Learner Support Services

The University of Bradford Institutional Repository

Author(s): Pearson, G.S.

Title: The Strengthened BTWC Protocol: An Integrated Regime

Project: Bradford Project on Strengthening the Biological and Toxin Weapons Convention (BTWC)

Publication year: 1998

BTWC Briefing Papers: 1st Series: No. 10

Publisher: University of Bradford (*http://www.brad.ac.uk*)

Publisher's repository: *http://bradscholars.ac.uk:8080/dspace*

THE STRENGTHENED BTWC PROTOCOL :

AN INTEGRATED REGIME

by Graham S Pearson*

Introduction

1. The Biological and Toxin Weapons Convention (BTWC) has no provisions for verification or for the monitoring of compliance. At the Third Review Conference in September 1991 following the Persian Gulf war of 1990/1991, the States Parties *"determined to strengthen the effectiveness and improve the implementation of the Convention"* established an Ad Hoc Group of Governmental Experts to examine possible verification measures from a scientific and technical viewpoint.[1] This Group (known as VEREX) met twice in 1992 and twice in 1993. Its final report was considered by a Special Conference in September 1994 which established an Ad Hoc Group (AHG) 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.

2. The AHG commenced its work in January 1995 and is now, in July 1998, in its eleventh session. In September 1996 the AHG decided to intensify its work and the July 1997 session saw the successful introduction of a rolling text for the Protocol to strengthen the BTWC. All the essential elements for the Protocol are now in the rolling text -- Mandatory Declarations, Non-Challenge Visits (both focussed and random) and Compliance Concern Investigations together with measures to strengthen the implementation of Article X (cooperation for peaceful purposes) and other Articles of the BTWC. Although some parts of the rolling text are in square brackets indicating alternatives, the essential contents of a Protocol to strengthen the BTWC are already present.

3. In 1998 the AHG met for 3 weeks in January and 1 week in March; it is meeting for 3 weeks in June/July and will meet for 4 weeks in September/October. There is consequently a real opportunity to complete the substantive negotiations this year -- particularly as President Clinton in his State of the Union address on 27 January 1998 said *"Now, we must act to prevent the use of disease as a weapon of war and terror. The Biological Weapons Convention has been in effect for 23 years. The rules are good, but the enforcement is weak -- and we must strengthen it with a new international system to detect and deter cheating."* The associated Fact Sheet[2] released by the White House at the same time said that "under the new initiative announced by the President today, the United States will seek to complete the framework of a strong BWC protocol by the end of 1998." In March 1998 the European Union issued a Common Position[3] that commits the 15 Member States as well as the 14 Associated States to *"Member States...shall actively promote decisive progress in the work of*

---

* Graham S Pearson is a Visiting Professor of International Security in the Department of Peace Studies at the University of Bradford, Bradford, West Yorkshire BD7 1DP, UK.

[1] 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 1992.

[2] The White House, Office of the Press Secretary, Washington, DC, Fact Sheet, *The Biological Weapons Convention*, 27 January 1998.

[3] United Nations, "*Working Paper submitted by the United Kingdom of Great Britain and Northern Ireland on behalf of the European Union"*, BWC/AD HOC GROUP/WP. 272, 9 March 1998.

the Ad Hoc Group, with a view to concluding the substantive negotiations by the end of 1998, so that the Protocol can be adopted by a Special Conference of States Parties early in 1999." In addition, Australia announced on 2 March 1998, an initiative to strengthen the BTWC *"aimed at fast-tracking the negotiations on a verification system for the Biological Weapons Convention by: - calling for the convening of a high level meeting to inject into the negotiations the necessary political commitment for urgent action,...to help secure early conclusion to the negotiations."* [4] A Statement by the Non-Aligned Movement (NAM) and other countries said inter alia that *"they will contribute fully to this work [of the Ad Hoc Group] in order to promote consensus on key issues which will facilitate the conclusion of this undertaking in an manner acceptable to all States Parties...".* [5]

4. Political attention has continued to be given to the importance of completing the negotiations for the strengthened BTWC Protocol. President Clinton at the Second Summit of the Americas held in Santiago, Chile on 18 - 19 April 1998 spoke strongly about his desire to achieve a successful completion of the negotiation on the Biological Weapons Convention Protocol which will give the Convention enforcement authority and an inspection system.[6] More recently, the Foreign Ministers of the G8 in the communiqué[7] issued following their meeting in London on 8-9 May 1998 said that they *"are committed to action in the following areas: - the intensification and successful conclusion of the negotiation on measures, includes those for effective deterrence and verification to strengthen the Biological and Toxin Weapons Convention with the aim of the earliest possible adoption of a legally-binding Protocol."* Some 10 days later, the Ministers of Foreign Affairs and Heads of Delegations of the Non-Aligned Movement in their communiqué[8] following their meeting at Cartagena des Indias, Columbia on 19 - 20 May 1998 said that *"The Ministers noted the progress achieved so far negotiating a Protocol to strengthen the Biological and Toxin Weapons Convention and reaffirmed the decision of the Fourth Review Conference urging the conclusion of the negotiations by the Ad Hoc Group as soon as possible before the commencement of the Fifth Review Conference and for it to submit its report...to be considered at a Special Conference."* This communiqué also reiterated the importance of progress in implementing Article X as being crucial for the conclusion of the Protocol to strengthen the BWC. Further emphasis came a couple of days later when President Clinton announced a major US initiative to counter attacks using biological weapons said[9] *"We must strengthen the international Biological Weapons Convention with a strong system of inspections to detect and prevent cheating. This is a major priority. It was part of my State of the Union address earlier this year, and we are working with other nations and our industries to make it happen."* It is thus evident that there is a serious international commitment to the negotiations and that the political will needed to complete the negotiations is there.

---

[4]Australian Permanent Mission, *Address by the Permanent Representative of Australia to the Conference of Disarmament, His Excellency Mr John B Campbell to the BWC Ad Hoc Group*, Geneva, 9 March 1998.

[5]Mision Permanente de Colombia, *Statement by the Non-Aligned Movement and other countries*, Geneva, 13 March 1998.

[6]The White House, *Press Briefing by National Security Adviser Sandy Berger*, 18 April 1998, Santiago, Chile.

[7]G8 Foreign Ministers Meeting, Conclusions, London, 9 May 1998. Available on http://birmingham.g8summit.gov.uk/docs

[8]Ministerial Meeting of the Coordinating Bureau of the Non-Aligned Movement, Cartagena de Indias, Colombia, 19 - 20 May 1998.

[9]The White House, *Remarks by the President at the United States Naval Academy Commencement*, Office of the Press Secretary, 22 May 1998.

5. This Briefing Paper considers the current rolling text[10] of the Protocol to strengthen the BTWC and draws together the likely elements of that Protocol in order to examine how together they will result in an integrated regime that will strengthen effectively the BTWC. It draws upon the earlier Briefing Papers Nos 1 to 9 and shows how the various elements of the regime will complement each other and together create a regime that will enhance transparency and build confidence in compliance and so *"strengthen the effectiveness and improve the implementation of the Convention"*

The Essential Elements for the Protocol

6. The central and essential elements to the future Protocol are measures which together will provide the BTWC with a compliance monitoring mechanism that will detect and deter cheaters and will build confidence over time in compliance with the Convention. These measures include:

a. Mandatory Declarations of those facilities and activities of most relevance to the Convention

b. Non-Challenge Visits, both focussed and random, to declared facilities

c. Both Facility and Field Investigations to address a compliance concern.

However, these measures in isolation will not suffice. It will be recalled that the Special Conference in its Final Declaration[11] stated that "the Conference, determined to strengthen the effectiveness and **improve the implementation of the Convention** and recognizing that effective verification could reinforce the Convention, decides to establish an Ad Hoc Group." [Emphasis added]. It went on to say that "the objective of this Ad Hoc Group shall be **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..."[Emphasis added]. It is thus evident that the aim of the AHG is both to strengthen the effectiveness and the implementation of the Convention.

7. Consequently, measures are needed also to ensure the full implementation of Article X (cooperation for peaceful purposes) as specifically required in the mandate for the Ad Hoc Group, as well as such other measures needed to improve the effectiveness and implementation of the Convention. Thus, measures to improve the implementation of Article IV (national implementation measures) and Article III (non-transfer for prohibited purposes) are also necessary. Such measures, if crafted appropriately, will also strengthen the effectiveness of the Convention.

