

The Regime To Prevent Biological Weapons: Opportunities For A Safer, Healthier, More Prosperous World

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Introduction

1. It has been argued that biological weapons -- the deliberate use of disease against humans, animals or plants -- presents the greatest danger of all weapons of mass destruction because the prohibition regime is currently the weakest.¹ In this paper, the prohibition regime for biological and toxin weapons is examined together with the developments over the past decade that have sought to strengthen that regime through the negotiations that are currently nearing completion in Geneva of a Protocol to strengthen the effectiveness and improve the implementation of the Biological and Toxin Weapons Convention.
2. The past decade has seen the States Parties engaged initially in the identification and examination of potential verification measures to strengthen the Convention and then in the negotiation of a Protocol to strengthen the effectiveness and improve the implementation of the Convention. This Protocol is now almost complete with the provision to delegations on 30 March 2001 of a Chairman's composite text . An overview of the Protocol will be presented outlining the central elements in the Protocol regime which include mandatory declarations, declaration follow-up procedures including randomly selected visits, declaration clarification procedures and assistance visits, investigations of alleged use or of non-compliance concerns, provisions to promote technical cooperation in microbiology and biotechnology for peaceful purposes together with an organization to implement the Protocol.
3. The elements of the regime are examined and compared with the comparable provisions in the Chemical Weapons Convention -- the arms control regime that is of the closest relevance to the Biological and Toxin Weapons Convention as both address toxins and both address dual use materials and technology. The paper will demonstrate that all the different elements of the verification regime are inter-related and together will have a considerable synergistic effect that will build confidence in compliance with the Convention, ensure that uncertainties, anomalies and concerns are swiftly investigated and improve the implementation of the Convention. It will also show that the strengthened regime is an important counter to the possible use of biological weapons by terrorist groups. Finally, the Protocol regime will be considered in the wider context of the international initiatives to counter outbreaks of disease, to protect the environment through the Convention on Biological Diversity and the Cartagena Protocol on Biosafety and to harmonise Good Manufacturing Practice around the world for pharmaceutical and biological products. These all share common objectives and together contribute towards a safer, healthier and more prosperous world.

Background

¹Graham S. Pearson, *Why Biological Weapons Present The Greatest Danger*, Seventh International Symposium on Protection Against Chemical and Biological Warfare Agents, Stockholm, Sweden, 15 - 19 June 2001.

4. Following the extensive use of chemical weapons during World War I, there was international agreement in 1925 to prohibit the use in war of asphyxiating, poisonous and other gases, and of bacteriological methods of warfare with the agreement of the Geneva Protocol² signed on 17 June, just over 76 years ago. As some of the States Parties entered reservations which stated that (a) the Protocol was only binding on that State Party as regards States that have signed or ratified the Protocol or may accede to it, and (b) the Protocol would cease to be binding on that State Party in regard to any enemy State whose armed forces or whose allies fail to respect the prohibitions laid down in the Protocol, the prohibition was in essence a prohibition of first use as those States Parties which had entered reservations were reserving the right to retaliate in kind should such weapons be used against them. It should, however, be noted that following the entry into force of the Biological and Toxin Weapons Convention (BTWC) in 1975 and the Chemical Weapons Convention (CWC) in 1997, most of the States parties to the Geneva Protocol who entered reservations have today given these reservations up.

5. During World War II there was considerable concern about the possible use of chemical and biological weapons and a number of countries developed retaliatory capabilities so as to be able to retaliate in kind should chemical or biological weapons be used against them.³ The work on biological weapons during World War II and in the post war years demonstrated that biological weapons would be effective by all means short of actual use. It is evident that in the immediate post war years that biological weapons were seen as a potent weapon of mass destruction capable of being used against humans, animals or plants and consequently considerable priority was given then to national programmes to develop biological weapons.

6. Nuclear weapons were also being urgently developed during the post war period and by the 1950s it was becoming clear that nuclear weapons were perceived as a more attractive ultimate weapon and the national programmes to develop biological weapons were terminated in a number of countries. This led to the negotiation in the late 1960s of the first international treaty to prohibit an entire class of weapons -- the Biological and Toxin Weapons Convention⁴ which was opened for signature on 10 April 1972 and entered into force when 22 countries had ratified the Convention on 26 March 1975. As of March 2001, the BTWC has 143 States Parties and 18 Signatory States⁵.

The Biological and Toxin Weapons Convention

²League of Nations, *Protocol for the Prohibition of the Use in War of Asphyxiating, Poisonous and Other Gases, and of Bacteriological Methods of Warfare*, signed at Geneva, June 17, 1925, Vol. XCIV, 1929, Nos 1,2,3 and 4, p.65

³For a history of the developments in biological weapons up to 1945 see Erhard Geissler & John Courtland-Moon (eds), *Biological and Toxin Weapons: Research, Development and Use from the Middle Ages to 1945*, Stockholm International Peace Research Institute, Oxford University Press, 1999.

⁴United Nations, *Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction*, General Assembly resolution 2826 (XXVI), 16 December 1971.

⁵United Nations, Preparatory Committee for the Fifth 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, *List of 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/CONF.V/PC/INF.5, 20 April 2001.

7. The basic prohibition is in Article I of the Convention which states that:

Each State Party to this Convention 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, **of 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. [Emphasis added]

This is a comprehensive prohibition which is strengthened by the General Purpose Criterion - the words emphasised in bold -- which ensures that the prohibition extends to any biological agent or toxin, however produced, that has no justification for peaceful purposes. This General Purpose Criterion ensures that the prohibition covers not only past biological agents but also any future developments. As will be shown later, the extension of the prohibition to cover all developments in microbiology and biotechnology is achieved through reaffirmations to this effect by the successive Review Conferences of the BTWC.

8. Another important obligation arising from the Convention relates to transfers which are addressed in Article III that states that:

Each State Party to this Convention undertakes not to transfer to any recipient whatsoever, directly or indirectly, and not in any way to assist encourage, or induce any State, group of States or international organizations to manufacture or otherwise acquire any of the agents, toxins, weapons, equipment or means of delivery specified in Article I of the Convention.

This effectively places a responsibility on each State Party to satisfy itself that any transfer of agents or equipment will not be used for prohibited purposes.

9. A further requirement in Article IV is for each State Party to take any necessary measures to implement the Convention in its territory or under its jurisdiction or control:

Each State Party to this Convention 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.

Several States Parties have enacted legislation to meet this requirement. One example is the UK Biological Weapons Act of 1974⁶ which states that:

No person shall develop, produce, stockpile, acquire or retain

⁶Her Majesty's Stationery Office, *Biological Weapons Act 1974*, 8 February 1974.

(a) any biological agent or toxin of a type and in a quantity that has no justification for prophylactic, protective or other peaceful purposes; or

(b) any weapon, equipment, means of delivery designed to use biological agents or toxins for hostile purposes or in armed conflict.

and goes on to state that any person contravening this shall be guilty of an offence and shall, on conviction on indictment, be liable to imprisonment for life.

10. A further Article in the BTWC which has attracted much attention in recent years is Article X which addresses the exchange of equipment, materials and scientific and technical information for peaceful purposes:

(1) The States Parties to this Convention 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. Parties to the Convention in a position to do so shall also cooperate in contributing individually or together with other States or international organisations to the further development and application of scientific discoveries in the field of bacteriology (biology) for the prevention of disease, or for other peaceful purposes.

