

**2008 Meeting
Geneva, 1-5 December 2008**

**Meeting of Experts
Geneva, 18-22 August 2008**
Item 5 of the provisional agenda
**Consideration of national, regional and
international measures to improve biosafety
and biosecurity, including laboratory safety
and security of pathogens and toxins**

IMPLEMENTATION OF LEGISLATION AND MEASURES RELATED TO BIOSAFETY AND BIOSECURITY IN EU MEMBER STATES

Submitted by Germany on behalf of the European Union

1. At the Sixth BTWC Review Conference in 2006, the European Union presented Working Paper 3 (BWC/CONF.VI/WP.3) explaining the need and obligation of all States Parties to translate the BTWC in national law and regulations, including penal and other enforcement measures. UNSC resolution 1540 (2004) also obliges all States to implement national legislation and other measures to prohibit and prevent the proliferation of biological weapons. UNSC resolutions 1673 (2006) and 1810 (2008) reiterate this obligation. National legislation to implement biosafety and biosecurity measures contributes substantially to prevent and prohibit proliferation of dangerous biological materials.
2. The EU Member States have taken stock of their national laws, regulations and other measures in fulfilling the obligation to implement biosafety and biosecurity measures in national legislation. The results of the stocktaking are annexed in the form of a matrix for each EU Member State.
3. The matrix addresses
 - (i) Measures for safe/secure production, use and/or storage;
 - (ii) Measures for safe/secure transport;
 - (iii) Licensing/registration of facilities/persons handling biological materials;
 - (iv) Reliability/security check of personnel;

- (v) Regulations for genetic engineering work;
- (vi) Control of importation and exports.

4. The matrix used is an adaptation of elements developed by the Committee established pursuant to UNSC Resolution 1540 (2004) with some minor modifications.

Biosafety and Biosecurity

Austria

03 July 2008

| Legislation and/or measures in place for safe handling, securing or otherwise protecting dual-use biological materials. Can violators be penalized? | | National legal framework ¹ | Enforcement: civil/criminal penalties and others |
|---|---|--|---|
| | | Indicate source document | Indicate source document |
| 1 | Measures for safe/secure production, use and/or storage | 1. Directive 2000/54/EC 2. Medicines Act 1983 last amended 2008 and ordinances 3. Chemicals Act 1996 last amended 1997 and ordinances 4. Genetic Engineering Act 1994 last amended 2004 and ordinances 5. Epidemics Act 1950 last amended 2008 6. Animal Infectious Disease Act 1909 last amended 2008 7. Crafts, Trade, Service and Industry Act 1994 last amended 2008 8. Employees Protection Act 1994 last amended 2001 and ordinances 9. General Employees Protection Ordinance 1983 last amended 2007 10. Ordinance on Work Equipment and Tools 2000 last amended 2004 11. Occupational Health Surveillance Ordinance 2000 last amended 2005 | |
| 2 | Measures for safe/secure transport | 1. Council Directive 96/49/EC 2. European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR)1957 as amended 3. Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal 1993 last amended 2000 | 1. Directive 95/50/EC 2. Party to ADR and RID 3. Criminal Code 1974 last amended 2007 |

¹ Working translations by Federal Ministry for European and International Affairs

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|---|--|--|--|
| | | <p>4. Transport of Dangerous Goods Act 1998 last amended 2007</p> <p>5. Transport of Dangerous Goods Ordinance 1999 last amended 2005</p> <p>6. Transport of Dangerous Goods by Inland Navigation Ordinance 2005 as amended 2006</p> <p>7. Animal Infectious Disease Act 1909 last amended 2008</p> | |
| 3 | Licensing/registration of facilities/persons handling biological materials | <p>1. Directive 2000/54/EC</p> <p>2. Medicines Act 1983 last amended 2008 and ordinances</p> <p>3. Genetic Engineering Act 1994 last amended 2004 and ordinances</p> <p>4. Crafts, Trade, Service and Industry Act 1994 last amended 2008</p> <p>5. Animal Infectious Disease Act 1909 last amended 2008</p> | Criminal Code 1974 last amended 2007 |
| 4 | Reliability/security check of personnel | Crafts, Trade, Service and Industry Act 1994 last amended 2008 | |
| 5 | Regulations for genetic engineering work | <p>1. Council Directive 90/219/EEC as amended by Council Directive 98/81/EC</p> <p>2. Genetic Engineering Act 1994 last amended 2004 and ordinances</p> | Criminal Code 1974 last amended 2007 |
| 6 | Control of importation | <p>1. Foreign Trade Act 2005 Art. 13 (2) and Art 14</p> <p>2. Animal Infectious Disease Act 1909 last amended 2008</p> | <p>1. Criminal Code 1974 last amended 2007, Section 117 a</p> <p>2. Foreign Trade Act 2005, Art. 37</p> |
| 7 | Control of exports | <p>1. Foreign Trade Act 2005</p> <p>2. Foreign Trade Decree</p> <p>3. Council Regulation (EC) No. 1334/2000 as amended</p> <p>4. Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and their Disposal 1993 last amended 2000</p> | <p>1. Criminal Code 1974 last amended 2007, Section 117 a</p> <p>2. Foreign Trade Act of 2005, Art. 37</p> |

Biosafety and Biosecurity

Belgium

06 June 2008

| Legislation and/or measures in place for safe handling, securing or otherwise protecting dual-use biological materials. Can violators be penalized? | | National legal framework | Enforcement: civil/criminal penalties and others |
|---|--|---|--|
| | | Indicate source document | Indicate source document |
| 1 | Measures for safe/secure production, use and/or storage | Directive 2000/54/EC | |
| 2 | Measures for safe/secure transport | 1. Council Directive 94/55/EC 2. Council Directive 96/49/EC | 1. Directive 95/50/EC 2. Party to ADR and RID |
| 3 | Licensing/registration of facilities/persons handling biological materials | Directive 2000/54/EC | |
| 4 | Reliability/security check of personnel | | |
| 5 | Regulations for genetic engineering work | Council Directive 90/219/EEC as amended by Council Directive 98/81/EC | |
| 6 | Control of importation | 1. Ministerial Order of 28 Sep 2000 2. Act of 05 Aug 1991 as amended 3. Royal Decree of 8 Mar 1993 | 1. Act of 11 Sep 1962 as amended 2. Act of 05 Aug 1991 as amended |
| 7 | Control of exports | 1. Council Regulation (EC) No. 1334/2000 as amended 2. Ministerial Order of 28 Sep 2000 3. Act of 05 Aug 1991 as amended 4. Royal Decree of 8 Mar 1993 | 1. Act of 11 Sep 1962 as amended 2. Act of 05 Aug 1991 as amended |

