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STIMSON CENTER

Biological Weapons Proliferation: Reasons for Concern, Courses of Action

Graham S. Pearson
Gillian R. Woollett
Marie I. Chevrier
Jonathan B. Tucker
Amy E. Smithson

January 1998

Report No. 18

The Henry L. Stimson Center
11 Dupont Circle, Ninth Floor, NW
Washington, DC 20036
tel 202-223-5956
fax 202-238-9604
e-mail info@stimson.org
http://www.stimson.org

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Preface and Acknowledgments

The proliferation and use of biological warfare agents is now widely recognized to be one of the most serious threats to national and regional security. Yet multilateral efforts to deal with this problem proceed at a snail's pace. This publication highlights ways to strengthen international norms against the development, production, possession, and use of biological weapons. By publishing thoughtful ideas by experts in this field, the Henry L. Stimson Center hopes to lend greater urgency to negotiating efforts in Geneva to adopt strengthening measures for the Biological Weapons Convention (BWC), an accord without verification arrangements of any kind. When the Nixon Administration agreed to conclude the BWC in 1972, verification did not seem very important. The passage of time has led most observers to a different conclusion. The Stimson Center hopes the Clinton Administration will play a more constructive role in this essential work. At present, most of the heavy lifting in Geneva is being undertaken by Great Britain, South Africa, and handful of other countries, while Washington strains at the mere task of adopting a formal negotiating position.

As noted in the essays that follow, there are significant difficulties associated with strengthening the BWC. Even the voluntary transparency measures now in place for this accord are poorly implemented. As the essays in this report acknowledge, even mandatory transparency may be insufficient to deter and detect cheating. Moreover, many representatives of the bio-technology and pharmaceutical industries are very wary of strengthening measures of any kind, unlike their counterparts in chemical industry who worked diligently with negotiators to craft intrusive verification methods for the Chemical Weapons Convention (CWC). In other words, there are many reasons for protracted delays in negotiating strengthening measures for the BWC—until a terrible incident of biological weapons use calls attention to the inaction of negotiators, the inattention of governments, and the reluctance of industry leaders to deal more constructively with this clear and present danger.

Admittedly, a strengthened BWC is only a partial solution to the problems posed by the threat of biological weapons use. Multiple solutions are clearly needed for a problem this complex and difficult. Diplomatic initiatives to deal with suspected biological weapons production or use will be weakened unless conventional military options are available and unless troops are properly trained, equipped, and led. Conversely, military options are likely to be undermined in the absence of diplomatic initiatives.

The argument is sometimes made that strengthening measures for the BWC would compound an already serious problem by lulling the general public into a false sense of security. Yet those who advocate most strongly strengthening measures do so out of a sense of alarm and deep understanding over the magnitude of the problem. If critics and advocates of strengthening measures are united in their belief that more must be done, who, then, would lull the public into a false sense of security? A full court press is needed to deal with the problems posed by biological weapons. Progress on

many different fronts is urgently needed, including the adaptation of meaningful strengthening measures for the BWC, many of which are described in the pages that follow.

This publication has been conceived and edited by Dr. Amy E. Smithson, director of the Stimson Center's Chemical and Biological Weapons Nonproliferation Project. Chemical and biological weapons have proliferated more widely than nuclear weapons. The international norms against the acquisition and use of chemical and biological weapons are weaker than those against nuclear weapons. In conjunction with the 1993 signing ceremony for the CWC, the Stimson Center decided to monitor domestic and international preparations to implement the CWC and to strengthen the BWC. We intend to offer constructive solutions, call attention to steps that would weaken proper implementation of these accords, and serve as an information clearinghouse for those interested in chemical and biological weapons proliferation.

The Stimson Center is grateful for the support of the Carnegie Corporation of New York, which has funded this work since its inception. In particular, we wish to thank David Speedie and Deana Arsenian for their longstanding support, without which the Center's work in this area would not be possible. In 1997 and 1998, the Stimson Center welcomed additional grant support from the Ploughshares Fund, the S.H. Cowell Foundation, the Compton Foundation, and from Margaret Spanel. We are grateful to Ms. Spanel, and to Sally Lilienthal and Naila Bolus at Ploughshares, Jess Erikson and Lorna Pimentel at the S.H. Cowell Foundation, and Edith Eddy at the Compton Foundation for allowing the Stimson Center to expand our work in this field.

The Chemical and Biological Weapons Nonproliferation Project has released several reports on a wide range of topics associated with the control and elimination of these weapons of mass destruction. In addition, the project issues a periodic newsletter and maintains a site on the World Wide Web, which can be accessed at: www.stimson.org/cwc.

Michael Krepon
President

About the Authors

Marie I. Chevrier is the Associate Director of the Harvard-Sussex Program on Chemical and Biological Warfare Armament and Arms Limitation and a Senior Research Fellow at the Center for Science and International Affairs at the John F. Kennedy School of Government, Harvard University. She is on leave from the faculty of the University of Texas at Dallas, where she is an Associate Professor of Political Economy. Her research has been widely published in journals and newsletters. She contributed to *Arms Control Toward the 21st Century* (Lynn Reinner Press, 1996) and *Biological Warfare and Defense in the Era of Genetic Engineering* (forthcoming). In July 1997, she served on the faculty and the organizing committee of a NATO Advanced Studies Institute symposium on New Scientific and Technical Aspects of Verification of the Biological and Toxin Weapons Convention in Budapest, Hungary. She was the recipient of a 1995 research grant from the US Institute of Peace to study the evolution of the neutral and non-aligned group in multilateral arms control negotiations. Dr. Chevrier earned her B.A. from the University of Nebraska and her M.A. and Ph.D. from Harvard University.

Graham S. Pearson is a Visiting Professor in International Security in the Department of Peace Studies at the University of Bradford in the United Kingdom. He was previously the Director General and Chief Executive of the Chemical and Biological Defense Establishment at Porton Down. He is engaged in an extensive range of activities relating to the non-proliferation of chemical and biological weapons, including the publication of numerous articles concentrating recently on the importance of strengthening of the Biological and Toxin Weapons Convention. He co-edited *Strengthening the Biological Weapons Convention: Key Points for the Fourth Review Conference*. He is a member of the Advisory Board of the Harvard-Sussex Program on CBW Armament and Arms Limitation, of the Research Council of the Chemical and Biological Arms Control Institute, of the Editorial Advisory Board of *Politics and Life Sciences*, and of the Senior Editorial Board of the *ASA Review*. He holds a doctorate from the University of St. Andrews in Scotland.

Amy E. Smithson is a Senior Associate at the Henry L. Stimson Center. She initiated and continues to direct the Chemical and Biological Weapons Nonproliferation Project, which conducts analytical research across the spectrum of complex topics associated with the control and elimination of chemical and biological weapons. A widely published author and the co-editor of *Open Skies, Arms Control, and Cooperative Security* (St. Martin's Press, 1992), she has testified before Congress and is frequently consulted by the media on chemical and biological weapons nonproliferation issues. Previously at the Stimson Center, she worked on projects addressing multilateral arms control and on the reshaping of US foreign policy and national security institutions in the post-Cold War era. Before joining the Stimson Center, she worked at Pacific-Sierra Research Corporation and the Center for Naval Analyses. She holds two B.A. degrees from the University of North Carolina (Chapel Hill), an M.A. from Georgetown University, and a Ph.D. from George Washington University.

Jonathan B. Tucker holds a B.S. in biology from Yale University and a Ph.D. in political science from the Massachusetts Institute of Technology with a concentration in defense and arms control studies. Currently, he is director of the chemical and biological warfare nonproliferation project at

the Center for Nonproliferation Studies of the Monterey Institute of International Studies in California. Before moving to Monterey, he worked as a policy analyst in the international security division of the congressional Office of Technology Assessment, a specialist in chemical and biological arms control at the US Arms Control and Disarmament Agency, and a senior policy analyst with the Presidential Advisory Committee on Gulf War Veterans' Illnesses. Dr. Tucker's perspective on monitoring the Biological Weapons Convention has been informed by field experience. In February 1995, he served as a biological weapons inspector in Iraq with the United Nations Special Commission.

Gillian R. Woollett is Assistant Vice President of Biologics and Biotechnology at the Pharmaceutical Research and Manufacturers of America (PhRMA). She earned her M.A. from the University of Cambridge, and D. Phil. from Oxford University. In 1987, Dr. Woollett joined the American Institute of Biological Sciences (AIBS) to manage scientific merit peer review on behalf of several US government agencies. She was Program Manager for the 1992, '93, and '94 scientific peer review for the Army Breast Cancer Research Program with awards totaling over a quarter of a billion dollars, and the Army FY '93 Neurofibromatosis Program. In 1996, Dr. Woollett joined PhRMA with responsibilities for all activities concerning biologics and biotechnology, including staffing the PhRMA Genomics Key Issue Team, which is providing a forum for the discussion of the promise, ethics, and impact of the rapidly developing new DNA technologies in health care. Additionally, her responsibilities include being the PhRMA media representative for biotechnology, especially genomics; expressing appropriate industry concerns and coordinating responses, domestically and internationally, to the Biological Weapons Convention protocol, and representing PhRMA in Geneva at the Ad Hoc Group negotiations. She publishes the PhRMA/AIBS "Genomics —A Global Resource" World Wide Web page.

List of Abbreviations

BWC - Biological and Toxin Weapons Convention
CBI - confidential or proprietary business information
CBMs - Confidence-Building Measures
CWC - Chemical Weapons Convention
FDA - Food and Drug Administration
OPCW - Organization for the Prohibition of Chemical Weapons
PhRMA - Pharmaceutical Research and Manufacturers of America
UNSCOM - United Nations Special Commission
WHO - World Health Organization
SCADA - supervisory control and data acquisition

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Introduction

***Amy E. Smithson,* Ph.D.**

The Geneva Protocol, which entered into force in 1925, banned the use of biological, toxin, and chemical weapons. Nearly half a century passed before the international community buttressed the Geneva Protocol with a more comprehensive prohibition against the production and possession of germ weapons. The Biological Weapons Convention (BWC) opened for signature on 10 April 1972. Article I of this treaty mandates several prohibitions:

> [E]ach State Party. . .undertakes never in any circumstances to develop, produce, stockpile, or otherwise acquire or retain (1) microbial or other biological agents, or toxins whatever their origin or method of production, or types and in quantities that have no justification for prophylactic, protective, or other peaceful purposes; (2) weapons, equipment, or means of delivery designed to use such agents or toxins for hostile purposes or in armed conflict.[1]

In addition, the BWC enjoins participating states not to transfer any of the agents, toxins, weapons, equipment, or means of delivery to any recipient for non-peaceful purposes and otherwise not to abet the proliferation or acquisition of biological agents or weapons. The BWC also requires states that possess biological weapons to destroy them within nine months of the treaty's activation.[2]

Since the BWC entered into force on 26 March 1975, it has been ratified by 140 countries and signed by an additional 18. Appendix 1 contains a list of the treaty's signatories and members. To the extent that membership is an indicator of success, then by far the world's nations view the BWC as an important arms control achievement that can enhance international security. However, this accord lacks what many see as a fundamental component of any arms control treaty—the means to verify compliance or to detect noncompliance.

The absence of cooperative verification provisions is typical of Cold War arms control accords. The BWC was negotiated in the early 1970s, a time period when the type of highly intrusive on-site inspections needed for effective verification were widely viewed as politically unacceptable, infeasible, or unnecessary. Moreover, the negotiators were not pressed to include verification measures in the BWC because at that time policy makers viewed biological weapons as lacking military utility. That perception has changed significantly over the last 25 years due to violations of the BWC and to advances in biotechnology.[3] In an example of the former, the USSR,

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[1] Convention on the Prohibition of the Development, Production, and Stockpiling of Bacteriological (Biological) and Toxin Weapons, Article I. Hereinafter referred to as the Biological and Toxin Weapons Convention.

[2] Biological and Toxin Weapons Convention, Articles II, III, and IV.

[3] Jonathan B. Tucker, "Strengthening the Biological Weapons Convention," *Arms Control Today* 25, no. 3 (April 1995): 9.

one of the BWC's co-depositaries, maintained a significant covert biological weapons program for decades. Many countries first recognized that the Soviet Union was cheating on the BWC in 1979, when a suspicious outbreak of anthrax occurred in the city of Sverdlovsk. The source of this outbreak was eventually traced to an accidental release from a Soviet biological weapons facility.[4] This incident raised concerns about the strength of the treaty and underscored the shortcomings of its mechanisms for resolving compliance problems. The BWC allows participating states to raise compliance "complaints" with the United Nations (UN) Security Council and requires an accused state to cooperate with any investigation to ascertain the validity of a complaint. The Security Council would initiate any non-compliance investigation.[5] The drawback of this approach is that any permanent member of the Security Council can veto the launch of an investigation.

In addition to blatant indications that some states were not adhering to their obligations under the BWC, the field of biotechnology has undergone something of a technical revolution in the latter part of this century. Technical advances have given biological weapons a greater potential military utility. For example, genetic engineering has made it possible to alter some biological agents so that they are more difficult to defend against, resistant to environmental stresses, and not susceptible to vaccines or antibiotics.[6] Thus, experts began to worry that advancements in biotechnology, microbiology, genetic engineering, and related scientific disciplines would make circumvention of the BWC's prohibitions easier to accomplish and more difficult to catch.

Given these circumstances, the BWC's members decided that the treaty needed to be strengthened with a legally binding verification protocol. The feasibility of strengthening the BWC and the appropriate means of doing so are, however, matters of strong debate within the international community. Briefly, proponents of creating a verification protocol argue that it would increase the cost and difficulty of a clandestine weapons program, enhance confidence among compliant states, provide a legal framework for challenge inspections, and ultimately decrease the number of sites of proliferation concern. They cite the 1993 Chemical Weapons Convention (CWC) as a model of a verifiable arms control agreement. Critics, on the other hand, argue that the BWC cannot be effectively verified. They point to obstacles such as the dual-use nature of biological production facilities, the likelihood that a verification protocol would generate false confidence in compliance, and the possibility that inspections would expose facilities to foreign espionage. Opponents to a

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[4] Although Soviet authorities initially claimed that the more than 60 deaths resulted from the consumption of contaminated meat, an independent group of scientists concluded that an accidental release of *Bacillus anthracis* was indeed the cause of the Sverdlovsk anthrax outbreak. Matthew Meselson et al., "The Sverdlovsk Anthrax Outbreak of 1979," *Science* 226, no. 5188 (18 November 1994): 1202–8. For more on the Soviet/Russian biological weapons program, see Milton Leitenberg, *Biological Weapons Arms Control*, Project on Rethinking Arms Control, Report No. 16 (University of Maryland, College Park: May 1996): 3–16.

[5] Biological and Toxin Weapons Convention, Article VI.

[6] US Congress, Office of Technology Assessment, *Technologies Underlying Weapons of Mass Destruction*, OTA-BP-ISC-115 (Washington, D.C.: Government Printing Office, December 1993): 114–5.

verification protocol also note that the BWC has a loophole because it does not directly prohibit research with biological agents.[7]

Despite the difficulty of the exercise, some measure of success in strengthening the BWC is anticipated. In his September 1996 address to the UN General Assembly, President Bill Clinton stated: "We must better protect our people from those who would use disease as a weapon of war, by giving the Biological Weapons Convention the means to strengthen compliance, including on-site investigations when we believe such weapons may have been used, or when suspicious outbreaks of disease occur. We should aim to complete this task by 1998."[8] Given the rate of progress thus far, however, this deadline is quite optimistic.

The Onset of Efforts to Strengthen the BWC

The BWC requires all member states to participate in review conferences to be held at five year intervals. The objective of these meetings is to undertake an article-by-article review of the BWC's operation, ascertaining whether the purposes of the treaty's preamble and main articles are being achieved. Each such review should "take into account any new scientific and technological developments relevant to the" BWC.[9] The culmination of each Review Conference is a Final Declaration that "can also serve as a basis for further strengthening of the Convention."[10]

The First Review Conference was held in March 1980. As the meeting unfolded, participating countries raised concerns about verification and compliance, but a majority finally agreed that the existing international procedures for consultation and cooperation would be adequate to resolve any problems that might arise concerning the BWC. In the Final Declaration, the participants thus reaffirmed their support for the treaty and found that Article I of the BWC "had

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[7] For a variety of opinions about the ability to verify the BWC, see S.J. Lundin, ed., *Views on Possible Verification Measures for the Biological Weapons Convention*, Stockholm International Peace Research Institute, Chemical and Biological Warfare Studies, Report No. 12 (London: Oxford University Press, 1991); Joseph Finder, "Biological Warfare, Genetic Engineering, and the Treaty That Failed," *Washington Quarterly* 9, no. 2 (Spring 1986): 5–14; Douglas J. Feith, "Biological Weapons and the Limits of Arms Control," *National Interest* (Winter 1986/87): 80–4; and Federation of American Scientists, "Progress in Identifying Effective and Acceptable Measures for a Compliance Protocol for the Biological Weapons Convention," Working Group on Biological and Toxin Weapons Verification, Working Paper (Washington, D.C.: May 1993).

[8] William Jefferson Clinton, "Remarks by the President in Address to the 51st General Assembly of the United Nations," UN General Assembly, 51st sess., Document A/51/PV.6, 24 September 1996, 2.

[9] Biological and Toxin Weapons Convention, Article XII.

[10] United Nations, *Third 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 Declaration,* Document BWC/CONF.III/23, Part II, 1991, 10.

proved sufficiently comprehensive to cover recent scientific and technological developments relevant to the Convention."[11]

The Second Review Conference took place in September 1986, amid a surge in concern about the "adequacy of the Convention in light of advances in genetic engineering and biotechnology. . . .and allegations of breaches of the Convention."[12] The BWC's members were faced with the challenge of restoring confidence in the effectiveness of the treaty. Perhaps fortuitously, the 1986 Review Conference coincided with the growing recognition of the value of confidence-building measures (CBMs), which encompass a variety of measures that states in regions of tension can undertake to promote openness in military matters and to build a climate of trust among nations.[13] The BWC's members sought to incorporate these mechanisms into the treaty regime. In the Final Declaration, the participants agreed to implement data exchanges in areas related to biological activities permitted under the treaty. Accordingly, in March/April 1987 an ad hoc meeting of scientific and technical experts assembled to design procedures for annual data exchanges among the BWC's members.[14] Beginning in 1987, states were asked to submit pertinent data voluntarily to the UN. Among the data to be declared annually was information on outbreaks of infectious diseases, the publication of scientific research results, and biological research laboratories that specialize in permitted protective, prophylactic, and other peaceful biological activities that are directly related to the BWC.[15]

Not long after these CBMs were instituted, members of the BWC arrived at a consensus that their non-legally binding nature was insufficient to produce meaningful results. The agreed CBMs did not authorize the UN to demand that states make declarations, and states that failed to submit data did not incur any penalty. Whether they were suspected of having covert biological weapons programs or not, most countries simply neglected to provide the information requested in the CBMs. Prior to the Third Review Conference in September 1991, most countries thus recognized the

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[11] Aida Luisa Levin, "Historical Outline," in *Strengthening the Biological Weapons Convention by Confidence-Building Measures*, Erhard Geissler, ed., Stockholm International Peace Research Institute, Chemical and Biological Warfare Studies, Report No. 10 (London: Oxford University Press, 1990): 8. For more on the early years of the BWC, see also Nicholas A. Sims, *The Diplomacy of Biological Disarmament: Vicissitudes of a Treaty in Force, 1975–85* (London: MacMillan Press, 1988); Barend ter Haar, *The Future of Biological Weapons* (New York: Praeger, 1991): 1–53.

[12] Levin, "Historical Outline," 9.

[13] For more on the origin, art, and practice of CBMs in a variety of contexts, see Johan Jorgen Holst and Karen Melander, "European Security and Confidence Building Measures,"in *Arms Control and Military Force*, Christoph Bertram, ed. (London: International Institute for Strategic Studies, 1980): 223–31; Richard E. Darilek, "The Future of Conventional Arms Control in Europe—A Tale of Two Cities: Stockholm, Vienna," *Survival* 29, no. 1 (January/February 1987): 5–19; Michael Krepon, ed., *A Handbook of Confidence-building Measures for Regional Security*, Handbook No. 1 (Washington, D.C.: Henry L. Stimson Center, January 1995).

[14] US Arms Control and Disarmament Agency, *Arms Control and Disarmament Agreements: Texts and Histories of the Negotiations* (Washington, D.C.: Government Printing Office, 1990): 132.

[15] Erhard Geissler, "Agreed Measures and Proposals to Strengthen the Convention," in *Strengthening the Biological Weapons Convention by Confidence-Building Measures*, 44–7.

inadequacy of relying solely upon voluntary CBMs for enhancing confidence in the compliance of the BWC.

In addition, other developments contributed to widening concerns about the BWC's weaknesses. The proliferation of biological weapons did not appear to be abating. A number of reports alleged that as many as ten countries possessed or were in the process of acquiring biological weapons.[16] Moreover, after the 1991 Gulf War, the UN Special Commission began to detect evidence that Iraq, then a signatory of the BWC, had a biological weapons program. The extent of this program—encompassing weaponization of several agents and deployment of germ-filled missiles and other munitions during the war—is still being investigated.[17] The situation in Iraq also highlighted the lack of an independent inspectorate to monitor the BWC's prohibitions. Aside from the difficulty of dealing with the proliferation of biological weapons at the state level, one 1991 report maintained that "an increased risk now exists that the acquisition and use of biological weapons is being contemplated not only by nations but by subnational groups."[18] Later underscoring this point, the Japanese cult Aum Shinrikyo, infamous for its use of poison gas in a March 1995 terrorist attack in Tokyo, also developed a biological weapons capability.[19]

Based on these concerns, the 1991 Review Conference authorized a group of governmental experts to identify and examine potential BWC verification measures from a scientific and technical standpoint. This Ad Hoc Group of Verification Experts, known as VEREX, examined and evaluated twenty-one measures that ranged from off-site surveillance of publications to on-site monitoring and inspections. VEREX evaluated each proposed verification measure according to the amount of data it can or cannot provide; its ability to differentiate between activities that are prohibited and permitted under the BWC; its capability to clarify ambiguities concerning compliance; its requirements for manpower, technology, equipment, or other material; its implications for the protection of confidential business information and for the development of permitted research and

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[16] Lundin, "Introduction," in *Views on Possible Verification Measures for the Biological Weapons Convention*, 9; US Congress, Office of Technology Assessment, *Proliferation of Weapons of Mass Destruction: Assessing the Risks*, OTA-ISC-559 (Washington, D.C.: Government Printing Office, August 1993): 14–5, 63–6; Testimony of James Woolsey, US Congress, Senate Committee on Governmental Affairs, *Proliferation Threats of the 1990's*, 103d Cong., 1st sess., S. Hrg. 103–208 (Washington, D.C.: Government Printing Office, 24 February 1993): 8–18; Office of the Secretary of Defense, *Proliferation: Threat and Response* (Washington, D.C.: Government Printing Office, November 1997).

[17] UN Security Council, "Note by the Secretary-General," Document S/1997/774, 6 October 1997. See also, R. Jeffrey Smith, "Iraq's Drive for a Biological Arsenal: U.S. Pursuing 25 Germ Warheads It Believes Are Still Loaded With Deadly Toxin," *Washington Post*, 21 November 1997, A1.

[18] Lundin, "Introduction," in *Views on Possible Verification Measures for the Biological Weapons Convention*, 7. For a more comprehensive look at attempts to use biological agents for terrorist purposes, see Ron Purver, *Chemical and Biological Terrorism: The Threat According to the Open Literature* (Ottawa: Canadian Security Intelligence Service, June 1995).

[19] US Congress, Senate Committee on Governmental Affairs, Permanent Subcommittee on Investigations, *Global Proliferation of Weapons of Mass Destruction*, 104th Cong., 1st sess., S. Hrg. 104–422, Part I (Washington, D.C.: Government Printing Office, 1996): 62–4.

scientific activities; and its financial, legal, organizational, and safety ramifications.[20] In all, VEREX met four times from March 1992 to September 1993. In its final report of September 1993, VEREX concluded that no single approach could adequately monitor the BWC. Rather, VEREX recommended a combination of means—including off-site and on-site measures—to make the BWC a more effective instrument. Off-site measures include national declarations of biological weapons defense programs, vaccines, and facilities handling specific organisms and toxins; on-site measures include short notice-inspections and information visits to declared facilities.[21]

In April 1992, Russian President Boris Yeltsin conceded that the Soviet Union had violated the BWC and issued a decree outlawing the continuation of the biological weapons program.[22] Acknowledging concerns about its biological weapons program, Moscow decided to work with the BWC's two other co-depositary nations to try to re-establish some confidence that Russia's offensive biological weapons program had indeed been curtailed. A trilateral process, formally initiated in September 1992, involved visits to military and non-military facilities of possible compliance concern.[23] US and British officials visited several Russian facilities and vice versa, but the trilateral process gradually lost momentum and did not significantly alleviate remaining compliance concerns about Russia's biological facilities.[24]

In September 1994, a Special Conference of BWC members convened in Geneva to discuss the findings of VEREX. This Special Conference called for the formation of the Ad Hoc Group to draft verification measures to be incorporated into a legally binding protocol to the BWC. In the course of its negotiations, the Ad Hoc Group is to address the creation of measures to investigate the alleged use of biological weapons, as well as the following issues:

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[20] US Arms Control and Disarmament Agency, "The Biological Weapons Convention," Fact Sheet, Office of Public Affairs (Washington, D.C.: 18 August 1993): 1–2.

[21] United Nations, *Special 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 Report*, Document BWC/SPCONF/1, 19–30 September 1994, 14–5.

[22] 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; "Decree of the Russian Federation on Fulfilling International Obligations with Regard to Biological Weapons," Moscow, 11 April 1992.

[23] Among other steps taken to end the offensive program, Russia stated that it had cut personnel in the program by fifty percent and reduced research funding by thirty percent. US Department of State, "Joint US/UK/Russian Statement on Biological Weapons," Press Release, Office of Public Affairs (Washington, D.C.: 14 September 1992). See also, "Proprietary Agreement: Procedures for Respecting Proprietary Information During Visits to Non-Military Biological Sites Pursuant to Paragraph 4(A) of the Joint US/UK/Russian Statement on Biological Weapons," Moscow, 12 May 1993.

[24] R. Jeffrey Smith, "U.S. Wary of Russian Germ Arms; Despite Assurances from Yeltsin, Effort May Be Continuing," *Washington Post*, 8 April 1994, A18; R. Jeffrey Smith, "U.S. to Press Moscow on Alleged Arms Violations," *Washington Post*, 9 May 1994, A22; US Arms Control and Disarmament Agency, *Threat Control through Arms Control: 1994 Report to Congress*, (Washington, D.C.: US Arms Control and Disarmament Agency, 13 July 1995): 70; US Department of Defense, *Proliferation: Threat and Response*, 46.

- the definition of terms and objective criteria (e.g., lists of biological warfare agents and possible threshold quantities);

- the possible incorporation of existing and additional enhanced CBMs into the verification regime;

- the development of a system of measures to promote compliance with the BWC; and,

- the delineation of a program for technical cooperation in the field of biotechnology for peaceful purposes.[25]

The Ad Hoc Group, which is open to all states parties to the BWC, began its negotiations in 1995**.** Eight rounds of negotiations were held through the end of 1997. Well over 60 member countries have been participating in the talks, with additional countries observing. Upon completion, the Ad Hoc Group is to present its draft text to a Special Conference of the BWC's members and then to the UN General Assembly for approval. If endorsed by these bodies, the new verification protocol must then be ratified by all of the BWC's members, taking effect for each participating state as it completes the ratification process.

Late in 1996, the Fourth Review Conference was held. An Iranian proposal to amend Article I by adding a prohibition against the use of biological weapons did not receive widespread support. Instead, seeking to reinforce the broad scope of the BWC's Article I prohibitions, the Final Declaration emphasized that those prohibitions apply to the emerging fields of molecular biology and genome studies. The Final Declaration called for the enactment of national penal legislation to criminalize individuals engaged in biological weapons activities. Although the Final Declaration stated the importance of adherence to the BWC's provisions, it made no specific reference to the Soviet/Russian and Iraqi biological weapons programs, the existence of which by that time was well-known.[26] This omission, indicative of the political sensitivity of directly naming BWC violators, was perhaps a harbinger of how challenging it would be to conclude a verification protocol.

Since the onset of negotiations, the Ad Hoc Group has made modest progress. Most notably, the series of papers that had been produced in previous meetings were presented as a rolling text in the July 1997 round of negotiations. At the close of the September 1997 negotiating session, the 246-page rolling text consisted of 23 articles, 7 annexes, and 5 appendices.[27] Virtually every line of this

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[25] United Nations, *Special Conference of the States*, Document BWC/SPCONF/1, 10.

[26] For more, see Malcolm R. Dando and Graham S. Pearson, "The Fourth Review Conference of the Biological and Toxin Weapons Convention: Issues, Outcomes, and Unfinished Business," *Politics and the Life Sciences* 16, no. 1 (March 1997): 105–26.

[27] Ad Hoc Group, *Procedural Report of the Ad Hoc Group 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*, Document BWC/AD HOC GROUP/38, 6 October 1997.

draft protocol is bracketed, indicating a lack of agreement on the proposed measure or language.

Observers and participants alike tend to attribute some forward momentum in the BWC negotiations to the entry into force of the CWC on 29 April 1997. The implementation of the CWC's sweeping multilateral verification provisions is likely to have a significant impact on the creation of future arms control verification regimes, including that of the BWC. According to the chairman of the Ad Hoc Group, the CWC's members, "which hitherto were not affected by such intrusive measures, have accepted for the first time that on-site inspections will be carried out on their territory. Such inspections will include both routine inspections and the possibility of challenge inspections. Thus an extremely important psychological and political barrier has been crossed by the entry into force of the CWC."[28] In short, the CWC is something of a test case for a new standard in multilateral arms control treaties. BWC members, closely watching the initial experiences with the CWC's data declarations and inspections, are likely to revise their negotiating positions according to how well or poorly they believe the CWC works in practice.

Organization of the Report

Over time, the experts involved in a particular field of work generate a specialized terminology. The group of individuals engrossed in the research and negotiation of a BWC protocol is no exception. To illustrate, the term "inspection" is used to describe the on-site monitoring activities undertaken to verify modern arms control treaties. However, in Geneva, those crafting the BWC protocol prefer to use the terms "investigation" or "visit" to describe on-site monitoring activities. This preference stems from a general agreement among the experts that on-site monitoring in the BWC will not be able to accomplish as much as similar activities under other treaties. An inspector at a nuclear or conventional weapons storage site can visually count nuclear missiles and tanks. In contrast, an inspector at a biological facility may find traces of a biological agent (e.g., anthrax) that could have originated in the facility or in the surrounding environment. Thus, BWC inspectors may not be able to uncover definitive evidence that a facility is engaged in legitimate or prohibited activities.

This report attempts to discuss the issues associated with biological weapons production and monitoring in a way that can be readily understood by the lay reader. At the risk of offending BWC experts, this report makes frequent use of the term inspection. This word is used despite the explanation above because the term inspection is more familiar to the layman. At numerous junctures in the report, however, the authors remind the reader of the constraints associated with any effort to monitor the BWC.

In the first major essay of this report, Dr. Graham Pearson, former director of Porton Down, the home of Great Britain's chemical and biological defense programs, offers a primer on the biological weapons threat. Pearson describes the nature of biological agents, how they are made,

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[28] Tibor Tóth, "A Window of Opportunity for the BWC Ad Hoc Group," *Chemical Weapons Conventions Bulletin,* no. 37 (September 1997): 2.

how they are dispersed, and what defensive measures can be taken against them. Pearson's narrative then moves on to list the countries believed to maintain offensive biological weapons programs and to explain briefly the implications of the scientific and technical advances of the past few decades for monitoring the BWC.

One of the industries likely to be most affected by the implementation of a BWC verification protocol is the pharmaceutical industry. In the next essay, Dr. Gillian Woollett of the Pharmaceutical Research and Manufacturers of America provides an industry perspective on what such a protocol should and should not contain. Her essay also contains explanations of how the industry works and the costs that the industry could incur if the eventual BWC protocol does not include sufficient measures to protect the confidential business information of pharmaceutical companies.

In the third major essay of this report, Dr. Marie Chevrier examines the utility of CBMs as a tool to enhance confidence that BWC's members are abiding by the treaty's prohibitions. Chevrier explains the CBMs that have been instituted to augment transparency under the BWC and reviews the poor track record of these measures to date. Along the way, she recommends which measures are appropriate for inclusion in the BWC's verification protocol. Chevrier also provides an analysis of the capabilities and limitations of CBMs for improving the international community's ability to verify arms control accords.

In the penultimate chapter of this report, Dr. Jonathan Tucker offers an insightful analysis of the potential applicability of the CWC's numerous verification concepts and provisions to the tasks that must be accomplished by a prospective BWC verification protocol. His essay begins by identifying the differences between chemical and biological agents and how they are made. Then, one by one, Tucker examines whether the approach taken to monitor a certain aspect of the CWC's prohibitions is suitable for application under the BWC. Given the dissimilarities between these two categories of mass destruction weapons, Tucker concludes that some of the CWC's verification measures should be adapted for use in the BWC protocol, but others should not.

The report's concluding chapter features an explanation of why the BWC negotiations have not managed to make any real headway to date. The lack of progress is due partly to the inherent difficulty of monitoring the BWC and partly to the parochial agendas of some of the Ad Hoc Group delegations, the insufficient focus of the US government, and the conservative approach taken thus far by industry. Similar to other chapters in the report, this essay contains a series of observations and recommendations that may prompt progress in the Ad Hoc Group negotiations.

Given the dangers that biological weapons present, the completion of a BWC verification protocol must be elevated on the list of the international community's most pressing priorities. As 1998 begins, the governments participating in the Ad Hoc Group must redouble their efforts to see this monumental task through to its successful conclusion and, afterwards, to move promptly to implement the resulting protocol.

The Threat of Deliberate Disease in the 21st Century

***Graham S. Pearson,* Ph.D.**

In 1996, President Bill Clinton listed among the priorities for global action the need to do more to "protect. . . people from those who would use disease as a weapon of war."[1] The threat to human health and international security that Clinton identified was not new, for the use of disease as a weapon of war dates back centuries. American soldiers, for example, gave Indians blankets infected with smallpox. The international community has twice mobilized to attempt to curtail the threat of biological warfare. The 1925 Geneva Protocol prohibits the use of chemical or biological materials in war and the 1972 Biological and Toxin Weapons Convention (BWC) bans the development, production, acquisition, stockpiling, and retention of this entire class of weapons. Clinton's remarks were motivated, however, by the recognition that since the BWC entered into force in 1975, the number of states proliferating biological weapons has increased to approximately a dozen, heightening international concerns about this particularly dangerous form of warfare.

The brevity of the BWC—some four pages long— is typical of Cold War treaties. The BWC shares another trait of that generation of arms control accords, the absence of verification provisions.[2] The international community since has begun to embrace on-site inspections and other intrusive measures to verify arms control accords. For instance, the 1993 Chemical Weapons Convention (CWC), which entered into force on 29 April 1997, contains a lengthy Verification Annex that enumerates how on-site inspections are to be executed. Although the dual-purpose nature of the chemical industry presented a challenge to devising effective verification measures, this treaty operates on the philosophy that participating states bear the burden of demonstrating compliance to inspectors. The dual-purpose nature of the biotechnology industry will present even greater challenges for the crafting of a BWC verification protocol.

Concerns about non-compliance with the BWC were sharpened when Russian President Boris Yeltsin admitted in 1992 that for twenty years the former Soviet Union continued an offensive biological weapons program in breach of the BWC.[3] Suspicions that the USSR was violating the BWC surfaced more than a decade earlier, when an outbreak of anthrax occurred at Sverdlovsk.[4]

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[1] William Jefferson Clinton, "Remarks by the President in Address to the 51st General Assembly of the United Nations," UN General Assembly, 51st sess., Document A/51/PV.6, 24 September 1996, 2.

[2] At this time, the United States and the USSR relied upon the use of national means of verification, namely satellites and other surveillance technologies, to monitor arms control treaties.

[3] J. Dahlburg, "Russia Admits it Violated Pact on Biological Warfare," *Los Angeles Times*, 15 September 1992, A1. The USSR was a co-depositary of the BWC, along with the United Kingdom and the United States.

[4] An unusual outbreak of anthrax occurred at Sverdlovsk, USSR, in April/May 1979. Soviet authorities claimed that contaminated meat caused the outbreak, but US officials asserted that the 64 deaths resulted from a release of anthrax from a military facility. For contending views on the Sverdlovsk incident, see Charles C. Flowerree, "Possible Implications of the Anthrax Outbreak in Sverdlovsk on Future Verification of the Biological Weapons Convention: A US Perspective," and Victor Issraelyan, "Possible Implications of the Anthrax Outbreak in Sverdlovsk on Future

Since the BWC lacked a verification protocol, members of the treaty lack an easy way to investigate these suspicions officially. Only with Yeltsin's statement was the existence of the Soviet biological weapons program confirmed. The international community's confidence that biological weapons were not seen as an option was further shaken in 1995 when BWC signatory Iraq was found to have a significant biological weapons program.[5] After years of obstructing the United Nations Special Commission (UNSCOM) inspectors, Iraq disclosed that it had produced major quantities of various biological agents and deployed agent-filled bombs and missiles during the 1991 Gulf War.[6] Both of these situations underscored the need to buttress the BWC with a meaningful verification protocol.

In addition to these serious violations of the BWC, the international community received another wake-up call in the Spring of 1995. On March 20th, a religious cult released the nerve gas sarin in Tokyo's subway at the height of the commuter rush hour. A dozen people were killed and over 5,500 were hospitalized as a result of this attack. To execute this attack, cult members placed several small, multi-layered, plastic containers of sarin on baggage racks or the floors of subway trains. At the designated time, the cult members punctured the bags with a sharp instrument, like the tip of an umbrella. Aum Shinrikyo clearly succeeded in manufacturing poison gas, but the cult was also closing in on a biological weapons capability. The cult was working with botulinum toxin and anthrax, and it had developed devices to disseminate such agents. The Aum sect also sent a team to Zaire in 1992 to assist in the treatment of Ebola victims, reportedly with the goal of obtaining a sample of the Ebola virus that could be cultured back in Aum's laboratories in Japan.[7] This group's attacks and dogged pursuit of chemical and biological weapons made the danger that these weapons of mass destruction can be used for terrorist purposes unmistakably clear. Individual governments and the international community have begun to recognize the seriousness of this threat.[8]

Verification of the Biological Weapons Convention: A Soviet Perspective," in *Views on Possible Verification Measures for the Biological Weapons Convention*, S.J. Lundin ed., Stockholm International Peace Research Institute, Chemical and Biological Warfare Studies, No. 12 (London: Oxford University Press, 1991): 108–24.

[5] Iraq signed the BWC, but did not ratify the BWC until April 1991 in response to UN Security Council Resolution 687 (1991).

[6] United Nations, *Eighth Report of the Secretary-General on the Status of the Implementation of the Plan for the Ongoing Monitoring and Verification of Iraq's Compliance with Relevant Parts of Section C of Security Council Resolution 687,* Security Council Document S-1995/864, 11 October 1995.

[7] For a detailed account of Aum Shinrikyo's activities, see US Congress, Senate Governmental Affairs Committee, Permanent Subcommittee on Investigations, *Global Proliferation of Weapons of Mass Destruction,* 104th Cong., 1st sess., S. Hrg. 104–422, Part I (Washington, D.C.: Government Printing Office, 1996). See also, David E. Kaplan and Andrew Marshall, *The Cult at the End of the World: The Incredible Story of Aum* (London: Hutchinson, 1996).

[8] For example, on 27 June 1996 leaders of the Group of Seven states declared that "special attention should be paid to the threat of utilization of nuclear, biological and chemical materials, as well as toxic substances, for terrorist purposes." See the United Nations, *Declaration on Terrorism*, letter dated 5 July 1996 from the Permanent Representative of France to the UN Secretary-General, UN General Assembly/Security Council Document A/51/208, S/1996/543, Annex V, 12 July 1996. At a subsequent Group of 7/8 Ministerial conference on terrorism, BWC members were urged to confirm "their commitment to ensure, through the adoption of national measures, the effective fulfillment of their obligations under the convention to take any necessary measures to prohibit and prevent the development, production, stockpiling, acquisition or retention of such weapons. . . . to exclude use of those weapons for terrorist

Other events have also helped to increase awareness of the susceptibility of humans, animals and plants to disease. Recent headlines have reported alarming outbreaks of deadly diseases. In October 1994, a World Health Organization (WHO) team visited the Indian town of Beed to help this town cope with an eruption of the bubonic plague. Later, the city of Surat, also located in the region of Bombay, suffered an outbreak of the pneumonic plague.[9] On another continent, the WHO reported that the Ebola virus resurfaced in Zaire in April 1995. Two months after the outbreak began, WHO records show that 93 infections and 86 deaths occurred. This 90 percent mortality rate is similar to an earlier Ebola outbreak in Zaire. In 1976, 290 died out of 318 people infected died.[10] While the tendency is to focus on diseases that effect humans, animals and plants are also susceptible to outbreaks of disease and can suffer devastating losses.

One of the most disturbing side-effects of modern life is the speed with which diseases can spread around the globe. Decades ago, it was much less likely that an outbreak of infectious disease occurring on one continent could cross oceans to another. Intercontinental air travel now makes it possible for a disease to arrive in other continents before signs of the original outbreak have been recognized. The World Health Assembly attributes the problem of new and emerging diseases to the following modern trends:

> With the increasing global population many are forced to live under conditions of overcrowding, inadequate housing, and poor hygiene; . . . more frequent international travel leads to rapid global exchange of human pathogens; . . . changes in health technology and food production, as well as its distribution (including international trade) and handling, create new opportunities for human pathogens; . . . human behavioural changes expose large segments of the global population to disease not previously experienced; . . . expanding areas of human habitation expose thousands of people to enzootic pathogens previously unknown as causes of human disease; and . . . microbes continue to evolve and adapt to their environment, leading to the appearance of new pathogens.[11]

While there are clearly advantages to modern life, there are also noteworthy drawbacks.