8. The additional elements needed for the Protocol thus include:

---

[10]The current rolling text is that produced following the January 1998 meeting together with the further changes issued following the March 1998 meeting. United 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/39, 2 February 1998 and United 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/40, 17 March 1998

[11]United 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. Measures to ensure full implementation of Article X (peaceful cooperation)

b. Measures to improve the implementation of Article IV (national implementation)

c. Measures to improve the implementation of Article III (non-transfer)

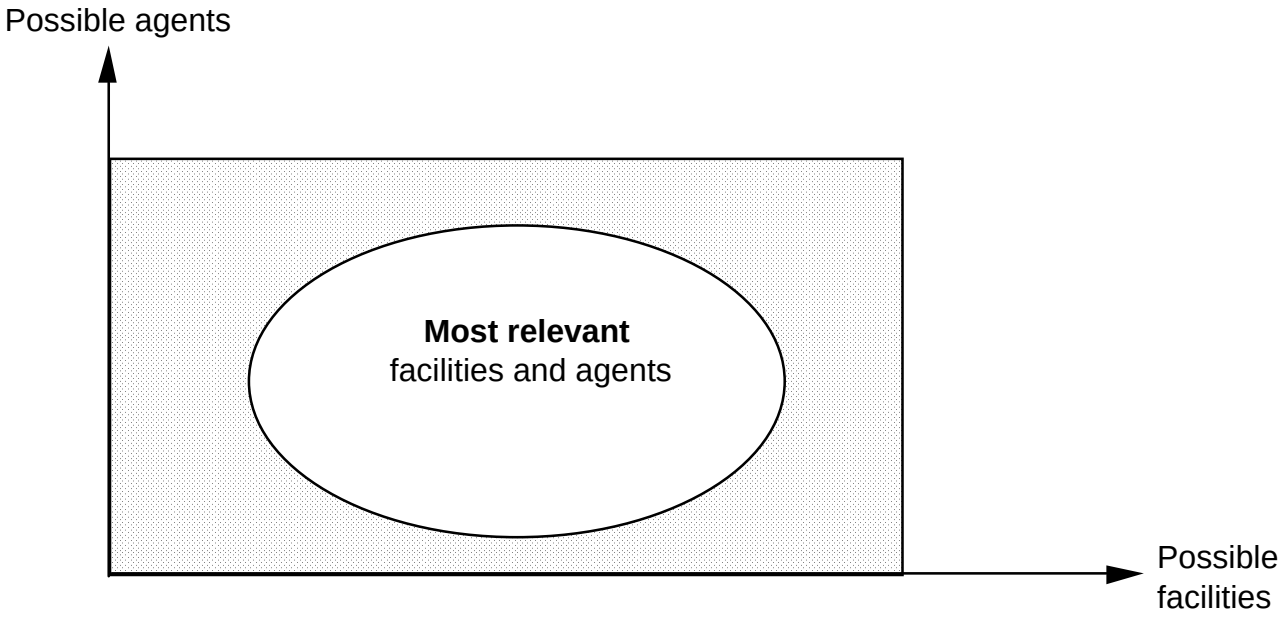
together with an appropriate organisation to implement the Protocol. Measures in isolation without an appropriate organisation would be ineffective.

9. In addition, it is important to recognise that strengthening of the BTWC should not be considered on its own. The technologies at the heart of the BTWC -- microbiology and biotechnology -- are central to the wealth and well-being of all in the 21st Century -- and are the subject of numerous national, regional and international initiatives.[12] Consequently, the measures for the Protocol to strengthen the BTWC need to be designed to complement and build on those activities already being implemented in other fora. This should not present a problem as these fora share common objectives -- the goal in many of these other fora is to protect human health and environmental safety whilst that of the strengthened BTWC is to ensure that human, animal and plant diseases are not used as weapons of war to cause harm to humans, animals or plants.

10. Furthermore, in considering the measures needed for an effective regime to strengthen the Convention, it is important to strike the right balance in capturing those activities and facilities of **most** relevance to the Convention and avoiding the potential information overload were attempts made to capture every activity and facility of **possible** relevance to the Convention. A similar philosophy applies to the most relevant agents rather than all possible agents. The regime has to be designed to be efficient and effective recognising that the **prohibition** in the Convention is all embracing and covers all possible facilities and all possible agents. The aim of the Protocol regime to capture the most relevant facilities and agents can be illustrated graphically:

[12]See, for example, University of Bradford, *Article X: Some Building Blocks*, Briefing Paper No 6, March 1998 and University of Bradford, *Article X: Further Building Blocks*, Briefing Paper No 7, March 1998. These are available on the web at http://www.brad.ac.uk/acad/sbtwc

BTWC Prohibition embraces all facilities and agents

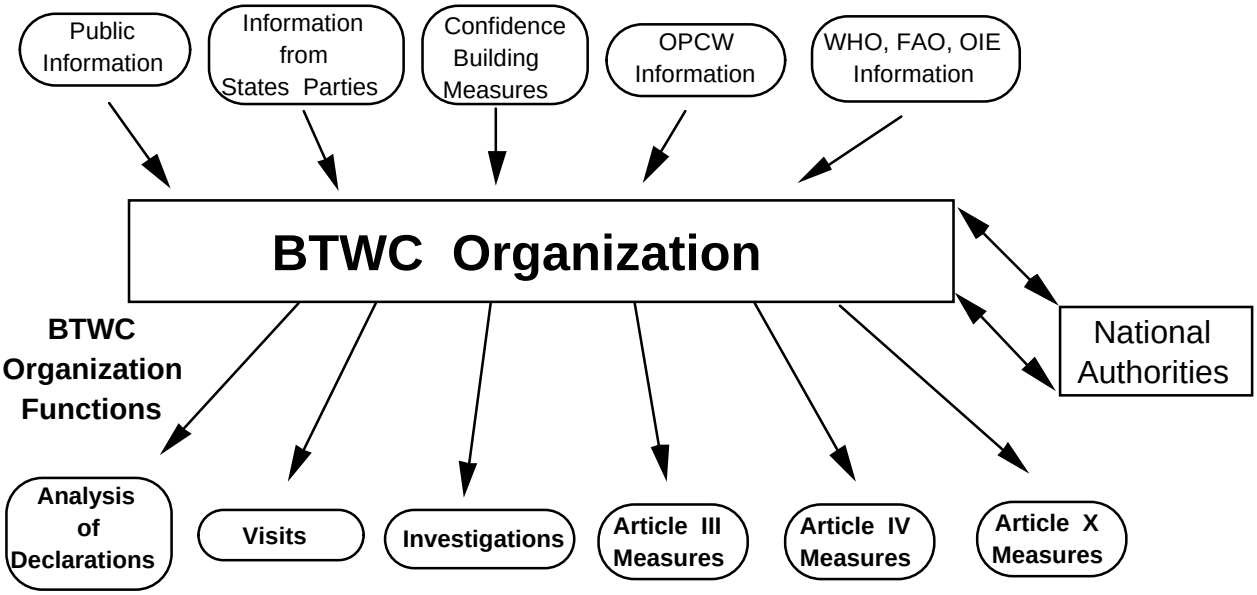


An Integrated Regime

11. In this section, the measures currently in the draft Protocol are examined in some detail together with some ideas as to how these might be further developed to see what the future regime is likely to comprise and how this would function. In doing this, it is helpful to consider schematically what the strengthened regime might comprise.

BTWC Organization

12. There is no credible or effective alternative to the establishment of a BTWC Organization. It has to be recognised that the function of the BTWC Organization is oversee the implementation of the BTWC Protocol and thereby to monitor and improve the implementation of the Convention. There is no other organization that could do this function.



However, this is not to say that the BTWC Organization should not develop effective working relationships with other international organizations and provide and receive information to and from these organizations. Thus the OPCW, WHO, FAO and OIE are all organizations that a future BTWC Organization should establish close links with -- however, those organizations rightly have their own specific functions and they cannot be a substitute for the BTWC Organization.

Inputs to the BTWC Organization

13. The BTWC Organization will need and be dependent on information received from a wide variety of sources in order to carry out its role and function. The draft Protocol has an Annexe E Confidentiality Provisions which currently comprises some 16 pages and addresses *inter alia* how confidential information will be handled and protected by the future BTWC Organization; these provisions closely mirror those in the CWC Confidentiality Annex. These information sources will range from public information such as that in the media and on the internet, to information provided under the Confidence-Building Measures (whether those agreed by the BTWC Review Conferences or as part of the Protocol), to information provided by the States Parties and available information from organizations such as the OPCW and the WHO, FAO and OIE. Thus, for example, the OPCW and the BTWC Organization will not only both address toxins, they will also have a great deal of common ground in their day to day activities and both organisations will benefit from adopting best practice from each other. It must, however, be recognised that information available to the BTWC Organization from such international organisations will not be tailored to the specific requirements of the BTWC Organization as to do so would be contrary to the charter of those organizations -- and indeed could jeopardize their primary functions. It will be up to the BTWC Organization to examine and analyse this information. These various types of information will need to be analysed and assimilated by the BTWC Organization in order that it should function as an effective professional agency which has a high international standing and reputation.

BTWC Organization Functions

14. The BTWC Organization will be required to carry out a number of functions in implementing the Protocol and thereby strengthening the implementation of the Convention. States Parties will be required to establish National Authorities whose responsibilities will include the collection of national data and information required for declarations and submit these declarations to the BTWC Organization. The BTWC Organization will need to protect confidential information should such information be included in these declarations. Declarations will need to be examined and analysed by the BTWC Organization and by the National Authority which will both wish to check that national declarations are accurate and complete. There is much to be gained by making these declarations publicly available at least in part as this demonstrates transparency and builds confidence both nationally and internationally. Publicly available declarations can be analysed by national and international experts thereby providing additional assurances of both their accuracy and their completeness.

