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1 Background and Objectives

The aim of this task is to prevent Microbial Biological Resource Collections (BRC's) from directly or indirectly contributing to the development, production or preservation of biological weapons, as described in the Biological and Toxin Weapons Convention (BTWC), or to any other misuse of biological material or derivatives.

The first step towards this aim is an overview of the existing important literature and documentation. The items of concern are:

1. Risk assessment. This involves several categories requiring different procedures:
 - a. humans
 - b. livestock
 - c. crops
 - d. environment (invasive potential)
 - e. toxins
2. Accessibility. This concerns limitations and barriers for the acquisition c.q. distribution of both material and information
3. Accountability
4. Information and communication
5. Shipment and transport

2 References and websites containing important information on biosecurity

2.1 Relevant literature

- ADR Accord européen relative au transport international des marchandises dangereuses par route. UN Economic Commission for Europe (UNECE), English version, 2009
- Anisimov, A.P. et al., 2004, Intraspecific diversity of *Yersinia pestis*, *Clinical Microbiology Reviews*, 17(2), 434
- Anon (1994). Approved Code of Practice for Biological Agents 1994. Health and Safety Executive. Sudbury: HSE Books.
- Atlas, R. M. and J. Reppy, Globalizing biosecurity, 'Biosecurity and bioterrorism: Biodefense strategy, practice, and science', Vol. 3, No. 3, (2005), pp 51-60.
- Barbeito, M.S. and Kruse, R.H., A History of the American Biological Safety Association
- Barletta, M., Biosecurity measures for preventing bioterrorism, Monterey Institute of International Studies, Center for Nonproliferation Studies, 27 November, 2002.
- Belton, V. and Stewart, T.J., 2002, Multiple Criteria Decision Analysis: An Integrated Approach, Norwell, MA; Kluwer Academic.
- Biological and Toxin Weapons Convention <http://www.opbw.org/convention/>
- Biotechnologie Overzicht van de Wetgeving in Vlaanderen: Vlarem II Hoofdstuk 5.51.
- Byers, K.B. and Harding, A.L., 2000, Epidemiology of laboratory-associated infections, in *Biological Safety: Principles and Practices*, Fleming, D.O. and Hunt, D.L., Eds., Washington, D.C.: ASM Press, pp. 35-54.