(2) This Convention shall be implemented in a manner designed to avoid hampering the economic or technological development of States Parties to the Convention or international cooperation in the field of peaceful bacteriological (biological) activities, including the international exchange of bacteriological (biological) agents and toxins and equipment for the processing, use or production of bacteriological (biological) agents and toxins for peaceful purposes in accordance with the provisions of the Convention.

11. Finally, Article XII sets out the requirement for periodic Review Conferences:

Five years after the entry into force of this Convention... a conference of States Parties to the Convention shall be held at Geneva, Switzerland, to review the operation of the Convention, with a view to assuring that the purposes of the preamble and provisions of the Convention ... are being realized. Such review shall take into account any new scientific and technological developments relevant to the Convention.

Review Conferences have been held in 1980, 1986, 1991, 1996 and the fifth one is scheduled for 19 November to 7 December 2001. At each Review Conference a Final Declaration is agreed by States Parties by consensus which provide extended understandings of the Convention.

12. The review of the relevant advances in science and technology is of particular importance as this enables the States Parties to reaffirm that all such advances are included in the basic

prohibition. Thus in 1996 at the Fourth Review Conference the Final Declaration⁷ stated that:

The Conference, conscious of apprehensions arising from relevant scientific and technological developments, inter alia, in the fields of microbiology, biotechnology, molecular biology, genetic engineering and any applications resulting from genome studies, and the possibilities of their use for purposes inconsistent with the objectives and the provisions of the Convention, reaffirms that the undertaking given by the States Parties in Article I applies to all such developments. [Emphasis added]

This reaffirmation makes it clear that all developments in the fields of microbiology and biotechnology are embraced in the basic prohibition in Article I of the Convention and thus that no such developments are excluded from the scope of the Convention.

13. Also at the Fourth Review Conference the States Parties usefully reaffirmed that the use of biological or toxin weapons is prohibited. There was language in the Final Declaration on both Article I (which addresses the basic prohibition):

The Conference reaffirms that the use by States Parties, in any way and under any circumstances, of microbial or other biological agents or toxins, that is not consistent with prophylactic, protective or other peaceful purposes, is effectively a violation of Article I of the Convention.

as well as on Article IV (which addresses national implementation measures):

The Conference reaffirms that under all circumstances the use of biological agents and toxins is effectively prohibited by the Convention.

These statements effectively extend the understanding by States Parties that use is prohibited, in any way and under any circumstances. The BTWC does not explicitly address use in its text although the Preamble contains the following:

Determined for the sake of all mankind, to exclude completely the possibility of bacteriological (biological) agents and toxins being used as weapons,

which makes it clear that the intention of the Convention is to exclude the possibility of use. The extended understanding at the Fourth Review Convention makes it clear that use would be regarded as a violation of Article I of the Convention and is thus a valuable strengthening of the Convention.

Strengthening the Biological and Toxin Weapons Convention

⁷ United Nations, *The Fourth 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*, Geneva, 25 November – 6 December 1996, BWC/CONF.IV/9, Geneva, 1996.

14. Steps have also been taken by successive Review Conferences to take other steps to strengthen the Convention. In 1986 at the Second Review Conference⁸ the States Parties agreed to implement some confidence-building measures:

1. Exchange of data, including name, location, scope and general description of activities, on research centres that meet very high national or international safety standards
2. Exchange of information on all outbreaks of infectious disease and similar occurrences caused by toxins that seem to deviate from the normal pattern
3. Encouragement of the publication of results of biological research directly related to the Convention
4. Active promotion of contacts between scientists engaged in biological research directly related to the Convention.

15. These confidence-building measures were amended and extended at the Third Review Conference⁹ in 1991 and three additional measures were also added:

* A simplified proforma on which to indicate "Nothing to declare" or "Nothing new to declare" was introduced

1. The exchange of data on research centres and laboratories (CBM A, Part 1 & Part 2), extended to include information on biological defence programmes and activities
2. The exchange of information on outbreaks of disease and similar occurrences caused by toxins (CBM B), and
3. The active promotion of contacts (CBM D).
4. The encouragement of publication of results and promotion of use of knowledge (CBM C)

The three new confidence-building measures were:

5. Declaration of legislation, regulations and other measures (CBM E),
6. Declaration of past activities in offensive and/or defensive biological research and development programmes (CBM F), and
7. Declaration of vaccine production facilities (CBM G).

⁸ United Nations, *The 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*, Geneva, 8 - 26 September 1986, BWC/CONF.II/13, Geneva, 1986.

⁹ United Nations, *The 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*, Geneva, 9 - 27 September 1991, BWC/CONF.III/23, Geneva, 1991.

16. However, the provision of information by the States Parties has been variable and patchy with only just over half of all States Parties making a single declaration and about 11 making the agreed annual declarations. The information provided under these confidence-building measures to the UN Department of Disarmament Affairs is simply collated and circulated to States Parties. There is no translation into other languages or any analysis of the information provided. The contribution to the declared aim of enhancing confidence in the implementation of the Convention is thus minimal.

VEREX

17. In addition, the Third Review Conference in 1991 stated in their Final Declaration that:

The Conference, determined to strengthen the effectiveness and improve the implementation of the Convention and recognising that effective verification could reinforce the Convention, decides to establish an Ad Hoc Group of Governmental Experts, open to all States Parties to identify and examine potential verification measures from a scientific and technical viewpoint.

The Group was to be chaired by Ambassador Tibor Toth of Hungary and to hold meetings to complete the work as soon as possible, preferably before the end of 1993.

18. The mandate for the Group required that measures be identified which could determine:

- *Whether a State Party is developing, producing, stockpiling, acquiring or retaining microbial or other biological agents or toxins, of types and in quantities that have no justification for prophylactic, protective or peaceful purposes;*
- *Whether a State Party is developing, producing, stockpiling, acquiring or retaining weapons, equipment or means of delivery designed to use such agents or toxins for hostile purposes or in armed conflict.*

Such measures could be addressed singly or in combination and were to be examined in terms of six main criteria:

- *Their strengths and weaknesses based on, but not limited to, the amount and quality of information they provide, and fail to provide;*
- *Their ability to differentiate between prohibited and permitted activities;*
- *Their ability to resolve ambiguities about compliance;*
- *Their technology, material, manpower and equipment requirements;*
- *Their financial, legal, safety and organizational implications;*
- *Their impact on scientific research, scientific cooperation, industrial development and other permitted activities, and their implications for the confidentiality of commercial proprietary information.*

19. The group should adopt by consensus a report on its work which would be circulated to all States Parties for their consideration. A Special Conference of States Parties to decide on

any further action would be then convened should a majority of States Parties request such a Conference.

20. The Ad Hoc Group (known as VEREX) met four times on:

- a. 30 March - 10 April 1992
- b. 23 November - 4 December 1992
- c. 24 May - 4 June 1993, and
- d. 13 - 24 September 1993

It identified and evaluated some 21 potential measures which were divided into two categories:

Off-site Measures

- Surveillance of publications
- Surveillance of legislation
- Data on transfers, transfer requests and production
- Multilateral information sharing
- Exchange visits (off-site)
- Declarations
- Surveillance by satellite
- Surveillance by aircraft
- Ground-based surveillance (off-site)
- Sampling and identification (off-site)
- Observation (off-site)
- Auditing (off-site)

On-site Measures

- Exchange visits - international arrangements
- Interviewing (on-site)
- Visual inspection (on-site)
- Identification of key equipment (on-site)
- Auditing (on-site)
- Sampling and identification (on-site)
- Medical examination (on-site)
- Continuous monitoring by instruments (on-site)
- Continuous monitoring by personnel (on-site)

21. In addition, VEREX evaluated some illustrative measures in combination. Its final report was prepared in September 1993 and circulated to all States Parties. The final report¹⁰ stated that:

¹⁰United Nations, *Ad Hoc Group of Governmental Experts to Identify and Examine Potential Verification Measures from a Scientific and Technical Standpoint*, Report BWC/CONF.III/VEREX/9, Geneva 1993.