Biosafety and Biosecurity

Bulgaria
06 June 2008

| Legislation and/or measures in place for safe handling, securing or otherwise protecting dual-use biological materials. Can violators be penalized? | | National legal framework | Enforcement: civil/criminal penalties and others |
|---|--|---|--|
| | | Indicate source document | Indicate source document |
| 1 | Measures for safe/secure production, use and/or storage | Directive 2000/54/EC | |
| 2 | Measures for safe/secure transport | Regulation for the Production, Trade, Stockpiling, Transportation and Use of highly Poisonous Substances (1973/01/12/2003-19) | Presence of licensed experts on safe transportation of dangerous goods is obligatory |
| 3 | Licensing/registration of facilities/persons handling biological materials | 1. Law on Foreign Trade Activity in Arms and Dual-use Goods and Technologies as amended and the Regulation for its Implementation 2. Regulation for the Production, Trade, Stockpiling, Transportation and Use of highly Poisonous Substances (1973/01/12/2003-19) 3. Law on Plant Protection 4. Regulation No. 1 of the Ministry of Agriculture and Forestry 5. Regulation on the Implementation of the Law on the Veterinary-Medical Activities (2000) 6. Regulation No. 4 for the Licensing of the Production of Veterinary Medicines and Preparations (2003) | |
| 4 | Reliability/security check of personnel | | |
| 5 | Regulations for genetic engineering work | Council Directive 90/219/EEC as amended by Council Directive 98/81/EC | |
| 6 | Control of importation | Law on Foreign Trade Activity in Arms and Dual-use Goods and Technologies as amended and the Regulation for its Implementation | Penal Code, Art. 353 b |
| 7 | Control of exports | Law on Foreign Trade Activity in Arms and Dual-use Goods and Technologies as amended and the Regulation for its Implementation | Penal Code, Articles 337 and 353 b |

Biosafety and Biosecurity

Cyprus

06 June 2008

| Legislation and/or measures in place for safe handling, securing or otherwise protecting dual-use biological materials. Can violators be penalized? | | National legal framework | Enforcement: civil/criminal penalties and others |
|---|--|---|---|
| | | Indicate source document | Indicate source document |
| 1 | Measures for safe/secure production, use and/or storage | 1. Directive 2000/54/EC 2. Safety and Health at Work Law – Law No. 89(I) of 1996 | |
| 2 | Measures for safe/secure transport | 1. Council Directive 94/55/EC 2. Council Directive 96/49/EC | 1. Directive 95/50/EC 2. Party to ADR and RID |
| 3 | Licensing/registration of facilities/persons handling biological materials | Directive 2000/54/EC | |
| 4 | Reliability/security check of personnel | | |
| 5 | Regulations for genetic engineering work | Genetically Modified Microorganism (Contained Use) Law – Law No. 15(I) of 2004 | Control of GMOs by the Department of Labour Inspection of the Ministry of Labour and Social Insurance |
| 6 | Control of importation | Customs Code Law No. 94(I) of 2004 | Customs Code Law No. 94(I) of 2004 |
| 7 | Control of exports | 1. Council Regulation (EC) No. 1334/2000 as amended 2. Defense (Exportation of Goods) Regulation of 1993 3. Ministerial Decrees 91/2000 (31 Mar 2000), 133/2002 (2 Jun 2000), 355/2002 (26 Jul 2002), 62/2003 (31 Jan 2003) and 601/2004 (Jun 2004) | 1. Defense (Exportation of Goods) Regulation of 1993 2. Customs Code Law No. 94(I) of 2004 |

Biosafety and Biosecurity

Czech Republic

18 June 2008

| Legislation and/or measures in place for safe handling, securing or otherwise protecting dual-use biological materials. Can violators be penalized? | | National legal framework | Enforcement: civil/criminal penalties and others |
|---|--|--|---|
| | | Indicate source document | Indicate source document |
| 1 | Measures for safe/secure production, use and/or storage | 1. Act No. 281/2002 on some measures related to prohibition of BW, as amended 2. Act No. 258/2000 on protection of public health, as amended 3. Government Resolution No. 178/2001, as amended 4. Directive 2000/54/EC | 1. Act No. 281/2002, Section 21 2. Criminal Code – Act No. 140/1961, Section 186 |
| 2 | Measures for safe/secure transport | 1. Act No. 281/2002 on some measures related to prohibition of BW, as amended 2. Act No. 186/2004 (amendment to Customs Code) 3. Directive 94/55/EEC 4. Council Directive 96/49/EEC | 1. Criminal Code – Act No. 140/1961, Section 186 2. Party to ADR and RID, as amended |
| 3 | Licensing/registration of facilities/persons handling biological materials | Licenses granted by State Office for Nuclear Safety | 1. Act No. 281/2002, Section 21: fines 3. Criminal Code – Act No. 140/1961, Section 186 |
| 4 | Reliability/security check of personnel | Act No. 281/2002 on some measures related to prohibition of BW, as amended | |
| 5 | Regulations for genetic engineering work | 1. Act No. 78/2004 on GMOs, as amended 2. Act No. 281/2002 on some measures related to prohibition of BW, as amended | 1. Act No. 78/2004, as amended 2. Act No. 281/2002, as amended |
| 6 | Control of importation | Act No. 281/2002 on some measures related to prohibition of BW, as amended | 1. Act No. 281/2002, Section 21: fines 2. Criminal Code – Act No. 140/1961, Sections 17-21 |
| 7 | Control of exports | 1. Council Regulation (EC) No. 1334/2000 as amended 2. Act No. 594/2004 on implementing European Community regime for the control of exports of dual-use items and technology 3. Act No. 281/2002 on some measures related to prohibition of BW, as amended 4. Act No. 38/1994 on foreign trade in military equipment, as amended | 1. Act No. 281/2002, Section 21: fines 2. Criminal Code – Act No. 140/1961, Sections 124 a-f 3. Act No. 38/1994 as amended 4. Act No. 594/2004, Sections 17-18 |

Biosafety and Biosecurity

Denmark

06 June 2008

| Legislation and/or measures in place for safe handling, securing or otherwise protecting dual-use biological materials. Can violators be penalized? | | National legal framework | Enforcement: civil/criminal penalties and others |
|---|--|---|--|
| | | Indicate source document | Indicate source document |
| 1 | Measures for safe/secure production, use and/or storage | Directive 2000/54/EC | Control by Medicines Agency |
| 2 | Measures for safe/secure transport | 1. Council Directive 94/55/EEC 2. Council Directive 96/49/EEC | 1. Directive 95/50/EC 2. Party to ADR and RID |
| 3 | Licensing/registration of facilities/persons handling biological materials | 1. Medicines Law No. 656 of 28 Jul 1995 2. Directive 2000/54 | |
| 4 | Reliability/security check of personnel | | |
| 5 | Regulations for genetic engineering work | Council Directive 90/219/EEC as amended by Council Directive 98/81/EC | |
| 6 | Control of importation | Weapons Act, Section 1(1)4 | 1. Weapons Act, Section 10 2. Criminal Code – Law No. 909 of 27 Sep 2005 - Sections 192 a(1) and 114(1)6 |
| 7 | Control of exports | 1. Council Regulation (EC) No. 1334/2000 as amended 2. Weapons Act, Section 6 3. Law No. 474 of 14 Jun 2005 | 1. Law No. 474 of 14 Jun 2005 2. Weapons Act, Section 10 2. Criminal Code – Law No. 909 of 27 Sep 2005 |