- Byers, K.B. and Harding, A.L., 2000, Epidemiology of laboratory-associated infections, in Biological Safety: Principles and Practices, Fleming, D.O. and Hunt, D.L., Eds., Washington, D.C.: ASM Press, pp. 35-54.
- Cartagena Protocol on Biosafety <http://www.cbd.int/biosafety/protocol.shtml>
- Casadevall, A. and Relman, D.A., 2010, Microbial threat lists: obstacles in the quest for biosecurity? Nature Reviews/Microbiology Vol. 8, 149-154.
- Centers for Disease Control and Prevention . US Department of Health and Human Services. Select Agent Program, final rules. Atlanta, Centers for Disease Control and Prevention, 2005
- Central Intelligence Agency Office of Transnational Issues, 2003, The Darker Bioweapons Future, Washington, D.C.: CIA.
- Communication from the Commission to the Council and the European Parliament, 2003, On Cooperation in the European Union on Preparedness and Response to Biological and Chemical Agent Attacks (Health Security), Brussels, COM(2003) 320 final, http://europa.eu.int/comm/health/ph_threats/Bioterrorisme/com2003_320_en.pdf.
- Council of the European Union, Life sciences and biotechnology – A strategy for Europe, Communication from the Commission to the Council, the European Parliament, the Economic and Social Committee and the Committee of the Regions, COM(2002) 27, 27 January, 2003.
- Council of the European Union, Proliferation of Weapons of Mass Destruction – report on the follow up to the Thessalonica European Council and on the state of execution of the Action Plan for the implementation of the Basic Principles for an EU Strategy against Proliferation of Weapons of Mass Destruction, Brussels, 12 September 2003.
- Council of the European Union, EU strategy against proliferation of weapons of mass destruction, Doc. 15708/03, Brussels, 10 December 2003, at URL <http://ue.eu.int/uedocs/cmsUpload/78367.pdf>
- Council of the European Union, Council Common Position 2006/242/CFSP of 20 March 2006 relating to the 2006 Review Conference of the Biological and Toxin Weapons Convention (BTWC), Official Journal of the European Union, No. L 88/65, 25 March, 2006.
- Council of the European Union, “Council Joint Action in support of the Biological and Toxin Weapons Convention, in the framework of the EU Strategy against the Proliferation of Weapons of Mass Destruction”, Document no. 5821/06, Brussels, February 22, 2006.
- Council of the European Union, Council Joint Action in support of the implementation of United Nations Security Council Resolution 1540 (2004) and in the framework of the implementation of the EU Strategy against the Proliferation of Weapons of Mass Destruction, Brussels, No. 9515/06, 6 June, 2006.
- CSIS, Assessing the G8 Global Partnership: From Kananaskis to St. Petersburg, Strengthening the Global Partnership Project, Center for Strategic and International Studies, Washington, July, 2006,
- CWA 15793:2008, CEN Workshop Agreement on Laboratory Biosafety and Biosecurity <http://www.cen.eu/cenorm/sectors/technicalcommitteesworkshops/workshops/ws31.asp>
- Draft Model Convention on the Prohibition and Prevention of Biological Terrorism, Terrorism and Political Violence, London, Vol 14, No 4, PP 163-208.
- EC Council Directive 2000/29/EEC on protective measures against the introduction into the Member States of harmful organisms of plant or plant products. OJ No. L. 169, p.1 of 10.07.2000
- EC Council Regulation 1504/2004 amending and updating Regulation 1334/2000 title!
- EC Council Directive 95/44/EC on establishing the conditions under which certain harmful organisms, plants, plant products and other objects listed in Annexes I to V to Council Directive 77/93/EEC may be introduced into or moved within the Community or certain protected zones thereof, for trial or scientific purposes and for work on varietal selections
- EC Council Directives 90/219/EEC and 98/81/EC on contained use of genetically modified organisms
- EC regulation 1946/2003 on the transboundary movement of genetically modified organisms (pertains to Cartagena Protocol on Biosafety)
- EC Council Directive 2000/54/EEC On the protection of workers from risks related to exposure to biological agents at work. OJ No. L. 262, pp.21-45 of 18.09.2000
- EC Council Regulation No 1334/2000 of 22 June 2000 setting up a Community regime for the control of exports of dual-use items and technology. OJ No L 159 of 30.6.2000 (Amended by:

- EC Council Regulation 149/2003 of 27 January 2003, OJ L 30 of 05.02.2003, corrigendum OJ L 52 of 27.02.2003).
- ECCO, 2009, Material Transfer Agreement ??????Details
- ECD International futures programme (IFP), 'Promoting Responsible Stewardship in the Biosciences: Avoiding Potential Abuse of Research and Resources', Chair's Summary, Frascati, Italy, 17-19 September, 2004
- EN 1619:1996 Biotechnology — large-scale process and production — General requirements for management and organisation for strain conservation procedures.
- EN 12128:1998, Biotechnology - Laboratories for research, development and analysis - Containment levels of microbiology laboratories, areas of risk, localities and physical safety requirements
- EN ISO 9001:2000, Quality management systems - Requirements (ISO 9001:2000)
- EN ISO 19011, Guidelines for quality and/or environmental management systems auditing (ISO 19011:2002)
- EN ISO 14001:2004, Environmental management systems - Requirements with guidance for use (ISO 14001:2004) EN ISO 9000:2005, Quality management systems - Fundamentals and vocabulary (ISO 9000:2005)
- EU Directive 98/81/EC of 26 October 1998 amending Directive 90/219/EEC on the contained use of genetically modified micro-organisms FAO. *Biosecurity in food and agriculture*. Committee on Agriculture. Seventeenth session, Rome, 31 March-4 April 2003. Rome, FAO, 2003
- EU Regulation (EC) No 851/2004 of the European Parliament and of the Council of 21 April 2004 establishing a European Centre for Disease Prevention and Control.
- EU Paper on biosafety and biosecurity, BTWC 6th Review Conference 2006, Germany, 19th September 2006.
- EU Paper on Assessment of National Implementation of the BTWC, BTWC 6th Review Conference 2006, Germany, 19th September, 2006.
- EU Paper on BTWC Implementation: need for concerted and coordinated approach, BTWC 6th Review Conference 2006, The Netherlands, 19th September, 2006.
- EU Paper on the enhancement of the CBM process, BTWC 6th Review Conference 2006, France, 19th September, 2006.
- EU Paper on The Intersessional Programme of Work: Its utility and contribution to fulfilling the object and purpose of the BTWC between 2003-2005 and a case for further intersessional work after 2006, BTWC 6th Review Conference 2006, United Kingdom and France, 19th September, 2006.
- European Council conclusions on strengthening chemical, biological, radiological and nuclear (CBRN) security in the European Union, an EU CBRN Action Plan, 15505/1/09 REV 1, Brussels, November 2009
- European Security Strategy, A secure Europe in a better world, Brussels, 12 December 2003, at URL http://ue.eu.int/ueDocs/cms_Data/docs/pressData/en/reports/78367.pdf
- FAO/WHO. Biosecurity risk analysis: an overview and framework manual. Chapter 4. Rome/Geneva, 2005, FAO/WHO (draft, May 2005).
- Fauci, A.S., Morens, D.M., and Folkers, G.K., 2004, The challenge of emerging and re-emerging infectious diseases, *Nature*, 430, 242-249.
- Fauci, A.S., 2006, Robert H. Ebert Memorial Lecture: Emerging and Re-Emerging Infectious Diseases; The Perpetual Challenge, New York: Milbank Memorial Fund.
- Feakes D. and G. Pearson, Achieving the outcomes of the Sixth Review Conference, pp 37-45, Disarmament Forum, No. 3, 2006.
- Freeman, J., Ambassador, "Statement on behalf of the European Union, United Nations General Assembly 60th Session First Committee", New York, October 12, 2005.
- Garcia, M.L., 2001, *The Design and Evaluation of Physical Protection Systems*, Butterworth-Heinemann, Boston, MA; Gregg, M. and Kim, D., 2005, *Inside Network Security Assessment: Guarding Your IT Infrastructure*, Sams Publishing, Indianapolis, IN.
- Gaudioso, J., Salerno, R.M., and Barnett, N., 2006, Developing a risk assessment and risk management approach to laboratory biosecurity, *Applied Biosafety*, 24-31.
- German Working Paper, Core elements of national measures to implement the prohibitions contained in the BTWC, BWC/MSP.2003/WP.2, 11 November, 2003.
- Graham S. Pearson, National Measures to Establish and Maintain the Security and Oversight of

Pathogenic Microorganisms and Toxins, University of Bradford, Department of Peace Studies, Briefing Paper No.4 (Second Series), April 2003.

G8, Statement by G8 leaders, Kananaskis Summit,,2002,

G7/G8 Summit Meeting, St. Petersburg Summit Document, Fight against infectious disease, July 16, 2006,

Health Canada. *Laboratory biosafety guidelines*. Third edition. Ottawa, Health Canada, 2004.

Hersh, M., A view to the BWC 2006 Review Conference: A focus on risk, Draft, Presented at Meeting the challenges of bioterrorism: Assessing the threat and designing biodefence strategies, The International Bioterrorism Conference in Furingen (Nidwalden), Switzerland, 22-23 April, 2005.

IATA - International Air Transport Association (2010) Dangerous Goods Regulations 51st edition Montreal; Geneva: IATA.

International Committee of the Red Cross, 2002, *Biotechnology, Weapons and Humanity: Appeal of the International Committee of the Red Cross*, Geneva: ICRC.

Interpol, 2005, Preventing Bioterrorism; The 1st Interpol Global Conference to Strengthen Law Enforcement Preparedness and Develop Effective Police Training,

Informal advance report of the meeting of experts - Sixth Review Conference of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction (BWC/CONF.VI/6),

Institute of Medicine and National Research Council. *Globalization, biosecurity, and the future of the life sciences*. Washington DC, The National Academies Press, 2006

International Committee of the Red Cross, 'Principles and practice', in Preventing Hostile Use of the Life Sciences: From ethics and law to best practice, 11 November, 2004.

ISO/IEC Guide 51:1999, Safety aspects - Guidelines for their inclusion in standards

ISO 7218:2000, Microbiology of food and animal feeding stuffs. General rules for microbiological examinations.

