



**Schriftenreihe der
Bundesanstalt für
Arbeitsschutz und
Arbeitsmedizin**

Sonderschrift

S xx



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National Profile

Anmeldestelle

ChemG

Chemicals Management in Germany

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Verlag/Druck: Wirtschaftsverlag NW
Verlag für neue Wissenschaft GmbH
Bürgermeister-Smidt-Str. 74-76, D-27568 Bremerhaven
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Herausgeber: Bundesanstalt für Arbeitsschutz und Arbeitsmedizin
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OVERVIEW OF CONTENTS

INTRODUCTION	8
CHAPTER 1 BACKGROUND INFORMATION	10
CHAPTER 2 PRODUCTION, EXPORT/IMPORT AND USE OF CHEMICAL SUBSTANCES	15
CHAPTER 3 SPECIAL PROBLEMS WITH CHEMICAL SUBSTANCES	20
CHAPTER 4 STATUTORY REGULATIONS AND VOLUNTARY AGREEMENTS	28
CHAPTER 5 PROCEDURES, PARTICIPATING MINISTRIES AND AUTHORITIES	51
CHAPTER 6 NON-GOVERNMENTAL ORGANIZATIONS	72
CHAPTER 7 COOPERATION BETWEEN THE FEDERAL AND REGIONAL AUTHORITIES	79
CHAPTER 8 DATA STOCKS AND DATABASES	93
CHAPTER 9 TECHNICAL INFRASTRUCTURE	102
CHAPTER 10 INTERNATIONAL RELATIONS	105
ANNEXES	107

LIST OF CONTENTS

INTRODUCTION	8
CHAPTER 1 BACKGROUND INFORMATION	10
1.1 Basic geographical and demographic conditions	10
1.2 Politico-geographical structure	12
1.3 Industry and agriculture	14
CHAPTER 2 PRODUCTION, EXPORT/IMPORT AND USE OF CHEMICAL SUBSTANCES	15
2.1 Turnover, number of employees, export/import	15
2.2 Use of chemicals according to classes of substances	17
2.3 Chemical wastes and environmental pollution	18
Chemical wastes	18
Environmental pollution	19
CHAPTER 3 SPECIAL PROBLEMS WITH CHEMICAL SUBSTANCES	20
3.1 Special environmental problems	20
Drinking water	21
Hazardous waste sites	22
CHAPTER 4 STATUTORY REGULATIONS AND VOLUNTARY AGREEMENTS	28
4.1 Basic administrative framework	28
4.2 Statutory regulations	28
4.2.1 Chemicals management in the narrower sense	29
EC Regulations, directives and guidelines	29
National laws and guidelines	32
National ordinances	32
National administrative provisions	33
Technical Rules for Hazardous Substance (TRGS)	34

4.2.2 Chemicals management in the wider sense	34
Biocides	34
Plant protection products and fertilizers	34
Pharmaceuticals	37
Laundry and cleaning products	37
Foods and consumer goods	37
Waste law	38
Protection against immissions	39
Water protection	41
Soil protection	42
Protection of animals	42
Chemical weapons	42
Transport of dangerous goods	43
4.2.3 Additional regulations specific to individual <i>Länder</i>	44
Baden-Württemberg (BW): as at 31.10.1999	44
4.3 Voluntary agreements with the chemical industry	46
4.3.1 At national level	46
4.3.2 In individual <i>Länder</i>	50
Hamburg	50
Lower Saxony	50
North Rhine-Westphalia	50
 CHAPTER 5 PROCEDURES, PARTICIPATING MINISTRIES AND AUTHORITIES	 51
5.1 Chemicals management in the narrower sense	51
5.1.1 European procedure for new substances	51
General information on the duty to notify chemical substances	51
Tonnage-based procedure	51
Prior inquiry duty / utilization of existing test reports	52
Good laboratory practice (GLP)	52
Submission of the notification documents	53
5.1.2 European procedure for existing chemical substances	54
5.1.3 International activities concerning existing chemical substances, SIDS	56
Screening Information Data Sets (SIDS)	57
5.1.4 Marketing, production and use of chemicals	59
Classification	59
Labelling, safety data sheet	60
Prohibitions and restrictions	60
Occupational safety rules	60
5.1.5 Export/Import of dangerous substances, PIC procedure	62
Notification procedure for the export from the EU of certain dangerous chemicals	62
Prior Informed Consent (PIC) procedure	62
Labelling rules	63
The European Commission's database "EDEXIM"	63
Import notifications by non-EU countries	63
5.1.6 CFC regulations	64
 5.2 Chemicals management in the wider sense	 65
5.2.1 Pharmaceuticals	65
5.2.2 Plant protection products	66
5.2.3 Laundry and cleaning products	67
5.2.4 Transport of Dangerous Goods	68
5.2.5 Chemical weapons	69

CHAPTER 6	NON-GOVERNMENTAL ORGANIZATIONS	72
6.1	Industry associations	72
6.1.1	The Chemicals Industry Association (VCI)	72
6.1.2	The Agricultural Industry Association (IVA)	74
6.1.3	The Chemical Trading Association (VCH)	74
6.2	German Statutory Accident Insurance Institutions and trade unions	74
6.2.1	The Federation of German Statutory Accident Insurance Institutions for the Industrial Sector (HVBG)	74
6.2.2	The Industrial Trade Union for the Mining, Chemicals and Energy Industries (IG BCE)	75
6.3	Environmental and consumer protection organizations	76
6.3.1	Greenpeace	76
6.3.2	Consumer Associations' Working Party (AgV)	77
6.4	Scientific organizations	78
6.4.1	Society of German Chemists (GDCh)	78
CHAPTER 7	COOPERATION BETWEEN THE FEDERAL AND REGIONAL AUTHORITIES	79
7.1	Interministerial commissions and general coordination mechanisms	79
	Federal/regional Committee on the Safety of Chemicals (BLAC)	79
	Federal/regional Working Group on Environmental Information Systems (BLAK-UIS)	79
	Federal/regional Expert Committee "Transport of Dangerous Goods" (BLFA-GG)	79
	Commission for the Identification and Treatment of Symptoms of Poisoning (Poison Information Centres, GIZ)	80
	Regional Committee on Protection against Immissions (LAI)	80
	Regional Working Group on Water (LAWA)	80
	Regional Working Group on Waste (LAGA)	80
	Regional Committee on Soil Protection (LABO)	80
	Regional Committee on Occupational Safety and Safety Technology (LASI)	80
	Committees for the Harmonization of Procedures for the Notification of New and Existing Chemical Substances	80
	Steering Group for Data Processing Procedures	81
	Committee on Hazardous Substances (AGS)	82
	MAK Commission	82
	Advisory Committee on Existing Chemicals of Environmental Relevance (BUA)	82
7.2	Enforcement at regional level	82
7.2.1	Hamburg	82
	Enforcement of the Chemicals Act	82
	Enforcement of the rules on the transport of dangerous goods	85
	Enforcement of the Foodstuffs and Commodities Act	86
7.2.2	Saxony	89
	Enforcement of the rules and regulations on chemicals	89
	Enforcement of the rules and regulations on plant protection	90
	Enforcement of the rules and regulations on waste and soil protection	91
	Enforcement of the rules and regulations on water	92
	Literature and databases:	92

CHAPTER 8 DATA STOCKS AND DATABASES	93
8.1 Databases available to the Notification Unit within the Chemicals Act (own and external)	93
Admin (administration relating to the Chemicals Act)	93
NST database for new chemical substances	93
EINECS (inventory of existing chemical substances)	94
HEDSET program for the recording of existing chemical substances	94
BUA substance reports	95
EDEXIM (European Export/Import database) and the national database EPA-notification	95
8.2 Joint substance-data pool shared by the Federal Government and the Länder	97
8.3 Joint Länder Database on Hazardous Substances (GDL)	98
8.4 Central substance-data pool	99
8.5 Further databases	99
 CHAPTER 9 TECHNICAL INFRASTRUCTURE	 102
9.1 GLP procedure	102
9.2 Good professional practice	103
 CHAPTER 10 INTERNATIONAL RELATIONS	 105
10.1 Participation in international organizations and bodies	105
10.2 Technical assistance projects	105
 ANNEXES	 107
Annex 1: List of abbreviations	107
Annex 2: List of addresses	111
Federal authorities	111
Regional authorities	112
International institutions	113
Non-governmental organizations	114

Introduction

In 1992 Rio de Janeiro was the setting for a United Nations (*Conference on Environment and Development - UNCED*). Known by the general public as the Rio Conference, it succeeded in turning "sustainable development" into a key international goal. The more than 170 participating countries passed Agenda 21, a programme of action for the 21st century. Implementation of the aims described in Agenda 21 is monitored by the *Commission on Sustainable Development (CSD)*.

Chapter 19 of Agenda 21 contains objectives for environmentally compatible handling of toxic chemicals, including measures for the prevention of the illegal international trade in toxic and dangerous products. An essential part of chapter 19 concerns the coordination of international and regional activities as well as the intensification of international cooperation.

For the purpose of controlling compliance with Chapter 19 and its harmonized implementation, in April 1994 the *United Nations Environment Programme (UNEP)*, the *International Labour Organization (ILO)* and the *World Health Organization (WHO)* held the Chemical Safety Conference in Stockholm. It was at this conference, which was attended by participants from 130 countries, that the *Intergovernmental Forum on Chemical Safety (IFCS)* was established. The *IFCS* elaborates recommendations for governments as well as for international and transnational organizations.

As an important element in improving global cooperation in the field of chemicals safety, the *IFCS* recommends that, as a matter of urgency, the individual states should take stock of the national structures for chemicals management in the form of a so-called "**National Profile**" (NP). The aim of the National Profile is to provide relevant information on the areas of responsibility and procedures associated with chemical substances as well as to make statements on the effectiveness of the specific rules and regulations. In addition, the National Profiles from the industrialized nations can serve as a model for developing countries and countries undergoing economic change. Together with the *IFCS* secretariat, the *United Nations Institute for Training and Research (UNITAR)* has published a guidance document which, by laying down a structure and providing useful advice on how to proceed, assists in the production of a NP and helps ensure international comparability. So far, more than 30 countries have published a NP, e.g.: Australia, Canada, France, Ghana, Hungary, Indonesia, Mexico, Nicaragua, Slovenia, Switzerland and the USA.

At the beginning of 1997 the **Federal Environment Ministry** asked the **Federal Institute for Occupational Safety and Health (BAuA)** - the **Notification Unit within the Chemicals Act** (Amst ChemG) - in Dortmund to produce a NP for Germany. This task is to be seen against the background of the fact that the BAuA-Amst ChemG is the central coordinator for the notification procedure according to the Chemicals Act as well as the competent authority for the enforcement of the following European regulations and agreements: Council Regulation (EEC) No 2455/92 concerning the export and import of certain dangerous chemicals, the Rotterdam Convention on protection against the import of dangerous chemicals, Council Regulation (EEC) No 793/93 on the evaluation and control of the risks of existing substances, Council Regulation (EEC) No 3093/94 on the prohibition of CFCs and the Montreal Protocol.

Publication of a NP for Germany, that is to say, a survey of national chemicals management, is expected to have a number of positive effects, inter alia:

- increased effectiveness of the work performed by the government/authorities through the provision of clear information on chemicals management;
- initiation or simplification of the information-exchange and dialogue procedures between authorities on the one hand and between authorities and non-governmental organizations on the other;
- the provision of more comprehensive information to the general public and to industry as a result of readily comprehensible descriptions of areas of responsibility;
- critical analysis of the procedural channels in order to avoid duplication of work.

Due to Germany's federal structure and the fact that, in its capacity as a subordinate federal authority, the Notification Unit within the Chemicals Act is only responsible for part of the relevant regulations on chemical substances, it has been necessary to undertake extensive data research. The NP was intended to record the production, the import and export as well as the use of chemical substances and the treatment of chemical wastes. For example, areas such as industrial chemicals (existing and new chemical substances), plant protection products containing biocides and fertilizers, pharmaceutical and medical products, dangerous drugs, food as well as cosmetics were envisaged. Relevant regulations and voluntary agreements, the participating authorities and the non-governmental organizations, the areas of competence and the dividing lines separating areas of competence as well as the available stocks of data were to be described in order to ensure that the stocktaking process was as comprehensive as possible.

In pursuance of this ambitious aim, over 50 authorities, associations and institutions nationwide were asked to cooperate in this project. The nature of the response made it necessary to differentiate between "chemicals management in the narrower sense" (under overall control of the Notification Unit within the Chemicals Act) and "chemicals management in the wider sense". With regard to the latter and the description of other authorities and organizations, it has only proven possible to produce lists which may serve as **examples**. However, the description of the frequently complex relationships has created a basis which will allow gaps in content to be filled during **continued** work on the NP. The currently available NP makes clear the need for further, in-depth discussion of this entire topic.

The editorial team wishes to thank all those who have supported the production of the NP. Special thanks are extended to Dr. Reiner Arndt, the former head of the Notification Unit, whose persistence enabled the foundations of the present NP to be laid.

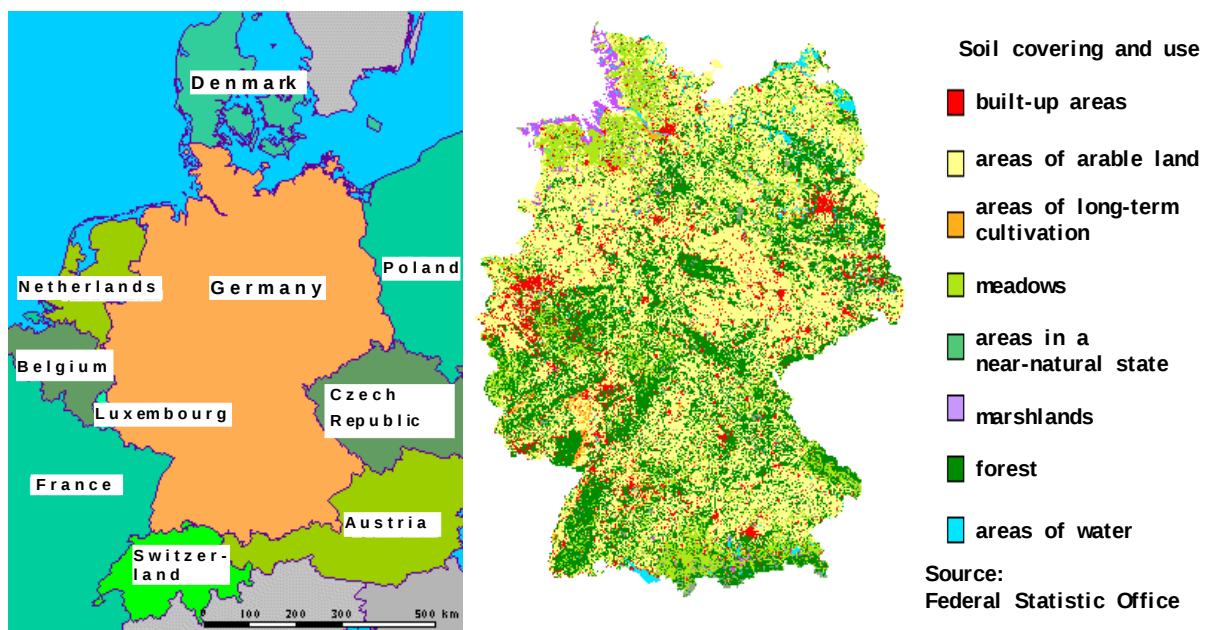
Further help, corrections and additions will be gratefully received.

Dortmund, October 1999
the editorial team

Chapter 1 Background information

1.1 Basic geographical and demographic conditions

With a total area of 357,022 km², the Federal Republic of Germany's territory borders on nine countries and includes a coastline from the North Sea to the Baltic. Topographically, three large zones can be distinguished: the lowland plain of northern Germany with its numerous lakes and marshlands, the low mountain range with elevations up to 1,200 m, and the mountainous south with mountain landscapes, large lakes and the Alpine chain reaching heights of up to 3,000 m.



At 54.1 % of the total area, agriculture accounts for the greatest share of land utilization. Forest areas make up 29.4 %. Traffic infrastructures and settlements constitute approx. 11.8 %. The remainder is divided up between aquatic environments, marshlands and land left in a natural state.

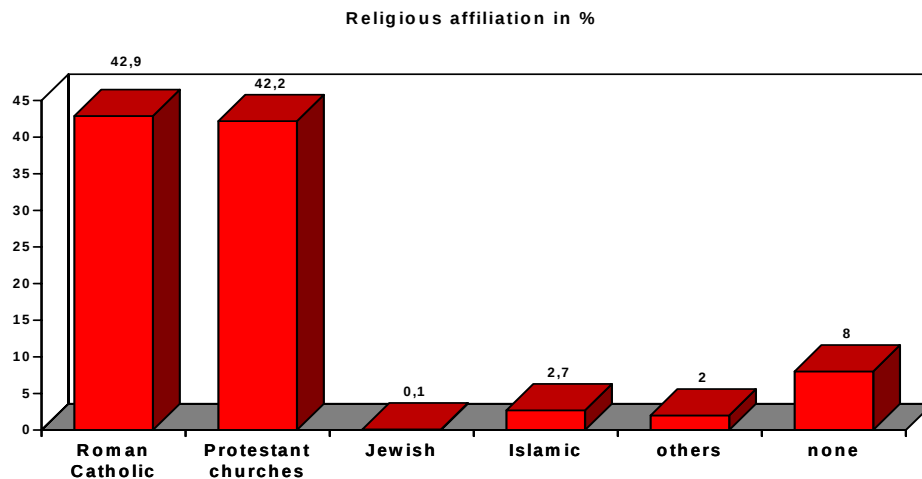
The climate in Germany is temperate and the weather very changeable. The average monthly temperatures are between -6° C in January and + 20° C in July, the average annual temperature amounting to +9° C. Prevalent west winds as well as precipitation throughout the year, with annual amounts of between 500 and 700 mm in the lowland plain region of northern Germany and up to more than 2,000 mm in the Alps, are typical. The climate zones are divided into a maritime climate in the north and a continental climate in central Germany and the south.

The official national language is German. The capital city is Berlin, the seat of government having transferred from Bonn to Berlin in 1999.

With 82 million inhabitants (229 inhabitants per km²), German is densely populated. The greatest population density is to be found in the Ruhr area, along the Rhine, in the area around Halle and Leipzig as well as in a few city conurbations in the south of the country. The most densely populated cities are Berlin (3.4 million), Hamburg (1.7 million) and Munich (1.2 million). Foreign nationals make up 9% of the population.

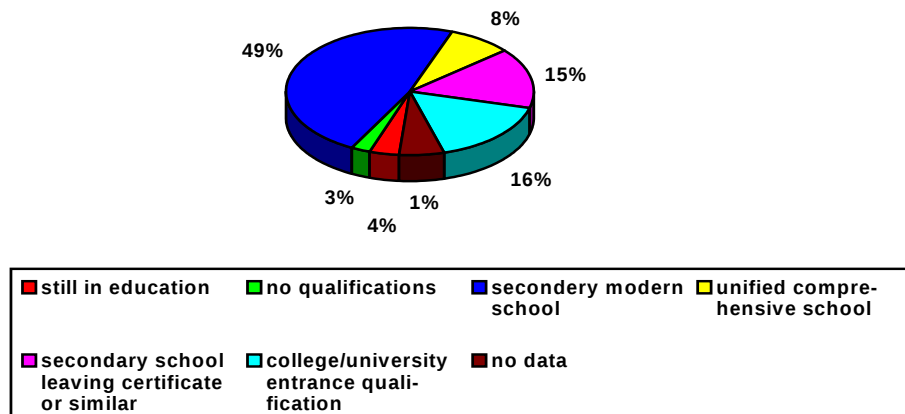
	women	men	total
average age	41.34	37.00	39.25
life expectancy	79.72	73.29	76.44

Birth rate: 9.9 live births per 1000 inhabitants



(situation in the former West German States according to the 1987 census)

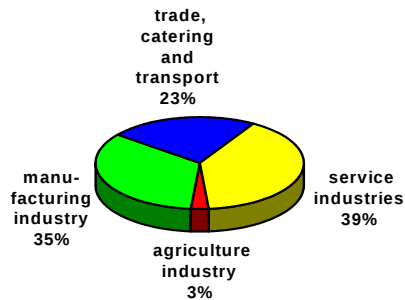
Level of education (persons over 15 years old)



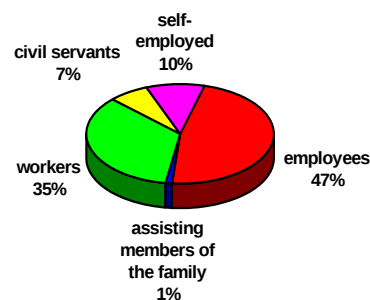
No. of employed persons: 35.805 million.
of whom 42.6% women

Unemployment rate: 12.7%

Percentage of persons employed in particular sectors of the economy



Percentage of employed persons according to professional status



(Source: Federal Statistics Office: 1996/97)

1.2 Politico-geographical structure

The Federal Republic of Germany is a federal constitutional state comprising the 16 **Länder**:

<i>Land</i>	Population	Area	<i>Land</i>	Population	Area
Baden-Württemberg	10.3 mio.	35 751 km ²	Bavaria	12 mio.	70 554 km ²
Berlin*	3.4 mio.	883 km ²	Brandenburg	2.5 mio.	29 060 km ²
Bremen*	0.6 mio.	404 km ²	Hamburg*	1.7 mio.	755 km ²
Hesse	6 mio.	21 114 km ²	Mecklenburg-W-Pomerania	1.8 mio.	23 835 km ²
Lower Saxony	7.8 mio.	47 349 km ²	North Rhine-Westphalia	17.9 mio.	34 068 km ²
Rhineland-Palatinate	4 mio.	9 849 km ²	Saarland	1 mio.	2 570 km ²
Saxony	4.5 mio.	8 338 km ²	Sachsen-Anhalt	2.7 mio.	20 444 km ²
Schleswig-Holstein	2.7 mio.	5 730 km ²	Thuringia	2.4 mio.	16 251 km ²

(* city states)

The **Lower House** of the German Parliament is the body which represents the will of the people. It consists of 669 members of parliament who are elected for a period of four years according to an electoral system combining elements from majority voting and proportional representation. Via the **Upper House** the *Länder* participate in legislation and the administration of the Federal Government. The Upper House consists of the minister-presidents and other representatives of the regional governments.

The Head of State is the **Federal President**, a role which is largely representative. As a rule, a politician from the largest political group in the Lower House of Parliament assumes the office of **Federal Chancellor**. It is the Chancellor's task to lay out policy guidelines.

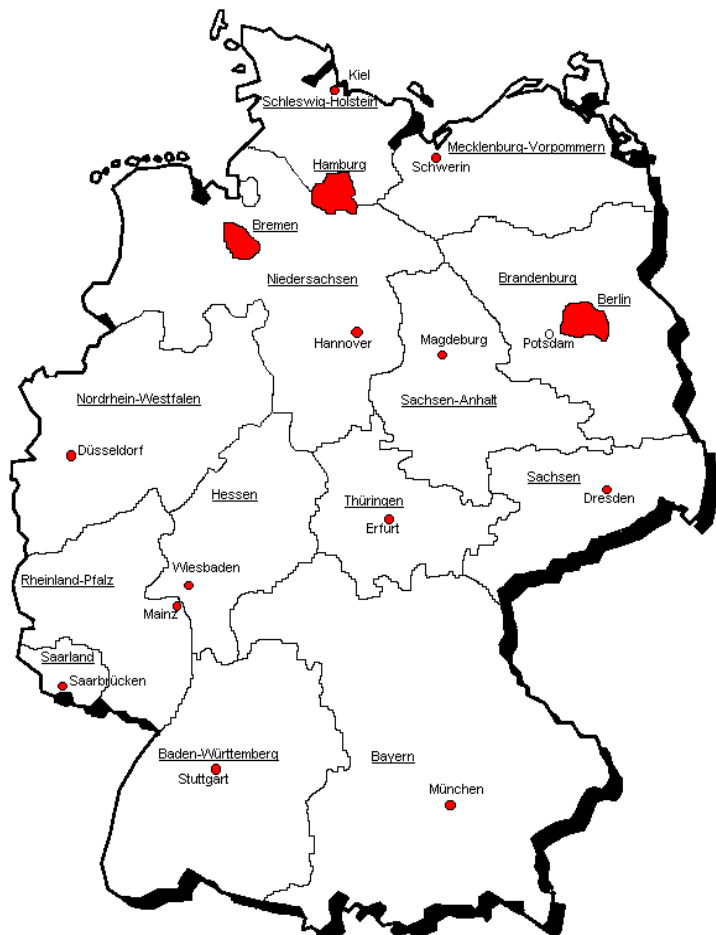
By means of the separation of powers, the state's responsibilities – legislative power, executive power and the administration of justice - are divided between the state organs - parliament, governments, including administrations - and the courts. Executive power and the administration of justice are bound by the law. By contrast, legislative power is bound by the constitutional order (the German Constitution).

State responsibilities are divided up between the Federal Government and the 16 *Länder*. The Constitution of the Federal Republic of Germany guarantees the separation of legislative powers between the Federal Government and the *Länder* as well as the execution of Federal laws.

The Federal Government has sole legislative power, inter alia, in the areas relating to foreign policy, defence, currency, customs duties, air transport and the postal service.

The 16 *Länder* possess the quality of states. They have their own power of jurisdiction – albeit limited to specific areas – which they exercise through their own legislative acts, enforcement and administration of justice.

The task of administrative enforcement of federal laws and, therefore, of exercising the powers vested in the state mainly falls to the *Länder*. Federal Authorities assume responsibility for matters which require uniform enforcement throughout the country but not a local presence of the competent authority.

