Chapter 2
Evaluating US Proposals to Monitor Compliance with the BWC

In comparison to treaties that limit or ban other types of weapons, the Biological and Toxin Weapons Convention (BWC) is singular in the compliance monitoring challenges that it poses. Inspectors can count tanks and missiles or use detectors to identify nuclear materials and chemical warfare agents definitively.[1] However, discerning the difference between offensive biological weapons activities and legitimate commercial and defense endeavors will be extremely difficult not only because the biowarfare agents themselves have their origins in nature, but because of the dual-purpose aspects of equipment, materials, skills, and activities in facilities scattered worldwide.

In this chapter, experts from the US pharmaceutical and biotechnology industries first evaluate the US government's July 2001 decision to reject the draft BWC monitoring protocol. Then, they critique two of several proposals that the US government introduced in November 2001 to substitute for a legally binding, multilateral monitoring protocol. These two alternatives might be categorized as "traditional" in that they would involve the use of inspectors to help determine whether a BWC violation had occurred. Briefly, one of the proposals would have nations agree in advance to allow the United Nations (UN) Secretary General to dispatch an international team of inspectors to investigate suspicious disease outbreaks and/or alleged biowarfare incidents. A second US proposal would have nations try to resolve compliance ambiguities bilaterally with consultations, data exchanges, and, perhaps, a voluntary visit to a facility of concern. Their viewpoints on these matters are drawn in no small part from prior discussions, captured in the May 2001 Stimson Center report entitled, *House of Cards: The Pivotal Importance of a Technically Sound BWC Monitoring Protocol*.

A DEAL BEST REFUSED

According to experts from the US pharmaceutical and biotechnology industries, the purpose of inspections to monitor the BWC would be two-fold. One principal objective would be to discover if a facility is engaged in illicit weapons activities. In the event that the inspectors did not uncover evidence of violations, unexplained inconsistencies with the facility's stated purpose, or other cause to suspect that something was amiss,[2] they would file a report briefly describing the evidentiary support

[1] To illustrate, the Conventional Forces in Europe Treaty provided for inspectors to keep tabs on the quantities of major conventional armaments (e.g., personnel carriers) in the European theater, and the Intermediate-Range Nuclear Forces Treaty dispatched inspectors to military bases as well as to facilities in Votkinsk, Russia, and Magna, Utah, that produced key stages for Russian and US nuclear missiles. Inspectors for the Nuclear Nonproliferation Treaty and the Chemical Weapons Convention are allowed to employ sensors and sampling that can detect weapons materials. The nuts and bolts of these treaties can be found in US Department of State, *Arms Control and Disarmament Agreements: Texts and Histories of the Negotiations* (Washington, DC: US Arms Control and Disarmament Agency, 1996).

[2] Examples of behavior that might generate suspicions among inspectors would be refusal of host officials to share requested data and grant access that would help inspectors understand factors at the facility that seemed inconsistent with its stated purpose. Inspectors would note both the inconsistencies and host official's uncooperative behavior in their inspection report.

that the facility was conducting legitimate activities. In short, the second major purpose of inspections was to affirm that compliant facilities were just that, clean.[3] Flowing from these two basic purposes, the industry experts defined effectiveness as the ability of monitoring techniques to help determine whether a facility was either compliant or intentionally violating the BWC.

When they reviewed the investigatory and non-challenge procedures in the draft BWC monitoring protocol,[4] the industry group concluded that what the Ad Hoc Group had crafted would not allow the inspectors to determine what was happening at facilities. Instead of clarifying compliance matters, the inspectors would end up adding to uncertainties by leaving a question mark hanging over legitimate facilities and covert weapons sites alike. The industry experts were so unimpressed with the draft BWC protocol that they gave it a grade of "D."[5]

Accordingly, the industry experts agreed with the Bush administration's decision to reject the draft BWC protocol. US officials listed three main reasons for their decision. First, they stated that the draft protocol would not resolve compliance concerns. Second, they said that the inspections would compromise national security and proprietary business data. Third, they noted that the inspections would pose a burden on sites that were monitored.[6]

The industry specialists took issue with the suggestion that inspections would pose an unacceptable burden and inevitably result in the loss of sensitive business data. Moreover, the industry

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[3] One of the industry experts explained that inspectors would have their hands full figuring out what some companies were doing. For example, some companies are exploring whether highly toxic agents can

> selectively kill cancers. That alone may not concern the inspectors, but this research involves developing high affinity antibodies that can target tumors specifically and don't react with other tissues, then conjugating these antibodies with highly toxic agents that will work at low concentrations to selectively destroy cancers. This work also involves animal facilities for monitoring affects of very low, sub-lethal doses. Given these dual-purpose capacities, this great research might not look straightforward in the eyes of inspectors. Legitimate facilities, though will have reams of documentation, knowledgeable personnel, business relationships, and regulatory agencies that will help inspectors understand that their facility is on the up-and-up.

