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THE BTWC PROTOCOL IMPLEMENTATION: PRACTICAL CONSIDERATIONS

by Graham S. Pearson

Introduction

1. The Ad Hoc Group (AHG) has now completed eleven sessions and has produced the fifth version[1] of the draft Protocol to strengthen the effectiveness and the implementation of the Biological and Toxin Weapons Convention (BTWC). Further progress was made at the June/July 1998 AHG meeting with clear signs of engagement by all participants with serious negotiations seeking to resolve language currently within square brackets. In addition, it is apparent that the AHG has turned the corner from adding reams of new text to reducing down and focussing on key issues. There was also evidence that text is now being consolidated and developed with a move towards production by the Friends of the Chair of clean texts in which language without square brackets was being prepared. This year has seen a continuing high level of political interest around the world in completing the negotiations as quickly as possible.[2] It is thus clear that the end game has already commenced and there are reasonable expectations that the substantive negotiations will have been completed by the end of 1998.

2. It is therefore time to address some practical considerations relating to the implementation of the future BTWC Protocol. It is evident that the key elements of the future integrated regime[3] will comprise:

a. Mandatory declarations of the facilities and activities of most relevance to the BTWC,

b. Infrequent non-challenge visits,

c. Facility and field investigations of non-compliance concerns,

together with:

d. Measures to strengthen the implementation of Article III (non-transfer) of the Convention,

e. Measures to strengthen the implementation of Article IV (national implementation) of the Convention, and

f. Measures to strengthen the implementation of Article X (peaceful cooperation) of the Convention.

3. The cornerstone of the future regime will be the declarations and the non-challenge visits as it is the information from these measures, complemented by the additional information from the Article III and the Article X measures, that will, over time, build confidence and

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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/41, 16 July 1998.

[2]See for example, Graham S Pearson, *BTWC Ad Hoc Group gains Political Momentum,* ASA Newsletter 98-2, 30 April 1998 and Graham S Pearson, *Further BTWC Ad Hoc Group Progress,* ASA Newsletter 98-4, 14 August 1998.

[3]Graham S Pearson, *The Strengthened BTWC Protocol: An Integrated Regime,* Briefing Paper No. 10, University of Bradford, July 1998. Available on http://www.brad.ac.uk/acad/sbtwc

trust between States parties that they are in compliance with the Convention. This Briefing Paper examines some practical aspects in respect of compiling declarations and making such non-challenge visits with a view to indicating how they might be achieved by building upon existing national capabilities. The implications for the implementation of the Protocol and of Article X of the Convention are outlined.

Declarations and Non-Challenge Visits.

4. The current version of the Protocol in Article III Compliance Measures D. Declarations includes the following triggers for declarations of facilities and activities of particular relevance to the Convention:

a. Past Offensive/Defensive Programmes

b. Current Defensive Programmes

c. Vaccine Production Facilities

d. Maximum Biological Containment Laboratories (BL 4)

e. Work with Listed Agents

f. Non-Vaccine Production Facilities

The other triggers for declarations in the draft Protocol have not been included above as they are of less relevance to the subject of this Briefing Paper.

5. Although detailed formats for these declarations have yet to appear in Annexe A of the Protocol, it is evident that consideration is being given to formats by the States Parties engaged in the AHG negotiations. There is general agreement that declaration formats need to be clear and simple to complete. It also appears that no confidential proprietary information will be required to complete the declarations for commercial facilities. The Austrian/UK contribution[4] to the EU seminar for the pharmaceutical industry on 13 May 1998 said that *"All are agreed that the forms should be simple and straightforward and should not seek any information which would be considered commercially sensitive."*

6. Insofar as Visits are concerned, the draft Protocol in Article III Compliance Measures F Visits and Investigations I. Visits contains provision for four types of visits called:

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

[It should be noted that whilst the body of I. Visits uses this terminology, the introductory paragraph is confusing as it still has an earlier terminology and has yet to be amended to be consistent with the rest of I. Visits.]

