he Biological Weapons Convention (BWC) has been in force since 1975 and currently has 139 states parties; an additional 18 nations have signed but not ratified the convention. The BWC bans the development, production, acquisition by any other means, and

the retention of biological weapons. As the first convention to ban an entire class of weapons, it represents an important landmark in arms control. However, the BWC has no verification provisions, nor are there provisions for assessing compliance of a state party or investigating allegations of development or use.

Since 1986, there have been attempts to overcome this weakness by increasing

the transparency of activities conducted at biological facilities and, more recently, through the development of a verification protocol for the BWC. As yet, there is no consensus with respect to the shape of a future protocol. Concerns have been expressed about the risks intrusive verification measures could pose to the intellectual property of legitimate biotechnology industries.

This essay presents an outline for a verification protocol intended to provide a high degree of confidence in compliance (or noncompliance) with the BWC, while minimizing any impact on legitimate activity. This protocol draws on the experience of the U.N. Special Commission on Iraq (UNSCOM) and is based upon regular declarations of relevant biotechnology facilities, a series of routine inspections of some of these declared facilities, and short-notice inspection of any facilities when a compliance concern arises. Central to this protocol is a "tool kit," a framework that could hold all the required means needed to ensure acceptable confidence levels, while minimizing the degree of intrusiveness. It is, in simple terms, a multilayered decisionmaking mechanism based on an "if, then" action sequence.

ATTEMPTS TO STRENGTHEN THE BWC

Confidence-Building Measures

At the second and third review conferences of the BWC held in 1986 and 1991, confidence-building measures

(CBMs) were negotiated in an attempt to strengthen the regime. Under the terms of the CBMs, states parties to the BWC should submit declarations each year to the U.N. Department (now-Center) for Disarmament Affairs. The CBMs relate to exchange of data on research centers

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and laboratories that meet very high national or international safety standards or that are engaged in biological defense research and development programs. The intention was that these CBMs would increase transparency of biological activities in a state party and thus strengthen confidence in compliance with the BWC. In reality, they have had limited effect. The CBMs are not le-

gally binding and participation has been poor; less than 50 percent of states parties have provided CBM data since 1987, and only nine percent have participated in all rounds of data exchange. Furthermore, there is no manpower to follow-up missing declarations and no mechanism for checking the accuracy of anomalous returns.

Ad Hoc Group of Governmental Experts to Examine Verification of the BWC from a Scientific and Technical Viewpoint

At the third review conference in 1991, there was a move to negotiate a verification protocol for the BWC in addition to extending the CBMs. Although this effort was unsuccessful, a mandate was given for a series of meetings of a group of scientific and technical experts that became known as "VEREX" to examine the feasibility of verification. VEREX identified potential verification measures and concluded that it was possible to verify

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compliance with the BWC from a scientific and technical point of view. However, no attempt was made, nor was the mandate given, for consideration of the political and commercial acceptability of these measures.

Verification Protocol

Then, in September 1994, a special conference of states parties to the BWC was convened specifically to consider the VEREX report and to decide upon further action. At this meeting, a separate *Ad Hoc* Working Group—open to all states parties to the BWC—was established under the chairmanship of Ambassador Tibor Toth of Hungary. The *Ad Hoc* Working Group was given the mandate to "consider appropriate measures, including possible verification measures and draft proposals to strengthen the Convention, to be included, as appropriate, in a legally binding instrument, to be submitted for the consideration of the States Parties." This group was to consider four major issues:

- 1. definitions of terms and objective criteria, such as lists of bacteriological (biological) agents and toxins, their threshold quantities, as well as types of activities (where relevant) for specific measures designed to strengthen the BWC;
- 2. the incorporation of existing and further enhanced confidence-building and transparency measures, as appropriate, into the regime;
- 3. a system of measures to promote compliance with the BWC, including, as appropriate, measures identified, examined, and evaluated in the VEREX report; and
- 4. specific measures designed to ensure effective and full implementation of Article X (promotion of international cooperation in the peaceful applications of biology), but which also avoid any restrictions incompatible with the obligations undertaken under the BWC.²

The complexity and interaction of these items must be considered against a backdrop of several basic requirements if the BWC is to be strengthened. One requirement is an acceptable degree of confidence that provisions of the BWC can or will be met, balanced against interests of national sovereignty, protection of state and commercial interests, minimization of negative effects on industry (i.e., an acceptable level of intrusiveness) consistent with verification requirements, and supportable costs. While such a balance may be dif-

ficult to contemplate or achieve, without it all efforts to achieve a strengthened BWC are doomed to failure.