The measure "Declarations" was most frequently identified for application in combination with other measures. The most frequently identified on-site measures in combination were on-site inspections (interviewing, visual inspection, identification of key equipment, sampling and identification, auditing). This does not mean that all the measures in parenthesis above always would be included in an on-site inspection.

The final report of VEREX concluded that:

The Ad Hoc Group of Governmental Experts concluded that the potential verification measures as identified and evaluated could be useful in varying degrees in enhancing confidence, through enhanced transparency, that the States Parties were fulfilling their obligations under the BWC. While it was agreed that reliance could not be placed on any single measure to differentiate conclusively between prohibited and permitted activity and to resolve ambiguities about compliance, it was also agreed that the measures could provide information of varying utility in strengthening the BWC.Some measure in combination could provide enhanced capabilities by increasing, for example, the focus and improving the quality of information, thereby improving the possibility of differentiating between prohibited and permitted activities and of resolving ambiguities about compliance.

Based on the examination and evaluation of the measures described above against the criteria given in the mandate, the Group considered, from the scientific and technical standpoint, that some of the potential verification measures would contribute to strengthening the effectiveness and improve the implementation of the Convention, also recognising that appropriate and effective verification could reinforce the Convention.

Following circulation of the VEREX Final Report to States Parties, a majority requested that a Special Conference be convened to consider the final report of VEREX and this Special Conference was held on 19 - 30 September 1994.

The Ad Hoc Group

22. At the Special Conference¹¹, States Parties agreed to establish a further Ad Hoc Group with the objective being 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. In this context, the Ad Hoc Group shall, inter alia, consider:

- *Definitions of terms and objective criteria, such as lists of bacteriological (biological) agents and toxins, their threshold quantities, as well as equipment and types of activities, where relevant for specific measures designed to strengthen the Convention;*
- *The incorporation of existing and further enhanced confidence building and transparency measures, as appropriate, into the regime;*

¹¹United 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, BWC/SPCONF/1 Geneva, 19–30 September 1994.

- *A system of measures to promote compliance with the Convention, including, as appropriate, measures identified, examined and evaluated in the VEREX Report. Such measures should apply to all relevant facilities and activities, be reliable, cost effective, non-discriminatory and as non-intrusive as possible, consistent with the effective implementation of the system and should not lead to abuse;*

- *Specific measures designed to ensure effective and full implementation of Article X, which also avoid any restrictions incompatible with the obligations undertaken under the Convention, noting that the provisions of the Convention should not be used to impose restrictions and/or limitations on the transfer for purposes consistent with the objectives and the provisions of the Convention of scientific knowledge, technology, equipment and materials.*

The mandate also required that

- Measures should be formulated and implemented in a manner designed to protect sensitive commercial proprietary information and legitimate national security needs.

- Measures shall be formulated and implemented in a manner designed to avoid any negative impact on scientific research, international cooperation and industrial development.

The remit for the Ad Hoc Group also made it clear that "*the regime would include, inter alia, potential verification measures, as well as agreed procedures and mechanisms for their efficient implementation and **measures for the investigation of alleged use.***" [Emphasis added].

23. The Ad Hoc Group held its first meeting in January 1995 and by June 2001 has held 23 meetings. Its next meeting, the twenty-fourth, will be held for four weeks from 23 July to 17 August 2001. In July 1997 the Ad Hoc Group successfully transitioned to the negotiation of a rolling text of the Protocol. The 15th draft Protocol¹² was issued in February 2000 following the twenty-second session of the Ad Hoc Group. This is essentially complete with only a few remaining issues still to be resolved. On 30 March 2001, Ambassador Tibor Tóth, The Chairman of the Ad Hoc Group issued to delegations his composite text¹³ which is firmly based on the rolling text of the Protocol; indeed, over 99 per cent of the language in the Chairman's composite Protocol text is language that is already in the rolling text. The composite Protocol text has adopted compromises, based on the written elements of the text issued by the Chairman following his extensive and intensive bilateral negotiations over the last nine months with delegations to explore conceptual solutions based on the rolling text, to address the remaining issues where there were differing views. At the twenty-third session of the Ad Hoc Group held from 23 April to 11 May 2001, it was evident that whilst all States Parties had reservations about some of the compromises adopted, a number of States regarded the Chairman's composite Protocol text as the basis for further negotiation.

¹²United Nations, *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*, BWC/AD HOC GROUP/55-1 and 55-2, 1 March 2001, Geneva.

¹³United Nations, *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/CRP.8(FUTURE), 30 March 2001, Geneva.

24. The following Table provides a comparison between the composite Protocol text (CRP.8) and the latest version of the rolling text (AHG/55).

Composite Protocol text (CRP.8)	Previously in rolling text (AHG/55-1 & 55-2)
Preamble	Preamble
Article 1 General Provisions	Article I General Provisions
Article 2 Definitions	Article II Definitions
Article 3 Lists and Criteria, Equipment and Thresholds	Article III A, B, C Lists and Criteria, Equipment and Thresholds
Article 4 Declarations	Article III D I Declarations
Article 5 Measures to ensure submission of declarations	Article III D III Measures to ensure submission of declarations
Article 6 Follow-up after submission of declarations	Article III D II Follow-up after submission of declarations
Article 7 Measures to strengthen implementation of Article III of the Convention	Article III F Measures to strengthen implementation of Article III (of the Convention)
Article 8 Consultation, Clarification and Cooperation	Article III E Consultation, Clarification and Cooperation
Article 9 Investigations	Article III G Investigations
Article 10 Additional provisions on declarations, visits and investigations	Article III H Additional provisions on declarations, visits and investigations
Article 11 Confidentiality provisions	Article IV Confidentiality provisions
Article 12 Measures to redress a situation and to ensure compliance	Article V Measures to redress a situation and to ensure compliance
Article 13 Assistance and protection against bacteriological (biological) weapons	Article VI Assistance and protection against bacteriological (biological) weapons
Article 14 Scientific and technological exchange for peaceful purposes and technical co-operation	Article VII Scientific and technological exchange for peaceful purposes and technical co-operation
Article 15 Confidence-building measures	Article VIII Confidence-building measures
Article 16 The Organization	Article IX The Organization
Article 17 National implementation measures	Article X National implementation measures
Article 18 Relationship of the Protocol to the Convention	Article XI Relationship of the Protocol to the Convention
Article 19 Settlement of disputes	Article XII Settlement of disputes
Article 20 Review of the Protocol	Article XIII Review of the Protocol
Article 21 Amendments	Article XIV Amendments
Article 22 Duration and Withdrawal	Article XV Duration and Withdrawal
Article 23 Status of the Annexes and Appendices	Article XVI Status of the Annexes and Appendices
Article 24 Signature	Article XVII Signature
Article 25 Ratification	Article XVIII Ratification
Article 26 Accession	Article XIX Accession

Composite Protocol text (CRP.8)	Previously in rolling text (AHG/55-1 & 55-2)
Article 27 Entry into Force	Article XX Entry into Force
Article 28 Reservations	Article XXI Reservations
Article 29 Depositary	Article XXII Depositary
Article 30 Authentic Texts	Article XXIII Authentic Texts

25. In this paper, reference is made primarily to the Chairman's composite Protocol text with references to the corresponding rolling text provided in parentheses.

