

BEIJING ON BIOHAZARDS: Chinese Experts on Bioweapons Nonproliferation Issues

Amy E. Smithson, Editor

THE JAMES MARTIN CENTER FOR NONPROLIFERATION STUDIES

The James Martin Center for Nonproliferation Studies (CNS) strives to combat the spread of weapons of mass destruction by training the next generation of nonproliferation specialists and disseminating timely information and analysis. A research center at the Monterey Institute of International Studies, CNS is the largest nongovernmental organization in the United States devoted exclusively to research and training on nonproliferation issues.

For more information about CNS, see www.cns.miis.edu

James Martin Center for Nonproliferation Studies
Monterey Institute of International Studies
460 Pierce Street, Monterey, CA 93940, USA
Tel: +1 (831) 647-4154; Fax: +1 (831) 647-3519; E-mail: cns@miis.edu

CNS gratefully acknowledges the support of the Carnegie Corporation of New York for the preparation and publication of *Beijing on Biohazards*.

Policy recommendations, statements of fact, and opinions expressed in this Occasional Paper are the responsibility of the authors alone and do not imply the endorsement of the Center for Nonproliferation Studies or Monterey Institute of International Studies. Authors' institutional affiliations are noted only for the purpose of identification.

ISBN 978-0-9798703-0-9

©Monterey Institute of International Studies, August 2007

TABLE OF CONTENTS

ABOUT THE CONTRIBUTORS	iii
LIST OF ACRONYMS	ix
LIST OF TABLES	x
1. INTRODUCTION — <i>Amy E. Smithson</i>	1
2. CONTEMPLATING THE THREAT OF BIOLOGICAL WEAPONS PROLIFERATION— <i>Liu Jianfei</i>	13
3. LABORATORY BIOSAFETY OF PATHOGENIC MICROORGANISM IN CHINA— <i>Li Jinsong</i>	31
4. CHINESE BIOSAFETY LAWS AND REGULATIONS, INCLUDING MATTERS OF BIOSECURITY AND OVERSIGHT OF GENETIC ENGINEERING ACTIVITIES— <i>Hu Longfei, Xiang Dapeng, Shi Yongxia, Huang Jicheng, Zheng Kui, Hong Ye, Li Xiaobo, and Xing Luqin</i>	47
5. EFFORTS TO STRENGTHEN BIOSAFETY AND BIOSECURITY IN CHINA— <i>Wang Qian</i>	71
6. BIOLOGICAL INSPECTIONS IN IRAQ: LESSONS FOR BWC COMPLIANCE AND VERIFICATION— <i>Yang Ruifu</i>	91
7. PUTTING THE NON-PROLIFERATION OF BIOLOGICAL WEAPONS ON THE RIGHT TRACK— <i>Pan Zhenqiang</i>	107
8. OBSERVATIONS ON CHINA’S NEW BIOSAFETY AND BIOSECURITY FRAMEWORK — <i>Julie E. Fischer</i>	131
9. READING THE NONPROLIFERATION TEALEAVES FROM <i>BEIJING ON BIOHAZARDS</i> ESSAYS — <i>Bates Gill</i>	137
APPENDIX: CHINA’S CURRENT LAWS AND REGULATIONS RELATED TO BIOSAFETY, BIOSECURITY, OVERSIGHT OF ACTIVITIES INVOLVING GENETIC ENGINEERING, BIOSAFETY EQUIPMENT AND FACILITIES, MANAGEMENT OF MEDICAL WASTES, AND STORAGE, PACKING, AND SHIPMENT OF PATHOGENS.....	A

About the Contributors

Amy E. Smithson, Ph.D.

Amy Smithson specializes in in-depth field research on issues related to chemical and biological weapons proliferation, threat reduction mechanisms, defense, and homeland security. Building issue alliances across communities that might not normally work together, Smithson's work recommends practical steps that blend technical and policy instruments to reduce chemical and biological weapon threats and to enhance disaster preparedness and response capabilities. Before joining the Center for Nonproliferation Studies, Smithson worked at the Center for Strategic and International Studies and the Henry L. Stimson Center, where in January 1993 she founded the latter's Chemical and Biological Weapons Nonproliferation Project to serve as an information clearinghouse, watchdog, and problem-solver regarding chemical and biological weapons issues. Previously, she worked for Pacific-Sierra Research Corporation and the Center for Naval Analyses. The author, co-author, or editor of over 15 books and book-length reports, as well as numerous articles, Smithson holds a Ph.D. in political science from George Washington University, an MA in international relations from Georgetown University, and a BA in political science and Russian from the University of North Carolina, Chapel Hill.

Liu Jianfei, Ph.D.

Liu Jianfei is a professor and research fellow at the Institute of International Strategic Studies, the Central Party School of the Communist Party of China, and director of the division of Chinese Foreign Affairs of the Institute. A specialist in international relations, Liu has most recently focused his research on international strategy and security, relationships between the great powers, China's foreign policy, and U.S. foreign policy. His more specific research projects include Japanese factors of Sino-U.S. relations in the 21st century, cultural factors of Sino-U.S.-Japan relations, Chinese democracy and Sino-U.S. relations, and reform of the United Nations and China's diplomacy. His major books include *America and Anti-Communism: Ideology-based U.S. Foreign Policy*, *Sino-U.S.-Japan Strategic Relations in 21st Century*, *Sino-U.S.-Japan Relations 1899-1999*, and *The Great Game: China's Tai Ji vs. America's Boxing*. Liu was also the editor-in-chief of the journal *Political Culture and Sino-U.S.-Japan Relations*. In addition, he has published dozens of articles in academic journals such as *World Economics and Politics*, *Contemporary International Relations*, and *American Studies Quarterly*. He is a contributor to *People Daily*, *Jiefangjun Bao*, *Outlook Weekly*, *Global Times*, *Study Times*, *Global*, and other publications. He is often interviewed by media such as CCTV.

Dr. Liu earned his B.A. in politics from Qiqihar Normal College in Heilongjiang (1982), his M.A. in international politics from China Renmin University (1989), and his Ph.D. in international politics from Peking University (1999). He also received graduate training in government at the London School of Economics and Political Science in

1993-1994. In 2003-2004, he was a visiting scholar at the Fairbank Center for East Asian Research of Harvard University and at the Atlantic Council of the United States.

Li Jinsong, MD

Li Jinsong currently serves in three capacities. He is a Professor of Environmental Microbiology Pollution and Assessment at the Institute of Microbiology and Epidemiology of the Academy of Military Medical Sciences, focusing on the microbiology of indoor air and airborne infection and on the environmental risk assessment of microbiology pollution. He is also the Deputy of the State Key Laboratory of Pathogens and Biosecurity and the Director-in-Chief of the Laboratory of Biosafety at the Institute of Microbiology and Epidemiology. His other research concentrations at present are microbial vaccine aerosol inhalation immunity, particularly the analysis of DNA vaccine and recombinant vaccine, where his work centers on the mucosal immunity and immune responses in both systemic and secretory immune compartments using a vaccine immunization administered by aerosol. Dr. Li's prior research at the Institute, where he served as assistant and associate professor prior to his promotion, was on the use of molecular and immunology techniques to detect and identify hantaviruses.

In 1987, he gained his B.A. degree in Biology from AnHui Normal University. Li subsequently earned both his M.A. in Microbiology in 1992 and his Doctor of Medicine in 2004 from the Academy of Military Medical Sciences. Dr. Li is widely published in national peer-reviewed journals, holds leadership positions in pertinent professional societies, has been a reviewer for over three professional journals, and serves on China's national laboratory biosafety accreditation committee. Since 2004, Dr. Li has also been a Plurality Professor at Beijing Industrial University.

Hu Longfei, MD, MPH

Since 1997, Hu Longfei has served as the director and chief epidemiologist, Department of Health and Quarantine, Guangdong Health and Quarantine Bureau, China. In addition to his routine duties, Dr. Hu has directed specialized efforts to detect, prevent, and respond to public health problems, such as a program of anti-SARS protective measures from February to July 2003 and a bioterrorist preparedness program related to anthrax from October to December 2001, both at Guangzhou Baiyun International Airport. Dr. Hu's research interests include epidemiology, the surveillance and control of communicable diseases, preparedness for public health emergencies, and biostatistics and biostatistics software. Prior to assuming his current position, Dr. Hu was a research fellow for a year at the Department of Epidemiology in the Medical Research Institute of Tokyo Medical and Dental University in Japan. From 1991 to 1996, he was an epidemiologist with the Huangpu Health and Quarantine Service in Guangzhou and from 1986 to 1988 an assistant researcher at the Health and Preventive Institute of Chenzhou City, Hunan Province.

Dr. Hu received his medical degree from Hunan Medical University (1986), his masters in public health, specializing in epidemiology, from the West China University of Medical Science (1991), and his bachelors of medicine from Hunan Medical University (1986). In August 2003, the General Administration of Quality Supervision, Inspection, and Quarantine of China recognized him with both the First Rank Hero-prize in anti-SARS activity and the National Outstanding Young Scientist awards. He has also been appointed as an expert to government panels and professional association committees addressing such matters as infectious disease control, health controls at international airports, and cholera prevention and control. Intermittently, Dr. Hu has taught courses in epidemiology and public health at the university level, and for well over a decade he has made presentations at numerous international conferences and published in the professional journals of epidemiology and public health.

Wang Qian

Wang Qian serves in the Department of Arms Control and Disarmament of China's Ministry of Foreign Affairs. She has worked in the department's biological and chemical division since May 2005. Ms. Wang earned her B.A. in English Language and Literature from Beijing Foreign Studies University in 2004. After a year of training with the Ministry of Foreign Affairs, she assumed her responsibilities in the Department of Arms Control and Disarmament. From February to May 2007, she was a visiting fellow at Center of Nonproliferation Studies of the Monterey Institute of International Studies. The focus of her research during this fellowship was China's efforts to strengthen biosafety and biosecurity.

Yang Ruifu, Ph.D.

Yang Ruifu holds three positions simultaneously. He is a professor of microbial genomics at the Institute of Microbiology and Epidemiology of the Academy of Military Medical Sciences, focusing on structural, comparative and functional genomic research on *Y. pestis* and SARS-CoV. He is also the Deputy Director of the State Key Laboratory of Pathogens and Biosecurity and the Director-in-Chief of the Laboratory of Analytical Microbiology at the National Center for Biomedicine Analysis. His other research concentrations at present are microbial forensics, particularly the analysis of different pathogens using DNA fingerprinting techniques, analytical chemical methods, and the gene chip, and microbial diagnostics, where his work centers on the rapid detection and identification of medically important microorganisms using different techniques, including DNA probe hybridization, PCR, biochips, and biosensors. Dr. Yang's prior research at the Institute, where he served as assistant and associate professor prior to his promotion, was on the use of molecular techniques to detect and identify medically important microorganisms and on *Legionella*. In 1996, Yang was also a visiting professor at Gifu University in Japan.

Awarded his B.A. degree in Medicine from Heibei Medical University in 1985, Yang earned both his M.A. in Microbiology and Immunology in 1988 and his Ph.D. in Microbiology in 2002 from the Academy of Military Medical Sciences. An invited lecturer and presenter at numerous peer-reviewed meetings, Dr. Yang is widely published in international peer-reviewed journals, holds leadership positions in pertinent professional societies, has been a reviewer for over fifteen professional journals, and sits on the editorial boards of five publications, namely *Genomics*, *Proteomics & Bioinformatics*, *Acta Microbiologica Sinica*, the *Medical Journal of the Chinese People's Liberation Army*, the *Journal of Preventative Medicine of the Chinese People's Liberation Army*, and the *Bulletin of the Academy of Military Medical Sciences*.

Major General Pan Zhenqiang (ret.)

Major General Pan Zhenqiang (ret.) is Deputy Chairman of China Foundation for International Studies and the former director and professor at the Institute of Strategic Studies of the National Defense University (NDU), People's Liberation Army. As a security analyst, he has conducted research and taught on a wide range of international security and arms control issues since the early 1970s. He has authored numerous papers and articles on strategic and military matters. In addition to his current post, General Pan is also a Senior Adviser to the International College of Defense of the NDU, to the Center for Strategic Studies of the Chinese Academy of Engineering Physics, and to the Chinese People's Association for Peace and Disarmament as well as a Senior Advisory Member of China's Committee at Council of Security Cooperation in the Asia-Pacific. General Pan is the Deputy President of Shanghai Institute for International Strategic Studies and a Council Member of the Chinese People's Institute of Foreign Affairs and of the China Arms Control and Disarmament Association. Furthermore, General Pan is an Executive Member of the Council of the China Reform Forum and a Guest Research Fellow at a number of China's research institutions and civilian universities.

General Pan has developed extensive contacts abroad through research and professional activities. He was a research fellow at a number of US universities, including the U.S. National Defense University (1987), Stanford University (1988-1989), and Harvard University (1999-2000). He is now a Member of the Executive Committee of the Council of Pugwash Conferences on Science and World Affairs; a Member of the Weapons of Mass Destruction Commission in Sweden; a Member of the Council Advisers of the Oxford Research Group in the United Kingdom; and a Member of the Pacific Council in the United States.

Julie E. Fischer, Ph.D.

Dr. Julie E. Fischer leads the Henry L. Stimson Center's Global Health Security program. Dr. Fischer is a former Council on Foreign Relations International Affairs Fellow (2003-04) and American Association for the Advancement of Science Congressional Fellow (2000-01). As professional staff with the Senate Committee on Veterans' Affairs, she worked on issues related to domestic terrorism preparedness and the consequences of biological, chemical, and radiological exposures during military service. She served as a senior research fellow at the University of Washington/Seattle Biomedical Research Institute, and an independent consultant to a Thai-U.S. collaboration aimed at strengthening Thai capacity to identify and control emerging infections of regional and global significance. Some of her recent publications include *Stewardship or Censorship: Balancing Biosecurity, the Public's Health, and the Benefits of Scientific Openness* (Stimson Center, 2006) and *Speaking Data to Power: Science, Technology, and Health Expertise in the National Biological Security Policy Process* (Stimson Center, 2004). Dr. Fischer received a BA from Hollins University and a Ph.D. in microbiology and immunology from Vanderbilt University.

The Global Health Security program explores the growing demands on the world's public health infrastructure, from policies intended to contain transnational disease threats to a new role for international health interventions in defense and diplomacy. This project centers on practical policies and approaches – including norms, administrative structures, and public and private sector partnerships – to strengthen regional and global capabilities for disease detection and prevention.

Bates Gill, MD

Since July 2002, Dr. Bates Gill has held the Freeman Chair in China Studies at the Center for Strategic and International Studies in Washington, D.C. He previously served as a Senior Fellow in Foreign Policy Studies and inaugural Director of the Center for Northeast Asian Policy Studies at the Brookings Institution. In addition, Dr. Gill serves on the Board of Directors of the National Committee on U.S.-China Relations, the U.S.-China Policy Foundation, the American Association for Chinese Studies, the Feris Foundation of America, and the China-Merck AIDS Partnership, as well as the editorial boards of several publications. A specialist in East Asian foreign policy and politics, his research focuses primarily on Northeast Asian political, foreign policy, and social issues, especially with regard to China. His current projects focus on U.S.-China-Europe relations, on China's growing influence in Asian regional affairs, and on China's challenging domestic policy agenda. In the past he has also focused on China's looming HIV/AIDS challenge, the U.S.-China economic and trade relationship, and many other issues.

He is the author, co-author, or co-editor of six books, including, *Rising Star: China's New Security Diplomacy* (Brookings, 2007), and *China: The Balance Sheet: What the World Needs to Know Now About the Emerging Superpower* (PublicAffairs, 2006) He has also published his work in several journals and issued opinion pieces in

major newspapers. Dr. Gill received his Ph.D. in Foreign Affairs from the Woodrow Wilson Department of Government and Foreign Affairs, University of Virginia, USA. He has lived more than two years in China and Taiwan, and more than five years in Europe (France, Sweden, Switzerland). A frequent visitor to East Asia, Dr. Gill speaks, reads, and writes in Chinese, English, and French.

LIST OF ACRONYMS

BSC:	Biological Safety Cabinet
BSL:	Biosafety Level
BWC:	Biological and Toxin Weapons Convention
CWC:	Chemical Weapons Convention
GMO:	Genetically Modified Organism
HEPA:	High-efficiency particulate air
IBC:	Institutional Biosafety Committee
NBACC:	National Bio-defense Analysis and Countermeasures Center
PI:	Principal Investigator
SARS:	Severe Acute Respiratory Syndrome
UN:	United Nations
UNSCOM:	United Nations Special Commission
WHO:	World Health Organization
WMD:	Weapons of Mass Destruction

LIST OF TABLES

Table 1: Chinese Regulations, Standards, Codes, and Lists Pertaining to Laboratory Biosafety.....	33
Table 2: Division of Responsibilities for Laboratory Biosafety Within the Chinese Government	49
Table 3: Chinese Regulations Governing Biological Safety Cabinets	53
Table 4: Regulations Related to the Proper Management of Medical Wastes	55
Table 5: China’s Lists of Pathogens of Risk to Humans and to Animals	57
Table 6: China’s System for Review and Approval of Genetic Engineering Activities...	65

Introduction

Amy E. Smithson, Ph.D.¹

China's attitudes towards arms control in general and biological weapons nonproliferation in particular have evolved over the last few decades. *Beijing on Biohazards* provides an informative and intriguing snapshot of current Chinese views on a variety of interlocking topics that fall under the umbrella of biological weapons nonproliferation. To introduce the collection of Chinese essays and the two commentaries on them by U.S. authors, the following paragraphs review China's early outlook on biological and chemical arms control matters, including Chinese concerns about the use of export controls, and summarize the discussion of biological weapons nonproliferation in Chinese defense white papers. The signs of an internal debate about one facet of biological weapons nonproliferation policy are then raised, and some observations are made about the need for more insight into Chinese thinking on biological weapons nonproliferation topics. A synopsis of the essays themselves is then presented.

The Chinese government was a non-participatory critic of arms control when the Biological and Toxin Weapons Convention (BWC) opened in 1972 for the nations of the world to sign it.² China first ventured into the multilateral arms control arena in 1980, taking a seat in Geneva at the Chemical Weapons Convention negotiations, where the Chinese delegation successfully advocated adding a ban on use to the treaty's prohibitions on development, production, and stockpiling of poison gas.³ A few years after China began to participate in the Chemical Weapons Convention talks, China acceded to the BWC in mid-November 1984.

¹ A Senior Fellow at the James C. Martin Center for Nonproliferation Studies of the Monterey Institute of International Studies, Smithson specializes in biological and chemical weapons nonproliferation issues.

² Negotiated by the British, U.S., and Soviet governments, the BWC opened for signature in London, Washington, and Moscow on 10 April 1972 and entered into force on 26 March 1975.

³ Given China's modest track record in arms control, some were surprised when China signed the Convention at the mid-January 1993 ceremonies in Paris opening the treaty for signature. Prevailing wisdom held that the Chinese saw advantage in the leverage they would have under the Convention's auspices to propel Japan to destroy the chemical weapons that the Imperial Army abandoned on Chinese territory during World War II. China signed on 13 January 1993, ratified the Convention on 25 April 1997, and deposited its instrument of ratification on 29 April 1997, the day the treaty took effect. The dates of China's actions are exactly the same as the U.S. dates for signature, ratification, and deposit. Go to: www.opcw.org.

Introduction

As with the chemical weapons ban, Beijing voiced concerns that the BWC did not forbid bioweapons use. The Chinese government also highlighted the treaty's lack of verification and compliance measures and expressed hope that these faults would be corrected.⁴ Because the 1925 Geneva Protocol outlaws the use of biological and chemical weapons, many governments and arms control observers did not share China's worries that not putting a use ban in the BWC would leave a gap in international legal prohibitions against biological weapons.⁵ Many countries did, however, agree that a legally binding monitoring protocol would strengthen the BWC, and international negotiations to accomplish that task began in 1995 with China among the participants.

Throughout these talks, China charged that the BWC's more industrialized members were not engaging in full trade and technology exchanges related to biological materials and equipment, even though Article X of the treaty expressly promotes free trade, scientific exchanges, and technical development.⁶ The focus of China's concerns was the Australia Group, the export control cooperative that in 1985 began restricting trade in high-proliferation risk chemicals, biological materials, and chemical and biological equipment to suspected proliferators.⁷ Several countries, including China, viewed the Australia Group's existence as a fundamental contradiction to the principles of Article X, and campaigned for the elimination of the organization.⁸ Other BWC

⁴ "Letter from Chinese Foreign Minister Wu Xueqian to U.S. Secretary of State George Shultz, regarding China's accession to the Biological Weapons Convention (BWC)," *Xinhua*, 16 November 1984. Text of letter in FBIS Special Memorandum, 18 December 1991.

⁵ For the exact prohibitions, *Protocol for the Prohibition of the Use in War of Asphyxiating, Poisonous or Other Gases, and of Bacteriological Methods of Warfare* (Geneva: 17 June 1925). Available at: www.opbw.org.

⁶ To underscore China's disgruntlement, Ambassador Sha Zhukang reportedly called the BWC a "fraud of sham disarmament" in 1997. Quoted in Eric Croddy, "China's Role in the Chemical and Biological Disarmament Regimes," *Nonproliferation Review*, vol. IX, no. 1 (Spring 2002), 34.

⁷ For more on the history and activities of the Australia Group, go to: www.australiagroup.net.

⁸ Expressing the view that existence of export controls under the Chemical Weapons Convention and the Australia Group create "two parallel export control mechanisms" that cause "confusion and disputes" in trade, an "imbalance in rights" of treaty members, and other problems for the full and universal participation in the treaty, Sha Zukang, "Next Steps," *OPCW Synthesis* (May 2000), 17. For more on China and the BWC's Article X, see Working Paper BWC/CONF.V/COW/WP.9, submitted by China, Cuba, India, Indonesia, Islamic Republic of Iran, Libyan Arab Jamahiriya, and Pakistan to the Fifth Review Conference (Geneva, 26 November 2001). Available at:

http://www.opbw.org/rev_cons/5rc/docs/rev_con_docs/cow/COW-WP.09.pdf. Also, Working Paper BWC/CONF.V/COW/WP.25, submitted by China, Cuba, India, Indonesia, Islamic Republic of Iran, Libyan Arab Jamahiriya, Pakistan, and Sri Lanka to the Fifth Review Conference (Geneva, 27 November 2001). Available at: http://www.opbw.org/rev_cons/5rc/docs/rev_con_docs/cow/COW-WP.25.pdf. "Specific Measures to Strengthen Implementation of Article X of the BTWC," Working Paper BWC/AD

members, recognizing that Article III of the treaty stipulates that BWC members not provide any assistance whatsoever to another state or organization's acquisition of biological weapons, saw no such contradiction and placed emphasis instead on crafting monitoring and inspection provisions for a protocol.⁹ A few months after the introduction of a draft protocol text in 2001, China was among several countries to reject it, stating concerns about discriminatory export control practices.¹⁰ When the talks began to fall apart after the United States rebuffed first the draft protocol and then the negotiating process itself, China reiterated its support for a balanced, effective monitoring protocol as "the best way to enhance the effectiveness of the BWC" and announced its willingness to return to the negotiating table.¹¹

More recently, China's objections to the practice of targeted export controls for nonproliferation purposes appear to have softened.¹² In fact, China has taken noteworthy steps to bring its export control policies in line with those employed in export control cooperatives (e.g., licensing, end-user monitoring) and has created control lists that include all the agents, equipment, and technologies covered by the Australia Group.¹³ These shifts may make it easier for other governments to find common ground with China on a various policies, practices, and mechanisms that have nonproliferation utility.

Over the years, the Chinese government has released a series of monographs,

HOC GROUP/WP.135, submitted by China to the Ad Hoc Group (Geneva, 11 March 1997). Available at: <http://www.opbw.org/ahg/docs/06th%20session/wp135.pdf>.

⁹ For the treaty's text, *Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction* (Washington, D.C.: 10 April 1972). Go to: www.opbw.org.

¹⁰ China assessed the draft protocol, introduced in March 2001, as conducive to the discriminatory practice of export controls. Iran, Cuba, Indonesia, and five other countries took a similar stance. "China, Iran Oppose Ban on Biological Weapons," United Press International Newswire, 9 May 2001.

¹¹ See the section on Chemical and Biological Disarmament, *China's National Defense in 2002*, Information Office of the State Council (Beijing: Government of the Peoples Republic of China, 2002).

¹² According to Vice Foreign Minister Wang Guangya: "Strengthened non-proliferation should not hinder international scientific and technological cooperation, nor should it impede developing countries' peaceful uses of science and technology. . . . We believe that since the proliferation of weapons of mass destruction has its complex causes, non-proliferation efforts should follow the principle of seeking both temporary and permanent solutions, and these solutions should be sought through political and diplomatic means." Wang Guangya, Vice Foreign Minister, "Keep on Improving Non-Proliferation Mechanism and Promote World Peace and Development -- China's Non-Proliferation Policy and Practice," *People's Daily* (Beijing), 16 October 2002.

¹³ See Regulations of the People's Republic of China on Export Control of Dual-Use Biological Agents and Related Equipments and Technologies, Decree no. 365 (Beijing: State Council, 14 October 2002). Note that China has taken similar steps with chemical, nuclear, and missile technology controls. Wang, "China's Non-Proliferation Policy and Practice," 16 October 2002.

Introduction

known generically as white papers, on arms control, disarmament, nonproliferation, and defense issues. These white papers often cover the full scope of classic security topics, including nuclear weaponry and testing, biological and chemical arms, missiles, and weapons in outer space. The 2005 edition, for example, underlined the great suffering of Chinese citizens under the Japanese Imperial Army's biological and chemical weapons attacks in World War II; expressed support for the goals and full implementation of the BWC; and encapsulated China's BWC-related activities, such as its annual filing of confidence-building data declarations since 1988; noted the establishment of biological export control regulations and consultation with the Australia Group on these matters; and stressed China's participation in international meetings associated with the BWC's governance and efforts to strengthen the treaty.¹⁴ The 2003 white paper listed eight laws and regulations pertinent to biological export controls. Briefly describing their purpose, this monograph noted that China had established a licensing and registration system for biological exports as well as criminal penalties for the illegal production, sale, transfer, stockpiling, and use of infectious pathogens.¹⁵ In the 1995 edition, China refrained from discussing specific measures, instead describing the circumstances needed for success in arms control and disarmament (e.g., peaceful resolution of disputes, special leadership burdens of major powers) and stating that the nonproliferation of unconventional weapons was "not in itself the ultimate goal. Only through complete prohibition and thorough destruction of such weapons can proliferation be effectively prevented."¹⁶

The white papers usually devote just a paragraph or two to the subject of biological weapons. The contents of these paragraphs are restrained to terse statements of overarching principles that are inherently unobjectionable (e.g., pursuit of peace) and mentions of China's domestic actions to implement its BWC obligations. Consequently, these white papers leave a considerable amount unsaid about China's views on many of

¹⁴ This monograph devotes just one paragraph to the topic of biological weapons nonproliferation. *China's Endeavors for Arms Control, Disarmament and Non-Proliferation*, Information Office of the State Council (Beijing: Government of the Peoples Republic of China, 2005) 26.

¹⁵ See Section IV: Concrete Measures for Non-Proliferation Export Control of *China's Non-Proliferation Policy and Measures* (Beijing: Information Office of the State Council of the People's Republic of China, December 2003).

¹⁶ *China: Arms Control and Disarmament* Information Office of the State Council (Beijing: Information Office of the State Council of the People's Republic of China, November 1995).

the current and pressing issues associated with biological weapons nonproliferation.¹⁷ For example, issues such as the oversight of genetic engineering research involving infectious pathogens and biosecurity measures to prevent the purposeful diversion, theft, or deliberate release of diseases do not appear to have figured prominently in the statements of the Chinese government. Nor are these subjects highlighted in articles by Chinese experts.

Interestingly, some Chinese views have emerged that suggest a debate in underway in Chinese national security circles as to whether a monitoring protocol should be added to the BWC. During the protocol talks Chinese officials reportedly opposed intrusive inspection measures and any requirement to reveal past bioweapons-related activities.¹⁸ Privately, Chinese officials have characterized verification of the BWC as a futile endeavor and referenced the implementation of the Chemical Weapons Convention as a cautionary tale for what could transpire if the BWC had an inspection regime. Chinese officials have complained about the bureaucracy necessary to inform China's chemical companies of the treaty's requirements, prepare declarations on the production and consumption of proliferation-risk chemicals, and host international inspections of pertinent industrial and military facilities.¹⁹ Along those lines, one Chinese expert cautioned against modeling a BWC protocol's provisions on the overly intrusive inspections of the Chemical Weapons Convention. Another Chinese expert concluded that the dual-utility of life sciences equipment, materials, and technology renders it impossible to monitor the BWC.²⁰ In Western and international settings, the public airing

¹⁷ Nor do the working papers that China has submitted in the BWC protocol negotiations and intercessional discussions shed much light on these matters. China has made statements supportive of the BWC's objectives, offered lists of China's relevant domestic regulations, and introduced a declaration format and a list of biological agents. See, for example, "A Compiled List of Laws and Regulations of China In Relation to the Implementation of the Biological Weapons Convention," Working Paper BWC/MSP.2003/MX/WP.9, submitted by China to the 2003 Meeting of Experts, Geneva, 15 July 2003, available at http://www.opbw.org/new_process/mx2003/bwc_msp.2003_mx_wp09.pdf; "Position of principle of the Chinese delegation on the Biological Weapons Convention and its third review conference," Working Paper BWC/CONF.III/18, submitted by China to the Third Review Conference, Geneva, 20 September 1991, available at http://www.opbw.org/rev_cons/3rc/docs/conf/BWC_Conf.III_18_E.pdf; "Declaration Formats," Working Paper BWC/AD HOC GROUP/WP.291, submitted by China to the Ad Hoc Group, Geneva, 3 July 1998, available at <http://www.opbw.org/ahg/docs/11th%20session/wp291.pdf>.

¹⁸ Croddy, "China's Role in the Chemical and Biological Disarmament Regimes," 25.

¹⁹ On several occasions, Chinese officials have made statements to this effect to the author. For a brief description of structure of China's bureaucracy to implement the Chemical Weapons Convention, see Croddy, "China's Role in the Chemical and Biological Disarmament Regimes," 33.

²⁰ According to Croddy, the first argument appears in Pan Zhenqiang's 1996 Chinese language edited book,

Introduction

of differing opinions is routine, but open debates on security policy are perhaps somewhat new and unexpected for some in China, as well as for China's foreign interlocutors. At the very least, these varying comments raise questions as to whether Beijing would throw its full commitment behind the negotiation of a BWC monitoring protocol should such talks resume.

While a handful of Chinese officials and analysts have spoken out about the merits and disadvantages of attempting inspections under the BWC, Chinese analysts appear to have published few works in Chinese or in English that convey their views on many other topics in the realm of biological weapons nonproliferation.²¹ In turn, few Western scholars have written about China's biological weapons arms control and nonproliferation positions and activities.²² The language barrier no doubt contributes to this dearth of analysis and discussion across borders.

Several reasons make it important for the world at large to have a better understanding of Chinese views on the full scope of biological weapons nonproliferation issues. As a permanent member of the UN Security Council and a global military and economic power, China has considerable leverage to exert, should it choose to do so, in international decisions regarding biological weapons nonproliferation laws, mechanisms, policies, and practices. China's large population, bustling economy, and improving standard of living will continue to invite the international pharmaceutical and biotechnology industry into China. Signs of a pharmaceutical and biotechnology industrial boom already abound, with 1,700 Chinese-foreign pharmaceutical joint ventures underway, approximately \$600 million in Chinese government investment in biotechnology research annually, and the migration of major multinational pharmaceutical giants to China because of the increased practice of Western research

International Disarmament and Arms Control, Guoji Caijun yu Junbei Kongzhi (Beijing: National Defense University Press, 1996); the second is made by Li Yimin in Liu Huaqiu's 2000 arms control compendium, *Arms Control and Disarmament Handbook* (Beijing: National Defense Industry Press, December 2000). Croddy, "China's Role in the Chemical and Biological Disarmament Regimes," 35.

²¹ The topic received some attention in Pan's *International Disarmament and Arms Control* and in Liu Huaqiu's *Arms Control and Disarmament Handbook*.

²² For example, Croddy, "China's Role in the Chemical and Biological Disarmament Regimes." For an evaluation of China's chemical and biological defense policies and capabilities, see Bates Gill, *Case Study 6: People's Republic of China, The Deterrence Series: Chemical and Biological Weapons and Deterrence* (Alexandria, VA: Chemical and Biological Arms Control Institute, 1998).

standards and savings in labor costs.²³ Because of the dual-use nature of biological research, development, and manufacturing, the expansion of the biopharmaceutical industry in China brings with it the onus of responsible governance of these activities. The experience gained from that process could also be the springboard for China to take more nuanced and pro-active positions on the global stage, perhaps advocating certain mechanisms or standards that would strengthen the international bioweapons nonproliferation regime.

Overview of the Report

To promote a better understanding of Chinese views on biological weapons nonproliferation, the Carnegie Corporation of New York generously provided grant support to explore the possibility that some Chinese experts and scholars might agree to write about topics associated with biological weapons nonproliferation. The essays in this report were commissioned in conjunction with a trip to Beijing in May 2006, following meetings with numerous Chinese government officials, laboratory scientists, and policy analysts specializing in national and international security issues. The individuals commissioned to prepare contributions to this volume number among China's top security analysts and scientific experts. Their qualifications are encapsulated below, but the annex to this report contains biographies of this prestigious group. The following paragraphs provide an overview of the *Beijing on Biohazards* essays.

While some aspects of a threat assessment are common across all countries, others differ depending on an individual state's military capacity, regional security environment, alliances, defense and foreign policies, and regional and international roles. Liu Jianfei, PhD, a professor and research fellow at the Institute of International Strategic

²³ The biotech boom had its origins in the mid-1980s with the participation of a few Chinese research institutes in the Human Genome project. Among the major pharmaceutical multinationals with a presence in China, Pfizer has a \$500 million investment and three manufacturing plants in operation; Eli Lilly has a manufacturing plant about an hour from Shanghai and collaborations underway with three other Chinese firms; and GlaxoSmithKline has four manufacturing facilities; and AstraZeneca has offices in 20 Chinese cities. See Matthew Chernavak, "An Emerging Biotech Giant?" *China Business Review*, May 2005. Available at: www.chinabusinessreview.com/public/0505/cheravenak.html. See also, Laura Santini, "Birth of a Biotech Industry Western Drug Makers Outsource R&D to Scientists in Shanghai and Beijing," *Wall Street Journal*, 19 November 2004. Available at: www.aegis.com/news/wsj/2004/WJ041110.html. Also, Robert Yuan, "Pharmaceutical Operations Expand in China," *Genetic Engineering & Biotechnology News*, 15 April 2007. Available at: www.genengnews.com/articles/chitem.aspx?aid=2098&chid=4.

Introduction

Studies at the Central Party School, gauges the biological weapons threat from a technical perspective and the factors in the international security environment that could propel states to acquire these weapons. On the technical side, Liu argues that the phenomenal advances taking place in the life sciences will change the dynamics of bioweapons proliferation for the worse, enabling the development of more dangerous weapons and increasing the chances for proliferation. Liu, who describes biological weapons as having the advantages of both nuclear and chemical weapons, sees non-state actors as more likely than national governments to proliferate biological weapons. He suggests that the most likely route to terrorist acquisition of biological weapons would be from states that decide to try to divert their opposition's attention from them by putting germ weapons in the hands of terrorists. Liu states that because the biological weapons proliferation threat is very high, specific improvements to the biological weapons nonproliferation regime are in order.

The middle trio of essays in the collection contends with topics associated with safe and responsible practice of life sciences activities. These three authors all point to the 2002 outbreak of Severe Acute Respiratory Syndrome as the catalyst that prompted the Chinese government to overhaul its regulatory framework for laboratory research activities between 2003 and 2006. The essay of Dr. Li Jinsong, a professor at the Institute of Microbiology and Epidemiology of the Academy of Military Medical Sciences, concentrates on China's revised biosafety regulations for pathogenic microbiology laboratories. Biosafety technologies and procedures minimize the risk to workers and the public of laboratory research involving highly infectious pathogens. Among other aspects of China's biosafety regulations, Li covers the requirements for the risk classification of pathogens and for the physical containment and biosafety procedures necessary for laboratories to host work with different risk categories of pathogens. Li also describes China's process for the approval of experiments involving highly infectious pathogens and for the oversight of such experiments. This approach, Li acknowledges, was generally patterned on the biosafety practices of the World Health Organization, the United States, and Canada. Li observes that a shortage of biosafety specialists in China will hinder the ability of China to implement these regulations.

The companion piece to Li's essay, prepared by a team of public health officials led by Dr. Hu Longfei, the director and chief epidemiologist of the Department of Health and Quarantine in the Guangdong Health and Quarantine Bureau, also delves into some aspects of China's new biosafety measures (e.g., requirements for biosafety cabinets), but for the most part discusses China's regulations governing genetic engineering activities and biosecurity. Both China's biosafety and biosecurity regulations are tied to reference lists for high-risk human and animal pathogens created in 2005 and 2006, respectively. Higher physical security precautions (e.g., separate storage and tracking, controlled access) are required for the highest-risk pathogens, and government officials must give additional authorizations before researchers may acquire these pathogens and conduct various experiments with them. Separate approvals are also required for genetic engineering work that involves recombinant DNA, infectious agents, animal or plant pathogens, and human blood or other potentially infectious materials. Scientists' proposals to engage in genetic engineering activities are reviewed at the institutional level. For genetic engineering activities that pose a higher risk, they must also secure approval from officials at the State Council, which is China's highest administrative office, and perhaps the National Genetic Engineering Biosafety Council. The evaluation of these proposals takes many factors into account (e.g., appropriate biosafety level). For experimental and intermediate research, the evaluation criteria include examination of whether the proposed activity would enhance the virulence of the pathogen or increase its transmissibility, change the natural host range of a pathogen, or render a non-pathogen virulent or increase the resistance of a pathogen to antibiotics or antivirals.