Biosafety and Biosecurity

Estonia
18 June 2008

| Legislation and/or measures in place for safe handling, securing or otherwise protecting dual-use biological materials. Can violators be penalized? | | National legal framework | Enforcement: civil/criminal penalties and others |
|---|--|---|--|
| | | Indicate source document | Indicate source document |
| 1 | Measures for safe/secure production, use and/or storage | Directive 2000/54/EC | |
| 2 | Measures for safe/secure transport | 1. Council Directive 94/55/EEC 2. Council Directive 96/49/EEC | 1. Directive 95/50/EC 2. Party to ADR and RID |
| 3 | Licensing/registration of facilities/persons handling biological materials | Directive 2000/54 | |
| 4 | Reliability/security check of personnel | | |
| 5 | Regulations for genetic engineering work | Council Directive 90/219/EEC as amended by Council Directive 98/81/EC | |
| 6 | Control of importation | Strategic Goods Act, 2004 | Penal Code of 2002, Art. 392 |
| 7 | Control of exports | 1. Strategic Goods Act, 2004 2. Council Regulation (EC) No. 1334/2000 as amended | Penal Code of 2002, Art. 392 |

Biosafety and Biosecurity

Finland

06 June 2008

| Legislation and/or measures in place for safe handling, securing or otherwise protecting dual-use biological materials. Can violators be penalized? | | National legal framework | Enforcement: civil/criminal penalties and others |
|---|--|---|---|
| | | Indicate source document | Indicate source document |
| 1 | Measures for safe/secure production, use and/or storage | 1. Directive 2000/54/EC 2. Communicable Diseases Act (583/1986 as amended), Section 10 3. Communicable Diseases Decree (786/1986 as amended) 4. Occupational Safety and Health Act (738/2002 as amended), Section 40 5. Government Decision on the Protection of Workers from Risks related to Exposure to Biological Agents (1155/1993) 6. Ministry of Social Affairs and Health Decision on the Classification of Biological Agents (229/1998) | 1. Penal Code (39/1889 as amended), Chapter 44, Section 2 2. Communicable Diseases Act (583/1986 as amended), Section 37 3. Act on Protecting Plant Health (702/2003), Section 29 4. Act on Animal Diseases (55/1980 as amended), Section 23 |
| 2 | Measures for safe/secure transport | 1. Communicable Diseases Act (583/1986 as amended), Section 33 2. Communicable Diseases Decree (786/1986 as amended) 3. Act on Protecting Plant Health (702/2003), Section 7 and related decrees 4. Act on Animal Diseases (55/1980 as amended), and related decrees 5. Act on Veterinary Border Control (1192/1996 as amended) and related decrees 6. Act on Transport of Dangerous Goods (719/1994 as amended) and related decrees | 1. Communicable Diseases Act (583/1986 as amended), Section 37 2. Act on Protecting Plant Health (702/2003), Section 29 3. Act on Animal Diseases (55/1980 as amended), Section 23 4. Act on Veterinary Border Control (1192/1996 as amended), Section 27 5. Penal Code (39/1889 as amended), Chapter 44, Section 2 and Chapter 46, Section 4 6. Act on Transport of Dangerous Goods (719/1994 as amended), Chapter 7 7. Party to ADR and RID |
| 3 | Licensing/registration of facilities/persons handling biological materials | 1. Directive 2000/54/EC 2. Communicable Diseases Act (583/1986 as amended), Section 10 3. Communicable Diseases Decree (786/1986 as amended) | 1. Penal Code (39/1889 as amended), Chapter 44, Section 2 and Chapter 47 Section 1 2. Communicable Diseases Act (583/1986 as amended), Section 37 3. Act on Protecting Plant Health (702/2003), Section |

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|---|--|---|---|
| | | <p>4. Occupational Safety and Health Act (738/2002 as amended)</p> <p>5. Government Decision on the Protection of Workers from Risks related to Exposure to Biological Agents (1155/1993)</p> <p>6. Act on Protecting Plant Health (702/2003), Chapter 2</p> <p>7. Act on Animal Diseases (55/1980 as amended)</p> | <p>29</p> <p>3. Act on Animal Diseases (55/1980 as amended), Section 23</p> <p>4. Occupational Safety and Health Act (738/2002 as amended), Section 63</p> |
| 4 | Reliability/security check of personnel | | |
| 5 | Regulations for genetic engineering work | <p>1. Gene Technology Act (377/1995 as amended)</p> <p>2. Government Decree on Gene Technology (928/2004 as amended)</p> <p>3. Ministry of Social Affairs and Health Decree on the Inspection Procedure under the Gene Technology Act (184/2005)</p> <p>4. Ministry of Social Affairs and Health Decree on the Principles of Risk assessment of Contained Use of Genetically Modified Organisms, on the Classification of Contained Use as well as on Containment and other Protective Measures (1035/2005)</p> | <p>1. Penal Code (39/1889 as amended), Chapter 34, Section 4 and Chapter 44 Section 9</p> <p>2. Gene Technology Act (377/1995 as amended), Section 42</p> |
| 6 | Control of importation | Biological Weapons Act (257/1975) | |
| 7 | Control of exports | <p>1. Act on the Export and Transit of Defense Material (242/1990) as amended (900/2002)</p> <p>2. Act on the Control of Exports of Dual-use Goods (562/1996)</p> <p>3. Government Decree on the Control of Export of Dual-use Goods (924/2000)</p> <p>4. Council Regulation (EC) No. 1334/2000 as amended</p> | <p>1. Penal Code (39/1889 as amended), Chapter 46, Sections 1-3</p> <p>2. Act on the Control of Exports of Dual-use Goods (562/1996)</p> <p>3. Act on the Export and Transit of Defense Material (242/1990)</p> |

Biosafety and Biosecurity

France

20 June 2008

| Legislation and/or measures in place for safe handling, securing or otherwise protecting dual-use biological materials. Can violators be penalized? | | National legal framework | Enforcement: civil/criminal penalties and others |
|---|--|---|---|
| | | Indicate source document | Indicate source document |
| 1 | Measures for safe/secure production, use and/or storage | 1. Order of 22 Sep 2001 as amended by Order of 15 Jan 2004 and Order of 30 Jul 2004 2. Ordinance No. 58-1371 of 29 Dec 1958: security management policy, system of physical and human protection, surveillance of personnel 3. Decree of 21 Sep 1977 and Ministerial Order of 10 May 2000: inventory of hazardous substances 4. Labour Code, Art. R231-63 5. Order of 16 Jul 2007 (NOR: MTST0756429A) 6. Labour Code, Book IV, Title I Public health Code 7. Environment Code, Book V, Title III. Genetically modified organisms GMOs | 1. Public Health Code, Art L5432-1 2. Security management plan 3. System of physical and human protection |
| 2 | Measures for safe/secure transport | Order of 22 Sep 2001 as amended by Order of 15 Jan 2004 and Order of 30 Jul 2004 | Public Health Code, Art L5432-1 |
| 3 | Licensing/registration of facilities/persons handling biological materials | Order of 22 Sep 2001 as amended: requirement of specific authorization | |
| 4 | Reliability/security check of personnel | 1. Ordinance No. 58-1371 of 29 Dec 1958: surveillance of personnel (administrative inquiries, authorizations, etc.) 2. Ministerial Instruction No. 486 of 01 Mar 1993: authorization by Senior Security Officer of the Ministry of Industry (enterprises) or Ministry of Research (laboratories) is necessary for access by non-EU nationals | Surveillance of personnel |
| 5 | Regulations for genetic engineering work | 1. Order of 30 Jul 2004 2. Environment Code, Book V, Title III. Genetically modified organisms GMOs | |
| 6 | Control of importation | 1. Public Health Code 2. Order of 22 Sep 2001 as amended | 1. Customs Code , Articles 414-429 2. Decree Law of 18 Apr 1939 |