Dr. Robert Hamilton, 9 August 2002. Dr. Hamilton is a senior scientist and group leader at a large US biotechnology firm, holds a PhD in microbiology and cell biology, and has over twenty-five years of experience in research and industry.

[4] Note that the industry experts did not review the rolling text of the BWC monitoring provisions until after they had developed their own monitoring strategies and tactics. They assessed the following iteration of the rolling text: United Nations, Draft Composite Text: Protocol to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction, BWC/Ad Hoc Group/CRP.8, 30 March 2001. The monitoring provisions of this version of the rolling text were essentially the same as the composite text that the US rejected in July 2001.

[5] "D," rather than "F" was the worst grade that the group could have conferred. As Dr. George Pierce, professor of applied and environmental microbiology at Georgia State University and twenty-plus year veteran of US industry, explained during a 23 August 2000 meeting of experts, "Sometimes an 'F' shows a little innovation."

[6] "The draft Protocol will not improve our ability to verify BWC compliance. It will not enhance our confidence in compliance and will do little to deter those countries seeking to develop biological weapons. In our assessment, the draft Protocol would put national security and confidential business information at risk." Ambassador Donald A. Mahley, "Statement by the United States to the Ad Hoc Group of Biological Weapons Convention State Parties," Geneva, 25 July 2001. Available online at http://usinfo.state.gov/topical/pol/arms/stories/01072501.

experts asserted that it would be worthwhile for commercial facilities to undergo inspection if monitoring could differentiate between cheating and legitimate facilities. Better to have strong inspections that would deter the use of industrial sites to camouflage weapons programs and be able to catch violators than to put a flimsy monitoring regime in place, they reasoned. They came to this conclusion after designing their own approach to monitoring, which is delineated in the coming paragraphs. Also, as an industry expert told Ad Hoc Group negotiators, the loss of trade secrets, a viewpoint long expressed by the Pharmaceutical Research and Manufacturers of America, was a "red herring" argument.[7] With each of the inspection procedures that they recommended, industry experts discussed the steps that they would take to avoid revealing valuable proprietary data to inspectors or giving them opportunities to steal it.

AN INDUSTRY APPROACH TO BWC MONITORING

According to the industry experts, no one monitoring tool in and of itself would necessarily get inspectors to the truth about whether a facility was researching or making pharmaceutical products or weapons. To get at this truth, the inspectors would need to concentrate on inconsistencies between the facility's stated purpose and what they found on site. No single incongruity is likely to be sufficient to label a facility "dirty," but an accumulation of them should raise suspicion. They recommended that the inspectors get to the bottom of things by first gathering information about the facility and then, once on site, using visual observation, review of documents, interviews, and, as a last resort, sampling and analysis. The industry experts argued that these methods, described below in turn, would lend clarity and confirm compliance or noncompliance.

Pre-Inspection Activities

Before going on site, the inspectors should obtain certain information from both the facility and from open sources. Data requested from the site itself should include what product(s) a plant is making and in what quantity, as well as a staff listing, including job titles. Among the open source data that could prove useful are annual reports, staff publications in journals, various news items (e.g., unusual disease outbreaks nearby), and patent estate and intellectual property portfolios. Knowing the stated purpose and size of a facility first allows the inspectorate to deploy a team of the appropriate size and skill sets. Such

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[7] Dr. Steve Projan, Director of Antibacterial Research at Wyeth-Ayerst Research, explained that job hopping of scientists from one company to another would be a more likely source of the loss of confidential business data. Presentation accompanying the report release, 6 May 2001, Geneva. According to a position paper on a BWC protocol,

> The provision of information about some of our facilities and the possibility of opening these facilities to inspections under some circumstances will need to be elements to the strengthening of the treaty. However, these elements also entail risks to commercial facilities including the potential loss of proprietary information, risks to commercial reputations, and added regulatory expenses that ultimately affect the cost and availability of medicines and other widely-used products.

