ARTICLE X: SPECIFIC MEASURES TO ACHIEVE IMPLEMENTATION

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Introduction

1. The mandate for the Ad Hoc Group (AHG) of the States Parties to the Biological and Toxin Weapons Convention (BTWC) considering measures *"to strengthen the effectiveness and improve the implementation of the Convention"* includes explicit mention of the need, *inter alia*, to consider *"Specific measures designed to ensure effective and full implementation of Article X,..."*. [1] Article X of the BTWC[2] 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 (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.

2. Successive Review Conferences have encouraged States Parties to do more to implement Article X. Thus the Final Declaration of the Fourth Review Conference held in November/December 1996 stated[3] that

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[1]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.

[2]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.

[3]United Nations, *Fourth Review Conference of the Parties to the Convention on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction,* Final Document, Geneva, 1996.

> *"This Conference once more emphasizes the increasing importance of the provisions of Article X, especially in the light of recent scientific and technological development in the field of biotechnology, bacteriological (biological) agents and toxins with peaceful applications, which have vastly increased the potential for cooperation between States to help promote economic and social development, and scientific and technological progress, particularly in the developing countries, in conformity with their interests, needs and priorities."*

It went on to say that

> *"The conference urges all States Parties actively to continue to promote international cooperation and exchange with States Parties in the peaceful uses of biotechnology, and urges all States Parties possessing advanced biotechnology to adopt positive measures to promote technology transfer and international cooperation on an equal and non-discriminatory basis, in particular with the developing countries, for the benefit of all mankind. At the same time, the Conference stresses that measures to implement Article X need to be consistent with the objectives and provisions of the Convention."*

3. Such language shows the tension that surrounds Article X -- the wish by the developing countries to benefit from the advances in biotechnology and the concern by the developed countries that such technology transfer should not be misused for activities prohibited by the Convention. However, measures that implement Article X which provide clear benefits to developing countries can also contribute to the effective implementation of the Convention and to the building of transparency and confidence between States Parties. Such measures are incentives for the universality of the Protocol, and thus of the Convention.

4. The Ad Hoc Group (AHG) has now met 11 times. From its outset, it has functioned through Friends of the Chair (FOC) who have led the discussions relating to particular elements of the mandate. The FOC for Article X measures was initially Ambassador Jorge Berguno of Chile and, following his retirement, this FOC has been Carlos Duarte of Brazil. In July 1997, the AHG successfully transitioned to negotiation of the rolling text of a Protocol and subsequent meetings have seen the elaboration of language for the various Articles and Annexes of the Protocol. There is a sense of growing momentum at the AHG negotiations which are engaged in serious negotiation. Earlier this year, several States Parties declared their objective of seeking to complete the substantive negotiation of the Protocol in 1998. A further AHG meetings is scheduled for 4 weeks in September/October 1998. It is thus apparent that the end game will come within the next year when it will be important to have addressed all elements of the mandate and to have identified potential measures to implement Article X of the Convention that gain consensus in the final Protocol.

5. Previous Briefing Papers (No 6, 7 and 8)[4] have identified some building blocks which could be used in devising measures to implement Article X of the Convention which could also contribute to building transparency and enhancing confidence in compliance with the Convention. This Briefing Paper utilizes the building blocks to identify specific measures to implement Article X that will also contribute to strengthening confidence in compliance and

[4]University of Bradford, *Article X: Some Building Blocks*, Briefing Paper No 6, March 1998, University of Bradford, *Article X: Further Building Blocks*, Briefing Paper No 7, March 1998 and University of Bradford, *Article X: Pharmaceutical Building Blocks*, Briefing Paper No 8, July 1998. These are available on the web at http://www.brad.ac.uk/acad/sbtwc

could with advantage be incorporated into the Protocol. References are to Articles in the current draft Protocol[5] unless otherwise stated.

