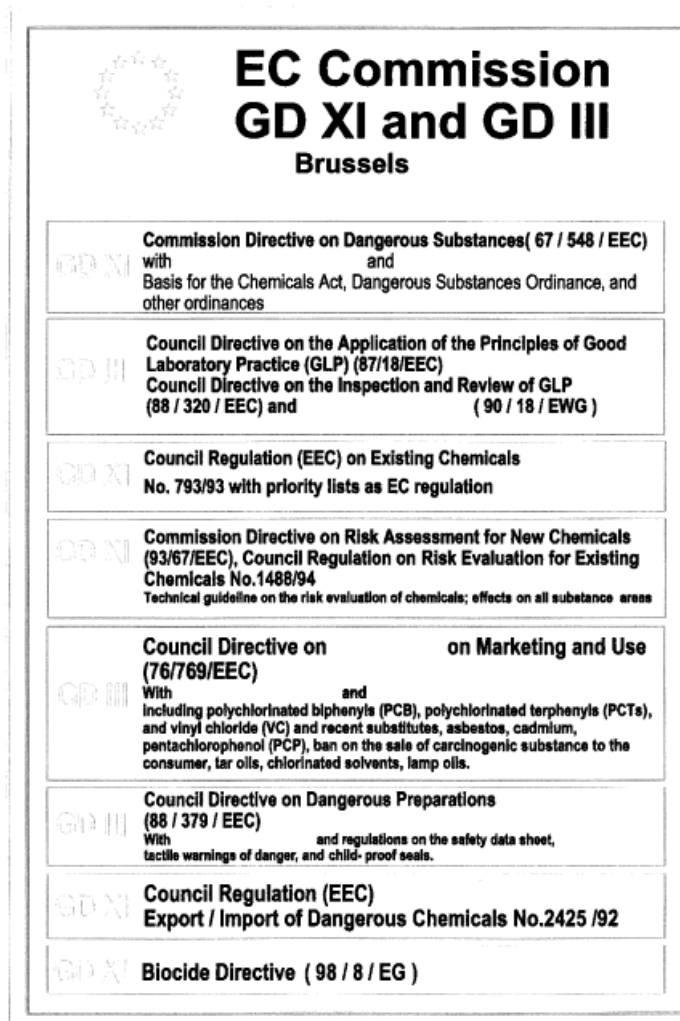


Figure 1. EC rulings on chemical safety.

evaluation. The criteria of risk evaluation, and the methodology to be employed, have been drawn up by experts from the member states at the EC level and summarized in a comprehensive document (*Technical Guidance Document* (TGD) on Risk Evaluation of Chemicals). The current state of the art regarding the evaluation of existing and new substances is reflected in this document. Essentially, evaluation involves comparing the concentration levels at which a substance occurs in the environment under given conditions (predicted environmental concentration, PEC), or to which humans may be exposed, with the concentration level not deemed likely to have an adverse impact on humans (*no observed adverse effect level*, NOAEL) and ecosystem (predicted *no-effect* concentration, PNEC). This creates the basis for a uniform EC approach to substance evaluation. Having been hampered by various problems, the first EC reports on existing substances were not completed until the end of 1997. These reports, which are prepared by the member states, also contain recommendations on whether or not measures should be taken to minimize the risks posed by a given substance. The EC Commission then distributes a proposal on possible measures amongst the member states.

The results are published in the official journal of the EC in the form of a "short report".

At the EC Commission, overall control of chemical safety is the responsibility of Directorate General (DG) XI (environment, nuclear safety, and civil protection), Directorate E (industry and environment), and in particular Directorate E2 (chemical substances and biotechnology). Directorate General XI is assisted by the European Chemicals Bureau (ECB), affiliated to the EC Commission's Joint Research Center (JRC, Ispra, Italy), which provides support on technical issues and overall handling of the labor-intensive risk evaluations. The ECB's work includes evaluation of existing substances, classification and labeling, the area of new substances, biocides, test methods, and issues relating to the export/import of chemicals. In its work, the ECB is dependent on intensive support from the member states, and therefore collaborates closely with them at a technical level.

In addition to the legal measures described, certain sectors of the German industry (e.g. wood preservatives, detergents) have also undertaken *voluntary commitments* as supporting measures. In these, for example, an industry may undertake to supply data on its products to a central authority, or to remedy existing data and knowledge deficiencies regarding the potential hazards of its products through appropriate studies. Voluntary commitments are always useful if they can respond to the need for action just as quickly, or indeed more quickly, than would be possible through the creation of a legal framework. In this way, unnecessary legislation procedures can be avoided. Admittedly, the observation, transparency, and efficiency of such voluntary commitments always needs to be accompanied by a government review in each individual case.