Pharmaceutical Research and Manufacturers of America, "Summary of PhRMA's Position on a Compliance Protocol to the Biological Weapons Convention," position paper, July 1998. Available at http://srpub.phrma.org/phrma/Jul.98.PhRMA.bwc.html.

data also create a set of expectations among the inspectors concerning containment, waste treatment, and other operational set-ups, which prepares them to discern departures from a normal operation once they are on site.

In addition, inspectors should consult satellite photographs of a facility to get their bearings on the layout and identify areas of interest. Comparison of photos taken just prior to and right after the announcement of an inspection might also reveal signs of unusual activity.

Site Tour

Once on the premises, simply observing what is going on will be crucial. For example, savvy inspectors will notice if a plant that is supposed to be making particular products is not configured and equipped accordingly. Inspectors should make their way around the facility with the floor layout, the architectural diagram, the as-built engineering diagram, and the piping and instrumentational diagram in hand. Such diagrams would allow the inspectors to tell quickly whether the plant layout made sense for its stated purpose, as well as if equipment was missing and pipes were connected in the right sequence, welded appropriately, and headed where they should. Inspectors could locate and account for key pieces of equipment (e.g., autoclaves, spray and freeze driers, aerosolizers), later comparing what they had seen with equipment lists as a double check against hidden items. Finally, these blueprints would let the inspectors know whether their hosts were steering them away from certain areas during the tour or taking them to the places they were supposed to see.

Matters deserving special attention from the inspectors include the isolation of reactors, air-handling systems, water cooling systems, and the like when the product(s) being made did not call for such measures. Post-production and purification capabilities appropriate for the declared product(s) should be present, consistent with a commercial enterprise supposedly concerned about product integrity and quality. Inspectors would want to check whether the containment was markedly out of step for the product(s)—unusually high containment for an animal vaccine plant or oddly low containment for a pharmaceutical for human consumption.

Industry experts counseled inspectors to watch for several things in storage areas, such as unlabelled supplies, unusual supplies, or large inventories of certain supplies (e.g., antibiotics). Stocks of high efficiency particulate arresting (HEPA) filters, gowns, and disinfectant should be in line with the facility's declared activities and operational status. With regard to media, the inspectors should be attuned not just to surplus quantities, but to the presence of media that was out of place, such as specialty media (e.g., oxide beef broth) not called for by the stated product(s).

Inspections of freezers should be done only if circumstances warrant and then with the understanding that sometimes seemingly unusual microorganisms get left behind or forgotten in the depths of freezers. Still, discovering a super virulent strain at a facility claiming to produce vaccine

should raise eyebrows. The level of containment present may provide clues to a facility's intent for questionable strains. Also, plant managers should be able to describe why they had such strains and provide supporting documentation (e.g. grant information).

Inspectors should check to see if design, construction, and operation of the waste handling system fit with what was needed to inactivate and treat the organism(s) and other facility wastes. Inspectors should be wary of a plant that declared it was making nontoxic waste with no biologic activity but still had procedures, equipment, and chemicals in place to treat hazardous wastes. Likewise, it would be odd if liquid waste from all phases of the production process were sent into treatment, particularly from purification and formulation areas.

If present, another area that should receive close scrutiny is the animal facility. The higher the species of animal and the more animals present, the harder the inspectors should look, especially if the animals are being kept isolated in individual, negative air flow chambers. Facility operators' concerns about possible contamination might make access to an animal facility unwelcome. However, inspectors might be able to view certain parts of it remotely, or one or two inspectors might be allowed in some rooms. Documentation (e.g., animal pathology records) might answer some questions, as might information from certification organizations, such as the American Association for the Advancement of Laboratory Animal Care or an equivalent. Should such activities prove inconclusive, a complete tour of this area might be scheduled for a time when there is a break in the testing process.

Finally, viewing the plant's staff performing their daily activities could be telling. Were inspectors to see personnel take stringent precautions while working with nonpathogenic, bacterial agents, it could indicate they are more accustomed to high-level containment work. Another telltale sign of personnel quickly pulled from high-level containment is dermatitis on the hands.[8] In all sectors of the plant, personnel should be executing their tasks and standard operating procedures (SOPs) smoothly. Should the inspectors note awkwardness, personnel might be putting on some type of masquerade.