ISO/IEC Guide 73:2002, Risk management - Vocabulary - Guidelines for use in standards

ISO 15190:2003, Medical laboratories - Requirements for safety

ISO/IEC 17025:2005, General requirements for the competence of testing and calibration laboratories

ISO 17025:2005, General requirements for the competence of testing and calibration laboratories.

Kaplan, S. and Garrick, B.J., 1981, On the quantitative definition of risk, *Risk Analysis*, 1(1).

Kellman, B., Criminalization and control of WMD proliferation, the Security Council acts & template of national measures to prevent bio-crimes, Presented at Workshop on Security Council Resolution 1540 and biological weapons, Geneva, 3 December, 2004.

Kirsop, B.E. & Doyle, A. (eds) (1991). *Maintenance of Microorganisms and Cultured Cells: A Manual of Laboratory Methods*, London: Academic Press.

Kwik, G. et al., 2003, Pathogen security: responsible stewardship in an age of catastrophic terrorism, *Biosecurity and Bioterrorism*, 1(1);

Lelieveld, H.L.M. et al., *Safe Biotechnology*. 8. Transport of infectious and biological materials.

Lengel, A., 2005, Little progress in FBI probe of anthrax attacks, *Washington Post*, September 16, p. A01.

Lennane, R., Biological Weapons Convention expert Meeting, June 13-24, 2005, *Biological Weapons Convention Expert meeting concludes*, UN Press Release, DC/2973, June, 24, 2005, Disarmament Diplomacy, The Acronym Institute,

Linkov, I., Satterstrom, K., Kiker, G., Bridges, T., Ferguson, E., and Nelson, J., Multi-criteria decision analysis and homeland security applications, *Proceedings of the 2005 Conference, Working Together: Research and Development (R&D) Partnerships in Homeland Security*, Boston, MA, April 27-28, 2005.

Littlewood, J., *Substance Hidden Under A Mountain of Paper: The BWC Experts' Meeting in 2003*, Disarmament Diplomacy, No. 73, October – November, 2003.

Ministerie van Sociale Zaken en Volksgezondheid. Beroepsmatige blootstelling aan infectieuze (micro)organismen en de daarmee samenhangende risico's voor de gezondheid.

Moodie, M., 2003, Chemical and Biological Arms Control Institute, Special Report 5, *Reducing the Biological Threat: New Thinking, New Approaches*, Washington, D.C.

National Academy of Sciences, 2003, *Biotechnology Research in an Age of Terrorism: Confronting the Dual Use Dilemma*, Washington, D.C.: National Academy Press.

