《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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议程项目 5

审议增强国内落实,包括执行国家立法的 方式方法,加强国内体制以及国内执法机 构之间的协调

# 中国关于《禁止生物武器公约》国家履约和 区域履约合作的工作文件

# 中国提交

中国一贯支持《禁止生物武器公约》(下称"公约")的宗旨和目标,全面忠实履行公约义务,在履约立法、执法、机构建设、相关合作方面采取有效措施,确保全面、严格地执行公约各项条款。中国在加强国家履约和区域履约合作方面的做法和建议如下:

一、中国的做法

(一) 立法

中国严格执行公约各项条款,颁布和实施了一系列法律法规,内容涵盖公约禁止条款、 出口管制、生物安全及安保、公共卫生、传染病监控等领域,形成了较为完备的履约法律 体系。相关法律法规详见中国在 2003 年专家组会上提交的工作文件《中国与履行〈禁止生

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物武器公约>相关的法律法规汇编》。2003年以来,根据履约需要,中国不断完善履约立法工作,进一步制定和修订了以下相关法律法规:

# 1. 生物防扩散与出口管制

2005年,中国颁布了《两用物项和技术进出口许可证管理办法》,对生物两用物项和技术出口的许可证制度、许可证的监督检查、许可证管理目录及惩处办法做了详细规定。

2006 年,中国修订了《中华人民共和国生物两用品及相关设备和技术进出口管制条例》的管制清单,增加了 SARS 病毒等 13 种病菌(毒)种和 1 种设备,扩大了管制范围。

# 2. 生物安全

在实验室安全、菌毒种保藏和运输方面,2003年以来,中国颁布了《病原微生物实验室生物安全管理条例》、《人间传染的高致病性病原微生物实验室和实验活动生物安全审批管理办法》、《人间传染的病原微生物名录》、《可感染人类的高致病性病原微生物菌(毒)种或样本运输管理规定》、《兽医实验室生物安全管理规范》、《高致病性动物病原微生物实验室生物安全管理审批办法》、《动物病原微生物分类名录》等多项法律规章。上述法规对病原微生物分类和管理,菌毒种或样本的运输和保藏,实验室资格及其活动的审批程序和要求,监督管理和法律责任等做出了明确规定。

在生物制品管理方面,中国于 2004 年至 2005 年修订了《兽药管理条例》,制定了《兽药注册办法》、《新兽药研制管理办法》,对兽药及兽用生物制品的注册、生产、科研、管理做出明确规定,并制定了相应罚则。

在转基因生物安全方面,中国于 2004 年颁布实施了《进出境转基因产品检验检疫管理办法》,规定由国家质量监督检验检疫总局负责全国进出境转基因产品的检验检疫管理工作,并对过境转移的农业转基因产品实行许可制度。

#### 3. 传染病监控及应对

2004年,中国重新修订了《中华人民共和国传染病防治法》,建立传染病监测制度,完善传染病的疫情报告、通报和公布制度。

2005年,中国制定了《国家突发公共卫生事件应急预案》和《国家突发公共事件医疗

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、监测、预警和报告、应急反应、善后处理等,作出详细规定。

2005年,中国制定了《重大动物疫情应急条例》,规范了疫情应急工作的程序和步骤,明确了政府主管部门、企业和个人的法律责任,完善了重大动物疫情快速反应机制。

# (二) 执法

中国政府高度重视执法,本着"执法必严,违法必究"的原则,采取有效措施,确保履约法律法规的贯彻落实,建立了由外交部、国防部、农业部、卫生部、商务部、海关总署等相关政府主管机构组成的履约机制。

- 1. 在生物防扩散与出口管制方面,中国政府对生物两用物项和技术实施了有效的出口管制,采取了国际通行的许可证管理制度、最终用户和最终用途证明制度、清单控制方法及全面控制原则。中国政府重视出口管制机构建设。商务部是国家许可证审批机关。许可证审批部际协调相关部门包括商务部、卫生部、农业部及国家发展和改革委员会。中国于 2004 年成立了由外交部、商务部、国家发展和改革委员会、海关总署等部门组成的防扩散出口管制应急协调机制,负责迅速查清、及时制止涉嫌违反出口管制法规的活动并依法处理。
- 2. 在生物安全方面,农业部、卫生部等国家主管部门加强对生物实验室的安全管理,严格执行菌毒种的供应、使用、包装、运输等方面的规定,强化进出境检验检疫工作,建立了农业部、国家发改委、商务部、科技部、卫生部等组成的转基因生物安全部际联席会议制度。
- 3. 在传染病监控及应对方面,农业部、卫生部等国家主管部门根据相关法律法规要求,在全国范围内建立了人类和动植物疫情监测与防控体系,完善重大疫情应急预案,成立应急专家队伍,强化疫情监测和报告,及时公布疫情,有效控制和消除重大突发疫情的危害。
- 4. 在法规宣传和企业教育方面,中国政府重视对履约执法人员的教育和培训,通过制定执法规范、开展执法培训等措施,提高其执法水平和能力。政府主管部门通过举办履约政策法规培训班、研讨会和发放宣传手册等形式,向企业宣传有关国际条约及国家履约

