

A. CHEMICALS

A.1. INTRODUCTION

The following report provides information on the implementation of chemicals policy in the Federal Republic of Germany. The report takes into account the programme areas laid down in Chapter 19 of Agenda 21 of the United Nations Conference on Environment and Development (UNCED, Rio de Janeiro, 1992). It also refers to the World Summit on Sustainable Development (WSSD, Johannesburg, 2002) and the Johannesburg Plan of Implementation (JPOI), which specifies in para. 23 further actions for improving the sound management of chemicals throughout their whole life-cycle as a contribution to sustainable development. The WSSD Conference also committed to the important "2020" objective "to achieve, by 2020, that chemicals are used and produced in ways that lead to the minimisation of significant adverse effects on human health and the environment".

The "National Profile of Chemicals Management in Germany" (see http://www.baua.de/en/Publications/Expert-Papers/Expert-papers.html?_nnn=true) provides an overview of the national structures for chemicals management in Germany.

The chemical industry is Germany's largest industrial sector (measured by sales volumes; it accounts for 13% of total German exports and 11% of all imported goods). The chemicals sector is therefore one of the most important cornerstones of German industry (data of 2007, source: Verband der Chemischen Industrie, VCI, see <http://www.vci.de/>).

The chemicals sector is mainly regulated by European legislation, which is implemented by Germany as one of the 27 Member States of the European Union. Therefore, this report should be read together with the planned report from the European Community. It endeavours to provide an overview of the main legislative projects and national initiatives in Germany since 2002.

Germany strives for a sound chemicals policy at the national level providing a high degree of protection. The objective is a systematic prevention policy to identify and reduce risks deriving from chemicals and industrial installations. It is based on a scientific assessment of substances for enhanced chemicals safety, high safety standards in the area of installations and related risk management, and monitoring mechanisms taking into account the whole life-cycle of chemicals. In this way, Germany wants to help improve chemicals management at both the national and the global level and thus also contribute to sustainable development.

"Chemicals" in this report is used to refer to industrial chemicals, pesticides (biocides and plant protection products), heavy metals and nanomaterials.

A.2. CHEMICALS LEGISLATION IN GERMANY

The field of chemicals is concerned with substances and products. That is why this policy area is already mainly regulated by European Community law. In the past, European chemicals law was mainly based on Directives, which the EU Member States had to implement into national legislation. More recently, the EU has agreed on

instruments (mainly Regulations) which have a direct binding effect on the 27 Member States (e.g. the REACH Regulation).

The national implementation and application of Community law in Germany is mainly based on the Chemicals Act of 1980 (“Gesetz zum Schutz vor gefährlichen Chemikalien – ChemG”), which was last updated in 2008. The ChemG also combines aspects of environmental, consumer and labour protection. Since 2002, the ChemG has also covered biocides. As far as detergents and cleaning supplies and the related existing Community law are concerned, Germany has an additional national detergent and cleaning supplies law, which was last updated in 2007 (“Gesetz über die Umweltverträglichkeit von Wasch- und Reinigungsmitteln – WRMG”).

Based on the ChemG and the WRMG, there are specialised legislative acts with independent national rules which complement Community law. The following deserve particular mention:

- rules relating to modalities for certain hazardous substances and preparations
- bans on some substances that are either not or only partly (sector-wide) regulated by Community law (e.g. formaldehyde, artificial mineral fibres)
- rules for the (bio)degradability of tensides in detergent and cleaning supplies going beyond the EC Regulation on detergents
- maximum limits for phosphates in detergent and cleaning supplies
- further regulations in the area of ozone depleting substances and fluorinated greenhouse gases (see below).

A.3. GLOBALLY HARMONISED SYSTEM OF CLASSIFICATION, LABELLING AND PACKAGING (GHS)

The WSSD (2002) requested the UN to implement by 2008 the Globally Harmonised System of Classification and Labelling of Chemicals (GHS) to provide a harmonised basis for globally uniform physical, environmental and health and safety information on hazardous chemical substances and mixtures (preparations) as well as a harmonised scheme for a safety data sheet. Over the years the OECD has also made a substantial contribution to progress in this regard.