Checking Paperwork for Clues

When it comes to paperwork, the military and legitimate pharmaceutical companies both document their activities voluminously. Inspectors can take advantage of that fact and use inconsistencies in paperwork to belie a violator. Conversely, a paperwork trail that cross-checks well would buttress giving a legitimate plant a clean bill of health. A genuine manufacturing facility will have a start-to-finish paperwork trail with several types of overlapping records.

At the outset, inspectors can survey the incoming ingredients via documents such as purchasing requisitions, receiving documents, disposition and warehousing records, and the bill of materials, which

[8] Dermatitis is a skin condition that can be caused by wearing protective gloves.

lists every ingredient used to manufacture product(s) at the facility. Inspectors can tell what kinds and amounts of materials the facility is regularly receiving and whether items are being ordered in types and quantities different from what the site needed for its research or manufacturing aims. For example, close scrutiny of amounts of personal protective equipment and other biosafety items consumed would be informative. Detailed paperwork on the media, namely material safety data sheets and the paperwork that certifies the media being used, should also be available in plants operating in many countries.

The operational pace of a facility can be traced through activity, equipment, and cleaning logs. Batch records will show how much product was processed within certain time periods, which inspectors can then check against ingredient inventory levels and the list of products that a facility manufactures at every step. Since normal plants do not operate perfectly, inspectors should see records of deviations from ideal operations, as well as records to investigate what went wrong on such occasions. In a similar vein, inspectors can learn about the tempo of plant operations by looking through the engineering control records for biosafety cabinets, HEPA filters, autoclaves, and decontamination operations as well as the documents about evaluating hazards operations. Moreover, certain equipment will generate pressure and temperature data, which inspectors should review to see that trends correspond to stated activities. Equipment validation and calibration records could indicate if there were attempts to recalibrate equipment before the arrival of the inspection team.

A manufacturing plant will have plenty of SOPs that inspectors can examine to see if they correspond to the plant's stated purpose. Oddities that should make inspectors wonder would be a facility making bacterial vaccines that does not have an SOP for a "kill step" after fermentation or a plant that has emergency response SOPs that do not match the kind of microorganisms declared. SOPs for quality control testing should make sense for the facility's stated product(s).[9]

If something appears out of order, these SOPs should be cross-matched against the list of quality control supplies and raw test data, which constitutes a huge paper trail. The lot release test records would also contain lot numbers that can be put side by side with batch records as well as product specifications. Faking this cross-cutting documentation would be no easy task. Should the inspectors have reason to believe commercial goods are not coming off the line, they can study the product billing, sales, and shipping records.

Inspectors should also closely eye records dealing with a facility's personnel and visitors. A review of the organizational charts would show whether staff ratios in different departments were reasonable for the facility in question. Training records should conform to the facility's stated activities, and personnel turnover rates should be within the expected range for the industry in that country. Likewise, visitor logs should show an expected level of traffic (e.g., maintenance contractors, business

[9] Products using bacteria, for example, should be tested for endotoxins (i.e., lipopolysaccharide) and pyrogens.

partners, regulatory inspectors) for that type of site. An explanation would be requested for military visitors or those who had specialized expertise out of step with a facility's purported line of work.

The beauty of having a wealth of documentation is that inspectors can compare various items against each other. Should the inspectors sense that a plant is really working around the clock instead of fielding just a day shift, they can pull gate records and timesheets. These items can be checked against utility expenditure documents (e.g., energy, water), airflow diagrams, and heating, ventilation and air conditioning maintenance records, among other things. Utility bills and filter changes would need to be in line with the number of shifts the plant says it is running. Inspectors could crosscheck visitor logs with service contracts, and if need be, subsequently interview contract personnel to confirm the nature of their activity on site. Inspectors that believe they have been fed a cover story can request project proposals and reports, service contracts, Institutional Animal Care and Use Committee documents, and records from internal review committees that govern project approval, biosafety, and waste management.

The industry experts noted that while documentation practices differed from country to country, even in countries with more modest regulatory requirements, commercial facility operators should have several paper trails (e.g., laboratory notebooks, construction records, waste treatment documents) for inspectors to examine. Moreover, the group observed that should enhanced biosafety, biosecurity, and research oversight standards be implemented worldwide, as they recommend in Chapter 4, facilities should have even more records that can be made available to inspectors. Given that the truth is often amidst the devilish details of such records, document review can be the tool in the inspectors' kit that clarifies or condemns.

