

Proposals for US Implementing Legislation for The Biological Weapons Convention Protocol¹

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The Biological Weapons Convention of 1972 (BWC)² prohibits the possession, development, and stockpiling of biological weapons but lacks verification measures. When the treaty was negotiated, many countries considered biological weapons to have little military utility, but it is increasingly apparent that others, including some signatories, disagree. The opportunity represented by the end of the cold war, as well as increasing suspicions and allegations that a few signatories were violating the Convention led the States Parties to agree to a politically-binding information exchange that started in 1987. When these "Confidence-Building Measures" appeared inadequate, international concern provided impetus for enhancing global security by negotiating a legally-binding regime to strengthen the effectiveness of the BWC. In 1991 a two-year study of the feasibility of measures to verify compliance was undertaken by verification experts from the Convention's Parties. The "VEREX" report, was presented at a Special Conference in 1994, which then established an Ad Hoc Group to negotiate a protocol to strengthen the BWC. Their mandate includes matters of trade and scientific cooperation as well as measures to promote compliance. The draft Protocol is to be presented to the States Parties at another Special Conference before the sixth BWC review conference is held in 2001.

The Protocol will address a number of areas including, among others: Compliance Measures, Confidentiality Provisions (i.e. for Confidential Business Information and National Security Information), Assistance and Protection Against Biological and Toxin Weapons, Scientific And Technological Exchange For Peaceful Purposes And Technical Cooperation, Confidence Building Measures, and National Implementation Measures.

Three major elements of the compliance regime under negotiation by the Ad Hoc Group are: (1) Annual declaration of dual-capable facilities; (2) challenge investigations; (3) non challenge visits. Dual-capable facilities are those that could be used for either BW or peaceful purposes. Both the Pharmaceutical Research and Manufacturers of America (PhRMA) and the Federation of American Scientists (FAS) support declarations and challenge investigations as elements of an effective Protocol, although the two groups disagree on some details of these Protocol elements. We also disagree on the value of non challenge visits, which include proposed transparency and declaration clarification visits. FAS believes that these visits are essential for an effective protocol; industry however does not believe their value overrides their risk to CBI and facility reputations. We agree, however, that managed access should apply to any and all on-site activities.³

On-site activities will almost certainly include challenge investigations based on evidence of non-compliance with the 1972 Convention. These investigations will require a vote of the Executive Council of States Parties to proceed. On-site activities may also include transparency visits to declared facilities and clarification visits to address questions arising from declarations that have not been resolved through a consultation process.

Managed access rules were developed for the Chemical Weapons Convention (CWC)⁴ with the help of the US chemical industry to protect confidentiality. Nearly identical managed access rules are in the draft (rolling) text of the BWC Protocol⁵, and may be adopted because of the wide support for such measures although differences in the issues for biologicals versus chemicals need to be addressed. The rules call first for negotiation between the visiting team and the visited State Party as to the extent and nature of access to particular places within the perimeter of the facility and the particular inspection activities to be conducted. States Parties may take such measures as they deem necessary to protect confidentiality, which inspection teams must fully respect. States Parties are obliged, however, to make every reasonable effort to provide alternative means to answer questions or concerns of the inspection team within the mandate of the visit.

FAS and PhRMA agree that industry's fears concerning possible loss of confidentiality during on-site activities could be reduced by US implementing legislation that maintains all inspectee's constitutional rights. Thus the Protocol also would have to be compatible with these rights.. Principally, the US implementing legislation should mandate that facility site managers, not the government, make all managed-access decisions during on-site activities, consistent with constitutional and national security requirements. The facility's management knows what is confidential business information, what information can be shared with the visiting team, and what are the best alternate means of satisfying requests of the visiting team.

FAS and PhRMA propose the following key points for inclusion in US implementing legislation:

- (The rules for, rights under, limits of, and obligations under managed access should be clearly defined in the Protocol and supported in the implementing legislation.
- (Site managers should have the right to make managed access decisions during on-site activities at non-governmental facilities.

Implementing legislation for any treaty essentially delegates implementation to individuals and groups, so delegating managed-access decisions to site managers would be consistent with precedent; it would also be consistent with search and seizure provisions of the US Constitution (4th Amendment).

- (Owners of the facilities should participate in the preparation and review of US declarations covering them, and both the US Government and the facility should approve the declaration before submission. In anticipation of possible disagreements, a resolution mechanism should be established prior to the declarations being required.
- (Industry and other relevant institutions should assist the US government in developing criteria for evaluating nominated inspectors, and the government should [solicit] and consider industry concerns when evaluating candidates. The US government should therefore notify owners of all declared facilities, publicly

announce the nominations of inspectors and invite comment before evaluating them.

- (We propose that the definition of confidential information in the Protocol and in US implementing legislation should parallel standard industry protections and exceptions for information already in the public domain. All participants in on-site activities should be subject to confidentiality agreements based on these standards.

Applying the standard legal language for exceptions to on-site activities under the Protocol would mean that: Proprietary Information shall not be deemed to include information that: (a) is in or becomes in the public domain without violation of this Agreement by the Inspectors; or (b) is already in the possession of Inspectors, as evidenced by written documents, prior to the disclosure thereof by the inspected facility; or (c) is rightfully received from a third entity having no obligation to the inspected facility and without violation of this Agreement by the Inspectors.

The industry strongly proposes including these key points in the implementing legislation, and FAS supports industry on these points.

Implementing legislation that is *in conformity with the Protocol* and protects the vital interests of US industry is essential for successful application of the Protocol in the United States. Inclusion of the points proposed here in the legislation, and development of the legislation in advance of ratification, would ease industry concerns regarding confidentiality and promote further industry support for the Protocol.

Notes:

1. Authors: Representing PhRMA, John J. Dingerdissen (Merck and Co., Inc.), Lynn Pritchard Ph.D (Glaxo, Inc.), Gillian R. Woollett PhD (PhRMA); representing FAS, Lynn C. Klotz PhD (biotechnology consultant), Marie I. Chevrier PhD (University of Texas, Dallas), Barbara Hatch Rosenberg PhD (State University of New York, Purchase), Mark Wheelis PhD (University of California, Davis).

2. The formal documents discussed in this paper, The BWC of 1972, the draft BWC Protocol (Rolling Text of October, 1999) and the Chemical Weapons Convention may be found on the FAS web site (www.fas.org) or the PhRMA web site (www.phrma.org).

3. Discussions of FAS and PhRMA positions on aspects of the BWC Protocol may be found on our web sites, www.fas.org and <http://www.phrma.org/srpub/bwc.html#phrma>

4. Convention on the Prohibition of the Development, Production, Stockpiling and Use of Chemical Weapons and on Their Destruction (Corrected version in accordance with Depositary Notification C.N.246.1994.TREATIES-5 and the corresponding Procès-

Verbal of Rectification of the Original of the Convention, issued on 8 August 1994), Part X, Paragraphs 38-52.

5. 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. BWC/AD HOC GROUP/47 (Part II) 20 October 1999 Sixteenth session Geneva, 13 September - 8 October 1999, Annex IV, Part G, Paragraph 29-35.