15. **Declarations.** The current rolling text contains language albeit in square brackets for the declaration of the following activities and facilities:

[(a) <u>Activities</u>

(i) The presence/absence of [military][civilian][national][biological]defence programmes [against biological and toxin weapons];

[(ii) Any additional information related to past offensive and/or defensive activities not provided in the initial declaration.]]

[(b) <u>Facilities</u>

(i) [Which as their main task are][taking part in][military][civilian][national][biological] defence [facilities taking part in]programme(s) [against biological and toxin weapons [as per listed agents and toxins]][and conducting work on microorganisms or toxins as well as material imitating their properties];

(ii) Which produce vaccines [and/or toxoids/anatoxins][licensed by the State Party] for the protection of humans [against listed agents or toxins][with a production capacity as specified in Annex...][with primary production containment];

(iii) Which produce vaccines [and/or toxoids/anatoxins][licensed by the State Party] for the protection of animals [against listed agents or toxins][with a production capacity as specified in Annex...][with primary production containment];

[(iv) Which produce plant inoculants and/or biological control agent(s) and have a plant quarantine capability [with primary production containment];]

(v) Which have any maximum containment laboratories meeting criteria designated as [Biosafety level 4 ((BL4) according to WHO Classification) or P4 (according to WHO Classification) or equivalent standards][maximum containment];

[(vi) Containing areas protected [by high containment][according to Biosafety Level 3 (BL3) [as specified in the 1993 WHO Laboratory Biosafety Manual]] [and working with listed agents or toxins]but excluding purely diagnostic [and medical]facilities;]

(vii) Which

[work with listed agents or toxins with the exclusion of facilities involved only in diagnostic and/or medical treatment activities;]

or

[have an aggregate fermenter capacity of 100 litres or more and work with or produce listed agents;]

or

[conduct any of the following activities with any of the agents or toxins listed in Annex A excluding those involved only in diagnostic and/or medical treatment activities:

[- research and development...
[- production of such agents and toxins...
[- maintain culture collections...
[- apply genetic modification...
[- aerobiology

[(viii) Other microbiological production facilities...not working with listed agents which have an aggregate fermenter production capacity of [100][1000]litres or more...

[(ix) Not working with listed agents or toxins which

[-possess aerosol {Explosive] test chambers of ...m^3 or above for work with microorganisms or toxins;]...

In addition there is language for the declaration of transfers of listed agents or toxins and equipment, of any relevant information on outbreaks of disease caused by listed agents or toxins for humans, animals and plants, and of the implementation of Article X of the Convention.

16. The major omission, in what is otherwise comprehensive language, is the absence of any specific mention of declarations of past BW facilities.[13] As it is well known from declarations made under Confidence Building Measure Form F that there are such past BW facilities in several countries, such as Canada, France, the Russian Federation, the UK and the US, there is a strong argument that such facilities should be specifically declared as they are undoubtedly of particular relevance to the Convention as they may well still contain the knowledge and in some cases some of the facilities required for BW. It is worth noting that under the Chemical Weapons Convention (CWC), chemical weapon (CW) production facilities[14] are required to be destroyed; they may only exceptionally be converted and are then subjected to an appropriately intrusive verification regime. Whilst it is not suggested

[13]Graham S Pearson, *Past Biological Weapons Facilities: An Opportunity for the Ad Hoc Group,* ASA Newsletter, 97-6, 1, 16-17, 4 December 1997.

[14]As defined in the Chemical Weapons Convention, *Article II Definitions and Criteria,* which makes it clear that chemical weapons production facilities are those which used Schedule 1 chemicals.

that past BW facilities should be destroyed because of their potential use for peaceful purposes, they should be subjected to an appropriately intrusive verification regime.

17. There is a good argument that the aim of declarations must be to have declarations of those activities and facilities of **greatest relevance** to the Convention and **not** to have declarations of all facilities of **possible relevance**. Indeed, it can be argued that the numbers of facilities declared by a country should be of the order of tens[15] resulting, for 160 States Parties in a total of some 1600 to 3200 facility declarations if an average of 10 to 20 is taken per country. This total is consistent with the number of 2500 estimated by others.[16] The Austrian/UK contribution[17] to the EU seminar for the pharmaceutical industry on 13 May 1998 said that *"the number of facilities in individual EU countries that would need to be declared can probably measured in tens rather than hundreds."* Consequently, the triggers for declarations need to catch the most relevant facilities whilst not endeavouring to catch all facilities.

18. Bearing this in mind, it is suggested that the triggers for Declarations that should appear in the Protocol are the following:

Activities

a. Biological defence programmes

b. Past offensive/defensive programmes

Facilities

a. Biological defence facilities

b. Past BW facilities

c. Human vaccine production facilities

d. Animal vaccine production facilities

e. Plant inoculant production facilities

f. Other microbiological production facilities

g. Maximum containment (BL 4) facilities

In addition, there should be a combination trigger for

h. Facilities working with listed agents or toxins

[15]University of Bradford, *Discriminating Triggers for Mandatory Declarations*, Briefing Paper No 3, September 1997.

[16]Federation of American Scientists Working Group on BW Verification, *Estimate of the Number of Declared Facilities*, revised September 1997.

[17]Austria and the United Kingdom, *Industry and Declarations*, UK Presidency and the European Commission: The BWC and the Pharmaceutical Industry, 13 May 1998.

and having an aggregate fermentation capacity of 100 litres or more.

It is judged that the reporting burden for such facilities would not be excessive -- after all, the microbiological industry in many countries is already tightly controlled for public health and environmental safety reasons -- and would be effective in catching the facilities of most relevance to the Convention. It also appears that no confidential proprietary information will be required to complete the declarations for commercial facilities. The Austrian/UK contribution to the EU seminar for the pharmaceutical industry on 13 May 1998 said that *"All are agreed that the forms should be simple and straightforward and should not seek any information which would be considered commercially sensitive."*

19. **Visits.** The current rolling text contains provision for four types of visits:

(a) [Random Visits];
(b) [Clarification Visits];
(c) [Voluntary Visits];
(d) [Voluntary Confidence-Building Visits];

The negotiations relating to visits are very active and terminology and purposes are changing from AHG meeting to meeting. In the present language, Random Visits are to confirm that *"declarations are consistent with obligations under this Protocol"*, Clarification Visits are to *"resolve any ambiguity, uncertainty, anomaly or omission in the declarations of a State Party"*, Voluntary Visits (previously known as Request Visits) are to help States Parties *"compile individual facility and national declarations"* and Voluntary Confidence-Building Visits are visits carried out under procedures in the Annex on Confidence-Building Measures to the Protocol. The latter class of visits is ill-defined in the current text as they appear to have developed from the VEREX measure of exchange visits into visits that may be bilaterally arranged or may be arranged by the BTWC Organization.

20. The basic premise that there should be a portfolio of different types of visits -- all of which are non-challenge in nature -- is a sound one. A two-pillar regime that had only declarations and challenge investigations would be ineffective and would be likely to reach erroneous judgements and thus fall into disrepute. There is a convincing argument for a three-pillar regime comprising declarations, visits to declared facilities and challenge investigations.[18]

21. An analysis of information available about the Organization for the Prohibition of Chemical Weapons (OPCW) has led to an estimate of the size of a future BTWC Organization of about 200, well under half that of the OPCW. About 70 would be inspectors, about a third of the number of OPCW inspectors.[19] This same analysis assumes that the BTWC Organization might make about 100 visits and inspections each year, about a third of the number planned by the OPCW. If it is assumed that there as many biological defence facilities as there are chemical defence facilities (and that the chemical defence facilities are the 40 Single Small Scale Facilities (SSSF) under the CWC) and that there are perhaps 20 past BW facilities under government control or funding, then it is possible to

[18]Douglas J MacEachin, *Routine and Challenge: Two Pillars of Verification,* CBW Conventions Bulletin, Issue No 39, 1-3, March 1998.

[19]Graham S Pearson, *A Lean Organization to Strengthen the Biological Weapons Convention,* CBW Conventions Bulletin, Issue No 39, 5 -12, March 1998. University of Bradford, *An Optimum Organization,* Briefing Paper No 4, January 1998.

make some estimates about the numbers of different kinds of visits might take place each year.

22. Such an estimate of 40 biological defence facilities is supported by analyses[20] of the declarations made under the Confidence Building Measure (CBM) A.2 which show that although 60 such facilities were declared by States parties between 1992 and 1997 only 43 were declared in 1997. As only just over half of the States Parties provide the required CBM information, the number of 43 is a conservative estimate. Insofar as past BW facilities are concerned, CBM F does not specifically call for such declarations. Nevertheless, some 5 countries (Canada, France, Russia, UK and US) have declared past offensive BW programmes under CBM F and it is clear from various studies[21] of these past offensive BW programmes that the numbers of facilities involved was as many as 20 in the former Soviet Union alone. Consequently, an estimate of 20 past BW facilities under government control is again conservative.

