THE COMPOSITE PROTOCOL TEXT: AN EVALUATION OF THE COSTS AND BENEFITS TO STATES PARTIES

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Introduction

1. On 30th March 2001, Ambassador Tibor Tóth, Chairman of the Ad Hoc Group, provided to States Parties both in capitals and in Geneva a composite Protocol text which was entirely based on the rolling text and adopted compromises to address the remaining differences in views. At the twenty-third session of the Ad Hoc Group in Geneva from 23 April to 11 May, Ambassador Tóth provided detailed explanations on an Article by Article basis of the compromises which had been adopted in the composite Protocol text. The procedural report of the April/May 2001 Ad Hoc Group session[1] contained the composite Protocol text as Annex B and the latest version of the rolling text as Annex A. The report stated that *"While recognizing the Rolling Text as the underlying basis for negotiations, the delegations expressed their views with regard to the compromise proposals contained in the Composite Text, both in formal and informal sessions."*

2. Ambassador Tóth in his press conference at the end of the Ad Hoc Group twenty-third session on 11 May 2001 said that the States Parties at the Ad Hoc Group had welcomed the provision of the Chairman's composite Protocol text. He went on to say that in their view it demonstrated that it was possible to meet the mandate of the Ad Hoc group to complete the Protocol by the Fifth Review Conference in November/December 2001. He added that quite a number of delegations had welcomed the balance struck in text although, as might be expected from the nature of compromises, there were delegations who were unhappy with particular aspects. He said that:

> *"What was emerging as a climate in the negotiations was that the delegations which used to form a silent majority in the negotiations had spoken massively in the course of the session. They spoke in favour of the fulfilment of the mandate and concluding the negotiations in the next session. … the question was whether delegations and capitals participating in these negotiations for practically seven plus three years would say yes or no to a Protocol, which in his judgement, would respect legitimate bio-defense, industrial and non-proliferation interests while providing for efficient, additional tools to strengthen the Biological Weapons Convention."*

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[1] 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/56-1 and 56-2, 18 May 2001, Geneva.

3. Evaluation Paper No 20[2] distributed at the twenty-third Ad Hoc Group session in April 2001 considered the composite Protocol text[3], compared it with the latest version of the rolling text[4] and evaluated the compromises that had been adopted to resolve the differing views of delegations. It then considered the potential contribution that the Protocol based on the composite text will make to strengthening the regime against biological weapons. It concluded that the Protocol regime brings significant and worthwhile benefits to all States Parties -- both developed and developing -- over and above the basic prohibitions and obligations of the BTWC.

4. Since the April/May Ad Hoc Group session, a technical correction[5] of the composite Protocol text has been issued. It has also been evident that each of the States Parties engaged in the negotiations have been considering the composite Protocol text and how best to take the negotiations forward. There has also been, disappointingly, a number of commentaries by outside observers which are based on misperceptions -- they are clearly not based on what is actually in the Chairman's composite Protocol text or they are evaluating the text against different criteria from those in the mandate agreed by the States Parties which has guided the Ad Hoc Group throughout its negotiations. These commentaries frequently fail to recognize that there is an extremely close relationship between biological and chemical agents and that there are compelling arguments for the BTWC Protocol and the Chemical Weapons Convention to function in parallel in the monitoring of compliance of dual-purpose agents.

5. This Evaluation Paper examines the value of the Protocol by making comparisons, first between the Biological and Toxin Weapons Convention (BTWC) with its Protocol regime and the BTWC alone, and then between the BTWC with its Protocol regime and the Chemical Weapons Convention (CWC) regime, given that both Conventions overlap -- and rightly so -- in the areas of toxins, bioregulators and peptides. The comparison with the BTWC alone shows that the Protocol brings significant and worthwhile benefits to all States Parties whilst the comparison with the CWC shows that 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.

6. Attention is then paid to a number of key issues:

a. The Effectiveness of the Protocol

b. Export Controls

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[2]Graham 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

[3]United 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.

[4]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/55-1 and 55-2, 1 March 2001, Geneva.

[5]United 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 (Technically corrected version), 30 May 2001, Geneva.

c. The Burden of the Protocol

d. Industry Concerns

e. Additional Mechanisms under Discussion

f. Other International Monitoring Systems

g. More time needed?

7. In the final section, a tabular comparison is made first on an Article by Article basis of the costs and benefits of the composite Protocol and then between the costs and benefits of signing the composite Protocol text and rejecting the composite Protocol. This leads to the conclusion that signing the Protocol brings a **net** benefit to **all** States Parties and furthermore that:

a. In signing and ratifying the composite Protocol text, States Parties will be seen to have **taken all possible practicable** multilateral steps to **obstruct** the proliferation of biological weapons.

b. Signing and ratifying the composite Protocol text will **reduce** the risk of biological weapons proliferation and use. Rejection of the Protocol would send the opposite signal and it can be argued that the risk of biological weapons proliferation and use will be increased.

c. Signing and ratifying the composite Protocol text will bring significant benefits to the infrastructure of States Parties in the areas of combatting infectious disease, biosafety and good manufacturing practice and thereby **benefits in health, safety and prosperity** for all States Parties, both developing and developed.

d. Overall, signing and ratifying the composite Protocol text **enhances** the security of all States Parties. It provides **a net gain** to collective security. Rejection of the Protocol misses this opportunity and decreases collective security.

The Value of the Protocol

8. The Chairman's composite Protocol text is firmly based on the rolling text – indeed over 99% is identical to language in the rolling text – in which compromises have been adopted where necessary. . A detailed evaluation[6], Article by Article, of the Chairman's composite Protocol text distributed to the delegations to the Ad Hoc Group in April 2001 concluded that *"Whilst these compromises will not satisfy the aspirations of all the delegations to the Ad Hoc Group, they do, in our view, 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."* [Emphasis added]

[6]Graham 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

9. It is critically important to consider what is **actually** in the Chairman's composite text and not to comment, as some commentaries have, on misperceptions based on incorrect or dated appreciations; the terminology used in some commentaries indicates a failure to read or study the Chairman's composite Protocol text. It has also to be recognized that the Protocol negotiations have seen the evolution of a text that reflects the inputs of the negotiators and the strengths and validity of the arguments put forward. It is, however, true that the elements identified in the first version of the rolling text in mid-1997 are all still there in the Chairman's composite Protocol text. It is the detail that has been developed and refined in the light of the negotiations.