2.1. Advisory Committees for Existing Substances

In 1982 the Chemicals Act empowered the Federal Government to have existing substances tested in the same way as new substances, provided there are grounds for suspicion that the substance poses a hazard. In 1982 the Advisory Committee on Existing Chemicals of Environmental Relevance (Beratergremium für umweltrelevante Altstoffe, BUA) of the German Chemical Society (Gesellschaft deutscher Chemiker, GDCh) was created at the request of the Federal Government, with the aim of systematically ascertaining the risk potential of existing substances. In accordance with the principle of cooperation, the BUA is composed of equal numbers of representatives from the authorities, industry, and science. It creates a forum for continuous, scientifically based dialogue between these three groups on the subject of existing substances. The *BUA Substance Reports* were devised as a foundation for decision makers in government and industry. The BUA has since published over 200 reports on some 250 substances, the benefits of which have been manifold (e.g., as a decision-making aid for risk management of chemicals). The substance reports are available in book shops.^[2] Whenever topical issues arise requiring special discussion, ad hoc working groups are

deployed by the BUA; the following working groups exist at present:

- Endocrine disruptors
- Selection criteria for persistent organic pollutants (POP)
- Structure–effect relationships
- Ecotoxicological significance of the algae test
- Evaluation criteria for the maritime sector
- Safety factors within the context of risk evaluation
- Assessing exposure in soils and sediments
- Hydrocarbons as solvents

To implement the Federal Government's existing substance programme of December 1988, the BUA assumed responsibility for selecting those existing substances most worthy of reports; this work continues today. The reports were translated into English to make them accessible to a wider international public. In addition, the BUA assists the Federal Ministry for the Environment, Nature Conservation, and Nuclear Safety (Bundesministerium für Umwelt, Naturschutz und Reaktorsicherheit, BMU) in implementing the EC Existing Substances Regulation. The BUA was reorganized in the course of adaptation to EC Regulation 793/93 (Existing Substances Regulation). In the future, the aspect of occupational safety is also to be taken into account by the BUA. As a result, it is being renamed as the Advisory Committee for Existing Substances, but will retain the acronym BUA. In addition, membership of the BUA has been limited to a total of 13 in order to increase its effectiveness. The new BUA was founded in December 1997.

Since 1986 the Employment Accident Insurance Fund of the Chemical Industry (Berufsgenossenschaft der chemischen Industrie, BG Chemie) has published *toxicological evaluations*,^[3] aimed primarily at protecting employees from health impairments associated with the handling of materials. The evaluations are coordinated with the work of other national and international bodies (e.g. BUA, European Centre for Ecotoxicology and Toxicology of Chemicals (ECETOC), EC), to avoid duplication. To date, some 190 evaluations have been produced, representing an important contribution to the toxicological evaluation of existing substances. In view of the keen international interest in these publications, they are also available in English (*Toxicological Evaluations*^[3]).

Thanks to the Chemicals Act and other statutory instruments such as the *Federal Immission Control Act* and the *Federal Water Act*, Germany enjoys extensive protection against the risks from chemicals to humans and the environment.

3. International Activities

Joint international action is of great importance given the pronounced levels of imports and exports in the chemicals and products trade, and also in view of the ubiquitous spread of certain chemicals through air, water, and the food chain. Its importance is underlined by the concrete example of chloro-fluorocarbons (CFC) and other ozone-depleting substances. To begin with, CFCs were distinguished by their excellent refrigeration properties and cost-effective production; only later were the grave effects of these substances on the ozone


layer realized. This emphasizes the need for a comprehensive, cross-media approach when evaluating the environmental relevance of a substance, and illustrates the drastic effects of failure to adopt such an approach.

Within the context of a legislative framework, and also thanks to a voluntary initiative by industry, the production of CFCs in Germany has been discontinued altogether, and their use reduced substantially. It is a well-known fact that depletion of the ozone layer is a global problem which cannot be solved by a single state acting in isolation. A joint approach, such as that agreed in the Montreal Protocol and its amendments, is the only way forward if we are to counteract the destruction of the ozone layer. At the 9th Conference of the Parties to the Montreal Protocol in September 1997, the parties intensified and concretized their commitments. Classified according to their production and use in industrialized and developing nations as well as according to the respective substances or substance groups CFCs have already been phased out completely in some cases, or are due to be phased out in the foreseeable future. However, the phasing out of partially halogenated CFCs (H-CFC) will take effect more slowly since, according to current agreements, complete curtailment by the industrialized countries is not due until 2030 (2040 in developing countries).

3.1. Intergovernmental Forum on Chemical Safety (IFCS)

Agenda 21 is the work programme for the 21st century signed by more than 170 states in Rio de Janeiro in 1992 at the United Nations Conference on Environment and Development. In chapter 19 (Table 1) there are detailed mandates on the “environmentally sound handling of toxic chemicals” (“toxic” is used here in the sense of “hazardous”). Key cornerstones include the intensification of international cooperation and the coordination of on-going international and regional activities. In the course of implementing this programme, in April 1994 the International Conference on Chemical Safety in Stockholm—staged by the United Nations Environment Programme (UNEP), the International Labour Organization (ILO), and the World Health Organization (WHO)—was attended by 110 states. The Intergovernmental Forum on Chemical Safety (IFCS) was founded at this conference; its main tasks are to control and harmonize the procedure for implementing Chapter 19. It is to draw up

Table 1. Key issues of Chapter 19 of Agenda 21 of the UNCED.