THE FIRST TOOLS: DECLARATIONS AND INSPECTIONS

The first meeting of the Working Group, held in January 1995, was largely procedural. The second meeting, in July 1995, began discussion on the four issues, including consideration of compliance monitoring procedures. It would be desirable to complete the tasks of the Working Group as soon as possible. To achieve this, the tools elaborated during VEREX need to be fitted into a workable framework. During the July 1995 meeting of the Working Group, as during VEREX, concerns were expressed over the intrusiveness of some of the proposed verification measures. These concerns, however, may have been overstated.

Much has been made of the fact that the sweeping powers of U.N. Security Council Resolutions 687 and 715—granting almost unlimited levels of intrusiveness to UNSCOM for the identification and verification of facilities potentially involved in the development and use of biological weapons (BW)—have borne fruit only with great difficulty. However, although UNSCOM had broad powers, the opportunity to exercise those powers came well after Iraq had discontinued its BW program. From 1991 to 1995, a total of 22 biological inspections were conducted in Iraq. The August 1995 defection of Hussein Kamel, who confirmed that Iraq had indeed carried out an offensive biological warfare program, has spurred an additional 23 inspections to date. Even without Kamel's confirmation, UNSCOM was eventually able to force an admission from the Iraqis through use of high-level interrogation missions and analysis of data from a number of sources. UNSCOM's experience underscores the need for a continual watch on biotechnological developments in order to identify potential problems early enough to stop them. Much of the evidence used to build the picture of the Iraqi BW program came from auditing data on equipment transfers and transfer requests, supporting letters of credit, and microbiological media purchases, transfers, and consumption, as well as exposure of anomalies in the Iraqi stories given to UNSCOM. These auditing methods were not highly intrusive, and their use in a strengthened BWC would cause few problems to legitimate business.

This experience could point the way towards a verifi-

cation instrument for the BWC. Such an instrument would be based upon relatively non-intrusive measures, such as declarations and routine inspections, but would also need to include more intrusive measures to be used where compliance concerns could not be resolved in any other way. One important guideline that would help to prevent the complications experienced by UNSCOM is that inspections must be carried out rapidly, before there can be any suggestion that a clean-up of a site has occurred.

Although most states parties accept in principle the need for declarations of facilities, experience with the politically binding declarations required under the current CBMs suggests that such declarations would need to be legally binding to be effective. The establishment of a secretariat empowered to request declarations, if they are not forthcoming, may also improve participation. However, while declarations of biological facilities may improve transparency, on their own they would not provide confidence that there were no violations. Declarations have been likened to tax returns: selective auditing of tax returns acts as a deterrent to tax evasion.³ Similarly, checks on declarations will encourage honesty.

In keeping with other arms control regimes, a system of inspections can be envisaged as a second step in the verification protocol for the BWC. Generally, two types of inspections are contemplated: routine and shortnotice. Short time lines should be utilized for all inspections of biological facilities if they are to be meaningful. This suggestion reflects the fact that biological facilities can be cleaned up much more rapidly than their chemical counterparts. Once time lines are negotiated, they may in fact be approximately the same for both types of inspection; the major difference between the two being the types of facilities inspected and the trigger for the inspection. Routine inspections would be carried out only at declared facilities, and those to be inspected would be selected by the secretariat. Short-notice inspections would have a political trigger, namely a request from a state party with compliance concerns. Declared or undeclared facilities could be inspected.