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|---|--------------------|---|--|
| | | 3. Framework Act on Public Health of 2004 4. Decree Law of 18 Apr 1939 | |
| 7 | Control of exports | 1. Decree Law of 18 Apr 1939 2. Public Health Code 3. Order of 22 September 2001 as amended 4. Council Regulation (EC) No. 1334/2000 | 1. Customs Code , Articles 414-429 2. Decree Law of 18 Apr 1939 |

Biosafety and Biosecurity

Germany

09 July 2008

| Legislation and/or measures in place for safe handling, securing or otherwise protecting dual-use biological materials. Can violators be penalized? | | National legal framework | Enforcement: civil/criminal penalties and others |
|---|--|--|---|
| | | Indicate source document | Indicate source document |
| 1 | Measures for safe/secure production, use and/or storage | 1. Biological Agents Ordinance of 27 Jan 1999 as amended 2. Genetic Engineering Act of 20 Jul 1990 as amended 3. Technical Regulations for Biological Agents (TRBA) | 1. Biological Agents Ordinance, § 18 2. Occupational Safety and Health Act of 07 Aug 1996 as amended, §§ 24 and 25 3. Genetic Engineering Act, §§ 38 and 39 |
| 2 | Measures for safe/secure transport | Law on the Transport of Dangerous Goods of 06 Aug 1975 as amended and related Ordinances on road, rail, waterway transports | 1. Law on the Transport of Dangerous Goods, § 10 2. Party to ADR and RID |
| 3 | Licensing/registration of facilities/persons handling biological materials | 1. Biological Agents Ordinance of 27 Jan 1999 as amended 2. Genetic Engineering Act of 20 Jul 1990 as amended 3. Protection Against Infection Act of 20 Jul 2000 as amended 4. Animal Infectious Disease Act of 26 Jun 1909 as amended and related Ordinances 5. Phytosanitary Ordinance of 10 May 1989 as amended | 1. Biological Agents Ordinance, § 18 2. Occupational Safety and Health Act of 07 Aug 1996 as amended, §§ 24 and 25 2. Genetic Engineering Act, §§ 38 and 39 3. Protection Against Infection Act, § 75 4. Animal Infectious Disease Act, § 76 5. Plant Protection Act, § 40 |
| 4 | Reliability/security check of personnel | 1. Protection Against Infection Act of 20 Jul 2000 as amended 2. Security Vetting Act of 20 Apr 1994 as amended 3. Security Vetting Identification Ordinance of 30 Jul 2003 as amended 4. Relevant Federal States Security Vetting Acts as well as relevant Federal States Identification Ordinances | 1. Protection Against Infection Act, § 47 2. Security vetting of persons working in security sensitive areas with pathogens and highly toxic substances |
| 5 | Regulations for genetic engineering work | Genetic Engineering Act of 20 Jul 1990 as amended and related Ordinances | Genetic Engineering Act, §§ 38 and 39 |
| 6 | Control of importation | 1. Protection Against Infection Act of 20 Jul 2000 as amended 2. Animal Pathogen Import Ordinance of 07 Dec 1971 as amended 3. Phytosanitary Ordinance of 10 May 1989 as amended 4. CWC Implementation Ordinance of 20 Nov 1996: | 1. Protection Against Infection Act, § 75 2. Animal Infectious Disease Act, § 76 3. Plant Protection Act, §§ 39 and 40 4. War Weapons Control Act, § 20 5. CWC Implementation Act of 13 Jan 1993 as amended, § 16, |

| | | | |
|---|--------------------|--|---|
| | | Ricin, Saxitoxin 5. War Weapons Control Act of 20 Apr 1961 as amended | |
| 7 | Control of exports | 1. Council Regulation (EC) no 1334/2000 as amended 2. Foreign Trade and Payments Act of 28 Apr 1961 as amended 3. Foreign Trade and Payments Ordinance of 18 Dec 1986 as amended | 1. Foreign Trade and Payments Act, §§ 33 and 34 2. War Weapons Control Act, § 20 |

Biosafety and Biosecurity

Greece

06 June 2008

| Legislation and/or measures in place for safe handling, securing or otherwise protecting dual-use biological materials. Can violators be penalized? | | National legal framework | Enforcement: civil/criminal penalties and others |
|---|--|--|--|
| | | Indicate source document | Indicate source document |
| 1 | Measures for safe/secure production, use and/or storage | Directive 2000/54/EC | |
| 2 | Measures for safe/secure transport | 1. Council Directive 94/55/EC 2. Council Directive 96/49/EC | 1. Directive 95/50/EC 2. Party to ADR and RID |
| 3 | Licensing/registration of facilities/persons handling biological materials | Directive 2000/54/EC | |
| 4 | Reliability/security check of personnel | | |
| 5 | Regulations for genetic engineering work | Council Directive 90/219/EEC as amended by Council Directive 98/81/EC | |
| 6 | Control of importation | Law No. 2991 of 27 Feb 2002, Art. 8 (declaration of import of Schedule I chemicals: Ricin, Saxitoxin) | Law No. 2991 of 27 Feb 2002, Art. 8 |
| 7 | Control of exports | 1. Law 936/1979 concerning external trade 2. Ministerial Decisions E3/1255/06.03.1991 and 2641/E3/3327/26.03.1992 3. Ministerial Decisions 125695/E3/5695/ 25.10.2000 on Control of Dual-use Items Transfer 4. Ministerial Decisions 85/E3/4136/09.06.1993 and 2026/E3/933/16.03.1994 | Law 936/1979 concerning external trade |