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

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

8. The basic premise that there should be a portfolio of different types of visits -- all of which are non-challenge in nature -- is a sound one. A two-pillar regime that had only declarations and challenge investigations would be ineffective and would be likely to reach erroneous judgements and thus fall into disrepute. There is a convincing argument for a three-pillar regime comprising declarations, visits to declared facilities and challenge investigations.[5]

Practical Considerations

9. Article X of the draft Protocol addresses National Implementation Measures and includes:

> *3. In order to fulfil its obligations under this Protocol [the Convention], each State Party shall designate or establish [a National Authority] and shall so inform the [Organization] upon entry into force of this Protocol for it. The [National Authority] shall serve as the national focal point for liaison with the [Organization] and with other States Parties.*

It is already evident from the deliberations by the AHG and from the experience gained in the implementation of the Chemical Weapons Convention (CWC) that the effective implementation of a strengthened BTWC will depend on both an independent international organization and on national authorities who will collect and collate the information required for national declarations and oversee the national implementation of the Protocol.

10. The importance of ensuring that provision is made for effective national authorities has been stressed in respect of the provision in the Protocol for national implementation measures[6]. Briefing Paper No 11 examined the implications of the CWC verification regime for the biotechnological and pharmaceutical industries and emphasised the important role of national authorities[7]. It is also evident that the facilities and activities of particular relevance to the BTWC are already in many countries highly controlled and regulated on health and safety grounds. The Briefing Papers on the building blocks[8] to be considered in developing

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

[6]Graham S Pearson & Nicholas A Sims, *National Implementation Measures*, Briefing Paper No. 4, University of Bradford, January 1998. Graham S Pearson & Nicholas A Sims, *National Implementation Measures : An Update,* Briefing Paper No. 14, University of Bradford, October 1998. Available on http://www.brad.ac.uk/acad/sbtwc

[7]J P Perry Robinson, *The CWC Verification Regime: Implications for the Biotechnological & Pharmaceutical Industry,* Briefing Paper No 11, University of Bradford, Briefing Paper No. 11, July 1998. Available on http://www.brad.ac.uk/acad/sbtwc

[8]Graham S Pearson, *Article X: Some Building Blocks,* University of Bradford, Briefing Paper No 6, March 1998, Graham S Pearson, *Article X: Further Building Blocks,* University of Bradford, Briefing Paper No 7,

measures to improve the implementation of Article X of the Convention[9] outlined the regulatory framework in a variety of countries.

11. It is apparent from both cost and effectiveness grounds that any new requirements for the BTWC Protocol should, as far as possible, build upon existing regulations and controls. This is a point that has been made on several occasions by the representatives of the biotechnology and pharmaceutical industries in considering the implications of the strengthened Protocol.[10] There would appear to be no necessity to introduce a new national bureaucratic arrangement if the required functions can be carried out by an extant national organisation.

12. This paper examines UK experience in respect of the implementation of another international agreement as a possible model for the implementation of the central pillar of a future BTWC Protocol -- the provision of mandatory declarations of facilities and activities of particular relevance to the BTWC. This other international agreement is that for Prior Informed Consent prior to the export and import of "banned or severely restricted" chemicals.

A Possible Model

13. **Prior Informed Consent.** The Prior Informed Consent (PIC) agreement requires an exporting country to provide information about particular hazardous chemicals to the importing country so that a national informed decision can be made prior to the chemical being imported. This has functioned through a voluntary procedure involving 152 countries which has controlled the export and import of "restricted and severely banned chemicals". Although the PIC procedure is currently being transformed into a legally binding Convention, the PIC procedure has been legally binding since 1992 insofar as the countries within the European Union are concerned.[11]

14. Following the growth in world trade in chemicals in the 1960s and 1970s, the Governing Council of the UN Environment Programme (UNEP) in 1977 urged[12] Governments to take steps to ensure that potentially harmful chemicals, which are unacceptable for domestic purposes in the exporting country, are not permitted to be exported without the knowledge and consent of appropriate authorities in the importing country. Some 5 years later, the United Nations General Assembly "*aware of the damage to health and the environment that the continued production and export of products that have been banned and/or permanently withdrawn on ground of human health and safety ....is causing in the importing countries"* and "*considering that many developing countries lack the necessary information and expertise to keep up with developments in this field"* requested[13] that the Secretary-General prepare and regularly update *"a consolidated list of products whose consumption and/or sale have been banned, withdrawn, severely restricted or not approved by Governments."* This