23. Under the CWC, the SSSF are to be visited once every two years. It would seem reasonable to adopt a similar frequency for visits by the BTWC Organization to both biological defence facilities and to past BW facilities still under government control or funding. Thus of the 100 visits and inspections each year, 20 would be to biological defence facilities and 10 to past BW facilities. The remaining 70 would be for random visits, clarification visits and voluntary visits; for this analysis, consideration of Voluntary Confidence-Building Visits has been excluded as their nature is ill-defined. In the early years of the Protocol, it is likely that there could be a number of Voluntary Visits to assist States Parties in compiling their national and facility declarations and that there could also be a number of Clarification Visits to resolve ambiguities, uncertainties, anomalies and omissions in declarations. It is suggested that there might be some 50 visits, both Voluntary and Clarification, in the early years which could be expected to reduce in number in later years as States Parties gained experience in compiling their declarations. The number of Random Visits thus might be some 20 a year in the early years and would increase as the numbers of Voluntary and Clarification Visits reduced but would be unlikely to exceed 70 a year should the numbers of Voluntary and Clarification Visits reach zero. This estimate corresponds closely to the Swedish/Netherlands paper[22] on visits at the EU seminar on 13 May 1998 which stated that *"...such visits will not be carried out routinely to all declared facilities, but will be limited to a relatively low number per year, in the order of 50 to 100."*

24. The distribution of Random Visits should be such as to maximise the benefit to the Convention. The current rolling text has language in Article III F as follows:

> *"There shall be no more than [50] Random Visits per calendar year [with the following groups of countries receiving no more than [10] Random Visits each: [Africa, Asia, Eastern Europe, Latin America and the Caribbean, and the Western Europeans and other States...][Such visits shall be distributed [fairly] among the [5][...][regional] groups of countries - [and proportional to the number of the*

[20]Iris Hunger, *Article V: Confidence Building Measures,* in Graham S Pearson & Malcolm R Dando (eds), *Strengthening the Biological Weapons Convention: Key Points for the Fourth Review Conference,* University of Bradford, September 1996. Available on the web at http://www.brad.ac.uk/acad/sbtwc Iris Hunger, private communication, Max Delbruck Centre, Berlin, April 1998.

[21]See, for example, Milton Leitenberg, *Biological Weapons Arms Control,* Contemporary Security Policy, 17, No 1, pp 1 - 79 (April 1996).

[22]Sweden and the Netherlands, *Industry and Visits,* UK Presidency and the European Commission: The BWC and the Pharmaceutical Industry, 13 May 1998.

declared facilities of each State Party].] No State Party shall receive more than [10] Random Visits in each five year period...."

Whilst, such a geographical distribution is laudable, attention should also be paid to which States Parties have received visits to biological defence facilities and past BW facilities or Voluntary and Clarification Visits so that Random Visits can be weighted towards those States Parties that have received no Visits. It should be recalled that one of the principal reasons why Random Visits are important is that these are to confirm the accuracy of declarations. They also help to ensure that the BTWC Inspectorate has gained some appreciation of the approaches to microbiology within a State Party prior to any challenge investigation being carried out in any State Party as in the absence of any prior Visits, the chance that the Inspectorate could reach an inaccurate and incorrect judgement during a challenge investigation will be increased.[23]

25. It also needs to be recognised that Random Visits are likely to be short and by small teams. Their prime purpose is to confirm the accuracy of the declaration for that site. One Working Paper presented to the Ad Hoc Group demonstrates that a group of 3 inspectors spending 2 days at a site can, without jeopardizing confidential proprietary information, gain a useful appreciation which would contribute over time to the gaining of a valuable additional level of information on activities relevant to the Convention that the BTWC organization inspectorate would not otherwise have.[24]

26. It is thus considered that the future Protocol should include provisions for the following categories of Visits, all being non-challenge and all to declared facilities. An indication of their frequency is provided based on an assumption of some 160 States Parties:

Facilities	**Number of facilities**	**Frequency of visits**	**Visits per year**
Biological defence	40	0.5/year	20
Past BW facilities	20	0.5/year	10
Random visits	2500	< 2/year per State	20 --> 70
Clarification visits	2500	as necessary	20 --> 0
Voluntary visits	160	on request	30 --> 0

27. It is reassuring that a recent paper[25] by the Chairman of the Compliance and Controls Task Group of the US Chemical Manufacturers Association has concluded that the values of the CWC far outweighs its costs. This paper noted the importance of the good protection in the CWC for commercial proprietary information and provided useful advice on how the chemical industry can prepare for routine visits.

28. Although there has been much debate about visits in the BTWC Protocol and whether commercial proprietary information might be put at risk by such visits, it has to be

[23]University of Bradford, *The Necessity for Non-Challenge Visits,* Briefing Paper No 2, September 1997.

[24]United Kingdom, Report on a Visit to a Pharmaceutical Research Facility, BWC/AD HOC GROUP/WP. 258, 9 January 1998.

[25]Richard H Burgess, Chairman, Compliance and Controls Task Group, Chemical Manufacturers Association, *CWC Implementation: Balancing Transparency and Confidentiality,* Paper presented at Pugwash Workshop, Noordwijk, Netherlands, 16 May 1998. (quoted with permission).

emphasised that the prime purpose of visits is to check that declarations are accurate[26] or, in the case of voluntary or clarification visits, to assist in preparing declarations or resolve ambiguities in declarations. It seems probable that visits, which will be very infrequent, will be short and not put commercial proprietary information at risk.

29. **Investigations.** The rolling text contains provision for three types of investigation:

> *(1) [Field] investigations [of the alleged use of biological weapons][, to be conducted 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 concern about non-compliance with Article I of the Convention by a State Party]*
>
> *(2) [Facility] investigations [of any other alleged breach of obligations under the provisions of the Convention][, to be conducted inside the perimeter of a particular facility(ies) for which there is a concern that it is involved in activities prohibited by Article I of the Convention]*
>
> *[(3) Investigations where there is a concern that a transfer has taken place in violation of Article III of the Convention]*

30. There has been considerable debate about natural outbreaks of disease with a NAM (Non-Aligned Movement) and other countries working paper[27] in January 1998 addressing the exclusion of all natural outbreaks of disease from investigations under the Protocol. This paper states that "the investigation, diagnosis, treatment and control of disease fall primarily within the domain of the public health care system of each country...Investigation and control of disease remains its sovereign responsibility, even if that country were to seek international assistance, including from international organizations such as the World Health Organization." It then goes on to state that "All natural outbreaks of disease fall in the domain of public health and do not pose a compliance concern to the Biological and Toxin Weapons Convention (BTWC) and are therefore of no concern to the Convention or to its proposed Protocol." The paper then quite rightly recognises that unusual outbreaks of disease could have natural causes or could arise as a result of use of biological or toxin weapons. It then goes on to say that "It is essential to differentiate between natural outbreaks of disease and an event of non-compliance with the BTWC."

31. Whilst it is undoubtedly true that in an ideal world, unusual outbreaks resulting from an event of non-compliance with the BTWC should be differentiated from unusual outbreaks, this is not a practically simple thing to do. It will be clear from consideration of all the past alleged events of non-compliance with the BTWC that it is very difficult to obtain evidence that clearly demonstrates non-compliance without carrying out an investigation. It is also quite evident that if investigations are not carried out promptly after the initiation of the outbreak, the evidence to differentiate between an event of non-compliance and a natural, albeit unusual, outbreak may not be forthcoming.

---

[26]The Swedish/Netherlands paper on visits at the EU seminar on 13 May 1998 stated that *"the purpose of visits is...to confirm that declarations are consistent with their requirements as stipulated in the Protocol, enhancing transparency and confidence in declarations, an essential element in strengthening compliance with the Biological Weapons Convention."* Sweden and the Netherlands, *Industry and Visits,* UK Presidency and the European Commission: The BWC and the Pharmaceutical Industry, 13 May 1998.

[27]Group of NAM and other countries, *Investigations: Exclusion of all natural outbreaks of disease,* BWC/AD HOC GROUP/WP. 262, 23 January 1998.

32. Insofar as the protocol to strengthen the BTWC is concerned, there would appear to be a pragmatic approach that would be applicable in those cases where the State Party has been subjected to an attack by biological or toxin weapons. Such a State Party would be keen to investigate the cause of the outbreak and could be expected to welcome all possible international assistance; in such circumstances, the aid of the BTWC Organization would be positively encouraged. The only possible reservation might be if the State Party was concerned that the outbreak might have resulted from poor national health standards -- and would not wish this advertised widely. This might be overcome by an arrangement that in the event of the BTWC Organization participating in an investigation of an unusual outbreak in a State Party and concluding that this was a natural outbreak then this would suffice as the report of the BTWC Organization to the other States Parties.

33. The more difficult case is when an unusual outbreak has resulted in a State Party because of activities within that State Party that are non-compliant with the BTWC. Understandably, such a State Party would be unwilling to have an investigation of such an outbreak. Nevertheless, the ability to investigate such unusual outbreaks quickly lies at the heart of an effective Protocol to strengthen the BTWC.

34. It will be important for the BTWC Organization to build up an appreciation of the patterns of outbreaks of disease so that it has the expertise to distinguish outbreaks of disease that may result from an event of non-compliance with the BTWC and is able to focus any investigation of outbreaks on those characteristics that are most likely to demonstrate whether the outbreak was the result of a natural cause or of deliberate action. It has to be recognised that this capability has to be acquired by the BTWC Organization as other international organizations such as the WHO, FAO and OIE could not carry out such a function without jeopardizing their neutrality and hence their ability to carry out their primary functions.