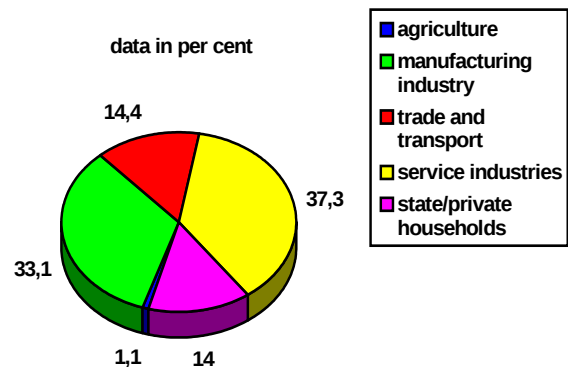


1.3 Industry and agriculture

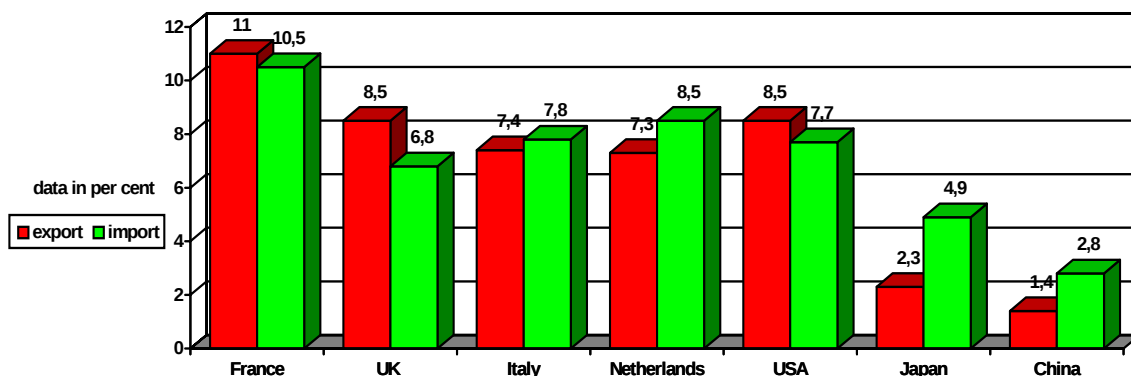
In 1997 the gross domestic product amounted to 3,641.8 thousand million German marks, 1.1% of the total being generated by agriculture, forestry and the fishing industry. The most significant areas here are cattle and pig farming as well as the cultivation of grain, fruit and wine.

Germany has only an insufficient supply of non-renewable natural resources. Significant mineral resources include, inter alia, brown coal and hard coal, iron ore, some petroleum and natural gas as well as mineral salts. With a combined workforce of 467,000 employees, the energy/water supply and coal mining sectors contributed 2.5% to the gross domestic product.

Manufacturing industry's total share of the gross domestic product amounted to 33.1%. Trade and transport generated 14.4% and the service sector 37.3 %. State budgets, private households and private non-profit organizations accounted for a 14% share.



Germany ranks second in world trade, coming behind the United States but ahead of Japan, both in terms of imports and exports. In 1997 goods to the value of 886.8 thousand million marks were exported and goods worth 755.9 thousand million marks were imported. With a 55.4% share, the most important foreign purchasers of German products were European countries. Likewise, almost half of Germany's expenditure on imported goods went to the EU.

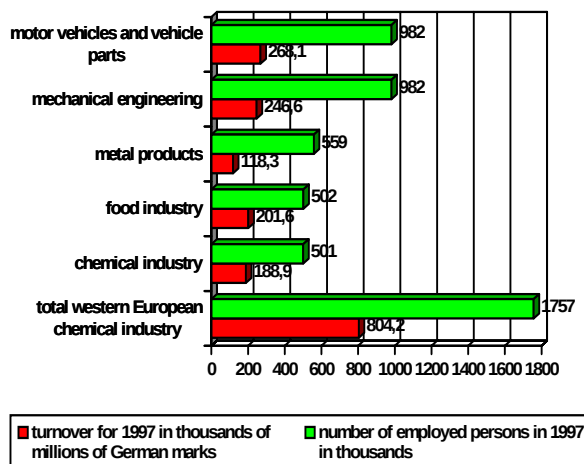


(Source: Federal Statistics Office)

Chapter 2 Production, export/import and use of chemical substances

2.1 Turnover, number of employees, export/import

The chemical industry accounts for a significant share of the German economy. It is impossible to imagine many areas of life without chemical products. They make a wide-ranging contribution to increased prosperity.



In 1997 the turnover per employee amounted to 462,000 German marks. By comparison, a turnover of 351,000 German marks per employee was achieved in the manufacturing industry.

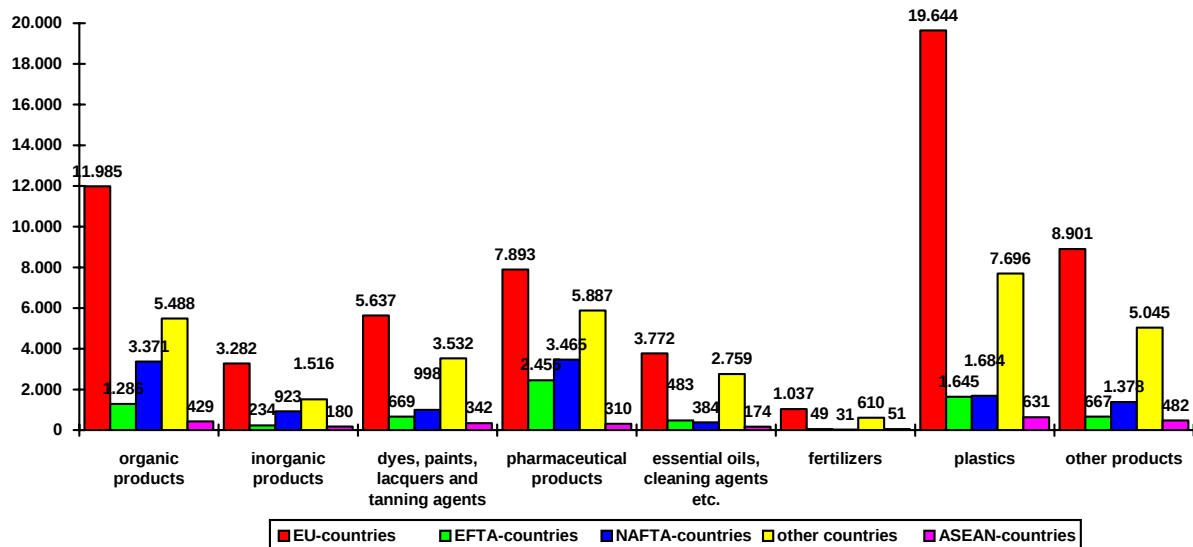
With a percentage share of 23.5% of the turnover achieved in the western European chemical industry, the German chemical industry is Europe's market leader. In an international comparison, Germany takes third place behind the United States and Japan.

(Quelle: VCI)

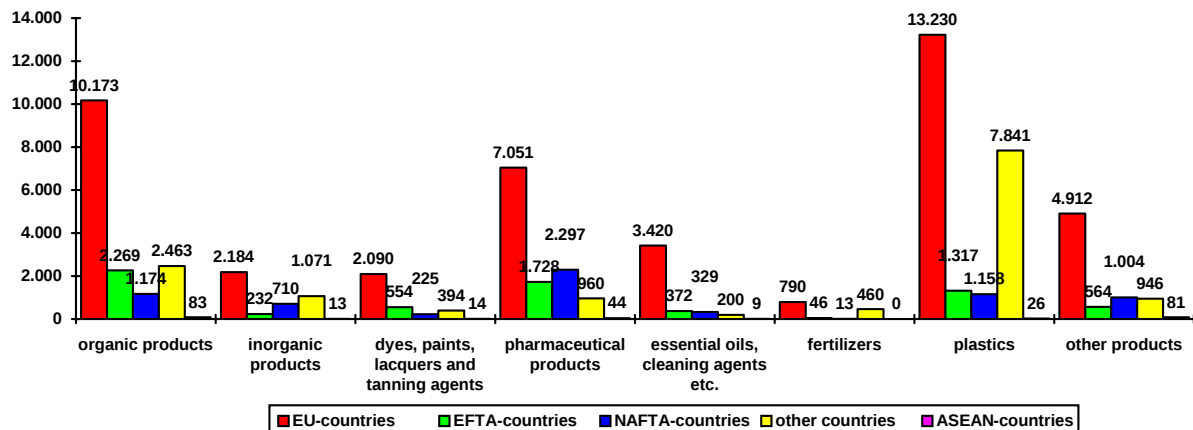
However, with regard to these data it is necessary to take account of the fact that, as a result of globalization, international comparison of turnover figures is becoming increasingly difficult. An ever-greater percentage of the turnover is namely being generated by German subsidiaries abroad, something which these statistics fail to record. In 1996 this share amounted to 108 thousand million marks.

51% of the turnover in the chemical industry was achieved in Germany, 49% abroad. With a percentage share of worldwide chemical exports of 15.5%, Germany was the world's leading exporter of chemicals in 1996, ahead of the United States, France and Japan.

Export of chemical products in 1996 in millions of German marks



Import of chemical products in 1996 in millions of German marks

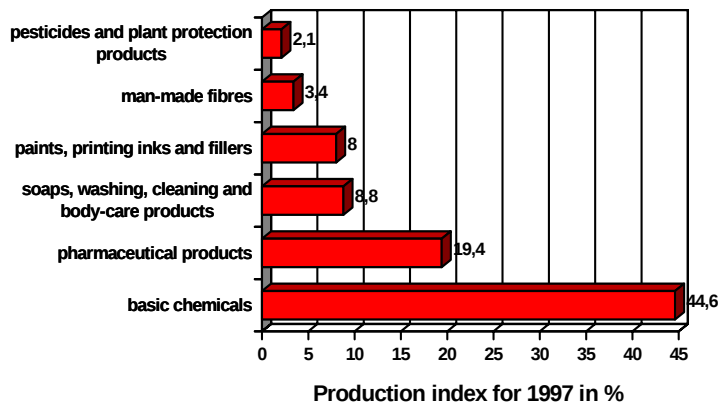


EU countries: Austria, Belgium, Denmark, Finland, France, Greece, Ireland, Italy, Luxembourg, Netherlands, Portugal, Sweden, Spain, United Kingdom
 EFTA countries: Iceland, Liechtenstein, Norway, Switzerland,
 NAFTA countries: Canada, Mexico, United States
 ASEAN countries: Brunei, Indonesia, Malaysia, Philippines, Singapore, Thailand, Vietnam

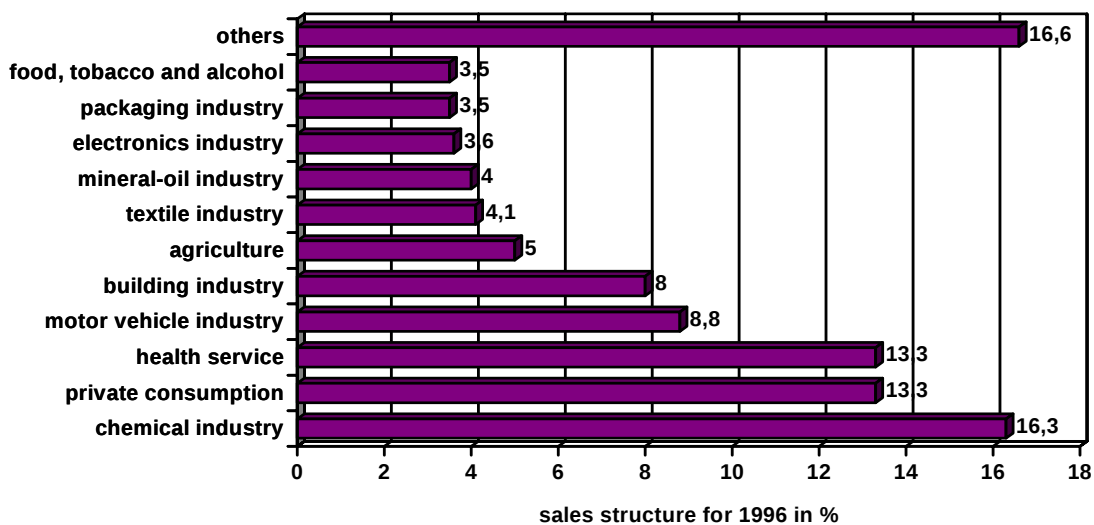
(Source: Federal Statistics Office 1997)

2.2 Use of chemicals according to classes of substances

The chemical industry has an extremely wide range of products, extending from intermediates for manufacturing processes in other branches of industry to finished products in areas relating to the environment, health and nutrition.



The sales structure of chemical products has hardly changed over recent years. The largest part remains within the chemical industry itself. This use category is followed by the areas relating to private consumption and the health service, the automobile and building industries.



(Source: VCI)

2.3 Chemical wastes and environmental pollution

Chemical wastes

In 1993 8,054,052 tonnes of waste/residual substances occurred in the chemical industry, 2,871,203 tonnes of which required special monitoring according to §2 section 2 of the Federal Waste Act. Of the wastes/residual substances in special need of monitoring, 706,783 tonnes were disposed of at landfill sites, 613,113 tonnes in incineration plants and 838,757 tonnes were recovered.

(Source: Federal Environmental Agency)

As a result of changes made to processes and utilization in the chemicals industry, it is generally possible to observe a clear reduction in the quantities of waste that are produced.

year	wastes requiring disposal (in millions of tonnes)
1995	3.97
1996	2.37
1997	2.55
1998	2.13

(Source: VCI)

To the greatest possible extent, cross-border shipment of wastes is regulated by provisions contained in European legislation. In Germany, rules relating to this area are to be found in the Transboundary Shipment of Waste Act, the Waste Avoidance, Recycling and Disposal Act as well as in the Ordinance on the Transboundary Shipment of Waste. Both the European and German regulations transpose the "Basle Convention of 22.03.1989 on the Control of Transboundary Shipment of Dangerous Wastes and their Disposal".

According to this convention, the export, import and transit of wastes are only permitted after all relevant countries have given prior informed consent. The shipment of wastes to non-signatory states is prohibited in principle, exceptions only being permitted in cases where relevant agreements conforming to the requirements of the Convention exist. The export of wastes to countries located to the south of the 60th parallel is prohibited. The exporter and, in a supporting capacity, the country of origin are responsible for compliance with the demands of the Convention. The duty to return the waste exists in the case of failed or illegal shipments.

Export of hazardous wastes in 1997

(Source: Secretariat of the Basle Convention (SEC))

Total quantity exported:	1,277,847 t
- for recovery	1,126,441 t
- for disposal	151,406 t

Environmental pollution

Improper use of chemical substances in the past has resulted in extensive soil contamination. Above all, soil contamination due to heavy metals, active substances and mineral-oil products must be mentioned in this connection. Military training areas and old production sites, principally in the new federal states, present a particular problem. In the old and new federal states about 300,000 areas are suspected of being hazardous waste sites (as at 1998).

Necessarily, the demands of environmental protection and waste disposal do not always fully coincide. To some extent there is a tension between the two. Environmental protection measures may themselves result in new instances of environmental pollution. For example, the more that heavy metals are removed from the waste water in waste-water treatment plants, the more they contaminate the sewage sludges which must, in turn, be disposed of as waste. Consequently, improvements in waste-water purification increase waste-disposal problems unless processes are employed which also take account of disposal. Efforts should therefore be directed at preventing the occurrence of pollutants at source.

Chapter 3 Special problems with chemical substances

3.1 Special environmental problems

The following problem areas have been identified:

Problem	Scale of problem	Level of concern	Ability to control problem	Availability of statistical data	Specific chemicals creating concerns	Priority ranking (1=high - 5=low)
Marine pollution	Local, regional, national, global	Dependent on the substance	Dependent on the substance	Insufficient	1998: OSPAR & HELCOM strategies for hazardous substances. A procedure for selecting substances which are to be dealt with on a priority basis is currently being elaborated, e.g.: PCDD, PCDF, PCB, PAK, PCP, HCH, Hg, Cd...	1
Pollution of inland waterways	National international	High	Medium	Insufficient Data source: Statistical year book (summary of use of pesticides)	Pesticides (protected asset: drinking water supply) Agricultural use: Diuron, isoproturon, terbutylazine, dichlorprop, mecoprop, atrazine, chloridazon, chlorotoluron, lindane Production: River Rhine: Chloridazon, diuron, metabenzthiazuron, melamitron, thiazaphos Rivers Elbe/ Saale/Mulde: Ametryn, dimethoate, parathionmethyl, prometryn, propazine, lindane, atrazine, simazine Industrial chemicals: Dichloromethane,	2

					hexachlorobenzene, trichloromethane, nitrobenzene, 1,4-dichlorobenzene	
Problem	Scale of problem	Level of concern	Ability to control problem	Availability of statistical data	Specific chemicals creating concerns	Priority ranking (1=high - 5=low)
Ground water pollution	Local, regional	Medium, high	Low	Insufficient Data sources: Nitrates: Nitrate report produced by LAWA Pesticides: PSM report produced by LAWA (in print)	N-containing fertilizers Pesticides, worldwide critical pesticides are listed in detail (PSM report produced by LAWA, see annex 9)	N-containing fertilizers: 1 Pesticides: 1-2
Drinking water contamination	Local	Low	High	Sufficient	Nitrates Pesticides (atrazine) Contamination of areas after the departure of the military and industrial production sites.	3
Hazardous waste treatment / disposal	National	High	High (for the purpose of occupational safety and health = average)	Adequate (for the purpose of occupational safety and health = insufficient)	PCB, CFCs	2
Storage / disposal of obsolete chemicals	National	High	Medium	Insufficient	PCP PCDD/OCDF	2
Persistent organic pollutants (POP)^{a)}	Global/ national Some POPs like PCB or PCDD/F cause local problems (contaminated sites)	Low (for pesticide POPs) Medium (for other POPs, mostly occurring as by-products)	High	Databases/ monitoring of individual POPs (e.g. PCB, PCDD): Information system belonging to the environmental sample bank Dioxin database (inter alia, all of the reports from the <i>Länder</i> arrive here)	PCB PCDD/PCDF	4

^{a)} The data refer to the substances currently identified by UNEP as priority POPs

Drinking water

The management of water resources, including ensuring an adequate supply of water in terms of both quantity and quality, has always been one of the tasks a community has had to perform. It represents the oldest environmental protection task of all. Consequently, the protection of aquatic environments includes protecting the environmental medium water against pollution and against too many demands being made upon it.

Only a few problems exist with regard to drinking water, e.g. lead in old drinking-water pipes. In general, the monitoring and control of the quality of drinking water as well as the quality of the sources and resources comply with European guidelines. Problems which do exist result from the fact that, in part, one and the same region is used for both the extraction of ground and surface water for the purpose of providing drinking water as well as for the cultivation of agricultural products (e.g. wine and asparagus).

Water pollution arising from the abandonment of military bases and industrial production sites also has a problematical impact on the protection of sources and resources.

Legislation on water protection and legislation on hazardous substances overlap. Their substance-related and environment-related regulatory approaches are also interlinked. This applies to the rules for limiting the use of agricultural chemicals in the interest of water and soil protection as well as to the protection against chemical accidents.

The act of spreading fertilizers on areas of land used for agricultural purposes does not constitute a case of water utilization even if the fertilizers which are washed out may enter surface waters. As a rule, fertilizers are used to improve the fertility of the soil. The Federal Government's concept for soil protection which, inter alia, has had an influence on the Federal Soil Protection Act, provides for a reduction in the release of harmful substances such as cadmium, heavy metals, nitrate and persistent organic compounds resulting from the use of plant protection products and fertilizers as well as sewage sludge.

Hazardous waste sites

Soil protection and hazardous waste sites number among the current topics in the area of environmental protection.

The soil is a sink for contaminants. As a rule, the contaminants which are released into the soil remain there for long periods. They may then slowly seep into the ground water and enter the plants growing there or they may be dispersed or released as gas.

Hazardous waste sites are themselves sources of contaminants for the surrounding soil, the ground water and the air. Consequently, when their emissions pose a risk, hazardous waste sites must be dealt with actively and restored.

The manner in which the protected asset 'soil' is to be treated is regulated in the Federal Soil Protection Act (BBodSchG), which came into force on 01.03.1999, and the Soil Protection and Hazardous Site Ordinance, which came into force on 16.07.1999. These pieces of legislation improve the prevention of adverse changes to the soil and create legal and investment-related certainty by placing uniform demands on hazard prevention throughout the Federal Republic of Germany.

Restoration technologies which fulfil the requirements of economical treatment and are adapted to the particular target of the restoration efforts are continuously being developed or refined.

The Federal Soil Protection Act differentiates between hazardous waste-disposal sites and hazardous waste sites. Hazardous waste-disposal sites include waste removal plant which has been shut down and other sites on which waste has been treated, stored or disposed of. Hazardous waste sites include plant which has been shut down and other industrially utilized sites on which environmentally dangerous substances have been handled. However, contamination caused by agricultural or gardening uses as well as contamination resulting from warfare agents or nuclear fuels is excluded here. Areas suspected of being hazardous waste sites are hazardous waste-disposal sites or hazardous waste sites about which there is concern that they may adversely affect the public good.

Decontamination and safeguarding measures may be employed to avert dangers as long as they ensure that dangers are permanently averted. The general restoration aim of the Federal Soil Protection Act is therefore to permanently avert dangers. In order to ensure this, monitoring and the subsequent restorability of the safeguarding effect are required in the case of safeguarding measures and, in particular, with regard to other protection and restriction measures. An additional rule for so-called "new cases" states that in instances where soil contamination or hazardous waste sites occur after the Act has come into force, removal of the contaminants (decontamination) shall always have priority over other restoration measures, account being taken here of the extent of the prior contamination.

Sequence of the work on hazardous waste sites

The first stage of work on hazardous waste sites involves the systematic and comprehensive recording and geographical localization of areas suspected of being hazardous waste-disposal sites or hazardous waste sites as well as the gathering or additional ascertainment of all of the information which is available on them. During the information-gathering phase, particular importance attaches to questions concerning possible effects of relevance to contamination and the possible contaminant inventory.

The data-recording phase is followed by a decision on whether, and how, intensively work on areas suspected of being hazardous waste-disposal sites or hazardous waste sites should continue, i.e. on whether they have to be examined and, if necessary, restored. Thorough research of all available data creates the requisite basis for further rational planning of a programme of investigation into an area suspected of being a hazardous waste-disposal site or a hazardous waste site.

Responsibility

According to the German Constitution, the *Länder* have the responsibility of recording hazardous waste sites, estimating the risk posed by them, and restoring them. On the basis of waste law and general police-law and water-law clauses contained in legislation pertaining to the *Länder*, the relevant competent

authorities are authorized to record areas suspected of being hazardous waste-disposal sites or hazardous waste sites.

The current state of the recording process

Differences between the *Länder* have developed with regard to the practice of recording hazardous waste sites. The available results can be found in the following table. The table reflects the state of the recording of areas suspected of being hazardous waste-disposal sites or hazardous waste sites in the individual *Länder*. The data that are provided are based on data which the *Länder* have made available to the Federal Environmental Agency.

Due to the fact that the term "area suspected of being a hazardous waste-disposal site or a hazardous waste site" has not been uniformly defined throughout the various *Länder*, the figures resulting from the recording process do not permit direct comparison between the *Länder*.

National overview of the recording of hazardous waste sites

Table showing the number of areas suspected of being hazardous waste-disposal sites or hazardous waste sites in the Federal Republic of Germany on the basis of the data conveyed by the *Länder*.

(Data collated by the Federal Environmental Agency on the basis of information provided by the *Länder* as at December 1998)

<i>Länder</i>	number of areas recorded as suspected hazardous waste-disposal sites or hazardous waste sites		
	hazardous waste-disposal sites	hazardous waste sites	total areas
Baden-Württemberg	15,074	27,487	42,561
Bavaria	9,725	3,194	12,919
Berlin	673	5,541	6,214
Brandenburg	5,585	8,580	14,165
Bremen	105	4,000	4,105
Hamburg	460	1,701	2,161
Hesse	6,502	60,372	66,874
Mecklenburg-West Pomerania	4,113	7,231	11,344
Lower Saxony	8,957	no data	8,957
North Rhine-Westphalia	17,155	14,874	32,029
Rhineland Palatinate	10,578	no data	10,578
Saarland	1,801	2,442	4,243
Saxony	9,382	22,197	31,579
Saxony-Anhalt	6,936	13,295	20,231
Schleswig-Holstein	3,076	14,497	17,573
Thuringia	6,192	12,368	18,560

<i>Total for the Federal Republic of Germany</i>	106,314	197,779	304,093
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N.B.

The figures indicate the current status of the recording of areas suspected of being hazardous waste-disposal sites or hazardous waste sites in the individual *Länder*. As a result of the lack of a uniform definition for areas suspected of being hazardous waste-disposal sites or hazardous waste sites, the data from the individual *Länder* are only comparable to a limited extent.

National overview of the status of the assessment of areas suspected of being hazardous waste-disposal sites or hazardous waste sites

(Source: Data collated by the Federal Environmental Agency on the basis of information provided by the *Länder* as at November 1998)

Land	Status of the investigations/estimations of risk				
	initiated		concluded		total
	hazardous waste-disposal site	hazardous waste site	hazardous waste-disposal site	hazardous waste site	
Baden-Württemberg	5,362 ¹	2,057 ¹			7,419
Bavaria	555	250	985	490	2,280
Berlin	95 ²	646 ²	73 ²	217 ²	1,031 ²
Brandenburg	no data	no data	no data	no data	
Bremen					
Hamburg	no data	no data	no data	no data	
Hesse			751	642	1,391 ³
Mecklenburg-West Pomerania					
Lower Saxony	no data	no data	no data	no data	
North Rhine-Westphalia	840	349	3,667	2,636	7,492
Rhineland Palatinate	no data	no data	no data	no data	
Saarland	no data	no data	no data	no data	
Saxony	8,875	17,158	approx. 1,950	altogether	27,983
Saxony-Anhalt	474	826	344	498	2,142
Schleswig-Holstein	150	292	680	609	1,731
Thuringia			2,795	altogether	2,795
Total for the Federal Republic of Germany					approx. 53,000

¹ Initiated and concluded; only local hazardous waste sites

² Investigation and restoration

³ Only concluded cases

National survey of the status of the restoration of hazardous waste sites

(Source: Data collated by the Federal Environmental Agency on the basis of information provided by the *Länder*, as at November 1998)

		state of restoration				type of restoration	
<i>Land</i>	Temporary protection and restriction or monitoring measures	initiated		concluded		safe-guarding measures	decon-tamination measures
		HWDS	HWS	HWDS	HWS		
Baden-Württemberg	no data	no data	no data	approx. 300		no data	no data
Bavaria		70	130	135	160	50	90
Berlin		95 ¹	646 ¹	73 ¹	217 ¹		
Brandenburg	no data	no data	no data	52	100	no data	no data
Bremen							
Hamburg							
Hesse	no data	15	133	17	138	28	248
Mecklenburg-West Pomerania							
Lower Saxony		no data	no data	no data	no data	no data	no data
North Rhine-Westphalia				333 ²	1092 ²	341	1,398 ³
Rhineland Palatinate							
Saarland							
Saxony	approx. 2,000	17	48	85	71	124	32
Saxony-Anhalt	no data	19	20	49	55	no data	no data
Schleswig-Holstein	307 ⁴	14	72	30	298	no data	no data
Thuringia		280		219			
Total for the Federal Republic of Germany							

1) Investigation and restoration

2) Initiated and concluded

3) 872 of which are relocations

4) Interim monitoring measures

Legend:

HWDS = Hazardous Waste-Disposal Sites

HWS = Hazardous Waste Sites

Chapter 4 Statutory regulations and voluntary agreements

4.1 Basic administrative framework

The concept of environmental protection is standardized in Article 20a of the German Constitution. However, environmental legislation is integrated into a wide variety of statutory areas. Although a uniform "Environmental Code" is in preparation it has not been realized yet.