Interviews

Industry experts opted to slate interviews after a site tour and a thorough review of documents because at that point inspectors should have a good idea of what questions to pose to the facility's personnel. Ideally, key people in each division would be made available for interviews. Were all of the key personnel conveniently on vacation or out-of-town "business" when the inspectors arrived, it would be a bad omen. The inspectors should also speak with the rank and file to find out whether they really know their jobs. If inspectors believe something is awry, they should have the worker bees run through their own SOPs, which should be no problem for personnel at a *bona fide* facility.

Sampling and Analysis

A final product sample would be the only type of sample that does not raise the specter of losing extremely valuable business data. Understandably, therefore, the industry experts approached the prospect of other types of sampling with considerable trepidation. Well aware that sampling is a powerful investigative tool that has tremendous potential to reveal proprietary information, the industry experts

proceeded to craft sampling and analysis ground rules that would satisfy the needs of inspectors and host facilities alike.[10]

Industry experts laid down a few governing principles for sampling. First, due to its intrusiveness, sampling should be a last-resort tool, reserved for occasions when inspectors seriously suspect prohibited activity, unless the industry facility volunteered a sample under other circumstances. Second, the inspectors should have the right to request samples, and the host facility the right to refuse that request, offering inspectors alternative ways to answer their concerns. Third, if inspectors found that samples were in order, ideally they would be taken on the first day of inspection by facility staff or a third party with proven sampling skills. Samples might be taken from points along the production process, the waste treatment system, personnel or test animals, and other general surface locations at the facility.[11] Fourth, the sampling techniques would be pre-stated with protocols based on accepted practice for different sample types (e.g., air, water). The sample would be split into blind or double blind sets for the inspectors and the host site and subsequently held in a lock box on site.

If the inspectors were able to conclude their work and resolve their concerns without analysis of the samples, then the host facility would have the right to destroy those items. In the event that the investigation needed to proceed to analysis to resolve ambiguities, the test(s) performed on the sample(s) would have to be pre-validated, with false positive rates specified. Preparing the assays for various samples would be a lengthy process, but the industry group reasoned that running unvalidated assays would not be scientifically credible and might not even catch a violator. Once validated assays were available, the samples would be taken from the dual-key lock box and preferably analyzed on site under the watchful eye of inspectors. Another, less desirable option would be to ship the samples under pre-agreed chain-of-custody procedures to certified third-party laboratories that are routinely tested for competency. In that case, the plant would have the right to have its personnel observe the analytical work from start to finish.

Inspection Formats

Timeframes and inspection teams will be crucial to the success of any inspection regime. The industry experts viewed a notice of at least five days sufficient time for the inspectors to gather and analyze the necessary pre-inspection information. In a challenge inspection setting, host officials should not receive much, if any, advance notice if a modicum of surprise is to be achieved.

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[10] To review their verbatim discussion on this topic, see Box 4.2 of *House of Cards: The Pivotal Importance of a Technically Sound BWC Monitoring Protocol* (Washington, DC: Henry L. Stimson Center, May 2001): 78-84.

[11] Note that a plant that claims to be making vaccines or biopharmaceuticals but does not have multiple sampling access points within its production process should automatically provoke questions from the inspectors. Pharmaceutical and biotechnology manufacturing facilities often retain samples from various points throughout their processes. If facility operators agreed, inspectors might examine such samples to resolve some ambiguities without interfering with the manufacturing process.

To try to assemble all the pieces into a coherent picture of a facility's activities, an inspection team tailored with an appropriate number of inspectors with the right disciplines must be deployed. At a minimum, the team should encompass the following areas of expertise: biochemical engineering; industrial microbiology; materials management; heating, ventilating, and air conditioning operations; infectious disease research; regulatory and quality control operations; and support/process /instrumentation/civil engineering. At least five or six individuals, but ideally six to eight inspectors should comprise a team because additional site-specific functional expertise would probably have to be added.[12] Also, even though the industry group recommended that legal and administrative support staff be on-call at inspectorate headquarters, someone on the team should have a working knowledge of service contracts and other routine legal matters.