Ad Hoc Group (AHG)

6. The 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. 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 thereby putting much of 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 retrograde steps as they unnecessarily cast doubts on the intention of the AHG 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,..."*. 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[6] at the end of the March AHG 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."* This NAM concern was underlined by the communiqué[7] issued by the Foreign Ministers and Heads of Delegations following their meeting in Cartagena de Indias, Columbia on 19 - 20 May 1998 when they expressed *"their concern at any attempts to reduce the scope and importance of issues related to Article X of the Convention. Ensured access for peaceful purposes to the relevant materials, equipment and technology is essential to safeguard the economic interests of developing countries. Substantive progress in strengthening the application and full operationalisation of Article X is thus crucial for the conclusion of a universally acceptable and legally binding instrument designed to strengthen the Convention."*

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[5]The current version of the 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.

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

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

7. 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 relating to Article X of the Convention elsewhere in the draft Protocol in Article III. D Declarations that requires:

> *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...*

8. Thus far, there has been little consideration by the AHG of specific measures that might be taken to enhance the implementation of Article X as the AHG 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.

Strengthening the BTWC through implementation of Article X

9. There are a number of areas in which States Parties could implement Article X through cooperation for peaceful purposes which would also contribute to the building of confidence in compliance with the BTWC:

a. Disease surveillance networks,

b. Safe handling, storage and transfer of pathogens and toxins,

c. Counters to the acquisition of pathogens and toxins for terrorist purposes,

d. Assurance that medicinal products are safe for humans and for animals,

e. Assistance in implementation of the BTWC and its Protocol.

Each of these is considered in turn.

10. **Disease surveillance networks.** Disease is of world wide concern and it was hardly surprising that the World Health Organisation chose to devote its 1996 World Health Report[8] to the subject of "Fighting disease, Fostering development". In the foreword, Hiroshi Nakajima, the Director General of WHO not only said that "*We stand on the threshold of a new era in which hundreds of millions of people will at last be safe from some of the world's most terrible diseases"* but that "*we also stand on the brink of a global crisis in infectious diseases. No country is safe from them. No country can any longer afford to ignore their threat."* This world wide concern about new and emerging disease was recognised at the May 1995 World Health Assembly which passed a resolution[9] calling on the Director General *"to establish strategies enabling rapid national and international action to investigate and combat infectious disease outbreaks and epidemics."* This resolution in its preamble summarised the problem accurately as follows:

> *Aware that with the increasing global population many are forced to live under conditions of overcrowding, inadequate housing, and poor hygiene; that more frequent international travel leads to rapid global exchange of human pathogens; that changes in health technology and food production, as well as its distribution (including international trade) and handling, create new opportunities for human pathogens; that human behavioural changes expose large segments of the global population to disease not previously experienced; that expanding areas of human habitation expose thousands of people to enzootic pathogens previously unknown as causes of human disease; and that microbes continue to evolve and adapt to their environment, leading to the appearance of new pathogens;*

The Division of Emerging and other Communicable Diseases Surveillance and Control in the WHO has taken steps to strengthen the infrastructure for disease surveillance and to encourage research to develop new and effective disease surveillance and control strategies. Similar surveillance activities are carried out for animal and plant diseases by the FAO and OIE respectively.

11. International concern about outbreaks of disease continues with the Heads of State or Government of the G8 in May 1998[10] stating that "*We therefore pledge ourselves to a shared international effort: ...to enhance mutual cooperation on infectious and parasitic diseases and support the World Health Organization's efforts in those areas."* The Foreign Ministers of the G8 at their meeting in London on 8 and 9 May in their concluding statement[11] stated that *"The impact of infectious diseases continues to cause concern. The G8 is committed to helping countries respond to these challenges...through...improving surveillance capacity... Experts from the G8 countries and WHO will meet later this month to review current surveillance systems throughout the world, and examine options for assisting WHO as it helps to develop global surveillance networks."*

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[8]World Health Organisation, *World Health Report 1996, Fighting disease, Fostering development"*, ISBN 92 4 156182 3, Geneva, 1996.

[9]World Health Organization, Forty-eighth World Health Assembly, *Communicable diseases prevention and control: new, emerging and re-emerging infectious diseases*, Resolution WHA 48.13, 12 May 1995.