<div>UNCED - Rio 1992</div> 	
Resolutions included in Chapter 19 of Agenda 21 with six key issues which were drafted by the IPCS:	
1. Risk assessment 2. Harmonization of classification 3. Exchange of information 4. Risk minimization 5. Management 6. Illegal traffic	

recommendations for governments as well as international and intergovernmental organizations. Six key issues were identified at the conference, and a plan of action with concrete activities along with timetable was drawn up for each. This plan of action was welcomed and accepted by the Commission on Sustainable Development (CSD), a UN body which monitors the implementation of Agenda 21.

Figure 2 illustrates the development of the IFCS over time.

Following the first meeting in Stockholm in 1994, the second forum (IFCS II) was held in Ottawa in February 1997 under the motto "In Partnership For Global Chemical Safety". It was attended by some 350 delegates from 116 states, 25 nongovernmental organizations (NGO), and 10 intergovernmental organizations (IGO). Topics of the meeting included the continued international approach to POPs, future work on substance evaluation, endocrine disruptors, and the development of national structures for chemical safety (capacity building), particularly in developing countries. The third forum (IFCS III) is due to be held in Brazil in the latter half of the year 2000.

In between these meetings, the Intersessional Group (ISG) is active. It consists of 26 government representatives as well as the President and four Vice-Presidents of the IFCS. Ad hoc

working groups may be deployed both by the forum itself and by the ISG to address certain issues (e.g., for POPs, see Section 3.1.3). Above and beyond this, the Forum Standing Committee (FSC) was formed from 14 states and 4 NGOs as a steering organization.

The foundation of the IFCS created a mechanism which allows all governments, as well as all interest groups, to become involved in the international approach to chemical safety, including NGOs. NGOs include industry, trade unions, environmental and consumer associations, and representatives from the world of science such as the International Council of Chemical Association (ICCA), the International Federation of Chemical, Energy, Mine and Federal Workers Union (ICEM), Greenpeace International, the World Wildlife Fund (WWF), GDCh, the International Union for Pure and Applied Chemistry (IUPAC), and the International Union for Toxicology (IUTOX). All groups have been involved since the inception of the IFCS.

In 1995 the UN organizations UNEP, WHO, ILO, Food and Agriculture Organization (FAO), United Nations Industrial Development Programme (UNIDO), and OECD established the Inter-Organization Programme for the Sound Management of Chemicals (IOMC) as a mechanism for coordinating the activities in Chapter 19 of Agenda 21. The foundations for this were created at the first meeting of the IFCS in Stockholm. It was joined by the United Nations Institute for Training and Research (UNITAR) in 1997. To help cut costs, the IOMC is integrated into the WHO infrastructure and is therefore based in Geneva. The Inter-Organization Coordinating Committee (IOCC) assumes a steering function within the IOMC. Summaries of the individual programmes and dates of the various meetings on key issues are available from the IOMC.

3.1.1. Capacity Building

To protect against potential dangers and minimize the risks from chemicals, an infrastructure is required to ensure appropriate chemical management. Elements of such a management system include relevant legislation, the option and capability of performing risk evaluations, information to avoid the incorrect handling of chemicals, and the ability to respond in the best possible way in the event of an accident or poisoning incident. Most industrialized countries have such structures, but developing countries and many countries whose economic systems are currently in the throes of transformation often have substantial deficits in this respect. Developing such infrastructures (capacity building) is also addressed by Chapter 19 of Agenda 21, and UNITAR plays a key role in this field. In 1996 UNITAR and the member organizations of the IOMC launched a pilot programme to assist governments with the development of infrastructures. In four countries (Argentina, Ghana, Slovenia, and Indonesia), the aim is to initiate development towards a chemical safety structure, with procedures being tailored to the specific requirements of each individual country. The first step involves the drafting of a national profile (NP), in which existing management structures are subjected to comprehen-