The EU implemented GHS-CLP (classification, labelling and packaging) via Regulation (EC) No 1272/2008 (with a few transitional periods) as a directly binding act for its Member States, including Germany, with effect from 20 January 2009. By using internationally agreed classification and labelling elements and safety data sheets, together with the new European Chemicals legislation REACH, Germany intends to better assess and transparently control chemical risks while facilitating trade with chemicals on the one hand and protecting worldwide human health and the environment on the other (see http://www.reach-clp-helpdesk.de/en/CLP-en/CLP-en.html?_nnn=true).

A.4. NANOTECHNOLOGIES AND NANOMATERIALS

Nanotechnologies and nanomaterials are developing rapidly because the nanometre scale of substances allows new functions and properties. However, there are many unanswered questions about the opportunities and risks of nanomaterials. The German government, together with stakeholders from all civil society groups, is addressing these

questions and has combined its various activities within the “NanoInitiative 2010” to provide a uniform framework of objectives and activities (see http://www.bmbf.de/pub/nano_initiative_action_plan_2010.pdf).

In autumn 2006, the German Minister for the Environment, Nature Conservation and Nuclear Safety initiated the multi-stakeholder “NanoDialogue 2006 to 2008” to further consider the opportunities and risks presented by nanotechnologies and nanomaterials and prepare recommendations by the end of 2008. The results of this NanoDialogue can be found at http://ec.europa.eu/health/ph_risk/documents/nanokommission.pdf. The NanoDialogue has now entered Phase 2 (2009-2010), and also comprises a NanoCommission and four Working Groups.

The joint German research strategy, developed by the Federal Institute for Occupational Safety and Health (BAUA) together with the Federal Institute for Risk Assessment (BfR) and the Federal Environment Agency (UBA), focuses on worker and consumer health and environmental issues (see http://www.umweltbundesamt.de/technik-verfahren-sicherheit-e/dokumente/research_strategy_final.pdf). A study on a nano-product register is under development (lead agency the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety, BMU). In addition, the Federal Environment Agency (UBA) has developed a legal appraisal of nanotechnologies in cooperation with the Öko Institut e.V. and the Society for Institutional Analysis SoFiA e.V (see www.umweltdaten.de/publikationen/fpdf-l/3198.pdf).

Germany actively participates in relevant international activities such as the OECD Sponsorship Programme of the Working Party on Manufactured Nanomaterials (WPMN). Here, Germany is lead sponsor for the testing of titanium dioxide, a co-sponsor for nano-silver and a contributor to further nanomaterials (see www.oecd.org/env/nanosafety).

Germany has also initiated a number of projects to identify the risks of nanomaterials, e.g. NanoCare which starts in a second Phase in 2009. The result of NanoCare1 is available under http://www.nanopartikel.info/fileadmin/user_upload/Publikationen/NanoCareFinalReport.pdf

A.5. REACH

The REACH Regulation for the **R**egistration, **E**valuation and **A**uthorisation of **C**hemicals in Europe (Regulation (EC) No 1907/2006) is at the heart of a new approach to European chemicals policy. REACH entered into force on 1 June 2007; it is the most innovative regional chemicals law and is legally directly binding for the EU Member States, including Germany.

Germany is in the process of implementing REACH effectively and is gaining initial experience from its application. Current aspects for further consideration include, for example, the quality control of data, the identification of candidate substances of very high concern and the promotion of substitution of substances of very high concern. In Germany, the Federal Institute for Occupational Safety and Health (BAUA) is the national helpdesk, see www.reach-helpdesk.de.

A.6. PESTICIDES (PLANT PROTECTION PRODUCTS AND BIOCIDES)

The term “pesticides” refers to plant protection products and pesticides for non-agricultural uses; the latter are referred to as “biocidal products” as defined by the relevant European legislation. The placing on the market of plant protection products and biocidal products is regulated by Community legislation (see report of the Commission of the European Community), which has been implemented into German law. Both legislative acts stipulate that products within their scope must not be placed on the market unless they have been authorised by the relevant national competent authority.

Directive 98/8/EC concerning the placing of biocidal products on the market was implemented in 2002 by the Chemicals Act (see above), accompanied by provisions of a technical and administrative nature which are laid down within ordinances. The German Ordinance on the notification of biocidal products introduced a very simple notification scheme in order to obtain an overview of biocidal products on the German market that were placed there before the relevant provisions on authorisation came into force in Germany. Currently, notification has been given of 23,000 individual biocidal products on the German market – a huge number, which is due to the fact that biocidal products had been unregulated in Germany before 2002 (also see <http://www.baua.de/>).