The competences of the various legislative organs in the federal system which exists in the Federal Republic of Germany are regulated by the German Constitution. Draft bills can be introduced by the German government, the Lower House of Parliament or the Upper House of Parliament. A decision on them is then taken in the Lower House. Implementation of the statutory regulations is generally the responsibility of the *Länder*.

The Federal Republic of Germany is a member of the European Union (EU) and is therefore subject to the "Treaty for the Foundation of the European Community (EC)". Areas such as the health service, consumer and environmental protection in the European single market are regulated in a uniform manner by means of Community legislation such as EC Directives - which must be transposed into national law by national regulations - and EC Regulations which enter into force directly.

4.2 Statutory regulations

The following tables provide an overview (as at November 1999) of the main areas of chemicals legislation. Regulations concerning chemicals management in the narrower sense are mainly listed. Related regulations such as, for example, the Plant Protection Act and the German Drugs Act (chemicals management in the broader sense) are also included.

The texts of the laws are in part available on the Internet (see Annex 2 for the Internet addresses).

4.2.1 Chemicals management in the narrower sense

EC Regulations, directives and guidelines

Regulation	competent authority	where to find the regulation/date	content	available translations
Directive 67/548/EEC of 27.06.1967 on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances	BMU	EC Official Journal L 196 of 16. 8.1967 p. 1; last amended on 15.11.1999 (EC Official Journal L 293 p. 1)	Notification of substances and assessment of the dangers they pose to man and the environment	Official EC languages
Council Directive 76/769/EEC of 27.07.1976 on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations	BMU	EC Official Journal L 262 of 27.09.1976 p. 201; last amended on 26.07.1999 (EC Official Journal L 207 p. 18)	Restrictions on the marketing and use of the dangerous chemicals listed in the annex	Official EC languages
Directive 88/379/EEC of 07.07. 1988 on the classification, packaging and labelling of dangerous preparations	BMA	EC Official Journal L 187 of 16.07.1988 p. 14; last amended on 11.10.1996 (EC Official Journal L 265 p. 15)	Rules on the classification, packaging and labelling of preparations	Official EC languages
Directive 1999/45/EC of the European Parliament and of the Council of 31.05.1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations	BMA	EC Official Journal L 200 of 30.07.1999 p. 1	Revision of the rules on the classification, packaging and labelling of preparations	Official EC languages
Directive 91/155/EEC of 05.03.1991 concerning the determination of details of a special information system for hazardous preparations (safety data sheet directive)	BMA	EC Official Journal L 76 of 22.03.1991 p. 35, last amended on 10.12.1993 (EC Official Journal L 314 p. 38)	Information required in the safety data sheet	Official EC languages
Council Regulation (EEC) No 793/93 of 23.03.1993 on the evaluation and control of the risks of existing substances	BMU	EC Official Journal L 84 of 05.04.1993 p.1, last amended on 03.09.1993 (EC Official Journal L 224 p.34)	Announcement duties and the assessment of existing substances	Official EC languages

Regulation	competent authority	where to find the regulation/date	content	available translations
Commission Regulation (EC) No 1179/94 of 25.05.1994 concerning the first list of priority substances as foreseen under Council Regulation (EEC) No 793/93	BMU	EC Official Journal L 131 of 26.05.1994 p.3	1st priority list	Official EC languages
Commission Regulation (EC) No 1488/94 of 28.06.1994 laying down the principles for the assessment of risks to man and the environment of existing substances in accordance with Council Regulation (EEC) No 793/93	BMU	EC Official Journal L 161 of 29.06.1994 p.3	Principles for the assessment of existing substances	Official EC languages
Commission Regulation (EC) No 2268/95 of 27.09.1995 concerning the second list of priority substances as foreseen under Council Regulation (EEC) No 793/93	BMU	EC Official Journal L 231 of 28.09.1995 p. 18	2nd priority list	Official EC languages
Commission Regulation (EC) No 142/97 of 27.01.1997 concerning the delivery of information about certain existing substances as foreseen under Council Regulation (EEC) No 793/93	BMU	EC Official Journal L 25 of 28.01.1997 p. 11	Parallel list of existing substances	Official EC languages
Commission Regulation (EC) No 143/97 of 27.01.1997 concerning the third list of priority substances as foreseen under Council Regulation (EEC) No 793/93	BMU	EC Official Journal L 25 of 28.01.1997 p. 13	3rd priority list	Official EC languages
Council Regulation (EEC) No 2455/92 of 23.07.1992 concerning the export and import of certain dangerous chemicals	BMU	EC Official Journal L 251 of 29.08.1992 p.13; last amended by EC Official Journal L 282 of 13.10.1998 p.12	Links exports to the previous duties to provide information, implementation of the PIC procedure	Official EC languages
Council Regulation (EC) No 3093/94 of 15.12.1994 on substances that deplete the ozone layer	BMU	EC Official Journal L 333 of 22.12.1994 p.1	Prohibitions and restrictions on CFCs, halons and other substances which damage the ozone layer	Official EC languages
Council Directive 88/320/EEC on the inspection and verification of Good Laboratory Practice (GLP)	BMU	EC Official Journal L 145 of 11.06.1999 p.35, last amended on 08.03.1999 (EC Official Journal L 77 p.2)	GLP provisions	Official EC languages

Regulation	competent authority	where to find the regulation/date	content	available translations
Directive 89/391/EEC of 12.06.1991 on the implementation of measures for improvement in occupational safety and health	BMA	EC Official Journal L 183 of 19.06.1989 p.1	Occupational safety outline directive on the handling of chemicals	Official EC languages
Directive 98/24/EC of 07.04.1998 on the protection of the health and safety of workers from risks at work related to chemical working substances (Working Substances Directive)	BMA	EC Official Journal L 131 of 05.05.1998 p. 11	Measures relating to the handling of chemical working substances	Official EC languages
Directive 90/394/EEC of 28.06.1990 on the protection of workers from risks at work related to carcinogens (Cancer Directive)	BMA	EC Official Journal L 196 of 26.07.1990 p. 1, last amended on 29.04.1999 (EC Official Journal L 138 p. 66)	Special protective measures during the handling of carcinogenic substances	Official EC languages
Directive 92/85/EEC of 19.10.1992 on the implementation of measures to improve the protection of the safety and health at work of pregnant workers, workers who have recently given birth and workers who are breastfeeding (Directive on nursing and expectant mothers)	BMFSFJ	EC Official Journal L 348 of 28.11.92 p. 1	Measures for improving safety and health	Official EC languages
Directive 80/1107/EEC on the protection of workers from the risks at work related to chemical, physical and biological agents	BMA	EC Official Journal L 327 of 27.11.1980 p. 8, last amended on 07.04.1998 (EC Official Journal L 131 p. 11)	Rule on the protection of occupational safety and health during the handling of certain working substances	Official EC languages
Technical Guidance Documents in Support of The Commission Directive 93/67/EEC on Risk Assessment for new Notified Substances and the Commission Regulation (EC) 1488/94 on Risk Assessment for Existing Substances	EC/ BMU/ Notification Unit/Assessment units	Office for Official Publications of the European Communities, 1996	Authorities' technical guidance document on the risk assessment of new and existing substances	English
Guide to Council Regulation (EEC) No. 2455/92 concerning the Export and Import of Certain Dangerous Chemicals	EC/JRC-ECB	European Commission, DG XI, 1998	Guidance document for exporters	English

National laws and guidelines

Regulation	competent authority	where to find the regulation/date	content	available translations
Act on the protection against dangerous substances (Chemicals Act - ChemG)	BMU	In the version of the announcement of 25.07.1994 (Federal Law Gazette I p. 1703); last amended on 14.05.1998 (Federal Law Gazette I p. 950).	Basic notification, classification, labelling and packaging duties as well as powers of decree (inter alia, in connection with the performance of risk assessments, the prohibition of substances etc.)	English
Guidance document for notifications of new substances pursuant to the Chemicals Act	Notification Unit	13.03.1997, 2nd edition	Information to producers or importers concerning the notification procedure	-

National ordinances

Regulation	competent authority	where to find the regulation/date	content	available translations
Ordinance on bans and restrictions on the placing on the market of dangerous substances, preparations and products pursuant to the Chemicals Act (ChemVerbotsV)	BMU	In the version of 19.07.1996 (Federal Law Gazette I p. 1151)	Marketing bans and restrictions for certain substances, preparations and products	English
Hazardous Substances Ordinance (GefStoffV)	BMA	Of 26.10.1993 (Federal Law Gazette I p. 1783); last amended on 18.09.1999, Federal Law Gazette I p. 2059	Classification, labelling and packaging duties, in particular in connection with preparations (flexible reference to EC Directives). Bans and restrictions on production and use; special rules for handling	-
Ordinance on evidence of testing and other notification and information documents under the Chemicals Act (ChemPrüfV)	BMU	Of 01.08.1994 (Federal Law Gazette I p. 1877)	Notification documents and test reports	English
Ordinance on obligations, pursuant to article 16e of the Chemicals Act, to provide notification: preventing poisoning and providing information in cases of poisoning (ChemGiftInfoV)	BMU	In the version of 31.07.1996 (Federal Law Gazette I p. 1198)	Obligations to provide information in cases of poisoning	English
Ordinance on the costs of official acts of the Federal Authorities under the Chemicals Act (ChemKostV)	BMU	Of 16.08.1994 (Federal Law Gazette I p. 2118), last amended on 21.10.1997 (Federal Law Gazette I p. 2492)	Costs of the notification and mini-notification procedures and official acts relating to GLP	English

Regulation	competent authority	where to find the regulation/date	content	available translations
Ordinance on the execution of regulations of the European Community on substances and preparations (ChemStrOWiV)	BMU	Of 25.04.1996 (Federal Law Gazette I p. 662), last amended on 18.10.1999 (Federal Law Gazette I p. 2059)	Assignment of violations of EU regulations (e.g. Council Regulation 793/93 on existing substances and Council Regulation 2455/92 concerning the export and import of certain dangerous chemicals) to the rules in chemicals law relating to criminal acts and fines	English
Ordinance on the prohibition of certain ozone-depleting halogenated hydrocarbons (FCKW-Halon-Verbots-Verordnung)	BMU	Of 06.05.1991 (Federal Law Gazette I p. 1090), last amended on 24. 06. 1994, (Federal Law Gazette I p. 1416)	Prohibition of certain ozone-depleting substances for particular applications	English

National administrative provisions

Regulation	competent authority	where to find the regulation/date	content	available translations
General administrative provision for the implementation of the assessment according to § 12 Section 2 Clause 1 of the Chemicals Act (ChemVwV-Bewertung)	BMU	Of 11.09.1997 (General information bulletin of 06.10.1997)	Cooperation between the authorities in connection with the notification of new substances	-
General administrative provision for the implementation of Council Regulation No 793/93 of 23 .03.1993 on the assessment and control of the environmental risks of existing substances (ChemVwV-Altstoffe)	BMU	Of 11.09.1997 (General information bulletin of 06.10.1997)	Cooperation between the authorities in connection with the assessment of existing substances	-
General administrative provision relating to official monitoring of adherence to the principles of Good Laboratory Practice (ChemVwV GLP)	BMU	New version of 15.05.1997 (General information bulletin p. 257)	Inspections for the control of compliance with the principles of GLP	-

Technical Rules for Hazardous Substance (TRGS)

Rule	competent authority	where to find the regulation/date	content	available translations
TRGS 900	BMA	Federal Labour Gazette 10/96, last amended in Federal Labour Gazette 9/99	Limit values for the workplace atmosphere	-
TRGS 903	BMA	Federal Labour Gazette 6/94, last amended in Federal Labour Gazette 7-8/99	Biological tolerance values for working substances in the workplace	-
TRGS 905	BMA	Federal Labour Gazette 6/97, last amended in Federal Labour Gazette 9/99	List of carcinogenic, mutagenic or reproductive toxic substances	-
TRGS 907	BMA	Federal Labour Gazette 1/98, last amended in Federal Labour Gazette 7-8/99	List of sensitizing substances	-
TRGS 200	BMA	Federal Labour Gazette 3/99	Classification and labelling of substances, preparations and products	-
TRGS 220	BMA	Federal Labour Gazette 9/93	Safety data sheet for hazardous substances and preparations	English
TRGS 500	BMA	Federal Labour Gazette 3/98	Protection measures: minimum standards	English

4.2.2 Chemicals management in the wider sense

Biocides

Regulation	competent authority	where to find the regulation/date	content	available translations
Directive 98/8/EC of 16.02.1998 concerning the placing of biocidal products on the market	BMU	EC Official Journal L 123 of 24.04.1998 p. 1	Rules on the licensing, marketing, use and control of biocidal products	Official EC languages

Plant protection products and fertilizers

Regulation	competent authority	where to find the regulation/date	content	available translations
Directive 91/414 of 15.07.1991 on the marketing of plant protection products	BML	EC Official Journal L 230 of 19.08.1991 p. 1; last amended on 28.07.1999 (EC Offi-	Rules on the licensing, marketing, use and control of plant protection products	Official EC languages

		cial Jour. L 210 p. 13)		
Regulation	competent authority	where to find the regulation/date	content	available translations
Regulation EEC No. 3600/92 of 11.12.1992 with implementing regulations for the first stage of the work programme according to Art. 8 Section 2 of Directive 91/414/EEC on the marketing of plant protection products	BML	EC Official Journal L 366 of 15.12.1992, p. 10; last amended on 15.09.1999 (EC Official Journal L 244, p. 41)	Work programme for the marketing of plant protection products	Official EC languages
Directive 76/116/EEC of 18.12.1975 on the approximation of the legal provisions of the Member States regarding fertilizers	BML	EC Official Journal L 24 of 30.01.1976 p. 21, last amended on 22.12.1998 (EC Official Journal L 18 p. 60)	Licensing, composition, labelling and packaging of EC fertilizers	Official EC languages
Directive 80/876/EEG of 15.07.1990 on the approximation of the legal provisions of the Member States regarding ammonium nitrate nutrient fertilizers with a high nitrogen content	BMA, BML	EC Official Journal L 250 of 23.09.1980 p. 7	The marketing of ammonium nitrate-containing fertilizers with a nitrogen content of 28 per cent and higher	Official EC languages
Directive 77/535/EEC of 22.06.1977 on the approximation of the legal provisions of the Member States regarding sampling and methods of analysis for fertilizers	BML	EC Official Journal L 213 of 22.08.1977 p. 1, last amended on 10.04.1995 (EC Official Journal L 86 p. 41)	Sampling and methods of analysis for official monitoring of the trade in EC fertilizers	Official EC languages
Directive 87/94/EEC of 08.12.1986 on the approximation of the legal provisions of the Member States regarding the examination of the characteristics, limit values and explosivity of ammonium nutrient fertilizers with a high nitrogen content	BMA, BML	EC Official Journal L 38 of 07.2.1987 p. 1, last amended on 22.12.1987 (EC Official Journal L 63 p. 12)	Methods for examining ammonium nitrate-containing fertilizers with a nitrogen content of 28 per cent and higher	Official EC languages
Directive 91/676/EEC of 12.12.1991 on the protection of waters against pollution caused by nitrates from agricultural sources	BMU, BML	EC Official Journal L 375 of 31.12.1991 p. 1	Reduction in the release of nitrogen into the waters. Inter alia, areas at risk are to be identified and programmes of action undertaken in these areas. Within the framework of the programmes of action, the Member States establish rules for good professional practice for the application of fertilizers which must be observed by farmers	Official EC languages
Law on the protection of cultivated plants (Plant Protection Act -	BML	In the version of 14.05.1998 (Federal Law Gazette I p. 971)	Protection of plants and cultivated plants against harmful organisms; averting dangers by means of plant	-

PflSchG)			protection products	
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Regulation	competent authority	where to find the regulation/date	content	available translations
Ordinance on evidence of specialist knowledge about plant protection (PflSchSachkV)	BML	Of 28.07.1987 (Federal Law Gazette I p. 1752; last amended on 14.10.1993 (Federal Law Gazette I p. 1720))	Specialist knowledge about plant protection	-
Ordinance on plant protection products and plant protection equipment (PflanzenschutzMGV)	BML	In the version of 17.08.1998 (Federal Law Gazette I p. 2161)	Regulates the licensing of plant protection products and plant protection equipment	-
Ordinance on prohibitions of use of plant protection products (PflSchAnwV)	BML	Of 10.11.1992 (Federal Law Gazette I p. 1887); last amended on 24.01.1997 (Federal Law Gazette I p. 60)	Prohibitions and restrictions of use of plant protection products	-
Ordinance on the principles of good professional practice in the area of plant protection	BML	Federal Gazette No. 220a of 21.11.1998	Principles for the realization of good professional practice in the area relating to plant protection	-
Fertilizer Act (DüngMG)	BML	Of 15.11.1977 (Federal Law Gazette I p. 2134); last amended on 27.09.1994 (Federal Law Gazette I p. 2705)	Licensing of types of fertilizer, - labelling and packaging, the principles of good professional practice during the application of fertilizers	-
Fertilizer Ordinance	BML	In the version of 11.08.1999 (Federal Law Gazette. I p. 1758), last amended on 17.11.99 (Federal Law Gazette. I p. 2206)	Licensing of types of fertilizer, - the listing and characterization of licensed types of fertilizer, rules relating to labelling and packaging	-
Ordinance on the principles of good professional practice during the application of fertilizers (DüngeV)	BML	Of 26.01.1996 (Federal Law Gazette I p. 118); last amended on 16.10.1997 (Federal Law Gazette I, p. 1835)	More precise determination of the principles of good professional practice, requirements for the application of fertilizers	-

Pharmaceuticals

Regulation	competent authority	where to find the regulation/date	content	available translations
Law on the distribution of medicines (German Drug Law - AMG)	BMG	In the version of 11.12.1998 (Federal Law Gazette I p. 3586); last amended on 26.07.1999 (Federal Law Gazette I p.1666)	Basic licensing and registration duties for drugs, homeopathic drugs and veterinary products	-
General administrative provision for application of the guidelines for the testing of drugs	BMG	New version of 05.05.1995 (Federal Gazette No. 96a of 20.05.1995)		-

Laundry and cleaning products

Regulation	competent authority	where to find the regulation/date	content	available translations
Law on the environmental impact of laundry and cleaning products (WRMG)	BMU	In the version of 05.03.1987 (Federal Law Gazette I p. 875); last amended on 27.06.1994 (Federal Law Gazette I p. 1440)	Rule on the environmentally compatible (marketing, consumption and use) of laundry and cleaning products	-

Foods and consumer goods

Regulation	competent authority	where to find the regulation/date	content	available translations
Foods and Consumer Goods Act (LMBG)	BMG	In the version of 09.09.1997 (Federal Law Gazette I p. 2296); last amended on 25.02.1999 (Federal Law Gazette I p. 374)	Prohibition of the use of foreign substances in foods, tobacco products, cosmetics and other consumer goods	-
Consumer Goods Ordinance (BedGgstV)	BMG	In the version of 23.12.1997 (Federal Law Gazette I p. 5); last amended on 18.10.1999 (Federal Law Gazette I p. 2059)		-
Ordinance on the Maximum Quantities of Hazardous Substances in Foods (SHmV)	BMU	Of 23.03.1988 (Federal Law Gazette I p. 422); last am. on 03.03.1997 (Federal Law Gazette I p. 430)		-

Regulation	competent authority	where to find the regulation/date	content	available translations
Ordinance on maximum quantities of certain solvents in foodstuffs (LHmV)	BMU	Of 25.07.1989 (Federal Law Gazette I p. 1568)		-
Ordinance on maximum quantities of residues of plant protection products and pesticides, fertilizers and other products in or on foodstuffs and tobacco products (RHmV)	BMU	In the version of 21.10.1999 (Federal Law Gazette I p. 2082)		-
Ordinance on Drinking Water and on Water for Food Processing Companies (TrinkwV)	BMG	In the version of 05.12.1990 (Federal Law Gazette I p. 2612); last amended on 01.04.1998 (Federal Law Gazette I p. 699)	Regulates the quality and monitoring of drinking water	-

Waste law

Regulation	competent authority	where to find the regulation/date	content	available translations
Waste Avoidance, Recycling and Disposal Act - a law to promote recycling and ensure environmentally compatible removal of wastes (KrW/AbfG)	BMU	Of 27.09.1994 (Federal Law Gazette I p. 2705); last amended on 25.08.1998 (Federal Law Gazette I p. 2455)	Principles relating to the avoidance or handling of wastes. Regulates waste disposal plants	-
Ordinance on the avoidance and utilization of packaging wastes (VerpackV)	BMU	Of 21.08.1998 (Federal Law Gazette I p. 2379); last amended on 18.10.1999 (Federal Law Gazette I p. 2059)		-
Ordinance on the utilization of biological wastes on soils used for agriculture, forestry and gardening (BioAbfV)	BMU	Of 21.09.1998 (Federal Law Gazette I p. 2955)		-
Ordinance on the Disposal of Waste Halogenated Solvents (HKWAbfV)	BMU	Of 23.10.1989 (Federal Law Gazette I p. 1918)	Demands on solvents which are to be utilized as waste or disposed of	-
Ordinance on Used Oil (AltöIV)	BMU	Of 27.10.1987 (Federal Law Gazette I p. 2335)	Demands on processing and disposal as well as sale to the end-user	-
Sewage Sludge Ordinance (AbfKlärV)	BMU	Of 15.04.1992 (Federal Law Gazette I p. 912); last amended on 06.03.1997 (Federal	Demands relating to the application of sewage sludge to agricultural areas	-

		Law Gazette I p. 446)		
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Protection against immissions

Regulation	competent authority	where to find the regulation/date	content	available translations
Federal Immission Control Act, Law protecting against harmful environmental influences due to air pollutants, noise, vibrations and similar processes (BImSchG)	BMU	In the version of 14.05.1990 (Federal Law Gazette I p. 880); last amended on 19.10.1998 (Federal Law Gazette I p. 3178)	Demands on plant, nature of fuels, monitoring of air quality	English
First general administrative provision relating to the Federal Immission Control Act (Technical Instructions on Air Quality Control - TA-Luft)	BMU	Of 27.02.1986 (General information bulletin p. 95, corrected p. 202)	Limit values for emissions of certain substances; demands in connection with the operation of plant	-
First ordinance on the implementation of the Federal Immission Control Act (Ordinance on Small Furnaces - 1.BImSchV)	BMU	In the version of 14.03.1997 (Federal Law Gazette I p. 490)	Emission demands on small furnaces not requiring licences	-
Second ordinance on the implementation of the Federal Immission Control Act (Ordinance on the restriction of emissions of highly volatile halogenated hydrocarbons - 2.BImSchV)	BMU	Of 10.12.1990 (Federal Law Gazette I p. 2694); amended on 05.06.1991 (Federal Law Gazette I p. 1218)	Requirements in the case of the use of highly volatile halogenated hydrocarbons in certain plants	-
Third ordinance on the implementation of the Federal Immission Control Act (Ordinance on the sulphur content of light heating oil and diesel fuel - 3.BImSchV)	BMU	Of 15.01.1975 (Federal Law Gazette I p. 264) last amended on 26.09.1994, (Federal Law Gazette I p. 2640)	Sulphur content of heating oil and diesel	-
Fourth ordinance on the implementation of the Federal Immission Control Act (Ordinance on plants requiring licences - 4.BImSchV)	BMU	In the version of 14.03.1997 (Federal Law Gazette I p. 504); last amended on 23.02.1999 (Federal Law Gazette I p. 186)	Names types of plant which require licences and licensing procedures	-
Seventh ordinance on the implementation of the Federal Immission Control Act (Ordinance on the emission limitation of wood dust - 7. BImSchV)	BMU	Of the 18.12.1975 (Federal Law Gazette I p. 3133)		-
Tenth ordinance on the implementation of the Federal Immission Control Act (Ordinance on the constitution of fuels and the labelling of fuel qualities -	BMU	Of 13.12.1993 (Federal Law Gazette I p. 2036); last amended on 08.12.1997 (Federal Law Gazette I	Constitution of fuels	-

