

BIOSAFETY AND BIOSECURITY

Submitted by the Implementation Support Unit

Summary

This background document introduces the terms *biosafety* and *biosecurity* and looks at how they are used and what they mean in different settings. Previous agreements, understandings and proposals on biosafety and biosecurity, from past meetings of the Convention, are then considered. Summary information on relevant activities undertaken by a number of international and regional organizations are included in Annex I (in English only). Sources of additional technical information are listed in Annex II (in English only).

I. What is meant by biosafety and biosecurity?

1. Concepts of biosafety and biosecurity deal with related but distinctly different issues. Biosafety is a well-established concept with a widely-accepted meaning and international guidance on how it is put into practice at the national level. Biosecurity is a comparatively new term, with divergent meanings depending upon the setting in which it is used.

Biosafety

2. The common understanding of *biosafety* is derived from the practical guidance issued by the World Health Organization on techniques for use in laboratories. The WHO Laboratory Biosafety Manual (LBM) considers biosafety to be "the containment principles, technologies and practices that are implemented to prevent unintentional exposure to pathogens and toxins, or their accidental release."¹ The LBM contains expert guidance on how to implement the relevant principles, technologies and practices. The WHO encourages all states to consider such concepts when developing and enhancing national regulatory regimes. The international guidance is then tailored to fit precise national requirements. Such concepts are consistent across public, animal and plant health sectors and close cooperation between the WHO, FAO and OIE contributes to the development of relevant guidance and understandings.

3. Biosafety correlates to the obligation under the Convention to ensure that the necessary safety precautions are taken, when conducting activities not prohibited by the BWC, to protect populations and the environment. (See the section on previous agreements, understandings and proposals below.)

¹ WHO, Laboratory Biosafety Manual – Third Edition,
http://www.who.int/csr/resources/publications/biosafety/WHO_CDS_CSR_LYO_2004_11/en/

Biosecurity

4. The term *biosecurity* is more complex as it can have different meanings in different contexts. According to the relevant WHO guidance², the phrase has evolved simultaneously in various processes and is used differently in each. In the setting of the BWC, it is most commonly used to refer to mechanisms to establish and maintain the security and oversight of pathogenic microorganisms, toxins and relevant resources, as discussed during the 2003 meetings of the Convention.

5. The term *biosecurity* does not seem to have a standardized meaning across human, animal and plant health sectors. In veterinary³ and agricultural⁴ fields the term has come to denote protecting biological resources from foreign or invasive species.

6. The connotations of biosecurity in public health settings, however, relate more closely to the BWC. The foreword to the Third Edition of the LBM, released in 2004, notes that in public health, biosecurity concerned "the protection of microbiological assets from theft, loss or diversion, which could lead to the inappropriate use of these agents to cause public health harm". Efforts continue to evolve within WHO to differentiate between this specific meaning and applications to which biosecurity is put in other settings. In 2006, when the WHO released its first dedicated guidance publication on this issue⁵, the phrase had evolved into *laboratory biosecurity*. Laboratory biosecurity describes "the protection, control and accountability for valuable biological materials⁶ within laboratories, in order to prevent their unauthorized access, loss, theft, misuse, diversion or intentional release."

7. Such concepts are not restricted to laboratories but have also been expanded to a variety of other facilities that work with resources which could be used for purposes prohibited by the Convention. The OECD, for example, has developed best practice guidelines⁷ for biosecurity at ancillary facilities (Biological Resource Centres)⁸. In this context, biosecurity means

² WHO, Biorisk Management: Laboratory Biosecurity Guidance, September 2006
http://www.who.int/csr/resources/publications/biosafety/WHO_CDS_EPR_2006_6.pdf

³ For example, the glossary of the FAO Basic Laboratory Manual for the Small-Scale Production and Testing of I-2 Newcastle Disease Vaccine considers biosecurity to be "precautions taken to minimize the risk of introducing an infectious agent into a population".

⁴ For example, the glossary of the New Zealand Parliamentary Commissioner for the Environment considers biosecurity to be "The exclusion, eradication and effective management of pests and unwanted organisms into New Zealand." http://www.pce.govt.nz/reports/pce_reports_glossary.shtml

⁵ WHO, Biorisk Management: Laboratory Biosecurity Guidance, September 2006
http://www.who.int/csr/resources/publications/biosafety/WHO_CDS_EPR_2006_6.pdf

⁶ Valuable Biological Materials (VBMs) in this context means "Biological materials that require (according to their owners, users, custodians, caretakers or regulators) administrative oversight, control, accountability, and specific protective and monitoring measures in laboratories to protect their economic and historical (archival) value, and/or the population from their potential to cause harm. VBM may include pathogens and toxins, as well as non-pathogenic organisms, vaccine strains, foods, genetically modified organisms (GMOs), cell components, genetic elements, and extraterrestrial samples.