Like Dr. Li, Dr. Hu and his colleagues state that China has established civil and criminal penalties for serious noncompliance with its biosafety, biosecurity, and oversight of genetic engineering regulations. These two essays also both underscore the importance of improving the biosafety training of Chinese scientists, technicians, and bureaucrats involved in biosafety management. Li proposes a pair of remedies for the shortage of biosafety specialists in China, and Dr. Hu and his co-authors seek the continual improvement of biosafety training available to China's scientists and technicians, as well as exchanges with scientists and biosafety professionals overseas to facilitate biosafety cooperation and education.

Introduction

Wang Qian, an official in the biological and chemical division of the Foreign Ministry's Department of Arms Control and Disarmament, examines China's biosafety and biosecurity measures in comparison to the approaches taken in other countries. China, she recognizes, has taken major steps to reinforce its biosafety and biosecurity regulations so as to be among the toughest standards in the world. As would be expected with any complicated regulatory framework in the early stages of implementation, however, she finds some shortcomings. For example, Wang sees problems in China's cumbersome oversight bureaucracy and asks that the various government agencies better define how they divide and share responsibilities in implementing these regulations. Wang also observes that for China's biosafety and biosecurity measures to be comprehensive, they must be applied not only to pathogenic microbiology laboratories but to all facilities in China working with high-risk pathogens, including hospitals, academic laboratories, and commercial facilities. Finally, Wang notes positively that China's academicians have established their own code of conduct but that specific operational codes and universal norms that apply to all life scientists need to be created to encompass all Chinese scientists engaged in this type of work.

The fifth essay, Yang Ruifu's account of his experience as a United Nations Special Commission (UNSCOM) bioweapons inspector in Iraq, directly challenges the views expressed by some of his countrymen as to verifiability of the BWC. UNSCOM, which exposed Iraq's covert bioweapons program, inspected dual-use sites that were actively masking illicit biological weapons activities and those that were engaged in legitimate activities. The inspectors went about their work in conditions that ranged from welcoming to overtly hostile. Yang, a PhD and professor of microbial genomics at the Institute of Microbiology and Epidemiology of the Academy of Military Medical Sciences, posits that the UNSCOM inspections offered considerable proof that experienced inspectors can successfully discern whether a facility is engaged in activities consistent with its stated peaceful purpose(s) or is disguising illicit weapons-related activities. Furthermore, Yang suggests that the UNSCOM experience can be adjusted to the BWC context and that the UNSCOM inspections are a highly valuable source of information about planning, inspector training, operational strategies, tactics, and technologies that could be useful to determine compliance with the BWC. Yang

therefore proposes a systematic examination of the UNSCOM experience, including the inspectors' first-hand accounts and the data from UNSCOM's confidential files, to assist efforts to strengthen the BWC.

The author of the capstone Chinese essay in this collection was asked to address how the international community should grapple with the challenge of biological weapons proliferation and to discuss how China's policy and activities will contribute to that process. First, in his description of the bioweapons threat, retired General Pan Zhenqiang, the vice-president of the Foundation for International Studies and Academic Exchanges, draws attention to a series of U.S. activities that raise concerns about U.S. compliance with the prohibitions of the BWC. The fast pace of discoveries in the life sciences will make the threat of bioweapons proliferation ever more difficult to contend with, so in Pan's view nonproliferation has an important grassroots component in the form of ethics training and codes of conduct for life scientists. Proliferation is at its roots a political problem, according to Pan, so he stresses the need for a cooperative, multilateral approach to nonproliferation since no single state can resolve nonproliferation problems on its own. With regard to strengthening the BWC, Pan is an advocate of greater transparency in biological activities, the addition of a monitoring protocol, a standing BWC inspectorate, universal adherence to the treaty, and assistance to states to improve pertinent domestic legislation and enforcement capabilities. Pan relates eight steps that Beijing is taking domestically to enhance China's own bioweapons nonproliferation efforts, and he identifies three areas where China could improve its activities in that regard.

Two U.S. experts, Drs. Bates Gill and Julie Fischer, provide commentary on the Chinese essays. For Gill, a specialist in East Asian foreign policy and politics, it is quite remarkable that Chinese experts are writing about these topics since not so long ago the Chinese government considered these matters too sensitive for public discussion. While applauding the willingness of Chinese experts to broach the subject of biological weapons nonproliferation, Gill questions the continuing reliance of Chinese security analysts on an approach to nonproliferation that centers on the factors in the international security environment that prompt or compel actors to attempt to acquire unconventional weapons. This "demand-side" approach, Gill suggests, does not pertain to the problem

Introduction

of terrorist proliferation. He also points out the authors' silence on such matters as the possible proliferation concerns that could accompany China's growing pharmaceutical and biotechnology industry and what, if any, threat China, with its megacities and as host of the 2008 Olympics, might perceive from terrorist acquisition and release of infectious pathogens. Fischer, a microbiologist who works at the intersection of life science and security policy, observes that the Chinese regulatory framework appears to integrate biosafety and biosecurity more closely than is the case in the United States. Both Fischer and Gill agree that thoroughly implementing these regulations in a country of China's size and diversity will be a hefty challenge. Similar to her Chinese counterparts, Fischer emphasizes that the provision of sufficient resources at the institutional level will be essential to success. Absent a significant investment in the plans, resources, and training to implement China's new biosecurity and biosafety regulations, she warns, this strong framework will be only a paper tiger.

With relatively little information available elsewhere regarding China's policies, activities, and priorities pertaining to biological weapons nonproliferation, this collection of essays is first and foremost a reflection of the readiness of Chinese experts to discuss and address these extremely important matters. Second, these essays indicate that Chinese views on bioweapons nonproliferation policies and mechanisms are evolving.²⁴ Third, these essays provide considerable information for their colleagues in the west to contemplate, to appreciate, to agree with, and to contest. These essays, in other words, are seeds for a dialogue between Chinese and Western policy analysts, scientists, and officials about the nature of the biological weapons threat and the tools that can be applied domestically and internationally to reduce the threat of biological weapons proliferation.

²⁴ Pan, for example, acknowledges the existence of a Soviet bioweapons program in his essay. Previous Chinese statements and writings, including by Pan, have made no mention of the Soviet bioweapons program, which even the Russian President Boris Yeltsin conceded existed in mid-1992. R. Jeffrey Smith, "Yeltsin Blames '70 Anthrax on Germ Warfare Efforts," *Washington Post*, 16 June 1992; J. Dahlburg, "Russia Admits It Violated Pact on Biological Weapons," *Los Angeles Times*, 15 September 1992.

Contemplating the Threat of Biological Weapons Proliferation

Liu Jianfei, Ph.D.¹

The proliferation of weapons of mass destruction (WMD) has become one of the most serious threats to human security. This danger will only increase should terrorists choose to acquire and use WMD. History shows that biological weapons, a major category of WMD, have been used to cause great harm. Soon after the terrorist attacks of September 11th and the anthrax attacks that followed, the potential proliferation of biological weapons attracted significant attention in the international community. More recently, the international community's concern about this problem has decreased because terrorists have not used biological weapons again, and nations have turned their focus instead to the nuclear crises in North Korea and Iran.

However, just because a new threat materializes does not mean that the old one disappeared, so the international community must ask itself, is there still a threat from biological weapons, and, if so, what measures can the international community take to deal with it? This essay will discuss the origins of and prospects for biological weapons proliferation from two perspectives, taking into account the characteristics of biological weapons that could facilitate proliferation and the political circumstances that could encourage or suppress it. The discussion will also include analysis of the problems and challenges that the international community faces with regard to stopping biological weapons proliferation.

The Characteristics and Proliferation of Biological Weapons

Biological weapons are composed of biological agents, the munitions the agents are put into, and the delivery systems for the munitions.² The type of biological agents employed gives the weapon its main characteristic. For example, a biological weapon could contain a disease that harms plants, animals, or people. Some diseases will only cause sickness; others can cause death. Also, the weapons could involve a human disease

¹ Liu Jianfei is a professor at the Institute for International Strategic Studies of the Central Party School of the Communist Party of China.

² Liu Huaqiu, ed., *Manual of the Control and Disarmament of Weapons* (Beijing: Publishing House of the National Defense Industry, 2000): 354. Bombs and spray tanks are examples of munitions, and biological weapons can be delivered by artillery, aircraft, or missiles.

Contemplating the Threat of Biological Weapons Proliferation

that is contagious (e.g., smallpox, plague) or one that does not spread from person to person (e.g., anthrax).

Compared with nuclear and chemical weapons, biological weapons boast a longer history. The earliest record of biological weapons can be traced to the 14th century. When Mongols besieged the port of Kafa on the Black Sea in 1346, they threw corpses infected with plague into the city, which caused the city's inhabitants to contract the disease and the troops defending the city to flee by ship. During the 1930s and 1940s, the Japanese Imperial Army engaged in biological warfare, killing more than 200,000 Chinese civilians and soldiers by dispersing typhoid, cholera, paratyphoid A, anthrax, and plague in over twenty provinces of China.³

The long history of biological weapons shows that it is easier to become truly proficient in making this type of weaponry than making nuclear or even chemical weapons. The advent of new technologies in microbiology makes it possible to manipulate diseases so that they are more lethal, more contagious, and therefore more effective as weapons. If one compares the characteristics of the three types of WMD, one finds that biological weapons have the “merits” of both chemical and nuclear weapons. For example, biological weapons can be a hundred, even a thousand times more lethal than chemical weapons. According to experts at the Monterey Institute of International Studies, “In many situations, [biological weapons] would also be more effective than nuclear weapons.”⁴ The U.S. Office of Technology Assessment determined that an aircraft spraying 100 kilograms of anthrax over Washington, D.C., on a clear, calm night could kill 1 to 3 million people, whereas the same aircraft spraying 1,000 kilograms of sarin would cause 3,000 to 8,000 casualties. In other words, a biological weapon would be vastly more effective than the chemical weapon.⁵

³ Another 10,000 were probably killed in laboratory experiments. Unit 731 of the Japanese Army, run by Dr. Shiro Ishii, was the centerpiece of Japan's biological weapons activities. For more, see Sheldon H. Harris, *Factories of Death: Japanese Biological Warfare, 1932-45 and the American Cover-up* (New York: Routledge, 2002).

⁴ Monterey Institute of International Studies, *Security and Arms Control in Northeast Asia*, Center for Nonproliferation Studies Programs, Course Materials, Lesson 5 (2005), 21. Available at: <http://cns.miis.edu/cns/projects/eamp/training/ttt/lessons/english/leo5.pdf>.

⁵ United States. Cong. Office of Technology Assessment, *Proliferation of Weapons of Mass Destruction: Assessing the Risks*, OTA-ISC-559 (Washington, D.C., U.S. Government Printing Office: August 1993): 54.

In comparison to nuclear weapons, biological weapons have several advantages.

Biological weapons are:

- Made with basic equipment and materials that can be readily obtained on the open market;
- Less costly than nuclear weapons;
- Easier to make than nuclear weapons (biological agents reproduce quickly in fermenters);
- Easily transported and hidden;
- Comprised of diseases that occur naturally, so the use of biological weapons can possibly be confused with a natural disease outbreak; and,
- Manufactured with dual-use materials and equipment that also have legitimate peaceful and commercial uses.

For these reasons, biological weapons have a reputation as the “poor man’s atomic bomb.” Governments and organizations (e.g., terrorist groups) that want to strengthen their military capability by acquiring WMD are more likely to choose biological weapons. This choice is especially true for governments and organizations that lack economic strength.

Some nations have always paid close attention to the threat of biological weapons proliferation. For example, the U.S. Department of Defense states: “Biological agent development is particularly troubling because virtually all the equipment, technology, and materials needed for biological warfare agent research and development and production are dual use. Thus, biological weapons applications are relatively easy to disguise within the larger body of legitimate commercial activity.”⁶ President George W. Bush’s administration has also emphasized that, “Unlike nuclear weapons, biological weapons do not require hard-to-acquire infrastructure or materials. This makes the challenge of controlling their spread even greater.”⁷

The European Union has also paid close attentions to the threat of biological weapons proliferation. A 2003 report from the European Union Council warned:

Although effective deployment of biological weapons requires specialized scientific knowledge including the acquisition of agents for effective dissemination, the potential for the misuse of the dual-use technology and knowledge is increasing as a result of rapid developments in the life

⁶ United States. Office of the Secretary of Defense. *Proliferation: Threat and Response*, (Washington, D.C.: U.S. Department of Defense, 2002): 4. Available at: <http://www.defenselink.mil>.

⁷ United States. The White House. *The National Security Strategy of the United States of America* (Washington, D.C.: March 2006): 21. Available at: <http://www.whitehouse.gov/nsc/nss/2006/>.

Contemplating the Threat of Biological Weapons Proliferation

sciences. Biological weapons are particularly difficult to defend against. Moreover, the consequence of the use may be difficult to contain depending on the agent used and whether humans, animals, or plants are the targets.⁸

As the century turned, concerns about the proliferation of biological weapons were clearly on the rise.

From a technical perspective, biological weapons are more likely to proliferate than nuclear or chemical weapons. The Monterey Institute for International Studies' experts claim that "Most developing nations would select an agent that is already well known so the technology of how to prepare it for weapons is not too complicated and is readily available. More than 100 countries already have plants to produce the agents required in biological warfare."⁹ If these countries want to make a biological agent, it is not that technically difficult to do so. Additionally, proliferators could profit from advances in biotechnology to develop qualitatively enhanced biological weapons and produce more biological agents. Monterey's experts underscore the proliferation potential inherent in the evolution of biotechnology: "In the past, only about 30 microorganisms or toxins have been considered for use as biological warfare agents. This number may increase in the future with advances in microbiology technology such as cloning and gene splicing."¹⁰

Several recent experiments, some involving diseases that could be used as warfare agents, demonstrate that the progress in biotechnology makes it easier to reproduce diseases, even from scratch. Over the course of three years, scientists at New York State University proved this principle by artificially creating the polio virus. They meticulously assembled key biological materials that they purchased from commercial warehouses. In 2003, another research group required only three weeks to assemble the

⁸ European Union. Council of the European Union. *Fight Against the Proliferation of Weapons of Mass Destruction: EU Strategy Against Proliferation of Weapons of Mass Destruction* (Brussels: 10 December 2003), 4. Available at: <http://ue.eu.int/uedocs/cmsUpload>.

⁹ The pharmaceutical and biotechnology industry has expanded considerably in the past decade, and industrial plants employ dual-use equipment. Monterey Institute of International Studies, *Security and Arms control in Northeast Asia*, Center for Nonproliferation Studies Programs, Course Materials, Lesson 5 (2005), 27. Available at: <http://cns.miis.edu/cns/projects/eamp/training/ttt/lessons/english/leo5.pdf>.

¹⁰ Monterey Institute of International Studies, *Security and Arms control in Northeast Asia*, Center for Nonproliferation Studies Programs, Course Materials, Lesson 5 (2005), 24. Available at: <http://cns.miis.edu/cns/projects/eamp/training/ttt/lessons/english/leo5.pdf>.

polio virus from separate segments of DNA.¹¹ One can very reasonably assume, then, that the developments taking place in the life sciences increase the potential for biological weapons proliferation. Continuing advances in biotechnology could provide for the development of biological weapons that are ever more lethal and make biological weapons easier to acquire.

History shows that progress in science and technology leads to the development of new, upgraded weapons. Consistent with that historical trend, a 2004 U.S. government report stated that “advances in biotechnology and the life sciences—including the spread of expertise to create modified or novel organisms—present the prospect of new toxins, live agents, and bioregulators,” and therefore that “preventing and controlling future biological weapons threats will be even more challenging.”¹² Ambassador Sha Zhukang expressed the Chinese government’s view on this issue, observing that given the “rapid development of biotechnology perhaps mankind faces a greater threat of biological weapons.”¹³

To offset the advantages discussed above, biological weapons also have some defects. One primary weakness of biological weapons is that their effectiveness is subject to meteorological conditions. Temperature, humidity, the presence of ultraviolet sunlight, and wind direction and speed can all degrade the potency of biological weapons. Additionally, chemical, biological, or nuclear weapons are primarily political tools. If WMD were used, the purpose would not be to kill enemy soldiers but to defeat the will of the enemy, to cause the public to panic. These types of political objectives cannot be effectively obtained with biological weapons because the country attacked could

¹¹ In the first experiment, the scientists combined the oligonucleotides of the polio virus, transcribed the complementary DNA into viral RNA using the RNA polymerase method, and then allowed the virus to replicate itself de novo in a cell-free extract. Jeromino Cello, Aniko V. Paul, Eckard Wimmer, “Chemical Synthesis of Poliovirus cDNA: Generation of Infectious Virus in the Absence of Natural Template,” *Science* 297, no. 5583 (9 August 2002): 1016-18. A second team of scientists, led by Craig Venter, required just two weeks to replicate the polio virus artificially. Smith, H. O., Hutchison, C. A., Pfannkoch, C. & Venter, J. C. “Generating a synthetic genome by whole genome assembly: PhiX174 bacteriophage from synthetic oligonucleotides,” *Proceedings of the National Academy of Sciences* (DOI: 10.1073/pnas.2237126100).

¹² United States. The White House. *Biodefense for the 21st Century* (Washington, D.C.: 28 April 2004): 1.

¹³ Ambassador Sha Zhukang, “Remarks of the Head of Chinese Delegation to The Fifth Review Conference of the BWC,” *Proceedings of The Fifth Conference of the BWC*, (Geneva: United Nations, 19 November 2001), 4. Available at: <http://www.china-un.ch/eng/gjhyfy/hy2001/t85217.html>.

Contemplating the Threat of Biological Weapons Proliferation

conclude that the disease outbreak occurred naturally, not from a deliberate attack. These factors could make biological weapons less attractive to proliferators.

With the twin crises of potential nuclear weapons development in North Korea and Iran in recent years, the international community has paid more attention to nuclear weapons proliferation than to biological weapons proliferation. The media reports frequently that nuclear weapons are more likely to proliferate than biological weapons, and the national security authorities of many countries are paying more attention to nuclear weapons than to biological weapons. Thus, if one were to assess the proliferation potential of biological weapons based on media reports and the statements of government officials, then the prospects for biological weapons proliferation are not so grave. However, that does not mean that the biological weapons threat is decreasing. On the contrary, the threat of WMD proliferation in general is increasing, and the threat of biological weapons proliferation is second only to the threat of nuclear weapons proliferation.

The Origins of Biological Weapons Proliferation

Although a major avenue for the proliferation potential of biological weapons resides in technology, as with the proliferation of all kinds of weapons, the ultimate cause of biological weapons proliferation is the international security environment. The current international security environment is such that many countries are forced to maintain their security by forging alliances with other nations or strengthening their military capabilities. Some countries do both. A country that decides to strengthen its military capabilities has an important choice to make when it comes to acquiring WMD. For a small or medium-sized country that perceives a threat to its security but has limited economic resources, biological weapons would be the best choice.

The international security environment has gotten significantly better since the end of the Cold War. This improvement manifests itself in two main ways. First, the end of the bipolar rivalry means that the great powers are inclined to cooperate, not to confront each other. Second, the demise of bipolarity situates the United Nations (UN) as the core mechanism of international order, increasing the UN's role in maintaining global

security. At the same time, many problems still afflict the international security environment, and these problems materialize in four ways.

First, anarchy remains the main feature of international society because the binding force of the UN and international law to govern and restrict the actions of sovereign states is only partial. The UN is not, after all, a world government; one of the central tenets of the UN is to maintain the sovereignty of states. Accordingly, the UN's regulations and resolutions have limited influence over the decisions and actions of nations. When a state breaks international law, the UN can lack the ability to enforce the law. However, if there is consensus among the great powers that a law has been violated, then the UN can maintain international security and justice. A case in point is Iraq's 1990 invasion of Kuwait, which was reversed when a military coalition under the auspices of UN Security Council Resolutions 660 and 687 forced the Iraqi military to withdraw from Kuwait. If there are differences among the great powers, then the UN can do little, as is the case with the Arab-Israeli conflict in the Middle East. Sometimes, a major power can publicly challenge the authority of the UN, such as when the North Atlantic Treaty Organization forces bombed Yugoslavia in 1999 and U.S. and British forces invaded Iraq in 2003. Absent a world government, nations still have to rely on their own resources to solve their security problems.

Second, many states continue to perceive threats to their security. At present, numerous countries, particularly the great powers, maintain their security by the traditional method of increasing their military strength. When the great powers lack confidence in their mutual strategic security, a resulting security dilemma stimulates them to develop their military capabilities further, including WMD capabilities. Although the United States has considerable military power, America continues developing its military capabilities while simultaneously articulating tough and even hostile policies toward some countries. As a result, some countries justify the development of their military capabilities in return.

Third, power politics and unilateralism still exist. Some great powers practice power politics. Such nations attend only to their own interests without considering the interests of other countries. In some cases, nations that employ power politics even do harm to other countries. Some countries view international society only through the

Contemplating the Threat of Biological Weapons Proliferation

prism of their own preferences, values, and ideology. They execute stringent policies towards some countries and in some instances they even try to pursue regime change in other countries. Such behavior can prompt minor or weak nations to enhance their military strength to protect their own security.

Fourth, the influence of nationalism is on the rise. The Cold War suppressed the differences of nationalities, but those differences are now becoming more prominent. Many regions of the globe are experiencing more tension because of increased nationalism. Some countries place too much emphasis on their own nationalism and interests, neglecting global interests and the interests of mankind as a whole. When such countries seek to increase their security and military strength, they do not hesitate to violate international law to develop WMD. At various times, several states are responsible for breaking the laws that prohibit the use, development, production, stockpiling, and transfer of chemical, biological, and nuclear weapons.

Aside from the inherent features of the international security environment, some countries have nonproliferation policies with obvious flaws that actually abet proliferation to a certain extent. U.S. nonproliferation policy is essentially a double standard because it calls on other countries not to develop weapons while at the same time the United States researches and develops new weapons, including strategic missile systems. The United States tolerates weapons development by its allies while harshly discouraging similar activity by its rivals. This type of policy can lead only to one result, and that is to stimulate rival countries to acquire WMD. The United States is not the only country to behave in this manner. Other countries, especially the great powers, have at times had weapons development programs that could potentially contradict their nonproliferation policies. However, as the world's lone superpower, the behavior of the United States most significantly influences other nations and therefore is more problematic.

In some respects, the international security environment also offers conditions favorable to the nonproliferation of biological weapons. The nature of warfare has changed in ways that limit the use of WMD. The main reason that some countries possess WMD is usually not to kill enemy soldiers during hostilities but to deter opposing countries from using WMD. Achieving deterrence with biological weapons is more

difficult than it is with nuclear weapons. To establish deterrence, a weapons program has to be out in the open, and historically, few governments have spoken publicly about their pursuit of biological weapons. Also, intelligence agencies have difficulty identifying covert biological weapons programs. A secret biological weapons program that is not at least seriously rumored presents no deterrent, unlike a nuclear weapons program that is publicly acknowledged or seriously suspected.

Some countries also try to realize domestic political objectives by acquiring WMDs, such as building national pride, enhancing national cohesion, and strengthening the authority of the government. As is the case with achieving deterrence, nuclear weapons are more likely to facilitate such domestic goals than biological weapons. Nations have been known to parade their nuclear weapons down the streets of their capitals, which is hardly the case with biological weaponry.

The tactics and weapons that terrorists have begun to employ recently complicate the biological weapons proliferation picture. The international community has always worried about the combination of terrorism and WMD, but that is particularly the case since September 11th. A pattern of activities indicates that terrorists are trying to obtain biological weapons, among other WMD. If terrorists can get their hands on WMD and use these weapons, the human loss could be a hundred or even a thousand times worse than on September 11th. The U.S. government concluded that “[t]here are few greater threats than a terrorist attack with WMD.”¹⁴ For its part, the Council of the European Union asserted that biological weapons “may have particular attractions for terrorists.”¹⁵ The prospects of terrorist acquisition of WMD constitute a new dimension of the proliferation problem. Terrorists will not seek to acquire WMD for purposes of deterrence. Rather, terrorists would want these weapons to kill as many people as possible so that they create panic in the country they target or the world at large. Any type of WMD—biological, nuclear, or chemical—would serve the objectives of terrorists.

In terms of the order of priority for WMD acquisition, some countries would seek nuclear weapons first and biological weapons second. Terrorists, however, would

¹⁴ United States. The White House. *The National Security Strategy of the United States of America* (Washington, D.C.: March 2006): 21. Available at: <http://www.whitehouse.gov/nsc/nss/2006/>.

¹⁵ European Union. Council of the European Union. *Fight Against the Proliferation of Weapons of Mass Destruction: EU Strategy Against Proliferation of Weapons of Mass Destruction* (Brussels: 10 December 2003, 4. Available at: <http://ue.eu.int/uedocs/cmsUpload>.

Contemplating the Threat of Biological Weapons Proliferation

possibly place first priority on obtaining biological weapons, simply because they are more easily obtained. Chinese scholar Liu Huaqiu has argued that “the possibility that biological weapons will be used is increasing, and the circumstances where these weapons can be used ranges from international war to civil war to terrorist attack. The means of using biological weapons is becoming easier and easier, and different warfare agents can be selected according to the target identified for attack.”¹⁶ Huaqiu refers to the potential to calibrate the amount of damage one seeks to inflict with biological weapons. Plant or animal crops can be targeted to damage a country’s economy, or the population of a city can be harmed by dispersing a non-contagious disease. An entire country can be targeted if a communicable disease is employed. Without the technical and financial assistance of a state, however, it is very difficult for terrorists to establish the capability to produce WMD. The most likely conduit for terrorists to acquire WMD is through the assistance of irresponsible countries. Most countries that behave irresponsibly are scarcely in possession of the considerable financial and technical resources needed to produce nuclear weapons, but biological weapons could be within their reach. Moreover, the international community has established stricter controls over nuclear weapons than it has for biological weapons. Whereas the Nuclear Nonproliferation Treaty requires international inspection of nuclear facilities to ensure that commercial and research reactors are not engaging in military activities, there are no monitoring provisions in place for the Biological and Toxin Weapons Convention.

As noted, some countries have the ability to make biological weapons because the equipment needed is easily purchased and the technical requirements of producing these weapons are relatively low. Just a handful of biologists can sometimes make biological weapons. The editors of the journal *Discover* argued that, “Although bioengineering probably lies well beyond the capabilities of a typical terrorist, one rogue biologist could wreak devastation.” To buttress their case, the *Discover* editors cited Gerald Epstein, senior fellow at the Center for Strategic and International Studies in Washington, D.C.,

¹⁶ Liu Huaqiu, ed. *Manual of the Control and Disarmament of Weapons* (Beijing: Publishing House of the National Defense Industry, 2000): 358.

on this matter: “I’m less worried about terrorists becoming biologists than biologists becoming terrorists.”¹⁷

The United States has paid special attention to the issue of bioterrorism since the anthrax attacks in the fall of 2001. On 12 June 2002, President Bush stated: “Bioterrorism is a real threat to our country. It’s a threat to every nation that loves freedom. Terrorist groups seek biological weapons; we know some rogue states already have them.”¹⁸ Reinforcing that point, a 2004 White House report observed that “[b]iological weapons in the possession of hostile states or terrorists pose unique and grave threats to the safety and security of the United States and our allies.”¹⁹ The Chinese government has also stated that “[n]owadays, the actual threat of bioterrorism is coming to us, so we should not avoid this issue.”²⁰ To punctuate international concerns about terrorism, the United Nations General Assembly requested the development of a comprehensive database on terrorist incidents involving biological materials, the convening of a meeting of the major biotechnology stakeholders (e.g., industry, scientists, governments) to agree on a common program to counter bioterrorism, and the updating of the UN’s roster of experts and technical procedures for the investigation of allegations of biological weapons use, among other initiatives to fight bioterrorism.²¹

Just as with the prospects for state-level proliferation of biological weapons, the threat of bioterrorism to some extent has its roots in the international security environment. Countries that possess biological weapons and make the decision to supply them to terrorists would do so mainly for political reasons. If such countries feel threatened by a great power or a rival state, they may diffuse the attention and resources of such state(s) by using terrorism to lessen the amount of pressure that the threatening state(s) place on them. Weaker countries might feel threatened when great powers

¹⁷ “The Future of Terrorism,” *Discover* 27, no. 7 (July 2006). Available at: <http://www.discover.com/issues/jul-06/cover>.

¹⁸ The United States. “President Signs Public Health Security and Bioterrorism Bill,” Remarks by the President at Signing of H.R. 3448, the Public Health Security and Bioterrorism Response Act of 2002 (Washington, D.C.: The White House, 12 June 2002).

¹⁹ United States. The White House. Biodefense for the 21st Century (Washington, D.C.: 28 April 2004): 1.

²⁰ Ambassador Sha Zhukang, “Remarks of the Head of Chinese Delegation to The Fifth Review Conference of the BWC,” Proceedings of The Fifth Conference of the BWC, (Geneva: United Nations, 19 November 2001), 4. Available at: <http://www.china-un.ch/eng/gjhyfy/hy2001/t85217.html>.

²¹ UN General Assembly, “The United Nations Global Counter-Terrorism Strategy,” Doc. A/60/L.62 (New York: 6 September 2006), 6-7. Available at: <http://www.un.org/terrorism/strategy>.

Contemplating the Threat of Biological Weapons Proliferation

engage in power politics, observe Cold War policies, or express a great power policy of regime change. Of course, it is also possible that governments influenced by extreme nationalism could decide to try to realize their political objectives by means of terrorism.

The way to resolve the problem of biological weapons proliferation, whether at the state or terrorist level, is to get to the root of the problem: namely, to improve the international security environment. The international community, especially the great powers, should abandon the old concept of security that depends mainly on increasing military strength to maintain national security and replace it with a new security framework. Accordingly, the authority of the UN and international law should be sustained and power politics and Cold War policies should be opposed. In dealing with countries that want to proliferate biological weapons and other kinds of WMD, a uniform, non-discriminatory approach should be observed. At the same time, the international community should take into consideration the security and developmental concerns of proliferating countries. In the fight against terrorism, the international community should collaborate to prevent some countries from pursuing their national interests under the guise of anti-terrorism. In order to prevent terrorists from getting these weapons, the international community's first step is to cooperate to improve the international nonproliferation system.

The Challenges Facing the International Nonproliferation System

Today, the roots of the problem of biological weapons proliferation have not yet been removed. The gravity of the biological weapons proliferation threat gives the international community an important opportunity to establish and improve the nonproliferation regime.

At present, the most significant component of the international biological weapons nonproliferation regime is the Biological and Toxin Weapons Convention (BWC), which was opened for signature on 10 April 1972 after receiving UN General Assembly approval and entered into force in 1975.²² Over 150 nations have signed the

²² This treaty's formal title is The Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction. As of 1 September 2006, 155 nations had joined the BWC, 16 nations had signed but not ratified the treaty, and 23 nations were non-signatories.

BWC and 140 have fully joined the treaty. The BWC consists of fifteen articles that are legally binding.²³ The treaty articulates tenets, principles, and objectives for the behavior of its members regarding the prohibition of biological weapons. Articles I and II state the main responsibilities for treaty members. Article I of the BWC obligates countries “never in any circumstances to develop, produce, stockpile or otherwise acquire or retain” biological agents or toxins in “types and in quantities that have no justification for prophylactic, protective or other peaceful purposes.” Article I also commits countries to forego biological weapons, equipment, and delivery systems, and in Article II, nations pledge not to transfer or assist any other country or entity to obtain biological weapons.

Although the BWC constitutes significant progress in establishing a biological weapons nonproliferation regime, the treaty has obvious defects. Chinese scholars have pointed out a shortcoming that even though the BWC does recognize the importance of the 1925 Geneva Protocol’s prohibition of the use of biological and bacteriological weapons in war, the BWC itself does not forbid the use of biological weapons.²⁴ The second defect in the BWC is that the treaty lacks concrete measures for effective monitoring and oversight. Also, the BWC does not specify sanctions or punishments for a violation of the treaty. The third weakness of the BWC is that the treaty has no binding force on nations that do not sign the treaty and proliferate biological weapons. Of the three flaws, the second is the most significant.

Since 1975, the members of the BWC have held five conferences to review the treaty’s operation and one special review conference. One of the most important objectives of these meetings has been for the international community to resolve the

For more information on the BWC and activities associated with it, go to: <http://www.opbw.org>.

²³ The prologue of the BWC reads: “The States Parties of this Convention, determined to act with a view to achieving effective progress towards general and complete disarmament, including the prohibition and elimination of all types of weapons of mass destruction, and convinced that the prohibition of the development, production and stockpiling of chemical and bacteriological (biological) weapons and their elimination, through effective measures, will facilitate the general and complete disarmament under strict and effective international control.”

²⁴ The second paragraph of the BWC’s prologue acknowledges the contribution that the 1925 Geneva Protocol’s prohibition on the use of poisonous gases and bacteriological warfare has made to “mitigating the horrors of war.” Article VIII of the BWC also stipulates that the nothing in the BWC should “in any way limit or detract” from a state’s obligations under the Geneva Protocol. Nonetheless, Chinese scholars have identified the failure to extend the BWC’s prohibitions to the use of biological weapons as a weakness. See Liu Huaqiu, ed., *Manual of the Control and Disarmament of Weapons* (Beijing: Publishing House of the National Defense Industry, 2000): 357; Xia Liping, *The Armament Control and Security in Asia-Pacific Region* (Shanghai: People’s Publishing House, 2002), 292.

Contemplating the Threat of Biological Weapons Proliferation

second defect mentioned above, the absence of monitoring provisions in the BWC. At the Third Review Conference in 1991, the BWC's members decided to establish a special group of experts to identify and evaluate the applicability of science, technologies, and other inspection methods to monitor the BWC. In 1994, the special conference discussed the twenty-one monitoring methods raised in the so-called VEREX report.²⁵ The momentum from the VEREX report propelled the BWC's members in 1996 to charter at the Fourth Review Conference an Ad Hoc group to negotiate the terms of a monitoring protocol for the BWC. The final report of the Fourth Review Conference called for negotiations to craft a monitoring protocol to be completed by 2001.²⁶

The Ad Hoc negotiating group did negotiate a draft BWC monitoring protocol and the final stages of negotiations were to occur in the summer of 2001, with the idea of having all BWC members approve the text at the Fifth Review Conference in November 2001. In May 2001, however, George W. Bush concluded an interagency review of the draft BWC protocol that found thirty-eight problems with the text. The U.S. government singled out five or six very serious problems and asserted they could not be fixed prior to the protocol's opening for signature.²⁷ The Fifth Review Conference convened in November 2001 in Geneva. When the U.S. representative insisted that the Review negotiations toward a BWC monitoring protocol be disbanded, many countries, including U.S. allies in Europe, voiced strong disapproval of the U.S. position. The Review Conference was not able to issue a final report at that time. Chinese scholar Xia Liping observed that the "Bush administration rejected the draft BWC protocol in order to protect the proprietary data of the U.S. pharmaceutical industry."²⁸ Indeed, U.S. officials listed safeguarding of sensitive commercial and national security data and the draft protocol's inability to monitor treaty compliance as their principal reasons for refusing to

²⁵ The United Nations. Ad Hoc Group of Governmental Experts to Identify and Examine Potential Verification Measures from a Scientific and Technical Standpoint, *Summary Report*, BWC/CONF.III/VEREX/8 (Geneva: 24 September 1993).

²⁶ The United Nations. Fourth Review Conference of the Parties to the Convention on the Prohibition of the Development, Production, and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction, *Final Declaration*, Doc. BWC/CONF.IV/9 (Geneva: 1996).

²⁷ Michael R. Gordon and Judith Miller, "U.S. Germ Warfare Review Faults Plan on Enforcement," *New York Times*, 20 May 2001. The Bush administration formally refused to sign the BWC protocol in late July 2001. The United States. Don Mahley, "Statement by the United States to the Ad Hoc Group of Biological Weapons Convention States Parties" (Geneva: U.S. Department of State, 25 July 2001).

²⁸ Xia Liping, *The Armament Control and Security in Asia-Pacific Region* (Shanghai People's Publishing House, 2002): 295.

accept the draft agreement.²⁹ No matter what the reasons of the Bush administration may have been, the U.S. position was a unilateral one.

At a continuation of the Fifth Review Conference in November 2002, the international community decided to hold three annual technical meetings prior to the Sixth Review Conference at the end of 2006.³⁰ In other words, the international community has not stopped its efforts to strengthen the BWC. In fact, the Sixth Review Conference decided to continue these annual technical meetings until 2010.³¹

The U.S. policy on the problem of biological weapons nonproliferation is ambivalent. On one hand, the United States, with its counter-terrorism and nonproliferation policies, emphasizes that the proliferation of biological weapons should be prevented, especially with regard to terrorist acquisition of these weapons. On the other, the unilateral nature of the U.S. policy undermines efforts to strengthen the nonproliferation regime, which hinders the ability of the international community to cooperate on measures to prevent biological weapons proliferation. Thus, the Bush administration's unilateralist policy constitutes a major barrier to the strengthening of the international biological weapons nonproliferation regime.