10.BImSchV)		p. 2858)		
Regulation	competent authority	where to find the regulation/date	content	available translations
Twelfth ordinance on the implementation of the Federal Immission Control Act (Hazardous Incident Ordinance - 12.BImSchV)	BMU	In the version of 20.09.1991 (Federal Law Gazette I p. 1891); last amended on 20.04.1998 (Federal Law Gazette I p. 723)	Measures to prevent hazardous incidents and limit the effects of hazardous incidents	-
Thirteenth ordinance on the implementation of the Federal Immission Control Act (Ordinance on large furnaces - 13.BImSchV)	BMU	Of 22.06.1983 (Federal Law Gazette I p. 719)	Erection, operation and construction of furnaces > 50 MW	-
Seventeenth ordinance on the implementation of the Federal Immission Control Act (Ordinance on incineration plants for wastes and similar combustible substances - 17.BImSchV)	BMU	Of 23.11.1990 (Federal Law Gazette I p. 2545, corrected p. 2832); last amended on 23.02.1999 (Federal Law Gazette I p. 186)	Erection, operation and construction of waste-incineration plants for solid and liquid wastes	-
Nineteenth ordinance on the implementation of the Federal Immission Control Act (Ordinance on chlorine and bromine compounds used as fuel additives - 19.BImSchV)	BMU	Of 17.01.1992 (Federal Law Gazette I p. 75)	Prohibition of chlorine and bromine compounds in fuels	-
Twenty-first ordinance on the implementation of the Federal Immission Control Act (Ordinance on limiting hydrocarbon emissions during the fuelling of motor vehicles - 21. BImSchV))	BMU	Of 07.10.1992 (Federal Law Gazette I p. 1730)	Protection against hydrocarbon emissions during the fuelling of motor vehicles	-
Twenty-second ordinance on the implementation of the Federal Immission Control Act (Ordinance on emission limit values - 22.BImSchV)	BMU	Of 26.10.1993 (Federal Law Gazette I p. 1819); last amended on 27.05.1994 (Federal Law Gazette I p. 1095)	Air-quality standards for particular substances	-
Twenty-third ordinance on the implementation of the Federal Immission Control Act (Ordinance on the determination of concentration levels – 23. BImSchV)	BMU	Of 16.12.1996 (Federal Law Gazette I p. 1962)		-
Twenty-fifth ordinance on the implementation of the Federal Immission Control Act (Ordinance on the limitation of emissions from the titanium oxide industry – 25. BImSchV)	BMU	Of 08.11.1996 (Federal Law Gazette I p. 1722)	Measures to reduce and put an end to pollution caused by the titanium oxide industry	-

Regulation	competent authority	where to find the regulation/date	content	available translations
Twenty-seventh ordinance on the implementation of the Federal Immission Control Act (Ordinance on plants used for cremation – 27. BImSchV)	BMU	Of 19.03.1997 (Federal Law Gazette I p. 545)		-
Twenty-eighth ordinance on the implementation of the Federal Immission Control Act (Ordinance on emission limits for combustion engines – 28. BImSchV)	BMU	Of 11.11.1998 (Federal Law Gazette I p. 3411)	Measures to combat gaseous pollutants and air-polluting particles from combustion engines for mobile machines and equipment	-
Law on the reduction in air pollutants as a result of lead compounds in fuels for motor vehicle engines (BzBIG)	BMU	Of 05.08.1971 (Federal Law Gazette I p. 1234); last amended on 24.06.1994, (Federal Law Gazette p. 1416)	Lays down the permissible lead content in motor fuel	-
First ordinance on the implementation of the law on the lead content of motor fuel (BzBIGDV)	BMU	Of 07.12.1971 (Federal Law Gazette I p. 1966)	Lays down the permissible lead content in motor fuel	-

Water protection

Regulation	competent authority	where to find the regulation/dates	content	available translations
Water Resources Management Act (WHG)	BMU	In the version of 12.11.1996 (Federal Law Gazette I p. 1695); last amended on 22.05.1998 (Federal Law Gazette I p. 2455)	Principles concerning the use of water and how to deal with water, in particular demands on the discharge of waste water and the protection of the ground water	-
Waste Water Levy Act Law on levies for discharging waste water into aquatic environments (AbwAG)	BMU	In the version of 03.11.1994 (Federal Law Gazette I p. 3370); last amended on 25.08.1998 (Federal Law Gazette I p. 2455)	Levies for the discharge of waste water into aquatic environments	-
Ordinance relating to water pollutants conveyed through pipelines (WassgefStBefV)	BMU	Of 19.12.1973 (Federal Law Gazette I p. 1946); amended on 05.04.1976, (Federal Law Gazette I p. 915)	Provisions relating to water pollutants which are conveyed through pipelines	-
Ordinance on the demands	BMU	Of 09.02.1999	Demands on waste water	-

on the discharge of waste water into aquatic environments (AbwV)		(Federal Law Gazette I p. 86)	which is discharged into the ground water	
Regulation	competent authority	where to find the regulation/dates	content	available translations
Ordinance for the implementation of Council Directive 80/68/EEC of 17 December 1979 on the protection of the ground water against pollution by certain dangerous substances (GrWV)	BMU	Of 18 March 1997 (Federal Law Gazette I p. 542)	Conditions for the discharge of certain substances into the ground water	-
General administrative provision relating to the Water Resources Management Act concerning the classification of water pollutants according to water-hazard classes (VwVwS)	BMU	Of 17th May 1999 (Federal Gazette 98a of 29.05.1999)	Classification rules	-

Soil protection

Regulation	competent authority	where to find the regulation/dates	content	available translations
Law on protection against harmful changes to the soil and restoration of hazardous waste sites (BBodSchG)	BMU	Of 17.05.1998 (Federal Law Gazette I p. 502)	Ensuring or restoring the sustainable functions of the soil	-
German ordinance on soil protection and hazardous waste sites (BBodSchV)	BMU	In the version of 16.07.1999 (Federal Law Gazette I p. 1554)	Monitoring and assessment of hazardous waste sites; demands on acts of restoration; prevention values	-

Protection of animals

Protection	competent authority	where to find the regulation/dates	content	available translations
Animal Protection Act (TierSchG)	BML	In the version of 25.05.1999 (Federal Law Gazette I p. 1105)	The regulation of animal experiments, the protection of the life and well-being of animals	-

Chemical weapons

Regulation	competent authority	where to find the regulation/dates	content	available translations
Implementing statute relating to the Agreement on Chemical Weapons (CWÜAG)	BMVg	Of 02.08.1994 (Federal Law Gazette I p. 1954)	Restrictions on chemical warfare agents, key chemicals, intermediates and organic chemicals	-
Implementing ordinance rela-	BMVg	Of 20.11.1996	Implementing provisions	-

ting to the Agreement on Chemical Weapons (CWÜVO)		(Federal Law Gazette I p. 1794)	relating to the Agreement on Chemical Weapons	
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Transport of dangerous goods

Regulation	competent authority	where to find the regulation/dates	content	available translations
Council Directive 93/75/EEC of 13.03.1993 on minimum requirements for vessels bound for or leaving Community ports and carrying dangerous or polluting goods	BMVBW	EC Official Journal L 247 of 05.10.1993 p. 19; last amended on 01.10.1998 (EC Official Journal L 276 p.7)		Official EC languages
Council Directive 94/55/EC of 21.11.1994 on the approximation of the laws of the Member States with regard to the transport of dangerous goods by road	BMVBW	EC Official Journal L 319 of 12.12.1994, p. 7; last amended on 21.05.1999 (EC Official Journal L 169, p. 1)		Official EC languages
Council Directive 95/50/EC of 06.10.1995 on standardized procedures for the control of the transport of dangerous goods by road	BMVBW	EC Official Journal L 249 of 17.10.1995 p. 35		Official EC languages
Directive 96/35/EC of 03.06.1996 on the appointment and vocational qualification of safety advisers for the transport of dangerous goods by road, rail or on inland waterways	BMVBW	EC Official Journal L 145 of 19.06.1996, p. 10		Official EC languages
Council Directive 96/49/EC of 23.07.1996 on the approximation of the statutory provisions of the Member States with regard to the transport of dangerous goods by rail	BMVBW	EC Official Journal L 235 of 16.11.1994 p. 25; last amended on 17.09.1996 (EC Official Journal L 169, p. 58)		Official EC languages
Directive 98/91/EC of 14.12.1998 on motor vehicles and motor vehicle trailers for the transport of dangerous goods by road and amending Directive 70/156/EEC with regard to the authorization of types of motor vehicles and motor vehicle trailers	BMVBW	EC Official Journal L 11 of 16.01.1999, p. 25		Official EC languages
Law on the transport of dangerous goods (GefahrgutG)	BMVBW	Of the 28.03.1980 (Federal Law Gazette I p. 2121); last amended on the 29.09.1998 (Federal Law Gazette I p. 3114)		-

Air-transport Act (LuftVG)	BMVBW	In the version of 27.03.1999 (Federal Law Gazette I p. 550)		-
Regulation	competent authority	where to find the regulation/dates	content	available translations
Dangerous Goods Ordinance - road (GGVS)	BMVBW	In the version of 12.12.1996 (Federal Law Gazette I p. 3993); last amended on the 23.06.1999 (Federal Law Gazette I p. 1435)		-
Dangerous Goods Ordinance - rail (GGVE)	BMVBW	In the version of 22.12.1996 (Federal Law Gazette I p. 3909)		-
Dangerous Goods Ordinance - inland waterways (GGVBinSch)	BMVBW	In the version of 21.12.1994 (Federal Law Gazette I p. 3971); last amended on 04.12.1997 (Federal Law Gazette I p. 2853)		-
Dangerous Goods Ordinance - sea (GGVSee)	BMVBW	Of 04.03.1998 (Federal Law Gazette I p. 1876); last amended on the 23.06.1999 (Federal Law Gazette I, p. 419)		-

4.2.3 Additional regulations specific to individual Länder

Within the framework of their responsibility at regional level, some *Länder* have further regulations which either go beyond the national regulations or supplement them. A few regulations from the State of Baden-Württemberg relating to the areas of chemical safety and plant protection product law are provided here as an example. Analogous regulations exist for the other areas of law cited in the previous chapter.

Baden-Württemberg (BW):

as at 31.10.1999

Regulation	competent authority	where to find the regulation/date	content
Ordinance on competences according to the Chemicals Act and the ordinances passed in accordance with this Act (ChemGZuVO)	UVM, WM, MLR, SM	23.01.1995, Law Gazette p. 133	Regulation of the competences in the state for enforcement of the Chemicals Act and its ordinances
Guidelines for the assessment and restoration of weakly bound asbestos	WM	Announcement of the 04.02.1997, Law Gazette	Demands relating to the assessment and restoration of asbestos in buildings

products in buildings (Asbestos guidelines, January 1996)		p. 207/226	
Regulation	competent authority	where to find the regulation/date	content
Guideline for the assessment and restoration of PCP-contaminated building materials and structural elements in buildings (PCP guideline)	WM	Announcement of the 04.02.1997 Law Gazette p. 207/233 corrected p. 468	Rules for the assessment of PCP-contaminated building materials and structural elements
Guideline for the assessment of PCB-contaminated building materials and structural elements in buildings (PCB guideline)	WM	Announcement of the 09.03.1995 Law Gazette p 220	Advice on the assessment and restoration of PCB-contaminated building materials
Regional government's report on air quality in interior spaces	SM, UVM, WM	Will be appearing soon in the form of a brochure	Description of the regional government's previous and planned measures for improving the quality of air in interior spaces
Ordinance for the implementation of the Plant Protection Act	MLR	14.05.1987 Law Gazette p. 235; last amended by the amending ordinance of the 07.01.1991 Law Gazette p. 15	Ordinance laying down areas of competence
Ordinance on the examination relating to the provision of evidence of expert knowledge in the area of the use and sale of plant protection products (PrOPfISch)	MLR	23.12.1998, Law gazette 1989 p. 7	Ordinance on the examination relating to the provision of evidence of expert knowledge in the area of plant protection
Administrative provision relating to the ordinance for testing expert knowledge in the area of plant protection products (VwVPrOPfISch)	MLR	12.08.1997 Law Gazette p. 501	Explanations relating to the ordinance for testing expert knowledge
Administrative provision of the Ministry for Rural Spaces concerning the recognition of qualifications as evidence of expert knowledge in the area of the use and sale of plant protection products	MLR	08.07.1992 Law Gazette, p.753	Certain vocational qualifications are recognized as evidence of expert knowledge
Ordinance on the admission of exemptions from the prohibition of use of plant protection products in the open air (plant protection product exemption ordinance)	MLR	27.07.1999 Law Gazette p. 363	Exemption of certain agents from the prohibition of the use of plant protection products in the open air

Law on the restriction of use of plant protection products	MLR	17.12.1990 Law Gazette p. 426	Further restriction of the use of plant protection products in the private sphere
Regulation	competent authority	where to find the regulation/date	content
Administrative provision of the Ministry for Rural Spaces concerning the recognition of inspection sites and the testing of plant protection equipment used in extensive cultivation	MLR	29.06.1993 Law Gazette, p. 501, corrected p. 671	Prerequisites for the performance of inspections of plant protection equipment

4.3 Voluntary agreements with the chemical industry

A number of voluntary, self-imposed obligations exist for the chemical industry in the Federal Republic of Germany. Some of them are listed here as examples. However, these agreements can only supplement state control in the area of chemicals management, and not replace it. These self-imposed obligations do not apply to companies which are not affiliated to the particular industry association.

4.3.1 At national level

- "Reduction in the use of CFCs as propellant gases in sprays"
1977 - 1999
- "Voluntary review of existing chemicals used in the chemical industry"
since 1982
- "Early fulfilment of obligations relating to the reduction of emissions from large furnaces (above all in NRW and Baden-Württemberg)"
1983 - 1st of July 1988
- "Voluntary agreement on the complete substitution of asbestos in products used in building construction"
13th of March 1984 - end of 1990
- "Dispensing with the use of alkyl phenol ethoxylates (APEO)"
since the 14th of January/22nd of January 1986
- "Code of conduct for the chemical industry in connection with the export of dangerous chemicals"
since March 1986
- "Self-imposed obligation on the part of the paint industry with regard to the reduction of the solvent and heavy-metal compound parts in lacquers and paints"
May 1986 - 1989

- "Voluntary agreement on the part of the paint industry to reduce polluting agents in underwater paints intended for use in painting boats" August 1986 - 1989
- "Declaration on the limited use of NTA and on the performance of, and financial participation in, the NTA research and monitoring programme" since the 12th of August 1986
- "The chemical industry's safety concept for plants involved in dealing with water pollutants"
- "Dispensing with the use of highly volatile, chlorinated hydrocarbons in laundry and cleaning products in the area of applicability of the Federal Republic of Germany" since the 27th of July 1987
- "The chemical industry's voluntary concept for a reduction in the use of CFCs in sprays" August 1987 - 31st of December 1989
- "Procedural rules for the announcement of the data according to § 9 of the law on laundry and cleaning products" since the 5th of December 1988
- "Declaration relating to the notification of solvents to the Federal Environmental Agency in accordance with § 9 section 1 of the law on the environmental impact of laundry and cleaning products (WRMG) and the voluntary announcement of data relating to § 9 section 2 of the law on the environmental impact of laundry and cleaning products (WRMG)" since the 31st of January 1989
- "The chemical industry's self-imposed obligation to progressively stop the production of all of the CFCs regulated in the Montreal protocol " May 1990 - 1993
- "The chemical industry's self-imposed obligation to take back and reutilize used CFCs from refrigeration and air-conditioning equipment as well as from insulating foams" since May 1990
- "Declaration on the reduction in the pollution of waters by EDTA" since the 31st of July 1991
- "The automobile industry's self-imposed obligation to provide CFC-free automobile air-conditioning systems by the autumn of 1993" July 1992 – autumn 1993

- "The self-imposed obligation on the part of the Federal Guild Association of the German Refrigeration Equipment Construction Trade to dispense with the use of CFCs in the construction of new refrigeration and air-conditioning systems" by the end of 1993
July 1992 - end of 1993
- "The self-imposed obligation on the part of the polyurethane solid foam industry to dispense with use of CFCs in the production of insulating materials by the end of 1993"
July 1992 - end of 1993
- "Declaration on the implementation of the EC Commission's recommendation concerning the labelling of laundry and cleaning products (89/542/EEC) of the 13th of September 1989"
since the 1st of October 1990
- "The self-imposed obligation on the part of the Central Association of the Electrical and Electronics Industry (ZVEI) to produce only CFC-free household refrigerators by 1994. Partially halogenated CFCs are also to be dispensed with."
March 1993 - July 1994
- "Declarations relating to the self-imposed obligation to use chemicals in the production of self-copying paper and thermal printing paper which do not represent any risk to the aquatic environment"
since February 1996
- "Declarations relating to the self-imposed obligation on the part of industry to switch the production of polystyrene extrusion foam (XPS foam) to expanding agents that are free from H-CFCs"
February 1996 - January 2000
- "Declaration relating to the self-imposed obligation to control the use of the impregnating agent FUNGITEX ROP"
since February 1996
- "Voluntary undertaking relating to the announcement of substance data by the producers of laundry and cleaning products"
since the 10th of July 1997
- "Voluntary self-imposed obligation on the part of the German chemical industry to record and assess substances (in particular intermediates) in order to improve the meaningfulness of the data"
since the 23rd of September 1997
- "Voluntary decision to dispense with the further marketing of leaded petrol"
since October 1996
- "Reduction in water pollution as a result of water-relevant, hardly degradable complexing agents in the waste water of photographic processes"
January 1998 - 2001

- Decision to dispense with the use of alkyl phenol ethoxylates (APEO) in polyacrylanide emulsion polymers for the purpose of treating waste water and sewage sludge"
June 1998 - 31.12.2001

See chapter 6 for further information

4.3.2 In individual *Länder*

(The information provided is merely intended to serve as an example)

Hamburg

- "Increased solvent emissions (per) in the proximity of dry cleaners" since February 1988

Lower Saxony

- "Agreement on reducing the use of low-boiling cleaning agents in offset printing" since the 18th of April 1987

North Rhine-Westphalia

- "Plan for the reduction of emissions from waste-incineration plants" February 1990 - 1st of December 1995
- "Self-imposed obligation to limit hydrocarbon emissions during the fuelling of motor vehicles" since the 1st of January 1993
- "Agreement on the voluntary self-monitoring of dry cleaners by external experts" since the 1st of January 1994

Chapter 5 Procedures, participating ministries and authorities

5.1 Chemicals management in the narrower sense

5.1.1 European procedure for new substances

Directive 92/32/EEC of 30 April 1992, amending for the seventh time Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances, was passed on the 30th of April 1992. It obliged the Member States to transpose into national law the regulations laid down in it. In the Federal Republic of Germany, the 7th Amendment was transposed by means of the 2nd amendment of the law on protection against dangerous substances (Chemicals Act).

General information on the duty to notify chemical substances

The Chemicals Act regulates the duties to notify, test and, if necessary, label new substances. New substances are all the substances not listed in EINECS, the European Inventory of Existing Commercial Chemical Substances. All substances, preparations or products which are regulated by special laws do not fall within the scope of the Act.

The notifier who produces, obtains or brings the substance or a preparation into the area of applicability of the Chemicals Act must reside or have his business premises in the Federal Republic of Germany. After a notification has been undertaken, producers or importers may freely market the substance throughout the entire EU area as well as in states within the European Economic Area which have transposed the 7th Amendment into national law.

Tonnage-based procedure

The Chemicals Act provides for the tonnage-related notification of each new substance placed on the market in quantities of ≥ 10 kg per year. Once the next tonnage threshold has been reached, further documents must be submitted. The decisive factor with regard to import notifications is the total quantity of the substance which is imported into the EU and the EEA states per producer.

Quantity placed on the market per year	Total quantity placed on the market	Type of notification
10 kg - < 100 kg	-	reduced notification
100 kg - < 1,000 kg	≥ 500 kg	reduced notification
≥ 1,000 kg	≥ 5,000 kg	base set
≥ 10,000 kg	≥ 50,000 kg	early level I
≥ 100,000 kg	≥ 50,000 kg	level I
≥ 1,000,000 kg	≥ 5,000,000 kg	level II

Prior inquiry duty / utilization of existing test reports

Each notifier has a duty to make a prior inquiry before performing animal tests for the purpose of preparing a notification or a mini-notification. Within the framework of this procedure the potential notifier must inquire about the need to perform animal tests. If the Notification Unit already possesses sufficient knowledge about the relevant substance from a third party's test reports, a procedure for the utilization of the third party's test reports is initiated whereby the initial notifier and the subsequent notifier have the opportunity to reach an agreement about joint utilization of the test reports. If no agreement is reached, so-called compulsory referencing is undertaken. According to this procedure, the third party whose test reports are utilized has the right to seek compensation from the subsequent notifier at a level of 50% of the saved expenditure. For his part, the subsequent notifier has a right to be provided with a copy of the utilized test report.

Good laboratory practice (GLP)

Non-clinical experimental tests whose results are to be submitted within the framework of the notification procedure must be performed in accordance with the principles of good laboratory practice (GLP). Proof that the test results satisfy these demands must be furnished in the form of

- a certificate from the competent authority (GLP certificate) that the test institute and the tests it performs comply with the principles of good laboratory practice and
- a written declaration from the test institute that the particular test has been performed according to the principles of good laboratory practice.

Test results are regarded as not having been submitted if one of the above-mentioned reports has not been provided.

Further explanations concerning GLP can be found in chapter 9.1

Submission of the notification documents

The notification procedure requires the completion of a form in the German language. Use of the SNIF format (Structured Notification Interchange Format) on disk is the preferred option here. The notification documents must be submitted to the Federal Institute for Occupational Safety and Health as the **Notification Unit within the Chemicals Act**. The submitted documents are checked for completeness and forwarded to the assessment units, **the Federal Institute for Occupational Safety and Health (BAuA)**, **the Federal Institute for Health Protection of Consumers and Veterinary Medicine (BgVV)** and **the Federal Environmental Agency (UBA)** for expert assessment. In certain cases **the Federal Biological Research Centre for Agriculture and Forestry (BBA)** and **the Federal Institute for Materials Research and Testing (BAM)** are included in the process.

The assessment units and the Notification Unit examine, within their area of competence, the plausibility and validity of the notification documents. In total a period of

- 30 days for reduced notifications and
- 60 days for a complete notification at base-set level

is available for this procedure.

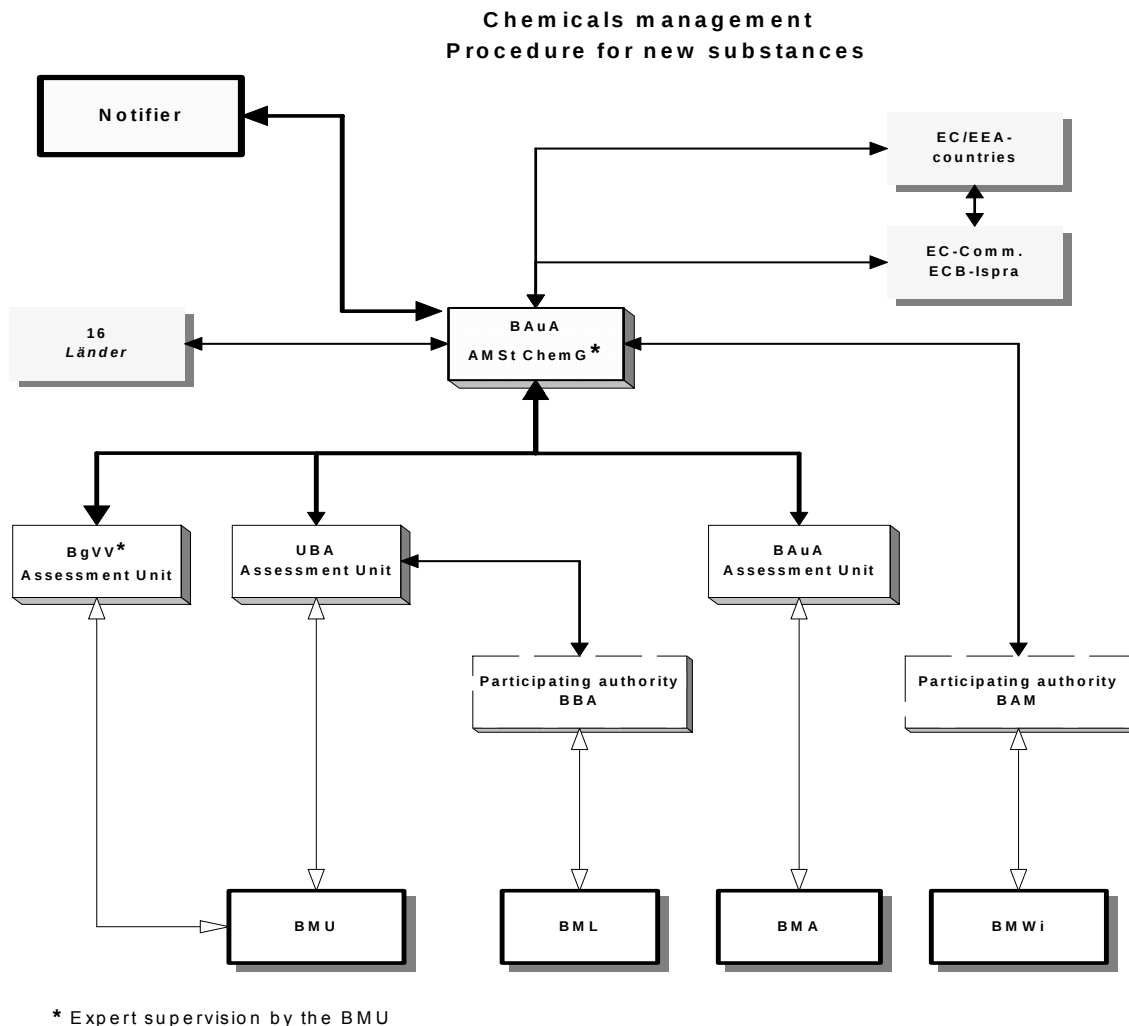
If the documents are in order the Notification Unit confirms this fact by issuing a notice of acceptance.

If the submitted notification documents and test reports do not permit adequate assessment of whether the notified substance has adverse effects on man or the environment and if this inability to perform an assessment is due to incomplete or incorrect notification documents, the Notification Unit asks the notifier to supplement or correct his documents within the 30/60-day period. For the notifier this means that the notified substance cannot be placed on the market until 30 or 60 days respectively after receipt of all the corrections or supplementary data which have been demanded. If adequate assessment is not possible even after the subsequent submission of further documents, the complaint procedure is repeated. On conclusion of the procedure the notifier is sent a notice of the relevant costs.

