

First Meeting
Geneva, 10 – 14 November 2003

Meeting of Experts
Geneva, 18 – 29 August 2003
Items 5 and 6 of the provisional agenda

**LEGISLATION IN THE FEDERAL REPUBLIC OF GERMANY RELATED
TO SECURITY AND OVERSIGHT OF PATHOGENIC
MICROORGANISMS AND TOXINS**

Prepared by the Federal Republic of Germany

1. German legislation on security and oversight of pathogenic microorganisms and toxins serves the purpose of minimizing the risks for human beings as well as for animals, plants, and the environment arising from the permitted handling of such materials. This legislation has a long history and has not been shaped by the present debate on bioterrorism. Depending on the areas to be protected, different laws and regulations govern the security and oversight of dangerous microorganisms and toxins in Germany. Some of the areas concerned are also regulated by EU legislation.
2. Lists of dangerous microorganisms based on risk assessment, as well as provisions regarding the licensing and control of the handling of such organisms, are generally included in the legislation regulating all these areas. Permission to handle dangerous microorganisms is granted by state authorities either in form of personalized licenses or licenses for facilities. In both cases the granting of a license is subject to scrutiny of personnel for professional competence as well as for other reasons. License-issuing authorities are also responsible for controlling involved persons, facilities and activities. Activities to be controlled normally include facility safety standards, the handling of microorganisms inside facilities as well as the transfer of biological agents between facilities and persons.
3. Detailed regulations can be found in the following Acts and Ordinances (this is merely a list of most important legislation, it is not exhaustive): the **Arbeitsschutzgesetz** (Health and Safety at Work Act) of 07 August 1996 and the **Biostoffverordnung** (Ordinance on safety and health protection related to work involving biological agents) of 27 January 1999, the **Infektionsschutzgesetz** (Infection Protection Act) of 20 July 2000, the **Tierseuchengesetz** (Animal Infectious Disease Act) of 20 April 2001 and the **Tierseuchenerreger-Verordnung** (Animal Pathogen Ordinance) of 25 November 1985, the **Pflanzenschutzgesetz** (Plant Protection Act) of 14 May 1998 and the

Pflanzenbeschau-Verordnung (Phytosanitary Ordinance) of 10 October 2000 as well as the **Gentechnikgesetz** (Genetic Engineering Act) of 16 December 1993 and five additional ordinances with provisions regulating different aspects of genetic engineering-related activities; all Acts and Ordinances as amended.

4. The above-mentioned specialized Acts and Ordinances as well as additional ordinances also regulate the import and export of pathogens for permitted peaceful activities or generally prohibit the import of certain listed microorganisms.
5. Licenses are granted and controls are executed either by Federal agencies or agencies of the Länder (Federal States), in line with the delimitation of competences set out in the German Basic Law. All the above-mentioned Acts and Ordinances contain specific penal provisions to enforce the respective legislation. Penal provisions in the areas mentioned include fines as well as imprisonment.
6. Some of the areas addressed are also regulated by EU legislation, such as **Council Directive 90/679/EEC** on protection of workers of 26 November 1990 **codified by 2000/54/EC**, **Council Directive 90/219/EEC** on contained use of genetically modified microorganisms of 23 April 1990, and **Council Directive 2000/29/EC** on protective measures against organisms harmful to plants of 8 May 2000. Germany has implemented these EU Directives by national law including penal provisions.
7. Requirements for safe shipping of biological materials in Germany are contained in the **Gefahrgutverordnung Straße und Eisenbahn** (Dangerous Goods Ordinance Road and Rail) of 11 December 2001, the **Gefahrgutverordnung See** (Dangerous Goods Ordinance Sea) of 04 March 1998 and the **Gefahrgutverordnung Binnenschifffahrt** (Dangerous Goods Ordinance Inland Waterways Navigation) of 21 December 1994, the **European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR)** of 30 September 1957, and the **Regulation concerning International Carriage of Dangerous Goods by Rail (RID)**, all as amended, as well as in international regulations.
8. Detailed information on German legislation related to the BTWC issues has been compiled in a questionnaire that addresses, among other things, specific areas of security and oversight of pathogenic microorganisms and toxins. The questionnaire will be provided on a CD-ROM that will also include all relevant German legal documents.
9. The laws and regulations referred to in this paper can be viewed on the Internet:
 - Arbeitsschutzgesetz vom 7. August 1996:
<http://bundesrecht.juris.de/bundesrecht/arbschg/index.html>
 - Biostoffverordnung vom 27. Januar 1999:
<http://de.osha.eu.int/legislation/verord/biostoffv.htm>
 - Infektionsschutzgesetz vom 20. Juli 2000:
<http://bundesrecht.juris.de/bundesrecht/ifsg/index.html>

- Tierseuchengesetz vom 20. April 2001:
<http://bundesrecht.juris.de/bundesrecht/viehseuchg/index.html>
 - Tierseuchenerreger-Verordnung vom 25. November 1985:
www.goinform.de/demo/allgem/lw/bu/tierserv.pdf
 - Pflanzenschutzgesetz vom 14. Mai 1998:
http://bundesrecht.juris.de/bundesrecht/pflschg_1986/index.html
 - Pflanzenbeschau-Verordnung vom 10 Oktober 2000:
<http://www.bba.de/ag/gesund/national/pbvo.htm> BWC/MSP.2003/MX/WP.13
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 - Gentechnikgesetz vom 16. Dezember 1993:
<http://www.bba.de/gentech/gentg.pdf>
 - Council Directive 90/679/EEC on protection of workers of 26 November 1990 codified by 2000/54/EC:
http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=EN&numdoc=32000L0054&model=guichett
 - Council Directive 90/219/EEC on contained use of genetically modified microorganisms of 23 April 1990:
http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=EN&numdoc=31990L0219&model=guichett
 - Council Directive 2000/29/EC on protective measures against organisms harmful to plants of 8 May 2000:
http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=EN&numdoc=32000L0029&model=guichett
 - Gefahrgutverordnung Strasse und Eisenbahn vom 11. Dezember 2001:
<http://www.goinform.de/demo/umwelt/gg/bu/ggvse.pdf>
 - Gefahrgutverordnung See vom 04. März 1998
<http://www.goinform.de/demo/umwelt/gg/bu/ggvsee.pdf>
 - Gefahrgutverordnung Binnenschifffahrt vom 21. Dezember 1994
<http://www.goinform.de/demo/umwelt/gg/bu/ggvbins.pdf>
 - European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR) of 30 September 1957:
<http://www.unece.org/trans/danger/publi/adr/adr2003/English/intro.pdf>
 - Regulation concerning International Carriage of Dangerous Goods by Rail (RID)
<http://www.otif.org>
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