Concluding Thoughts

Taking into account the status of developments in life sciences technology, the international security environment, and the nonproliferation regime, the potential for biological weapons proliferation is very high. From the technological perspective, the requirements for the equipment needed to make biological weapons and the costs of biological weapons are both low. In addition, it is difficult to distinguish when the equipment is being used for civilian or for military purposes, which means that biological

²⁹ The United States. Don Mahley, "Statement by the United States to the Ad Hoc Group of Biological Weapons Convention States Parties" (Geneva: U.S. Department of State, 25 July 2001); The United States. John R. Bolton, "Remarks to the 5th Biological Weapons Convention RevCon Meeting" (Geneva: U.S. Department of State, 19 November 2001).

³⁰ The United Nations. Fifth Review Conference of the States Parties to the Convention on the Prohibition of the Development, Production, and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction, *Final Document*, BWC/CONF.V/17 (Geneva: 2002). Available at: <http://www.opbw.org>.

³¹ The United Nations. Sixth Review Conference of the States Parties to the Convention on the Prohibition of the Development, Production, and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction, *Final Document*, BWC/CONF.VI/6 (Geneva: 8 December 2006). Available at: <http://www.opbw.org>.

Contemplating the Threat of Biological Weapons Proliferation

weapons can be easily hidden. The potential deadliness of biological weapons is higher than for most other types of weapons. When all of these factors are taken into consideration, biological weapons have the highest potential for proliferation of all WMD. As advances continue to occur in biotechnology and the life sciences, the potential for biological weapons to proliferate will become ever greater.

From the perspective of the international security environment, governments and terrorist groups must both be considered as possible proliferators of biological weapons. The contemporary environment for international security makes small and medium countries feel threatened by the great powers, which forces the smaller countries to try to master WMD to enhance their military strength. Because they are relatively cheap, biological weapons will naturally be among the choices that proliferators will consider.

One positive factor in this quandary is that modern practices of war and the contemporary international security environment limit use of biological weapons. The main objective for some countries in possessing WMD is to deter rivals and to prevent war, but biological weapons are far less effective as deterrents than nuclear weapons. Moreover, some countries try to reach some political objectives by acquiring WMD. In this respect, biological weapons are not as effective as nuclear weapons, which is one of the reasons that the international community pays more attention to nuclear weapons than to biological weapons.

The most likely proliferators of biological weapons will be terrorists. Biological terrorism will be one of the most significant threats to international security. The objective of many terrorists today is to kill as many people as possible. Therefore, they are actively trying to acquire biological weapons, which are easy to obtain and as lethal as nuclear weapons. The most likely route for terrorists to get biological weapons is from irresponsible countries that already have them.

Taking technology and international security into consideration, the motivation and conditions exist for the proliferation of biological weapons. The international community has to cooperate to strengthen and improve the nonproliferation system so that it can fulfill the purpose it is intended to serve, namely to prevent the proliferation of biological weapons. The BWC, which is the most significant tool in the international biological weapons nonproliferation system, contains some serious flaws. The most

important of those defects is that the BWC continues to lack mechanisms for monitoring and verification. The international community has done a great deal to lay the foundation to establish monitoring and verification for this treaty, but the policies of the Bush administration did not permit adaptation of the proposed BWC monitoring protocol. Thus, the international biological weapons nonproliferation regime continues to be faced with severe challenges.

Contemplating the Threat of Biological Weapons Proliferation

Laboratory Biosafety of Pathogenic Microorganisms in China

Li Jinsong, M.D.¹

In the past ten years, many threats from newly emerging, re-emerging, and even deliberately disseminated infectious agents have challenged the public health and infectious disease research communities worldwide. Several newly emerging pathogens, such as the SARS-associated coronavirus and avian influenza viruses; re-emerging pathogens, such as tuberculosis and the West Nile Virus; and deliberately disseminated diseases, such as the anthrax spread in attacks in the United States in 2001, have caused illness and deaths in humans and animals in China and elsewhere around the globe. Over the past decade, strains of common microbes such as *Staphylococcus aureus* and *Mycobacterium tuberculosis* have continued to develop resistance to the drugs that once were effective against them.²

The mission of China's microbiological and biomedical laboratories is to play a leading role in national efforts to develop diagnostics, vaccines, and therapeutics to combat emerging and re-emerging infectious diseases. These laboratories range in size and complexity from large, comprehensive research and clinical laboratories to the office laboratories of China's physicians. These laboratories employ many workers who could be exposed to a variety of occupational health risks due to their work with infectious materials and cultures. These types of occupational biological hazards are also present in clinical, research, and industrial production laboratories. Globally, laboratory-acquired infections are a common problem and many cases have been reported.³ For instance, in China, a problem with accidental, laboratory-acquired SARS infection occurred in 2004. Exposure to infectious aerosols was considered the most common source of laboratory

¹ Li Jinsong is a Professor of Environmental Microbiology Pollution and Assessment at the Institute of Microbiology and Epidemiology of the Academy of Military Medical Sciences, focusing on the microbiology of indoor air and airborne infection and on the environmental risk assessment of microbiology pollution. He is also the Deputy of the State Key Laboratory of Pathogens and Biosecurity and the Director-in-Chief of the Laboratory of Biosafety at the Institute of Microbiology and Epidemiology.

² David M. Morens, Gregory K. Folkers, and Anthony S. Fauci, "The Challenge of Emerging and Re-emerging Infectious Diseases," *Nature* 430, no. 6996 (8 July 2004):242-9; "Bad Bugs, No Drugs as Antibiotic Discovery Stagnates...A Public Health Crisis Brews," Policy White Paper (Washington, D.C.: Infectious Diseases Society of America, July 2004). Available at: http://www.idsociety.org/pa/IDSA_Paper4_final_web.pdf.

³ David L. Sewell, "Laboratory-Associated Infections and Biosafety," *Clinical Microbiology Review* 8, no. 3 (July 1995): 389-405.

infection. In 1979, Pike concluded that “the knowledge, the techniques, and the equipment to prevent most laboratory infections are available.”⁴

Many microbiological and biomedical laboratories play an important part of China’s efforts to prevent and control infectious diseases nationwide. Good biosafety practices in these laboratories are therefore crucial. Recognizing the importance of laboratory biosafety, the Chinese government began placing a renewed emphasis on the topic in 2003. To strengthen the management of biosafety in laboratories handling pathogenic microorganisms and to protect the health of laboratory personnel and the public, the Chinese government has considerably upgraded its biosafety regulations and criteria associated with laboratory biosafety.

Regulations and Criteria Associated with Laboratory Biosafety in China

A complete system of laboratory biosafety involves many different aspects, including proper laboratory procedures, sound guidelines for transfer of pathogenic microorganisms between facilities, regulations governing the correct use of certain equipment, and standards for building laboratories where personnel will work with highly infectious and/or pathogenic diseases. From 2003 to 2006, the Chinese government issued and implemented fourteen separate laboratory biosafety regulations and measures, which are summarized in Table 1.⁵ In other words, the Chinese government has instituted a comprehensive new set of biosafety regulations and guidelines applicable to all microbiological and biomedical laboratories.

Classification and Management of Pathogenic Microorganisms

The term “risk” implies the probability that harm, injury, or disease will occur. In the microbiological and biomedical laboratories, a risk assessment focuses primarily on the prevention of laboratory-acquired infections. When laboratory activities involve infectious or potentially infectious material, a risk assessment must be done.

⁴ R.M. Pike, “Laboratory-Associated Infections: Incidence, Fatalities, Causes and Prevention,” *Annual Review of Microbiology* 33 (October 1979): 41-66.

⁵ A comprehensive list of China’s current laws and regulations related to biosafety, biosecurity, and genetic engineering activities can be found in the Appendix.

Table 1: Chinese Regulations, Standards, Codes, and Lists Pertaining to Laboratory Biosafety.

Responsible Government Organization	Area of Authority	Identification Number of Measure	Date of Issuance/ Implementation
State Council	Management of biosafety in laboratories working with pathogenic microorganisms	424-2004	5 November 2004
Ministry of Health	General biosafety standards for microbiological and biomedical laboratories	WS233-2002	December 2002/August 2003
Ministry of Agriculture	Code for biosafety management of veterinary laboratories	302-2003	October 2003
General Administration of Quality Supervision, Inspection, and Quarantine and the Standardization Administration	General biosafety requirements for laboratories	GB19489-2004	April 2004/October 2004
Ministry of Construction and the General Administration of Quality Supervision, Inspection, and Quarantine	Architectural and technical code for biosafety in laboratories	GB50346-2004	August 2004/September 2004
State Council	Managerial regulations for the treatment of medical wastes	308-2003	June 2003
Ministry of Agriculture	Regulations for the biosafety management, examination, and certification for zoo laboratories handling highly pathogenic microorganisms	52-2005	2005
Ministry of Agriculture	List of pathogens contagious to animals	53-2005	2005
Ministry of Agriculture	Regulations for the packaging and transport of pathogenic bacteria, viruses, and other pathogenic microorganisms that are contagious to animals	503-2005	2005
State Food and Drug Administration	Regulations for the proper installation and performance of biosafety cabinets	YY0569-2005	July 2005/January 2006

Table 1: Chinese Laboratory Biosafety Regulations and Measures (Continued).

Responsible Government Organization	Area of Authority	Identification Number of Measure	Date of Issuance/ Implementation
Ministry of Health	Regulations for the packaging and transport of pathogenic bacteria, viruses, and other pathogenic microorganisms that are contagious to humans	45-2005	December 2005
Ministry of Health	List of pathogens contagious to humans	Not applicable	January 2006
State Environmental Protection Administration	Managerial regulations for laboratories working with pathogenic microorganisms to safeguard the exterior environment	32-2006	March 2006
Ministry of Health	Regulations for the management, examination, and certification for laboratory biosafety and laboratory activities involving work with highly pathogenic microorganisms that are contagious to humans	50-2006	September 2006

The purpose of a risk assessment is to help choose the appropriate biosafety levels for facilities, equipment, and laboratory practices to reduce to an absolute minimum the risk of exposure to facility workers and the environment. In general, the more infectious and pathogenic the material, the higher the biosafety level to be applied. Another general rule of thumb is that when the infection risk of the material is unknown, conservative or high biosafety containment levels should be applied until the exposure risk is determined.

The factors of interest in a risk assessment include the *pathogenicity* of the infectious or suspected infectious agent, including disease incidence and severity (i.e., mild morbidity versus high mortality, acute versus chronic disease). The *route of transmission* (e.g., parenteral, airborne, by ingestion or aerosol route), which may not be definitively established for newly isolated agents, is also taken into consideration. The *agent stability*, which involves not only aerosol infectivity but also the agent's ability to survive over time in the environment, is contemplated (e.g., from spore-forming bacteria), along with the *infectious dose* of the agent. The infectious dose can vary from one to hundreds of thousands of units. The complex nature of the interaction of microorganisms and the host presents a significant challenge even to the healthiest immunized laboratory worker and may pose a serious risk to those with lesser resistance.

The *concentration*, or number of infectious organisms per unit volume, will be important in determining the risk, as is the volume of concentrated material being handled.

Also critical to a risk assessment is the *origin* of the potentially infectious material. The biohazard level of the material needs to be understood by the receiving facility so that personnel can choose the appropriate biosafety level to handle that material.⁶ Moreover, the *availability of data from animal studies*, in the absence of human data, may provide useful information in a risk assessment. Information about the pathogenicity, infectivity, and route of transmission in animals may provide valuable clues for the behavior of the microorganism in humans. Finally, the established *availability of an effective prophylaxis* or therapeutic intervention is another essential factor to be considered. The most common form of prophylaxis is immunization with a proven vaccine, hence, the availability of effective immunizations and/or other medications (e.g., antibiotics, antivirals) that could be applied in the event of infection to mitigate the disease is also considered.

At a minimum, eight different factors are taken into account in a risk assessment for work with a microorganism and weighed against each other to determine what level of risk the microorganism presents. The next segment of this essay describes how the results of a risk assessment are categorized. In turn, the risk group in which an individual microorganism is placed informs the appropriate biosafety containment precautions warranted for the planned activities with that microorganism.

Risk Categorizations for Microorganisms

The results of the risk assessment help to classify etiologic agents in groups according to the level of hazard they present to humans, animals, the environment, and community. Appropriate government authorities classify pathogenic microorganisms into four categories determined by the infections they cause and the seriousness of their harm to the individual and the community as a whole. These risk group categories guide decisions about the level of biosafety appropriate for work with infectious pathogens.

⁶ Appropriate precautions should always be taken when opening a sample. For example, strict precautions might be taken with material originating directly from field samples (e.g., environmental, human, animal) where the biohazard level has not been firmly established.

Laboratory Biosafety of Pathogenic Microorganisms in China

These classifications presume ordinary circumstances in a research laboratory, or growth of the microorganism in small volumes for diagnostic and experimental purposes.

Pathogenic microorganisms in **Risk Group 1** are considered of high risk to the individual and to the community. Such microorganisms usually cause serious human or animal disease and can be readily transmitted from one individual to another, directly or indirectly. Effective treatment and preventive measures are not usually available. For example, the causative agents for Marburg virus, Ebola virus, Congo-Crimean hemorrhagic fever virus, and Jenin virus (visceral leishmaniasis) fall into Risk Group 1.

Pathogenic microorganisms are categorized in **Risk Group 2** if they present high individual risk, but low risk to the community. Pathogens in this group usually cause serious human or animal disease but do not ordinarily spread from one infected individual to another. Sometimes, effective treatment and preventive measures are available for these diseases. *Mycobacterium tuberculosis*, *Coxiella burnetii*, St. Louis encephalitis virus, and Hantavirus are in Risk Group 2. Working from this system of classification, pathogenic microorganisms in Risk Groups 1 and 2 are jointly referred to as the “highly pathogenic microorganisms.”

The third category of pathogenic microorganisms poses a moderate risk to the individual and a limited risk to the community. **Risk Group 3** refers to pathogens that can cause human or animal disease but are unlikely to be a serious hazard to laboratory workers, the community, livestock, or the environment. Laboratory exposures may cause serious infection, but effective treatment and preventive measures are available and the risk of further spread of infection is limited. To illustrate, Hepatitis B virus, *Salmonella*, and *Toxoplasma* spp are classified in Risk Group 3.

Pathogenic microorganisms in **Risk Group 4** present low risk to the individual and the community. Risk Group 4 pathogens are unlikely to cause disease in healthy workers or animals. The fourth risk group includes microorganisms such as *Bacillus subtilis*, *Naegleria gruberi*, and infectious canine hepatitis virus.

Among other actions, the 2004 State Council regulation on the management of laboratory biosafety resulted in the formulation, publication, and implementation of lists of pathogenic microorganisms capable of spreading to humans and to animals. These lists are used to guide decisions related to biosafety risk assessments as well as decisions

about the appropriate biosecurity precautions to be taken with specific pathogens.⁷ Laboratories that plan to work with these listed human and animal pathogens must have specific permission to do so. Otherwise, laboratories that are not permitted to work with these microorganisms have a grace period to destroy historical reference strains or send any samples of these pathogens that might be in their institutional culture collections to facilities certified to possess such materials.

Biosafety Containment Levels

Another major component of biosafety is the containment level established to indicate the grade of containment required for handling the microorganism safely in a laboratory setting. The biosafety containment level includes the engineering, operational, technical, and physical requirements for manipulating a particular pathogen. Each pathogen has different inherent characteristics, but, as described above, a risk assessment makes it possible to group pathogens into risk levels. The biohazard level of microorganisms determines the biosafety containment level to be employed. Prior to the establishment of new laboratory biosafety standards in China, a Biosafety Level (BSL)-3 laboratory in China was roughly equivalent to BSL-3 laboratories in the United States or Europe. Based largely on the standards of the World Health Organization and the guidelines used in the United States and Canada, the Chinese government has established four grades of containment for work involving pathogenic microorganisms.⁸ With the revised biosafety standards, a BSL-3 laboratory in China is somewhere between a BSL-3 and a BSL-4 facility in Europe or the United States. As a general rule, laboratories in the Biosafety Level 1 and 2 shall not perform experimental activities with highly pathogenic microorganisms.

⁷ China. Ministry of Agriculture, "List of Animal Pathogenic Microorganisms," Regulation 53-2005 (Beijing: 13 May 2005); Ministry of Health, "Directory of Pathogenic Microorganisms Transmissible Between Humans," (Beijing: 11 January 2006).

⁸ Switzerland. World Health Organization, *Laboratory Biosafety Manual*, 3rd ed. (Geneva: 2004); The United States. Centers for Disease Control and Prevention and National Institutes of Health, *Biosafety Microbiological and Biomedical Laboratories*, 4th ed. (Washington, D.C.: U.S. Government Printing Office, May 1999); *Biosafety Microbiological and Biomedical Laboratories*, 3rd ed. (Toronto: Health Canada, 2004).

Biosafety Containment Level 1

The practices, safety equipment, and facility design and construction of BSL-1 facilities are appropriate for undergraduate and secondary educational training and teaching laboratories, and for other laboratories in which work is done with defined and characterized strains of viable microorganisms that are not known to consistently cause disease in healthy human adults. A BSL-1 facility has four major characteristics. First, this type of laboratory requires no special design features beyond those suitable for a well-designed and functional laboratory. Second, biological safety cabinets are not required in a BSL-1 facility. Work may be done on an open bench top. Third, containment is achieved through the use of practices normally employed in a basic microbiology laboratory. Fourth, laboratory personnel have specific training in the procedures conducted in the laboratory and work under the supervision of a scientist with general training in microbiology or a related science. Although there are some differences, Chinese laboratory biosafety practices are modeled largely on those of the World Health Organization.

Biosafety Containment Level 2

The practices, equipment, and facility design and construction are applicable to clinical, diagnostic, teaching, and other laboratories that work with Risk Group 3 microorganisms. A BSL-2 facility has several major characteristics. To begin with, access to the laboratory is limited or restricted at the discretion of the laboratory director when experiments are in progress. A biohazard sign must be posted on the entrance to the laboratory when etiologic agents are in use. Another major characteristic of a BSL-2 laboratory are the precautions taken to limit work with sharp objects to a minimum. Needles, syringes, or other sharp instruments should be used only when there is no alternative, such as parenteral injection, phlebotomy, or aspiration of fluids from laboratory animals and diaphragm bottles. In addition, plastic ware should be substituted for glassware whenever possible. Another defining characteristic of a BSL-2 facility is the presence of properly maintained biological safety cabinets, preferably Class II. If biosafety cabinets are not present, personnel must employ other appropriate personal protective equipment or physical containment devices when conducting procedures with

a potential for creating infectious aerosols or splashes and when high concentrations or large volumes of infectious agents are used. In the event of an accident, BSL-2 facilities must have an eyewash station readily available. Finally, according to the size of the facility, one or more autoclaves to decontaminate infectious materials are essential in all BSL-2 facilities.

Biosafety Containment Level 3

The practices, safety equipment, and facility design and construction are applicable to clinical, diagnostic, teaching, research, or production facilities conducting work with large volumes and high concentrations of Risk Group 3 microorganisms and/or with Risk Group 2 microorganisms, where the risk of aerosolization is high and the consequences of subsequent infection are life-threatening. Construction of BSL-3 laboratories must follow specific guidelines.⁹ BSL-3 laboratories should be registered or listed with national or other appropriate health authorities. This category of laboratory has several defining characteristics.

A BSL-3 laboratory should be separated from other areas of the facility that are open to unrestricted traffic flow within the building. To accomplish this, a BSL-3 laboratory should consist of the clean area, the potentially contaminated area, and the contaminated area. The clean area and the potentially contaminated area are linked by an air lock, and the potentially contaminated area and the contaminated area are linked by a second air lock. The structure of the BSL-3 laboratory is called “three areas and two buffers.” The author first proposed this concept of “three areas and two buffers” in the 2004 general biosafety requirements for laboratories.¹⁰ Additional buffers are established with the use of biosafety cabinets. While Class II biological safety cabinets are normally used in BSL-3 laboratory, a Class III biological safety cabinet may be needed for high-risk procedures involving Risk Group 2 microorganisms, in accordance with national

⁹ China. Chinese General Administration of Quality Supervision, Inspection and Quarantine and Chinese Standardization Administration, *General Biosafety Requirements for Laboratories*, Regulation GB19489-2004 (Beijing: 2004); China. Chinese Ministry of Construction and Chinese General Administration of Quality Supervision, Inspection, and Quarantine, *Architectural and Technical Code for Biosafety Laboratories*, Regulation GB50346-2004 (Beijing: 2004).

¹⁰ China. Chinese General Administration of Quality Supervision, Inspection and Quarantine and Chinese Standardization Administration, *General Biosafety Requirements for Laboratories*, Regulation GB19489-2004 (Beijing: 2004).

rules. Biological safety cabinets should be situated away from areas of high foot traffic and out of cross-currents from doors and ventilation systems. A final buffer for laboratory workers is personnel protective equipment and other physical protective equipment, which must be used in BSL-3 laboratories.

BSL-3 facilities also have stricter requirements for the control of air and other materials exiting the area. The ventilation system must establish a directional air flow from the clean area into the contaminated area. At all times, staff must ensure that proper directional air flow into the contaminated area is maintained. The building ventilation system must be also constructed so that air from the BSL-3 laboratory is not recirculated within that laboratory or to other areas within the building. Exhaust air from the BSL-3 laboratory (other than from biological safety cabinets) must be filtered through high-efficiency particulate air (HEPA) filters and must be discharged outside of the building. Exhaust air outtakes are separate from air intake vents and from occupied buildings. The exhaust air from Class II and/or Class III biological safety cabinets must be passed through individual HEPA filters for each biosafety cabinet and must be discharged in a way that avoids interference with the air balance of the cabinet or the exhaust system for the building. All HEPA filters for the biosafety cabinet(s) and general BSL-3 laboratory must be installed in a manner that permits gaseous decontamination and testing. For liquid and solid materials, an autoclave for the decontamination of waste material must be available in the BSL-3 laboratory. Autoclaves are to be installed in the wall between the clean area and the potentially contaminated area so that all autoclaved materials can be removed in the clean zone. All laboratories that meet the construction, equipment, and other pertinent biosafety standards for BSL-3 are to be accredited by the proper authorities working on behalf of the State Council. The certificate of accreditation is valid for a five-year period.

Biosafety Containment Level 4

The practices, safety equipment, and facility design and construction are applicable to clinical, diagnostic, research, or production facilities in which work is performed with Risk Group 1 microorganisms and/or with large volumes and high concentrations of Risk Group 2 microorganisms, where there is a high risk of aerosol

spread and subsequent life-threatening consequences from infection. As of yet, there are no BSL-4 laboratories in China. For the time being, Risk Group 1 microorganisms are being studied in BSL-3 laboratories using BSL-4 practices and strengthened individual protection for the personnel working with these pathogens.

The Management of Specific Work within a BSL-3 Laboratory

A variety of procedures can be performed in a laboratory; some procedures generate a low or very restricted risk of accidental exposure, others create a higher risk of exposure. To illustrate, a Risk Group 3 virus being grown in liter-sized cultures to make reagents or to deactivate it for the manufacture of a vaccine might require BSL-3 biosafety precautions. Also, careful attention must be taken selecting the appropriate biosafety measures for procedures (e.g., grinding, centrifugation) that create a risk of micro-aerosolization of the pathogenic microorganism or that involve the handling of dry forms of Risk Group 2 microorganisms that are electrostatic. A combination of the type of laboratory procedures to be done and the Risk Group of the pathogenic microorganism(s) are used to select specific biosafety measures for work within a BSL-3 laboratory. Such factors are used to determine the size of the BSL-3 facility required, the proper class of biosafety cabinet and other physical containment devices, and the personal protective equipment needed for specific procedures. Following the risk assessment, a biosafety plan specific to each proposed experiment can be created.

For all experiments with highly infectious human or animal pathogens, an accredited laboratory must present a plan for the experiments that is in conformance with the biosafety regulations of the appropriate authorities (e.g., veterinary for animal pathogens). BSL-3 laboratories must also ensure that the staff that will be involved in these experiments are trained appropriately in the practices, procedures, and biosafety requirements for the proposed experiments. If these preconditions are met, the appropriate national health or veterinary authorities will review suitability of the proposed experiment.

In conjunction with the facility's biosafety capacities, two aspects of the research plan are closely evaluated. First, the laboratory must have attained the appropriate corresponding level of biosafety to be able to apply for acquisition of a highly pathogenic

microorganism. A BSL-1 laboratory, therefore, cannot apply to work with a microorganism in Risk Group 3 unless and until the laboratory is certified as having completed the required improvements to bring its infrastructure, laboratory equipment, biosafety management, biosafety practices and standard operational procedures, personnel training, and personal protective gear up to BSL-3 standards. Second, the laboratory must state a scientific research requirement for the proposed work with highly pathogenic microorganisms.

If there is a scientific need for the research and all of the requisite biosafety requirements have been met, then the relevant health or veterinary authorities will grant the requesting BSL-3 laboratory credentials to proceed with the proposed experiment(s) and will also give approval to receive the seed culture for the highly pathogenic microorganism(s) from a central culture collection. At the conclusion of the experiment(s), a report describing the work undertaken and its results must be filed with the relevant authorities.

Institutional Management of BSL-3 Laboratories

An institution that establishes a BSL-3 laboratory is responsible for overseeing laboratory biosafety so that the required national standards for strict scientific, technical, and managerial regulations are implemented and updated, as needed, for the BSL-3 facility. Under this managerial system a National Accreditation Service for Conformity committee, consisting of biosafety experts, was established. This committee conducts initial and periodic inspections to ensure the implementation of the biosafety regulations and the proper maintenance and repair of the BSL-3 facilities, equipment, and material. The Ministries of Health and of Agriculture, which oversee pathogenic human and animal microorganisms respectively, are also engaged in authorizing specific activities in BSL-3 laboratories.

The institution with a BSL-3 laboratory shall create a three-tiered system for biosafety management that consists of the Institutional Biosafety Committee (IBC), the BSL-3 laboratory director, and the principal investigators (PIs) for various programs conducted within the laboratory. The IBC has four major responsibilities. First, the IBC is accountable for establishing biosafety policies, procedures, and regulations that are

consistent with national and international laws, regulations, and standards and making sure that these are carried out in the institution. If personnel at the BLS-3 propose projects involving biohazardous substances that are not specifically listed in the risk groups, the IBC has the authority to review, approve, and oversee the execution of such projects. The IBC is also responsible for guaranteeing that the institution's Biosafety Office makes biosafety information services, training programs, and emergency assistance available. Finally, the IBC is to supervise and assist the institution's Biosafety Officer and his support staff in carrying out their responsibilities.

Concurrent with the IBC, the director of the BSL-3 laboratory holds primary responsibility for laboratory biological safety. The BSL-3 director reviews and renews the certificates for the proper operation of laboratory safety equipment, facilities, and personnel training. To underscore this responsibility, these certificates bear the laboratory director's personal signature. Assessments of the potential safety and environmental hazards of proposed research programs and procedures are the responsibility of the laboratory director, who also develops standard operating procedures specific to the laboratory and, if needed, for individual projects. In sum, the laboratory director supervises the biosafety of all experiments and practices within the BSL-3 facility and sees that all personnel comply with all applicable regulations and guidelines.

The laboratory director is also responsible for seeing that there is adequate surveillance of the health of laboratory personnel. Given the potentially hazardous nature of the work, BSL-3 laboratories are not to employ individuals who are highly susceptible to disease (e.g., pregnant women,¹¹ immuno-compromised individuals). The objective of the surveillance is to monitor for occupationally acquired diseases. Appropriate health surveillance activities include the mandatory medical examination of all BSL-3 laboratory personnel, beginning with a detailed medical history and a physical examination. After a satisfactory clinical assessment, the examinee should be provided with a medical contact card that the individual is always to carry that contains their picture and identifies them as an employee of a BSL-3 laboratory. During the initial examination, a baseline serum sample should be obtained and stored for future reference.

¹¹ For the safety of mother and child, pregnant women are restricted from engaging in certain activities with biohazardous agents for the duration of their pregnancy.

Laboratory Biosafety of Pathogenic Microorganisms in China

Health monitoring allows for the provision of active or passive immunization against one or more diseases, where indicated, and of effective personal protection equipment and procedures.¹²

The PIs in a BSL-3 laboratory are to assess the risks of their experiments and, if required, to submit proposed experiments for initial review and approval by the IBC, other relevant managerial departments of the institution, and subsequently by the appropriate national authorities. PIs must register the following types of experiments for institutional and national biosafety oversight: 1) recombinant DNA activities; 2) work with infectious agents; 3) experiments involving the use of human blood or other potentially infectious materials, such as unfixed human tissues, primary human cell lines, and certain body fluids; and, 4) work animal and plant pathogens. Other major biosafety duties of the PI are to ensure the safe operation of their laboratory; to establish plans and capacities for emergency treatment in the event of an accident; to train their personnel in safe work practices; and to comply with all applicable state and local or institute regulations and guidelines.

The institution with the BSL-3 laboratory or the laboratory itself is to provide initial and annual training to laboratory personnel to ensure their mastery of the standardized laboratory technology, operational procedures, and biosafety precautions, knowledge, and operational and technical know-how. All laboratory personnel are to be evaluated on their knowledge of these matters before beginning work in the laboratory, and only those assessed as having the requisite knowledge will be permitted to resume their duties.

Finally, all institutions with BSL-3 laboratories are to have a general system of safety and security for the BSL-3 laboratory and take specific additional measures to ensure that the BSL-3 laboratory guards strictly against the theft, misplacement, and/or unauthorized diversion of the pathogenic microorganisms in its possession. These security measures are to be reviewed and improved, as needed. In case of any theft, misplacement, or diversion of a microorganism from a BSL-3 laboratory, the incident must be reported to the appropriate authorities.¹³ The BSL-3 laboratory is also to advise

¹² This type of health monitoring would also be required for personnel working in a BSL-4 laboratory, but not for those working in BSL-2 or BSL-1 laboratories.

¹³ See Article 17, in China's *Managerial Regulation Governing the Biosafety in Laboratories Working with Pathogenic Microorganisms*, Regulation 424-2004 (Beijing: State Council, 2004).

local law enforcement agencies of its activities related to highly pathogenic microorganisms and is to accept their counsel and supervision on matters of facility security.

Laboratory accidents and instances of regulatory noncompliance at microbiological or biomedical laboratories in China are to be reported to the management of the institution and, as appropriate, to the national authorities overseeing the laboratory's activities. Depending on the seriousness of the accident or noncompliance, an investigation would be conducted. If the situation involves laboratory-acquired infection, the laboratory would be closed during the investigation of the incident. Once the cause of the problem is understood, a new standard operating procedure or guideline would be established to address the problem, or perhaps the governing regulation would be revised. The laboratory where the incident occurred would have to be recertified to work at the appropriate biosafety level prior to resuming operations.

Concluding Observations

In recent years, the Chinese government has made considerable revisions to its regulations and standards for laboratory biosafety. Additional improvements to China's laboratory biosafety measures will certainly be made in the future. For the time being, the issue of concern for laboratory biosafety in China relates to a shortage of officials, experts, and scientists who specialize in laboratory biosafety. This dearth of professionals has made it a challenge to implement the new regulatory system in a timely and complete manner. Furthermore, this personnel shortage has also made it difficult to review and compare China's existing regulations with the upgraded standards and technologies of other countries to help determine where China's regulations might be even further improved. To augment China's expertise in biosafety, the Chinese government has begun to send scientists to work in laboratories overseas to gain first-hand experience with practices in other countries. To continue building on the recent improvements that have been made, individuals involved in laboratory biosafety in China welcome cooperation with specialists in other countries and from the World Health Organization on matters of laboratory biosafety. Areas of potential collaboration include

Laboratory Biosafety of Pathogenic Microorganisms in China

biosafety training in universities, research laboratories, and other facilities; institutional management of biosafety; novel laboratory biosafety technologies; new laboratory biosafety concepts; and biosecurity.

Chinese Biosafety Laws and Regulations, Including Matters of Biosecurity and Oversight of Genetic Engineering Activities

Hu Longfei (MD, MPH), Xiang Dapeng (MPH, ML), Shi Yongxia (Ph.D.), Huang Jicheng (Ph.D.), Zheng Kui (BS), Hong Ye (MD, MS), Li Xiaobo (MS), and Xing Luqin (BS)¹

Prior to the outbreak of severe acute respiratory syndrome (SARS) in 2002, China had many measures related to biosafety dispersed among departmental rules and standards related to work with pathogens, but specific biosafety laws and regulations did not exist. China's network of biosafety measures was not systematic, nor was it comprehensive, particularly for laboratory biosafety. After the SARS outbreak, the Chinese government further realized the importance of biosafety to Chinese and human development. The relevant departments of the Chinese government have since been paying close attention to biosafety matters, studying the problems of biosafety and the developments that have been taking place to improve biosafety around the world. The Chinese government began to reorganize, revise, elaborate, and update its laws and regulations on biosafety, some of which have been issued to keep pace with advances in science and technology. For example, some recent regulations are designed to manage genetic engineering research and also the development, testing, and production of genetically modified organisms.

China has therefore improved its biosafety management system with a series of regulations that concern different aspects of biosafety. In conjunction with a 2004 State Council umbrella regulation on biosafety, two additional national standards and several subsidiary standards addressing specific aspects of biosafety have been issued. By early 2007, the Chinese State Council and responsible institutions of government had announced and implemented a series of revised and new biosafety regulations and

¹ The lead author of this essay, Hu Longfei, is the director and chief epidemiologist at the Department of Health and Quarantine, Guangdong Entry-Exit Inspection and Quarantine Bureau, No. 66 Huacheng Avenue, Zhujiang Xincheng, Guangzhou City, Guangdong Province, China. A brief biography of Dr. Hu can be found in an annex to this report. Xiang Dapeng, Shi Yongxia, Huang Jicheng, Zheng Kui, Hong Ye, Li Xiaobo, and Xing Luqin are employed at Health Quarantine Laboratory, Technology Center, Guangdong Entry-Exit Inspection and Quarantine Bureau, No. 13 Gangwan Avenue, Huangpu District, Guangzhou City, Guangdong Province, China. Dr. Shi is the corresponding author. e-mail: syx0817@yahoo.com.cn. Tel: 86-20-82270685. Fax: 86-20-82270685.

Chinese Biosafety Laws and Regulations, Including Matters of Biosecurity and Oversight of Genetic Engineering Activities

standards². The result is that China is on the verge of completely establishing and implementing an almost ideal system of technical biosafety standards and regulations.

The General Framework for Biosafety Management of Biomedical and Pathogenic Microbiology Laboratories

The State Council established and implemented China's principal overarching framework for laboratory biosafety with the "Regulation on the Biosafety Management of Pathogenic Microbiology Laboratories" on 12 November 2004. This regulation established the basic pattern of biosafety management for microbiology laboratories that work with pathogens and defined the duties of all pertinent government departments and requirements for biosafety laboratories in China. This regulation, which articulates clear laboratory biosafety requirements, is divided into seven chapters: 1) the general rule; 2) classification and management of pathogenic microbiology laboratories; 3) the establishment and management of pathogenic microbiology laboratories; 4) infection control in pathogenic microbiology laboratories; 5) supervision and management; 6) legal liability; and, 7) supplementary provisions.

This ordinance also defined, as shown in Table 2, governmental responsibilities for the management of laboratory biosafety in accordance with the functions of various government agencies. Within these overall areas of responsibilities, the duties are further divided between the relevant bureaus and offices in each of the departments named.

In terms of the infectious threat that a microorganism presents to an individual or the community, a pathogenic microorganism is rated in four grades, with the first risk group posing the most serious harm and the fourth group the least serious health risk. Laboratories are divided into four levels of biosafety containment according to the risk level of the pathogenic microorganism and national standards for biosafety laboratories. The construction and accreditation procedures for pathogenic microorganism laboratories and for their personnel must meet the requirements stipulated in the ordinance.

This ordinance also specifies the essential terms for the collection, packaging, transportation, storage, and destruction of an infectious or pathogenic microorganism.

² A comprehensive list of China's biosafety regulations can be found in the Appendix.

Table 2: Division of Responsibilities for Laboratory Biosafety within the Chinese Government.

Governmental Department	Area of Responsibility
National Development and Reform Committee	Overall laboratory planning
General Bureau of Environmental Protection	Evaluation and certification of the environmental impact of laboratories
Ministry of Construction	Establishment of the construction standards and inspection of laboratories to ensure construction quality
National Accreditation Board for Laboratories	Accreditation of a laboratory's biosafety equipment and management system
Ministry of Health	For experiments related to human health, approval of the laboratory and its planned experiments; corresponding biosafety oversight
Ministry of Agriculture	For experiments related to animal research and health, approval of the laboratory and its planned experiments; corresponding biosafety oversight

Moreover, the ordinance requires that laboratories have measures in place for infection control and treatment protocols in the event of an accident in the laboratory. Should an accident with serious consequences occur, the relevant governmental departments that have oversight responsibility for the aspect(s) of a laboratory's infrastructure and/or operational procedures found to be at fault will bear legal liability.