The Notification Unit can make further demands due to incomplete or incorrect test reports even after expiry of the notification period if, for example, test reports are required due to an EU legal instrument or because new aspects have come to light after expiry of the specified period.

In addition, in cases where an assessment of the notified substance would not otherwise be possible, supplementary information can also be demanded in the case of complete and correct documents, too. Furthermore, the Notification Unit can demand the early submission of test reports if there are grounds for suspecting a particular substance of being dangerous. Such grounds may, for example, result from structure-activity-relationships and exposure to the substance or exist in cases where the test reports are required for performance of

the risk assessment. In addition, the Notification Unit can order that certain substances may only be placed on the market if conditions are fulfilled or after a future event has occurred. If documents are not submitted within the specified period or if obligations or conditions are not met, the Notification Unit can prohibit the marketing of the substance concerned.



5.1.2 European procedure for existing chemical substances

Council Regulation No. 793/93 on the Evaluation and Control of the Risks of Existing Substances came into force on the 04.06.1993. It takes direct effect in the Member States and does not require special transposition into national law.

About 100,000 substances, which in principle can be freely traded and used, are listed in the European Inventory of Existing Commercial Chemical Substances (EINECS). It was therefore necessary for existing substances to be regulated on their own - in analogy to the procedure for new substances - in order to be able to perform, at EU level, systematic assessments of the risks posed by chemicals

from which - if necessary - specific protection measures for workers, consumers and the environment can be derived.

Work on existing substances in accordance with Council Regulation No. 793/93 takes place in four phases:

1. The collation of available information, at first for substances produced or imported in quantities > 1,000 t/year, at a later date for substances produced or imported in quantities between 10 and 1,000 t/year.

This phase has been concluded. The **European Chemicals Bureau** in Ispra/Italy possesses an extensive pool of data on substances produced in large volumes. In particular, data on producers, quantities and intended uses are available.

2. The drawing up of priority lists and the division of the priority substances among the Member States.

Substances in quantities > 1,000 t/year for which, as a result of gaps in the data, there is a need for testing or for which there is a need for regulation due to problems relating to handling are included in a priority list after joint discussion between the European Commission and the Member States. Three priority lists, containing a total of 109 substances, currently exist. Each substance is assigned to a Member State which then acts as *rapporteur*.

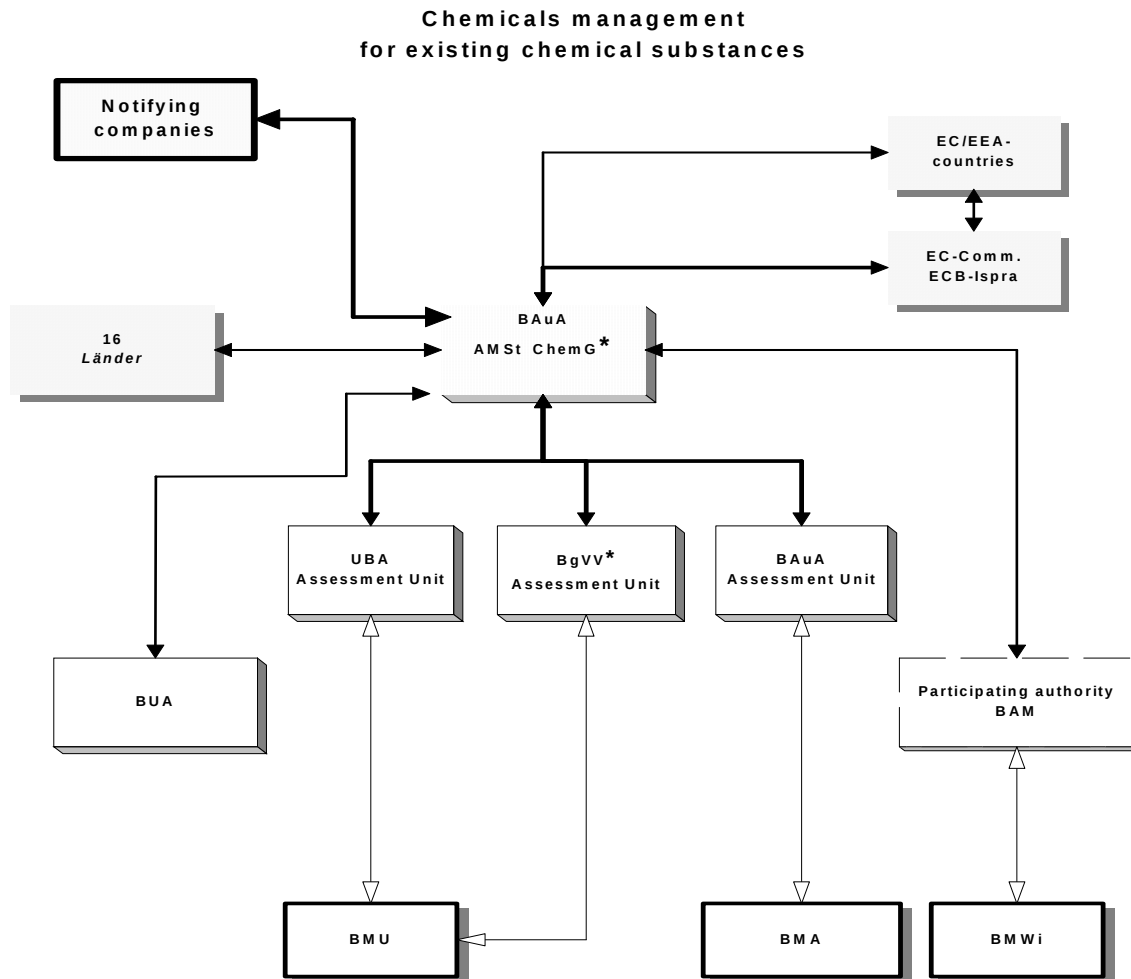
3. The supply of test protocols, data relating to use, exposure data and other knowledge concerning the priority substances by the manufacturing or importing companies. Examination of usability and, if necessary, demands for further investigations. The minimum amount of data required in connection with the properties of the substance depends on the extent of testing at base-set level within the framework of the procedure for new substances.
4. Assessment of the risks to workers, consumers and the environment which are posed by the substance. A proposal for protective measures and, if necessary, the indication of substitute substances and their risks and availability.

Using the documents conveyed to them and available knowledge, the Member States produce comprehensive risk assessments. In Germany, the responsibility for performing this work is regulated by the Administrative Provision for Existing Commercial Chemical Substances (ChemVwV-Altstoffe) of the 11.09.1997. Accordingly, the national rapporteur is the **Notification Unit within the Chemicals Act** and the assessment units are the **Federal Environmental Agency (UBA)**, the **Federal Institute for Health Protection of Consumers and Veterinary Medicine (BGVV)** and the **Federal Institute for Occupational Safety and Health (BAuA)**, each having responsibility for the specific areas targeted by them for protection. The above-mentioned state bodies receive support in their work from the **Advisory Committee on Existing Chemicals of Environmental Relevance (BUA)** which comprises experts from the scientific field, industry and the authorities.

The draft risk assessments produced by the individual Member States are distributed to the European Commission and all other Member States. In several

different phases of work, the risk assessments are discussed and, if necessary, altered before being accepted by all of those participating in the procedure. Subsequently, the results which are obtained are published in the Official Journal of the European Communities.

Necessary measures such as, inter alia, classification, labelling, restrictions, and prohibitions must then be derived from the generally accepted risk assessments and pushed through politically.



* Expert supervision by the BMU

5.1.3 International activities concerning existing chemical substances, SIDS

An important player in international efforts to ensure the safety of chemicals is the OECD. Approximately 78 % of worldwide production of chemicals takes place in the 29 OECD Member States. In the last 20 years the OECD has shown considerable commitment to ensuring the safety of chemicals while at the same time giving due consideration to the safeguarding of economic growth and environmental-protection issues. Examples of the activities of the OECD in the area relating to the safety of chemicals are as follows:

Main focus of work:

International harmonization of measures for the identification and prevention of dangers resulting from chemicals:

- Mutual recognition of data
 - Test methods for chemicals and plant protection products
 - Good Laboratory Practice (GLP) for pharmaceuticals, chemicals and plant protection products
- Work relating to existing chemical substances
 - Assessment of substances in the Member States according to the principle of shared responsibility for the work involved in the process.
 - Proposal of measures in connection with selected substances
- Risk identification and minimization
- Accidents involving chemicals
- Biotechnology

Working groups, inter alia:

- test methods for chemicals
- GLP
- existing chemical substances
- risk assessment
- plant protection products
- harmonization of classification

Organization of the work:

- Joint meeting every 9 months
- Combined session with the group responsible for plant protection products
- Steering body (bureaux)

Screening Information Data Sets (SIDS)

Since 1990 there has been intensive cooperation between the Member States and industry to produce so-called Screening Information Data Sets (SIDS) for existing chemical substances. These data sets include data on substances, on the dangers posed by them and, in part, on exposure to them. Consideration is given to substances which are produced either in quantities above 1,000 t in one Member State or above 1,000 t in at least two Member States. The work is coordinated with the activities of the EC and the International Programme on Chemical Safety (IPCS). Between 1992 and 1996 approx. 100 chemicals were considered. Work is currently continuing on about a further 200 chemicals.

The SIDS Initial Assessment Reports (SIAR) produced on the basis of the SIDS are not as comprehensive as the substance reports produced by the IPCS (EHC reports: Environmental Health Criteria) or the EC substance reports which are in the process of being written. The SIAR are primarily intended to show whether there is sufficient data on a particular substance and whether, on the basis of currently available data, there are grounds for considering the substance further, e.g. within the framework of a risk assessment.

The SIDS contact point for Germany is the **Notification Unit within the Chemicals Act**. The **Federal Institute for Health Protection of Consumers and Veterinary Medicine**, the **Federal Environmental Agency** and – within the framework of the EC procedure for existing chemical substances – the assessment unit of the **Federal Institute for Occupational Safety and Health** – are all involved in the production of the SIARs, each having responsibility for the relevant area targeted for protection.

5.1.4 *Marketing, production and use of chemicals*

The outline directives listed in chapter 4.2.1, i.e. 67/548/EEC (classification, packaging and labelling of dangerous substances), 88/379/EEC (in future 1999/45/EC, classification, packaging and labelling of dangerous preparations) and 76/769/EEC (restrictions on marketing and use) apply with regard to placing chemicals on the market in the EU.

These outline directives, including the relevant adaptation directives or independent directives, have been mainly transposed into German law in the Chemicals Act, the Hazardous Substances Ordinance and the Prohibition of Chemicals Ordinance. With the 4th Amendment of the Hazardous Substances Ordinance of 30th of October 1999, with regard to the classification, packaging and labelling of dangerous substances, preparations and products, the previous transposition practice via amendments will be replaced by flexible references to the relevant EU directives in their current version.

Directive 98/24/EC includes the minimum European requirements for the handling of chemicals in the workplace. It supersedes the previous outline directive 80/1107/EEC on the protection of workers from risks related to chemical, physical and biological working substances. In addition, there are further chemicals-related regulations, e.g. Directive 90/394/EEC (in the version of the amendment 1999/38/EC) on the protection of workers from risks related to carcinogens or Directive 92/85/EEC on the improvement of the health protection of pregnant workers, workers who have recently given birth and workers who are breastfeeding.

Directive 98/24/EC has not yet been explicitly transposed into German law. However, many of the rules contained therein are already constituent parts of today's Hazardous Substances Ordinance. The requirements contained in Directive 90/394/EEC are also to be found in the Hazardous Substances Ordinance. In 1997 Directive 92/85/EEC was transposed into German law as an independent maternity-protection ordinance.

Classification

Classification is the substance-related assignment of danger categories (e.g. flammable, toxic, carcinogenic, dangerous for the environment) on the basis of statutorily defined criteria. It triggers duties on the part of the person placing chemical substances and preparations on the market to label them and provide relevant information. In accordance with Article 95 of the European Treaty, the EU is striving for harmonization of classification within the single market. The regularly updated Annex I of Directive 67/548/EEC contains a list of dangerous substances for which an EU-harmonized, binding classification already exists ("legal classification"). The "definition principle" applies to all other substances and preparations, i.e. the person placing them on the market is solely responsible for the decisions he takes on the basis of the predetermined criteria contained in Annex V to Directive 67/548/EEC or Directive 88/379/EEC (in future 1999/45/EC).

Labelling, safety data sheet

A labelling duty for the substance and for preparations containing the substance in amounts above certain concentration limits ensues from the classification. The Directives 67/548/EEC and 88/379/EEC (in future 1999/45/EC) contain an EU-harmonized, detailed system of labelling rules which brings together the insights gained in the course of the classification process in order to provide initial information for the customer which is oriented towards the principle risks posed by the substance or preparation. As a result of this concentrated form of information, applying in particular to the labelling of preparations, there is, however, the need for further information in connection with particular areas targeted for protection. This is above all the case with regard to occupational safety and health since the users of chemical products may be exposed to very different risks dependent on the type and frequency of handling. Consequently, Directive 88/379/EEC provided for the establishment of the safety data sheet as an additional instrument. Directive 91/155/EEC then ensured that the safety data sheet successfully established itself in Europe.

Labelling and the safety data sheet represent the first and basic items of information for the user of chemical products without which he is unable to fulfil his statutory obligations to protect workers from dangerous substances.

Prohibitions and restrictions

Directive 76/769/EEC contains harmonized rules for the removal of trade restrictions within the EU that result from restrictions on dangerous substances, preparations and associated finished products imposed by individual Member States. In addition, it includes requirements relating to areas in which there is agreement between the Member States about the need for restrictions in order to protect human health, the environment and the interests of consumers. As a rule, the restrictions relate to particular use categories. Complete prohibitions of the marketing of substances and preparations are rare (e.g. occurring in the case of PCBs and asbestos).

The European prohibitions and restrictions are transposed into German law in the Hazardous Substances Ordinance and the Prohibition of Chemicals Ordinance.

Occupational safety rules

In accordance with Article 138 of the European Treaty, Directive 98/24/EC and the other EU safety directives relating to the handling of chemicals (production and use) contain minimum requirements for the particular provisions in individual Member States. Consequently, the requirements of national statutory rules can exceed those laid down in European legislation. The safety data sheet should draw attention to particular national rules and the safety measures ensuing from them.

The occupational safety provisions for the handling of hazardous substances which apply in Germany are mainly to be found in the Hazardous Substances Ordinance. The scope of the measures that are to be taken are oriented towards

the classification of the utilized hazardous substances. Therefore, in the case of a carcinogenic substance, for example, any exposure must be prevented according to the current state of technology. By contrast, in the case of an irritant substance, adherence to a predetermined occupational exposure limit may suffice.

The duty to examine substitutes and alternative processes with a lower risk takes priority in industrial management of hazardous substances. If this is either not possible or cannot be expected of the company, combating risks at source always takes priority over personal protective measures. Work processes must therefore be designed in such a way that hazardous substances are either not released or harmful contact with the skin cannot occur. Taking into consideration the appropriateness of the means, the use of closed processes, local exhaust ventilation or technical ventilation measures is therefore required. By contrast, respiratory protection and full protective suits are not acceptable as long-term protective measures.

Industrial management of hazardous substances also includes the design of the working premises and the organization of the sequence of operations, the provision of both oral and written information to workers and, in some cases, medical surveillance. The utilized hazardous substances, the result of examining substitute solutions, the adherence to occupational exposure limits and the instruction of the workers must be documented in such a way that they can serve as proof vis-à-vis the monitoring authorities.

Important assistance in the application of the Hazardous Substances Ordinance is provided by the Technical Rules for Hazardous Substances (TRGS). They are elaborated by the **Committee on Hazardous Substances** (AGS), involve active participation on the part of the social partners, are passed according to the principle of consensus and announced in the Federal Labour Gazette by the **Federal Ministry of Labour and Social Affairs** (BMA). The Technical Rules describe in concrete terms the current state of technology with regard to the demands of the Hazardous Substances Ordinance, e.g. for particular substances or activities. However, only the Hazardous Substances Ordinance is directly binding in law. It is therefore permitted to deviate from the stipulations of the Technical Rule if the area targeted for protection can be safeguarded through the application of measures of similar value (however not through the use of respiratory protection or chemical protection suits on a permanent basis).

Notification duty in the case of new knowledge concerning carcinogenic, mutagenic or reproductive toxic properties of chemical substances

If the producer or importer classifies as carcinogenic, mutagenic or reproductive toxic a substance which is not yet included in Annex I to Directive 67/548/EEC as a "legally" classified substance he must immediately announce the data forming the basis for his decision to the **Notification Unit within the Chemicals Act**. The same applies in cases where the substance is already named in Annex I due to other dangerous properties. The conveyed data should include a bibliography of all the important literature references as well as all relevant unpublished data.

5.1.5 *Export/Import of dangerous substances, PIC procedure*

Council Regulation (EEC) No 2455/92 of 23 July 1992 concerning the export and import of certain dangerous chemicals (export/import regulation) was announced in the Official Journal of the EC on the 29th of August 1992 and came into force on the 29.11.1992.

Notification procedure for the export from the EU of certain dangerous chemicals

The exporter of a substance listed in the regulation, or of a preparation containing the substance at a percentage of relevance to labelling, must make an announcement to the competent national authority at least 30 days prior to the first export to the particular outside country. In Germany, the **Notification Unit within the Chemicals Act** has been chosen as the Designated National Authority (DNA).

The **European Commission** assigns to each announced first export a reference number relating to the notified substance and the importing country. If the notified substance is exported by the same or another exporter to the same outside country, the reference number provided on the occasion of the first export must be listed in the accompanying papers. Renewal of the export announcement is only necessary if the statutory EU regulations for placing on the market or for using or labelling the substance concerned have significantly altered or if the composition of the relevant preparation has changed to such an extent that its labelling also changes.

Prior Informed Consent (PIC) procedure

The European Union participates in the previously voluntary PIC procedure within the environmental programme of the United Nations (**UNEP**) and the Food and Agricultural Organization (**FAO**). At an international conference (the Rotterdam Convention) held in September 1998, this procedure was laid down as binding in international law. The German Federal Government has designated the **Federal Biological Research Centre** as the competent national authority vis-à-vis the FAO in connection with plant protection products and the **Notification Unit within the Chemicals Act** as the competent national authority vis-à-vis UNEP with regard to all other chemicals.

The exporter of a chemical subject to the PIC procedure is compelled to follow the import decision of a country participating in this procedure if it has been published in Council Regulation (EEC) No 2455/92. If the export of one of these chemicals is intended, it is necessary to first examine whether a PIC decision has already been taken by the particular importing country. If so, the relevant PIC decision must be followed. Non-compliance with these rules is punished by application of the ordinance on punishment and fines.

Labelling rules

The packaging and labelling rules which are in force in the EU in connection with dangerous substances and preparations must be applied to all dangerous chemicals intended for export. Consequently, it is not only the substances and preparations listed in Annexes I and II of the Regulation which have to be labelled in accordance with the relevant EC directives as though they are being placed on the EU market. Instead, this duty applies to all dangerous substances and preparations. Any special provisions in force in the importing non-EU countries are unaffected by this obligation.

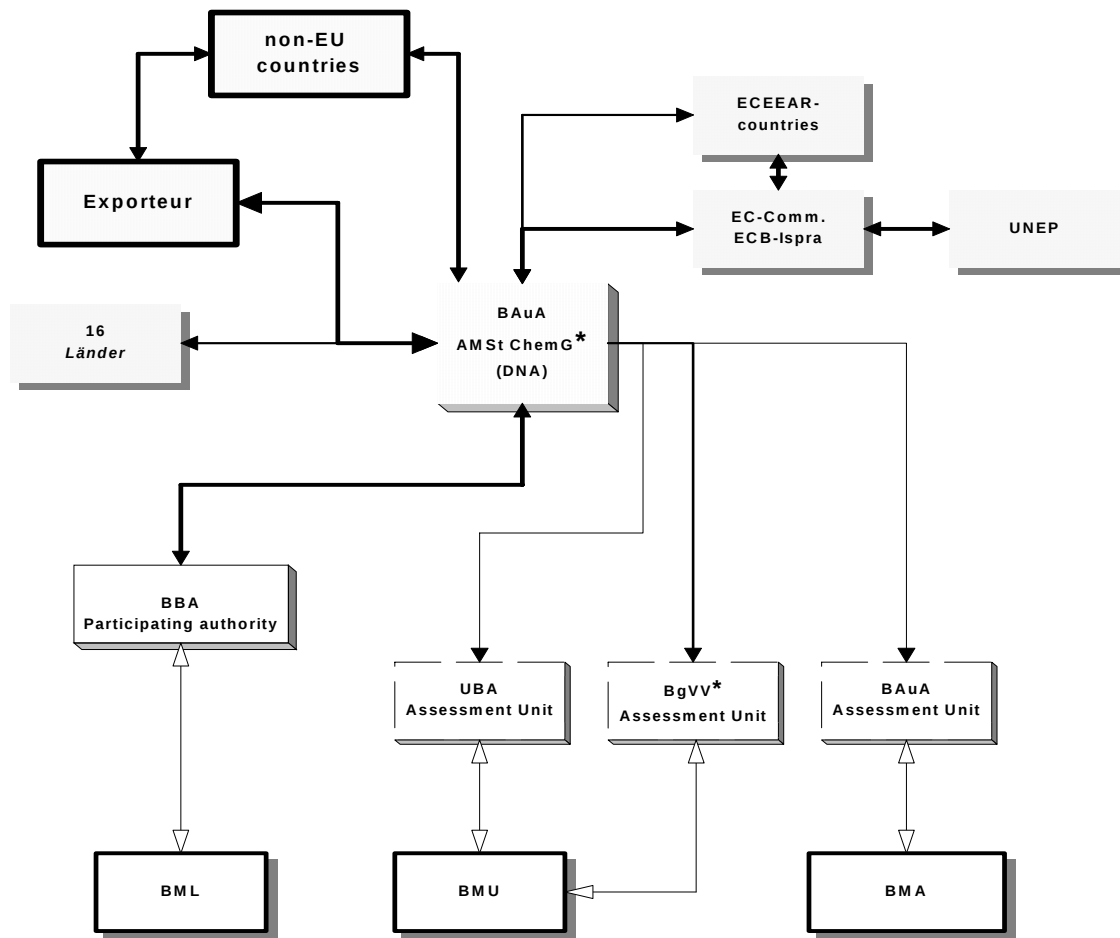
The European Commission's database "EDEXIM"

The **joint research unit of the European Chemical Bureau** in Ispra/Italy makes the information version of the European database on the export and import of certain dangerous chemicals "EDEXIM" available to the chemical industry. The database was produced to help the Commission and the Member States with the implementation of Council Regulation (EEC) No 2455/92. Besides the annexes of the Regulation, EDEXIM also contains the labels of all notified preparations, the addresses of all DNAs, the PIC decisions taken by the **FAO** and **UNEP** as well as identity data such as CAS, EINECS and CUS numbers. In addition, the Commission has created a non-confidential online version of "EDEXIM" which can be viewed via the Internet. The address is: <http://edexim.ei.jrc.it>.

Import notifications by non-EU countries

The EU Member States also receive notifications from outside countries. In Germany's case (the Notification Unit within the Chemicals Act), these are mainly notifications from the United States and Switzerland. The notifications which are based on prohibitions or important restrictions which are imposed by the exporting countries are reported to the **European Commission** which, in turn, forwards them to all the other Member States.

Chemicals management Ex- Import, PIC-procedure



* Expert supervision by the BMU

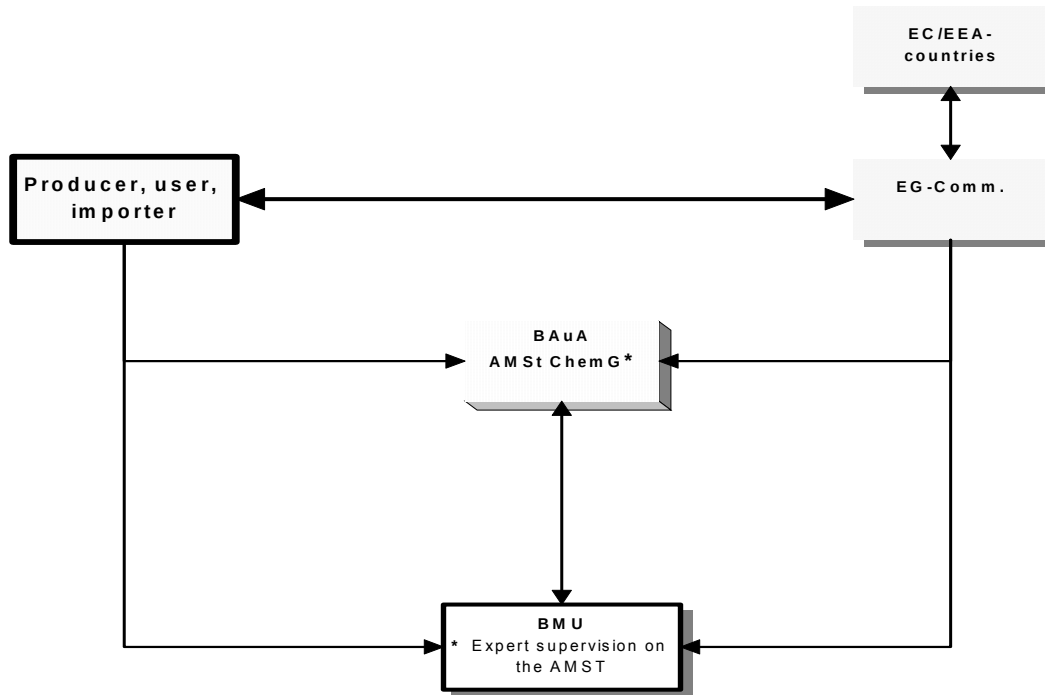
5.1.6 CFC regulations

Council Regulation No 3093/94 of the 15th of December 1994 on substances which lead to depletion of the ozone layer restricts the production, consumption and import of CFCs, halons and other substances harmful to the ozone layer. The **Notification Unit within the Chemicals Act** is the competent authority according to the meaning of this regulation.