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purposes." United Nations, *Measures to Eliminate International Terrorism*, letter dated 1 August 1996 from the Permanent Representative of France to the UN Secretary-General, General Assembly Document A/51/261, 1 August 1996. John Deutch, the Director of the Central Intelligence Agency, said: "In the post-Cold War era, terrorists have become increasingly capable, lethal and wide-ranging. . . . Indeed, the prospects for chemical and biological terrorism will increase with the spread of dual-use technologies and expertise." Testimony of John Deutch, US Congress, US Senate Select Committee on Intelligence, *Worldwide Threat Assessment Brief*, 104th Cong., 2nd sess. (Washington, D.C.: Government Printing Office, 22 February 1996).

[9] Declan Butler, "India Ponders the Flaws Exposed by Plague. . . ," *Nature* 372, no. 6502 (10 November 1994): 119. See also K. S. Juryman, "India Confirms Identity of Plague," *Nature* 373, no. 6516 (23 February 1995): 650.

[10] "The Hobbled Horseman," and "Disease Fights Back, *Economist* 335, no. 7915 (20 May 1995): 83–9 and 15–6, respectively.

[11] World Health Organization, *Communicable Diseases Prevention and Control: New, Emerging and Re-emerging Infectious Diseases*, Forty-eighth World Health Assembly, Resolution No. WHA 48.13, 12 May 1995.

Given these circumstances, global health authorities are attempting to mobilize the international community for a war on infectious diseases. In May 1995, the World Health Assembly issued a resolution calling for the organization "to establish strategies enabling rapid national and international action to investigate and combat infectious disease outbreaks and epidemics." For instance, the traditional tactic of stemming the rapid spread of disease by sealing off or isolating areas experiencing an outbreak needs to be buttressed by new strategies to curtail the propagation of diseases. The WHO has also sounded the alarm. Hiroshi Nakajima, Director General of WHO, said: "We stand on the threshold of a new era in which hundreds of millions of people will at last be safe from some of the world's most terrible diseases. . . .We also stand on the brink of a global crisis in infectious diseases. No country is safe from them. No country can any longer afford to ignore their threat."[12]

The nature of the biological weapons threat is discussed in a detailed, yet lay-friendly way in the following pages. First, the basic facts are presented about biological agents, how they are made, and their military significance. A review of delivery systems and the defensive methods used to protect troops against a biological attack is next, followed by a synopsis of information about the biological weapons status of several countries of proliferation concern. The discussion then moves to a description of how advances in biotechnology have made the task of implementing a BWC verification protocol more complicated. Finally, some recommendations are made about steps that should be taken to hinder the further proliferation of biological weapons.

The ABCs of Biological Warfare

Biological warfare programs consists of several components, the main ones being research, development, and production of agent, delivery system development and testing, and storage and stockpiling. Although biological warfare was the subject of detailed examination in the 1920s, major research and development programs first emerged in the late 1930s and early 1940s. At that time, Great Britain and the United States mounted programs to enable a retaliatory capability should biological weapons be used against Allied forces in World War II. Great Britain abandoned its offensive biological weapons capabilities in the late 1950s, and the United States discontinued its offensive biological weapons program in the late 1960s.[13] Throughout the following discussion,

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[12] World Health Organization, *Fighting Disease, Fostering Development*: *1996 World Health Report,* 1996, v.

[13] G.B. Carter and Graham S. Pearson, "Past British Chemical Warfare Capabilities," *RUSI Journal* 141, no. 1 (February 1996): 59–68; G.B. Carter, "Biological Warfare and Biological Defense in the United Kingdom 1940–1979," *RUSI Journal* 137, no. 6 (December 1992):67–74. On 25 November 1969, President Richard M. Nixon abolished America's offensive biological warfare program with the following statement: "The United States shall renounce the use of lethal biological agents and weapons, and all other methods of biological warfare. The United States will confine its biological research to defensive measures, such as immunization and safety measures. The Department of Defense has been asked to make recommendations as to the disposal of existing stocks of bacteriological agents." Richard M. Nixon, "Statement on Chemical and Biological Defense Policies and Programs," 25 November 1969, *Public Papers of the Presidents: Richard M. Nixon, 1969* (Washington, D.C.: Government Printing Office, 1971):

which also addresses the issues of military significance, examples are drawn from the US and British programs to illustrate certain points.

Biological warfare is the deliberate spreading of disease amongst humans, animals, and plants. Diseases are caused when small numbers of living micro-organisms enter into the target population of humans, animals, or plants. These micro-organisms multiply, and, after an incubation period, the symptoms of the disease become apparent. In some cases, micro-organisms produce toxins—non-living toxic chemicals—that cause symptoms. Depending upon the biological agent chosen, the resulting disease cause incapacitation or death of the target population.

Biological Warfare Agents

A would-be proliferator first needs to determine which micro-organisms would be suitable for a biological warfare program. Generically speaking, the following groups or classes of micro-organisms can cause disease:

- **Bacteria** are single-cell organisms that cause such diseases as anthrax, plague, and tularemia. Bacteria vary greatly in their level of lethality and infectivity. Although many pathogenic bacteria are susceptible to antibiotic drugs, strains can be selected that are resistant to antibiotic and occur naturally. Bacteria can be readily grown in artificial media using facilities similar to those found in the brewery industry.

- **Viruses** are 100 times smaller than bacteria and occur in large numbers in nature. Viruses can infect animals, crops, and humans. Among the disease-producing viruses are smallpox, Ebola, and Venezuelan equine encephalitis. Viruses must be grown on living tissue. They can mutate naturally or be genetically engineered to increase their effectiveness.

- **Rickettsiae** are similar to bacteria in structure and form, but must be grown in living tissue. Diseases caused by rickettsiae include Q-fever, typhus, and Rocky Mountain spotted fever.

- **Fungi** occur in great variety in nature. Relatively few species appear to have potential for deliberate use against humans, although many more could be used to destroy crops. Among the fungal pathogens that can cause hardship and famine are potato blight and cereal rust.

- **Toxins** are the non-living products of micro-organisms (e.g., botulinum toxin and *Staphylococcal* enterotoxin B), of plants (e.g., ricin, from castor beans), or of living creatures (e.g., saxitoxin, from shellfish). Toxins can also be produced by chemical synthesis. Toxins, like chemical warfare agents, can only affect those exposed to the toxin and cannot produce transmissible diseases. Because they are non-living organisms, producing a large quantity

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of toxins requires more time than would be needed to make a similar quantity of other biological agents.

Article I of the BWC prohibits the misuse of "microbial or other biological agents, or toxins whatever their origin or method of production," and successive Review Conferences have reaffirmed that this also includes any genetic modifications of these micro-organisms.[14]

A significant amount of work has already been conducted to determine what specific micro-organisms within the above-named generic categories would be useful for military purposes. In 1942 to 1943, the British conducted trials on Gruinard Island off the northwest coast of Scotland to investigate the feasibility of biological warfare.[15] Great Britain developed a retaliatory capability to kill German cattle by delivering linseed meal cakes laced with anthrax through the flare chutes of aircraft. Approximately 5 million anthrax-spiked cattle cakes—about three centimeters in diameter and a couple of centimeters thick—were stockpiled. In its early years, the US retaliatory capability consisted of three anti-crop agents: stem rust of wheat, rice blast, and stem rust of rye.[16] Biological weapons were not, however, used in the European theater during World War II.[17]

After the war, policy makers in Washington and London recognized the strategic potential of biological warfare, considering biological weapons of an importance comparable to nuclear weapons. The British and American programs broadened to explore agents that would effect humans. Some micro-organisms, such as those that cause the plague or smallpox, are transmissible from person to person and can therefore cause epidemics. US and British scientists purposefully selected diseases that could not passed from one individual to another. Prior to 1972, when the BWC was signed, the British and US biological weapons programs developed, tested, and produced several anti-human agents, including the bacterial agents *Bacillus anthracis* (causes anthrax), *Brucella suis* (causes brucellosis), and *Pasteurella tularensis* (causes tularemia). In addition, the rickettsial agent *Coxiella burnetii* (causes Q-fever), the viral agent Venezuelan equine encephalitis**,** and the toxins *Clostridium botulinum* and *Staphylococcal* enterotoxin B were produced.[18] For humans, the exposure risk for a biological agent is rarely from skin contact with the agent. Rather, infection and ensuing illness results from inhalation of an agent into the respiratory tract. Symptoms

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[14] For example, see United Nations, *Final Declaration of the 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*, Document BWC/CONF.IV/9, 25 November – 6 December 1996, Part II, 15.

[15] The British government decontaminated Gruinard Island in 1986 and returned the island to its original owners in 1990.

[16] United Nations, *Annex VI: Confidence Building Measure F*, Document No. CDA/BWC/1997/CBM, 30 May 1997, 688.

[17] Biological agents were used in China during the late 1930s and early 1940s. Japanese forces used plague-infected fleas to attack several areas. For more detail, Sheldon H. Harris, *Factories of Death: Japanese Biological Warfare 1932–45 and the American Cover-up* (New York: Routledge, 1994).

[18] United Nations, *Annex VI: Confidence Building Measure F*, 695.

and other characteristics of several biological agents can be found in Table 1. *Bacillus anthracis* and Venezuelan equine encephalitis can also be used to attack animals.

Any country or group seeking to establish a biological weapons capability is likely to select one or more the micro-organisms known from the literature to have been thoroughly tested and successfully produced in a biological weapons program. Otherwise, a government or sub-national group considering whether a particular pathogen or toxin might be used as a biological agent needs to know several things about the micro-organism in question. For example, knowledge is required about:

- the infective dose of the potential agent;
- the method of attack on the target population (e.g., inhalation, ingestion, or by an insect vector);
- the means of dispersion of the agent;
- the ability of the agent to survive until it reaches the target;
- the ability to deliver an effective dose to the target population;
- the practicality of an infective dose being achieved in the target population, or the amount of agent the target population retains;
- the time to effect or cause disease in the target population; and,
- whether the agent causes a contagious disease.

In addition, the candidate agent also needs to be producible.

Unlike exposure to a chemical agent, where the effects are generally almost instantaneous, the effects of biological agents take time to develop. Typically, a number of days or a week or two must transpire, depending on the micro-organism and the rate at which it multiplies in the body. This time-to-effect factor can be regarded as both a disadvantage and an advantage. While the absence of an immediate effect detract from the potential battlefield application of a pathogen, a delayed effect can be advantageously used to attack fixed targets such as airbases, ports, naval task

Table 1: Characteristics and Symptoms of Some Anti-Human Biological Agents.

Type of Agent	Name of Agent	Rate of Action	Effective Dosage	Symptoms/Effects
Bacteria	*Bacillus anthracis* (causes anthrax)	*Incubation:* 1 to 6 days *Length of illness:* 3 to 5 days	10,000 spores or less	Fever and fatigue; often followed by a slight improvement, then abrupt onset of severe respiratory problems; shock; pneumonia and death within 2–3 days
	Yersinia pestis (causes bubonic plague)	*Incubation:* 2 to 10 days *Length of Illness:* 1 to 2 days	100 to 20,000 organisms	Malaise, high fever, tender lymph nodes, can lead to hemorrhage, circulatory failure, and death
	Brucella suis (causes brucellosis)	*Incubation:* 1 to 3 weeks *Length of Illness:* days	1,300 organisms	Fever and chills, headache, loss of appetite, mental depression, extreme fatigue, aching joints and sweating
	Pasteurella tularensis (causes tularemia)	*Incubation:* 3 to 5 days *Length of Illness:* 30% to 60% of victims die within 30 days	10 to 50 organisms	General pain, an irritant, cough, feeling of general illness
Rickettsiae	*Coxiella burnetii* (causes Q-fever)	*Incubation:* 10 to 20 days *Length of Illness:* 2 days to 2 weeks	10 or less organisms	Pneumonia, cough, chest pain
Viruses	Venezuelan equine encephalitis	*Incubation:* 1 to 5 days *Length of Illness:* days to weeks	25 infectious units	Fever, chills, gastrointestinal hemorrhage, severe headache, nausea, vomiting, delirium; can lead to coma, shock, and death

Type of Agent	Name of Agent	Rate of Action	Effective Dosage	Symptoms/Effects
Toxins	Saxitoxin	*Time to effect:* minutes to hours *Length of Illness:* Fatal after inhalation of lethal dose	150 micrograms	Dizziness, paralysis of muscles of respiration, and death within minutes
	Botulinum toxin	*Time to effect:* hours to days *Length of Illness:* 24 to 72 hours	70 nanograms	Weakness, dizziness, dry throat and mouth, blurred vision, progressive weakness of muscles; abrupt respiratory failure may cause death
	Ricin	*Time to effect:* hours *Length of Illness:* days	200 micrograms	Rapid onset of nausea, vomiting, sever cramps, vascular collapse; can start with nonspecific symptoms of weakness, fever, and cough
	Staphylococcus enterotoxin B	*Time to effect:* a few hours *Length of Illness:* 4 to 6 days	2,000 micrograms	Severe nausea, diarrhoea, and vomiting

Sources: United Nations, *Report of the Secretary General, Chemical and Bacteriological (Biological) Weapons and the Effects of their Possible Use*, Documents A/7575/Rev.1, S/9292/Rev. 1, 1969; Graham S. Pearson, "Biological Weapons: Their Nature and Arms Control in Nonconventional Weapons Proliferation" in *The Middle East: Tackling the Spread of Nuclear, Chemical and Biological Capabilities*, Efraim Karsh, Martin S. Navias, and Philip Sabin, eds. (Clarendon Press, Oxford: 1993): 100–33; United Nations, *Report of the Secretary General, Chemical and Bacteriological (Biological) Weapons and the Effects of their Possible Use*, Documents A/7575/Rev.1, S/9292/Rev. 1, 1969; David R. Franz et al., eds., Office of the Surgeon General, *Medical Aspects of Chemical and Biological Warfare: Textbook of Military Medicine, Part I: Warfare, Weaponry, and the Casualty* (Washington, D.C.: Government Printing Office, 1997).

forces, troop assembly areas, and logistic concentrations. Additionally, the delayed effect of a biological agent makes attribution difficult, especially where an endemic disease is used. Therefore, it is plausible to both hide and deny a biological weapons attack.

In addition, the effects of a biological attack will vary across a large population. On an individual level, a person's response to exposure to a particular biological warfare agent will depend on the concentration of the agent involved. A person's response will also vary depending upon their natural resistance to the agent and whether they have been vaccinated—if there is a vaccine—against the disease.

Production of Biological Agents

The first and most elemental step for the production of biological agents is acquisition of a seedstock of agent, which is quite easy to accomplish. Biological agents can be isolated from their natural source. Or, a seedstock can be requested from culture collections or obtained from anyone who has the micro-organisms for medical or other research purposes. Once obtained, the next step is to grow the amount of agent desired. Actual production of agent requires simple equipment, such as fermenters and other containers, and an understanding of microbiology and how growth media work. The scientific know-how and equipment to culture micro-organisms are essential capabilities pervasive in the biotechnology industry.

Biological agents such as bacteria are living micro-organisms that cause disease through multiplication within the target human, animal, or plant. Likewise, such bacteria in a suitable medium will multiply. To illustrate the point, milk left out of a refrigerator will quickly deteriorate through the growth of microbiological organisms that are naturally present. Another well-known example of microbiological growth occurs during the fermentation of wine or beer, a process that provides the optimum circumstances under which micro-organisms can react with the growth media. Fermentation is typically initiated by adding a small amount of the microbiological species, known as a culture, to a much larger volume of a suitable media. Held under appropriate temperature conditions, the microbiological species will multiply and grow. The growth of such cultures is widely used in the commercial production of yogurt, beer, wine, antibiotics, and vaccines. Some cultures require the exclusion of atmospheric oxygen to favor growth.

Consequently, a biological warfare program requires cultures of the biological agent(s), which can either be extracted from circumstances in nature where the disease has been present (e.g., the carcases of animals that have died from anthrax) or from culture collections maintained to facilitate scientific research. Such cultures can then be used to seed the appropriate growth media either in simple flasks or in larger fermenters operated on a batch or continuous basis. Any student of microbiology knows the skills required to seed and grow a culture. As kilograms of product can be grown readily within days, less than ten people would be needed to run a small biological agent production plant.

In order for a biological agent to be inhaled and cause the effects listed above, it needs to be disseminated in such a way that it will both travel to the potential target and will be retained on inhalation. Small particles of agent in the size range of 1 to 10 microns are required because larger particles settle out of the atmosphere rapidly and are not inhaled into the lung. Agent can therefore either be dispersed as a slurry so that the droplets produce particles of the desired size or, with greater difficulty, freeze dried to produce to the desired particle size.[19] Freeze drying an agent is technically more demanding, but makes the agent easier to store than a liquid slurry. While aspiring proliferators may find it relatively easy to ferment a sufficient quantity of agent, achieving the

[19] For another discussion, see US Congress, *Technologies Underlying Weapons of Mass Destruction*, Office of Technology Assessment, OTA-BP-ISC-115 (Washington, D.C.: Government Printing Office, December 1993): 71–117.

required particle size for effective dissemination is considered one of the more technically demanding aspects of weaponization.

While the above description may make the production of biological agents sounds easy, not everything is on the side of the would-be proliferator. Some fairly unusual skills are needed to mount a sophisticated biological weapons program, including specialized techniques related to the growth media and the precise conditions for producing micro-organisms; the distillation of concentrated product from the growth media, achieving the required particle size; an understanding of the factors that cause micro-organisms to decay in the atmosphere so that decay rates can be taken into account in planning the quantities needed for an attack; and tactical calculations about the dissemination point to enable a successful attack of a particular target population. However, even these more esoteric skills can be more readily obtained as the field of biotechnology continues to expand.

When compared to the cost of a nuclear weapons program, biological weapons are extremely cheap. In one analysis, the comparative cost of civilian (unprotected) casualties is "$2,000 per square kilometer with conventional weapons, $800 with nuclear weapons, $600 with nerve-gas weapons, and $1 with biological weapons."[20] The costs of establishing a biological weapons program are being reduced further by the advances in microbiology and biotechnology that make agent production so much easier. Given their relative affordability and their relatively high effectiveness, some countries may regard biological weapons as an equalizer capable of compensating for inadequacies in their conventional forces and offsetting the otherwise superior military strength of an opponent. Not surprisingly, biological weapons have long since become known as the poor man's atom bomb.

Biological Warfare and Military Significance

One of the questions most frequently asked about a military capability is what constitutes a militarily significant threat. When it comes to biological agents, there is no simple answer to that question. Once a pathogen infects its target population, all biological agents (except toxins) multiply inside the host. Small amounts—just a few micro-organisms of a biological agent—may therefore suffice to devastate a crop, a herd of animals, or a city's inhabitants if the right quantity of agent is delivered precisely to the target population. In practice, however, the quantity of agent needed to create the intended effect is considerably larger than the effective dose listed in Table 1 because only a small fraction of the agent disseminated is inhaled by the target population.

The militarily significant quantity of agent depends on the concept of operations envisaged for the use of biological weapons—single overt attack, single covert attack, or multiple simultaneous attacks of either type, in which case larger amounts of agent would be required. To execute an attack on a significant military target such as a port or an air base using a missile or an aircraft with a

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[20] Julian Perry Robinson, with Carl-Goran Heden and Hans von Schreeb, *The Problem of Chemical and Biological Warfare: CB Weapons Today*, vol. II (New York: Stockholm International Peace Research Institute, 1973): 135.

dissemination system, at least 100 kilograms of agent would be needed. In one well-known scenario, a single aircraft leaving a trail of 100 kilograms of anthrax along a line upwind of Washington, D.C., could result in 1 to 3 million deaths. In comparison, a one megaton hydrogen bomb dropped over the US capitol would only cause some 0.5 to 1.9 million deaths.[21] This quantity-to-effect ratio elevates biological agents to a strategic weapon, whether the pathogens are used against humans, crops, or livestock. Consequently, military and civilian leaders the world over regard biological weapons with a great deal of apprehension. "The one that scares me to death, perhaps even more so than tactical nuclear weapons, and the one we have less capability against is biological weapons," said Gen. Colin Powell, then Chairman of the Joint Chiefs of Staff.[22]

A few kilograms of biological agent would be adequate to carry out a smaller clandestine attack. If an aggressor opts not to stockpile agent, but rather to produce the required quantity just prior to an attack, then all that is required is a small seedstock—a vial containing just a few grams. This starter culture can be the springboard to grow even a large quantity of agent within a few days.[23]

A militarily significant quantity of toxins must be calculated in a different way. As non-living chemicals, toxins achieve their effect as biological weapons primarily through inhalation. Because toxins are more toxic than chemical nerve agents (e.g., sarin, soman), the amount of toxin for an attack is somewhat less than the quantity of chemical agent required for an attack. For example, 1 to 7 tons of nerve agent would be needed to attack an air base. The amount of toxin needed for a similar attack will be about ten fold less, 100 kg to 700 kg.[24]

Delivery of Biological Agents

Effective dissemination is challenging because the biological agent is a fragile living organism that has to survive until it reaches the target. If bombs or rockets are employed to disseminate the agent, explosives will probably be used to open the munition and to disperse the agent into the atmosphere. The detonation of the explosive produces heat and shock, which can kill the living micro-organisms. Dispersion by a spray system is thus potentially less damaging to the agent than an explosive delivery system, although both are technically challenging if the desired

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[21] US Congress, Office of Technology Assessment, *Proliferation of Weapons of Mass Destruction: Assessing the Risks*, OTA-ISC-559 (Washington, D.C.: Government Printing Office, August 1993): 52–5; United Nations, *Report of the Secretary General, Chemical and Bacteriological (Biological) Weapons and the Effects of their Possible Use*, Document A/7575/Rev.1, S/9292/Rev. 1, 1969; Stephen Fetter, "Ballistic Missiles and Weapons of Mass Destruction: What is The Threat; What Should Be Done," *International Security* 16, no. 1 (Summer 1991): 5–42.

[22] Testimony of Gen. Colin Powell, US Congress, House Committee on Armed Services, *Hearings on National Defense Authorization Act FYI 1994 - H.R. 2401*, 103rd Cong., 1st sess., H201–33 (Washington, D.C.: Government Printing Office, 1993): 112.

[23] In contrast, the US and British programs focused on a retaliatory capability and consequently selected stable agents that could be stored for years .

[24] Office of Technology Assessment, *Assessing the Risks*, 60. For more on toxins, see "Defense Against Toxin Weapons," in David R. Franz et al., eds.,Office of the Surgeon General, *Medical Aspects of Chemical and Biological Warfare: Textbook of Military Medicine, Part I: Warfare, Weaponry, and the Casualty* (Washington, D.C.: Government Printing Office, 1997): 603–19.

particle sizes are to be achieved. Once it has been dispersed into the atmosphere, the agent is exposed to the natural environment (e.g., ambient temperature, sunlight), which will cause the micro-organism to die.

The effectiveness of biological agents will also be determined by the meteorological conditions. The localized weather conditions will determine the distance downwind at which an infective dose will be delivered to the target populations. Under ideal conditions, such as a calm night with a steady wind, the agent will probably be disseminated over hundreds of kilometers. Under turbulent, sunny conditions, the distance that the agent will be carried downwind will be greatly reduced. The susceptibility of biological agents to the meteorological conditions is sometimes viewed as a drawback. If the direction of the wind were to suddenly vary, the disseminated agent could blow back over one's own forces. However, the former US and British warfare programs demonstrated the feasibility of effectively delivering biological agents to achieve military objectives. In addition, the ability to accurately forecast weather and wind conditions has improved immensely over the past few decades.

A delivery system must have two major attributes. First, the delivery system needs to expel the agent efficiently from its container. Second, assuming an agent that attacks through the respiratory system, the delivery system must produce 1 to 10 micron sized particles of agent. During their heyday, the British and American biological warfare programs tested and evaluated a number of systems to deliver biological agents against humans, including aerial bombs, bomb submunitions, aerial spray tanks, ballistic missile warheads, artillery shells, rockets, cruise missile warheads, and clandestine systems. For example, the 4 lb. Mark I British bomb was designed to deliver anthrax and botulinum toxin, while another 4 lb. bomblet, the E-48-R2, later the M114, was developed to deliver *Brucella suis*. Different delivery means were used for anti-animal and anti-crop agents. For instance, in addition to the afore-mentioned anthrax-laced cattle cakes, the United States developed a "feather" bomb to deliver anti-crop agents, so called because the bomb was filled with feathers that were used to carry the anti-crop agent. One point to keep in mind is that delivery of agent using a missile or rocket has a definite signature, because of the military delivery system employed. However, biological agent can be disseminated without immediate and obvious signs that an attack is underway by using a spraying system, especially one traveling across the wind, upwind of the target.

Of course, for terrorist purposes, a sophisticated delivery system may not be required. Biological agents can be disseminated by cross-winds with few, if any, indications of hostile intent. Commercially available equipment, such as agricultural sprayers, can be used to attack broad area targets.[25] A single aircraft, for example, flying across the wind can disseminate a line of source agent approximately 200 kilometers long to infect an area of some 200 square kilometers downwind. Or, a vehicle driven across the wind could be used to disperse agent in a similar manner over a proportionately smaller area. The Aum Shinrikyo cult, for example, equipped a van with a fan and

[25] Office of Technology Assessment, *Technologies Underlying Weapons of Mass Destruction*, 71–117.

specialized vents. On one occasion, cult members drove this van on the streets of Tokyo, attempting to release botulinum toxin. Apparently, no one was harmed as a result of this test drive.[26]

As long as a terrorist group has managed to achieve the required particle size, then the prevailing wind can serve as the delivery system. The United States carried out its first open-air tests in the 1950s with biological simulants to evaluate US vulnerability to a biological weapons attack in a variety of locations. *Bacillus globigii* was frequently used because of its similarities to *Bacillus anthracis*, the agent that causes anthrax. These tests showed that the wind would carry the agent downwind.[27] In short, terrorists could use a vehicle, a small aircraft, or simply an upwind location to disperse biological agent over a designated area.

Defenses Against Biological Weapons

Just as defensive postures can be taken to protect troops or a civilian population against a poison gas attack, so can protective measures counter the use of biological agents. The two categories of measures are active and passive defenses. Active defenses are actions taken to prevent delivery systems reaching the vicinity of the target population. The range of counter-force options runs the gamut from preemptive strikes against the potential aggressor's biological weapons facilities to the interception and destruction of incoming delivery vehicles.[28] Several passive defense measures are also available, including hazard assessment, detection, physical protection, medical countermeasures, and contamination control.

Hazard assessment is the ability to evaluate the area and the size of the population at risk in the event of the biological attack, factors that are crucial to determine the appropriate operational responses to an attack. Models are used to predict the dispersion of the biological agent from the point of release, taking into account the meteorological conditions and the likely decay rate of the agent. If the time at which the hazard cloud will arrive at and pass through a given location can be predicted, people can make use of whatever physical protection is available while the hazard cloud is overhead.

A detection capability furnishes an alarm alerting officials that a biological agent attack is imminent. Ideally, detection systems are situated a sufficient distance upwind of the asset being protected to enable sufficient warning before the agent cloud arrives over the target downwind. The first objective is to detect a cloud of agent rapidly. After the initial alarm, efforts can focus on identifying the precise biological agent involved, which facilitates more accurate hazard assessment.

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[26] Kaplan and Marshall, *The Cult at the End of the World*, 93–4. See also Senate Permanent Subcommittee on Investigations, *Global Proliferation of Weapons of Mass Destruction*, 62–4.

[27] David R. Franz, C. Parrott, and E. Takafuji, "The US Biological Warfare and Biological Defense Programs," in *Medical Aspects of Chemical and Biological Warfare: Textbook of Military Medicine*, 603–9.

[28] The in-air, explosive destruction of an incoming delivery vehicle filled with biological agent is unlikely to result in dispersal of the agent in the optimum aerosol particle size (1 to 10 microns). Moreover, interceptive destruction is likely to occur at a considerable altitude and distance from the target. This distant point of interception increases the unlikelihood of the agent reaching the ground level as well as the opportunity for the atmosphere to dilute the agent, and thereby decreases the likelihood of harm to the target population.

Physical protection refers to the use of physical barriers to protect the target population from exposure to a biological agent. The risks of illness from skin exposure to biological agents are minimal. Therefore, respirators and masks are the principal personal protective gear. Respirators designed for military personnel contain a particulate filter to prevent the 1 to 10 micron particles from entering the respiratory system. Oronasal masks also provide good protection against particles and can be useful especially for personnel at some distance downwind of the attack.[29] For collective protection, people can enter a building or vehicle equipped with filtration systems that capture the particles of biological agent.

Whether before or after an attack, medical countermeasures can negate or blunt the effects of some biological agents. Personnel can be vaccinated against some agents, increasing the body's defenses against subsequent exposure to those agents. Vaccinations are available to counteract some biological agents, such as anthrax, plague, Q-fever, and tularemia.[30] Medical countermeasures can also be administered after exposure to a biological agent, either before or after the appearance of symptoms. However, administration of medical countermeasures such as antibiotics after the appearance of symptoms is unlikely to be very effective for several biological agents such as anthrax. The effectiveness of medical treatment will be enhanced with advance knowledge of the specific biological agent involved.

In the aftermath of a biological weapons attack, there will only be a slight continuing hazard, and, consequently, unlike chemical weapon attacks, no necessity to clean up surfaces, terrain, or other areas where biological agent may have been deposited. Such deposited biological agents do not present a persistent or continuing hazard to personnel. First, dissemination efficiencies are such that only about one percent of a biological aerosol will deposit on the surface over which it passes. Second, ultraviolet rays, sunlight, and other environmental conditions will further degrade this remaining agent. Third, even if the deposited agent were to be reaerosolized, the resulting airborne concentration would be only about one percent of the deposited agent. This quantity is well below the amount needed for an infective dose and hence is insufficient to present a hazard. Despite this, there is likely to be a perceived concern that there are some micro-organisms from the attack remaining on surfaces. Therefore, authorities may decide to decontaminate surfaces with substances, like formaldehyde, that can kill micro-organisms.

Countries of Proliferation Concern

Partly because of the availability of technology and material, a number of countries and sub-national actors have perhaps managed to acquire biological weapons. The British government stated

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[29] Karl Lowe et al., "Potential Values of a Simple BW Protective Mask," IDA Paper P-3077 (Alexandria, VA: Institute for Defense Analyses, September 1995); Richard Danzig, "Biological Warfare: A Nation at Risk—A Time to Act," *Strategic Forum*, no. 58, National Defense University, Institute for National Strategic Studies (Ft. McNair, Washington, D.C.: January 1996): 1–4.

[30] David R. Franz et al., "Clinical Recognition and Management of Patients Exposed to Biological Warfare Agents, *Journal of the American Medical Association* 278, no. 5 (6 August 1997): 399–411.

in 1992 that "about ten countries are assessed as having biological weapons programmes."[31] American officials have issued repeated warnings in the past few years that "at least 20 countries have or may be developing nuclear, chemical, biological weapons and ballistic missile systems to deliver them."[32] Great Britain has indicated that proliferation concerns, including biological weapons programs, "are largely concentrated in three regions: the Middle East, South Asia, and North Korea."[33] American intelligence officials describe the biological weapons programs of two great powers, Russia and China, as being in the process of change and have identified Iran, Iraq, North Korea, and Libya as rogue nations seeking to acquire weapons of mass destruction.[34] Aside from such general characterizations of the threat, relatively few explicit details are offered about which countries have biological weapons and how advanced their programs may be. A handful of public sources, however, present more details about the countries of proliferation concern listed in Table 2.

Table 2: Biological Weapons Programs: Countries of Proliferation Concern.

! China	! Libya
! Egypt	! North Korea
! Israel	! Russia
! Iran	! Syria
! Iraq	! Taiwan

Iraq

The United Nations Special Commission (UNSCOM) mission to destroy Iraq's weapons of mass destruction, including the Iraqi biological weapons program, has been fraught with difficulty from the outset. When responding to United Nations (UN) Security Council resolution 687 (1991), which requires elimination of Iraq's weapons of mass destruction as a condition of the cease-fire, Iraq said in April 1991 that it "does not possess any biological weapons or related items."[35] After its first inspection of Iraqi biological weapons facilities, UNSCOM announced that Iraq had declared

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[31] Her Majesty's Stationary Office, "Statement of the Defense Estimates 1992," London, July 1992, 7.

[32] See, for example, Senate Select Committee on Intelligence, *Worldwide Threat Assessment Brief,* 22.

[33] Her Majesty's Stationary Office, "Statement on the Defense Estimates 1995: Stable Forces in a Strong Britain," London, May 1995, 7.

[34] Senate Select Committee on Intelligence, *Worldwide Threat Assessment Brief*, 22.

[35] Letter to Secretary-General from Ambassador Abdul Amir Al-Anbari of Iraq, dated 18 April 1991, as quoted in Stephen Black, "The UN Special Commission and CBW Verification," *Chemical Weapons Convention Bulletin*, no. 31 (June 1996): 1, 7–8.

offensive and defensive research on *Clostridium botulinum*, *Clostridium perfringens*, and *bacillus anthracis*. UNSCOM added that Iraq's Salman Pak facility had the capability to research, produce, test, and store biological agents.[36] Iraq quickly backtracked on some of these admissions, but UNSCOM maintained that it had collected "conclusive evidence that Iraq was engaged in an advanced military biological research programme." However, Iraq claimed to have terminated the program in August 1990 and destroyed all stockpiles of agent.[37]

From the outset, UNSCOM and Iraq have engaged in a deadly serious game of cat-and-mouse. Iraq repeatedly purported to have submitted full, final, and complete disclosures about its biological weapons program and continued to thwart the inspectors. UNSCOM reported time and again on Iraq's obfuscation and lack of cooperation.[38] Iraq eventually acknowledged an offensive biological weapons program—admitting production, but denying weaponization—in the Summer of 1995. Further developments occurred when Gen. Hussein Kamel Hassan left Baghdad on 7 August 1995. Hassan, the son-in-law of Iraqi leader Saddam Hussein, had been a key figure in Iraq's biological weapons program. Following his departure from Iraq, the Iraqi authorities invited the executive chairman of UNSCOM to visit a chicken farm originally owned by Hassan. Over 145 boxes of documents on Iraq's nuclear, biological, and chemical weapons programs were recovered from Hassan's farm.[39]

The Iraqi biological warfare program disclosed to UNSCOM is said to have begun in 1975 and continued until early January 1991. Iraqi scientists worked with anthrax, botulinum toxin, *Clostridium perfringens* (gas gangrene), aflatoxin, trichothecene mycotoxin, wheat cover smut, ricin, and viruses such as the camel pox virus.[40] Iraq produced 19,000 liters of botulinum toxin; 8,500 liters of anthrax; and 2,200 liters of aflatoxin. Large-scale weaponization of biological agents is reported to have begun in December 1990. For delivery systems, the Iraqis developed spray tanks, remotely piloted vehicles, aerial bombs, rockets, and missiles. Over 160 aerial bombs and 25 Al Hussein warheads were filled with anthrax, botulinum toxin, and aflatoxin. In early January 1991, these warheads and bombs were deployed to four locations and field commanders were delegated the authority to launch them during the Gulf War. Iraq also had an indigenous missile development

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[36] United Nations, "Inspection Team Reports on Iraq's BW Capacity," UN Press Release, 14 August 1991.

[37] In its first report, UNSCOM stated that "No evidence of weaponization has been found." Iraq claimed to have begun the program in mid-1986. United Nations, *The United Nations and the Iraq-Kuwait Conflict 1990–1996*, Blue Books Series, vol. IX, Document 92-S/23165, 1996, 345.

[38] For example, UNSCOM stated in 1993 that "The information so far provided is tailored to what the Iraqi authorities consider the Special Commission to know already, rather than constituting a frank and open disclosure of all the true facts." See United Nations Document 165-S/25977, 21 June 1993, 572. See also, UN Documents 200-S/1994/1422 and S/1994/1422/Add. 1, 15 December 1994, 699; Document 210-S/1995/494, 20 June 1995, 758.

[39] United Nations, Document 214-S/1995/864, 11 October 1995, 771.

[40] The reasons for the Iraqi work on aflatoxin, which is a carcinogen, are not yet evident. This situation illustrates the importance of Iraq providing UNSCOM with a complete and full account of its past biological weapons program and its objectives.

program that was working on the design of missile systems capable of delivering chemical or biological warheads to the range of 3,000 kilometers.[41]

UNSCOM continues to investigate the Iraqi biological weapons program, attempting to confirm whether Iraqi indeed destroyed its biological warfare stocks, and Iraq persists in hindering UNSCOM's efforts.[42] According to UNSCOM, Iraq's September 1997 full, final, and complete disclosure failed "to give a remotely credible account of Iraq's biological warfare programme."[43] In the Fall of 1997, another show-down between Iraq and the United Nations took shape, precipitated by Iraq's's refusal to accept Americans as UNSCOM inspectors and his threats to shoot down the US U-2 surveillance aircraft flying missions on behalf of UNSCOM.[44] While UNSCOM has made noteworthy progress in shutting down Iraq's weapons of mass destruction programs, more work obviously remains to be done to eliminate Iraq's biological weapons capability.

Russia

As revealed by Yeltsin, the Soviet Union maintained an offensive biological weapons program from 1972 until 1992. Yeltsin signed a decree in April 1992 to terminate this program.[45] In September 1992, the Russian government stated that it had terminated its offensive research, dismantled experimental biological agent production lines, closed a biological weapons testing facility, cut the number of personnel in the program by fifty percent and the funding by thirty percent, and submitted information about its biological weapons program to the UN.[46]

According to its declaration, Russia maintained an offensive research and development program until March 1992 that worked with anthrax, tularemia, brucellosis, plague, Venezuelan equine encephalitis, typhus, and Q-fever. With respect to toxins, Russia claimed that the only natural

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[41] United Nations, Document 214-S/1995/864, 11 October 1995, 771.

[42] Even though Iraq's June 1996 declaration was 622 pages long, UNSCOM labeled the biological component of this declaration was "not credible. Major sections are incomplete, inaccurate or unsubstantiated. Expert estimates of production quantities of biological weapons agents, either by equipment capacity or by consumption of growth media, would far exceed declared amounts." UN Security Council, *Report by the Secretary-General on the Activities of the Special Commission Established by the Secretary-General Pursuant to Paragraph 9 (b) (I) of Resolution 687 (1991)*, Document S/1996/848, 11 October 1996. See also United Nations, "Note by the Secretary-General," Document S/1996/258, 11 April 1996.

[43] UN Security Council, "Note by the Secretary-General," Document S/1997/774, 6 October 1997, 19.

[44] John M. Goshko, "Inspections: U.N. Leader May Pull Mission From Iraq," *Washington Post*, 7 November 1997, A3; James Bennet, "Clinton Urges Strong U.N. Action on Iraq," *New York Times*, 10 November 1997, A1.

[45] This decree stated: "The development and implementation of biological programmes in breach of the Biological and Toxin Weapons Convention is not permitted on the territory of the Russian Federation." President Boris Yeltsin, Russian Federation Decree No. 390, Moscow, 11 April 1992.

[46] Information was provided under a confidence-building measure, agreed at the Third Review Conference of the BWC in 1991, requiring declaration of past offensive and/or defensive research and development programs. Richard Boucher, US Department of State, "Joint US/UK/Russian Statement on Biological Weapons," Press Release, Office of Public Affairs (Washington, D.C.: 14 September 1992).

toxin studied in its program was botulinum toxin.[47] Apparently, Russian scientists developed a genetically manipulated strain of the plague.[48] Russia provided little information about delivery systems, other than a statement that "military-technical evaluation of experimental specimens of biological formulations loaded into mock-ups of airborne and rocket-borne biological weapons and atomizing equipment were performed" as part of its program.[49]

Little information is publicly available on the size of the former Soviet biological weapons program, although statements from Western governments make it evident that this program was indeed large.[50] In addition to Ministry of Defense facilities, the Soviet Union maintained an extensive network of nominally civilian research institutes know as Biopreparat. Created in 1973, Biopreparat served as a cover for the USSR's biological weapons program. Biopreparat was a huge organization, employing more than 25,000 people at 18 or more research and development facilities, including six mothballed production plants and a major storage complex in Siberia.[51]

In information submitted to the UN in 1987, the Soviet Union declared some five institutes as being under Ministry of Defense control—Leningrad (now St. Petersburg), Kirov, Sverdlovsk (now Ekaterinberg), Zagorsk (now Sergiyev-Prosad), and Aralsk. Russia's 1992 declaration about this program referred to Sverdlovsk, Kirov, and Zagorsk, as well as to Kol'tsovo, Obolensk, Chekhov, Leningrad, and an experimental facility on Vozrozdheniya Island in the Aral Sea. The UN confidence-building measures require declaration only about research and development programs, so these declarations could exclude production or other facilities that might also be associated with the Soviet offensive program. The 1992 declaration noted that at the beginning of the 1970s, the USSR decided to accelerate the development of molecular biology, genetics, and genetic engineering and to utilize the achievements in these fields to benefit the national economy. Consequently, the Soviet government began to establish scientific and study bases under the auspices of the USSR Academy of Sciences, the USSR Academy of Medical Sciences, the Ministry of Health, Glavmikrobioprom, and other ministries and departments. Given the size of this biological weapons

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[47] Boucher, "Joint US/UK/Russian Statement on Biological Weapons."

[48] Mark Urban, "The Cold War's Deadliest Secret," *Spectator* (21 January 1993): 9–10; John Barry, "Planning a Plague," *Newsweek* 121, no. 5 (1 February 1993): 20–2; James Adams, "The Weapon of Special Designation," in *The New Spies; Exploring the Frontiers of Espionage* (London: Hutchinson, 1994): 270–83.