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March 1998 and Graham S Pearson, *Article X: Pharmaceutical Building Blocks,* University of Bradford, Briefing Paper No 8, July 1998. Available on http:// www.brad.ac.uk/acad/sbtwc

[9]Graham S Pearson, *Article X: Specific Measures to Achieve Implementation,* University of Bradford, Briefing Paper No 9, July 1998. Available on http:// www.brad.ac.uk/acad/sbtwc

[10]See for example, Graham S Pearson, *A Strengthened BTWC: Three Specialist Conferences,* ASA Newsletter 98-4, Issue number 67, pp. 10-12, 14 August 1998.

[11]Some further detail about the PIC procedure and the development of the legally binding Convention are provided in Graham S Pearson, *Article III: Further Building Blocks,* University of Bradford, Briefing Paper No 13, October 1998. Available on the web at http:// www.brad.ac.uk/acad/sbtwc

[12]United Nations Environment Programme, Governing Council decision 85(V), 25 May 1977.

[13]United Nations General Assembly, Resolution 37/137, *Protection against Products Harmful to health and the Environment,* 109th Plenary Meeting, 17 December 1982.

list is prepared[14] and regularly updated jointly by the United Nations, the World Health Organization and the United Nations Environmental Programme/International Register of Potentially Toxic Chemicals (UNEP/IRPTC). This is part of a continuing effort in the United Nations system aimed at disseminating information internationally on products harmful to health and the environment. It provides information on restrictive regulatory decisions taken by Governments on pharmaceutical, agricultural and industrial chemicals, and consumer products. The Fourth Edition covers regulatory actions taken by 92 Governments on over 600 products. The introduction to the Fourth Edition[4] notes that "*It is important to realize that all pharmaceutical and chemical products are potentially harmful if not correctly used."* and that *"The list does not include many widely used industrial chemicals to which occupational exposure limits have been assigned by national authorities, and on which information is available in ILO* (International Labour Organization) *and UNEP/IRPTC publications."*

15. In order to ensure that the list focusses on products harmful to health and the environment, criteria for the inclusion of products were developed in 1985 and transmitted to Governments for their comments. These criteria, revised in the light of the comments received, are reproduced in an Annex to the Consolidated List. Those for chemical products are "Banned", "Withdrawn" and "Severely restricted" which are defined as:

> *Banned - A product that has been prohibited for all uses nationally in one or more countries by final government regulatory action because of health or environmental reasons*
>
> *Withdrawn - A product formerly in commerce that has been withdrawn for all uses nationally in one or more countries by final voluntary action of the manufacturer because of health or environmental reasons*
>
> *Severely restricted - A product for which virtually all uses have been prohibited nationally in one or more countries by final government regulatory action because of health or environmental reasons, but for which certain specific uses remain authorized.*

16. UNEP in 1987 adopted[15] the London Guidelines for the Exchange of Information on Chemicals in International Trade[16] which were aimed at enhancing the sound management of chemicals through the exchange of scientific, technical, economic and legal information. Special provisions were included regarding *"the exchange of information on banned and severely restricted chemicals in international trade, which call for cooperation between exporting and importing countries, in the light of their joint responsibility for the protection of human health and the environment at the global level."* UNEP in adopting these guidelines also identified that additional measures were required to enable importing countries to give or withhold their consent to particular exports following receipt of adequate information from exporting countries and that such measures, based on the principle of prior informed consent should be incorporated in the London Guidelines as expeditiously as possible.

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[14]United Nations Department of International Economic and Social Affairs, *Consolidated List of Products Whose Consumption and/or Sale Have Been Banned, Withdrawn, Severely Restricted or not Approved by Governments,* Fourth Edition, United Nations, New York, 1991.

