

Means for Protecting US Industry Within an Effective Compliance Regime for the Biological Weapons Convention

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The Biological Weapons Convention of 1972, which has no verification measures, has not prevented the proliferation of biological weapons, even in some countries that are parties to the Convention. The international community now has an unusual opportunity and a responsibility to strengthen the BWC with measures that will be truly effective.

Essential components of an effective BWC compliance regime include:

- Declaration of dual-use capabilities;
- Challenge investigations based on evidence for possible non-compliance; and
- Non-challenge visits to confirm the accuracy of declarations and clarify unresolved questions about declarations.

US bio-related industry is concerned about the potential loss of confidential proprietary information and property (CPI) and damage to its reputation from non-challenge visits. However, means are available for protecting the industry without undermining the efficacy of the compliance regime.

The Need for Non-challenge Visits in an Effective Compliance Regime

In the absence of non-challenge visits, challenge investigations would be the only means for on-site access; but challenges are expected to be rare because they will require evidence for BWC violation and will inevitably exact political costs. Annual declarations not subject to on-site validation have been in effect since the adoption of Confidence-Building Measures at the BWC's second review conference in 1986, and have proved ineffective. Without the possibility of visits, biological weapons development could be carried out within carefully-declared "dual-use" facilities that also conduct legitimate activities. Visits to such a facility might raise suspicions, signalling national intelligence to focus on the suspect facility and keep it under surveillance. Thus, visits would help deter misuse of declared facilities and force illicit activities into undeclared, clandestine sites, making operations and procurement of dual-use materials much more difficult.

Protection of CPI in Non-challenge Visits

There are a variety of means under consideration for protecting CPI during non-challenge visits under the protocol. Many of these are listed below. The first five items will be discussed in more detail subsequently.

1. Rules and penalties governing the selection and conduct of inspectors;
2. Negotiated access on site, using "managed access" procedures;
3. Special protections for proprietary microorganisms;
4. US government agreements with industry regarding the conduct of visits;
5. Limited, specific mandate for each visit;
6. Review and comment on inspectors' draft visit report by officials of the visited facility;
7. Right of a visited facility to file a report on the compliance of the visiting inspectors with confidentiality rules;
8. Periodic review of the protocol's confidentiality rules and procedures, and recommendations for their improvement, by an international committee of private industry experts reporting to the Conference of States Parties; and
9. Development of an international agreement among private enterprises potentially subject to visits or challenge investigations under the BWC protocol, that they will:
 - (a) not directly or indirectly seek information obtained in the course of visits or challenge investigations from any person, entity or government;
 - (b) report immediately to their governments and the BWC Organization any person or country that offers them such information without authorization; and
 - (c) cooperate with other companies in implementing systems for protecting CPI while complying with the BWC protocol's compliance regime.

US facilities that will be declared are already subject to a variety of national and international inspections, many of which have fewer protections than these and are more intrusive than is necessary for visits under a BWC compliance regime.

1. Rules and Penalties Governing the BWC Organization and its Inspectors

- The Inspectorate must be permanent and professional, with no borrowing of personnel from private industry;

- Each State Party must have the right to specify (in advance) which inspectors are acceptable for visits or challenge investigations within its territory; and
- Rules must be adopted for safe handling and non-disclosure of CPI by the BWC Organization and its inspectors, as well as penalties for disclosure.

These provisions are already part of the Chemical Weapons Convention and are expected to be adopted by the BWC protocol.

2. Managed Access: A Powerful Protection for Industrial CPI

Bio-industry differs from the chemical industry in the valuable proprietary strains of microorganisms possessed by some pharmaceutical and biotechnology facilities. These have to be protected from theft. In other respects, however, such as proprietary processes and economic data, the confidentiality concerns of the two industries are essentially the same and can be protected by the same procedures.

"Managed access" procedures were developed for the Chemical Weapons Convention with the help of the chemical industry, which avidly campaigned for a strong and effective Convention with adequate protection for CPI. The US chemical industry does not regard inspections and visits conducted under managed access procedures to be a threat. Visitors who are carefully watched and who have limited, negotiated access to a facility present little risk of theft of CPI.