[49] Boucher, "Joint US/UK/Russian Statement on Biological Weapons."

[50] In November 1996, British Minister of State David Davis said: "The existence of a massive offensive biological weapons programme conducted illegally for years in the Soviet Union has also recently come to light." Statement of David Davis, Fourth Review Conference, Geneva, 26 November 1996. Also, the US government reported that "the Soviet offensive [biological weapons] program was massive, and included production, weaponization, and stockpiling." US Arms Control and Disarmament Agency, *Adherence to and Compliance with Arms Control Agreements: President's Report to Congress on Soviet Noncompliance with Arms Control Agreements* (Washington, D.C.: Government Printing Office, 14 January 1993): 14.

[51] Lester C. Caudell III, "The Biological Warfare Threat," in *Medical Aspects of Chemical and Biological Warfare: Textbook of Military Medicine,* 451–66.

program, there is clearly a need for greater transparency about this program, its facilities, and its activities.[52]

In 1992, Russia, Great Britain, and the United States initiated a trilateral process of data exchanges and sites visits to foster more openness and transparency regarding the former Soviet biological weapons program. Russia agreed to provide, on request, up-to-date data about the dismantlement of its biological weapons facilities and to clarify information provided to the UN. For a variety of reasons, progress under this trilateral arrangement has been slow. Therefore, Washington has stated that the trilateral process "has not resolved all US concerns" about Russia's program.[53]

China

China, a member of the BWC since 1984, is believed to have maintained an offensive biological weapons program throughout most of the 1980s that included "development, production, stockpiling or other acquisition or maintenance of biological warfare agents."[54] Within the US intelligence community there is concern that China may have revived and possibly expanded its offensive biological weapons program in recent years. The concern is based partly on evidence that China is pursuing biological research at two ostensibly civilian-run research centers controlled by the Chinese military. The research centers were known to have been previously involved in the production and storage of biological weapons. Moreover, in 1991 one of the suspected biological centers was expanded. Information that China has provided to the UN for the purposes of confidence building have not resolved US concerns about this program, and there are strong indications that China probably maintains an offensive program.[55]

Syria

Syria has signed but not ratified the BWC. Israel has expressed concerns that Syria has biological agents for contaminating drinking water. However, no reliable information is available about the existence of biological weapons in Syria or a directed program for the creation of an

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[52] For more detail, see Milton Leitenberg, "Biological Weapons Arms Control," *Contemporary Security Policy* 17, no. 1 (April 1996): 1–79; Milton Leitenberg, "The Conversion of Biological Research and Development Facilities to Peaceful Uses," in *Control of Dual-Threat Agents: The Vaccines for Peace Programme*, Erhard Geissler and John P. Woodall, eds., Stockholm International Peace Research Institute, Chemical and Biological Warfare Studies, Report No. 15 (London: Oxford University Press, 1994): 77–105.

[53] US Arms Control and Disarmament Agency, *Threat Control Through Arms Control* (Washington, D.C.: Government Printing Office, 26 July 1996): 67; Boucher, "Joint US/UK/Russian Statement on Biological Weapons."

[54] US Arms Control and Disarmament Agency, *Adherence to and Compliance with Arms Control Agreements: 1996 Annual Report to Congress* (Washington, D.C.: Government Printing Office, 26 July 1996): 6.

[55] R. Jeffrey Smith, "China May Have Revived Germ Weapons Program, U.S. Officials Say," *Washington Post*, 24 February 1993, A22; US Arms Control and Disarmament Agency, *Adherence to and Compliance with Arms Control Agreements*, 1996, 6.

offensive potential in the biological realm. Syria nonetheless remains among those countries that the United States believes to be developing an offensive biological warfare capability.[56]

Iran

Iran, which joined the CWC on 3 November 1997, has been a member of the BWC since 1973. Iran has the technical infrastructure to support a significant biological warfare program and needs little foreign assistance. Nonetheless, Western countries have noted attempts by Iranian representatives to buy, unofficially, technology and biological materials used specifically for the production of biological weapons, in particular mycotoxin. Iran conducts legitimate biomedical research at various institutes, which are suspected of involvement in this biological weapons program. Iran has not provided the UN with any confidence-building measures data on its biotechnical activities.[57] The Iranian biological weapons program has been embedded within Iran's extensive biotechnology and pharmaceutical industries so as to obscure its activities. The Iranian military has used medical, education, and scientific research organizations for many aspects of biological agent procurement, research, and production. The US finding is that Iran probably has produced biological agents and apparently has weaponized a small quantity of those agents.[58]

Egypt

Egypt, a signatory but not a member of the BWC, has a program of military-applied research in the area of biological weapons dating back to the 1960s. In the 1970s, President Anwar Sadat confirmed that a stockpile of biological agents was stored in refrigerated facilities on Egyptian soil. Egypt has been studying various toxins, and techniques for their production and refinement are presently being developed by a national research center. No publicly available data to date indicates that Egypt has produced its own biological agents.[59]

Egyptian researchers have been cooperating with US military and civilian laboratories in areas related to biological defense research, specifically those based on highly pathogenic micro-organisms and dangerous vectors. The level of bilateral cooperation is such that the US Navy has a military-medical laboratory in Egypt where research is focused on defenses against particularly dangerous infectious diseases. This laboratory is recognized as one of the region's leading medical-biological centers, equipped with the latest equipment and staffed with highly qualified American

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[56] US Congress, Senate Committee on Governmental Affairs, *Proliferation Threats of the 1990's*, 103rd Cong., 1st sess., S. Hrg 103–208 (Washington, D.C.: Government Printing Office, 1995): 103.

[57] Senate Committee on Governmental Affairs, *Proliferation Threats of the 1990's*: 98; US Arms Control and Disarmament Agency, *Adherence to and Compliance with Arms Control Agreements*, 1996, 6.

[58] US Arms Control and Disarmament Agency, *Adherence to and Compliance with Arms Control Agreements*, 1996, 6.

[59] Senate Committee on Governmental Affairs, *Proliferation Threats of the 1990's*, 93.

specialists. The research conducted by this laboratory is highly classified.[60] The US assessment is that it remains likely that Egypt continues to maintain a capability to conduct biological warfare.[61]

Libya

A great deal has been written about Libya's chemical weapons program, particularly the "pharmaceutical" facility at Rabta and the cavernous underground production site at Tarhunah.[62] Although Libya is thought to be attempting to weaponize biological agents, less is known about Libya's biological weapons program. While Libya has been a member of the BWC since 1972, there is information indicating that it is engaged in initial testing of biological weapons. Presently, Libyans are expressing interest in information on work overseas involving biological agents. In contacts with representatives of other Arab countries, Libyan specialists are displaying a willingness to fund joint biological programs, including ones of a military-applied nature, provided they are not undertaken on Libyan territory. Libya has also failed to submit a confidence-building data declaration to the UN.[63] According to the US assessment, Libya is seeking to acquire the capability to develop and produce biological agents.[64]

Taiwan

Taiwan, which joined the BWC in 1973, is another country suspected of proliferating both chemical and biological weapons. Taiwan is said not to have biological weapons, but it continues to manifest an active interest in conducting biological research of a military-applied nature. Taiwan has a significant scientific and technical base in microbiology and a large number of skilled biotechnology specialists, mostly trained in America and Western Europe. Taiwan is moving to upgrade its biotechnology sector, which makes wide use of technologies basic to the production of biological weapons.[65]

Taiwan participates internationally in scientific and technical cooperation of biology, and engages actively in industrial cooperation with the United States, Japan, France, and other Western countries. Also, various joint biomedical programs are underway in such areas as immunology, genetic engineering, and tropical medicine. Taiwan's military biological centers train personnel in medical and biological specialties. Sufficient evidence to determine if Taiwan is producing or weaponizing biological agents does not exist, but Taiwan's advanced scientific research and industrial base would enable the country to produce biological weapons with relative ease.[66]

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[60] Ibid., 93.

[61] US Arms Control and Disarmament Agency, *Adherence to and Compliance with Arms Control Agreements*, 1996, 6.

[62] Office of Technology Assessment, *Technologies Underlying Weapons of Mass Destruction*, 42; R. Jeffrey Smith, "Germ, Nuclear Arms Top Pentagon's List of Threats," *Washington Post*, 12 April 1996, A1.

[63] Senate Committee on Governmental Affairs, *Proliferation Threats of the 1990's*, 100.

[64] US Arms Control and Disarmament Agency, *Adherence to and Compliance with Arms Control Agreements*, 1996, 6.

[65] Ibid., 104.

[66] Ibid.

North Korea

North Korea, a member of the BWC since 1987, is one of the most closed and heavily militarized societies on Earth. During the early 1960s, North Korea initiated an offensive biological warfare program. Presently, North Korea is engaged in applied military-biological research at universities, medical institutes, and specialized research centers. Research being conducted at these centers involves pathogens for malignant anthrax, cholera, and bubonic plague. Evidence indicates that North Korea has been testing biological weapons on its island territories.[67]

Israel

As they are about many issues associated with a weapons of mass destruction capability, Israeli officials have been tight-lipped about any national biological weapons program. An Israeli biological weapons program is likely to be patterned, however, after those formerly maintained by the United States and the former Soviet Union. In other words, the agents likely to be involved in an Israeli program are anthrax, botulinum toxin, tularemia, plague, Venezuelan equine encephalitis, and Q-fever. Similarly, Israeli delivery systems are likely to mirror those developed by the United States, namely spray systems or missile warheads and submunitions.[68] Israel is one of the few states that has not signed the BWC.

Dramatic Changes in the Field of Biotechnology

In the past two decades, the science and business of biotechnology has burgeoned. Advances in microbiology, genetic engineering, and biotechnology have already produced immense benefits for the health of people and animals worldwide. The biotechnology industry offers the prospect of more new and improved diagnostic techniques and medical countermeasures to an increasing range of naturally occurring diseases. In order to counter diseases, the ways in which they attack target populations must be understood. As scientists dissect how diseases spread and work, they also gain an understanding of how these very diseases could be used for military purposes. Those working in the biotechnology industry are thus constantly dealing with dual-purpose materials and concepts that could be wielded to help or to devastate mankind. Increased knowledge about diseases and the availability of advanced technology have made biological weapons a more attractive option for governments seeking to acquire weapons of mass destruction. Moreover, the modernization of biotechnology has made it much easier to produce biological materials and to modify these materials to enhance their effects.

The modern biotechnology industry, based on molecular biology, has its roots in prehistoric times (e.g., brewing, baking, cheese-making). This industry developed significantly as scientific knowledge grew in the second half of the last century, and again from the mid-1900s onwards as

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[67] Secretary of Defense, *Proliferation: Threat and Response*, Office of the Secretary of Defense (Washington, D.C.: US Department of Defense, April 1996): 7. Senate Committee on Governmental Affairs, *Proliferation Threats of the 1990's*, 99.

[68] Office of Technology Assessment, *Proliferation of Weapons of Mass Destruction: Assessing the Risks*, 65, 82.

more sophisticated processes and quality controls were developed to make antibiotics, vaccines, and other medicines.[69] In particular, the medical products of the biotechnology industry have been of high value. While emerging applications of biotechnology in the chemical, energy, and waste treatment sectors may not turn out to be commercially successful, biotechnology may have a significant impact on the agro-food sector. In the view of some experts, a new "Green Revolution" is very possible.[70] Indeed, experts reasonably estimate that biotechnology will become "a major basis for new investment and growth" in the early decades of the next century.[71] Past technological/industrial revolutions have flourished because of rapid interaction between scientific and technological developments. Three other technological/industrial revolutions—in information technology, materials science, and neuroscience—are currently running alongside and interacting with the advances being made in biotechnology. The potential relevance of these scientific revolutions to the BWC can be expected to accelerate over the coming decades.[72]

Despite the well-publicized failures of a few products during trials, the biotechnology industry continues to grow spectacularly in the developed world. One way to track the growth of the industry is via its sales. For US research-based pharmaceutical companies, sales at home and abroad increased from $4.5 billion in 1970 to $11.7 billion in 1980. By 1990, the sales of US companies had reached $38.6 billion and are estimated at over $66 billion for 1997.[73] In addition, a recent report stated:

> In the past decade, the market value of the top ten US biotechnology companies has increased more than four times, from $6.2 bn in 1986 to $26.5 bn in 1996. . . .The London Stock Exchange quoted that the market capitalization of bioscience companies traded on this exchange shot up from £1 billion to £3.1 billion during 1995. Much of the reason for this growth was the London market's response to certain clinical milestones being achieved by the key European [companies].[74]

This report suggested that about 50 successful biotechnology products had been marketed in the last decade, but over 450 were under development, with "more than 120 in phase III clinical trials and

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[69] D. G. Springham, "The Established Industries," in *Biotechnology: The Science and the Business,"* V. Moss and R. Cape, eds. (Switzerland: Harwood Academic, 1994).

[70] M. Sharp, "Applications of Biotechnology: An Overview," in *The Biotechnology Revolution*, M. Fransman et al., eds. (Oxford: Blackwell, 1995): 163–73.

[71] C. Freeman, "Technological Revolutions: Historical Analogies," in *The Biological Revolution*, 7–24.

[72] M. R. Dando, "New Developments in Biotechnology and their Impact on Biological Warfare," in O. Thraenert, ed., *Enhancing the Biological Weapons Convention* (Bonn: J. H. W. Dietz Verlag, 1996): 21–56.

[73] See Table 11 in *PhRMA Annual Survey: 1997* (Washington, D.C.: Pharmaceutical Research and Manufacturers of America, 1997): 66.

[74] K. B. Lee and L. S. Hu, "Biotechnology: Past, Present, Future," *Chemistry and Industry* (6 May 1996): 334–7.

beyond in the US."[75] The young biotechnology companies have also begun to pursue a variety of strategies to ensure their long-term sustainability, including links with major pharmaceutical giants.

The growth of the biotechnology industry—in both the size and the number of companies—has obvious implications for the BWC protocol. More and larger companies leads to the employment of more dual-use equipment and more specialists trained in state-of-the-art skills that can be used for peaceful purposes or misused covert biological warfare programs. Thus, the compliance regime needs to be designed to cope with the expansion of this industry.

Novel technologies that have been identified in the biotechnology area include the sequencing of genes and proteins; genetic engineering; fused cell techniques in which two cells are fused to produce new cells; protein engineering altering the structure and properties of proteins; and fermentation and cell culture enabling the growth of large amounts of microbial or animal or plant cells.[76] These advances mean that there is now a much greater understanding of micro-organisms and of their interactions with other living systems, namely man, animals, and plants. These understandings offer great advances for the benefit of mankind, yet it is now possible to engineer biological agents that defeat current vaccines. Therefore, concerns about the possible misuse of human genome information led the Fourth Review Conference to confirm that the use of "any applications resulting from genome studies" for biological warfare purposes are covered by the prohibition in Article I of the BWC.[77]

Conclusions

Several factors make biological weapons attractive to countries seeking a weapon of mass destruction. Biological weapons are not costly and they are flexible in that they can be used to attack plants, animals, or humans. Furthermore, both incapacitating or lethal agents can be selected. A biological weapons program can be hidden amidst dual-purpose industries that work with microbiology and biotechnology, allowing for a rapid breakout capability. With the growth of the biotechnology industry, materials and technology that may be misused for prohibited biological weapons purposes are more widely available than ever. Recent technological and scientific advances also make it easier for a proliferator to produce sufficient quantities of biological agents. Finally, biological weapons offer the aggressor potential for deniability, especially if the agent used occurs naturally in the state attacked. All of these factors increase the prospects that the risk of biological warfare may be greater today than in the past.

Consequently, efforts to reduce disease, whether of natural or deliberate origin, should be amongst the highest priorities on the agendas of governments and industry worldwide. A number of steps that should be taken to confront the spread of biological weapons. First, protective measures against biological warfare need to be strengthened, thereby making the acquisition of biological

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[75] Ibid., 334.

[76] Malcolm R. Dando, *Biological Warfare in the 21st Century* (London: Brassey's, 1994): 101.

[77] United Nations, *Final Declaration of the Fourth Review Conference*, Document BWC/CONF.IV/9, 13.

weapons an unattractive option. Nations that invest in more robust passive and active defense measures can decrease their vulnerability to biological weapons attack in numerous ways.[78]

Second, domestic laws against biological weapons should be enacted, criminalizing the misuse of biological materials. Article IV of the BWC requires the passage of national laws, but Great Britain is one of only a relatively small contingent of countries that have illegalized a wide range of activities associated with biological weapons.[79] Other states should take similar action to deter the terrorist acquisition and use of biological weapons within their borders. The current negotiations to strengthen the BWC should seize the opportunity to require, as the CWC does, that all participating states implement penal legislation. In the longer term, attention should be given to criminalizing any biological weapons work carried out by individuals anywhere. Accordingly, anyone who uses or knowingly aides in the production, acquisition, or use of biological weapons would have committed an illegal act, subject to penalties under international law.[80] In addition, states should give serious consideration to buttressing their laws to control biological materials in ways that enhance the safety of the community and the environment.

Perhaps most importantly, the BWC should be strengthened through a legally binding instrument comprising declarations of relevant activities, routine on-site inspections, and challenge inspections. Completion of a verification protocol for the BWC should be achievable within a fairly short time frame. After all, nothing new needs to be invented for the BWC's verification regime: All of the measures required are already incorporated in one or another of the existing agreed arms control treaties.[81] As the international community works to achieve this objective, it should also make a significant effort to encourage universal adherence with this important treaty.

Additional steps that are needed to diminish the threat of biological warfare are the widespread adoption of broad export controls of pathogens and dual-purpose equipment and a determined national and international response to violations of the BWC.[82] All of these measures

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[78] Graham S. Pearson, "Chemical and Biological Defense: An Essential National Security Requirement," *RUSI Journal* 140, no. 4 (August 1995): 20–7. For other commentaries on the importance of biological weapons defenses, see House of Commons, "Implementation of Lessons Learned from Operation Granby" Fifth Report, Defense Committee, Her Majesty's Stationary Office, London, 25 May 1994, ix–xiii; Swedish National Defense Research Establishment, "A Briefing Book on Biological Weapons" (Stockholm: 1995): 2–59; Danzig, "Biological Warfare: A Nation at Risk," 1–4.

[79] The BWC mandates that each participating state "shall, in accordance with its constitutional processes, take any necessary measures to prohibit and prevent the development, production, stockpiling, acquisition or retention of the agents, toxins, weapons, equipment and means of delivery specified in Article I of the Convention, within the territory of such State, under its jurisdiction or under its control anywhere." For the British law, which carries a life imprisonment penalty, see the Biological Weapons Act of 1974, Her Majesty's Stationary Office, Chapter 6.

[80] "Criminalizing BW," *Chemical Weapons Convention Bulletin*, no. 31 (March 1996): 1.

[81] Gordon K. Vachon, "Verifying the Biological and Toxin Weapons Convention: The Role of Visits and Inspections," in *Enhancing the Biological Weapons Convention*, 147–53.

[82] Graham S. Pearson, "Prospects for Chemical and Biological Arms Control: The Web of Deterrence," *Washington Quarterly* 16, no. 2 (Spring 1993): 145–62.

are mutually reinforcing, and no one element alone can sufficiently cope with the biological weapons threat.[83] Governments, collectively and individually, have a great deal of work to do if they are to counter and defeat natural or deliberate outbreaks of disease.

[83] The North Atlantic Treaty Organization has adopted this strategy of using multiple, reinforcing tools to confront the proliferation of weapons of mass destruction. North Atlantic Treaty Organization, "NATO's Response to Proliferation of Weapons of Mass Destruction," Press Release 95(124), Brussels, 20 November 1995.

Industry's Role, Concerns, and Interests in the Negotiation of a BWC Compliance Protocol

Gillian R. Woollett, **M.A., D. Phil.**

The companies of the Pharmaceutical Research and Manufacturers of America (PhRMA) support reducing the threat of biological weapons. PhRMA, described in more detail in Box 1, is a trade association representing companies that develop over ninety percent of the new medicines used around the globe. For the past couple of years, PhRMA has been working with the US and other governments, as well as with colleagues in industry, to create a compliance protocol to the 1972 Biological Weapons Convention (BWC) that is based on sound and rational science. The research-based pharmaceutical industry is only too aware of the challenges in preparing medicines to cure devastating infectious diseases, and this industry is a strong proponent of the prevention of biological weapons use. A good compliance protocol will give legitimate confidence to the international community that the threat from biological weapons is reduced and, as such, will represent a valuable contribution to meaningful arms control worldwide. The technical expertise of PhRMA companies is available to facilitate this process wherever the negotiators need assistance.

An oft-heard refrain is that the pharmaceutical industry has nothing to fear from a BWC compliance protocol that is devised to find treaty violators. While no PhRMA company is making biological weapons, the industry recognizes that many of the technologies that it uses to develop new drugs and biologics could be used to make biological agents with little or no modification to equipment or processes. Of necessity, the pharmaceutical industry uses technology in a highly sophisticated manner, with processes designed to enhance the purity, consistency, and safety of medical products.

These dual-capability technologies, which include the rapidly emerging biotechnologies, are not unique to the pharmaceutical industry. To varying degrees, these technologies are found in such industries as brewing, industrial fuel manufacturing, cheese and yogurt production, baking, and also extensively in academic and government research laboratories. The production capacity of these other industries and establishments vastly exceeds that of the pharmaceutical industry. Capability is a legitimate requirement for the manufacture of biological weapons. However, PhRMA contends that this capability is so widely spread throughout many industries and other legitimate endeavors that it does not make sense to over-emphasize, and thereby over-implicate, the capability of the pharmaceutical industry in a new compliance protocol. In other words, capability will be necessary, but not sufficient, to identify an illegal biological weapons program.

The pharmaceutical industry in America and in the developed world is a very tightly regulated and licensed industry. The US Food and Drug Administration (FDA), which oversees the industry to ensure that the safety and efficacy of US-produced medicines, monitors pharmaceutical plants thoroughly and continuously. A company that obtains and maintains FDA approval makes a significant investment in order to produce medicines to US standards. FDA approval is increasingly recognized internationally, particularly by those countries unable to assemble a comparable drug-approval process of their own. These circumstances underscore a major flaw in the hypothetical cheating scenario wherein biological agents would be covertly made at an FDA-licensed pharmaceutical facility. Any facility embarking on such a foolhardy project already risks exposure during the FDA's routine site inspections. This risk of exposure under domestic regulation may not always apply in other countries, but in countries where the pharmaceutical industries are already heavily regulated, it represents a further reason for those negotiating the BWC protocol to direct enforcement mechanisms towards facilities that are the most likely offenders.

Box 1: An Overview of PhRMA.

PhRMA is the leading trade group of the research-based, ethical pharmaceutical industry in America. A list of PhRMA's members can be found in Appendix 2. PhRMA represents the pharmaceutical companies that discover, develop, and manufacture prescription drugs and biologics. PhRMA companies develop over ninety percent of the new medicines worldwide. PhRMA's mission is to facilitate the industry's ability to successfully meet its goal of discovering, developing and bringing to market medicines to improve human health, patient satisfaction, and the quality of life around the world, as well as to reduce the overall cost of health care. Hence, PhRMA does represent the pharmaceutical industry and its contribution to the debate on a compliance protocol to the BWC.

While many PhRMA companies are American, many are also multi-national and have their headquarters overseas. The pharmaceutical industry is increasingly made up of large companies with a global presence for their research and development activities, for product manufacture, and also for their ultimate retail markets. The interests of the US pharmaceutical industry reflect similar opinions and concerns of sister companies in Europe and elsewhere.

As Box 2 describes, the pharmaceutical industry's investment in research and development (R&D) is critical to the development of new medicines. On average, a new medicine takes 12 to 15 years to develop at a total cost of $350 to 500 million per medicinal product.[1] To maintain the industry's ability to produce new drugs and biologics, individual companies must be able to sustain investment and build on their research results over decades. For every 5,000 to 10,000 compounds that are discovered and initially investigated, only one will make it to the marketplace

[1] These averages are accurate for medicines that are already on the market, which entered clinical trials in the late 1970s. Current regulatory and research practices may well cause increases in cost and time of development.

as an effective drug or biologic. Of these tested and available products, only one in five will make a positive return on its R&D investment.

When a drug or biologic moves from the development phase into production, the research on which that drug is based becomes even more valuable to a competitor. Research results do not become obsolete within a few years, but form the foundation for future R&D and remain within companies' research organizations indefinitely as confidential or proprietary business information (CBI). Therefore, the US pharmaceutical industry has an enormous cumulative level of investment in legitimate CBI. Beyond the industry's abhorrence of biological weapons, the potential for loss of this CBI is the single greatest and most conspicuous reason that PhRMA is interested in the development of a BWC protocol.

In contrast to the rest of the world, the US pharmaceutical industry is in a unique position for the potential loss of CBI under a BWC compliance protocol. The BWC's monitoring regime must, therefore, be developed cautiously and carefully. Badly conceived, it represents an opportunity for the other countries to tap inappropriately into a very valuable pool of legitimately proprietary information. Concerns over the potential loss of CBI are real, not theoretical. During the past several years, a number of US corporations have experienced theft of their biotechnological information and organisms. The annual sales for the products compromised by this corporate espionage exceed three billion dollars.

At least as important, but more difficult to define in financial terms, is the potential negative impact of having BWC monitoring activities unfairly tarnish the reputations of PhRMA companies with unfounded suspicions that they are making biological agents. In the past, consumers have reacted severely to incidents of product tampering, and the incorrect notion that PhRMA companies might somehow be involved in a biological warfare program would devastate patient confidence in the industry's life-saving and life-enhancing medications. In some respects, this misguided guilt-by-association could be more detrimental to public health than the very biological weapons the BWC seeks to eliminate. Finally, PhRMA hopes that any new BWC protocol will not be too onerous in terms of regulatory or reporting burdens imposed on its companies.

The Pharmaceutical Industry's Role in the BWC Negotiations

Neither PhRMA nor its member companies should be perceived as drivers in the negotiation of a BWC protocol. Although PhRMA does not formally have a seat at the negotiating table, PhRMA appreciates the need for a BWC protocol because its member companies aim to save life, not destroy it. Moreover, PhRMA companies employ over a quarter of a million US citizens who find the idea of biological weapons inimical to the development of ethical pharmaceuticals. Therefore, on 16 May 1996, PhRMA's Board adopted the following statement of principle on the BWC:

Box 2: From Laboratory to Market: How the Pharmaceutical Industry Works.

The pharmaceutical advances that have vastly improved life expectancy and health since World War II have been powered by an increasing commitment to research into new drugs and biologics. PhRMA companies annually invest a tremendous amount of money in the development of new medicines. As shown in Chart 1, PhRMA members will expend an estimated $18.9 billion in research and development (R&D) in 1997. These expenditures include $15.1 billion spent within the United States by both US and foreign-owned firms, plus an additional $3.8 billion spent abroad by US-owned firms. Since 1990, research-based companies have more than doubled their R&D expenditures.

Over the last two decades, the percentage of domestic sales revenue allocated to R&D has increased from eleven percent to over twenty-one percent. In 1995, the US chemical manufacturing industry reinvested about 4.7 percent of its sales from chemical and allied products into R&D.† Across all US industries, the average R&D to sales ratio is less than four percent. Pharmaceutical manufacturers invest a higher percentage of sales in R&D than such high-technology industries as electronics, aerospace, office equipment (including computers), and automobiles.‡

The US pharmaceutical industry leads the world in the development of important medicines. Of the 152 major global drugs developed between 1975 and 1994, almost half were of US origin. The second leading contender, Great Britain, developed fourteen percent of the

† This figure is among the data compiled by the National Foundation and presented in the *1997 US Chemical Industry Statistical Handbook* (Washington D.C.: Chemical Manufacturers Association, 1997): 91. Mike Walls of the Chemical Manufacturers Association estimates that the percentage for 1996 will be 4.9 percent of the sales revenue invested in R&D. Telephone interview, 10 December 1997.

‡ This statement is based on corporate tax data compiled by Standard and Poor's Compustat.

> PhRMA supports the international goals and objectives of the Biological Weapons Convention. Classical microbiology and the newly emerging biotechnologies have enabled, and will continue to enable, many new health care products to be developed. Their development should continue, while appropriate restrictions on the potential misuse of the technologies to create weapons is enforced in a manner which does not expose American industry to the loss of its legitimate competitive trade secrets and other confidential business information.

Hope that the eventual BWC protocol will incorporate strong measures to protect the industry's legitimate CBI has heightened awareness within PhRMA of the industry's ability to contribute technical expertise to the development of that very protocol. On 9 January 1997, the PhRMA Board approved a more extensive presentation of the PhRMA position, which can be found in Appendix 3.

Box 2 (cont'd.): From Laboratory to Market: How the Pharmaceutical Industry Works.

globally-important drugs launched during that period. In the emerging field of biotechnology, US firms have an even greater lead over their overseas competitors. US applicants received 122 of the 150 genetic engineering health care patents issued by the US Patent and Trade Mark

Chart 1: R&D Expenditures, Ethical Pharmaceuticals, Research-based Pharmaceutical Companies, 1980 to 1997.*

The proposed BWC protocol will leave the treaty's main text unaltered. The sole purpose of this protocol is to provide teeth to a treaty that currently contains no enforcement mechanism. A prospective BWC compliance protocol must fulfill the political and public policy needs for an enforcement mechanism while protecting the CBI and hard-earned commercial reputation of private-sector companies. While these goals may sometimes conflict, PhRMA does not believe they are incompatible. PhRMA considers the use of the term "verification protocol" inappropriate because of the inability of available procedures to ensure compliance as accurately and extensively as this term would imply. To over-reach what is technically feasible is to unnecessarily intrude on industry *and* foster a false sense of security—the worst combination imaginable.

The challenges of monitoring the BWC are significant: Relatively small and simple facilities are adequate to make biological weapons. In order to fashion a workable monitoring regime, the negotiators of the BWC protocol will need to draw upon real-world experts to gain insight into the capabilities and processes of the biotechnology industry. Accordingly, the role of PhRMA and its member companies in the development of an effective protocol is to explain the possibilities and

limitations of the technologies in a manner that can best answer the questions of the international negotiators.

PhRMA is not suggesting that industry contribute directly to the negotiations. Rather, industry can help identify what is technically feasible for the ultimate compliance regime. To the extent that industry is included in the development of such definitions and in subsequent discussions, the perception that the pharmaceutical industry might be unfairly targeted under the proposed BWC protocol will be dispelled.

The CWC: Not a Good Model for the BWC Protocol

The Chemical Weapons Convention (CWC), which bans the development, production, stockpiling, transfer, and use of poison gas, entered into force on 29 April 1997. The international community had a strong incentive to conclude this treaty in 1993 because there were no existing prohibitions on the acquisition and manufacture of chemical weapons. This landmark treaty also includes extensive verification measures. The US chemical industry strongly supported the negotiation and ratification of the CWC. In fact, the US chemical industry offered extensive and constructive assistance to the CWC's negotiators. PhRMA also supported Senate ratification of the CWC, which occurred on 24 April 1997.[2]

In contrast, the BWC's ban against the manufacture and stockpiling of biological and toxin agents has been in force since 1974 and has already been ratified or acceded to by 140 countries. With such prohibitions already established, the international community may not be as motivated to conclude a protocol to the BWC. Similarly, the pharmaceutical industry has reasons to perceive the task of negotiating a BWC protocol differently from the manner in which the chemical industry approached the drafting of the CWC. The ban against biological weapons is already in place, and since US pharmaceutical firms are not violating it, they understandably lack enthusiasm for intrusive monitoring procedures that could place their livelihoods at risk.

The second fundamental difference between the CWC and a BWC protocol is the nature of the technologies involved: A chemical is very different from a biological micro-organism. A chemical is a precise, well-defined entity used in varying amounts, often as a raw material, in a variety of other industries. The molecular composition of a chemical is often known, usually only limited precursor chemicals are used in its production, and accurate testing methodologies are usually available to identify and measure it. Although the CWC allows small quantities of chemical warfare agent to be employed for defensive research, a chemical agent has no legitimate commercial

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[2] For an explanation of the US chemical industry's views, see Kyle B. Olson, "Why the US Chemical Industry Can Live With a Chemical Weapons Convention," *Arms Control Today* 19, no. 9 (November 1989): 21–5; Testimony of Will B. Carpenter, US Congress, Senate Foreign Relations Committee, *Hearings on the Chemical Weapons Convention*, 103d Cong., 2d. sess., S. Hrg. 103–869, (Washington, D.C.: Government Printing Office, 1994): 88–92. PhRMA joined the Chemical Manufacturers Association and several other industry trade associations advocating US ratification of the CWC.

uses. Some of the raw materials used to make a chemical agent are not frequently used elsewhere and so can provide significant markers for an offensive program. Further, substantial quantities of the raw materials need to be available in order to create significant stockpiles of chemical agents.

The biological products of the pharmaceutical industry may be well-defined, but often they represent complex mixtures of materials that may have been isolated—rarely to homogeneity or purity—from nature. Biological products are also manufactured with genetically manipulated systems that are sufficiently defined to optimize production and ensure the integrity of the product. However, bacteria and mammalian protein expression systems will not be completely characterized beyond what is required to achieve fidelity of biotechnology products (i.e., as essential to production or required under existing FDA regulations). In other words, pharmaceutical manufacturers may not know, much less be able to depict, everything that occurs during the manufacture and purification of a product in a living system. Also, pharmaceuticals, especially biologics, are usually produced in areas closed to the ambient environment. These manufacturing processes are sophisticated and often use unpatented trade secrets. The product is destined for human and animal consumption, and so extensive quality control procedures are employed. Clean room procedures are used as much to protect the product from the workers as *vice versa*. Proprietary production processes make the final product in small to medium quantities for final dispensing as vials, pills, and capsules. Unlike chemicals, the final volumes are relative small.

The ultimate in sensitive information for the pharmaceutical industry is the nature of the genetically modified micro-organism used in the latest state-of-the-art biotechnologies. An individual bacterium strain can represent a large proportion of a company's investment in a given pharmaceutical product and forms the basis of any financial return. One sample during an inspection could conceivably lead to the loss of CBI worth billions of dollars. Whether alive or dead, the micro-organism contains proprietary genetic information. In contrast, the chemical industry, which also has legitimate CBI concerns, is process-oriented and uses specific raw materials to build the final product that is usually traded as a commodity. Chemicals are fundamentally unable to reproduce themselves, and therefore samples are of less value to a competitor. Substantial overlap does exist in the products of the chemical and pharmaceutical industries. Some of PhRMA's member companies may be subject to declarations and inspections under both treaties, but the pharmaceutical industry can anticipate being considerably more exposed by the BWC's monitoring provisions than by those under the CWC.

The nature of a biological product also complicates the value of declarations of agreed categories of facilities or the use of production records to confirm that a legitimate product is being made. Raw materials are difficult to use as an indicator of manufacturing one product versus another because the same raw materials in a fermenter can be used to produce a wide variety of different products. The key variable is the nature of the inoculum—the proprietary micro-organism—used to charge the fermenter. Therefore, declarations may have less inherent value for monitoring the BWC than they do for CWC verification purposes.

Thus, the pharmaceutical industry is extremely wary of over-reliance upon the CWC model for the purposes of constructing a BWC protocol. While some of the CWC's monitoring concepts apply, others clearly do not. For good reason, PhRMA urges the negotiators to take note of the important differences between chemical and biological weapons, as well as between the chemical and biotechnical industries and the technologies on which they are based, as they shape the BWC protocol.

PhRMA's Position on a BWC Compliance Protocol

As already noted, PhRMA endorses the goal of catching violators of the BWC by creating a compliance protocol. For each monitoring measure proposed for the protocol, however, a cost/benefit analysis must be performed. The pharmaceutical industry and other enterprises around the world that would incur potential costs (e.g., other industries, universities, non-profit and government-funded research institutes) need to be given an opportunity to explain the limitations of any proposed measure and encouraged to suggest alternative means of achieving the specified compliance objective. Governments in various countries will engage industry, some inviting industry's participation more than others. Given the opportunity to contribute to this process, industry and the other affected organizations can offer constructive suggestions based upon their state-of-the-art knowledge. The negotiations could benefit greatly from such contributions.

The US government does not currently have a formal negotiating position, the following discussion covers a number of measures that may or may not ultimately form part of the US position or the final BWC protocol. This discussion is a preliminary PhRMA assessment of the possible options for a BWC protocol, including definitions of terms and measures for declarations, inspections, and technology-sharing.

Definitions

Before something can be looked for, it must be defined. While the definition of biological weapons should not be so precise that it cannot accommodate a minor change in the design or source of the organism, some common definition of what comprises a weapons-grade agent would greatly facilitate the development of a BWC protocol. The pharmaceutical industry is concerned that current definitions are so imprecise that the BWC protocol could become a vehicle to look for anything being done anywhere. These open-ended definitions would seriously complicate the ability of the pharmaceutical industry to protect CBI and the reputation of its companies.

Once the international community defines biological agents/weapons/warfare, it will become easier to develop criteria for what would then be needed to generate such weapons. This definition will enable industry to give clearer responses to questions about its capabilities, equipment, and the nature of the micro-organisms it employs to make medicines. Dual-capability technologies will still be suspect in some circumstances, but it may be possible to develop exclusionary as well as inclusionary criteria. In short, a definition can hopefully lead to more productive discussions in which industry's technical capability would be much more useful to the international negotiators.

After all, technology is the industry's *forte*. Industry knows best how different types of equipment can be employed to produce various amounts and qualities of microbiological product.

Declarations

At present, BWC signatories can voluntarily submit declarations on the publicly and privately owned firms within their borders that are producing licensed human vaccines. As chapter 4 discusses, these declarations are intended to foster transparency about the activities of a state's biotechnical facilities. The US government provides such annual declarations for its own facilities and those of the US-based pharmaceutical industry. Various federal agencies compile the required data. The private sector currently plays no role in this process and only a minimal one in assembling the final declarations report for the United Nations. Vaccine manufacture, it should be noted, represents only one of a variety of dual-capability technologies that could be of relevance in an offensive biological weapons program.

The effectiveness of mandatory declarations in a compliance regime is debatable. Clearly, countries will not declare activities that they would prefer to hide: Declarations in and of themselves will provide a marginal return in catching BWC violators. Nonetheless, the US pharmaceutical industry appreciates the confidence-building value of these declarations and has no objection, in principle, to the present voluntary declarations becoming compulsory. The international community will scrutinize mandatory declarations more closely than the current voluntary ones, so it is essential that such declarations be one hundred percent accurate and one hundred percent complete. Thus, it will be important that the declarations made on behalf of a company, academic institution, or other entity be checked by that organization prior to submission.

In addition to vaccine manufacturers, other types of declarations are being discussed. Again, the negotiators need to define what is being looked for and why. For example, definitions need to distinguish what is critical—the dual-capability of the technology or the nature of the organisms. A variety of triggers for declarations can be envisioned. Any proposed trigger should be defined in terms of the item's potential to be used to make a biological warfare agent. Furthermore, for each candidate trigger accurate tracking must be feasible so that a country can account for all identified capabilities within its borders.[3] By the sheer size of the US industry, poorly conceived declarations could result in a new and costly administrative burden, not to mention making it extremely difficult to obtain completely accurate declarations. Therefore, PhRMA does not currently support any expansion of the present declarations to encompass a larger number of companies or to increase the detail that industry is now being asked to report. PhRMA will reconsider this position if other types of declarations are proposed. A full scientific justification should be the basis of any potential declaration requirement. Moreover, declarations should be unambiguous and administratively simple.

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[3] For instance, if fermentation capacity is a trigger, then breweries, which have a vastly greater capacity than pharmaceutical plants, must be declared.

Administrative simplicity in declarations can greatly ease the potential burden on industry. For instance, the present declarations only require limited information, such as the name and address of the institution and a general description of the types of diseases for which they manufacture vaccines. This type of declaration is not onerous. More expansive declaration formats that request details of both the nature and capacities of equipment used, the types of technologies employed, and details of the organisms used could very quickly become a significant ordeal for the private sector. This flood of requested data could outstrip the ability of governments to compile accurate declarations.

All declarations should be made public if they are to fulfill the aspirations for achieving transparency concerning the BWC. The dissemination of such information, perhaps on the Internet, can increase public confidence in the BWC. This approach also takes into account the fact that no security system can be effective if 140 governments have access to the data in these declarations. Hence, PhRMA does not believe any CBI should be included in any declaration.

On-Site Inspections

PhRMA considers inspections to have a legitimate but limited value in a compliance protocol. The nature and sophistication of current, widely used technologies undermine the ability of an international inspection team to enter a plant and catch the violators before the site has been effectively purged of any evidence of biological agent production. Some form of inspection, however, may be useful to deter potential cheaters. Therefore, inspections may have a role to play in the BWC protocol.

Nonetheless, it is important to acknowledge that a violation of the BWC may be impossible to "verify" even after intrusive on-site inspections. United Nations inspectors, for example, have made considerable progress in uncovering Iraq's biological warfare program, but have still not resolved numerous uncertainties about Iraq's biological weapons activities after several years of intrusive inspections. PhRMA urges the negotiators to exercise caution in determining how on-site inspection activities will be employed to monitor the BWC. If the utility of inspections is over-estimated, the protocol will be unable to fulfill expectations. PhRMA is particularly concerned that the capabilities of the emerging biotechnologies, in particular recent progress on DNA-based diagnostics and forensics, not be inflated and used to misrepresent the overall ability of on-site inspection activities.

The protocol may combine different inspection procedures for use in conjunction with each other, so it is difficult to discuss any form of inspection independently. PhRMA's concerns about the limitations of on-site inspections are largely determined by the technology and as such different types of inspections can be discussed in a manner akin to the links in a chain—the strongest link in a chain cannot compensate for the weakest link. From a business perspective, CBI that is lost via one inspection technique cannot be retrieved by protections elsewhere.