10. It is **now timely and necessary** after years of detailed negotiation about words and paragraphs in the Articles to stand back and examine the Chairman's composite Protocol text as a whole in order to consider its value. It is also necessary to recognize that what has been negotiated is a Protocol to strengthen the effectiveness and improve the implementation of the Convention – it is not and never has been a "verification" Protocol. Rather its whole thrust has been to focus on compliance – to increase transparency as well as the quantity and quality of information about activities and facilities within States Parties of particular relevance to the Convention. Over time this transparency will help to build confidence between States Parties that they are in compliance with the Convention. In addition, the Protocol will help States Parties determine whether other States Parties are behaving in a way that is consistent with the Convention. It will also deter States Parties from considering violation of the Convention as non-compliant activities may be exposed and the non-compliant State Party isolated. Whilst the Protocol could have been stronger, it has to be recognized that stronger measures would not have attracted wide support and that the composite Protocol text is **the best** that can be negotiated at this time. A further period of negotiation would not strengthen the composite Protocol text and could well lead to unravelling of what is already a good Protocol. In standing back to examine the Protocol, a useful analogy is to a tree where the Ad Hoc Group have been considering which way the branches will go and what the shape of the leaves should be. It is now time to consider the whole tree.

11. In considering the Chairman's 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. The Protocol makes **no** changes to the basic prohibitions and obligations. The Protocol regime is supplementary and additional to the Convention. It does not undermine the prohibitions in Article I, but rather the Protocol safeguards Article I -- a long standing objective of many delegations.

12. 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.

Table 1. Comparison of the Convention and its Protocol Regime with the Convention alone

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
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**

13. Considering all the elements that make up 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:

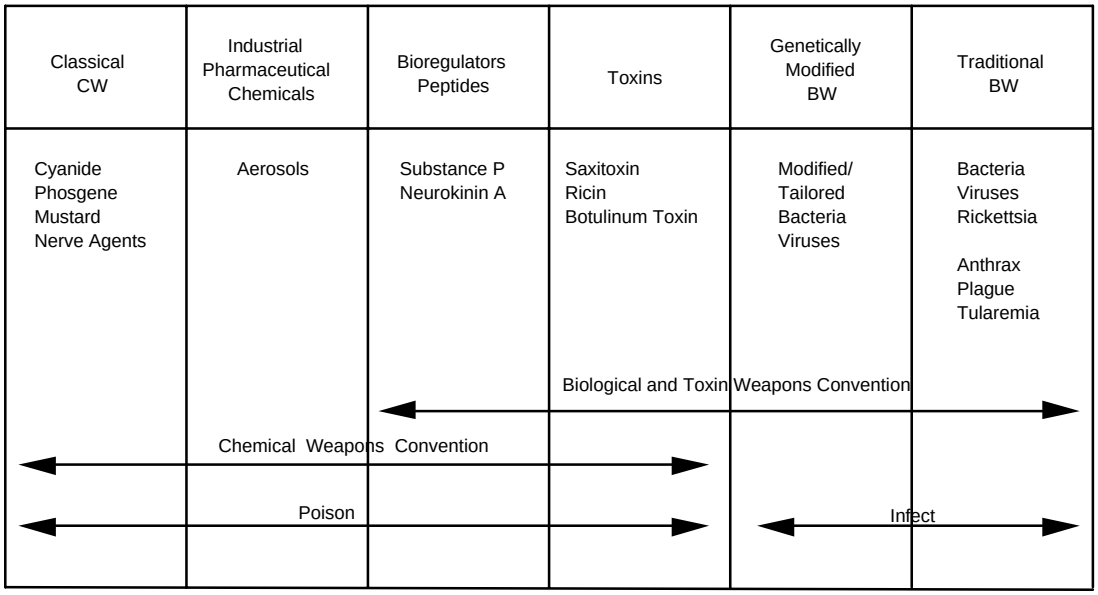
Table 2: Principal benefits from the BTWC and its Protocol Regime compared to the BTWC alone.

BTWC and its Protocol Regime	BTWC alone
Measures to increase transparency and build confidence	Suspicions **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 enhancing infrastructure, transparency and building confidence	**No** action despite aspirations at successive Review Conferences

14. The above comparisons show that the Protocol regime brings significant and worthwhile benefits to **all** States Parties -- both developed and developing -- over and above the provisions 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 international cooperation and assistance provisions address a genuine need to counter outbreaks of disease and through improvements in infrastructure in areas such as biosafety and good manufacturing practice to meet internationally accepted standards bring benefits for health and safety as well as for prosperity. The Protocol as a whole thus brings improved health, safety, security and prosperity to all States Parties.

15. It is also appropriate to compare the BTWC Protocol regime with the CWC regime -- both Conventions address toxins, bioregulators and peptides and thus rightly have a significant area of overlap, both have general purpose criteria which embrace all possible agents, past, present and future, and both address dual use materials and technology.



The CWC regime is the one of **greatest** relevance to the BTWC Protocol regime and it is already evident that National Authorities for the two regimes are likely to be colocated in a number of countries.

16. It is hardly surprising that the BTWC Protocol regime has adopted some concepts where appropriate from the CWC regime. It is not, however, just a simple copy which ignores the fundamental differences between the two areas. The Protocol is, however, much more elaborated than the CWC and has been finely tailored to address the fundamental difference in the nature of biological agents as well as to capture the facilities of greatest relevance to the Convention. If we ignore the chemical weapon and chemical weapon production facility elements[7] of the CWC, then the basic architecture of the BTWC Protocol regime and the

[7]This difference results because the CWC was negotiated when a number of States had admitted to having stockpiles of chemical weapons and to having chemical weapon production facilities which are required to be destroyed under the CWC. In contrast, when the BTWC was negotiated in the early 1970s the US had already announced that it would destroy its stockpile and no other State admitted to having stockpiles of biological weapons or to biological weapon production facilities. Consequently, Article II of the Convention makes no mention of production facilities and simply states that:

> *Each State Party to this Convention undertakes to destroy, or to divert to peaceful purposes, as soon as possible but not later than nine months after entry into force of the Convention, all agents, toxins, weapons, equipment and means of delivery specified in article I of the Convention, which are in its*

CWC regime is the **same.** The qualitative differences between the regimes are in the detail: the BTWC Protocol regime has built on the confidence-building measures agreed by **all** the States Parties at the Second Review Conference in 1986 and extended at the Third Review Conference in 1991. 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.

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possession or under its jurisdiction or control. In implementing the provisions of this article all necessary safety precautions shall be observed to protect populations and the environment.

As the BTWC has been in force since 1975 and no State has admitted to a stockpile of biological weapons there are no provisions in the Protocol requiring the declaration and destruction under verification of such weapons.