35. The other point of debate has related to the initiation of such investigations, whether field or facility, and what type of filter mechanism should be devised. The rolling text has the following language:

> *[Requests for an investigation [into a non-compliance concern][may][shall]be submitted to [the United nations Security Council] for decision on whether to initiate an investigation and on the need to conduct an inspection.[[Requests for an investigation into a non-compliance concern [may][shall]be submitted to the [politically representative body of States Parties][the Director-General]. Providing the request satisfied agreed requirements, the investigation would proceed [if formally approved by [at least a two-thirds majority][a three-quarters majority][present and voting] of this representative body][unless this body decides by a three-quarters majority of all its members against carrying out the investigation.]]*

This contains both the green light filter (a majority required to vote in favour of the investigation) and the red light filter (a majority required to vote to stop an investigation) mechanisms. The Chemical Weapons Convention[28] has a red light filter mechanism as Article IX contains the following language:

[28]United Nations, *Convention on the Prohibition of the Development, Production, Stockpiling and Use of Chemical Weapons and on their Destruction*, United Nations 93-05070, 1993.

The Executive Council may, not later than 12 hours after having received the inspection request, ***decide by a three-quarter majority of all its members against carrying out the challenge inspection,*** *if it considers the inspection request to be frivolous, abusive or clearly beyond the scope of this Convention as described in paragraph 8. Neither the requesting nor the inspected State Party shall participate in such a decision. If the Executive Council decides against the challenge inspection, preparations shall be stopped, no further action on the inspection request shall be taken, and the States Parties concerned shall be informed accordingly.* [Emphasis added]

36. There is much to be said for the BTWC Protocol containing a similar red light filter mechanism to that in the CWC. It would be unfortunate if an investigation relating to a toxin were to be handled differently depending on which Convention it was being investigated under. It is also apparent from recent international events such as the confrontation with Iraq earlier this year that it can be very difficult to gain an international majority even when the evidence is as clear cut as it was in the case of the Iraqi non-compliance with the United Nations Security Council Resolutions. The BTWC Protocol should have a red light filter mechanism.

37. It is thus considered that the future Protocol should have provision for the following investigations:

a. Field Investigations

b. Facility Investigations

c. Article III Transfer Investigations (discussed in the next section)

and that these should have a red light filter mechanism. The BTWC Organization will need to collect data on outbreaks of disease so that over time it will build expertise that it can draw upon in distinguishing an outbreak resulting from an event of non-compliance with Article I of the Convention and a natural outbreak.

38. **Article III Measures (Non-Transfer).** The current rolling text has language in Article III. F of the Protocol on measures to strengthen the implementation of Article III of the Convention:

[States Parties, in order to ensure compliance with Article III of the BTWC, shall only transfer dual-use microbial and other biological agents and toxins for purposes not prohibited by the Convention, in accordance with the following guidelines.

...the guidelines shall be as follows:

(a) Any request made by a State Party for the procurement of a specific agent/toxin reagent shall be accompanied by information on purpose, quantity required, site or facility for proposed use, quantity to be produced at the site or facility, place where intended to be stored and end-use certificate;

(b) Any request for transfer or procurement of equipment envisaged to be declared under CBMs, for use by a State participating in the compliance regime in a BL4

facility, including details of its proposed application and the site/facility for intended use, shall be intimated to [the BTWC Organization];

(c) Any transfer of technology related to means of delivery, aerosol dispersion of toxins and pathogens, stabilization of agents/toxins to environmental stress shall be intimated to [the BTWC Organization]

(d) Transfer of agents, equipment and material shall not be allowed to non-States parties of the compliance regime under the Convention without the prior approval of [the BTWC Organization];]

39. Alternative proposals are also elaborated in the same part of the draft Protocol. Elsewhere in the draft Protocol is language relating to declarations (Article III. D) which states that:

[Transfers

Each State Party shall declare annually all international transfers of listed agents or toxins, equipment [or means of delivery].

Each State Party declaring such transfers shall submit information according to the format in Annex...]

Whilst there is provision in the current draft for investigations where there is a concern that a transfer has taken place in violation of Article III of the Convention, there is currently no language in the relevant Annex (D. IV) of the Protocol.

40. The subject of measures to strengthen the implementation of Article III of the Convention is contentious because of the relationship to the Australia Group harmonization of export controls which are regarded by many developing States as being discriminatory. However, it is becoming evident that States are concerned about transfers of biological agents and toxins for prohibited purposes and some countries have introduced rigorous national controls on transfers of pathogens because of human, animal and plant health and environmental concerns, and more recently, to counter possible acquisition of agents and toxins for terrorist purposes. It is also clear that negotiations are advanced for a biosafety protocol which will introduce transborder controls for living modified organisms.[29]

41. It is thus considered that the future Protocol should indeed contain measures to strengthen the implementation of Article III including:

a. Guidelines for transfers of biological agents, toxins and equipment

b. Requirement for annual declarations by States Parties

c. Provisions for the investigation of concerns that a transfer has occurred in breach of Article III of the Convention.

[29]For an account of national controls on transfers of pathogens and on the development of the biosafety protocol see University of Bradford, *Article X: Some Building Blocks*, Briefing Paper No 6, March 1998 and University of Bradford, *Article X: Further Building Blocks*, Briefing Paper No 7, March 1998.

42. **Article IV Measures (National Implementation).** The current rolling text has language in Article X of the draft Protocol which addresses national implementation measures. This addresses both the implementation of the Protocol and implementation of the Convention in stating that:

> *1. Each State Party shall, in accordance with its constitutional processes, take any necessary measures [including enacting penal legislation with respect to the obligations under the Protocol] to implement its obligations under this Protocol. [In particular, it shall:*
>
> > *[(a) Prohibit natural and legal persons anywhere on its territory or in any other place under its jurisdiction [or control] as recognized by international law from undertaking any activity prohibited [to a State Party] under the Convention[, including enacting penal legislation with respect to such activity];]*
> >
> > *[(b) Prohibit natural and legal persons from undertaking any such activity anywhere under its control; and]*
> >
> > *[(c) Prohibit, in conformity with international law, natural persons possessing its nationality from undertaking any such activity anywhere.]]*
>
> ....
>
> *[3. In order to fulfil its obligations under this Protocol [the Convention], each State Party shall designate or establish a [National Authority] and shall so inform the [Organization] [upon] entry into force of this Protocol for it. The [National Authority] shall serve as the national focal point for liaison with the [Organization] and with other States Parties.]....*

43. Although, there is some reluctance by some States to engage in addressing how the Protocol might strengthen the implementation of the BTWC, it is clear from Final Declaration of the Special Conference that established the mandate for the Ad Hoc Group that they were "determined to strengthen the effectiveness and **improve the implementation of the Convention.**" [Emphasis added]. When the efforts taken at the successive Review Conferences of the BTWC are considered, it becomes clear that the Protocol being negotiated by the Ad Hoc Group presents **the** opportunity to strengthen the implementation of Article IV of the Convention.[30]

44. There would be benefits in the Protocol containing language, comparable to that which is present in respect of measures to improve the implementation of Article III, which requires States parties to provide information on the laws and regulations to implement the Article. The Article III language (in Article III. F. II of the Protocol) states that:

> *[(b) (i) Each State Party shall report to [the Organization] on the national laws and regulations it has adopted to implement Article III of the BTWC not later than [...] days after entry into force of this Protocol for that State Party and whenever an amendment thereto is made.*

[30]Graham S Pearson and Nicholas A Sims, *National Implementation Measures,* University of Bradford, Briefing Paper No. 4, January 1998.

(ii) Each State Party shall report to [the Organization] on its administrative and other national measures to implement Article III of the BTWC not later than [...] days after entry into force of this protocol for that State party and whenever an amendment thereto is made.

[(iii) Such reports shall contain detailed information. If available, the information contained in these reports may be subject to examination during a visit under the Article I investigation provisions of this Protocol.]

Similar language in respect of the measures to implement Article IV would be beneficial.

45. It is thus considered that the future Protocol should contain measures to strengthen the implementation of Article IV including:

a. Requirements for States Parties to enact penal legislation to implement the prohibition of any activity prohibited under the Convention

b. Requirement for States Parties to set up a National Authority to implement the Protocol

c. Requirements for States Parties to report to the BTWC Organization on the national laws, regulations, administrative and other national measures that it has taken to implement Article IV of the Convention.

46. **Article X Measures (Cooperation for Peaceful Purposes).** The current rolling text has language in Article VII of the draft Protocol which addresses scientific and technological exchange for peaceful purposes in order to enhance the implementation of Article X of the Convention. Article X of the Biological Weapons Convention (BWC)[31] promotes the peaceful use of biological materials, equipment and information for peaceful purposes as States Parties are committed as follows:

"(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

[31]United Nations General Assembly, *Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction,* Resolution 2826(XXVI), 16 December 1971.

(biological) agents and toxins for peaceful purposes in accordance with the provisions of the Convention."