[10]The Birmingham Summit: Final Communique, Birmingham, Sunday 17 May 1998. Available at http://birmingham.g8summit.gov.uk/docs/final.shtml

[11]Conclusions of G8 Foreign Ministers, London, 9 May 1998. Available at http://birmingham.g8summit.gov.uk/forfin/foreign.shtml

12. 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 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.

13. **Safe handling, storage and transfer.** The bacteriological (biological) agents and toxins that are at the heart of the BTWC all occur in nature and cause disease and intoxinations in humans, animals or plants. There is consequently an urgent need for public health and environmental safety reasons to study the characteristics of these agents and toxins in order to protect humans, animals and plants from such diseases and intoxinations.

14. The past decade has seen considerable progress through several health and environment initiatives which received considerable encouragement at the UN Conference on Environment and Development held in Rio de Janeiro in June 1992, known as the Earth Summit. This agreed Agenda 21, a set of principles, intended to address the global objective of achieving sustainable development whilst protecting the environment. Chapter 16 of Agenda 21 addresses the environmentally sound management of biotechnology and has five Sections:

* Increasing the availability of food, feed and renewable raw materials;
* Improving human health;
* Enhancing protection of the environment;
* Enhancing safety and developing international mechanisms for cooperation; and,
* Establishing enabling mechanisms for the development and the environmentally sound application of biotechnology.

The penultimate of these Sections specifically states that there is a need for further development of internationally agreed principles on risk assessment and management of all aspects of biotechnology. These have subsequently been developed as the UNEP International Technical Guidelines on Biosafety. In addition, Chapter 16 says that "only when **adequate and transparent safety and border-control procedures** are in place will the community at large be able to derive maximum benefit from, and be in a much better position to accept the potential benefits and risks of, biotechnology." This has led under the Convention on Biological Diversity (CBD)[12] to negotiations which are nearing completion of a Biosafety Protocol which includes the principle of advance informed agreement for transfers of living modified organisms.

15. Article 19 of the CBD[13] which is entitled 'Handling of Biotechnology and Distribution of its Benefits' addresses the distribution of the benefits of biotechnology and includes consideration of safety and transfer aspects. It states that *"The Parties shall consider the*

[12]The Convention on Biological Diversity (CBD) opened for signature at the Rio summit; it entered into force in December 1993 and it currently has 171 States Parties; two notable exceptions are the USA and North Korea.

[13]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.

need for and the 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 which may have adverse effect on the conservation and sustainable use of biological diversity." The implementation of the CBD and negotiation of such a Protocol has been taken forward by the Conferences of the Parties.

16. The first Conference of the Parties in Nassau, Bahamas from 28 November to 9 December 1994 decided to establish an Open-ended Ad Hoc Group of Experts on Biosafety (BSWG) with a mandate to consider the need for and modalities of a protocol setting out appropriate procedures, including, in particular, advance informed agreement, in the field of safe transfer, handling and use of any living modified organism resulting from biotechnology that may have an adverse effect on the conservation and sustainable user of biological diversity. The second Conference of the Parties to the CBD in Jakarta on 6 to 17 November 1995 agreed a two track approach in which an Open-ended Ad Hoc Working Group would begin negotiations on a biosafety protocol with the aim of completing this by 1998 in parallel with the finalisation of the United Nations Environmental Programme (UNEP) International Technical Guidelines on Safety on Biotechnology. These are complementary in that the Protocol will be a binding agreement setting out what States must do and the UNEP Guidelines indicating how to do it.