Table 3. Comparison of the BTWC and its Protocol Regime with that of the CWC

BTWC and its Protocol Regime	CWC Regime
Mandatory declarations -- range of facilities (BL-4, BL-3*, work with listed agents*, production, …) -- requires declaration of biological defence -- measures to ensure submission	Mandatory declarations -- focussed on chemical production facilities -- **no** declarations yet of chemical defence -- **no** measures to ensure submission
Declaration follow-up procedures -- explicit and structured -- analysis of declarations -- randomly-selected transparency visits	Declaration follow-up procedures --implicit and unstructured -- 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 -- includes investigation of releases	Investigation of alleged use -- **no** investigation of other releases
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 --targeted on genuine need to counter disease -- real benefits over time >>health, prosperity	International Cooperation -- **not** elaborated in detail -- **no** provision for Cooperation Committee
Organization -- CoSP, ExC & Technical Secretariat -- TS has role to analyse epidemiological info	Organization -- CoSP, ExC & Technical Secretariat -- **no** parallel role
Confidentiality Provisions -- elaborated in detail in Article and Annex	Confidentiality Provisions -- **no** Article but an Annex -- **not** as elaborated
National implementation -- Penal legislation required -- National Authority	National implementation -- Penal legislation required -- National Authority

* Indicates that only selected facilities meeting certain combinations of conditions, **not** all such facilities are to be declared.

17. This comparison demonstrates that the two regimes are indeed comparable and effective. Indeed, the **quality** of the Protocol regime is certainly **as good as**, **if not better than**, that of the CWC. Both address dual purpose materials and technologies. Lessons have been learned from the CWC implementation experience. The Protocol text has successfully been crafted so that it will achieve the requirement for an effective and reliable regime which, in accordance

with the AHG mandate, will strengthen the effectiveness and improve the implementation of the BTWC and thereby strengthen the norm against biological weapons. There is no doubt that the Protocol will be of immense value to **all** States Parties -- both developed and developing – bringing improved health, safety, security and prosperity. Indeed it should be noted that there is a relationship between the co-operative measures and international security: improving the international community's ability to deal with the consequences of infectious disease will help make it easier to identify deliberate outbreaks of disease that are the result of the use of biological weapons. National improvements in biosafety, good manufacturing practice and the regulations covering the handling, transportation and use of biological agents and toxins through the Protocol cooperation measures will improve national infrastructure as well as transparency and over time will contribute to building confidence.

18. The Protocol is also important for its contribution to the web of deterrence[8] which comprises:

- A strong international and national prohibition regime reinforcing the norm that biological weapons are totally prohibited

- Broad international and national controls on the handling, storage, use and transfer of dangerous pathogens

- Preparedness including both active and passive protective measures and response plans that have been exercised

- Determined national and international response to any use or threat of use of biological weapons ranging from diplomatic sanctions through to armed intervention,

which are together mutually reinforcing and lead a would-be possessor, whether a "rogue State" or a non-State actor to judge that acquisition and use of BW would not be valuable, would be detected and incur an unacceptable penalty. Any single element of the web of deterrence alone is insufficient -- all elements are vital and all need to be strengthened as they thereby reinforce the deterrent effect. The Protocol through its strengthening of the international prohibition regime not only reinforces the norm that biological weapons are totally prohibited, its requirements also strengthen the international and national controls on the handling, storage, use and transfer of dangerous pathogens and the determined international response to any use or threat of use of biological weapons. In other words, the Protocol contributes to the strengthening of all the elements of the web of deterrence.

19. The States Parties to the Protocol will over time gain confidence in the compliance of the other States Parties and any State Party contemplating breaching the Convention will be deterred through the prospect that such a breach will be detected by the measures in the Protocol. Increasingly, States not Party to the Protocol will be isolated and any proliferators can be countered better by the multilateral body of the States Parties to the Protocol.

20. When considering the composite Protocol regime to prevent biological weapons, it is all too easy to focus exclusively on security and arms control considerations and to fail to

[8]Graham S. Pearson, *The Vital Importance of the Web of Deterrence*, Sixth International Symposium on Protection against Chemical and Biological Warfare Agents, Proceedings, Stockholm, 10 - 15 May 1998, pp. 23-31. Graham S. Pearson, *Prospects for Chemical and Biological Arms Control: The Web of Deterrence*, The Washington Quarterly, Spring 1993, pp.145 - 162.

recognise that there are wider perspectives that are relevant to biological agents and toxins and which should and need to be taken into account in considering how States can increase transparency and build confidence that activities are indeed for peaceful purposes. Article 14 of the composite Protocol aims to foster international cooperation for peaceful purposes. It provides for the future Protocol 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. The range of cooperation topics identified in Article 14 include the following:

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

21. The cooperation topics identified in the composite Protocol are related to wider international perspectives and initiatives which bring benefits to **all** States Parties, both developing and developed. The following international initiatives are considered here:

a. to counter outbreaks of disease whether in humans, animals or plants;

b. to protect the environment through the Convention on Biological Diversity and its International Guidelines on Biosafety and, more recently, the Cartagena Protocol on Biosafety;

c. to prevent the illicit use of narcotic drugs and psychotropic chemicals; and

d. to harmonize Good Manufacturing Practice for safe and reproducible pharmaceutical and biological products.

22. Each of these is examined 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 Diversity[9] 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 Guidelines[10] 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[11] 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 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[12], the 1971 Convention on Psychotropic Substances[13] and the 1988 Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances[14]) 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

[9]United 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.

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

[11]United Nations Environment Programme, Convention on Biological Diversity,*Cartagena Protocol on Biosafety to the Convention on Biological Diversity*, 29 January 2000. Available at http://www.biodiv.org/biosafety

[12]Single Convention on Narcotic Drugs of 1961 and the Protocol of 25 March 1972 amending the Single Convention on Narcotic Drugs of 1961. Available at http://www.incb.org/e/conv/menu.htm

[13]Convention on Psychotropic Substances, 1971. Available at http://www.incb.org/e/conv/menu.htm

[14]United Nations Convention against Illicit Traffic in Narcotic Drugs and Psychotropic Substances, 1988. Available at http://www.incb.org/e/conv/menu.htm

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[15].

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 products[16]. 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 a tabulation addressing relating product and manufacturing licences:

Table 4: International Harmonization Schemes for Product and Manufacturing Licenses

[15]For additional information see Graham S. Pearson, *Further Chemical Control Regimes: Narcotic Drugs and Psychotropic Substances*, CBW Conventions Bulletin, No. 51 (March 2001). Available at http://fas-www.harvard.edu:80/~hsp.pdf.html The HSP Draft Convention to Prohibit Biological and Chemical Weapons under International Criminal Law, No 42 (December 1998).

[16]See 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

	Requirements for Industry	Regulatory Authority Action
Marketing Authorization *Product Licence*	Safety, efficacy & quality data **EU, ICH**	Evaluation, Licensing **EU, PER**
Manufacturing Authorization ***Manufacturer's Licence***	Good Manufacturing Practice **EU, PIC, WHO**	Inspection, Licensing **EU, PIC, MRAs**

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

Manufacturers' 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 is 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 14 of the composite Protocol 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.