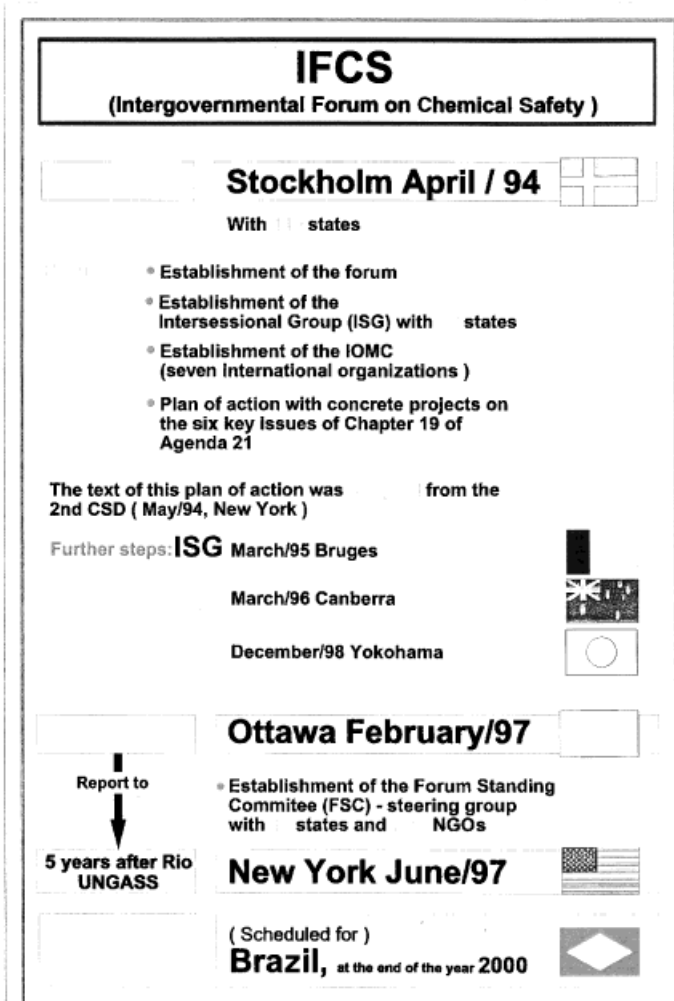


Figure 2. Development of the IFCS.

sive analysis. UNITAR has devised a guide to simplify and standardize the procedure for preparing an NP. Although NPs are primarily designed for developing countries, some industrialized nations (e.g. the USA, Australia) have also drawn up their own NPs. The NPs may serve as examples to other states, or aid in the critical review of the structures in the own country. Germany, too, is currently in the process of preparing an NP. The UNITAR project also involves assistance with the preparation of appropriate training documents, and, finally, the promotion and coordination of all on-going bilateral and multilateral initiatives in this field. The Federal Government has also commissioned the Deutsche Gesellschaft für Technische Zusammenarbeit (GTZ) to implement a capacity building project which includes the following aspects:

- There is a provision of technical background information to serve as a decision-making basis for developing countries.
- The concepts will be tested in selected developing countries (a maximum of six).
- The opportunities afforded by alternative products will be taken into account.
- A contribution will be made to national and international coordination and cooperation.

At the planning stage, care was taken to ensure sufficient scope, so that the needs of the partner countries could be accommodated in a targeted manner. The project is being implemented in collaboration with other bilateral and international programmes

3.1.2. Prior Informed Consent (PIC)

Within the context of the UNEP and the FAO, the *PIC Convention* was drawn up to protect developing countries from hazardous chemical imports. It aims to obligate exporting countries to notify the importing country in advance of their intention to transfer hazardous chemicals, and not to import them without the consent of the latter. In the past, this occurred internationally on a voluntary basis; Agenda 21 calls for the creation of a legally binding convention. Negotiations on the PIC were completed in March of this year, with ratification expected in September 1998 in Rotterdam. Table 2 lists the substances included in the PIC Convention.

3.1.3. Persistent Organic Pollutants (POP)

Persistent organic pollutants represent a particular problem for humans and the environment around the world, as their physical-chemical properties, persistency, and propensity for bioaccumulation mean that they can be transported across national borders and may accumulate in certain organisms. They are highly soluble in fat, which encourages bioaccumulation in the fatty tissues of organisms. They are deposited as a result of, for example, "global distillation" or condensation in the colder regions of the planet. This explains why northern states such as Canada are particularly interested in a global limitation of such substances. POPs are manufactured primarily in industrialized countries, but used predominantly in

Table 2. Lists of chemicals of the PIC Convention.

2,4,5-T ("agent orange")
aldrin
captafol
chlordane
chlordimeform
chlorbenzilate
DDT
dieldrin
dinoseb and dinoseb salts
1,2-dibromoethane
fluoroacetamide
HCH (mixed isomers)
heptachlor
hexachlorobenzene
lindane
mercury compounds
PCP
monocrotophos
methamidophos
phosphamidon
methylparathion
parathion
crocidolite
polybrominated biphenyls (PBBs)
polychlorinated biphenyls (PCBs)
polychlorinated terphenyls (PCTs)
tris(2,3-dibromopropyl) phosphate

newly industrializing and developing countries, since they are relatively cheap and simple to produce and have a low *acute* toxicity.