A quota, which is granted by the **EC Commission**, is required in each case for the production and use of regulated substances. If regulated substances are to be imported from outside countries, the importer must apply to the EC Commission for a licence. The **Notification Unit within the Chemicals Act** as well as the **Federal Environment Ministry** both receive a copy of the granted licence.

The above-mentioned regulation is currently being revised. An amended version is planned for 1999. Essential alterations include, inter alia, the introduction of licences for exports, too, as well as a reduction in the quotas.

Chemicals management CFC procedure



Over and above the requirements of the European regulation, the national CFC/halon Prohibition Ordinance regulates the use of 12 substances harmful to the ozone layer in pressurized-gas packaging, coolants, extinguishing agents, foams, cleaning agents and solvents

5.2 Chemicals management in the wider sense

The areas listed in this chapter provide, as an example, an overview of the other regulations relating to chemical substances.

See chapter 7.1 for the integration of the *Länder* in the enforcement of federal laws.

5.2.1 Pharmaceuticals

The act concerning trade in pharmaceuticals (the German Drugs Act) regulates the licensing of pharmaceuticals and the registration of homeopathic

pharmaceuticals. Finished pharmaceutical products may only be placed on the market if they have been licensed or registered by the competent authority. A distinction is made between three licensing procedures:

- centralized licensing procedures
- decentralized licensing procedures
- national licensing procedures

In the case of the centralized licensing procedure for pharmaceuticals which are either produced by the application of biotechnology or are highly innovative in character, the organizational sequence is controlled by the **European Agency for the Assessment of Pharmaceuticals** (EMA - London, GB). The Member States participate in the examination of the documents. The resulting licence is valid Europe-wide.

The decentralized licensing procedure is a national procedure which is harmonized throughout Europe. An application for a licence must be processed within a period of 90 days. The licence which is issued is recognized by the other Member States.

National licensing is required in the case of pharmaceuticals which are only placed on the market in the Federal Republic of Germany.

The licensing or registration authority for human pharmaceuticals and homeopathic pharmaceuticals is the **Federal Institute for Pharmaceuticals and Medical Products** (BfArM). The **Federal Office for Sera and Vaccines** is responsible for sera, vaccines, test allergens, test sera and test antigens. Veterinary pharmaceuticals are licensed by the **Federal Institute for Health Protection of Consumers and Veterinary Medicine**.

5.2.2 Plant protection products

Directive 91/414/EC on placing plant protection products on the market regulates the licensing procedure within the European Union in a uniform manner and is transposed into German law by the law on the protection of cultivated plants (Plant Protection Act - PflSchG). This law is targeted at protecting in equal measure the health of man and animal on the one hand and the ground water and the environment on the other.

A distinction is made between the procedure for active substances and the procedure for the actual plant protection products.

Active substances in plant protection products are tested at EU level. The **EU Commission** decides, together with the Member States, on the acceptance of an active substance and its inclusion in Annex I of the Directive. Inclusion in this positive list is a prerequisite for the licensing of plant protection products containing the tested active substance.

The licensing of the plant protection products is the responsibility of the Member States. In Germany, the **Federal Biological Research Centre (BBA)** grants a licence to the applicant for the plant protection product if the application meets the demands and testing shows that

- the plant protection product is sufficiently effective
- the demands relating to the protection of man and animals during the handling of dangerous substances are met in full
- during proper use as intended, the plant protection product
 - a) does not have any adverse effects, in particular with regard to human and animal health and the ground water and
 - b) does not have any other effects, in particular on the balance of nature, which, according to the current state of scientific knowledge, are not acceptable.

The **Federal Biological Research Centre** decides on the existence of the prerequisites in agreement with the **Federal Institute for Health Protection of Consumers and Veterinary Medicine** and the **Federal Environmental Agency**.

5.2.3 Laundry and cleaning products

With regard to the areas targeted for protection (environmental protection as well as health protection/protection of consumers), the Laundry and Cleaning Products Act (WRMG) ("the law on the environmental impact of laundry and cleaning products") represents a piece of precautionary legislation. Accordingly, as a matter of principle, "laundry and cleaning products" may only be placed on the market in such a way that, after their use, no avoidable impairment of the nature of aquatic environments, in particular in respect of the balance of nature and the supply of drinking water, occurs".

According to the meaning of this law, laundry and cleaning products (mixtures of substances) are products used in cleaning or in aiding the cleaning process which may subsequently enter aquatic environments. This category also include products containing surface-active substances (tensides) or organic solvents if they are used for cleaning purposes and may enter aquatic environments after use.

In implementation of the statutory demands, legislation prohibiting certain substances with a negative impact on the environment has been passed (Tenside Ordinance, Ordinance on Maximum Quantities of Phosphate). This aim is supported by voluntary renunciation declarations in which the industry unilaterally agrees, for example, to dispense with the use of alkyl phenol ethoxylates and to

minimize the use of EDTA and NTA. An important rule for the consumer imposes the obligation on the producer of laundry products to indicate on the packaging recommended amounts for use as well as the most important constituents (consumer protection). As a result, consumer and environmental organizations are better able to provide recommendations about the purchase of more environmentally compatible laundry products.

Prior to placing such products on the market for the first time, the producer, importer or person marketing them must inform the **Federal Environmental Agency** in writing about the basic recipes involved, indicating at the same time the environmental compatibility of the products. The **Federal Environmental Agency** then evaluates the data relating to environmental compatibility with regard to the adverse effects on water quality. The agency then informs the regional control authorities about its findings.

5.2.4 Transport of Dangerous Goods

The law on the transport of dangerous goods of 1975, in the amended version of 1998 (see 4.2.2), provides the Federal Republic of Germany with a uniform statutory basis for decision-making. It includes the basic rules, uniform for all types of transport (road, rail, sea, inland waterways, air) relating to the following key words:

Scope of the law, authorization to pass ordinances and administrative provisions, definition of terms, assignment of areas of competence, rules on the participation of industry in the development of new rules, general exemptions, authorization of emergency measures to avert danger as well as acts of monitoring, which are also to be undertaken in companies belonging to the transport industry, questions concerning administrative cooperation, data protection and administrative offences.

The individual regulations relating to particular forms of transport are in part extremely comprehensive and full of technical detail. They are included in special ordinances to permit continuous revision at relatively short notice and further development. In accordance with the powers granted by the law on the transport of dangerous goods, the individual provisions of the ordinances (the Dangerous Goods Ordinances – road, rail, inland waterways, sea – an ordinance for air transport does not currently exist, the Air Traffic Act still being applied directly) relate in particular to the following points:

1. the licensing of the goods for the purpose of transport,
2. the requirements relating to packaging, packing together, loading together and
the separation of goods,
3. the labelling of pieces to be dispatched and vehicles,
4. the construction, nature, equipment and examination of means of transport,
5. transport licences, accompanying documents,

6. the duty to provide information, keep records and notify,
7. manning/accompanying the vehicles,
8. training, further vocational training, examination, the provision of evidence that persons involved in the transport of dangerous goods are qualified,
9. behaviour, measures to provide protection and assistance after accidents,

in so far as this is necessary to provide protection against risks and considerable nuisance related to the transport of dangerous goods. The statutory orders must take account of the current state of technology. The fundamental right to freedom from bodily harm is restricted by the requirement contained in point 8. The statutory orders may also require the conclusion of additional liability insurance policies.

Statutory orders and general administrative provisions may also be introduced in order to implement or transpose legal instruments of the EU. Relevant EU directives or regulations on the transport of dangerous goods by road and rail, the training of lorry drivers, the control of the transport of dangerous goods by road, the introduction of safety advisers into companies which transport dangerous goods by road, rail or on inland waterways as well as minimum requirements on ships bound for or leaving Community ports and carrying dangerous goods have already been passed and transposed into national law.

An essential aim of future law-making procedures is to harmonize international recommendations and agreements with national and European regulations in order to avoid parallel, but different, regulation of comparable procedures. Harmonization efforts in the international bodies of the ILO, the UN and the IMO are directed towards dealing with the problem of the uniform classification and labelling of dangerous substances from both the point of view of occupational safety and consumer protection as well as transport safety and environmental protection.

Fulfilment of the tasks in the area relating to the federal railway, air transport as well as travel by sea and on federal waterways, including federally-owned ports, is the responsibility of the Federal Government, one discharged via the federal administrative system. This means that the *Länder* are left with the task of implementing transport regulations relating to transport by road, rail and via regionally-owned ports and waterways as well as regulations concerning port safety. In addition, there are agreements between the coastal *Länder* and the Federal government concerning the fulfilment of enforcement duties by maritime and inland-waterway police which relate, inter alia, to the monitoring of the transport of dangerous goods by sea and inland-waterway vessels (§ 5 of the law on the transport of dangerous goods).

5.2.5 Chemical weapons

The Chemical Weapons Convention of the 13.01.1993 (Federal Law Gazette II p. 806) is a disarmament and arms control treaty whose aims are the prohibition of chemical weapons worldwide and the destruction of existing stocks of chemical

weapons. Apart from the prohibition of chemical weapons, the Chemical Weapons Convention also includes a comprehensive notification and inspection system for the production, processing, consumption of, and trade in, chemicals which may be misused for the purpose of producing chemical weapons.

The Federal Republic of Germany dispensed with the production of chemical weapons more than 40 years ago and, the only country to do so, has submitted to voluntary controls. Consequently, the Chemical Weapons Convention was ratified – Germany among the leading group of countries - on the 12.08.1994 and transposed into national law by means of the implementing statute and the implementing regulation relating to the Chemical Weapons Convention. The Chemical Weapons Convention includes lists of the chemicals it controls:

- highly effective warfare agents (e.g. soman, sarin, tabun) and certain of their direct precursors. In Germany, their production is prohibited as a matter of principle. Almost any form of handling requires notification and approval;
- key chemicals which are used, for example, for the production of insecticides, herbicides, flame retardants, lubricants and pharmaceuticals etc. as well as plastics (e.g. amiton, thiodiglycol). Their production, processing and consumption are notifiable as from certain tonnage thresholds (1 kg, 100 kg, 1 t per year);
- Intermediates with wide civilian uses, for example, in the production of insecticides, pharmaceuticals, paints and lacquers, coating agents and lubricants etc. (e.g. phos-gene, phosphorus oxygen chloride). A notification duty exists at annual production levels of 30 t and above.

In addition, the Chemical Weapons Convention also includes certain organic chemicals (BOC) which do not feature in the above-mentioned lists but which can be characterized on the basis of a chemical name, structural formula and, if necessary, CAS no. The production of BOCs is notifiable as from 200 t per year.

Certain organic chemicals containing phosgene, sulphur or fluoride (PSF chemicals) are recorded separately and are notifiable at annual production levels of 30 t and above. Furthermore, a notification duty exists in the case of the import and export of certain of the chemicals named in the above. Export to countries which are not signatories to the treaty always requires approval. Compliance with the treaty is monitored by the international **Organization for the Prohibition of Chemical Weapons** (OPCW) which is based in Den Haag (NL). The organization examines the accuracy of the notified data by undertaking on-site inspections. The inspections are carried out after a relatively short announcement period and may include, inter alia, the inspection of plant, the examination of company books, interviews as well as analyses of samples. They are repeated at irregular intervals.

The **Federal Export Office** (BAFA) is responsible for granting licences and gathering and processing notification data. In addition, it also makes the

organizational preparations for the sequence of events during the inspections and provides the group of persons accompanying the inspectors.

Chapter 6 Non-governmental organizations

The complex and highly differentiated German industrial landscape is reflected by the existence of a variety of non-governmental interest groups. Industrial associations, trade unions, environmental and consumer protection associations as well as scientific organizations participate in chemicals management at national level. A few important organizations are listed here as examples together with a brief description of their particular areas of activity.

6.1 Industry associations

6.1.1 The Chemicals Industry Association (VCI)

The Chemicals Industry Association represents the economic interests of nearly 1,700 member companies at national and international level. Its 8 regional associations deal with specific matters of concern at regional level in the individual *Länder*. 11 specialist associations look after specific groups of products or product areas (for example, organic chemistry, surfactants, food additives etc.). In addition, 21 independent specialist associations belong to the VCI as cooperating members (e.g. the Industrial Association for Agriculture - see also 6.1.2 in this regard).

The VCI provides its member companies with a great deal of information, advice and support in the area of safe chemicals management. The "Environmental Advisory Society for the Chemical Industry - CUB", which provides advice on all matters relating to the protection of the environment and health, occupational safety and technical safety, was founded specifically to serve the needs of small and medium-sized companies. The "Monitoring Association of Chemical Plant Operators - ÜChem" supports companies which handle water pollutants in their plants.

The VCI and the specialist associations have introduced a number of voluntary self-imposed obligations which, in some cases, have since been adopted as part of national legislation. These include, for example, the decision to stop using PCB, the introduction of the safety data sheet and the VCI guideline for classification and labelling. In 1983 the advisory committee on existing substances relevant to the environment, the forerunner of the Advisory Committee on Existing Chemicals of Environmental Relevance (BUA), was formed at the suggestion of the VCI. In 1986 the VCI conducted a survey which aimed to record relevant existing chemicals. Comprehensive data sets, which are distributed worldwide in disk form, were created for all substances produced in large volumes, i.e. > 1,000 tonnes t/y.

In 1996 the companies which had come together within the framework of the VCI decided to participate in the worldwide Responsible Care (RC) Initiative of the International Council of Chemical Associations (ICCA).

6.1.2 The Agricultural Industry Association (IVA)

The professional association IVA is a cooperating member of the VCI and is committed to the aims of ensuring the competitiveness of its member companies and meeting the needs of sustainable agriculture. It represents about 60 companies involved in the production of plant protection products and fertilizers.

Together with its member companies, the IVA has published a so-called "active-substance book". This book describes active substances as well as plant protection and pest control agents in terms of their physico-chemical and toxicological properties, signs of intoxication, the course of intoxication and therapeutic measures. In addition, specimen instructions for use were developed for the less comprehensively regulated non-agricultural pest-control agents. Above and beyond the labelling required by law, the plant protection industry voluntarily provides safety information or safety data sheets to the wholesale and retail trades as well as to professional users of these products.

Since 1990 a voluntary disposal concept (known as PAMIRA) enabling the return of used plant protection product packaging has been developed and introduced. The collected plastic packaging is comminuted, processed and gasified in furnaces for use in steel production in place of heavy oil.

6.1.3 The Chemical Trading Association (VCH)

The association known as the VCH comprises approximately 100 member companies from the German wholesale and retail trades. They have selected the "sustainable development" model as the guiding principle in the areas relating to product responsibility, plant safety, occupational and transport safety, health and environmental protection as well as in the sphere of information provided to the public.

6.2 German Statutory Accident Insurance Institutions and trade unions

6.2.1 The Federation of German Statutory Accident Insurance Institutions for the Industrial Sector (HVBG)

The 35 German Statutory Accident Insurance Institutions, which are divided up according to particular branches of industry, are responsible for statutory accident insurance in Germany. Their umbrella organization is the HVBG, the Federation

of German Statutory Accident Insurance Institutions for the industrial sector. The relevant institution for the chemical industry (BG Chemie) plays a particularly important role within the framework of chemicals management. Supported by a committee of expert advisers in the field of toxicology, it examines the properties of chemicals, e.g. by means of toxicological assessments within the framework of the "Programme of the Statutory Accident Insurance Institution for the Chemical Industry for the Prevention of Damage to Health as a result of Working Substances".

The statutory accident insurance institutions create and manage databases. Their data is gathered in particular by performing measurements of the concentrations of hazardous substances in the workplace atmosphere. Within the framework of the "Statutory Accident Insurance Institutions' Measurement System for Hazardous Substances" (BGMG) the data are collated, archived and evaluated. The preparatory work performed by the Statutory Accident Insurance Institutions' working group on existing substances during the process of "working through" the EU priority lists is based to an essential degree on the results provided by this measurement system.

The BG Institute for Occupational Safety (BIA) has the means to examine the physico-chemical properties of substances and preparations. In particular, the characteristic values for the explosivity of dusts are determined there.

The reduction of risks to workers in the workplace is one main aspect of the prevention work undertaken by the statutory accident insurance institutions. Relevant advice is provided to companies by the technical supervisory services belonging to the insurance institutions. The statutory accident insurance institutions work hard to supply workers with necessary information, e.g. by means of informational publications, posters and video films.

On the basis of the rules contained in the code of social law (SGB VII), the statutory accident insurance institutions are both entitled and obliged to publish accident prevention rules as autonomous law. These accident prevention rules have the same immediately binding effect on those subject to the law as state statutory regulations and, if necessary, can be enforced using state means. In addition, the experts from the statutory accident insurance institutions intensively advise state institutions on the development and design of state statutory regulations, also offering advice in the area of chemicals law.

6.2.2 The Industrial Trade Union for the Mining, Chemicals and Energy Industries (IG BCE)

Through its specialist departments for occupational safety and environmental protection, economic, research and technology policy, the industrial trade union for the mining, chemicals and energy industries (IG BCE) participates in the national discourse on chemicals policy and chemicals management.

Questions of design concerning the safe production and handling of chemicals are subjects constantly discussed in Statutory Accident Insurance Institution committees, state bodies as well as, however, in work groups with the Chemicals Industry Association. The aim here is to develop standards and recommendations for industrial chemicals management.

Under the overall control of the Federal Ministry for Education and Research, efforts are currently being made, within the framework of the working title "sustainable chemistry", to elaborate proposals for greater orientation of the process of chemicals management towards the model of sustainability.

In addition to these national activities, the topic complexes of chemicals policy, chemicals management and the chemical industry are regularly discussed within the "European Federation of the Trade Unions for the Mining, Chemical and Energy Industries" (EMCEF) as well as within the "International Federation of Trade Unions for Chemical, Mining and Factory Workers".

6.3 Environmental and consumer protection organizations

6.3.1 Greenpeace

The environmental protection organization Greenpeace, which was founded in 1971, has also had a German office since 1980. Greenpeace does not enter into any relationships with political parties and remains independent of governments or economic interest groups. The organization draws attention to environmental problems, names polluters and employs positive projects to indicate possible solutions. Greenpeace has divided the area with which it is concerned into four general topic areas:

- | | |
|--------------------------------------|---|
| - nuclear power, energy, disarmament | - climate, transport |
| - chemistry, gene technology | - diversity of species (seas and forests) |

Each of these areas concentrates on individual campaigns which are carried out after international consultation.

Greenpeace maintains extensive databases, produces political analyses and informs the public with regard to the problem areas of gene technology in agriculture, chlorine chemistry, PVC, toxic waste exports, chemical accidents, pollution of the ground water as well as sustainable chemistry. In addition, research programmes into alternatives to PVC and CFCs also exist.

6.3.2 Consumer Associations' Working Party (AgV)

The non-profit Consumer Associations' Working Party has been in existence since 1953. It is the umbrella organization for 37 German consumer and socio-political organizations. Its member associations include, for example, the Consumer Advice Centres in all of the federal states, the German Tenants' Association and the German Housewives' Association.

The Consumer Associations' Working Party has the task of representing the economic, legal, health-related and ecological interests of consumers vis-à-vis the legislator, authorities and providers at national and international level. The Working Party is a member of the "European Consumers' Association" (BEUC) and the international association "Consumers International".

Together with its member associations, the Working Party produces materials designed to provide consumers with independent information. With regard to the chemicals sphere, the Working Party shows particular commitment in the areas relating, for example, to

- achieving a lasting improvement in the quality of the air in interior spaces by reducing emissions from furniture, floor coverings and chemicals used in construction
- prohibiting volatile plasticizers in children's toys
- restricting the use of pesticides in interior spaces
- clearly extending ecological agriculture
- ensuring a full declaration of the formulation of household and do-it-yourself chemicals.

6.4 Scientific organizations

6.4.1 Society of German Chemists (GDCh)

With more than 28,000 members, the Society of German Chemists is the largest comprehensive scientific body representing chemists in Germany and, in the European context, numbers among the societies with the richest tradition. It provides the forum for the exchange of scientific opinion. Its members are chemists, biochemists, food chemists, chemical engineers, teachers as well as other scientists from various disciplines with an interest in chemistry and students engaged in study courses related to the above-mentioned areas.

The 22 specialist groups - ranging from analytical chemistry, environmental chemistry and ecotoxicology through to hydrochemistry - form the main basis for the work performed by the Society. They use their specialist knowledge and experience to define and assess new fields of research, presenting the latest information from the particular disciplines at their conferences and via their own publications. They also promote active cooperation by members. Each year the Society initiates and organizes 20 to 30 national and international congresses, symposia and conferences of various sizes. In addition to the large international events, particular importance attaches to the conferences for expert groups. The expert groups represent the special strengths of the Society to the outside world: work of a highly scientific nature and neutrality.

The 60 local associations - chemists have local organizations throughout Germany - regularly organize a large number of regional events. Scientists from home and abroad report, for example, on the results of current research, new methods and technologies. In this way, chemists are offered more than 1,000 scientific talks every year.

The public relations work performed by the Society aims to make the benefit and importance of chemistry understandable to a wider public and promote knowledge of chemistry among the general public. The Society publishes comments on particular issues as well as information provided by the expert groups and local associations. Represented in international bodies, the Society cooperates with national and international sister societies. The "Scientific Press Service for Chemistry" provides daily newspapers, specialist magazines, radio and television with current news from the world of chemistry.

Chapter 7 Cooperation between the federal and regional authorities

7.1 Interministerial commissions and general coordination mechanisms

As already explained (see chapters 4 and 5), chemical management in Germany is characterized by a high regulation density as well as a large number of participating authorities and institutions with different levels of responsibility. Harmonization of activities, both among the federal authorities themselves and between the federal authorities and regional authorities, is crucial if efforts in the area of environmental and health protection are to be successful. Achieving this requires coordination efforts which go beyond the statutory framework. This explains the existence of a large number of committees and working groups for the different areas targeted for protection. The **Environment Ministers' Conference**, involving the Environment Ministers from the *Länder* and the Federal Environment Minister is of particular importance in this connection.

The committees and working groups listed in the following as an example only represent a small selection from the large number of institutions in the field of environmental protection.

Federal/regional Committee on the Safety of Chemicals (BLAC)

Members: the highest regional authorities, the Federal Environment Ministry
Topics: Specialist questions relating to the enforcement of the Chemicals Act, legal questions, GLP and further quality assurance systems

Federal/regional Working Group on Environmental Information Systems (BLAK-UIS)

Members: the highest federal and regional authorities responsible for information about the environment
Topics: the exchange of environment-related data between the federal government and the *Länder*, e.g. a joint pool of substance data shared between the federal government and the *Länder* (GSBL)

Federal/regional Expert Committee "Transport of Dangerous Goods" (BLFA-GG)

Members: the highest regional authorities, Federal Ministry of Transport and Housing
Topics: Harmonization of specialist and legal matters as well as procedures for amendment of the law relating to the transport of dangerous goods

Commission for the Identification and Treatment of Symptoms of Poisoning (Poison Information Centres, GIZ)

Members: the Federal Institute for Health Protection of Consumers and Veterinary Medicine, the highest regional authorities

Topics: the exchange of information on symptoms of poisoning

Regional Committee on Protection against Immissions (LAI)

Members: the highest federal and regional authorities with responsibility for immission protection as well as the Federal Environmental Agency

as a guest

Topics: specialist questions and legal questions relating to the implementation of the Federal Immission Protection Act

Regional Working Group on Water (LAWA)

Members: the highest regional authorities with responsibility for water legislation and water management. The Federal Government is a permanent guest.

Topics: specialist questions and legal questions relating to the implementation of water legislation

Regional Working Group on Waste (LAGA)

Members: the highest regional authorities responsible for waste legislation and waste management. The Federal Government is a permanent guest.

The Federal Environmental Agency is a member of working groups.

Topics: specialist and legal questions relating to waste management and hazardous waste sites

Regional Committee on Soil Protection (LABO)

Members: the highest federal and regional authorities with responsibility for soil protection

Topics: the protection of soil

Regional Committee on Occupational Safety and Safety Technology (LASI)

Members: the highest federal authorities responsible for occupational safety, the Federal Government is a guest, Federal Institute for Occupational

Safety and Health

Topics: occupational safety and safety technology

Committees for the Harmonization of Procedures for the Notification of New and Existing Chemical Substances

Members: the Notification Unit within the Chemicals Act, the assessment units

Topics: harmonization of the notification procedure within the framework of

the Chemicals Act/Council Regulation (EEC) No 793/93, the exchange of information (statutory regulations, test methods)

Steering Group for Data Processing Procedures

Members: the Notification Unit within the Chemicals Act, the assessment units

Topics: the coordination and further development of Itapplications

Committee on Hazardous Substances (AGS)

Members: industry, trade unions, authorities, the scientific community and associations

Topics: questions concerning occupational safety, including the classification and labelling of dangerous substances and preparations.

MAK Commission

Members: scientists from different areas of specialization (chemistry, medicine)

Topics: the assessment of substances and the establishment of MAK-values

(MAK = maximum workplace concentration) as well as the classification of carcinogenic substances

Advisory Committee on Existing Chemicals of Environmental Relevance (BUA)

Members: industry, assessment units, scientists

Topics: cooperation in the area of the assessment of existing chemical substances

7.2 Enforcement at regional level

In accordance with the German Constitution, the *Länder* are entrusted with the task of enforcing environmental legislation. The organizational arrangements required for this are determined by the *Länder* themselves. Consequently, there is room for a wide variety of organizational forms to develop. As a rule, there are three administrative levels: the Regional Environment Ministry, the district level and the local level. Tasks are frequently delegated to a lower regional administrative level or to parish level. In cases where extensive technical knowledge is required, special authorities are commissioned to undertake enforcement.

The city-states of Hamburg and Saxony serve here as examples for the 16 *Länder*.

7.2.1 Hamburg

Enforcement of the Chemicals Act

The Office of Labour, Health and Social Affairs and, in turn, above all the Occupational Safety Department, which is anchored in the Public Health Department, are responsible for enforcement of the Chemicals Act in the vast majority of cases. Individual areas are covered by the Environmental Agency (e.g.

CFC/halon Prohibition Ordinance) or by the district administration (examination to determine expert knowledge, licences and notifications according to the Prohibition of Chemicals Ordinance).