Managed access is described in the following excerpts from the Chemical Weapons Convention. Similar procedures have also been inserted in the draft text of the BWC protocol, and almost certainly will be adopted.

Negotiation: "The extent and nature of access to a particular place or places within these perimeters [of the facility] shall be negotiated between the inspection team and the inspected State Party on a managed access basis."

"The inspection team and the inspected State Party shall negotiate: the extent of access to any particular place or places within the final and requested perimeters...; the particular inspection activities, including sampling, to be conducted by the inspection team; the performance of particular activities by the inspected State Party; and the provision of particular information by the inspected State Party."

Procedures: ". States Parties may take such measures as they deem necessary to protect confidentiality... Inspection teams shall... fully respect the procedures designed to protect sensitive installations and to prevent the disclosure of confidential data."

"...the inspected State Party shall have the right to take measures to protect sensitive installations and prevent disclosure of confidential information and data not related to

chemical weapons. Such measures may include, *inter alia*: (a) Removal of sensitive papers from office spaces; (b) Shrouding of sensitive displays, stores, and equipment; (c) Shrouding of sensitive pieces of equipment, such as computer or electronic systems; (d) Logging off of computer systems and turning off of data indicating devices; (e) Restriction of sample analysis to presence and absence of chemicals listed in Schedules 1,2 and 3 or appropriate degradation products; (f) Using random selective access techniques whereby the inspectors are requested to select a given percentage or number of buildings of their choice to inspect; the same principle can apply to the interior and content of sensitive buildings; (g) in exceptional cases, giving only individual inspectors access to certain parts of the inspection site."

Obligations: "If the inspected State Party provides less than full access to places, activities, or information, it shall be under the obligation to make every reasonable effort to provide alternative means to clarify...the concern..."

3. Protection of Proprietary Microorganisms

Multiple precautions can be taken to protect proprietary microorganisms during a visit or investigation. Those listed below are all technically feasible and compatible with an effective compliance regime.

- Gowning and showering of inspectors, at the option of the visited facility;
- Watchful monitoring of inspectors by accompanying site personnel;
- Requiring demonstrable reason for sampling and analysis during visits, and negotiating the request according to managed access rules;
- Permitting sampling of process microorganisms only at normal sampling points.
- Allowing facility personnel to take requested samples, render them nonviable and selectively destroy proprietary genetic information before turning a part of each sample over to the inspectors for analysis;
- Carrying out all analyses on site unless removal and chain of custody are agreed;
- Utilizing rapid analytical methods that have been developed and validated for ISO 9000 use, with negligible false positives, for on-site identification of killed, nonviable microorganisms, and requiring substantiation of any positive results by other methods; and

- "Blinding" analytical procedures to irrelevant information by making them capable of recognizing only specified, non-confidential information relevant to the BWC.

4. US Government Actions to Protect Bio-industry

The US Congress will have an opportunity to add domestic protections for bio-related industry in implementing legislation that, at the same time, is in harmony with the protocol.

- US implementing legislation should guarantee site managers of commercial facilities the right to make managed access decisions during non-challenge visits. Although responsibility under the protocol will lie with the US government, not the visited facility, site managers, not government representatives, are in the best position to decide what is confidential and what is not. Giving site managers the decision-making power during visits will relieve industry concern that the US government might divulge CPI when it seems politically expedient to do so. Non-challenge visits are meant to be friendly and to be conducted by inspectors under the assumption that the facility is in compliance. By allowing site managers to make managed access decisions the US government will show similar confidence in industry's good faith.
- US implementing legislation for the protocol should mandate significant facility participation in the preparation and review of US declarations. This would decrease industry fear of being penalized for mistakes in declarations.
- To prevent any possible misunderstanding about the meaning of a non-challenge visit and to protect the reputation of visited industrial facilities, the US National Authority should provide the visited facility with a statement at the conclusion of each visit, thanking the facility for hosting the visit and citing its contribution toward world peace.

Conclusion

Strengthening the BWC with an effective compliance regime is a much-needed step toward protecting our country and the world against the growing threat of biological weapons. But the vital interests of US bioindustry must be guarded. The multiple stringent protections for CPI discussed here would shield US industry from undue risk without undermining the effectiveness of the compliance regime.