In accordance with decision 18/32 of the UNEP Governing Council in May 1995, the ad hoc working group on POPs was set up by the IFCS. Its task is to compile data on the sources, chemical and toxicological properties of POPs, and their modes of transfer as well as possible substitutes. From June 17–22, 1996 this working group held a conference in Manila. The conference was divided into a session of international experts and the working-group session; it was attended by 32 states, 7 NGOs and 7 IGOs. Assisted by the experts, the working group drafted a report on possible approaches for reducing or eliminating POPs. The key point of this report is the IFCS's concluding recommendation to the UNEP Governing Council and the World Health Assembly (WHA), the decision-making body of the WHO: It calls for the creation of a globally valid, internationally binding instrument to minimize the risks emanating from POPs. An Intergovernmental Negotiating Committee (INC) will be deployed to prepare such an agreement. Initially, it will focus on 12 POPs (aldrin, chlordane, DDT, dieldrin, endrin, heptachlor, mirex, toxaphene, hexachlorobenzene, PCBs, dioxine, furans), which also form part of negotiations by the UN and the Economic Commission for Europe (ECE) on the *Geneva Convention on Long-Range Transboundary Air Pollution* (LRTAP). These substances are pesticides, industrial chemicals, and unwanted by-products of production processes. In compiling the substances, no uniform criteria were applied. Consequently, in the future, a UNEP/IFCS group of experts, using the work of the IFCS working group as a basis, is to draw up scientifically validated criteria for considering additional POPs with regard to international activities.

3.1.4. Endocrine Disruptors

There is unanimous international agreement that the effects of certain chemicals on the hormone system will constitute a key aspect of chemical safety in future, and hence for evaluating substance-inherent properties. There is growing suspicion that certain substances in this group may adversely affect fertility. However, there is a major need for research in this field. To ensure that the necessary resources are utilized in a targeted manner (and avoid duplication), and to obtain substantiated results as quickly as possible, international cooperation is needed. As agreed at IFCS II, the IOMC is to adopt a coordinating role in this respect. Germany has also earmarked substantial resources for research into these substances and their effects. The IPCS is endeavouring to draw up an international inventory of on-going research projects. In addition, the OECD will work on developing appropriate test methods.

3.2. International Programme on Chemical Safety (IPCS)

The IPCS was founded in 1980 as a cooperation between the UNEP, the WHO, and the ILO. The objective of the IPCS is to determine scientific foundations for assessing the risk to human health and the environment from chemicals, with the aim of strengthening national and international endeavours in the field of chemical safety. A total of 36 states are involved in the IPCS's work. It is not only the states involved who benefit from this work, but also, and in particular, those countries with little experience in the creation of chemical safety structures.

3.2.1. Results

One key focus of the IPCS's work is undoubtedly the compilation and dissemination of findings concerning the risks to humans and the environment from chemicals which may be of industrial or natural origin. To this end, numerous monographs have been prepared on substances (generally existing substances) and evaluation methods (Figure 3), and there have been collaboration between the nations involved in IPCS and internationally recognized experts from around the globe. The following results have been published:^[4]

- *Substance reports* (Environmental Health Criteria, EHC)

These reports are designed for scientific experts and contain the latest findings on health hazards and risks for a given substance or group of substances. More recent EHCs also contain details of impact on the environment. There are currently some 190 EHCs.

- *Safety guidance documents* (Health and Safety Guides, HSG)

HSGs contain details of toxicity in a language which is also accessible to nonexperts as well as information on usage, handling, storage, and first-aid treatment. They are aimed at decision makers in industry and administration. Some 100 HSGs have been published to date.

- *Safety data sheets* (International Chemical Safety Cards, ICSC)

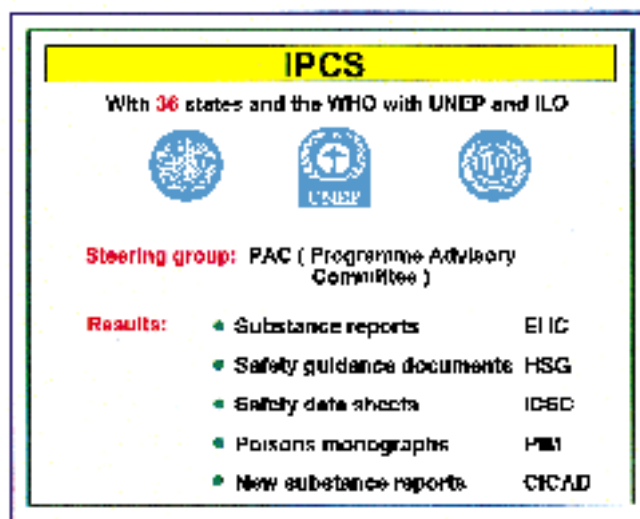


Figure 3. IPCS publications.

These contain essential data on individual products and information about health protection and safe handling, tailored to the use of the product (e.g. in factories or agriculture). There are currently some 1000 chemical safety cards at the UN level, which have also been translated into German by the BgVV.