Germany introduced the authorisation of plant protection products as early as 1968, with the plant protection act (“Pflanzenschutzgesetz - PflSchG”). Directive 91/414/EEC concerning the placing of plant protection products (PPP) on the market was implemented by means of the revision of the German plant protection act as a legislative instrument, accompanied by specifying ordinances on technical and administrative details. The relevant German legislation on plant protection products will soon be adapted to the new EC legislation on plant protection products that was adopted on 24 September 2009. For an overview of key legal provisions on plant protection, see also Federal Ministry of Food, Agriculture and Consumer Protection (www.bmelv.bund.de) and Federal Office of Consumer Protection and Food (Bundesamt für Verbraucherschutz und Lebensmittelsicherheit, BVL) at www.bvl.bund.de. Whereas the EC Regulation on the placing of plant protection products on the market will provide for executing laws in each EU Member State, the EC Directive establishing a framework for Community action to achieve the sustainable use of pesticides needs a legislative act for implementation. The core element of such an implementing act will be a legally binding obligation to set up a National Action Plan with quantitative objectives, targets, measures and timetables to reduce the risks and impacts of pesticide use on human health and the environment and to encourage the development and introduction of integrated pest management and of alternative approaches or techniques in order to reduce dependency on the use of pesticides.

A.7. SAICM

Germany contributed to the activities and initiatives of the voluntary UN Strategic Approach to International Chemicals Management (SAICM) as the overarching chemicals strategy to reach the “2020” objective right from its beginning in February 2006 (International Conference on Chemicals Management, ICCM1). Germany provides financial support to the SAICM Secretariat and its current financial mechanism, the Quick Start Programme (QSP), which is aimed in particular at facilitating the activities of

eligible developing countries and countries with economies in transition. The German government backs initiatives that help to create effective synergies for the benefit of foundational capacity building in the chemicals area within available resources and in kind. As far as the German implementation of the SAICM Global Plan of Action (GPA) is concerned, many of the activities contained therein have already been put in place by European and national legislative and other acts, as described in this report.

On 6 June 2008, the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety (BMU) and the SAICM National Focal Point, the Federal Environment Agency (UBA), invited stakeholders to a conference on the “National Implementation of the Strategic Approach on International Chemicals Management – SAICM”. With regard to the manifold chemicals-related activities in Germany, the conference assessed the objectives of the Overarching Political Strategy (OPS) as well as the 36 work areas of the Global Plan of Action (GPA) to assess the current state of the national SAICM implementation (see website <http://www.umweltbundesamt.de/chemikalien-e/saicm.htm>). Further implementation activities are continuing in line with the results of the ICCM2 Conference (May 2009, Geneva) in close cooperation with relevant stakeholders.

A.8. THE STOCKHOLM CONVENTION (POPs), THE UNECE POPs PROTOCOL AND REGULATION (EC) No 850/2004

Germany is a Contracting Party to both the Stockholm Convention on Persistent Organic Pollutants (POPs, in force since 17 May 2004) and to the POPs Protocol to the UNECE Convention on Long-range Transport of Air Pollution (CLRTAP) (in force since 23 October 2003). The contents of both legally binding instruments were transposed into a national act in April 2002. The Federal Environment Agency (UBA) acts as the POPs Focal Point (see <http://www.umweltbundesamt.de/chemikalien-e/pops.htm>) The Agency cooperates closely with the Federal Institute for Occupational Safety and Health (<http://www.baua.de/>), which is the Designated National Authority (DNA).

The POPs Convention and the POPs Protocol were transposed into European Community law by Regulation (EC) No 850/2004 and are therefore directly legally binding for Germany. In some respects, the regulation goes beyond the commitments of the Stockholm Convention, e.g. in the area of management of waste containing POPs.

Since the production and use of the POPs listed in the Stockholm Convention and the POPs Protocol have been already banned in Germany, the national focus is on identifying POPs emission sources, quantifying annual releases in an emission inventory, and identifying new POPs and integrating them into internationally coordinated action. Germany has compiled extensive data for a national emission inventory for unintentionally released POPs and information on the state of the environment with respect to PCDD/Fs and PCBs (see also the dioxin data bank of Germany and its federal states, <http://www.pop-dioxindb.de/>).