Routine inspections to confirm the accuracy of a facility's declaration would presumably be conducted according to a long-term schedule that enables both the inspectorate and the inspected facility to plan well ahead of the actual "visit." Only declared facilities would be inspected. Long notice could allow a facility's officials to prepare their site to reveal only what they wanted to show to inspectors. Minor infractions may be found, but these would be relatively insignificant to a BWC compliance assessment. For these reasons, PhRMA concludes that the most probable outcome of a routine inspection at one of its companies would be the loss of CBI and damage to a company's reputation. PhRMA believes that routine inspections would be expensive and extremely unlikely to catch significant violators. Therefore, PhRMA opposes the inclusion of routine inspections or visits in a BWC protocol.

Another type of inspection, known as a validation inspection or "challenge-lite" visit, would be conducted on shorter notice (e.g., 48 hours) at declared sites. This inspection concept, which is a variation of a routine inspection, suffers the same limitations as routine inspections. A violator using current biologic technologies could scrub a site before the inspectors arrived in country. Using just a manual flushing system, a vaccine manufacturer could clean an entire production pathway in less than eight hours. More daunting for an inspectorate trying to detect cheating, many pharmaceutical plants have modern clean-in-place technology, which gives them the ability to purge an entire system in a hour. Given these standard cleaning capabilities, even samples taken during an *unannounced* inspection would not indicate what a plant was making shortly before the arrival of the inspectors. In other words, the widespread use of these sophisticated technologies within the US pharmaceutical industry undermines the reasoning behind such inspections. In all likelihood, such validation inspections would again place industry's CBI at an unacceptable risk, not to mention the adverse publicity that an inspection could generate about a company. Consequently, PhRMA opposes the incorporation of validation inspections in a BWC protocol.

Although PhRMA objects to the monitoring approaches that have been proposed thus far, PhRMA would encourage the negotiators in Geneva to develop an alternative to long-notice and validation inspections. One possible approach would have the inspectorate monitor everything coming out of a given facility for a determined period. As appropriate, sampling of final product could be conducted to confirm that these plants are indeed making legitimate peaceful products. If indeed the ultimate concern is to check that a company is really making what it declares, then the output of a facility should be the focus of inspections.

With certain constraints, short-notice challenge inspections are the only form of inside-the-fence inspection that PhRMA supports. Since the US pharmaceutical industry is not involved in the development or production of biological agents, PhRMA assumes that any allegation against a US firm will be politically motivated. Therefore, the BWC protocol must be structured to protect sites from frivolous or malicious challenge inspection requests. Specific safeguards are necessary to prevent the abuse of challenge inspections. For instance, the state requesting a challenge inspection must provide substantial and convincing evidence to support a charge concerning the development, production, or stockpiling of biological agents or evidence of their alleged use. An unusual outbreak of disease that could represent inadvertent release of a biological agent could also be evidence of a

contravention of the BWC. A "green light" process should also be instituted, wherein the requesting state must persuade a three-quarters majority of the BWC's executive governing body of the validity of the allegation before a challenge inspection proceeds.[4] PhRMA considers the green light approach essential to protect industry from inherently damaging allegations. Finally, no representatives from the nation requesting the challenge inspection should be on the inspection team. PhRMA advocates the employment of full-time professional inspectors, not *ad hoc* inspectors chosen from a roster of consultants.

The purpose of a challenge inspection is to substantiate the specifics of the allegation. Such a mandate is not an open license to look at anything at the challenged site. Upon arrival, PhRMA asserts that the inspectors must clearly state their purpose, providing the specific data supporting the allegation in order for the challenged facility to provide an explanation and evidence of its activities that refutes the allegations. The dual-capability of the industry's production facilities makes it highly unlikely that a pharmaceutical plant could prove itself innocent of any possibility of making any disease organism. However, a pharmaceutical facility may be able to show that it could not have been growing organism "X" in building "Y" on a specified date. If the inspectorate does not find evidence of noncompliance, then the challenged facility must be cleared of the charges.

A challenge inspection must be conducted under managed access procedures, where the facility being visited retains the final say of what is or is not CBI. An inspected facility would still be under obligation to answer the inspectors' questions as fully and fairly as possible and to go to great lengths to provide reasonable alternative forms of evidence. Ultimately, however, a pharmaceutical company must be able to refuse to share information it deems proprietary. PhRMA companies would consider sharing this evidence with the US government, but only if domestic legislation precludes the government from over-riding the company's recommendation concerning its CBI. Only with the involved company's explicit, written permission can such information be relayed to the inspectors.

During a challenge inspection, the host facility may volunteer samples, if the inspectors provide a sound reason for them. Beyond that, PhRMA is absolutely opposed to compulsory sampling or to the transport of any samples, particularly live organisms, from the inspected site. Even samples with dead organisms may contain critical CBI worth multi-millions or billions of dollars. After all, the first step in cloning a gene is to kill one cell and extract the organism's DNA. In any instance where samples are taken, managed access rules must apply. Any tests that the inspectors propose for a sample must be of extremely high standards, fully validated, and performed by the company's own scientists. PhRMA is particularly concerned that some concepts for testing for biological agents may overstate the capabilities of emerging biotechnologies. Sample analysis can result in false positive and false negative results that could be extremely damaging, if not devastating, to the industry. In addition, many of the potential biological agents represent endemic

[4] In contrast, the CWC has a "red light" approach. When a CWC challenge inspection is being launched, a three-quarters vote of the 41-member Executive Council is needed to halt the inspection.

environmental contaminants (e.g., *Yersinia pestis,* which causes human bubonic and pneumonic plagues) that are routinely found in soil samples. Further caution must therefore be exercised because positive test results may have nothing to do with what a facility produces.

Finally, appropriate safety standards and immunization protocols for inspectors must be established well before any challenge inspections are conducted. The suggested time line for a challenge inspection—48-hours notice—is insufficient to introduce the measures needed to protect the inspectors' safety. An inspection must not jeopardize a batch, production facilities, or the integrity of a pharmaceutical plant's product, and therefore the safety and standard-operating-procedure rules of the inspected facility must apply during any visit.

Although PhRMA objects to most forms of inspection at private facilities, the pharmaceutical industry might consider helping the inspectorate train its inspectors in general state-of-the-art technology that is not confidential. Such assistance may be offered if the companies involved received the appropriate assurances about the caliber and discretion of the inspectors.[5] As the relationship between PhRMA and the inspectorate matures, some companies might be willing to consider additional aid. Ideally, the inspectors could keep abreast of current technical developments through a cooperative relationship with the industry, not just via their actual inspection duties.

Technology Transfers

Some delegations at the BWC negotiations advocate the activation of mandatory provisions to share technology, equipment, and know-how under the auspices of Article X of the treaty.[6] The US pharmaceutical industry does not support changes in import and export controls to facilitate the transfer of US biotechnology to other countries. Such transfers could require PhRMA companies to divulge CBI developed with substantial private investment capital. The secrecy of this CBI is essential to the competitiveness of the US pharmaceutical industry and to its ability to invest further in the development and production of medicines for sales in world markets.

PhRMA does, however, realize the problems associated with a lack of disease surveillance capabilities in some regions of the would. More technically advanced countries will need to provide assistance to support the epidemiological surveys to monitor unusual outbreaks of disease in these regions. The pharmaceutical industry does not anticipate being heavily involved in the provision of such assistance because disease surveillance expertise is the domain of the US government, particularly the Centers for Disease Control.

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[5] For instance, inspectors that benefitted from such training would probably be asked to sign a separate confidentiality agreement with their host company.

[6] Among other matters, Article X states that participating countries "undertake to facilitate, and have the right to participate in, the fullest possible exchange of equipment, materials and scientific and technological information for the use of bacteriological (biological) agents and toxins for peaceful purposes." For the full text, see US Arms Control and Disarmament Agency, *US Arms Control and Disarmament Agreements: Texts and Histories of the Negotiations* (Washington, D.C.: Government Printing Office, 1996): 99–100.

Conclusion

No one has yet suggested that any of PhRMA's companies have ever made biological weapons, but the industry is acutely aware of the first principle in science: A negative can **never** be proved. In other words, if falsely accused a pharmaceutical company can never prove that it has not made biological weapons. Hence, PhRMA's insistence that the BWC's monitoring regime be founded on due process and the presumption of innocence.

PhRMA advocates a sound and reasonable compliance protocol to the BWC, but will not support a poorly conceived one that risks the legitimate and laudable aims of the pharmaceutical industry to use existing and emerging biomedical technologies to create medicines. An analysis of the costs and benefits of all aspects of the protocol will be critical to avoid unnecessarily sacrificing unmet medical needs and the general public health to overly ambitious or unrealistic concepts for a BWC protocol. PhRMA's principle concerns remain the loss of CBI, unwarranted damage to the reputation of pharmaceutical companies, and new, onerous, and expensive regulations. While not a principal force behind the development of such a protocol, as responsible corporate citizens PhRMA companies will provide expert assistance to clarify for the negotiators what can be achieved technically so that they can craft a BWC protocol based on solid science.

Doubts About Confidence: The Potential and Limits of Confidence-Building Measures for the Biological Weapons Convention

***Marie I. Chevrier,* Ph.D.**

The common meaning of the term "confidence" is widely understood. Confidence has to do with belief or faith in something, with one's own ability or others' willingness to act, for example. Yet, confidence is tinged with uncertainty. Confidence is only relevant in the realm of the future and of things not known. The study of probability and statistics has quantified the uncertainty and the degree of confidence in many different contexts, standardizing the notion of "confidence intervals" and "confidence levels." Confidence has also entered into the lexicon of international security and arms control. The concept has taken on new meanings in that arena while retaining much of its ordinary meaning and that developed in mathematical applications.

This essay is a reflection on confidence building in the context of a particular arms control agreement, the Biological Weapons Convention (BWC).[1] Briefly, it describes confidence-building measures (CBMs) and their development as a concept in international security. The essay next examines the CBMs drafted and implemented among the parties to the BWC and their disappointing performance during the last decade. The discussion then moves to a description of the CBMs which have been proposed in the negotiations to strengthen the BWC and evaluates their potential for building confidence. Finally, the essay analyzes the factors that play a role in building confidence in the BWC. The analysis finds that CBMs play an important but limited role in building confidence in nations' compliance with the prohibitions of the BWC and in the treaty as an instrument to achieve biological weapons disarmament. Generally, their potential is limited to building confidence in the compliance of countries that are neither beyond reproach nor the usual arms control suspects, but those in between. Moreover, CBMs should not be entered into lightly; their implementation is neither free from cost nor certain to create the desired level of trust. CBMs are not a substitute for legally binding compliance measures and cannot be relied upon in isolation to sustain the BWC.

The Purpose of Confidence-Building Measures

Confidence-Building Measures (CBMs) are an assortment of activities that states engage in to become more sure that each understands the true actions and/or intentions of the others.[2] An individual CBM is usually centered around a specific military or security issue. For example, during the Cold War the North Atlantic Treaty Organization and the Warsaw Pact employed CBMs to

[1] The author wishes to thank Amy Gordon, Iris Hunger, Paul Jargowsky, and Amy Smithson for their helpful comments on earlier drafts of this essay.

[2] This definition differs somewhat from Holst's classic definition, "arrangements designed to enhance such assurance of mind and belief in the trustworthiness of states and the facts they create." Johan Jorgen Holst, "Confidence-building Measures: A Conceptual Framework," *Survival* XXV, no. 1 (January/February 1983): 2.

reduce the possibility that one side would misinterpret the other's actions as hostile and to reduce the reliance on potential military actions. The kinds of activities that comprise CBMs are tailored to the underlying concern, but have typically taken the form of declarations, notifications of military training maneuvers or troop movements, and invitations to observe military or other activities. CBM proponents posit that these activities lead to openness and transparency, which reduces suspicion. In this manner, CBMs lessen the likelihood that a misunderstanding or miscalculation would lead to accidental war.[3]

Arms control, like CBMs, does not have a universally accepted definition. At its narrowest interpretation, arms control consists only of negotiated and ratified treaties that limit or prohibit the types or numbers of arms that a country can posses or use. A much broader understanding of the scope of arms control would include "disarmament, negotiated constraints, nonproliferation, export controls, confidence and security-building measures, unilateral defense policies, aspects of diplomacy, international law, defense conversion, and certain activities related to international peacekeeping."[4] Arms control has a long history. The purpose of arms control is threefold: "reducing the likelihood of war, its scope and violence if it occurs and the political and economic costs of being prepared for it."[5]

Arms control and CBMs have distinctions as well as areas of overlap. CBMs, for instance, can be incorporated into formal arms control agreements. CBMs could be implemented to prepare countries to enter into arms control agreements. CBMs can also cover activities that are unrelated to arms control, such as prior notification of troop movements or maneuvers. Monitoring in arms control refers to the observation, usually through a technical apparatus or with human inspectors, of relevant equipment or activities.

In the context of arms control, CBMs are undertaken not necessarily to lower the probability of war, but "to reinforce or bolster the primary obligations in a given treaty or to provide mechanisms for guarding against circumvention and for verification of compliance."[6] In a less than completely transparent world, some uncertainty always exists regarding the intentions of other countries and their actual compliance with arms control treaties, even with those treaties that have relatively extensive and intrusive verification regimes. To the extent that surreptitious cheating on arms control obligations leads to a military or security advantage for the cheater, other treaty parties have a strong interest in accurately ascertaining the compliance with arms control accords. The problem

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[3] Richard E. Darilek and Geoffrey Kemp, "Prospects for Confidence- and Security-Building Measures in the Middle East," in *Arms Control and Confidence Building in the Middle East,* Alan Platt, ed. (Washington, D.C.: US Institute of Peace Press, 1992): 14–5.

[4] Ronald F. Lehman, " Forward," in *Arms Control: Toward the 21st Century,* Jeffrey A. Larson and Gregory J. Rattray, eds. (Boulder: Lynne Rienner Press, 1996): vii.

[5] Thomas C. Schelling and Morton H. Halperin, *Strategy and Arms Control* (New York: Twentieth Century Fund, 1961): 2.

[6] Holst, "Confidence-building Measures: A Conceptual Framework," 5.

of confidence in treaty compliance can be stated as: "Facing a potentially hostile enemy, what one wants is not to *be* confident, but to be *as* confident as the true state of affairs justifies. What one wants is *grounds for confidence*, evidence that confidence is justified."[7]

CBMs are one way to create the groundwork for increased confidence regarding treaty compliance. They do so if they provide evidence, not otherwise readily available, that is consistent with compliance behavior.[8] Secondly, CBMs can increase confidence regarding the true state of a country's compliance. In that regard, CBMs decrease uncertainty about other states' intentions and their compliance with arms control obligations. This reduction in uncertainty can be either an increased confidence in compliance or in suspicions of noncompliance. To avoid false confidence, countries are likely to consider a CBM desirable if it can reduce uncertainty and thereby build confidence in the observing nation's assessment regarding a state's actions or intentions. Third, CBMs in the arms control context can enhance confidence in the instrument (or treaty) to accomplish its intended purpose. If a state is more confident that potential adversaries are complying with a particular treaty by eliminating a military capability or reducing their weapons to the number stipulated, then confidence in the arms control treaty grows. Any effect CBMs have on deterring or detecting noncompliance, while valuable, goes beyond the primary purposes of the measures.

The distinctions between *measures* that are intended to build confidence and the *process* of building confidence are important to keep in mind. The process of building confidence depends on many factors in addition to CBMs. Thus, CBMs may or may not achieve their desired ends. While CBMs can enable increased confidence, that outcome is by no means automatic for several reasons. Often, CBMs are voluntary, not legally binding. Not only are states not legally bound to participate, mechanisms to police or compel compliance with CBMs ordinarily do not exist. Increased confidence materializes only if the information revealed by the CBMs is sufficient to warrant movement along the confidence scale. Distinctions should also be made between confidence in another state's actions and confidence in the treaty.

The Potential Utility for CBMs in the Biological Weapons Convention

The essence of the obligations undertaken by parties to the BWC are contained in Article I and are worth reiterating. States agree not to develop, produce, stockpile, or acquire biological agents and toxins of types and in quantities that have no justification for prophylactic, protective, or other peaceful purposes. The same prohibitions apply to weapons, equipment, or means of delivery to use such weapons for hostile purposes. These prohibitions offer several discrete, substantive areas for the application of CBMs.

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[7] Thomas C. Schelling, "Confidence in Crisis," *International Security* 8, no. 4 (Spring 1984): 56.

[8] For a thorough treatment of the process of confidence building see James Macintosh, "Confidence Building in the Arms Control Process: A Transformation View," *Arms Control and Disarmament Studies*, no. 2 (Ottawa, Canada: Department of Foreign Affairs and International Trade, 1996).

CBMs could concentrate on the types of agents possessed and/or the quantities of agents possessed. Every state participating in the BWC has the obligation to provide a peaceful purpose justification for all types and quantities of agents that it possesses. CBMs could provide an opportunity to reveal this justification to the international community. In addition, CBMs could focus on weaponization and examine equipment or the means of delivery to ascertain whether such equipment was designed for hostile purposes. *Ideally*, CBMs would help countries do two things: 1) to know that what a country **says** it is doing with biological agents and equipment at a known facility is in fact what is going on; and, 2) to know that neither declared nor undeclared facilities are being used for biological weapons purposes. The former is a notably easier task than the latter.

CBMs vary according to the strictness of the obligation, if any, to comply with them. CBMs can be voluntary, legally binding, or "politically binding."

- **Voluntary CBMs** are actions taken unilaterally or by groups of states to build confidence. Although voluntary CBMs are not required, formally or informally they can be specified in a formal document. For example, the Final Declaration of a BWC Review Conference could urge or encourage states to participate in visits to biological facilities in other countries on a voluntary basis.

- **Legally binding CBMs** embodied in an agreement that governments sign and ratify have the force of international law. Any CBMs contained in the BWC verification protocol under negotiations will be legally binding for those states that ratify the protocol, unless they are clearly designated as voluntary measures.[9]

- **Politically binding CBMs** fall somewhere in between voluntary and legally binding activities. The data exchanges and other measures agreed to at past BWC Review Conferences are often referred to as politically binding CBMs. As such, they are measures that nations formally agreed to abide by, though the commitment does not have the force of international law. The formal agreement adds political muscle and a certain degree of moral suasion to push countries to fulfill their commitments and thus sharply distinguishes them from voluntary CBMs.

The distinctions between these types of CBMs are important because many countries are more likely to participate in legally binding CBMs than the other two types. Thus, information from countries of interest will more likely be obtained by making CBMs legally binding.

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[9] Iris Hunger, an authority on CBMs in the BWC, states that "I do not believe that [making CBMs legally binding] is making them better, because the aim they should achieve—building confidence—can not be forced on someone." Correspondence with Hunger, 12 December 1997. The author believes that within the context of the BWC legally binding CBMs are more likely to yield information that will lead to increased confidence and are therefore preferable to the other alternatives. Nevertheless, she agrees with Hunger that although one can make *measures* legally binding, one cannot force confidence building.

CBMs Established Under the BWC

Members of the BWC have long recognized the treaty's deficiencies, namely the absence of mechanisms to provide reassurance of compliance. Over a decade ago, they attempted to reduce the uncertainty concerning biological research laboratories and activities and to enhance confidence in others' compliance by initiating CBMs to decrease secrecy. To that end, states participating in the Second Review Conference of the BWC agreed in 1986 to exchange information annually in three areas: 1) biological research, and other activities that the treaty also allows for "prophylactic, protective or other peaceful purposes;" 2) laboratories that "meet very high national or international safety standards. . . [or] specialize in permitted biological activities directly related to" the BWC; and, 3) the outbreak of diseases that might raise suspicions regarding compliance with the BWC.[10] Beginning in 1987, all BWC member states were to submit this data to the United Nations (UN), which functions as the repository for it.

The Third Review Conference, held in 1991, clarified and added details to the information exchange established in 1986. Four information declarations were added to those already adopted. The first requires states to describe all of its offensive and defensive biological weapons programs dating back to 1946. The second measure requires nations to declare on-going research and development programs in biological and toxin weapons defense. The third requires countries to declare details of all human vaccine production facilities. The fourth new declaration requires governments to report what they have done to implement the BWC domestically. To make submission of these CBMs simple, a form was prepared for countries to complete, including a "nothing to declare" option.

These information exchanges, or CBMs, were thought to reduce the uncertainty surrounding the extent and purposes of permitted biological research and other activities. Another anticipated result was that they would build confidence in the arms control process, leading to the development and implementation of more stringent measures. Finally, to the extent that fear of discovery and the ease with which violations can be detected are factors in any government's decision to cheat on an arms control agreement, these CBMs were expected to deter violations of the BWC.

The Performance of the CBMs for the BWC[11]

The international response to these agreed politically binding CBMs has been disappointing. The majority of BWC members, have not devoted sufficient resources to recurring and timely

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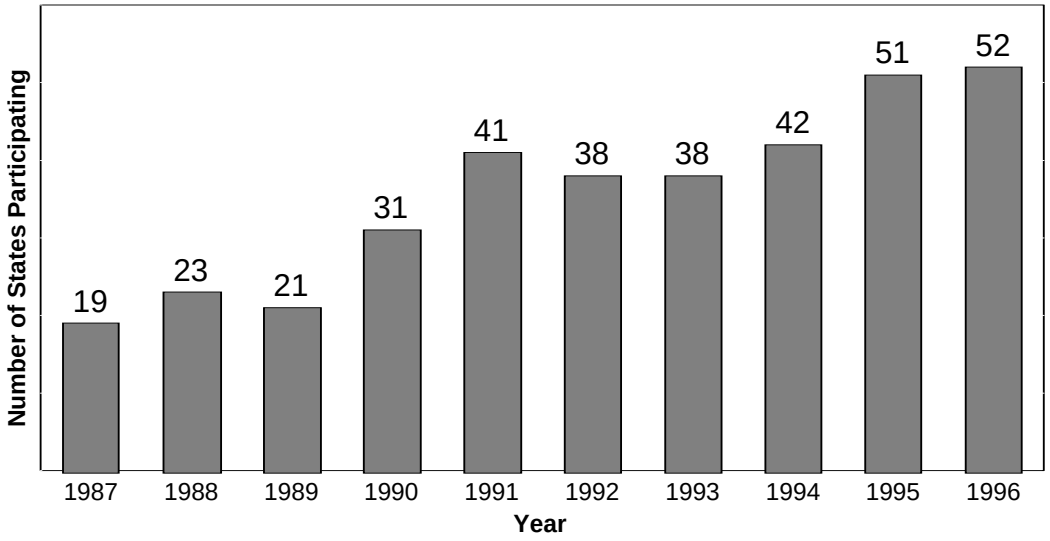
[10] United Nations, *Second Review Conference of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction: Final Document*, Document BWC/CONF.II/13/2, 1986.

[11] Much of information in this section and both of the charts are taken from Iris Hunger, "Article V: Confidence Building Measures," in *Strengthening the Biological Weapons Convention: Key Points for the Fourth Review Conference*, Graham S. Pearson and Malcolm R. Dando, eds. (Geneva: Quaker United Nations Office, 1996): 78–9. The data was updated in 1996 through correspondence.

completion of the declarations.[12] From 1987 (the first year of the data exchange) to 1996 (the last year for which complete data are available to non-governmental researchers), there has not been a single year in which a majority of the states parties have participated. Chart 2 shows the number of states that provided data each year between 1987 and 1996.[13] Only eleven countries have made

Chart 1: BWC Information Exchange



declarations every year since 1987, as Chart 3 shows.[14]

Several factors may account for these lackluster results. One explanation is that few, if any, consequences emanate from states' failure to participate. Countries may suffer international criticism for their failure to provide the required information, but no penalties or other sanctions are imposed. Another explanation is that completion of the declaration forms was more complicated than anticipated, requiring the assembly of data that not all states had previously collected. Brazil has argued that the paltry response to the information exchange is evidence of the difficulties of keeping track of relevant industries. Consequently, delays in submitted declarations and information gaps in the data would not necessarily indicate deliberate disregard of a country's obligations.

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[12] Erhard Geissler, "The First Three Rounds of Information Exchanges," in *Strengthening the Biological Weapons Convention by Confidence-Building Measures*, Erhard Geissler, ed., Stockholm Institute for International Peace, Chemical and Biological Warfare Studies, Report No. 10 (London: Oxford University Press, 1990): 71–9.

[13] The data for years 1 to 9 of this chart are taken from Hunger, "Article V: Confidence Building Measures," 78. Data for year 10 was obtained from Iris Hunger in correspondence, 15 December 1997.

[14] These countries are Canada, Denmark, Finland, Germany, The Netherlands, Norway, the Russian Federation, Spain, Sweden, the United Kingdom and the United States. Hunger, "Article V: Confidence Building Measures," 78.

Rather, such lapses might reflect an inability to perform the required duties.[15] Inability in obtain information may play a role in explaining why several large and influential countries—Indonesia, Iran, Nigeria, and Pakistan—have never participated in the information exchange.[16] Increasingly, however, benign explanations for negligence or half-hearted participation is met with skepticism on the part of those countries that have fully complied. Finally, countries may be ignoring their obligations because they are hiding biological weapons programs. Most countries do not even offer an explanation for their lack of participation. Whatever the reasons, the evidence seems irrefutable that a large number of BWC members have not taken these politically binding CBMs seriously.

Beyond the simple question of whether or not countries have submitted declarations, analyses of the contents of the data and how they have changed over time are not readily available. BWC members have not established an organization to manage the administrative work of the treaty. Consequently, the documents are not officially translated and made available through the UN documents center. Comprehensive analyses of the declarations, which would presumably play the biggest role in building confidence, are difficult, time-consuming, and expensive. Some governments may be doing appropriate analyses and not releasing them publicly. Nonetheless, to enable these CBMs to fulfill their purpose, it would seem imperative that BWC members commit the resources necessary to conduct such analysis. The upshot of this situation is that in spite of the disappointing response to the CBMs, the task of publicly reviewing this data has fallen to non-governmental researchers.[17]

Still, the endeavor has not been totally without merit. Through 1996, more than half of the treaty parties—75—have made at least one such declaration. The number of countries that comply regularly has been steadily increasing from 19 countries in 1987 to 52 countries in 1996.[18] Forty-nine of the 75 countries participating in the exchange have made declarations during four or more years.

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[15] Government of Brazil, Ad Hoc Group,"Strengthening the BWC: Elements for a Possible Verification System," *Special 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*, UN Document BWC/SPCONF/WP.4, 1994.

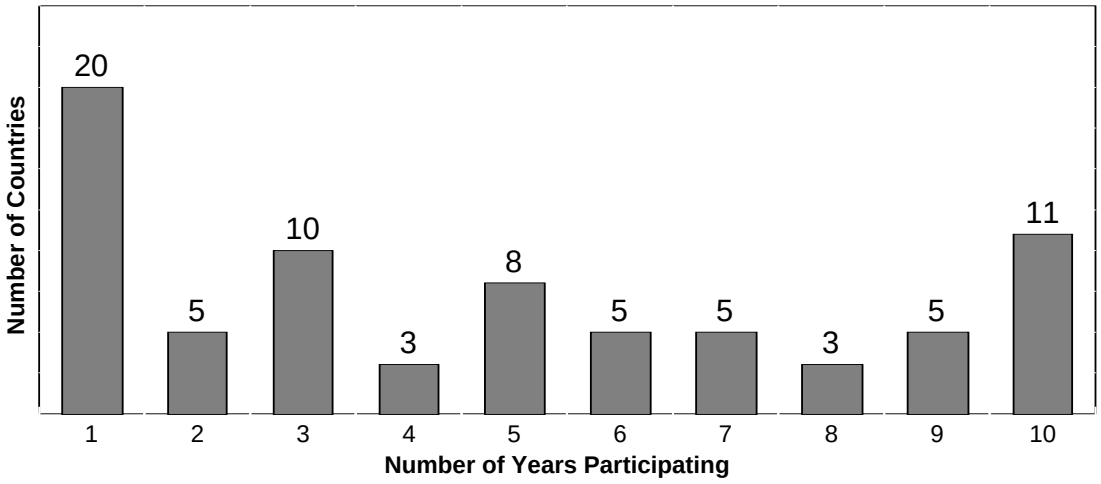
[16] Hunger, "Article V: Confidence Building Measures," 78. India submitted a declaration for the first time in 1997; detailed data as well as information on whether any of the other countries submitted declarations in 1997 is not yet available to non-governmental researchers. Correspondence with Iris Hunger.

[17] See, most notably, Geissler, "The First Three Rounds of Information Exchanges," 1990. Hunger, "Article V: Confidence Building Measures," 78–9.

[18] Hunger, "Article V: Confidence Building Measures," 78–9.

The information contained in the declarations also tells something about the biotechnological capabilities of the participating countries. In particular, the details of past biological weapons programs could be helpful in ascertaining ways to identify current or future programs. Nevertheless, what were billed as CBMs have done little to build confidence in treaty compliance. Indeed, spotty

Chart 2: CBM Declarations



compliance *with the CBMs* can be considered a relevant factor propelling the international community to complete negotiations and begin implementation of a BWC protocol with legally-binding declarations and other provisions that are much more demanding than these CBMs.

The Fourth Review Conference, held 25 November to 6 December 1996, considered the performance of the CBMs established at the earlier review conferences. Noting the continued importance of the CBMs, the conference urged states to submit full and timely reports, while recognizing that some parties experienced technical difficulties in doing so.[19] Mindful of the possibility of undermining the work of the Ad Hoc Group at a critical juncture, however, the Fourth Conference refrained from any action that would have changed the Ad Hoc Group's mandate or interfered with its work.

Clearly, the efforts to institutionalize and augment CBMs have not to date lived up to expectations. Nearly all observers recognize that these CBMs have attempted to carry a Herculean burden—that of building confidence in compliance in the absence of legally binding verification

[19] With a flourish of diplomatic rhetoric, the Final Declaration affirmed that participation in the information exchanges established at the earlier review conferences "has contributed to enhancing transparency and building confidence."

measures. Compared to a strong compliance protocol, these CBMs are a feeble bag of tools. Told to build a house, the international community allotted itself a window, a door, and a typewriter to complete construction, when what it really needed to construct a house was mortar, bricks, and energetic masons.

International events might also account for the dissipation of much of the optimism with which some participants viewed the value of the BWC's information exchanges. Particularly chilling were the revelations regarding the Soviet biological weapons program that operated for over two decades in violation of the BWC and its continued existence in Russia and the UN Special Commission's (UNSCOM's) discoveries of the Iraqi biological weapons program.[20]

The US government had long suspected that the USSR harbored a biological weapons program and viewed the 1979 outbreak of anthrax in the city of Sverdlovsk (now Ekaterinberg) as confirmation of that suspicion. The United States alleged that the outbreak was due to an accidental release of spores from a biological weapons facility. Ultimately, President Boris Yeltsin admitted that the Soviet Union had a secret biological weapons program and that the program continued after the break-up of the USSR.[21] Yeltsin stated that he would terminate the Russian program and to that end he agreed to trilateral inspections with the United States and the United Kingdom, the three co-depositaries of the BWC. While the impetus behind the process was to inspect Russian facilities, the United States and the United Kingdom agreed to have some reciprocal inspections. The trilateral process is secret and therefore no public information is available to provide assurance to other treaty parties that Russia is fulfilling its BWC obligations. In fact, the trilateral process has thus far failed

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[20] An excellent summary of the information on Iraq's biological weapons program is contained in Raymond A. Zilinskas, "Iraq's Biological Weapons: The Past as Future?" *Journal of the American Medical Association* 278, no. 5 (6 August 1997): 418–24. For more detailed information on Iraq's program see: 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)*, UN Security Council Report S/1995/284; 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)*, UN Security Council Report S/1995/864, 1995; 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)*, UN Security Council Report, S/1996/848, 1996; 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)*, UN Security Council Report S/1997/301, 1997.

[21] J. Dahlburg, "Russia Admits It Violated Pact on Biological Warfare," *Los Angeles Times*, 15 September 1992, A1.

to demonstrate to its participants that Russia has terminated its program.[22] Worse yet, the trilateral process has stalled. No visits have taken place in any of the countries since 1994.[23]

Prior to the 1991 Gulf War, intelligence sources suspected that Iraq had "an ambitious biological warfare program"[24] including weapons using anthrax and botulinum toxin.[25] The extent of Iraq's program and the equipment involved, however, was completely hidden for an extended period of time and only partially uncovered by UNSCOM's determination.[26] Even now, UNSCOM does not know the full story of Iraq's biological weapons program, and the inspectors remain skeptical that Iraq has destroyed all of its biological weapons as it has claimed.[27] Moreover, the political leaders that sought to acquire biological weapons are still in power, the scientists and engineers that developed and produced biological weapons remain employed much as before, and much of the equipment, facilities, and biological infrastructure underpinning the biological weapons program is still in place. UNSCOM believes that it would be easier for Iraq to reconstitute its biological weapons program than it would be for Iraq to reacquire either nuclear or chemical weapons.[28] Given the evidence uncovered by UNSCOM, Iraq appears to be in violation of its BWC obligations.

The disclosure of biological weapons programs in Russia and Iraq has sparked heightened international concerns about biological weapons proliferation. The existence of the Soviet and Iraqi programs also helped to extinguish any hope that CBMs alone can be relied upon to provide confidence in the BWC's ability to eliminate biological weapons. Thus, many BWC members have begun to put more effort into concluding a legally binding protocol to strengthen the treaty regime.

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[22] US Arms Control and Disarmament Agency, *Threat Control Through Arms Control: 1995 Annual Report to Congress* (Washington, D.C.: Government Printing Office, 1996): 66–7.

[23] On-the-record information regarding the trilateral process is difficult to come by. In a December 1997 Op-Ed in the New York Times, Raymond Zilinskas states that US and British inspectors were denied access first to Russian military installations and ultimately to all sites in Russia. Raymond A. Zilinskas, "The Other Biological Weapons Worry," *New York Times*, 28 November 1997. The information regarding the last inspection in Russia was obtained by the author in a conversation with a US government official speaking off the record.

[24] Lt. Col. George W. Christopher et al., "Biological Warfare: A Historical Perspective," *Journal of the American Medical Association* 278, no. 5 (6 August 1997): 416.

[25] For an extensive list of sources see W. Seth Carus, *"The Poor Man's Atomic Bomb: Biological Weapons in the Middle East,"* Policy Paper No. 23 (Washington, D.C.: Washington Institute for Near East Policy, 1991): 5–18, and W. Seth Carus, *The Genie Unleashed: Iraq's Chemical and Biological Weapons Production*, Policy Paper No. 14, (Washington, D.C.: Washington Institute for Near East Policy, 1989): 29–35.

[26] UNSCOM Chief, Rolf Ekèus, his successor, Richard Butler, and their teams of international inspectors have shown noteworthy persistence.

[27] 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)*, Report S/1997/301, 1997.

[28] The author is indebted to Raymond Zilinskas of the University of Maryland Biotechnology Institute for his contribution to a number of these arguments. Dr. Zilinskas participated in two inspections in Iraq in 1994.

Not all participants in the Ad Hoc Group are approaching the negotiations with equal enthusiasm. Indeed, members of some delegations fear that these negotiations could be headed for a protracted stalemate, where there is much activity but little progress. The Ad Hoc Group's mandate directs the delegations to consider four separate areas in the context of drafting proposals to strengthen the BWC: 1) definitions of terms and objective criteria; 2) confidence building and transparency measures; 3) measures to promote compliance; and, 4) measures to implement Article X of the BWC.[29] Working from a rolling text introduced in July 1997, CBMs are thus among the issues under negotiation for inclusion in a BWC protocol.[30]

Although President Bill Clinton has called for the completion of the protocol in 1998, that goal is unlikely to be met. Recognizing that the full and universal implementation of a protocol to the BWC may not take effect for some time, states are unwilling to cast off the existing CBMs in favor of any that may become part of the future protocol. At the same time, CBMs are included in the 1994 mandate that established the Ad Hoc Group. A number of CBMs are included in the October 1997 rolling text. To date, however, the Ad Hoc Group has devoted little effort to discussing the role CBMs could play in augmenting and reinforcing the other components of a protocol.

CBMs Under Consideration by the Ad Hoc Group

The Ad Hoc Group is likely to incorporate many of the existing politically binding CBMs as legally binding declarations. Many of these CBMs already appear in the rolling text. For example, the negotiators are considering declarations of: 1)biological defense programs and facilities; 2) past programs, both offensive and defensive; 3) high containment facilities; and, 4)vaccine production facilities.[31] The tabling of these measures indicates a prevalent view within the Ad Hoc Group that required declarations, backed up by some type of on-site measures, are the essential components of a protocol. Two types of on-site measures are under consideration. The first type, known in the BWC negotiations as "noncompliance concern investigations," would investigate the alleged use of biological weapons and compliance concerns at pertinent facilities. The second type would not be

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[29] Article X of the BWC establishes the obligation of states to facilitate, and establishes their right to participate in "the fullest possible exchange of equipment, materials and scientific and technological information for the use of bacteriological (biological) agents and toxins for peaceful purposes." The language of the article is patterned after Article IV of the NPT.

[30] If and when parties to the BWC agree to a legally binding protocol, each BWC member would be required to ratify it before the legal obligation to comply with provisions *of the protocol* took effect. In all likelihood, a number of BWC parties will not ratify the protocol swiftly. Thus, states that are now party to the BWC will consist of two groups, those which are bound by the provisions in the treaty only and those which have taken on the supplementary obligations of the protocol.

[31] Ad Hoc Group, *Procedural Report of the Ad Hoc Group 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,* Document BWC/AD HOC GROUP/38, 6 October 1997, 25–30. Hereinafter referred to as the "rolling text."

associated with a compliance concern and are often referred to as "non-challenge visits."[32] While these non-challenge visits share some characteristics of routine inspections under the Chemical Weapons Convention, important differences discourage the use of that more familiar term in the BWC context.[33]

The following list of CBMs have been evaluated previously for their contributions to verifying the BWC and are included in the October 1997 rolling text: 1) surveillance of publications; 2) surveillance of legislation; 3) data on transfers and transfer requests; 4) multilateral information sharing; 5) exchange visits; and, 6) confidence building visits.[34] Each of these is discussed in greater detail below. In a somewhat perverse turn of events, the Ad Hoc Group is currently discussing these measures as voluntary measures only. In other words, the delegations are not contemplating these CBMs as legally binding, as other components of the protocol would be, nor as having the politically binding status of the 1986 and 1991 CBMs. However, very few meetings have taken place to discuss CBMs, in contrast to those devoted to other topics. Perhaps as the negotiations proceed, the Ad Hoc Group will give more serious attention to CBMs and their role in the protocol.

Surveillance of Publications

The collection of publications from scientific and policy journals is an activity that could be relevant to the BWC in two distinct ways. First, this CBM could help international authorities keep track of the activities of scientists with the skills needed to make biological weapons. The treaty parties maintain that basic and much applied research in the biosciences should not be classified.[35]

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[32] See for example, "The Necessity for Non-Challenge Visits," *Strengthening the Biological Weapons Convention,* Briefing Paper No. 2, Graham S. Pearson and Malcolm R. Dando, eds. (Bradford, United Kingdom: University of Bradford, September 1997) and its executive summary by Graham S. Pearson and Marie I. Chevrier. Also available on the Internet at: http://www.brad.ac.uk/acad/sbtwc.

[33] The Chemical Weapons Convention (CWC) features a routine inspection regime designed to focus monitoring activities on the facilities deemed to be of"highest risk" to proliferation. A wide spectrum of industry facilities will declare data on an initial and annual basis. All chemical facilities declared under the CWC's Schedules 1 and 2 will receive a baseline inspection, after which the frequency of subsequent routine inspections will be determined depending on the type of chemical(s) produced at the facility. From facility to facility, the frequency of these subsequent inspections could vary considerably. In contrast, only a percentage of industry facilities that fall under the CWC's Schedule 3 will be inspected routinely on an annual basis. For more on the CWC's routine inspections, see chapter 5 of this report. As of yet, no proposals have been made to inspect all biological facilities declared under a BWC protocol. Nor are there proposals to schedule follow-up inspections to all the facilities, however infrequently. A non-challenge visit of a declared facility in the BWC context would either be tied to ambiguities in declarations that did not reach the level of evidence required to launch a challenge inspection, or it would be a random choice in order to deter would-be violators from using declared facilities as a cover for illegitimate activities.

[34] For the evaluation of CBMs, see Ad Hoc Group, *Ad Hoc Group of Governmental Experts to Identify and Examine Potential Verification Measures from a Scientific and Technical Standpoint,* Document BWC/CONF.III/VEREX/9, 1993. See also pages 202–19 of the October 1997 rolling text.

[35] An Ad Hoc Group of Verification Experts, know as VEREX, met from March 1992 to September 1993 to evaluate these and other proposals. Ad Hoc Group, *Third 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*: *Annex to Final Declaration on Confidence-Building Measures*, Document

Research in biological defense, especially that conducted in government facilities, is expected to be published and openly available. Keeping track of the literature could provide evidence that scientists are engaged in legitimate activities and publishing their results. Conversely, an open or non-classified literature review might show that a well-trained scientist was conspicuously missing from the list of published authors and therefore might be spending time on other activities, including clandestine biological weapons work.[36] Second, this literature review could compile a central repository of scientific and other articles. If all treaty parties were given access to this scientific library, this measure would help fulfill the intentions of the BWC's requirement to facilitate "the fullest possible exchange of. . . scientific and technological information for the use of. . . agents and toxins for peaceful purposes."[37]

This CBM would go beyond the existing CBM, which encourages parties to publish results and promote the use of knowledge.[38] This enhanced version would create the means by which any future BWC administrative agency would have the responsibility to collect and archive publications on an on-going basis. Given the quantity of published information, this task would be one of the more daunting ones facing the BWC's yet to be established inspectorate. The current format for collecting information emphasizes reporting publications on: 1) the results of research conducted in national biological defense research and development programs, and 2) outbreaks of infectious diseases and similar occurrences caused by toxins. Since its initiation in 1991, reporting on this CBM has varied.[39] The low level of responsiveness suggests that additional reporting burdens should not be imposed in the absence of a compelling justification. Rather, the capacity within the BWC inspectorate should be created to survey the literature more extensively. Creating the capacity within the organization to survey publications in the open literature is likely to be relatively inexpensive and an alternative preferable to the proposed CBM.