23. When wider perspectives are considered, it is evident that the composite Protocol regime to *strengthen the effectiveness and improve the implementation* of the BTWC brings benefits in the context of an international scene in which there is increasing transparency about the nature of activities and facilities within countries. This transparency 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 composite Protocol regime -- declarations, visits, investigations -- are complemented by the provisions to promote scientific and technological exchange for peaceful purposes as these provisions help all States Parties to develop their infrastructure -- and thereby reap benefits in safety and health as well as in international trade and commerce which over time contribute to increasing transparency and enhancing confidence in compliance -- and thereby enhancing collective security.

The Issues

24. A number of issues are likely to be considered by States Parties in considering the Chairman's composite Protocol text and what their objectives should be in the July/August 2001 session of the Ad Hoc Group.

The Effectiveness of the Protocol

25. The aim of the Protocol throughout has been to create a package of measures that will increase transparency and build confidence between States Parties that they are in compliance with the Convention. It is a **not** a verification Protocol in the narrow sense – it is misleading to suggest otherwise. The heart of the Protocol is thus made up of mandatory declarations, the declaration follow-up procedures and the provisions for investigations. A balance has necessarily to be struck as to which facilities are to be declared: the Protocol declaration triggers embrace a wide range of the facilities and activities of most relevance to the Convention:

a. Biodefence programmes and facilities.

b. Maximum biological containment facilities

c. High biological containment facilities engaged in certain specified production or genetic modification activities

d. Plant pathogen containment facilities over a particular floor area

e. Work with listed agents and/or toxins of a particular character: production above a certain capacity; genetic modification activities; and intentional aerosolisation

f. Production facilities in excess of certain capacities or producing human or animal vaccines.

26. The scope of the facilities to be declared is thus much broader than those required to be declared under the comparable elements of the CWC. The CWC declarations primarily address chemical production facilities and have yet to include agreed modalities, as required under Article X of the CWC, for declarations of chemical defence programmes or facilities. Furthermore, the Protocol has provisions to help ensure submissions of declarations – provisions that have no parallels in the CWC, with a variety of tiered penalties, some automatic and some after consideration – should declarations fail to be submitted.

27. Those who argue that the CWC regime is not relevant to considerations of the BTWC Protocol regime are ignoring the facts that **both** regimes address dual-use materials and technology, **both** have general purpose criteria in the basic prohibition which ensures that past, present and future agents are all covered and **both** cover the prohibition of toxins, bioregulators and peptides. It is evident that the Protocol regime has been developed from that of the CWC and had been tailored to address the particular nature of biological agents and toxins.

28. The declaration follow-up procedures comprising the randomly-selected transparency visits and the carefully tiered provisions for clarification of any ambiguity, uncertainty, anomaly or omission in a declaration made by a State Party are vital for ensuring the consistency of declarations. No State Party would make inaccurate or incomplete declarations if they recognize that the deficiencies in their declaration will be exposed either by the randomly-selected transparency visits or by the declaration clarification procedures. The Protocol provisions enable either the future Organization or individual States Parties to initiate the declaration clarification procedures. Consequently, a State Party to the Protocol contemplating violation of the Convention would have either to carry out its activities in a declared facility -- and risk exposure both through the Organization or through another State Party seeking clarification -- or to use an undeclared facility and again risk exposure both through the Organization or through another State Party seeking clarification of the omission of that facility from the declarations. A useful analogy in considering the necessity of backing up mandatory declarations with follow-up procedures comes from self assessment under the UK and the US tax systems – how accurate would self assessment be if there were to be no follow up by the national tax authorities?

29. In considering the numbers of randomly-selected transparency visits carried out each year under the Protocol – limited to greater than 60 and less than 90 – their duration of no more than 2 days involving no more than 4 members in the visiting team, it has to be recognised that this is a remarkably effective way of enhancing transparency and generating confidence in the consistency of declarations. Remember that the purpose is to demonstrate compliance and to deter would-be violators rather than to find cheaters or catch out States Parties. In building compliance, there is indeed a bonus in that a State Party would be highly unlikely to carry out prohibited activities at declared facilities because of the risk that inconsistencies would be detected. If such prohibited activities were to be carried out at undeclared facilities, then again there would be a risk that inconsistencies would lead to clarification being sought about ambiguities, uncertainties, anomalies or omissions – and such clarification can be sought directly by a State Party and is not dependent on the future Organization. Regular visits to States Parties means that the inspectorate will develop an appreciation of how regulatory frameworks apply in specific States parties, the national standards that apply and improve understanding of national processes. All this will be indispensable knowledge in the event of an investigation. If a facility investigation were to be carried out within a State Party, would it not better if the inspectorate had some prior knowledge or the regulatory

frameworks, norms, practices and degree of sophistication or otherwise that applied within that State Party? Such understandings will go a long way in preventing investigation teams misinterpreting what they see and reduce the risk that they might draw the wrong conclusion.

30. The investigation provisions are for both field and facility investigations of non-compliance concerns. The Protocol includes within field investigations provisions for the investigation of releases of biological agents or toxins.

31. In sum, the Protocol regime of declarations, follow-up procedures and investigations provides a structured and elaborated framework for the provision of accurate information about the activities and facilities of the most relevance to the Convention. This brings immense benefits as was noted by Dr John Gee, Deputy Director General of the OPCW, addressing the success of the declarations made under the CWC, who said[17] that:

> *What is significant is the fact that declarations have been made and the key parts of each State Party's declarations are available to all other States Parties….This has been a considerable confidence-building measure….This process has answered a lot of questions that were out there prior to entry into force….all the other countries had to go on were press reports and intelligence estimates and so forth. The whole process of having declarations available to other States Parties has been a great success and a very substantial confidence-building measure.*

32. If the situation with the Protocol in place is compared with the alternative of simply continuing with the Convention, it is impossible to see how a conclusion -- as has been stated recently within one State Party -- can be reached that "*a Protocol would not improve our ability to effectively verify compliance with the BWC either in terms of certifying that a country is in compliance with, or in violation of, its obligation*". Without the Protocol all that any country has to go on are press reports, intelligence estimates and so on; intelligence estimates have necessarily to be worst case assumptions and may well give undue credence to rumour and innuendo or simply fail to recognise perfectly legal reasons for an activity. Indeed, an analysis[18] of the history of biological weapons programmes up to 1945, has shown that misperceptions can lead to the initiation of offensive biological weapons programmes. However, with the Protocol in place, there will also be mandatory declarations from States Parties with the means to clarify any ambiguities, uncertainties, anomalies or uncertainties, providing hard evidence as to activities and facilities within the State Party. Any inconsistencies between parts of declarations can be addressed by States Parties as well as by the future Organization leading to a more comprehensive and soundly based appreciation of the activities and facilities within the State Party.