In May 2006, Germany tabled in Geneva a National Implementation Plan (NIP, see <http://chm.pops.int/Countries/NationalImplementation/>). As a follow-up activity to the Fourth Contracting Parties' Conference of the Stockholm Convention (POP COP4, May 2009, Geneva), at which, amongst other things, nine new POPs were listed, Germany will update this NIP.

Furthermore, the German government regards a functioning compliance system and the evaluation of the effectiveness of the Stockholm Convention as important issues with a view to further reducing pollution levels in the medium and long term. Germany also supports the pilot activities to enhance coordination and cooperation (“synergies”) among the Basel, Rotterdam and Stockholm Conventions, which are to be followed up at the exCOP of the three conventions in February 2010 on Bali (Indonesia). This process also contributes to foundational capacity building in developing countries/countries in transition and to UN reform in the environment area.

A.9. ROTTERDAM CONVENTION (PIC) AND PIC REGULATION 689/2008/EC

Germany is also a Contracting Party to the Rotterdam Convention on the Prior Informed Consent Procedure (PIC) for Certain Hazardous Chemicals and Pesticides in International Trade which has been in force since 24 February 2004. Germany was one of the first Parties to ratify the PIC Convention in January 2001. The Federal Institute for Occupational Safety and Health (BAUA) in Dortmund acts as the designated national authority (DNA) along with the Federal Office for Consumer Protection and Food Safety, which is responsible for the authorisation of plant protection products (see also website http://www.baua.de/en/Chemicals-Act-biocide-procedure/Export-Import-Regulation/Special-Conventions.html?_nnn=true&_nnn=true and http://www.bvl.bund.de/cln_007/nn_492270/DE/04_Pflanzenschutzmittel/10_RechtlicheRahmenbedingungen/03_intern_abk/pic.html). The DNAs have a well-established cooperation with the national customs authorities.

The PIC Convention has been transposed into European Community law by Regulation (EC) No 689/2008, which is directly legally binding for Germany.

At the international level, Germany pro-actively supports PIC objectives. Germany does not only provide funding for the Rotterdam Convention through its assessed contributions to the Convention but also helps with additional travel and training support for developing countries/countries with economies in transition (developing countries/countries in transition). This contribution is aimed at enhancing foundational capacity to better address the risks involved with certain products in trade. Germany also co-sponsored and co-organised in April 2009 an International Expert Conference on Asbestos and POPs held in Kazakhstan to highlight the health risks associated with crysothile-asbestos and provide information about legislative measures for crysothile-asbestos in other countries.

Germany considers it vital to improve the effectiveness of the Convention with regard to the inclusion of new substances to be subject to the PIC procedure, such as crysothile-asbestos.

A.10. OTHER HAZARDOUS SUBSTANCES, ESPECIALLY HEAVY METALS SUCH AS MERCURY, LEAD AND CADMIUM, IN THE UNEP AND LRTAP CONTEXT

A.10.1.MERCURY

Germany is a Contracting Party to the UNECE Heavy Metals Protocol of 29 December 2003 to the Convention on Long-range Transport of Air Pollution (CLRTAP).

After eight years of discussions, the international community agreed at the 25th UNEP Governing Council (UNEP/GC/25-5) in February 2009 to take joint action to counter the proven global threat of mercury to the environment and human health, to start negotiations on a multilateral treaty in 2010 and to undertake additional voluntary measures complementing these efforts. Germany agrees to a multilateral legally binding agreement for long-lasting worldwide policy development, coordination and effective implementation covering the whole life cycle of mercury (see also decision UNEP/GC/24-3). It is hoped that the much stricter German and European environment standards and related best available techniques and best available practices will also be applied on a global scale so as to help improve the situation regarding the environment and health worldwide.

In the European Union, considerable progress has been made towards addressing the global challenges of mercury since the second half of the 1970s in more than 30 legal acts including recent restrictions on the sale of measuring devices containing mercury, the ban of exports of mercury from the EU and new rules on safe storage (see <http://ec.europa.eu/environment/chemicals/mercury/>).