⁷ OECD Best Practice Guidelines on Biosecurity for Biological Resource Centres, 2007
http://www.oecd.org/document/36/0,3343,en_2649_34537_38777060_1_1_1_1,00.html

⁸ Biological Research Centres include: service providers and repositories of the living cells, genomes of organisms, and information relating to heredity and the functions of biological systems.

"institutional and personal security measures and procedures designed to prevent the loss, theft, misuse, diversion or intentional release of pathogens, or parts of them, and toxin-producing organisms, as well as such toxins that are held, transferred and/or supplied by Biological Resource Centres".

Differentiating between biosafety and biosecurity

8. At the BWC meetings in 2003, one delegate used this simple formulation to assist participants differentiate between biosafety and biosecurity issues:

Biosafety protects people from germs – biosecurity protects germs from people.

While these objectives are related, and both are linked to the Convention, their purposes remain distinct. As a result, biosecurity concepts differ from biosafety concepts. The approaches used to achieve them are often similar or mutually reinforcing, but in some cases may conflict. A common example of conflict arises with the transport of dangerous pathogens: in the interests of biosafety, such pathogens should be clearly labelled during transport, but from a biosecurity perspective, labelling the pathogen being shipped may increase the risk of theft or diversion.

II. Previous agreements, understandings and proposals

Biosafety and the Convention

9. Biosafety is connected with the aims and objectives of the Convention, and the concept is explicitly mentioned in Article II. This article requires States Parties to "destroy, or to divert to peaceful purposes" any biological weapons they have, and specifies that in implementing this requirement "all necessary safety precautions shall be observed to protect populations and the environment".

10. Subsequent review conferences agreed that "States parties should take all necessary safety precautions to protect populations and the environment in relation to activities not prohibited by the Convention."⁹ This understanding has thus extended the requirement for biosafety measures, from the destruction and diversion activities under Article II to all activities not prohibited by the Convention – including all peaceful scientific and technological activities in the life sciences, as well as those for protective and prophylactic purposes.

Biosecurity and the Convention

11. Biosecurity concepts under the Convention developed in concert under both Article III and Article IV.

12. The Second, Third and Fourth Review Conferences noted "the importance of... legislation regarding the physical protection of laboratories and facilities to prevent unauthorised

⁹ Final Document of the Third Review Conference, BWC/CONF/III/23, Art. I, Para. 5

access to and removal of pathogenic or toxic material"¹⁰. The Sixth Review Conference called "for appropriate measures by all States Parties to ensure that biological agents and toxins relevant to the Convention are protected and safeguarded, including through measures to control access to and handling of such agents and toxins"¹¹.

13. The Sixth Review Conference also called upon States Parties "to adopt, in accordance with their constitutional processes, legislative, administrative, judicial and other measures, including penal legislation, designed to... ensure the safety and security of microbial or other biological agents or toxins in laboratories, facilities, and during transportation, to prevent unauthorized access to and removal of such agents or toxins."¹²

14. The 2003 Meeting of States Parties agreed on the value of "comprehensive and concrete national measures to secure pathogen collections and the control of their use for peaceful purposes. There was a general recognition of the value of biosecurity measures and procedures, which will ensure that such dangerous materials are not accessible to persons who might or could misuse them for purposes contrary to the Convention." The Meeting also stressed "the need for undertaking activities at the national level in keeping with their obligations and responsibilities to strengthen and implement the Convention. The States Parties agreed, to that end, on the value of... review[ing], and where necessary, enact[ing] or updat[ing] national legal, including regulatory and penal, measures which ensure effective implementation of the prohibition of the Convention, and which enhance effective security of pathogens and toxins"¹³.

15. The Meeting of States Parties in 2007, which considered various aspects of national implementation, agreed on "the importance of regular national reviews of the adopted measures, including by ... updating lists of agents and equipment relevant to safety, security and transfer regimes"¹⁴.

Past proposals on biosecurity

16. Current agreements and understandings, therefore, cover the desirability of biosecurity measures, their purpose, the need to ensure the efficacy of domestic action, and a mechanism to review and enhance current arrangements. Proposals made by individual States Parties during the 2003 meetings of the BWC related closely to these understandings, and covered the *scope* and *content* of biosecurity measures, as well as means of *enhancing domestic cooperation*. These proposals were not formally considered or adopted by the meetings and thus have no formal status; they were circulated in a conference room paper prepared by the then Chairman, dated 14 November 2003. The proposals are included here for ease of reference.

17. Proposals on the *scope* of relevant biosecurity arrangements were that such arrangements should:

¹⁰ Final Document of the Second Review Conference, BWC/CONF.II/13, Art. IV, Para. 4(b), Final Document of the Third Review Conference, BWC/CONF.III/23, Art. IV, Para. 3(b), Final Document of the Fourth Review Conference, BWC/CONF.IV/9, Art. IV, Para. 3(b)

¹¹ Final Document of the Sixth Review Conference, BWC/CONF.VI/6, Art. III, Para. 9.