Monitoring according to the Chemicals Act places the emphasis on the legal obligations on companies in relation to hazardous substances. In respect of the Prohibition of Chemicals Ordinance, enforcement focuses on producers, importers and the wholesale trade. Examination of control of compliance with chemicals legislation is integrated into the general occupational safety monitoring programme.

Apart from task elements determined by third parties, such as the processing of notifications and applications, the activity is designed according to the so-called SAS concept (supervision, advice, system monitoring): A key element is the branch-oriented organization of the department ("specialist districts"). The specialist districts are supported in their supervisory activity by the occupational safety laboratory. In matters concerning occupational medicine, they work in conjunction with the state medical officer for the industrial sector. Specialist areas requiring a high degree of specialist knowledge (e.g. matters relating to explosives) are dealt with centrally. Utilization of the specialist chemicals legislation knowledge available to the department is optimized by means of information exchange and the clarification of specific problems in a specialist working group for "hazardous substances".

A further important starting point is the risk-related assignment of companies to the categories A, B and C. Annual standard inspections are scheduled for companies belonging to the highest risk category A (approx. 1 % of companies). In the case of B-companies (approx. 20 % of companies) these inspections take place at intervals of several years. C-companies are only inspected on an event-driven basis. This system is overlaid by approaches for system monitoring as well as a branch-related supervisory activity in connection with companies from the categories B and C. In the case of system monitoring the particular company's occupational safety system is examined on site on the basis of a system control list. If the main demands of the list are met, the standard monitoring which is undertaken may be suspended for a certain period of time. Each year particular branches are selected as the main focus of monitoring. In accordance with the number of defined branches, a 4-5 year rhythm is achieved here. Only some of the companies belonging to a particular branch are inspected. An essential component of the projects is the provision of information to all of the companies belonging to a particular branch. In order to effectively achieve this aim, informational material is produced (information sheets, press announcements), questionnaire-based activities are undertaken and informational events organized. Cooperation with institutions such as the accident insurance institutions, chambers of trade and commerce, guilds, trade unions etc. has an important part to play. Standard inspections of category B companies are dispensed with in the event of assignment to a branch selected as a special focus of interest.

The advisory service offered by the Department is rounded off by the occupational safety telephone. Demands are enforced by notices of appeal and orders. If necessary, coercive measures are used and action taken in the case of administrative offences.

Hazardous substance monitoring in figures (the Occupational Safety Department's annual report for 1998)

3,087	examinations/inspections,
2,354	complaints,
535	measurements,
5	investigations of occupational diseases, accidents and cases of harm,
47	inquiries and complaints processed,
132	statutorily prescribed notifications processed,
640	instances of providing comments/reports,
45	cases of granting authorization, permits, licences and exemptions,
3	refusals
336	notices of appeal,
62	orders,
14	notices rejecting objections (2 accepted)
7	cases of use of coercive measures

Monitoring of the rules oriented towards the end user, an activity not based at the Occupational Safety Department, as well as of the rules contained in the Prohibition of Chemicals Ordinance and the labelling and packaging rules for the retail trade is only undertaken in response to particular events.

The Occupational Safety Department has a number of databases at its disposal. These databases are either available to all employees on the DP network (A) or can be used by inquiring at the office with internal responsibility for information on hazardous substances (B).

name of the database	access	name of the database	access
GDL (joint <i>Länder</i> database on hazardous substances)	B	CHEMCAT1 (Merck)	B
CCINFO-disc (collection of Canadian databases), consisting of:	B	MSDS (Merck)	B
RTECS (Registry of Toxic Effects of Chemical Substances)		RESY-B (stand-by call and first action system belonging to the environmental authority in Hamburg)	A
NIOSHTIC		Dangerous Goods Ordinance - road (UB-Media)	B
CISILO		Auerdata	B
MSDS and numerous smaller databases		Information sheets on hazardous working substances - substance information sheets known as "yellow pages" (ecomed)	A
Chemis 2.0 (Federal Institute for Health Protection of Consumers and Veterinary Medicine)	B		
RENOCS (EC new and	B	ZH1 rules (Heymanns)	A

existing chemical substances)		Hazardous substances legislation (UB-Media)	A
WINGIS (Information system on hazardous substances belonging to the German Statutory Accident Insurance Institution for the building industry - GISBAU)	A	Opfermann/Streit working premises (Forkel)	A
IGS list of substances, part for which a licence is not required (North Rhine-Westphalia)	B	A = all authority employees B = competent unit at the authority	

Consequently, in the case of a large number of substances, physico-chemical data, data on toxicity, environmentally behaviour, risk phrases and indications of use, limit and guidance values as well as fields of application can be ascertained at short notice.

Enforcement of the rules on the transport of dangerous goods

Enforcement of the rules on the transport of dangerous goods is, in so far as it is the responsibility of the *Länder*, mainly the task of the Office of Internal Affairs. The technical tasks relating to the licensing, examination and technical monitoring of tanks, tankers, tank wagons, tank containers, set-down tanks, vessels and battery-driven vehicles have been entrusted to the Office of Labour, Health and Social Affairs.

In contrast to other *Länder* and the Federal Ministry of Transport and Housing, with the exception of the tasks relating to the Office of Labour, Health and Social Affairs, the functions of the regional authority have been centralized under the aspect "safety", for all transport operators, at the Office of Internal Affairs. A further important feature here was the fact that, even prior to this, fulfilment of these tasks was the responsibility of the port and river police. Since this police force operated in the port region anyway and since, in comparison with the lowlands, the Hamburg area is relatively compact, it was active in the rest of the city area, too.

In Hamburg, a point of intersection for transport involving different land and sea vehicles, efforts have long been directed towards achieving the highest possible degree of consistency in the national and international rules applying to all of the transport operators, thus eliminating the problems which previously occurred as a result of these differences whenever the means of transport changed (so-called harmonization). The port and river police can retain an overview of all of the relevant dangerous goods transport rules applying to the different transport operators thanks to its activity in all transport areas as well as in the port. It uses this knowledge to guarantee safety and for the benefit of the transport business, too. In Hamburg, the Central Office of Port Safety and Dangerous Goods – WS 22 – of the port and river police assumes the implementation duties of the specialist competent authorities. Inter alia, it is responsible for granting exemptions on a case-by-case basis in accordance with § 5 of the Dangerous

Goods Ordinance – Road, for all technical questions concerning the implementation of the rules contained in the Port Safety Ordinance which are specific to the state of Hamburg as well as for monitoring transport by road, regional railways, sea and inland-waterway vessels in the port of Hamburg. The fact that this office's radius of action covers the whole transport spectrum has led to it being increasingly contacted for information and advice and consulted in matters related to dangerous goods. This helps the office fulfil its tasks as the competent monitoring authority with responsibility for implementation of the rules on representatives in the area relating to dangerous goods.

Apart from the Central Office, so-called port safety officers from the port and river police districts are engaged in the monitoring of port safety and application of the rules relating to transport by sea and inland-waterway vessels. Inter alia, the examinations which are undertaken concern the classification of substances, the prescribed packaging, the stowing and separation of the dangerous goods on ships, the equipment available on ships and the training of personnel with regard to compliance with the relevant transport safety rules. A special office of the port and river police – WS 21 – is actively involved in the sphere of police monitoring of transport by road and rail throughout the entire city area.

The work of the various offices is supported by a dangerous substance information system (GEGIS) which was developed for the Office of Internal Affairs by the Hamburg company DAKOSY-Datenkommunikationssystem GmbH and which is in continuous operation. The component parts of this system are various databases such as the database for rules and regulations, substance databases (joint *Länder* database on hazardous substances - GDL), the service belonging to the Federal Environmental Agency which provides rapid information on dangerous goods (GSA), the Hamburg Environmental Agency's stand-by call and first-action system (Resy) as well as substance registers from various chemical-producing companies, a database on the places where dangerous goods awaiting transfer are located at the Hamburg port as well as information on the type, quantity and location of dangerous goods stowed on the notified sea vessels in the port of Hamburg. These data are used, for example, by the notification system in accordance with the EU directive on minimum requirements for vessels bound for or leaving Community ports and carrying dangerous or polluting goods and as required, for example, in the case of an accident aboard vessels on the high seas where information on the ship's cargo of dangerous goods is needed to combat the effects of the accident.

Enforcement of the Foodstuffs and Commodities Act

The enforcement of the Foodstuffs and Commodities Act as well as of the statutory regulations based on the Act, such as the ordinance on the maximum amounts of residues, is the responsibility of the *Länder*. In Hamburg the district offices are mainly responsible for enforcement. As the expert authority, the Office of Labour, Health and Social Affairs – and, within it, the department for the health protection of consumers and veterinary medicine - assumes responsibility for overall control and the Hygiene Institute in Hamburg has the task of performing investigations. The most important aim of official foodstuffs monitoring is to protect the consumer from health risks, from being misled or deceived, to protect the interests of all those involved in the trade and to provide comprehensive

information to consumers. Monitoring is performed according to the rules contained in the Foodstuffs and Commodities Act as well as Community law and other regulations relating to foodstuffs.

In order to achieve these aims, interest has focused on the following aspects:

- Monitoring of companies, the frequency of monitoring depending on the risk factors which are present. Inspections of the companies' own inspection systems at the points of input, production and output are included in the monitoring process. In addition to the inspection and the checking of documents, samples are also taken for the purpose of further investigations. Monitoring of the companies is undertaken by so-called expert teams whose members possess both scientific knowledge and specialist knowledge about enforcement. The monitoring acts affect all companies involved in the production and sale of foodstuffs and commodities such as producers, importers, and the wholesale and retail trades.
- Investigation of samples, and their assessment in terms of foodstuffs legislation, according to the principle of random sampling. Sampling is either performed regularly or in campaigns with a special focus of interest in accordance with a defined sampling concept elaborated by all of the participating state monitoring authorities. In turn, the sample contingents are allotted on the basis of risk factors which include the type of foodstuff and the distribution level in the food trade. A particular focus of interest in Hamburg are the import checks on foodstuffs from outside countries which are intended for import into the EU area. In addition, there are national and EU-wide inspection programmes which lay down the numbers of samples to be taken as well as the range of the particular investigation, especially in the area relating to checks on residues of substances of concern to health. If grounds for suspicion result from the investigations based on random sampling, the frequencies of the checks are increased up to 100 % (duty to present the foodstuff or commodity in question). Within the framework of import controls, relevant consignments are stopped at the border and examined. If, for example, it is established that maximum quantities of certain substances have been exceeded, the good may not be imported.
- PR means are employed for the purpose of providing consumers with comprehensive information. Included here are press announcements, annual press conferences with leading politicians at which audits are presented, podium discussions, information sheets, annual reports, talks and the health telephone etc. In the case of a potential risk to health, warnings given by the authorities about eating certain foodstuffs or using particular commodities are disseminated via the media.

Hamburg's philosophy is to prevent violations of regulations by offering advice and explanations to the relevant responsible persons. In general, foodstuffs and commodities which do not meet legal requirements are unsuited to being placed on the market and are therefore withdrawn. Should coercive measures be necessary in individual cases, the Foodstuffs and Commodities Act provides for administrative offence procedures, in the case of a proven risk to health, criminal prosecution, too.

The structure and aims of foodstuffs monitoring required cooperation between all the participants in the procedure. In addition to further state authorities in Hamburg such as the customs service, the Office of Economic Affairs and the Office of Internal Affairs, these primarily include the producers and traders themselves or the groups representing their interests – for example, the Merchandise Society of the Hamburg Stock Exchange or the Association of Hanseatic Fruit Importers and Wholesalers, all of whom have, and fulfil, their statutory duty to exercise due care. Today, control of compliance with foodstuffs legislation is, however, integrated into a nationwide and EU-wide system. EU-wide notification duties for all monitoring activities, centralized evaluation and an information feedback system extending as far as an institutionalized rapid warning system, to which Hamburg is, of course, connected, ensure an effective flow of information. Additional information can obviously be acquired from the specialist press, the Internet and relevant databases (e.g. MED-LINE, DIMDI). Via the FHH-Info-Net, to which all Hamburg authorities are connected, items of information are passed on within Hamburg almost in real time.

Foodstuffs Monitoring Data for Hamburg in 1998:

100,832 company inspections, number of violations established (administrative offences): 1419
 16,754 samples examined. Complaints in 2009 cases: (= 12%)
 of which 12 samples were the subject of complaint for constituting a danger to health:
 1927 samples (= 11.5%) examined for residues and contaminants:
 of which 106 samples (= 5.5 %) were the subject of complaint.

7.2.2 Saxony

Enforcement of the rules and regulations on chemicals

In the Free State of Saxony responsibility for enforcement of the Chemicals Act and related statutory orders lies, in so far as matters concerning the environment and general consumer protection are involved, with the State of Saxony's Ministry for the Environment and Agriculture. Areas of responsibility include in particular,

- control of compliance with the notification duties for new and existing chemical substances,
- control of compliance with prohibitions of and restrictions on the marketing and use of certain dangerous substances,
- enforcement of the CFC/halon Prohibition Ordinance,
- tasks connected with the rules on good laboratory practice.

As a rule, on-site inspections are performed by the 5 Specialist Regional Environmental Departments.

Structure of the sphere of activity of the State of Saxony's Ministry for the Environment and Agriculture:

Highest authority	regional	State of Saxony's Ministry for the Environment and Agriculture
Higher authorities	regional	Saxony's Regional Institute for the Environment and Geology, Saxony's Regional Institute of Agriculture Saxony's Regional Institute of Forestry
Middle-level authorities	regional	Regional Councils in Dresden, Chemnitz, Leipzig, 2 Forestry Directorates, 3 Regional Departments for Rural Reorganization
Subordinate authorities	regional	Specialist Regional Environmental Departments, State Departments of Agriculture Saxony's Forestry Departments
Institutions		Regional Environmental Operations Society, State of Saxony's Ministry Foundation for Nature and the Environment.

The State of Saxony's Ministry of Labour and Economic Affairs, the Regional Institute for Occupational Safety and Health and the five factory inspectorates are responsible for matters relating to occupational safety and health. Enforcement activities performed by the factory inspectorates include, inter alia,

- control of compliance with the classification, labelling and packaging rules relating to dangerous substances and preparations,
- examination of the safety data sheets required according to § 14 of the Hazardous Substances Ordinance and the accident information sheets required according to dangerous goods legislation.
- the granting of permission to place substances or preparations on the market (§ 2 of the Prohibition of Chemicals Ordinance)
- control of compliance with the duties to record sales to third parties (§ 3 of the Prohibition of Chemicals Ordinance)
- the granting of permission for the performance of fumigation.

Structure of the sphere of activity of Saxony's State Ministry of Labour and Economic Affairs in the area of occupational safety and health:

Highest authority	regional	State Ministry of Labour and Economic Affairs,
Higher authorities	regional	Higher Mining Office,
Middle-level authorities		Regional Councils in Dresden, Chemnitz, Leipzig, dept. 3 "Labour and Economic Affairs",
Subordinate authorities	regional	Factory inspectorates, mining offices,
Institutions		Regional Institute for Occupational Safety and Health.

Enforcement of the rules and regulations on plant protection

Responsibility for the area relating to plant protection/fertilizers is assigned to the State of Saxony's Ministry for the Environment and Agriculture in conjunction with Saxony's Regional Institute of Agriculture. Areas of competence are laid down in the ordinance on the determination of competences in the sphere of agriculture, forestry and nutrition.

Empowered to do so by the Plant Protection Act (§ 8 of the Plant Protection Act), the Free State of Saxony has established regional regulations for specific areas of plant protection, for example,

- an administrative provision on the use of plant protection products on outdoor areas which are not used for the purpose of agriculture, forestry or gardening,
- an ordinance on the announcement of use of plant protection products,
- an ordinance on evidence of expert knowledge in the area concerning the use and sale of plant protection products

- an ordinance on inspection workshops for the examination of plant protection equipment used in extensive cultivation

In the area relating to fertilizers the Free State of Saxony has passed an administrative provision relating to the enforcement of the ordinance on the principles of good professional practice. The provision is intended to serve as a guidance document for enforcement of the individual rules which exist within the framework of currently applicable legislation.

Enforcement of the rules and regulations on waste and soil protection

The legal basis for action is created by the Waste Avoidance, Recycling and Disposal Act, the Soil Protection Act, and Saxony's legislation on disposal management and soil protection. Saxony's State Ministry for the Environment and Agriculture is the highest authority for matter relating to waste and soil protection, the Regional Councils being the higher waste and soil protection authorities. The administrative districts and the towns which are a district in their own right represent the subordinate waste authorities. As the bodies responsible for the fulfilment of public-service disposal duties, the administrative districts and towns classed as districts in their own right have a duty to devise a waste management concept (waste-management planning measure) and to continue to develop it further as well as to produce annual waste audits. The waste-management concept elaborated by the Free State of Saxony provides the basis for the strategies employed in waste management in Saxony and furnishes the bodies responsible for public-service waste disposal with the basic and comparative data they require for their own waste-management concepts.

The subordinate waste authorities are fundamentally responsible for the enforcement of the rules on waste. The higher waste authorities assume responsibility for the following tasks in particular:

- granting certain licences (e.g. transport licences, licences for landfill sites)
- duties in connection with the procedure for furnishing proof in the area relating to disposal (e.g. confirmation of the permissibility of an intended form of disposal)
- authorization of waste-disposal plant
- provision of information about suitable waste-disposal plants.

The specialist Regional Environment Departments are obliged to provide specialist support to the waste authorities.

Enforcement of the rules and regulations on water

Saxony's Water Act forms the legal basis for action in this area. In addition, further rules relating to water legislation (ordinances, administrative provisions and official decisions) have been announced, for example,

- an ordinance on protection provisions and payments to compensate for increased use of water by agriculture and forestry in water-protection areas,
- an ordinance on the type and frequency of own checks on waste-water plant and waste-water discharges,
- an administrative provision relating to plans for water-management projects
- an administrative provision for the promotion of water-management measures

The highest water authority is the State of Saxony's Ministry for the Environment and Agriculture, the higher water authorities are the Regional Councils and the subordinate water authorities are the Rural Council Departments and the towns which are districts in their own right. The Regional Institute for the Environment and Geology acts as a specialist technical authority (for the highest water authority) as do the specialist Regional Environmental Departments (for the higher and subordinate water authorities).

Literature and databases:

Comprehensive specialist libraries are available to the individual authorities. Inter alia, the State of Saxony's Ministry for the Environment and Agriculture has access to the databases RENOCS (EC existing and new chemical substances) and EINECS as well as to the IGS list of substances

Chapter 8 Data stocks and databases

In order to ensure successful chemicals management, those participating in the process have numerous national and international databases and sources of literature at their disposal. A small selection is provided here, taking as an example the **Notification Unit within the Chemicals Act** and a joint project between the Federal Government and the *Länder*.

8.1 Databases available to the Notification Unit within the Chemicals Act (own and external)

The **Notification Unit within the Chemicals Act** records the data from notifications and mini-notifications of new chemical substances. The data stocks also include chemical structural formulae, for which the MOLEFile format is used. In the course of fulfilment of its duties the Notification Unit within the Chemicals Act uses a variety of databases:

- **Admin (administration relating to the Chemicals Act)**

The procedure helps keep track of the progress of work on particular notifications and provides support in monitoring deadlines during enforcement of the Chemicals Act, offering in particular the following information:

- the main data relating to the notification procedures
- reproduction of the correspondence in the notification procedures, related to individual dossiers
- documentation of internal deadlines
- search functions
- monitoring of unanswered letters
- monitoring of forthcoming deadlines
- follow-up function in the case of forthcoming expiry dates and letters
- statistical evaluations relating to the notification procedures.

The requisite data are entered on receipt of an announcement and, if necessary, brought up to date.

- **NST database for new chemical substances**

In the course of the notification the identity data (of a new substance submitted in Germany for the purpose of notification or mini-notification) are recorded in the NST database. On average, the identity data amount to between three and five DIN A4 forms. Searches, in external online databases too (STN/Express), are

performed to check the data. The notification data are exchanged between the national Notification Units.

EU notifications conveyed on data media are transferred to the database. The EU exchange format known as SNIF is used not only for the exchange of information with other EU Member States but also in the exchange of data with the federal and regional authorities asked to participate in the process. 90% of notifications are currently submitted in the SNIF format. With the exception of the identity data, all of the submitted data can be read into the database via an import interface.

- **EINECS (inventory of existing chemical substances)**

The acronym EINECS stands for the European Inventory of Existing Commercial Chemical Substances. Produced by the Commission of the European Communities, this inventory lists those chemical substances which were on the market in the European Community between the 1st of January 1971 and the 18th of September 1981. According to Article 1 Section 4 of Council Directive 67/548/EEC, the notification duty laid down in the Directive does not apply to these substances. EINECS is the only point of reference for identification of these substances. In principle, the inventory is closed.

The EINECS database contains 100,106 substance entries, 33,000 of which originate from the European Communities' Core Inventory (ECOIN) and 67,000 from additional notifications from the chemical industry. Of these, 82,000 substances are regarded as well-defined and about 18,000 as inadequately defined or as "substances of unknown or variable composition, reaction products and biological materials" (UVCB substances). However, these 18,000 UVCB substances include about 5,000 which, in addition to being named are also briefly described.

Besides the EINECS numbers, the database also includes CAS numbers, chemical names, trade names, empirical formulae and, in the case of UVCB substances, a description of the substance.

- **HEDSET program for the recording of existing chemical substances**

Council Regulation (EEC) No 793/93 requires every manufacturer or importer who produces or imports an existing chemical substance in certain quantities to provide data to the Commission (European Chemical Bureau [ECB]) in Ispra. These data include information such as the name of the substance, the quantity produced, the classification according to hazard classes, risk and safety phrases, physico-chemical properties, acute and subacute toxicity, ecotoxicity, environmental behaviour and use categories. On the basis of the information submitted by the producers and importers and in response to proposals from the Member States, the Commission produces priority lists of substances to be examined on a priority basis. The special attention paid to them is due to their possible effects on man and the environment.

The producers and importers must submit their substance information to the ECB on disk only, using the EU Commission's HEDSET recording program

(Harmonized Electronic Data Set). The ECB imports the incoming data into the IUCLID database (International Uniform Chemical Information Database) and conveys the data obtained in this way to the **Notification Unit within the Chemicals Act** as the national competent authority.

In the case of the substances included in the priority lists, producers and importers must provide further data. The extent and quality of this information are oriented towards the tests which are also demanded in the case of new substances. The further data are submitted on disk to the Notification Unit within the Chemicals Act as updated HEDSET data.

The HEDSET data provided by the companies and the available ECB data are combined to create a substance data sheet. The substance data sheet is exported in a transfer format and sent in this form to the assessment units for processing. The assessment units utilize the data to produce the risk assessment for the substance. They validate the data set in accordance with their area of competence and then send the revised data set back to the Notification Unit within the Chemicals Act. The validated and confidential data set produced in this way is exported in a transfer format. This data set is then forwarded to the ECB together with the risk assessment which has been produced in parallel. At the same time, a non-confidential data set is sent, inter alia, to the OECD Member States as well as to the industrial associations participating in this process.

- **BUA substance reports**

In order to determine systematically the hazard potential of existing chemical substances, in 1988 the Federal Government adopted a concept for the systematic recording and assessment of existing chemical substances according to the Chemicals Act. It received advice in this regard from the Advisory Committee on Existing Chemicals of Environmental Relevance (BUA) which belongs to the German Chemists' Society (GDCh). In accordance with the principle of cooperation, the BUA comprises, on a parity basis, representatives of the state, industry and science. The BUA provides the opportunity for on-going, science-based dialogue between these three groups on the subject of existing chemical substances. The BUA substance reports were elaborated to act as the basis of decision-making in authorities and industry. The BUA has since published over 200 reports on about 300 substances. It has been possible to use their contents in a number of different ways, for example, as an aid to decision-making in the area of the risk management of chemicals. Ad hoc working groups are set up by the BUA when current problems requiring special discussion occur, for example, in the case of endocrine disruptors and selection criteria for POPs. In order to implement the Federal Government's existing chemical substances programme of December 1998 the BUA assumed the task of selecting the existing chemical substances for which reports were to be produced on a priority basis. This work is ongoing. The reports have been translated into English in order to make them accessible to a wider international public.

- **EDEXIM (European Export/Import database) and the national database EPA-notification**

The Notification Unit within the Chemicals Act is responsible for receiving and forwarding information relating to Council Regulation (EEC) No 2455/92 concerning the export /import of certain dangerous chemicals. According to this regulation, each person intending to export for the first time one of the substances listed in Annex 1 of the Regulation to a particular country must first submit certain items of information to the competent authority of the Member State concerned. Within a specified period of time the Notification Unit within the Chemicals Act must inform the Commission of the European Communities as well as the recipient country about the intended export. In addition, the EU and UNEP/FAO PIC procedure (prior informed consent) must be observed. These organizations have asked all countries to report their prohibited substances. Predetermined criteria have been used to select particularly relevant substances for which Decision Guidance Documents relating to these substances are then sent out. An essential aspect of the procedure is that recipient countries are able to object to the export of a particular substance. Although the FAO and UNEP PIC procedure is voluntary, the PIC decisions adopted by the EU are binding for European exporters.

In order to be able to carry out the procedure which has just been described, the European Commission has developed the "EDEXIM" database (European Database on the Export and Import of certain dangerous chemicals). Inter alia, the US EPA's (United States Protection Agency's) export notifications are also included in the database if they are notifications which have to be announced to the European Commission.

The core of the database comprises the substances listed in Annexes 1 and 2 of Council Regulation (EEC) No 2455/92. In particular, the number according to Annex 1, the substance name, the CAS numbers, the EINECS number, the classification and labelling as well as the EU export reference numbers are included. A file containing information on individual events, for example, the date of an instance of export/import, the exporting and recipient country, is linked to this database.

The forms required to carry out the procedure according to Council Regulation (EEC) No 2455/92 are generated and printed by PC. Search and list functions / statistics etc. which allow a rapid review of individual procedures and the enforcement process as a whole are additionally available.

In addition, all of the EPA notifications which are received, even those not relating to a substance prohibited by the USA, are identified and stored in the national database. The database consists of a substance file to which a corresponding file containing information on the particular notification is linked. The information includes, inter alia, the notification number, the date of receipt, the name used by the EPA, the IUPAC name, the CAS number, the EINECS number and the empirical formula.