In sum, the inspectors will be confronted with a constant stream of seeming contradictions, so a cross-disciplinary team would be essential to unravel the complexities and determine whether a facility was engaged in commercial work or illicit weapons activities. The industry group stressed that the monitoring tools would only be as good as the inspectors. Intentional BWC violations may be difficult to prove definitively, but the industry group had mostly high confidence that the inspection strategies and tactics they recommended would prove successful in the field.[13]

EVALUATING THE US GOVERNMENT'S ALTERNATIVE BWC MONITORING PROPOSALS

As noted briefly above, the US government has advanced two proposals ostensibly to supplant a formal BWC monitoring protocol. First, the US government proposed that the BWC members agree to use the following procedures to investigate suspicious outbreaks of disease or allegations of use. Any BWC member could ask another treaty member to clarify and resolve concerns, requesting, if necessary, an investigation under the terms of the 1925 Geneva Protocol, which prohibits the use of germ weapons. The country receiving such a request would be required to provide an international inspection commissioned by the UN Secretary General timely access to the site of the outbreak. This inspection team would subsequently file a factual report, which the UN Secretary General would distribute. During the inspection, the host state would control "all access within the area of investigation" so that national security and business interests would not be jeopardized.[14]

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[12] Inspectors must be able to understand the native tongue of host officials, so having good interpreters on the inspection team will be essential. Also, since business practices vary from country to country, it will be important that someone on the inspection team understand the local business culture.

[13] See Table 4.2 in *House of Cards*, where the industry experts rated the expected effectiveness of monitoring in a particular functional area (e.g., medical facilities, supplies, downstream processing). In two areas, the group gave a low expected effectiveness rating, followed by a one low to medium rating, two medium ratings, three medium to high ratings, six high ratings, and one rating of very high expected effectiveness. *House of Cards*, 76.

[14] This summary was drawn from US Department of State, "New Ways to Strengthen the International Regime Against Biological Weapons," fact sheet, 19 October 2001, 6. Available at http://www.state.gov/t/ac/bw/fs/2001/7909.htm.

In the second US proposal, any BWC member that receives a bilateral request from another treaty member to clarify and resolve compliance should respond "promptly and fully" with explanatory information. If that data exchange is insufficient to dispel compliance ambiguities, the two states concerned can enter into an arrangement to exchange additional data or to conduct visits and other procedures at the site(s) involved.[15] In an abbreviated version of this proposal, the US government characterized it as setting up "a voluntary cooperative mechanism" for addressing compliance concerns.[16] In shorthand, the proposal is described as involving "voluntary visits."

In a word, industry experts deemed both of these proposals toothless. The group observed that the proposal to have states pledge to cooperate with the Secretary General's inspectors would do little more than perpetuate current circumstances. The General Assembly and Security Council have already strengthened the investigatory responsibility that the BWC originally vested with the Security Council by allowing the UN's leader to deploy inspection teams without getting approval to do so from a majority of UN member states. In the 1980s and early 1990s, Iran, Iraq, Mozambique, and Azerbaijan cooperated when the Secretary General sent inspectors to investigate allegations of chemical or toxin weapons use, but other governments denied UN inspectors access.[17] Since Article VI of the BWC already stipulates that member countries should cooperate with UN inspections,[18] a tougher US proposal is needed if BWC members are to be obligated unequivocally and fully to cooperate with future inspections.

The industry group identified three essential ingredients that would set the stage for successful challenge inspections. First, challenge investigations would be as isolated as possible from politics, which would indicate a set-up similar to the provisions of the Chemical Weapons Convention, where a challenge inspection proceeds automatically unless halted by a three-quarters vote of that treaty's governing body.[19] Second, the governing provisions must provide for investigation of facilities suspected

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[15] US Department of State, "New Ways to Strengthen the International Regime," 6.

[16] Ibid, 1.

[17] In each and every instance UN inspectors were deployed, but they were looking into suspicions of chemical weapons use, not germ warfare use or accidental releases. For more detail on these inspections, see Jonathan B. Tucker and Raymond A. Zilinskas, "Assessing U.S. Proposals to Strengthen the Biological Weapons Convention," *Arms Control Today* 32, no. 3 (April 2002): 10-4.