- National Academy of Sciences, 2006, Globalization, Biosecurity, and the Future of the Life Sciences, Washington, D.C.: National Academy Press.
- National Institutes of Health/Centers for Disease Control and Prevention. *Biosafety in microbiological and biomedical laboratories*. Fourth edition. Atlanta, CDC, 1999.
- National Intelligence Council, 2004, Mapping the Global Future, Pittsburgh, PA: NIC.
- Nederlands Normalisatie-instituut. Europese normen voor veiligheid in de biotechnologie.
- Nixdorff, K. and Bender, W., March 2002, Biotechnology, Ethics of Research, and Potential Military Spin-off. INESAP Bulletin, 19,
- OECD (2001). Biological Resource Centres. Underpinning the future of life sciences and biotechnology.
- OECD (2006). Creation and Governance of Human Genetic Research Databases.
- OECD (2007). OECD Best Practice Guidelines for Biological Resource Centres.
- OECD (2007). OECD Best Practice Guidelines on Biosecurity for Biological Resource Centres
- Office of Biotechnology Activities, National Institutes of Health, National Science Advisory Board for Biosecurity, 2005, Plant Protection Service, 2002, Summary of the Plant Health Regulations of the Netherlands, 107 pp.
- OHSAS 18001:2007, Occupational health and safety management systems - Requirements
- Pearson, G., Maximizing the security and improving oversight of pathogenic microorganisms and toxins, Briefing Paper No. 5, (Second Series), Strengthening the Biological Weapons Convention, July, 2003.
- Pearson, G. S., BTWC Meeting of experts, Geneva, 19 to 30 July 2004, pp 1 and 9-11, The ASA Newsletter, Issue number 103, 27 August 2004.
- Pearson, G. S., BTWC Meeting of States Parties, Geneva: 6-10 December 2004, ASA Newsletter – 051b
- Pearson, G., Preparing for the BTWC Sixth Review Conference in 2006, Review Conference Paper No. 10, Strengthening the Biological Weapons Convention, Department of Peace Studies, University of Bradford, February, 2005.
- Rappert, B., McLeish, C. 2007, A Web of Prevention Biological Weapons, Life Sciences and the Governance of Research [Science in Society Series](#), 224 pp.
- Roffey R, The sixth Review Conference of the BTWC, developing the consultative procedure and improving the CBMs, Presented at the 23rd Workshop of the Pugwash Study Group on the Implementation of the Chemical and Biological Weapons Conventions: Achieving a successful outcome of the Sixth Review Conference, Geneva, Switzerland, 3-4 December 2005.
- Roffey R, From Bio Threat to EU Biological Proliferation Prevention Cooperation, Background paper 4, Presented at the European Commission, UNIDIR/ISIS/SIPRI Conference on Strengthening European Action on Non-Proliferation and Disarmament – How can Community Instruments Contribute, Brussels, December 7-8, 2005, Roffey R, The need for a more active EU partnership to promote biosecurity and biosafety in Russia and NIS, Presented at Cooperation on Bio-Initiatives in Russia and the NIS toward a true Partnership, Third LNCV-IWG and RANSAC Workshop, Como, Italy, 28-29 September, 2006.
- Roffey R and F Kuhlau, Enhancing biosecurity: the need for a global strategy, Appendix 14A, pp 732-748, in SIPRI Yearbook 2006, Armaments, Disarmament and International Security, Stockholm International Peace Research Institute, Oxford University Press, 2006.
- Roffey, R., J. Hart and F. Kuhlau, Crucial guidance: A code of conduct for biodefense scientists, Arms Control Today, September, 2006.
- Salerno, R.M. et al., 2004, A biological weapons risk assessment based on historical and technical perspectives, The Nonproliferation Review, 11(3), 24-55.
- Salerno, R.M. et al., 2004, A biological weapons risk assessment based on historical and technical perspectives, The Nonproliferation Review, 11(3);
- Salerno, R.M. Gaudio, J., 2007, Laboratory Biosecurity Handbook. CRC Press, 188 pp.
- Schellekens, H. (ed.), Veilig werken met micro-organismen, parasieten en cellen in laboratoria en andere werkruimten. Theorie en praktijk.
- Scheuer, M., 2002, Through Our Enemies' Eyes: Osama Bin Laden, Radical Islam, and the Future of America, Dulles, VA: Brassey's; Petro, J.B. and Relman, D.A., 2003, Understanding threats to scientific openness, Science, 302, 1898; Office of the Press Secretary, The White House, 2004, Commission on the Intelligence Capabilities of the United States Regarding Weapons of