Export Controls

33. It is widely recognised that the provisions in the Protocol relating to controls of transfers of biological agents or equipment have been one of the most controversial issues. It is,

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[17] John Gee, *The CWC at the Two-Year Mark: An Interview with Dr John Gee*, Arms Control Today, April/May 1999. Available at http://www.armscontrol.org/ACT/aprmay99/jgam99.htm

[18] Erhard Geissler, John Ellis van Courtland Moon and Graham S. Pearson, *Lessons from the History of Biological and Toxin Weapons*, in Erhard Geissler and John Ellis van Courtland Moon (eds), *Biological and Toxin Weapons: Research, Development and Use from the Middle Ages to 1945*, SIPRI Chemical and Biological Warfare Studies, No. 18, Oxford University Press, 1999, pp. 255 - 276.

however, essential to examine the issue in perspective and not to get carried away by emotional arguments. First of all, it has to be recognised that the formula adopted in the CWC in the early 1990s in its Article XI that the States Parties shall:

> *c. Not maintain among themselves any restrictions, including those in any international agreements, incompatible with the obligations undertaken with the Convention, which would restrict or impede trade and the development and promotion of scientific and technological knowledge in the field of chemistry for industrial, agricultural, research, medical, pharmaceutical or other peaceful purpose.*

would not be acceptable some 10 years later for the language of the Protocol. To think that time has stopped and the same language would be acceptable would be naïve. However, it is equally naïve to think that the world has moved to a situation in which controls of transfers are no longer required and can be dismantled. The facts are that governments around the world, in **both** developing **and** developed countries, are increasingly requiring prior notification of the imports of any potentially harmful materials – whether these be banned and severely restricted chemicals under the Rotterdam Prior Informed Consent Convention[19], genetically modified organisms under the Cartagena Protocol on Biosafety[20], narcotic drugs and psychotropic chemicals and their precursors under the various UN Drug Conventions[21] or chemical and biological materials relevant to chemical and biological weapons under the CWC and the BTWC Protocol.

34. The obligation under Article III of the BTWC is very clear:

> *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 this Convention.*

The mandate of the Ad Hoc Group – *to strengthen the effectiveness and improve the implementation of the Convention* -- is equally clear. The language in the Chairman's composite Protocol text does precisely that – it seeks to improve the implementation of Article III of the Convention – by requiring *Each State Party…to review and, if necessary, amend or establish any legislation, regulatory or administrative provisions to regulate the transfer of agents, toxins, equipment and technologies relevant to Article III of the Convention….* There are thus clear benefits – both in countering proliferation and the availability of materials and equipment for bioterrorism – for the international community from this requirement for **all** States Parties to establish the regulation of such transfers.

The Burden of the Protocol

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[19]The Rotterdam Convention on the Prior Informed Consent (PIC) Procedure for Certain Hazardous Chemicals and Pesticides in International Trade, 10 September 1998. Available at http://www.pic.int

[20]United Nations Environment Programme, Convention on Biological Diversity,*Cartagena Protocol on Biosafety to the Cinvention on Biological Diversity*, 29 January 2000. Available at http://www.biodiv.org/biosafety

[21]For additional information see Graham S. Pearson, *Further Chemical Control Regimes: Narcotic Drugs and Psychotropic Substances*, CBW Conventions Bulletin, No. 51 (March 2001). Available at http://fas-www.harvard.edu:80/~hsp.pdf.html

35. The mandate for the Ad Hoc Group required that consideration be given to:

> *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;*

In addition, 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.*

36. The Ad Hoc Group have been aware throughout of these requirements in the mandate. It was evident that especially in developed countries there was concern that any requirements in the Protocol should be the minimum necessary for an effective Protocol so that the additional burden whether it be for declarations or for declaration follow-up procedures should be minimized. Consequently, there is no requirement for the provision of commercial proprietary information or national security information in the Protocol declarations. There was also widespread recognition that many of the facilities to be declared under the Protocol are already subject to visits from both national and international regulatory authorities be it for health and safety, for good manufacturing practice or for other reasons. Consequently, the declaration follow up procedures in the composite Protocol text have been crafted to ensure that the measures are sufficient to encourage the consistency of declarations and the clarification procedures are carefully tiered again to minimise the burden. The declaration formats have been developed and elaborated in the Protocol – and not left as with the CWC to be developed during the Preparatory Commission stage. These formats have been trialled with industry in a number of developed countries to ensure that they are easy to complete and require the provision of relevant information that will contribute to the increasing of transparency between the States Parties. It is simply **not** true to allege, as has been done in some countries, that the Protocol's requirements compromise industry's ability to research and manufacture or that the Protocol establishes mechanisms to expose confidential information. Rather the opposite applies, in that the Protocol has gone to great lengths to protect confidential information, much more so than the CWC did when it emerged from Geneva.

37. In addition to all of this, the Chairman's composite Protocol text has introduced limits to the numbers of randomly-selected transparency visits as well as to clarification visits which distribute the burden of the Protocol more equably between States Parties with large numbers of declared facilities and those States with small numbers of declared facilities. There is an overall ceiling to the number of randomly-selected transparency visits of not more than 90 and not less than 60 a year. Within this ceiling, no State Party shall receive more than seven randomly-selected visits in any calendar year – given the range of declared facilities and the requirement that the randomly-selected visits be spread among a representative range of facilities, it follows that number of such visits to vaccine facilities in a country with a large number of declared facilities, such as the US, will depend on the numbers of facilities

declared by that country in the different declaration categories and is unlikely to be more than three or four a year at most – yet this has been alleged to be an undue burden on the vaccine production facilities of the United States. On the other hand, the composite Protocol text requires that each State Party that declares facilities shall receive at least two such randomly-selected visits in any five year period so it again cannot be argued that the burden is excessively placed upon the States Parties with the greatest number of declared facilities.

Industry Concerns

38. The concerns of industry have been borne in mind by the Ad Hoc Group throughout. In most countries, those engaged in the negotiations have maintained a dialogue on a continuing basis with their national industry to ensure that the emerging Protocol regime would be effective without being unduly burdensome. There is no sense in which it can be argued that vaccines are the bull's eye of the Protocol -- as has been claimed in testimony from a PhRMA representative to a US House of Representatives Sub Committee! The Protocol regime has evolved from the agreement by the States Parties some 10 years ago that declarations should be submitted under the Confidence-Building Measures for the facilities agreed to be of greatest relevance to the Convention – maximum containment facilities, biological defence programmes, human vaccine production facilities. The Protocol declaration requirements have built upon these and added the other most relevant activities and facilities.