The Mandatory Standards for Laboratory Biosafety

The Ministry of Health and the Ministry of Agriculture, respectively, issued the "General Biosafety Standard for Microbiology and Biomedical Laboratories" on 3 December 2002 and the "Veterinary Laboratory Biosafety Guidelines" of 15 October 2003. This pair of standards focuses on biosafety operational procedures, laboratory cleanliness, and management. Penalties for noncompliance are not included in these standards. To clarify and strengthen these standards, a mandatory national standard was issued on 5 April 2004 and implemented formally on 1 October 2004. This standard, "Laboratories—General Requirements for Biosafety," is largely patterned on the World Health Organization's *Laboratory Biosafety Manual*.³ This standard raised the overall

³ The General Administration of Quality Supervision, Inspection and Quarantine and the Standardization Administration issued this standard base on *Laboratory Biosafety Manual*, 3rd ed. (Geneva: World Health Organization, 2004).

Chinese Biosafety Laws and Regulations, Including Matters of Biosecurity and Oversight of Genetic Engineering Activities

threshold for laboratory biosafety in China, resulting in the regulation of many aspects of laboratory biosafety, including management and construction principles, biosafety ratings, the disposition of the facility equipment, personal protection, and biosafety practices. The Ministry of Health and the Ministry of Agriculture also issued two major subsidiary regulations under this standard.

The containment level for a given laboratory is determined by the relative pathogenic and infectious risk of the organisms the laboratory works with and the strictness of the procedures taken to safeguard employees, the public, and the environment. Containment levels are rated in four grades, from biosafety level 1 (BSL-1) for the lowest containment safeguards to BSL-4 for the highest. The corresponding containment levels for animal biosafety laboratory one (ABSL-1) to four were also established. This standard confirmed the fundamental requirements and evaluation criteria for the four biosafety containment level facilities and regulates in detail laboratory biosafety practices and personal protection. The regulations in this standard apply to medical laboratories and also to all kinds of biosafety laboratories (e.g., teaching, production).

Additional Standards for Biosafety in China

“Methods for the Biosafety Environmental Management of Pathogenic Microbiology Laboratories,” issued by the State Environmental Protection Administration on 2 March 2006 and implemented on 1 May 2006, concretely establishes a demand for an environmental impact appraisal for biosafety laboratories according to their containment level, which is divided into four grades. The environmental impact assessment should be carried out when a biosafety laboratory is being built, renovated, or expanded. This ordinance also points out the approval procedures for building a new biosafety laboratory, for renovating or expanding a BSL-3 and BSL-4 laboratory engaged in activities with highly pathogenic microorganisms, and for importing and installing a mobile or trailer-like BSL-3 and BSL-4 laboratory. The organization conducting the environmental impact appraisal should be qualified to do appraisals of BSL-3 and BSL-4 laboratories.

An existing biosafety laboratory should register its systems for pollution and waste control with the appropriate authorities and file regular reports for its discharges of waste water and waste gas. All biosafety laboratories should set up a system for the monitoring and appropriate disposition of all solid hazardous wastes. All hazardous wastes generated during the course of laboratory activities are to be collected in special-purpose containers qualified for hazardous wastes. The laboratory should have different kinds of hazardous waste containers depending on the type of hazardous wastes being generated (e.g., liquids, sharp objects, solids). In addition, the laboratory should provide a temporary storage cabinet or other receptacle suitable for the needed levels of hazardous waste. In a timely fashion, hazardous waste should be decontaminated inside the laboratory and then transferred to a nearby business licensed to dispose of hazardous waste properly. The frequency of a laboratory's decontamination activities will depend on the size of the facility and its biosafety level. BSL-3 and BSL-4 laboratories should decontaminate their hazardous wastes following each experiment, with a decontamination method (e.g., autoclave, chemical disinfection) appropriate for the type of waste generated. All handling and transfers of a laboratory's solid hazardous waste should be accomplished and documented according to Chinese laws on "Prevention of Environmental Pollution Caused by Solid Waste" and relevant regulations of State Lead Bureau for Environmental Protection.

Mandatory Construction Code for Biosafety Laboratories

The Ministry of Construction issued another mandatory national standard, the "Architectural and Technical Code for Biosafety Laboratories," on 3 August 2004 and implemented it on 1 September 2004. This standard was based on an extensive survey and study of relevant domestic and foreign standards that took into account widespread domestic experience in engineering and construction. The standard stipulates some technical requirements about construction layout and the structure and fitting of major features of the laboratory. The central component of the regulation concerns the laboratory ventilation system, and the standard specifies the appropriate ventilation approach, design, and construction to achieve the proper directional flow of air, including the system-wide ventilation schematic and the construction material to be used. Likewise,

Chinese Biosafety Laws and Regulations, Including Matters of Biosecurity and Oversight of Genetic Engineering Activities

the standard sets control principles for water supply and plumbing, gas supply, power distribution, automation, and fire control in the facility. In addition, the principles and methods of construction, testing, and examination, and certification of BSL-3 and BSL-4 laboratories are necessarily regulated.

Rules on Biological Safety Cabinets

Biological Safety Cabinets (BSCs) are designed to greatly reduce the airborne hazards (e.g., aerosols, gases, vapors, dusts) generated by the activities performed inside the BSC. Class I BSCs protect the workers from these hazards before workers can inhale those contaminants; Class II BSCs protect the workers, the work inside the cabinet, and the environment from the airborne hazards.⁴ The State Food and Drug Administration and the Ministry of Construction are responsible for the two central regulations governing biological safety cabinets in China. These regulations are very detailed, but their main contents concern the design, manufacture, examination, testing, packing, transport, and installation of BSCs. These two regulations will play an important role in standardizing the market for BSCs in China. As Table 3 indicates, the State Food and Drug Administration's YY0569 and the Ministry of Construction's regulation JG170-2005 are modeled on the Standardized Committee of Europe EN12469: 2000 and the National Standards Institute NSF49-2002. For instance, the State Food and Drug Administration regulation YY0569 adopts the KI-Discus test from the European standard for BSCs, EN12469: 2000.⁵

While the Chinese regulations are patterned on European and American BSC standards, they also include improvements on those models. For instance, regulation YY0569 states the performance standards for BSC, including an instant display for air

⁴ Class III BSCs also exist for work with highly infectious pathogens and are totally contained, without a front opening. Negative air pressure is maintained inside the BSC, an airlock is used to bring materials into the BSC, and work inside the BSC is performed using ports with flexible gloves.

⁵ The KI-Discus test is designed to allow measurement of how well the BSC will protect individuals who are using it. A disk containing potassium iodide is placed inside the BSC and generates an aerosol when it is made to spin. For a specific period of time, the air outside of the front opening of the BSC is sampled and analyzed to see how many potassium iodide particles can be detected. For example, a BSC is considered to provide good protection if no more than 1 particle from every 100,000 potassium iodide particles released inside the BSC can be detected outside of the BSC.

exchange rate and the air intake and an audio and visual warning system to alert workers to performance malfunctions of the BSC.

Table 3: Chinese Regulations Governing Biological Safety Cabinets.

Chinese Authority Overseeing the Standard	Identification Number of the Standard	Date Issued	Date Implemented	Models for the Standard
State Food and Drug Administration	YY0569-2005	18 July 2005	1 June 2006	American National Standards Institute NSF49-2002; Standardized Committee of Europe EN12469: 2000
Ministry of Construction	JG170-2005	25 March 2005	1 June 2005	

NSF49-2002 does not include these requirements, which were added to provide additional safety guarantees for the personnel working in Chinese biosafety facilities. In some instances, the test requirements (e.g., cleanliness) and product characteristics (e.g., noise level when operating) stated for BSCs in regulation JG170-2005 are also more rigorous than those stated in NSF49-2002 and EN12469: 2000.

Other main differences between Chinese, U.S., and European standards are first that while the European requirements only have a basic definition for Class II BSCs, the Chinese and U.S. regulations specify four types of Class II BSCs.⁶ The European, Chinese, and U.S. standards all regulate in detail every testing method and the certification standards for the operational function of BSCs. As previously mentioned, the Chinese regulations, like the European ones, use the KI-Discus test to certify the level of protection from aerosol hazards that BSCs provide to laboratory workers. The American BSC regulation does not stipulate a permissible range for a reduced air velocity in Class II BSCs, but the Chinese and European regulations do.⁷ The Chinese regulation divides reduced air velocity in two operational modes, namely, “even reduction” and

⁶ The Chinese and U.S. Class II types are A1, A2, B1, and B2. Class II BSCs are defined mainly by the speed of the air current flowing into the front window of the cabinet, the air circulation in the cabinet, and the filter precautions for the exhaust.

⁷ The range for reduced air velocity in YY0569 and EN12369 is 0.25-0.5m/s.

Chinese Biosafety Laws and Regulations, Including Matters of Biosecurity and Oversight of Genetic Engineering Activities

“non-uniform reduction.” Finally, all of the standards identify numerous testing spots for operational tests.

Unlike the European and U.S. regulations, Chinese regulation YY0569 also clearly stipulates the design standard of cabinet body structure of class II BSCs (A2, B1, B2 types). The workspace of BSCs should be adopted on four sides (left, right, rear, and bottom sides) and in a double-deck structure. Consistent with the purpose of BSCs, which are designed to contain biological hazards, all of the air pressure gauges should be set to maintain negative flow or the BWC should be located in a negative pressure room with the appropriate ventilation system. The uncovered wall board of three sides of the Class II and Class III BSCs should be shaped into an integrated structure and sealed. Regulations require that BSCs in China undergo official examination and certification at least once annually.

To test the leakage of the BSC cabinet body, the Chinese regulation YY0569 adopts the U.S. and European standards of the pressure decay method, which uses a pressure gauge or pressure sensor system to show the pressure in the cabinet and can quantitatively measure the extent to which the cabinet body is airtight. Whereas the U.S. standard stipulates that manufacturers use the soap bubble method for their routine leakage test of all BSCs, EN12469 requires that leakage testing be done by an independent authentication laboratory.

While the three BSC standards discussed above have very much in common, the Chinese standards adopt the best from both the U.S. and the European standards and then improve on those models by including more accurate and rigorous methods for some key tests. Therefore, the Chinese testing standard for BSCs is one of the strictest in the world.

Biosafety Management of Medical Wastes

The management of medical wastes is linked to many activities, such as the collection, storage, handling, alteration, and transport of waste material. Many departments of the Chinese government, including the State Council, the Ministry of Health, and State Environmental Protection Agency have issued regulations and standards pertinent to the management of medical wastes. Table 4 lists these measures.

Table 4: Regulations Related to the Proper Management of Medical Wastes.

Title of the Regulation	Implementation Date
Management System for Hazardous Waste Transfers and Associated Documentation	1 October 1999
Requirements for the Discharge of Sewage from Medical Organizations	1 March 2002
Technical Standards for Disinfection	1 April 2003
Regulations on the Administration of Medical Wastes	16 June 2003
List of Medical Wastes	10 October 2003
Measures for Medical Waste Management at Medical and Health Institutions	15 October 2003
Regulation of Standards and Warnings for Special-Purpose Packaging or Containers for Medical Wastes	20 November 2003
Technical Guidelines for Waste Water Treatment at Hospitals	10 December 2003
Technical Specifications for Handling Medical Wastes	26 December 2003
Design Code for the Hospital Waste Water Treatment System	1 May 2004
Administrative Punishment Measures for Medical Waste Management	1 June 2004

The regulations in Table 4 create a comprehensive, concentrated, and strong system of management with responsibilities appropriately divided among participating organizations. These regulations cover activities from the generation to the treatment of medical wastes and strict safety controls are imposed throughout the entire process.

Among the detailed requirements for medical waste management are that the relevant administrative staff should receive training in the professional skills necessary to manage the proper disposition of medical wastes and should have effective hygiene safeguards in place. Medical wastes should be categorized and collected according to the waste categories in the “Classified Catalogue of Medical Wastes” and placed separately into the appropriate hazardous waste packaging containers. Any transportation of medical wastes from one location to another within the facility should be documented, and the special-purpose receptacle or barrel and the vehicle used to transport these wastes must meet relevant standards. The temporary storage area for medical wastes must be separated from the storage area for ordinary trash, posted with identification and warning signs, constructed to prevent exposure of the stored wastes to rain, rodents, or insects, and

Chinese Biosafety Laws and Regulations, Including Matters of Biosecurity and Oversight of Genetic Engineering Activities

have security to guard against theft of the medical wastes. The facilities that treat medical wastes have such features as a disinfection room, incinerators, a sewage disposal pool (e.g., septic tank, disinfection pool), and mud dehydration treatment facilities.

Another requirement of these standards is that medical organizations build waste water treatment facilities and institute regular monitoring of the generation of waste water. Several branches of local government are involved in the management of medical wastes. County, city, provincial, and national government authorities are responsible for building treatment facilities for medical wastes. The sanitation departments at these levels of governments are accountable for supervising measures to prevent disease during the process of collecting, handling, storage, and transport of medical wastes, as executed by sanitation departments. Finally, country, city, provincial, and national environmental protection agencies are in charge of the supervision and control of measures to prevent environmental pollution in the handling and disposition of medical wastes.

Noncompliance with the regulations governing medical waste management is to be penalized according to the “Administrative Punishments for Medical Waste Management.” An organization that does not handle medical waste according to the regulations will be warned and ordered to come into regulatory compliance within a specific period of time. Should the organization not fix the problem within the time period identified, a fine of 1000 to 5000 Yuan (approximately \$130 to \$645) will be imposed. An institution that has not converted to the new, centralized system of hazardous waste management or that delivers medical waste to an organization that is not properly qualified to transport, store, or handle hazardous wastes will be directed to cease the illegal activities and to correct its noncompliance within a particular period of time. A fine of 50,000 Yuan (approximately \$6,450) will be imposed if corrective action is not taken within the specified time period.

Reference Lists of Pathogenic Microorganisms

To enable the proper implementation of the regulations on biosafety management in laboratories, the Ministry of Health and the Ministry of Agriculture announced reference lists for human and animal pathogens on 13 May 2005 and 11 January 2006,

respectively.⁸ The list of animal and human pathogenic microorganisms has 123 species and 380 species, respectively, as Table 5 shows. Based on a risk assessment of the pathogenic microorganisms, the regulations state that live pathogenic microorganisms (e.g., bacteria, viruses) in the Class I and Class II categories of risk should generally be restricted to BSL-3 or BSL-4 laboratories. Deactivated pathogens from these two risk categories can be worked with in BSL-2 laboratories. Activities with pathogenic microorganisms of the class III or IV risk are to be handled in BSL-2 or BSL-1 laboratories. These reference lists also factor into decisions about the appropriate biosecurity measures to be taken for the listed human and animal pathogens, as discussed later in this essay.

Table 5: China’s Lists of Pathogens of Risk to Humans and to Animals.

List Category	Type of Pathogens	Category of Risk	Examples	Number of Pathogens in Risk Class
Animal Pathogens		Class I	Foot-and-mouth disease virus, highly pathogenic avian influenza virus, African horse sickness virus, Rinderpest virus, Peste des petits ruminants virus	10
		Class II	Classical swine fever virus, Newcastle disease virus, rabies virus, sheep smallpox virus, goat small pox virus, rabbit hemorrhagic disease virus, <i>Bacillus anthracis</i>	8
		Class III	Influenza virus with low pathogenicity, Pseudorabies virus, <i>Clostridium tetani</i> , <i>Clostridium chavuoai</i> , <i>Mycobacterium bovis</i>	107
		Class IV	Microorganisms with low infectivity, low pathogenicity and/or low toxicity not included in Class I, Class II and Class III	Not applicable

⁸ The Chinese government has not established a similar reference list for plant pathogens.

Chinese Biosafety Laws and Regulations, Including Matters of Biosecurity and Oversight of Genetic Engineering Activities

Table 5: China's Lists of Pathogens of Risk to Humans and to Animals, Continued.

List Category	Type of Pathogens	Category of Risk	Examples	Number of Pathogens in Risk Class
Human Pathogens	Viruses	Class I	Alastrim virus, Eastern equine encephalitis virus, Ebola virus, Lassa fever virus, Monkeypox virus	29
		Class II	Foot-and-mouth disease virus, Herpesvirus saimiri, highly pathogenic avian influenza virus, Human immunodeficiency virus (HIV) type 1 and 2 virus, Japanese encephalitis virus	51
		Class III	Adenoviruses, Bunyavirus, Adeno-associated virus, Astrovirus, newly emerging viruses	74
		Class IV	Guinea pig herpes virus, Mouse leukemia virus, Mouse mammary tumor virus, Rat leukemia virus	6
	Prions	Class II	Transmissible spongiform encephalopathies (e.g., Creutzfeldt-Jakob disease, Gerstmann-Straussler-Scheinker syndrome)	5
		Class III	Scrapie	1
	Bacteria, actinomyces, mycoplasma, spirochaeta, etc.	Class II	<i>Bacillus anthracis</i> , <i>Brucella</i> spp, <i>Mycobacterium tuberculosis</i> , <i>Vibrio cholerae</i> , <i>Yersinia pestis</i>	10
		Class III	<i>Acinetobacter lwoffii</i> , <i>Acinetobacter baumannii</i>	145
	Fungi	Class II	<i>Coccidioides immitis</i> , <i>Histoplasma farcinimosum</i>	4
		Class III	<i>Absidia corymbifera</i>	55

Sources: “List of Animal Pathogenic Microorganisms” (Beijing: Ministry of Agriculture, 13 May 2005); “Directory of Pathogenic Microorganisms Transmissible Between Humans” (Beijing: Ministry of Health, 11 January 2006).

The Framework for Biosecurity in China

The system for biosecurity in China requires different approvals and increasingly rigorous security measures for the authorization to possess, to transfer, and to experiment with microorganisms, depending on the risk the microorganisms pose to human and

animal health and the environment. China's regulations for the proper storage of strain collections date back to 1980. The first of these regulations was the Ministry of Agriculture's "Methods on the Trial Management of the Preservation of Veterinary Microbial Strains," implemented on 25 November 1980 and revised on 1 July 2004. In the interim, the Ministry of Public Health "Methods on Management of Preservation of Medical-Microbiology Strains in China" on 23 March 1985 and the State Science and Technology Commission issued "Rules on Management of the Preservation of Microbial Strains in China" on 8 August 1986. These regulations all apply to human and animal microorganisms and are very detailed. They include: guidelines for the classification of strains, sample procedures for the collection of strains, the proper conditions for strain storage, the supply or sale of strains, the use of strains, and the acquisition, transfer, and exchange of strains with outside organizations. Under these regulations, the Ministry of Public Health and Ministry of Agriculture have appointed culture collection centers and laboratories to receive, preserve, and store microbial strains and samples. Thus, since 1980, any laboratories or culture collections across China not specifically designated to receive, preserve, and store pathogens but that had strains and samples of pathogens in their historical collections were required to destroy those strains or samples immediately or to deliver them to an authorized culture collection center.

The biosafety level of the laboratory and the reference lists created in 2005 and 2006 for the pathogens serve to establish two other levels for biosecurity in that organizations must meet certain additional criteria to work with any of the human and animal species on these lists, which are elaborated in Table 5. To qualify to receive and handle human and animal pathogens on these reference lists, an institution must be legally established and have a laboratory certified to engage in experimental activity with highly pathogenic microorganisms. The receiving institution must also obtain approval from the particular government offices responsible for experimental activity with highly pathogenic microorganisms, storage of microbial strains and samples, production of biological substances, or the other relevant activities. The third tier of the management and security system for highly pathogenic microorganisms is that culture collections and laboratories must receive an additional designation from the Ministry of Public Health and the Ministry of Agriculture to possess human and animal pathogens from Risk Groups 1 and

Chinese Biosafety Laws and Regulations, Including Matters of Biosecurity and Oversight of Genetic Engineering Activities

2. In addition, the laboratories must also obtain approval for the conduct of experimental research with individual highly pathogenic microorganisms from these risk groups or microorganisms suspected of falling into the Risk Groups 1 and 2 categories. Furthermore, the laboratories are to report to the public health or veterinary authorities above the provincial level for approval of shipment requests for pathogens from the reference lists. Three separate and additional approvals, in other words, are required to work with Risk Group 1 and 2 pathogens.

Any laboratory certified to work with highly pathogenic microorganisms should establish a sound security system for the laboratory and take measures to prevent the theft, robbery, loss, or release of any pathogenic microorganism. The level of security to be established is tied to the Risk Group of the reference list pathogens and to the biosafety level of the laboratory. For example, a BSL-4 laboratory working with Risk Group 1 microorganisms would have the tightest level of security.

Any facility applying to receive human and animal species from the reference lists has to have certain physical security and accountability measures in place to receive these strains. The personnel responsible for managing the organization's culture collection should make strict rules for the storage of and access to these highly pathogenic microorganisms. The facility should have a separate filing system to track all activities with these microorganisms, with a member of the staff specifically appointed to register when these strains and samples are originally received and each time thereafter they are accessed by facility personnel. All strains and samples from the reference list are to be kept in a special facility or in a separate, double-locked storage container. In addition, the areas where the listed pathogens are stored and worked with should have additional security measures, which might include video surveillance, a double fire-security door with a separate pass code or other entry system, and a guarded entrance where all who access the area can be observed. Finally, any individual handling a pathogen from Risk Group 1 or 2 is not allowed to work alone; at least two partners must be in the laboratory with them when an experiment involves these high-risk microorganisms.

Should theft or diversion of a pathogen from the reference lists occur, the institution must report it to local law enforcement and public health or veterinary authorities within two hours. The local authorities must in turn report the incident to the Ministry of Public

Health or the Ministry of Agriculture, as appropriate, within an hour. Penalties for the theft or diversion of pathogens, for the unauthorized possession or shipment of pathogens, and for experimenting with pathogens without the required approvals include the issuance of a warning, the loss of a job, and the loss of a license for the institution. Should the laws be broken and the consequences be deemed serious enough, the individual responsible would be investigated for criminal responsibility.

Standards for the Packaging and Authorized Transport of Microbial Strains and Pathogenic Microorganism Samples

To strengthen the biosafety management of pathogenic microorganisms and regulate the packaging and transport of microbial strains or samples of pathogenic microorganisms, the Ministry of Agriculture implemented on 24 May 2005 “Packaging Criterion on Transportation of Highly Pathogenic Animal Microbial Strains or Samples.”⁹ This criterion is based on the Dangerous Goods Regulations of the International Air Transport Association. This criterion establishes detailed regulations related to interior and exterior packaging materials, packaging precautions, and special requirement for the shipment of microbial strains or samples aboard civilian aircraft.

In addition, the Ministry of Public Health issued “Regulations on Transportation Management of Highly Pathogenic Microbial Strains or Samples of Microorganisms Contagious to Humans” on 1 February 2005 and implemented these regulations exactly a year later. These regulations establish firm requirements to qualify the shipping and receiving organizations for the transfer of human pathogens and strains and other details such as the formal application procedures for transfer, the procedures to verify the transfer, and the transportation requirements.

Shipment of any of the highly pathogenic animal or human strains or samples in Risk Groups 1 and 2 requires prior approval by the veterinary or public health authority at the provincial or national level. When transfers of highly pathogenic strains or samples from Risk Groups 1 and 2 occur, at least two trained escorts from the organization requesting the shipment must hand carry the vial(s) in appropriate packaging, never allowing the

⁹ Storage, packaging, and transport activities are also accomplished in accordance with the relevant sections of the “Law on the Prevention and Treatment of Infectious Diseases,” the “Regulation on the Biosafety Management of Pathogenic Microbiology Laboratories” and “Measures for the Examination and Approval of the Biosafety Administration of Pathogenic Microbiology Laboratories.”

Chinese Biosafety Laws and Regulations, Including Matters of Biosecurity and Oversight of Genetic Engineering Activities

vial(s) to leave their sight. The containers and/or wrapping used to ship these highly pathogenic strains and samples must be in conformance with the packing standards for infectious substances issued by the International Civil Aviation Organization.¹⁰ The commercial capacity to ship highly pathogenic substances in accordance with these standards is still being established in China.

Biosafety Oversight of Activities Involving Genetic Engineering

In December 1993, the State Science and Technology Commission released “Safety Administration Regulation on Genetic Engineering.” This regulation was designed to govern all genetic engineering work in the People’s Republic of China, including experimental research, intermediate experiments, the manufacture of commercial products, the release of genetically engineered microorganisms, and the use of genetically engineered products. The regulation defines “genetic engineering” as the direct introduction of alien DNA into a living organism using recombinant DNA technology (e.g., chemical methods, vector systems, physical methods). On a national level, the State Science and Technology Commission is responsible for the biosafety oversight of genetic engineering work and established the National Genetic Engineering Biosafety Council, which is responsible for the day-to-day supervision and coordination of activities related to the safe and responsible conduct of genetic engineering work.

The December 1993 regulation divided safety for genetic engineering work into four grades, but in some respects, this approach lacked operability or a plainly stated methodology to implement the four safety grades. To improve the oversight of genetic engineering activity, the Ministry of Agriculture issued “Safety Administration Implementation Regulation for Agricultural Biological Genetic Engineering” in July 1996. This second regulation was stronger because it clearly explained the security appraisals required of different genetic engineering bodies and their products, establishing the declaration and ratification system for agricultural bioengineering work.

Genetic engineering work is divided into four biosafety grades ranging from low to high risk according to the potential danger that the activity poses to human health and the

¹⁰ Specifically, the requirement to be met is the Category A packing standard of “Infectious Substances: Technical Instructions for the Safe Transport of Dangerous Goods by Air,” Guidance Doc. 9284 (Montreal: International Civil Aviation Organization: 2005/2006).

environment. Depending on the type of genetic engineering activity they are involved in, the responsible institution must evaluate different aspects of its project to enable the review and approval of the activity. For example, institutions performing genetic engineering experiments should carry out a comprehensive biosafety appraisal of the experiment encompassing the DNA donor, vector, host and genetic engineering body. The main contents of appraisal focus on the pathogenicity, carcinogenicity, drug resistance, and environment effects of the experiment. From this assessment, the appropriate level of biosafety procedures and physical containment controls can be authenticated. For experimental and intermediate level genetic engineering research, the evaluation would include such factors as whether the work will confer resistance to therapeutically useful antibiotics or antivirals, will enhance the virulence of a pathogen or render a non-pathogen virulent, will increase the transmissibility of a pathogen, and will change the natural host range of a pathogen.

Institutions conducting intermediate experimentation and industrial production that involves genetic engineering should identify the necessary physical containment barriers for the equipment and facilities used to culture, ferment, isolate, and purify genetically engineered material. Institutions engaging in the release of genetically engineered materials should evaluate genetic engineering body security, the purpose of release, the ecological conditions of the area where the material will be released, the methods of release and the monitoring of the release, control measures, and confirmation of the corresponding biosafety grade. The biosafety of the use of the genetically engineered products should be examined to confirm its possible influence on public health and the environment.

Review and approval for genetic engineering activities begins at the institution engaged in the genetic engineering activity. At the institutional level, scientists are required to register experiments for oversight if their experiment involves recombinant DNA activities; work with infectious agents; the use of human blood or other potentially infectious materials, such as unfixed human tissues, primary human cell lines, and certain bodily fluids; and/or work on animal and plant pathogens. For activities involving the higher grades of genetic engineering, the review and approval process moves to higher authorities, including the offices of the State Council and the National Genetic

Chinese Biosafety Laws and Regulations, Including Matters of Biosecurity and Oversight of Genetic Engineering Activities

Engineering Biosafety Council. Table 6 shows this progression, as well as circumstances where a record of the activity is registered, but approval of that organization is not required. After a project is reviewed and approved, the regulations require the institution engaged in the genetic engineering activity to submit progress reports and final reports on the outcome of the research or other activities to the authorizing organization(s).

Violations of the national regulations for oversight of genetic engineering work fall into three general categories: 1) conduct of genetic engineering work without prior review and approval; 2) use of devices, instruments, and laboratory facilities in discord with the regulations; and, 3) violation of the biosafety guidelines related to genetic engineering work. In the event of a violation, the genetic engineering activity must stop temporarily while an investigation is conducted. When someone breaks the regulations, their institution administers the following types of punishment, which escalate in their level of severity according to whether the violation is in the first, second, or third category of misbehavior. The punishments include a warning notice, dismissal from work, stopping of funds for the improper work, and confiscation of income gained through the illegal activity.

Chinese authorities have also addressed the biosafety management of genetic engineering involving human genetic resources. In June 1998, the Ministry of Science and Technology and The Ministry of Public Health also jointly issued “Interim Measures for the Administration of Human Genetic Resources” in June 1998.¹¹ The term “human genetic resources” refers to the genetic materials such as human organs, tissues, cells, blood specimens, preparations of any types or recombinant DNA constructs, which contain human genome, genes, or gene products as well as to the information related to such genetic materials. At the State Council, the administrative departments of science and technology and of public health share joint responsibility for the national administration of human genetic resources in China and jointly established the Human Genetic Resources Administration to carry out routine duties.

¹¹ Previously, the pertinent regulation on this subject was the Ministry of Agriculture’s “Regulation on the Implementation of Safety Administration for Agricultural Biological Genetic Engineering,” which was released in June 1996 and replaced in 2002 by the “Administrative Rules for the Safety Assessment of Agricultural GMOs.”

Table 6: China's System for Review and Approval of Genetic Engineering Activities.

Genetic Engineering	Experimental Research	Intermediate Experiments	Industrial Production, Release of Genetically Engineered Material, Use of Genetically Engineered Products
Grade One (No Risk)	Administrative Director of Institute Approves	Administrative Director of Institute Approves	Appropriate Administrative Offices of State Council Approves + National Genetic Engineering Biosafety Council Records
Grade Two (Low Risk)	Administrative Director of Institute Approves	Administrative Director of Institute Approves + Appropriate Administrative Offices of State Council Approves	Appropriate Administrative Offices of State Council Approves + National Genetic Engineering Biosafety Council Records
Grade Three (Medium Risk)	Administrative Director of Institute Reviews + Appropriate Administrative Offices of State Council Approves	Administrative Director of Institute Examines + Appropriate Administrative Offices of State Council Approves + National Genetic Engineering Biosafety Council Records	Appropriate Administrative Offices of State Council Approves + National Genetic Engineering Biosafety Council Records
Grade Four (High Risk)	Appropriate Administrative Offices of State Council Examines + National Genetic Engineering Biosafety Council Approves	Appropriate Administrative Offices of State Council Examines + National Genetic Engineering Biosafety Council Approves	Appropriate Administrative Offices of State Council Examines + National Genetic Engineering Biosafety Council Approves

The Human Genetic Resources Administration of China performs the following activities: 1) drafting relevant rules and forms for the implementation of the rules,

Chinese Biosafety Laws and Regulations, Including Matters of Biosecurity and Oversight of Genetic Engineering Activities

disseminating approved rules to enable their entry into force, and ensuring enforcement of the rules through coordination and supervision; 2) managing the registration and administration of important pedigrees and genetic resources in the specified regions; 3) reviewing and examining international collaborative projects that involve human genetic resources in China; 4) reviewing and approving applications to export human genetic resources; and, 5) other duties related to the administration of human genetic resources in China.

If any Chinese institution or individual violates the rules by exporting the human genetic materials without authorization, whether by hand carrying, mailing, or otherwise transporting these materials, Chinese Customs authorities are to confiscate the materials. The punishment for the institution or individual responsible for the illegal export ranges from administrative sanctions to judicial prosecution, depending on the seriousness of the circumstances. Any individual or institution responsible for providing human genetic materials to foreign institutions or individuals without permission will be fined and the human genetic materials confiscated. For serious violations of this nature, the individual will be investigated for legal responsibility for his actions.

Biosafety Management of Activities Involving Genetically Modified Organisms

Building on the establishment of four grades of biosafety for genetic engineering activities, the State Council issued “Safety Administration Regulations for Agricultural GMOs” in May 2001, which extended biosafety management of agricultural genetically modified organisms (GMOs) to the production, processing, management, and import and export of GMO products. Since 2002, the Ministry of Agriculture announced four biosafety management standards related to the May 2001 regulations, specifically the identification, safety assessment, examination and processing approval, and safe import of agricultural GMOs. As indicated by the implementation of these laws and regulations, a standardized, legal approach has been taken with the biosafety management of agricultural GMOs in China. An additional thirty-two national and professional standards related to GMO testing supplement this framework.

Depending on the type of agricultural GMO activity, many biosafety management systems are being employed to oversee this work. These systems include differentiated

controls to identify, appraise, approve, and permit diverse agricultural GMO activities at various stages of research, testing, production, and sales activity. Chinese regulations state that agricultural GMO activities must be categorized into four grades of biosafety and into one of five stages of activity, namely experimental research, intermediate experimental research, environmental release, production testing, and application for biosafety certification. In each stage, a biosafety evaluation of the plant, animal, or microbiology GMO is completed, and approval is required and reported.

Individual biosafety certificates must be obtained for transgenic plant seeds, animal breeding stocks and birds, aquatic seedlings, and all other agricultural GMO products. Any organization that produces agricultural GMOs, including the production facility as whole and the individual production units therein, has to undergo a biosafety evaluation. If approved, the Ministry of Agriculture will issue the facility a business and a production license to make one or more certified agricultural GMOs. Manufacturing of agricultural GMO products can begin once the appropriate product certificates and facility licenses are secured. Local agricultural authorities at the provincial level of government are also responsible for assessing the regulatory compliance of manufacturing facilities, including individual production units that process raw materials (e.g., genetically modified plants, animals, crops), including activated GMOs that have a biological activity such as replication. Such manufacturing facilities must also be licensed before they can engage in processing agricultural GMOs.

All GMO products sold in China must be correctly identified, and an agricultural GMO catalogue has been established for that purpose. This catalogue lists, for example, agricultural GMOs for soybean seed, soybeans, soybean flour, soybean oil, soybean meal, maize seed, maize, maize oil, maize flour, rapeseed, rapeseed oil, rapeseed meal, cotton seed, tomato seed, delicious tomatoes, and tomato ketchup, all of which have received Chinese government approval. Any agricultural GMOs imported into China must be researched, tested, produced, and processed according to applicable Chinese standards to protect China's food and environmental security.

Nationwide, the Ministry of Agriculture is responsible for the supervision of the biosafety of agricultural GMO activities. The ministry's Biosafety Management Office for Agricultural GMOs has the lead in this regard. However, given the wide scope of

Chinese Biosafety Laws and Regulations, Including Matters of Biosecurity and Oversight of Genetic Engineering Activities

scientific and commercial activity involved in agricultural GMOs, an interdepartmental conference that draws specialists from the departments of agriculture, science and technology, hygiene, commerce, environmental protection, and inspection and quarantine is charged with studying and coordinating important biosafety management issues related to agricultural GMOs. To provide additional technical support, an advisory system for biosafety evaluation has been established. The national biosafety councils for agricultural GMOs consist of many experts engaged in distinct areas of agricultural GMO activity, such as research, production, processing, inspection and quarantine, hygiene, and environmental protection. These councils are responsible for the biosafety appraisal of GMOs. In addition, three organizations have been created to detect agricultural GMOs for environmental security, food security, and product inspection. The purpose of this detection activity is to demonstrate that agricultural GMOs are not present in food or other products that are not supposed to contain agricultural GMOs and that certified GMOs have not drifted to fields adjacent to the areas growing certified agricultural GMO crops. With this comprehensive approach, China's system of biosafety standards and management for agricultural GMOs is being progressively improved.

Concluding Observations

Governments and scientists around the world care about and pay attention to biosafety because of its importance to the both survival and enrichment of human society. In recent years, China has made rapid progress in the improvement of its biosafety standards and the implementation of those standards in many areas. These improvements encompass the areas of laboratory biosafety procedures and management, biosafety construction and equipment requirements, biosecurity of transfers for pathogens that are highly infectious to humans and to animals, oversight of genetic engineering, and biosafety appraisal and management of agricultural GMO activities.

Given the rapid developments taking place in biotechnology and the severe threat of global epidemics that could arise from outbreaks of infectious diseases, however, additional steps to improve biosafety should be taken in China and around the globe. Two important measures, for example, should be taken to enhance biosafety. A continuous program to improve the biosafety training of scientists and technicians who

work with highly pathogenic microorganisms should be instituted. Also, scientists, technicians, and bureaucratic specialists from around the world should be encouraged to participate in exchanges and cooperation on matters of biosecurity. To strengthen this international scientific, technical, and managerial cooperation on biosafety, governments should provide support for such exchanges. The extent to which biosafety is rigorously implemented in China as well as in all other countries will significantly influence the well-being of society.

Chinese Biosafety Laws and Regulations, Including Matters of Biosecurity and Oversight
of Genetic Engineering Activities

Efforts to Strengthen Biosafety and Biosecurity in China

Wang Qian¹

The safety of facility employees and the public are best served if sites that contain, produce, store, or transfer dangerous pathogens, toxins, and bacteria have strong biosafety and biosecurity regimes in place. Biosafety and biosecurity should be addressed in an interdisciplinary manner to achieve the best policies and practices. In recent years, the Chinese government has overhauled biosecurity and biosafety regulations and practices in China to initiate important improvements in that regard.

This essay examines China's biosafety and biosecurity infrastructure in comparison with the standards and practices of the World Health Organization (WHO) and the United States. First, an effort is made to define and distinguish the terms biosafety and biosecurity and discuss the current gaps in cross-cultural understanding of these issues. China's biosafety and biosecurity infrastructure is then introduced and contrasted with the WHO and U.S. standards and practices. Measures for the improvement of China's biosafety and biosecurity standards and practices are proposed before the essay concludes with an analysis of the current status of the Biological and Toxin Weapons Convention (BWC) and recommendations on effective international endeavors to strengthen this treaty.