法律法规,要求企业认真执行,依法经营。

### (三) 区域履约合作

近年来,中国积极开展履约合作,举办并参与了一系列履约相关研讨会,与区域各国 交流履约经验和做法,探讨提升履约能力的应对措施,取得了良好效果。

中国于 2006 年 7 月举办了安理会第 1540 号决议亚太地区执行情况研讨会。来自亚太地区的 20 多个国家和国际组织就执行多边防扩散条约、加强出口管制及执法措施等问题进行了深入的讨论。

中国参加了去年日本举办的"生物恐怖主义预防与危机管理"亚洲地区研讨会,介绍了中国在防范生物恐怖主义及危机管理方面的做法及主张。

中国多次举办生物安全和传染病监控国际研讨会,并与美国、加拿大、东盟、欧盟等保持着双边交流。

#### 二、中国的看法和建议

- (一)制定国家履约措施是缔约国履行公约的基本义务,也是全面加强公约有效性的重要内容。缔约国可从以下几方面进一步加强国家履约:
- 第一,缔约国有义务根据公约规定及其宪法程序,建立符合各国国情的履约法律体系,并定期对履约立法进行审议和评估,适时加以修订。第二,采取有效措施,严格执法,依法惩处违法行为。第三,加强履约相关部门之间的分工及协调,完善机制建设,提高执法能力。第四,宣传和普及履约政策法规,提高企业、科研、教育机构和人员知法、守法和自律意识。
- (二)促进全面、忠实履行公约义务符合各国利益,需要国际社会的共同努力。缔约国应积极支持并参与履约领域的国际合作和区域合作,在平等、协作、互相尊重的基础上,通过技术交流、资金支助、地区性研讨会等形式,相互借鉴成功的经验和做法,帮助有关国家提升履约能力和水平。

[UNOFFICIAL TRANSLATION]

# National Implementation and Regional Cooperation on Implementation of the Biological Weapons Convention

Working Paper Submitted by the People's Republic of China

China has all along supported the principles and objectives of the Biological Weapons Convention (hereinafter referred to as "the Convention") and fulfilled its obligations in a comprehensive and earnest manner. A series of effective measures have been taken in the fields of national implementation legislation, law enforcement, institutionalization and international cooperation to ensure the comprehensive and effective implementation of the Convention. Hereunder are China's practice and proposals on national implementation measures and regional cooperation.

#### I. China's Practice

# i. National Legislation

The Chinese Government has rigorously implemented all articles of the Convention. A series of laws and regulations, which cover the whole range of prohibition, export control, biosafey and biosecurity, public health and infectious diseases surveillance, have been promulgated and implemented. A comprehensive implementation legal system has taken shape. The detailed information can be found in the working paper entitled "National Implementation Measures and Biosecurity and Oversight Mechanism: Practice and Proposals" submitted by China to the 2003 Meeting of Experts to the Convention. In recent years, reviews and updates have been carried out to meet the requirements of the changing situation. Since 2003, laws and regulations were promulgated or revised as follows:

#### a. Non-proliferation and Export-control

In 2005, Measures on Administration of Import and Export License of Dual-use Goods and Technologies was promulgated. It clearly stipulates the licensing system of

biological dual-use items and technologies, examination and grant of license, control list and punishment for violations.

In 2006, the Export Control List of Regulations of the People's Republic of China on Export Control of Dual-Use Biological Agents and Related Equipment and Technologies was updated by adding thirteen kinds of pathogens, bacteria and virus, including SARS and one kind of equipment.

# b. Biosafety and Biosecurity

With regard to the safety and security of biological laboratory, storage and transport of pathogens and virus, the following laws and regulations have been put in place since 2003: Regulations on Biosafety Management in Pathogenic Microorganism Laboratories, Measures on the Administration of the Examination and Approval of Human Infected Highly Pathogenic Microorganism Laboratories and Biosafety of such Laboratory's Activities, List of Human Infected Pathogenic Microorganisms, Regulations on Transportation of Human Infected Highly Pathogenic Bacterium (virus) or Its Specimen, Guidelines on Biosafety of Veterinary Laboratories, Measures on the Administration of the Examination and Approval of Biosafety Management in Highly Pathogenic Animal Microorganism Laboratories, List of Animal Pathogenic Microorganisms. They stipulate in detail the classification and management of pathogens and microorganisms, the storage and transport procedures of bacteria, virus and their specimens, examination and grant procedures regarding the qualifications of laboratories and their activities, the supervision and liabilities, etc.

With regard to the supervision of biological products, from 2004 through 2005, the Regulations of the People's Republic of China on the Administration of Veterinary Drugs was revised and Measures for Registration of Veterinary Drugs, Measures on the Administration of the Research and Production of Veterinary Drugs promulgated. They establish detailed procedures on the registration, production, research and supervision of the veterinary drugs and veterinary biological products, as well as the punishment provisions.

