Efforts to Strengthen Biosafety and Biosecurity in China

Wang Qian[1]

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 biosecugrity 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 compass; separate words in Chinese for biosafety and biosecurity now exist.[2] An elaboration of the

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[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.

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.

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.

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[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.

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[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).

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).

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

[21]One 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.

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.

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:

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[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).

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.

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.

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[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.

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.