26. The principal elements in the Protocol are the following:

- Article 4 Declarations
- Article 5 Measures to ensure submission of declarations
- Article 6 Follow-up after submission of declarations
- Article 7 Measures to strengthen implementation of Article III of the Convention
- Article 8 Consultation, Clarification and Cooperation
- Article 9 Investigations

(in the rolling text Article III Compliance Measures

-- declarations; declaration follow-up procedures; declaration clarification procedures; voluntary assistance visits; consultation, clarification and cooperation; and investigations.

and Article III F

-- measures to strengthen implementation of Article III of the Convention (non-transfer obligations))

Article 13 Assistance and protection against bacteriological (biological) weapons
(Article VI)

Article 14 Scientific and technological exchange for peaceful purposes and technical co-operation (Article VII)

Article 16 The Organization (Article IX)

Article 17 National implementation measures (Article X)

The essential provisions in each of these principal elements are considered in turn.

Article 4: Declarations

27. The requirements for initial and annual declarations are as follows:

Initial Declarations

Offensive biological and toxin weapons programmes from 1 January 1946 until the entry into force of the Convention for the State Party

Defensive biological and toxin weapons programmes for ten years prior to the entry into force of the Protocol for the State Party

Annual Declarations

Defensive biological and toxin weapons programmes during the previous year

Maximum biological containment (BL-4) facilities

High biological containment (BL-3) facilities

Plant pathogen containment facilities

Work with listed agents and/or toxins

Production facilities

Article 5: Measures to ensure the submission of declarations

28. The measures to ensure submission of declarations which consist of the following:

- a. Director-General to issue written request for overdue declarations
- b. Director-General to report to each Conference of the States Parties and Executive Committee on the implementation of the declaration obligations
- c. If initial declarations are 12 months late or annual declarations 6 months late, the State Party shall not have access to declarations submitted by other States Parties
- d. The Executive Council/ shall decide on whether to invoke further measures such as denial of declaration clarification procedures, removal of vote in the and suspension of Executive Council membership
- e. If initial declarations are 24 months late or annual declarations 12 months late, then the State Party shall have no vote in the Conference of the States Parties and it shall not be eligible for election to the Executive Council, and if already a member of the Executive Council then it shall be suspended from membership.

These provisions largely to ensure the submission of declarations are as a result of the experience under the CWC when several declarations were very late in being submitted.

Article 6: Follow-up after submission of declarations

29. Declaration follow-up procedures require the Technical Secretariat to process and make a technical analysis of the declarations and to carry out a limited number per year of randomly-selected transparency visits to declared facilities in order to increase confidence in the consistency of declarations with the activities seen during a visit and encouraging submission of complete declarations. The total number of such visits will be limited initially to not more than 90 and not less than 60 per year; no State Party shall receive more than seven such visits in any calendar year, each State party that declares facilities shall receive at least two such visits in any five year period, and no individual facility shall receive more than three such

visits in any five year period. The visiting team will not exceed four and the duration of the visit will not exceed two working days unless an extension is agreed by the visiting team and the visited State Party. If requested by the visited State Party, the visit can be extended by up to two days to provide advice on scientific and technical exchange and cooperation under Article 14 of the Protocol or on Protocol implementation assistance.

30. Article 6 also includes declaration clarification procedures to address any ambiguity, uncertainty, anomaly or omission in a declaration. There are tiered provisions: first, clarification is sought in writing. If this fails to resolve the matter, then a consultative meeting will be held to address the issue in the capital of the State Party and then if this fails to resolve the matter a voluntary clarification visit may be requested. No State Party shall receive more than five such clarification visits in any five year period; the size of the visiting team shall not exceed four and the duration of the visit is in no case to exceed 2 days. There are safeguards so that if a State Party declines to offer a voluntary clarification visit then the matter can be referred to the Executive Council. Insofar as an omission of a facility that appears to meet the criteria for declaration as set out in Article 4, this can be addressed either through this procedure or through the provisions of Article 8 for consultation, clarification and cooperation.

31. In addition, Article 6 includes provisions for the Technical Secretariat to carry out visits to provide technical assistance and information under Article 14 or to provide Protocol implementation assistance. The total number in any year shall be not less than 6 and not more than 30 with the size of the visiting team and the duration of the visit to be agreed between the Director-General and the State Party requesting the assistance.

Article 7: Measures to strengthen implementation of Article III of the Convention

32. Article 7 addresses measures to strengthen the implementation of Article III of the Convention -- the obligation on States Parties not to transfer agents, materials or equipment for purposes prohibited under the Convention. Article 7 has been developed from the provisions and language in Article III. F. of the rolling text and has been restructured thereby improving clarity into five sections:

- A. Implementing Legislation*
- B. Transfer Guidelines*
- C. Notifications*
- D. Consultations*
- E. Review*

a. **Section A** on implementing legislation contains language from Article III. F of the rolling text requiring States parties to review, amend or establish any legislation, regulatory or administrative provisions to regulate the transfer of agents, toxins, equipment and technologies relevant to the Convention, providing assistance from the Technical Secretariat in this respect and requiring States Parties to report any legislative, regulatory or administrative provisions or other measures it has taken to implement Article III of the Convention.

b. **Section B** on transfer guidelines draws upon language from Article III. F of the rolling text and requires States Parties to take all measures they deem necessary to ensure that obligations under Article III of the Convention are implemented fully and

effectively. Measures are also required to ensure that transfers to any recipient whatsoever of dual-use items are only used for prophylactic, protective or other peaceful purposes; these may include four measures which are set out. Four particular dual-use items are identified to which such measures are to be applied to ensure that their use is only for prophylactic, protective or other peaceful purposes are to be taken.

c. **Section C** on notifications requires States Parties to use the reporting format in Appendix I to notify the Director-General annually of aggregate data on exports of the four particular dual-use items identified in Section B.

d. **Section D** on consultations provides for States Parties to consult among themselves on the implementation of the provisions of this Article and also with a view to specifying the context of a request for a transfer. It also provides for a State Party, which has a concern that an authorised transfer could be in violation of Article III of the Convention, to consult directly with the transferring State Party. Additional supporting information that might be provided during these consultations is elaborated.

e. **Section E** provides for the first Conference of States Parties held after the first Review Conference of the Protocol to review the operation of the provisions of this Article and to consider whether the introduction of restrictions or prohibitions on transfer to States not party to the Protocol or the Convention of the four particular dual-use items identified in Section B would further universal adherence to the Protocol. Subsequent Review Conferences shall keep under review the provisions of this Article.

33. Article 7 has struck a balance between the range of different views as to how the implementation of Article III of the Convention should be improved. It was concluded in the University of Bradford Briefing Paper No 33¹⁴ in February 2001 that:

The issue of how to improve the implementation of Article III of the Convention has been an emotive and sensitive topic for the Ad Hoc Group. In a world in which transfers of dual use materials – whether of chemicals, biological agents or drugs – are increasingly being monitored and controlled, it is not an option to ignore measures to improve the implementation of Article III of the Convention. It is also unrealistic to consider the removal of such monitoring and controls between States Parties as the trend is the opposite. However, under a regime in which there is greater transparency as to what transferred materials are to be used for and are used for together with assurances that there are the necessary national internal and interstate controls of transfers, the probability over time will increase that transfers between States Parties will be made. A pragmatic approach would be to make provision for some initial controls of transfers of both biological agents and equipment, with a requirement for States Parties to report to the Organization annually on such transfers, along with provisions enabling this transfer regime to be reviewed and developed by States Parties at the Review Conferences of the Protocol.