- *Poisons monographs* (Poisons Information Monographs, PIM)

These contain a brief description of the principal chemical, physical and toxicological properties of each substance, and advice on the diagnosis and treatment of poisoning victims. PIMs are designed for poisons information centers and other advice agencies.

The IPCS will continue to produce these publications, which are to be made available to as many interested individuals as possible. With this in mind, the expectations of the users of these reports are taken very seriously. Interested parties in developing countries and in countries in the throes of economic transformation can obtain the publications at a reduced price. Germany is actively involved in the preparation of EHCs and HSGs and bears the printing costs for these documents.

3.2.2. Pilot Phase for New Substance Reports

In addition to the monographs cited above, a pilot phase is currently underway to produce "Concise International Chemical Assessment Documents" (CICAD) containing data on the hazard potential of a given substance, dosage/effect ratios, and risk characterizations based on sample exposure data. CICADs are generally based on preexisting substance reports. These national or regional substance reports are to be updated within the context of the IPCS; in other words, any studies published since the report was drawn up are to be included. Where available and meaningful, exposure data will also be logged. This is implemented under the aegis of scientific authorities or institutes, who will then hand over the revised report to international experts for their opinion. Institutions who do not produce any substance reports

themselves can also get involved in the preparation of CICADs, by collaborating with the country or institution which produced the original report. Experts hope that the CICAD procedure will enable existing national substance reports to be converted into internationally applicable, recognized substance reports at a comparatively low cost and reasonable manpower input and within a relatively short amount of time. The BUA substance reports described above are particularly well-suited to inclusion in the CICAD procedure. Some states have also expressed an interest in preparing CICAD reports on substances not previously covered by other documents. Following conclusion of the pilot phase, which comprises 15 substance reports, a critical review will be needed to determine whether expectations have been met. The BMU has donated financial and manpower resources to the CICADs. The first six CICADs (over 1,2-dichloroethane, 3,3-dichlorobenzidine, 1,1,2,2-tetrachloroethane, methyl methacrylate, limonene, and *o*-toluidine) are scheduled for publication in early 1998.

3.2.3. Preserving Transparency and Acceptance

To gain general international acceptance, the IPCS has always placed great value on the scientific integrity and independence of the experts involved in its work and the transparency of its procedures. Consensus can generally be reached on the overall message of reports such as EHCs or HSGs. Should this prove impossible in individual cases, dissent may be documented in the report at the insistence of one or more experts. To promote transparency, working-group meetings at which evaluations, summaries, or recommendations are drafted are also open to observers not directly involved in the preparation process.

Beginning with an inventory of all existing methods, the IPCS is currently involved in an extensive project to compare the various procedures for evaluating chemicals. The aim of this project is to promote mutual understanding and acceptance.

3.3. OECD Activities

Another key international player in the field of chemical safety is the OECD.^[5] Together, the 29 OECD member states cover some 78 % of global chemical production. Over the past 20 years the OECD has demonstrated great commitment to chemical safety, from the point of view of securing economic growth whilst embracing environmental protection considerations (Table 3). In 1971 the OECD set up a chemicals programme specifically for this purpose, which underwent a major expansion in 1978 (Environmental Health and Safety Programme, EHS). The objectives are to protect humans and the environment from chemicals, to render chemical policy transparent, and to avoid trade barriers. Its activities encompass new chemicals, pesticides, pharmaceutical products, and existing substances. The OECD has emerged as a central coordinator in the preparation of substance reports.

Governments and industry have derived significant benefits from the EHS programme. The mutual recognition of data on

Table 3. Activities of the OECD, Paris, in chemical safety (with 29 states).



Principal focuses of work: international harmonization of measures to identify and prevent risks from chemicals.
– Mutual acceptance of data
• Test methods for chemicals and pesticides
• GLP for pharmaceuticals, chemicals, and pesticides
– Processing of existing chemicals
• Evaluation of substances, with the work to be shared between member states
• Proposed measures for selected substances
– Risk identification and minimization
– Chemical accidents
– Biotechnology
Working groups:
– Chemical test methods
– GLP
– Existing substances
– Risk evaluation
– Plant-protection agents
– Harmonization of classification
Organization of the work:
– Plenum (joint meeting) every nine months
– Combined session with the pesticides group
– Steering committee

new products, the avoidance of work duplications, the exchange of expertise and information, and the harmonization of regulations have led to substantial savings. The OECD estimates that savings to date for industry and the member states, after deducting the expenses for the secretariat and the contributions of the member states, amount to some 100 million DM. Added to this are other benefits, such as the reduction in the number of animal experiments and the advantages for health and the environment.

