

《关于禁止发展、生产和储存细菌(生物)
及毒素武器和销毁此种武器的公约》
缔约国特设小组

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专家会议

2008 年 8 月 18 日至 22 日，日内瓦

临时议程项目 5

审议改善生物安全和生物安保，包括实验室病原体和
毒素的安全和安保的国家、区域和国际措施

生物安全和生物安保

履约支助股提交

摘 要

本背景说明介绍生物安全和生物安保两项术语，并研究了这两项术语的应用方式以及在不同场合的含义。随后审议了自上一次《公约》会议以来，以往关于生物安全和生物安保的协定、认识和提案。附件一(仅以英文)列示一些国际和区域组织开展相关活动的简要情况。附件二(仅以英文)列示新增技术信息的资料来源。

一、生物安全和生物安保的含义

1. 生物安全和生物安保概念处理相互关联但又截然不同的问题。生物安全是由来已久的一个概念，含义被广为接受，并有国际指南说明如何在各国付诸实施。生物安保是相对较新的术语，跟据使用场合不同意义也各有差异。

生物安全

2. 对生物安全的通常理解源自于世界卫生组织发布的关于实验室应用技术的实践指南。世卫组织《实验室生物安全手册》认为生物安全是“用以防止发生病原体或毒素无意中暴露及意外释放的防护原则、技术以及实践。”¹《实验室生物安全手册》列示专家对相关原则、技术和做法实施方式的指导。世卫组织鼓励所有会员国在制订和增强国家监管体制时，考虑此类概念。从而对国际指南做出调整，以适合各国确切要求。此类概念在公共、动物和植物卫生部门中是一致的，而且世卫组织、粮农组织和国际兽疫局之间的密切合作有助于制定相关指南与谅解。

3. 生物安全与《公约》规定的义务有关，即在开展《生物武器公约》未加禁止的活动时，确保采取必要安全预防措施，保护人口和环境。(见下文“以往的协定、谅解和提案”一节)。

生物安保

4. 生物安保一词在不同背景下可具有不同含义，因而更为复杂。根据有关世卫组织指南²，此短语同时从不同过程中演变而来，而且各自的应用方式也不相同。在《生物武器公约》中，最常见的运用是指建立和维护致病微生物、毒素和相关资源的安全与监督的机制，如《公约》2003年会议期间所讨论的。

¹ 世卫组织，《实验室生物安全手册》——第三版，http://www.who.int/csr/resources/publications/biosafety/WHO_CDS_CSR_LYO_2004_11/en/

² 世卫组织，生物风险管理：实验室生物安全保障指南，2006年9月，http://www.who.int/csr/resources/publications/biosafety/WHO_CDS_EPR_2006_6.pdf

5. 生物安保一词在人类、动物和植物卫生部门似乎并没有统一的含义。在兽医³和农业⁴领域，该词指保护生物资源不受外来或侵入物种的危害。

6. 但是，公共卫生领域的生物安保含义与《生物武器公约》更为接近。2004 年发布的《实验室生物安全手册》第三版前言指出在公共卫生领域，生物安保涉及“保护微生物资源免受盗窃、遗失或转移，以免因微生物资源的不适当使用而危及公共卫生”。世卫组织内部仍在不断努力，区分这一具体含义与其他场合生物安保应用之间的差异。2006 年，当世卫组织发布关于这一主题的首份详细指导出版物⁵时，这一短语已演变成为实验室生物安保。实验室生物安保指“对实验室内重要生物材料⁶的保护、控制和问责制，以避免未经许可接触、遗失、盗窃、滥用、转用或有意释放”。

7. 此类概念并非仅限于实验室，还可以扩展至各类使用用途为《公约》所禁止的资源开展工作的其他设施。例如，经合组织已制订了附属设施(生物资源中心)⁷生物安保最佳做法指南⁸。在这方面，生物安保指“机构和人员的安全保障措施和程序，用于防止病原体或部分病原体与有毒生物体以及生物资源中心保有、转让和/或提供的毒素的遗失、盗窃、滥用、转用或有意释放。”

³ 例如，《粮农组织 I-2 新城疫疫苗小规模生产和试验实验室基本手册》的术语汇编认为是“采取预防措施，减少传染致病剂流入人群的风险”。

⁴ 例如，《新西兰环境议会委员会》的术语汇编认为生物安保是“禁止害虫和有害生物进入新西兰，并根除与有效管理境内的害虫和有害生物”。http://www.pce.govt.nz/reports/pce_reports_glossary.shtml

⁵ 世卫组织，生物风险管理：实验室生物安全保障指南，2006 年 9 月，http://www.who.int/csr/resources/publications/biosafety/WHO_CDS_EPR_2006_6.pdf