17. The Open-ended Ad Hoc Working Group on Biosafety met for the first time in Aarhus, Denmark from 22 to 26 July 1996. It has subsequently met again in Montreal, Canada on 12 to 16 May 1997, 13 to 17 October 1997 and 9 to 18 February 1998 at which the draft protocol was further developed. Further meetings are planned in August 1998 and a final meeting in February 1999 to be followed by a two-day extraordinary meeting of the Conference of Parties to adopt the Biosafety Protocol. The UNEP International Guidelines 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[14]. These International Guidelines were developed and have been taken forward by a series of regional consultations on International Technical Guidelines for Safety in Biotechnology and Related Capacity-Building Requirements. These Regional Consultations included meetings in Harare, Zimbabwe (11-14 October 1993), San Jose, Costa Rica (28 February - 3 March 1995), Bangkok, Thailand (6 - 8 March 1995), Keszthely, Hungary (4 - 6 September 1995) and Smolenice, Slovak Republic (16 - 18 October 1996) as well as in Cartagena, Columbia and Budapest, Hungary.

18. Considerable progress has thus been made with extensive international consultation that has led to the agreement of the UNEP International Guidelines for Safety in Biotechnology and the negotiations due to be completed within the next 12 months of the Biosafety Protocol.

19. Although the Rio Summit and subsequent action has focussed world attention on protection of human health and the environment, many States have long recognised the potential danger from dangerous diseases to their people and to the livestock and crops on which they depend. Consequently, national regulations have been introduced in many countries to control the handling, use, storage and transfer of hazardous pathogens. More

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

recently, countries have sought to harmonise their national regulations with those used in other countries in the region and internationally thereby facilitating cooperation and trade.

20. In many countries, those wishing to work with or use pathogenic organisms are required to provide information to national authorities who will frequently carry out inspections of the facility in which the pathogens are to be handled. Such notification and inspection can be required prior to any work being carried out on the pathogen. In addition, transfers of pathogens that are perceived to present a particular danger are controlled and monitored in several countries. In many countries, additional regulations control the handling and use of genetically modified organisms. The net effect of all these controls and regulations is to provide a framework within a country aimed at ensuring that the danger to public health and to environmental safety from pathogens is minimized and thereby providing assurance to the public in the country concerned. Such controls and regulations also help to strengthen the national counters to the possible acquisition of such materials for terrorist purposes.

21. Increasingly, there are moves to harmonize these controls and regulations both regionally and internationally as it is recognised that an outbreak of human, animal or plant disease in one country can all too easily spread into other countries in the region or even more widely in this era of increasing international trade and travel. There is thus both a regional and international initiative to extend national frameworks for control and regulation of dangerous pathogens into regional and global frameworks thereby increasing public assurance that the dangers from disease outbreaks at home and abroad have been minimized. This extends also to work with living modified organisms, recognising that their hazards are based on those of the parent microorganism. Consequently, increasingly countries are introducing regulations to ensure that such biological agents and toxins and living modified organisms are handled, stored and transferred in controlled ways so as to prevent outbreaks of disease causing harm to trade and prosperity.[15] It is all too clear that outbreaks of disease prevent a real danger and it is widely accepted that work with the causative agents must be supervised and controlled.

22. **Counters to the acquisition of pathogens and toxins for terrorist purposes.** The risk that biological materials may be acquired for terrorist purposes was brought into sharp public focus by the reports of the interest of the Aum Shinrikyo sect in Japan in acquiring biological weapons. This led to the recognition by the G7 Heads of State or Government at their meeting in Lyon, France in June 1996 that *"Special attention should be paid to the threat of utilization of nuclear, biological and chemical materials, as well as toxic substances, for terrorist purposes. "* [16] This has subsequently led to States, such as the US, introducing national regulations that require facilities handling, storing and transferring select agents to be registered and inspected. The list of select agents includes pathogens and toxins that are regarded as potential biological warfare agents.