¹² Final Document of the Sixth Review Conference, BWC/CONF.VI/6, Art. IV, Para. 11(c).

¹³ Report of the Meeting of States Parties, BWC/MSP/2003/4, Part II, Para 3(b)

¹⁴ Report of the Meeting of States Parties, BWC/MSP/2007/5, Para 23.

- (i) Cover agents, toxins and critical equipment;
- (ii) Cover facilities, storage, transport, and personnel;
- (iii) Be cost efficient;
- (iv) Be based on a risk management approach;
- (v) Be based upon clear national guidelines;
- (vi) Be site-specific, as variations in circumstances preclude common universal regulations;
- (vii) Make use of standards and supervisions mechanisms
- (viii) Adapt, wherever possible, existing oversight and regulatory frameworks;
- (ix) Address differences in aims and tools for biosafety and biosecurity; and
- (x) Be regularly reviewed.

18. Proposals on the *content* of biosecurity arrangements were that such arrangements should include:

- (i) Good Science Practices;
- (ii) Flexible national control lists;
- (iii) Packaging and labelling requirements;
- (iv) Access control and supervision systems in relevant institutions;
- (v) Background screening of personnel;
- (vi) Comprehensive and integrated monitoring activities;
- (vii) The identification and registering of relevant facilities, transport systems and staff;
- (viii) A mechanism to create and maintain detailed, accurate records of possession, transport, storage, use, and personnel approved to work with, relevant resources.

19. Proposals on *enhancing domestic cooperation* were to:

- (i) Identify a lead government agency or create a new centralised oversight authority;
- (ii) Develop a national biosecurity implementation plan;
- (iii) Use governmental and non-governmental ethical oversight bodies to create a national biosecurity culture;
- (iv) Pursue coordinated awareness and training programmes; and
- (v) Incorporate biosecurity measures into best practices and other non-legally binding guidelines.

Building biosafety and biosecurity capacity

20 The Meeting of States Parties in 2003 agreed on the value of "the positive effect of cooperation between States Parties with differing legal and constitutional arrangements. States Parties in a position to do so may wish to provide legal and technical assistance to others who request it in framing and/or expanding their own legislation and controls in the areas of national implementation and biosecurity."¹⁵

¹⁵ Report of the Meeting of States Parties, BWC/MSP/2003/4, Part II, Para 3(b)(ii)

21. A number of States Parties (and groups of States Parties) have explicitly expressed a willingness to consider providing assistance on biosafety and biosecurity, including: Australia, Canada, Cuba, the European Union, Germany, Russian Federation, Switzerland, the United Kingdom of Great Britain and Northern Ireland, and the United States of America. Additional details are available to States Parties on the restricted access pages of the BWC website (<http://www.unog.ch/bwc/restricted>). Interested parties are also encouraged to contact the ISU.

22. A number of the proposals made at the 2003 meetings of the Convention related to building relevant capacity through bilateral arrangements, including: exchanges of biosecurity personnel, including in national oversight bodies; biosecurity training; intelligence sharing; development and implementation of minimum standards; infectious disease surveillance and response; and ethical best practices. Other proposals focused on enhancing capacity through greater international cooperation, including: developing common understandings on what is meant by biosecurity; developing international norms on biosafety and biosecurity; harmonizing domestic biosecurity regimes; and encouraging WHO, OIE, and FAO to develop international biosecurity standards.

Annex I

[ENGLISH ONLY]

BIOSAFETY AND BIOSECURITY ACTIVITIES OUTSIDE THE CONVENTION

1. Issues of biosafety and biosecurity fall within the remit of various international, regional and professional organisations. These organisations have undertaken considerable work on these issues, much of which is relevant to the Convention. A basic outline of these organisations and major initiatives is provided below. Many of the organisations listed have been invited to participate in the Meeting of Experts and will make presentations and provide information which will supplement the contents of this paper. All of these resources will be available online at www.unog.ch/bwc.

American Biological Safety Association (ABSA)

<http://www.absa.org/>

2. ABSA has participated in past meetings of the BWC. Founded in 1984 to promote biosafety as a scientific discipline, ABSA is the regional professional society for biosafety and biosecurity personnel in North America. It is also active internationally. ABSA pursues four aims: developing and maintaining professional standards; advancing biological safety as a scientific discipline through education and research; providing members with sustained opportunities for biosafety communication, education and participation in the development of biological safety standards, guidelines and regulations; and expanding biosafety awareness and promoting the development of relevant work practices, equipment and facilities.

3. ABSA has also been active on biosecurity concepts for several years. In 2001 it founded a task force on the issue and in 2003 the task force released a White Paper on Understanding Biosecurity¹⁶. This document examines the complexity of addressing security concepts in the biological sphere and concludes that it is necessary to: understand the unique aspects of biological work and material; identify assets and vulnerabilities associated with biological activities; and develop measures that address and solve these problems. Additional information is provided to assist in the development and implementation of tailored biosecurity efforts. ABSA also provides guidance to its members on the regulatory regime present in North America.