⁶ 重要生物材料在此指“（根据生物材料所有人、使用者、保管人、看管人或监管者）要求对实验室内生物材料实行行政监督、控制、问责制以及特定的保护和监测措施，保护经济和历史（档案）价值，和/或保护人口不受其潜在危害。”重要生物材料可包括病原体和毒素，以及非病原体生物剂、疫苗株、食品、转基因生物、细胞成分、基因要素和外星生物样品。

⁷ 生物研究中心包括活细胞的服务提供者和贮藏室、生物体基因组以及生物系统遗传和功能的相关信息。

⁸ 经合组织生物资源中心生物安保最佳做法指南，2007 年 http://www.oecd.org/document/36/0,3343,en_2649_34537_38777060_1_1_1_1,00.html

生物安全与生物安保的区别

8. 2003 年《生物武器公约》会议中，一名代表使用了下列简洁陈述，帮助与会者区分生物安全和生物安保问题。

生物安全保护人们避免细菌的危害，而生物安保保护细菌免受人们不当使用。

尽管这些目标是相关的，而且均与《公约》有联系，但其目的仍截然不同。因此，生物安保概念有别于生物安全概念。实现这些目标的方式通常是类似的或相互增强的，但在有些情况下是相互冲突的。常见的冲突例子发生于危险病原体的运输中：出于生物安全考虑，此类病原体在运输过程中应予以明确标示，但从生物安保角度来看，运输病原体的标识可能增加盗窃或转用的风险。

二、以往的协定、谅解和提案

生物安全与《公约》

9. 生物安全与《公约》的宗旨与目标有关，《公约》第二条明确提及这一概念。该条要求缔约国将其拥有的任何生物武器“销毁或转用于和平目的”，并具体规定在实施时“应遵守一切必要的安全预防措施以保护居民和环境”。

10. 随后的审查会议一致认为“各缔约国应采取一切必要的安全预防措施，保护居民和环境，使之不受公约未加禁止的活动之害。⁹”这一项谅解从而拓展了对生物安全措施的要求，从第二条中的销毁与转用活动扩大至所有《公约》未加禁止的活动——包括生命科学领域内所有和平用途的科学和技术活动，以及所有保护和预防用途的活动。

生物安保与《公约》

11. 《公约》第三条和第四条一致发展了生物安保概念。

⁹ 第三次会议的最后文件，BWC/CONF/III/23，第一条第 5 段。

12. 第二、三和四次审查会议表示：“重视……关于实际保护实验室和设施的立法，以防未经许可获得或转移致病或毒性材料”¹⁰。第六次审查会议呼吁“所有缔约国采取适当措施，确保与公约相关的生物剂和毒素受到保护和保障，包括通过控制接触和操作此种物剂和毒素的措施。”¹¹

13. 第六次审查会议还呼吁缔约国“按照其宪法程序，采取立法、行政、司法和其他措施，包括刑事立法，旨在……确保实验室、设施和运输中的微生物剂或其他生物剂或毒素的安全和安保，以防止未经授权接触和移动此种物剂或毒素。”¹²

14. 缔约国 2003 年会议一致认为“全面而具体的国家措施”很重要，“以维护病原体收藏的安全并确保用于和平目的。各方一致确认生物安全措施和程序的重要作用，它们可确保这类危险物质不致落入有可能为了与《公约》相违反的目的而不当地使用这类危险物质的人的手中。”该会议还强调“有必要根据其义务和责任在国家一级开展活动，以加强和执行《公约》。为此，各缔约国一致认为以下几点很重要：审查各项可确保有效执行《公约》的禁止规定和可加强病原体及毒素的有效安全的国家法律措施，包括管制措施和刑事措施，并在必要时制定或修订这类措施。”¹³

15. 缔约国 2007 年会议审议了国家执行措施的不同方面，一致同意“对通过的措施进行定期国家审查的重要性，包括……更新与安全、安保和转让制度相关的物剂和设备清单。”¹⁴

以往关于生物安保的提案

16. 因此，现有的协定和谅解涵盖生物安保措施的必要性、用途、确保国内行动功效的需要以及现有安排的审查和增强机制。个别缔约国在《生物武器公约》2003 年会议期间提出的提案与这些谅解密切相关，涵盖生物安保措施的范围和内容，以及加强国内合作的方式。会议没有正式审议或通过这些提案，因此这些提案并无正式地

¹⁰ 第二次审查会议的最后文件，BWC/CONF.II/13，第四条第 4(b) 段，第三次审查会议的最后文件，BWC/CONF.III/23，第四条第 3(b) 段，第四次审查会议的最后文件，BWC/CONF.IV/9，第四条第 3(b) 段。