- Mass Destruction: Report to the President of the United States, Washington, D.C.: White House.
- Salerno, R.M. and Hickok, L.T., forthcoming 2007, Strengthening Bioterrorism Prevention: Global Biological Materials Management, Biosecurity and Bioterrorism, 5(2).
- Sewell, D.L., 1995, Laboratory-associated infections and biosafety, *Clinical Microbiology Reviews*, 8(3), 389-405.
- Sims N., Towards the BWC Review Conference: Diplomacy still in the doldrums, *Disarmament Diplomacy*, No. 82, Spring 2006.
- Smith, D, Rohde, C. (2002). The implication of the biological and toxin weapons convention and other related initiatives for WFCC members. *WFCC Newsletter* 34: 4-11.
- Smithson, A.E. and Levy, L.-A., 1999, Stimson Center Report No. 35, Ataxia; The Chemical and Biological Terrorism Threat and the U.S. Response, Washington, D.C.; Stimson Center.
- Somerville, M. A. and Atlas, R., 'Ethics: a weapon to counter bioterrorism', *Science*, 25 Mar. 2005, pp. 1881-82.
- Steinbruner, J., E. D. Harris, N. Callagher and S. Okutani, 'Controlling dangerous pathogens: a prototype protective oversight system', *CISSM Monograph*, December. 2005
- Stern, P.C. and Fineberg, H.V., Eds., 1996, National Research Council, Committee on Risk Characterization, *Understanding Risk: Informing Decisions in a Democratic Society*, Washington, D.C.: National Academy Press, available online at; <http://darwin.nap.edu/books/030905396X/html>.
- Stichting voor Publieksvoorlichting over Wetenschap en Techniek. Biotechnologie, veiligheid en regelgeving.
- Swings, J. et al. (2002). WFCC's Handling Bioterrorism Issues. *WFCC Newsletter* 34: 1-3.
- Technical Instructions for the Safe Transport of Dangerous Goods by Air. Doc 9284-AN/905. Council of ICAO, International Civil Aviation Organisation.
- Tucker, J.B., 2003, Biosecurity; Limiting Terrorist Access to Deadly Pathogens, United States Institute of Peace, *Peaceworks* 52.
- Tucker, J., Preventing the Misuse of Pathogens: The need for global Biosecurity Standards, *Arms Control Today*, June, 2003.
- Tucker, J.B., Historical Trends Related to Bioterrorism: An Empirical Analysis. Details!!!!
- Tumpey, T.M. et al. 2005, Characterization of the 1918 Spanish Influenza Pandemic Virus, *Science*, 310(5745), pp. 77-80.
- United Nations General Assembly, Chemical and Bacteriological (Biological) Weapons, Report of the Secretary-General, Annex I, report of the Group of qualified experts in pursuance of General Assembly resolution 42/37 C, October 4, 1989, A/44/561.
- United Nations, Meeting of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons: Report of the Meeting of Experts, Document BWC/MSP.2003/MX/4, Part I, Geneva, 18-29 August 2003.
- United Nations, Meeting of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons: Report of the Meeting of States Parties, Document BWC/MSP.2003/MX/4 (Vol. I), Part II, Geneva, 10-14 November 2003.
- UN report from the High level Panel on Threats, Challenges and Change, A/59/565, December 2004.
- U.N. Security Council Resolution 1540, 2004, New York: United Nations,
- United Nations Secretary-Generals forward in: A more secure world: Our shared responsibility, Report of the Secretary-General's High-level Panel on Threats, Challenges and Change, 2004.
- United Nations Security Council resolution 1540 (2004) of 28 April 2004, UN document S/RES/1540(2004), 28 April 2004.
- United Nations Security Council 1540 Committee, Legislative data-base, at URL <http://disarmament2.un.org/Committee1540/legalDB.html>
- United Nations Security Council, Report of the Committee established pursuant to resolution 1540, S/2006/257, 25 April, 2006.
- United Kingdom National Culture Collection (1998) Quality manual. UKNCC Secretariat CABI Bioscience UK Centre, Egham, UK.

Universal Postal Convention, Bucarest Convention and Letter Post Regulations Bern, International Bureau of the Universal Postal Union, 2004.

UN Model Regulations on the Transport of Dangerous Goods, United Nations, New York, 16th ed.

U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, and National Institutes of Health, 1999, Biosafety in Microbiological and Biomedical Laboratories (BMBL), 4th ed., Washington, D.C.: publisher?

U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, and National Institutes of Health, 1999, Biosafety in Microbiological and Biomedical Laboratories (BMBL), 4th ed., Washington, D.C.; World Health Organization, 2004, Laboratory Biosafety Manual, 3rd ed., Geneva: WHO.

U.S. Environmental Protection Agency, Integrated Risk Information System,.

U.S. FEMA, 2003, FEMA 426; Reference Manual to Mitigate Potential Terrorist Attacks against Buildings, Washington, D.C.; FEMA.

U.S. GAO, 1999, Combating Terrorism: Need for Comprehensive Threat and Risk Assessments of Chemical and Biological Attacks, Washington, D.C.; U.S. GAO, GAO/NSAID-99-163.

U.S. Government Accountability Office has endorsed a risk management approach for addressing mitigating security threats, U.S. GAO, 2001, Homeland Security; A Risk Management Approach Can Guide Preparedness Efforts, Washington, D.C.: U.S. GAO-02-208T. Also see U.S. GAO, 2003, Combating Bioterror-ism: Actions Needed to Improve Security at Plum Island Animal Disease Center, Washington D.C.; GAO-03-847.