Definitions: Biosafety vs. Biosecurity

Whereas in English two words are used to refer to “biosafety” and “biosecurity,” in many other languages, a single term encompasses these two concepts. The lack of distinct terminology in some languages has caused confusion even among those who are dealing with these issues (e.g., government officials, scientists, technicians). Until fairly recently, the Chinese language used one term to encompass both concepts; separate words in Chinese for biosafety and biosecurity now exist.² An elaboration of the

¹ Wang Qian is an official in the Department of Arms Control and Disarmament of China's Ministry of Foreign Affairs. The views expressed in this essay result from her personal study of China's biosafety and biosecurity provisions and therefore are not intended to represent the official policy of the People's Republic of China.

² In Chinese, *shengwu anquan* means biosafety and *shengwu anbao* means biosecurity.

Efforts to Strengthen Biosafety and Biosecurity in China

differences in meaning and scope in this the terminology will facilitate the forthcoming discussion of how to strengthen biosafety and biosecurity.

Biosafety, or to be more accurate, laboratory biosafety, describes a set of comprehensive principles, technologies, and practices implemented to prevent the unintentional exposure of facility workers to pathogens and toxins and also to reduce the possibility that an accident with these materials might result in their release outside of the laboratory. To put it simply, biosafety is about how to work safely and properly with pathogens and toxins that can be harmful to people, animals, and plants. As concern has grown about the possibility of infectious diseases spreading across national boundaries, disease control and surveillance have become a prominent part of an expanded concept of biosafety.

Conversely, biosecurity has a broader scope of meaning and is interpreted varyingly by individuals with different professional and cultural backgrounds. The more recent definition of laboratory biosecurity refers to the protection and control of pathogens and toxins to preventing their deliberate theft, misuse, or diversion for the purposes of biological warfare or terrorism. For quite some time, the Food and Agriculture Organization of the United Nations and the World Animal Health Organization have employed the term biosecurity to mean the biological and environmental risks related to food and agriculture, “a sector that covers food safety, and the life and health of plants and animals. The risks include everything from the introduction and release of genetically modified organisms and their products, the introduction and spread of invasive alien species... to the erosion of biodiversity, the spread of transboundary cattle diseases, or the preservation of food supplies after production.”³ The definition relevant to this essay relates to the prevention of unauthorized access to the dangerous pathogens, toxins, and bacteria.

Though there are distinctions between these two words, they do overlap and interact with each other in some respects. For example, laboratory biosafety provisions may contain the practices to prevent unauthorized access to, theft of, or misuse of the pathogens and toxins. Thus, a well-developed biosafety system is a necessary platform

³ *Biorisk Management: Laboratory Biosecurity Guidelines* (Geneva: World Health Organization, September 2006), 4.

for the strengthening of biosecurity. Ignorance or bad practice of either biosafety or biosecurity would degrade and perhaps even jeopardize the sound implementation of the other. Therefore, measures to implement biosafety and biosecurity should work in a cooperative and complementary manner.

Gaps in Biosafety and Biosecurity

Biotechnology and the life sciences have developed with startling speed in recent years, giving rise to significant concerns about the possible negative byproducts of these scientific and technical development, such as: laboratory accidents, the spread of infectious disease, and bioterrorism. An example of these risks from China is pertinent.

In April 2004, approximately one year after the first outbreak of Severe Acute Respiratory Syndrome (SARS) in China, two new cases were reported in Beijing and Anhui. An investigation jointly conducted by the Chinese Ministry of Health and the WHO confirmed that laboratory accidents caused the new cases of SARS. Both of the infected patients were researchers working for the laboratory of the Institute of Viral Disease Control and Prevention of the Chinese Center for Disease Control and Prevention. The investigation showed that these two individuals conducted experiments with SARS specimens in a common laboratory instead of one that was properly equipped and operating at Biosafety Level-3 or Biosafety Level-2 conditions. Moreover, this laboratory at the Institute of Viral Disease Control did not follow the procedures for the proper and safe disposal of contaminated waste. WHO's recommendation on biosafety and handling of contaminated wastes have theoretically and operationally been proven effective.⁴

⁴ For more information on these two cases, see "China's latest SARS outbreak has been contained, but biosafety concerns remain: Update 7" (Geneva: World Health Organization, 18 May 2004). Available at: http://www.who.int/csr/don/2004_05_18a/en/index.html. See also, SARS in China: investigation continues – Update 6" (Geneva: World Health Organization, 5 May 2004). Available at: http://www.who.int/csr/don/2004_05_05/en/index.html. See also, "The suspect SARS patient from Anhui died, Experts analyze that the source of virus might come from laboratory infection" (Beijing, Ministry of Health, 23 April 2004). Available at: <http://www.moh.gov.cn/newshtml/118.htm>.

Efforts to Strengthen Biosafety and Biosecurity in China

Unfortunately, these two cases from April 2004 were not the only instances of laboratory-acquired SARS infection. Between November 2002 and June 2003, a large number of human specimens were collected from suspected and confirmed SARS cases and sent to different countries for a variety of tests. Even though WHO had by that time published its *Laboratory Biosafety Manual* and *Biosafety Guidelines for Handling of SARS Specimens*, laboratory-acquired cases of SARS infection were reported in Singapore, Taiwan, and mainland China.⁵ These circumstances demonstrate two things. First, a major cause of laboratory accidents is the lack of awareness of proper biosafety principles and procedures on the part of scientists, technicians, and laboratory managers. Second, steps should be taken to strengthen the implementation and management of biosafety regulations.

With regard to biosecurity, the problems are numerous. The threat of bioterrorism is genuine and on the rise. To illustrate, the Rajneeshee cult used put *Salmonella typhimurium* in salad bars in The Dalles, Oregon in 1984 to sicken local citizens so that they would not be able to vote in an election. In 2001, letters containing anthrax were mailed to U.S. politicians and reporters. The Rajneeshee salad bar poisoning sickened over 751 and the 2001 anthrax letter attacked killed 5 and resulted in 22 additional confirmed or suspected cases of anthrax.⁶ While the death and casualty numbers from these incidents might not be considered to be large, the 2001 anthrax letter attacks in particular incited fear and some panic in the American public, with some citizens rushing to purchase the antibiotic ciprofloxacin and gas masks. The 2001 anthrax letter attacks also temporarily disrupted the function of the of U.S government, disturbed the U.S. economy, and upset the social lives of Americans. The outcome of these two incidents

⁵ On the Singapore and Taiwanese laboratory acquired cases, see Poh Lian Lim et al., "Laboratory Acquired Severe Acute Respiratory Syndrome," *New England Journal of Medicine* 350, no. 17 (22 April 2004): 1740-5; "Severe acute respiratory syndrome (SARS) in Singapore - update 2: SARS case in Singapore linked to accidental laboratory contamination" (Geneva: World Health Organization, 24 September 2003). Available at: http://www.who.int/csr/don/2003_09_24/en/; "Confirmed SARS Case in Research Laboratory in Taiwan - December 17, 2003" (Taipei City: Department of Health, 17 December 2003). Available at: sars.doh.gov.tw/news/2003121701.html. For the WHO Biosafety Guidelines for SARS Specimens, issued 23 April 2003, go to: http://www.who.int/csr/sars/biosafety2003_04_25/en/.

⁶ W. Seth Carus, "The Rajneeshees (1984)," in *Toxic Terror: Assessing the Terrorist Use of Chemical and Biological Weapons*, ed. Jonathon B. Tucker (Cambridge, Mass.: MIT Press, 2000), 116-37. On the 2001 anthrax attacks, see Tom Inglesby et al., "Anthrax as a Biological Weapon, 2002," *Journal of the American Medical Association* 286, no. 17 (1 May 2002). Available at: <http://jama.ama-assn.org/cgi/content/full/287/17/2236>.

has led some to conclude that terrorists are likely to regard biological pathogens and toxins as “weapons of mass disruption.”⁷

Compared to nuclear and chemical weapons, not only are biological weapons cheaper, they are easier to acquire because of the availability of dual-use equipment and materials on the open market.⁸ The rapid advances in the life sciences and biotechnology have made the dual-use dilemma—how and whether to regulate or control equipment, materials, and technologies that have legitimate uses but could also be diverted to make weapons—more complicated. For instance, genetic engineering has made it possible to increase the virulence of disease agents or make them more contagious or environmentally persistent.⁹ One state, the former Soviet Union, actually employed genetic engineering to make biowarfare agents resistant to known medical treatments.¹⁰ These developments point to a need for stricter measures to safeguard deadly and highly infectious pathogens.

The need to take steps to improve security is one that merits the attention of nations around the globe. For example, a May 2002 report indicated that many of the U.S. Department of Agriculture’s research laboratories could not account properly for their seed culture collections of plant and animal pathogens, and that these culture collections were vulnerable to theft.¹¹ One reason for the weak practice of laboratory biosecurity might be the lack of international standards by which measures can be compared.

⁷ Helen E. Purkitt, “Biowarfare Lessons, Emerging Biosecurity Issues, and Ways to Monitor Dual-Use Biotechnology Trends in the Future,” *INSS Occasional Paper 61* (September 2005), 10.

⁸ U.S. Congress, Office of Technology Assessment, *Technologies Underlying Weapons of Mass Destruction*, OTA-BP-ISC-115 (Washington, D.C.: U.S. Government Printing Office, December 1993), 71-117.

⁹ Mark Wheelis, “Will the ‘New Biology’ Lead to New Weapons?” *Arms Control Today*, July/August 2004, pp. 6-13. See also, Reid AH, Janczewski TA, Raina M. Lourens RM, Elliot AJ, Rod S, et al., “1918 Influenza pandemic caused by highly conserved viruses with two receptor-binding variants,” *Emerging Infectious Disease* 9 no. 10 (2003 Oct). Available from: <http://www.cdc.gov/ncidod/EID/vol9no10/02-0789.htm>.

¹⁰ Ken Alibek, with Stephen Handelman, *Biohazard* (New York: Random House, 1999).

¹¹ *Oversight and Security of Biological Agents at Laboratories Operated by the U.S. Department of Agriculture*, Audit Report no. 50099-13-At (Washington, D.C.: U.S. Department of Agriculture, Office of the Inspector General, 29 March 2002).

Building A National System of Biosafety and Biosecurity

China has a large and rapidly growing biotechnology and pharmaceutical industry. Statistics show that by 2004 China had built 200 major laboratories sponsored by national and local governments, employing 20,000 personnel in research and development of biological sciences and technologies.¹² A number of universities and colleges have established departments of life sciences and biotechnology, some with their own laboratories. Registries showed that more than 500 enterprises associated with life science and biotechnology with 50,000 employees existed in China by 2004.¹³ The fast pace of industrial development is indicated by the appearance of one hundred new biotechnologies enterprises every year in China. Roughly twenty bioscience and technology Industrial Parks have been set up in Beijing, Shanghai, Guangzhou, Shenzhen and other cities of China.¹⁴ A 2005 study of China's bio-industry development strategy included a survey of 1,500 biological companies and research organizations,¹⁵ another indicator of the speedy growth of life sciences companies and laboratories.

The outbreak of SARS in 2003 triggered the Chinese government to review and strengthen the laws and regulations on biosafety and to speed up its efforts to improve its capability to counter the outbreak of infectious disease or a bioterrorist attack. China's system of biosafety and biosecurity consists of three major components. Pertinent regulations and standards are the backbone of this system. The brains and muscle of this system are the governmental organizations that create and implement these regulations. Finally, the codes of conduct to further guide the proper behavior of personnel working in the life sciences might be called the conscience of this system. In turn, the following paragraphs provide an overview of these segments of the biosafety and biosecurity system being built in China.

¹² "An Introduction to The Development of Biotechnology and Bio-Industry in China" (Beijing: China National Center for Biotechnology Development, July 2004). Available at: <http://www.bioon.com/industry/bioeconomy/57519.shtml>.

¹³ Ibid.

¹⁴ Ibid.

¹⁵ "Research on China's Bio-Industry Development Strategy," March 2005. Available at: http://www.most.gov.cn/gnwkjdt/200503/t20050320_19782.htm. Note that this study, led by the Chinese National Development and Reform Commission, also involved the Chinese National Academy of Sciences, and the Ministries of Health, of Agriculture, of Science and Technology, and of Education, among other government organizations.

The basis for China's system of biosafety dates to a set of 1993 requirements for the review, approval, and construction of production facilities for biological products. Other major features of this biosafety system were added in 2002, with the establishment of measures for the safe use of toxic substances in work places and a general biosafety standard for laboratories. The April 2004 publication of *Laboratories: General Requirements for Biosafety* promulgated a new national laboratory biosafety practices.¹⁶ Compared to the pre-2004 regulation, the new standards attach more importance to effective laboratory administration and oversight of biosafety. The 2004 regulation defines responsibilities for both laboratory managers and laboratory workers on biosafety and contains detailed provisions on matters such as the safe design and construction of laboratories, the establishment of standard operational procedures, the annual review of the facility's safety plan, the maintenance of research records, and the provision of reports to oversight authorities. This national standard was modeled after the second edition of the WHO *Laboratory Biosafety Manual* and the U.S. *Biosafety in Microbiological and Biomedical Laboratories*. In 2004, the Chinese State Council also passed the *Regulations on Administration of Biosafety in Pathogenic Microorganism Laboratories*. These regulations are meant to safeguard the health of laboratory researchers and the general public amidst concerns about the rise in outbreaks and spread of infectious diseases.

Biosafety standards are based on the classification of pathogens, toxins, and bacteria according to their risk level that particular pathogens present to cause disease, taking into account such factors as a microorganism's pathogenicity, infectious dose, and the available of effective medical treatments. Four levels of laboratory biosafety have been defined, with Biosafety Level 4 for work with the pathogens of highest risk. A laboratory must establish the necessary physical containment infrastructures and laboratory practices to be accredited by national authorities to work with pathogens in the different risk categories. A laboratory accredited to operate at Biosafety Level 1 would

¹⁶ See *Measures on the Administration of Plant Manufacturing Biological Products* (Beijing: Ministry of Health, October 1993); *Regulations on Labor Protection in Workplaces Where Toxic Substances Are Used* (Beijing: State Council, April 2002); *General Biosafety Standard for Microbiological and Biomedical Laboratories* (Beijing: Ministry of Health, 3 December 2002); *Laboratories---General Requirements for Biosafety* (Beijing: General Administration of Quality Supervision, Inspection and Quarantine and the Standardization Administration, 5 April 2004).

Efforts to Strengthen Biosafety and Biosecurity in China

not be allowed to work with a high-risk, level 1 pathogen (e.g., Ebola virus). Since the outbreak of SARS, the Chinese government has made great efforts to improve its biosafety laws and regulations.

As mentioned above, biosecurity has a broader scope than biosafety. China's approach to biosecurity has grown out of its regulations governing the storage of strain collections. Three different regulations, tracing back to 1980, specify the details of how strains are to be categorized, stored, sold, used, acquired, transferred, and exchanged among laboratory facilities in China. Only laboratories designated by the Ministries of Health and of Agriculture are authorized to receive, handle, and store strains of different levels of risk to human health, animal health, and the environment.¹⁷ In addition, China established reference lists of 380 species of human pathogenic microorganisms in May 2005 and 123 species of animal pathogenic microorganisms in January 2006. These reference lists are used to guide decisions about the appropriate level of biosafety and biosecurity to be employed with the strains on the list.¹⁸

To illustrate the higher level of security required for work with the most dangerous pathogens, the reference lists separate pathogenic microorganisms into four categories of risk. Laboratories that wish to work with human or animal pathogenic microorganisms on the reference lists that carry the Risk Group 1 or 2 designations must also obtain three additional approvals from the Ministries of Public Health or of Agriculture, respectively. The laboratory must be certified to work at a level of biosafety appropriate to the risk level of the agent, which for Risk Group 2 or 1 microorganisms would be either Biosafety Level 3 or Biosafety Level 4. Moreover, the laboratory must gain specific approval for the experimental activities planned with the individual pathogenic microorganism and also for the shipment of that pathogen. From the time at which a Risk Group 1 or 2 microorganism is received, a file specific to that microorganism is established to document all activities with it. These high-risk

¹⁷ "Methods on Trial Management of Preservation of Veterinary-Microbiology Strains," Ministry of Agriculture (issued 25 November 1980, revised 1 July 2004); "Methods on Management of Preservation of Medical-Microbiology Strains in China," Ministry of Health (issued and implemented 23 March 1985); "Rules on Management of the Preservation of Microbial Strains in China," State Science and Technology Commission (issued and implemented 8 August 1986).

¹⁸ "List of Animal Pathogenic Microorganisms" (Beijing: Ministry of Agriculture, 13 May 2005); "Directory of Pathogenic Microorganisms Transmissible Between Humans" (Beijing: Ministry of Health, 11 January 2006).

microorganisms are to be stored separately and with additional security (e.g., electronic entrance codes to guarded entrance area), and no scientist is allowed to work alone with a pathogen from Risk Groups 1 or 2.

Moreover, the 2004 laboratory biosafety regulations stipulate that two or more escorts are to accompany the transport of strains or samples of highly pathogenic microorganisms (e.g., bacteria, viruses), employing appropriate protection measures.¹⁹ These regulations further require that should highly pathogenic microorganisms be stolen or diverted, the incident should be reported to the competent authorities within two hours. Laboratories handling with highly pathogenic microorganisms must also establish and improve their security system, adopt security measures, and strictly guard against any theft, robbery, loss, or leakage of highly pathogenic microorganisms. Penalties for breaking these regulations have been established (e.g., loss of institute's license).

Another important dimension of China's system of biosecurity occurred in 2001 with legislation that criminalized the manufacture, trade, transportation, storage, or release of toxic substances or infectious pathogens and established penalties for these crimes. Whereas the punishment for crimes that do not cause serious harm ranges from three to ten years of imprisonment, the perpetrator(s) of crimes that cause severe injury or death and/or tremendous loss of public property could be sentenced to ten years to life in prison or even receive the death penalty.²⁰ The next year, China established strict export controls for biological agents, equipment, and technologies and control lists, creating a system to govern China's commerce in these dual-use materials. China's export control list, which was updated in July 2006, is based on the control lists of the Australia Group and is therefore quite similar. Anyone who exports dual-use biological agents, technologies, or equipment from the control lists without obtaining a license; who exports controlled items beyond the scope of their export license without specific authorization; or who in other ways violates the export control regulations will be punished in accordance with China's Customs Law. Penalties differ according to the severity of the

¹⁹ General Principles, Article 12, Chapter II, 2004 *Regulations on Administration of Biosafety in Pathogenic Microorganism Laboratories*. See also, "Packaging Criterion on Transportation of Highly Pathogenic Animal Microbial Strains or Samples" (Beijing: Ministry of Agriculture, 24 May 2005); "Regulations on Transportation Management of Highly Pathogenic Microbial Strains or Samples of Microorganisms Contagious to Humans" (Beijing: Ministry of Public Health, 1 February 2005).

²⁰ *Amendment III to the Criminal Law* (Beijing: Standing Committee of the National People's Congress of China, December 2001).

Efforts to Strengthen Biosafety and Biosecurity in China

crime: minor violations will result in a warning but more serious cases will result in confiscation of the income illegally obtained through the export fines ranging from 50,000 to 250,000 yuan (\$6,536 to \$32,682). If an export license is fraudulently or illegally obtained, the department of the Chinese government that oversees that type of export could enforce several penalties, including revoking the license, confiscating the illegal income from the export, imposing a fine of 20,000 to 100,000 (\$2,614 to \$13,071) yuan, and suspending or even revoking the licensing for all of the violator's foreign trade operations.²¹

While all of these provisions are helpful to some extent, they are limited to preventing the unauthorized access to dangerous pathogens, toxins, or bacteria in laboratories and therefore leave plenty of room for China to do more in the context of biosecurity. What about the use, production, and/or storage of these same highly pathogenic microorganisms in a range of other facilities in China? Biosecurity safeguards that have their basis in laboratory biosafety regulations may not apply as efficiently to other facilities in need of biosecurity regulation (e.g., commercial enterprises, hospital facilities). Therefore, while constructive steps have already been taken to institute biosecurity measures in laboratories, China needs to take a different approach to develop a more comprehensive regulatory framework for biosecurity.

China's Organizational Structure for Biosafety and Biosecurity

The 2004 biosafety regulations also specified the offices in the Chinese government that are responsible for overseeing the implementation of the regulations.²² Under the State Council, the Health Department and the Veterinary Department are to manage all biosafety matters associated with activities in laboratories that deal with human and animal health, respectively. As appropriate, other departments of the State Council are also responsible, according to their functions and duties, for administering

²¹One difference between the Chinese export control list and the Australia Group's is that the Chinese list includes the SARS virus, whereas the Australia Group control list does not. Article 18 of the regulations stipulates the penalties. *Regulations on the Export Control of Dual-Use Biological Agents and Related Equipment and Technologies and Export Control List* (Beijing: State Council, October 2002). For more information on the Australia Group, please go to: <http://www.australiagroup.net>.

²² Article 3, Chapter I, 2004 *Regulations on Administration of Biosafety in Pathogenic Microorganism Laboratories*.

biosafety in laboratories. Thus, these offices of governmental oversight also help to regulate biosafety activities at the laboratory level.

This managerial structure is also augmented by biosafety advisory counsels. In 2005, an Experts' Committee was established under the leadership of the Principal Group on Biosafety of Pathogenic Microorganism Laboratories, which is affiliated with the State Environmental Protection Administration. The purpose of this Experts' Committee is to conduct biosafety assessments and technical consultation and deliberation on the establishment and operation of laboratories. Similar expert committees have been created at the local level as well.

The governmental oversight structure for biosecurity appears to be under development. Four ministries are in charge of various aspects of biosecurity in China: 1) Ministry of Education; 2) Ministry of Foreign Affairs; 3) Ministry of Health; and 4) Ministry of Science and Technology.²³ Given the possibility of some confusion and the distinctions between biosecurity and biosafety, as well as their complementary nature, some of the government departments might have an overlap in oversight responsibilities on these two issues.

To establish a full governmental oversight structure, the Ministry of Agriculture and the health units under the General Logistic Department of the People's Liberation Army should also be assigned responsibility for oversight of biosecurity. The former is responsible for veterinary drugs and the prevention of epidemics in the animal population. The latter is in charge of the health of military personnel and the biosafety and biosecurity of military laboratories. Agencies such as the State Food and Drug Administration, the Chinese Center for Disease Control and Prevention, the Chinese Academy of Sciences, and the National Natural Science Foundation should also be engaged in governing biosecurity and biosafety matters in China. The responsibilities of and expertise resident in these organizations are highly diversified, but they all have contributions to make to the safeguarding of pathogens and toxins and preventing unauthorized access to them.

²³ See the database established by the Organization for Economic Cooperation and Development at: <http://www.biosecuritycodes.org>.

Efforts to Strengthen Biosafety and Biosecurity in China

In summary, there is no single agency or department that is responsible for biosecurity in China. Several departments are working together toward this end. Since the national regulatory framework on biosecurity in China is still evolving, the responsibilities of these agencies and departments are probably not efficiently defined and designated within the context of biosecurity.

Other Means to Govern the Behavior of Scientists in China

The scientific community of China has taken a series of measures to prevent scientific accomplishments from being abused or misused. In November 2001, the Chinese Academy of Science adopted the *Self-Disciplinary Guidelines for the Scientific Ethics of Academicians*, which requires all academicians to abide by scientific ethics, to always put the interests of humankind first, and to insist on science serving human civilization, peace, and development. Academicians should strictly comply with and safeguard the ethics related to national security, as well as ecological, environmental, and health safety.

Institutions have been set up to supervise the implementation of these guidelines. For instance, the Chinese Association of Science and Technology has set up a Commission on Ethics and Rights of Scientists and Engineers to supervise scientists' conduct and moral behavior. The Chinese Academy of Science has also set up a Committee on Scientific Ethics, which has a mandate to adopt or amend the code of conduct of academicians, investigate violations of the scientific ethics, and provide suggestions to solve such cases.

At an experts' meeting held under the auspices of the Biological Weapons Convention in 2005, some treaty members reached a consensus on measures to improve on codes of conduct for life scientists by developing three layers of codes, namely "a top layer describing the universal norms; a middle layer of more detailed codes developed or adapted by scientific bodies; and a bottom layer of operational codes specific to particular institutions."²⁴ This architecture provides a model of codes that Convention members may apply to improve the governance of science in their own countries. Thus far, China

²⁴ *Biological and Toxin Weapons Convention, Report of the Meeting of States Parties*, BWC/MSP/2005/3, (Geneva: 14 December 2005).

has only developed the middle layer of code. To fulfill this architecture, it will be necessary for China to develop the other two layers as well.

International Standards and Models of Biosafety and Biosecurity

As mentioned before, in 2004 WHO published the *Laboratory Biosafety Manual* that is widely regarded as the model for drafting biosafety measures. In September 2006, WHO issued the *Laboratory Biosecurity Guidance*. This second volume is limited to addressing only problems in the fields of human and animal public health rather than in the area of security. Nevertheless, it introduces “a new concept and approach to minimize or prevent the occurrence and consequences of human error within the laboratory environment: the ‘biorisk management approach,’ composed of biosafety, laboratory biosecurity and ethical responsibility.”²⁵ As such, WHO’s biosecurity guidelines are useful to nations that wish to develop domestic measures for the security of biological materials. WHO also stresses that “laboratory biosecurity should be built upon a firm foundation of good laboratory biosafety.”²⁶

The United States is a pioneer of biosafety practice. The U.S Centers for Disease Control and Prevention (CDC) and the National Institutes of Health (NIH) published the *Biosafety in Microbiological and Biomedical Laboratories*. Now in its fifth edition, this publication is a leading resource in biosafety and served as the model for WHO’s biosafety guidelines.

In the last ten years, the United States also established a stringent biosecurity framework with an emphasis on bioterrorism. In 1996, the U.S Congress required the Department of Health and Human Services to regulate transfers of dangerous human pathogens and toxins and to take steps to prevent their acquisition by terrorists and criminals.²⁷ In the following year, according to the new federal regulations, anyone who shipped or received the listed bacteria, viruses, rickettsiae, fungi or toxins on the original list of microorganisms designated as of concern for their possible use as biowarfare

²⁵ *Biorisk Management: Laboratory Biosecurity Guidelines* (Geneva: World Health Organization, September 2006), 5.

²⁶ *Ibid.*, 7.

²⁷ 18 USC, Sections 175-8 and 2332; 42 CFR 72. See also Antiterrorism and Effective Death Penalty Act, Public Law 104-132, 24 April 1996.

Efforts to Strengthen Biosafety and Biosecurity in China

agents by the U.S. government was required to register with the CDC and declare a legitimate scientific or medical use for the material.²⁸

This list of select human and animal pathogens expanded after President Bush signed the USA PATRIOT Act into law in October 2001. The USA PATRIOT Act also criminalized the possession of bioweapons delivery systems and biological agents or toxins without reasonable justification for peaceful purposes (e.g., prophylactic, protective, medical research). Any violation would be punished with a \$10,000 fine, ten year's imprisonment, or both.²⁹ The Public Health Security and Bioterrorism Preparedness and Response Act considerably expanded the original select agent rules and the framework for biosecurity in the United States. All federal, state, or local government organizations; academic institutions, corporations, companies, partnerships, societies, associations, firms, sole proprietorships, or other legal entities and persons in the United States that possess, use, or transfer human, animal, or plant pathogens and toxins on the select agent lists to register with CDC or the U.S Department of Agriculture's Animal and Plant Health Inspection Service. The select agent lists were to be updated regularly, training and physical security was required at facilities certified to possess and use agents on the select lists, registered facilities were to be inspected for the adequacy of their biosecurity measures, and "restricted persons" or individuals that the U.S. government suspected of an association with terrorist activities were to be denied access to possession or use of listed agents.³⁰ By 2003, an estimated 1,469 facilities had registered either with CDC or Animal and Plant Health Inspection Service according to the new U.S. biosecurity regulations.³¹ Therefore, these facilities have been certified that they have the appropriate biosafety and security standards in place to be able to work with the agents on the select lists.

In summary, U. S. biosecurity safeguards are based on the list of select pathogens and toxins and the registration of facilities that deal with these materials. The key points of the U.S. biosecurity framework include:

²⁸ See U.S. Code of Federal Regulations, Title 42, Part 72.6. Effective 15 April 1997.

²⁹ See Section 817, The Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act of 2001, Public Law 107-56, 26 October 2001.

³⁰ Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Public Law 107-188, 12 June 2002.

³¹ Estimated number of registered U.S. facilities cited in Jonathan B. Tucker, "Biosecurity: Limiting Terrorist Access to Deadly Pathogens," *Peaceworks* no.52 (November 2003), 21.

- an effective mechanism to account for pathogens that are being stored, used during experiments, or transferred or exported;
- the registration and licensing of facilities that work with pathogens; and,
- punishments and penalties for those who violate the framework.

One reason that this system was established was to assist investigators in the aftermath of another possible bioterrorist event. The unique forensic properties of the bacteria, viruses, and toxins in each facility's culture collection could help investigators trace the particular pathogen used in an attack back to its origin, thereby leading them to the perpetrator(s).

One of the questions debated about the select human, animal, and plant agent lists is whether the pathogens and toxins on them are complete enough to address all the concerns. Another concern raised is whether the tightened biosecurity regulations could have a negative effect on U.S. research, cause a loss of privacy of those conducting research with select agents, and present heavy financial burdens to small laboratories. Problems certainly presented themselves with the initial implementation of the U.S. biosecurity measures, and the effectiveness of these measures in providing advances to guard against the diversion and deliberate abuse of select agent pathogens is still being evaluated.³² However, the U.S. biosecurity measures, based in a control list of agents and the licensing and regulation of facilities to work with them, have provided an efficient approach to enhance the security of activities associated with dangerous pathogens and toxins at these sites.

Proposals to Build and Improve China's Biosafety and Biosecurity System

China has made noteworthy strides to establish a national infrastructure on biosafety and biosecurity in the past several years. The oversight of complex safety and security activities in a changing environment is a complex issue, however, and therefore room for improvement will almost always exist. When China's laws and measures are compared to the WHO standards and U.S. practices, gaps in China's biosafety and biosecurity measures can be identified. From that point, proposals can be developed for feasible ways to strengthen the weak links in China's system.

³² For an analysis of the U.S. biosecurity measures, Julie E. Fischer, *Stewardship or Censorship? Balancing Biosecurity, the Public Health and the Benefits of Scientific Openness* (Washington, D.C.: Henry L. Stimson Center, February 2006).

Efforts to Strengthen Biosafety and Biosecurity in China

Although the initiation of the new biosafety regulations in China did include the establishment of some training programs for the scientists working in high-containment laboratories, the Chinese government should develop additional education and training programs for those granted access to biological agents and toxins. This training would raise awareness among scientists of the potential threat of the misuse of dangerous pathogens, the problems of biosafety and biosecurity, and the measures that exist to address those problems. This training program could include an exchange program between Chinese scientists and their colleagues working overseas so that Chinese scientists could gain first-hand knowledge of other advanced biosafety and biosecurity practices to further improve China's measures. The foreign scientists who work for a short period of time in Chinese laboratories would also be able to see the progress already made in China's biosafety and biosecurity practices, which would encourage additional collaboration and investment in China's growing biotechnology industry.

In addition to improvements in education and training, three distinct proposals can be made to address the loopholes identified above in China's framework of biosafety and biosecurity. First, China should continue its efforts to align its existing laws and regulations with the international biosafety and biosecurity standards and models. Foremost in this area, China should consider expanding the scope of its current biosafety and biosecurity regulations beyond the current set of facilities that are covered by its existing regulations, namely pathogenic microbiology laboratories. In short, universally agreed-upon principles and practices for biosecurity and for biosafety are needed for all activities in China that involve high-risk pathogenic microorganisms. Special attention should be paid to the implementation of biosafety and biosecurity standards in China's vast system of hospitals. Moreover, the system of regulation, registration, and licensing employed for pathogenic microbiology laboratories should be expanded to include academic institutions, corporations, companies, associations, firms, and other entities that receive, possess, use, or transfer dangerous pathogens or toxins. This extended system would carry with it specified civil and criminal penalties for violation of the biosafety and biosecurity regulations. Another measure that could further strengthen the biosafety and biosecurity framework in China would be the establishment of a reference list for plant

pathogens.³³ Taken together, these additional steps would certainly enhance the formal system of biosecurity in China.

Second, a clearer distribution of responsibilities and duties related to biosafety and biosecurity among China's government agencies and departments needs to be established. Steps need to be taken to reduce duplication of effort among agencies and also to increase cooperation and exchange of information between the offices involved in biosafety and biosecurity matters. Licensing of facilities and monitoring their operation is a complicated, resource-intensive endeavor. Cooperation among China's government agencies will be essential if China's existing standards are to be implemented well. Moreover, China's biosafety and biosecurity regulations and its select list of pathogens and toxins need to be reviewed and updated regularly, so clear division of responsibilities and cooperation will be essential if the needed improvements needed are to be made.

Finally, the code of conduct for scientists in China should be augmented with a universal norm and an operational code specific to the laboratories, universities, hospitals, research institutions, and commercial enterprises involved in life sciences activities. The Academy of Sciences has moved forward with a detailed code for its membership and a system to oversee the responsible behavior of academicians. However, a great many scientists and technicians working in the life scientists in China have not reached the august rank of academician. Moreover, the code of conduct should apply not just to scientists, but to all persons involved in scientific activity, including funders, publishers, managers, and technical and ancillary staff. Measures need to be enacted to educate all of these individuals about the responsibilities that come with work in this field. Establishing the institutional codes, the bottom tier of this system of codes will be particularly important to providing a more active bottom-up avenue to strengthen biosafety and biosecurity. Finally, this three-tiered system of codes and oversight will need to be updated to ensure that the codes are sufficiently broad in scope to apply to new and unexpected scientific results and developments.

³³ Note that China has established a control list for plant pathogens for the purposes of export controls and for quarantine of microorganisms and insects that might cause harm to indigenous species in China.

Proposals to Strengthen the BWC

The task of enhancing biosecurity needs to be approached in a more comprehensive fashion, as is widely recognized among scientific and policy professionals in China and elsewhere around the globe. As two U.S. biological weapons nonproliferation experts observed, “Tighter national regulations on access to dangerous pathogens, although desirable, will not significantly reduce the global threat of bioterrorism unless such controls are implemented internationally.”³⁴ The BWC is the principal international mechanism outlawing biological weapons, and strengthening its effectiveness by improving biosecurity as well as biosafety serves the security interests of all nations.

The objective of the BWC is to prevent and eliminate biological and toxin weapons, so admittedly this treaty is not primarily designed for strengthening biosafety and biosecurity. Nonetheless, several articles of the BWC address biosafety and biosecurity concerns from various perspectives. Articles III and IV require treaty members to take measures to safeguard their biological pathogens and toxins and to prevent them from falling into the hands of others, whether these actors be governments or non-state actors, for the purposes of biological warfare. Article X calls for the exchange of equipment, materials, and information about biological agents and toxins for peaceful purposes among the treaty members. The challenges of implementing Article X have become more apparent with the wide recognition that the advances in biotechnology equipment and know-how would not only promote cooperation among BWC members but also increase the potential for misuse of biological pathogens and toxins. Thus, BWC members have frequently discussed the need to improve biosafety and biosecurity in the context of Article X.

The BWC is generally considered a weak instrument because it lacks the provisions, organizational structure, and resources to verify compliance or investigate alleged breaches of its prohibitions against the development, production, and stockpiling of biological weapons. After negotiations to develop a legally binding verification protocol collapsed in 2001, BWC members have tried to strengthen the multilateral

³⁴ Jonathan B. Tucker and Raymond A. Zilinskas, “Assessing U.S. Proposals To Strengthen the Biological Weapons Convention,” *Arms Control Today* 32, no. 3 (April 2002): 11.

process of biological arms control by holding of intercessional meetings of experts and treaty members. Biosafety and biosecurity problems were discussed extensively during these intercessional meetings between 2003 and 2005. BWC members shared the practices, standards, and legislation that they had already enacted or were contemplating to govern biosafety and biosecurity in their countries. The result was a collection of national measures and practices on biosafety and biosecurity. These matters will be further discussed under the topic of “National, Regional and International Measures to Improve Biosafety and Biosecurity, including Laboratory Safety and Security of Pathogens and Toxins” at the intercessional meetings of 2008. The rules governing the discussion, however, preclude coordinated multilateral action on this agenda.³⁵

Perhaps outside of any activity that might occur under the BWC umbrella, experts and scholars are calling for a new international treaty, a biosecurity convention, to establish a set of legally binding standards for pathogen security. The current U.S. position opposing multilateral arms control certainly calls the feasibility of this recommendation into question for the time being. For this reason, scholars believe that “any short-term strategy for controlling access to dangerous pathogens will have to be based on international standards implemented through national legislation.”³⁶ However, in the longer term, legally binding international standards could and should be considered.

In the interim, members of the BWC should be encouraged to consider possible measures to strengthen biosafety and biosecurity within BWC. Those measures include:

- promoting the development of international biosecurity guidelines within the BWC intercessional review process;
- developing and updating a systematic catalogue of biosafety and biosecurity measures based on the data that BWC members provide in the intercessional process; and,
- working closely with WHO, Food and Agriculture Organization of the United Nations, and the World Animal Health Organization, and other international organizations to address biosafety and biosecurity issues such as the surveillance and combating of infectious disease.

³⁵ *Biological and Toxin Weapons Convention, Final Document of the Sixth Review Conference of the States Parties*, Doc. BWC/CONF.VI/6 (Geneva: 2006), 21.