The first paragraph of Article X is referred to as the promotional aspect and the second paragraph as the regulatory aspect. The aim is to devise measures that implement both the promotional and the regulatory elements.

47. At the end of the March 1998 AHG meeting, the title for Article VII had changed to:

ARTICLE VII [SCIENTIFIC AND TECHNOLOGICAL EXCHANGE FOR PEACEFUL PURPOSES][IMPLEMENTATION ASSISTANCE] AND TECHNICAL COOPERATION

The words [Implementation Assistance] had been introduced as an alternative title thus putting the title into square brackets where none had appeared before. In addition the whole section within Article VII entitled *"Measures to avoid hampering the economic and technological development of States Parties"* has now been placed within square brackets as has the title *"International Cooperation"* of another section. These are seriously retrograde steps as they unnecessarily cast doubts on the intention of the Ad Hoc Group to address the element of its mandate requiring it *inter alia* to consider *"Specific measures designed to ensure effective and full implementation of Article X,..."*. As will be shown below, measures to facilitate the implementation of Article X can be devised to directly contribute to increasing transparency building confidence in compliance with the Convention. The need to consider measures relating to the implementation of Article X has been generally recognised as an issue that is of particular importance to the developing countries. It is therefore not surprising that the NAM statement[32] at the end of the March Ad Hoc Group meeting expressed *"their concerns at attempts to reduce the scope and importance of issues related to Article X of the Convention."* and went on to say that *"Substantive progress in strengthening the application and full operationalisation of Article X is crucial to the conclusion of a universally acceptable and legally binding instrument designed to strengthen the Convention. They reaffirm readiness to work with other delegations in order to achieve an appropriate balance in the Protocol."*

48. The language in Article VII contains the following Sections

[(A) [General Provisions]
(B) Measures to promote scientific and technological exchanges
[(C) Measures to avoid hampering the economic and technological development of States Parties
(D) [[Institutional Mechanisms and] International Cooperation] [Protocol Implementation Assistance]
[(E) Cooperative Relationships with other international organizations]
(F) [Safeguards and limitations

In addition, there is language in Article III. D Declarations of the Protocol that requires:

[32]Mision Permanente de Colombia, *Statement by the Non-Aligned Movement and other countries*, Geneva, 13 March 1998.

Each State Party shall declare annually the measures taken individually or together with other States and international organizations in implementing Article X of the Convention.

Each State party shall submit a declaration on the implementation of Article X of the Convention according to the format in Annex...

49. Thus far, there has been little consideration by the Ad Hoc Group of specific measures that might be taken to enhance the implementation of Article X as the Ad Hoc group has understandably concentrated on compliance measures which lie at the heart of the Protocol to strengthen the BTWC. As, however, the Protocol text advances it is becoming timely to consider specific measures to enhance the implementation of Article X. In doing this, it is important to consider initiatives being taken in other fora that are separate from yet are relevant to the BTWC. The challenge is to identify measures that will enhance the implementation of Article X whilst **at the same time** contributing to the building of confidence that States Parties are compliant with the Convention and avoiding duplication with activities in other fora.

50. Whilst it will be important to avoid duplication of activities such as those under Agenda 21 and the Convention on Biological Diversity, it is becoming apparent that there are common goals in respect of both international security and public health and environmental safety that can complement the moves being taken by the Ad Hoc Group to increase transparency and build confidence. Two recent studies[33] have examined possible building blocks that might be utilised in devising measures to enhance the implementation of Article X.

51. These show that there is already considerable international effort to harmonize national and international regulations relating to pathogens that present danger to public and animal health and to the environment. It is evident in that in many countries, for public health and environmental safety reasons, national authorities are already establishing regulations, collecting relevant information about facilities and activities and inspecting these facilities and activities. Similar measures are also being taken to counter the possible acquisition of such materials for terrorist purposes. As the BTWC Protocol is likely to contain declarations and inspections of facilities and activities together with national implementation measures, as well as measures to improve implementation of Articles III and X of the Convention, there is potential for a two way synergy between the strengthening of the BTWC and the strengthening of national procedures for the handling, use and transfer of harmful pathogens for reasons of public health and environmental safety. Consequently, in regard to the strengthening of the implementation of Article X of the BTWC, there appears to be scope for measures that are both promotional and regulatory to facilitate the harmonization of national, regional and international safety rules for pathogens involving both the collection of data and the inspection of facilities thereby enhancing both national public confidence as well as regional and international security.

52. Another area in which there is scope for measures to strengthen Article X whilst at the same time strengthening confidence in compliance with the BTWC is that related to the licensing of pharmaceutical and biotechnological production facilities. It is apparent that the

[33]University of Bradford, *Article X: Some Building Blocks*, Briefing Paper No 6, March 1998 and University of Bradford, *Article X: Further Building Blocks*, Briefing Paper No 7, March 1998. These are available on the web at http://www.brad.ac.uk/acad/sbtwc

guidelines for Good Manufacturing Practice (GMP) for medicinal products issued by the European Community[34], by the Pharmaceutical Inspection Cooperation Scheme[35] and by the World Health Organization[36] have successfully been harmonised. These guidelines, or equivalent standards, are required to be met in order for the regulatory authority of one country to accept the reports of inspections of manufacturers carried out by the inspectorate of another country. Such international acceptance is already accepted within the European Community and between the members of the Pharmaceutical Inspection Convention. Mutual Recognition Agreements have been negotiated between countries to achieve the same goal. The incentives for the harmonization of GMP and for the international acceptance of inspections is the facilitation of trade which is becoming increasingly more international.

53. The relevance of these harmonised guidelines for GMP for medicinal products and the international acceptance of inspections is that facilities which meet these standards for GMP for medicinal products are subject to repeated inspections about once every two years by national inspectorates. The GMP requirements are such that it would not be easy for a GMP inspected manufacturing facility to carry out covert manufacture of prohibited products. Consequently, pharmaceutical and biotechnological facilities that meet these harmonised international standards and are subject to regular inspection are unlikely to present a risk to the Convention -- in other words, there are grounds for confidence that such GMP inspected facilities are engaged in activities that are in compliance with the BTWC. Consequently, measures to assist developing countries to adopt national standards for GMP of pharmaceutical products that are the same as those that have been internationally harmonised and adopted and to establish national inspectorates to carry out regular inspections of pharmaceutical manufacturers would be a specific measure that would enhance the implementation of Article X whilst at the same time contributing to increased confidence in compliance.

54. There are benefits to be gained from the future Protocol containing both promotional and regulatory measures to strengthen the implementation of Article X:

55. Promotional Measures. The OPCW experience has shown that the setting up of National Authorities to implement the CWC is a non-trivial activity. There are immense benefits to be gained for the implementation of a strengthened BTWC Protocol through measures to assist in the setting up of national Authorities covering aspects such as draft enacting legislation for States to adapt for their own national systems, the training of personnel for National Authorities and assistance in setting up systems for the collection and collation of the data needed for the mandatory annual declarations and in receiving incoming visits and investigations from the future BTWC Organisation.

56. As biological warfare is a deliberate outbreak of disease in humans, animals or plants, an important element of the future BTWC regime requires the continuing surveillance worldwide of outbreaks of disease in humans, animals and plants. It would be unrealistic to

---

[34]European Community, *Guide to Good Manufacturing Practice for medicinal products,* reproduced in Medicines Control Agency, *Rules and Guidance for Pharmaceutical Manufacturers and Distributors 1997,* The Stationery Office. London, 1997.

[35]Pharmaceutical Inspection Convention - Pharmaceutical Inspection Cooperation Scheme (PIC - PIC/S), *Guide to Good Manufacturing Practice for medicinal products,* Document PH 1/97, February 1997, EFTA Secretariat, Geneva.

[36]World Health Organization, *Good manufacturing practices for pharmaceutical products,* Annex 2 of WHO Expert Committee on Specifications for Pharmaceutical Preparations, Thirty-second report, WHO Technical Report Series 823, Geneva, 1992.

expect such a surveillance system to be set up by the personnel of the future BTWC organisation. Rather the BTWC organisation will need to be a recipient of information arising from surveillance carried out by the existing WHO, FAO and OIE international organisations. As the existing surveillance arrangements have various deficiencies, measures to implement Article X through the improvement in States Parties of national components of the WHO, FAO and OIE surveillance networks would contribute both to the improved implementation of the BTWC **and** would serve as an important incentive to encourage States to accede to the Protocol (and the Convention) in order to gain these benefits. It is encouraging that the G8 Foreign Ministers in May 1998 recognised[37] that *"the impact of infectious and parasitic diseases continue to cause concern. The G8 is committed to helping countries respond to these challenges...through improving surveillance capacity..."*. They went on to say that *"experts from G8 countries and WHO will meet later this month to review surveillance systems throughout the world, and examine options for assisting WHO as it helps to develop global surveillance networks."*

57. Regulatory Measures Worldwide concerns about the potential dangers to public health and to the environment have led States to introduce national regulatory systems to ensure that dangerous pathogens, toxins and living modified organisms are handled, stored and transferred in ways that protect the public and the environment. Increasingly in order to promote trade, these systems and biosafety standards are being improved and harmonised regionally and internationally. Consequently, such measures could contribute to both the regulatory and the promotional elements of Article X. In addition, as a counter to the possible acquisition of pathogens and toxins for terrorist purposes, some States Parties such as the United States have introduced controls on the facilities in which such materials can be handled and stored as well as on their transfers. All of these regulatory controls help to ensure that such materials are only used for permitted, peaceful purposes. Measures to implement Article X through actions to promote the harmonisation of such regulatory systems internationally will contribute to enhancing confidence that dangerous pathogens and toxins are being used for controlled and peaceful purposes and thus over time to building confidence in the Convention.