39. There is a concern by industry in a number of countries, following on from the CWC experience, that there should be a uniform requirement on industry around the world to submit comparable information – or in other words, a level playing-field. The elaborated declaration formats coupled with the measures to ensure that declarations are submitted with its tiered automatic and considered penalties together with randomly-selected transparency visits will promote the consistency of declarations and, through the tiered declaration clarification procedures, will ensure that declarations are complete and comprehensive.

40. The argument that randomly-selected transparency visits to all declared facilities is not a useful concept is incorrect and short-sighted as such visits help to ensure the consistency of declarations. Furthermore, in the absence of randomly-selected transparency visits, the probability will be high that when the first facility investigation is carried out in that State Party an incorrect conclusion may be reached because of the lack of knowledge of the future Organization of the normal approaches to microbiology and biotechnology in that country.

41. As the maximum number of randomly-selected transparency visits that any State Party can receive in a year is 7, this means that for the maximum number of such visits in any year to a State Party with a large number of declared facilities is 7 in total to facilities out of **all** the facilities declared by that State Party -- whether biological defence, maximum containment (BL-4), high containment, plant pathogen containment, work with listed agents and toxins or production. The burden on the vaccine industry nationally in a country with a large number of declared facilities is unlikely to be more than perhaps four visits per year -- lasting no longer than 2 days each and with no more than four members in a visiting team. This burden pales into insignificance when compared to other national and international regulatory body inspections of such vaccine facilities. In the United States, the Food and Drug Administration (FDA) makes some 22,000 inspections each year of about a third of the US

firms inspectable by the FDA[22]. A further handful of visits -- totalling 7 at the most -- is hardly a significant additional burden to an already highly regulated industry. These visits are, however, sufficient to meet the transparency objectives set for them in the Protocol.

Alternatives to the Protocol

42. In the United States, there has been some consideration in a House of Representatives subcommittee[23] of possible alternatives to the Protocol. These additional mechanisms all relate to the surveillance and reporting of disease through international or voluntary disease reporting systems. Whilst these disease surveillance and reporting systems are all helpful and provide information that is complementary to the Protocol, they are all **necessarily** voluntary in nature and cannot be **mandatory.** It would be unrealistic – and could actually harm the health monitoring regime of the international community which depends critically upon participating States having confidence that, in reporting outbreaks of disease, they will not in some way be penalised – if a situation were to be sought in which reporting to the WHO, FAO and OIE were to be made mandatory in order to enable a body associated with the Biological and Toxin Weapons Convention to use such data to try to determine whether some outbreak had been deliberate and thus in breach of the Convention. The Chairman's composite Protocol text requires the Technical Secretariat of the future Organization *inter alia* to collect, process and analyse relevant epidemiological information. Furthermore, the Technical Secretariat is also explicitly required to develop a framework for States Parties to support an international system for the global monitoring of emerging diseases in humans, animals and plants. It is **not** true, as has been alleged in testimony to the House subcommittee, to say that the Protocol does not have any provisions to create, expand or mandate systems to monitor disease occurrence.

43. It should be recalled that there has been agreement between the States Parties to submit information on outbreaks of disease as a confidence-building measure under the Biological and Toxin Weapons Convention. Few States have provided such information and the information submitted has been variable and raises more queries than answers – yet there is no mechanism by which such queries could be resolved. The **voluntary** nature of disease surveillance and reporting means that the data-sharing system mentioned as an additional mechanism would not be a credible contribution to biological weapons prohibition. However, improved disease surveillance and reporting would indeed be a valuable adjunct to the Protocol – but this is something that is best addressed through the relevant international organizations – the WHO, FAO and OIE – thereby making best use of their competencies and avoiding duplication.

Other International Monitoring Systems

44. There are no other existing international monitoring systems which could make a legally-binding contribution to the strengthening of the effectiveness and improving the

[22]Food and Drug Administration, *Food and Drug Administration FY 2001 Congressional Budget Request.* Available at http://www.fda.gov

[23]See United States House of Representatives, Subcommittee on National Security, Veterans Affairs and International Relations, 5 June 2001 and 10 July 2001 hearings. Available at http://www.house.gov/reform/ns/web_resources/news_briefing_june_5.htm and http://www.house.gov/reform/ns/web_resources/shays_pr_july_10. htm

implementation of the Biological and Toxin Weapons Convention. In other words, there is no credible or realistic alternative to the Protocol – and the Protocol is needed **now** to counter the increasing danger from the already prohibited misuse of recent scientific and technological developments in microbiology and biotechnology.

45. In the longer term, the norm against chemical and biological weapons could be usefully enhanced by the international criminalization of work on chemical and biological weapons. This could be achieved by making such work into a crime against humanity in a similar way to piracy, hijacking and torture. A draft treaty to do this has been prepared[24] by the Harvard-Sussex Program – this needs to be taken by one or more States to the UN General Assembly for consideration by the 6th Committee. Such an international criminalization would be complementary to the BTWC and its Protocol and the CWC.

More time needed?

46. It has been suggested by some that more time is required. The negotiations have already taken six years; if we include the VEREX process then we are looking at a decade of effort. In essence the core issues have not really changed. Many of the differences between delegations today are the same as they were in 1995. Another six months or a year or two of negotiations will not make any significant difference to, for example, the diverging views on export controls. More time will **not** make the text stronger, it will only lead to its unravelling. There were many Western and non-aligned delegations that would have wished to see stronger procedures for visits; this was one of the most intensely disputed part of the negotiations. However, more time is not going to lead to additional provisions in the visits text or to persuade others that they should be introduced. What is available in the Chairman's composite Protocol text is the **best** compromise that can be had now, or achieved, for the foreseeable future given the reality of the diversity of views. The whole point of the Chairman's composite text was to break the logjam with a balanced text that is aimed at meeting the aspirations of **all** delegations, both large and small. While no State Party will have achieved all of its objectives, that in itself should not be the criterion by which this achievement is judged. It is vital that all States answer the question -- are they better with the Protocol regime than without it? Careful consideration shows that the Protocol provides a **net gain** to all States Parties with the benefits significantly outweighing the costs.

Conclusions: The Bottom Line

47. There is no doubt at all to those who have closely examined the intricacies of the Protocol and the details of the prohibition regime of closest relevance to the Biological and Toxin Weapons Convention – the Chemical Weapons Convention – that the Protocol brings **significant benefits** to the multilateral regime to prevent biological weapons. The world does not stand still and it is important to recognise that the international community reacts to what happens. The Chemical Weapons Convention with its attention to the dual use of chemicals was a significant step forward that is widely recognised as strengthening the security of **all** States Parties. The Protocol to the Biological and Toxin Weapons Convention in the form of the Chairman's composite Protocol text provides another opportunity to make the world a safer, more secure place. Without a Protocol to the Convention, biological

[24] *The HSP Draft Convention to Prohibit Biological and Chemical Weapons under International Criminal Law,* CBW Conventions Bulletin, No 42 (December 1998). Available at http://fas-www.harvard.edu:80/~hsp.pdf.html

weapons will continue to present the **greatest** danger of all weapons of mass destruction – a point that is well recognised around the world[25]. The Protocol provides **a net gain** to all States Parties. There is a real opportunity and a real benefit here for all States – for any State Party to reject the Protocol would be short-sighted and foolish in the extreme and would not best serve the interests of that State Party or the world.