³⁶ Tucker, “Biosecurity: Limiting Terrorist Access to Deadly Pathogens,” 14.

Efforts to Strengthen Biosafety and Biosecurity in China

Meaningful collaboration on these measures could pave the way for the initiation of international negotiations to create legally binding biosafety and biosecurity standards, should such negotiations be deemed advisable.

Conclusion

To strengthen biosafety and biosecurity, China and other nations have to improve their domestic practices by building a set of comprehensive laws and regulations on biosafety and biosecurity, including penalties sufficient to motivate the regulated facilities to abide carefully by the rules; by updating of these measures on a regular basis; by establishing competent government agencies and organizations to administer and oversee these matters; and by developing and updating codes of conduct for the scientists and technicians involved in the life sciences. Meanwhile, because of the nonproliferation norm embodied in the BWC and the significant discussions that have been held in that context on biosafety and biosecurity, it would be advisable for the BWC's members to participate actively in international efforts to strengthen the BWC and to shape it into a more effective international regime to counter biowarfare and the possible terrorist acquisition and use of biological pathogens. The enhancement of biosafety and biosecurity are important facets of such nonproliferation efforts.

**Biological Inspections in Iraq:
Lessons for BWC Compliance and Verification
Yang Ruifu, Ph.D.¹**

The 1972 Biological and Toxin Weapons Convention (BWC), which entered into force in 1975, prohibits the development, production, and stockpiling of germ weapons. Iraq signed this treaty on 11 May 1972, but did not ratify the accord until about two decades later.² In the interim, Iraq developed, tested, and produced several different types of biological weapons, most notably anthrax and botulinum toxin. The inspections that finally uncovered the evidence of Iraq's biological weapons program were not conducted under the auspices of the BWC, in part because the treaty does not have any provisions for such inspections.³ Instead, the unique circumstances existing after Iraq's defeat in the first Persian Gulf War led to the formation of the United Nations Special Commission (UNSCOM) on Iraq, a small inspectorate that reported directly to the Security Council. UNSCOM executed the inspections that led Iraq to admit on 1 July 1995, after over four years of denial, its past offensive biological weapons program.⁴

Iraq was not the only country confirmed in the 1990s to have ignored the BWC's prohibitions; one of the three states principally responsible for negotiating the BWC secretly maintained a biological weapons program for decades. In 1969, the United Kingdom proposed a ban on biological weapons. Efforts to draft the BWC moved

¹ Dr. Yang Ruifu is a professor at the Institute of Microbiology and Epidemiology at the Academy of Military Medical Sciences. He is also the deputy director of the key state laboratory of pathogens and biosecurity, and the director-in-chief of the laboratory of analytical microbiology at the National Center for Biomedicine Analysis.

² The BWC opened for signature 10 April 1972 and entered into force 26 March 1975. Iraq ratified the BWC on 19 June 1991. For more about the treaty and its current status, go to: <http://www.opbw.org>. Security Council Resolution 687 set the terms for a ceasefire in the Gulf War, established UNSCOM, and obligated Iraq to ratify the BWC, which it finally did in June 1991. See United Nations Security Council Resolution 687, 3 April 1991.

³ The BWC provides for states to bring compliance complaints to the United Nations Security Council, which can in turn launch an investigation of the compliance concerns. This mechanism remains unused in part because of the assumption that one of the five permanent members of the Security Council would exercise its veto power to block an investigation. See Article VI, *Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction*.

⁴ United Nations, *Report of the Secretary-General on the Status of the Implementation of the Special Commission's Plan for the Ongoing Monitoring and Verification of Iraq's Compliance with Relevant Parts of Section of Security Council Resolution 687 (1991)*, 11 October 1995). Available at: <http://www.un.org/Depts/unscom/sres95-864.htm>.

Biological Inspections in Iraq: Lessons for BWC Compliance and Verification

quickly forward after the United States renounced its offensive biological weapons program and the Soviet Union joined the negotiations.⁵ Given the USSR's status as one of the BWC's founders, Russian President Boris Yeltsin's 1992 admission that the USSR had maintained an offensive biological weapons program shocked many even though signs of the USSR's program had previously appeared.⁶ In 1979, when 64 people near the city of Sverdlovsk died from anthrax, the U.S. government accused the Soviet Union of cheating on the BWC, charging that the deaths were attributable to an anthrax production facility located there, not the consumption of tainted meat, as the Soviets said.⁷ A senior scientist, Vladimir Pasechnik, who defected from the Soviet Union in 1989, told the British of his part in the covert Soviet biological weapons program.⁸ Not until 1999, however, did the basic story of the Soviet biological weapons program reach the public with the publication of Ken Alibek's autobiography. Alibek was the second highest ranking official in Biopreparat, the complex of supposedly commercial facilities that served as a cover for much of the USSR's biological weapons program.⁹

Long before Soviet and Iraqi cheating on the BWC was revealed, arguments were made to strengthen the BWC by adding inspections and other monitoring provisions to the BWC similar to the ones that enabled compliance monitoring of the Nuclear Nonproliferation Treaty and the Chemical Weapons Convention.¹⁰ Such monitoring

⁵ For an overview of the BWC's negotiating history, see U.S. Arms Control and Disarmament Agency, *Arms Control and Disarmament Agreements: Texts and Histories of the Negotiations* (Washington, D.C.: U.S. Department of State, 1996): 95-6.

⁶ R. Jeffrey Smith, "Yeltsin Blames '79 Anthrax on Germ Warfare Efforts," *Washington Post*, 16 June 1992, A1; J. Dahlburg, "Russia Admits It Violated Pact on Biological Warfare," *Los Angeles Times*, 15 September 1992, A1. Yeltsin also took steps to close down the program, cutting its funding by 30 percent and its personnel by 50 percent. The United States. Richard Boucher, U.S. Department of State, "Joint U.S./UK/Russian Statement of Biological Weapons, Press Release, Office of Public Affairs (Washington, D.C.: 14 September 1992); Decree of the Russian Federation on Fulfilling International Obligations with Regard to Biological Weapons, Moscow, 11 April 1992.

⁷ The United States. Department of State. *Soviet Noncompliance with Arms Control Agreements* (Washington, D.C.: 2 December 1987); Mathew Meselson, Jeanne Guillemin, et al., "The Sverdlovsk Anthrax Outbreak of 1979," *Science* 226, no. 5188 (18 November 1994): 1202-8.

⁸ Pasechnik ran the Institute of Ultra Pure Biopreparations in St. Petersburg. Among other activities, scientists at this institute developed an antibiotic resistant strain of *Yersinia Pestis*, the causative agent of the plague. "Vladimir Pasechnik," *The Telegraph*, 29 November 2001. Available at: <http://www.telegraph.co.uk/news/main.jhtml?view=DETAILS&grid=&targetRule=5&xml=/news/2001/11/29/db2903.xml>.

⁹ Ken Alibek, with Stephen Handelman, *Biohazard* (New York: Random House, 1999).

¹⁰ Article III of the 1970 Treaty on the Non-Proliferation of Nuclear Weapons calls for members to accept safeguards inspections from the International Atomic Energy Agency to assure the peaceful use of the atom. The United States. *Arms Control and Disarmament Agreements: Texts and Histories of the Negotiations*,

provisions, it was believed, would correct a major weakness in the BWC. On-site inspections were not widely incorporated into arms control treaties until the late 1980s, when it was deemed advisable to augment national technical means of verification (e.g., satellite imagery) with other, more intrusive monitoring measures.¹¹ Revelation of the Soviet and Iraqi biological weapons programs helped to motivate the initiation of international negotiations in 1995 to add a monitoring protocol to the BWC. Leading into the negotiations, the BWC's members examined 21 measures that might be useful to determine compliance with the BWC.¹²

The negotiations to craft a monitoring protocol for the BWC, however, began to collapse in 2001. The first blow to the process came with the U.S. government's rejection of the draft monitoring protocol in July 2001.¹³ The culminating blow to international talks came in December 2001, when the U.S. government proposed that all negotiations cease.¹⁴ Instead, the 155 members of the BWC had the option of participating in discussions from 2003 to 2005 of various topics associated with BWC compliance.¹⁵ Similar talks are slated to continue until 2010, but resumption of negotiations to draft a monitoring protocol is on hold for the indefinite future.¹⁶

72. For other inspection provisions, see the Verification Annex, *Convention on the Prohibition of the Development, Production, Stockpiling and Use of Chemical Weapons and on Their Destruction*.

¹¹ In particular, see the on-site monitoring provisions of the 1987 Intermediate-Range Nuclear Forces Treaty, *Arms Control and Disarmament Agreements: Texts and Histories of the Negotiations*, 329-40. Following the inspection breakthrough in 1987, the 1990 Conventional Forces in Europe Treaty and the 1991 Treaty between the United States of America and the Union of Soviet Socialist Republics on the Reduction and Limitation of Strategic Offensive Arms (START) also contained extensive monitoring provisions.

¹² The United Nations. Ad Hoc Group of Governmental Experts to Identify and Examine Potential Verification Measures from a Scientific and Technical Standpoint, *Summary Report*, BWC/CONF.III/VEREX/8 (Geneva: 24 September 1993).

¹³ The United States. Department of State. M.D. Kellerhals, Jr., "Proposed Biological Weapons Protocol Unfixable, U.S. Official Says," International Information Programs, 25 July 2001. Available at: <http://usinfo.state.gov/topical/pol/arms/stories/01072503.htm>. See also Michael R. Gordon and Judith Miller, "U.S. Germ Warfare Review Faults Plan on Enforcement," *New York Times*, 20 May 2001, 1; A.G. Higgins, "Germ Warfare Group Suspends Negotiations Following U.S. Pullout," Associated Press, 3 August 2001.

¹⁴ "BWC: Review Conference Collapses," Global Security Newswire, 10 December 2001.

¹⁵ The topics discussed were biosecurity and domestic criminalization legislation; disease surveillance and response and investigation of suspicious disease outbreaks; and codes of ethics for scientists. Fifth Review Conference of the States Parties to the Convention on the Prohibition of the Development, Production, and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction, *Final Document*, BWC/CONF.V/17 (Geneva: United Nations; 8 December 2006). Available at: [http://www.opbw.org/rev_cons/5rc/docs/final_dec/BWC-CONF.V-17-\(final_doc\).pdf](http://www.opbw.org/rev_cons/5rc/docs/final_dec/BWC-CONF.V-17-(final_doc).pdf).

¹⁶ The topics to be discussed include domestic implementing measures and regional cooperation; biosecurity, biosafety, and various measures, including scientific codes of conduct, to discourage the

Arguably, the UNSCOM inspections could be a goldmine of knowledge about the planning, inspector training, and operational strategies, tactics, and technologies for inspections to determine compliance with the BWC. The UNSCOM inspections were conducted at numerous types of sites, including those actively masking illicit biological weapons activities and those engaged in legitimate commercial and other peaceful work. Iraqi officials at some facilities cooperated reasonably with the inspectors, but at others, Iraqi officials deliberately tried to mislead the inspectors and hide the truth. In other words, the UNSCOM biological inspections demonstrated many of the real-world contingencies critical to understanding the feasibility of monitoring compliance with the BWC. With the objective of learning from the UNSCOM biological inspections in mind, this essay will seek to convey one former UNSCOM inspector's insights into the utility of on-site monitoring of dual-use facilities.

Selected Observations from UNSCOM's Biological Inspections in Iraq

On 15 June 1998, UNSCOM dispatched an inspection team to Iraq for the purposes of on-going monitoring and verification, confirming the location and status of critical pieces of equipment that could be employed for both civilian and military activities. This UNSCOM team visited numerous sites over the next three months, including academic and commercial facilities, departing on 14 September 1998. This inspection team was designated Biological Group 16 (BG16), for the 16th of UNSCOM's 17 biological monitoring groups. The BG16 team was one of over 70 UNSCOM biological inspection missions in Iraq. Most of these missions involved inspections of multiple Iraqi facilities. UNSCOM's biological inspection missions had different basic objectives, including inspections to clarify Iraq's declaration and conduct initial site visits; to establish baseline data for ongoing monitoring and verification; to inventory, tag, and document dual-use equipment; to conduct interim monitoring activities; to initiate ongoing monitoring and verification; to analyze the parameters for monthly

misuse of advances in the life sciences; the enhancement of infectious disease surveillance and response and international cooperation, exchange, and assistance in biological science and technology; the provision of assistance to any BWC member requesting aid in the event of a suspected germ weapons attack. The United Nations. Sixth Review Conference of the States Parties to the Convention on the Prohibition of the Development, Production, and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction, *Final Document*, BWC/CONF.VI/6. (Geneva: 8 December 2006). Available at: <http://www.opbw.org>.

monitoring; to destroy equipment and facilities used in Iraq's biological weapons program; to review documentation pertinent to dual-use activities; to interview pertinent Iraqi personnel; and to clarify Iraq's past bioweapons program activities. Some UNSCOM inspections were conducted jointly with other groups in UNSCOM's Baghdad office or with an inspection team deployed for a special mission. Before his involvement in BG16, the author also participated in a special visiting team that worked with members of BG15 to inspect presidential sites in Iraq, which included the palaces of Iraqi president Saddam Hussein as well as other facilities that Iraq deemed sensitive.

UNSCOM staffed its inspection teams with personnel from many nations.¹⁷ The nations that provided inspectors to UNSCOM often sent top professionals in their respective areas of expertise but many, if not most, of these individuals had no prior experience as inspectors. UNSCOM therefore provided a week of training, sometimes more, for inspectors entering Iraq for the first time. The training took place mostly at UNSCOM's field office in Bahrain, although the last segment of the training was often held at UNSCOM's office in Baghdad. The instruction covered the terms and provisions governing UNSCOM's inspections to ensure that personnel knew their rights as inspectors as well as the rights and obligations of the Iraqis. In anticipation that inspectors would go to sites where materials hazardous to their health would be present, another featured topic of instruction was the use of the appropriate personal protection equipment (e.g., gloves, masks). The training reviewed such technical matters as the procedures for the collection of samples and other pertinent evidence, the rules for maintaining chain of custody for evidence, and methods of documentation. Finally, the instruction provided some background information about Iraqi culture to help the inspectors understand how the Iraqis might behave in certain situations.

Prior to each inspection, UNSCOM's BG16 team met to review many aspects of the plan for the coming inspection. All UNSCOM chief inspectors had a certain amount

¹⁷ Nations providing inspectors to UNSCOM paid the salaries of personnel they loaned to UNSCOM, which otherwise operated on a modest budget with very few permanent staff at its headquarters in New York City. See paragraphs 5, 7, and 9 of "Report of the Secretary-General on setting up a Special Commission (UNSCOM) to carry out on-site inspection of Iraq's biological, chemical and missile capabilities," Doc. S/22508 (New York: United Nations Special Commission, 18 April 1991). See also "Plan for the implementation of relevant parts of Section C of Security Council resolution 867 (1991), Report of the Secretary-General, Doc. S/22614 (New York: United Nations Special Commission, 17 May 1991).

Biological Inspections in Iraq: Lessons for BWC Compliance and Verification

of discretion in the field as to how they were to accomplish their mission, including the right to withhold from the inspectors certain particularly sensitive details of the next inspection until the team's arrival at the inspection site. The practices and leadership skills of the team leader, as well as the interpersonal skills of the other team members, can have a significant influence on how well an inspection team performs when its members have never worked together before but are required to establish positive team dynamics virtually overnight to accomplish a mission in a setting that some find quite challenging. BG16 worked collaboratively and effectively.¹⁸ In these inspection planning meetings, the team leader usually notified the inspectors of their assignment(s) for the coming day. Each inspector's skills and qualifications were often the determining factor in their assignments, but on occasion even highly specialized technical experts were asked to perform guard duty to help secure the inspected site or to assist with other more generic inspection tasks (e.g., photography, logistics, note-taking). Otherwise, some inspectors were assigned to examine documentation, others to speak with selected personnel at the facility, others to locate and examine dual-use equipment, and still others to examine the collections of seed cultures at facilities.¹⁹

In these planning meetings, the chief inspector usually shared with the team data about what was expected to be found at the site,²⁰ and a group discussion would ensue. From that discussion, the team would devise a target list of inspection priorities. Often, there was a general expectation within the inspection team that equipment would not be found where it was supposed to be or that the inspection would uncover other misbehavior. Especially during inspections of its nuclear and biological activities, Iraq at times went to extensive lengths to hinder the inspectors. For instance, UNSCOM inspectors who discovered the blueprints for Iraq's nuclear weaponry were detained for

¹⁸ One factor that influenced BG16's cohesiveness was the encouragement team members received from the team leader, an American with a military background, to socialize together in the evenings. Very often, various inspectors would engage in some activity together (e.g., bowling, ping-pong, dining).

¹⁹ Because of my technical skills, my principal duties on most inspections involved examination of culture collections and of equipment.

²⁰ By this time, UNSCOM had an extensive database of the dual-use equipment in Iraq. A series of baseline inspections that visited over eighty sites in Iraq in 1994 to inventory, tag, and document dual-use equipment were the basis of this database, which was updated thereafter when inspectors visited the facilities. The major baseline inspections, conducted from April to September 1994, were UNSCOM 72/BW4, UNSCOM 78/BW5, UNSCOM 84/BW6, UNSCOM 86/BW7, and UNSCOM 87/BW8. Nations cooperating with UNSCOM also occasionally provided information about other pieces of equipment that Iraq may have acquired but did not declare to UNSCOM or that Iraq may have manufactured indigenously.

four days in a downtown Baghdad parking lot in September 1991 when Iraq refused to hand over the documentation.²¹ New inspectors were aware of such uncooperative behavior even if they had not encountered it themselves. For their part, some veteran inspectors often assumed that the Iraqis would “misplace” keys to rooms, be unable to locate records that a facility would normally keep, claim that essential personnel were not available for interviews when the inspectors arrived, or engage in other activities that would obstruct the inspections.

The receptivity of the Iraqis to the inspection team appeared to differ according to the type of facility being inspected. When BG16 visited universities, the Iraqis were quite cooperative. The inspectors were able to enter laboratories and other facilities and to engage in professional discussions with the Iraqi scientists about the pathogens they were working with and their research objectives, methodologies, and results. When BG16 went to factories, the reception from the Iraqis was sometimes less hospitable. The Iraqi officials and the factory owners were not pleased that the inspections were interrupting factory operations. They complained that the presence of the inspectors, their tour of the facilities, discussions with facility personnel, examination of equipment and documents, and other activities interfered with their production of milk, fruit juices, and other commercial products. The tensest inspections, however, were those conducted at the sites the Iraqis declared as sensitive. For instance, when BG16, which was conducted in conjunction with a special visiting team, inspected the headquarters of the Iraqi Air Force, the size of the UNSCOM team expanded to include almost 100 inspectors. The Iraqis also sent an increased number of Iraqi security personnel. The higher number of people interacting with each other escalated the tension and also multiplied the potential for problems to occur. The inspection team spent an entire day at this site, and both the Iraqis and the inspectors were apparently worried about the outcome of the inspection of this and other sensitive sites.

Among the inspectors, there appeared to be different thresholds for suspicion about whether an isolated piece of evidence indicated that a facility may or may not have been involved in prohibited activity. Various reasons could exist for these different

²¹ Paul Lewis, “Iraq Appears Ready to Yield Over U.N. Inspectors,” *New York Times*, 26 September 1991; John M. Goshko, “Standoff is Over,” *Washington Post*, 28 September 1991, A1.

Biological Inspections in Iraq: Lessons for BWC Compliance and Verification

thresholds. As noted, experienced inspectors who had previously encountered misconduct on the part of the Iraqis anticipated that the Iraqis would comport themselves poorly. Another factor influencing the threshold for suspicion was whether an inspector was truly familiar with the working conditions of the type of facility being inspected. Inspectors who had worked in a laboratory or commercial plant were likely to make informed judgments as to whether something unusual was a typical human error or was indicative of activity related to the research, development, or production of biological weapons. For example, when checking the contents of a freezer storing strains of diseases, at times the Iraqis did not have documentation for some of their vials or their vials were labeled incorrectly, with the accurate name of the bacteria but the wrong American Type Culture Collection number for that particular strain. For some inspectors, this created suspicions of misbehavior; perhaps because without having worked in a laboratory these inspectors had unrealistic expectations about how accurately laboratory staff should or can keep records. Their counterparts with laboratory experience understood that clerical errors occur in all laboratories, and if the inventory of the freezer contents uncovered only a few small errors among hundreds of vials, then it did not cause an inspector with laboratory experience any undue concerns that the Iraqis were trying in some way to hide biological weapons-related research. Conversation with the laboratory workers could usually spell out how and why the mistake(s) had been made, but if reasonable suspicions remained, additional investigatory steps, such as culturing the contents of the vial in question, could be taken to clarify the situation.

As inspectors consider whether the evidence before them should raise concerns about illicit activity, they need to be alert to differences in the level of biosafety practiced in other countries. At one facility, BG16 inspectors came across a senior scientist performing inoculations with *B. subtilis* on the bench but not wearing any protection—no mask, no gloves, no cap. The BG16 team quickly withdrew from the work area and put on appropriate personal protection gear. When asked about the normal safety precautions observed at this facility, another Iraqi scientist said that they never used such precautions for that type of procedure. In other words, the Iraqi scientists appeared to have no hesitation about working in biosafety conditions that outsiders viewed as inadequate to

protect their health and safety.²² Two lessons for inspectors emerge from this encounter. First, as soon as possible, inspectors should assess a facility's biosafety standards to ensure that the inspectors are wearing the proper personal protection equipment. Second, in making their assessments, inspectors need to think with an open mind about what is possible in the biosafety conditions that are present. A scientist accustomed to advanced biosafety conditions might not be willing to perform certain procedures with highly infectious diseases in less stringent biosafety conditions, but that does not mean that others would not be willing to or compelled to work in those circumstances. In short, biological weapons can be researched, developed, and produced in very limited safety conditions if the scientists do not know about better biosafety, if they are forced to work in such conditions, and if political and military leaders do not understand that this activity will put at risk their personnel and the public.

Other than the visual and physical examination of facilities, one of the most useful tools at the disposal of inspectors is to speak with the facility personnel about their work. UNSCOM inspectors were able to examine carefully the set-up of a facility's fermenters, continuous centrifuges, and other equipment and to talk with the plant operators about how and why they were doing certain things. At the Al Kindi Veterinary Vaccine Production Plant, an inspector who observed their production process and engaged in technical discussion with the facility staff could understand that at this plant the Iraqis did not have sufficient knowledge of modern vaccine production techniques to make advanced vaccines. An Al Kindi senior scientist said that they were unable to use more advanced production processes because they did not have access to the internet or to recent scientific journals or the ability to travel to scientific conferences to gain such information. The taking of samples was another tool that inspectors could employ, but inspectors used sampling sparingly. For example, samples were taken of the drippings that were found on the ground beneath a holding tank on the grounds of a presidential site so that the contents of the tank could be specifically determined.²³

²² Biosafety practices were strengthened considerably in the 1990s, and one reason that the Iraqis may not have kept pace with safety improvements is that after the first Gulf War they had little or no access to the outside world.

²³ Two of the reasons that sampling was used infrequently were the time and cost of sample analysis. For analysis, UNSCOM was reliant on the use of the analytical laboratories of cooperating nations. Therefore, one of the recommendations from BG16 was for UNSCOM to establish its own analytical laboratory

Biological Inspections in Iraq: Lessons for BWC Compliance and Verification

In the first four or five inspections that BG16 conducted, the team found all of the equipment that they expected to locate. Everything, in other words, was pretty much in order at these sites. After that, instead of beginning each new inspection with a prevailing expectation that something improper would be discovered, the mindset of new inspectors could adjust to a more reasonable barometer of suspicion. The inspectors were still very vigilant, doing whatever they could to determine if the Iraqis were employing the dual-use equipment for the legitimate purpose(s) they stated. In addition to the previously mentioned inspection activities, the team examined the videos from the inspected facilities very closely, looking at who was entering and exiting the facilities, the specific buildings where dual-use equipment was located, and at the film records of the equipment operations. They found nothing seriously out of order. So, the BG16 inspections largely confirmed the findings of previous UNSCOM teams but did not uncover any significant misconduct on the part of the Iraqis.

Considering the Adjustment of the UNSCOM Experience to a BWC Context

The UNSCOM inspections in Iraq were comparable to a major, ongoing experiment in how to monitor the ban on biological weapons. So much experience was gained, and in the end the UNSCOM inspections offered considerable proof that experienced inspectors can discern whether a facility is engaged in activities consistent with its stated purpose(s) or is covering for illicit weapons-related activities. The UNSCOM experience can be adjusted for the BWC context. To begin with, although Iraq had no rights under the ceasefire resolution to refuse UNSCOM inspection, a BWC inspection regime could use many of the same basic inspection tools and procedures as UNSCOM but the framework for the inspections would be that they unfold in a collaborative manner with the inspected state.²⁴ In contrast to UNSCOM, BWC inspectors would give the inspected state notice about the facilities to be visited. Advance notice of inspections could make the job challenging for BWC inspectors

capacity. This recommendation was accepted and equipment was purchased, but before the laboratory could be created, Iraq completely stopped its cooperation with UNSCOM.

²⁴ The possible exception to this collaborative approach would be if a BWC inspection regime included challenge inspections similar to those of the Chemical Weapons Convention. All members of the Chemical Weapons Convention are obligated to accept a challenge inspection at any time at any place on their territory in the event that allegations of cheating arise.

because the inspected state would have many days prior to the arrival of inspectors to conceal any prohibited activities. For example, a production plant can be switched from prohibited activity to civilian drug manufacture within just 48 hours. However, much the same situation existed with UNSCOM inspections. Although Iraqi officials did not always know when and where UNSCOM inspector teams were going, they certainly understood that UNSCOM's mandate under Resolution 687 was to continue inspections at least until the inspectorate could report to the Security Council completion of the elimination of Iraq's weapons of mass destruction and their means of delivery. Iraq had ample time to hide evidence from UNSCOM inspectors, yet the inspectors still managed to uncover sufficient evidence to force Iraq to admit its covert biological weapons program.²⁵

In a BWC context, one key to the success of inspections would be the assembly of inspection teams with the appropriate skills and proper preparation. Many of the individuals that nations seconded to UNSCOM were from the military or other professions that allowed them little understanding of the science and technology involved in bioweapons research, development, testing, and production. Just as the best inspection team for a facility thought to be manufacturing biological munitions would consist of engineers and military professionals knowledgeable in munitions, the appropriate inspection teams for research and commercial sites employing dual-use equipment would be comprised of professionals who have worked in laboratory and production facilities. As UNSCOM did, incoming inspectors should be provided with appropriate training to familiarize them with their duties and background information about the safety, regulatory, and cultural environment of the inspected state. This training should also inform the inspectors that host officials are likely to interact differently with various team members not only because of their respective technical skills but because of their nationalities.²⁶ A sound inspection strategy would take advantage of this tendency to

²⁵ For example, UNSCOM built its case to establish the real purpose of Al Hakam as a dedicated biological weapons production facility rather than a commercial manufacturing plant on Iraq's attempts to purchase equipment more suited to bioweapons production (e.g., specialized ventilation equipment) and its purchases of extremely large quantities of growth media. United Nations, *Report of the Secretary-General on the Status of the Implementation of the Special Commission's Plan for the Ongoing Monitoring and Verification of Iraq's Compliance with Relevant Parts of Section C of Security Council Resolution 687 (1991)*, Doc. S/1995/284 (10 April 1995), paras. 59-76.

²⁶ Officials that are serving as hosts to the inspection and local private citizens will interact differently with

Biological Inspections in Iraq: Lessons for BWC Compliance and Verification

obtain the maximum possible amount of pertinent information from host officials in a collaborative fashion.

Before going on site, BWC inspectors would be able to gather enough information even from open sources (e.g., product and capability advertisements, staff scientific publications) so that they could develop an understanding of a facility's work and equipment prior to the inspectors' arrival on site. The inspection team could outline the facility compound, identifying what they would expect for that type of facility in terms of biosafety containment areas, the distribution of buildings, and basic capacities (e.g., waste management, storage, medical support). Very soon after arrival, the inspection team would want to allow the individual(s) in charge of major buildings to introduce the building, listening closely to see if their description fits with what the inspectors expected. The inspectors should examine all of a facility's capabilities, including those that are in operation, as closely as possible. The initial tour should include all relevant parts of a site, including biosafety and other laboratory facilities, development and production facilities, pre-clinical testing (animal) facilities, air handling capabilities, storage and waste handling capabilities (e.g., incinerator). As the tour proceeds, inspectors should take the opportunity to interact with facility personnel in a collegial manner, asking questions about their recent activities, the standard operational procedures and self-protection measures for their part of the facility, the length of their employment at the facility, the different jobs they have held at the facility and prior to joining the staff, and problems that have occurred in the facility's operations and how they were resolved. From this type of site observation and discussion, as well as from examination of a facility's documents, experienced inspectors can begin to analyze whether the facility is engaged in legitimate operations. Depending on the size and complexity of the facility being inspected, additional discussion with personnel, inspection of equipment, review of documents, and perhaps even sampling may be needed for inspectors to make a judgment in which they have significant confidence.

individual inspectors based on their perceptions, whether accurate or not, about people from different countries. Locals will be very friendly with inspectors of some nationalities (e.g., offering free taxi rides, extending invitations to dinner), but not so friendly or even confrontational and hostile with inspectors from other countries.

The success of BWC inspections will depend not just on the skill of the inspectors and the procedures and equipment at their disposal, but also on the extent to which politics take a back seat to technical facts and the informed judgments of inspectors. The reports from UNSCOM inspections stated only the technical, observable facts, such as the equipment, pathogens, and capabilities of a facility. UNSCOM inspectors did not include their analysis of the circumstances they found in the field. Such analysis could have played a more important role in the decisions taken about the frequency with which Iraqi facilities in Iraq should be inspected. Instead, politics may have influenced such decisions. While it may be impossible to subtract politics totally from treaty monitoring, decisions about the planning, execution, and outcome of inspections are best made by those with the appropriate technical expertise as opposed to those with political objectives uppermost in mind.

Concluding Observations

Although no plans currently exist to resume international efforts to draft a compliance protocol for the BWC, one cannot rule out the possibility that such negotiations could be reconvened at some point in the future. In that case, the negotiators would certainly benefit from an across-the-board understanding of UNSCOM's inspections of Iraq's dual-purpose biological facilities. Some initiatives were taken to introduce some insights from these inspections to the BWC protocol negotiations held from 1995 to 2001.²⁷ Moreover, some of UNSCOM's biological weapons inspectors have prepared articles and lengthier manuscripts that convey some aspects of their personal experiences with UNSCOM, and some studies by close observers of the UNSCOM inspections have been prepared.²⁸ UNSCOM filed numerous reports providing updates on its inspection activities, and the United Nations Monitoring, Verification, and

²⁷ The United Nations. "UN Special Commission BW Inspections in Iraq: Lessons for the Ad Hoc Experts' Group on Verification," United Kingdom, White Paper, BWC/CONF-III/VEREX-WP5 (Geneva: 30 March-10 April 1992).

²⁸ For example, see Rod Barton, *The Weapons Detective: The Inside Story of Australia's Top Weapons Inspector* (Melbourne: Black Inc. Agenda, 2006); Tim Trevan, *Saddam's Secrets: The Hunt for Iraq's Hidden Weapons* (London: HarperCollins, 1999); Ray A. Zilinskas, "Iraq's Biological Weapons: The Past as Future?" *Journal of the American Medical Association* 278, no. 5 (6 August 1997): 418-24; Graham S. Pearson, *The UNSCOM Saga: Chemical and Biological Weapons Non-proliferation* (New York: St. Martin's Press, 1999); Graham S. Pearson, *The Search for Iraq's Weapons of Mass Destruction: Inspection, Verification and Non-Proliferation* (New York: Palgrave Macmillan, 2005).

Biological Inspections in Iraq: Lessons for BWC Compliance and Verification

Inspection Commission has made efforts to report on these experiences.²⁹ However, no truly comprehensive and independent review of UNSCOM's inspections of Iraq's biological facilities has been done based on the first-person accounts of the individuals actually involved in these inspections and unfettered access to UNSCOM's internal records.

For the benefit of any future efforts to create monitoring provisions for the BWC, the international community needs to examine the experience of the UNSCOM inspections systematically. The nature of the inspection process is that each inspector is assigned certain duties and only experiences a slice of what occurs during an inspection. In addition, each inspector brings somewhat unique skill sets to the task, which also contributes to the varying experiences that inspectors have in the field. An individual's account, no matter how valuable, cannot therefore accurately capture the totality of the lessons that should be learned from the UNSCOM biological weapons inspection process.

The type of examination needed would involve a significant percentage of the UNSCOM biological weapons inspectors that either played key roles at certain junctures in the inspections or were involved in an on-going capacity in multiple inspections. Based on interviews with these individuals and supporting documentation that resides in UNSCOM's files, which are stored at United Nations headquarters in New York, a critical assessment could be made of the role that technology can play in on-site inspections and of why certain inspection procedures worked well in some circumstances and not as well in others. This appraisal would also look into the types of training and support that inspectors found most beneficial to the effective performance of their jobs and into the essential skill sets that individuals should possess to qualify as inspectors and perform well in that capacity. In addition, the inspectors' personal accounts of various experiences in the field could be incredibly instructive to individuals who may one day be

²⁹ Note, for example, UNSCOM's successor released a compendium report in June 2006. The summary of this document was made publicly available, and approximately ten pages of it relate solely to the biological weapons inspections. This report's extensive appendices were not publicly released. Other UNSCOM and UN Monitoring, Verification, and Inspection Commission reports have also addressed various aspects of the inspections process. The United Nations. "Summary of the compendium of Iraq's proscribed weapons programmes in the chemical, biological and missile areas," Doc. S/2006/420 (New York: United Nations Monitoring, Verification, and Inspection Commission, 21 June 2006).

Yang Ruifu, Ph.D.

called on to follow in their footsteps. Failure to capture UNSCOM's experience thoroughly would be a missed opportunity to further efforts to eliminate biological weapons, an objective that is in the utmost interests of mankind.

Putting the Nonproliferation of Biological Weapons on the Right Track

Pan Zhenqiang¹

The recent years have seen the rising threat of the spread of biological weapons. Despite the fact that biological weapons have been outlawed since the Biological and Toxin Weapons Convention (BWC) went into force in 1975, problems concerning the potential development, production, stockpiling, acquisition and even the use of these weapons have not been truly solved. With the rapid development of the life sciences and other related advanced technologies as well as the rise of international terrorism, a potential threat posed by the acquisition and use of these weapons by terrorists seems to loom even larger. In short, the rising threat of biological weapons proliferation seems to be far outpacing international nonproliferation efforts, which adds a great amount of urgency to the need to strengthen international efforts to curb the spread of this category of deadly weapons. Yet the international community is still struggling to find a concerted approach to put biological weapons nonproliferation efforts on the right track.

Two fundamental questions are at the root of the international community's difficulty in addressing the biological weapons proliferation problems. The first question concerns how to arrive at an accurate picture and understanding of the threat of the spread of biological weapons. Without the right diagnoses, one can hardly find the right therapy. The second issue of equally vital importance is related to the therapy itself and that is if the international community is able to define an effective and sustained strategy to head off the threat. Unfortunately, thus far, there has been no consensus on either of these two questions.

Understanding the biological weapons threat

With regard to the first question, although there is an increasing awareness in the international community of the biological weapons threat, views seem to be polarized in terms of the nature and scope of this threat. The Western world, and the United States in particular, has appeared to focus solely in recent years on the rising danger of

¹ Professor Pan is the Vice-President of the Foundation for International Studies and Academic Exchanges. He wishes to stress that views expressed in the paper are the author's own and do not necessarily represent those of any other individuals or any organizations.

Putting the Non-Proliferation of Biological Weapons On The Right Track

bioterrorism. Serious concerns about bioterrorism have been discussed in major U.S. newspapers and in Congressional hearings.² According to a 2006 article, a German-born molecular geneticist by the name of Eckward Wimmer declared that he had found it not so difficult “to create live and artificial viruses” in his lab at the State University of New York from nonliving parts, using equipment and chemicals on hand. “The most crucial part, the genetic code, was picked up for free on the Internet. Hundreds of tiny bits of viral DNA were purchased online, with final assembly in the lab,” Wimmer said. He reckoned that “...tens of thousands of scientists worldwide already are capable of doing [this]”³. Supporting this point is Stanford University biophysicist and former president of the Biophysical Society Steven M. Block: “The biological weapons threat is multiplying and will do so regardless of the countermeasures we try to take. You can’t stop it, any more than you can stop the progress of mankind. You just have to hope that your collective brainpower can muster more resources than your adversaries.”⁴ Reinforcing the message that the new life sciences technologies have opened the door simultaneously to new tools for defeating disease and saving lives as well as to horrific new weapons, Block states: “Today, in hundreds of labs worldwide, it is also possible to transform common intestinal microbes into killers. Or to make deadly strains even more lethal. Or to resurrect bygone killers, such as the 1918 influenza. Or to manipulate a person’s hormones by switching genes on or off. Or to craft cheap, efficient delivery systems that can infect large numbers of people.”⁵ Numerous other reports on the same subjects in the public discussion in the United States also highlight the primary Western fear that the growing threat of bioweapons may chiefly result from the development of science and high-technology, offering terrorists easier access to biological weapons.