58. In addition, to ensure the safety of the humans and animals to whom human medicinal products and veterinary products are administered, national and regional regulatory systems are increasingly requiring that manufacturer's authorizations or licences are issued for the facilities in which such products are produced. These authorizations are based on repeated inspections by national inspectorates of such facilities to ensure that internationally harmonised standards of Good Manufacturing Practice for pharmaceuticals are being met. Article X measures to assist States Parties to establish equivalent regulatory authorities and regimes would both implement Article X thereby bringing significant trade benefits to States Parties **and** would build confidence that such production facilities are being used for permitted purposes.

59. Conclusions Such measures, which would facilitate the implementation of **both** the promotional and regulatory elements of Article X of the BTWC, would **also** contribute to the effective implementation of the Protocol to strengthen the BTWC. Article X promotional measures could include ones to assist States Parties in the setting up of national Authorities to implement the Protocol to the BTWC, to improve their biosafety standards and controls and to assist States Parties in improving their national components of the WHO, FAO and OIE

[37]G8 Foreign Ministers Meeting, Conclusions, London, 9 May 1998. Available on http://birmingham.g8summit.gov.uk/docs

surveillance networks. Article X regulatory measures could include ones to assist the establishment of national systems to ensure that dangerous pathogens, toxins and living modified organisms are handled, stored and transferred in ways that present no danger to the public or to the environment and the setting up of regulatory systems to ensure that human medicinal and veterinary products are manufactured safely and will not present a danger to the humans and animals to whom they are administered.

60. Article X implementation measures such as these will provide both clear benefits and incentives for States to become Parties to the Protocol (and the Convention). Over time, they will serve as a first stage towards the creation of a climate in which States Parties have gained the necessary degree of confidence in the compliance of other States Parties with the Convention that present trade restrictions between States Parties can be relaxed. The benefits to States Parties from these proposed measures to implement Article X are summarised below.

Article X Measure	**Benefits to States Parties**
Promotional	
Assistance in setting up National Authorities and in implementing the BTWC Protocol	Enhanced world-wide confidence in the implementation of the BTWC Protocol (and thus of the Convention) by all States Parties
Assistance to national elements of WHO, FAO and OIE Surveillance Networks	Improved national, regional and international surveillance of outbreaks of disease enabling counters to outbreaks to be rapidly instituted Information from the WHO, FAO and OIE Surveillance Networks will be important for the effective operation of the BTWC Organisation in its oversight of the implementation of the BTWC Protocol
Regulatory	
Regulatory frameworks for dangerous pathogens, toxins and living modified organisms	Improved public confidence that such materials are only being used for controlled and permitted purposes Contribute to ensuring that such materials are not available for terrorist purposes

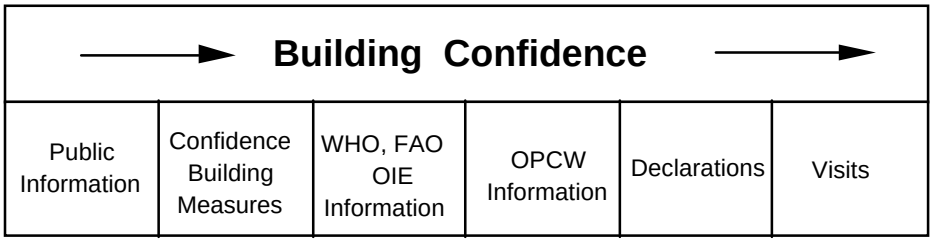
Regulatory pharmaceutical inspectorates and licences	Improved assurance of safety for humans and animals receiving the medicinal/veterinary products Promotion of trade in pharmaceuticals Enhanced confidence that pharmaceutical production facilities are only being used to produce licensed permitted products

61. Such measures will also bring significant benefits to States Parties that do not already have equivalent national health and safety or GMP standards and inspectorates. These measures would be additional to the proposals already in the draft Protocol for the BTWC Organization to establish cooperative arrangements with relevant organizations such as the OPCW, WHO, FAO, OIE, UNIDO, ICGEB, and UNEP and for the promotion of scientific and technological exchanges.

Analysis

62. It is useful to examine how the various elements of the integrated regime for the strengthened BTWC will complement one another and enhance the effectiveness of the overall regime. There are at least two main functions of the Protocol -- to strengthen confidence in compliance and to address concerns in a timely way.

63. **Building Confidence in Compliance.** Several elements of the Protocol will contribute to this:



Public information whether from the media, the internet, official communications or from academic and other publications provides a baseline of understanding within the BTWC Organization about the standing of a particular country in respect to its perceived compliance with the BTWC. It will be recalled that at the Fourth Review Conference in November 1996[38] the Final Declaration on Article I made an appeal through the States Parties to their scientific communities *"to lend their support only to activities that have justification for prophylactic, protective and other peaceful purposes, and refrain from undertaking or supporting activities which are in breach of the obligations deriving from the provisions of the Convention."* There is thus a clear need for States parties to provide public information to inform the scientific community about the Convention. Furthermore, there are benefits to

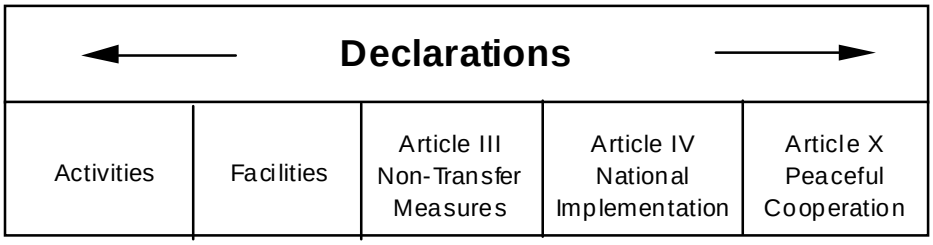
[38]United Nations, *The Fourth Review Conference of the States Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction*, Geneva, 25 November - 6 December 1996, BWC/CONF. IV/9, Geneva 1996.

be gained from involving the scientific community in contributing to the implementation of the Convention. Public information is augmented by the information provided by States Parties in the declarations made under the Confidence Building Measures (CBMs) agreed at the Second Review Conference in 1986 and extended at the Third Review Conference in 1991; under the Protocol to strengthen the BTWC, additional CBMs may be agreed which could require either the mandatory or voluntary provision of information. Thus far, the Ad Hoc Group has paid little attention to CBMs as emphasis has rightly been focussed on the central mandatory measures to strengthen the Convention. One advantage of a future BTWC Organization will be the collation and analysis of CBM information together with the reminding of States Parties of the need to provide CBM declarations.

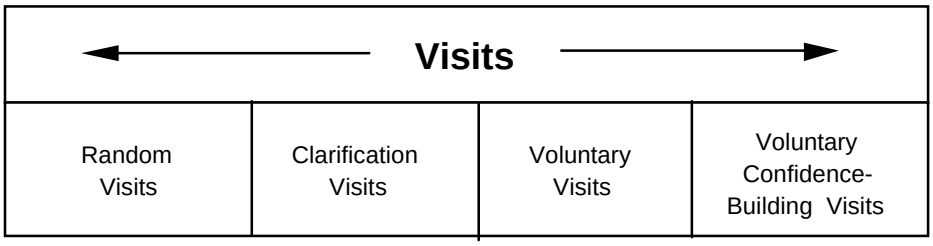
64. WHO, FAO and OIE information will be an important input to the future BTWC organization which will need to analyse this information so as to build up an expertise and understanding over time of the pattern of natural outbreaks of disease within States Parties against which the BTWC Organization will be able to evaluate outbreaks that appear to be unusual. Close links will need to be established with these organisations (WHO, FAO, OIE) so that maximum benefit is derived by the BTWC Organization from the analyses carried out by these other organizations, always recognizing that these other organizations will not be able to point out outbreaks that might be caused by a BTWC non-compliant event.

65. OPCW information will also be important to the BTWC Organization as the CWC also covers the prohibition of toxins and there is likely to be, and rightly so, an overlap between the two Conventions in this respect. A close link between the two Organizations will also be valuable because of the links between chemical and biological weapons which mean that the two Conventions will have more in common with one another than with any other international treaty or convention. Both Organizations will benefit from exchanging information on their experience in implementing the similar, albeit different in detail, provisions in the two Conventions so that both can benefit from best practices and avoid common difficulties. It is also true that traditionally States which have sought chemical weapons have often gone on to seek biological weapons. Consequently, close liaison between the two Organizations will help to ensure that there is an effective prohibition to all chemical and biological weapons. It will, however, be important if the two organizations are to maximise their benefits to ensure that appropriate provisions are made for the handling of confidential information. It is good that the draft Protocol already contains language which in both Articles VII and IX refers to the BTWC Organization concluding *"agreements and arrangements with relevant organizations"* such as the OPCW.