48. The Protocol is an opportunity that is available **now** – to reject it would be to send the message unequivocally that States do not care about establishing a stronger regime to prevent biological weapons and their proliferation. It would be **contrary** to the collective determination and political will that States Parties have shown over the past 50 years in building a world in which weapons of mass destruction are increasingly prohibited and their proliferation countered by **all** possible measures. If an individual State chooses to reject the composite Protocol text, that State is:

-- **Missing** the opportunity to take a big step forward to make work on biological weapons a penal offence around the world with benefits for both international security and for countering biological terrorism wherever it occurs;

-- **Failing** to take the opportunity to require all States Parties to review, amend or establish controls of the transfers of pathogens and dual use technologies;

-- **Failing** to move forward to a world in which there is much greater transparency about activities and facilities relevant to the Biological and Toxin Weapons Convention and in which over time confidence will be built between States Parties that they are indeed compliant with the obligations and undertakings under the Convention.

-- **Failing** to realize a world in which there is a more and accepted mechanism to address concerns about non-compliance with the Convention. The quarter century since the entry into force of the Convention has been marked by the inability of the States Parties to address such non-compliance concerns – a situation in which the United States at the Fourth Review Conference in 1996 said that twice as many States were then seeking or had biological weapons than when the Convention entered into force in 1975 is hardly a testimony to a successful and effective regime.

-- **Failing** to take the cooperation opportunities provided under the Protocol to enhance national capabilities to counter outbreaks of disease, to improve biosafety and to promote GLP and GMP standards bringing benefits in health, safety and prosperity.

Indeed, rejection of the Protocol by an individual State will undermine other efforts that that State might wish to pursue internationally at the bilateral, regional or multilateral level. Diplomatic leverage may be weakened and attempts to mobilize international opinion and support will be made much more difficult if that State has cast aside an internationally negotiated text, especially one which protects so many avowed interests of States Parties.

[25]See Graham S. Pearson, *Why Biological Weapons Present the Greatest Danger*, Seventh International Symposium on Protection against Chemical and Biological Warfare Agents, Proceedings, Stockholm, 15 - 19 June 2001. Available at http://brad.ac.uk/acad/sbtwc

Rejection of the Protocol sets that State at variance with every other nation in the world which recognizes that **collective** security is **vital** for peace and security in the 21st Century.

49. An analysis, on an Article by Article basis, of the principal costs and benefits of the Chairman's composite Protocol text demonstrates that the composite Protocol text is effective and efficient in bringing significant benefits to all States Parties at minimal costs for those States who are already implementing the provisions and obligations of the Biological and Toxin Weapons Convention.

Table 5 : Article by Article analysis of the principal costs and benefits of the composite Protocol

Composite Protocol Article	**Costs**	**Benefits**
Preamble	• None	• Reaffirmation by States Parties of obligations under the Convention
Article 1 General provisions	• Take any measures required to implement obligations under Protocol	• Assurance of protection of CPI and NSI • Receipt of information on implementation of Protocol
Article 2 Definitions	• None	• Assurance that Protocol measures will be applied consistently
Article 3 Lists and Criteria, Equipment and Thresholds	• None • Collection of information and calculation of threshold at biodefence facilities	• Assurance that Protocol measures will be applied consistently • Improved transparency relating to production of specified material at biodefence facilities
Article 4 Declarations	• Collection of information required in declarations -- modest when building on arrangements already in place to collect information for CBMs	• Receipt of declaration information submitted by other States Parties • Improved transparency relating to key biological activities
Article 5 Measures to ensure submission of declarations	• None if declarations submitted on time	• Encouragement of all States Parties to submit declarations on time -- level playing field

Composite Protocol Article	Costs	Benefits
Article 6 Follow-up after submission of declarations	• Receipt of randomly-selected visits -- but not > 7 per year • Receipt of clarification inquiries -- minimal if declarations are completed accurately and comprehensively • Receipt of technical assistance visits -- if requested	• Assurance of consistency of declarations by States Parties • Ability to seek clarification of any ambiguity, uncertainty, anomaly or omission in declarations by other States Parties • Availability of Protocol implementation assistance or of technical assistance
Article 7 Measures to strengthen implementation of Article III of the Convention	• Review, amend or establish any legislation or regulatory procedures to regulate transfers relevant to Article III -- minimal if State Party has already implemented Convention obligations	• Assurance that all States Parties are regulating transfers relevant to Article III • Reduced risk of proliferation or bioterrorism
Article 8 Consultation, Clarification and Cooperation	• Receipt of clarification inquiries -- minimal if State fully transparently compliant with Protocol and Convention	• Ability to seek clarification of any matter relating to the aim and purpose of the Convention -- helps give substance to Article V of the Convention
Article 9 Investigations	• Receipt of field or facility investigations. Minimal if State investigates outbreaks of disease transparently and has been fully transparently compliant with the Convention and Protocol • Training and preparation for handling incoming investigations. Minimal as training and preparation for CWC incoming challenge inspections will cover most aspects	• Ability to request investigation should there be substantive and compelling grounds for concern about compliance with the Convention -- considerable improvement over current procedures based on Article VI of the Convention, and on the UN Secretary-General procedures for investigating alleged CBW use
Article 10 Additional provisions on declarations, visits and investigations	• None for most States Parties	• Enables situations involving more than one State Party or a State not party to the Protocol to be addressed
Article 11 Confidentiality provisions	• Measures required for the secure handling of information and data received from the Organization	• Assurance that information and data provided to the Organization -- and thus to other States Parties -- will be protected appropriately

Composite Protocol Article	Costs	Benefits
Article 12 Measures to redress a situation and to ensure compliance	• None for States fully transparently compliant with the Convention and the Protocol	• Assurance that any situation that contravenes the provisions of the Convention and the Protocol will be redressed and remedied
Article 13 Assistance and protection against bacteriological (biological) weapons	• Provision of such information on protection against biological and toxin weapons as State may decide to provide • Provision of assistance to the extent possible	• Access to databank of protection information maintained by the Organization • Receipt of assistance in the event of use or threat of use of biological weapons • Provides greater substance to Article VII of the Convention
Article 14 Scientific and technological exchange for peaceful purposes and technical co-operation	• Provision of annual declaration • National contributions to technical cooperation efforts	• Receipt of cooperation and assistance in wide range of areas -- countering disease, biosafety, GMP etc • More effective implementation of existing efforts in these areas
Article 15 Confidence-building measures	• Provision of information as decided by State Party -- minimal if State already providing CBM information	• Receipt of information provided by other States Parties
Article 16 The Organization	• Provision of representation to COSP and ExC as appropriate • National annual contribution costs to Organization	• Assurance that Protocol implemented effectively and efficiently
Article 17 National implementation measures	• Take any measures required to implement obligations under Protocol -- modest if Convention already implemented	• Assurance that other States Parties have enacted legislation to implement Protocol • Benefits from strengthened national prohibition -- counters to bioterrorism
Articles 18 - 30	• None	• Assurance that Protocol implemented effectively

When the comparison with the Chemical Weapons Convention made earlier is considered, this above analysis also shows why several States Parties have decided to colocate their national Authorities for both the BTWC Protocol and for the Chemical Weapons Convention.