4. ABSA is also allied with the Sandia National Laboratory's International Biological Threat Reduction Program which is designed to ensure the safe and secure use of pathogens and toxins through: training activities; technical consultations at institutions which are national or regional leaders in infectious disease diagnostics and research; efforts to increase professional affiliations and interactions between biosafety professionals; and encouraging the development of local biosafety associations.

¹⁶ ABSA Task Force on Biosecurity White Paper on Understanding Biosecurity, <http://www.absa.org/0301bstf.html>

Asia-Pacific Biosafety Association (A-PBA)

<http://www.a-pba.org/>

5. A-PBA was founded in 2005 to act as a professional society for biosafety professionals in the Asia-Pacific region. It has members from Singapore, Brunei, China, Indonesia, Malaysia, Thailand, the Philippines and Myanmar. A-PBA fosters recognition of biosafety as a distinct scientific discipline; promotes safe management of microorganisms and the products of biological processes; establishes a forum for the dissemination and continued exchange of information on biological safety; promotes biosafety in the Asia-Pacific region; and establishes links with other biosafety associations internationally. It is an active member of the International Biosafety Working Group and directly contributes to the development of biosafety best practices.

6. Since its inception, A-PBA has held numerous conferences, workshops and seminars, including those on: Principles and Practices of Biohazard Containment in a BSL-3 Laboratory; Biological Risk Assessment - Developing an Effective Biosafety Programme; Biosafety Management Course; and Design and Engineering for Biosafety Emergency Preparedness and Response.

European Biological Safety Association (EBSA)

<http://www.ebsaweb.eu/>

7. EBSA was founded in June 1996. It is a not-for-profit organisation which aims to provide a forum for its members to discuss and debate issues of concern and to represent those working in the field of biosafety and associated activities. EBSA strives to establish and communicate best practices amongst its members and to encourage dialogue and discussions on developing biosafety and biosecurity issues. EBSA seeks to influence and support emerging legislation and standards in the areas of biological safety, biosecurity, biotechnology, transport and associated activities and acts as a focal point for the consolidation of views on these issues.

8. EBSA is currently engaged in six projects: Biosafety Professional Competence (defining the tasks, skills and a curriculum to train biosafety professionals, and setting a framework for establishing training programmes, as well as certifying biosafety professionals); a Biorisk Laboratory Management Standard (to safeguard life, property and the environment from biological risks through the development and adoption of recognized standards in the area of management of biological organisms and their products within laboratory environments); Biosafety Europe (a project mandated by the European Commission within the Sixth Framework Programme on Research and Technological Development for coordination, harmonization and exchange of biosafety and biosecurity practices within a pan-European network); European Biosecurity and Bio-preparedness (contributing to various European Union biosecurity initiatives on transport of bio-materials, import control, traceability of bio-materials, detection technologies, and food security); OECD Quality Standards for Microbiological Resource Centers; and international forums on the transport of dangerous goods.

Food and Agriculture Organization (FAO)

<http://www.fao.org/biosecurity/>

9. Given the different use of the term *biosecurity* in the FAO setting (one denoting protection against the introduction of plant pests, animal pests and diseases, and zoonoses, genetically modified organisms, and alien species), the activities of FAO are not so obviously linked to the topics under discussion at the BWC Meeting of Experts. Nevertheless, certain elements, especially as they relate to the development of biosafety best practices, are closely related; others contain resources which could be extrapolated to fit the BWC context, such as principles of capacity building in disease-related fields. The FAO has conducted a technical consultation on biological risk management in food and agriculture in Thailand in 2003; created an international portal on food safety, animal and plant health; established a Working Group on Biosafety; detailed examples of national approaches to biosecurity; conducts a capacity building programme; and has reviewed certain thematic areas, including biotechnology in food and agriculture, biotechnology and food safety, and animal and plant health.

International Biosafety Working Group (IBWG)

<http://www.internationalbiosafety.org>

10. Through collaboration among national and regional biosafety organizations, the International Biosafety Working Group aims to support and promote biosafety on a national and international level. It is made up of a variety of sectoral, geographical and national groups, including EBSA, A-PBA, ABSA, ABSA Canada, ANBio, the Japanese Biosafety Association, the International Level-4 Users Group, the International Veterinary Biosafety Workgroup, the Pharmaceutical Biosafety Group, the US Centers for Disease Control, the Public Health Agency Canada, and the International Society for Biosafety Research. The IBWG provides technical biosafety information on: biosafety concepts; establishing national programmes; containment laboratory capacity; and biosafety research. The IBWG also acts as a clearing-house for a number of relevant training tools, including CDs and videos, course curricula and presentations. The group has also produced a Biosafety Compendium on Regulations, Guidelines and Information Sources from around the world¹⁷.