66. Declarations made by States Parties will complement the information already mentioned. These declarations are likely to be not only of activities and facilities of relevance to the Convention but also of measures taken by States Parties to implement Articles III (non-transfer), IV (national implementation) and X (peaceful cooperation) of the Convention. Together these will provide the Organization with an appreciation of the approaches being taken by the State Party to implement the Convention and the quality of these declarations will be indicative of the importance ascribed by that country to compliance with the BTWC and the Protocol.



67. Confidence in these declarations and all other information available to the BTWC organization, such as publicly available information or information provided under Multilateral Information Sharing -- a possible CBM for which language is included in Annex G IV of the Protocol -- will be significantly augmented by Visits carried out by the BTWC Organization. Random Visits to declared sites will ensure that declarations are accurate whilst Clarification Visits will address ambiguities, uncertainties, anomalies or omissions in declarations and Voluntary Visits will help States Parties in their compilation of individual and national declarations.

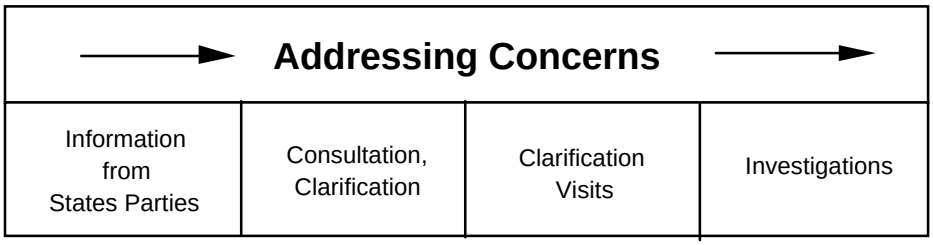


68. It is anticipated that the BTWC Organization will produce an annual report in which it will set out its appreciation of the building of confidence in compliance with the BTWC resulting from its analysis of all information available to it. Such a report could be similar to that which the OPCW has produced[39] on the implementation of the CWC.

Addressing Concerns about Compliance

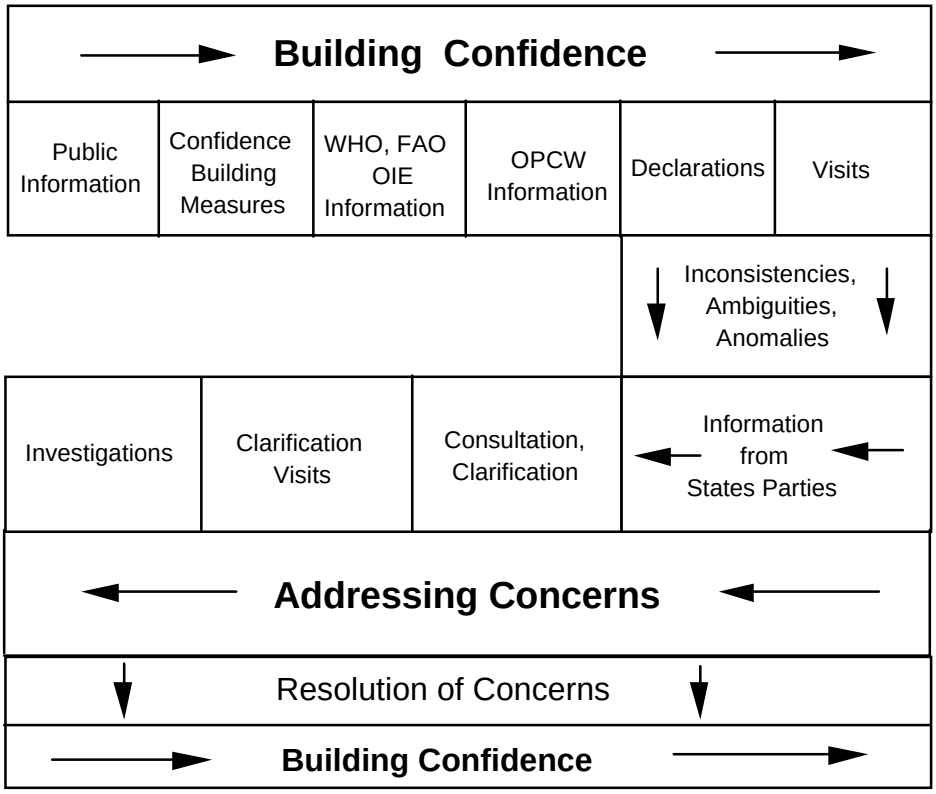
69. The second key function of the Protocol will be to provide a mechanism through which inconsistencies, anomalies and concerns can be addressed in a timely fashion. It is important that concerns be addressed rapidly as if these are left unaddressed for a period of time they are likely to grow and become of greater concern. The Protocol will enable a graduated response to concerns through consultation and clarification which may take place directly between the States Parties concerned, with the assistance of the Director-General of the BTWC Organization, or by requesting the Executive Council to obtain clarification. The Protocol also contains provision for the Technical Secretariat to seek clarification from any State Party of any ambiguity, uncertainty, anomaly or omission. Should such consultation and clarification not resolve the issue, then a Clarification Visit may take place to address any ambiguity, uncertainty, anomaly or omission; the extent to which such Clarification Visits can be initiated by the BTWC Organization or by a request of a State Party is all in square brackets in the current text as is the question as to whether such Clarification Visits should be after appropriate review by the Executive Council. Should a Clarification Visit not satisfactorily resolve the concern, it will then be open for States Parties to lodge a request for an Investigation. This is shown schematically in summary form below.

[39]Organization for the Prohibition of Chemical Weapons, Conference of States Parties, *Report of the Organisation on the Implementation of the Convention (29 April - 28 October 1997),* C-II/2/Rev. 2, 5 December 1997.



70. The building of confidence and the addressing of concerns are closely connected. Whilst the accumulation of information over time about activities and facilities within a State Party will build confidence within the BTWC Organization that they have an accurate appreciation of that State Party, the building of confidence in compliance will depend on the consistency of the information being accumulated, the quality of the declarations by the State Party and the response by the State Party to any queries whether about when declarations will arrive or about any aspect of a declaration as well as the way in which visits to that State Party by the BTWC Organization have been received.

71. The heart of the building of confidence lies in the analysis of declarations and the carrying out of visits by the BTWC Inspectorate. In essence, the integrated regime can be represented as a combination of the two principal activities of building confidence and addressing concerns:



Conclusions

72. The Protocol being negotiated by the Ad Hoc Group in Geneva has all the key elements required for a highly effective integrated regime already in the draft text. The additional detailed measures identified here that have yet to be elaborated should not present an undue difficulty -- declarations of past BW facilities, visits to BW defence and government owned past BW facilities at about once every two years intervals, measures to improve implementation of Articles III, IV and X of the Convention designed to also contribute to strengthening confidence in compliance. This Briefing Paper has demonstrated that all the different elements are all inter-related and together will have a considerable synergistic effect that will create an effective regime building confidence in compliance with the Convention, ensuring that uncertainties, anomalies and concerns are swiftly investigated and improving the implementation of the Convention.

73. Such an integrated regime should achieve the required consensus support from all the States Parties engaged in the work of the Ad Hoc Group because it will achieve the necessary balance to meet the aims and objectives of both the developed and the developing world. Both developed and developing countries share a common desire to see the elimination of the use of deliberate disease to attack humans, animals and plants and a strengthening of global, regional and national counters to natural outbreaks of disease. The regime against biological weapons will be strengthened effectively so that States considering acquisition of biological weapons will judge that this is not worthwhile whilst access for peaceful purposes to materials and equipment in a transparent manner will be promoted so that States Parties can benefit from the burgeoning advances in biotechnology. The regime should be crafted so that where the biotechnology industry is already highly regulated this is taken into account and valuable commercial proprietary information protected. Additionally, assistance needs to be provided to States Parties to build the necessary infrastructure to implement the Protocol and achieve additional benefits for public health, environmental safety and increased trade.

74. It has become apparent that measures can be devised that will both achieve the effective implementation of Article X of the Convention **and** contribute directly to the enhancing of transparency and the building of confidence and thus to the strengthening of the effectiveness of the Convention. Although the final elaboration of the integrated regime has yet to occur, it does appear that the additional burden for both developing and developed countries will be modest and bring tangible benefits for security, public health, environmental safety and trade. The biotechnology industry is already highly regulated in many countries; measures that seek to harmonise such regulations will contribute both to the promotion of trade and the building of confidence that dual purpose materials and facilities are only being used for permitted peaceful purposes.

75. The benefits to national and international security are clear. It is also evident that a strengthened BTWC will build international confidence which will facilitate and encourage international trade safe in the knowledge that the dual purpose biological agents and toxins, equipment and facilities will not be misused for prohibited weapons. The recent political initiatives to encourage completion of the substantive negotiations of the Protocol this year are welcomed and it behoves us all to do what we can to facilitate and aid the negotiations of the Ad Hoc Group during its final few months.