50. Building on the consideration of the costs and benefits of the composite Protocol, a succinct comparison can be made in the Table below of the gains and costs of signing the Composite Protocol compared to the costs and gains of rejecting the Protocol. Overall conclusions are then drawn about the net value of signing the Composite Protocol -- and the net costs of rejecting it. Before examining the detail in the Table, it is important to recognise that there are areas where the interests of States Parties will remain the same whether or not they sign the Protocol. First, there is no change to the total prohibition as all States Parties to the Convention have already committed themselves to this undertaking. Second, there is no change in the intelligence priorities of any State Party for collection and analysis of potential threats. The main impact of signing the Protocol will be to make available to all States Parties, an additional body of information which can be used nationally in guiding the employment of national intelligence resources.

51. The overall conclusions that emerge from examination of the Table are the following:

a. In signing and ratifying the composite Protocol text, States Parties will be seen to have **taken all possible practicable** multilateral steps to **obstruct** the proliferation of biological weapons.

b. Signing and ratifying the composite Protocol text will **reduce** the risk of biological weapons proliferation and use. Rejection of the Protocol would send the opposite signal and it can be argued that the risk of biological weapons proliferation and use will be increased.

c. Signing and ratifying the composite Protocol text will bring significant benefits to the infrastructure of States Parties in the areas of combatting infectious disease, biosafety and good manufacturing practice and thereby **benefits in health, safety and prosperity** for all States Parties, both developing and developed.

d. Overall, signing and ratifying the composite Protocol text **enhances** the security of all States Parties. It provides **a net gain** to collective security. Rejection of the Protocol misses this opportunity and decreases collective security.

52. In evaluating the composite Protocol text, it has to be remembered 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 is evident from the analysis of the principal costs and benefits on an Article by Article basis of the composite Protocol that the Protocol will bring significant and worthwhile benefits to **all** States Parties -- both developed and developing. Furthermore, a consideration in a wider perspective shows that signing and ratifying the composite Protocol will bring a **net gain** for all States Parties. The Protocol will be effective, over time, in increasing transparency and 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 will bring improved health, safety, security and prosperity to **all** States Parties.

Table 6 The Costs and Gains from the Composite Protocol

SIGN COMPOSITE PROTOCOL	REJECT COMPOSITE PROTOCOL
GAINS	**COSTS**
Reinforcement of international norm that biological weapons totally prohibited	**No** reinforcement of international norm that biological weapons totally prohibited **Risk** that norm is weakened as State Party seen to have declined opportunity to strengthen
Deterrence of would-be violator significantly **enhanced**	**Perception** that biological weapons unimportant Would-be violator **encouraged** by continued international inaction on BTWC
Increased transparency of activities in other States through mandatory declarations	Confidence-building measure submissions if the State decides to submit
Anomalies, uncertainties and **omissions** in declarations can be addressed	**No** means of addressing anomalies, uncertainties and omissions
Mechanisms established to address **non-compliance concerns** through investigations	Continuing **ineffective/unused** provisions (take concerns to UN Security Council)
All States required to enact **penal** legislation -- **reduced** possibility of bioterrorism	**No** requirement for penal legislation
All States required to establish **transfer controls** -- **reduced** possibility of agent/equipment acquisition by States or by non States actors	**No** requirement for establishment of transfer controls
COSTS	**GAINS**
Costs of Protocol implementation -- Modest. International organization half size of OPCW National authority could be colocated with that for CWC -- additional data collection modest compared to that for existing CBMs	Avoidance of cost of Protocol implementation
OVERALL CONCLUSIONS	**OVERALL CONCLUSIONS**
State Party has taken **all possible** multilateral steps to prevent biological weapons -- collective security augmented by strengthening effectiveness of the BTWC	State Party **lack of interest** in multilateral world community -- sets State Party at variance with collective security objectives of the rest of the world
Reduced risk of BW proliferation	**Continuing** (increased?) BW proliferation risk
Reduced risk of BW use	**Continuing** (increased?) risk of BW use
State Party security **enhanced**	Opportunity **missed**

A summary of the key points is provided in the Box:

• All States Parties **need** this Protocol to enhance their security against the deliberate use of disease against humans, animals or plants – biological weapons.

• Why do we need this Protocol? Without it, there is no mechanism to challenge the potential violator. With the Protocol, there are mechanisms to challenge the potential violator – by facility or field investigations – and thereby raise the cost to the violator of pursuing this option.

• To make the challenge mechanism effective, we must have declarations. Why? Because they offer the possibility of finding the smoking gun and if the smoking gun is not found then may find equipment – such as fermenters or facilities – that should have been declared and is thus a violation. And uncertainties, ambiguities, anomalies – or **omissions** – in declarations can all be addressed through the clarification mechanisms.

• To make challenge and declarations effective, we must – as in other security agreements such as the Chemical Weapons Convention – have visits (inspections) to let the potential violator know that work on biological weapons at a declared site exposes the violator to the risk of discovery. In countries such as the UK and the US, the possibility of auditing of income tax returns keeps the self-assessment tax system from being disregarded.

• All three elements – challenge investigations, declarations and visits – create an architecture within which the potential violator faces the risk of being exposed if he uses a declared facility and if he uses an undeclared facility even the mere presence of undeclared agents or equipment would raise serious questions.

The composite Protocol text provides all of this – and more – efficiently and effectively so giving us worthwhile security gains whilst sending all would be violators a clear message that biological weapons are totally prohibited and that their acquisition will not be tolerated.

Any country which doesn't sign and ratify the Protocol will become more and more isolated in many ways. All States Parties **need** this Protocol. A failure to accept the Protocol sends the message that States do not care about the danger from biological weapons, and are not prepared to make the very modest commitments called for by the Protocol. Any State Party that takes steps that results in the failure of the Ad Hoc Group negotiations will rightly attract wide-spread condemnation from the international community.