International Veterinary Biosafety Workgroup (IVBWG)

<http://www.vetbiosafety.org/>

11. The IVBWG is a specialist international forum for dealing with biosafety issues in high containment (BSL 3 and above) large animal facilities. It contributes to the development of generic biosafety guidance and participates in the International Biosafety Working Group. It publishes the Veterinary Containment Facilities: Design and Construction handbook¹⁸.

12. The IVBWG came about through a shared recognition that most countries throughout the world share similar problems in operating veterinary containment facilities and conducting research on livestock and poultry diseases: how to prevent the introduction of foreign animal

¹⁷ IBWG Biosafety Compendium on Regulations, Guidelines and Information Sources from around the World
<http://www.internationalbiosafety.org/english/internlCompendium.asp>

¹⁸ Veterinary Containment Facilities: Design and Construction handbook,
http://tecrisk.com/projekte/projekt1/Handbook_070323.pdf

diseases into the country; strategies for control and eradication of foreign diseases; the need to conduct research involving animals without release of viable agents into the environment; the necessity to provide a safe and healthy work environment for employees; prevent cross contamination among research materials and animals; and biosafety issues and facility requirements.

Organization for Economic Cooperation and Development (OECD)

13. The OECD currently has two projects of particular relevance to biosafety and biosecurity: the Biotechnology Division; and the International Futures Programme.

Biotechnology Division

http://www.oecd.org/topic/0,3373,en_2649_37437_1_1_1_1_37437,00.html

14. The Biotechnology Division covers five primary areas: biotechnology policies; bioeconomy; biosafety (through its BioTrack Online); intellectual property rights; and a research programme on biological resources in agriculture. Of these, the activities on biotechnology policy and BioTrack Online are perhaps most relevant.

15. Biotechnology policy activities included work on what the OECD calls Biological Resource Centres (BRCs) – functionally similar to culture collections. Over several years, the OECD has been developing best practice guidelines for BRCs¹⁹. These guidelines cover a range of quality assurance issues relevant to this year’s BWC meetings. It has also developed comparable guidance specifically addressing biosecurity at these facilities – the Best Practice Guidelines on Biosecurity for BRCs²⁰. This document complements the work done by the WHO for laboratories and covers the application of risk management approaches, physical security, management of personnel and visitors, training, material control and accountability, transport security, incident response, and information security.

16. BioTrack Online focuses on information related to the regulatory oversight of products of modern biotechnology, including genetically engineered organisms or transgenic organisms, in the field of environmental safety and food and feed safety. It includes a number of free documents (including consensus documents, guidance and other publications); an online database of products of modern biotechnology; and links to regulatory contacts in OECD member countries (where available) and other related web sites.

International Future Programme

http://www.oecd.org/department/0,3355,en_2649_33707_1_1_1_1_1,00.html

17. The International Futures Programme was home to the Project on Emerging Systemic Risks from 2000-2002. The project was conducted under the supervision of a steering group composed of the representatives of 19 governmental departments, seven corporations and three international organisations. It led to the publication of *Emerging Risks in the 21st Century: An*

¹⁹ OECD Best Practice Guidelines for BRCs, http://www.oecd.org/document/36/0,3343,en_2649_34537_38777060_1_1_1_1,00.html

²⁰ OECD Best Practice Guidelines on Biosecurity for BRCs, <http://www.oecd.org/dataoecd/6/27/38778261.pdf>

*Agenda for Action*²¹, a cross-sectoral analysis of risk management issues in the 21st Century. This publication laid the foundations for subsequent risk management concepts and lays out the principles for: emerging systemic risks; risk assessment; risk prevention; emergency management; and recovery issues.

UN Environment Programme (Global Environment Facility) (UNEP-GEF)

<http://www.gefweb.org/>

18. In the UNEP context, biosafety is often related to the Cartagena Protocol on Biosafety of the Convention on Biological Diversity. The Cartagena Protocol describes the concept of *biosafety* as "ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements"²². In November 2000, the the *Global Environment Facility Initial Strategy on Biosafety* was adopted. This strategy was designed to assist in the development of National Biosafety Frameworks²³ through capacity building initiatives; to promote information sharing and collaboration, especially at the regional and sub-regional level; and to promote collaboration with other organizations to assist capacity-building for the Protocol. In order to realise these aims, the GEF runs three programmes: developing national biosafety frameworks; implementing national biosafety frameworks; and supporting countries to participate in the biosafety clearing-house. As of March 2008, 99 countries had completed their draft national biosafety frameworks, eight countries had completed implementing their national biosafety frameworks, 11 countries started implementing their national biosafety frameworks, and 122 countries are currently setting up their participation in the biosafety clearing-house.