¹⁴Graham S. Pearson, *The BTWC Protocol: Improving the Implementation of Article III of the Convention: Pragmatic Considerations*, University of Bradford, Department of Peace Studies, Briefing Paper No. 33, February 2001.

34. Article 7 has successfully addressed the difficult issue of how to improve the implementation of Article III of the Convention through requiring States Parties to take necessary implementing legislation; setting out transfer guidelines; requiring annual notifications of aggregate data for four particular dual-use items; providing for consultations; and requiring the implementation of these provisions to be kept under review. The approach adopted in Article 7 provides a reasonable compromise that will contribute over time to the strengthened effectiveness and improved implementation of the Convention.

Article 8: Consultation, Clarification and Cooperation

35. The Protocol makes provision for the States Parties to consult and cooperate on any matter relating to the Convention, or to the implementation of the Protocol, and to clarify and resolve any matter which may cause concern about possible non-compliance with the obligations of this Protocol or the Convention. Procedures are elaborated including requests for written clarification, involvement of the Director-General or of the Executive Council. There is an expectation -- but not a requirement -- that these procedures are likely to be invoked prior to a State Party requesting an investigation.

Article 9: Investigations

36. The Protocol includes provision that *"Each State Party shall have the right to request an investigation...for the sole purpose of determining the facts relating to a specific concern about possible non-compliance with the Convention by another State Party."* Two types of investigation are detailed:

a. Field investigations to be carried out *"in geographic areas where the release of, or exposure of humans, animals or plants, to microbial or other biological agents and/or toxins has given rise to a possible concern about possible non-compliance under Article I of the Convention or use of bacteriological (biological) and/or toxin weapons"*, and

b. Facility investigations to be carried out *"inside the perimeter around a particular facility at which there is a substantive basis for a concern that it is involved in activities prohibited by Article I of the Convention"*.

37. The provisions for a field investigation require the request from the State Party to include detailed evidence to substantiate that an outbreak of disease is not naturally occurring and is directly related to activities prohibited by the Convention. The provisions for a facility investigation require the request from the State Party to include a description of the specific event or activity which gave rise to a non-compliance concern, including specific information regarding agents and delivery means.

38. A request for an investigation has to be considered by the Executive Council with different decision-making procedures being followed depending on the particular circumstances relating to the investigation:

a. A request for a field investigation of alleged use of biological weapons on the territory or other place under the control of the requesting State Party shall proceed unless a three-quarters majority of members present and voting decide otherwise.

b. A request for a field investigation of alleged use of biological weapons on the territory or other place under the control of another State Party shall proceed unless a simple majority of members present and voting decide otherwise.

c. A request for a field investigation on the territory or other place under the control of a requesting State Party where there is a concern that an outbreak of disease is related to prohibited activities shall proceed unless two-thirds of members present and voting decide otherwise.

d. A request for a field investigation on the territory or other place under the control of another State Party when there is a concern that an outbreak of disease is related to prohibited activities shall proceed only if approved by a simple majority of members present and voting.

e. A request for a facility investigation should proceed only if approved by a simple majority of members present and voting.

The key thing is that in all these cases an investigation will take place if the Executive Council so decides thereby providing the Protocol with the essential ultimate measure to address concerns about non-compliance with the Convention.

39. A field investigation will be carried out by an investigation team that will not exceed 30 persons who will be full time Technical Secretariat staff who may, if necessary, be supplemented by previously designated and trained ad hoc experts nominated by States Parties. The duration of the investigation is not to exceed 30 days.

40. A facility investigation will be carried out by an investigation team that will not exceed 25 persons who will all be full time Technical Secretariat staff. The duration is not to exceed 84 hours.

Article 13: Assistance and protection against bacteriological (biological) weapons

41. This is closely similar to the corresponding provisions in *Article X Assistance and Protection against Chemical Weapons* of the CWC. The Protocol includes the provision that nothing shall impede the right of a State party to carry out work on protection against biological and toxin weapons. The Technical Secretariat is required to establish a data bank on protection against biological and toxin weapons and to provide assistance to States Parties, if so requested, on protection against biological and toxin weapons. In addition, each State Party undertakes to provide assistance to the extent possible, including measures such as making contributions to a voluntary fund. A State Party can request assistance and protection if it considers that biological or toxin weapons have been used against it.

Article 14: Scientific and Technical Exchange for Peaceful Purposes and Technical Cooperation

42. This Article is much more extensive than the corresponding Article XI *Economic and Technological Development* in the CWC reflecting the emphasis placed in the mandate of the Ad Hoc Group of inter alia measures to ensure the full and effective implementation of Article X of the BTWC. The aim of Article 14 is to foster international cooperation for peaceful purposes. It provides for the Organization to provide a forum for consultation and creation of opportunities for cooperation with the Technical Secretariat to promote and

facilitate cooperation and technical exchange, to provide cooperation and assistance in visits as well as to provide Protocol implementation assistance. In addition the Organization is encouraged to develop cooperative relationships between States Parties and with relevant international organizations such as the WHO, OIE and FAO.

43. A wide range of cooperation topics are identified in the Article including:

- a. Collection and dissemination of information on peaceful uses
- b. Information on environmental release of genetically modified organisms (GMOs)
- c. Good Manufacturing Practice (GMP)
- d. Good Laboratory Practice (GLP)
- e. Biological containment
- f. Biosafety
- g. Diagnosis, surveillance, detection ,treatment and prevention of diseases caused by biological agents or toxins, and
- h. Regulations governing the handling, transportation, use and release of biological agents and toxins.

Article 16: The Organization

44. This is another Article that closely follows the corresponding *Article VIII The Organization* of the CWC. The principal organs of the Protocol Organization are:

- Conference of the States Parties (COSP)
- Executive Council
- Technical Secretariat

In addition, the COSP shall establish a Cooperation Committee and a Confidentiality Commission and may direct the Director-General to establish a Scientific Advisory Board.

45. The size of the Organization will depend on the number of visits to be made each year as well as on the number of States Parties. Various analyses based on a similar number of States Parties to the Protocol as to the Convention and about 100 visits a year, have suggested a strength of about 220 staff including some 70 inspectors and about 20 staff for international cooperation and assistance activities¹⁵ with an annual budget of about 30M US dollars -- less than half the size and budget of the OPCW (Organization for the Prohibition of Chemical Weapons).

Article 17: National Implementation Measures

46. This Article is closely similar to the parallel *Article VII National Implementation Measures* in the CWC. It requires each State Party to take any measures required to implement its obligations under the Protocol and in particular it shall enact penal legislation. Each State Party shall also designated or establish a National Authority to serve as the national focal point with the Organization and with other States Parties. In addition, each

¹⁵See Graham S. Pearson, *The Emerging Protocol: A Quantified Evaluation of the Regime*, University of Bradford, Department of Peace Studies, Briefing Paper No 27, November 1999. Graham S. Pearson, *An Optimum Organization*, University of Bradford, Department of Peace Studies, Briefing Paper No 5, January 1998. Both available at <http://www.brad.ac.uk/acad/sbtwc>.