² See, for example, Senate Governmental Affairs Subcommittee on International Security, Proliferation, and Federal Services, *Hearing on Multilateral Non-proliferation Regimes, Weapons of Mass Destruction Technologies and the War on Terrorism* (Washington, D.C.: U.S. Congress, 12 February 2002); Senate Governmental Affairs Subcommittee on International Security, Proliferation, and Federal Services, *Hearing on Federal Efforts to Coordinate and Prepare the United States for Bioterrorism: Are They Adequate?* (Washington, D.C.: U.S. Congress, 17 October 2001); House Committee on Energy and Commerce Subcommittee on Oversight and Investigations, *A Review of Federal Bioterrorism Preparedness Programs From a Public Health Perspective* (Washington, D.C.: U.S. Congress, 10 October 2001).

³ See Joby Warrick, “Custom-Built Pathogens Raise Bioterror Fears,” *Washington Post*, 31 July 2006. http://www.washingtonpost.com/wp-dyn/content/article/2006/07/30/AR2006073000580_pf.html

⁴ Ibid.

⁵ Ibid.

In fact, the U.S. experts, politicians, and the media began to discuss bioterrorism concerns publicly during the aftermath of Aum Shinrikyo's 1995 attack in the Tokyo subway, when the Japanese cult used a chemical agent, sarin, to kill a dozen people and seriously injure over 100 others.⁶ Although Aum Shinrikyo used a nerve agent in that attack, it was known afterwards that they had also made serious efforts to acquire biological weapons, although that program failed.⁷ Another news report noted the possibility that terrorists may use disease as a tool of choice. They, for example, could genetically alter the smallpox virus utilizing biotechnological techniques and equipment that are inexpensive and widely available, including in the developing countries, to make a "juiced up" virus that would not only be more lethal than "ordinary smallpox" but also impervious to smallpox vaccines.⁸

According to the Western specialists, there are many reasons why biological and toxin weapons are likely to become ever more attractive to criminals and terrorists as mankind moves further into the 21st century. First, as the biotechnology, pharmaceutical, environmental, and health care industries grow, more and more people will possess expertise in microbiology and the related biosciences. Second, information on how to produce and disseminate pathogens and toxins is already readily available in open sources. Third, a modest quantity of pathogens delivered effectively can cause a great many people to become ill and die.⁹ Fourth, pathogens or toxins can be produced in small facilities so that they can be easily hidden. Police and nearby citizens are unlikely to discover a terrorist or criminal producing, transporting, or using a biological weapon. Fifth, the delivery systems for biological agents do not necessarily require sophisticated methods. A sprayer will suffice. Sixth, although efforts are being made to improve defensive technologies, none are available that are, or could be, deployed at civilian

⁶ Aum's 20 March 1995 attack is described in D.W. Brackett, *Holy Terror: Armageddon in Tokyo* (New York: Weatherhill, 1996); David E. Kaplan and Andrew Marshall, *The Cult at the End of the World* (New York: Crown Publishers, Inc., 1996).

⁷ Milton Leitenberg, "Aum Shinrikyo's Efforts to Produce Biological Weapons: A Case Study in the Serial Propagation of Misinformation," *Terrorism and Political Violence* (1999); Milton Leitenberg, "Biological Weapons and Bioterrorism in the First Years of the 21st Century," *Politics & the Life Sciences* 21, no. 2 (2002).

⁸ Lawrence Lessig, "Insanely Destructive Devices", WIRED, April 2004.
<http://www.wired.com/wired/archive/12.04/view.html>.

⁹ The quantity of biological agent used can be particularly small if a contagious agent is employed. In that scenario, the original delivery system does not have to expose thousands of people to the agent because soon enough, the disease will begin to spread from person to person, multiplying casualties considerably.

Putting the Non-Proliferation of Biological Weapons On The Right Track

facilities to detect and identify deliberately disseminated biological agents in real or near real time. The fact that a biological attack has occurred would therefore not become known until some time later, when many individuals become simultaneously begin to fall ill.¹⁰

No one questions the legitimacy of the U.S. apprehension about the rising possibility of terrorists' acquisition of biological weapons, particularly after the events of September 11th and the anthrax letters attacks that followed, nor can one afford to ignore the growing danger of bioterrorism. That said, however, one should not lose sight of the fact that the ambiguous attitude of many countries towards biological weapons with their possible ongoing biological warfare programs presents a stark background against which all other problems concerning the spread of biological weapons is generated.

Historically, nations, particularly the major powers, have traditionally sought biological weapons.¹¹ At least one nation, Japan during World War II, even used these weapons in modern warfare.¹² As the Cold War began, the United States and the Soviet Union were both developing large-scale biological weapons programs. More than a dozen other countries were also believed to have their own biological programs. The end of the Cold War evidently abated the interests of some nations to retain biological weapons, providing further incentive for the international community to push for the thorough implementation of the BWC. However, deep-rooted mistrust among global and regional powers remains a factor driving nations to maintain biological programs under the pretext of self-defense, allegedly to “hedge” against the possibility of other countries engaging in covert biological weapons development, production, and stockpiling.

Against that backdrop, activities of the two former military superpowers – the Soviet Union/Russia and the United States – have been most noteworthy. The Soviet Union ratified the Biological Weapons Convention (BWC) in 1975. Nevertheless, the world learned that Moscow had, in fact, continued to develop a secret offensive biological

¹⁰ Raymond Zilinkas, “Assessing the Threat of Bioterrorism,” testimony to the House Subcommittee on National Security, Veterans Affairs, and International Relations (Washington, D.C.: U.S. House of Representatives, 20 October 1999). Available at: <http://cns.miiis.edu/pubs/reports/zilin.html>.

¹¹ Erhard Geissler and John van Courtland Moon, *Biological and Toxin Weapons: Research, Development, and Use from the Middle Ages to 1945*, Stockholm International Peace Research Institute Chemical and Biological Warfare Series, vol. 18 (London: Oxford Univ. Press, 1999).

¹² Sheldon H. Harris, *Factories of Death: Japanese Biological Warfare, 1932-45 and the American Cover-up* (New York: Routledge, 2002).

weapons capability throughout the 1970s and 1980s. Soviet defectors began to give detailed descriptions of this program's nature and scope in the late 1980s and early 1990s. Accordingly, the Soviet/Russian biological warfare program was evidently aimed at wartime production of large quantities of a range of biological agents, including those that cause plague, tularemia, glanders, anthrax, smallpox, and Venezuelan equine encephalitis. When necessary, formulated agents would have been loaded into a variety of delivery systems, including aerial bombs and ballistic missile warheads. In short, the Soviet Union is believed to have developed a comprehensive bioweapons program that comprised dozens of research, development, production, and test facilities that employed tens of thousands of personnel over a few decades.

After the Soviet Union collapsed, Russia, to its credit, officially announced the banning of the offensive biological weapons work. Moreover, in 1992 Russian President Boris Yeltsin explicitly acknowledged the existence of the Soviet biowarfare program. Russia currently participates in the treaties pertaining to biological weapons nonproliferation, and Russia's current leaders deny involvement in the further development of biowarfare agents. Although most of the former Soviet biological weapons facilities continue to operate, they apparently focus only on civilian research activities, which was in part also a result of a project undertaken under the auspices of the Cooperative Threat Reduction Program in conjunction with the International Science and Technology Center. A small number of biological facilities that are part of the Ministry of Defense have yet to allow any foreign visitors or to participate in any collaborative research. This lack of transparency causes some Western officials to worry that although the biowarfare agent stockpiles have been destroyed, activities that contravene the BWC may still continue at military biological facilities in Russia.

Another proliferation concern stemming from the vast former Soviet bioweapons complex is the possibility of "brain drain," which refers to the potential for former Soviet bioweapons scientists to spread their knowledge to other states or to subnational actors. Once the USSR fell, lack of funding for the continuation of extensive biowarfare programs could have driven many of the underpaid or unpaid weapons scientists to immigrate to developing countries that for various reasons had a strong interest in acquiring biological weapons. A considerable amount of relevant technology may also

Putting the Non-Proliferation of Biological Weapons On The Right Track

have been exported to these countries legally or illegally. Longstanding domestic turbulence and instability in some parts of Russia has led many Western countries to express concern that the radical Muslim insurgents, the mafia, or other crime organizations in unstable areas of the former Soviet empire may ply illicit trade to exacerbate the prospects for bioweapons proliferation.¹³

The United States also had a long history of developing offensive biological warfare programs and weaponized a variety of pathogens and toxins for use against humans and plants. During the Korean War, charges were made that the United States engaged in germ warfare although Washington has vehemently denied that this was the case.¹⁴ In 1969, President Nixon decided to terminate the offensive biological warfare program, thereby destroying the U.S. stockpiles of warfare agents. In the meantime, Washington ratified the BWC in 1975, and played a significant role in the process of developing confidence-building measures during several BWC review conferences. This situation began changing when George W. Bush was elected president. The Bush administration has clearly decided to rely on U.S. military power rather than international laws and institutions to cope with various threats in the post-Cold War era. The Bush administration found justification for an active biodefense program in the 9/11 terrorist attacks and the 2001 anthrax letter attacks in particular, which became a powerful catalyst for new activities said to ensure America's security. No matter what their justification, many suspect these biodefense activities are in violation of the BWC.

In addition to sponsoring research on detectors for biological agents and new vaccines and other medical treatments for bio-warfare agents, the Bush administration has funded the construction of over a dozen, new, high-level bio-containment facilities. One such facility, being constructed on the grounds of Ft. Detrick, which is home to the U.S. Army Medical Research Institute for Infectious Diseases, will be a massive

¹³ For more discussion on the biowarfare program of the Soviet Union and Russia, see "Biological overview of Russia," Nuclear Threat Initiative, February 2006. Available at: http://www.nti.org/e_research/profiles/Russia/Biological/index.html. See also, Christopher J. Davis, "Nuclear Blindness: An Overview of the Biological Weapons programs for the Former Soviet Union and Iraq," Johns Hopkins University Center for Civilian Biodefense Studies, July 1999. Available at: <http://www.cdc.gov/ncidod/EID/vol5no4/davis.html>. Finally, see C.L. Staten, "EmergencyNet Exclusive: Questions and Answers on Bio-Warfare/Bio-Terrorism with Dr. Ken Alibek," EmergencyNet NEWS Service Special Report, 14 July 1999. Available at: <http://www.emergency.com/1999/alibec99.html>.

¹⁴ "Evidence of U.S. Waging Germ Warfare Is Firmly Established and Brooks No Denial," Editorial, *China People's Daily*, 12 November 1953.

laboratory “unlike any seen since biological weapons were banned 34 years ago.”¹⁵ The institution is called the National Bio-defense Analysis and Countermeasures Center (NBACC), to which only individuals with a high-level security clearance will have access. Few U.S. government facilities, including the U.S. national nuclear laboratories, operate with such a high level of secrecy. The mission of the NBACC is:

to get inside the head of a bioterrorist. It considers the wide array of potential weapons available. It looks for the holes in society’s defenses where an attacker might achieve the maximum harm. It explores the risks posed by emerging technologies, such as new DNA synthesizing techniques that allow the creation of genetically altered or man-made viruses. And it tries in some cases to test the weapon or delivery device that terrorists might use.¹⁶

For example, NBACC could simulate anthrax attacks or create viruses that are genetically engineered to be resistant to vaccines. Officials from the Department of Homeland Security, which will operate NBACC, insist that NBACC’s work “is purely defensive and thus fully legal.”¹⁷

Some U.S. scientists quickly objected to the terms of operation set for NBACC, but the Department of Homeland Security rejected calls for oversight by independent observers.¹⁸ Without outside oversight, no one has a chance of being able to tell whether NBACC’s activities are offensive or defensive. The description of NBACC’s work agenda by its own officials leads to questions as to whether some of NBACC’s work would violate the BWC’s prohibitions, so the opaqueness of the whole effort is creating a very bad precedent that could undermine international biological weapons nonproliferation norms and mechanisms. In this manner, it can be argued that NBACC and the other U.S. programs have opened doors to the spread of these weapons by others under the cover of legitimate motivations.

Reports also surfaced that the United States has been developing a dangerous fungus, making use of the talents of former Soviet scientists who used to create anti-crop and anti-livestock pathogens. The fungus reportedly could be used to destroy drug crops in

¹⁵ Joby Warrick, “The Secretive Fight against Bioterror,” *Washington Post*, 30 July 2006. Available at: http://www.washingtonpost.com/wp-dyn/content/article/2006/07/29/AR2006072900592_pf.html.

¹⁶ Ibid.

¹⁷ Ibid.

¹⁸ Ibid. For an example of such criticism, see Milton Leitenberg, James Leonard, Richard Spertzel, “Crossing the Line,” *Politics & the Life Sciences* 22, no. 2 (2003).

Putting the Non-Proliferation of Biological Weapons On The Right Track

countries like Colombia and Afghanistan, which grows the opium poppy, the source of heroin. The U.S. objective is allegedly to eradicate the source of the illegal drugs being smuggled into America, but the environmental and human effects from these fungi could be very serious. Control of the use of this agent to destroy drug crops reportedly lies not with the Pentagon, but with the State Department's anti-narcotics division.¹⁹ While the U.S. government may feel justified in taking extraordinary steps to stop the illegal trade in drugs, others would question whether the use of fungi is appropriate, particularly given the prohibitions of the BWC and the 1925 Geneva Protocol, which bans the use of biological and chemical weapons.

Another U.S. program that could be crossing the line from proper to prohibited research is the Joint Non-Lethal Weapons Program, which utilizes both biological and chemical substances, among other materials and technologies. Non-lethal weapons are supposed to incapacitate humans, but they could cause much more grievous harm. The Joint Non-Lethal Weapons Program has considered proposals to develop chemical and biological substances for use against people (e.g., rioters), such as sedatives, calmatives, opioids, muscle relaxants, and bad-smelling substances. “[This program] has weighed using genetically engineered microbes to destroy enemy vehicles, machinery, and supplies. . . .The Pentagon claims. . . .that these arms are not chemical and biological weapons, rather, that they are a potentially less bloody way to conduct peacekeeping operations, isolate terrorists, and squelch civil disobedience.”²⁰ But, again, the Pentagon has not released public information about the status of these non-lethal programs. The mere fact that such research proposals are being entertained gives rise to the impression of activity that is hardly benign and could be inconsistent with international treaties.

Biological weapons programs are of course not merely confined to the two most significant military powers. According to a Western calculation, over a dozen mid-sized countries may also be conducting offensive biological warfare programs.²¹ Many of these countries—Egypt, Israel, Syria, Algeria, Iran, Sudan—are located in the most

¹⁹ Edward Hammond, “Averting Bioterrorism Begins with U.S. Reforms,” Director, Sunshine Project, Winter 2002. Available at: <http://www.greens.org/s-r/27/27-15.html>.

²⁰ Ibid.

²¹ “Chemical and Biological Weapons: Possession and Programs Past and Present,” CBW Resource Homepage, Center for Nonproliferation Studies (CNS), 4 September 2002. Available at: <http://cns.miis.edu/research/cbw/possess.html>.

turbulent region of the world, the Middle East. Most of them have either refrained from joining the BWC, or failed to ratify the treaty after signing it. In the framework of the Arab-Israeli confrontation, many Arab countries take biological and chemical weapons as “the poor man’s nuclear bomb,” providing a countermeasure to offset Israeli military superiority.

To summarize, the threat of biological weapons is multifaceted with diverse sources. While bioterrorism is no doubt part of the threat of proliferation of biological weapons, it is only part of the picture. At the root of the biological weapons threat is the attitude and behavior of the nation-states. An unbalanced emphasis on bioterrorism may obscure the complex nature of the spread of biological weapons and will not be helpful to the nonproliferation efforts in the end.

The Need for a New Vision for Biological Weapons Nonproliferation

Like the lack of consensus regarding the threat of biological weapons, there is no consensus as how to deal with the threat of proliferation. Essentially, two approaches exist concerning an effective strategy for the nonproliferation of weapons of mass destruction, including biological weapons.

The Bush Administration embodies one approach, a unilateralism that focuses on military superiority to ensure security rather than global approaches and treaty making. Washington has promoted a counterproliferation policy as its principal means to deal with perceived weapons of mass destruction threats. Counterproliferation encompasses such activities as the Proliferation Security Initiative, which involves the seizure of materials and/or equipment that could be employed to proliferate weapons of mass destruction.²² The Bush administration’s unilateral approach has disturbed the international community profoundly and been criticized even by U.S. elected officials.

²² According to the Bush administration, these measures were intended to eliminate the immorality of mutually assured destruction, to provide the United States with more flexible options to develop new military capabilities, and to give the United States maximum freedom of action in the international arena. For more details about the U.S. new strategic doctrine, see *Quadrennial Defense Review* (Washington, D.C.: Department of Defense, 30 September 2001); “Briefing on the Nuclear Posture Review” (Washington, D.C.: Department of Defense, 9 January 2002). Available at: <http://www.defenselink.mil/news/Jan2002/d20020109npr.pdf>. See also, State of the Union Address, White House, (Washington, D.C.: Office of the President, 20 January 2002). Available at: <http://www.defenselink.mil/news/jan2002/t01092002-0109npr.html>.

Putting the Non-Proliferation of Biological Weapons On The Right Track

“Our country’s lost credibility,” lamented Democratic Congressman Dennis J. Kucinich. “One of the biggest challenges to our nonproliferation goals may, in fact, be our own policies and actions. The U.S. has rejected the comprehensive test ban treaty, refused to sign the land mine treaty, withdrawn from the ABM treaty, unsigned the Kyoto Protocol, blocked the verification protocol for the biological weapons convention.”²³ The United States has also withdrawn from the Anti-Ballistic Missile Treaty, which paved the way for its new missile defense systems, and undermined efforts to curb the spread of biological weapons.

In addition to rejecting the draft monitoring protocol for the BWC in July 2001, later that year the Bush administration blocked any further negotiating efforts toward a monitoring protocol. One factor that might have affected the American position is the attitude of the U.S. pharmaceutical industry, which seemed reluctant to see the introduction of monitoring arrangements, lest they have adverse impacts on corporate interests.²⁴ Such a view is short-sighted. In fact, the pharmaceutical and biotechnology industry has much to gain in the prevention of the abuse of biological materials, equipment, and know-how, as was the case with the nuclear and chemical industries, which are monitored under the Nuclear Nonproliferation Treaty and the Chemical Weapons Convention. The draft verification protocol was designed to give teeth to the BWC by, inter alia, mandating declaration of biodefense research and permitting the regular inspection of facilities engaged in pertinent activities (e.g., high level containment laboratories, pharmaceutical production plants) and inspection of sites suspected of bioweapons activities, all of which should have gone a long way to curbing illegal activities. The U.S. government said that implementation of the proposed verification protocol might compromise U.S. national security and trade secrets and that the monitoring measures therein would not enable verification of treaty compliance.²⁵

²³ See transcript of the Hearing on Nuclear Nonproliferation by the House Committee on Government Reform: Subcommittee on National Security, Emerging Threats and International Relations, Washington, September 26, 2006. (C) 2006 CQ Transcriptions, Inc.

²⁴ Pharmaceutical Research and Manufacturers of America, “PhRMA Position on a Compliance Protocol to the Biological Weapons Convention” (Washington, D.C.: PhRMA board, May 1998); “Summary of PhRMA’s Position on a Compliance Protocol to the Biological Weapons Convention” (Washington, D.C.: PhRMA board, July 1998); “PhRMA Position on a Compliance Protocol to the Biological Weapons Convention” (Washington, D.C.: PhRMA board, 9 January 1997)

²⁵ Don Mahley, “Statement by the United States to the Ad Hoc Group of Biological Weapons Convention States Parties” (Geneva: U.S. Department of State, 25 July 2001). See also, Michael R. Gordon and Judith

Arguably, the reasoning for the United States putting the brakes on efforts to negotiate a verification protocol is so that it could retain maximum freedom of action to maintain an absolute global superiority in weaponry.

Washington's unilateral policies and actions have drawn the world's attention away from the other approach to the threat of weapons of mass destruction, an approach articulated largely through an international Commission on Weapons of Mass Destruction, known as the Blix Commission for its chairman, Hans Blix. The Blix Commission proposed roughly sixty recommendations, including short- and mid-term steps towards the eventual elimination of all weapons of mass destruction, which merit serious attention. More importantly, the Blix Commission offered a vision that should serve as spiritual guidance for the nonproliferation of WMD.²⁶ In a nutshell, this vision stresses that there is no alternative to a multilateral, cooperative, and comprehensive approach to the nonproliferation of all weapons of mass of destruction. For several reasons, this approach is particularly relevant to the international efforts to check the spread of biological weapons.

First of all, this multilateral, cooperative, and comprehensive approach is based on the understanding that nonproliferation is essentially a political matter. The international community is no more than an aggregation of sovereign states, some of which wish to resort to the acquisition of the WMD as a result of a careful calculation to ensure their national security and interests. For better or for worse, it must be acknowledged that decisions to that effect fall within the rights of sovereign states. Thus, under certain circumstances a state with considerable indigenous capabilities to develop WMD is virtually unstoppable if it is determined to do so. A state's decision to pursue such a course of action is more often than not closely related to its perception of the global strategic and political environment and to its regional security concerns in particular.

Miller, "U.S. Germ Warfare Review Faults Plan on Enforcement," *New York Times*, 20 May 2001.

²⁶ The Swedish government launched this commission in Stockholm on 16 December 2003 in response to the recent developments in international security and in particular to investigate ways of reducing the dangers from nuclear, biological, chemical, and radiological weapons. Chaired by Dr. Hans Blix, the commission comprised 14 members representing a broad and geographical and political base with a vast expert knowledge and political experience. The commissioners met periodically, discussed the issues, assessed a range of expert studies, and contributed their analyses, thoughts, and proposals. For more detail, see *Weapons of Terror: Freeing the World of Nuclear, Biological and Chemical Arms* (Stockholm: Commission on Weapons of Mass Destruction, 1 June 2006). Available at: <http://www.wmdecommission.org>.

Putting the Non-Proliferation of Biological Weapons On The Right Track

While coercive measures under Chapter VII of the United Nations (UN) Charter could be taken as a last legitimate resort, outside pressure, including sanctions or military strikes to dissuade or block the efforts of a state to obtain WMD, may serve to prolong the process of the acquisition but can never guarantee a permanent resolution of the issue.

The only sustained and effective way to stop proliferation, in the view of the author, is to create a political and security environment in which states feel no need to seek WMD as a weapon of last resort or have better alternatives to secure its interests than the acquisition of these horrible weapons. A good nonproliferation strategy, therefore, requires international cooperation in an atmosphere of mutual trust and confidence among states rather than perpetual confrontation caused by deep-rooted suspicion and hatred. Actions taken must be in complete accordance with the UN Charter and the fundamental principles of the international relations. The devastating consequences of the 2003 invasion of Iraq in the name of counterproliferation of chemical and biological weapons should have provided enough lessons to learn that a unilateral and confrontational approach is just dead wrong.

Secondly, this multilateral, cooperative, and comprehensive approach is based on the understanding that no country can single-handedly cope with the threat of WMD proliferation. In fact, faced with the common scourge of this rising danger, all states are stakeholders and must be included in the effort. To achieve the goal of curbing the proliferation of WMD, it is imperative to attend to the core interests of all the members of the international community, not just the interests of one nation or a group of nations at the expense of other states. This approach involves international collaboration on the basis of equality and mutual respect among states, a cooperative rule-based international order, applied and enforced through effective multilateral institutions, with the UN Security Council as the ultimate global authority.

Thirdly, this multilateral, cooperative, and comprehensive approach is based on the understanding that nonproliferation must ensure broad participation. National governments no doubt bear the greatest share of the responsibility. Governments make the decisions whether or not to develop biological weapons; governments have the most valuable resources, the legitimacy, and all sorts of means to affect fundamentally the progress of nonproliferation. To illustrate the point, the acquisition or use of the WMD

by terrorists or organized crime groups would virtually be inconceivable without their close association with the political, social, and economic background of the country that these groups are operating in and the “host” government’s specific policies with regard to terrorism or organized crime. Some of these policies may be deliberate, others may be inadvertent. Thus, a broad and solid basis for the success of efforts to prevent bioterrorism will be firmly established as long as all governments are able to implement in good faith the obligations of the existing international legal documents like the BWC or other nonproliferation mechanisms like UN Security Council Resolution 1540,²⁷ taking all necessary national preventive measures.

Nonproliferation efforts, however, should extend beyond sovereign states. In fact, everyone must contribute. Research communities, businesses, non-governmental organizations, the media, and the general public all share ownership of the challenges of WMD nonproliferation. This shared responsibility is particularly true in the case of biological weapons nonproliferation. Unlike nuclear or chemical weapons, which are usually manufactured with certain materials, adequate expertise, and significant infrastructure, most bacteria, viruses, and toxins that have the potential to be used as weapons exist in nature. Thus, in comparison to other weapons categories, access to biological agents is far wider and more divergent. Moreover, biological weapons can be used to injure and kill not only humans, but also animals and plants. They can also be designed, or genetically engineered, to make them resistant to known vaccines, antibiotics, and antiviral medications. According to some, the greatest potential biological threat from terrorists or criminals is the possible use of pathogens to wage economic warfare by destroying important agricultural crops and/or livestock.²⁸ Against this backdrop, the roles of the international organizations like the World Health Organization, the World Organization for Animal Health, and the UN Food and Agriculture Organization are all indispensable in the fight against the spread of biological weapons and also in the response to any possible biological attacks.

²⁷ This resolution asks states to take domestic action to prevent sub-national actors from obtaining WMD or their means of delivery. United Nations Security Council, 4956th Meeting. “Resolution 1540 (2004)” Doc. S/Res/1540. 28 April 2004.

²⁸ Zilinskas, “Assessing the Threat of Bioterrorism.”

Putting the Non-Proliferation of Biological Weapons On The Right Track

Next, this multilateral, cooperative, and comprehensive approach is also based on the understanding that the nonproliferation of biological weapons cannot be isolated from the international progress towards peace, order, and the reduction of arms. In the first place, nonproliferation is closely linked with the arms competition of major powers. As mentioned above, the efforts of a major or regional power to create new military capabilities or the maintenance of biodefense programs that appear to be crossing the line to offensive activity would inevitably generate fears of other nations, pushing them to accelerate their military programs in response. Precisely in this context, the great powers, the United States in particular, have a special responsibility to contribute to nonproliferation efforts by exercising restraint in their own arms build-ups and by playing a leading role in revitalizing true and effective arms control and disarmament.

Nonproliferation is also linked to regional stability. The chaotic and conflict-ridden Middle East provides a living example how the Israeli-Arab confrontation underpins the growing threat of proliferation of WMD in the region. Israel's acquisition of nuclear weapons actually has led many Arab countries to keep as a deliberate countermeasure chemical and biological weapons options. Thus, a regional security arrangement plus the creation of a zone free of weapons of mass destruction would go a long way towards sustained and effective efforts to curb the spread of biological weapons in the region.

Last but not least, nonproliferation has much to do with the technical and economic circumstances of developing countries. The probability that biological attacks would occur in developed countries, not developing ones, is assumed. However, the poor living conditions of the citizenry, inadequate public health capabilities, unscientific modes of development, and the lack of expertise, funds, and mechanisms to deal with the outbreak of disease in most developing countries have all combined to have a negative impact on the fight against the spread of biological weapons worldwide. First, a large group of the developing countries are poorly positioned to implement the BWC. Second, disease could spread quickly around the world if an outbreak occurs in a developing country unable to detect and quickly contain the disease. The spread of the disease will be enabled by the ever-expanding global transport of goods and livestock and the growth in international travel. Third, particularly at the early stages of a pandemic, it may be extremely difficult to tell if the source of the outbreak is a deliberately induced biological

attack or a natural eruption of a communicable disease. In short, biological weapons nonproliferation efforts will have to encompass a strong public health infrastructure; enhanced health and safety regulations, measures, and resources; controls on transfers of materials and equipment relevant to proliferation; the building of norms against biological weapons among all those engaged in the life sciences and in society as a whole; and public education about the importance of preventing biological weapons proliferation. These measures all require the concerted efforts of all the members of the international community. Most developing countries, however, have great difficulties putting such measures into practice.

Three Major Areas for Action

Under the above guidelines and also in view of the current obstacles to biological weapons nonproliferation, the Commission on Weapons of Mass Destruction offered six specific recommendations as essential to strengthening the international biological weapons nonproliferation regime.²⁹ At the risk of oversimplifying these recommendations, three major areas can be defined as focal points in the author's view.

The first area for nonproliferation activity involves promoting the effective enforcement of the relevant international agreements on biological weapons. In that respect, strengthening the role of the BWC should be the focal point of international efforts. Despite its shortcomings, the BWC remains the only treaty with a broad consensus that provides an international standard by which biological activities can be judged. As of March 2007, the Convention had 155 members, reflecting the strong political will of the overwhelming majority of states to outlaw biological weapons. Thus, the BWC will continue to constitute the primary cornerstone of whatever biological weapons nonproliferation mechanisms evolve in the future. In the meantime, it must also be acknowledged that the treaty needs to be strengthened in many ways.

First, the parties to the BWC need to promote further universal adherence to the treaty. So far, the BWC has fewer members than either the Nuclear Nonproliferation Treaty or the Chemical Weapons Convention (CWC). Sixteen states have signed but not

²⁹ *Weapons of Terror: Freeing the World of Nuclear, Biological and Chemical Arms* (Stockholm: Commission on Weapons of Mass Destruction, 1 June 2006), 117-23. Available at: <http://www.wmdecommission.org>.

Putting the Non-Proliferation of Biological Weapons On The Right Track

ratified the treaty, while more than twenty remain fully outside of the BWC regime.³⁰ Most of these non-members come from the developing countries, indicating either indifference to the BWC or reluctance to give up the biological weapons option on the part of those countries. Thus, expansion of the BWC's membership will be significant in augmenting the overall effectiveness of the international biological weapons nonproliferation regime.

Second, the treaty needs to establish arrangements to verify compliance with its prohibitions. Unlike the CWC, the BWC has no provisions for the formal monitoring of the compliance. Negotiations to close this loophole in the BWC were made and came close to actual results but, as mentioned, the Bush administration thoroughly obstructed that process. Even today, many proposals are still on the table aimed at introducing some monitoring mechanisms like strengthening the BWC's verification capabilities, either directly associated with the BWC or as part of a broader effort to build on the lessons and institutional capabilities of the UN Special Commission in Iraq or its successor, the UN Monitoring, Verification, and Inspection Commission. The key to the success of the efforts, at least to regaining some momentum in the process, evidently lies in the U.S. policy. If the United States is willing to modify its policy and commit to a multilateral approach and instruments, then progress will be possible. Of course, the ultimate success of such endeavors will also depend on whether all states at the negotiating table can come to agreement on the proposed measures.

Third, the BWC has no standing institution to monitor and oversee compliance and implementation. Just as no other monitoring institution is able to perform the functions that the Technical Secretariat of the Organization for the Prohibition of Chemical Weapons carries out for the CWC or that the International Atomic Energy Agency performs for the Nuclear Nonproliferation Treaty, the institutional deficit for the BWC needs to be rectified to enable permanent support for the BWC. Like the discussion on the verification provisions, the debate on the introduction of a standing BWC inspectorate has been going on for years, but without substantial agreement. Consensus seems in sight at least on two matters. One is the establishment of a standing secretariat to handle

³⁰ For a list of members, signatories, non-signatories, and other details about the BWC, go to: <http://www.opbw.org>.

organizational and administrative matters related to the treaty, such as Review Conferences and expert meetings.³¹ The other is the use of UN capabilities to investigate allegations of biological weapons use or suspicious disease outbreaks pending the establishment of the BWC's own inspectorate.³²

The second area of activity is to ensure better national participation in the biological weapons nonproliferation regime. As discussed above, the prospect of nonproliferation lies almost solely in the attitudes of various states, the major powers in particular. Even the future of the BWC lies in the willingness of the state members to implement all its obligations and to develop the international nonproliferation regime on the basis of the agreed rules of the game. Like any other arms control agreement, the BWC is no more than an agreement of intention among states that is codified in law. A law is only as good as its implementation and enforcement, so the positions of the member states truly matter. The success in implementing the BWC in the future will rely on a combination of the policies and capabilities of the treaty's member states. With respect to policies, the challenge is how to regulate the related behavior of the treaty's members. All states should understand that in the implementation of the BWC, there is only one standard to be followed: the BWC's provisions. Double or multiple standards should not and will not be allowed to apply. Stress again must be placed on the role by major powers, particularly the United States. America has such a great impact on nonproliferation efforts that it is particularly disappointing for many to see the United States practice double standards. "They are always suspicious of the normal scientific research and production activities under the Convention carried out by other states parties in the area of biology, while frequently lecturing others," said Chinese Ambassador Sha Zhukang.

³¹ At the 2006 Review Conference, agreement was reached to provide modest institutional support to the series of technical discussion meetings scheduled from 2007 to 2010. The small three-person Implementation Support Unit is also to facilitate the confidence-building measures of the BWC, established at the 1986 Review Conference, that ask states to report data on biological research, high containment laboratories, and the outbreak of diseases. The 1991 Review Conference also asked states to provide data on offensive and defensive bioweapons programs back to 1946, current biodefense programs, vaccine production facilities, and steps to implement the BWC. Sixth Review Conference of the States Parties to the Convention on the Prohibition of the Development, Production, and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction. *Final Document*. 8 December 2006 (BWC/CONF.VI/6). Geneva, 2006. Part III, 5. Available at: <http://www.opbw.org>.

³² In 2006, agreement was reached to update the roster of experts that might conduct investigations on behalf of the UN Secretary General as well as the inspection procedures that are to be employed in the field. UN General Assembly. "The United Nations Global Counter-Terrorism Strategy." 6 September 2006 (Doc. A/60/L.62). New York, 2006. 6-7. Available at: <http://www.un.org/terrorism/strategy>.

Putting the Non-Proliferation of Biological Weapons On The Right Track

“They remain silent about their own relevant activities and facilities. By way of analogy, this is like a man with a flashlight in hand only to cast light on others while he himself stays in the dark.”³³

From the technical point of view, this problem can be addressed in part by encouraging greater transparency in all biological activities by states parties, no matter what the purpose of the activity. In fact, it was agreed as early as in the second BWC Review Conference in 1987 that confidence-building measures, namely voluntary annual declarations on various biological weapons-related activities, could play an important role in enhancing transparency. But over the years far too few states have provided declarations on a regular basis.³⁴ This situation requires improvement. Discussions need to be held to seek more effective ways to expand the implementation of these confidence-building measures so that nations can begin to demonstrate the status of their implementation of the BWC and pave the way for the future of multilateral verification.

With regard to the capacity, the challenge is how to improve the capability of most developing countries to implement the BWC. The top priority is to help such states develop national legislation and enforcement procedures. Given the uneven level of activity and expertise among the BWC state members, the Commission on Weapons of Mass Destruction suggested that states should be in a position to help

promote a network of designated national authorities or functional focal points. Such a network could coordinate implementation support and assistance. It could promote best-practice models for national legislation and training in the range of activities needed to ensure national compliance; it could share information to assist parties to comply with all their BTWC obligations; and it could serve as a clearing-house for technical assistance and advice.³⁵

³³ Ambassador Sha Zhukang, “Remarks of the Head of Chinese Delegation to The Fifth Review Conference of the BWC.” (Geneva, 19 November 2001). Available at: <http://www.china-un.ch/eng/gjhyfy/hy2001/t85217.html>.

³⁴ For more on these confidence-building measures, briefly, see footnote 31, or, at length, Marie I Chevrier, “Doubts About Confidence: The Potential and Limits of Confidence-Building Measures for the Biological Weapons Convention,” in *Biological Weapons Proliferation: Reasons for Concern, Courses of Action*, report no. 24 (Washington, D.C.: Henry L. Stimson Center, January 1988): 53-75; Erhard Geissler, ed., *Strengthening the Biological Weapons Convention by Confidence-Building Measures*, Stockholm International Peace Research Institute Chemical and Biological Warfare Series, vol. 10 (London: Oxford Univ. Press, 1990).

³⁵ *Weapons of Terror: Freeing the World of Nuclear, Biological and Chemical Arms* (Stockholm: Commission on Weapons of Mass Destruction, 1 June 2006), 117-8. Available at: <http://www.wmdcommission.org>.

To a certain extent, the staff of the 1540 Committee is attempting to provide some assistance, and the Implementation Support Unit established at the BWC's Sixth Review Conference may also be able to provide modest help to states seeking implementation aid.³⁶

The third major area for nonproliferation activity is to manage the impact of the advancement of life sciences and the related technologies on the nonproliferation of biological weapons. This aspect of nonproliferation involves the eternal dilemma of how to deal with the development of the dual-use technologies, which can be summarized as follows:

New developments in biotechnology have always taken a central position in the debate over biosecurity issues with regard to strengthening the Biological and Toxin Weapons Convention (BWC). Biomedical research employing advances in biotechnology, including modern methods of molecular biology, genetic engineering and genomics, is explicitly pronounced in its dual-use character. The application of these modern methods in biomedical research is absolutely essential for elucidating pathogenic mechanisms that will define targets for countermeasures, allowing a more precise and directed battle to be waged against infectious diseases. At the same time, it is quite evident that the advances in biotechnology may be misused to develop and produce biological agents more dangerous than natural pathogens. Biosecurity measures designed to counteract misuse of biotechnology for biological warfare and bioterrorist activities will invariably affect biomedical research developments and must therefore be carefully drafted so as not to impede this research and the benefits that can be gained from it.³⁷

Many proposals have been advanced in the hopes of striking a balance between the maintenance of national security and facilitating scientific development. The mainstream view is that reasonable monitoring and regulation of research activities, control of related sensitive material, and enhancing of the sense of social responsibility of the scientists and

³⁶ The 1540 Committee is attempting to match states seeking assistance with national implementation measures to prevent the proliferation of weapons of mass destruction and their means of delivery to states that have indicated a willingness to provide such aid. For more, go to:

<http://disarmament2.un.org/committee1540/dir-assist.html>. On the charter for the Implementation Support Unit, see The United Nations. Sixth Review Conference of the States Parties to the Convention on the Prohibition of the Development, Production, and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction, *Final Document*, BWC/CONF.VI/6 (Geneva: 8 December 2006), Part III, 5. Available at: <http://www.opbw.org>.