Surveillance of Legislation

BWC members are required to "take any necessary measures" to assure that the prohibitions set forth in Article I are achieved "within the territory of each State, under its jurisdiction or control anywhere."[40] Nations that have taken measures to ensure implementation of the BWC domestically have generally done so through legislation making the possession or transfer of biological or toxin weapons a crime. Enacting legislation that criminalizes activities associated with biological weapons and stipulates penalties according to the severity of the offense could be an indication that countries

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BWC/CONF.III/23, Part II, Annex, 1991, 39.

[36] Legitimate reasons certainly exist for scientists to be absent from a list of published authors.

[37] See Article X of the Biological Weapons Convention.

[38] See CBM C in United Nations, *Third 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, Annex to Final Declaration on Confidence-Building Measures,* Document BWC/CONF.III/23, Part II, Annex, 1991.

[39] Hunger, "Article V: Confidence Building Measures," 83.

[40] See Article IV of the Biological Weapons Convention.

are taking their BWC responsibilities seriously. The ability to punish *individuals* convicted under such legislation could also deter sub-national or terrorist groups from acquiring biological or toxin weapons or make it more difficult for such groups to acquire these weapons. Nonetheless, a July 1996 paper on CBMs states that the "existence or absence of legislation may not be an indication of compliance or non-compliance."[41] This quote shows considerable ambivalence about the ability of the surveillance of legislation to contribute substantially to confidence in compliance.

The proposed surveillance of legislation CBM is similar to an existing CBM.[42] Despite the apparent indifference about this particular measure, surveillance of legislation is under discussion because many countries would need to enact enabling legislation as they ratified a BWC protocol. The data that states provide under this CBM could be used to draft model legislation to guide countries still in the process of composing their own legislation. As a voluntary measure, this CBM seems to have little merit. Providing a copy of any legislation enacted relevant to the BWC would be a trivial task for nations and should therefore be included as a legal obligation.

Data on Transfers and Transfer Requests and on Production

Reports on the transfer and requests to transfer biological materials and equipment could increase confidence in supplier states' compliance with the BWC's Article III obligation not to assist biological weapons proliferation. Furthermore, this CBM could increase transparency by enabling insight into the biological activities of countries without the indigenous capacity to produce dual-use equipment. This data could therefore provide valuable assistance to BWC inspectors who could confirm the uses of biological materials in peaceful projects and inquire about the location of transferred equipment.

The Ad Hoc Group is also considering including reports on actual and requested transfers of equipment and materials as a mandatory compliance measure.[43] The role of mandatory reporting of export and import data in a legally binding protocol is reportedly quite controversial.[44] Mandatory reporting of transfer data could make a significant contribution to strengthening the BWC. If the Ad Hoc Group approves a mandatory measure, it would clearly supersede any similar, voluntary CBM.

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[41] Ad Hoc Group, Friend of the Chair, *Procedural Report of the Ad Hoc Group of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) Weapons and on Their Destruction*, Document BWC/AD HOC GROUP/31/CORR1, July 1996, 81.

[42] CBM E, added to the BWC information exchange in 1991, requires nations to report "legislation, regulations and other measures" relevant to the BWC.

[43] Rolling text, Document BWC/AD HOC GROUP/38, Annex I, 30.

[44] Some countries oppose export controls such as those imposed by the members of the Australia Group on the grounds that they are discriminatory and inhibit economic development. They would prefer that any trade restrictions in biological agents and equipment become part of a negotiated agreement. Australia Group members, on the other hand, support the informal system of the Australia Group. They think this approach is more effective at hindering proliferation because the Australia Group controls its own membership and can deny export licenses to any country thought to be harboring a biological weapons program. See Richard Latter, "Deterring Biological Warfare: What Needs to be Done?" Short Report on Wilton Park Conference 96/5, 27–29 September 1996, 4–5.

Multilateral Information Sharing

The umbrella of multilateral information sharing covers a wide variety of activities. Apparently, a number of Ad Hoc Group participants seem to envision the future BWC monitoring agency as a hub of information that parties to the treaty and various international organizations (primarily in the health field) could contribute to and access. The BWC inspectorate could compile and make available electronically to BWC members any data submitted under mandatory declarations and voluntary CBMs.[45] The multilateral information sharing CBM would enable states requiring assistance in gathering and interpreting information required under CBMs to seek assistance from the inspectorate.[46] The following are all included in the rolling text as areas of possible multilateral information sharing:

- CBM reports as agreed in 1991;
- Consultation in completing CBM requirements and reporting obligations;
- Surveillance of human disease outbreak and unusual disease outbreak reports;
- Information on pharmaceutical and vaccine production, good manufacturing practices, and biosafety capabilities and procedures;
- Information concerning research and exchange programs covering areas related to the BWC and the protocol, including, for example, any exchange programs of scientific personnel established under other CBMs. This CBM would provide information on the consequences of the exchanges to other states that did not participate in the exchanges; and,
- Information related to obligations under the BWC.[47]

Taken in total and over time, the multilateral information sharing CBM could contribute to transparency by helping states meet their CBM obligations.

The downside of this particular CBM is that a glut of data could bury the relevant and interesting information in a sea of non-essential data, thereby obscuring the very activities in need of clarification. Creating the capacity within the BWC organization to accept multilateral information seems worthwhile. The priority should be responding to assistance requests rather than cataloguing information. The organization should be not be under the obligation to accept, catalogue, and make all information available. Instead, the organization should be given the discretion to select only that information which it judges to be most relevant and likely to be beneficial to others. The capacity to acquire and dispense information electronically is likely to be key to assessing the net benefit of this measure. Inspectorate personnel could also respond to requests for assistance from countries seeking aid in fulfilling their declaration obligations.

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[45] The inspectorate could make this data available via the Internet or another mechanism.

[46] Government of Brazil, Ad Hoc Group, "Strengthening the BWC: The Next Steps," *Special 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*, Document BWC/SPCONF/WP.5, 1994 for a discussion of the merits of a proposal to assist countries in the compilation of data for submission under the CBMs.

[47] All of these can be found in the 1997 rolling text, Document BWC/AD HOC GROUP/38, 202–19.

Exchange visits

One proposed CBM would have BWC members voluntarily undertake exchange visits on a bilateral or multilateral basis. The concept would have scientific personnel in fields ranging from agriculture to virology visiting a related laboratory or other facility, for short-term or continuing interaction. The goal of exchange visits is to create transparency regarding biological research and development activities. Also, because research practices vary from country to country and even within a country, exchange visits could help establish a standard of "usual or customary practice" that could benefit inspectors trying to distinguish between common and unusual activities.

This CBM would open biological facilities to outsiders who, even though they are not trained inspectors, might gain an impression over time of whether covert activities were taking place at a certain facility or whether key scientific personnel were engaged in secret research and development. However, the value of this CBM would depend on the quality and quantity of the access to people and facilities the visiting scientists were given. Access can be expected to vary from facility to facility. Such visits would be arranged with long notice and the host country would completely determine access in most cases.[48] Thus, the confidence gained would ordinarily be limited to a specific facility. Nevertheless, the willingness of a country to participate in exchange visits could be an indication of a positive attitude toward compliance.

Confidence-Building Visits

One of the most controversial issues in the protocol negotiations is whether to include on-site inspections that are not initiated by a challenge concern, the so-called non-challenge visits. The United States, China, Russia, Japan, and India appear to be skeptical of the value of on-site inspections at declared facilities other than through a challenge mechanism. The European Union, Sweden, Canada, Brazil, South Korea, and Australia favor including some random inspections that are not tied to compliance concerns. Presumably in an attempt to find a compromise position, South Africa proposed the concept of "confidence-building visits," which is included in the list of voluntary CBMs. South Africa's initial proposal had a number of intriguing features. Although participation in a system of such visits would be voluntary, participating states would commit to a set of agreed upon conditions governing the visits. The BWC inspectorate would coordinate unscheduled, relatively short-notice, confidence-building visits. For example, one week is suggested for notice to the country being visited, with shorter notice given to the specific facility involved. An expert staffer of the BWC inspectorate could supervise the potential "visitors" nominated by particular states. Other factors that could govern confidence-building visits are: limits on the number of days visits could take place within a country or region; the nature of facility access; a country's right to refuse a particular visitor; and the types of facilities that could be selected for a visit.[49]

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[48] Visitors could perhaps request access to an area or an individual as they go along, but host officials are under no legal obligation to grant access under a voluntary CBM.

[49] While not all of the features of the South African working paper appear in the rolling text, the text is a work in progress, and those details could be incorporated later.

These confidence-building visits, have some, but not all, of the advantages of mandatory random inspections. The major drawback of confidence-building visits lies in their voluntary nature and the ability of the visited country to "take any measure they deem necessary to ensure that commercial and other information is not jeopardized."[50] Thus, although they appear to have more rigor, confidence-building visits would likely have similar potential and limitations to build confidence as exchange visits. The ability of the visiting team to choose a site at short notice would be a noteworthy advantage. In fact, the longer duration of exchange visits could yield information to an exchange scientist not readily apparent in a visit of short duration.

If mandatory, random inspections—non-challenge visits—are included in the eventual BWC protocol, any additional CBMs, particularly the confidence-building and exchange visits, are likely to have little additional value in increasing confidence in compliance. Mandatory on-site measures would, of course, be a more rigorous approach to assessing treaty compliance; CBMs are obviously a weaker alternative. Should the Ad Hoc Group reject non-challenge visits, it will probably fall back to incorporating the proposed voluntary exchange and confidence-building visits within the protocol. This outcome would engender an overall weaker protocol. The Ad Hoc Group should not squander the opportunity to establish strong, legally binding measures by substituting voluntary CBMs for the more stringent alternative.

Building Confidence in Compliance with the BWC

In contrast to CBMs negotiated in different contexts, the measures established to build confidence in the BWC are extensively multilateral. The path-breaking CBMs of the Conference on Security and Cooperation in Europe, although multilateral, were primarily intended to reduce tensions in Central Europe between the two superpowers and their allies.[51] Arms control CBMs among a small number of countries can be more easily targeted to facilities and activities of concern. Building confidence among a much more divergent group, such as the 140 members and 17 signatories of the BWC, is a more daunting task.

One thorny aspect of creating and sustaining confidence in compliance with the BWC is that the judgment of whether or not a country is in compliance is integrally linked to an individual country's identity. For better or for worse, each participating state has generated a behavioral reputation via its actions and rhetoric. This track record gives rise to assumptions and judgments in other nations, as well as to differing standards of evidence. If a country is democratic, scrupulously compliant with other treaty obligations, not an aggressor in recent international conflicts, and unfailingly cooperative with respect to inquiries, a relatively low standard of evidence

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[50] Government of South Africa, Ad Hoc Group, *Working Paper on Confidence Building Visits*, September 1996.

[51] See, for example, Richard E. Darilek, "East-West Confidence-building: Defusing the Cold War in Europe" in *A Handbook of Confidence-building Measures for Regional Security*, 2d. Ed., Michael Krepon, ed. (Washington, D.C.: Henry L. Stimson Center, 1995): 13–4; and Jeffrey D. McCausland, "Conventional Arms Control," in *Arms Control: Toward the 21st Century*, 138–54.

is sufficient to convince most countries of this state's compliance. Alternatively, a closed country with a totalitarian or autocratic form of government that has been lax in its compliance with other agreements, has an aggressive reputation, and hinders or delays responses to treaty-related inquiries will be held to a more stringent standard of proof. Moreover, the relationship between the individual countries inevitably influences judgment about compliance. Hypothetically, if Egypt and Pakistan were both assessing India's adherence to the BWC, considerably more evidence would probably be required to convince Pakistan than Egypt that India was acting in compliance. While this problem exists with other multilateral arms control agreements, it plays a larger role in assessing compliance with the BWC because such compliance is more difficult to judge on independent factors. The production and development of biological weapons is relatively easy to conceal.

When a nation submits data for CBMs or legally mandated declarations, the extent to which this data increases confidence is dependent on the prior estimation of a country's compliance and the quality of the information in the declaration submitted. The following matrix illustrates the effect of these two factors on the confidence level of any particular country. The matrix columns represent countries, divided into three categories, according to the degree of suspicion regarding compliance prior to the receipt of CBM data. The two rows in the matrix distinguish between the effect of trustworthy and complete information that is consistent with compliance and data that is absent altogether, incomplete, inadequate, or inconsistent with information from other sources. The boxes of the matrix show the effect of varying circumstances on confidence.

Reading down the columns and then across, the effect on confidence might include the following possible reactions:

Box 1. A country suspected of noncompliance submits information consistent with compliance. Reaction: So what? This country's prior poor behavior overrides what is seen as non-convincing information, especially given the fact that biological weapons are easy to manufacture and hide. This country continues to be regarded as noncompliant.

Matrix 1: The Effect of Information and Prior Suspicion on Confidence in the BWC Context.

QUALITY OF INFORMATION SUBMITTED BY A COUNTRY	PRIOR DEGREE OF SUSPICION		
	Very Suspicious of Country	**Uncertain, Slightly Suspicious of Country**	**Not Suspicious of Country**
Complete, Consistent	1. No change in estimate of compliance.	3. Changes estimate of compliance; more confident of compliance.	5. No change in estimate of compliance.
Inadequate, Incomplete, Inconsistent, Absent	2. More certain of estimate of noncompliance.	4. Changes estimate of compliance; more confident of estimate of noncompliance.	6. Less confident of instrument; undermines the regime.

Box 2. A country suspected of noncompliance submits information inconsistent with compliance. Reaction: Some states are more convinced than ever that this country is not in compliance and has something to hide.

Box 3. A country that is slightly suspected submits information consistent with compliance. Reaction: Suspicions about this state decrease and the view that this country may be complying increases.

Box 4. A country that is slightly suspected submits information inconsistent with compliance. Reaction: In general, states become more suspicious and estimates of that country's compliance have decreased.

Box 5. A country that is not suspected submits information consistent with compliance. Reaction: The information contained in this declaration is expected and therefore does not change prevailing estimates of compliance.

Box 6. A country that is not suspected submits information inconsistent with compliance. Reaction: What is the matter? Why did this country not take its commitment to submit CBM data seriously? When countries under no suspicion of violation do not fulfill their obligations, confidence in the regime, *but not necessarily the country,* is undermined.

This analysis suggests that CBMs, particularly those that are not legally binding, are successful only with a small group of countries. The typical success story entails a country that is the object of other governments' notable, but not grave concerns. Therefore, other governments are looking for more information to ameliorate their concerns. When a country falls into this undecided category, other states are willing to accept data that increases their confidence of compliance.[52] For these countries, confidence in compliance can be increased, especially over time, if the CBM data submitted is consistently complete, addresses areas of previous concern, and is presented in an open and straightforward manner. Eventually, confidence may increase to the point where countries move from the middle column of the matrix to that on the right. Similarly, to the extent that a country submits information that is inconsistent with compliance and does not cooperate with attempts to resolve data discrepancies through confidence-building visits, other states will be more confident in their suspicions. As countries reduce their uncertainty about another state's compliance, they avoid false confidence. The need to avert false confidence is particularly important because some observers mistakenly believe that arms control and CBMs induce false confidence, which renders a country vulnerable to a threat that it does not sufficiently appreciate. In practice, however, false confidence is not a guaranteed result of either arms control or CBMs.

The box 6 situation reveals an interesting and somewhat counter-intuitive situation. Establishing CBMs is not an endeavor without costs. If CBMs are so time-consuming and onerous that compliant countries begin to let their obligations slide, their negligence could undercut rather than bolster confidence in the treaty involved. In particular, the value of collecting information that is readily available elsewhere could overburden states that are otherwise sincerely trying to meet their CBM or treaty obligations. Proposals requiring collection of data about disease outbreaks or BWC-relevant publications may fall into this category of dubious-value CBMs.[53] Preferably, only those measures that are likely to contribute meaningfully to building confidence would be selected. Also, they should be tailored as precisely as possible to avert collecting information simply for the sake of doing something.

The matrix analysis also indicates that the international community should not attempt to place the whole confidence-building burden on measures that have an effect on a relatively small proportion of countries. Serious compliance concerns require measures more stringent than legally binding declarations and voluntary CBMs. While non-challenge visits of declared facilities and investigations of compliance concerns may not find conclusive evidence of a violation, the ease with which host officials admit inspectors to facilities, the completeness of a facility's records, and other factors all contribute to a picture of compliance or noncompliance. Sustaining strong suspicions of a country's noncompliance would become increasingly difficult in the face of information from on-

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[52] James Macintosh, "Confidence Building in the Arms Control Process: A Transformation View," *Arms Control and Disarmament Studies*, no. 2 (Ottawa, Canada: Department of Foreign Affairs and International Trade, 1996).

[53] Iris Hunger makes this point in an unpublished paper, "Confidence Building Measures Within the Instrument."

site measures that supports compliance.[54] Equally, the UNSCOM experience in Iraq showed that while inspectors did not find clear evidence of biological weapons production for a long time, the observations of the inspectors and the behavior of the Iraqis was consistent only with the existence of a covert biological weapons program. Over time, UNSCOM became more confident of their suspicions that the Iraqis were hiding information about their biological weapons program and with persistence found evidence to confirm those suspicions.

CBMs and their legally binding equivalents (e.g. declarations) are nevertheless valuable, primarily because of their effects on countries that fall into the middle category. CBMs can increase confidence in some countries' compliance even if they cannot increase confidence in all countries' compliance. Moreover, CBMs can maintain incentives to keep countries from undertaking activities that could place them under suspicion. In other words, CBMs help keep countries from moving from the far right-hand column of the matrix to the middle column. Similarly, CBMs may resolve minor discrepancies or questionable activities having the effect of moving countries from the middle column of the matrix to the far right.

A fourth set of countries—the perpetrators or inheritors of clandestine biological weapons programs—also pose problems for CBMs and the BWC. The two countries that fit most readily into this category are Iraq and Russia. Thus far, Russia and Iraq are special cases that have required a set of measures outside the parameters of the BWC. The trilateral process and UNSCOM have attempted to uncover information about past programs in the Soviet Union and Iraq, respectively, and bring these countries into compliance. The trilateral process has had very limited success, and UNSCOM has no evidence indicating that Iraq has eliminated its biological weapons program.

Despite some surface similarities, the situations in the two countries are very different. Unlike Iraq, Russia is under no international obligation to submit to inspections, has not been defeated in war, and is a fledgling democracy. The Soviet Union's biological weapons program may have involved officials who currently hold positions of power and responsibility in Russia or other former Soviet states. These circumstances may be an impediment to revealing full information about the past program, and Russia's current compliance status will continue to be unclear. Conversely, the only way to establish that Iraq is now in compliance with the BWC may be to have a full picture of its past program, its capabilities, and its output.

Given these significant differences, the approaches for dealing with Russia and Iraq should be reconsidered. This reevaluation should examine the progress, or lack thereof, of the approaches underway, and the options available at a national and an international level to bring countries into BWC compliance. On several occasions, the UN and the Security Council have reviewed the Iraqi situation, deciding wisely to support continuing UNSCOM inspections until Iraq conclusively abolishes it weapons of mass destruction programs. At a minimum, the United Kingdom and the United States should reevaluate the goals, accomplishments, and limitations of the trilateral process.

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[54] Pearson and Dando, "The Necessity for Non-Challenge Visits."

Russia, for its part, should take steps to make its current activities at biological facilities within the Ministry of Defense as transparent as possible.

In the face of strong and long-standing suspicions of noncompliance, the BWC will stand as an articulation of the norm against the acquisition and use of biological weapons, which should provide the international community with the basis to keep the politicians' "feet to the fire" in getting to the bottom of compliance concerns. Doing so will likely require measures beyond those negotiated for the BWC. UNSCOM stands as a stark reminder that international cooperation of long duration may be necessary to confront egregious violations on a case-by-case basis. The UN Security Council is the appropriate forum for such decisions because the BWC designates it as the authority to initiate investigations of compliance concerns.[55] Military force and economic sanctions are additional options for responding to the proliferation or use biological weapons. Implementing a convention that creates a crime under international law of the possession, development, or production of biological weapons is yet another avenue that should be pursued. All of these tools, and the political will to impose them, are needed to confront one of the most dangerous threats to world peace and security.

Conclusions

CBMs, as traditionally defined and implemented in the BWC, cannot be a substitute for a legally binding framework to enhance treaty compliance. The tendency of many countries to neglect the obligations of politically binding CBMs has eroded initial optimism regarding the potential value of the CBMs established in 1986 and 1991. Moreover, without random checks on the accuracy of information, states have little incentive to complete what, for some, may be burdensome reporting requirements. A compliance protocol, with strong complementary measures that reinforce the goals of deterring the acquisition and use of biological weapons is a necessary foundation. Such a protocol, implemented through an independent inspectorate, is the only way to provide constant professional attention to biological activities in BWC member states.

Despite the limits to CBMs in the BWC arena, CBMs can and do play a role in building confidence in some countries' compliance with the BWC. Building confidence in compliance is generally limited to those countries that are in a middle ground on a scale of confidence. Such nations are not a country's close allies, about whose behavior one would have no suspicions. Neither are they a country's enemies, about whose behavior one would always be suspicious. Confidence in these in-between countries' compliance with the BWC can be enhanced if they submit accurate, timely information in response to reporting requirements. Similarly, confidence in these countries' compliance can be eroded if they do not submit required information or do so in a slipshod fashion.

As for the CBMs that are included in the rolling text:

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[55] Article VI of the Biological Weapons Convention.

- Surveillance of publications should not be an obligation of states. The BWC organization should have sufficient staff to survey publicly available publications.

- Surveillance of legislation should be a legally binding obligation of states.

- Data on transfers and transfer requests needs further development. The negotiators need to elaborate this CBM and devote more analysis to how it could be implemented.

- Multilateral information sharing and exchange visits should be encouraged to show states' willingness to comply with their Article X obligations, not because these measures are likely to yield much confidence in compliance.

- Confidence-building visits are inferior to legally binding non-challenge visits.

CBMs ought to be drafted with care and tailored to activities likely to yield the most relevant information. Although this comment might seem obvious, negotiators should be careful not to approach CBMs as a source of data that would be nice to have or that might prove useful in the future. Increasing the amount of data to be reported, even if the response is voluntary, could drown the most useful information in a sea of irrelevant facts. Moreover, onerous reporting requirements could lead conscientious countries to default on their obligations. Such actions could lead, in turn, to a general erosion in confidence in the BWC as a whole.

Verification Provisions of the Chemical Weapons Convention and Their Relevance to the Biological Weapons Convention

***Jonathan B. Tucker,* Ph.D.**

In crafting a compliance monitoring protocol for the Biological and Toxin Weapons Convention (BWC), the Ad Hoc Group of BWC member states meeting in Geneva has looked to the verification provisions of the 1993 Chemical Weapons Convention (CWC) for guidance. At first glance, the two treaties have much in common, since they both require the elimination of existing stocks of warfare agents and prohibit their acquisition in the future.[1] Both treaties must also address the challenge of distinguishing the production of chemical or biological weapons from the peaceful applications of industrial chemistry and biology. In view of these similarities, some countries favor adopting the basic elements of the CWC verification regime in the BWC compliance protocol.

At the same time, however, important differences between chemical and biological weapons limit the applicability of CWC verification measures to the BWC. The fact that certain microbial and toxin agents are highly potent per unit weight means that a militarily significant quantity is measured in kilograms, compared with tons for chemical nerve agents. Moreover, whereas production of a chemical arsenal requires a fairly large industrial plant, a stockpile of biological or toxin agents could be produced to order in a pilot-scale facility over a period of weeks. For these reasons, the threshold for militarily significant cheating, or "treaty breakout," is considerably lower for the BWC than for the CWC. Finally, the ambiguities between offensive and defensive research on infectious agents and the lack of well-defined indicators of biological or toxin agent production make it more difficult to distinguish between "treaty-prohibited" and "treaty-permitted" activities at dual-capable biological facilities. For this reason, assessing intent is as important as physical evidence in determining BWC compliance. Table 3 describes the differences between chemical and biological weapons and shows where these differences complicate BWC compliance monitoring.

The following sections review the major verification provisions of the CWC and assess their applicability to the BWC. Taken together, the various elements of the CWC verification regime provide a useful model for a workable BWC compliance protocol. Depending on the specific issue, however, the CWC model is sometimes readily adaptable, sometimes in need of adjustment for the BWC context, and sometimes incapable of meeting the unique challenges of monitoring biological weapons activities.

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[1] Under the BWC, all biological and toxin warfare agents, munitions, and specialized delivery systems were to have been destroyed or diverted to peaceful purposes within nine months after the treaty's entry into force on 26 March 1975. Countries that accede to the BWC after that date must destroy their stockpiles as soon as possible. CWC members must eliminate their existing stockpiles of chemical weapons, if any, within 10 years, with the possibility of a five-year extension in exceptional cases. The CWC also requires the destruction or conversion of former chemical weapons production facilities.

Table 3: Technical Differences Between Chemical and Biological Weapons and Implications Thereof for BWC Compliance Monitoring.

Parameters	Chemical Weapons	Biological Weapons	Implications for BWC Monitoring
Agent types	Man-made toxic chemicals that do not exist in the natural environment.	Pathogenic microbes and toxins produced by living bacteria, plants, and animals.	Disease agents can be cultivated for legitimate purposes, such as vaccine production, complicating the process of BWC compliance monitoring.
Range of agents potentially suitable for military use	Relatively few chemicals have the necessary toxicity and physical properties, but the development of novel agents is possible.	The range of potential agents is nearly unlimited because of the occasional emergence of natural diseases and the potential for genetic manipulation of microorganisms and toxins.	The broad, purpose-based coverage of the prohibitions in Article I of the BWC (the "general-purpose criterion") must be preserved.
Militarily significant quantity of agent	80 to 1,000 metric tons of chemical agent, depending on type and lethality.	Kilograms to tens of kilograms of agent, depending on type and lethality.	Militarily significant production of biological and toxin agents in small-scale facilities may elude detection. Stockpiles may also be small enough to permit easy concealment.
Stockpiling requirement	Must be stockpiled in multi-ton quantities in stabilized or binary form, or produced in large volume prior to use.	Militarily significant quantities of agent can be produced to order in a few days or weeks, obviating the need for long-term storage.	Dual-use production facilities such as vaccine plants may have a "latent" capacity to produce biological agents in wartime.
Peaceful medical applications of agents and materials	Very small quantities of some Schedule 1 chemicals (e.g., nitrogen mustard, saxitoxin, ricin) are used in biomedical research and medical therapeutics.	Microbial pathogens may be grown in large quantities for the production of vaccines. Also, natural toxins such as botulinum and ricin are increasingly used in medical therapeutics.	Production of microbial pathogens and toxins for legitimate medical uses may serve as a cover for acquiring a biological-weapons capability.
Specific precursor materials	Chemical-warfare agents are made from a limited number of precursor chemicals that must be imported or synthesized. A few industrial chemicals (e.g, chlorine, phosgene, hydrogen cyanide) were used as chemical weapons in World War I.	Microbial seed cultures and nutrient growth media are widely available from commercial or natural sources. No precursor materials or feedstocks are used solely for production of biological warfare agents.	Since so many microbial and toxin agents are available from natural sources (e.g. diseased animals or castor beans), controlling the availability of seed cultures and source materials is extremely difficult.
Input-output ratio of precursor materials to product	The volume of chemical precursors is directly proportional to the amount of agent produced.	A small quantity of seed culture can be cultivated in a fermentor into a large quantity of agent.	Imposing threshold limits on quantities of biological precursor materials or products is not a feasible monitoring approach.

Parameters	Chemical Weapons	Biological Weapons	Implications for BWC Monitoring
Size of production facilities	A full-scale chemical agent production facility would require a fairly large industrial site.	If continuous-flow fermentors were used, a biological agent production facility could be confined to a small warehouse building.	Clandestine production of biological agents is hard to detect without human intelligence (e.g., reports from defectors or spies), which tends to be unsystematic and fortuitous.
Dual-use production equipment and ease of converting commercial facility to illicit production	Nerve-agent production requires corrosion-resistant vessels and special containment and ventilation systems, although some countries may cut corners on worker safety and environmental production. Conversion of a pesticide plant to nerve-agent production would take several weeks.	Fermentation equipment used to make vaccines, antibiotics, and other legitimate products can be converted to production of warfare agents. Biocontainment measures are advisable but not essential, assuming vaccination of plant workers. Conversion of a vaccine plant to biological agent production would take about a week, or periodic production could occur in an ostensibly civilian facility.	Intent to produce biological weapons cannot be easily inferred from dual-capable production capabilities. Moreover, supply-side approaches such as nonproliferation export controls are unlikely to be effective over the long-term.
Size of relevant commercial industry	Dual-capable production facilities are ubiquitous in a very large, worldwide chemical industry.	Dual-capable facilities are ubiquitous in the rapidly expanding, worldwide pharmaceutical and biotechnology industries.	Monitoring all potentially relevant dual-capable production sites would be difficult given limited financial and human resources.
Need for containment measures at production facilities	Specialized containment measures and ventilation systems are required only for the final stage of live agent production. These demands can be reduced through production of binary warfare agents.	Containment is needed primarily for steps that generate agent aerosols, such as drying and milling. The US and British production programs in the 1950s and 1960s used rudimentary containment, and in the early 1990s, Iraq took minimal precautions.	Biocontainment facilities (at Biosafety Level 3 or 4) are not required for the acquisition of an offensive biological-warfare capability and hence are not a reliable indicator of illicit activities. However, all high-containment facilities that work with dangerous pathogens should be declared and monitored, especially those under military control.
Proprietary sensitivity of dual-use facilities	Most chemical products are not highly proprietary. Industry's main concern is protection of unpatented or non-patentable manufacturing processes.	Genetically engineered microorganisms, new drugs, and manufacturing process steps are highly proprietary, and large sums of money are at stake in their protection.	A BWC compliance protocol will require extensive measures and procedures to safeguard confidential proprietary information.

Parameters	Chemical Weapons	Biological Weapons	Implications for BWC Monitoring
Physical forms of agent suitable for delivery	Chemical agents may be delivered as a liquid mist, vapor, or aerosol, or adsorbed onto a fine powder ("dusty" agents). Droplet size varies depending on the volatility of the agent and its ability to penetrate the skin.	Microbial and toxin agents generally cannot penetrate intact skin and would be inhaled, ingested, or injected. Only microscopic particles are retained in the lungs. Large-area coverage would require delivery as a particulate aerosol of dried agent (powder) or wet agent (slurry). Dry agent is much easier to aerosolize than wet agent.	Delivery of a biological or toxin agent as a respirable aerosol is the only effective means of inflicting mass casualties. Equipment for drying microbial cultures (e.g. freeze-driers or spray-driers), or the presence of aerosol chambers for testing agent dissemination, may be telltale signs of weaponization.
Delivery systems	Artillery shells, bombs, mines, rockets, missile warheads, and aerial sprayer systems mounted on low-flying tactical aircraft or drones.	Bombs and missile warheads containing low-explosive bursters (with or without specialized submunitions), and aerosol generators mounted on vehicles, ships, aircraft, drones, or cruise missiles.	Highly specialized delivery systems are not a prerequisite for a weaponized biological-warfare capability. For example, agricultural sprayers for dissemination of bacterial pesticides could be modified to generate respirable aerosols of biological warfare agents.
Environmental persistence of agent residues or degradation products	Distinctive degradation products of blister and nerve agents tend to persist in the environment for weeks and in some cases, for years.	Microbial and toxin agents generally persist for hours to weeks. Some agents may be identical to indigenous pathogens or toxins already present in the environment.	Investigation of biological-weapons use is complex, since it requires distinguishing natural disease outbreaks from deliberate or accidental release of biological warfare agents.
Availability of analytical methods to detect illicit agents	Known chemical-warfare agents can be reliably detected and identified with analytical techniques such as combined gas chromatography and mass spectrometry.	Each microbial or toxin agent requires specific antibodies or DNA probes for detection. However, biotechnology may offer ways to develop genetically modified agents that are undetectable through routine testing. Some agents (e.g. anthrax) may also be present naturally in the environment in low concentrations, complicating the interpretation of results.	Sampling and analysis for biological warfare agents requires advance knowledge of which agents are likely to be present. Control samples may also be required to rule out natural sources of contamination. Still, the potential for false-positive or false-negative results means that evidence obtained by sampling and analysis must be corroborated with information from other sources, such as interviews, visual inspection, and audits of production records.

Parameters	Chemical Weapons	Biological Weapons	Implications for BWC Monitoring
Ability to clean up a production facility to prevent detection of illicit agent(s)	Because of the durability and persistence of the carbon-phosphorus bond characteristic of nerve agents, a thorough clean-up of a nerve-agent production facility to remove all traces of contamination is difficult.	A dual-capable facility such as a vaccine plant could be cleaned manually in about 8 hours or with clean-in-place systems in only a few hours. Even so, thorough cleaning may require the disassembly of fermentor systems. Also, residual DNA molecules may be detectable with advanced analytical techniques even after routine sterilization.	The shorter the advance warning prior to a challenge inspection of a suspected biological-weapons production facility, the greater the probability that clean-up will be incomplete and the inspectors will detect traces of illicit agents.

Analysis of CWC Provisions

Scope of Treaty Prohibitions

CWC provisions. The CWC handles the dual-use nature of certain chemical agents and facilities by focusing its prohibitions on *purposes* rather than on specific chemicals. An inclusive definition of chemical weapons, known as the General Purpose Criterion, bans all toxic chemicals obtained or employed for offensive military purposes but allows their use for peaceful ends "as long as the types and quantities are consistent with such purposes." In this way, the CWC permits the beneficial applications of dual-use chemicals in commercial industry, agriculture, medical therapeutics, scientific research, and the development of chemical defenses. The General Purpose Criterion also addresses the problem of technological surprise by banning any novel chemical agents that might be developed in the future as a means of warfare. Thus, a participating state could not legally circumvent the CWC by inventing new types of chemical weapons, such as the *novichok* class of binary nerve agents allegedly developed by the Soviet Union and then Russia.[2]

The CWC verification regime is based on an extensive but not exhaustive inventory of known chemical warfare agents and their key ingredients or "precursors." These compounds are grouped into three lists, or "schedules," based on the potential threat they pose to the aims of the CWC and the extent of their legitimate commercial use. Schedule 1 covers known chemical warfare agents (e.g., sarin and mustard gas) and their immediate precursors, which have few if any legitimate uses; Schedule 2 includes toxic chemicals and precursors that are utilized in small quantities for legitimate purposes; and Schedule 3 covers toxic chemicals such as hydrogen cyanide, some of

[2] See Vil S. Mirzayanov, "Dismantling the Soviet/Russian Chemical Weapons Complex: An Insider's View," in *Chemical Weapons Disarmament in Russia: Problems and Prospects*, Report No. 17 (Washington, D.C.: Henry L. Stimson Center, 1995): 21–34; "Mirzayanov, Fedorov Detail Russian CW Production [Interview]," *Novoye Vremya* in Russian, no. 44 (October 1992): 4–9, translated in Foreign Broadcast Information Service, JPRS-TAC-92-033 (Washington, D.C.: 14 November 1992): 44–9.

which were employed as weapons in World War I. All Schedule 3 chemicals are currently produced and consumed by industry in large quantities. To prevent the verification regime from being overtaken by technological developments, the CWC includes an expedited mechanism for amending the schedules of controlled chemicals as new toxic agents and precursors are identified.

The General Purpose Criterion sets up a system of "indirect verification" based on an objective assessment of observed facts, namely the types and quantities of scheduled chemicals produced at declared facilities.[3] In addition to these facts, however, compliance determinations involve a judgment of intent. For example, a large holding of phosgene gas—employed as a chemical weapon in World War I—would be legitimate if it were being used to produce polyurethane plastics but would be a violation of the CWC if no such legitimate application was evident.

Another category of permitted activity where intent can be difficult to discern is the development of defenses against chemical weapons. The CWC guarantees the right of participating states to develop gas masks, protective clothing, detectors, alarms, decontaminating solutions, and medical antidotes on the grounds that effective defenses create a disincentive to the acquisition and use of chemical weapons. At the same time, however, a CWC violator could use defensive research as a cover for offensive activities. Some degree of ambiguity is unavoidable because the development of detectors and protective gear requires testing with small quantities of chemical warfare agents. To increase transparency and help guard against the misuse of defensive programs to circumvent the CWC, participating states are required to submit annual reports on their chemical-defense activities.[4]

Relevance to the BWC protocol. Much like the CWC, the BWC addresses the problem of dual-use materials, equipment, and facilities by defining biological and toxin warfare agents in terms of their intended use. Article I of the BWC bans the development, production, stockpiling, acquisition, or possession of microbial agents or toxins "of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes."[5] This definition is designed to be all-inclusive, covering not only known biological and toxin agents but also those that may be discovered or intentionally developed in the future.

Although the BWC's broad prohibitions cover all the requisite bases, the ambiguities of judging intent are even greater in the BWC context than they are in the CWC. For example, the preparation of a vaccine against botulinum toxin necessitates the cultivation of large quantities of active toxin, which is then inactivated with formalin. Since the inactivation step occurs late in the

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[3] Barend ter Haar, "Indirect Verification: The Example of the Chemical Weapons Convention," *UNIDIR Newsletter*, no. 2 (June 1991): 8.

[4] Convention on the Prohibition of the Development, Production, Stockpiling and Use of Chemical Weapons and on Their Destruction, Article X, paragraph 4. Hereinafter referred to as the Chemical Weapons Convention.

[5] US Arms Control and Disarmament Agency, *Arms Control and Disarmament Agreements: Texts and Histories of the Negotiations* (Washington, D.C.: Government Printing Office, 1996): 98.

manufacturing process, determining the intent of production is not a clear-cut task.[6] Similarly, a growing number of natural toxins have legitimate applications in medicine and biomedical research, yet the quantity of toxins used for these scientific and therapeutic purposes is approaching a level that is militarily significant.[7]

Given the difficulty of assessing and proving intent, some countries have sought to redefine Article I more precisely to distinguish unequivocally between treaty-permitted and -prohibited activities. Such efforts, however, create another dilemma: Any attempt to establish objective criteria for a BWC violation runs the risk of narrowing the treaty's basic prohibitions and opening legal loopholes that a determined cheater could exploit. Negotiators of the BWC compliance protocol should therefore maintain a clear distinction—as in the CWC—between the broad set of treaty-prohibited activities and the subset of those activities that, as a practical matter, can be subjected to compliance monitoring at any given time. To avoid creating dangerous loopholes, the Ad Hoc Group should neither amend the General Purpose Criterion nor attempt to define its prohibitions more precisely in the compliance protocol. Instead, the negotiators should reaffirm the comprehensive coverage of Article I of the BWC, while developing illustrative lists of facilities, equipment, and activities as a basis for making declarations.

Coverage of Toxins

CWC provisions. Toxins are lethal or incapacitating poisons synthesized by a wide variety of bacteria, plants, invertebrates, and vertebrates. For example, botulinum toxin is produced by a bacterium, ricin is extracted from the seeds of the castor bean plant, saxitoxin is synthesized by a single-cell organism that contaminates shellfish, and batrachotoxin is present in the skin secretions of poison-arrow frogs. Relatively simple toxin molecules and chemical derivatives thereof can also be synthesized in the laboratory. Since toxins are nonliving chemicals made by living organisms, they constitute a "gray area" between chemical and biological weapons. For this reason, the CWC and the BWC explicitly overlap in their coverage of toxins. Two toxins, saxitoxin and ricin, are included on the CWC's Schedule 1, which lists chemicals that are considered warfare agents and are banned except for production in small quantities for permitted, monitored purposes.[8]

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[6] The BWC does not ban offensive research because it is next to impossible to determine the intent behind basic laboratory research on infectious agents and toxins. Even so, given the rather fuzzy line between research and development, the BWC protocol should include a measure requiring states to provide information about research activities involving particularly hazardous microbial and toxin agents.

[7] Jonathan B. Tucker, "Dilemmas of a Dual-Use Technology: Toxins in Medicine and Warfare," *Politics and the Life Sciences* 13, no. 1 (February 1994): 51–62.

[8] During the CWC negotiations, much debate occurred over whether to list botulinum toxin on Schedule 1, but its extensive legitimate uses for the production of vaccine and the treatment of various neurological conditions militated against its inclusion. Saxitoxin and ricin were intended as "placeholders" to ensure that the CWC's verification regime covers toxins at least until comparable monitoring measures can be implemented for the BWC. Under the CWC, any facility that produces, processes, or consumes more than 100 grams of ricin or saxitoxin must be declared and undergo routine inspection. Moreover, production of these two toxins for scientific, medical, defensive, or commercial purposes at any given facility may not exceed a total of 10 kilograms per year. These aggregate production limits may eventually constrain the beneficial applications of ricin in the treatment of cancer and of saxitoxin in neurophysiological

Relevance to the BWC protocol. Since Article I of the BWC explicitly bans the development, production, and stockpiling of toxins for warfare purposes, toxins should be included in any compliance protocol. Monitoring the production of certain toxins, however, is not a straightforward task. Consider the quandary presented by castor oil production, which generates large quantities of ricin as an unintended byproduct. Approximately one million tons of castor beans are processed annually worldwide for the production of castor oil.[9] The residue left over after the oil has been extracted by cold pressing is three to five percent ricin by weight, yet it would be impossible to verify that all of the toxin has been inactivated. Another problem is that the purification of toxins involves a series of biochemical steps. At each stage, the preparation contains a significant percentage of toxin and is potentially usable as a warfare agent. Indeed, some toxins are actually most stable and potent in impure form.[10]

Given the large number of natural toxins identified to date and the fact that new ones are continually being discovered, it would be desirable to narrow the focus of the BWC compliance regime. To this end, declarations and monitoring should focus on those toxins that have both the high toxicity and the physiochemical characteristics needed to inflict mass casualties when disseminated as an aerosol cloud. Although more than 400 natural toxins have been characterized, less than 20 have a lethal dose in aerosol form of under 0.025 micrograms (millionths of a gram) per kilogram of body weight, or (like ricin) are easily extracted in large quantities. Still fewer are stable, persistent, and weaponizable. These parameters limit to a manageable number the list of toxin agents that would have to be declared and closely monitored.[11] Legitimate research laboratories and pharmaceutical plants that produce or work with such high-risk toxins would have to provide an estimate of the quantities extracted or consumed on a yearly basis and also give a full accounting of their activities.