Biosafety and Biosecurity

Hungary
06 June 2008

| Legislation and/or measures in place for safe handling, securing or otherwise protecting dual-use biological materials. Can violators be penalized? | | National legal framework | Enforcement: civil/criminal penalties and others |
|---|--|--|--|
| | | Indicate source document | Indicate source document |
| 1 | Measures for safe/secure production, use and/or storage | 1. Directive 2000/54/EC 2. Ministry of Public Health Decree No. 61/1999 on the Protection of Workers from the Risks related to Biological Agents | Penal Code, Section 264/C and 284 |
| 2 | Measures for safe/secure transport | 1. Council Directive 94/55/EC 2. Council Directive 96/49/EC | 1. Directive 95/50/EC 2. Party to ADR and RID |
| 3 | Licensing/registration of facilities/persons handling biological materials | Directive 2000/54/EC | |
| 4 | Reliability/security check of personnel | | |
| 5 | Regulations for genetic engineering work | Council Directive 90/219/EEC as amended by Council Directive 98/81/EC | Penal Code, Section 173 |
| 6 | Control of importation | 1. Government Decree 50/2004 2. Government Decree 16/2004 | Penal Code, Sections 287 and 288 |
| 7 | Control of exports | 1. Government Decree 16/2004 on the licensing of export, import, transfer and transit of military equipment and technical assistance 2. Government Decree 50/2004 on the licensing of foreign trade in dual-use goods and technologies 3. Council Regulation (EC) No. 1334/2000 as amended | Penal Code, Sections 287 and 288 |

Biosafety and Biosecurity

Ireland

06 June 2008

| Legislation and/or measures in place for safe handling, securing or otherwise protecting dual-use biological materials. Can violators be penalized? | | National legal framework | Enforcement: civil/criminal penalties and others |
|---|--|--|--|
| | | Indicate source document | Indicate source document |
| 1 | Measures for safe/secure production, use and/or storage | 1. Directive 2000/54/EC 2. Safety, Health and Welfare at Work (Biological Agents) Regulations – S.I. 146/1994 as amended | |
| 2 | Measures for safe/secure transport | 1. Council Directive 94/55/EC 2. Council Directive 96/49/EC | 1. Directive 95/50/EC 2. S.I. 235 of 1980 (road transport) |
| 3 | Licensing/registration of facilities/persons handling biological materials | Directive 2000/54/EC | |
| 4 | Reliability/security check of personnel | | |
| 5 | Regulations for genetic engineering work | Council Directive 90/219/EEC as amended by Council Directive 98/81/EC | |
| 6 | Control of importation | Importation of Pathogenic Agents Order – S.I. 302 of 22 Sep 1997 | License of Minister of Agriculture and Food is required |
| 7 | Control of exports | 1. Commission Regulation (EC) No. 1334/2000 as amended 2. Control of Exports Act 1983 3. Control of Exports Order – S.I. 884 of 2005 | 1. Customs Act 1956, Section 3 2. Control of Exports Act 1983, Section 3(4) |

Italy

06 June 2008

Biosafety and Biosecurity

| Legislation and/or measures in place for safe handling, securing or otherwise protecting dual-use biological materials. Can violators be penalized? | | National legal framework | Enforcement: civil/criminal penalties and others |
|---|--|---|---|
| | | Indicate source document | Indicate source document |
| 1 | Measures for safe/secure production, use and/or storage | 1. Directive 2000/54/EC 2. Law No. 626 of 19 Sep 1994, Art. 73 to 88 and Annexes IX, XI to XIII | Law No. 626 of 19 Sep 1994 |
| 2 | Measures for safe/secure transport | 1. Council Directive 94/55/EC 2. Council Directive 96/49/EC 3. Decree of Minister of Transports of 02 Aug 2005 4. Memorandum of the Ministry of Health No. 16 of 20 Jul 1994 | 1. Directive 95/50/EC 2. Party to ADR and RID 3. Code of Land Transports, Art. 168 4. Code of Air and Maritime Navigation, Art. 1199 |
| 3 | Licensing/registration of facilities/persons handling biological materials | 1. Directive 2000/54/EC 2. Law No. 626 of 19 Sep 1994, Art. 76, 77 and 87 | Law No. 626 of 19 Sep 1994 |
| 4 | Reliability/security check of personnel | Law No. 626 of 19 Sep 1994, Art. 85 | Law No. 626 of 19 Sep 1994 |
| 5 | Regulations for genetic engineering work | Legislative Decree No. 206 of 12 Apr 2001 | Legislative Decree No. 206 of 12 Apr 2001 |
| 6 | Control of importation | Law No. 185 of 9 Jul 1990: armaments | |
| 7 | Control of exports | 1. Council Regulation (EC) No. 1334/2000 as amended 2. Law No. 185 of 09 Jul 1990 3. Legislative Decree No. 96 of 09 Apr 2003 | 1. Legislative Decree No. 96 of 09 Apr 2003, Art. 16/1, 16/2, 16/4, 16/6 and 16/7 2. Law No. 438 of 15 December 2001 |

Biosafety and Biosecurity

Latvia

06 June 2008

| Legislation and/or measures in place for safe handling, securing or otherwise protecting dual-use biological materials. Can violators be penalized? | | National legal framework | Enforcement: civil/criminal penalties and others |
|---|--|--|---|
| | | Indicate source document | Indicate source document |
| 1 | Measures for safe/secure production, use and/or storage | Directive 2000/54/EC | Criminal Law of 01 Apr 1999, Art. 98 and 233 |
| 2 | Measures for safe/secure transport | 1. Council Directive 94/55/EC 2. Council Directive 96/49/EC | 1. Directive 95/50/EC 2. Party to ADR and RID 3. Criminal Law of 01 Apr 1999, Art. 98 and 233 |
| 3 | Licensing/registration of facilities/persons handling biological materials | Directive 2000/54/EC | Criminal Law of 01 Apr 1999, Art. 207 and 208 |
| 4 | Reliability/security check of personnel | | |
| 5 | Regulations for genetic engineering work | Council Directive 90/219/EEC as amended by Council Directive 98/81/EC | |
| 6 | Control of importation | Law on Circulation or Movement of Goods of Strategic Importance of 01 May 2004 | Code of Administrative Violations, Art. 181, 183 and 201 |
| 7 | Control of exports | 1. Council Regulation (EC) No. 1334/2000 as amended 2. Law on Circulation or Movement of Goods of Strategic Importance of 01 May 2004 3. Cabinet of Ministers Regulations on Control of Strategic Goods and Licenses, of 29 April 2004 | Code of Administrative Violations, Art. 181, 183 and 201 |

Biosafety and Biosecurity

Lithuania
06 June 2008

| Legislation and/or measures in place for safe handling, securing or otherwise protecting dual-use biological materials. Can violators be penalized? | | National legal framework | Enforcement: civil/criminal penalties and others |
|---|--|---|---|
| | | Indicate source document | Indicate source document |
| 1 | Measures for safe/secure production, use and/or storage | 1. Directive 2000/54/EC 2. Law on Environmental Protection of 1992, Art. 22.1 | |
| 2 | Measures for safe/secure transport | 1. Council Directive 94/55/EC 2. Council Directive 96/49/EC 3. Law on Environmental Protection of 1992, Art. 22.1 | 1. Directive 95/50/EC 2. Party to ADR and RID |
| 3 | Licensing/registration of facilities/persons handling biological materials | Directive 2000/54/EC | Code of Administrative Offences (CAO), Art. 189(9) |
| 4 | Reliability/security check of personnel | | |
| 5 | Regulations for genetic engineering work | Council Directive 90/219/EEC as amended by Council Directive 98/81/EC | |
| 6 | Control of importation | Government Resolution No. 932 on the Approval of Regulations for Licensing Export, Import, Transit and Brokerage of Strategic Goods and on Regulations Enforcing the Control of Strategic Goods of 22 Jul 2000 | Code of Administrative Offences (CAO), Art. 189(9) |
| 7 | Control of exports | 1. Law Amending the Law on the Export, Import and Transit Control of Strategic Goods of 29 Apr 2004 2. Government Resolution No. 932 on the Approval of Regulations for Licensing Export, Import, Transit and Brokerage of Strategic Goods and on Regulations Enforcing the Control of Strategic Goods of 22 Jul 2000 3. Law on Economic and Other International Sanctions of 2004 4. Council Regulation (EC) No. 1334/2000 as amended | 1. Criminal Code, Art. 199 and 253(1) 2. Code of Administrative Offences (CAO), Art. 42(2), 51(5) and 189(9) |