¹¹ 第六次审查会议的最后文件，BWC/CONF.VI/6，第三条第 9 段。

¹² 第六次审查会议的最后文件，BWC/CONF.VI/6，第四条第 11(三) 段。

¹³ 缔约国会议报告，BWC/MSP/2003/4，第二部分，第 3(b) 段。

¹⁴ 缔约国会议报告，BWC/MSP/2007/5，第 23 段。

位；这些提案以暑期 2003 年 11 月 14 日由主席编写的会议室文件形式分发。为便于参考，在此列出提案。

17. 关于相关生物安保安排范围的提案认为此类安排应：

- (一) 涵盖物剂、毒素和关键设备；
- (二) 涵盖设施、储存、运输和人员；
- (三) 具有成本效益；
- (四) 以风险管理方式为基础；
- (五) 以明确的国家准则为基础；
- (六) 区分场合，因为具体情况的差异导致无法统一管制；
- (七) 使用标准和监督机制；
- (八) 酌情修改现有监督和监管框架；
- (九) 处理生物安全和生物安保之间的宗旨与工具差异；及
- (十) 接受定期审查。

18. 关于相关生物安保安排内容的提案认为此类安排应包括：

- (一) 良好科学做法；
- (二) 灵活的国家控制名单；
- (三) 包装和标识要求；
- (四) 相关机构的接触控制和监督制度；
- (五) 人员的背景筛查；
- (六) 全面的整合监测活动；
- (七) 相关设施、运输系统和职员的身份识别与登记；
- (八) 对保有、运输、储存、使用相关资源和获准使用资源开展工作的人员，
创建并保存详细准确的记录。

19. 关于加强国内合作的提案应：

- (一) 确定政府领导机构或创建新的集中监督主管机构；
- (二) 制定国家生物安保执行计划；
- (三) 利用政府和非政府伦理监督团体，创立国家生物安保文化；
- (四) 努力协调认识并开展培训方案；及
- (五) 在最佳做法和其他没有法律约束力的准则中纳入生物安保措施。

建设生物安全与生物安保能力

20. 缔约国 2003 年会议一致认为“法律和宪法安排不同的各缔约国之间进行合作可产生积极的效应”很重要。“有能力这样做的缔约国不妨向提出请求的其他缔约国提供法律和技术援助，以协助它们拟订和/或扩大其在国家执行和生物安全领域的法律和管制条例。”¹⁵

21. 一些缔约国(和缔约国集团)明确表示，愿意考虑提供生物安全和生物安保方面的援助，包括澳大利亚、加拿大、古巴、欧洲联盟、德国、俄罗斯联邦、瑞士、大不列颠及北爱尔兰联合王国和美利坚合众国。缔约国可在《生物武器公约》的有限制访问网页上(<http://www.unog.ch/bwc/restricted>)获取更多详情。还欢迎感兴趣的各方与履行支助股联系。

22. 《公约》2003 年会议中提出的一些提案与通过双边安排建设相关能力有关，其中包括：生物安保人员交流，包括在国家监督机构内；生物安保培训；情报交流；制定和执行最低标准；传染病监测和应对；及伦理最佳做法。其他还有些提案着重于通过更多国际合作增强能力，其中包括：发展对生物安保含义的共识；制定生物安全和生物安保国际规范；统一国内生物安保体制；及鼓励世卫组织、国际兽疫局和粮农组织制定国际生物安保标准。

¹⁵ 缔约国会议报告，BWC/MSP/2003/4, 第二部分, 第 3 (b)(二)段。

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 organizations. These organizations have undertaken considerable work on these issues, much of which is relevant to the Convention. A basic outline of these organizations and major initiatives is provided below. Many of the organizations 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 Biosecurity¹. 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.

¹ 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 world².

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 handbook³.

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

² IBWG Biosafety Compendium on Regulations, Guidelines and Information Sources from around the World
<http://www.internationalbiosafety.org/english/internlCompendium.asp>

³ Veterinary Containment Facilities: Design and Construction handbook,
http://tecrisk.com/projekte/projekt1/Handbook_070323.pdf

research on livestock and poultry diseases: how to prevent the introduction of foreign animal 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 BRCs⁴. 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 BRCs⁵. 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

⁴ OECD Best Practice Guidelines for BRCs, http://www.oecd.org/document/36/0,3343,en_2649_34537_38777060_1_1_1_1,00.html

⁵ OECD Best Practice Guidelines on Biosecurity for BRCs, <http://www.oecd.org/dataoecd/6/27/38778261.pdf>

international organisations. It led to the publication of *Emerging Risks in the 21st Century: An Agenda for Action*⁶, 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"⁷. 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 Frameworks⁸ 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.