3.3.1. Screening Information Data Sets (SIDS)

With the intensive collaboration of the member states and industry since 1990, Screening Information Data Sets (SIDS) on existing substances have been drawn up, containing details of substances, risks, and in some cases, exposure.^[6] SIDS target substances produced in volumes of more than 10 000 tonnes in one member state, or more than 1 000 tonnes in at least two member states. The work is coordinated with the activities of the EC and the IPCS. Between 1992 and 1996 some 100 chemicals were considered; a further 200 or so are currently in progress. The SIAR (SIDS Initial Assessment Reports) prepared on the basis of SIDS are not as extensive as EHCs or the EC substance reports currently under preparation. They are intended primarily to indicate whether the existing data on a given substance is in need of supplementation, and whether the substance is worthy of further investigation on the basis of the data available (e.g. within the context of a risk evaluation).

3.3.2. Mutual Acceptance of Data (MAD)

The OECD also plays a key role in the mutual recognition of test data. In collaboration with the member states, industry, and science, it has drawn up guidelines for test methods which

are recognized and applied by all member states. There are currently some 90 test methods in existence, which are continually updated. These test methods are supplemented by the principles of good laboratory practice (GLP), which lays down international standards governing the manner in which experiments are performed on substances (particularly for chemicals, pharmaceuticals, and pesticides). These GLP principles were revised and updated in 1997. Texts and comments on the test methods and GLP are available in book shops.^[7, 8]

3.3.3. Harmonization of Classification and Labeling

Chapter 19 of Agenda 21 also calls for a harmonized international system for the classification and labeling of chemicals by the year 2000. This means specifying a common basis for all chemicals and preparations, including the various forms of use. The systems currently in place make a distinction between dangerous goods and dangerous substances. It is hoped that the new system will be based as far as possible on existing systems, such as those of the USA, the EC, and the United Nations Committee of Experts on the Transport of Dangerous Goods (UNCETDG). There are numerous factors favoring the introduction of a harmonized international system, such as the elimination of trade barriers, reduced costs, avoidance of duplication of tests (which in turn means fewer experiments with animal), and a higher degree of acceptance through transparency.

The harmonization of criteria for the classification of health and environmental risks is being spearheaded by the OECD. In addition, a working group set up by the ILO and UNCETDG is currently reviewing the criteria for the classification of physical-chemical risks, whilst the ILO is reviewing the harmonization of hazard disclosure (labeling/safety data sheets). The organizations have agreed that the criteria for classification and labeling should be completed during the course of 1998.

3.4. Improved Coordination of Cooperation

Programme area A of Chapter 19 of Agenda 21 includes the obligation to evaluate chemicals on an international basis. At the first IFCS meeting, delegates formulated the ambitious target of conducting international evaluations of some 200 substances by 1997, and a further 300 substances by the turn of the millennium. In view of the limited financial and staff resources available, it is all the more important to coordinate on-going work as effectively as possible, particularly if duplication is to be avoided. Consequently, the OECD and IPCS are endeavoring to harmonize their sub-

stance evaluation involvement even more closely. The formation of a joint IPCS/OECD steering group could aid progress. Possible members of such a group would include the secretariats of the IPCS and OECD as well as representatives of involved member states and international organizations. Such a steering group could define the framework within which evaluation of a substance or group of substances is to take place (e.g. EHC, CICAD, SIAR). Consequently, EC studies on existing substances are likewise included, since the EC submits drafts of the EC reports on existing substances to the OECD, and these are discussed at the SIDS Initial Assessment Meetings (SIAM) before being subjected to final discussion amongst EC experts. Figure 4 summarizes the activities involved in the preparation of substance reports.

4. Outlook

The implementation of Chapter 19 of Agenda 21 has made good progress compared with other topics in the Agenda, and tangible achievements have already been made. Nevertheless, international negotiations are by their very nature highly complex and generally hard-going. Linking official tasks, scientific findings, and economic concerns at the international level makes it even more difficult to achieve concrete improvements in chemical safety.

In the future, continuing the work on substance reports will remain an essential task at the national and international level, since the vast diversity of existing substances means that a knowledge of their potential risks is very limited or only accessible to certain groups. Without a doubt, future international cooperation in the field of chemical safety will continue to focus on the central themes of POPs and the development of national structures for chemical safety (capacity building) in developing countries and countries in the throes of economic transformation.