Biosafety and Biosecurity

Luxembourg

06 June 2008

| Legislation and/or measures in place for safe handling, securing or otherwise protecting dual-use biological materials. Can violators be penalized? | | National legal framework | Enforcement: civil/criminal penalties and others |
|---|--|---|--|
| | | Indicate source document | Indicate source document |
| 1 | Measures for safe/secure production, use and/or storage | Directive 2000/54/EC | |
| 2 | Measures for safe/secure transport | 1. Council Directive 94/55/EC 2. Council Directive 96/49/EC | 1. Directive 95/50/EC 2. Party to ADR and RID |
| 3 | Licensing/registration of facilities/persons handling biological materials | Directive 2000/54/EC | |
| 4 | Reliability/security check of personnel | | |
| 5 | Regulations for genetic engineering work | Council Directive 90/219/EEC as amended by Council Directive 98/81/EC | |
| 6 | Control of importation | 1. Act of 05 Aug 1963 as amended 2. Grand Ducal Regulation of 31 Oct 1995 | General Act on Customs and Excise, Art. 231, 249-253 and 263-284 |
| 7 | Control of exports | 1. Council Regulation (EC) No. 1334/2000 as amended 2. Act of 05 Aug 1963 as amended 3. Grand Ducal Regulation of 31 Oct 1995 4. Grand Ducal Regulation of 05 Oct 2000 | General Act on Customs and Excise, Art. 231, 249-253 and 263-284 |

Biosafety and Biosecurity

Malta
06 June 2008

| Legislation and/or measures in place for safe handling, securing or otherwise protecting dual-use biological materials. Can violators be penalized? | | National legal framework | Enforcement: civil/criminal penalties and others |
|---|--|--|--|
| | | Indicate source document | Indicate source document |
| 1 | Measures for safe/secure production, use and/or storage | Directive 2000/54/EC | |
| 2 | Measures for safe/secure transport | 1. Council Directive 94/55/EC 2. Council Directive 96/49/EC | 1. Directive 95/50/EC 2. Party to ADR and RID |
| 3 | Licensing/registration of facilities/persons handling biological materials | Directive 2000/54/EC | |
| 4 | Reliability/security check of personnel | | |
| 5 | Regulations for genetic engineering work | Council Directive 90/219/EEC as amended by Council Directive 98/81/EC | |
| 6 | Control of importation | Importation Control Regulations – Legal Notice 242 of 2004 as amended by L.N. 341 of 2004 | |
| 7 | Control of exports | 1. Dual-Use Items (Export Control) Regulations, 2004 - Legal Notice 416 of 2004 2. Military Equipment (Export Control) Regulations, 2001 - Legal Notice 269 of 2001 and Government Notice No. 103 of 2004 | Penalty for not providing correct information |

Biosafety and Biosecurity

Netherlands

06 June 2008

| Legislation and/or measures in place for safe handling, securing or otherwise protecting dual-use biological materials. Can violators be penalized? | | National legal framework | Enforcement: civil/criminal penalties and others |
|---|--|---|--|
| | | Indicate source document | Indicate source document |
| 1 | Measures for safe/secure production, use and/or storage | Directive 2000/54/EC | |
| 2 | Measures for safe/secure transport | 1. Council Directive 94/55/EC 2. Council Directive 96/49/EC | 1. Directive 95/50/EC 2. Party to ADR and RID 3. Security plan for transport |
| 3 | Licensing/registration of facilities/persons handling biological materials | Directive 2000/54/EC | |
| 4 | Reliability/security check of personnel | | |
| 5 | Regulations for genetic engineering work | Council Directive 90/219/EEC as amended by Council Directive 98/81/EC | |
| 6 | Control of importation | | |
| 7 | Control of exports | 1. Strategic Goods (Import and Export) Decree: import, export, transit controls of military materials, military technology, and dual-use items 2. Council Regulation (EC) No. 1334/2000 as amended | 1. Strategic Goods (Import and Export) Decree: right to carry out controls, to investigate and prosecute criminal offences and impose penalties 2. Economic Offences Act: degree of penalty |

Biosafety and Biosecurity

Poland
06 June 2008

| Legislation and/or measures in place for safe handling, securing or otherwise protecting dual-use biological materials. Can violators be penalized? | | National legal framework | Enforcement: civil/criminal penalties and others |
|---|--|--|--|
| | | Indicate source document | Indicate source document |
| 1 | Measures for safe/secure production, use and/or storage | Directive 2000/54/EC | |
| 2 | Measures for safe/secure transport | 1. Council Directive 94/55/EC 2. Council Directive 96/49/EC | 1. Directive 95/50/EC 2. Party to ADR and RID |
| 3 | Licensing/registration of facilities/persons handling biological materials | 1. Directive 2000/54/EC 2. Law on Infectious Diseases of 06 Sep 2001 3. Ordinance of the Minister of Health of 03 Jul 2002 concerning characteristics cards for hazardous substances and preparations 4. Ordinance of the Minister of the Environment of 29 Nov 2002 concerning the list of pathogenic organisms and their classification, and also the measures required for the respective degrees of containment 5. Ordinance of the Minister of Health of 11 Jul 2002 on the marking of packaging of hazardous substances and preparations 6. Gene Law of 22 Jun 2001 7. Ordinance of the Minister of the Environment of 06 Jun 2002 concerning applications for permits to conduct activity involving GMOs 8. Law of 11 May 2001 on the health requirements for food and feed 9. Ordinance of the Minister of the Environment of 02 Jun 2003 on the criteria to be met by organizational units conducting tests on chemical substances and on control of the fulfilment of those criteria | |
| 4 | Reliability/security check of personnel | | |
| 5 | Regulations for genetic engineering work | 1. Gene Law of 22 Jun 2001 2. Ordinance of the Minister of the Environment of 06 | |