Some countries have advanced ideas about different methods available to inspectors depending upon whether inspections are routine or short notice. There have been suggestions that more intrusive tools, such as sampling, should be used only during short-notice inspections. It is difficult to see how this approach could work. Inspectors should have a full range of tools available at all times,

a condition that would be in the interest of the inspectorate and of the facility being inspected. A compliance concern noted during a routine inspection would need to be investigated immediately, using as many of the available tools as required to allay that concern. Rapid action would be needed for three main reasons:

- 1. Destabilization caused by suspicions of illicit activity. No legitimate biotechnology facility can afford to have a suspicion of BW activity hanging over it for any period of time.
- 2. Convenience. While no facility likes inspections, they are needed and, as such, are tolerated; however, minimal numbers of inspections would be preferable. Optimally, one would seek to resolve all problems in one inspection, rather than to require multiple visits to the same site.
- 3. Validity. If the compliance concern arose because the facility was indeed in contravention of the BWC, the probability is high that evidence will have been eliminated before a second, more intrusive inspection could be organized. The nature of biological processes means that a site could be "sanitized" relatively rapidly by discharging and sterilizing production vessels and effluents from those vessels and destroying stock microbial cultures. Such a sanitation would typically not require more than 24 hours.

For example, an occasion may arise where doubt is cast upon particular activities in a facility. While these activities may not be serious enough to risk the political fallout of a full short-notice challenge inspection *per se*, they could engender a lingering, uncomfortable suspicion. A moderately intrusive action, such as taking samples for biochemical analysis, might rapidly remove any ambiguity. Conceivably, this solution could be suggested by the inspected party. It is difficult, therefore, to comprehend a verification plan that would prohibit samples from being collected merely because an inspection being conducted was routine rather than short-notice; such a prohibition could leave lingering unresolved doubts.

During the Working Group meetings, concerns were expressed by some delegations that industry is not prepared to accept the burden of yet more inspections. Many regulatory bodies (e.g., the U.S. Food and Drug Administration), inspect industrial biotechnology facilities regularly. A suggestion was made that these agencies could be asked to take on the role of ensuring that facilities are in compliance with the BWC. This idea is unworkable

because such agencies likely would be unwilling to take on the role of policeman for an arms control treaty. More importantly, they are not neutral, but are answerable to their national governments. Thus, not all nations would have confidence in their impartiality. However, there is a pointer here to the way ahead.

Regulatory authorities require detailed documentation to establish audit trails. The main purpose of an inspection under the auspices of the BWC, regardless of type, is to establish what is being done in a facility. To do this, inspectors need access to all the instruments in the tool kit, including the most intrusive. This access does not mean, however, that they will always need to use all such tools. Once sufficient information is provided for the inspectors to ascertain the nature of the work being carried out in the facility, the inspection can be concluded, assuming, of course, that the work is found to be legitimate. The documentation that companies are required to maintain to be certified by licensing and regulatory authorities could also be made available to the BWC inspectorate. This documentation would show quickly what activity had been performed in the facility and would enable inspectors to come to a decision very rapidly as to its bona fide (or otherwise) nature. Thus, those companies that maintain good records will be unlikely to be subjected to intrusive inspections.

Overall, it is clear that the first two important tools for a verification protocol reside in declarations and the inspections needed to verify them. In this context, it may be useful to configure declarations in such a way that verifiable data are embedded in them (e.g., the date and source of equipment acquisition, documentation relevant to compliance with ISO 9000 standards,4 and information required by regulators). Originally published in 1987, the ISO 9000 family is a set of five universal standards for a quality assurance system accepted by 90 countries on a national basis. The most comprehensive of the standards is ISO 9001, which applies to industries involved in the design, development, manufacturing, installation, and servicing of products or services. Plants built to conform to good manufacturing practice would have this information available so that its use for BWC verification would not constitute an unacceptable burden to many facilities. Not only would such data significantly reduce the risk of double bookkeeping, but it also would delineate a clear path for verification inspections. To avoid voluminous declarations, a facility could indicate the availability of supporting documentation by a simple code, and have the material submitted independently or appended to a simple declaration.