U.S. Homeland Security Presidential Directive 10 (HSPD-10), Also known as National Security Presidential Directive 33 (NSPD-33), 2004, Biodefense for the 21st Century, Washington, D.C.: White House.

U.S. Secret Service and CERT Coordination Center/SEI, May 2005, Insider Threat Study: Computer System Sabotage in Critical Infrastructure Sectors, Washington, D.C., p. 22 [by Michelle Keeney, J.D., Ph.D., Eileen Kowalski at the National Threat Assessment Center, and Dawn Cappelli, Andrew Moore, Timothy Shimeall, Stephanie Rogers at the Software Engineering Institute].

World Federation for Culture Collections (1999). Guidelines for the establishment and operation of collections of cultures of micro-organisms. UK: WFCC Secretariat. (2nd ed.).

World Federation for Culture Collections (2008). WFCC Information Resource on International Regulations for Packaging & Transport of Genetically Modified Microorganisms. http://www.wfcc.info/wfcc_transport.pdf

World Federation for Culture Collections (2008). WFCC Information Resource on International Postal Regulations for Shipping Biological Materials. The current UPU regulations and their background. http://www.wfcc.info/wfcc_regulations.pdf

WHO. *Global health security: epidemic alert and response*. World Health Assembly resolution WHA54.14, May 2001

WHO Public Health Response to Biological and Chemical Weapons, 2nd ed., 2002 .

WHO. *Global public health response to natural occurrence, accidental release or deliberate use of biological and chemical agents or radionuclear material that affect health*. World Health Assembly resolution WHA55.16, May 2002.

WHO. Deliberate use of biological and chemical agents to cause harm. World Health Assembly resolution WHA55.20, May 2002

WHO Office in Lyon, Department of Communicable Disease Surveillance & Response, Report of activities, 2001-2004, WHO/CDS/CSR/LYO/2004.17.

World Health Organization, Laboratory Biosafety Manual, third edition (revised) (2004),

WHO, Enhancement of laboratory biosafety, The Fifty-eighth World Health Assembly, 25 may, 2005,

WHO, Revision of the International Health Regulations, 58 WHO World Health Assembly, Agenda item 13.1, Doc. WHA58.3, May, 2005,

WHO Biorisk Management, Laboratory biosecurity guidance, Department of communicable disease surveillance and response, WHO/CDS/EPR/2006.6, September 2006. See above

WHO Global Outbreak Alert & Response Network, <http://www.who.int/csr/outbreaknetwork>.

WHO Guidance on regulations for the Transport of Infectious Substances, WHO/CDS/EPR/2007.2

WHO, Primary Health Care, "Now More Than Ever", The World Health Report 2008

William P., Statement at the International Conference "G8 Global Partnership Against the Spread of

Weapons and Materials of Mass Destruction”, Moscow, 23 April 2004 (available at <http://www.pircenter.org/rus/club/steno.html>)

Woodward, A., Time to lay down the law, national legislation to enforce the BWC, VERTIC Report, Oct. 2003.

World Medical Association, ‘Declaration of Washington on Biological Weapons’, Document 17.400, September 2001