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|---|------------------------|---|--|
| | | Jun 2002 | |
| 6 | Control of importation | 1. Law of 29 Nov 2000 on Foreign Trade as amended 2. Ordinance of the Minister of Economy of 02 Oct 2002 on the list of military goods | Under polish law: fines up to 2000.000 PLN and imprisonment up to 10 years |
| 7 | Control of exports | 1. Law of 29 Nov 2000 on Foreign Trade as amended 2. Law of 21 May 1999 on arms and munitions 3. Ordinance of the Minister of Economy of 02 Oct 2002 4. Ordinance of the Minister of the Environment of 06 Jun 2002 (GMO) 5. Council Regulation (EC) No. 1334/2000 as amended | 1. Law of 29 Nov 2000 on Foreign Trade as amended 2. Law of 21 May 1999 |

Biosafety and Biosecurity

Portugal
06 June 2008

| Legislation and/or measures in place for safe handling, securing or otherwise protecting dual-use biological materials. Can violators be penalized? | | National legal framework | Enforcement: civil/criminal penalties and others |
|---|--|--|---|
| | | Indicate source document | Indicate source document |
| 1 | Measures for safe/secure production, use and/or storage | Directive 2000/54/EC | |
| 2 | Measures for safe/secure transport | 1. Council Directive 94/55/EC 2. Council Directive 96/49/EC | 1. Directive 95/50/EC 2. Party to ADR and RID |
| 3 | Licensing/registration of facilities/persons handling biological materials | Directive 2000/54/EC | |
| 4 | Reliability/security check of personnel | | |
| 5 | Regulations for genetic engineering work | Council Directive 90/219/EEC as amended by Council Directive 98/81/EC | |
| 6 | Control of importation | 1. Decree Law 371/80, 11 Sep 1980 2. Decree 436/91, 8 Nov 1991 3. Decree 439/94, 29 Jun 1994 | 1. Penal Code, Art. 275 2. Decree Law 371/80, 11 Sep 1980 3. Decree 436/91, 8 Nov 1991 4. Decree 439/94, 29 Jun 1994 |
| 7 | Control of exports | 1. Council Regulation (EC) No. 1334/2000 as amended 2. Decree Law 436/91 of 08 Nov 1991 3. Decree Law 371/80, 11 Sep 1980 4. Decree Law 1/86, 2 Jan 1986 5. Decree 439/94, 29 Jun 1994 | 1. Decree Law 436/91 of 08 Nov 1991 2. Decree Law 371/80, 11 Sep 1980 3. Decree Law 1/86, 2 Jan 1986 4. Decree 439/94, 29 Jun 1994 |

Biosafety and Biosecurity

Romania

06 June 2008

| Legislation and/or measures in place for safe handling, securing or otherwise protecting dual-use biological materials. Can violators be penalized? | | National legal framework | Enforcement: civil/criminal penalties and others |
|---|--|---|---|
| | | Indicate source document | Indicate source document |
| 1 | Measures for safe/secure production, use and/or storage | Directive 2000/54/EC | |
| 2 | Measures for safe/secure transport | 1. Council Directive 94/55/EC 2. Council Directive 96/49/EC | Directive 95/50/EC |
| 3 | Licensing/registration of facilities/persons handling biological materials | Directive 2000/54/EC | |
| 4 | Reliability/security check of personnel | | |
| 5 | Regulations for genetic engineering work | Governmental Ordinance 49/2000 on Genetic Engineering | |
| 6 | Control of importation | 1. Government Ordinance No.158/2000, approved by Law No. 585/2004 2. Law No. 387/2003 | 1. Delivery verification certification 2. Government Ordinance No.158/2000, approved by Law No. 585/2004 3. Law No. 387/2003 |
| 7 | Control of exports | 1. Government Decision No. 594/1992 2. Government Ordinance No. 31/1994 3. Law No. 93/1994 4. Government Ordinance No. 158/1999 5. Law No. 387/2003 6. Government Ordinance No. 158/1999, approved by Law No. 595/2004 | 1. Penal Code, Art. 302 2. Law No. 387/2003 3. Government Ordinance No. 158/1999, approved by Law No. 595/2004 4. Law No. 301/2004 (Penal Code) 5. Law No. 56/1997, modified and republished in 2004 6. Government Resolution 920/2005 concerning function of ANCEX 7. Law No. 595/2004 concerning the military products export and import schedule |

Biosafety and Biosecurity

Slovakia
06 June 2008

| Legislation and/or measures in place for safe handling, securing or otherwise protecting dual-use biological materials. Can violators be penalized? | | National legal framework | Enforcement: civil/criminal penalties and others |
|--|--|--|--|
| | | Indicate source document | Indicate source document |
| 1 | Measures for safe/secure production, use and/or storage | Directive 2000/54/EC | Penal Code – Law No. 300/2005, Art. 298 |
| 2 | Measures for safe/secure transport | 1. Council Directive 94/55/EC 2. Council Directive 96/49/EC | 1. Directive 95/50/EC 2. Party to ADR and RID 3. Penal Code – Law No. 300/2005, Art. 298 |
| 3 | Licensing/registration of facilities/persons handling biological materials | Directive 2000/54/EC | Penal Code – Law No. 300/2005, Art. 298 |
| 4 | Reliability/security check of personnel | | |
| 5 | Regulations for genetic engineering work | Council Directive 90/219/EEC as amended by Council Directive 98/81/EC | Penal Code - Law No. 300/2005, Art. 309 |
| 6 | Control of importation | Act 26/2002 | Act 26/2002 |
| 7 | Control of exports | 1. Act 26/2002 2. Act 179/1998 3. Council Regulation (EC) No. 1334/2000 as amended | 1. Act 26/2002 2. Act 179/1998 |

Biosafety and Biosecurity

Slovenia

06 June 2008

| Legislation and/or measures in place for safe handling, securing or otherwise protecting dual-use biological materials. Can violators be penalized? | | National legal framework | Enforcement: civil/criminal penalties and others |
|---|--|---|--|
| | | Indicate source document | Indicate source document |
| 1 | Measures for safe/secure production, use and/or storage | Directive 2000/54/EC | Penal Code – Law No. 300/2005, Art. 298 |
| 2 | Measures for safe/secure transport | 1. Council Directive 94/55/EC 2. Council Directive 96/49/EC 3. Transport of Dangerous Substances Act of 1999, Art. 22 and 39 | 1. Directive 95/50/EC 2. Party to ADR and RID |
| 3 | Licensing/registration of facilities/persons handling biological materials | Directive 2000/54/EC | |
| 4 | Reliability/security check of personnel | | |
| 5 | Regulations for genetic engineering work | Council Directive 90/219/EEC as amended by Council Directive 98/81/EC | |
| 6 | Control of importation | | Penal Code, Art. 310 and 335 |
| 7 | Control of exports | 1. Export of Dual-Use Goods Act of 2000 2. Commission Regulation (EC) No. 1334/2000 as amended 3. Customs Service Act of 1999e 4. Defense Act of 1994 as amended | 1. Export of Dual-Use Goods Act of 2001 as amended 2. European Customs Rules Implementation Act of 2004 |