[15]United Nations Environment Programme, Proceedings of the Governing Council at its Fourteenth Session, UNEP/GC.14/26, 10 July 1987. Decision 14/27 of 17 June 1987.

[16]United Nations Environment Programme, Programme Matters, UNEP/GC.14/17, 2 April 1987, Annex IV: London Guidelines for the Exchange of Information on Chemicals in International Trade

17. This principle of Prior Informed Consent (PIC) was incorporated[17] in the amended London Guidelines[18] in 1989. These provide a mechanism for importing countries to formally record and disseminate their decisions regarding the future importation of chemicals which have been banned or severely restricted in the exporting countries and outlines the shared responsibilities of importing and exporting countries and exporting industries in ensuring that these decisions are heeded. The Introduction to the Guidelines states that *"Although these Guidelines have not been prepared specifically to address the situation of developing countries, they nevertheless provide a framework for the establishment of procedures for the effective use of chemicals in these countries. Implementation of the Guidelines should thus help them to avoid serious and costly health and environmental problems due to ignorance about the risks associated with the use of chemicals, particularly those that have been banned or severely restricted in other States."*

18. The PIC procedure is being implemented jointly by the Food and Agriculture Organization (FAO) of the United Nations which leads for pesticides and UNEP through the IRPTC (International Register of Potentially Toxic Chemicals) which leads for chemicals. Each participating country - of which, by February 1998, there were 152 - nominates a Designated National Authority (DNA)[19] to serve as a focal point for the operation of the PIC procedure. Some countries have designated one authority for all chemicals while others have designated two, one with responsibility for pesticides and the other for other chemicals. The DNA is generally a government department or office responsible for broad policy decisions with the authority to decide which chemicals may be used in the country. In the UK, it is the Chemicals and Biotechnology Division of the Department of the Environment[20] while in the USA it is the Assistant Administrator, Prevention, Pesticides and Toxic Substances of the Environmental Protection Agency.

19. The functions of the DNA in respect of the import of banned or severely restricted chemicals are to receive information on exports from exporting States, to transmit requests for further information as required to exporting States, to advise and assist import control authorities, to strengthen national decision-making procedures and import control mechanisms, to ensure that decisions apply uniformly to all import sources and to domestic production of chemicals for domestic use, and to encourage that chemicals subject to PIC be purchased only from sources in exporting countries which are participants in that procedure. Insofar as exports of banned or severely restricted chemicals are concerned, the function of the DNA is to ensure the provision or transmittal of information on exports, to respond to requests for information from other States, especially as regards sources of precautionary information on the safe use and handling of the chemicals concerned, to communicate PIC decisions to their export industry, and to implement appropriate procedures, within their authority, designed to ensure that exports do not occur contrary to the PIC decisions of participating importing countries.

20. The aim of the PIC procedure is to ensure that a banned or severely restricted chemical is not exported without the consent of the importing country. The Guidelines require that if

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[17]United Nations Environment Programme, Governing Council Decision 15/30 of 25 May 1989.

[18]United Nations Environment Programme, London Guidelines for the Exchange of Information on Chemicals in International Trade, Amended 1989.

[19]UNEP/FAO Register of Designated National Authorities for the Implementation of the Information Exchange and PIC Procedures of the London Guidelines and the International Code of Conduct, Geneva and Rome, February 1998. Available on the web at http://irptc.unep.ch/pic/

[20]Referred to as the Department of the Environment in this Briefing Paper for simplicity although the full title of the Department is currently the Department of the Environment, Transport and the Regions (DETR).

an export is planned of a chemical banned or severely restricted in the exporting State, then the exporting State should ensure that the DNA of the importing State is provided with relevant information to remind the importing State of the original notification by the exporting State of control action and to alert it to the fact that an export is planned. The minimum information to be provided is a copy of the information provided at the time of notification of the control action, the indication that tan export of the chemical will occur and an estimate of the quantity to be exported annually as well as any shipment-specific information that might be available. Such information is to be provided to the State of final destination and to UNEP/IRPTC. It is also clear that the PIC procedure is applied to chemicals that have multiple use. For example, the six monthly PIC circular of import decisions for some chemicals has in the column headed "Final Decision on Import" the words "Prohibit for plant protection use" and then in the column headed "Conditions for Import" has the words "For uses other than plant protection, written authorization is required for import".