A.10.2. LEAD AND CADMIUM

At the global scale, UNEP is also considering further internationally coordinated action (closing of data gaps, finalisation of scientific review and assessment including trade-related challenges) on the hazardous heavy metals lead and cadmium covering their whole life-cycle (UNEP/GC/25-5) for reporting and further decision-making at GC26 (2011). These efforts were backed by the German Federal Ministry for the Environment, Nature Conservation and Nuclear Safety (BMU) as lead sponsor of the agenda item “International transport of lead and cadmium via trade: an international concern?” at the Sixth Forum of the UN Conference on International Chemicals (IFCS) in September 2008 in Dakar (Senegal).

On 20 March 2009, the European Food Safety Authority’s Panel on contaminants in the food chain set a reduced tolerable weekly intake (TWI) for cadmium from all sources of 2.5 micrograms per kilogram of body weight ($\mu\text{g}/\text{kg bw}$), based on an analysis of new data. The TWI is the level at which no adverse effects are expected. Average dietary exposure to cadmium for adults across Europe is around this level. Some population groups – vegetarians, children, smokers and people living in highly contaminated areas – can have a level of exposure up to twice the TWI. The Panel concluded that current exposure to cadmium should be reduced. The German government is currently considering measures in addition to those already existing at national, European and international level to reduce cadmium emissions into the environment and therefore in the food chain.

A.10.3. ENVIRONMENT-RELATED FOOD SAFETY

Environmental protection is also a fundamental aspect of food safety. Numerous regulations on lead and cadmium also exist at EU level to which Germany is bound. One example is food safety. This also backs efforts to amend consumer protection in Germany. Regarding environment-related contaminants in food, the German aim is to protect human health at the source, notably by hindering any release of contaminants into the environment. It is, therefore, necessary to integrate compartment- and product-related regulations, together with flanking measures to replace polluted food. Since 1993, there have been EU maximum levels for mercury in fish and fish products. These were complemented in 2002 by maximum levels for lead, cadmium and dioxins in various foods (such as cereals, vegetable, fruits and fish and fish products). Since 2006, EU limit values have existed for the sum of dioxins and dioxin-like PCBs for food made of animals. This means that those polluted products have to be taken off the market (for further information, see http://www.bmu.de/english/food_safety/general_information/doc/5720.php and Leitfaden "Dioxin- und PCB-Einträge in Lebensmittel vermeiden", http://www.bmu.de/gesundheit_und_umwelt/downloads/doc/40840.php)

A.11. CONSUMPTION OF OZONE-DEPLETING SUBSTANCES

Production and consumption of ozone-depleting substances is regulated internationally by the Vienna Convention on the Protection of the Ozone Layer and its Montreal Protocol on Substances that Deplete the Ozone Layer, to which Germany is a contracting Party. EU Member States meet their obligations under the Montreal Protocol via an EU Regulation with phase-out targets going beyond the requirements of the Montreal Protocol for the production and consumption of substances including CFCs, halons, HCFCs and methyl bromide. The most recent recast of the current Ozone Regulation (EC) No 2037/2000 will enter into force in January 2010. Additional national legislation based on the Chemicals Act provides for the necessary implementation measures for the EU regulation and adds even stricter national phase-out provisions for a range of applications, as well as additional measures including labelling, book-keeping and redemption obligations for producers and traders (see <http://bundesrecht.juris.de/bundesrecht/chemozonschichtv/gesamt.pdf>).

Following a self-commitment on the part of the aerosol industry to terminate the use of CFCs in aerosol cans in Germany in 1988, CFC production was completely phased out by Germany in 1994. In addition, the production of products containing CFCs for export purposes is prohibited. Since January 2006 CFCs have no longer been allowed in medical applications. Methyl chloroform and CFCs have been prohibited in solvents since 1992. Halons have generally been prohibited in Germany since 1992, with restricted exemptions for fire extinguishing applications where these substances are vital to the protection of human lives (military, civil aviation). HCFCs have been prohibited in aerosols and rubber foams since 1991, in construction foam since 1993 and as refrigerants in new applications since 2000. Production of methyl bromide in Germany ended in the second half of the 1990s and as of 1 September 2006 the use of methyl bromide for fumigation has been prohibited.