State Party is required to inform the Organization of the legislation and administrative measures that it has taken to implement the Protocol.

Analysis of the Composite Protocol Text

47. It is evident from an evaluation¹⁶ of the composite Protocol text that it is in many areas identical to the language in the rolling text and is firmly based on the agreed language out of square brackets in the rolling text. Compromises have been adopted to address those issues where there continued to be a divergence of views. These compromises have emerged from the bilateral informal consultations held by the Chairman and have been explored through the written elements addressing conceptual solutions based on the rolling text which had been circulated by the Chairman for virtually the whole of the Protocol to all delegations by February 2001. Whilst these compromises will not satisfy the aspirations of all the delegations to the Ad Hoc Group, they do successfully ensure that the composite Protocol text achieves its mandate of strengthening the effectiveness and improving the implementation of the Convention. The composite Protocol text has successfully retained all the essential elements for an effective Protocol ranging from definitions and objective criteria, through compliance measures to measures for scientific and technological exchange for peaceful purposes and technical cooperation.

The Value of the Protocol

48. In considering the composite Protocol text, it is important to remember that the BTWC with its basic prohibitions and obligations has been **in force** for over 25 years and that the Protocol is to strengthen the effectiveness and improve the implementation of the Convention. It makes **no** changes to the basic prohibitions and obligations. The Protocol regime is supplementary and additional to the Convention.

49. The key comparison is thus between the BTWC Protocol regime and the BTWC alone, including the procedures devolved from its provisions. A tabulation of the principal measures in the regime, compared with the procedures of the BTWC alone, clearly brings out the significant benefits from the Protocol.

BTWC and its Protocol Regime	BTWC alone
Mandatory declarations -- measures to ensure submission	Confidence-Building Measures -- patchy and variable (if made)
Declaration follow-up procedures -- analysis of declarations -- randomly-selected transparency visits	None -- none -- none
Declaration clarification procedures -- clarification visits	None -- none
Voluntary assistance visits	None
Non-compliance concerns -- Consultations >>> Investigations	Art V consultation procedures Art VI complaint to UN Security Council

¹⁶Graham S. Pearson, Malcolm R. Dando & Nicholas A. Sims, *The Composite Protocol Text: An Effective Strengthening of the Biological and Toxin Weapons Convention*, University of Bradford, Department of Peace Studies, Evaluation Paper No. 20, April 2001. Available at <http://www.brad.ac.uk/acad/sbtwc>

Field investigation	Possible UN Secretary-General investigation if invited by State Party concerned
Facility investigation	None
Transfer procedures	None
Assistance -- provisions detailed	Art VII assistance if UN Security Council decides a Party has been exposed to danger
International Cooperation -- elaborated in detail -- Cooperation Committee	Art X provisions -- no implementation procedures -- none
Organization -- CoSP, ExC & Technical Secretariat	None
National implementation -- Penal legislation required -- National Authority	Art IV National implementation -- No penal legislation requirement -- None

50. Taking all of the elements of the BTWC Protocol regime as a whole, it is clear that there are overall three particularly **significant** benefits that will accrue from the BTWC Protocol regime and which are not available with the Convention alone:

BTWC and its Protocol Regime	BTWC alone
Measures to increase transparency and build confidence	Suspicious not addressed -- and over time reduce international confidence in the regime
Procedures to address non-compliance concerns	Art V consultations (no teeth) Art VI complaints to UN SC (not used)
International cooperation and assistance provisions	No action despite aspirations at successive Review Conferences

51. It is evident from the above comparisons that the Protocol regime brings significant and worthwhile benefits to all States Parties -- both developed and developing -- over and above the procedures to uphold the basic prohibitions and obligations of the BTWC, which remain unchanged. In addition, the Protocol will be effective, over time, in building confidence between States Parties that other States Parties are indeed in compliance with the Convention, thereby reinforcing the norm that work on biological weapons, whether directed against humans, animals or plants, is totally prohibited. The Protocol thus brings improved health, safety, security and prosperity to all States Parties.

The Relevance of the CWC to the Protocol

52. It is also appropriate to compare the BTWC Protocol regime with the CWC regime. The CWC regime is of considerable relevance to the BTWC Protocol regime for a number of reasons. First, there is a close relationship between chemical and biological weapons which is shown by the CBW spectrum:

Classical CW	Industrial Pharmaceutical Chemicals	Bioregulators Peptides	Toxins	Genetically Modified BW	Traditional BW
Cyanide Phosgene Mustard Nerve Agents	Aerosols	Substance P Neurokinin A	Saxitoxin Ricin Botulinum Toxin	Modified/ Tailored Bacteria Viruses	Bacteria Viruses Rickettsia Anthrax Plague Tularemia
← Chemical Weapons Convention →			← Biological and Toxin Weapons Convention →		
← Poison →			← Infect →		

This shows that the two Conventions -- the BTWC and the CWC -- rightly overlap in the area of toxins with the CWC listing two toxins -- ricin and saxitoxin in Schedule 1.

53. Both Conventions address dual-use materials and technology, both totally prohibit a class of weapons which cause death or harm to humans primarily through inhalation or ingestion, and both have general purpose criteria in their basic prohibition:

The BTWC in Article I requiring States Parties to undertake *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, of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes; [Emphasis added]

The CWC in Article I requiring States Parties to undertake never under any circumstances to develop, produce, otherwise acquire, stockpile or retain chemical weapons... with chemical weapons defined in Article II as meaning:

Toxic chemicals and their precursors, except where intended for purposes not prohibited under the Convention, as long as the types and quantities are consistent with such purposes; [Emphasis added]

54. In many countries, it is probable that the National Authorities for the CWC and the BTWC Protocol will be colocated. From all these considerations it is evident that the CWC is the regime of greatest relevance to the BTWC Protocol.

A Comparison of the BTWC Protocol and the CWC

55. It is hardly surprising that the BTWC Protocol regime has been largely developed from the CWC regime; it is, however, much more elaborated than the CWC and has been finely tailored to address those biological agents and facilities of greatest relevance to the Convention. There are, however, some particular differences between the CWC regime and the BTWC Protocol regime largely arising from the fact that the CWC came into force in

1997 with a number of States known to be possessors of chemical weapons and chemical weapon production facilities whilst the BTWC came into force over 25 years ago. These differences are summarised in the Table:

Differences

BTWC Protocol Regime	CWC Regime
Biological weapons (BW) not addressed (no declared stockpiles)	Chemical weapons (CW) declared
Biological weapon production facilities (BWPFs) not addressed	Chemical weapons production facilities (CWPFs) declared
Destruction of BW not addressed	CW to be destroyed and verified
Destruction of BWPF not addressed	CWPFs to be destroyed and verified
No tight timelines for declaration and verification	Tight timelines for the declaration and verification of CW, CWPF and their destruction
List of agents and toxins -- No equivalent to SSSF -- Declaration trigger	Scheduled chemicals -- Single Small Scale Facility (SSSF) -- Varying regime for different Schedules

56. If the CW and CWPF elements of the CWC are ignored, then the basic architecture of the BTWC Protocol regime and the CWC regime is the **same**. The differences between the regimes are in the detail with the BTWC Protocol regime having built on the confidence-building measures agreed at the Second Review Conference in 1986 and extended at the Third Review Conference in 1991 as well as being developed from the CWC regime. In respect of the monitoring of dual-purpose materials and facilities, the two regimes are very comparable with the Protocol regime imposing a less onerous but more focussed burden in respect of declarations and visits whilst the international cooperation provisions are much more extensive than those of the CWC. In comparing the BTWC Protocol regime with that of the CWC, the fact that the BTWC is **already** in force has to be remembered.