Quantitative Limits on Agent Production

CWC provisions. The CWC imposes an absolute ceiling of one metric ton on the total amount of Schedule 1 chemical agents that a participating state may possess at any time for

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research. In response, the CWC members may decide in the future to move the two toxins from Schedule 1 to Schedule 2, which has no quantitative production limits, or to drop toxins entirely from the CWC verification regime.

[9] David R. Franz, "Defense Against Toxin Weapons" (Ft. Detrick, MD: US Army Medical Research Institute of Infectious Diseases, undated) at http://www.nbc-med.org/FMs/datw/cover.htm, 5.

[10] According to one assessment, "For the most lethal toxins, even with good reporting of all institutions (for these minute quantities, this reporting could be very problematic), it would be very easy to siphon off, under-report, or whatever, and to accumulate enough of these toxins to employ them as a toxin weapon. The likelihood of detecting such actions is very remote. . . . Tests for detection are not quantitative, many are not standardized, and unless performed in real-time, any test would likely produce negative results. . . . Monitoring would have to be totally intrusive and continuous." Richard O. Spertzel et al., *Technical Ramifications of Inclusion of Toxins in the Chemical Weapons Convention (CWC)*, Technical Report No. DNA-TR-92-116 (Ft. Detrick, MD: US Army Medical Research Institute of Infectious Diseases, February 1993): 34–5.

[11] Franz, "Defense Against Toxin Weapons," 7.

nonprohibited purposes.[12] Furthermore, all Schedule 1 chemicals utilized in the development of defenses must be produced at a single small-scale facility with limited capacity. The treaty also imposes an annual limit of ten kilograms on the quantity of Schedule 1 chemicals that can be produced at any other facility for medical, therapeutic, or pharmaceutical purposes.[13] These quantitative ceilings make sense because, unlike microbial pathogens, chemical warfare agents are nonliving and do not reproduce.

Relevance to the BWC protocol. In principle, it would be desirable to find an objective criterion for assessing BWC compliance that would avoid the need to draw subjective distinctions between treaty-permitted and -prohibited activities. One such proposal, based on the CWC model, would establish maximum quantities of microbial pathogens and toxins that a state may possess for all purposes. Since microbial and toxin agents vary widely in toxicity and lethality, each agent would need a different quantitative ceiling, presumably set in terms of a number of lethal doses. Possession of such agents in quantities above the specified limits would be prohibited. The quantitative ceilings would therefore provide an objective basis for a finding of noncompliance if inspectors discovered an agent stockpile exceeding the specified amount.[14]

In fact, because of the technical differences between chemical warfare agents and microbial and toxin agents, the CWC concept of quantitative production limits is not transferrable to the BWC context. First, whereas chemical agents have few if any legitimate uses, thousands of government and private organizations are engaged in research, development, and manufacturing activities involving dual-use microbial and toxin agents. Determining or controlling the aggregate amounts of such agents within a large country such as the United States at any given time would be extremely difficult, if not impossible, since the figure is in constant flux.

Second, since many biological agents are lethal in small doses, the quantities intended for legitimate purposes may overlap with those having military utility. In these cases, intent is the only criterion of compliance or noncompliance.[15] Establishing a quantitative limit on possession would not remove the need to assess the motivation behind the observed activities.

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[12] No quantitative ceilings have been placed on the annual production of Schedule 2 and Schedule 3 chemicals. However, states parties must declare annually the locations, purposes, and amounts of such chemicals produced, processed, or consumed above certain quantitative thresholds.

[13] Chemical Weapons Convention, Verification Annex Part IV, 125.

[14] Marie Chevrier et. al., *Beyond VEREX: A Legally Binding Compliance Regime for the Biological and Toxin Weapons Convention*, Working Group on Biological and Toxin Weapons Verification (Washington, D.C.: Federation of American Scientists, July 1994): 6–7.

[15] "There is a range of quantities of nearly any biological agent or toxin that would be consistent with both peaceful and non-peaceful purposes. That range of quantities would always constitute a gray area where a judgement of the intent of the possessor is inescapable." Marie Isabelle Chevrier, "From Verification to Strengthening Compliance: Prospects and Challenges of the Biological Weapons Convention," *Politics and the Life Sciences* 14, no. 2 (August 1995): 211.

Third, unlike chemical agents, micro-organisms reproduce at an extraordinary rate, and although bacterial toxins are nonliving, the bacteria that make them are self-replicating. Since microbial seed cultures can be cultivated in fermenters into large quantities of agent in a matter of days, the amount of agent present in a facility at any particular time has little significance and, indeed, can change overnight. For these reasons, setting a quantitative ceiling on the possession of microbial agents would be impractical, particularly for large countries with numerous research and commercial facilities.

Fourth, establishing production ceilings that would not interfere with any legitimate need would result in quantitative limits so high that they would have little value as an indicator of intent. Setting a single level of legitimate production for all BWC members would also be inappropriate, since countries vary greatly in the extent to which they grow microbial agents or toxins for nonprohibited purposes.

Finally, proponents of a production limit caution that the specification of a quantitative ceiling "should not imply. . . that lesser quantities could not constitute a [biological warfare] threat."[16] Despite this caveat, the designation of a legal upper limit might be misinterpreted as an absolute standard, enabling a state possessing a stockpile of agent below the designated ceiling to claim that it deserves an automatic seal of approval. Consequently, a quantitative production limit might let BWC violators off the hook by creating a "safe-harbor" for illicit biological or toxin weapon activities below the designated threshold. For all of these reasons, specifying quantitative ceilings for possession of biological and toxin agents would be impractical and counterproductive.

Imposing quantitative ceilings on the production of microbial agents and toxins by individual facilities would be equally ineffective. Given the ability to cultivate seed cultures into kilograms of agent, a fermentation plant could be in compliance with the production limit on the day of an inspection but in violation a few days later. Even worse, cheaters could deliberately circumvent a quantitative production ceiling by producing biological or toxin agents in smaller, legal amounts at multiple facilities.

Criteria for Facility Declarations

CWC provisions. The CWC determines whether a given chemical industry facility is declarable on the basis of two criteria: 1) whether it produces, processes, or consumes one or more chemicals listed on the schedules; and, 2) whether the annual amount of the scheduled chemical(s) exceeds specified quantitative thresholds.[17] Basing the CWC's verification regime for chemical

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[16] Federation of American Scientists, *Beyond VEREX*, 7.

[17] The quantitative declaration thresholds in the CWC are defined according to threat level: no threshold for the chemical warfare agents on Schedule 1; a threshold of 1 kilogram, 100 kilograms, or 1 metric ton for the various subcategories of chemicals on Schedule 2; and a threshold of 30 metric tons for the industrial dual-use chemicals on Schedule 3. Somewhat arbitrarily, facilities whose yearly production falls below the thresholds need not be declared. The CWC declaration requirements also cover "other" production facilities that manufacture more than 200 metric tons per year of unscheduled "discrete organic chemicals" on the grounds that such plants could be used to manufacture scheduled chemicals at some time in the future.

industry on the types and quantities of chemicals produced, processed, or consumed at various plant sites makes sense because a finite number of chemicals possess both the high toxicity and physiochemical properties required for warfare use. Moreover, Schedule 1 chemicals have few if any peaceful applications, and Schedule 2 chemicals are used in relatively small amounts for legitimate purposes.

Relevance to the BWC protocol. Although countries participating in the Ad Hoc Group agree that mandatory national declarations of treaty-relevant facilities should be the basis for a BWC compliance regime, there is no consensus on what types of facilities should be declared. Each of the proposed formulas has significant disadvantages, making the determination of criteria for declaring facilities one of the most vexing aspects of the negotiation.

One proposed approach modeled on the CWC schedules would base the BWC declaration criteria on the types of biological agents and toxins produced or utilized at a given facility. According to one non-governmental organization, "the possession of controlled agents is the most important criterion for declarations, i.e., to identify sites of potential concern."[18] A related approach would be to declare all facilities that work with hazardous biological and agents and toxins in quantities above a specified number of lethal doses.[19] However, the technical differences between chemical and biological weapons make the CWC schedule concept difficult to transfer to the BWC context. Most Schedule 1 chemicals have historically been developed or employed as chemical weapons and have few, if any, peaceful uses, so finding an undeclared stock of such a chemical would provide strong evidence for a CWC violation. In contrast, microbial threat agents such as anthrax are inherently "dual-use" in that they can serve either as an offensive weapon or as the basis for making a protective vaccine. Thus, the mere presence of anthrax spores in a facility is not necessarily proof of a BWC violation, particularly if the suspect plant is a declared producer of anthrax vaccine.

Although the list of known chemical warfare agents is reasonably short, compiling a comprehensive inventory of microbial and toxin agents and subdividing them into risk categories would be difficult at best. In addition, since recombinant-DNA technology provides the capability to cut and splice microbial genes, including those coding for protein toxins, the number of genetically modified biological agents is theoretically unlimited. Thus, any list of microbial and toxin agents would be inevitably incomplete and would require continual updating as new micro-organisms and toxins are discovered in nature or manipulated genetically in the laboratory. If the list were used as the basis for compliance monitoring, violators might attempt to circumvent the BWC by deliberately producing an unlisted agent. A list of microbial and toxin agents is therefore of limited utility except to provide *illustrative examples* of the various types of agents that exist or might be produced in the future.

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[18] Federation of American Scientists, *Beyond VEREX*, 3.

[19] Chevrier, "From Verification to Strengthening Compliance," 214.

An alternate approach to declarations of dual-capable production facilities would be to base them on plant capacity and throughput, which may be significant factors in determining the potential to produce large quantities of microbial and toxin agents for illicit use. For example, it has been suggested that if a facility's batch fermentation capacity exceeds a specified level—say, individual fermenters with a capacity of more than 50 liters, or an aggregate capacity of more than 200 liters—the facility should be declared.[20] Yet, this proposal has serious drawbacks as well. First, information on production capacity is highly proprietary, and companies are generally reluctant to reveal such data to any degree of precision. Second, biological fermentation capacity is ubiquitous in advanced industrial countries, particularly if laboratory-scale equipment is included. Countries with extensive microbiological research and production capabilities would therefore be hard-pressed to make accurate declarations that kept up with changes in commercial capacity driven by market factors. Third, at many commercial vaccine plants, batch fermenters stand idle at various times of year because of fluctuations in vaccine supply and demand. Since it would be uneconomical to destroy or sell this capital equipment when it is temporarily not in use, only a portion of a plant's production capacity is in operation at any given time. Even with detailed record-keeping, it could be difficult for such facilities to prove that they were not maintaining a latent mobilization capacity for biological agent production.

Other proposed declaration criteria for biological development and production facilities include level of biocontainment and military ownership. Each of these criteria, viewed in isolation, is not a reliable indicator. Prevalent safety standards dictate that the more deadly the agent being handled, the higher the level of biocontainment required. Nonetheless, the United States and Great Britain used fairly low levels of containment in their offensive biological production programs of the 1950s and 1960s. More recently, Iraq deliberately cut corners on worker safety and environmental protection at its bioweapons production facilities to make them harder to detect. Direct military ownership of a facility is not a foolproof indicator either: The Soviet Union concealed the vast scale of its offensive biological weapons program by conducting extensive development and production activities within a large complex of ostensibly civilian biotechnology institutes known as Biopreparat.[21]

Thus, in contrast to the CWC, no single indicator offers a reliable means of identifying which biological facilities should be declared under the BWC protocol. A better approach would be to require annual declarations from development or production facilities that meet any *two or more* of the following criteria:

a) annual production of hazardous microbial or toxin agents above a specified aggregate amount;
b) activities involving the genetic manipulation of microbial pathogens or toxins;

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[20] Federation of American Scientists, *Beyond VEREX*, 3.

[21] Anthony Rimmington, "From Military to Industrial Complex? The Conversion of Biological Weapons Facilities in the Russian Federation," *Contemporary Security Policy* 17, no. 1 (April 1996): 80–112.

c) the presence at a facility of suites providing the two highest levels of biocontainment, known as Biosafety Levels 3 and 4;
d) an ownership or contractual relationship with the national government or military; and,
e) a capability to generate biological aerosols for research or testing purposes.

This multiple-criterion approach would capture all military biological defense facilities, some vaccine production plants, and biological suppliers that cultivate natural microbes and toxins and ship them in small amounts to research laboratories and hospitals.

One potential difficulty with annual declarations is that production activities at multi-use plants or batch-processing facilities tend to change frequently. Since annual reports would cover the plant's activities over the previous year, ongoing production activities observed during on-site visits may not be consistent with prior-year reporting. Similar to the CWC's approach, the BWC could require declared facilities to submit both retrospective annual reports and *prospective* reports on planned production activities for the coming year. Furthermore, under the CWC, the prospective report must be amended if actual production diverges significantly from the intended plan. Adopting these measures would help focus BWC monitoring efforts and avoid unwarranted suspicions based on discrepancies between declared and observed activities.

Routine On-Site Inspections

CWC provisions. The CWC's international inspectorate is authorized to conduct two types of inspections: routine and challenge. The former are periodic, pre-announced visits to declared government and commercial facilities to check the accuracy of declarations and to verify the *absence* of undeclared illicit production of chemical agents or the diversion of dual-use chemicals for military purposes. Whereas challenge inspections must be requested by a member state based on a suspicion of cheating, routine inspections are carried out automatically by the inspectorate and hence are politically low-profile and non-confrontational. The frequency and intrusiveness of routine inspections are determined by the types of chemicals present at each facility, with the most in-depth inspections at Schedule 1 facilities and the least comprehensive at Schedule 3 facilities. By keeping declared facilities continually at risk of inspection, the regime seeks to force potential cheaters to move any illicit production to clandestine facilities, increasing the costs and risks of noncompliance and helping to deter violations.

Relevance to the BWC protocol. Under a BWC protocol, routine or "non-challenge" visits to declared facilities would assess whether the observed activities are consistent with the declared ones. Unlike the CWC, which subjects all declared Schedule 1 and 2 facilities to baseline and subsequent routine inspections, relatively few declared biological sites would have to host routine visits. Conducting the inspections on short-notice and without right of refusal would help to deter illicit development or production at all such sites.

So far, however, there is no consensus in the Ad Hoc Group on whether a routine inspection mechanism like that in the CWC is desirable or feasible. The US pharmaceutical industry, in particular, adamantly opposes routine inspections on the grounds that they would jeopardize valuable

trade secrets while providing little verification benefit.[22] Some US industry representatives have proposed exempting all drug companies from routine inspection and relying instead on records of inspections conducted by national regulatory authorities such as the US Food and Drug Administration. However, regulators in some countries could be pressured to conceal a biological weapons program in private industry, and other countries have yet to establish significant regulatory authority over their private sector.

The CWC approach to routine inspections should be adjusted to the BWC context. Although the United States and Western Europe will have the most biological production facilities to declare, the BWC compliance protocol must monitor relevant facilities in all participating countries. To this end, the BWC monitoring agency should select facilities for routine inspection on a "weighted-random" basis that distributes the visits equitably among participating countries while targeting the facilities of greatest concern.[23] Table 4 illustrates some objective weighting factors that might be employed. A point system would categorize declared facilities according to the potential risk they pose to the BWC, so that the frequency and intensity of compliance monitoring could be tailored to each category. For example, facilities might be designated high-risk if they have more than 15 points, moderate-risk between 7 and 15 points, and low-risk less than 7 points. A somewhat different approach would be to allocate countries annual *quotas* of routine visits they would be obligated to accept, based on the number of high-risk declared facilities on their territory. A separate category of "clarification" visits might serve to address compliance concerns, such as a failure to declare a relevant facility, that warrant investigation but are not serious enough to trigger a challenge inspection based on an alleged violation.[24]

Challenge Inspections

CWC Provisions. Any state participating in the CWC can request a challenge inspection of a suspect facility, declared or undeclared, on the territory of another member country. In this way, challenge inspections constitute a "safety net" to capture clandestine production at undeclared sites. Challenged facilities are obligated to provide some access to the inspection team not later than 108 hours after its arrival in the host country.[25] This timeline is designed to allow the challenged facility to protect sensitive equipment and information unrelated to CWC compliance, yet without providing

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[22] Pharmaceutical Research and Manufacturers of America, "PhRMA Position on a Compliance Protocol to the Biological Weapons Convention" (Washington, D.C.: 9 January 1997): 2. See also, chapter 3 of this report.

[23] A "weighted lottery" system has been proposed wherein facilities would be chosen for inspection on the basis of relevant capabilities and risk to the BWC as defined by several criteria or "triggers." Federation of American Scientists, *Working Paper: Triggers for Declarations and Inspections/Visits Under a BWC Compliance Regime*, Working Group on Biological and Toxin Weapons Verification (Washington, D.C.: July 1996).

[24] Graham S. Pearson, "Forging an Effective Biological Weapons Regime," *Arms Control Today* 24, no. 5 (June 1994): 17.

[25] Chemical Weapons Convention, Verification Annex, Part X, paragraph 39.

Table 4: Criteria for Assessing the Potential Military Threat Posed by Dual-Capable Biological Production Facilities.

Family Characteristics	Weighting Factor (Points)
Is the facility military-owned or related to national biological weapons defense activities?	No = 0 Yes = 2
Does it incorporate high-biocontainment suites, such as Biosafety Level (BL) 3 or BL 4?	No = 0 BL-3 = 1 BL-4 = 2
Does the facility work with dangerous pathogens or lethal toxins?	No = 0 Yes = 2
Is the production process batch fermentation (lower risk) or continuous fermentation (higher risk)?	Batch = 1 Continuous = 2
Is the plant single-purpose (lower risk) or multipurpose (higher risk)?	Single-purpose = 1 Multipurpose = 2
What is the production capacity or throughput?	x < 1,000 liters = 1 1,000 < x < 5,000 liters = 2 x > 5,000 liters = 3
Does the plant have specialized production equipment designed to minimize leaks and to contain pathogens?	No = 0 Yes = 1
Does the facility have a freeze- or spray-drier and/or a microencapsulation capability?	None = 0 Drier only = 1 Drier plus microencapsulation = 2
Does the facility have high-efficiency air filters and/or negative air pressure?	No = 0 Air filters = 1 Air filters plus negative air pressure = 2
Does the facility have autoclaves and/or self-cleaning fermentors?	No = 0 Autoclaves = 1 Autoclaves and self-cleaning fermentors = 2
Does the facility have cages for large animals such as monkeys?	No = 0 Yes = 2
Is the plant partially or totally automated?	None = 0 Partial = 1 Total = 2
Is production line closed or are there sampling ports?	Sampling ports = 0 No sampling ports = 1
Does the facility include an aerosol test chamber?	No = 0 Yes = 2

enough time for cheaters to clean up all indications of illicit production. Most analysts consider these timelines and procedures adequate to assess treaty compliance with a reasonable degree of confidence.

To discourage the abuse of challenge inspections for harassment or espionage, the requesting country must provide preliminary evidence of a treaty violation before triggering an inspection. To this end, the CWC has a "red light" filtering mechanism: The CWC's 41-member Executive Council must vote by a three-quarters majority within 12 hours to *block* a challenge inspection if it considers the request "frivolous, abusive or clearly beyond the scope of the Convention."[26] This requirement is considered by some to be a veto-proof approval mechanism; at the very least, the large majority of challenge requests will be allowed to proceed.

Whether a challenge inspection will uncover evidence of a violation depends on the nature and scale of the prohibited activity, the quality of the intelligence supporting the inspection request, and the sophistication of the violator's efforts to conceal its illicit behavior.[27] While it is unlikely that CWC inspectors will find a "smoking gun" (e.g., filled chemical munitions), on-site inspections may reveal a pattern of anomalies or discrepancies strongly indicative of illicit activity, much as the United Nations Special Commission (UNSCOM) has uncovered in Iraq.[28]

Relevance to the BWC protocol. As with the CWC, the BWC inspectorate would conduct a challenge inspection at the request of a member state at a suspect facility, declared or undeclared, anywhere on the territory of another participating nation. Since a challenge request would be based on allegations of cheating, challenge inspections are likely to be rare, politically high-profile events.

To initiate a challenge inspection, a requesting member state would have to back up its suspicions with concrete evidence that would be presented to the BWC's future equivalent of an Executive Council. In contrast to the approval system in the CWC, several countries in the Ad Hoc Group want BWC challenge inspections to be based on a "green light" system, in which a super-majority of the Executive Council must vote to *allow* a challenge inspection to proceed. With this requirement in place, requests for challenge inspections—particularly those at privately owned facilities—would have to be based on detailed evidence similar to that needed to obtain a criminal search warrant. The dilemma facing policy makers is that such information may either not be available or it may be derived from secret intelligence sources and methods, making it too sensitive to release to other countries. For this reason, it would be preferable to implement a red light approval system for BWC challenge inspections, although the majority vote in the Executive Council

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[26] Chemical Weapons Convention, Article IX, paragraph 17.

[27] Raymond R. McGuire, "A Perspective on the Chemical Weapons Convention: 'Lessons Learned' from the Preparatory Commission," *Director's Series on Proliferation*, no. 7, Document No. UCRL-LR-114070-7 (Livermore, CA: Lawrence Livermore National Laboratory, 27 December 1994): 51.

[28] United Nations, *Tenth Report of the Executive Chairman of the Special Commission Established by the Secretary-General Pursuant to Paragraph 9 (b) (I) of Security Council Resolution 687 (1991), and Paragraph 3 of Resolution 699 (1991) on the Activities of the Special Commission*, UN Security Council Document S/1995/1038, 17 December 1995, 12–4.

required to block a frivolous or abusive challenge request might be reduced to sixty percent from the seventy-five percent specified in the CWC.

In principle, BWC challenge inspections could incorporate a variety of synergistic measures, including visual inspection, record audits, interviews with plant officials, and sampling and analysis for undeclared pathogens or toxins suspected of being produced at the site. The relative ease with which evidence of biological agent production can be eliminated suggests that challenge inspections should be carried out on short notice. With manual cleaning techniques, standard dual-use production facilities can eliminate most traces of illicit biological warfare agent production in about 8 to 10 hours.[29] The most advanced production facilities are equipped with clean-in-place fermenters that require only about one hour to sterilize and can switch rapidly from one product to another.[30] Although microorganisms are killed by routine sterilization procedures, microbial DNA molecules are rugged and may well survive. Such trace residues would provide an indicator of illicit production, but they would not provide a means of quantifying the amounts produced.

The shorter the notice of a challenge inspection, the greater the likelihood that the clean-up of a suspect facility will be incomplete, leaving behind telltale indicators. Ideally, the elapsed time between notification of a challenge inspection and the arrival of the inspection team at the challenged site should be less than 24 hours. One problem is that the procedure for approving challenge inspection requests could tip off the intended target, giving the challenged country sufficient advance warning to clean up an illicit facility. A possible solution would be for the BWC Executive Council to weigh the evidence presented for a challenge inspection without being told the specific country or facility involved. The location of the challenged site would be revealed only after the inspectors arrive in the host country.[31]

A challenge inspection is most likely to uncover a BWC violation when there are clear discrepancies among the declared capabilities of a facility, its actual capabilities, and the explanation or cover story offered by the facility managers. The experience of the UNSCOM biological inspection teams in Iraq has shown that while even highly intrusive inspection measures are rarely able to uncover "smoking gun" evidence, inspectors may find indicators or anomalies that, taken together, are strongly suggestive of illicit activity. For example, the presence of equipment designed to contain dangerous pathogens would be anomalous if a plant's declared activities involved only harmless micro-organisms. Similarly, the scale and technical parameters of a declared plant's freeze driers, separators, filling equipment, ventilation, and biocontainment systems may be inconsistent with legitimate commercial production.

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[29] Government of Sweden, Ad Hoc Group, "First Step Towards a Trial Inspection of a Vaccine Production Plant," *Ad Hoc Group of Governmental Experts to Identify and Examine Potential Verification Measures from a Scientific and Technical Standpoint*, Document BWC/CONF.III/VEREX/WP 20, 5 April 1992.

[30] Pharmaceutical Research and Manufacturers of America, "Reducing the Threat of Biological Weapons: A PhRMA Perspective" (Washington, D.C.: November 1996): 4.

[31] While such an approach would be ideal from the standpoint of verification, it may not be negotiable in a multilateral forum.

Sampling and Analysis

CWC provisions. The CWC explicitly permits sampling and analysis during routine and challenge inspections, although the host country has the right to negotiate where samples may be taken so as to protect unrelated proprietary or national security information. Identification by sampling and analysis of an undeclared Schedule 1 chemical in a suspect facility would provide strong evidence of a CWC violation. Since some chemical agents and their degradation products persist for long periods in the environment, sampling can also detect the past production and use of chemical weapons. For example, soil samples taken in late 1992 from bomb craters near a Kurdish village in northern Iraq were found to contain degradation products of sarin and mustard gas more than four years after an alleged chemical attack by Iraqi government forces.[32]

Relevance to the BWC protocol. Most experts agree that biological samples taken during on-site inspections could provide key information to help resolve uncertainties about BWC compliance.[33] Several powerful analytic techniques make it possible to identify micro-organisms at extremely low concentrations.[34] The possibility of ambiguous or false analytical results can be minimized by analyzing several samples from the same site, corroborating results with at least two analytical techniques based on different scientific principles, and employing sampling and analysis in conjunction with other monitoring measures.

During UNSCOM inspections of the Al Hakam fermentation plant in Iraq, sampling and analysis revealed anomalies that were inconsistent with the declared production of the bacterial pesticide *Bacillus thuringiensis* (BT). When BT bacteria cultivated at Al Hakam were examined under the electron microscope, they lacked the characteristic protein-crystal inclusions needed for insecticidal activity. This finding suggested that the bacteria were serving as a simulant for biological agents such as anthrax, which grow under similar culture conditions. In addition, sampling of the spray drier in the BT production line revealed that the finished dry powder had a particle size of less than 10 microns—too fine for the legitimate application of biopesticide but suitable for the dissemination of a bacterial agent as a biological weapon.[35] These two anomalous findings were

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[32] Lois Ember, "Chemical Weapons Residues Verify Iraqi Use on Kurds," *Chemical & Engineering News* 71, no. 18 (3 May 1993): 8–9.

[33] Ad Hoc Group, *Ad Hoc Group of Governmental Experts to Identify and Examine Potential Verification Measures From a Scientific and Technical Standpoint*: *Report*, Document BWC/CONF.III/VEREX/9, 1993, 18.

[34] Immunoassays and the use of DNA probes in conjunction with the polymerase chain reaction (PCR) have become widely used analytical techniques. See, for example, Barbara J. Mann, *Detection of Biological Warfare Agents Using the Polymerase Chain Reaction*, DTIC No. AD-A259391(Research Triangle Park, NC: Battelle Memorial Institute, September 1992,); Takeshi Sano, Cassandra L. Smith, and Charles R. Cantor, "Immuno-PCR: Very Sensitive Antigen Detection by Means of Specific Antibody-DNA Complexes," *Science* 258 (2 October 1992): 120–2; and O.V. Norkina et al., "Development of a Diagnostic Test for *Yersinia pestis* by the Polymerase Chain Reaction," *Journal of Applied Bacteriology* 76 (1994): 240–5.

[35] This particle size is appropriate for dissemination of a biological agent as a respirable aerosol but counterproductive for dispersal of a bacterial biopesticide, because the particles would be too small to settle out of the air onto crops. Richard O. Spertzel, "Sampling and Analysis as a Monitoring Tool: Lessons from the UNSCOM Experience," in *The Utility of Sampling and Analysis for Compliance Monitoring of the Biological Weapons Convention*, Jonathan B. Tucker, ed., Report No. CGSR-97-001 (Livermore, CA: Lawrence Livermore National

suggestive of Iraqi preparations for biological weapons production at the site, under the very noses of the United Nations (UN) inspectors. On the basis of this and other evidence, UNSCOM razed the Al Hakam factory in June 1996.[36]

Sampling and analysis for BWC compliance monitoring has some technical limitations that do not exist in the chemical weapon context. Whereas chemical warfare agents and precursors are man-made synthetic materials, biological and toxin agents occur naturally in the environment. For example, since anthrax spores and natural toxins may be present in soil at low concentrations, simply detecting trace amounts does not constitute proof of a BWC violation. To rule out environmental contamination as the source of a positive result, suitable control samples must be taken from nearby locations and analyzed as a basis for comparison.

Moreover, unlike persistent chemical warfare agents such as mustard and VX, most microbial and toxin agents—with the notable exception of spore-forming bacteria—do not survive for long in the environment and are rapidly degraded by sunlight, oxidation, and soil micro-organisms. If samples are not collected shortly after a release, the agents may no longer be detectable. For this reason, a failure to find illicit agents does not necessarily rule out prohibited activities or resolve all ambiguities related to BWC compliance.

Even if sampling detects a microbial pathogen or toxin, one must assess whether the activity associated with the putative agent is legitimate or not. Merely finding traces of anthrax at a production site does not prove a violation of the BWC, unless there is a clear smoking gun such as a rack of filled biological munitions. Indeed, the amount of anthrax or botulinum toxin suitable for many military scenarios is not substantially larger than the quantities made for legitimate uses such as vaccine production. Thus, while sampling and analysis is a powerful tool for BWC compliance monitoring, interpreting the results entails greater complexities and ambiguities than in the CWC context. To minimize the problem of false positives or false negatives, BWC inspectors should corroborate their analytical results with other investigative techniques, such as staff interviews and record audits.

Protection of Confidential Information

CWC provisions. The CWC includes detailed measures to prevent the disclosure of national security and proprietary information unrelated to chemical weapons. In this way, the treaty seeks to balance effective verification with the need to safeguard legitimate secrets.[37] For routine inspections, pre-negotiated "facility agreements" specify which parts of a plant are subject to inspection and

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Laboratory, February 1997): 17–25.

[36] Associated Press, "U.N. and Iraqis Begin to Dismantle Arms Plant," *New York Times*, 10 June 1996, A6; R. Jeffrey Smith, "Iraq's Drive for a Biological Arsenal: UN Pursuing 25 Germ Warheads it Believes are Still Loaded with Deadly Toxins," *Washington Post*, 21 November 1997, A1.

[37] US, European, Australian, and Japanese chemical industry trade associations helped the CWC's negotiators draft a "Confidentiality Annex" that safeguards intellectual property contained in data declarations and inspection reports.

where sampling, photography, and other intrusive activities may take place. In the case of challenge inspections, the CWC provides for "managed access," a process of negotiation between the inspectors and the host facility to address compliance concerns without enabling the inspectors to understand proprietary aspects of the manufacturing process. Examples of managed access techniques include shrouding sensitive equipment, turning off computers, locking up documents, specifying locations where samples may be taken, and permitting selective access to a sensitive facility by allowing inspectors to visit rooms selected at random. Although the challenged country can deny the inspectors access to areas of the site considered proprietary, it must provide alternative means of demonstrating that the excluded areas are treaty-compliant and make "every reasonable effort" to address the inspectors' concerns.

Relevance to BWC protocol. According to a preliminary industry census, roughly 3,000 dual-use commercial facilities in the United States could be declarable under a BWC compliance regime.[38] Although the chemical industry was initially concerned about how the CWC would protect proprietary information, sensitivities are even greater in the pharmaceutical and biotechnology industries, which are more research-intensive and on the cutting edge of scientific innovation. As explained in chapter 3, fears of industrial espionage are well-founded.[39] Companies are most concerned about the loss or compromise of a proprietary micro-organism that may be worth hundreds of millions of dollars. Indeed, the genetically engineered bacterium that mass produces human insulin has been valued at more than $1 billion.[40] In addition, much relevant manufacturing know-how is not patentable but consists of proprietary processing techniques or equipment that are incremental improvements on earlier innovations.[41]

Given these legitimate industry concerns, the BWC protocol must include detailed procedures for safeguarding confidential proprietary information. For example, wherever possible, sample analysis should be carried out on site. If off-site analysis is required, established procedures must provide a clear chain of custody and protect trade secrets. Concerns over the possible theft of proprietary micro-organisms could be minimized by killing sampled micro-organisms prior to analysis so they cannot replicate if a sample is removed from the site. Since DNA fragments containing proprietary gene sequences might still be recovered from dead micro-organisms, the microbial DNA could be partially digested with restriction enzymes prior to genetic analysis. In principle, such treatment would destroy proprietary DNA sequences while leaving enough

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[38] Terence Taylor and L. Celeste Johnson, *The Biotechnology Industry of the United States: A Census of Facilities*, Center for International Security and Arms Control (Stanford, CA: Stanford University, July 1995): 6.

[39] For more detail, see chapter 3 of this report. See also, Thomas Copmann and Alan Goldhammer, "Industrial Information Paper on Concerns Regarding Disclosure of Proprietary Information to the International Community," undated, 4–5.

[40] William L. Muth, "Industry Views on Sampling and Analysis," in *The Utility of Sampling*, 28.

[41] Copmann and Goldhammer, "Industrial Information Paper," 8.

characteristic microbial DNA to verify the identity of an illicit agent.[42] This proposed methodology will need to be validated, however, both in the laboratory and in the field.

The British, Dutch, and Canadian governments have conducted preliminary BWC trial inspections of industrial sites and found that it was possible to satisfy compliance concerns without compromising confidentiality.[43] Some critics contend, however, that these trials were not conducted under realistic conditions, in that the attitude of inspectors is presumably different when inspecting a facility in their own country. Additional trial inspections of industrial plants should be conducted with the aim of simulating as closely as possible the confrontational atmosphere of a challenge inspection.

In addition to procedures to safeguard proprietary information during inspections, measures for the storage, handling, and classification of sensitive data derived from declarations and inspection reports will need to be devised, along the lines of the CWC's Annex on the Protection of Confidential Information. The following measures might be considered. First, all professional staff members of the future BWC inspectorate should sign a non-disclosure agreement, the violation of which would make them liable to firing and criminal prosecution. Second, inspectors should be hired on long-term contract so that they would have less of a financial incentive to steal secrets. Third, all BWC members should have the right—provided under the CWC—to screen proposed BWC inspectors and bar certain questionable individuals from participating in inspections on their territory.

Investigations of Alleged Use

CWC provisions. The CWC sets out detailed procedures for investigating cases of alleged use of chemical weapons. In the event of an alleged chemical attack, any CWC member state may request an investigation by providing the inspectorate information about the time and location of the incident, the types of chemical agent(s) employed, the extent of use, and the reported effects on humans, animals, and vegetation. On request, the CWC inspectorate must dispatch a team of experts

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[42] "Inactivation of samples would safeguard CPI [confidential proprietary information] in the instance that a proprietary sample would have to be analyzed off-site, or if traces of the sample should remain on the inspectors' equipment or clothing after on-site analysis. Inactivation could be carried out by means such as fixation, heat, lysis, etc. Restriction enzyme treatment could be used to fragment proprietary genes so that they could not be identified or recovered. . . . Testing of live proprietary organisms would only be necessary for specific concerns regarding pathogenicity." Barbara Hatch Rosenberg, "Sampling and Analysis of Proprietary Microorganisms While Protecting Confidential Proprietary Information," Presentation at the Pugwash Workshop on Strengthening the BWC, 2–3 December 1995, 2.

[43] Government of the United Kingdom, "BTWC Practice Compliance Inspection (PCI) Programme: Summary Report," in *Special 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 Report*, BWC/SPCONF/1, 19–30 September 1994; Governments of the Netherlands and Canada, "Bilateral Trial Inspection in a Large Vaccine Production Facility: A Contribution to the Evaluation of Potential Verification Measures," Document BWC/CONF.III/VEREX/WP.112, 24 May 1993.

to investigate at the earliest safe opportunity.[44] The investigative team has the right to gain access "to any and all areas which could be affected by the alleged use of chemical weapons. . . [and] to hospitals, refugee camps and other locations it deems relevant to the effective investigation of the alleged use of chemical weapons."[45] Inspectors are also entitled to interview and examine persons who were allegedly affected by chemical weapons and to collect environmental and biomedical samples. On completion of the field investigation, the team must submit a final report within 30 days.

Relevance to BWC protocol. The BWC currently has limited provisions for investigating cases of alleged use of biological or toxin agents. According to Article VI, any participating state that believes another party is violating the BWC may file a complaint with the UN Security Council, along with available supporting evidence. All BWC parties are then enjoined to cooperate with any investigation that the Security Council may initiate.[46] In practice, however, this procedure has proved ineffective because accused countries have prevented UN experts from entering areas where an alleged biological weapon attack occurred. During the late 1970s and early 1980s, the United States accused the Soviet Union and its Laotian and Vietnamese allies of employing toxin warfare agents against the Hmong tribespeople in Laos and the Khmer Rouge troops and civilians in Cambodia.[47] A team of UN experts sent to Southeast Asia in December 1990 to investigate these charges was denied access to the contested areas and thus was unable to draw definitive conclusions.[48]

Such experiences have demonstrated the need to incorporate detailed investigative procedures into the BWC protocol, including the right of access without refusal to areas where use of biological weapons has purportedly taken place. Since cases of alleged use are likely to be rare, and specialized expertise is required to conduct field investigations, a separate pool of professional epidemiologists and other experts should be established. These individuals would be rapidly mobilized and deployed when allegations of use occur. Field investigations would involve a variety of epidemiological techniques, including interviews with witnesses, medical examination of victims, and environmental

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[44] In case of an alleged use of chemical weapons involving a non-member of the CWC or in territory not controlled by a CWC party, the Organization for the Prohibition of Chemical Weapons will put its technical resources at the disposal of the UN Secretary-General upon request.

[45] Chemical Weapons Convention, Verification Annex, Part XI, paragraph 15.

[46] US Arms Control and Disarmament Agency, *Arms Control and Disarmament Agreements: Texts and Histories of the Negotiations* (Washington, D.C.: Government Printing Office, 1990): 134–5.

[47] The accusations of use of trichothecene mycotoxin agents, known as "yellow rain," were extensively publicized. The US Department of State issued two detailed reports on the subject: US Department of State, *Chemical Warfare in Southeast Asia and Afghanistan, Report to the Congress from Secretary of State Alexander M. Haig, Jr.*, Special Report No. 98 (Washington, D.C.: Government Printing Office, 22 March 1982); and US Department of State, *Chemical Warfare in Southeast Asia and Afghanistan: An Update, Report from Secretary of State George P. Schultz*, Special Report No. 104 (Washington, D.C.: Government Printing Office, November 1982).

[48] H.B. Schiefer, "Study of the Possible Use of Chemical Warfare Agents in Southeast Asia," Annex to UN Document A/37/308, 25 June 1982.

and biomedical sampling.[49] In addition to situations in which one member of the BWC is charged with using biological agents against another, field investigations should cover allegations of use against minorities or insurgents within countries. For example, an investigation conducted by Physicians for Human Rights was able to obtain compelling scientific evidence that Iraq had employed chemical weapons against its own Kurdish minority during the late 1980s.[50]

Unusual outbreaks of disease, which might be linked to the covert use of biological weapons or an accidental release from a clandestine production facility, also warrant investigation under the BWC compliance protocol. In April 1979, an epidemic of anthrax occurred in the Soviet city of Sverdlovsk. The United States alleged that the outbreak had resulted from an accident at a Soviet military microbiological facility, but senior Soviet officials claimed that the cause was ingestion of contaminated meat. The truth was not confirmed until 27 May 1992, when Russian president Boris Yeltsin admitted that the source of the outbreak had been an accidental release of anthrax spores into the atmosphere from a secret military facility.[51] Subsequent pathological and epidemiological studies confirmed this conclusion.[52]

Investigating unusual outbreaks of disease is complex because the early detection of epidemics requires the cooperation of a global network of epidemiological surveillance stations. The BWC inspectorate should take steps to gain access to information generated by international organizations active in the fields of human, animal, and plant health, such as the World Health Organization, its regional affiliates, and the UN Food and Agriculture Organization. Whenever a suspicious disease outbreak is detected on the territory of a state party that involves a putative biological or toxin warfare agent and an apparent non-natural etiology, the BWC Executive Council would decide whether or not to deploy a field investigation team to the site. This procedure should include a red light approval system that allows a field inspection to proceed unless a three-quarters majority of the Executive Council votes to block it.

Treaty Organization

CWC provisions. Upon the entry into force of the CWC in April 1997, a new international agency called the Organization for the Prohibition of Chemical Weapons (OPCW) was founded in

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[49] As noted earlier, collection of samples would be a time-sensitive matter, since most biological and toxin agents do not persist in the environment for long. Federation of American Scientists, *Report of the Subgroup on Investigation of Alleged Use or Release of Biological or Toxin Weapons Agents*, Working Group on Biological and Toxin Weapons Verification (Washington, D.C.: April 1996). See also, Peter Barss, "Epidemic Field Investigations as Applied to Allegations of Chemical, Biological, or Toxin Warfare," *Politics and the Life Sciences* 11, no. 1 (February 1992): 5–22.

[50] Physicians for Human Rights, *Winds of Death: Iraq's Use of Poison Gas Against Its Kurdish Population, Report of a Medical Mission to Turkish Kurdistan* (Boston, MA: February 1989).

[51] Yeltsin made the admission in an interview with the Russian newspaper *Komsomolskaya Pravda.* R. Jeffrey Smith, "Yeltsin Blames '79 Anthrax on Germ Warfare Efforts," *Washington Post*, 16 June 1992, A1, A15.