Developing national biosafety frameworks

http://www.unep.org/biosafety/Development_Projects.aspx

19. This project was started in June 2001, and aimed to assist up to 100 countries comply with the Cartagena Protocol, and takes into account the lessons learned from the UNEP-GEF *Pilot Project on Development of National Biosafety Frameworks*. In January 2004, the GEF approved additional funding for a further 20 countries. There are currently 123 countries participating in the Development project. Under this project UNEP-GEF has held a series of regional and sub-regional workshops; produced a range of case studies (including those for Ghana, Grenada, Guatemala, the former Yugoslav Republic of Macedonia, the Philippines, and Samoa); published a toolkit (which contains resources for four phases: starting the project; taking stock; consultation and analysis; and drafting the national biosafety frameworks); and has proposed a framework for creating national biosafety frameworks.

Implementing national biosafety frameworks

http://www.unep.org/biosafety/Implementation_Projects.aspx

²¹ OECD Emerging Risks in the 21st Century: An Agenda for Action, <http://www.oecd.org/dataoecd/23/56/19134071.pdf>

²² Cartagena Protocol on Biosafety, Article 1, <http://www.cbd.int/biosafety/articles.shtml?a=cpb-01>

²³ A National Biosafety Framework is a combination of policy, legal, administrative and technical instruments that are set in place to address safety for the environment and human health in relation to modern biotechnology.

20. This project started in December 2002 and 19 countries are currently participating. A further eight countries have completed the project. It is designed to ensure that participating countries have a workable and transparent regulatory regime consisting of enabling legislation, implementing regulations and complementing guidelines that are consistent with the Biosafety Protocol and other relevant international obligations. This requires the development of systems for handling of notifications or requests for approvals (including systems for administrative processing, risk assessment and decision making); enforcement and monitoring; and public information and public participation. Key documents produced by this project include a survey of national policies on biosafety and a manual for the implementation of national biosafety frameworks.

Supporting participation in the biosafety clearing-house
<http://bch.cbd.int/>

21. In March 2004, the GEF approved a new project to assist Parties of the Cartagena Protocol to strengthen capacity in eligible countries through: the training of key stakeholders; creating an enabling environment for Parties to meet their obligations; and supporting capacity building through the development and dissemination of an interactive computer-based training package. The project provides resources to participating countries: to assist in the design and development of the national participation in the clearing house; for the initial equipment set up, (including, where required, intranet and Internet connectivity); an interactive guide to the clearing house; a database template that could be used with existing computer programs to store data at a national level; a training package and user-friendly computer-based training manual; resources to hold national workshops; and follow-up by the project team to ensure that the training is useful.

World Health Organization (WHO)
<http://www.who.int/csr/bioriskreduction/>

22. The WHO has at least two sets of relevant activities: the *Biosafety and Laboratory Biosecurity Programme*; and the project of the Biorisk Reduction for Dangerous Pathogens Team on *Life Science Research and Development for Global Health Security*.

Biosafety and Laboratory Biosecurity Programme

23. The WHO Biosafety and Laboratory Biosecurity programme is designed to assist Member States understand, adopt and implement biorisk management strategies to minimize risks of infections through safe and secure practices in laboratory and transport environments, and to accomplish these goals in a cost-effective manner. It is part of WHO's efforts to establish a biosafety and laboratory biosecurity culture worldwide. To this end, the programme provides guidance on, and promotes the use of, safe and secure workplace practices, appropriate protective equipment, engineering and administrative controls in the handling of pathogenic organisms in laboratories, during transportation, in field investigations and in vaccine manufacturing facilities, to protect workers, the environment and the community from exposure, infection, and subsequent development of disease. Five WHO biosafety collaborating centres support the Global Biosafety and Laboratory Biosecurity Programme. They each have nominated a focal point to be a member of the WHO Biosafety Advisory Group (BAG) to support the

programme. The BAG meets regularly to address outstanding biosafety and laboratory biosecurity issues, to discuss activities, projects and collaborations.

24. The Biosafety and Laboratory Biosecurity programme operates at the international, regional and domestic levels. Underpinning current efforts is the resolution on the enhancement of laboratory biosafety adopted in 2005, at the 58th World Health Assembly²⁴. This resolution mandates the organisation to undertake certain relevant activities and urges Member States to do likewise. The programme is involved with ongoing international efforts to ensure the safekeeping of eradicated dangerous pathogens. It also supports the work of the BAG and contributes to international frameworks for the transport of infectious substances. At the regional level the programme holds workshops to raise awareness of biosafety and laboratory biosecurity and coordinates the relevant activities of the WHO regional and country offices.

25. The programme produces a range of important publications, including: the 1997 Guidelines for the safe transport of infectious substances and diagnostic specimens²⁵; 2004 Transport of Infectious Substances: background to the amendments adopted in the 13th revision of the United Nations Model Regulations guiding the transport of infectious substances²⁶; 2004 Laboratory Biosafety Manual - Third Edition²⁷; 2005 Guidance on regulations for the Transport of Infectious Substances²⁸; 2006 Biorisk management: Laboratory biosecurity guidance²⁹; and 2007 Guidance on Regulations for the Transport of Infectious Substances 2007-2008³⁰. It also provides a number of training resources, including: a biosafety and laboratory biosecurity train-the-trainers manual; laboratory risk assessment guidelines; transport of infectious substances, web-based training tool (work in progress); transport of infectious substances, training DVD; appropriate use of biosafety cabinets, training DVD; and maintenance and operation of containment equipment (work in progress).