THE TOOL KIT

A variety of tools must be accessible to inspectors to ensure that adequate confidence levels can be attained in the verification process. However, inspectors would not, and possibly should not, require use of all tools, only those necessary for a given situation. Currently lacking in the *Ad Hoc* Working Group discussions is the concept of a "tool kit," a framework that could hold all of the required tools to ensure acceptable confidence levels, while minimizing intrusions on state sovereignty and commercial interests. What is being suggested is a multilayered decisionmaking mechanism based on an "if, then" action sequence. At each decision level, an inspector could envisage a set of possible actions, all of which would cease once the acceptable level of confidence had been achieved.

The following example assumes the existence of a BWC secretariat to which declarations on relevant activities and facilities would be submitted. The secretariat would oversee the work of a competent, well-trained, neutral inspectorate that would, furthermore, have offsite and on-site tools available to it. The more the inspectorate used off-site and relatively non-intrusive on-site tools, the less likely would be the need for more intrusive measures. Thus, it is desirable that declarations include information on legislation relevant not only to the BWC (i.e., penal codes for BW activity) but also information on legislation relating to national occupational health and safety (OHS) standards. Also, the secretariat would have the right and manpower to conduct literature searches, if deemed appropriate. Thus, an inspection of a given site would start off-site with inspectors examining the legislation of the host nation, perhaps conducting a literature search for the facility to be inspected, and becoming familiar with any available data on transfers of equipment, products, or raw material on or off-site, if such information were available. The following simplified example describes a sequence of events that might be used to determine the depth and level of inspection, bearing in mind that the trigger for an inspection would have a major impact. On arrival at the site, inspectors would then look for indicators, using relatively non-intrusive measures:

1. *Observation*. Are the physical surroundings consistent with what would be expected, given the OHS

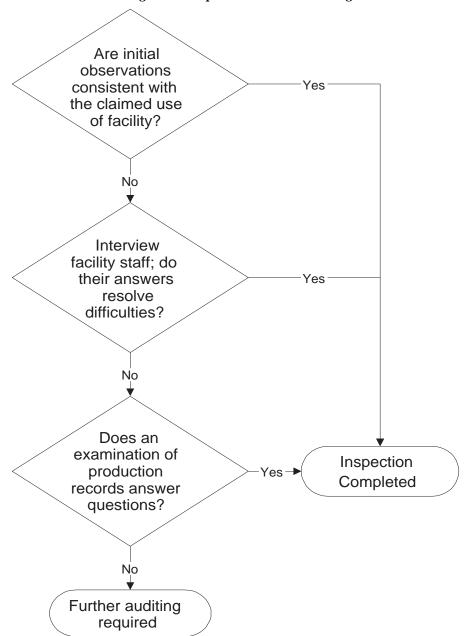


Figure 1: Inspection Decisionmaking

standards for the host nation and the type of facility?

2. *Identification of key equipment*. Is the equipment consistent in type and capacity with the claimed use of the facility? Is the size of the equipment consistent with the data available on production and shipment levels from the facility?

If the answers to the above questions are "yes," there may be no need to proceed much further. If inconsistencies are revealed, then a further stage of the inspection would be required. This next stage could proceed as indicated in Figure 1 above.

In this context, further auditing requirements might cover information regarding fermenter runs, electricity usage, water usage, media consumption, and so on. Admittedly, although this example may be considered simplistic and does not take into account a myriad of factors, it does illustrate that a generic framework might function well to ensure compliance, while limiting the level of intrusiveness. If such a logic-driven process, leading from lesser to extreme degrees of intrusiveness, had been available for use in Iraq, a more focused type of inspection system might have evolved.