Spain

06 June 2008

Biosafety and Biosecurity

| Legislation and/or measures in place for safe handling, securing or otherwise protecting dual-use biological materials. Can violators be penalized? | | National legal framework | Enforcement: civil/criminal penalties and others |
|---|--|---|---|
| | | Indicate source document | Indicate source document |
| 1 | Measures for safe/secure production, use and/or storage | 1. Law 15/1994 on Biosecurity 2. Royal Decree 951/1997 which approves the General Regulations for the implementation of the Law 15/1994 3. Law 31/1995 on the prevention of professional risks 4. Royal Decree 664/1997 on the protection of workers against the risks of biologic agents during work 5. Directive 2000/54/EC | Law 15/1994 on Biosecurity, Chapter VI: offences and sanctions |
| 2 | Measures for safe/secure transport | 1. Council Directive 94/55/EC 2. Council Directive 96/49/EC 3. Royal Decree 2115/1998 4. Royal Decree 1566/1999 | 1. Directive 95/50/EC 2. Party to ADR and RID |
| 3 | Licensing/registration of facilities/persons handling biological materials | 1. Law 15/1994 on Biosecurity 2. Royal Decree 951/1997 3. Law 31/1995 4. Royal Decree 664/1997 5. Directive 2000/54/EC | Law 15/1994 on Biosecurity, Chapter VI: offences and sanctions |
| 4 | Reliability/security check of personnel | | |
| 5 | Regulations for genetic engineering work | Law 15/1994 on Biosecurity | Law 15/1994 on Biosecurity |
| 6 | Control of importation | 1. Royal Decree 1782/2004 2. Order of the Ministry of Industry, Trade and Tourism 60/2006 | Royal Decree 1782/2004 |
| 7 | Control of exports | 1. Council Regulation (EC) No. 1334/2000 as amended 2. Royal Decree 1782/2004 of 30 Jul 2004 | 1. Criminal Code 2. Organic Law 12/1995 of 12 December 1995 3. Royal Decree 1782/2004 |

Biosafety and Biosecurity

Sweden

30 June 2008

| Legislation and/or measures in place for safe handling, securing or otherwise protecting dual-use biological materials. Can violators be penalized? | | National legal framework | Enforcement: civil/criminal penalties and others |
|---|--|---|---|
| | | Indicate source document | Indicate source document |
| 1 | Measures for safe/secure production, use and/or storage | 1. Directive 2000/54/EC 2. Regulations for the Protection of Workers from Risks related to Exposures to Biological Agents – AFS 2005:1 | |
| 2 | Measures for safe/secure transport | 1. Council Directive 94/55/EC 2. Council Directive 96/49/EC | 1. Directive 95/50/EC 2. Act on Transport of Dangerous Goods – SFS 2006:263 3. Party to ADR and RID |
| 3 | Licensing/registration of facilities/persons handling biological materials | 1. Directive 2000/54/EC 2. Notification or permission by the Work Environment Authority (SWEA) | SWEA controls handling of work with biological agents |
| 4 | Reliability/security check of personnel | | |
| 5 | Regulations for genetic engineering work | 1. Contained use of GMO must be notified to/permitted by SWEA - SFS 2000:271 2. Contained use of GMOs - AFS 2000:5 | |
| 6 | Control of importation | | |
| 7 | Control of exports | 1. Council Regulation (EC) No. 1334/2000 as amended 2. Act on the Control of Dual-use Items and Technical Assistance - SFS 2000:1064 and respective Ordinance - SFS 2000:1217 3. Supplementary provisions issued by the Swedish Customs - TFS 2000:29 | 1. Act on Penalties for Smuggling - SFS 2000:1225 2. Act on the Control of Dual-use Items and Technical Assistance - SFS 2000:1064 |

Biosafety and Biosecurity

United Kingdom

20 June 2008

| Legislation and/or measures in place for safe handling, securing or otherwise protecting dual-use biological materials. Can violators be penalized? | | National legal framework | Enforcement: civil/criminal penalties and others |
|---|--|---|--|
| | | Indicate source document | Indicate source document |
| 1 | Measures for safe/secure production, use and/or storage | 1. Directive 2000/54/EC 2. Anti-terrorism, Crime and Security Act (2001), Section 59: notify Home Office of holding/use of any Schedule 5 biological agent or toxin 3. Statutory Instrument 2007, No. 926, The part 7 of the Anti-terrorism, Crime and Security Act 2001 (Extension to Animal Pathogens) Order 2007 4. Statutory Instrument 2007, No. 929, The Schedule 5 of the Anti-terrorism, Crime and Security Act 2001 (Amendment) Order 2007 | Anti-terrorism, Crime and Security Act (2001): notify police of holding of specified disease-causing micro-organisms and toxins and to comply with security requirements imposed by authorities |
| 2 | Measures for safe/secure transport | 1. Regulation 24 of the Carriage of Dangerous Goods by Road Regulations (1996) as amended 2. Code of Practice for the Security of Dangerous Goods by Road 3. Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2004 | 1. Carriage of Dangerous Goods and Use of Transportable Pressure Equipment Regulations 2004 2. Party to ADR and RID |
| 3 | Licensing/registration of facilities/persons handling biological materials | 1 Directive 2000/54/EC 2. Control of Substances Hazardous to Health (COSHH) Regulations 3. Genetically Modified Organisms (Contained Use) Regulations (2000) and Statutory Instruments 2005 No. 2466 The Genetically Modified Organisms (Contained Use) (Amendment) Regulations 2005 4. Specified Animal Pathogens Order (1998) and (2008) SAPO 5. Plant Health (Great Britain) Order (1993)* | The Specified Animal Pathogens Order (SAPO) 2008 provides a legal basis for the formal transfer of the inspection and enforcement role for this legislation from the Department for Environment, Food and Rural Affairs, the Veterinary Laboratories Agency and local authorities to the Health and Safety Executive (HSE). The legislation came into effect on 28 April 2008. |
| 4 | Reliability/security check of personnel | Anti-terrorism, Crime and Security Act (2001): furnish police on request with details of persons with access to specified dangerous substances | Home Secretary to direct that named individuals must not be allowed access |

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|---|--|--|--|
| 5 | Regulations for genetic engineering work | 1. Genetically Modified Organisms (Contained Use) Regulations (2000) 2. Statutory Instruments 2005 No. 2466 The Genetically Modified Organisms (Contained Use) (Amendment) Regulations 2005 | 1. Genetically Modified Organisms (Contained Use) Regulations (2000) 2. Genetically Modified Organisms (Contained Use) (Amendment) Regulations 2002 |
| 6 | Control of importation | 1. Importation of Animal Pathogens Order IAPO (1980) 2. Plant Health (Great Britain) Order (1993) | Customs and Excise Management Act 1979 |
| 7 | Control of exports | 1. Export of Goods, Transfer of Technology and Provision of Technical Assistance (Control) Order (2003) 2. Trade in Goods (Control) Order (2003) | 1. Export of Goods, Transfer of Technology and Provision of Technical Assistance (Control) Order (2003) 2. Trade in Goods (Control) Order (2003) |

* Note that the devolved administrations for Scotland, Northern Ireland and Wales issue amendments to SAPO and the Plant Health Order from time to time as required.