With regard to biosafety of transgenic living things, Measures for the Administration of Quarantine Inspection on Import and Export of Transgenic products was promulgated and implemented in 2004. It stipulates that the General Administration of Quality Supervision Inspection and Quarantine is the competent authority responsible for quarantine inspection on import and export of transgenic products. A licensing system is established on the agriculture transgenic products in transit.

# c. Infectious diseases surveillance and response

The amended Law of the People's Republic of China on the Prevention and Control of Infectious Diseases was published in 2004, which establishes the infectious diseases surveillance system and improves the system of reporting, notifying and publishing regime for infectious diseases.

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

Regulations on Response to Severe Animal Epidemics was promulgated in 2005, which standardizes the procedures for diseases emergency response, stipulates the responsibilities of the competent authorities, enterprises and individuals, and improves the emergency response mechanism.

#### ii. Law Enforcement

The Chinese Government attaches great importance to the law enforcement and adheres to the principle of "enforcing the law strictly and punishing all offenders". A series of effective administrative measures has been taken and improved to ensure the implementation of relevant laws and regulations. A national implementation mechanism, which consists of such government's organs as Ministry of Foreign Affairs, Defense, Agriculture, Health, Commerce and Chinese Customs, has been put in place.

- a. In non-proliferation export control, the Chinese Government imposes effective export control on dual-use biological agents and related equipment and technologies. China's legislation on export control embraces such international practice as licensing system, end-user and end-use certification, the establishment of list control and the "catch-call" principle. The Chinese Government attaches great importance to the establishment of an effective export control mechanism. Ministry of Commerce is the national licensing authority. The competent government departments involved in inter-agency license review include Ministry of Commerce, Health, Agriculture, and National Development and Reform Commission. In 2004, China established an inter-agency contingency mechanism for export control, which consists of Ministry of Foreign Affairs, Ministry of Commerce, National Development and Reform Commission. The mechanism is responsible for investigating suspected proliferation cases, stopping proliferation activities and punishing violations accordingly.
- b. With regard to biosafety and biosecurity, management of the safety of biological laboratories has been strengthened. The regulations on supply, use, packing and transportation of bacteria and virus have been rigorously implemented. The quarantine inspection of import and export of related items has been enhanced. An inter-ministerial mechanism on the safety of transgenic products has been established, which consists of Ministry of Agriculture, Commerce, Science and Technology, Health.
- c. With regard to infectious diseases surveillance and response, Ministry of Agriculture, Ministry of Health and other competent authorities jointly established a nation-wide human, animal and plant diseases surveillance, prevention and control system. The preparedness of emergency response has been improved, an expert team established, and the diseases surveillance, reporting and publishing system enhanced. Therefore, the effective control and reduction of the harmful consequences of severe outbreak of diseases can be achieved.
- d. The Chinese Government made unremitting efforts in improving law enforcement capacity through adopting best practices for law enforcement and educating and training law enforcement personnel. The publicity of relevant laws and regulations has been enhanced through organizing regular training courses and lectures and distributing

pamphlets, with a view to helping the enterprises rigorously implement relevant laws and regulations and run their business accordingly.

# iii. Regional Cooperation on implementation of the Convention

In recent years, China has been fully engaged in cooperation on implementation of the Convention. By holding and taking part in a series of seminars, China exchanged practice and experience with regional countries on national implementation measures with a view to improving implementation capacity.

In July 2006, China hosted the Seminar on Implementing the Resolution 1540 in the Asia Pacific. Representatives from more than 20 Asian Pacific countries and Inter-governmental Organizations held in-depth discussions on implementing multilateral non-proliferation treaties, strengthening export control and law enforcement.

At the 2006 Asian Seminar on Prevention and Crisis Management of Biological Terrorism held in Japan last year, China provided detailed information on its practice and propositions on combating against bio-terrorism and crisis management.

China organized several international seminars on biosafety and infectious diseases surveillance. Bilateral exchanges have been carried out between China and the USA, Canada, ASEAN, and EU, etc.

#### II. China's Perspectives and Proposals

i. Adopting effective national implementation measures constitutes basic obligations for the States Parties, as well as important elements for strengthening the effectiveness of the Convention in a comprehensive manner. States Parties could further enhance their national implementation in the following respects:

Firstly, States Parties are obligatory to establish an implementation legal system in accordance with the Convention and respective constitutional process and in light of

national situations. Reviews, assessment and updates should be carried out in a timely manner.

Secondly, a series of effective administrative measures should be adopted to ensure the strict law enforcement and punish the violations accordingly.

Thirdly, a national implementation mechanism with clear division of responsibility and effective coordination should be enhanced and the law enforcement capacity improved.

Fourthly, the publicity of relevant policies and laws should be enhanced with a view to raising the awareness and self-discipline of relevant enterprises, research and education institutions and personnel.

ii. Promoting comprehensive and forceful implementation of the Convention is in the interest of all and demands joint efforts of the international community. States Parties should actively support and take part in international and regional cooperation on implementing the Convention. On the basis of equality, cooperation and mutual respect, States Parties should exchange successful experience and practice and provide assistance to those countries in need through technological exchanges, financial support and regional workshop, to help improve implementation capacity.

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