23. **Assurance that medicinal products are safe for humans and for animals.** There has long been recognition that pharmaceutical products need to be manufactured under controlled Good Manufacturing Practice conditions to ensure that they are safe, effective and

[15]Further detail is available in two Briefing Papers: 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

[16]United Nations, Letter dated 5 July 1996 from the Permanent Representative of France to the UN Secretary-General, UN General Assembly/Security Council document A/51/208, S/1996/543, Annex V, 12 July 1996. G7/8 Lyon Summit, Declaration on Terrorism, 27 June 1996**.**

reproducible and cause no harm to the humans or animals to whom they are administered. Equally, it is recognised that risks to the BTWC can arise from those facilities that can produce biological agents and toxins in quantity for peaceful purposes because of the potential dual purpose nature of the pharmaceutical and biotechnological industry. Consequently, 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 guidelines for Good Manufacturing Practice (GMP) for medicinal products issued by the European Community[17], by the Pharmaceutical Inspection Cooperation Scheme[18] and by the World Health Organization[19] 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 of inspection reports is already accepted within the European Community and between the members of the Pharmaceutical Inspection Convention. Mutual Recognition Agreements have been and are being negotiated between countries which contain sectoral agreements on good manufacturing practice for pharmaceuticals in order to achieve this goal. The incentives for the harmonization of GMP and for the international acceptance of inspections is the facilitation of trade in licensed medicinal products for both humans and animals which is becoming increasingly more international.[20]

24. The relevance of these harmonised international 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.

25. **Assistance in implementation of the BTWC and its Protocol.** The arms control treaty of greatest relevance to the BTWC is that of the CWC which addresses all chemicals including toxins which are also covered by the BTWC. The CWC has a closely similar Article (XI) to Article X of the BTWC which addresses international cooperation and

[17]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.

[18]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.

[19]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.

[20]University of Bradford, *Article X: Pharmaceutical Building Blocks,* Briefing Paper No 8, July 1998.

likewise contains two main elements -- first the promotional aspect which encourages international collaboration and second the regulatory aspect which encourages the removal of trade restrictions between States Parties. Following the entry into force of the CWC on 29 April 1997, the Organisation for the Prohibition of Chemical Weapons (OPCW) has successfully initiated several promotional cooperative measures which, as well as fostering international cooperation through actions such as internship and laboratory improvement programmes, have also included various cooperative measures addressing the effective implementation of various CWC provisions through such as declaration assistance, the setting up of national Authorities, training programmes and regional seminars. On the regulatory side, progress has understandably been slow as it is still very early days in the implementation of the CWC and time is needed for the confidence of States Parties to grow in the compliance of other States Parties with the CWC thus creating a climate in which the trade restrictions required to meet the non-transfer obligations of the CWC can be relaxed between States Parties.

26. It is evident that there will be benefits in the implementation of the future BTWC Protocol from similar promotional cooperative measures to those which have been implemented under the CWC especially in respect of cooperative measures providing aid in achieving effective implementation of various BTWC and its Protocol provisions by actions such as declaration assistance, the setting up of national Authorities, training programmes and regional seminars.

Analysis

27. There is clearly a common goal between on the one hand, the frameworks for national, regional and international controls of the handling and transfer of biological agents and toxins and of living modified organisms for peaceful purposes and of the facilities manufacturing licensed medicinal products for humans and animals, and on the other hand of the negotiations of a Protocol to strengthen the BTWC through increased transparency and enhanced confidence that States Parties are not using biological agents and toxins for purposes prohibited by the Convention. Consequently, measures designed to facilitate the use of such agents and toxins for peaceful purposes through the regional and international harmonization of the regulatory frameworks for the handling, storage and transfer of biological agents and toxins and through the promotion of internationally accepted standards and regulatory inspections of facilities producing licensed medicinal products for humans and animals will **both** implement Article X of the Convention **and** contribute to strengthening the BTWC through increasing transparency and building confidence in compliance. Such Article X measures can contribute to the implementation of the promotional and of the regulatory elements of Article X. For simplicity, measures in this Briefing Paper have been attributed to one or other element even though some can contribute to both elements.

28. The potential benefits of promotional measures to implement Article X through cooperation to achieve full and effective implementation of the provisions of the Protocol to strengthen the BTWC and to address the need for surveillance of outbreaks of emerging and re-emerging diseases are evident. Secondly, the importance of addressing the regulatory aspects of Article X is recognised; it is clear that there can be no sudden change to the present situation. The need is to build increased transparency and thus enhanced confidence in compliance with the BTWC by all States Parties to the BTWC. Some initial measures can be identified that could serve as a first stage towards the creation over time of a situation in which States Parties have the necessary degree of confidence in the compliance by other

States Parties with the BTWC that current control mechanisms can be relaxed between States Parties.