[52] Matthew Meselson et al., "The Sverdlovsk Anthrax Outbreak of 1979," *Science* 266, no. 5188 (18 November 1994): 1202–8.

The Hague, the Netherlands, to administer the treaty. The OPCW has a Technical Secretariat that is carrying out the treaty's verification requirements.[53]

Relevance to BWC protocol. Since the memberships of the BWC and CWC are not identical, a separate organization will have to be established to implement the BWC compliance protocol. The BWC inspectorate will probably resemble the OPCW in overall structure but will require different areas of technical expertise to monitor biological weapons. Moreover, having recently experienced the difficult and costly process of establishing the OPCW, states negotiating the BWC protocol will probably not wish to create another agency of similar scale. Compared with the OPCW's staff of approximately 475, the BWC Technical Secretariat may well be considerably smaller. As another means of reducing expenses, the BWC organization should be located in or near The Hague and rely on the OPCW for administrative services, such as payroll and travel, and support facilities such as libraries.[54]

Trade Restrictions

CWC provisions. The CWC creates an incentive for countries to participate in the treaty regime by restricting trade in scheduled chemicals with nations that do not join, while promising liberalized trade in chemicals and technology among participating countries. Trade in Schedule 1 chemicals, which constitutes a tiny segment of the overall chemical marketplace, is limited to treaty members.[55] In May 2000, trade in Schedule 2 chemicals will be restricted to CWC states; until then, end-use certificates are required.[56] Schedule 3 chemical transfers to non-members also require end-use certificates; in 2002, a decision will be made on possible trade restrictions on these chemicals.[57]

Some developing countries strongly object to any restrictions on trade in scheduled chemicals among CWC members. The focal point of this dispute is the Australia Group, an informal mechanism established in 1985 for harmonizing national nonproliferation export controls on chemical weapons precursors and production equipment among 30 industrialized states. Although developing countries contend that export controls directed against parties to the CWC are redundant and discriminatory, the Australia Group counters that CWC members suspected of being proliferators must demonstrate their compliance over a period of time before all export controls

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[53] The OPCW's three constituent bodies are the Conference of the States Parties, the Executive Council, and the Technical Secretariat. All parties to the CWC are members of the Conference, the major policy body of the regime that meets once a year and can also be called into special session. Day-to-day decision-making is the responsibility of the Executive Council, which has a membership of 41 states, some permanent and some rotating. Finally, the Technical Secretariat is the professional staff responsible for compiling and processing data declarations and conducting on-site inspections.

[54] Confidentiality concerns may preclude the sharing of computer servers and communications between the CWC and BWC inspectorates.

[55] Chemical Weapons Convention, Verification Annex, Part VI(B), 3–4.

[56] Ibid., Part VII(C), 31– 2.

[57] Ibid., Part VIII(C), 26–7.

should be lifted.[58] This controversy reflects the different provisions of the treaty that the industrialized and developing countries have chosen to emphasize. Whereas the industrialized countries stress the CWC's obligation not to abet chemical weapons proliferation, the developing countries emphasize the treaty's obligation to promote trade and cooperation among participating states in the peaceful applications of chemicals.[59]

Relevance to BWC protocol. In the BWC context, there is a similar conflict between Article III, which bans the transfer of biological weapons or assistance in their development, and Article X, which requires parties to engage in technical cooperation and assistance in the use of biotechnology for peaceful purposes. Since 1993, the Australia Group has encouraged its members to impede biological weapon proliferation by harmonizing national export controls on seed cultures of hazardous micro-organisms and advanced fermentation equipment.

The promise of expanded trade in biotechnology is a powerful incentive for developing countries to participate in the BWC regime. Conversely, the belief that the advanced industrialized states will continue to restrict or deny these technologies to the developing world has generated strong North-South tensions. A possible way out of the current impasse would be to implement biological export controls in a way that permits the transfer to developing countries of dual-use technologies vital for public health and agricultural productivity. To this end, the Australia Group "core list" of micro-organisms and equipment subject to trade controls should be pared down to focus more narrowly on high-threat pathogens and toxins and specialized production equipment designed for use with the most hazardous agents.

Conclusions

Because of the many technical differences between chemical and biological weapons and their methods of production, the wholesale transplant of measures from the CWC verification regime to the BWC protocol is not appropriate. Despite this caveat, however, several elements of the CWC verification regime, as shown in Table 5, are relevant to the BWC compliance protocol. Like the chemical treaty, the BWC protocol should establish a set of mutually reinforcing measures ranging from facility declarations to on-site inspections. In addition, the BWC protocol should adopt a CWC-like system of "carrots" and "sticks" to reward states that comply with the treaty while punishing those that remain outside or that fail to adhere to its provisions.

Although there are limitations on the effectiveness of on-site activities, a combination of short-notice routine visits to high-risk facilities and occasional challenge inspections would create a useful deterrent effect. Combining the obligation to declare relevant facilities with the obligation

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[58] For a complete discussion of this controversy and its origins, see Amy E. Smithson, *Separating Fact from Fiction: The Australia Group and the Chemical Weapons Convention*, Occasional Paper 34 (Washington, D.C.: Henry L. Stimson Center, March 1997).

[59] Chemical Weapons Convention, Article I and Article XI, paragraphs 2(b) and 2(c).

to accept challenge inspections at any site, declared or undeclared, would force potential BWC violators into a quandary.[60] While declaring a relevant facility would make it potentially subject to a routine inspection, not declaring the facility would increase the risk of being caught red-handed during a challenge inspection. Thus, an integrated regime of this type would be stronger than the sum of its parts.

Other conclusions from the previous analysis are as follows:

- To avoid creating legal loopholes that could invite circumvention, nothing should be done to limit or qualify the broad prohibitions contained in Article I of the BWC.

- Proposals to establish absolute quantitative ceilings for the possession of biological or toxin agents are not technically feasible, either for countries as a whole or particular facilities.

- Mandatory declaration of dual-capable facilities is essential for BWC compliance monitoring, but no single criterion is sufficient to determine which facilities should be declared. Instead, a combination of criteria should be employed, with the aim of identifying a subset of "high-risk" government and commercial facilities.

- Challenge inspections of suspect sites should ideally be conducted with no more than 24-hours notice, to increase the probability of detecting traces of illicit production.

- To safeguard national security and proprietary information unrelated to BWC compliance, the protocol should incorporate measures to screen inspectors and hold them accountable for protection of privileged information, guard against frivolous or abusive challenge requests, and allow sensitive facilities to manage access during inspections.

- Although sampling and analysis will be more problematic under the BWC than the CWC, techniques are available to allow inspectors to analyze samples on site without compromising proprietary information.

- The BWC compliance protocol should specify procedures for investigating allegations of use and unusual outbreaks of disease, with guaranteed access to all relevant areas.

- A dedicated, separate BWC monitoring agency will be required to implement the compliance protocol, including processing data declarations and conducting on-site inspections. This small agency should be located in The Hague so that it can share administrative and support services with the OPCW.

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[60] ter Haar, "Indirect Verification," 9.

Table 5: Applicability of CWC Verification Measures to the BWC Compliance Protocol.

Measure in the CWC	Rationale for Inclusion in the CWC	Applicability to the BWC Protocol
Lists (schedules) of agents as the basis for declaring treaty-relevant facilities	A limited number of chemical families possess the toxicity and physiochemical properties making them suitable for warfare. The CWC verification regime focuses on facilities that produce, process, or consume these chemicals, with a provision to amend the schedules as novel agents are discovered.	Naturally occurring disease agents are discovered from time to time (e.g., Legionellosis, AIDS, Ebola), and the capability to genetically manipulate microorganisms and genes means that the number of warfare agents is potentially unlimited. Thus, schedules of agents are of limited utility except as illustrative lists for structuring declarations.
Declarations of "other relevant" production facilities (producers of discrete organic chemicals above quantitative thresholds)	Such facilities have the potential to produce scheduled chemicals, and hence might be diverted to production of chemical agents or precursors.	Nearly all biological fermentation plants have the potential to produce biological agents, so such a distinction does not apply in the BWC context.
Quantitative declaration thresholds for Schedules 2 and 3	To minimize the monitoring burden on the chemical industry, facilities that produce Schedule 2 and 3 chemicals below certain quantitative thresholds need not be declared.	Small quantities of biological agents are militarily significant and seed cultures can be quickly grown into large volumes of agent. Thus, quantitative thresholds are not relevant to the BWC context.
Routine inspections	Routine inspections are designed to verify the information provided in initial declarations and annual reports on declared facilities, and to confirm the absence of undeclared Schedule 1 chemicals and the non-diversion of scheduled chemicals for military purposes.	Routine inspections of high-risk declared facilities would confirm the accuracy of declarations and help deter illicit production. Deterrence would be strengthened if such routine inspections were conducted on short notice.
Challenge inspections	Challenge inspections provide a "safety net" mechanism to detect clandestine chemical weapons production. Managed-access procedures have been structured to allow a compliance assessment while protecting legitimate national-security and industrial secrets.	Challenge inspections are the only viable means of detecting and deterring illicit activities. Managed-access procedures should be structured to allow a compliance assessment while protecting legitimate national security and industrial secrets.

Measure in the CWC	Rationale for Inclusion in the CWC	Applicability to the BWC Protocol
Sampling and analysis	Sampling and analysis may be conducted during routine or challenge inspections. The host facility has the right to manage access (e.g., by specifying sampling points). Although initial analysis should be on-site, off-site analysis may be required for clarification of anomalies.	Sampling and analysis should be used as needed to confirm that the agents present on-site are consistent with the facility's declared activities, or to confirm suspicions of illicit production of undeclared agent(s). Managed-access procedures will be required to protect trade secrets.
Investigation of alleged use	Part XI of the Verification Annex contains detailed provisions on procedures for investigating the alleged use of chemical weapons.	The BWC protocol should include a stronger mechanism to investigate alleged use of biological agents and to determine whether unusual outbreaks of disease are linked to accidental release of biological warfare agents from a clandestine facility.
International treaty organization	The CWC established the Organization for the Prohibition of Chemical Weapons (OPCW) to administer the treaty, with a Technical Secretariat responsible for processing declarations and conducting on-site inspections.	Implementation of the BWC compliance protocol will require the creation of a legally distinct BWC monitoring agency, which could share administrative resources and overhead with the OPCW to reduce costs.

- After the BWC protocol enters into force, biological export controls should be implemented in a highly targeted manner to minimize restrictions on dual-use biotechnologies important for the public health, agriculture, and economic growth of developing countries.

Today, both the CWC and the BWC are at delicate turning points that could lead either to a significant strengthening of the international norm against these heinous weapons or to the weakening of one or both treaties and an acceleration of chemical and biological weapons proliferation. The CWC entered into force on 29 April 1997 and more than 105 countries are now parties. Already, the CWC's inspectorate has sifted through masses of information contained in data declarations and conducted over 100 inspections. Practical experience being gained through the implementation of the CWC verification provisions should offer useful lessons for the negotiators crafting the BWC compliance protocol.

More broadly, the fate of the chemical and biological disarmament regimes are linked. The emergence of serious problems with CWC implementation could discourage states from attempting to create a strong verification regime for the BWC. Conversely, successful implementation of the CWC would build confidence in the arms control process and give new impetus to the BWC protocol negotiations.

Man Versus Microbe: The Negotiations to Strengthen the Biological Weapons Convention

***Amy E. Smithson,* Ph.D.**

One of the events generating global attention and apprehension in the Fall of 1997 was the standoff between Iraq and the United Nations (UN). Few believed the claims of Iraqi leader Saddam Hussein that Iraq had destroyed its entire cache of biological weapons, especially those at the UN Special Commission (UNSCOM) who were doggedly pursuing this matter. A crisis flared when Saddam kicked Americans working for UNSCOM out of the country and threatened to shoot down a US U-2 aircraft conducting surveillance for the UN's inspectorate. The United States attempted to rally UN Security Council members to stand firm against Saddam's attempt to defy the 1991 Gulf War cease-fire resolution requiring Iraq to eliminate its weapons of mass destruction. Washington also demonstrated resolve by deploying two aircraft carrier battle groups to the region.[1] Throughout this crisis, Saddam appeared willing to risk a rain of bombs on Baghdad. In turn, the United States appeared willing to risk the resumption of hostilities with Iraq and the rancor of nations that thought Iraq had endured inspections and sanctions long enough. This high stakes struggle over 25 germ-filled warheads and Iraq's residual capability to produce more biological agents highlighted both the dangerous prospects of biological warfare and the difficulty of eliminating a biological weapons program in a noncooperative country.

Not long after this crisis subsided, nations reconvened in Geneva for the ninth round of talks to create a verification protocol for the Biological and Toxin Weapons Convention (BWC), which bans the development, production, and stockpiling of biological weapons. Although the negotiations began in 1995, they had barely gotten out of the starting block by January 1998. President Bill Clinton called for the conclusion of a protocol by the end of 1998,[2] but the rolling text of a draft protocol was clearly in its infancy. One reason for the lack of process was that the US delegation was still in want of a formal position for the negotiation in the Ad Hoc Group. In Washington and in many other capitals, senior policy makers apparently had not yet mustered any genuine enthusiasm for the BWC, the world's front-line defense against the proliferation of biological weapons. The lack of momentum in these negotiations stood in sharp contrast to a willingness to threaten military

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[1] Steven Lee Myers, "Iraq Bars U.S. Arms Inspectors," *New York Times*, 31 October 1997, A1; Tim Weiner, "Iraq's Top Secret: Intent Is the Ultimate Mystery," *New York Times*, 16 November 1997, A1; R. Jeffrey Smith, "Iraq's Drive for a Biological Arsenal: U.N. Pursuing 25 Germ Warheads It Believes Are Still Loaded With Deadly Toxin," *Washington Post*, 21 November 1997, A1; "Naval Commanders Protecting U-2 Warn Saddam Not To Attack," *Washington Times*, 12 November 1997, 11; John M. Goshko, "U.N. Arms Inspectors Returning to Iraq in Reversal by Baghdad," *Washington Post*, 21 November 1997, A1. On the cease-fire resolution, see United Nations Security Council, Resolution 687, Document S/RES/687, 1991.

[2] William Jefferson Clinton, "Remarks by the President in Address to the 51st General Assembly of the United Nations," UN General Assembly, 51st sess., Document A/51/PV.6, 24 September 1996, 2.

action to address the threat of biological weapons. Common sense dictates that all available tools be drawn upon to cope with a problem as complex as biological weapons proliferation.

Both horizontally and vertically, the biological weapons proliferation problem has gotten more complex since the BWC entered into force in 1975. More countries—roughly a dozen—are thought to be running biological weapons programs.[3] Dual-use technologies, materials, and equipment have spread around the globe as the biotechnology and pharmaceutical industries have grown. The community of researchers feeding the scientific and technical advances in biotechnology, genetic engineering, and other related disciplines has also expanded. In short, new frontiers have opened for those seeking biological weapons, including the possibility of manipulating genes to create novel, treatment- and detection-resistant biological agents.[4]

Indeed, the roots of a biological weapons program can be relatively easy to plant. The Iraqi biological weapons program provides a telling example. Iraq obtained cultures for anthrax and botulinum toxin from the American Type Culture Collection, located outside of Washington, D.C. Some of the pathogen strains that Iraq purchased from 1985 to 1989 had origins in the now-terminated US and British biological warfare programs. Iraq also ordered warfare-suitable cultures from the Pasteur Institute in Paris. While British and Swiss firms filled Iraqi orders for growth media, Italian, Swiss, and German companies sold the Iraqis fermenters. To cap it off, two British-trained Iraqi scientists reportedly master-minded the development, testing, production, and weaponization of Iraq's biological arsenal.[5]

The widespread presence of dual-use technologies, equipment, and materials in countries around the globe promises to make monitoring the BWC extremely difficult. Telltale signs of a covert biological weapons program are scarce. Indicators of the direction of a country's research and development might be discerned through the published literature of a nation's scientific community or through human intelligence resources. Satellites might pick up signs of the testing, production, and weaponization phases of a biological weapons program, but visual signatures are not plentiful

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[3] See chapter 2 of this report. Other helpful sources on biological weapons proliferation include Office of the Secretary of Defense, *Proliferation: Threat and Response* (Washington, D.C.: Government Printing Office, November 1997); US Arms Control and Disarmament Agency, *Annual Report to Congress* (Washington, D.C.: US Arms Control and Disarmament Agency, 7 August 1996); US Congress, Office of Technology Assessment, *Proliferation of Weapons of Mass Destruction: Assessing the Risks*, OTA-ISC-559 (Washington, D.C.: Government Printing Office, August 1993).

[4] For more discussion, see Jonathan B. Tucker, "Gene Wars," *Foreign Policy*, no. 57 (Winter 1984/85):58–79; Malcolm Dando, *Biological Warfare in the 21st Century: Biotechnology and the Proliferation of Biological Weapons* (London: Brassey's, 1994): 86–156.

[5] Raymond A. Zilinskas, "Iraq's Biological Weapons: The Past as Future?" *Journal of the American Medical Association* 278, no. 5 (6 August 1997): 418–21; Smith, "Iraq's Drive for a Biological Arsenal," 48. More detail on acquiring a biological weapons capability can be found in chapter 2 of this report and US Congress, Office of Technology Assessment, *Technologies Underlying Weapons of Mass Destruction*, OTA-BP-ISC-115 (Washington, D.C.: Government Printing Office, December 1993): 82–99.

(e.g., burial of dead animals from tests, specialized aerosol chambers, advanced air filtration equipment, large cold-storage facilities, heightened security measures). Human intelligence could provide another tip-off—evidence of special immunization or safety programs for workers involved in a clandestine weapons program.[6]

Unfortunately, most, if not all, of the requisite research, development, testing, and production of biological weapons can be conducted indoors, shielded from satellite lenses and the eyes of spies. The most common cheating scenario places the facilities of a weapons program amidst a nation's biotechnology industry. Just as the USSR used Biopreparat facilities as the cover for its biological weapons program, the industrial sector helped to mask offensive biological weapons activities in Iraq. Al Hakam, one of the main sites that Iraq used to produce anthrax, botulinum toxin, and *Chlostridium perfringens* had none of the telltale signs typically associated with a biological weapons program. "The site looked like normal industrial sheds, with nothing from the air that would identify it," said a UN official.[7] In other words, even more of the discrete signatures of a covert weapons program can disappear if a government is willing to pursue germ warfare without such modern safety precautions as special containment facilities and worker vaccination.[8]

In addition, advanced industrial equipment can quickly sweep away traces of biological agent that inspectors might detect, even if they arrive within hours. Many pharmaceutical plants now make use of clean-in-place technology, which flushes fermenters and pipes throughout a facility with microbe-killing chemicals and hot water. Within a few brief hours, an entire facility can be cleansed of evidence. Plant workers also scrub floors daily and walls and ceilings weekly. Such meticulous cleanliness and maintenance procedures, required by regulatory authorities to keep contaminants from infiltrating medical products,[9] are the enemy of inspectors trying to unearth a secret biological weapons program. While useful, inspections of such facilities might only yield a fleeting impression of what these plants are doing while the inspectors are there, but will result in little confidence of what was going on shortly before or soon after the inspections. The nature of dual-use biological

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[6] For more on the indications of a biological weapons program, see Office of Technology Assessment, *Technologies Underlying Weapons of Mass Destruction*, 99–113.

[7] *Chlostridium perfringens*, one of the less familiar agents in Iraq's arsenal, causes gas gangrene. UNSCOM demolished the Al Hakam plant in June 1996. Smith, "Iraq's Drive for a Biological Arsenal," 49.

[8] Indeed, some aspects of the US biological weapons program were conducted without such safety measures. US government official, interview with author, Washington, D.C., 2 January 1998.

[9] On 5 December 1997, the author received a first-hand view of current industrial capabilities during a day-long tour of a US pharmaceutical production plant. She thanks this company, which wishes to remain anonymous, for its cooperation with her research. In particular, she is grateful for the patience this company's officials demonstrated while explaining the plant's capabilities and for their willingness to help her brainstorm about ideas for monitoring the BWC.

In general the industry takes extensive precautions to protect their products from contamination by outside organisms, but practices vary from facility to facility, depending upon the regulatory requirements for the product being made. Typically, a plant will have areas of increasing containment, with the innermost manufacturing areas being glove boxes inside of pressurized rooms, surrounded by pressurized rooms. Employee access is tightly controlled, and workers wear sterilized gowns, shoe coverings, hair-nets, and gloves, sometimes in double layers.

equipment and scientific capabilities is such that not even rigorous short-notice inspections can ensure high confidence of compliance with the BWC's prohibitions.

Returning again to the Iraqi case, some observers have been quick to criticize UNSCOM for not eradicating Saddam's biological weapons program soon enough. Such complaints reflect a limited understanding of the immensely difficult task facing UNSCOM. The Iraqi government has taken extensive steps to conceal its biological weapons program and to foil inspectors at every turn. UNSCOM's inspectors cannot count and destroy what they (or satellites) cannot see. Even when a sample picks up traces of biological agent at a suspect facility, which decay quickly when exposed to the elements, the inspectors must confirm that the agent was man-made and not already present in the environment. The task may be exasperating, but the costs of not pursuing this matter are high. If lack of support from the international community forces UNSCOM to abandon its mission, then Iraq will be left with sufficient biological agent to kill the world's population several times over, not to mention the capacity to resume production of even more deadly germs.[10]

The ongoing test of wills between Iraq and the UN is really a battle over what many view as the ultimate weapons, the "weapons of choice" for the 21st century. Biological weapons earned this distinctive label because: 1) very small quantities can kill very large numbers of people; 2) advanced delivery systems are not required to disperse biological agents; 3) biological weapons can be readily acquired; and, 4) biological warfare programs are relatively easy to conceal. Populations are also extremely vulnerable to a biological weapons attack.[11] A very small percentage of the world's population has been vaccinated against known biological agents, and vaccinations are available only for a few, such as plague and anthrax.[12] Given the vulnerability of humans to such viruses as Ebola, Marburg, and Machupo, every effort must be made to ensure that these and other lethal germs are not manufactured for warfare purposes. The shockingly high mortality rates of some biological agents make the stakes in the Iraqi situation and in the negotiation to strengthen the BWC very high indeed.[13]

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[10] With regard to botulinum toxin, "Iraq has acknowledged making 3,117 gallons or enough toxin to wipe out the Earth's population several times over, and U.S. officials say Iraq's actual production may have been two to three times this amount . . . . Iraq has acknowledged making 2,265 gallons of anthrax, enough to kill billions." Among other germ agents, Iraq also admitted making ricin, *Chlostridium perfringens*, and aflatoxin and to filling missile warheads and bombs with germs and toxins. Smith, "Iraq's Drive for a Biological Arsenal," A48. See also, Zilinskas, "Iraq's Biological Weapons: The Past as Future?" 418–24.

[11] *The NBC Threat in 2025: Concepts and Strategies for Adversarial Use of Nuclear, Biological and Chemical Weapons*, Center for Counterproliferation Research (Ft. McNair, Washington, D.C.: National Defense University, September 1996): 33, 35.

[12] For a description of known agents and available medical treatments, see David R. Franz et al., "Clinical Recognition and Management of Patients Exposed to Biological Warfare Agents," *Journal of the American Medical Association* 278, no. 5 (6 August 1997): 399–411.

[13] To illustrate the point, the plague is lethal in ninety percent of all cases, anthrax in eighty percent; and Lassa virus in seventy percent. Other germ warfare agents are not as deadly. If not treated, tularemia is fatal for thirty to sixty percent of its victims within 30 days. Brucellosis has a low mortality rate—about two percent. For more on agents that have been weaponized, see chapter 2 of this report and Office of Technology Assessment, *Technologies Underlying*

One of the most important lessons of the Iraqi-UNSCOM saga is that policy makers need to adjust their expectations about what a monitoring regime for the BWC can accomplish. Unless a BWC violator is careless, the results of BWC inspections will not be instantaneous and conclusive. Instead, as UNSCOM's experience illustrates, an incriminating case against a biological weapons proliferator will be made over time by diligently assembling pieces of evidence. An aspiring proliferator can be constrained by destroying dedicated weapons production facilities (e.g., UNSCOM blowing up Iraq's Al Hakam in June 1996), cutting off the flow of dual-use equipment and materials into a country, and continually monitoring that state's existing dual-use capabilities.

What remains to be seen is whether the Ad Hoc Group negotiations will produce a BWC protocol equivalent to the challenge of monitoring this treaty. Already, the negotiators seem to be coming to grips with the enormity of the task facing them. Hence, in Geneva, the preference for using the terms "visit" and "investigation" instead of the more familiar term "inspection," which connotes an ability to produce concrete results from an on-site monitoring activity. The next section of this essay recounts the reasons why the conclusion of a protocol will be a feat in and of itself. This discussion is followed by a series of observations and suggestions intended to spur progress in the negotiations.

Policy Quicksand

A pit of quicksand is composed of individual grains of loose, wet sand. The stuff of nightmares, quicksand swallows anything that falls into it. Over the past several years, developments related to monitoring a biological weapons ban have been taking place within the US pharmaceutical industry, among the delegations working on the BWC protocol in Geneva, and within the US government. Taken individually, these events and positions, like grains of sand, would seem to be more irritating than disastrous. Collectively, they could sink the chances for the negotiation of a meaningful BWC protocol.

Industry Enters the Arms Control Arena

The US pharmaceutical industry was abruptly introduced to the intricacies of biological weapons monitoring as a result of the September 1992 trilateral agreement between Russia, Great Britain, and the United States. This trilateral arrangement was intended to enhance confidence that Russia had halted its offensive biological weapons program and was abiding by its BWC obligations since the treaty was devoid of any verification measures.[14] However, the initial trilateral inspections

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Weapons of Mass Destruction, 76–82. For more on germs that might be used for warfare purposes, see Laurie Garrett, *The Coming Plague: Newly Emerging Diseases in a World Out of Balance* (New York: Farrar, Straus and Giroux, 1994); Dando, *Biological Warfare in the 21st Century*, 130–56.

[14] The origins of the trilateral process stem from US intelligence information, derived from a very credible defector, that the Soviet/Russian biological weapons program was still operating. The trilateral process was created so that the Soviets and then the new Russian government could, without the embarrassment of having this intelligence data

in the United States unfolded in a manner that alarmed and disturbed the American pharmaceutical industry, by far the world's largest.

After the trilateral confidence-building agreement was reached, no one in the US government bothered to warn US industry officials that Russians would request entry to a handful of their facilities. Auxiliary provisions were negotiated to protect proprietary information during these inspections, but the trilateral agreement itself did not contain specific authority to compel the cooperation of US industry. During trilateral inspections, industry officials were to allow complete access or explain why an area could not be viewed. Photographs and audio- and videotapes could also be made and environmental samples could be taken.[15] Granting such extensive access to someone other than US regulatory authorities was highly irregular for US pharmaceutical companies, which assiduously restrict entrance to their facilities. As one US bureaucrat recalled, "The trilateral process was a textbook illustration of how not to handle a situation with industry."[16]

Following an initial round of inspections in Russia in October 1993,[17] the Russians requested inspection of an American commercial facility in mid-February 1994. During World War II, the selected plant in Terre Haute, Indiana, had been built to make biological agents, although no offensive production reportedly ever occurred there.[18] According to individuals who were present or very familiar with this event, during the visit and later in writing the Russians charged that the presence of such items as idle fermenters indicated that this facility may have been engaged in the production of biological agents. Such allegations stunned representatives of the commercial firm involved.[19]

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made public, provide reassurances that offensive biological weapons activities had indeed ceased. US government official, interview with author, Washington, D.C., 6 January 1998.

[15] US Department of State, "Joint US/UK/Russian Statement on Biological Weapons," Press Release, Office of Public Affairs (Washington, D.C.: 14 September 1992). See also, "Proprietary Agreement: Procedures for Respecting Proprietary Information During Visits to Non-Military Biological Sites Pursuant to Paragraph 4(A) of the Joint US/UK/Russian Statement on Biological Weapons," Moscow, 12 May 1993.

[16] US government employee, interview with author, Washington, D.C., 31 December 1997. The author has tracked events regarding the pharmaceutical industry, the trilaterals, and the BWC since 1993, but she also conducted several interviews to reconfirm her understanding of events.

[17] US and British inspectors went to two suspected biological weapons research sites, the Pokrov facility near Moscow and to a facility in Berdsk, near Novosibirsk. About the possibility that offensive activities occurred at these locations, a US official stated: "Although there was no smoking gun, it was perhaps what could have been a holster." See "Biological Weapons Convention: Chronology 1993," *Arms Control Reporter* 12, no. 11 (3 October 1993): 701.B.119–20.

[18] Apparently, the facilities that the Russians visited were owned by Pfizer, Inc. "Biological Weapons Convention: Chronology 1994," *Arms Control Reporter* 13, no. 3 (14 February 1994): 701.B.123–4.

[19] The fermenters in question were obsolete, and simply pad-locking the building was cheaper than destroying them. US government officials, interviews with the author, Washington, D.C., 30 December 1997, 31 December 1997, 2 January 1998, 6 January 1998. US industry official, interview with author, Washington, D.C. 2 January 1998.

On the heels of the Indiana visit, the Russians requested an inspection of a second facility owned by the same commercial firm. This company's representatives were apparently very reluctant to grant access to this second site, an extremely sensitive research facility located in Groton, Connecticut. The US government exerted significant, high-level pressure to encourage the company to cooperate.[20] This firm relented, and the inspection proceeded from 22 to 25 February 1994.[21] The Russians reportedly made similar allegations, none of which were proven, that offensive biological activities were underway at the Groton site.[22]

For the US pharmaceutical industry, these trilateral inspections constituted an ominous introduction to what efforts to monitor compliance with the BWC might be like. Stories about these events soon circulated within the industry. Just like "Remember the Alamo!" became the rallying cry for American soldiers during the Texas War of Independence against Mexico, the Terre Haute and Groton inspections became crystallizing experiences for some in industry, who vowed that a future BWC protocol would not be a repeat of the trilaterals. To compound the situation, a negative atmosphere seeped into the interactions between some US government and industry officials. During meetings including company presidents and CEOs, some industry officials thought that their US government hosts did not receive them with proper respect. The tenor of some meetings was such that industry representatives believed that US government officials disregarded and even refuted the very views that the government had asked them to present.[23]

Consequently, the US industry took a conservative opening position regarding a BWC protocol.[24] Both verbally and in writing, the US government told the Pharmaceutical Research and Manufacturers of America that a US position would be forthcoming by January 1997, then by July 1997, or, at the latest, by September 1997.[25] From industry's perspective, the government's failure to conclude a negotiating position was a sign of more trouble ahead. In 1997, American industry officials began approaching their counterparts overseas to express their concerns and to seek their support of the US industry position.[26]

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[20] Some interviewees recalled Vice President Albert Gore, Jr., having made a telephone call to ask this company to allow the second inspection to proceed, while others said that the persuading was accomplished by senior White House staff. US government officials, interviews with the author, Washington, D.C., 30 December 1997, 31 December 1997, 2 January 1998, 6 January 1998.

[21] "Biological Weapons Convention: Chronology 1994," *Arms Control Reporter*, 701.B.124.

[22] US government officials, interviews with the author, Washington, D.C., 30 December 1997, 31 December 1997, 2 January 1998, 6 January 1998.

[23] US industry official, interview with author, Washington, D.C., 2 January 1998. US government officials, interviews with author, Washington, D.C., 30 December 1997, 2 January 1998, 6 January 1998.

[24] From the Pharmaceutical Research and Manufacturers of America, see "PhRMA Paper on a Compliance Protocol to the Biological Weapons Convention," dated 9 January 1997, in Appendix 2 of this report. See also chapter 3 of this report.

[25] On the pledge to complete an overall US position before the July 1997 round of Ad Hoc Group negotiations, see Gary Samore, Senior Director for Nonproliferation and Export Controls, letter to Alan Holmer, President, Pharmaceutical Research and Manufacturers of America, 11 February 1997.

[26] US industry official, interview with author, Washington, D.C., 2 January 1998.

The Status of Ad Hoc Group Negotiations

In Geneva, a dizzying array of inspection proposals was being floated and debated. To begin with, there was widespread agreement that some type of declarations were needed as a foundation for any on-site monitoring activity. At the very least, submission of the data that some countries had been providing since 1987 for confidence-building purposes would become mandatory.[27] Beyond that, the extent and format of any data declarations were still a matter of debate. For instance, Moscow argued that because of the spread of dual-use technologies and materials, intent could not be the basis of a BWC compliance judgment. Russia, therefore, maintained that the BWC protocol should incorporate lists of prohibited agents, as well as thresholds for the possession of quantities of agent for permitted activities. In their view, the backbone of verification was the specification of what a treaty does and does not prohibit.[28] Russia's position was disputed on the basis that lists would constrain the broad prohibitions embodied in Article I. Moreover, a covert biological weapons program could flourish with new natural or genetically engineered agents, making a mockery of any list. As for the use of agent thresholds, they had little meaning since a small culture can be quickly grown into a significant quantify of agent.[29]

With respect to inspections, the delegations were only close to general consensus on one matter—that an alleged use of biological agents necessitates speedy investigation. Otherwise, two types of challenge inspections had been proposed. One type of challenge, a facility investigation, would be prompted by a concern that a particular facility was involved in the development, acquisition, production, or stockpiling of biological weapons. Any facility, declared or not, could be subject to a challenge inspection. A second type of challenge—a field investigation—would be initiated when humans, animals, or plants appear to have been exposed to a biological or toxin agent. This latter type of challenge would investigate the affected geographic area. A field investigation could be initiated by a suspicious outbreak of disease or an accidental release or the purposeful use of biological agent. If a suspect facility were within the affected geographic area being investigated, that facility could also be challenged. Any state party could request that the BWC inspectorate conduct a facility or field investigation of any other treaty member. The extent of access to the facility or the affected area would be negotiated, and the investigation would involve medical examinations, sampling, interviewing, and collection of background data, as needed. Measures to

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[27] Among other items, states were asked to provide data on outbreaks of suspicious disease, research laboratories that have high-level containment capabilities, and published scientific research. For more on these and other proposed measures, see chapter 4 of this report. Proposals regarding definitions and declarations can be found on pages 106–31 and 230–46 of the rolling text, Ad Hoc Group, *Procedural Report of the Ad Hoc Group 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*, Document BWC/AD HOC GROUP/38, 6 October 1997.

[28] US government officials, interviews with author, Washington, D.C., 30 December 1997, and 2 January 1998.

[29] For more discussion of these points, see chapter 5 of this report.

guard against the abuse of challenge inspections and to protect sensitive data unrelated to BWC-pertinent activities would be incorporated.[30]

The most prominent of the safeguards against the abuse of challenge inspections is the so-called green light, wherein requests for challenge inspections would be reviewed and specifically approved before an inspection could proceed. Several developing countries strongly advocated the use of a green-light screening mechanism. Off the record, these governments were worried that the monitoring provisions of the Chemical Weapons Convention (CWC) were far too intrusive, and they cautioned against duplicating them in the BWC protocol.[31] The CWC has a red light challenge inspection process, wherein three-quarters of a 41-member Executive Council must vote within 12 hours to halt a challenge inspection.[32] Alternately, Russia argued that the BWC's existing Article VI structure for initiating an inspection through the UN Security Council should remain intact. The Security Council would first screen an inspection request and, if approved, refer it to a politically representative technical body, which would need a two-thirds majority vote to launch an inspection. Furthermore, Russia contended that no human intelligence data should be used to support a challenge inspection request.[33] If Russia's positions were adopted, as a Security Council member Russia would retain veto rights over challenge inspections and countries requesting challenge inspections would be deprived of the use of some of the most persuasive data available about biological weapons programs, the information gathered by human intelligence contacts.

Several different constructs for a routine inspection regime were being considered. Among the proposed concepts were mandatory non-challenge visits, clarification visits, random non-challenge visits, and voluntary visits. None of these concepts was intended to address concerns of noncompliance. Rather, these variants of routine inspections were supposed to check the accuracy of declarations, establish a regular monitoring presence at declared facilities, and deter their use for prohibited activities. Some countries also noted that routine monitoring activities would also be useful for training inspectors for the more difficult and sensitive task of challenge inspections. Mandatory, short-notice, non-challenge visits at key declared facilities would be regulated by a quota

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[30] These concepts were proposed in Ad Hoc Group, "Working Paper Submitted by the Friend of the Chair on Compliance Measures," Document BWC/AD HOC GROUP/WP.136, 12 March 1997. See also, the rolling text, Document BWC/AD HOC GROUP/38, 134–86. Another term used for the challenge inspection concept is "inspections on request." Marie Chevrier et al., *Beyond VEREX: A Legally Binding Compliance Regime for the Biological and Toxin Weapons Convention*, Working Group on Biological and Toxin Weapons Verification (Washington, D.C.: Federation of the American Scientists, July 1994): 5–6.

[31] US government officials, interviews with author, Washington, D.C., 30 December 1997, and 2 January 1998.

[32] Article IX, Paragraph 17, Convention on the Prohibition of the Development, Production, Stockpiling and Use of Chemical Weapons and on Their Destruction.

[33] Specifically, Russia's position is: "Evidence obtained in violation of the law either of the country requesting the inspection or of the country where the inspection is to be conducted shall be treated as having no legal value and may not be used as the basis for any accusation or as confirmation of the allegations made in a request." Ad Hoc Group, "Basic Principles and Procedures for Consideration of Requests Relating to Alleged Violations of the Convention on the Prohibition of Biological Weapons: Working Paper Submitted by the Russian Federation," Document BWC/AD HOC GROUP/WP.181, 22 July 1997, 2–3.

system distributing inspections among regions. The number of declared sites per region would be factored into the quota.[34] A clarification visit could be done at the request of a state party or of the BWC inspectorate to settle any ambiguity or other anomaly concerning the information provided about a declared site. The number of clarification visits per state would be limited within a specified period of time.[35] For random visits, a percentage of a state's declared sites (e.g., five percent) would be randomly chosen to receive mandatory, non-challenge inspections.[36] Finally, in the event that consultations between the inspectorate and a BWC member did not resolve an ambiguity about a particular facility's declaration, the state could volunteer to host an inspection.[37]

Perhaps the strongest proponent in Geneva of CWC-type routine inspections in a BWC verification protocol was the United Kingdom. With a flood of position papers, the British argued that managed access inspections had the ability to detect cheating and to protect the confidential business information of industry. Great Britain's convictions about the utility of inspections in the BWC context were based on four trial inspections conducted in 1993 and 1994 at large, multipurpose commercial facilities during which a hypothetical compliance concern was investigated at each facility. From these trials, the British government concluded that the "managed access provisions [used in these instances] provided ample scope for the companies to protect commercially sensitive information" and that "in-depth inspections are practicable" and capable of identifying "strong indicators of [non-compliant] activity."[38] Great Britain, in sum, backed the use of the CWC's panoply of intrusive monitoring provisions.

In contrast, the Russian government opposed any type of routine inspection and even the investigation of suspicious outbreaks of disease. During the March 1997 round of negotiations, the Russian delegation defended this position by reverting to the old Soviet explanation for the 1979 Sverdlovsk incident, asserting that more than sixty individuals died from consumption of

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[34] Ad Hoc Group, "Other Visits/Measures: Working Paper Submitted by the Friend of the Chair on Compliance Measures," Document BWC/AD HOC GROUP/WP.138, 13 March 1997, 1–2.

[35] Ibid., 2–3. This inspection concept is also sometimes called a "challenge-lite"visit.

[36] In the rolling text, there is a place-holder for this concept, which is similar to one proposed by the Federation of American Scientists. See page 132 of the rolling text, Document BWC/AD HOC GROUP/38 and the discussion of "validation visits" in Federation of the American Scientists, *Beyond VEREX*, 5.

[37] Ad Hoc Group, "Other Visits/Measures: Working Paper Submitted by the Friend of the Chair on Compliance Measures," 2–3.

[38] Government of the United Kingdom, Foreign and Commonwealth Office, "BTWC Practice Compliance Inspections Performed in the United Kingdom in 1993/4: Overall Report," London, 16 March 1995, 14. For other British views on a variety of BWC verification topics, see Government of the United Kingdom, Ad Hoc Group, "Clarification and Consultation Procedures: Working Paper Submitted by the United Kingdom," Document BWC/AD HOC GROUP/WP.159/Rev.1, 16 July 1997; Government of the United Kingdom, Ad Hoc Group, "Implementation by the Investigation Team of Specific On-Site Measures: Working Paper Submitted by the United Kingdom," Document BWC/AD HOC GROUP/WP.162–6, 11 July 1997; Government of the United Kingdom, Ad Hoc Group, "The Role and Objectives of Information Visits: Working Paper Submitted by the United Kingdom," Document BWC/AD HOC GROUP/21, 13 July 1995.

contaminated meat, not an accidental release of anthrax from a Soviet biological weapons facility.[39] On almost every issue in the negotiations, Russia was on the opposite end of the spectrum from Great Britain.

Another aspect of the negotiations frequently broached by the developing countries pertained to economic concerns. The governments of India and China, for instance, stipulated that a BWC inspectorate should help fulfill the goals of the BWC's Article X regarding the facilitation of "the fullest possible exchange of equipment, materials and scientific and technical information" for peaceful purposes. Among the proposed tasks for the inspectorate were the creation of a technical databank; help with furnishing instruments, equipment, and technologies developed by BWC members; and aid to establish national defense research centers and train personnel in bio-defense activities.[40] Similarly, Iran suggested measures to facilitate trade and technical development, such as the establishment of research centers in developing countries to pursue work on biology, biotechnology, and vaccine production projects of mutual interest.[41] Iran also proposed the complete elimination of export control regulations among participating states and the use instead of end-user certifications "that will entail no restrictions or impediments on access to biological materials, equipment or technological information."[42] Such proposals were reminiscent of those advanced by developing countries during the CWC negotiations in an effort to gain negotiating leverage. Some developing nations hoped to extract technical and economic assistance concessions in exchange for their approval of tough verification provisions.[43]

A wide gulf between the negotiating positions of various Ad Hoc Group delegations is evident. To wit, the 246-page rolling text was riddled with brackets. Absent the injection of some new, compelling proposals and/or high-level political momentum, there was little reason to anticipate that these gaps would be bridged anytime soon.