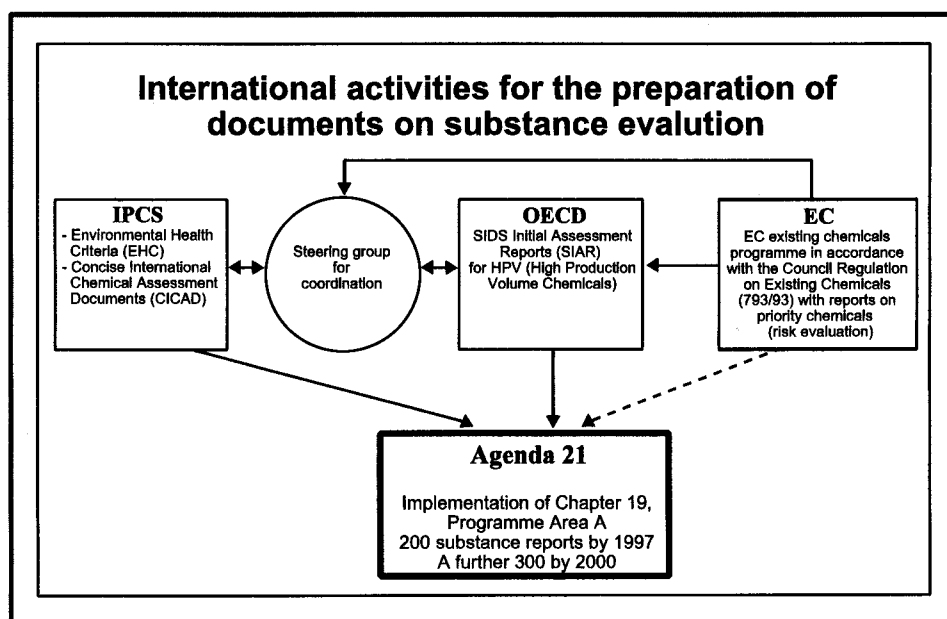


Figure 4. International preparation of substance reports.

With financial and staff resources becoming increasingly limited, in the future it will become all the more important to prioritize. Only those problems requiring an *international* solution, or which can only be solved *internationally*, should be addressed.

In addition to all these activities, we also need to consider whether developments in the chemical sector are consistent with the principle of sustainable development. Without a doubt, risk evaluations and substance regulations are only part of such a development, since they do not take effect until a product becomes tradable and not at the design stage. A farther reaching approach to sustainability lies in excluding the potential hazard features and associated risks at the development stage of a chemical compound. In addition, we also need to consider whether it is actually expedient for risk reduction to focus on individual substances, or whether we need to find ways of reducing the volume of chemicals used. Added to this are the aspects of resource conservation and energy saving, which have been neglected to date.

Appendix: List of Abbreviations

BAuA	Federal Institute for Occupational Safety and Health
BG Chemie	Employment Accident Insurance Fund of the Chemical Industry
BgVV	Federal Institute for Health Protection of Consumers and Veterinary Medicine
BMU	Federal Ministry for the Environment, Nature Conservation, and Nuclear Safety
BUA	Advisory Committee on Existing Substances
CFC	Chlorofluorocarbon
ChemG	Chemicals Act
CICAD	Concise International Chemical Assessment Document
CSD	Commission on Sustainable Development
DG	Directorate General of the EC Commission
EC	European Community
ECB	European Chemicals Bureau
ECE	Economic Commission for Europe
ECETOC	European Centre for Ecotoxicology and Toxicology of Chemicals
EHC	Environmental Health Criteria
FAO	Food and Agriculture Organization of the United Nations
FSC	Forum Standing Committee of the IFCS
GDCh	German Chemical Society
GefStoffV	Dangerous Substances Ordinance
GLP	Good Laboratory Practice
GTZ	Deutsche Gesellschaft für Technische Zusammenarbeit
H-CFC	Partially halogenated chlorofluorocarbon
HSG	Health and Safety Guide
ICCA	International Council of Chemical Association
ICEM	International Federation of Chemical, Energy, Mine and General Workers Union
ICSC	International Chemical Safety Cards
IFCS	Intergovernmental Forum on Chemical Safety

IGO	Intergovernmental Organization
ILO	International Labour Organization
INC	Intergovernmental Negotiating Committee
IOCC	Interorganization Coordinating Committee
IOMC	Interorganization Programme for the Sound Management of Chemicals
IPCS	International Programme on Chemical Safety
ISG	Intersessional Group of the IFCS
IUPAC	International Union for Pure and Applied Chemistry
IUTOX	International Union of Toxicology
JRC	Joint Research Center
LRTAP	Long-Range Transboundary Air Pollution
MAD	Mutual Acceptance of Data
NGO	Nongovernmental Organization
NOAEL	No Observed Adverse Effect Level
OECD	Organization for Economic Cooperation and Development
PAC	Programme Advisory Committee of the IPCS
PEC	Predicted Environmental Concentration
PIC	Prior Informed Consent Procedure
PIM	Poisons Information Monograph
PNEC	Predicted No-Effect Concentration
POP	Persistent Organic Pollutant
SIAM	SIDS Initial Assessment Meeting
SIAR	SIDS Initial Assessment Report
SIDS	Screening Information Data Set
UBA	Federal Environmental Agency
UNCED	United Nations Conference on Environment and Development
UNCETDG	United Nations Committee of Experts on the Transport of Dangerous Goods
UNEP	United Nations Environment Programme
UNGASS	United Nations General Assembly Special Session, June 1997, New York
UNIDO	United Nations Industrial Development Organization
UNITAR	United Nations Institute for Training Research
WHA	World Health Assembly
WHO	World Health Organization
WWF	World Wildlife Fund

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