[18] Article VI of the BWC allows member states to complain to the UN Security Council, which may initiate an inspection. Paragraph 2 of this article says: "Each State Party to this Convention undertakes to cooperate in carrying out any investigation which the Security Council may initiate, in accordance with the provisions of the Charter of the United Nations, on the basis of the complaint received by the Council." Throughout the treaty's early history, the willingness of states to cooperate was not put to the test largely because one of the permanent five Security Council members, each of which carry a veto power, would presumably step forward to defend the interests of a country under suspicion of cheating. For example, the USSR would have vetoed any attempt to investigate the 1979 outbreak of anthrax at Sverdlovsk, which killed at least sixty-eight. Russian President Boris Yeltsin conceded in April 1992 that this outbreak was caused by an accident at an anthrax production facility. Decree of the Russian Federation on Fulfilling International Obligations with Regard to Biological Weapons, Moscow, 11 April 1992; R. Jeffrey Smithson, "Yeltsin Blames '79 Anthrax on Germ Warfare Efforts," *Washington Post*, 16 June 1992. In the early 1990s, an authoritative investigation of the Sverdlovsk outbreak was conducted by outside experts. Mathew Meselson, Jeanne Guillemin, et al., "The Sverdlovsk Anthrax Outbreak of 1979," *Science* 266, no. 5188 (18 November 1994): 1202-8.

[19] Within a twelve-hour window before the inspection begins with the landing of the team at the port of entry in the challenged state, the forty-one members of the Executive Council of the Chemical Weapons Convention can vote to halt a challenge inspection if, after hearing the reasons underpinning the challenge, they deem the inspection frivolous or unwarranted.

of conducting prohibited activities, not just suspicious outbreaks of disease or allegations of uses. Third, a sufficient number of appropriately skilled inspectors must be dispatched promptly once a situation meriting challenge inspection is identified. Once there, the inspectors must be allotted sufficient time to sort allegation from fact, employing a panoply of inspection tools.

With regard to the voluntary inspection proposal, the industry experts were stumped as to why it would be tabled in the first place. Any facility that opened its doors for such a visit would have ample time to scour their grounds of evidence of cheating prior to inviting the inspectors. Therefore, the monitoring value of voluntary inspections is questionable, if not negligible because of the emptiness of the exercise. Another negative aspect of this formulation is that a government could decide for political reasons to "volunteer" an industry facility for such an inspection.[20] Since the inspection format could well produce meaningless outcomes, then voluntary inspections could be a costly nuisance to industry. For these reasons, the industry group did not see voluntary visits as a constructive monitoring approach.

CHARTING A COURSE FORWARD

In introducing these two alternative monitoring proposals, the US government publicly reasserted "it is impossible to verify compliance with the BWC."[21] Obviously, experts from the US pharmaceutical and biotechnology industry take issue with that statement. They believe that if multidisciplinary inspection teams are allowed sufficient time on site and empowered to use pre-inspection research and analysis, site tours, document reviews, interviews, and sampling, they can discern legitimate from cheating facilities. Moreover, the industry experts stated that the operators of commercial facilities, well versed in hosting all manner of regulatory inspections, would be able to protect their proprietary business data during such inspections at the same time that they helped the inspectors achieve their aims.

Article IX, paragraph 17, *Convention on the Prohibition of the Development, Production, Stockpiling and Use of Chemical Weapons and on Their Destruction*.

[20] This concern arises out of the experience of one US firm during inspections conducted under the September 1992 trilateral agreement between Russia, Great Britain, and the United States. In mid-February 1994, the Russians requested an inspection of a Pfizer, Inc. site in Terre Haute, Indiana, part of which was originally built to produce biowarfare agents. That portion of the plant was mothballed before it became operational. The Russians accused the firm verbally and in writing of possibly violating the BWC because the fermenters in question had not been destroyed, even though corporate officials explained that it was cheaper to padlock that building than destroy the equipment. A week later, the Russians asked to inspect a Pfizer research and development facility in Groton, Connecticut. Pfizer officials wanted to decline the visit, but agreed to it under considerable White House pressure. Russian inspectors made similar allegations of cheating. Later, US government officials described these trilateral visits as voluntary. On the trilateral agreement, see US Department of State, "Joint US/UK/Russian Statement on Biological Weapons," press release, 14 September 1992. On the Pfizer trials, briefly, "Biological Weapons Convention: Chronology 1994," *Arms Control Reporter* 13, no 3 (14 February 1994): 701.B.123-4. Also, US government officials, interviews with Amy E. Smithson, Washington, DC, (30 December 1996, 31 December 1997, 2 January 1998, 6 January 1998); US industry official, Washington, DC, (2 January 1998).