Promotional Measures

29. 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.

30. 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 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.

Regulatory Measures

31. 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.

32. 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.

33. 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 for 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

Article X Measure	Benefits to States Parties
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

Over time increased transparency and enhanced confidence that dangerous pathogens, toxins and living modified organisms are only being used for controlled and peaceful purposes will create a climate in which States Parties have the necessary degree of confidence that other States Parties are in compliance with the Convention so that existing trade restrictions between States Parties can be relaxed.

36. A study[21] of the likely size of the BTWC Organization concluded that it was likely to number about 200, well under half the size of the OPCW. Nevertheless, provision was made in that study for an International Cooperation and Assistance section in the BTWC Organization with a similar strength (10 posts) to the number of posts (11) actually in the OPCW in its Cooperation and Assistance section as it was anticipated that the measures to implement Article X of the BTWC would require a small dedicated staff. It is envisaged that the staff in the proposed International Cooperation and Assistance section of the BTWC Organization would keep track of the progress being made by States Parties to introduce safety regulations covering
the handling, storage and transfer of pathogens and toxins as well as their adoption of internationally harmonised standards for GMP of pharmaceutical products and establishment of national inspectorates to carry out regular inspections of pharmaceutical manufacturers. They could report on such progress in the reports that the BTWC Organization is expected to make on the implementation of the Convention to the States Parties in a similar way to the OPCW reports.[22] These progress reports could identify where action is needed to provide help to the States Parties in their implementation of these Article X measures. Such aid could then be provided by other States Parties.

[21]Graham S Pearson, *An Optimum Organization*, Briefing Paper No 5, University of Bradford, January 1998. Available on the web at http://www.brad.ac.uk/acad/sbtwc Graham S. Pearson, *A Lean Organization to Strengthen the Biological Weapons Convention*, CBW Conventions Bulletin, Issue No 39, March 1998.

[22]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.

Incorporation into Article VII of the Protocol

37. Consideration can now be given to how such measures might be incorporated into the language of Article VII of the Protocol.

a. **Title.** Clearly the title of Article VII which is currently

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

needs to reflect the content of the measures within this Article. It is proposed that a consolidated Title free from square brackets might be:

> *ARTICLE VII IMPLEMENTATION OF SCIENTIFIC AND TECHNOLOGICAL EXCHANGE FOR PEACEFUL PURPOSES AND TECHNICAL COOPERATION*

b. **Section A. General Provisions.** Paragraph 1. In the light of the change in the Title, this might with advantage be recast along the following lines:

> *The objective of this Protocol is to strengthen the effectiveness and improve the implementation of the Convention through inter alia measures designed to achieve effective and full implementation of Article X of the Convention which also contribute to the strengthening of the Convention.*

c. **Section D. Institutional Mechanisms and International Cooperation/ Protocol Implementation Assistance.** This already includes language in paragraph 8 (a) (b) and (c) for a range of activities *"To facilitate the implementation of this Protocol"* which include :

> *(a) Assist[ance to] States Parties [to obtain advice], if requested, [for][on] the establishment and functioning of national authorities;*
>
> *(b) Assist[ance to] States Parties [to obtain advice], if requested, [for][on] the preparation of declarations [required under this protocol][in accordance with Article... and section... of Annex...];*
>
> *(c) Assistance to States Parties, if requested, in drawing up internal legislation necessary under the provisions of this Protocol;*

There is thus already provision for assistance in the setting up of National Authorities, on the drawing up of national legislation and the preparation of declarations. The alternatives "[to obtain advice]" in both (a) and (b) appear unnecessary. There could also be advantage, in the light of the CWC experience for a more general clause that could cover other forms of assistance in the implementation of the Protocol using language such as