BTWC and its Protocol Regime	CWC Regime
Mandatory declarations -- range of facilities (BL-4, BL-3, production.. -- requires declaration of biological defence -- measures to ensure submission	Mandatory declarations -- focussed on production of chemicals -- no declaration of chemical defence -- no measures to ensure submission
Declaration follow-up procedures -- analysis of declarations -- randomly-selected transparency visits	Routine inspections of production facilities for Scheduled chemicals and DOCs (discrete organic chemical)

Declaration clarification procedures -- clarification visits	No declaration clarification procedures -- implicit not elaborated
Voluntary assistance visits	No provision for voluntary assistance visits -- implicit not elaborated
Non-compliance concerns -- Consultations >>> Investigations	Non-compliance concerns -- Consultations >>> Investigations
Field investigation	Investigation of alleged use
Facility investigation -- team size and duration limited	Challenge inspection -- duration limited
Transfer procedures	Transfer controls
Assistance -- provisions similar to CWC	Assistance
International Cooperation -- elaborated in detail -- Cooperation Committee	International Cooperation -- not elaborated in detail -- no provision for Cooperation Committee
Organization -- CoSP, ExC & Technical Secretariat	Organization -- CoSP, ExC & Technical Secretariat
National implementation -- Penal legislation required -- National Authority	National implementation -- Penal legislation required -- National Authority

57. The BTWC Protocol regime is much more elaborated throughout with much more constraint on the Organization and its activities than in the CWC. This greater constraint has arisen in part from the reactions of States Parties to their experience and their perceptions during the early stages in the implementation of the CWC and in part from the perception that commercial confidentiality is more important in microbiological and biotechnological facilities. There has frequently been a failure to recognise that under the CWC regime as two toxins -- ricin and saxitoxin -- are included as Schedule 1 chemicals, there could be a challenge inspection under the CWC of a microbiological or biotechnological facility and that the BTWC Protocol regime does not therefore necessarily present a greater challenge to commercial confidentiality in such facilities.

58. The BTWC Protocol regime also contains provisions that have no equivalent in the CWC regime -- examples are the measures to ensure submission of declarations (which clearly reflect the CWC experience where some States Parties were very late in submitting declarations of Scheduled chemical facilities) and the much greater attention given in the Protocol to technical cooperation to peaceful purposes. It is noteworthy that the Director-General of the OPCW has recently been emphasising the importance to the CWC regime of the technical cooperation and assistance aspects when he said¹⁷ that *"The fostering of international cooperation in the peaceful application of chemistry is more than a desirable spin-off of our Organisation's work. It is in fact at one and the same time one of its foundation blocks and one of the Convention's strategic objectives."* He went on to say that *"Enhanced international cooperation is also a powerful tool to attract countries that have yet to join the Convention's regime The fostering of international cooperation is thus an important instrument for making the Convention a truly universal and steadfast norm against chemical warfare."* The value of fostering scientific and technical exchange and

¹⁷Organisation for the Prohibition of Chemical Weapons, *Statement by the Director-General under Agenda Item Seventeen: Fostering International Cooperation for Peaceful Purposes in the Field of Chemical Activities*, Conference of the States Parties, Fifth Session, 15 -19 May 2000, C-V/DG.13, 18 May 2000.

international cooperation for peaceful purposes -- and its contribution to increasing transparency and enhancing confidence -- has been recognized clearly in the negotiation of the BTWC Protocol regime and has resulted in the much greater elaboration of the Article in the Protocol.

Discussion

59. The BTWC Protocol regime has been crafted to incorporate a range of measures -- mandatory declarations of the activities and facilities of greatest relevance to the BTWC, declaration follow-up procedures including randomly-selected transparency visits, declaration clarification procedures and voluntary assistance visits, measures to ensure submission of declarations, consultation, clarifications and cooperation, field and facility investigations, as well as measures to promote scientific and technical exchange and international cooperation. These elements together increase transparency within a State Party and enhance confidence between States Parties that the activities carried out within States Parties are in compliance with the Convention. There is considerable scope for interaction and synergism between the elements in the different measures and it is evident that the elements are indeed complementary.

60. Insofar as the danger from bioterrorism is concerned, the Protocol provides a useful tool that helps to counter this danger. The requirements in *Article 17 National Implementation Measures* for the enactment of national legislation including penal legislation makes it an offence for any individual within a State Party to develop, produce, acquire, stockpile biological agents or toxins for other than in types and quantities that have justification for peaceful purposes. It is also evident that the obligations in Article III (non-transfer) of the Convention require States Parties to introduce national regulations to control the possession, handling, storage and use of biological agents and toxins -- and such national regulations are also necessary to protect public health and the environment. The overall effect of the Protocol and its implementation nationally is to enhance awareness of the potential dangers from biological agents and toxins and so to increase the attention given to ensuring that such materials are not diverted for prohibited purposes. The provisions in the Protocol for the promotion of scientific and technological exchange will help States Parties develop the necessary national infrastructure to achieve the safe handling, storage and use of biological agents and toxins.

61. The BTWC Protocol regime has been successfully developed from both the previous confidence-building measures agreed by the BTWC States Parties at the Second Review Conference in 1986 and extended and strengthened at the Third Review Conference in 1991 and from the experience and the perceptions of the CWC regime which opened for signature in 1993 and entered into force in 1997. Although there are differences between the BTWC Protocol and the CWC regimes, a quantified and comparative evaluation¹⁸ of the two regimes has shown that an effective and efficient BTWC Protocol regime is being developed. It is clear that the provisions for the two regimes will both be effective in strengthening the norm against biological and chemical weapons -- and the BTWC Protocol regime will achieve its objective of strengthening the effectiveness and improving the implementation of the Convention.

¹⁸ Graham S. Pearson & Malcolm R. Dando, *The Emerging Protocol: An Integrated, Reliable and Effective Regime.*, University of Bradford, Department of Peace Studies, Briefing Paper No 25, September 1999. Available at <http://www.brad.ac.uk/acad/sbtwc>.

Wider Perspectives

62. When considering the regime to prevent biological weapons, it is all too easy to focus exclusively on arms control considerations and to fail to recognise that there are wider perspectives that are relevant to biological agents and toxins and which need to be taken into account in considering how States can increase transparency and build confidence that activities are indeed for peaceful purposes. These wider considerations relate to the international initiatives: to counter outbreaks of disease whether in humans, animals or plants; to protect the environment through the Convention on Biological Diversity and its International Guidelines on Biosafety and, more recently, the Cartagena Protocol on Biosafety; to prevent the illicit use of narcotic drugs and psychotropic chemicals; as well as to harmonize Good Manufacturing Practice for safe and reproducible pharmaceutical and biological products. Each of these is considered briefly:

a. **Countering outbreaks of disease.** It is widely appreciated that an outbreak of disease in one country can in this age of rapid international travel and trade rapidly spread to other countries often before the initial outbreak has been diagnosed. After all, diseases know no frontiers. There is consequently considerable emphasis nationally, regionally and internationally on improving disease surveillance and reporting for diseases in humans, animals and plants. States in which there is effective surveillance and reporting of outbreaks of disease increase transparency within that State and also build confidence that outbreaks are not being concealed for whatever reasons. Over time there is much greater international transparency as to what diseases are endemic in a particular country as well as confidence that outbreaks that appear unusual will be investigated and their causes determined.