Life Science Research and Development for Global Health Security

26. This project was created to raise awareness of, and provide information and guidance on, risk management approaches on the potential for the malign use of the life sciences to WHO Member States. It underlines the importance of carrying out life science research and development for improving public health and, at the same time, highlights the necessity of understanding that access to, and research on, any type of dangerous or new agent may pose

²⁴ WHA58.29: Enhancement of laboratory biosafety, http://www.who.int/gb/ebwha/pdf_files/WHA58/WHA58_29-en.pdf

²⁵ WHO 1997 Guidelines for the safe transport of infectious substances and diagnostic specimens, http://www.who.int/entity/csr/resources/publications/biosafety/WHO EMC_97_3/en/index.html

²⁶ WHO 2004 Transport of Infectious Substances: background to the amendments adopted in the 13th revision of the United Nations Model Regulations guiding the transport of infectious substances, http://www.who.int/entity/csr/resources/publications/WHO_CDS_CSR_LYO_2004_9/en/index.html

²⁷ WHO 2004 Laboratory Biosafety Manual - Third Edition, http://www.who.int/entity/csr/resources/publications/biosafety/WHO_CDS_CSR_LYO_2004_11/en/index.html

²⁸ WHO 2005 Guidance on regulations for the Transport of Infectious Substances, http://www.who.int/entity/csr/resources/publications/biosafety/WHO_CDS_CSR_LYO_2005_22/en/index.html

²⁹ WHO 2006 Biorisk management: Laboratory biosecurity guidance, http://www.who.int/entity/csr/resources/publications/biosafety/WHO_CDS_EPR_2006_6/en/index.html

³⁰ WHO 2007 Guidance on regulations for the Transport of Infectious Substances 2007-2008, http://www.who.int/entity/csr/resources/publications/biosafety/WHO_CDS_EPR_2007_2/en/index.html

risks to public health and raise ethical and security concerns. To this end, the project works with issues related to working with dangerous pathogens; health research policy; collaboration and support; global health security; and ethics.

27. To date, the main achievements of the project include: establishing a network of relevant experts; a working paper identifying relevant issues³¹; creation and meetings of a Scientific Working Group (to provide guidance on project activities); co-sponsorship of the meeting "International Roundtable on Dual Use Life Sciences Research", February 2007; online consultations on project activities; holding a regional workshop on "Research Policy and Management of Risks in Life Science Research for Global health Security", Bangkok Thailand, December 2007; outreach activities, publications and participation in meetings. The team has also participated in Biosafety and Laboratory Biosecurity meetings in Iran (in October 2006) and Kenya (May 2007). The project is currently refining a guidance document that will address how to evaluate need and capacities to address relevant risks as well as possible options to manage these risks. On completion of this framework, the team will then develop technical materials to provide training, including through the integration of risk management best-practices. To this end it is planning to hold a second meeting of its Scientific Working Group and another meeting for external experts.

World Organization for Animal Health (OIE)

<http://www.oie.int>

28. The OIE has actively participated in both the current and previous BWC intersessional processes. It has examined issues directly related to the Convention, such as in *Scientific and Technological Review: Biological Disasters of Animal Origin*³². In addition to collaborating with other international organisations on the development of generic biosafety and safe transport guidance, the OIE produces a number of key documents specifically targeting animal-related fields. The OIE produces the international health standards for animals and animal products – trade standards and biological standards: the *Terrestrial Animal Health Code*³³; the *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals*³⁴; the *Aquatic Animal Health Code*³⁵; and the *Manual of Diagnostic Tests for Aquatic Animals*³⁶. These standards deal with a range of pertinent issues: risk management approaches and principles; biosecurity consideration (especially in the animal and agricultural use of the term); identification and traceability of live animals; hygiene precautions; and disinfection and disinsectisation.