[21] US Department of State, "New Ways to Strengthen the International Regime," 7. This was certainly not the first time that the US government has made such a statement. The administration of George H.W. Bush likewise stated that the BWC was "unverifiable." "The convention is not effectively verifiable and we do not know any way to make it so." Ronald F. Lehman, Arms Control and Disarmament Agency Director, "Address to Third Review Conference of the Biological and Toxin Weapons Convention," Geneva, 10 September 1991. Available at http://www.fas.org/nuke/control/bwc/news/910910-196372.htm.

What remains something of a mystery to US industry experts is why their government has failed to do the requisite research and field-testing to identify once and for all what methods could be used to monitor the BWC. Given the inchoate results of the two US field trials held in the mid-1990s and the existence of a congressional mandate to conduct additional field trials at government, academic, and pharmaceutical sites,[22] the industry group believed that it is incumbent on the US government to forge ahead as swiftly as possible with such field trials. Absent the conduct of such trials, the Bush administration can hardly declare the BWC "unverifiable," particularly since inspectors who spent time at former Soviet and Iraqi sites repeatedly encountered evidence—sometimes blatant, sometimes very subtle—of these nations' bioweapons programs.[23] The industry group stated that US companies and the trade associations representing them—namely the Pharmaceutical Research and Manufacturers of America and Biotechnology Industry Organization—should assist with such field trials.

To encourage the US government and industry to move ahead with field trials, experts from the US pharmaceutical and biotechnology industries agreed to draft plans of work for trial inspections at two types of industry sites, research and development and manufacturing facilities. The purpose of these trial plans is to put inspectors through their paces in a tough and realistic, but controlled environment so that data can be gathered for the type of cost-benefit analysis that should underpin the US position on BWC inspections.[24] Upon completion, this group of industry experts intends to share these trial inspection plans with the US government, industry trade associations, and other interested governments to facilitate the testing of various monitoring strategies, tactics, and technologies.

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[22] The 1999 National Security and Corporate Fairness Under the Biological Weapons Convention Act. This law requires trial investigations and visits at US government facilities, installations, and national laboratories; academic institutions; and vaccine production, pharmaceutical, and biotechnology facilities. Following these trials, the Executive Branch is to report to Congress describing the monitoring results that can be expected and the risks of monitoring to US national security and business interests. See Public Law 106-113. As for the two prior US trials, one was a three-day exercise conducted in late October 1995 at a US facility that was producing anthrax vaccine and making botulinum toxin for medicinal treatments. A second one-day trial was conducted at a trio of research facilities in Albuquerque, New Mexico, on 26 March 1996. At the conclusion of both trials, inspectors could not definitively state that the sites were not covertly engaged in prohibited activities, nor could they prove that such illicit activity was underway. The report from the October 1995 trial was never released publicly, but the second trial is described in a limited distribution report. See *DOE Exercise to Determine the Potential Impact of a Legally Binding BTWC Regime on DOE Sites*, report number PNNL-11015, prepared by Pacific Northwest National Laboratory under Contract DE-AC06-67RLO 1830 (Richland, Wash.: June 1998).

[23] US and British inspectors visited several former Soviet bioweapons facilities under the 1992 Trilateral Agreement. Several veterans of these inspections related anecdotes of their experiences, which included visual observation of blatantly missing or disabled equipment and statements by scientists being interviewed that discussed weapons work. Round table discussions held on 27 April 2000 at the Henry L. Stimson Center, Washington, DC. On the United Nations Special Commission on Iraq inspections that uncovered the details of that country's biological weapons program, see 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: US Pursuing 25 Germ Warheads It Believes Are Still Loaded With Deadly Toxin," *Washington Post*, 21 November 1997. UN inspections in Iraq were aborted in 1998, when Iraq insisted that the inspectors leave the country. Barbara Crossette, "Iraqis Break Off All Cooperation with Inspectors," *New York Times*, 6 August 1998.

[24] As one industry expert explained, their actions are based on "tried but true scientific method. . . .this is based on the premise of hypothesis and testing. We are putting forth our hypothesis of the best method, think inspections will work, but the hypothesis must by definition pass or fail, when it comes to testing." Dr. Robert Hamilton, senior scientist and group leader at a large US biotechnology firm, 10 August 2002.