

《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》  
缔约国会议

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CHINESE ONLY

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2008 年会议

2008 年 12 月 1 日至 5 日，日内瓦

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

中国关于生物安全与生物安保的工作文件<sup>1</sup>

一、生物安全与生物安保的概念

1. 《禁止生物武器公约》(下称“公约”)要求缔约国采取必要措施，禁止和防止发展、生产、储存、获取、保有或转让生物武器。加强生物安全和生物安保对实现上述目标具有重要意义，是缔约国履行公约义务的重要内容之一。另一方面，确保缔约国全面、严格履约也是加强全球生物安全的重要、有效途径。

2. 生物安全和生物安保的概念既有重叠，又有区别。一般而言，在公约框架下，生物安全主要指防止致病微生物的意外泄露、加强从业人员的安全防护以保护人员及环境等实物保护措施。公约框架下的生物安保则指为防止未经授权获取、保存、使用、运输或蓄意释放致病微生物、从事生物恐怖主义活动而建立实施的生物材料保护、安全防范制度。两者相辅相成，互相促进，都应得到重视与加强。

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<sup>1</sup> 文后附有非正式英文译文。

## 二、中国的做法

3. 中国支持公约的宗旨和目标，高度重视生物安全与生物安保问题，严格执行公约相关条款及安理会第 1540 号决议，在加强生物安全与安保方面取得了很大进展。中国在 2003 年以来提交的相关工作文件中对此进行了详细介绍。现就近年来与公约有关的生物安全与安保工作做一些补充说明：

### (一) 实验室生物安全与安保

4. 进一步加强有关实验室安全的立法建设和执法力度。颁布多项实验室生物安全管理法律规章，制定了实验室生物安全操作规程，实验室物理防护等级分类以及实验室感染控制措施，防止实验室致病微生物意外泄漏。在执法方面严格了监管制度，明确了实验室资格审批程序和要求，不断完善对实验室的监督检查，普及了实验室认证管理制度，将农业、卫生医疗、教学、生产等领域的相关实验室、菌毒种库、生产设施等全部置于监管体系内。

5. 2007 年，启动《病原微生物实验室生物安全管理模式及示范研究》。该项目选择了一些具有代表性、不同类型、不同级别的生物实验室做出示范，旨在全面提高全国实验室生物安全建设和管理水平。

6. 为确保 2008 年北京奥运会期间生物实验室安全，制定相关预案并采取有力措施。

### (二) 人员防护和安保措施

7. 加强对生物领域科学家和从业人员的人员防护措施，要求其采用与其实验室安全等级相适应的人员防护装具，对进出生物实验室的程序进行严格规定。在安保方面，对上述人员实施准入审批管理。上岗前须通过专业和生物安全培训考核，要求其掌握相关法规、生物安全知识和防护技能。工作期间实施年度考核，建立培训、考核和健康记录，确保其遵守生物安全制度。

### (三) 病原微生物管理

8. 强化病原微生物管理，颁布《人间传染的病原微生物名录》、《动物病原微生物分类名录》等法律法规，对菌毒种的分类、保存、使用、运输、包装等进行严格管理。

9. 对病原微生物及生物制品的出入境也进行了严格规定。微生物、生物制品等特殊物品在出入境时，必须予以申报并接受卫生检疫，未经卫生检疫机关许可，不准出入境。

### (四) 应急机制建设

10. 2005 年，出台了《国家突发公共卫生事件应急预案》和《国家突发公共卫生事件医疗卫生救援应急预案》。对突发公共卫生事件的应急组织体系及职责，突发公共卫生事件的分级、预测预警和监测报告、应急反应和处理等作出详细规定。建立“国家病原微生物卫生应急实验室网络”，提高应对突发公共卫生事件的能力和病原微生物应急检测能力，促进相关工作的标准化和规范化。

## 三、中国的看法和建议

11. 加强生物安全与安保是缔约国履约工作的重要内容之一。缔约国应进一步加强生物安全体系和生物安全能力建设，保证致病微生物和毒素仅用于公约不加禁止的和平目的，防止其被用于生物武器或生物恐怖目的。建议缔约国在全面加强生物安全与安保建设时着重加强以下几方面工作：

- (一) 制定、完善实验室标准操作规范，加强实验室防护措施，防止致病微生物的意外泄漏；实行准入控制，防止未经授权的人员进入高风险设施。
- (二) 对致病微生物的保存、包装、运输、转让等环节严加管理，加强保卫措施。
- (三) 对从事与生物安全有关的生物科学研究和开发的机构和个人进行资格和能力认证。
- (四) 对生命科学研究做好风险评估，降低生命科学研究发表成果被滥用的风险。

## **BIOSAFETY AND BIOSECURITY**

Submitted by the People's Republic of China

[Unofficial translation]