³¹ Life Science Research: Opportunities and Risks for Public Health. Mapping the Issues, WHO/CDS/CSR/LYO/2005.20,

http://www.who.int/csr/resources/publications/deliberate/WHO_CDS_CSR_LYO_2005_20/en/

³² OIE Scientific and Technological Review: Biological Disasters of Animal Origin,

http://www.oie.int/eng/publicat/rt/A_RT25_1.htm

³³ OIE Terrestrial Animal Health Code, http://www.oie.int/eng/normes/mcode/en_sommaire.htm

³⁴ OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals,

http://www.oie.int/eng/normes/mmanual/A_summry.htm

³⁵ OIE Aquatic Animal Health Code , http://www.oie.int/eng/normes/fcode/en_sommaire.htm

³⁶ OIE Manual of Diagnostic Tests for Aquatic Animals, http://www.oie.int/eng/normes/fmanual/A_summry.htm

29. The OIE also produces a number of other resources. The OIE *Quality Standard and Guidelines for Veterinary Laboratories: Infectious Diseases*³⁷ sets out the management and technical competence for the accreditation of testing for infectious animal disease. This quality control system contributes to ensuring the safe and secure operation of relevant facilities. The standards cover: management requirements (including quality systems, document control, records, internal audits and management reviews); technical requirements (including personnel issues, equipment, measurement traceability and handling of specimens); validation of laboratory techniques; and international reference standards. The *Handbook on Import Risk Analysis for Animals and Animal Products*³⁸ sets out in detail the concepts and necessary steps for qualitatively and quantitatively analyzing, managing and applying controls for risk in the animal sphere. It also provides guidance on a number of related issues including: terminology, acceptable risk, transparency, and developing a risk communication strategy.

³⁷ OIE Quality Standard and Guidelines for Veterinary Laboratories: Infectious Diseases, http://www.oie.int/eng/publicat/ouvrages/A_112.htm

³⁸ OIE Handbook on Import Risk Analysis for Animals and Animal Products, http://www.oie.int/eng/publicat/ouvrages/A_IRAvol1.htm

Annex II

[ENGLISH ONLY]

ADDITIONAL BIOSAFETY AND BIOSECURITY RESOURCES

- (i) ABSA Task Force on Biosecurity White Paper on Understanding Biosecurity
<http://www.absa.org/0301bstf.html>
- (ii) IBWG Biosafety Compendium on Regulations, Guidelines and Information Sources from around the World <http://www.internationalbiosafety.org/english/internlCompendium.asp>
- (iii) IVBWG Veterinary Containment Facilities: Design and Construction handbook,
http://tecrisk.com/projekte/projekt1/Handbook_070323.pdf
- (iv) OECD Best Practice Guidelines for BRCs,
http://www.oecd.org/document/36/0,3343,en_2649_34537_38777060_1_1_1_1,00.html
- (v) OECD Best Practice Guidelines on Biosecurity for BRCs,
<http://www.oecd.org/dataoecd/6/27/38778261.pdf>
- (vi) OECD Emerging Risks in the 21st Century: An Agenda for Action,
<http://www.oecd.org/dataoecd/23/56/19134071.pdf>
- (vii) OIE Aquatic Animal Health Code ,
http://www.oie.int/eng/normes/fcode/en_sommaire.htm
- (viii) OIE Handbook on Import Risk Analysis for Animals and Animal Products,
http://www.oie.int/eng/publicat/ouvrages/A_IRAvol1.htm
- (ix) OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals,
http://www.oie.int/eng/normes/mmanual/A_summry.htm
- (x) OIE Manual of Diagnostic Tests for Aquatic Animals,
http://www.oie.int/eng/normes/fmanual/A_summry.htm
- (xi) OIE Quality Standard and Guidelines for Veterinary Laboratories: Infectious Diseases,
http://www.oie.int/eng/publicat/ouvrages/A_112.htm
- (xii) OIE Terrestrial Animal Health Code,
http://www.oie.int/eng/normes/mcode/en_sommaire.htm
- (xiii) WHO 1997 Guidelines for the safe transport of infectious substances and diagnostic specimens,
http://www.who.int/entity/csr/resources/publications/biosafety/WHO EMC_97_3/en/index.html

- (xiv) WHO 2004 Laboratory Biosafety Manual - Third Edition,
http://www.who.int/entity/csr/resources/publications/biosafety/WHO_CDS_CSR_LYO_2004_11/en/index.html
 - (xv) WHO 2004 Transport of Infectious Substances: background to the amendments adopted in the 13th revision of the United Nations Model Regulations guiding the transport of infectious substances,
http://www.who.int/entity/csr/resources/publications/WHO_CDS_CSR_LYO_2004_9/en/index.html
 - (xvi) WHO 2005 Guidance on regulations for the Transport of Infectious Substances,
http://www.who.int/entity/csr/resources/publications/biosafety/WHO_CDS_CSR_LYO_2005_22/en/index.html
 - (xvii) WHO 2006 Biorisk management: Laboratory biosecurity guidance,
http://www.who.int/entity/csr/resources/publications/biosafety/WHO_CDS_EPR_2006_6/en/index.html
 - (xviii) WHO 2007 Guidance on regulations for the Transport of Infectious Substances 2007-2008,
http://www.who.int/entity/csr/resources/publications/biosafety/WHO_CDS_EPR_2007_2/en/index.html
 - (xix) WHO Life Science Research: Opportunities and Risks for Public Health. Mapping the Issues,
http://www.who.int/csr/resources/publications/deliberate/WHO_CDS_CSR_LYO_2005_20/en/
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