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[39] US government officials, interviews with author, Washington, D.C., 30 December 1997 and 2 January 1998. Epidemiological research by a joint Russian-American team conclusively refuted the contaminated meat theory. See Matthew Meselson et al., "The Sverdlovsk Anthrax Outbreak of 1979," *Science* 226, no. 5188, 18 November 1994, 1202–8.

[40] Ad Hoc Group, "Measures to Strengthen Implementation of Article X of the BTWC: Working Paper by India," Document BWC/AD HOC GROUP/WP.131, 10 March 1997, 1–2; Ad Hoc Group, "Specific Measures to Strengthen the Implementation of Article X of the BTWC: Working Paper Submitted by China," Document BWC/AD HOC GROUP/WP.135, 11 March 1997, 1–2. Other types of assistance proposals can also be found in the rolling text, Document BWC/AD HOC GROUP/38, 64–73.

[41] Ad Hoc Group, "Article X: Economic and Technological Development: Working Paper Submitted by the Islamic Republic of Iran," Document BWC/AD HOC GROUP/WP.149, 20 March 1997, 1.

[42] Ad Hoc Group, "Transfer Guidelines: Working Paper Submitted by the Islamic Republic of Iran," Document BWC/AD HOC GROUP/WP.148, 19 March 1997, 1.

[43] Amy E. Smithson, "Tottering Toward a Treaty," *Bulletin of the Atomic Scientists* 48, no. 6 (July/August 1992): 8–11. For more on the controversy over trade provisions, export controls, and the CWC, see also Amy E. Smithson, *Separating Fact from Fiction: The Australia Group and the Chemical Weapons Convention*, Occasional Paper No. 34 (Washington, D.C.: Henry L. Stimson Center, March 1997).

Policy Making Entanglements in Washington

The Reagan administration vigorously charged the USSR with violating the BWC but also argued that it would be fairly futile to attempt to verify this treaty.[44] Likewise, the Bush administration stated that the BWC was unverifiable according to the American standards of effective and adequate verification.[45] Therefore, the position of the US delegation at that time was that "bad verification was worse than none" at all.[46] Initially, the US delegation was among the most skeptical of those participating in the Ad Hoc Group of Verification Experts meetings in 1992 and 1993.[47] With the onset of the Clinton administration in 1993, the US policy changed to support the negotiation of a legally binding protocol.[48] However, some of the individuals that espoused the more conservative views of the Bush and Reagan administrations remained in the US government, particularly within the Defense Department.

One of the more revealing jokes about the birth of an arms control treaty is that it is far more difficult to hammer out a US position than it is to negotiate the agreement with other delegations.[49]

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[44] The US government raised not only the Sverdlovsk anthrax incident, but also charged the USSR with conducting research on advanced, genetically engineered biological agents. US Arms Control and Disarmament Agency, *Soviet Noncompliance with Arms Control Agreements* (Washington, D.C.: US Arms Control and Disarmament Agency, 1 February 1986): 13–5; US Arms Control and Disarmament Agency, *Soviet Noncompliance with Arms Control Agreements* (Washington, D.C.: US Arms Control and Disarmament Agency, 2 December 1988): 8–10. On the lack of utility of a BWC verification protocol, see Reagan administration official Douglas J. Feith's "Biological Weapons and the Limits of Arms Control," *National Interest* (Winter 1986/87): 80–4. See also Joseph Finder, "Biological Warfare, Genetic Engineering, and the Treaty That Failed," *Washington Quarterly* 9, no. 2 (Spring 1986): 5–14.

[45] Briefly, suitable verification measures would provide the US government very high confidence that monitoring would give sufficient warning of a militarily significant treaty violation to allow the appropriate response to be taken. For a sampling of articles on US standards of arms control verification, see Robert J. Einhorn, "Treaty Compliance," *Foreign Policy* 45 (Winter 1981/82): 29–47; Stephen M. Meyer, "Verification and Risk in Arms Control," *International Security* 8, no. 4 (Spring 1984): 111–26; Fred Charles Ikle, "After Detection—What?" *Foreign Affairs* 39, no. 2 (January 1961): 208–20; Joseph R. Biden, Jr., "The Five Myths of Reagan's Arms Control," *Arms Control Today* 16, no. 7 (October 1986): 3–6; Colin S. Gray, "Moscow is Cheating," *Foreign Policy* 56 (Fall 1984):141–52.

[46] Michael Moodie, "Bolstering Compliance with the Biological Weapons Convention: Prospects for the Special Conference," *Chemical Weapons Convention Bulletin*, no. 25 (September 1994): 2.

[47] At the first VEREX meeting, the US delegation did not make any proposals. The US delegation was instructed "to oppose any ineffective verification provisions and any measures that would limit the U.S. government's ability to pursue its biological defense programs and impair the U.S. biotechnology industry's competitive edge. . . . The delegation was to explain that. . . evidence of an offensive [biological warfare] program is. . . not easily identifiable." US Congress, *Arms Control: U.S. and International Efforts to Ban Biological Weapons*, US General Accounting Office, GAO/NSIAD-93-113 (Washington, D.C.: General Accounting Office, December 1992): 19.

[48] The United States supports "negotiation of a legally binding protocol that provides for reasonable, cost-effective, and mutually reinforcing mandatory measures that enhance compliance with the BWC. These measures would include both off-site and on-site measures as a means of providing openness and transparency." US Arms Control and Disarmament Agency, *Threat Control Through Arms Control: 1994 Annual Report to Congress* (Washington, D.C.: US Arms Control and Disarmament Agency, 13 July 1995): 26.

[49] Of the interagency process, one scholar concluded: "Domestic political impediments to negotiated arms control regularly triumph over its substantive possibilities. . . . The structure of the [arms control] game is simple: each of the organizations involved will seek, within the limits of its influence and effectiveness in the bureaucratic politics of the situation, to preserve its own interests or, at the least, to avoid having them badly violated." Steven E. Miller,

When it came to the desirability and feasibility of a BWC protocol, differences of opinion were evident within the US bureaucracy. In general, neither the Defense Department nor the intelligence community believed a BWC verification protocol would provide sufficient compliance information to warrant the risk of possibly compromising US defense and trade secrets. The Defense Department in particular wanted to safeguard the secrecy of US biological weapons defense capabilities. For its part, the Commerce Department took positions that were very protective of industry's interests. Officials at the State Department were concerned mainly that a BWC protocol not impinge on existing export control policies. Within the Arms Control and Disarmament Agency, the view of most staffers was that a carefully crafted verification protocol would provide a modicum of useful compliance information. Apparently, the only strong believers in the utility of on-site inspections to deliver significant compliance data were the staffers of the National Security Council. White House personnel strenuously defended the CWC's extensive verification provisions as the appropriate model for a BWC protocol.[50]

Just as with the US industry, the experience of the trilateral inspections contributed to the hardening of viewpoints within different parts of the US government. In early March 1994, the Russians went to the Animal Disease Center at Plum Island, a site run by the US Department of Agriculture on Long Island, New York. Used in 1994 for research on animal viruses, the Army originally built the Plum Island laboratories in 1954 for biological weapons research.[51] All totaled, the Russians visited eight facilities in America under the umbrella of the trilateral agreement. In return, US and British teams made four trips to Russia, visiting ten facilities. Over the course of these on-site exchanges, the American participants felt that the purpose of the exercise shifted from building confidence in Russian compliance with the BWC to an effort by Russian participants to allege offensive activities in the United States. Many US officials were therefore content to allow the trilateral process to disintegrate.[52]

"Politics over Promise: Domestic Impediments to Arms Control," *International Security* 8, no. 4 (Spring 1984): 68, 80.

[50] US government officials, interviews with the author, Washington, D.C., 30 December 1997, 2 January 1998, 5 January 1998, and 6 January 1998. The author has followed developments in the US interagency since 1993, but she conducted a series of interviews to reconfirm her understanding of pertinent issues and events.

[51] Biological Weapons Convention: Chronology 1994, *Arms Control Reporter* 13, no. 3 (28 February–2 March 1994): 701.B.124.

[52] One interviewee noted that the trilateral process took a wrong turn at the outset, when the US and British agreed to reciprocal visits in the September 1992 trilateral statement even though the situations in the three countries were sharply different. Russia—*not* the United States and Great Britain—had maintained an offensive biological weapons program into the 1990s. From that point on, the Russians played the diplomatic situation very well, trying to compel the Americans to reveal sensitive national security and commercial information during each visit. US government official, interview with author, Washington, D.C., 6 January 1998. Even as the trilateral process collapsed, the Army established a Biological Arms Control Treaty Office at Ft. Dietrick, Maryland, and prepared over a dozen military sites for a possible trilateral inspections. The harder the Russians pushed, the more difficult it became for US officials to convince them that America no longer had an offensive biological weapons program. For some in the interagency, the trilateral process had degenerated into "a big farce, with American officials playing right into their hands." US government official, interview with author, Washington, D.C., 5 January 1998. Also, US government officials, interviews with the author, Washington, D.C., 30 December 1997, 31 December 1997, and 2 January 1998.

In late October of 1995, government authorities conducted a three-day trial challenge visit at a US vaccine plant that provided some daunting monitoring challenges. Not only was anthrax being made at this site for vaccines, but botulinum toxin was also being produced for medical treatments. In the past, local law enforcement authorities had used some of the facilities at this location. Such circumstances would make it difficult to discern whether this plant was involved in legitimate peaceful activities or an offensive biological weapons program. Representatives of the various US government agencies participated in the trial inspection. The resulting report, which elaborated both the promise and the pitfalls of using managed access for BWC inspections, was never released because the National Security Council disagreed with its findings.[53]

A similar outcome, however, resulted from another trial inspection at a US National Laboratory on 26 March 1996. Only Energy Department personnel participated in the inspection of this laboratory, which had facilities to test items ranging from explosives to air bags. Just as with the vaccine plant, this facility had some capabilities that could be considered hallmarks of an offensive biological weapons program. This inspection apparently showed how even a BWC-compliant facility that wanted to demonstrate its compliance would have difficulty doing so. Managed access techniques were insufficient to prove definitively that this site was cheating or compliant. For one participant, a veteran of arms control verification concepts and technologies, this exercise illustrated that the standard US verification paradigm might have to change dramatically for the BWC. For this treaty, monitoring would not be about securing a "yes" or "no" answer regarding compliance, but about managing an acceptable level of intrusiveness while attempting to understand the "grey" areas that would be characteristic of many government and commercial facilities.[54]

For quite some time, the results of the trilateral and trial inspections were fodder for countless meetings during which the various offices of the US government vigorously debated the advantages and drawbacks of different BWC monitoring proposals.[55] The lessons of the UNSCOM experience in Iraq, particularly the importance of intelligence information to the ability to make significant progress in stripping Iraq of its biological weapons program, were also frequently discussed.[56]

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[53] One interviewee said that the report should not have been released anyway, that it was intended for internal US government consumption and therefore served its purpose. US government officials, interviews with author, Washington, D.C., 30 December 1997, 2 January 1998, and 6 January 1998.

[54] US government scientist, interview with author, Washington, D.C., 17 April 1996. Also, US government official, interview with author, Washington, D.C., 30 December 1997.

[55] Aside from the mock inspections at the vaccine facility and National Laboratory, the United States has held only one other exercise to evaluate BWC monitoring concepts. A defense contractor was hired to conduct a "tabletop" inspection exercise involving a hypothetical disease outbreak. Officials from the Centers for Disease Control and the Defense and Energy Departments participated in this 26 August 1996 event.

[56] Saddam Hussein's son-in-law, Gen. Hussein Kamel Hassan, defected to Jordan in August 1995. Not long afterwards, Iraqi officials led UNSCOM inspectors to Hassan's farm, where numerous documents detailing Iraq's biological and chemical weapons programs were found. Stephen J. Hedges, Peter Cary, and Linda Fasulo, "Baghdad's Dirty Secrets," *U.S. News & World Report* 119, no. 10 (11 September 1995): 41–3. See also United Nations, *Report of the Secretary-General on the Activities of the Special Commission Established by the Secretary-General Pursuant*

UNSCOM's ups and downs were a "beacon of light informing perspectives in the US interagency."[57] Therefore, comparatively small policy differences remained; almost all participants in the interagency found common, if very cautious ground concerning a prospective BWC protocol.[58] Traditionally, the role of the National Security Council staff has been to coordinate the interagency debate and set deadlines for various tasks.[59] Certainly not for the first time in this or other administrations, however, the White House took an active policy position regarding the shape of a BWC protocol. As a result of the impasse, the views of the interagency views were not translated into an official position on the desirable specifics of a BWC protocol.[60] In January 1998, the US delegation was once again sent to Geneva without detailed negotiating instructions.

Man Versus Microbe

One of the most demanding aspects of the CWC negotiations was the crafting of this treaty's delicate balance between the rights of inspectors to access CWC-relevant facilities, equipment, materials, and data and the rights of host officials to safeguard items not related to the treaty. When the CWC was opened for signature in 1993, governments and arms control experts hailed the treaty as having rewritten the arms control verification rulebook. If there is to be any chance for monitoring this treaty's prohibitions in a meaningful way, so too must a new path be carved for a BWC protocol.

Just as with the CWC, challenge inspection procedures will be the heart of the BWC's verification protocol. When use of biological agents, an unusual outbreak of disease, or a covert biological weapons program is suspected, inspectors must be able to arrive at the site quickly and use intrusive methods to investigate the situation. If the Ad Hoc Group agrees on inspection procedures sufficient to give a challenge team real opportunities to gather evidence to ascertain compliance, then another key to the likelihood that BWC challenge inspections will be effective is the ability to launch them without delay. The quick initiation of challenge inspections is unlikely to occur if the BWC protocol institutes unreachable standards of evidence to support requests (e.g., prohibits use of human and other intelligence sources) and/or green-light screening of challenge requests. Therefore, the BWC protocol should follow the CWC's challenge inspection model regarding reasonable standards of evidence and red-light approval of challenge requests. The Ad

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to Paragraph 9(b)(I) of Resolution 687 (1991), Document S/1996/848, 11 October 1996, 14.

[57] US government official, interview with author, Washington, D.C., 5 January 1998.

[58] Ibid., US government officials, interviews with author, Washington, D.C., 30 December 1997, 2 January 1998, and 6 January 1998.

[59] For more on the National Security Council's role in government, see Henry M. Jackson, ed., *The National Security Council: Jackson Subcommittee Papers on Policy-Making at the Presidential Level* (New York: Praeger, 1965); Carnes Lord, *The Presidency and the Management of National Security* (New York: Free Press, 1988); Christopher C. Shoemaker, *Structure, Function and the NSC Staff: An Officers' Guide to the National Security Council, Strategic Studies Institute* (Carlisle Barracks, Penn: US Army War College, 1989).

[60] US government officials, interviews with author, Washington, D.C., 30 December 1997, 2 January 1998, 5 January 1998, and 6 January 1998.

Hoc Group should do its utmost to ensure that challenge inspections —the core of the BWC's verification protocol—are worthwhile exercises. If, however, the Ad Hoc Group cannot reach consensus on rigorous on-site procedures for challenge inspections, then green-light approval should be employed because without intrusive capabilities, the inspectors will have little chance of fulfilling their mission.

Most experts concede that the difficulties of monitoring the BWC are so great that the likely results from a routine inspection regime will be meager. The dilemma is that if the BWC relies solely on challenge inspections to monitor compliance, then challenge inspections, which are political and technical high-wire acts to begin with, will become even more sensitive. Therefore, some type of routine inspection activity geared to provide moderate confidence in compliance is probably needed.

Any routine inspection regime in the BWC protocol must balance the possibility of meaningful results against the possible costs of undue burdens on the pharmaceutical, biotechnology, and other industries. If the BWC's routine inspections jeopardize the proprietary research and thereby the financial viability of pharmaceutical companies, then the international community will have traded one unacceptable situation for another. The US pharmaceutical industry is responsible for developing over ninety percent of the world's new medicines. To a certain extent, therefore, the continued health of the world's populace depends on the ability of these pharmaceutical and biotechnology firms to keep pushing medical frontiers. Thus, the stakes in getting the balance right in the BWC protocol are significant not only for the control and elimination of biological weapons, but for global health.

If the CWC experience is any indicator, some of the most promising solutions to this BWC monitoring dilemma are likely to come from industry. The chemical industry took a very proactive role in helping negotiators draft and test the CWC's verification provisions. Chemical companies volunteered their plants for national trial inspections to test the benefits and disadvantages of verification proposals. The industry routinely worked with the US government, trade associations overseas, and diplomats in Geneva to help focus the CWC's verification regime on the facilities of highest proliferation risk.[61] As a result of this collaboration, the CWC centers around verification procedures that give inspectors a fighting chance to catch cheaters, yet do not overly burden industry. The US chemical industry applauds the CWC because it contains reasonable declaration requirements, feasible routine and challenge inspection procedures, and extensive, strong measures to protect the confidentiality of industry data made available through declarations or inspections.

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[61] The chemical industry's role is explained in Will Carpenter, "The Perspective of the Western Chemical Industry," in *Shadows & Substance: The Chemical Weapons Convention*, Benoit Morel and Kyle Olson, eds. (Boulder: Westview Press, 1993): 115–26. See also, Carpenter's testimony in US Congress, Senate Foreign Relations Committee, *Hearings on the Chemical Weapons Convention*, 103d Cong., 2d sess., S.Hrg. 103–869 (Washington, D.C.: Government Printing Office, 1994): 88–90.

Given their negative and limited experience with arms control monitoring under the trilateral agreement, some in the US pharmaceutical industry are understandably concerned about what a BWC protocol might mean for their industry. With the amount of testing that the pharmaceutical industry conducts to bring a product to market, however, one would expect industry officials to realize that more trial inspections are necessary for the appropriate balances to be designed for the BWC protocol. The political undercurrents driving the trilateral inspections in Indiana and Connecticut made these two visits particularly unpleasant. Such will not be the norm for BWC inspections. US industry officials should put the trilateral experience behind them and move ahead with helping to shape US policy and the BWC protocol. The US pharmaceutical industry, chocked with the world's foremost scientific and technical experts, knows best how to protect its own secrets and can also be a font of ideas for how to catch BWC violators.

Finally, the pharmaceutical industry should not wait to be asked by the US government or the Ad Hoc Group to take a more proactive role. The need for a meaningful BWC monitoring protocol is just as self-evident as the need for medicines to fight cancer, AIDS, and other diseases. The presidents, CEOs, plant managers, scientists, and technicians of the US pharmaceutical industry pride themselves on investing in the research necessary to discover medicines to treat and cure sickness. Along the same line, helping to design a BWC monitoring protocol may be one of the most important services that the pharmaceutical industry ever provides to mankind. Therefore, the pharmaceutical industry should seek to emulate the constructive example set by the chemical industry in the CWC negotiations.

Not unlike the US pharmaceutical industry, which justifiably lays claim to being the world's leader in the discovery of medicines, US officials are fond of describing America as a global leader in nonproliferation and arms control matters. Thus far, however, the US government has lagged far behind others in making proposals for a BWC protocol. Anyone familiar with Washington knows that the staples of the US policy making process are goals, interagency meetings, and research. Clinton has articulated the goal—completion of a BWC protocol by the end of 1998—and the interagency structure is in place. What seems to be missing is research to provide the foundation for a US negotiating position. Two national trial inspections over just a few days do not constitute a research program.

More research and trial inspections will be essential to resolve the differences of opinion that still exist on several important issues. For example, some argue that sampling at commercial and government sites can be conducted in a way that detects biological agents but does not compromise proprietary information. Others counter that not only will sensitive data be lost, but savvy cheaters can avoid detection by engineering around sampling probes or otherwise spoofing analysis.[62] More research conducted under field conditions is needed to determine the real utility of sampling and

[62] For more detail on the technologies and issues associated with sampling, see Jonathan B. Tucker, ed., *The Utility of Sampling and Analysis for Compliance Monitoring of the Biological Weapons Convention* (Livermore, CA: Lawrence Livermore National Laboratory, February 1997).

other inspection techniques. Whether Washington ends up supporting or opposing various inspection concepts and techniques, the US position needs to be based on sound scientific evidence.

US policy makers also need to ponder the scope of a BWC monitoring regime, how wide to cast the declaration and routine inspection net, so to speak. To date, discussion about monitoring in the industrial sector has focused principally on the pharmaceutical industry, which undoubtedly works with the most advanced equipment available. However, several other industries (e.g., breweries, cheese manufacturers) widely employ pertinent dual-use equipment. A would-be proliferator might also seriously consider concealing a biological weapons program at such sites. For a proliferator, almost any fermenter will suffice. Also, while the pharmaceutical industry is located disproportionately in the United States, breweries and bakeries can be found around the globe in large numbers. In addition, the US government is not giving sufficient attention to how to monitor colleges, universities, and other research centers that utilize dual-use equipment. Designing monitoring procedures for these far flung industrial and academic sites will be very difficult, but a BWC verification protocol that does not in some fashion take these other dual-capable facilities into account will be significantly deficient.

As US decision makers formulate specific policies on the BWC verification protocol, they should recognize, as one insider put it, that "the road to a protocol goes through Article X."[63] In the CWC negotiations, the United States and other industrialized nations strongly resisted providing economic assistance to developing countries. The reasoning was that a *quid pro quo* was not warranted when all participating states were required to eliminate their chemical weapons capabilities. Moreover, the US chemical industry would not have been likely to tolerate an economic assistance program that in any way enhanced the competitiveness of chemical companies overseas. Similarly, the BWC requires all states to foresake biological warfare programs, and the US pharmaceutical industry can be expected to oppose any economic assistance targeted at industries abroad.

Economic assistance, however, can be provided in a manner that satisfies the interests of developed and developing countries. One attractive proposal is to provide aid aimed at strengthening national and international capabilities to detect emerging diseases. Assistance could be targeted at individual countries and/or at international entities such as the World Health Organization and the Food and Agriculture Organization. Economic assistance for disease surveillance accomplishes two goals at once by addressing the Article X issue and providing a much-needed boost for a global early warning system of disease outbreaks.[64] A relatively small investment would be required. Absent

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[63] US government official, interview with author, Washington, D.C., 19 May 1996.

[64] Mark L. Wheelis provides an in-depth description of this proposal in "Strengthening Biological Weapons Control Through Global Epidemiological Surveillance," *Politics and the Life Sciences* 11, no. 2 (August 1992): 179–89. For a related proposal requiring states to supply data on domestic pathologies or epidemics, see Ad Hoc Group, "Proposal Concerning the Establishment of an International Epidemiological Monitoring Network: Working Paper Submitted by France," Document BWC/AD HOC GROUP/WP.134, 10 March 1997.

such common-sense assistance, developing countries may force long delays in concluding a BWC protocol, and states will be less capable of identifying disease outbreaks before they reach dangerous, epidemic proportions.

If Washington does not proceed expeditiously with research, trial inspections, and policy formulation, the United States may lose its opportunity to influence the content of a BWC protocol. As the 1997 landmines ban has shown, the international community is willing to forge ahead and conclude arms control accords without the United States.[65] Should the landmines outcome be repeated with the BWC protocol, it would be a serious setback for US nonproliferation policy , not to mention America's leadership role.

Given the widespread use of clean-in-place equipment in the pharmaceutical industry, BWC inspectors might find that the documentation at these plants provides some of the most reliable evidence of a facility's activities. Verification experts prefer not to rely on documentation as a primary source of evidence because of the comparative ease with which records can be altered or dummy documents substituted to disguise a clandestine weapons program. By comparison, measurement of various items and sampling usually provide much more reliable evidence. However, documentation played a crucial role in UNSCOM's ability to uncover Iraq's weapons of mass destruction programs.[66] Also, in pharmaceutical production facilities, it may prove tougher for plant managers to "cook the books" than to clean the facilities.

Two significant factors work in favor of placing more credence in documentation review at biotechnology facilities. First, regulatory authorities require pharmaceutical companies to keep excruciatingly detailed log-books and charts that record each step of the manufacturing process (e.g., when ingredients are added, when fermentation parameters are changed). The employee responsible notes the requisite information, and normally a co-worker or supervisor also signs off on each change. Later, more senior supervisors review these records and sign off on them. US plants often keep years worth of records on site, available for review by Food and Drug Administration inspectors.

In addition to hand-written records, most modern pharmaceutical plants have records generated by computerized equipment. For example, computers record several process parameters in the columns that purify the product. Companies also have fermenters that feature supervisory control and data acquisition, or SCADA, computers. When product is being manufactured, these

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[65] This agreement's formal title is, The 1997 Convention on the Prohibition of the Use, Stockpiling, Production and Transfer of Anti-Personnel Mines and on Their Destruction. On the treaty signing, see Anthony DePalma, "As U.S. Looks On, 122 Nations Agree to Land Mine Ban," *New York Times*, 4 December 1997, A1. For more on this treaty, see "Convention on the Prohibition of the Use, Stockpiling, Production and Transfer of Anti-Personnel Mines and on Their Destruction: Analysis and Text," *Arms Control Today* 27, no. 6 (September 1997): 11–8.

[66] For an insider's account, see David A. Kay, "Denial and Deception Practices of WMD Proliferators: Iraq and Beyond," *Washington Quarterly* 18, no. 1 (Winter 1995): 85–105.

SCADA systems operate 24 hours a day, conducting measurements once per second of specified parameters of the fermentation process (e.g., temperature, pressure, and pH, oxygen, and carbon dioxide levels). For the most part, these records are not product-specific, but they can provide very supportive documentation that a legitimate product is being manufactured, thereby narrowing the possibility that a biological agent was being illicitly made at a particular plant. The dated, multi-colored charts that these computers produce allow a facility to provide extensive historical evidence in addition to the hand-written records.

Critics will caution that even computerized records can be duplicated or spoofed, which is true. However, in the case of these SCADA system records, it would be difficult to write a specialized computer program that could by-pass the computer's sensors and create convincing fake records. During routine manufacturing of a product, a number of fluctuations in process parameters occur. A cheater would find that such anomalies, due for example to air bubbles in a process line, are not easy to mimic. Knowledgeable inspectors would be tipped off that documentation was not authentic if they did not find certain irregularities in a plant's computerized records. Thus, while some verification experts may be tempted to overlook the utility of a documentation review, there are reasons to take a fresh look at documentation review in the BWC context. Documentation may provide one of the more promising avenues to help confirm that a pharmaceutical or biotechnology firm is indeed engaged in legitimate activities.

Ad Hoc Group negotiators might also want to consider the utility of modifying for the BWC protocol the concept of portal-perimeter inspection, used to monitor missile production facilities in nuclear arms control accords. An unprecedented concept at the time it was conceived, the United States and the USSR agreed to verify that certain types of missiles were *not* coming out of sensitive production facilities. This approach puts a contingent of inspectors at the perimeter of a facility 24 hours a day, 365 days a year, armed with various types of equipment to ascertain the dimensions of missile stages emerging from the facility.[67] In the BWC, what might be called a "perimeter validation" inspection would focus on ascertaining that a company is indeed making the product it declares to be manufacturing. A strict perimeter would not be observed, but inspectors would not be automatically granted access to the most sensitive manufacturing areas in the interior of a plant unless anomalies were detected or host officials volunteered such access. Rather, inspectors would zero in on an industrial facility's documentation, examining a percentage of records selected at random. Also, the inspectors would monitor the end-of-the-line product, sampling only finished product.

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[67] The portals for the 1987 Intermediate-Range Nuclear Forces Treaty are located at Magna, Utah, and Votkinsk, in the Urals Mountains, east of Moscow, Russia. For more on the origins and implementation of this inspection technique, see Joseph P. Harahan, *On-Site Inspections Under the INF Treaty: A History of the On-Site Inspection Agency and INF Treaty Implementation, 1988-1991* (Washington, D.C.: Government Printing Office, 1993): 67–98. Portals can also be used to monitor mobile missile production under the START I and II strategic nuclear accords.

To add some rigor to the perimeter validation concept, the inspectors would arrive at a declared industry facility with no notice. In order not to make such a tactic an undue burden on industry, the size of a perimeter validation team would be very small, perhaps just a trio of inspectors.[68] A no-notice arrival decreases the ability of a covert facility to hide telltale evidence and increases the chances that inspectors might detect abnormalities. After presenting their credentials to plant managers, the inspection team would be given immediate access to a facility's records, which are usually located in a plant's administrative offices. The documentation to be reviewed would be selected and secured, and host officials would then proceed with briefing the inspection team with an overview of the facility's product, layout, and manufacturing process and schedule. In addition to the administrative area of the plant, the only other parts of the facility where the inspectors would be guaranteed access would be the product bottling/packaging and laboratory areas. If a product sample is taken, plant officials and inspectors would negotiate whether the sample should be analyzed at the facility's laboratories or taken off-site. Inspectors would observe all on-site analysis done by facility personnel in the plant's laboratory.[69] The object of a perimeter validation inspection would be to confirm, however briefly, that an industrial site appears to be manufacturing legitimate product(s). Therefore, the duration of this type of an inspection would be more a matter of hours than days.

Given the difficulty of verifying the BWC, the task of drafting and implementing a verification protocol will be one of the most daunting ever attempted by the international community. In Geneva, the Ad Hoc Group will need to consider new monitoring concepts and techniques. Back in capitals, policy makers will have to lower their demands of what a BWC protocol must accomplish. Otherwise, less will be achieved and more will be expected than a BWC monitoring regime can deliver.

In sum, the BWC protocol negotiations are part of a larger battle of man versus microbe, one that is usually fought by doctors trying to treat ailing patients. Anyone who has seen or read about the havoc that viruses such as Lassa fever and Ebola can wreak upon the human body will confirm that microbes can be mightier than man. The world's human and animal populations, as well as vegetation, are all vulnerable to germ warfare. Inequalities may exist among nations, but all nations should equally fear the prospect of biological warfare. For this reason, senior decision makers in Washington and elsewhere must move promptly to strengthen the BWC with a meaningful and effective verification protocol. Man must unite to combat the microbes.

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[68] Moreover, US companies are accustomed to no-notice inspections by US regulatory authorities.

[69] Manufacturing facilities routinely analyze numerous samples on a daily basis to monitor the status of both the product and the plant environment, so the addition of inspection sample(s) should not be much of an imposition. Laboratory equipment and techniques are pretty standardized, but inspectors would of course have the right to question any unusual equipment or analytical techniques that a facility might use. If necessary, the inspectors could insist that the product analysis be done off-site. While on site, inspectors would observe the safety rules of the facility.

Appendix 1
Parties and Signatories of the Biological Weapons Convention

MEMBER STATES: 140

Afghanistan	Cyprus	Paraguay
Albania	Czech Republic	Jordan
Argentina	Denmark	Kenya
Armenia	Dominica	Korea, Democratic People's Republic of
Australia	Dominican Republic	Korea, Republic of
Austria	Ecuador	Kuwait
Bahamas	El Salvador	Laos
Bahrain	Equatorial Guinea	Latvia
Bangladesh	Estonia	Lebanon
Barbados	Ethiopia	Lesotho
Belarus	Fiji	Libya
Belgium	Finland	Liechtenstein
Belize	France	Luxembourg
Benin	Gambia	Macedonia, formerYugoslav Republic of
Bhutan	Georgia	Malaysia
Bolivia	Germany	Maldives
Bosnia Herzegovina	Ghana	Malta
Botswana	Greece	Mauritius
Brazil	Grenada	Mexico
Brunei Darussalam	Guatemala	Mongolia
Bulgaria	Guinea-Bissau	Netherlands
Burkina Faso	Honduras	New Zealand
Cambodia (Kampuchea)	Hungary	Nicaragua
Canada	Iceland	Niger
Cape Verde	India	Nigeria
Chile	Indonesia	Norway
China, People's Republic of	Iran	Oman
Colombia	Iraq	Pakistan
Congo	Ireland	Panama
Costa Rica	Italy	Papua New Guinea
Croatia	Jamaica	
Cuba	Japan	

Peru	Sierra Leone	Turkey
Philippines	Singapore	Turkmenistan
Poland	Slovak Republic	Uganda
Portugal	Slovenia	Ukraine
Qatar	Solomon Islands	United Kingdom
Romania	South Africa	United States
Russian Federation	Spain	Uruguay
Rwanda	Sri Lanka	Uzbekistan
St. Kitts and Nevis	Suriname	Vanuatu
St. Lucia	Swaziland	Venezuela
San Marino	Sweden	Vietnam
Sao Tome and Principe	Switzerland	Yemen
Saudi Arabia	Thailand	Zaire
Senegal	Togo	Zimbabwe
Serbia-Montenegro (formerly Yugoslavia)	Tonga	
Seychelles	Tunisia	

SIGNATORIES: 18

Burundi	Haiti	Nepal
Central African Republic	Liberia	Somalia
	Madagascar	Syria
Cote d'Ivoire	Malawi	Tanzania
Egypt	Mali	United Arab Emirates
Gabon	Morocco	
Guyana	Myanmar (Burma)	

Appendix 2
PhRMA Member Companies

PhRMA Member Companies:

Alza Corporation
American Home Products
- Genetics Institute
- Wyeth-Ayerst International Inc.
- Wyeth-Ayerst Laboratories
- Wyeth-Ayerst Research

Amgen Inc.
B.F. Ascher & Company, Inc.
Astra USA, Inc.
Athena Neurosciences, Inc.
Bayer Corporation
- Bayer Corporation Pharmaceutical Division

Biogen, Inc.
Boehringer Ingelheim Corporation
- Boehringer Ingelheim Pharmaceuticals, Inc.
- Roxane Laboratories, Inc.

Bristol-Myers Squibb Company
- Bristol-Myers Squibb Pharmaceutical Group

Fujisawa USA, Inc.
Genentech, Inc.
Genzyme Corporation
Gilead Sciences, Inc.
Glaxo Wellcome Inc.
Hoechst Marion Roussell, Inc.
Hoffman-La Rouche Inc.
Johnson & Johnson
- Cordis Corporation
- Ethicon Endo-Surgery, Inc.
- Ethicon, Inc.
- Janssen Pharmaceutica, Inc.
- Johnson & Johnson Clinical Diagnostics, Inc.
- Johnson & Johnson Health Care Systems Inc.
- Johnson & Johnson Medical, Inc.

Johnson & Johnson Professional, Inc.
R. W. Johnson Pharmaceutical Research Institute
Ortho Biotech Inc.
Ortho Diagnostic Systems Inc.
Ortho-McNeil Pharmaceutical
Therakos, Inc.
Vistakon, Inc.
Knoll Pharmaceutical Company
Eli Lilly and Company
Hybritech Incorporation
Merck & Co., Inc.
The DuPont Merck Pharmaceutical Company
Merck Human Health Division—U.S. Human Health
Novartis Pharmaceuticals Corporation
Nycomed Inc.
Organon Inc.
Pasteur Merieux Connaught
Pfizer Inc.
Pharmacia & Upjohn, Inc.
The Procter & Gamble Company
Purdue Pharma L.P.
Rhone-Poulenc Rorer Inc.
Sanofi Pharmaceuticals, Inc.
Schering-Plouch Corporation
Schwarz Pharma
Searle
Serono Laboratories, Inc.
Smithkline Beecham, p.l.c.
Smithkline Beecham Pharmaceuticals
Solvay Pharmaceuticals, Inc.
3M Pharmaceuticals
Warner-Lambert Company
Parke-Davis
Zeneca Pharmaceuticals Group

PhRMA International Affiliates:
Eisai, Inc.
Daiichi Pharmaceutical Corporation
Otsuka American Pharmaceutical, Inc.
Sankyo U.S.A. Corporation
Sigma-Tau Pharmaceuticals, Inc.
Yamanouchi U.S.A. Inc.

PhRMA Research Affiliates:
Affymax Research Institute
Agouron Pharmaceuticals
Alkermes, Inc.
Aronex Pharmaceuticals, Inc.
Arris Pharmaceutical
Astra Arcus USA
Aviron
Beacon Laboratories
Block Drug Company, Inc.
Cambridge Neuroscience, Inc.
Celgene Corporation
Cephalon, Inc.
Covance Inc.
Cygnus, Inc.
Cytotherapeutics, Inc.
Icos Corporation
Isis Pharmaceuticals, Inc.
Ligand Pharmaceuticals Inc.
The Liposome Company, Inc.
North American Vaccine, Inc.
Penwest Pharmaceuticals Group
Pharmacopeia, Inc.
Scios Inc.
Sepracor, Inc.
Theratech, Inc.
Vertex Pharmaceuticals Incorporated

PhRMA Associates:

AAI
Aerojet Custom Chemicals
American Family Physician
American Medical Association Business and Management Services
Andersen Consulting
Arista Marketing Associates Inc.
Robert A. Becker, Inc.
Clark-O'Neill, Inc.
Corbett Healthconnect
CSC Healthcare
FCB Healthcare
IBM Consulting Group
IMS America Ltd.
International Medical News Group
Jobson Publishing Corporation
A.T. Kearney, Inc.
Kelly/Waldron and Company
Klemtner Advertising, Inc.
KPMG Peat Marwick LLP
Lally, McFarland & Pantello/Euro RSCG
Lowe McAdams Healthcare
Lyons Lavey Nickel Swift, Inc
McGraw Hill Healthcare Information Group
Medical Economics
Medicus Group International Inc.
Medimedia USA, Inc.
Medi-Promotions, Inc.
Nelson Communications, Inc.
Scott-Levin
Source Informatics

Appendix 3

PhRMA Position on a Compliance Protocol to the Biological Weapons Convention

The Biological Weapons Convention (BWC) prohibits the development, production, and stockpiling of biological weapons. Ratified by the US in 1972 and in effect since 1975, the BWC does not include any enforcement mechanism. Concern about lack of enforcement has intensified since the Gulf War in 1990-1991.

Signatory Governments decided in November 1996 to begin negotiating a Compliance Protocol to the BWC in early 1997. Possible provisions of such a Protocol have been discussed informally and the U.K. is expected to offer a draft early next year. So far, the US Government (with which PhRMA has been discussing a Compliance Protocol for more than five years) has taken no position on any Protocol provisions.

On May 16, 1996, the PhRMA Executive Committee approved a statement supporting the goals and objectives of the BWC. While a Compliance Protocol could reduce the threat from biological weapons, it would have to be carefully drafted to fully preserve the ability of pharmaceutical companies to research and develop new life-saving medicines. PhRMA member companies could be significantly affected by a Compliance Protocol, even though no company is involved in the development, production, or stockpiling of biological weapons. The areas of greatest concern to PhRMA companies are: (1) the loss of legitimate confidential business information, (2) the loss of good name by being linked to the manufacture of biological weapons, and (3) the adoption of onerous implementing regulations. This document sets forth PhRMA's position on key issues regarding a Compliance Protocol to the BWC.

Confidence-building Measures: Signatory Governments have voluntarily adopted seven measures intended to build confidence in compliance with the BWC by increasing transparency. The only measure applicable to commercial facilities requires Governments to declare (i.e., identify) producers of human vaccines licensed in their countries. PhRMA believes that the seven confidence-building measures have value and should become mandatory to strengthen the BWC, but no further requirements to declare any information or activities should be adopted that would affect commercial enterprises.

On-site Inspections Should be Limited to Challenge Inspections: PhRMA is skeptical that any site inspection would be able to detect a violation of the BWC. Experience indicates that it is easy to quickly obliterate traces of any development, manufacture, or storage of a biological-warfare agent. However, it is likely that some Government will propose inspections. If this occurs, PhRMA's position is that:

- Inspections must not interfere with legitimate commercial operations.
- Routine inspections of commercial operations must not be permitted.
- Only challenge inspections—short-notice inspections based on specific allegations of violation of the BWC, alleged use of biological weapons, or unusual outbreaks of disease – should be authorized, and only if based on strong evidence that a violation has occurred.

Authorization to Inspect: Challenge inspections under the BWC should require the authorization of an Executive Council of Government representatives, similar to the Council established under the Chemical Weapons Convention (CWC). While a CWC inspection proceeds unless blocked by a vote of three quarters of the Council members, a BWC challenge inspection must be approved by a three-quarters vote. This approach would permit inspections where serious violations are alleged, but curtail frivolous inspections. It also would help to ensure that such essential industries as the health-care and food industries would not be compromised by an improper or unsubstantiated claim of violation.

Managed Access: "Managed access"—under which site managers control access to different parts of a facility—must be used during any on-site inspection. The aim is to help inspectors gain access to desired information while protecting the right of a facility to be inspected through a negotiated agreement between the two parties. A managed-access agreement would minimize the potential for loss of confidential business information. Procedures also must be devised to resolve disputes in cases where the inspection team and the facility to be inspected cannot agree on inspection terms.

Proprietary Determination: A private commercial enterprise must have the right to make the final determination as to what constitutes confidential business information. This must include the right to deny specific requests for samples or photographs. In addition, either the Compliance Protocol or US implementing legislation must allow an inspected facility to use "reasonable alternate means" to satisfy an inspection team's request. In the US, PhRMA believes that the inspected party could share with the US Government confidential business information it does not want to disclose to international inspectors.

Right to Respond: The inspected facility must receive a copy of the on-site inspection report and have the right to respond before its release. In the absence of clear and convincing evidence of biological weapons development, production, stockpiling, or use, the report must state that the allegations could not be substantiated.

Conclusion: PhRMA wants to be an active participant in working to reduce the threat of biological warfare, but will oppose any Compliance Protocol that does not fully protect the confidential business information of its member companies, which enables them to lead the world in discovering and developing new life-saving medicines. PhRMA will offer expert assistance to the US Government to help ensure that any Compliance Protocol to the Biological Weapons Convention is scientifically and technically sound.

Approved, PhRMA Board Executive Committee,
January 9, 1997