A.12. EMISSIONS OF FLUORINATED GREENHOUSE GASES (F-GASES)

Fluorinated greenhouse gases are covered by the UNFCCC and controlled by the Kyoto Protocol. Regulation (EC) No 842/2006 and Directive 2006/40/EC target the reduction of stocks and emission factors of F-Gases. Key objectives of these legal acts are therefore the prohibition of certain products and equipment containing F-Gases, containment provisions and the training and certification of personnel.

In July 2008, a German supplementary ordinance entered into force which not only establishes the required certification system for the personnel and businesses involved but also introduces additional obligations such as emission thresholds, containment provisions for refrigerated transports and redemption of used gases by producers and traders (see <http://bundesrecht.juris.de/chemklimaschutzv/index.html>).

Beyond that, Germany is following a concerted policy to achieve its ambitious national emission reduction targets, including financial assistance for investors (see http://www.bmu.de/klimaschutzinitiative/nationale_klimaschutzinitiative/impulsprogramm_kaelteanlagen/doc/41744.php) to stimulate the use of natural refrigerants as a substitute for CFCs and F-Gases.

A.13. POLICIES AND PREVENTION OF MAJOR ACCIDENTS

As far as the safety of installations is concerned, the German statutory order on hazardous incidents (“Störfall-Verordnung”) transposes the requirements of the European Seveso II Directive (Directive 96/82/EC of 9 December 1996 on the control of major-accident hazards involving dangerous substances, amended in 2003) into national legislation (last amendment in 2005). The objective is to prevent major accident hazards involving dangerous substances. As accidents do continue to occur, the regulations also aim to limit the consequences of such accidents not only for human beings (safety and health aspects) but also for the environment (environmental aspect). The main instruments cover safety management systems, safety reports and emergency plans.

The last amendment to the statutory order on hazardous incidents introduced stricter threshold levels, e.g. for hazardous and explosive substances to enhance the prevention of major accidents in industry. At the same time, the possible impacts of industrial accidents were further limited. For instance, an appropriate distance has to be maintained between industrial installations and sensitive areas such as important transport routes or areas for recreation. Moreover, tailing ponds and dams (like the one in Baia Mare, Romania, that broke in 2000 and led to a cyanide contamination of the river Danube) also became part of the scope of the statutory order on hazardous incidents.

Since 2006, Germany has been engaged in bilateral cooperation with China in the area of risk assessment of installations that may constitute a potential hazard to the environment. The aim is to achieve sustainable improvements in protection of water bodies against impermissible releases from hazardous installations.

A.14. OTHER GERMAN ENGAGEMENT IN INTERNATIONAL CHEMICALS PROGRAMMES

For many years, the German Federal Ministry for the Environment, Nature Conservation and Nuclear Safety (BMU), the Federal Environment Agency (UBA) and the Federal Institute for Risk Assessment (BfR) have been actively contributing to projects in various

ways (financially and in kind). In the context of the OECD Chemicals Programme and the WHO International Programme on Chemical Safety (IPCS) they further contribute to enhanced risk assessment, including of a toxicological nature, and other research on chemicals substances. The Federal Ministry for the Environment, Nature Conservation and Nuclear Safety (BMU) has also contributed within the context of the International Forum on Chemicals Safety (IFCS), founded as a UN entity in 1994 on the basis of Chapter 19 of Agenda 21 to inform and communicate the results of the EU, OECD and other international chemicals-related working groups to developing countries/countries in transition. This is done in close cooperation with the other international organisations on chemicals management (IOMC) as well as civil society representatives from science, trade unions, industry, environment, health and consumer protection.

A.15. BILATERAL COOPERATION IN THE CHEMICALS POLICY AREA

The Federal Ministry for the Environment, Nature Conservation and Nuclear Safety (BMU) is also bilaterally active in the chemicals area, e.g. with China on REACH or with the Democratic People's Republic of Korea on POPs. In line with the multilateral chemicals conventions, the Federal Ministry for Economic Cooperation and Development (BMZ) supports partners in selected developing countries and emerging economies in implementing international chemical conventions through various bilateral initiatives under the Convention Project "Chemical Safety (CHS)", implemented by the German Gesellschaft for Technische Zusammenarbeit (GTZ). Further details on the various initiatives are can be found in the case studies attached to this report.