21. The banned and severely restricted chemicals thus far subject to the PIC procedure are pesticides and industrial chemicals; last September five organophosphates -- methamidophos, methyl parathion, monocrotophos, parathion and phosphamidon -- were added to some 17 pesticides and 5 industrial chemicals which were already the subject of DGDs.[21]. In some cases, a specific chemical is the subject of a DGD such as fluoroacetamide, parathion or ethylene oxide, whilst other DGDs apply to a group of chemicals such as mercury compounds and polychlorinated biphenyls (PCB), except mono- and dichlorinated.

22. **EU Regulation.** In the European Union (EU), a legally binding Council Regulation (EEC) No 2455/92 was adopted[22] in 1992 which established a common system of notification and information for imports from and exports to countries which are not members of the EU of certain dangerous chemicals and implemented the UNEP/FAO PIC scheme in the EU. This regulation requires exporters of chemicals which are banned or severely restricted in the EU to provide information to importing countries about these chemicals. Member Governments of the EU are legally required, as well as formally committed, to implement EEC Regulations. Consequently it is a legal requirement within the EU for an exporter to provide the designated national authority of the Member State in which he is located with information about the export from the Community to a third country for the first time of a chemical subject to the Regulation no later than 30 days before the export is due to take place. The designated national authority has then to ensure that the appropriate authorities of the country of designation receive notification at least 15 days before export; copies of the notification are to be copied to the Commission which shall forward it to the designated national authorities of the other Member States and to UNEP/IRPTC. The notification provides information about the identity of the chemical, information on precautions to be taken, summary of the regulatory restrictions and the reasons for them, the expected date of first export, country of designation, use category (whether plant protection product, industrial chemical or consumer chemical) and the estimated amount of the chemical to be exported to

[21]FAO/UNEP Joint Programme for the Operation of Prior Informed Consent, Update on Implementation as of 30 June 1996. FAO/UNEP, Prior Informed Consent, *News & Highlights,* Rome 23 September 1997. Available on the web at http://irptc.unep.ch/pic/

[22]Council Regulation (EEC) No 2455/92 of 23 July 1992 concerning the import and export of certain dangerous chemicals, Official Journal of the European Communities, L251, Volume 35, 29 August 12992, pp 13-22. See also European Chemicals Bureau, Informing the Importer, Guide to Council Regulation (EEC) No 2455/92 concerning the import and export of certain dangerous chemicals, 1996. Council Regulation [EEC] No 2455/92 is amended periodically when the list of chemicals subject to the PIC procedure is amended. An example is Commission Regulation [EC] No 1237/97 of 27 June 1997 amending Annex II to Council Regulation [EEC] No 2455/92 concerning the export and import of certain dangerous chemicals, Official Journal of the European Communities, L173/37 - 67, 1 July 1997.

the destination country in the next year. The regulation requires the exporter to comply with the decision of the country of destination participating in the PIC procedure.

23. **UK Implementation.** Although in the United Kingdom the Designated National Authority for the PIC procedure is, as noted above, the Chemicals and Biotechnology Division of the Department of the Environment[23], the actual implementation is carried out by the Health and Safety Executive[24]. The logic behind this reflects the responsibility of the Health and Safety Executive to ensure that the Health and Safety at Work Act 1974[25] is effectively implemented. This Act is

> *"to make further provision for securing the health, safety and welfare of persons at work, for protecting others against risks to health and safety in connection with the activities of persons at work, for controlling the keeping and use and preventing the unlawful acquisition, possession and use of dangerous substances,..."*

The Act in Section 20 details the enforcement powers of health and safety inspectors which are considerable and include:

> *(a) at any reasonable time (or, in a situation which in his opinion is or may be dangerous, at any time) to enter any premises...*
>
> *(c) ...to take with him --*
>
> > *(i) any other person duly authorised by his (the inspector's) enforcing authority; and*
> > *(ii) any equipment or materials required for any purpose for which the power of entry is being exercised;...*
>
> *(g) to take samples of any articles or substances found in the premises which he has power to enter, and of the atmosphere in or in the vicinity of any such premises;...*
>
> *(j) to require any person whom he has reasonable cause to believe to be able to give any information...to answer...such questions as the inspector thinks fit to ask and to sign a declaration of the truth of his answers;*
>
> *(k) to require the production of, inspect and take copies of or of any entry in*
>
> > *(i) any book or documents which by virtue of any of the relevant statutory provisions are required to be kept; and*
> > *(ii) any other books or documents, which it is necessary for him to see...*
>
> *(m) any other power which is necessary...*

24. Section 13 of the Act enables the Health and Safety Commission and thereby the Health and Safety Executive to undertake functions on behalf of other government departments:

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[23]Referred to as the Department of the Environment in this Briefing Paper for simplicity although the full title of the Department is currently the Department of the Environment, Transport and the Regions (DETR).

[24]United Kingdom, Statutory Instrument, *The Export of Dangerous Chemicals Regulations 1992,* SI 1992/2415, 9 October 1992.

[25]United Kingdom, *Health and Safety at Work etc. Act 1974,* 1974 Chapter 37, The Stationery Office, London.

(b)...to make agreements with any Minister of the Crown, government department or other public authority for the Commission to perform on behalf of that Minister, department or authority (with or without payment) functions...which in the opinion of the Secretary of State can appropriately be performed by the Commission in connection with any of the Commission's functions;

(c) to provide (with or without payment) services or facilities ... in so far as they are required by any government department or other public authority in connection with the exercise by that department or authority of any of its functions;...

25. Whilst the implementation of the PIC regulation is one example of such an agreement, another example is the agreement between the Health and Safety Executive and the Department of the Environment and the Ministry of Agriculture Fisheries and Food in regard to the control and regulation of contained uses and deliberate releases of genetically modified organisms (GMOs). This agreement makes the Health and Safety Executive who are responsible for all human health and safety issues relating to GMOs also responsible for the enforcement of the environmental aspects of contained use of GMOs and of all aspects of the deliberate release of GMOs. A particular benefit of this agreement is that *"All the parties are committed to close co-operation in order both to protect the environment and human health and safety and t**o ensure that users of GMOs are not faced with conflicting demands which may unnecessarily inhibit research or industry."*** [Emphasis added]

26. In respect of both the PIC regulation and the additional GMO environmental responsibilities, it is clear that the Health and Safety Executive with its considerable powers to enter premises and to require the provision of information is well suited to the enforcement of various regulations even though these are both matters on which the Department of the Environment leads.

Analysis

27. In considering how this experience might be used as a possible model for the provision of mandatory declarations of facilities and activities of particular relevance to the BTWC, it will be recalled that Briefing Papers No 6[26] and No 7[27], which considered possible building blocks for the implementation of Article X (international cooperation for peaceful purposes) of the BTWC, identified the potential benefits to the BTWC Protocol of measures involving national health and safety regulatory frameworks.

28. **Health and Safety Frameworks.** The subsequent Briefing Paper No 9[28], which addressed specific measures to achieve implementation of Article X, noted that although the Rio Summit and subsequent action had focussed world attention on protection of human health and the environment, many States had 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 recently, countries have

[26]Graham S Pearson, *Article X: Some Building Blocks,* University of Bradford, Briefing Paper No 6, March 1998. Available on the web at http:// www.brad.ac.uk/acad/sbtwc

[27]Graham S Pearson, *Article X: Further Building Blocks,* University of Bradford, Briefing Paper No 7, March 1998. Available on the web at http:// www.brad.ac.uk/acad/sbtwc

[28]Graham S Pearson, *Article X: Specific Measures to Achieve Implementation,* University of Bradford, Briefing Paper No 9, July 1998. Available on the web at http:// www.brad.ac.uk/acad/sbtwc

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

29. In many countries, those wishing to work with or use pathogenic organisms are required to provide information to national authorities who will periodically 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.