### **I. Concepts of Biosafety and Biosecurity**

1. According to the provisions of the Biological Weapons Convention (hereinafter referred to as "the Convention"), States Parties should take appropriate measures to prohibit and prevent developing, producing, stockpiling, acquiring, retaining or transferring biological weapons. On one hand, enhancing biosafety and biosecurity capacity is of great importance to the realization of this goal and one of important aspects in the implementation of the Convention. On the other hand, ensuring the full and strict implementation of the Convention is an important and effective way to strengthen biosafety and biosecurity at the global level.
2. Concepts of biosafety and biosecurity deal with related but different issues. Biosafety correlates to the obligation under the Convention to ensure that physical protection measures are taken, which prevent the accidental release of pathogenic microorganisms and strengthen personal protection, with a view to protecting population and the environment. In the setting of the Convention, biosecurity is commonly used to refer to security and oversight mechanism of pathogenic microorganisms and relevant resources, to prevent unauthorized acquisition, retention, use, transportation or deliberate release of these materials and bioterrorism activities. These two concepts supplement and improve each other and should be enhanced at the same time.

### **II. China's Practice**

3. China has all along supported the principles and objectives of the Convention and attached great importance to biosafety and biosecurity. China has implemented all the provisions of the Convention related to biosafety and biosecurity as well as the Security Council Resolution 1540 in a comprehensive and stringent manner. We made great achievements in this area and the detailed information can be found in the working papers submitted by China to the Meetings of Experts since 2003. The latest developments were made as follows:

#### **Laboratory Biosafety and Biosecurity**

4. National legislation and law enforcement have been further enhanced. Laws and regulations on laboratory biosafety management were promulgated, which established handling guidelines of laboratory biosafety, physical protection levels of laboratories and measures on laboratory infection control, so as to prevent accidental release of pathogenic microorganisms. On law enforcement, an oversight mechanism has been strengthened, which made clear the procedures and requirements of laboratory qualification licensing, improved the supervision and inspections

of the laboratories, and popularized the laboratory accreditation system. In doing so, all the relevant laboratories, bacteria or virus reserve and production facilities in the areas of agriculture, health, medical treatment, education and production have been put under the oversight of relevant competent authorities.

5. In 2007, China started a project on mode and demonstration study on laboratory biosafety management. This project chose some typical biological laboratories of different types and levels to play an exemplary role in the purpose of enhancing biosafety capacity building and management of laboratories nationwide.

6. In order to ensure the safety of biological laboratories during the 2008 Beijing Olympic Games, emergency response preparedness and concrete measures have been put into place.

### **Personnel Protection and Biosecurity Measures**

7. Personnel protection measures of biological scientists and staff have been strengthened. Relevant personnel have to be equipped with personnel protection equipment according to the safety level of the laboratories. There are also stringent regulations on the procedures of entering and exiting biological laboratories. With regard to security approaches, a licensing system on the access to the laboratories has been set up. Personnel working in the laboratories must receive training on professional and biosecurity knowledge and go through relevant exams to ensure that they know well relevant laws, regulations, biosecurity knowledge and protective skills before they get licenses for their jobs. An annually check-up system has been set up. The records of training, check-up and health status have to be kept to make sure that biosafety and biosecurity rules and regulations are strictly observed.

### **Control of Pathogenic Microorganisms**

8. China enhanced the control of pathogenic microorganisms and strengthened the management on classification, storage, use, transportation and wrapping of bacteria and virus through promulgating laws and regulations such as List of Human Infected Pathogenic Microorganisms, List of Animal Pathogenic Microorganisms etc.

9. There are also strict regulations on the import and export of pathogenic microorganisms and biologics. Anyone who is going to import or export special items such as pathogenic microorganisms or biologics, has to declare and receive quarantine. Without licenses from quarantine office, it is not allowed to import or export.

### **Emergency Response System**

10. National Preparedness of Response to Public Health Emergencies and National Preparedness of Response to Medical Rescue on Public Emergencies were promulgated in 2005, which stipulated the functions and responsibilities of relevant competent authorities responding to public health emergencies, and the classification, surveillance, reporting, emergency response, damage control of such emergencies. With the setting up of National Laboratories Network on Response to Public Health Emergencies, the capacity of response to public health emergencies

and detection of pathogenic microorganisms have been enhanced, and the relevant standardized procedures promoted.

### **III. China's Perspectives and Proposals**

11. Strengthening biosafety and biosecurity is one of important aspects in the implementation of the Convention. States Parties should further improve their biosafety and biosecurity systems and relevant capacity building, assuring pathogenic microorganisms and toxins be used for peaceful purposes not prohibited by the Convention, and not be used for biological weapon or bioterrorism purposes. When States Parties building their biosafety and biosecurity capacity, the following aspects may be paid more attention:

- (i) To establish or improve laboratory standardized biosafety practice and strengthen laboratory protective measures with a view to preventing the accidental release of pathogenic microorganisms. To implement licensing approval on the access to facilities with high risks so as to prevent unauthorized access.
- (ii) To reinforce security measures and management in the storage, wrapping, transportation and transfer of pathogenic microorganisms.
- (iii) Organizations and individuals engaged in biological research and development activities which have high risks in biosecurity aspect should be accredited according to the evaluation of their qualifications and capabilities.
- (iv) To carry out risk assessments on the research of life sciences and reduce the risks of abusing the achievements in this field.

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