ANCILLARY TOOLS

To be workable, as noted above, the foregoing proposals require an independently empowered, neutral secretariat whose key requirements would be a skilled cadre of inspectors and administrative support staff. Again, the UNSCOM inspection process in Iraq provides some hardwon lessons. UNSCOM was, and is, limited with respect to both its human and financial resources, and it was charged with the responsibility of addressing concerns on many fronts in a timely manner. Perhaps because of these obstacles, its approach to problem solving was predicated on ad hoc action and tended to be reactive. We have identified two major pitfalls that limited the effectiveness of UNSCOM in Iraq and suggest ways to strengthen the BWC. First, in Iraq, full-time analytical and record-keeping resources to collate the results of inspections were less than ideal. As a result, the feedback loop to elaborate and facilitate follow-on inspections was also less than ideal. Designation of this item as a pitfall is not to be construed as lack of adequacy or culpability on the part of UNSCOM. Its data-handling and analysis capabilities have evolved over time, but have been constrained by limited resources. The means by which UNSCOM's mechanisms for analyses and recordkeeping evolved, however, could provide a useful guide for a permanent BWC inspectorate.

Second, UNSCOM inspections in Iraq suffered from a lack of sufficient inspector preparation. Sufficiency in this context refers not to the qualification or expertise of inspectors, the majority of whom (to UNSCOM's credit) were generally of high caliber, motivation, and commitment. Rather, it refers to a system—at least in the biological sector—that did not have a unified framework for assessment of BW capability. The lack of that framework resulted in variations at many different levels, even as to what qualified as "taggable," inventoried dual-use biological equipment, according to the interpretation of the chief inspector. To be fair, UNSCOM was on a steep learning curve during the early stages of its biological inspections in Iraq, and the Iraqis often resisted cooperating with the inspectors.5 As the process evolved, attempts were made to harmonize various inspection parameters. But because these guidelines were perceived to have changed in midstream, their implementation was problematic. This experience illustrates the principle that the mandate of BWC inspectors must be clear and unambiguous and that inspectors must be highly conversant, not only with technical issues, but also in the rights, limitations, and forensic elements of a strengthened BWC.

CONCLUSION

Despite the sweeping, very intrusive powers of UNSCOM in Iraq, no "smoking gun" was ever found; the breakthrough did not come until the Iraqis admitted to having a BW program. By the time BW inspections started in Iraq, several months had elapsed since the end of the Gulf War and much of the evidence had been destroyed. Only careful auditing and checking of records, within Iraq and in other countries, revealed enough evidence to force the Iraqis to eventually admit that they did indeed have an offensive BW program. Notably, it was not sampling that turned up most of the information, but less intrusive measures (such as auditing of imports of culture media and dual-use biological equipment). These methods offer little threat to legitimate commercial concerns.

A strengthened BWC might be able to overcome the problems revealed by UNSCOM in Iraq. The major components would be a system of declarations of relevant facilities and activities; the establishment of a permanent, neutral secretariat responsible for processing declarations and arranging inspections to verify the declarations and to address compliance concerns; and well-trained, full-time inspectors who could provide the continuity and experience so important in assessing compliance with the BWC. With these components in place, the use of a well-constructed decisionmaking mechanism would allow inspectors to determine the legitimacy of a biotechnology facility with minimal impact and intrusiveness.

¹ The opinions in this paper are those of the authors and do not necessarily reflect those of their respective governments. The authors acknowledge with gratitude the insights and suggestions offered by Rolf Ekéus, Chairman of UNSCOM; Stephen Black, UNSCOM; Gordon Vachon, Department of Foreign Affairs and International Trade, Canada; and Susan Hamilton, Department of Foreign Affairs and Trade, Australia in the preparation of this work.

² 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* (Geneva, 19-30 September 1994), Document No. BWC/SPCONF/1, Part II, p. 10.

³ Ter Haar, *The Future of Biological Weapons, The Washington Papers* (New York: Praegar Publishers, 1994), p. 107.

⁴ Leland R. Beaumont, *ISO 9001: The Standard Interpretation*, 2nd edition (The International Standard System for Assuring Product and Service Quality, 1995).

⁵ See, Jonathan B. Tucker, "Monitoring and Verification in a Noncooperative Environment: Lessons from the U.N. Experience in Iraq," *The Nonproliferation Review* 3 (Spring-Summer 1996), pp. 5-10.