30. 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, an increasing number of 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. 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.

31. As a result, Briefing Paper No 9 went on to propose regulatory measures to aid the implementation of Article X of the BTWC as follows:

> ***"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."*

32. **UK National Considerations.** The involvement of the Health and Safety Executive in the implementation of United Kingdom regulations concerning the handling, storage and use of human pathogens was outlined in Briefing Paper No. 7 Article X: Further Building Blocks[27]. These regulations require notification to and, in some cases, approval by the Health and Safety Executive of activities involving human pathogens and genetically modified human pathogens. There is a requirement for notification to the Health and Safety Executive at least 30 days in advance of first use of biological agents in Groups 2, 3 and 4 where there is an intention to propagate, concentrate or store such biological agents. All work including diagnostic work relating to Group 4 agents and a few speciied Group 3 agents has to be so notified. The premises in which Group 3 and 4 agents are handled are inspected by specialist microbiologist HSE inspectors whose aim is to inspect all facilities working with Group 4 agents annually and all facilities working with Group 3 agents once every three years. These inspections focus on the facilities, procedures and practices as well as the management of health and safety within the facility and include reviews of the risk assessments which have been prepared by the facility as required under the regulations. The specialist microbiologist HSE inspectors can also be called in by the regular inspectors of other facilities such as those using Group 2 and Group 1 agents.

33. As the human pathogens that are currently listed in the draft Protocol are all primarily either Group 4 or Group 3 agents, it is evident that, in the United Kingdom, facilities engaged in working with such agents are regularly inspected by specialist microbiologist HSE inspectors.

34. When this is taken into consideration along with the extent of the powers which the Health and Safety Executive exercise in visiting premises of all types within the United Kingdom -- and their responsibility for oversight of the safe use of both materials and equipment -- it becomes apparent that there could well be advantages in an organization such as the Health and Safety Executive being charged with the collection of the information that will be required for Declarations under the Protocol for the strengthening of the BTWC.

35. The intimate knowledge that organizations such as the Health and Safety Executive have as a result of their repeated inspections of relevant facilities would engender confidence in the accuracy and completeness of the declarations required to be made nationally under the future Protocol if these were to be the responsibility of such organizations. Furthermore, the relationship between organizations such as the Health and Safety Executive and the relevant facilities that is required to build national confidence in the quality of the future BTWC Protocol declarations is closely parallel to that necessary to carry out the principal function of organizations such as the Health and Safety Executive. Further consideration would, however, need to be given to how best to make arrangements for declarations of animal and plant pathogen facilities where such pathogens present no hazard to human health.

Conclusion

36. In considering how the Protocol to strengthen the BTWC might be implemented in regard to the collection of the information needed for national declarations of activities involving pathogens, there are apparent advantages from the viewpoints of **both** Protocol implementation **and** from the implementation and strengthening of Article X of the BTWC in utilising existing national health and safety agencies, such as the Health and Safety Executive in the United Kingdom, which are already engaged in examining information on and inspecting activities involving the use of pathogens. Confidence would be enhanced that declarations prepared by such agencies were both complete and accurate.

37. There are thus potential benefits to be gained from building upon and utilizing existing national health and safety agencies to colect the information required for national declarations under the future BTWC Protocol. These arise not only from the greater confidence that such declarations are accurate and complete but also ensure that the users of dangerous pathogens are not faced with conflicting demands which might unneccessarily inhibit research or industry. The reality of the potential confusion arising from the demands of multiple Government authorities is recognised by the UK chemical industry which has argued strongly for a single enforcement agency thereby avoiding confusion both within Government and within the industry.[29] There is much therefore to be said for "single stop shopping" in respect of the national control, regulation and reporting of dangerous pathogens. There are benefits to be gained by States Parties in building upon their national health and safety frameworks to bring them security benefits through the efficient and effective implementation of the Protocol.

[29]See for example, David E Wakeford, Imperial Chemical Industries PLC on behalf of the Chemical Industries Association Limited, *Controls on International Trade in Chemicals,* Combating Environmental Crime Seminar, 16 October 1996.