2.2 Relevant websites

http://www.who.int/csr/ihr/IHRWHA58_3-en.pdf
http://www.cdc.gov/od/sap/final_rule.htm
<http://www.fao.org/DOCREP/MEETING/006/Y8453E.HTM>
http://ftp.who.int/gb/pdf_files/WHA54/ea54r14.pdf
http://www.who.int/gb/ebwha/pdf_files/WHA55/ewha5516.pdf
http://www.who.int/gb/ebwha/pdf_files/WHA55/ea5520.pdf
<http://www.absa.org>
<http://www.absa.org/abohistl.html>
<http://www.anbio.org.br>
<http://www.biosecuritycodes.org/>
<http://www.biosecuritycodes.org/leg.htm>
<http://www.ebsaweb.eu>
<http://www.interpol.int/Public/BioTerrorism/NationalLaws/>
<http://www.phac-aspc.gc.ca/ols-bsl/lbg-ldmbl/index.html>
<http://mat.gsia.cmu.edu/mstc/multiple/node4.html>
<http://www.biosecurityboard.gov/index.asp>
<http://www.biodiv.org/doc/legal/cartagena-protocol-en.pdf>
<http://www.biodiv.org/biosafety/default.aspx>
<http://www.opbw.org>
<http://ott.od.nih.gov/pdfs/Bmlintrn.pdf>
<http://www4.nationalacademies.org/iap/iaphome.nsf>
<http://www.wma.net/e/policy/b1.htm>
<http://www.cissm.umd.edu/documents/pathogensmonograph.pdf>
<http://www.interpol.int/Public/BioTerrorism/default.asp>
<http://www.sipri.org/contents/expcon/euppconfmaterials.html>
<http://www.who.int/wer/2004/en/wer7933>
<http://www.interpol.int/Public/BioTerrorism/default.asp>
<http://www.sgpproject.org/publications/SGPAssessment2006.pdf>
<http://www.g8.gc.ca/2002Kananaskis/kananaskis/globpart-en.sp>
<http://www.g7.utoronto.ca/summit/2006stpetersburg/infdis.html>
<http://www.interpol.int/Public/BioTerrorism/Conferences/1stGlobalConference.asp>
<http://www.acronym.org/docs/0506/doc02.htm>
<http://www.inesap.org/bulletin9/bull9art05.htm>
<http://www.asanltr.com/newsletter/05-1/articles/051b.html>
http://www.un.org/Docs/sc/unsc_resolutions04.html
<http://www.epa.gov/iris/intro.htm>
<http://www.gao.gov>
http://www.who.int/emc/book_2nd_edition.htm
http://www.who.int/csr/resources/publications/biosafety/who_cds_csr_lyo_20034/en/
http://www.who.int/csr/labepidemiology/WHA58_29-en.pdf

2.3 Portuguese legal documents and standards

Directive 90/679/EEC, 26 November ; Directive 93/88/EEC, 12 October ; Directive 95/30/EC, 30 June

Portaria nº 405/98 de 11 de Julho

Approves the classification of biological agents.

Directive 95/30/EC, 30 June

Portaria nº 1036/98 de 15 de Dezembro

Alters the list of biological agents, approved by Portaria nº 405/98.

Directive 97/59/EC

Decreto-Lei nº 126/93 de 20 de Abril

Regulates the use and release to the environment of genetically modified organisms, as well as the commercialization of products containing GMOs, with a view to protect human health and the environment.

Directive 90/219/EEC, 23 April; Directive 90/220/EEC, 23 April

Decreto-Lei nº 436/91 de 8 de Novembro

On operations of import and export of equipments, products and technologies which may jeopardise the defence or national strategic interests.

Portaria nº 1129/95 de 15 de Setembro

Approves the list of biological agents, animal and plant pathogens and equipments for biological proliferation, under the terms of article 5 of Decreto-Lei nº 436/91.

Decreto-Lei nº 154/2005 de 6 de Setembro

Defines measures of phytosanitary protection against the introduction and dispersal within the National Territory and the Community, including protected zones, of organisms harmful to plants and plant products, whichever their origin.

Directive 2002/89/EC, 28 November; Directive 2004/102/EC, 5 October; Directive 2004/103/EC, 7 October; Directive 2004/105/EC, 15 October; Directive 2005/15/EC, 28 February; Directive 2005/16/EC, 2 March; Directive 2005/17/EC, 2 March; Directive 2005/18/EC, 2 March

Decreto-Lei nº 4/2009 de 5 de Janeiro

Alters Decreto-Lei nº 154/2005 and recognizes protected zones exposed to particular plant health risks in the Community.

Directive nº 2008/64/CE, 27 July; Regulation (EC) 690/2008/CE

STANDARDS

NPEN 12128:2000

Laboratories of research, development and analysis. Containment levels of microbiology laboratories, areas of risk, localities and physical safety requirements.

NPEN 12738:1999

Guidance on containment of animals inoculated with microorganisms in experiments.

NPEN 1620:1999

Significance of this deliverable

This deliverable is the first step summarising the main legislation and websites related to biosecurity. This represents the elements to build a Draft Code of Conduct on Biosecurity (milestone ML.NA1.2.2 due M30).