> *( ) Assistance to States Parties, if requested, for other assistance required to implement this Protocol*

d. **Section D. Institutional Mechanisms and International Cooperation/ Protocol Implementation Assistance.** Although this includes language in paragraph 8 (h) for an

activity *"To facilitate the implementation of this Protocol"* which relates *inter alia* to disease surveillance:

> *(h) Creating [a framework for donor countries], [including a [voluntary fund]] [to support an international system for the global monitoring of emerging diseases in humans, animals and plants, and] additional assistance for training of expert personnel and for the financing of scientific and technical cooperation and assistance projects;]*

there would be advantage if a separate clause that specifically addresses the strengthening of national and international elements of human, animal and plant disease surveillance networks and avoids the implicit exclusion of other common diseases in the term *"emerging diseases"*. A clause including language such as the following is suggested:

> *( ) Assistance to States Parties, if requested, in the strengthening of the national, regional and international disease surveillance networks for human, animal and plant diseases;*

e. **Section D. Institutional Mechanisms and International Cooperation/ Protocol Implementation Assistance.** Although this includes language in paragraph 8 (e) for an activity *"To facilitate the implementation of this Protocol"* which relates *inter alia* to cooperative programmes in biosafety:

> *(e) [If requested and in the context of visits to States Parties:]*
>
> > *(i)...*
> > *(ii) Information sharing concerning cooperative programmes in biosafety,...*

as well as provision in Section E *"Cooperative Relationships with Other International Organizations"* which encourages the BTWC Organization to gain the greatest possible benefits from *"biological containment and other biosafety regulations and practices"*, there would be advantage in a separate clause in Section D that specifically addresses the establishment of harmonized regulatory frameworks and the associated national inspectorates for the handling, storage and transfer of pathogens and toxins. Language along the following lines is suggested:

> *( ) Assistance to States Parties, if requested, on the establishment of internationally harmonized regulatory frameworks and the associated national inspectorates for the handling, storage and transfer of human, animal and plant pathogens and toxins.*

f. **Section D. Institutional Mechanisms and International Cooperation/ Protocol Implementation Assistance.** Although there is language in Section E *"Cooperative Relationships with Other International Organizations"* which requires the BTWC Organization to establish working relationships in order to:

> *(a) Derive the greatest [possible synergy][benefits] in such fields as:*
>
> *...*
> *(iii) Good manufacturing practices (GMP), good laboratory practice (GLP), biological containment and other biosafety regulations and practices;*

this language relates primarily to the BTWC Organization and not to the States Parties and is a general rather than a specific encouragement for the achievement of equivalent regulatory systems and inspectorates for medicinal products for humans and animals. There would be benefit in a separate clause in Section D along the following lines:

> *( ) Assistance to States Parties, if requested, on the establishment of internationally equivalent regulatory frameworks and the associated national inspectorates for the manufacture of medicinal products for humans and animals.*

Conclusions

38. It is concluded that specific measures to implement both the promotional and regulatory elements of Article X of the Convention, such as

> a. The provision of assistance to States Parties in implementing the Protocol such as in the setting up of National Authorities, the drawing up of national legislation to implement the Protocol and the Convention and the preparation of declarations,
>
> b. The improvement of national elements in the WHO, FAO and OIE disease surveillance networks for human, animal and plant diseases,
>
> c. The harmonization of national, regional and international safety rules for the handling, storage and transfer of pathogens and toxins,
>
> d. The adoption of internationally harmonised standards for GMP of pharmaceutical products and establishment of national inspectorates to carry out regular inspections of pharmaceutical manufacturers,

would **also** contribute directly to the strengthening of the BTWC through building transparency and enhancing confidence in compliance. The resources needed to do this could be readily accommodated in a small and efficient BTWC Organization of about 200 people well under half the size of the OPCW. Furthermore, such measures to implement Article X of the Convention would contribute over time to the building of a climate in which States Parties have the necessary degree of confidence in the compliance of other States Parties with the Protocol that trade restrictions between States Parties to the Protocol could be relaxed.