b. **Protection of the environment.** The Convention for Biological Diversity¹⁹ opened for signature at the Rio Summit in June 1992 and entered into force in December 1993. This Convention includes in its Article 19 Handling of Biotechnology and Distribution of its Benefits the requirement that the States Parties shall consider the need for and modalities of a protocol setting out appropriate procedures, including, in particular, advance informed agreement, in the field of the safe transfer, handling and use of any living modified organism resulting from biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity. The States Parties decided to adopt a twin-track approach developing International Technical Guidelines on Safety on Biotechnology as well as negotiating a Protocol on Biosafety. The International Guidelines²⁰ were adopted by a meeting of the Global Consultation of Government-designated Experts held in Cairo, Egypt from 11 to 14 December 1995 and issued by UNEP. The Cartagena Protocol on Biosafety was finalized in January 2000. It is widely appreciated that biological agents, whether genetically modified or not, can cause harm to those working with these agents or, if released, to the surrounding population. Increasingly, States are adopting national regulations for the handling, use and storage of such materials and of genetically modified organisms. These national regulations may be harmonized regionally, as for example in the European Union, and may require the inspection and certification of facilities working with such materials. As more States adopt such

¹⁹United Nations, *Convention on Biological Diversity*, opened for signature at Rio de Janeiro 5 June 1992, UNEP/CBD/94/1, Geneva, November 1994. Also available as HMSO, Cm 2127, January 1993.

²⁰United Nations Environment Programme, *UNEP International Technical Guidelines for Safety in Biotechnology*, UNEP Nairobi, Kenya.

regulations so transparency is increased and confidence gained that such materials are being used for peaceful purposes.

c. **Illicit use of narcotic drugs and psychotropic chemicals.** Many narcotic drugs and psychotropic chemicals are or are produced from naturally occurring materials. They and their precursors also have dual use in that they have significant medicinal purposes as well as illicit use. There are three key drug conventions (the 1961 Single Convention on Narcotic Drugs as amended by the Protocol of 1972, the 1971 Convention on Psychotropic Substances and the 1988 Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances) which together control a significant number of narcotic drugs (118), psychotropic substances (111) along with their precursors and essential chemicals (22) used in the illicit manufacture of narcotic drugs and psychotropic substances. The number of States Parties to all three Conventions is close to 160 and it is evident that States continue to accede to them as a result of the efforts of the INCB (International Narcotics Control Board) to further the aims of the treaties and achieve universality. The narcotic drugs, psychotropic substances, precursors and essential chemicals are assigned to Schedules or Tables which are associated with various control measures. The materials controlled are all dual purpose with the Conventions and the INCB seeking to limit the cultivation, production, manufacture and use of drugs to an adequate amount required for medical and scientific purposes whilst preventing illicit cultivation, production and manufacture of, and illicit traffic in and use of drugs. The essential chemicals controlled under the 1988 Convention include materials such as acetic anhydride and potassium permanganate, key chemicals in the manufacture of heroin and cocaine respectively, although the quantities diverted for illicit drug production is very much less than 1 per cent of the permitted use of these chemicals. The control measures include both national monitoring and controls as well as export and import measures.

d. **Good Manufacturing Practice (GMP)** . It is evident that there is considerable harmonization world-wide in respect of the GMP standards to be achieved in facilities producing medicinal products for humans and for animals so as to ensure safe and reproducible products²¹. There is already mutual recognition of inspections and standards between countries within the European Union. MRAs (Mutual Recognition Agreements) have been initialled between the European Community and countries such as the US, Canada, Australia, New Zealand and Switzerland and a start made in the negotiation of MRAs with other countries such as Japan and the candidate states for the expansion of the EU. There are several international harmonization schemes which can usefully be put into context using the schematic relating product and manufacturing licences:

	Requirements for Industry	Regulatory Authority Action
Marketing Authorization <i>Product Licence</i>	Safety, efficacy & quality data EU, ICH	Evaluation, Licensing EU, PER

²¹See Graham S. Pearson, *Article X: Pharmaceutical Building Blocks*, University of Bradford, Department of Peace Studies, Briefing Paper No 8, July 1998. Available at <http://brad.ac.uk/acad/sbtwc>

<p style="text-align: center;">Manufacturing Authorization <i>Manufacturer's Licence</i></p>	<p style="text-align: center;">Good Manufacturing Practice EU, PIC, WHO</p>	<p style="text-align: center;">Inspection, Licensing EU, PIC, MRAs</p>
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EU = European Union, ICH = International Conference on Harmonization,
 PER = Scheme for the Mutual Recognition of Evaluation Reports on Pharmaceutical Products
 PIC = Pharmaceutical Inspection Convention, WHO = World Health Organization

Manufacturer's authorizations (product licences) usually have a five year life and the aim generally is to reinspect manufacturers every two years. The purpose of those inspections are to ensure that the facilities being used to manufacture a licensed medicinal product are compliant with GMP and that the processes used are such that cross-contamination of the product will not occur. Consequently, the inspection is limited to those parts of a manufacturing facility used in the production of the licensed product -- this will include everything from receipt and storage of raw materials, through production to packaging together with all aspects of the quality control of the product. Other parts of the facility which are not involved in the product manufacture will not be inspected. Although there is much commercial sensitivity, the existence of both manufacturing and product licences are in the public domain -- although the linkage between a product licence and where that product is manufactured is commercially secret.

Consequently, it is clear that in pharmaceutical and biotechnological production facilities engaged in manufacturing licensed products, these facilities will increasingly be inspected at regular intervals by national regulatory authorities to monitor their compliance with internationally harmonised standards for GMP in order for these facilities to be licensed. Insofar as the Protocol being negotiated by the Ad Hoc Group is concerned, the information as to whether a production facility is licensed to GMP standards should be part of the information to be provided in declarations of such facilities. This information, together with the GMP standard to which it has been inspected, and the date of the last such inspection by the national regulatory authority will help to build confidence that the facility is compliant and is engaged in permitted purposes. It follows that measures to assist developing countries establish a national regulatory system of product and manufacturers' licences to internationally agreed standards would both directly implement Article X of the BTWC and also contribute to building confidence in compliance with the Convention. Such measures would also be in accord with the actions being taken by developed countries following the Rio Summit of 1992 and the emphasis on aiding capacity building in developing countries.

Conclusions

63. When a wider perspective is considered, it is evident that the BTWC Protocol regime to *strengthen the effectiveness and improve the implementation* of the BTWC needs to be considered in the context of an international scene in which there is increasing transparency about the nature of activities and facilities within countries which is facilitated by the information increasingly being made available on the internet and the recognition by more and more countries that they share common goals for a safer, more prosperous world -- a world in which there is greater recognition that the dangers from dual-use materials and

technology in general and biological agents and toxins in particular know no frontiers and that an outbreak in one country can spread all too quickly to its neighbours and, indeed, around the world through international travel and trade. The compliance elements of the Protocol regime -- declarations, visits, investigations -- are complemented by the provisions to promote scientific and technological exchange for peaceful purposes as these provisions help States Parties to develop their infrastructure -- and thereby reap benefits in international trade and commerce as well as increasing transparency and enhancing confidence in compliance. The BTWC Protocol regime will thus enhance international security and counter bioterrorism as well as also contribute directly to achieving a safer, healthier, more prosperous world bringing benefits to all countries, both developed or developing.