The following literature and databases are additionally available to the Notification Unit within the Chemicals Act:

- Environmental Health Criteria Documents (WHO)
- Material Safety Data Sheets
- OECD Guidelines for the Testing of Chemicals

- Good Laboratory Practice Principles
- Chemical Abstract Services Database
- STN (Scientific & Technical Information Network) database.

Evidently, the Notification Unit within the Chemicals Act is increasingly becoming an information pool for stocks of data in the field of the regulation of chemical substances, both in a national and international context.

8.2 Joint substance-data pool shared by the Federal Government and the Länder

An administrative agreement between the federal and regional environment ministries lays down the tasks associated with a joint substance data pool. Forms of cooperation in which there is division of the work required to input and update the substance data are intended to avoid duplication of the work and fill any gaps which may exist.

The aim is to set up a joint central substance data pool and to operate the system at the Federal Environmental Agency. Users of the joint central substance data pool are, inter alia:

- Federal institutions (Federal Environment Ministry/Federal Environmental Agency, Federal Ministry of Transport and Housing, Federal Institute for Health Protection of Consumers and Veterinary Medicine, Federal Institute for Materials Research and Testing, the federal finance authorities)
- the *Länder*, local government

The joint data pool was produced by bringing together existing databases, applying uniform registration rules for substances and utilizing harmonized data models of the factual data.

The joint central substance data pool contains data relating to:

- identification (such as structure, the registration numbers used in other systems)
- legal characteristics (such as national and European chemicals law, transport law, immission law, soil law, water law etc.)
- physico-chemical data (such as melting point, solubility, oxidation-reduction potential etc.)
- general hazards
- health hazards/first aid
- advice to the workforce or task forces concerning the handling of the substance
- environmental behaviour / ecotoxicology
- toxicology

All of Germany's public-service institutions and institutions which perform sovereign tasks have the right of access to the data. Transmission to third parties is intended.

Further national and international databases are to be included in the joint central substance data pool. For example, the inclusion of data gathered within the framework of the European programme for existing chemical substances (IUCLID) is planned. Interface programs between IUCLID and the joint central substance data pool ensure that in future there will be a permanent stream of data from IUCLID to the joint central substance data pool. Fairly large gaps in the data are still to be found in the areas of "substance classification according to European and national statutory regulations" and "ecotoxicological data". In the last mentioned area, valid data-gathering investigations and measurements are also missing. Substance classification data must therefore be acquired, in particular in the case of substances which are named in the regulations as a substance group or which appear there under a different summarizing name.

8.3 *Joint Länder Database on Hazardous Substances (GDL)*

The GDL is an information system for hazardous substances which primarily serves to support the competent authorities during enforcement of chemicals legislation. It was established by the specialist group GDL, which was founded in 1982, with the aid of experts from federal and regional authorities responsible for occupational safety and health. This specialist group is chaired by the State of Hesse, the Federal Institute for Occupational Safety and Health (BAuA) being the coordinating authority.

The database currently contains information relating to approx. 24,000 substance entries (pure substances, substance groups, and products). Included here are basic data such as substance names with a comprehensive list of synonyms, substance registration numbers, general chemical characterization and physico-chemical properties. In addition, the GDL provides all the substance-related information on current rules and regulations required by the occupational safety and health authorities. It also takes into account a large number of data on substances and preparations obtained as a result of enforcement by the occupational safety and health authorities.

Together with the GESTIS database belonging to the Federation of German Statutory Accident Insurance Institutions for the Industrial Sector (HVBG) and the BG Institute for Occupational Safety (BIA) (<http://www.hvbg.de/bia/stoffdatenbank>), an Internet version of the GDL (<http://www.gefahrstoff-info.de>) is offered in the form of a "joint *Länder* and German Statutory Accident Insurance Institution database on hazardous substances". Further information can be found at the above Internet address.

8.4 Central substance-data pool

An Internet version of a database known as GEFAHRGUT has been developed in a project jointly conducted by the Federal Institute for Materials Research and Testing (BAM) and the Federal Ministry of Transport and Housing (BMVBW). The main target groups are intended to be federal and regional authorities for whom free access or access at cost price is planned.

The database provides processed information in compact form such as is required for the safe transport of hazardous substances and products. The complex research technology permits a previously unachievable overview of widely different aspects of regulations on dangerous goods, e.g. for the purpose of self-monitoring of compliance with current legislation.

The physico-chemical substance data considered in the substance data records facilitate, inter alia, the selection of packaging and means of transport which have been authorized for use. Many substances not expressly mentioned in rules and regulations relating to dangerous goods have been included. As a result, the possibilities for monitoring have been considerably extended.

8.5 Further databases

The following tables list further databases which are available within the framework of chemicals management. Due to the large number of participating institutions, the tables only provide an excerpt of the databases actually in use.

Type of data	location	data source	Who has access?	How is access provided?	format
Danger categories for existing chemical substances	European Chemicals Bureau of the EC	Industry	European Chemicals Bureau of the EC and competent authorities of the EU member states	Via CD-ROM	On CD-ROM
Poisoning	Federal Institute for Health Protection of Consumers and Veterinary Medicine (BgVV)	Doctors	The general public	Doctors report to the central authority (Federal Institute for Health Protection of Consumers and Veterinary Medicine - BgVV). The BgVV then forwards the report on a data carrier to the regional Poison Information Centres which are in direct contact with	By telephone (emergency call in case of poisoning)

				citizens.	
Statistics on the occurrence of poisoning	Federal Institute for Health Protection of Consumers and Veterinary Medicine (BgVV)	Doctors, regional Poison Information Centres	The general public, EC Commission	Request submitted to the BgVV	Information brochure
Self-imposed obligation on the part of industry with regard to intermediates	At the individual chemical companies	Literature, tests	Each individual company, monitoring authorities	On request, e.g. by telephone in the case of accidents	Varies from company to company

Name	Purpose	Content	location
Retrieval System for Existing And Notified Substances (RENOCS)	Identification of substance identities during monitoring measures	EINECS data and data on notified substances	Notification Unit within the Chemicals Act, the <i>Länder</i>
CHEMIS	Assessment of substances; the elaboration of water quality targets	Data on about 12,000 substances with high production volumes	Federal Institute for Health Protection of Consumers and Veterinary Medicine (BgVV) Federal Environmental Agency (UBA)
Rapid information service for hazardous substances	Information on substances, inter alia, for use by the fire and police services	Substance data for the introduction of measures in the case of accidents and catastrophes	Federal Environmental Agency (UBA)
Database application for use in connection with water pollutants (RIGOLETTO)	Classification of substances according to water-hazard classes	Substance data, literature sources	Federal Environmental Agency (UBA)
Database for laundry and cleaning products	Recording of constituents; determination of pollution of aquatic environments	Basic recipes, data on environmental compatibility	Federal Environmental Agency (UBA)
Enforcement of the Chemicals Act	Assessment within the framework of the notification of new substances	Substance data sets for substances that are to be notified	Federal Environmental Agency (UBA)
Information system on hazardous and environmentally relevant substances (IGS)	Information required for enforcement and in case of accidents	Laws and rules; substance data; measures in the case of damage; occupational safety measures	MURL (North Rhine-Westphalia)
Stand-by call and first-action system RESY	Systems for combating accidents involving hazardous substances for use in connection with maritime shipping, coasts	Substance properties; risks to health and the environment; protection measures; classifications	The Environment Protection Authority in Hamburg

	and ports		
Database for the enforcement of the Plant Protection Act	Assessment within the framework of the licensing of plant protection products	Substance data sets relating to preparations and active substances	Federal Environmental Agency (UBA)

Chapter 9 Technical infrastructure

The technical infrastructure of the companies, authorities and institutions participating in chemicals management corresponds both in terms of quantity and quality to that of a modern industrial state. Consequently, detailed enumeration is superfluous. Extensive DP support, sufficient laboratory capacities, access to international databases and connections to e-mail and Internet services are available.

In order to convey a more detailed impression, two areas are presented here as an example.

9.1 GLP procedure

As a consequence of a growing awareness of health and environmental issues, a series of statutory regulations have been passed in recent years - above all in western industrial nations and Japan - with the aim of testing chemical substances for their risk potential to man, animal and the environment before they are actually used.

Producers or importers have been obliged to submit reports on non-clinical, experimental tests on safety or harmlessness to the assessment authorities involved in licensing, authorization, registration, notification or mini-notification procedures. This applies to all substance areas such as, for example, chemicals, pharmaceuticals and plant protection products. The assessment authorities must then undertake a scientific risk assessment only on the basis of the incoming reports on physico-chemical, ecotoxicological and toxicological tests which may have been produced by contracted institutes, industrial laboratories or scientific institutes - even by institutions abroad. Particular importance therefore attaches to the reliability and quality of the test data.

It is against this background that, as early as 1981, experts from the OECD states elaborated rules designed to improve the validity, integrity and transparency of experimental test data as well as ensure harmonization at international level. The body of rules on good laboratory practice (GLP) evolved in the course of this work. GLP lays down the quality criteria for both the performance of laboratory investigations and substance monitoring by the authorities. The intention here is to provide a framework of conditions to ensure the comprehensibility, reconstructability and precision of the demanded tests so that they are of a comparable high standard.

In Germany, the GLP principles were first laid down in law and made obligatory in 1990. Serving as the central coordination and initial contact point for the federal government and the *Länder* as well as for international matters, the federal GLP office was established at the Federal Institute for Health Protection of Consumers and Veterinary Medicine (BgVV). As is the case with many other statutory rules in the Federal Republic of Germany, it is the task of the *Länder* to control compliance with the GLP principles in German test establishments. The most important state control instruments are

inspections of test establishments and retrospective examination of tests which have been performed.

The federal GLP office keeps a current inventory of all GLP-inspected test establishments in Germany, publishing the inventory on an annual basis in the Federal Gazette. Among other things, the publication provides potential contract-placing companies with an overview of the laboratories of relevance to their needs. Overall, more than 193 German test establishments have received state certification of adherence to the principles of GLP.

A regular, internationally harmonized exchange of information takes place between the Member States on the basis of EU rules and OECD recommendations. Lists of foreign test establishments are collated at the federal GLP office in order to be able to provide the assessment authorities with the information they require. The inventories of the foreign test establishments are important with regard to the mutual recognition of GLP-inspected test establishments and the test results which are produced there. This recognition is assured for the EU Member States which follow the GLP rules as well as for the USA, Japan and Switzerland.

Test establishments from non-EU states without a mutual agreement for the recognition of GLP which are contracted by German companies to perform experiments to GLP standards for submission to German assessment authorities are monitored by the federal GLP office at the request of a German company.

9.2 Good professional practice

It is laid down in § 6 of the Plant Protection Act that plant protection products may only be used in accordance with good professional practice. Good professional practice includes the need to consider the principles of integrated plant protection. Accordingly, plant protection products may not be employed if the user must expect their use to have harmful effects on human or animal health or on the ground water or any other effects, particularly on the balance of nature, which cannot be justified.

Integrated plant protection represents a combination of methods by means of which the use of chemical plant protection products is limited to the necessary amount, prime consideration being given to biological, plant-breeding as well as cultivation measures (§ 2 of the Plant Protection Act). Consequently, non-technical plant-protection measures are preferred and chemical plant protection measures are placed at the end of the chain of temporary and non-technical defence mechanisms. Integrated plant protection is one of the most important measures for avoiding and reducing any remaining risks which plant protection products might pose in spite of having been licensed for use. In the Federal Republic of Germany, high priority is given to the further development and widespread implementation of integrated plant protection.

Integrated plant protection is promoted and realized thanks to a large number of programmes and activities undertaken by the federal and regional Governments and relevant organizations. In addition, an initiative started by various cultivation associations (e.g. fruit, vegetables, wine, and hops) also exists. These associations

voluntarily allow the implementation of integrated plant protection methods to be checked.

Chapter 10 International relations

10.1 Participation in international organizations and bodies

The Federal Republic of Germany participates actively, both in terms of personnel and financial support, in the EC, OECD and in international activities to ensure the safety of chemicals such as IPCS and IFCS. Capacity building in cooperation with UNITAR is a further area of special emphasis.

Within the framework of the United Nations environmental programme (UNEP) and the United Nations Food and Agriculture Organization (FAO), Germany is a signatory to the Rotterdam Convention on Protection Against the Import of Dangerous Chemicals.

10.2 Technical assistance projects

On request and within the financial means available to it, the Federal Republic of Germany supports developing countries in their efforts to introduce and implement internationally accepted standards in the field of chemicals management. The guidelines contained in Agenda 21, in particular chapter 19 "environmentally compatible handling of dangerous chemicals", form the basis for cooperation with the partner countries.

The Federal Ministry for Economic Cooperation and Development (BMZ), which is responsible for cooperation with development, supports bilateral country-specific and transnational projects in this sphere. The BMZ commissions the German Society for Technical Cooperation (GTZ) GmbH to undertake these projects. Projects involving financial cooperation which mainly relate to the area of chemicals management are not undertaken.

In an approach coordinated in particular with the Federal Environment Ministry (BMU) the nationwide "chemicals management pilot project" was set up in order to be able to react in a focused manner to questions from developing countries about the handling of dangerous chemicals. As the central coordination unit, this project has the task of promoting contact between the particular competent institutions or partners in Germany and selected developing countries as well as of bringing together available resources and achieving synergetic effects through the creation of networks with existing projects and programmes, also with those belonging to other sponsors and other international organizations.

Within the framework of technical cooperation, further transnational projects are concerned with the development of concepts and the implementation of particularly emphasized aspects of chemicals management in developing countries, especially the

substitution of chlorofluorocarbons/halons by natural substances, the largely safe use of plant protection products, the disposal of plant protection products that are no longer usable and the reduction of subsidies in the area of plant protection. In addition, the Federal Ministry for Economic Cooperation and Development supports a number of developing countries through bilateral projects designed to tackle problems in the area of chemicals management that have been specifically identified by the partner countries (see table).

Country	duration	description of project
transnational	3 years	Pilot project in the area of chemicals management
transnational	4 years	'Proklima' – substitution of CFCs/halons by natural substances
transnational	10 years	Plant Protection Product Service Project
transnational	5 years	Disposal of plant protection products
transnational	8 years	Reduction of subsidies in the area of plant protection
Argentina	5 years	Environmental protection in small and medium-sized chemical companies
Argentina	10 years	Support provided to the Faculty of Physical and Analytical Chemistry at the University of Buenos Aires
Brazil	5 years	Control of plant protection products, CATIE/IB
China	4 years	Quality control of plant protection products
El Salvador	10 years	Integrated plant protection
India	2 years	Advice provided to the chemical laboratory of the Footwear Design and Development Institute
India	11 years	Support provided to the Central Pollution Control Boards
Jamaica	3 years	Support provided to the Pesticide Control Authority
Mauritania	3 years	Removal of dangerous waste sites caused by plant protection products
Mexico	7 years	Air pollution control in Mexico City
Morocco	8 years	Environmental management
Thailand	6 years	Environmentally friendly plant protection
Thailand	4 years	Transport of dangerous goods
Yemen	10 years	Support provided to the national plant protection service

- **A**

- **C**

ChemVwV	General administrative provision for the implementation of assessments	GDL	Joint <i>Länder</i> database on hazardous substances
CSD	Commission on Sustainable Development	GefahrgutG	Act on the Transport of Dangerous Goods
CUB	Environmental Advisory Society for the Chemical Industry	GefStoffV	Hazardous Goods Ordinance
CUS	Customs Union Service	GGVBinSch	Dangerous Goods Ordinance – Inland waterways
CWÜ	Agreement on Chemical Weapons	GGVE	Dangerous Goods Ordinance – railways
CWÜAG	Implementing statute relating to the Agreement on Chemical Weapons	GGVS	Dangerous Goods Ordinance – road
CWÜVO	Implementing ordinance relating to the Agreement on Chemical Weapons	GGVSee	Dangerous Goods Ordinance – sea
		GISBAU	Information system on hazardous substances belonging to the German Statutory Accident Insurance Institution for the building industry
• D		GIZ	Poison Information Centre
DGD	Decision Guidance Documents	GLP	Good Laboratory Practice
DüngMG	Fertilizer Act	GLP-BSt	Federal GLP Office
DNA	Designated National Authorities	GMBI	Joint ministerial bulletin
DüngeV	Ordinance on the Principles of Good Professional Practice in the application of fertilizers	GrWV	Ordinance for the implementation of Council Directive 80/68/EEC on the protection of the ground water
DV	Data processing	GSBL	Joint substance data pool shared by the Federal Government and the <i>Länder</i>
		GTZ	German Society for Technical Cooperation
• E		• H	
EC	European Commission	HEDSET	Harmonized Electronic Data Set
ECB	European Chemicals Bureau	HELCOM	Helsinki Commission for the Protection of the Marine Environment of the Baltic
ECOIN	European Communities Core Inventory		
EDEXIM	European Database on Export-Import of certain dangerous chemicals	HKWAbfV	Ordinance on the Disposal of Waste Halogenated Solvents
EEC	European Economic Communities	HVBG	The Federation of German Statutory Accident Insurance Institutions for the Industrial Sector
EFTA	European Free Trade Association		
EG	European Community	• I	
EHC	Environment Health Criteria	ICCA	International Council of Chemical Association
EINECS	European Inventory of Existing Commercial Substances	IFCS	International Forum of Chemical Safety
ELINCS	European List of Notified Chemical Substances	IG BCE	Industrial Trade Union for the Mining, Chemicals and Energy industries
EMEA	European Agency for the Evaluation of Medicinal Products	IGS	Information system on hazardous and environmentally relevant substances
EPA	United States Protection Agency	ILO	International Labour Organization
EU	European Union	IMO	International Maritime Organization
EWG	European Economic Community	IPCS	International Programme on Chemical Safety
EWR	European Economic Area	IRPTC	International Register of Potentially Chemicals
• F		IT	Information technology
FAO	Food and Agriculture Organization of the United Nations	IUCLID	International Uniform Chemicals Information Database
FCKW	chlorofluorocarbons	IUPAC	International Union of Pure and Applied Chemistry
• G		IVA	Agricultural Industry Association
GABI	Joint Official Journal		
GDCh	Society of German Chemists		

• J		PAMIRA	Concept for the return of used agricultural product packaging
	JRC	PflSchAnwV	Ordinance on prohibitions of use of plant protection products
		PflSchG	Plant Protection Act
• K		PflSchMGV	Ordinance on plant protection products and plant protection equipment
	KrW-/AbfG	PflSchSachkV	Ordinance on evidence of specialist knowledge about plant protection
		PIC	Prior information Consent
• L		POP	Persistent Organic Pollutants
		PSF	Phosgene, sulphur, fluorine
• M	LABfG	State Waste Act	
	LABO	Regional Committee on Soil Protection	
	LAGA	Regional Working Group on Waste	
• N	LAI	Regional Committee on Protection against Immissions	
	LASI	Regional Committee on Occupational Safety and Safety Technology	
	LAWA	Regional Working Group on Water	
• O	LMBG	Foods and Consumer Goods Act	
	LuftVG	Air-transport Act	
• P			
• R		RC	Responsible Care
		RENOCS	Retrieval System for Existing and Notified Substances
		RESY	Stand-by call and first action system
• S		RIGOLETTO	Database application for water pollutants
		RL	Directive
		RTECS	Registry of Toxic Effects of Chemical Substances
• T			
• U			
• V			
• W			
• X			
• Y			
• Z			

National Profile

UNITAR	United Nations Institute for Training and Research	VwVwS	General administrative provision relating to the Water Resources Management Act concerning the classification of water pollutants according to water-hazard classes
UVCB	Substances of Unknown or Variable Composition, Complex reaction products and biological materials		
		• W	
		WassgefStBefV	Ordinance relating to water pollutants conveyed through pipelines
• V		WHG	Water Resources Management Act
VCH	The Chemical Trading Association	WHO	World Health Organization
VCI	The Chemicals Industry Association	WRMG	Law on the environmental impact of laundry and cleaning products

Annex 2: List of addresses

Federal authorities

Bundesministerium für Umwelt, Naturschutz
und Reaktorsicherheit
Bernkasteler Str. 8

53175 Bonn

www.bmu.de

www.umweltbundesamt.de
Bundesministerium für Arbeit und Sozialordnung
Postfach 14 02 80

53107 Bonn

www.bma.de

Bundesministerium für wirtschaftliche
Zusammenarbeit und Entwicklung
Friedrich-Ebert-Allee 40

53113 Bonn

www.bmz.de

Biologische Bundesanstalt für Land- und
Forstwirtschaft
Königin-Luise-Str. 19

14195 Berlin

www.bba.de

Bundesanstalt für Arbeitsschutz
und Arbeitsmedizin
- Anmeldestelle Chemikaliengesetz
- Abt. AS 2 – "Gefährliche Stoffe"
Friedrich-Henkel-Weg 1 – 25

44149 Dortmund

www.baua.de

Bundesanstalt für Materialforschung
und –prüfung
Unter den Eichen 87

12205 Berlin

www.bam.de

Bundesausfuhramt
Frankfurter Str. 29-35

65760 Eschborn

www.bafa.de

Bundesinstitut für Arzneimittel
und Medizinprodukte
Friedrich-Ebert-Allee 38

53113 Bonn

www.bfarm.de

Bundesinstitut für gesundheitlichen
Verbraucherschutz und Veterinärmedizin
Thielallee 88 - 92

14195 Berlin

www.bgvv.de

Paul-Ehrlich-Institut
Bundesamt für Sera und Impfstoffe
Paul-Ehrlich-Str. 51-59

63225 Langen

www.pei.de

Umweltbundesamt
Seecktstr. 6 - 10

13581 Berlin

Regional authorities

Baden-Württemberg

Ministerium für Umwelt und Verkehr
Kernerplatz 9

70029 Stuttgart

Mecklenburg-Vorpommern

Umweltministerium
Schloßstr. 6 – 8

19053 Schwerin

Bayern

Staatsministerium für Arbeit und Sozialordnung,
Familie, Frauen und Gesundheit
Winzerstr. 9

80792 München

Niedersachsen

Umweltministerium
Archivstr. 2

30169 Hannover

Berlin

Senatsverwaltung für Gesundheit und Soziales
Oranienstr. 106

10969 Berlin

Nordrhein-Westfalen

Ministerium für Umwelt, Raumordnung
und Landwirtschaft
Schwannstr. 3

40476 Düsseldorf

Brandenburg

Ministerium für Umwelt, Naturschutz und
Raumordnung
Albert-Einstein-Str. 42- 46

14473 Potsdam

Rheinland-Pfalz

Ministerium für Umwelt und Forsten
Kaiser-Friedrich-Str. 7

55116 Mainz

Bremen

Senator für Arbeit
Faulenstr. 69

28195 Bremen

Saarland

Ministerium für Umwelt, Energie und Verkehr
Halbergstr. 50

66121 Saarbrücken

Hamburg

Behörde für Arbeit, Gesundheit und Soziales
Adolph-Schönfelder-Str. 5

22083 Hamburg

Sachsen

Sächsisches Staatsministerium für Umwelt
und Landwirtschaft
Wilhelm-Buck-Str. 2

01097 Dresden

Hessen

Ministerium für Umwelt, Energie, Jugend,
Familie und Gesundheit
Mainzer Str. 80

65189 Wiesbaden

Sachsen-Anhalt

Ministerium für Raumordnung und Umwelt
Olvenstedter Str. 4

39108 Magdeburg

Schleswig-Holstein

Ministerium für Umwelt, Natur und Forsten
Grenzstr. 1 – 5

24149 Kiel

Thüringen

Ministerium für Landwirtschaft, Naturschutz
und Umwelt
Beethovenplatz 3

99096 Erfurt

International institutions

European Commission

Rue de la Loi 200

B - 1049 Brüssel

Belgium

www.europa.eu.int

www.who.org

JRC-ECB

European Chemicals Bureau
Joint Research Center

I - 21020 Ispra (VA)

Italy

<http://ecb.ei.jrc.it>

EMA

European Agency for the Assessment of
Pharmaceuticals

7 Westferry Circus

Canary Wharf

GB - London E14 4HB

Großbritannien

www.eudra.org/emea.html

IFCS

Intergovernmental Forum on Chemical Safety

Health Protection Branch

Health Canada

Tunney's Pasture, PL0701A1

CAN - Ottawa, ON K1A 0L2

Canada

ILO

International Labour Organization

4, route des Morillons

CH - 1211 Geneva 22

Switzerland

www.ilo.org

OECD

Environmental Health and Safety Division

15, Boulevard Amiral Bruix

F - 750016 Paris

France

www.oecd.org

UNEP Chemicals

Case Postale 356

11-13, Chemin des Anémones

CH - 1219 Châtelaine, Genève

Switzerland

www.unep.org

UNITAR

United Nations Institute for Training

and Research

Palais des Nations

CH - 1211 Geneva 10

Switzerland

www.unitar.org

WHO

20 Avenue Appia

CH - 1211 Geneva 27

Switzerland

Non-governmental organizations

Arbeitsgemeinschaft der
Verbraucherverbände
Heilsbachstr. 20

53123 Bonn

www.agv.de

Deutsche Gesellschaft für Technische
Zusammenarbeit GmbH
Dag-Hammarskjöld-Weg 1 – 5

65760 Eschborn

www.gtz.de

Gesellschaft Deutscher Chemiker
Varrentrappstr. 40 – 42

60486 Frankfurt/M.

www.gdch.de

Greenpeace
Große Elbestr. 39

22767 Hamburg

www.greenpeace.de

Hauptverband der gewerblichen
Berufsgenossenschaft
Alte Heerstr. 111

53757 Sankt Augustin

www.hvbg.de

IG Bergbau, Chemie, Energie
Königsworther Platz 6

30167 Hannover

www.igbce.de

Industrieverband Agrar (IVA)
Karlstr. 21

60329 Frankfurt/M.

www.iva.de

Verband Chemiehandel
Große Neugasse 6

50667 Köln

Verband der Chemischen Industrie e.V.
Karlstr. 21

60329 Frankfurt/M.

www.vci.de