⁶ OECD Emerging Risks in the 21st Century: An Agenda for Action, <http://www.oecd.org/dataoecd/23/56/19134071.pdf>

⁷ Cartagena Protocol on Biosafety, Article 1, <http://www.cbd.int/biosafety/articles.shtml?a=cpb-01>

⁸ 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.

Implementing national biosafety frameworks

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

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 Assembly⁹. This resolution mandates the organization 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 specimens¹⁰; 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 substances¹¹; 2004 Laboratory Biosafety Manual - Third Edition¹²; 2005 Guidance on regulations for the Transport of Infectious Substances¹³; 2006 Biorisk management: Laboratory biosecurity guidance¹⁴; and 2007 Guidance on Regulations for the Transport of Infectious Substances 2007-2008¹⁵. 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).

⁹ WHA58.29: Enhancement of laboratory biosafety, http://www.who.int/gb/ebwha/pdf_files/WHA58/WHA58_29-en.pdf

¹⁰ 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

¹¹ 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

¹² 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

¹³ 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

¹⁴ WHO 2006 Biorisk management: Laboratory biosecurity guidance, http://www.who.int/entity/csr/resources/publications/biosafety/WHO_CDS_EPR_2006_6/en/index.html

¹⁵ 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

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 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 issues;¹⁶ 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*.¹⁷ 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*;¹⁸ the *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals*;¹⁹ the *Aquatic Animal Health Code*;²⁰ and

¹⁶ 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/

¹⁷ OIE Scientific and Technological Review: Biological Disasters of Animal Origin, http://www.oie.int/eng/publicat/rt/A_RT25_1.htm

¹⁸ OIE Terrestrial Animal Health Code, http://www.oie.int/eng/normes/mcode/en_sommaire.htm

¹⁹ OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals, http://www.oie.int/eng/normes/mmanual/A_summry.htm

²⁰ OIE Aquatic Animal Health Code, http://www.oie.int/eng/normes/fcode/en_sommaire.htm

the *Manual of Diagnostic Tests for Aquatic Animals*.²¹ 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.

29. The OIE also produces a number of other resources. The OIE *Quality Standard and Guidelines for Veterinary Laboratories: Infectious Diseases*²² 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*²³ 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.

²¹ OIE Manual of Diagnostic Tests for Aquatic Animals, http://www.oie.int/eng/normes/fmanual/A_summry.htm

²² OIE Quality Standard and Guidelines for Veterinary Laboratories: Infectious Diseases, http://www.oie.int/eng/publicat/ouvrages/A_112.htm

²³ 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

1. ABSA Task Force on Biosecurity White Paper on Understanding Biosecurity
<http://www.absa.org/0301bstf.html>
2. IBWG Biosafety Compendium on Regulations, Guidelines and Information Sources from around the World <http://www.internationalbiosafety.org/english/internlCompendium.asp>
3. IVBWG Veterinary Containment Facilities: Design and Construction handbook,
http://tecrisk.com/projekte/projekt1/Handbook_070323.pdf
4. OECD Best Practice Guidelines for BRCs,
http://www.oecd.org/document/36/0,3343,en_2649_34537_38777060_1_1_1_1,00.html
5. OECD Best Practice Guidelines on Biosecurity for BRCs,
<http://www.oecd.org/dataoecd/6/27/38778261.pdf>
6. OECD Emerging Risks in the 21st Century: An Agenda for Action,
<http://www.oecd.org/dataoecd/23/56/19134071.pdf>
7. OIE Aquatic Animal Health Code,
http://www.oie.int/eng/normes/fcode/en_sommaire.htm
8. OIE Handbook on Import Risk Analysis for Animals and Animal Products,
http://www.oie.int/eng/publicat/ouvrages/A_IRAvol1.htm
9. OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals,
http://www.oie.int/eng/normes/mmanual/A_summry.htm
10. OIE Manual of Diagnostic Tests for Aquatic Animals,
http://www.oie.int/eng/normes/fmanual/A_summry.htm
11. OIE Quality Standard and Guidelines for Veterinary Laboratories: Infectious Diseases,
http://www.oie.int/eng/publicat/ouvrages/A_112.htm
12. OIE Terrestrial Animal Health Code,
http://www.oie.int/eng/normes/mcode/en_sommaire.htm
13. 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

14. 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
 15. 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
 16. 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
 17. WHO 2006 Biorisk management: Laboratory biosecurity guidance,
http://www.who.int/entity/csr/resources/publications/biosafety/WHO_CDS_EPR_2006_6/en/index.html
 18. 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
 19. 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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