³⁷ Statement on Biosecurity, International Network of Engineers and Scientists Against Proliferation, INES Working Group on Biological and Toxin Weapons Control, Bulletin 22-Role of Scientists in Disarmament, December 2003. Available at: <http://www.inesap.org/bulletin22/bul22art14.html>.

Putting the Non-Proliferation of Biological Weapons On The Right Track

researchers are not only essential but also feasible. In this regard, it is of special importance for all countries and competent institutions to provide bioweapons awareness training for biologists and biotechnologists working in the public and private sectors. After all, at the end of the day, it is these men and women who would carry out any conceivable good or bad activities. Active consideration should therefore be given to centering these educational programs on two kinds of normative approaches—a code of ethics and a code of conduct.³⁸

On the other hand, restrictions in the name of counterterrorism and the nonproliferation of biological weapons should not go beyond what is reasonably necessary. A balance should carefully be maintained in the relationship between the prevention of proliferation and international cooperation. “Both the prevention of the proliferation of biological weapons and the promotion of the peaceful use of biological technology constitute the purposes and objectives of the Convention. They should be complementary and mutually reinforcing.”³⁹ Already there are complaints that “[t]he impact of the September 11 terrorist attacks on security questions brought new barriers for scientific exchange between the First and the Third World.”⁴⁰ The Bush administration has enacted new regulations to enable U.S. immigration authorities to determine if foreign scholars or students can remain in the United States beyond their visa permits. Some have argued that these regulations have been implemented in an excessive manner, which could impede normal academic exchanges and would not be conducive to the peaceful use of biological technology, or, for that matter, exchanges in all fields of science.

³⁸ *Weapons of Terror: Freeing the World of Nuclear, Biological and Chemical Arms* (Stockholm: Commission on Weapons of Mass Destruction, 1 June 2006), 121-2. Available at: <http://www.wmdecommission.org>.

³⁹ Ambassador Sha Zhukang, “Remarks of the Head of Chinese Delegation to The Fifth Review Conference of the BWC,” 4.

⁴⁰ Fernando de Souza-Barros, “Counterterrorism and Third World Science,” International Network of Engineers and Scientists Against Proliferation, INES Working Group on Biological and Toxin Weapons Control, Bulletin 22-Role of Scientists in Disarmament, December 2003. <http://www.inesap.org/bulletin22/bul22art14.html>.

China's Position on the Nonproliferation of Biological Weapons

In the last century, China suffered greatly from the use of biological weapons on its citizenry during the Second World War as well as the Korean War. Audaciously, the Japanese Imperial Army even used Chinese civilians and the prisoners of war in live experiments to develop the biological weapons that the Japanese later used on Chinese soil in multiple attacks. This bitter and painful history has added to China's determination that biological weapons should be outlawed, never to be manufactured and used again. For its part, China has never developed or manufactured any biological weapons, nor has it ever assisted, encouraged, or induced any state, group of states or international organizations to manufacture or otherwise acquire biological weapons.

China holds that the BWC has played an irreplaceable role in the prohibition and complete destruction of biological weapons and in the prevention of their proliferation. China consistently supports the objectives and purposes of the BWC, advocating thorough prohibition and complete destruction of biological weapons. China is firmly opposed to the proliferation of biological weapons. In the current circumstances, the Chinese government contends that it is an important common historical mission to strengthen the authority, universality, and effectiveness of the BWC, to promote the biological arms control and disarmament process, and to prevent and address the threat of biological weapons through multilateral efforts.

Accordingly, China calls for all members of the BWC to do everything possible to strengthen national legislation against biological weapons and to adopt comprehensive and specific measures to provide international legal and technical assistance among states to enhance capabilities to prevent bioterrorism and to promote biosafety. China encourages all states parties to conduct confidence-building measures, which are an important dimension of the BWC's implementation. Currently, participation rates in submitting confidence-building declarations remain very low. China calls on more BWC members to provide their confidence-building data voluntarily and in a timely fashion.

The Chinese government contends that while biotechnology has been playing an increasingly important role in improving human health and the environment in recent years, the potential danger of the abuse of this technology is also on the rise. While benefiting from the achievements in the development of biotechnology, the international

Putting the Non-Proliferation of Biological Weapons On The Right Track

community should work together to meet the new common challenge of its possible misuse. International exchanges and cooperation in the peaceful uses of biotechnology should parallel efforts at biological arms control and nonproliferation and bioterrorism prevention efforts. In this regard, all BWC members should adopt measures to ensure that developing countries truly benefit from related international cooperation and realize their legitimate rights to the peaceful use of biotechnology, as enshrined in the Convention.⁴¹

In the meantime, China has taken a number of important measures with the aim of fully implementing its various obligations under the BWC. China's actions include:

- 1) promulgating a series of laws and regulations to enhance the power of the government to implement the BWC;
- 2) exercising more strict control over exports of dual-use biological agents and related equipment and technologies in line with common international practices;
- 3) collecting and submitting to the UN annually and in a timely manner confidence-building data on activities pertinent to BWC compliance;
- 4) taking active part in international cooperation in the life sciences, including extensive and useful cooperation and exchanges with many countries and with international organizations (e.g., World Health Organization) for effective monitoring and prevention of infectious human, animal, and plant diseases;
- 5) proceeding to strengthen nationwide disease surveillance capabilities and to ensure effective crisis management during disease outbreaks;
- 6) developing a code of conduct concerning all the scientific activities for individuals (e.g., scientists, technicians) engaged in the life sciences in China;⁴²

⁴¹ For the detailed discussion of China's position on the nonproliferation of biological weapons, see "China's Endeavors for Arms Control, Disarmament and Non-Proliferation," (Beijing: Information Office of the State Council, September 2005); "Statement by Ambassador Cheng Jingye," Head of the Chinese Delegation, Sixth Review Conference of the BWC (Geneva, 20 November 2006). Available at: <http://www.fmprc.gov.cn/eng/wjz/zjg/jks/jkxw/t281262.html>.

⁴² The Chinese Academy of Sciences passed guidelines in November 2001 about the ethical conduct of science and peace. In addition, China Association of Science and Technology established a Commission on Rights of Scientists and Engineers to attend with the behavior of scientists. A Committee on Ethics was also created to strengthen scientific codes and to investigate cases where scientists have violated the ethics code. "China's Views and Practices in Adopting Code of Conduct of Scientists," Meeting of Experts, BWC/MSP/2005/MX/WP.20. (Geneva: People's Republic of China, 14 June 2005), 2. Available at: <http://www.opbw.org>.

7) making great efforts to strengthen education to enhance the awareness of Chinese citizens of the importance of combating the spread of biological weapons and their significance in contributing to the success of nonproliferation; and,

8) promoting biological security, particularly strengthening the effective protection and management of pathogenic human and animal bacteria, viruses, and toxins.⁴³

Due to these activities, it can be argued that China is a proactive and strong partner in international efforts to prevent the proliferation of biological weapons.

Of course, like other developing countries, China is faced with new challenges. Some Western countries have expressed suspicion that China may be developing a biological weapons capability. Such assertions are made in official government documents and elsewhere.⁴⁴ However, such groundless, irresponsible speculation has at times made China indignant. Nonetheless, these accusations raise a legitimate issue for China, and indeed, for all BWC members, as to what should be done to promote further trust and confidence among nations to facilitate the true and full implementation of the BWC. Given the size of China's territory and population and the uneven development of the country, the Chinese government also perhaps needs to make greater efforts to prepare domestically to deal with the risks of biological weapons proliferation. These efforts should particularly include, for example, enhancing the awareness of the general public about the possible consequences of a biological attack or a disease disaster, further improvement of China's capabilities in disease surveillance and crisis management, and effective implementation of all the pertinent laws and regulations. China has already made considerable progress in this regard but a lot of additional improvements need to be made.

⁴³ For more description of China's efforts to implement the BWC, see "National Report on the Implementation of the BWC," Chinese Government White Paper, Sixth Review Conference on the BWC (Geneva, 9 October 2006). Available at: <http://www.fmprc.gov.cn/chn/wjb/zzjg/jksfyywj/t295044.html>.

⁴⁴ See, for example, page 14, *Proliferation: Threat and Response 2001* (Washington, D.C.: U.S. Department of Defense, 2001). Available at: <http://www.defenselink.mil/pubs/ptr20010110.pdf> See also, "Chemical and Biological Weapons: Possession and Programs Past and Present," CBW Resource Homepage, Center for Nonproliferation Studies, 4 September 2002. Available at: <http://cns.miis.edu/research/cbw/possess.html>.

Conclusion

Nonproliferation of biological weapons may be a dream that mankind will never be able to completely fulfill, as science sees no limit in its advancement. From a technical perspective, when governments or sub-national actors find ways to overcome the old challenges to the acquisition of biological weapons, fresh problems will invariably crop up as new discoveries are made. Thus, the progress of science and the spread of the pharmaceutical and biotechnology industry will inevitably generate new uncertainties in the fight against the spread of biological weapons. The march of science and the growth of industry need not pose insurmountable impediments to nonproliferation efforts. Provided there is adequate political trust between states, the proliferation of these deadly weapons can be controlled or managed. In a sense, therefore, biological weapons nonproliferation is essentially a question of whether human beings have the will to control technology or will allow technology to destroy humans. Confronted with such a life-and-death challenge, one must firmly believe that mankind will have enough wisdom to understand fully the common threat and its implications, and to take concerted efforts to curb it before it is too late. The international community cannot afford to fail to do so.

Observations on China's New Biosafety and Biosecurity Framework

Julie E. Fischer, Ph.D.¹

The challenge of creating a regulatory framework in the arena of biosafety and biosecurity—a challenge to which the Chinese have set themselves as several of these essays describe—is to strike a balance between preventing the accidental or deliberate release of dangerous or even deadly biological agents and unduly infringing upon the liberties of researchers who are conducting perfectly legitimate and necessary public health research. Part of the difficulty in creating such a framework may stem from confusion surrounding the concepts of biosafety and biosecurity. Biosafety can simply be defined as the collection of procedures and technologies developed to protect researchers from infecting or affecting themselves with the diseases they are studying, or from accidentally releasing them into the broader population or the environment.

Historically, in the United States, biosafety has been a largely voluntary regulatory framework based on risk assessment recommendations. The U.S. Centers for Disease Control and Prevention, the CDC, regularly updates the manual on which these regulations are based. The World Health Organization also routinely releases updated recommendations on biological safety. Despite heavy reliance on voluntary compliance, this framework has, so far, been enormously effective in the United States. Practically speaking, scientists do not want to become ill or die from their work, and it would damage any institution's public trust and reputation to release a pathogen into the environment. So, for the most part, U.S. laboratories have welcomed and implemented the proposed guidance points for self-regulation.

In contrast, biosecurity has seen its most dramatic regulatory progress in the past ten years, aside from the lack of international action under the umbrella of Biological and Toxin Weapons Convention intercessional discussions. Particular emphasis has been placed on biosecurity following the 2001 anthrax assaults on the United States. Laboratory biosecurity measures aim to prevent the theft or diversion of pathogens for malicious use. The majority of the United States' regulatory efforts have focused on the “guns, gates, and guards” approach, essentially locking up the pathogens and limiting

¹ Dr. Julie Fischer is a Senior Associate at the Henry L. Stimson Center in Washington, D.C.

Observations on China's New Biosafety and Biosecurity Framework

access to them, and developing criminal penalties for those who gain or provide unauthorized access or who otherwise violate biosecurity regulations.

In the United States, there is some overlap between these two fields because both are based on risk assessment of particular pathogens. Biosafety provides published guidance to determine how inherently risky it is (to the researcher as well as others in and beyond the laboratory) to study or conduct certain procedures with an organism, as well as what practices should be followed to prevent accidental exposure to the organism. Biosecurity is intended to prevent the deliberate theft, diversion, or intentional release of certain organisms deemed to be highly at risk for potential misuse as biological weapons. All scientists are concerned with biosafety because of their interest in protecting themselves, their colleagues, and their communities; the subset of these scientists who handle pathogens classified as “select agents”—a list of specific organisms judged as posing a high risk to the public if intentionally released—are concerned with biosecurity. Some overlap between the two areas therefore exists in practice, but the regulatory framework for each evolved along different assumptions and norms.

The Chinese framework described in these essays combines the concepts of biosafety and biosecurity much more thoroughly than in the United States. According to the essay authors, the Chinese regulations are drawn from the “best practices” of international biosafety and biosecurity regulations. While there is great conflation of the terms, infractions of the regulations of either type carry approximately the same penalties.

Discussions of biosafety and biosecurity are equally relevant in the context of these essays. Quite a few organisms, even if they are not deliberately weaponized, could cause considerable harm if released into the general population. The field of biosafety is currently undergoing major changes: as reported by *Science* magazine in 2006, total global expenditures on health research and development rose from \$30 billion in 1986 to almost \$106 billion in 2001, demonstrating the expanding scope of this field. The total expenditure on health research is now even higher than in 2001 because of mega-philanthropy projects (e.g., Gates Foundation) as well as investment by individual nations. With the expansion of public health research, governments and other organizations are increasingly recognizing the importance of biosafety. Another factor driving increasing awareness of the significance of biosafety is the number of emerging

infectious diseases in the world. Outbreaks of these diseases, which may have recently appeared for the first time in human populations or may have reappeared in a form that is difficult to fight with available treatments and public health tools, have proliferated in Asia, particularly Southeast Asia. The countries in that region have a definite stake in increasing the amount of research they do on these emerging or re-emerging diseases, many of which are novel and have no medical remedy.

The outbreak of SARS provides a compelling example of the problem of emerging infectious diseases. Between the first description of the disease in November 2002 and July 2003, there were approximately 8,000 probable cases and just fewer than 800 deaths worldwide. The epidemic cost Asia approximately \$30 billion in terms of losses in tourism and business and in other direct costs. However, from August 2003 to November 2004—when the natural course of infection appeared to have burned itself out—there were seventeen confirmed cases of SARS. Of these cases, four appeared to be community-acquired from Guangdong province; a direct source for these infections was never found, but it appeared to be naturally occurring and probably stemmed from exposures at an animal market. Six other cases were laboratory-acquired, including one in Singapore, one in Taiwan, and four in China. One of the laboratory-acquired infections led to seven additional infections and one death. Evidently, in the second year of SARS, the vast majority of SARS cases came from laboratories that were studying the disease. In none of these cases has it been assumed that there was a profound failure of technology or equipment. The problem was that the people who were working with those organisms lacked the training, the resources, or the energy to follow through with good biosafety practices and consequently put themselves and others at risk.

The case of H5N1 avian influenza is equally relevant. The World Health Organization and the Food and Agricultural Organization of the United Nations have tracked outbreaks of H5N1 in poultry and wild birds from 2003 to mid-2007.² Not surprisingly, the countries most affected are the ones most interested in conducting research on the disease, which is now endemic throughout Southeast and East Asia. Currently, H5N1 influenza does not pass easily from person to person, but if a strain

² For more information on the World Health Organization's response to avian influenza, including maps showing outbreaks geographically, see: www.who.int/csr/disease/avian_influenza/en/.

Observations on China's New Biosafety and Biosecurity Framework

appears that is more communicable, the same countries will be collecting specimens and conducting research on them. Biosafety failures involving a highly infectious strain of H5N1 avian influenza similar to those that occurred with SARS would be far more disastrous than the SARS “laboratory escapes.” The need for improved training and resources in these countries’ biosafety regulations is obvious.

Oversight and regulation of any activity is composed of several layers of regulatory frameworks and implementation. As can be seen with regard to oversight and regulation of biosafety and biosecurity in the United States and elsewhere, the devil is in the details of implementation. One essayist in this collection, Dr. Hu Longfei, makes the observation that by drawing on the best practices of international biosafety and biosecurity recommendations from a lot of countries, China has created “an almost ideal regulatory framework.” While it is true that the framework that Dr. Hu and his colleagues describe is very comprehensive, the laws and regulations it comprises must be implemented thoroughly at the national, provincial, and local levels of government. The framework addresses minutely what the regulatory controls and technological demands are and contains penalties for noncompliance. The implementation of such a complex system at multiple levels is a considerable undertaking. On the plus side, China’s new regulatory framework also inherently conveys certain norms—the cultural implication that both biosafety and biosecurity are important and worth investment.

What the essays on this framework do not address is what happens at the next level below that of local government. Most of the responsibilities for implementation of these regulations lie with the individual institutions or laboratories, and this creates two problems. The first, as Wang Qian observes in her essay, is that the regulatory framework does not apply to every laboratory. In fact, China’s regulations appear to apply to a fairly narrow number of laboratories with a specific definition and government funding. As described here, they apparently do not apply to academic laboratories, to hospitals, and to some commercial facilities; the regulatory framework is therefore limited in its requirements of compliance. The second problem is that it is unclear who will provide the resources and training to implement the regulations and to oversee the laboratories within these institutions. Resource shortfalls are a particular difficulty at the

institutional level, because the responsibility falls on the lead researcher in each laboratory to directly oversee and train his or her staff.

This issue exposes a more general problem: a shortage of experts, which is an observation made by several of the essayists. Worldwide, there is a dearth of biosafety professionals sufficient to meet the growing demand. In the United States, there are not enough trained biosafety professionals to contribute to widespread training in the expanded U.S. biosecurity regulatory requirements, and there are certainly not enough in China to meet the new demands imposed by an enormously complex, brand-new regulatory framework. The number of people who could possibly understand these regulations and implement them at a policy level is probably quite small, but the number of people technically trained to implement them is even smaller. Additionally, most of the global experts in handling highly infectious diseases are in the United States and Europe; they may be barred from easily inviting their Chinese counterparts to their laboratories to observe their practices with specific pathogens and how their regulations are implemented because of the select agent rules and other regulatory obstacles. China must therefore import experts from other countries to train scientists locally. So, the shortage of biosafety professionals and the need to import them will complicate China's efforts to implement its new regulatory framework and improve it subsequently.

Currently, China's regulatory framework is just that—a very well-described, detailed *framework*. Because it applies to biosafety and biosecurity equally, it may well be very powerful, but the proof of its success will be in its implementation at the local level. The potential difficulty in local execution of a centrally designed policy is suggested by a January 2000 National Intelligence Council study that classified China among “countries with less developed health care infrastructures,” noted for concentration of epidemiology and health care capacities in the capitals and uneven facilities elsewhere.³ The SARS crisis emphasized the worrisome public health consequences of China's troubled health care system reforms, and subsequent assessments of health indicators suggest that the Chinese Ministry of Health has experienced considerable obstacles in enforcing government policy decisions at the local

³ Dr. David F. Gordon, “The Global Infectious Disease Threat and Its Implications for the United States,” NIE 99-17D, National Intelligence Council, Washington, D.C., January 2000, http://fas.org/irp/nic/infectious_diseases_paper.html.

Observations on China's New Biosafety and Biosecurity Framework

level following the massive decentralization of the Chinese health care system, particularly given the funding environment for local hospitals. One observer of China's efforts to implement regulations throughout its health care infrastructure has dubbed this situation a problem of "creative local implementation," implying a lack of implementation at all.

The implementation of the new biosafety and biosecurity regulatory framework at the local level may well pose a similar problem for China, particularly if the framework is applied, as it should be, to the full range of laboratories that work with highly contagious infectious diseases. Without a well-designed plan and resources to ensure effective implementation of regulations and oversight of practices at all levels in China, the advances in biosecurity and biosafety thinking that are described in these essays will, quite frankly, serve no purpose.

Reading the Nonproliferation Tea Leaves from *Beijing on Biohazards* Essays

Bates Gill, Ph.D.¹

Even for those who closely follow official statements and other assorted writings from Beijing, gaining knowledge and insight into Chinese arms control policies and practices has historically been difficult, especially with regard to biological weapons issues. Determining China's views and priorities on these matters has also been a challenge. For this reason, this collection of essays is particularly welcome, given that it provides a new perspective on China's arms control policies. More importantly, these essays also provide evidence of a largely favorable broader trend. Ten or fifteen years ago, such a study by Chinese authors would have been impossible given China's categorization of these topics as sensitive and the lack of confidence from the Chinese about what motivations might lie behind U.S. efforts to explore these issues.

So, to begin with, these essays should be recognized not only for the substance they offer, but also for being one more important indicator of China's increasing willingness to be more open on current and emerging issues and to work with the United States and the international community on issues that only a few years ago they considered extremely sensitive and entirely off-limits for discussion with foreigners. This set of essays is remarkable, both for the technical substance they contain and the interesting information they provide, and also as a tangible marker for all who hope to encourage China to take a more open and responsible approach to the issues of arms control.

The question, then, is what is to be done with the interesting and unique foundation provided by these essays? Where are the potential areas for improvement? What should the next steps be? The Chinese approach to arms control has given rise to some persistent difficulties that do not seem to be lessening, even with this newfound openness. One issue that does not seem to change in the way that China views questions of nonproliferation and arms control is their insistence on a predominantly "demand-side" approach to the challenges of proliferation, perhaps best typified in Liu Jianfei's

¹ Bates Gill is currently the Freeman Chair in China Studies at the Center for Strategic and International Studies in Washington, D.C.

Reading the Nonproliferation Tea Leaves

essay on the threat of biological weapons proliferation. This demand-side strategy is typified by a belief that the most sensible approach to nonproliferation is to deal first and foremost with the threat proliferators believe they are facing, thereby removing the reason behind their demand for access to and eventual use of biological weapons. Liu's emphasis on fixing what ails the international system exemplifies this approach and is conveyed by his flat statement: "The way to resolve the problem of biological weapons proliferation, whether at the state or terrorist level, is to get to the root of the problem: namely, to improve the international security environment."

Of course, Liu's statement fits into a longstanding debate in the nonproliferation community, but what is disturbing about the Chinese emphasis on it is that it too often removes the onus from potential proliferators and does not allow for enough concentration on the supply side of the equation. Supply side nonproliferation strategies focus on identifying and protecting dual-use technologies of significant proliferation risk and preventing them from getting into the wrong hands. The demand-side approach is also somewhat old-fashioned in that it is most pertinent to the way states might seek to acquire and potentially use biological weapons or other weapons of mass destruction, but has less relevance in the context of non-state actors, particularly those driven by ideologies or theologies. In short, a traditional demand-side approach is seriously constrained in addressing proliferation to non-state actors.

Secondly, the essays by Dr. Yang Ruifu and General Pan Zhenqiang, both of whom have military backgrounds, do not pull their punches in asserting that the United States is to blame for the problems of nonproliferation efforts. General Pan goes furthest along this track, saying that the American over-emphasis on bioterrorism in recent years actually obscures and makes even more difficult the possibilities of gaining traction internationally in efforts to strengthen the biological weapons nonproliferation regime. That argument has merits and demerits, but the idea that the blame belongs to the sole superpower is a consistent theme from the Chinese, perhaps because it absolves them of the responsibility to take a more proactive stance.

More generally, there is little comment in these essays on China's role and its interest in being a more active contributor in the global fight against the potential proliferation of biological weapons. For example, there is little real discussion in the

essays of whether China's burgeoning biotechnology and pharmaceutical industry is something that might pose a problem to the bioweapons nonproliferation regime. The fact that the new regulatory framework described in these essays apparently does not apply to all pertinent commercial facilities, as Wang Qian notes, raises all sorts of interesting questions about whether this new industry's rapid growth in a "cowboy capitalist" society without any regulatory checks on its safety poses any concern. In all fairness, Western nations are also struggling with how to govern some aspects of life sciences research and this industry, so these are sensitive and difficult issues. These very issues, therefore, are areas of research that should be probed further with Chinese technical experts and policy makers.

In addition, there is also little sense in these papers of how important bioterrorism is to China specifically, rather than to the United States, the West, or the international community. None of the authors discuss why China, either domestically or in its role as a major global power concerned with nonproliferation, sees bioterrorism and proliferation of biological weapons as threats to China's domestic interests. Nary is there a mention of the problems that deliberate release of disease could cause at the upcoming 2008 Beijing Olympics or in other Chinese cities such as Shanghai, Shenzhen, Tianjin, or Shenyang. The Chinese have multiple security challenges to deal with; clarification on how big a threat bioterrorism really poses to China might provide a better sense of how committed the Chinese want to be in combating this problem. Also lacking in this set of essays is any discussion of the extent to which China is becoming a threat to the international community, not because it is developing biological weapons, but because it is becoming a potential source for the spread of technologies that could be used to contribute to a biological weapons program somewhere else. Wang notes that China's export control list is modeled on the control lists of the Australia Group, but this essay is silent on the Chinese government's track record and organization to enforce these controls. Given the expansion of this industry, as noted, it is reasonable to ask how thoroughly and vigilantly China's export controls are being implemented.

Finally, aside from Wang's comments, the other essays barely mention the problems of implementation of the new biosafety and biosecurity regulatory framework. China has ample regulatory rules and laws, but China also has a consistent problem of

implementation. Part of the problem may be that the Chinese government is taking a normative “top-down” approach to implementation. What is needed to implement a new regulatory system successfully and effectively are resources and training and an encouragement of normative acceptance of the framework at the grassroots level, in this case among the scientists and managers of the facilities working with these pathogens. In addition to Wang’s points about the need for better bureaucratic organization at the top and the need to implement the new standards at all pertinent facilities in China, the essays by Drs. Li Jinsong and Hu Longfei briefly recognize that the importance of training and the need to grow a cadre of biosafety and biosecurity specialists in China at the institutional level. However, all of the authors appear to look outside of China for answers, namely toward collaboration with other technical specialists and to the standards set in other countries as models that China can continue to follow.

China is a very large, diverse country, so implementation at the local levels becomes all the more problematic because of the discrepancies in technical skill, financial revenues, and competing priorities, among other issues. The laboratory-acquired infections with SARS originated in Beijing’s premiere laboratory for the handling of infectious pathogens, the Institute of Viral Disease Control and Prevention of the Chinese Center for Disease Control and Prevention. Since this institute is China’s top-flight, most advanced, most specialized laboratory, it is reasonable to ask how successful the Chinese might be in implementing regulations in other, less-developed areas, particularly given the country’s uneven distribution of resources.

Laboratory outbreaks are clearly not just a problem in China. In recent years the principal U.S. and Russian defense laboratories have had problems with laboratory acquired infectious, specifically of *Burkholderia mallei*, the causative agent of glanders, at the US Army Medical Research Institute of Infectious Diseases in May 2000 and of Ebola at the Kolstovo Center for Virology and Biotechnology in May 2004. In fact, the frequency of laboratory-acquired diseases is a matter of concern to workers, government authorities, and the public worldwide, so this is a subject matter ripe for international discussion and cooperation. All nations and facilities working with infectious diseases have a responsibility to ensure that such facilities have proper safeguards in place. Hu, Li, and Wang are all looking for international collaboration on these matters, and that is

welcome and necessary, but a considerable Chinese investment in resources and training will also be needed to ensure the successful implementation of these new regulations.

China may be making progress in this direction: General Pan states that the Chinese are taking a number of interesting steps to spread out resources and implementation capacities, which is very encouraging. The code of conduct he mentions will also be a very important step in moving forward with raising awareness and education of China's most senior scientists, but as Wang indicates, this educational process should extend through codes that apply to all Chinese specialists working in the life sciences. General Pan does observe, however, that the Chinese are not prepared to deal with the threat of biological weapons proliferation given the discrepancies across the country in terms of talent, knowledge, preparation, and resources. This observation is a powerful admission of a gap in the system of disease surveillance, disaster preparedness, and biodefense, an admission that would have been impossible for a Chinese statesman to make in an international publication ten years ago. Pan's statement simultaneously reveals the progress China has made in its efforts toward a nonproliferation regime and remarks on the areas in which they can continue to improve.

Beijing on Biohazards is a unique collection of essays, and like all good sets of papers, it raises more questions than it answers. This collection is a starting point, hopefully one that can continue to be built on through the relationship developed with these writers and broadened to include more Chinese technical and policy specialists. Those involved in biological weapons nonproliferation and disease outbreak prevention outside of China can make discoveries through these essays to facilitate that process.

Appendix

China's Current Laws and Regulations Related to Biosafety, Biosecurity, Oversight of Activities Involving Genetic Engineering, Biosafety Equipment and Facilities, Management of Medical Wastes, and Storage, Packing, and Shipment of Pathogens

1. China. Standing Committee of the National People's Congress. "Frontier Health and Quarantine Law of the People's Republic of China." (issued 2 December 1986, implemented 1 May 1987).
2. China. Ministry of Health. "Rules for the Implementation of Frontier Health and Quarantine Law of the People's Republic of China." (issued and implemented 6 March 1989).
3. China. Standing Committee of the National People's Congress. "Law of the People's Republic of China on the Entry and Exit Animal and Plant Quarantine." (issued 30 October 1991, implemented 1 April 1992).
4. China. State Council. "Regulations for the Implementation of the Law of the People's Republic of China on the Entry and Exit Animal and Plant Quarantine." (issued 2 December 1996, implemented on 1 January 1997).
5. China. Standing Committee of the National People's Congress. "Law of the PRC on the Prevention and Treatment of Infectious Diseases." (issued 21 February 1989, revised 28 August 2004).
6. China. Ministry of Health. "Methods of the Implementation of Law of the PRC on the Prevention and Treatment of Infectious Diseases." (issued 4 October 1991, implemented 6 December 1991).
7. China. Standing Committee of the National People's Congress. "Animal Epidemic Prevention Law of the People's Republic of China." Congress (issued 3 July 1997, implemented 1 January 1998).
8. China. Standing Committee of the National People's Congress. "Environmental Protection Law of the People's Republic of China." (issued and implemented 26 December 1989).
9. China. Standing Committee of the National People's Congress. "Law of the People's Republic of China on Appraising of Environment Impacts." (issued 28 October 2002, implemented 1 September 2003).
10. China. State Council. "Regulations on Preparedness for and Response to Emergent Public Health Hazards." (issued and implemented 9 May 2003).
11. China. State Council. "Regulations of the People's Republic of China on Certification and Accreditation." (issued 3 September 2003, implemented 1 November 2003).

12. China. State Council. "Regulation on Handling Major Animal Epidemic Emergencies." (issued 18 November 2005).
13. China. State Council. "Regulation on the Bio-safety Management of Pathogenic Microbe Laboratories." (issued and implemented 12 November 2004).
14. China. Ministry of Agriculture. "Measures for the Examination and Approval of the Bio-Safety Administration of Highly Pathogenic Animal Pathogenic Microbe Laboratories." (issued and implemented 20 May 2005).
15. China. Ministry of Health. "Measures for the Examination and Approval of the Bio-Safety Administration of Highly Pathogenic Human Pathogenic Microbe Laboratories and Experimental Activity." (issued and implemented 15 August 2006).
16. China. Chinese State Environmental Protection Administration. "Methods for the Bio-safety Environmental Management of Pathogenic Microbe Laboratories." (issued 8 March 2006, implemented 1 May 2006).
17. China. Ministry of Science and Technology, Ministry of Health, the State Food and Drug Administration, and Chinese State Environmental Protection Administration. "Methods for Provisional Management of SARS-associated Corona virus Laboratories." (issued and implemented 6 May 2003).
18. China. State Science and Technology Commission. "Regulations for the Administration of Affairs Concerning Experimental Animals." (issued and implemented 14 November 1988).
19. China. Ministry of Health. "General Biosafety Standard for Microbiological and Biomedical laboratories." Standard WS233-2002 (issued 3 December 2002, implemented 1 August 2003).
20. China. Ministry of Agriculture. "Veterinary Laboratory Biosafety Guidelines." (issued and implemented 15 October 2003).
21. China. Chinese General Administration of Quality Supervision, Inspection, and Quarantine and Chinese Standardization Administration. "Laboratories—General Requirements for Biosafety" Regulation GB 19489-2004 (issued 5 April 2004, implemented 1 October 2004).
22. China. Ministry of Construction. "Architectural and Technical Code for Biosafety Laboratories." Regulation GB 50346-2004 (issued 3 August 2004, implemented 1 September 2004).
23. China. Chinese General Administration of Quality Supervision, Inspection, and Quarantine. "Laboratory Animal Requirements of Environment and Housing

- Facilities.” Regulation GB14925-2001 (issued 29 August 2001, implemented 1 May 1 2002).
24. China. Ministry of Agriculture. “List of Animal Pathogenic Microorganisms.” (issued and implemented 24 May 2005).
 25. China. Ministry of Agriculture. “Directory of Pathogenic Microorganisms Transmissible Between Humans.” (issued and implemented 11 January 2006).
 26. China. Ministry of Agriculture. “Packing Criterion on Transportation of Highly Pathogenic Animal Microbial Strains or Samples.” (issued and implemented 24 May 2005).
 27. China. Ministry of Health. “Regulations on Transportation Management of Highly pathogenic Microbial Strains or Samples Infecting the Human.” (issued 28 December 2005, implemented 1 February 2006).
 28. China. State Science and Technology Commission. “Rules on Management of the Preservation of Microbial Strains in China.” (issued and implemented 8 August 1986).
 29. China. Ministry of Health. “Methods on Management of Preservation of Medical-Microbiology Strains in China.” (issued and implemented 23 March 1985).
 30. China. Ministry of Agriculture. “Methods on Trial Management of Preservation of Veterinary-Microbiology Strains.” (issued 25 November 1980, revised 1 July 2004).
 31. China. Chinese Ministry of Science and Technology. “Methods on Provisional Management of Preservation, Usage and Infectious Animal Models of SARS-Associated Corona virus.” (issued and implemented 6 May 2003).
 32. China. Standing Committee of the National People's Congress. “Law of the People’s Republic of China on the Prevention and Control of Environmental Pollution by Solid Wastes.” (issued 29 December 2004, implemented 1 April 2005).
 33. China. State Council. “Regulations on the Administration of Medical Wastes.” (issued and implemented 16 June 2003).
 34. China. Ministry of Health. “Measures for Medical Wastes Management of Medical and Health Institutions.” (issued and implemented 15 October 2003).
 35. China. Ministry of Health and Chinese State Environmental Protection Administration. “Administrative Punishment Measures for Medical Waste Management.” (issued 27 May 2004, implemented 1 June 2004).

36. China. Ministry of Health. "List of Medical Wastes." (issued and implemented 10 October 2003).
37. China. Chinese State Environmental Protection Administration. "Management Method for the Hazardous Waste Transfer and Combined Documents." (issued 22 June 1999, implemented 1 October 1999).
38. China. Ministry of Health. "Technical Standard for Disinfection." (issued 15 November 2002, implemented 1 April 2003).
39. China. Chinese State Environmental Protection. "Technical Guide for Waste Water Treatment at Hospitals." (issued and implemented 10 December 2003).
40. China. China Association for Engineering Construction Standardization. "Code for Design of Hospital Waste Water Treatment." Sector Standard CECS07: 2004 (implemented 1 May 2004).
41. China. Chinese General Administration of Quality Supervision, Inspection, and Quarantine. "Requirements for Medical Organization Sewage Discharge." Regulation GB18466-2001 (issued 22 October 2001, implemented 1 March 2002).
42. China. Chinese State Environmental Protection Administration. "Technical Specification of Dealing with Medical Wastes." (issued 26 December 2003).
43. China. Chinese State Environmental Protection Administration. "Regulation of Standard and Warning for Special-Purpose Packing or Container of Medical Wastes." (issued and implemented 20 November 2003).
44. China. Ministry of Construction. "Biological Safety Cabinets." Sector Standard JG170 2005 (issued 25 March 2005, implemented 1 June 2005).
45. China. "Biological Safety Cabinets." Sector Standard YY0569-2005 (issued 18 July 2005, implemented 1 June 2006).
46. China. State Science and Technology Commission. "Safety Administration Regulation on Genetic Engineering." (issued and implemented 24 December 1993).
47. China. Ministry of Agriculture. "Safety Administration Implementation Regulation on Agricultural Biological Genetic Engineering." (issued 10 June 1996, implemented 10 July 1996).
48. China. State Council. "Safety Administration Regulations on Agricultural GMO." (issued and implemented 23 May 2001).
49. China. Ministry of Health. "Administration Measures for Genetically Modified Food Hygiene." (issued 8 April 2002, implemented 1 July 2002).

50. China. Ministry of Agriculture. “Administrative Rules for Safety Assessment of Agricultural GMO.” (issued 5 January 2002, implemented 20 March 2002).
51. China. Ministry of Agriculture. “Measures for the Administration of the Safe Import of Agricultural GMO.” (issued 5 January 2002, implemented 20 March 2002).
52. China. Ministry of Agriculture. “Measures for the Administration of Identification of Agricultural GMO.” (issued 5 January 2002, implemented 20 March 2002).
53. China. Ministry of Agriculture. “Measures for the Examination and Approval of Processing of Agricultural GMO.” (issued 27 January 2006, implemented 1 July 2006).